Prevention and Treatment of Pressure Ulcers:

Technical Documents: Data ExtractionTables

EUROPEAN PRESSURE ULCER ADVISORY PANEL

NATIONAL PRESSURE ULCER ADVISORY PANEL

PAN PACIFIC Pressure Injury Alliance

INTRODUCTION

This document reports the master tables for data extraction used in the development of the second edition of the International Pressure Ulcer Guideline (see citation below). The full development process is outlined in the *Methodology Addendum*, available at the guideline website. An abridged version of the methodology is published as an appendix in the *Clinical Practice Guideline*.

The Small Working Groups (SWGs) involved in the guideline development were responsible for reviewing potential literature for inclusion in the section of the guideline addressing the SWG area of interest; conducting critical appraisal (see *Technical Documents: Critical Appraisal*) on studies meeting the inclusion criteria; and summarizing relevant material from the studies in data extraction tables. The tables presented within this document support the recommendations and evidence summaries presented in the *Clinical Practice Guideline.* **Users should not rely on data extraction tables alone.**

Printed copies of the English version of the *Clinical Practice Guideline* are available through links provided on the following websites:

NPUAP website:	www.npuap.org
EPUAP website:	www.epuap.org
Australian Wound Management Association (AWMA) website:	www.awma.com.au
Hong Kong Enterostomal Therapist Society website:	www.etnurse.com.hk
New Zealand Wound Care Society (NZWCS) website:	www.nzwcs.org.nz
Wound Healing Society Singapore website:	www.woundhealingsociety.org.sg
International Pressure Ulcer Guideline website:	www.internationalguideline.com

A *Quick Reference Guide* version that contains excerpts from the *Clinical Practice Guideline* is also available. The quick reference guide is intended for busy health professionals who require a quick reference in caring for individuals in the clinical setting. **Users should not rely on excerpts from the *Quick Reference Guide* alone.**

Guideline Citation:
National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline. Emily Haesler (Ed.). Cambridge Media: Osborne Park, Western Australia; 2014.

Table of Contents

Background

PREVALENCE AND INCIDENCE OF PRESSURE ULCERS

Reference	Subject	Design/method	Incidence & Follow up	Prevalence	Stage/category	Clinical site	database (DB) clinical (CL)	Limitations and comments
Medical/surgical/acute care								
(Molon and Estrella, 2011)	• Admitted to orthopedic ward within 8 month period in 2009 • Patients aged over 19 years, expected to be confined to chair or bed for at least 5 days and without pre-existing PU (n=43)	Cross sectional survey	**HAPU within 8 weeks of admission** • cummulative incidence 20% • Median time to PU development 7 days from admission • Only stage II or greater		EPUAP grading system, only stage II or above included	Othopedic ward (Phillipines)	CL	• Small sample size • Patients who were not expected on admission to be confined to bed/chair were excluded
(Gunningberg, Donaldson et al., 2012)	Adult inpatients in medical/surgical units • 33 Swedish university hospital units (n = 630) • 14 Swedish general hospital units (n = 253) • Over 1,100 USA Collaborative Alliance for Nursing Outcomes (CALNOC) hospital units (benchmark registry hospitals) (n = 3506)	Cross-sectional	**Hospital acquired PU categories 3 and 4** 2.7% university hospitals 2.0% general hospital s 0 to 0.5% CALNOC hospitals • 100% of CALNOC sample received risk and skin assessments and prevention protocol for patients at risk • In the Swedish hospitals risk and skin assessment varied from 6% to 60% and prevention protocol from 16.1% to 28.6%.	**Point prevalence** • 9.5% general hospitals • 17.6% university hospitals • 6.3 to 6.7% CALNOC hospitals	HAPU was limited to categories III and IV	Medical/surgical units in university and general hospitals Sweden and USA	CL	Differences in EU and US definitions existed at the time of the study with respect to deep tissue injury (included in category 4 in Swedish data and Category 1 or greater in US data)
(Inan and Öztunç, 2012)	Study conducted in one university hospital in Turkey and included medical/surgical/acute care wards (n =404)	Cross sectional		**Point prevalence PU** • Category/stage 1 to IV • 10.4% (95% CI 7.4 to 13.4) • Sacrum 43.9% • Trochanter 17.9% • Heels 13.7%	• Stage I 30.1% • Stage 2 45.2% • Stage 3 17.8% • Stage 4 6.9% • Most severe PUs were on sacrum and trochanter.	University hospital (Turkey)	CL	
(Gunningberg, Stotts et al., 2011)	1192 patients ≥18 yrs admitted to two County County Councils in Sweden	Cross sectional	**HAPU** • Mean1.3 HAPU per patients (SD=0.61, range=1 to 4)	**Point prevalence** • 14·9%	• EPUAP/NPUAP grading system • 4.8% (n=57) had moisture	medical-surgical, critical care, geriatric	CL	Lack of admission documentation of skin assessment in

Reference	Subject	Design/method	Incidence & Follow up	Prevalence	Stage/category	Clinical site	database (DB) clinical (CL)	Limitations and comments
	before midnight on the study day • County Council A: university setting, small general hospital. • County Council B: non-university setting, three general hospitals		• 78% of PUs were HAPU **Community-acquired PU** • PUs documented at time of admission to the hospital or within the first 24 hours • 3·3%		lesions but no PU. • 55% category 1 • Most severe HAPU: • sacrum (n=44, 32.6%), • heel (n=50, 37.0%), • hip (n=4, 3.0%) and other locations (n=37, 27.4%)	or gero-psychiatric units. Excluded psychiatric units, maternity units, day care and hospice units.		many patients might (60%) have led to failure of the nurses to record community-acquired admission (present at the time of admission), leading to false-positive HAPU.
(Gunningberg, Hommel et al., 2013)	Conducted in hospitals and nursing homes 2011 in Sweden (total n=over 35,000) Hospital setting n = 16,466	Cross-sectional		**Point prevalence PU** • categories I to IV = 16.6% • 11% of the PU were present on admission • 15.5% in university hospitals to 17.8% in general hospitals • Around 50% PUs category 1	• The Modified Norton Scale was used to assess the risk to develop PU • EPUAP-NPUAP PU classification	Entire hospitals in Sweden (part of a larger study that included nursing homes)	CL	Approx 70% of hospitalized persons in Sweden were included
(Mulligan, Prentice et al., 2011)	Conducted in 86 public hospitals in Australia (WA) for 4 years (2007 – 2011 excl 2010) excluded psychiatric, unqualified newborns, hospital in the home, day surgery 2007 n = 2777 2008 n= 3024 2009 n = 3110 2011 n = 3194	Cross-sectional	**HAPU** 2007: 7.8% (95% CI 6.8 to 8.8) 2008: 9.3% (95% CI 8.3 to 10.3) 2009: 6.3% (95% CI 5.4 to 7.1) 2011: 7.4% (95% CI 6.5 to 8.3)	**Point prevalence** 2007: 10.9% (95% CI 9.8 to 12.1) 2008: 12.5% (95% CI 11.3 to 13.6) 2009: 9.5% (95% CI 8.5 to 10.5) 2011: 11.0% (95% CI 9.9 to 12.0)	Stage 1: 38 to 45% of all PUS over the 4 surveys Stage II: 40 to 44% Stage III 4 to 7& Stage IV: 5 to 7%	Hospitals in Australia	CL	• Surveyors all underwent education and competency prior to data collection • Included 88 to 93% of eligible inpatients each year
(Dugaret, Videau et al., 2012 (epub))	Conducted in one emergency department in France over 15 days • n=602 adult patients • mean age 53.6 years (range 18 to 101 years)	Prospective	• Cumulative incidence: 4.9% • Cumulative incidence in patients > 75yrs: 15.7%	• Prevalence on admission: 7.8% (n=47) • **Prevalence at discharge**: 12.3% (n=74) • New PUs were primarily Stage I (89.5%)	• Heels and sacrum were main sites of PUs • 89.5% stage 1 PU	Emergency department	CL	Only one ED included
(Sato and Ichioka, 2012)	N=226 (hospital 78 and home care group 148) One month after the great east Japan earthquake	Retrospective study	• 6 (7.7%) home care group • 39 (26.4%) community group • Total= 45 (19.15%)		Community group most were Stage I and Stage II Inpatients 6 developed Stage	Hospital and community (Japan)	CL	No information about PU stage 1 and 2

Reference	Subject	Design/method	Incidence & Follow up	Prevalence	Stage/category	Clinical site	database (DB) clinical (CL)	Limitations and comments
	(during the power failure).				III and Stage IV pressure ulcers, 4 required surgical debridement			
Aged care settings								
(Gunningberg, Hommel et al., 2013)	Conducted in hospitals and nursing homes 2011 in Sweden (total n=over 35,000) Nursing home setting n = 18 592	Cross-sectional		**Point prevalence PU** • Categories I to IV = 14.5% • range from 12.3% in dementia care to 21.9% in short term care • Category 1 PU only ranged from 47.7% (short term care) to 61.5% (dementia care)	• The Modified Norton Scale was used to assess the risk to develop PU • EPUAP-NPUAP PU classification	Nursing homes in Sweden (part of a larger study)	CL	Approx 70% of hospitalized persons in Sweden were included
(Barba, Martínez et al., 2011)	Database analysis of minimal basic data from older adult internal medicine admissions to National Health Service hospitals in Spain between 2005 and 2007. • n= 90,679 aged >90 years. • n= 1,044,744 aged 65 to 90 years	Multivariate and descriptive analysis comparing demographic variables between patients aged >90 years old and patients aged 65 to 90 years old	**Cumulative incidence** • 5.0% in those aged over 90 years • 2.8% in those aged 65 to 90 years • Predictor death for PU (odds ratio [OR] 1.55, 95% CI 1.45 to 1.66)		Not reported	Medical inpatients in Spanish hospitals	DB	• Database analysis • Only includes patients discharged from an internal medicine department
(Moore and Cowman, 2012)	Conducted in 12 urban and rural long-term aged care settings in Ireland (n=1100) • 70% sample female, 75% aged 80 years or over, all Irish and white	Cross-sectional		**PU prevalence** (unclear over what specified period the data was collected) 9% 56% of PUs occured in aged 80 to 89 age group.	PUs were graded using the EPUAP pressure ulcer classification • Stage I 28% • Stage 2 33% • Stage 3 15% • Stage 4 24% • Primarily located on sacrum (58%) and heel (25%)	Long term aged care in Republic of Ireland	DB/CL	Data for this study were obtained from nursing notes and verified by clinical inspection: may have underestimated PU rate
(Igarashi, Yamamoto-Mitani et al., 2013)	Conducted in a random selection of 720 hospitals in Japan, of which 180 returned useable data, only 135 included in survey	Cross sectional	1.9% ± 3.1%	**Point prevalence** 9.6% ±7.9% • Sacrum 60.5% ± 33.6 • Calcaneal bone 9.7% ± 17.6	• Stage I 15.4% ± 28.2 • Stage 2 40.0% ± 36.1 • Stage 3 38.0% ± 36.2 • Stage 4 7.3% ± 20	Long term care hospitals in Japan	CL	• Response rate only 25% • Excluded long term care insurance beds

Reference	Subject	Design/method	Incidence & Follow up	Prevalence	Stage/category	Clinical site	database (DB) clinical (CL)	Limitations and comments
	• Mean age 50.2 yrs ±6.8 yrs			• Trochanter 15.7% ± 26.0 • Other 24.0% ± 30.9				• Unclear how many beds
Operating room								
(Scarlatti, Michel et al., 2011)	• n=199 surgery patients in a private general hospital • data collected between February and May 2007 • inclusion criteria: conscious, age >18 years, scheduled for surgery >2 hours • Exclusion: preoperative skin lesion, impaired physical mobility, reduced tissue perfusion, poly-trauma	Longitudinal case series study	• **Hospital acquired PU in OR** • Physical examination was conducted pre-op and first day post-op • 20.6% (95% CI 15.2% to 26.9%) • 74 PU developed on 48 patients • 61% had only one PU, 39% had > 1 PU		• 98.6% Stage I or II PU using NPUAP classification Locations: • 56.7% on trunk region • 35.1% frontal trunk	Surgical Brazil	CL	• Possible underestimation of incidence as physical exam performed one day post operatively
(Bulfone, Marzolil et al., 2012)	• 102 patients who underwent major surgery who were on the operating table for > 2 hrs and observable for at least 6 days post-op. • Excluded: transfer to ICU or other hospital after surgery	Longitudinal study	• Overall Incidence during intraoperative period: 13/102 (12.7%) • During general surgery: 4/13 (38.4%) • During vascular surgery: 2/13 (15.3%)		Pressure ulcers were graded as per NPUAP classification	Operating theatres in a teaching hospital (North Italy)	CL	
Critical care								
(Bry, Buescher et al., 2012)	• General and critical care admissions over 12 to 17 months (only adult patients) • Excluded: paediatric, obstetric, and psychiatric units • Mean age 67.3 years • 74.4% patients were black, 5.8% Hispanic, 8.5% white	Prospective study on PU prevention strategies Retrospective chart review to identify risk factors	**HAPU Incidence rate** • ranged from 3.7 to 7.2 per 1000 patient days over 6 quarters • average 5.0 per 1000 patient days		• HAPU reported by nurses to researchers who then assessed and staged PU • No information about PU staging system reported ○ SDTI 45% ○ Stage II PU 14.6% ○ Stage III PU 20.7% ○ Unstageable 19.5%	Urban trauma unit (USA)	CL	• Single center data • No direct observation on management strategies • Lack of information about HAPUs identified
Community care								
(Tsai, Lin et al., 2012)	• Matched pairs of home care patients and their caregivers (n=168) followed for 4 to 6 weeks	Cross-sectional	Incidence of new PU while in home care was 14.3%		Used NPUAP classification • Stage I 20.8% • Stage II 75% • Stage III 4.2%	Home care setting (Taiwan)	CL	Participants readmitted to hospital were excluded

Reference	Subject	Design/method	Incidence & Follow up	Prevalence	Stage/category	Clinical site	database (DB) clinical (CL)	Limitations and comments
	• Exclusion: existing PU, readmission to hospital • Mean age 76 years							
Rehabilitation								
(Ploumis, Kolli et al., 2011)	Patients admitted to rehabilitation from level 1 SCI trauma center (n = 78) and admitted from non-SCI level 1 trauma centers (n = 131) from 2005 to 2007 Total n= 209	Retrospective study		**Point prevalence on admission** More patients from non-SCI centres (n = 44, 34%) than SCI centres (n = 24, 12%) had PUs (p=0.001) Percentage of patients with grade III and IV pressure ulcers (6% SCI, 11% non-SCI)	• Pressure ulcers were graded as per NPUAP classification. •	Inpatient rehabilitation traumas	DB (SCI patients) CL	Incomplete discharge notes from the acute care hospital were excluded.
Pediatric populations								
(Schluer, Halfens et al., 2012)	• n= 412 • Inclusion: hospitalised children (ages 24 hours to 18 years) in 14 paediatric in 24 hour period in June 2009. • Inclusion: hospitalised for at least 1 day • Exclusion: psychiatric wards, no consent or refusal	Cross-sectional		**Overall PU prevalence** 35% • 80% category 1 ulcers • Prevalence highest in PICU (16/36, 44%) and neonatology (47/109, 43%). • prevalence PUs for patients with external device was 40%	EPUAP classification 94% PUs were Category I Category II and above was 3%	14 paediatric hospitals including PICU, neonatal intensive care units (NICU), surgical, medical and rehabilitation (Switzerland)	CL	Category 1 PUs may be over- or underdiagnosed in this study remains unclear, although the interrater reliability suggest the scores are reliable.

References

Barba, R., J.M. Martínez, A. Zapatero, et al. (2011). "Mortality and complications in very old patients (90+) admitted to departments of internal medicine in Spain." European Journal of Internal Medicine **22**(1):49-52.

Bry, K.E., D. Buescher and M. Sandrik. (2012). "Never say never: a descriptive study of hospital-acquired pressure ulcers in a hospital setting." Journal of Wound, Ostomy and Continence Nursing **39**(3):274-81.

Bulfone, G., I. Marzolil, R. Wuattrin, et al. (2012). "A longitudinal study of the incidence of pressure sores and the associated risks and strategies adopted in Italian operating theatres." Journal of Perioperative Practice **22**(2):50-6.

Dugaret, E., M.N. Videau, I. Faure, et al. (2012 (epub)). "Prevalence and incidence rates of pressure ulcers in an Emergency Department." International Wound Journal.

Gunningberg, L., N. Donaldson, C. Aydin, et al. (2012). "Exploring variation in pressure ulcer prevalence in Sweden and the USA: Benchmarking in action." Journal of Evaluation in Clinical Practice **18**(4):904-10.

Gunningberg, L., A. Hommel, C. Bååth, et al. (2013). "The first national pressure ulcer prevalence survey in county council and municipality settings in Sweden." Journal of Evaluation in Clinical Practice **19**(5):862-7.

Gunningberg, L., N.A. Stotts and E. Idvall. (2011). "Hospital-acquired pressure ulcers in two Swedish County Councils: cross-sectional data as the foundation for future quality improvement." International Wound Journal **8**(5):465-73.

Igarashi, A., N. Yamamoto-Mitani, Y. Gushiken, et al. (2013). "Prevalence and incidence of pressure ulcers in Japanese long-term-care hospitals." Archives of Gerontology and Geriatrics **56**(1):220-6.

Inan, D. and G. Öztunç. (2012). "Pressure ulcer prevalence in Turkey: A sample from a university hospital." Journal of Wound, Ostomy and Continence Nursing **39**(4):409-13.

Molon, J.N.D. and E.P. Estrella. (2011). "Pressure ulcer incidence and risk factors among hospitalized orthopedic patients: Results of a prospective cohort study." Ostomy Wound Management **57**(10):64-9.

Moore, Z. and S. Cowman. (2012). "Pressure ulcer prevalence and prevention practices in care of the older person in the Republic of Ireland." Journal of Clinical Nursing **21**(3-4):362-71.

Mulligan, S., J. Prentice and L. Scott. WoundsWest Wound Prevalence Survey 2011 State-wide Overview Report. . Perth, Western Australia: Ambulatory Care Services, Department of Health 2011.

Ploumis, A., S. Kolli, M. Patrick, et al. (2011). "Length of stay and medical stability for spinal cord-injured patients on admission to an inpatient rehabilitation hospital: a comparison between a model SCI trauma center and non-SCI trauma center." Spinal Cord: The Official Journal Of The International Medical Society Of Paraplegia **49**(3):411-5.

Sato, T. and S. Ichioka. (2012). "Pressure ulcer occurrence following the great East Japan earthquake: observations from a disaster medical assistance team." Ostomy Wound Management **58**(4):70-5.

Scarlatti, K.C., J.L.M. Michel, M.A. Gamba, et al. (2011). "[Pressure ulcers in surgery patients: incidence and associated factors]." Revista da Escola de Enfermagem da U S P **45**(6):1372-9.

Schluer, A.B., R.J. Halfens and J.G.A. Schols. (2012). " Pediatric pressure ulcer prevalence: A multicenter, cross-sectional, point prevalence study in Switzerland." Ostomy Wound Management **58**(7):18-31.

Tsai, Y.-C., S.-Y. Lin, Y. Liu, et al. (2012). "Factors related to the development of pressure ulcers among new recipients of home care services in Taiwan: A questionnaire study." International Journal of Nursing Studies **49**(11):1383-90.

Prevention of Pressure Ulcers

RISK FACTORS

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	P value; odds ratio (OR); CI	Limitations	
(Almirall, Leiva et al., 2009)	Prospective cohort study **to analyse total APACHE III score association to PU development**	Participants admitted to an ICU between 01/2001 and 12/2001 (n=351 patients). Inclusion: • Adults admitted to ICU for ≥48hrs • No PU on admission Exclusion: • PU at hospitalisation Characteristics: • n=236 males; n=115 females • mean age 65 (SD 14.8) yrs; range unknown • No loses to follow up (FU) • Sample without baseline PU Mean time of hospitalization: 7 days.	• Merging the APACHE III (objective medical score used at ICUs to predict the severity and mortality rate of a disease) and Norton Scale scores. • Skin inspected for PU within 48hrs after hospitalization. • After measurement a follow-up diary was used for PU progress and reference to scoring. Personnel using diary blinded to APACHE III score.	Outcome definition: development of ≥grade 1 PU. Skin inspected within 48hrs and follow-up diary created to detect PU appearance and progress • Mean length of hospitalization 7 days (mean length of follow-up and range unknown) PU definition for regression: ≥Grade 1 NPUAP staging system Statistical methods: Multivariate analysis was adjusted to age and sex.	N=44 (12.5% incidence) developed PUs (grades not reported) No. in final model: 351 N=6 risk factors entered into multivariate analysis: • age, sex, duration of ICU hospitalisation (days), Norton score, APACHE III scale score, number of PU (grade I or higher) developed during hospitalization. N=3 risk factors from final multivariate analysis (MV) model: • Days of hospitalization ICU • Norton scale scoring ≤14 • APACHE III ≥50	Patients having the highest risk of PU were those whose Norton score was less than or equal 14 and the APACHE III scale score higher than or equal to 50 (Odds Ratio: 37.9, 95% CI 11.16-128.47) **Days of hospitalization ICU** OR raw: 1.13, CI: 95% 1.07 to 1.19; adjusted OR: 1.14, CI 95% 1.08 to 1.20 **Norton scale scoring ≤14** OR raw: 14.68, CI 95% 4.45 to 48.43; adjusted OR: 14.16, CI 95% 4.27 to 46.92 **APACHE III ≥50** OR raw: 16.12, CI 95% 7.15-36.33; adjusted OR: 16.19, IC 95% 7.16 to 36.61	• Insufficient number of events • Not adequate strategy for model • No confounders considered • PU categories for developed PU not reported • raters not clearly described • no rational for Norton cut-off 14	**Level of evidence: 4** **Quality: low**
(Baumgarten, Rich et al., 2012)	Prospective cohort study **investigating care-related risk factors for hospital-acquired PU in elderly adults with hip fractures**	Participants recruited from 9 acute care hospitals (n=658 surgical patients) Inclusion: • Elderly adults aged ≥65 yrs • surgery for hip fracture Characteristics: • n=152 males; n=506 females • mean age 83.2 yrs; range	Not reported	• Outcome definition: development of ≥ 1 new Stage 2 or higher hospital-acquired PU. • PU definition for regression: ≥ Stage 2 NPUAP staging system • Skin inspected for PU at baseline and alternating days until hospital discharge (11 assessments) • mean follow-up 3 days	N=96 (14.6%) developed 121 hospital-acquired PUs • 88% PUs were stage 2; remainder unstageable No in final: 560 – 643/658 (sample varies for factors); fully adjusted n=456 N=16 risk factors entered into MV analysis (13 covariates + 3 care-related factors (group 1 or 2): • Co-variates: mini mental state	Risk factors from final model: **Length of stay (hrs) in ED** >4-6 hrs: p=0.03;OR 0.68; 95% CI 0.48 to 0.96 >6 hrs:p = 0.047;OR 0.68; 95% CI 0 0.46 to 0.99 **Time (hrs) from admission to surgery** ≥24 hrs: <.001; 1.62; 1.24-2.11 **General anesthesia** P=0.005; OR= 0.66; 95% CI 00.49 to 0.88	• Not clear how variables categorized • Only presented partial model (i.e. data for allrisk factors (RFs) explored not presented) • Insufficient number of events • Data dependent	**Level of evidence: 4** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	P value; odds ratio (OR); CI	Limitations	
		not reported • n=0 lost to follow-up • N=19 (3%) with baseline PU – no grade provided		(range 0.5 to 21 days) • Statistical methods: Poisson regression model with log link function. Two groups of care factors were considered and a modelling strategy applied.	examination (MMSE) score; history chronic deficit; risk nutrition-related complications; body mass index (BMI); activity level; preexisting PU; Rand sickness admission score; age; sex; preadmission residence; albumin level; no. orientations at baseline; admission hospital • Group 1 factors: timing (day) of transport to hospital; type of transport to hospital; length of stay in ED • Group 2 factors: time between inpatient admission and surgery; surgery duration; type of anesthesia			
(Bergquist-Beringer & Gajewski, 2011)	Retrospective cohort study **investigating predictors of PU development in older home health patients**	Participants recruited from home healthcare between Sept 30, 2007 to Jan 30, 2009 (non-hospice) (n=5395 non-surgical patients); n=5116 PU free at baseline Inclusion: • Nonhospice patient • Aged ≥60 • Admitted for intermittent skilled home healthcare • Only first admission considered for patients admitted more than once Characteristics: • n=2072 males; n=3323 females • mean age 78.2 yrs; range 60 – 103 yrs • n=0 lost to follow-up • N=279 with baseline PUs - no grade provided.	Not reported	• Outcome definition: Development of new ≥ Stage 1 PU according to OASIS Skin and Wound Status M0 Items (uses NPUAP classification). • PU definition for regression: development of new PU • OASIS data are gathered on admission, every 60 days while on the active caseload, following an inpatient facility stay of ≥24 hrs with return for more home, after significant change in condition, and discharge. • mean length of follow-up 35.1 days (range unknown) • Statistical methods: Multiple logistic	Model 1 N=71/5395 (1.3% incidence) developed 92 PUs; • n=31 stage 1 PU; n=43 stage 2 PU; n=10 stage III PU; n=5 stage IV PU; n=3 nonobservable Model 2 N=49/5116 (0.96%) No in final: 5% of overall sample lost; 2nd model 30% of PU sample excluded N=21 risk factors entered into MV analysis: • Indwelling or suprapubic catheter; enteral nutrition; live with paid help; PU on admission; urinary incontinence; bowel incontinence; frequency of confusion; cognitive functioning; depressed mood; memory deficit; impaired decision making; verbal	*Model 1 (n=71/5393; includes those with PUs on admission)* **Bowel incontinence** 0.042; 2.84; 1.04-7.72 **Physical aggressive behaviour** 0.046; 4.57; 1.03-20.37 **Grooming** 0.032; 1.97; 1.06-3.66 **Ability to dress the upper body (someone must help)** 0.052; 1.97; 0.99-3.92 **Ability to dress the upper body (depends entirely on another)** 0.303; 1.78; 0.60-5.29 **Ability to dress the lower body (depends entirely on another)** 0.016; 2.97; 1.23-7.19 **Toileting (unable to get to/from)** 0.013; 5.30; 1.42-19.77 **Toileting (totally dependent)** 0.125; 2.23; 0.80-6.24 **Transferring (unable to transfer self/can weight bear and pivot** <0.001; 5.20; 2.27-11.89 **Transferring (unable to transfer**	• Only 3 FU points at long intervals but community setting • Insufficient number of events	**Level of evidence: 4** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	P value; odds ratio (OR); CI	Limitations	
				regression	disruptive behavior; physical aggressive behavior; frequency of behavior problems; grooming, ability to dress the upper body; ability to dress the lower body; bathing; toileting; transferring; ambulation N=9 risk factors from final model:	**self/weight bear/pivot when transferred by another person** 0.017; 4.22; 1.30-13.73 **Transferring (bedfast)** 0.130; 3.01; 0.72-12.53 **Ambulation (chairfast: unable to ambulate/able to wheel self)** 0.009; 5.52; 1.52-20.05 **Ambulation (chairfast: unable to ambulate or wheel self)** 0.009; 5.70; 1.53-21.24 **Ambulation (bedfast)** 0.175; 3.52; 0.571-21.74 **PU on admission** <0.001; 4.47; 2.44-8.21 <u>Model 2</u> *(n=49/5116; excludes those with PUs on admission)* **Bowel incontinence** 0.005; 4.81; 1.61-14.34 **Ability to dress lower body (depends entirely on another)** 0.026; 3.26; 1.15-9.21 **Transferring (unable to transfer self/can weight bear and pivot)** 0.001; 5.12; 1.89-13.87 **Transferring (unable to transfer self/weight bear/pivot when transferred by another person** 0.010; 6.40; 1.55-26.50 **Ambulation (chairfast: unable to ambulate/able to wheel self)** 0.019; 6.18; 1.35-28.36 **Ambulation (chairfast: unable to ambulate or wheel self)** 0.007; 7.91; 1.74-35.96		
(Chan, Pang et al., 2009)	Prospective cohort study **investigating the predictive validity of the modified**	Participants recruited from2 orthopaedic wards of an acute care hospital (n=197 Inclusion: • Chinese • Aged ≥18 yrs	"Standard care" - nurses performed preventive nursing interventions without knowing Braden and modified Braden scores	Outcome definition: development of new Stage 1 or higher PU. Skin inspected for PU daily • mean length of follow-up not reported	N=18 developed 18 PUs • n=4 stage 1; n=14 stage 2 No. in final: n=197 (assumed) N=4 risk factors: • Sensory perception (Braden);	N=3 risk factors from final model: **Sensory perception (Braden)** 0.016; 0.214; 0.061-0.746 **Body build for height** 0.030; 0.470; 0.238-0.929 **Skin type** 0.002; 0.217; 0.084-0.561	• Do not discuss mobility as a risk factor • Insufficient number of events	**Level of evidence: 4** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	P value; odds ratio (OR); CI	Limitations	
	Braden scale for prediction of PU risk in orthopaedic patients	• Expected ≥5 admission • Not ambulant • No PU on admission. Characteristics: • n=30 males; n=167 females • mean age 79.4 yrs; range 35 – 98 yrs • Numbers lost to follow-up not clearly stated • N=0 with baseline PU	assigned to subjects.	(average hospital stay 10.8 day; range 5- 53 days) PU definition for regression: ≥Stage 1 NPUAP staging system Statistical methods: Logistic regression	Mobility (Braden); Body build for height; Skin type			
(Connor, Sledge et al., 2010)	Prospective cohort study **examining peri-operative factors predictive of PUs in patients undergoing urologic surgical procedure**	Participants recruited from academic center with urologic-specific OR and inpatient urologic surgery unit (n=538) Inclusion: • English speaking adults • Undergoing scheduled inpatient urologic surgical procedures • Admitted for ≥24 hrs of post-operative care Exclusion: • Pre-existing PU or open skin wound on dependent areas subject to pressure during surgery Characteristics: • n=379 (76%) males; n=119 (24%) females • mean age 58.9 (SD 12.66) yrs; range 20-89 yrs • N=40 enrolled patients excluded • Sample without baseline PU	• When a patient arrived in the post-anesthesia recovery room (PAR), a data collector determined the manner in which patient positioning in OR and turned the patient away from the side that was dependent during surgery. • Minimum 10 min wait before visually inspecting and palpating the skin to determine presence of pressure and/or actual skin breakdown.	• Outcome definition: development of new PU in the PAR. • Skin inspected for PU pre-operatively and post-operatively (PO) when patient arrived to PAR, and PO daily until PO day 3 • mean length of follow-up not reported • PU definition for regression: development of new ≥grade 1 PU NPUAP staging system • Statistical methods: Binary logistic regression with multiple predictors	N=25 (5%) developed Stage 1 PUs No in final: n=498 (assumed) N=8 risk factors entered into MV analysis: • Braden scores (pre- and post-op); length of surgery; length of anesthesia time; time BP <50 mmHg diastolic; BMI; position; type of fluids on table surface; type of support device used intra-operatively.	N=2 risk factors from final model: **BP <50** 0.046; 1.007; 1.000-1.014 **Perfusion time (anesthesia)** 0.038; 1.005; 1.000-1.010 **Constant** 0.000; 0.011	• Insufficient number of events	**Level of evidence: 4** **Quality: Low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	P value; odds ratio (OR); CI	Limitations	
(Cremasco, Wenzel et al., 2013)	Prospective cohort study investigating **the relationship between nursing workload, illness severity and PU risk in the ICU**	Participants recruited from 3 ICUs of one university hospital (n=160 mixed patients) Inclusion: • Without PU at admission to ICU • Minimum stay 24 hrs Characteristics: • n=46.2% males; n=53.8% females • mean age 55.5 yrs; range 19-87 yrs • No. lost to follow-up not reported • N=0 with baseline PU	NAS includes nursing activities: monitoring and control procedures; lab, biochem and micro investigations; medications; hygiene; drain care; mobilisation; positioning; support (incl relatives); administrative tasks; ventilatory, cardiovascular, renal, neurological and metabolic support; and specific interventions.	Outcome definition: development of new PU. Skin inspected daily for PU until PU development, discharge or death mean length of follow-up not reported (average ICU stay 14.1 days) PU definition for regression: development of new PU, ≥grade 1 EPUAP staging system Statistical methods: Logistic regression using stepwise procedure	N=55 (34.4%) developed PUs (no. and grade not stated) No in final: n=160 (assumed) N=7 risk factors entered into MV analysis: • age: sex; length of ICU stay; length of hospital stay; Braden scores; NAS scores; SAPSII scores	N=4 risk factors from final model 4(clinically relevant predictors): **Sex** 0.014; 5.603; 1.421-22.091 **Length of ICU stay** 0.002; 1.120; 1.043-1.202 **NAS scores** 0.011; 0.196; 0.855-0.980 **SAPSII scores** 0.035; 1.058; 1.004-1.114	• Insufficient number of events • Unclear how data on PU incidence were retrieved • Uncertainty about validity and reliability of measurement of data, • unclear sample size for regression analysis, • missing information on quality of regression analysis	**Level of evidence: 4** **Quality: low**
(de Souza & de Gouveia, 2010)	Prospective cohort study **investigating associations between PU occurrence and socio-demographic and clinical factors.**	Participants recruited from 4 long-term care facilities (n=94 elderly care, non-surgical patients) Inclusion: • Elderly adults aged ≥60 yrs • Braden Scale score ≥18 Characteristics: • n=37.2% males; n=62.8% females • mean age 79.1 yrs; range 60-103 yrs • n=0 lost to follow-up • N=27 with baseline PU – no grade provided	Facilities had similar professional and physical resources; none had a specific protocol to assess PU risk and prevent or treat PU. Empiric treatment was initiated when a ≥stage II PU was detected.	Outcome definition: development of Stage 1 or higher PU. Skin inspected for PU 3-times weekly on alternate days • follow-up for 90 days PU definition for regression: ≥Stage 1 NPUAP staging system Statistical methods: Stepwise logistic regression.	N=37 developed 48 PUs • n=26 patients developed stage 1 PU; n=11 stage 2; no stage 3 or 4 PU developed during study period No. in final: 94 (assumed) N=12 risk factors entered into MV analysis: • Age; BMI; Total Braden score; Gender; previous PU; regular use of neuroleptic or psychotropic medications; Braden subscale moisture; Braden subscale nutrition; Braden subscale friction and shear; time residing in long term care facility; smoking; presence of a number of comorbidities	N=2 risk factors from final model: **Female gender** 0.012; 3.46; 1.32-9.09 **Previous PU** 0.038; 2.76; 1.06-7.20	• Insufficient number of events	**Level of evidence: 4** **Quality: low**
(Kwong, Pang et al., 2009)	Prospective cohort study investigating **factors**	Participants recruited from 4 private-for-profit nursing homes (n=346 non-surgical patients)	Not reported	• Outcome definition: development of new PU • Skin inspected for PU	N=80/318 developed at-least one PUs (range 1-5) • n=57 stage 1; n=18 stage 2; n=3 stage 3; n=2 non-stage	N=6 risk factors from final model 3: **Activity (bedfast)** ≤0.001; 24.64; 7.81-77.73	• Insufficient number of events	**Level of evidence: 4** **Quality:**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	P value; odds ratio (OR); CI	Limitations	
	influencing PU development in older nursing home residents	Inclusion: • Aged ≥65 yrs • Present in nursing home on days of data collection • Willing to participate Characteristics: • n=129 males; n=217 females • mean age 82.3 yrs; range 65-100 yrs • n=0 lost to follow-up • N=318/346 PU free at PU – no grade provided for the 28 with PUs		every two days • follow-up for 4 weeks • PU definition for regression: ≥Stage 1 NPUAP staging system • Statistical methods: Logistic regression applied.	No. in final: 318/346 PU free at baseline N=10 risk factors entered into MV analysis (Braden and modified-Braden): • Pneumonia Yes; renal failure Yes; stroke Yes; No. nurses working in the home; No. nursing assistants per 100 residents; Sensory perception completely limited; activity-bedfast; activity-chairfast; mobility-completely immobile; friction and shear problem	**Activity (chairfast)** ≤0.001; 8.23; 2.86-23.66 **Pneumonia Yes** Not statistically significant **Renal failure Yes** 0.014; 3.66; 1.29-10.38 **Stroke Yes** 0.009; 2.33; 1.24-4.39 **No nurses working in the home** ≤0.001; 0.26; 0.13-0.53 **No. nursing assistants per 100 residents** ≤0.001; 1.09; 1.05-1.12		**Low**
(Man & Au-Yeung, 2013)	Retrospective cohort study **examining whether a hypotensive episode (systolic blood pressure less than or equal to 90 mm Hg) is associated with PU occurrence.**	Participants recruited from a convalescence ward in Pok Oi Hospital in Hong Kong (n=229 medical patient admitted through the ED with acute illness) Inclusion: • Aged ≥65 yrs • Stay in convalescence was ≥5 days Characteristics: • n=109 males; n=120 females • mean age 83.35 yrs (SD 7.69) • n=0 lost to follow-up • N=90/229 with baseline PU	Not reported	• Outcome definition: development of new PU any stage; PU on admission regarded as pre-existing PU • Not reported frequency of skin inspection; medical records for entire hospital stay for each patient reviewed. • number, stage, and site of PU recorded. • Mean length of stay (LOS) 24.02 days (SD 17.65) • PU definition for regression: ≥ stage 1 NPUAP staging system • Statistical methods: multiple logistic regression	N=17 developed 24 new PU (n=6/24 stage 1; n=16/24 stage 2; n=2/24 suspected deep tissue injury) N=7/90 with baseline PU developed a new PU (stage not reported) No. in final model=229 assumed N= 5 risk factors entered into MV analysis: • SBP ≥90 mm Hg; use of restraint; congestive heart failure (CHF); pulse pressure on admission; LOS	N=3 from model adjusted for pre-existing PU, age, sex: **SBP ≥90 mm Hg** 0.002; 6.80; 2.07-22.34 **Use of restraint** 0.04; 3.61; 1.04-12.51 **LOS** 0.03; 1.03; 1.002-1.06 N=2 from model on incident PU: **SBP ≥90 mm Hg** 0.001; 6.71; 2.07-21.7 **LOS** 0.03; 1.03; 1.002-1.05	• Insufficient number of events	**Level of evidence: 4 Quality: low**
(Manzano, Navarro et al., 2010)	Prospective cohort study **to determine the incidence of PUs and**	Participants recruited from 9 medical-surgical ICUs (n=299 mixed patients) Inclusion:	Protocolised preventative measures clearly reported as follows: ICU A: turning every	Outcome definition: development of new PU Skin inspected daily for PU during ICU stay or until PU	• N=47 developed PU (≥grades II) • No. in final not reported; n=299 assumed • N=at least 19 risk factors entered into MV analysis:	N=6 risk factors from final model: **Age** 0.004; 1.042; 1.013-1.072 **Winter period** <0.001; 4.60; 1.99-10.59	• Not clear exactly how variables entered into model (e.g. SOFA)	**Level of evidence: 4 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	P value; odds ratio (OR); CI	Limitations	
	risk factors for their development	• Patients on mechanical ventilation (MV) with either endotracheal intubation or noninvasive ventilation for 24hrs • Aged >18 yrs Exclusion: • Pregnant patients Characteristics: • n=205 males; n=94 females • mean age 60 yrs +/-17 • n=0 lost to follow-up • N=291/299 PU free (no grade provided)	4hrs on standard hospital mattress; ICU B: turning every 2hrs on standard hospital mattress; ICU C: turning every 4hrs on alternating-pressure mattress; ICU D: turning every 4hrs on alternating-pressure mattress ICU E: turning every 2hrs on alternating-pressure mattress	developed • Mean length of stay before PU onset 14 days (range 1-54 days) PU definition for regression: ≥Grade 2 EPUAP staging system Statistical methods: Forward Stepwise logistic regression	• Age; body weight ≤60 kg; winter season; days of pre-ICU hospital stay; reason for surgical admission; first-day respiratory SOFA score; first-day Pao2/FIo2; medical admission; total Sequential organ failure assessments (SOFA); septic shock; acute respiratory distress syndrome (ARDS); pneumonia; no multiple organ failure; length of ICU stay before PU onset; duration of MV before PU onset; hospital LOS; hospital; mortality; respiratory failure on days 1,2,4 or 10 of ICU; cardiovascular failure	**Time on MV before PU** 0.024; 1.042; 1.005-1.080 **First-day respiratory SOFA** 0.037; 1.56; 1.026-2.360 **Fourth-day cardiovascular SOFA** 0.012; 1.33; 1.066-1.664	• Inappropriate strategy for model building (i.e. time dependent covariates) • Insufficient number of events	
(Roca-Biosca, Velasco-Guillen et al., 2012)	Prospective cohort study **investigating risk factors related to PU development in critically ill patients**	Participants admitted to one ICU (n=236 patients) Inclusion: • Adults admitted to ICU for >24hrs • Patients who already had PU at hospitalization were also included Characteristics: • n=70.3% males; n=29.7% females • mean age 56 (SD 17.7) yrs; range unknown • Number lost to follow-up not reported but assumed 0% • N=18 with baseline PU	PU preventative interventions not reported For risk evaluation of developing PU, the risk scale EMINA was used and for seriousness of disease determination at hospitalization the APACHE II score was used.	Outcome definition: development of new PU Follow up until new PU developed, patient transfered or death • Mean time in ICU 12.39 days (mean length of FU and range unknown) PU definition for regression: ≥Grade 1 (location and stage according to the definition of Group Institut Catalá de la Salut (ICS) staging system) Data analyses: Kaplan-Meyer survival and COX regression analysis (significance p <0.05)	N=26 developed 38 PUs (11.02% incidence (IC 95% 6.81-15.22)) no. and grade of PUs not reported) • N=8/218 developed new Pus (incidence 3.7%) • Total N of PUs=38; 13 (34.2%) grade I; n=24 (63.2%) grade II; n=1 (2.6%) grade III • PU locations: n=12 faceal (ear, nose, mouth); n=12 sacral region; n=2 trochanter; n=1 occipital; n=3 genital area; n=5 feet (heel and external lateral region); n=3 Other • No. in final: unknown • N=6 risk factors entered into MV analysis: • risk assessment score (EMINA); BMI; support surface (dynamic); nutrition; norepinephrine; sedation (days)	BMI ≥30, EMINA and norepinephrine are predictive risk factors. Sedation days, dynamic support surfaces, hyperproteic nutrition, turning and polyurethane nasogastric feeding tube established as protective factors against PU. N=6 risk factors from final model: **EMINA mean** 0.044; 1.6; 1.0-2.7 **Hyperproteic nutrition** 0.063; 0.9; 0.9-1.0 **Sedation in days** 0.036; 0.9; 0,9-1.0 **Dynamic support surface** <0.001; 0.9; 0.8-0.9 **Norepinephrine** 0.031; 3.7; 1.1-12.1 **BMI mean** 0.218; 1.0 1.0-1.1;	• Insufficient number of events • Not adequate strategy for model • Patients with existing PUs were included in the final model • Incidence measure not valid	**Level of evidence: 4** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	P value; odds ratio (OR); CI	Limitations	
(Slowikowski & Funk, 2010)	Prospective 2-phase study investigating factors associated with PUs in surgical intensive care patients	Participants recruited from 14-bed hospital ICU (level-1 trauma centre) (n=369) Inclusion: • In ICU between March 2005 and May 2008 Characteristics: • n=208 males; n=161 females • mean age 58.3 yrs; range 16-103 • n=0 lost to follow-up • PU status at baseline not reported	Not reported	Outcome definition: development of new grade 1 or higher hospital-acquired PU. Skin inspected for PU very 2 to 3 days • length of follow-up not reported PU definition for regression: ≥Grade 1 NPUAP staging system Statistical methods: Stepwise logistic regression	N=88 (23.9%) developed hospital-acquired PUs (no. and grade of PUs not reported) No. in final: 369 N=8 risk factors entered into MV analysis: • Diabetes; not repositioned; age ≥70; edema; ventilator support; orthotics; hemodialysis or continuous renal replacement therapy; Braden Scale score	N=3 risk factors from final model: **Braden Scale score** <.001; 1.30; 1.15-1.47 **Diabetes** 0.019; 1.93; 1.11-3.35 **Age ≥70** 0.004; 2.14; 1.27-3.62	• Medical records reviewed	**Level of evidence: 2** **Quality: High**
(Tescher, Branda et al., 2012)	Retrospective record review to identify risk factors for PU	Participants recruited from 2 acute care hospitals including 10 ICUs and 7 progressive care units (n=12566 mixed patients from general medicine and surgery, including ICUs) Inclusion: • Aged ≥18 yrs • Discharged from hospital by end of 2007 • ≥1 Braden Scale score of ≤18 during hospital stay Exclusion: • PUs present on admission • Length of hospital stay <1 day Characteristics: • n=7244 males; n=5322 females • mean age 64 yrs • n=0 lost to follow-up • No PU on admission	Not reported	Outcome definition: Time to event was calculated from admission to PU occurrence or hospital discharge. Skin inspected for PU until first PU developed or discharge from hospital • Frequency of follow-up not reported PU definition for regression: ≥Stage 2 NPUAP staging system Statistical methods: Proportional hazards regression models.	N=416 developed hospital-acquired PUs (no. and grade of PUs not reported) No. in final: not reported (14% missing BMI values) N=7 risk factors entered into MV analysis (Braden): • acute respiratory; friction/ shear; patient activity level; mobility; sensory perception; skin moisture; surgery (within 5 days/ ≥5 days)	Results reported below are parameter Estimate; SE; P N=7 risk factors from final model: **Friction (score 2)** 1.789; 0.346; <0.001 **Friction (score 1)** 4.100; 0.347; <0.001 **Activity (score 2)** 0.585; 0.182; 0.001 **Mobility (score 2)** 0.416; 0.153; 0.007 **Sensory perception (score 3)** 0 .484; 0.170; 0.004 **Sensory perception (score 2)** 0.535; 0.189; 0.005 **Moisture (score 3)** 0.585; 0.139; <0.001 **Moisture (score 2)** 0.570; 0.198; 0.004 **Acute respiratory failure** 0.305; 0.111; 0.006 **Surgery within 5 days** -0.840; 0.198; <0.001 **Surgery ≥5 days** -0.987; 0.143; <0.001	• Record review • Sample selection bias • Categorized continuous data	**Level of evidence: 4** **Quality: High**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	P value; odds ratio (OR); CI	Limitations	
(Tschannen, Bates et al., 2012)	Retrospective cohort study **investigating patient-specific and surgical factors in the development of PUs**	Participants recruited from 5 units (3 ICUs; 2 intermediate care) from one hospital (n=3225 surgical patients) Inclusion: • Aged ≥18 yrs • Had a surgical procedure completed during Nov 1, 2007, to Aug 31, 2009 • Admitted to 1 of the 5 study units for >48 hrs. Characteristics: • n=1910 males; n=1315 females • mean age 58.9 yrs; range 18-96 yrs • lost to follow-up and baseline PU not reported	Not reported	Outcome definition: development of ≥1 new Stage 1 or higher hospital-acquired PU. Skin inspected for PU not reported • length of follow-up duration not reported PU definition for regression: ≥Stage 1 NPUAP staging system Statistical methods: Logistic regression	N=383 developed hospital-acquired PUs (no. or grades not reported) No. in final: not reported but assumed complete N=9 risk factors entered into MV analysis: • age; sex; BMI; Braden score at admission; history of diabetes; risk of mortality; use of vasopressors; number of surgeries; total operating room time	N=7 risk factors from final model: **BMI** <.001; 0.97; 0.95-0.98 **History of diabetes** <.001; 1.49; 1.14-1.96 **Use of vasopressors** 0.03; 1.33; 1.03-1.73 **Number of surgeries** <.001; 2.23; 1.45-3.44 **Total operating room time** <.001; 1.07; 1.03-1.11 **Braden score at admission** <.001; 0.89; 0.86-0.93 **Risk of mortality (score 2)** <.001; 2.32; 1.49-3.62 **Risk of mortality (score 3)** <.001; 5.50; 3.58-8.45 **Risk of mortality (score 4)** <.001; 11.15; 7.1-15.5	• Record review • Conceptual framework limited • Strategy for model building based on a restricted conceptual framework	**Level of evidence: 4** **Quality: Moderate**
(Webster, Coleman et al., 2011)	A RCT evaluating the effectiveness of two PU screening tools against clinical judgement in preventing PU.	Participants recruited from one hospital (n=1231 non-surgical patients from internal medicine and oncology) Inclusion: • All patients admitted to medical or oncology ward from A&E or out-patients Exclusion: • Expected hospital stay <3 days • In hospital for >24 hrs before baseline assessment. Characteristics: • n=619 males; n=612 females • mean age 62.6 yrs; range	• Allocation to treatment concealed to investigator and patient after randomisation. The patient and outcome assessor were blinded to group assignment. • Staff used instrument found in the chart. No other changes to routine care. • Identified PUs were documented and reported to the nurse assigned to patient's care. • On day 3 after hospital admission,	Outcome definition: development of new PU, or any increase in the stage of existing ulcer Skin inspected daily (except weekends) for PU development • length of follow-up duration not reported PU definition for regression: ≥Stage 1 NPUAP staging system Statistical methods: Logistic regression	N=81 developed 81 PUs (PU grade not reported) No. in final: 984/1231 N=9 risk factors entered into MV analysis: • unable to turn independently; wheel-chair bound; PU on admission; >1 comorbidity; not admitted from home; required dietetic referral; age: 50-64 yrs, 65-74 yrs, and 75-84 yrs; mean length of stay ; mean weight	N=3 risk factors from final model: **Dietician referral** <0.001; 7.35; 4.27-12.36 **Not admitted from home** 0.005; 2.41; 1.31-4.43 **Age 65-74 yrs** 0.045; 2.96; 1.02-8.56 **Age 75-84 yrs** 0.002; 4.91; 1.77-13.59 **Age ≥85 yrs** <0.001; 8.65; 3.12-23.98	• Insufficient number of events	**Level of evidence: 3** **Quality: Low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	P value; odds ratio (OR); CI	Limitations	
		18-100 yrs • n=0 lost to follow-up (i.e. intention-to-treat) • n=71 with baseline PU (n=26 stage 1 ; n=28 stage 2 ; n=6 stage 3 ; n=5 stage 4 ; n=6 unstageable)	the data collector observed whether the participant was nursed on a special mattress, if they had a documented pressure care plan), and whether specialist skin integrity nursing service or dietician review performed.					

References

Almirall, S., R. Leiva, P. Gabasa. (2009). "Apache III Score: A prognostic factor in pressure ulcer development in an Intensive Care Unit." Enferm Intensiva **20**(3): 95-103.

Baumgarten, M., S. Rich, M. Shardell, W. Hawkes, D. Margolis, P. Langenberg, et al. (2012). "Care-related risk factors for hospital-acquired pressure ulcers in elderly adults with hip fracture." Journal of the American Geriatrics Society **60**(2): 277-83.

Bergquist-Beringer, S., B. J. Gajewski. (2011). "Outcome and assessment information set data that predict pressure ulcer development in older adult home health patients." Advances in Skin & Wound Care **24**(9): 404-14.

Chan, W., S. Pang, E. Kwong. (2009). "Assessing predictive validity of the modified Braden scale for prediction of pressure ulcer risk of orthopaedic patients in an acute care setting." Journal of Clinical Nursing **18**(11): 1565-73.

Connor, T., J. A. Sledge, L. Bryant-Wiersema, L. Stamm, P. Potter. (2010). "Identification of pre-operative and intra-operative variables predictive of pressure ulcer development in patients undergoing urologic surgical procedures." Urologic Nursing **30**(5): 289-305.

Cremasco, M., F. Wenzel, S. Zanei, I. Whitaker. (2013). "Pressure ulcers in the intensive care unit: the relationship between nursing workload, illness severity and pressure ulcer risk." Journal of Clinical Nursing **22**: 2183-91. Epub 2012.

de Souza, D., S. V. de Gouveia. (2010). "Incidence of pressure ulcers in the institutionalized elderly." Journal of Wound, Ostomy, and Continence Nursing **37**(3): 272-6.

Kwong, E. W.-y., S. M.-c. Pang, G. H. Aboo, S. S.-m. Law. (2009). "Pressure ulcer development in older residents in nursing homes: influencing factors." Journal Of Advanced Nursing **65**(12): 2608-20.

Man, S., T. Au-Yeung. (2013). "Hypotension is a risk factor for new pressure u lcer occurrence in older patients after admission to an acute hospital." J Am Med Dir Assoc.

Manzano, F., M. J. Navarro, D. Roldán, M. A. Moral, I. Leyva, C. Guerrero, et al. (2010). "Pressure ulcer incidence and risk factors in ventilated intensive care patients." Journal of Critical Care **25**(3): 469-76.

Roca-Biosca, A., M. Velasco-Guillen, L. Rubio-Rico, N. García-Grau, L. Anguera-Saperas. (2012). "[Pressure ulcers in the critical patient: detection of risk factors]." Enferm Intensiva **23**(4): 155-63.

Slowikowski, G., M. Funk. (2010). "Factors associated with pressure ulcers in patients in a surgical intensive care unit." Journal of Wound, Ostomy, and Continence Nursing **37**(6): 619-26.

Tescher, A. N., M. E. Branda, T. J. Byrne, J. M. Naessens. (2012). "All At-Risk Patients Are Not Created Equal: Analysis of Braden Pressure Ulcer Risk Scores to Identify Specific Risks." Journal of Wound, Ostomy and Continence Nursing **39**(3): 282-91. Epub 2012/05/04.

Tschannen, D., O. Bates, A. Talsma, Y. Guo. (2012). "Patient-specific and surgical characteristics in the development of pressure ulcers." American Journal of Critical Care **21**(2): 116-26.

Webster, J., K. Coleman, A. Mudge, L. Marquart, G. Gardner, M. Stankiewicz, et al. (2011). "Pressure ulcers: effectiveness of risk-assessment tools. A randomised controlled trial (the ULCER trial)." British Medical Journal Quality & Safety **20**(4): 297-306.

RISK ASSESSMENT

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	PU and inter- or intra-rater reliability results	Limitations	
Reliability studies							
(Suriadi, Sanada et al., 2008)	Prospective cohort study **to evaluate the predictive validity and accuracy of a Suriadi and Sanada risk assessment scale (RAS)**	Participants recruited from 2 ICUs in Indonesia (n=253 ICU patients) Inclusion: • Aged ≥18 yrs • Admitted to ICU at 24hrs before study enrolment • Bedfast • No existing PU • Ability to consent to study participation • Of Indonesian origin Exclusion: • Active disease that would interfere with PU assessment Whole sample characteristics: • n=158 males; n=95 females • mean age 55.2 and 42.6, unit A and B respectively • n=0 lost to follow-up • Sample without PUs at baseline	Patients were provided with standard equipment mattresses, which were commonly used in the ICU setting, and during pressure measurement the patients were first positioned in the lateral recumbent posture. N=2 data collection point • assessed by 2 assessors after study enrolment • Assessments conducted at two intervals: 24 and 72 hrs after admission Assessments: Upon completion of training programme, the nurse practitioners completed the S.S. scale for any patients newly admitted to the ICU. Assessments were made at the same time and each patient was assessed independently by both nurse practitioners. Training and professional experience: • Two nurse practitioners in the ICU received instructions on how to use the S.S. scale, both orally and in writing. • Both had the same level of education and experience	Statistical methods: Inter-rater reliability between observers was computed using Pearson product moment correlation. Number of raters: • Two nurse practitioners in the ICU Independency of data collection: each patient independently assessed by both nurse practitioners. Selection of raters and inclusion criteria: not reported Length of follow-up: not applicable	Reliability sample: n= 16 patients rated/paired assessments Characteristics of patients assessed: • Age range: 20 to 80 yrs (mean age 46.9 yrs) • 63% males; 37% females. Risk estimates not reported Pearson correlations between assessors were r = 1.00 for the first assessment and r = 1.00 for the second assessment ($p < 0.001$).	• Question about validity, not reliability (sub-study) • No data on how reliability sample was selected or if they were included in main study • Not stated how many of the sickest patients were excluded (if a lot of sick pts excluded the scale may not be relevant).	**Quality: Low**
(Webster, Coleman et al., 2011)	Prospective cohort study to assess the **validity of the Waterlow scale in a cohort of**	Participants recruited from the Royal Brisbane and Women's Hospital (RBWH) (n=274 patients admitted to internal medicine wards)	Risk tool evaluated: reliability testing of: 1. Staging PUs, using 4 multiple-choice questions and photographs of PUs	Statistical methods: Inter-rater reliability assessed using intraclass correlation coefficient (ICC) statistic with 95% CIs.	N=12 (4.4%) developed a PU during hospital stay (grades not reported) Reliability sample: number and sample characteristics not reported.	•Does not discuss mobility as a risk factor •>25% lost to follow-up	**Quality: Low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	PU and inter- or intra-rater reliability results	Limitations	
	internal medicine patients	Inclusion: • Patients admitted to any internal medicine ward at the RBWH • expected to remain in hospital for ≥3 days Characteristics: • n=137 males; n=137 females • mean age 65.7 yrs (range not reported) • n=74 lost to follow-up (unable to calculate Waterlow • Sample with and without PUs at baseline ; n=15 (5.5%) with baseline PU (grades not reported)	2. Scoring the Waterlow screening tool, using a series of case studies. Waterlow scores were categorized as: 0–10 low risk; >10 at risk; >15 high risk; and ≥20 very high risk. Waterlow screening is routine procedure at the RBGH - a total score of ≥16 is the generally accepted cut-off point for at-risk patients. Staff in participating wards advised of the study, but no changes were made to routine care. Data collection points: • Patients screened using the Waterlow scale by a research nurse • Presence of existing PUs was documented • Patients reviewed every second day until PU developed or discharge Training and professional experience: • Training provided but not described • Professional experience not reported	Number of raters: • Seven research nurses participated in data collection Not stated whether assessments were independent of each other Selection of raters and inclusion criteria: not reported Length of follow-up: not applicable	• Intraclass correlation for 'staging' PUs was 0.78 • Interrater reliability for Waterlow screening tool scoring was 1, indicating substantial agreement between raters.	•Selection of raters not reported • Number of patients used for reliability testing not reported; only mentions a series of patients • Question about validity, not reliability (sub-study) • Used case studies • Assumed raters blind • Multiple use of same case study • Poor explanation of the excluded cohort	
(Fossum, Olle Söderhamn et al., 2012)	Cross-sectional study to **translate and test the psychometric properties of the Norwegian language version of the Risk Assessment Pressure Sore (RAPS) scale.**	Participants recruited from 15 nursing homes in rural Southern Norway (n=481 residents needing long-term 24hr care (i.e. assistance with ADL and medical care)). Inclusion: • Residents in 1of 46 nursing home units • Resided for >24hrs • Without terminal illness Exclusion:	Risk tool evaluated: Norwegian-language version of the RAPS scale. Data collection points: residents assessed two times by 5 pairs of RNs on the same day. Training and professional experience: Clinicians, RNs and NAs, in the nursing homes were trained to use the scale and conduct a skin examination (as a part of the RAPS scale)	Statistical methods: Reliability assessed as equivalence by means of a two-way mixed intraclass correlation coefficient (ICC) with a 95% CI between the two assessments. ICCs were also calculated between each item of the two RAPS assessments. Number of raters: • Five pairs of RNs assessed patients with the RAPS Two RNs, independent of each	Reliability sample: n= 26/481 residents from two nursing homes Reliability sample characteristics: • Mean age 86.2 yrs • n=5 males; n=20 females Reliability of the RAPS, reflected as equivalence reached an ICC of 0.95 (95% CI 0.89 to 098, p<0.001, n=26) between the two obtained total scores of the RAPS scale. ICC values at item level ranged 0.58 –	• Unclear if the Norwegian exclusion criteria are the same as the English version. Presume so but do not know.	**Quality: Moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	PU and inter- or intra-rater reliability results	Limitations	
		• Lower extremity amputation or receiving enteral and/or parenteral nutrition Whole sample characteristics: • n=121males; n=360 females • mean age 84.5 yrs; range 55 – 102 yrs • Not stated if sample without PUs at baseline		other, completed the RAPS scale on the same residents. Selection of raters and inclusion criteria: not reported Length of follow-up: not applicable	0.92.		
(Bååth, Hall-Lord et al., 2008)	Cross-sectional study examining **interrater reliability between RNs using Modified Norton Scale, PU card (PUC), and Short Form-mini Nutritional Assessment (MNA-SF).**	Participants recruited from 2 county councils (n=114; n=82 hip fracture and n=32 who suffered a stroke); N=50 RNs and 61 enrolled nurses (EN) working at the orthopaedic and stroke wards in two county councils in Sweden Inclusion: • Aged ≥65yrs • Patients with a hip fracture or who suffered a stroke Patient sample characteristics not reported	"Regular" nursing care Risk tool evaluated: Modified Norton Scale, PUC, and MNA-SF. Data collection points: • RNs and ENs, responsible for one patient during their shift, assessed skin and PU risk during morning and afternoon shift as part of regular nursing care independently. • The time between the first and second pair did not exceed 2 hrs. • Assessments made on day 3 and 4 of patients ward admission Training and professional experience: • RNs and ENs received instructions on how to use the assessment tools for approx. 45 mins • Mean yrs work experience for RNs 16.2 (SD 12.54); mean yrs work experience for ENs 19.8 (SD 10.78)	Statistical methods: Interrater reliability and agreement between the two observations of the methods was assessed using Cohen's kappa, weighted kappa, and intraclass correlation. Number of raters: • 50 RNs (49 female; 1 male) • Mean age for RNs 41.2 yrs (SD 10.56); mean age for ENs 45.8 yrs (SD 10.02) • ENs significantly older than RN but no difference in yrs of work experience RNs and ENs assessed risk independent of each other. Selection of raters and inclusion criteria: not reported Length of follow-up: not applicable	N=228 assessments between RN and ENs; n=50 RNs completed 114 assessments; n=61 ENs completed 114 assessments. Between RN and EN assessments ICCs ranged 0.528 to 0.761: **MNS** **ICC** **CI** Mental condition 0.705; 0.625-0.785 Physical activity 0.761; 0.702-0.819 Mobility 0.649; 0.577-0.721 Food intake 0.654; 0.579-0.729 Fluid intake 0.528; 0.431-0.624 Incontinence 0.635; 0.551-0.720 Gen physical con 0.557; 0.462-0.652 Total score 0.695; 0.599-0.790 Among RN assessments, ICCs ranged 0.295 to 0.821: **MNS** **ICC** **CI** Mental condition 0.726; 0.622-0.831 Physical activity 0.566; 0.322-0.810 Mobility 0.681; 0.574-0.789 Food intake 0.634; 0.530-0.739 Fluid intake 0.341; 0.182-0.499 Incontinence 0.676; 0.571-0.781 Gen physical con 0.295; 0.136-0.454 Total score 0.821; 0.715-0.926 Among EN assessments, ICCs ranged 0.438 to 0.758:		**Quality: High**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	PU and inter- or intra-rater reliability results	Limitations	
					MNS **ICC** **CI** Mental condition 0.566; 0.436-0.697 Physical activity 0.758; 0.674-0.844 Mobility 0.671; 0.607-0.735 Food intake 0.619; 0.510-0.729 Fluid intake 0.438; 0.295-0.580 Incontinence 0.558; 0.429-0.689 Gen physical con 0.463; 0.315-0.611 Total score 0.750; 0.625-0.876		
(Kottner & Dassen, 2008)	Cross-sectional study to measure the interrater reliability of the Braden scale and its individual items, and to study different statistical approaches regarding interrater reliability estimation.	Participants recruited from 2 nursing homes in Berlin as part of an annual national prevalence survey (n=152 residents from 8 units) Inclusion: • Nursing home resident • Able to give informed consent or obtain from relative on their behalf Sample characteristics: • n=26 males; n=126 females • mean age 85.6 yrs; range 51-101 yrs • Not stated if sample without PUs at baseline	Risk tool evaluated: Braden Scale N=2 data collection points: 1. Risk assessment as part of a prevalence survey 2. risk assessment up to 3 days later, carried out by raters not involved in first data collection Assessments carried out by specifically instructed nurses of participating nursing home units Training and professional experience: • All participating nurses perceived to be familiar with the Braden Scale • Study-related instruction prior to data collection: 2-hr training using a standardised PowerPoint presentation, amongst others including information on the Braden Scale and handling of data collection forms, complemented by a written data collection manual • With exception of one nurse belonging to two pairs of raters, all nurses assumed to have been familiar with the residents assessed by them • Years of professional experience ranging from 1 to 22 years	Statistical methods: Inter-rater agreement (exact and relative agreement) for every item as well as total Braden score was calculated, including percentage of agreement, Cohen's kappa (unweighted and weighted (quadratic weights)), and ICCs (two-way random effects model). Number of raters: • 1 pair of raters per each unit • Raters of either pair independently assessed all participants at respective unit at different time points • Raters were single nurses (3 raters) or a team of 2 nurses (13 raters) (this difference not taken into account during analysis) • Except one nurse, all participating nurses only assessed residents of their own unit; one nurse was involved in rater teams at two units Independency of data collection • Nurses not blinded to the study, but ensured that there was no communication regarding assessment results between the nurses involved. • Risk assessments were to be made independently from	N=152 residents assessed twice N=28 participating nurses Risk estimates not reported All results reported per unit (minimum n=15, maximum n=25) Braden sum score • Range of differences among pairs of raters: lowest 0-2, highest 0-9 • Lowest % agreement = 0%, highest = 33% • Unweighted kappa (exact agreement): lowest -0.06 (95% CI -0.17 to 0.05), highest 0.21 (95% CI 0.07 to 0.34) • Weighted kappa (relative agreement): lowest 0.72 (95% CI 0.23 to 1.20), highest 0.95 (0.49-1.41) • ICC(2,1) (relative agreement): lowest 0.73 (95% CI 0.26 - 0.91); highest 0.95 (95% CI 0.87 - 0.98) Individual Braden items • Consistently **highest** reliability estimates for **'Activity'** (lowest ICC 0.74, 95% CI 0.50 to 0.88, highest 0.97, 95% CI 0.93 to 0.99) and **'Mobility'** (lowest ICC 0.68, 95% CI 0.38 to 0.85, highest 0.85, 95% CI 0.66 to 0.94) • Consistently **lowest** reliability estimates for **'Sensory perception'**	• Selection of raters not reported • Low sample size within single nursing home units which were analysed separately → Mostly rather wide confidence intervals.	**Quality: High**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	PU and inter- or intra-rater reliability results	Limitations	
				existing nursing documentation Selection of raters and inclusion criteria: not reported Length of follow-up: not applicable	(lowest ICC 0.09, 95% CI -0.43 to 0.55, highest 0.68, 95% CI 0.14 to 0.88) and **'Nutrition'** (lowest ICC 0.06, 95% CI -0.31 to 0.48, highest 0.89, 95% CI 0.75 to 0.95) • Remarkably low reliability observed in single units for items 'Moisture' and 'Friction and Shear' Further findings • Marked variance of reliability estimates among participating units • No indication of influence of nurses' training or professional experience on reliability estimates Estimates of relative agreement (ICC (2,1), weighted kappa) are more informative for clinical purposes than exact agreement as they take degree of single divergences into account; ICC estimates below 0.90 likely to indicate clinically relevant error variance (likely score differences >±3)		
(Kottner & Dassen, 2010)	Observational (cross-sectional) study to compare the interrater reliabilities of the Braden and Waterlow scores and subjective PU risk assessment and to determine the construct validity of these three assessment approaches. Two interrater reliability studies were conducted.	Participants recruited from two ICUs of a large University Hospital in Germany (n=45 patients: n=21 ICU 1; n=24 ICU 2) Inclusion criteria: • informed consent either by patients themselves or, in case of impaired abilities to consent, by their reference person Whole sample characteristics: • ICU 1 males n=11, females n=10; ICU 2 males n=23; females n=11 • mean age 69.7 yrs; range 64.5-76.5 yrs (ICU 1) and	Risk tool evaluated: • Braden Scale • Waterlow Scale • 10-cm horizontal Visual Analogue Scale (VAS) with anchor phrases "not at risk at all" (0 mm) and "maximum risk" (100 mm) in order to capture nurses' subjective risk estimates N=1 data collection point: • Each patient assessed by 3 raters, with each rater applying one of the three instruments • All assessments carried out within 15 minutes per patient Assessments carried out by nurses of participating ICUs	Statistical methods: Inter-rater reliability: • ICC (1,1) (one-way random effects model) • Standard error of measurement (SEM) Number of raters: • 3 nurses per each participating patients • 53 nurses in total ICU 1 n=22, ICU 2 n=31) Independency of data collection: 'Nurses conducted 3 subsequently risk assessments alone and independently from each other. The researchers supervised data collection and watched that there was no communication between	N=21 (ICU 1) and 24 (ICU 2) patients assessed N=22 (ICU 1) and 31 (ICU 2) participating nurses Risk estimates: Median (IQR) ICU 1/Median (IQR) ICU 2 • Braden: 12.3 (9-13.9)/13.8 (10.3-18.5) • Waterlow: 31.3 (26.7-35.5)/22.8 (19.0-28.3) • VAS: 60.7 (49.5-75.7)/62.7 (30.5-81.8) ICC estimates (95% CI) for sum scores ICU 1/ICU 2: • Braden: 0.72 (0.52-0.87)/0.84 (0.72-0.92) • Waterlow: 0.36 (0.09-0.63)/0.51 (0.27-0.72)	• Not enough detail to assess sampling method (not detailed how many pts approached) • Low sample size within single ICUs which were analysed separately = Mostly rather wide confidence intervals.	**Quality: High**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	PU and inter- or intra-rater reliability results	Limitations	
		mean age 67.2 yrs; range 65-73 yrs (ICU 2) • Not stated if sample without PUs at baseline	Training and professional experience: • Nurses were assumed to be familiar with the Waterlow Scale as this instrument had been implemented in routine nursing practice at either ward • At either participating ward: additional standardised training for nurses with regard to application of the Braden Scale and the VAS (no further information on content and duration of training provided) • Nurses were assumed to be familiar with the patients to be assessed • Years of professional experience: not reported	the nurses. Selection of raters and inclusion criteria: • Randomly selected from the larger teams of all nurses working at respective ICU at the point of data collection • Written informed consent Length of follow-up: not applicable	• VAS: 0.51 (0.26-0.74)/0.71 (0.53-0.85) SEM estimates for sum scores ICU 1/ICU 2: • Braden: 1.67/1.64 • Waterlow: 5.63/4.78 • VAS: 17.4/15.5 ICC estimates for individual items • **Braden** items with **highest relative agreement**: '**Sensory perception'** (ICU 1, ICC 0.64, 95% CI 0.40 to 0.81) , '**Moisture'** and '**Mobility'** (ICU 2, each ICC 0.75, 95% CI 0.58 to 0.87) • **Braden** items with l**owest relative agreement** (ICC not different from 0): **'Activity'** (ICU 1, ICC 0.08, 95% CI -0.16 to 0.39) , '**Sensory perception'** (ICU 2, ICC 0.17, 95% CI -0.06 to 0.45) • **Waterlow** items with **highest relative agreement** (ICC>0.65, ICC not extracted): '**Skin type'** (ICU 1), '**Major surgery'** (ICU 1), **'Build/weight'** (ICU 2), **'Continence'** (ICU 2), '**Sex'** (ICU 1, ICU 2), 'Age' (ICU 1, ICU 2) • **Waterlow** items with **lowest relative agreement** (ICC not different from 0, ICC not extracted): **'Build/weight'** (ICU 1), **'Continence'** (ICU 1), **'Mobility'** (ICU 1), **'Tissue malnutrition'** (ICU 1), **'Medication'** (ICU 1), '**Major surgery'** (ICU 2) Further findings/conclusions: • Estimates of inter-rater reliability not sufficient to precisely differentiate PU risk among ICU patients • Likely reasons for insufficient reliability: variance introduced by different risk perceptions of the nurses, and homogeneity of PU risk		

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	PU and inter- or intra-rater reliability results	Limitations	
					among ICU patients Correlation estimates (Pearson *r*) and coefficients of determination estimated for the association between the three risk assessment instruments revealed that 41% to 74% of the variances of risk scores remained unexplained, indicating that all three instruments only partly measured the same construct (overlap was weakest between VAS and Waterlow scale).		
(Kottner, Halfens et al., 2009)	Cross-sectional study to determine interrater reliability and agreement of PU risk and PUs using the Braden scale and the EPUAP system.	Random sub-samples of home care clients involved in two PU prevalence surveys in the Netherlands: • Survey in 2007: n=352 clients of 27 institutions • Survey in 2008: 339 clients of 21 institutions Inclusion criteria: • informed consent Sample characteristics: • n=68% (2007 survey) and n=62.8% (2008 survey) females • mean age 77.8 yrs; median age 80 yrs; range 74-86 yrs (2007) • mean age 77.4 yrs;median 80 yrs; range 73-86 yrs (2008) • Not stated if sample without PUs at baseline	Risk tool evaluated: • Braden Scale • (Detection of PUs based on the EPUAP classification) N=2 data collection points in either survey year: • First risk assessment as part of the prevalence survey • Second risk assessment up to 3 days later, carried out by expert raters (nurses specifically qualified in wound management) not involved in first data collection Assessments carried out by nurses of participating institutions (first risk assessment) and nurses specifically trained in wound management (second risk assessment) Training and professional experience: • Nurses in charge of data collection for the prevalence survey (first risk assessment) received training by institution-based coordinator for data collection, including oral (PowerPoint presentation) and written information on the	Statistical methods: Inter-rater reliability of Braden risk estimates: • Exact agreement: percentage of observed agreement p_O and SEM • Relative agreement: ICC (1,1) (one-way random effects model) • Bland-Altman plots and 95% limits of agreement per Braden sum score (Inter-rater reliability of PU detection: percentage of observed agreement and Scott`s π statistics (equivalent to Kappa statistics) Number of raters: • Not clearly reported • Assumingly 2 raters per client Independency of data collection: 'Nurses who conducted the first rating did not know which clients were selected for a second rating and the second raters were unaware of the results of the first ratings.' Selection of raters and inclusion criteria: not reported Length of follow-up: not applicable	Number of PUs detected: Survey 2007 39 PUs (21 grade 1, 10 grade 2, 8 grade 3 or 4) in 352 clients; Survey 2008 36 PUs (17 grade 1, 9 grade 2, 10 grade 3 or 4) in 332 clients Reliability sample: n= 691 Risk estimates not reported Braden sum score • Percent agreement 2007/2008: 66%/63% • ICC (95% CI) 2007/2008: 0.90 (0.88-0.92)/0.88 (0.85-0.91) • SEM 2007/2008: 1.00/0.98 • 95% limits of agreement 2007/2008: -2.8 to 2.8/-2.7 to 2.7 Individual Braden items • Item with **highest relative agreement**: '**Activity'** (Survey 2007, ICC 0.91, 95% CI 0.89-0.93), and Survey 2008, ICC 0.88, 95% CI 0.85-0.90) • Items with **lowest relative agreement**: '**Sensory perception'** (Survey 2007, ICC 0.71, 95% CI 0.65-0.76)/'**Moisture'** (Survey 2008, ICC 0.64, 95% CI 0.57-0.71) PU detection (PU absent or present)	• Sampling procedures for recruitment of the raters not reported. • Professional background poorly reported (e.g. lacking information on the degree of nursing qualification, years of experience, familiarity with the scale under investigation, familiarity with the clients under investigation) • Institution-related variance of reliability estimates not reported	Quality: High

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	PU and inter- or intra-rater reliability results	Limitations	
			Braden Scale, EPUAP classification and data collection forms (no further information on content and duration of training provided) • No information on routine use of risk assessment scales or degree of training of specifically qualified nurses responsible for second risk assessment • Familiarity with clients: Not reported, but presumably given at least for nurses in charge • Professional experience not reported		• Percent agreement 2007/2008: 96%/96% • Scott`s π (95% CI) 2007/2008: 0.87 (0.77-0.93)/0.89 (0.79-0.95)  PU classification (absent or 4 PU grades): • Scott`s π (95% CI) 2007/2008: 0.81 (0.73-0.88)/0.79 (0.72-0.87) Highest amount of disagreement with regard to detection of PUs grade 1		
(Rogenski & Kurcgant, 2012)	Prospective exploratory study with inclusion of data from nursing records (e.g. characteristics of PUs) to verify interrater reliability in risk assessment, using the Braden Scale	Participants recruited from surgical, internal medicine, adult ICU, and semi-ICU units in one University hospital in Sao Paulo (n=87 patients) Inclusion criteria not reported. Whole sample characteristics: • n=46 males; n=41 females • mean age 56.6 yrs; range 16-92 yrs • n=0 lost to follow-up • Sample with and without PUs at baseline	Risk tool evaluated: Braden scale Data collection points not clearly stated, assumed one: Data collection conducted by six collaborators, properly trained, who did the physical examination and risk assessment for PU development, on all admitted patients, by clinical application of the Braden Scale Training and professional experience: • Training provided but not described • Professional experience not reported	Statistical methods: Inter-rater reliability of the clinical application of the Braden scale was determined by the Kappa test for the total score and each of the subscores. Number of raters: • 6 collaborators Independency of data collection not reported Selection of raters and inclusion criteria: not reported Length of follow-up: not applicable	Reliability sample: number of rated/paired assessments not reported Characteristics of reliability sample not clearly stated; assumed the original 87 patients comprised the reliability sample Low kappa values observed for subscores moisture (0.473) and nutrition (0.514); Strong to very strong kappa values observed for subscores sensory perception (0.746), activity (0.807), mobility (0.665), friction and shear (0.829), indicating strong to very strong agreement between observers, and for the total scale score; A strong linear correlation found between the two evaluations (Pearson correlation = 0.949), and strong consistency between the two ratings (ICC = 0.946).	• Not reliability (sub-study) • Poorly reported methods • Patient inclusion criteria not stated • Selection of raters not reported	Quality: Low
(Simão, Caliri et al., 2013)	A descriptive exploratory study evaluating the agreement between nurses	Participants recruited from four ICUs at a base hospital in Brazil (n=72 patients) Inclusion criteria (patients):	Risk tool evaluated: Braden scale Data collection points not clearly stated, assumed one:	Statistical methods: agreement between nurses analysed using intraclass correlation coefficient. The Kappa coefficient used for assessment of patient risk from the	Reliability sample: number of rated/paired assessments not reported Characteristics of reliability sample not stated; assumed 72 patients comprised	• Not clear exactly how many paired assessment were performed • Characteristics of	Quality: Low

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	PU and inter- or intra-rater reliability results	Limitations	
	regarding classification and assessment of patients for risk of developing PU, using the Braden scale	• LOS (ICU) ≥48 hrs so that there were no significant changes in patient`s health and that all nurses could do the assessments in the same individuals Patient sample characteristics not reported	Data collected by the researcher, a certificated clinical nurse specialised in Dermatology and Stomatherapy, who conducted the physical examination and risk assessment of patients by applying the Braden scale. Patient evaluation was made twice weekly during the month of data collection in each ICU ward. Nurses performed the evaluation on the same day or at most the next day as the researcher during their work shift. Total and subscale scores were compared. Training and professional experience: Researcher: Nurses specialised in Dermatology and Stomatherapy Nurses: • Mean time of profession 5 yrs • Mean experience time in ICU 4 yrs • Mean experience time in the current ICU 2 yrs and 8 months	total score of the Braden Scale: no risk, mild risk, moderate risk, high risk and very high risk. Number of raters: • 1 researcher • 22 nurses: 3 from emergency ICU, 7 from general ICU, 6 from health insurance coverage ICU, 6 from Coronary ICU Independency of data collection: nurses instructed not to make comments on each others assessment Selection of raters and inclusion criteria: • Nurses scheduled and working in ICUs on any shift during the entire period of data collection. Length of follow-up: not applicable	the sample for interrater reliability estimates for individual Braden subscales and 56 patients for interrater reliability estimates for Braden sum scores ICC estimates for Braden subscales agreement between nurses and researcher: • **Sensory perception**: Highest 0.99 (95 % CI 0.99-1.00), Lowest 0.85 (0.62-0.95) • **Moisture**: Highest 0.84 (95 % CI 0.64-0.94), Lowest -0.04 (-0.47-0.44) • **Activity**: Highest 0.77 (95 % CI 0.50-0.91), Lowest 0.00 (-0.50-0.50) • **Mobility**: Highest 0.96 (95 % CI 0.89-0.98), Lowest 0.80 (0.50-0.93) • **Nutrition**: Highest 0.60 (95 % CI 0.22-0.83), Lowest -0.55 (-0.80 to -0.14) • **Friction & shear**: Highest 0.91 (95 % CI 0.79-0.97), Lowest 0.64 (0.21-0.86) Kappa (p-value) agreement between nurses and researcher on total Braden and classification of patients at risk: • ICU 1: 0.561 (0.0001); ICU 2: 0.862 (0.0001); ICU 3: 0 (0); ICU 4: 0.333 (0.76)	reliability sample not stated • Not clear why 16 patients excluded from interrater reliability estimates for Braden sum scores	

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Sensitivity, specificity, positive and/or negative predictive value, likelihood ratio, area under receiver operating curve (ROC)	Limitations	
Validity Studies							
(Moura De Araújo, Moura De Araújo et al., 2011)	Longitudinal quantitative study, to validate the Braden and the Waterlow scales in critical patients	Participants from 3 ICUs from one hospital (n=42 critical care patients) Inclusion: • Aged ≥18 yrs • No PU on admission • Max. 48h of ITS Exclusion: • Patients hemodynamically unstable • Diagnosis of brain death • Expected length of stay <15 days Characteristics: • n=81% males • mean age 35.3 yrs (range not reported) • n lost to follow-up not reported/unclear • Sample without PUs at baseline	Not reported	Outcome definition: PU according to EPUAP staging system Skin inspected daily (morning) for PU • length of follow up 14.2 days Risk tool: translated versions of the Braden and Waterlow scales. Waterlow scale: risk (score 10-14) , high risk (score 15-19), very high risk (score ≥20); Braden scale: low risk (score>16) and high risk (score ≤ 16). Each patient was examined once a day (morning) by 2 nurses, each one completing one scale, for 15 days, but at least 10 consecutive days, average Statistical methods: sensivity (Se), specificity (Sp), positive predictive value (PPV) and negative predictive value (NPV)	N=25/ 42 (59.5%) developed PUs, average PU development time 9.6 days. No. in analysis: 42 • Braden: sensitivity of 75.9%; specificity 88.2%; PPV 71.4%; NPV 64.4%. • Waterlow: sensitivity of 100%; specificity 11.7%; PPV 100%; NPV 100%. Conclusion: With exception of specificity (11.7%), all the studied coefficients of the Waterlow scale were superior to the Braden scale. Waterlow scale predicted better risk of PU compared to the Braden scale	• Inconsistency with the Braden scale: moderate risk not defined • Follow up time (10-15) not sufficient to observe complete wound healing • Small sample size	
(de Souza, Santos et al., 2010)	Secondary analysis of a prospective cohort study **evaluating the predictive validity of the Braden Scale for predicting PU risk in elderly residents**	Participants recruited from 4 LTCF in 3 Brazilan cities (n=233 LTCF residents) • Two groups considered: total group (n=233) and subsample risk group (n=94) Inclusion: • Elderly adults aged ≥60 yrs	No protocols or use of instruments to evaluate RFs had been implemented; prevention of PUs was limited to change of patient's position and minimization of skin exposure to moisture. Nurses in charge were informed about RFs and PU development, but investigators did not	Outcome definition: development of new PU NPUAP staging system Skin inspected for PU every 2 days for 90 consecutive days until death, transfer to another facility, transfer to a hospital, return home, or end of study period; for at-risk patients, development of PU was another outcome • mean length and range of follow-up not reported • Patients assessed for 3	N=39.4% of at-risk group developed a PU (PU grade not reported) No. in analysis: 233/233 • Total group: cutoff scores of 18 and 17; sensitivity of 75.9% and 74.1%; specificity of 70.3% and 75.4%; PPV 43.6 and 47.6; NPV 90.7 and 90.6; and AUC-ROC of 0.79 and 0.81 at the first and last assessments, respectively. • Risk group: cutoff scores of 16 and 13; sensitivity of 83.8% and 56.8%; specificity of 36.8% and 71.9%; PPV 46.3 and 56.8; NPV 77.8 and 71.9; and AUC-ROC	• No participant flowchart • Analysis strong • No data on specific nursing care provided • No data on grade of PU that developed • Nursing care not directed by risk score	**Quality: Moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Sensitivity, specificity, positive and/or negative predictive value, likelihood ratio, area under receiver operating curve (ROC)	Limitations	
		• Underwent complete skin examination and Braden scale rating every 2 days for 3 mths • Agreed to study participation Characteristics: • n=104 males; n=129 females • mean age 76.6+/-9.2 yrs • n=0 lost to follow-up • Sample without PUs at baseline	interfere with patient care; researchers stated information provided did not lead to prophylactic measures because appropriate procedures for prevention and treatment of PUs were not part of routine protocol in the institutions.	consecutive mths; data from first and last (before any of the outcomes) assessments were used for statistical analysis. Risk tool: Braden scale assessed every 2 days for 3 mths Statistical methods: predictive validity (sensitivity and specificity by ROC curve and likelihood ratio (LR)); positive and negative predictive values; Fagan's nomogram presents the LR results graphically	of 60.3 and 69 at the first and last assessments, respectively. • Probability of a patient in the total group developing PUs, according the first assessment data (cutoff score 18), was 44% for a positive test and 9% for a negative test, and according to the last assessment data (cutoff score, 17), the probability increased to 48% for a positive test and remained 9% for a negative test. • Cutoff score 13 (last assessment) yielded the highest probability of a patient in the risk group developing PUs with a positive test (57%) and a probability of 28% with a negative test. Conclusion: The Braden Scale showed good predictive validity in elderly LTCF residents.		
(González-Ruiz & et al., 2008)	Prospective, descriptive study of the validity of a current risk assessment scale of PUs in intensive care (EVARUCI)	Participants recruited from an ICU (n=62 patients) Inclusion: • Adult patients admitted to ICU (18+ years) Exclusion: • Length of stay < 3 days • No PU present at admission Characteristics: • n=38 males • mean age 61.4 yrs (recalculated based on table 2a) • n=0 lost to follow-up	Not reported	Outcome definition: not precisely defined, but grades I, II, III, and IV were used Skin inspected for PU daily until ulcer development or transfer to another ward or death • mean length of follow-up 10.1 days; range not reported Risk tool: Data on EVARUCI were collected daily and the patients were studied until they developed PU or left the ICU (death or transferred to another hospital ward. In addition, each patient was measured according to the Norton Scale Statistical methods: Sensitivity, Specificity, positive predictive value, negative predictive value and AUC of ROC	N=11/62 developed a PU • N=57.69% grade I PU • Sacral area (26.92%) and heels (23.08%) most frequent sites No. in analysis: 62/62 Mean scores on the EVARUCI mean, initial and final score were: sensitivity (100%, 100%, and 90.91%), specificity (68.63%, 49.02%, and 92.16%), and positive predictive value (40.74%, 29.73%, and 71.43%) and negative predictive value (100%, 100%, 97.2%) AUC of ROC was 0.938, 0.909, and 0.952, respectively. Conclusion: the EVARUCI is a valid tool for detecting patients at risk of developing PU in ICU	• Small sample size	

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Sensitivity, specificity, positive and/or negative predictive value, likelihood ratio, area under receiver operating curve (ROC)	Limitations	
(Suriadi, Sanada et al., 2008)	Prospective cohort study to evaluate the predictive validity and accuracy of a new PU RAS	Participants recruited from 2 ICUs in Indonesia (n=253 ICU patients) Inclusion: • Aged ≥18 yrs • Admitted to ICU at 24hrs before study enrolment • Bedfast • No existing PU • Ability to consent to study participation • Of Indonesian origin Exclusion: • Active disease that would interfere with PU assessment Characteristics: • n=158 males; n=95 females • mean age 55.2 (ICU A) and 42.6 ICU B) • n=0 lost to follow-up • Sample without PUs at baseline	Patients were provided with standard equipment mattresses, which were commonly used in the ICU setting, and during pressure measurement the patients were first positioned in the lateral recumbent posture.	Outcome definition: development of new ≥Stage 1 PU (NPUAP staging) Skin inspected for PU within 24hrs of admission and then daily • mean length of stay 8.6 and 7.3 days (range not reported) Risk tool evaluated: the Suriadi and Sanada (S.S.) scale assessed by 2 assessors after study enrolment Statistical methods: diagnostic probabilities (sensitivity, specificity, PPV, NPV, likelihood ratio (LR)) were calculated for the range of the S.S. score; AUC-ROC	N=47 patients (27%) developed a PU in ICU A (n=20 stage I; n=22 stage II; n=5 stage III ulcers). N= 25 patients (31.6%) developed a PU ICU B (n=12 stage I; n=13 stage II) No. in analysis: 253/253 **Score; Sensit'y%; Specific'y%; PPV; NPV; LR** 9 7 100 100 53 - 7 58 95 81 85 10.6 6 61 92 75 86 7.4 5 72 87 68 89 5.4 4* 81 83 65 91 5.0 3 97 53 45 98 2.0 2 97 42 40 97 1.7 1 100 0 0 100 1.0 *Cut-off score The SS scale was found to be a moderate diagnostic tool with a LR of 5. AUC (ROC) was 0.888 (95% CI: 0.84–0.93).	• Excluded pts if couldn't assess skin and post-enrolement if LOS was <72hrs (selection bias) • Not described standard care • Not reported how ward staff assessed risk or whether blind to SS scale	Quality: Moderate
(Serpa & et al., 2011)	Secondary analysis of prospective cohort data analysing the predictive validity of the Braden scale in critical care patients	Participants recruited from four ICUs (2 neurology; one cardiology; one general ICU) of a non-profit charitable general hospital (n=82 recruited, n=72 completed) Inclusion: • Admitted to ICU during study period • Age ≥18 yrs • Free of PU at first	Since the beginning of the study, all healthcare team members were informed about patients who were at risk of developing PU and preventive measures were the responsibility of the institution. Once a PU was detected, the same procedure was adopted and the nursing staff was responsible for the adoption of the	Outcome definition: development of PU (NPUAP staging) Frequency of skin inspection for PU not reported • min. length of hospital stay 6 days; mean 17.1 days+/-9.0 days Risk tool evaluated: Braden scale. Applied at first assessment and at 48-hr intervals, as long as patient remained at-risk or until: development of PU, discharge, death or transfer from the ICU.	Classification on first assessment: low risk 30.5%; moderate risk 40.3%; high risk 29.2%. N=8 patients developed PU (11.1% incidence) • N=42.9% stage 1 PU and n=57.1% stage II PU on day 2 of admission No. in analysis: 72/82 **Cutoff; Sen'ty; Spec'ty; PPV; NPV; AUC** 12 85.7% 64.6% 20.7% 97.7% 78.8 13 71.4% 81.5% 29.4% 96.4% 78.9 13 71.4% 83.1% 31.3% 96.4% 80	• Only included pts with Braden ≤18 • Staff not blind to risk score • At-risk pts flagged to nursing staff • Small sample size (n=72; n=7 dev. PU)	Quality: Moderate

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Sensitivity, specificity, positive and/or negative predictive value, likelihood ratio, area under receiver operating curve (ROC)	Limitations	
		assessment • Hospitalised for min. 24 hrs and max. 48 hr period • Total Braden score ≤18 • Consent to study participation Exclusion: • Chronic renal failure • Under dialysis for >1 mth • Liver insufficiency with acuities Characteristics: • n=48 males; n=24 females • mean age 60.9 • 72.2% classified as surgical • n=10 (17%) lost to follow-up • Sample without PUs at baseline	necessary therapeutic measures, without interference from the researchers.	Only data from patients with at least three consecutive assessments were used for the analyses. Statistical methods: Predictive validity of Braden scale • Sensitivity • Specificity at the cut off score of 12 calculated using ROC curves • Likelihood ratio	Cut-off score 12 identified in first assessment Cut-off score 13 identified in second and third assessments Risk of PU development elevated at 72 hours: cut off score of 13 in the third assessment best predictive value LR+ was higher in third assessment, with patients with score 13 presenting a 4.22 times higher chance of developing PU, compared to a 3.87 and 2.42 times higher chance in the second and first assessment, respectively. The lowest LR- was observed in the first assessment (0.22) and the highest in the second assessment (0.35). In the third assessment, using score 13, the probability of developing PU was 31% when the test was positive and 4% when the test was negative. In the other assessments, cut-off scores yielded lower probabilities of 29% and 21% for positive tests and 4% and 2% for negative tests in the second and first assessments, respectively.		
(Chan, Pang et al., 2009)	Prospective cohort study investigating the predictive validity of the modified Braden scale for prediction of PU risk in orthopaedic patients	Participants recruited from2 orthopaedic wards of an acute care hospital (n=197 mixed patients) Inclusion: • Chinese • Aged ≥18 yrs • Expected to stay in ward for ≥5 days following admission • Not ambulant • No PU on admission. Characteristics:	"Standard care" - nurses performed preventive nursing interventions without knowing Braden and modified Braden scores assigned to subjects.	Outcome definition: development of new ≥Stage 1 NPUAP staging system. Skin inspected for PU daily • mean length of follow-up not reported (average hospital stay 10.8 day; range 5- 53 days) Risk tool evaluated: An experienced nurse trained to use the modified Braden scale, screened all newly admitted patients meeting inclusion criteria. Statistical methods: ROC curve to	N=18 developed 18 PUs • n=4 stage 1; n=14 stage 2 No. in final: n=197/197 The AUC (ROC) for the Braden scale (BS) and modified Braden scales (MBS) were 0.684 and 0.736 respectively. The BS cut-off score 16 and MBS cut-off score 19 yielded the best balance of these two scales' sensitivity (BS: 67%, MBS: 89%) and specificity (BS: 64%, MBS: 62%).	• Only included pts with Braden ≤18 • Staff not blind to risk score • At-risk pts flagged to nursing staff • Small sample size (n=72; n=7 dev. PU) • Not reported aim • Researcher unblind but ward staff blind to scores • Not described what normal care is	Quality: Moderate

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Sensitivity, specificity, positive and/or negative predictive value, likelihood ratio, area under receiver operating curve (ROC)	Limitations	
		• n=30 males; n=167 females • mean age 79.4 yrs; range 35 – 98 yrs • Numbers lost to follow-up not clearly stated • Sample without PUs at baseline		determine the predictive validity of the Braden and modified Braden scales. The significance value was set at p <0.05. Sensitivity and specificity calculated.			
(Eun-Kyung, 2009)	Prospective cohort study to compare the predictive validity of three PU risk scales: the Braden, the Song and Choi, and the Cubbin and Jackson scales.	Participants recruited from one University hospital ICU (n=219 ICU patients) Inclusion: • Aged ≥16 yrs • Admitted to ICU • No existing PU on admission Characteristics: • n=145 males; n=74 females • mean age 58.1 (range 16-98) • n=0 lost to follow-up • Sample without PUs at baseline	All patients received ordinary nursing interventions, especially those related to PU prevention. Their position was changed every two hours and they were dried, cleaned and friction/shear managed to prevent PU.	Outcome definition: development of new ≥Stage 1 Agency for Health Care Policy and Research 4 staging system (1994). Skin inspected for PU daily until termination of ICU care • mean length of follow-up 11.3 days (range 3-90 days) Risk tool evaluated: the Braden, the Song and Choi, and the Cubbin and Jackson scales. A research nurse trained to administer the three scales, assessed all newly admitted patients meeting inclusion criteria. Statistical methods: Sensitivity, specificity, PPV and NPV, and the AUC of the ROC curve of the three scales	N=40 (18.3%) developed PUs • n=15 stage 1; n=25 stage 2 No. in final: n=219/219 **Cutoff; Sen'ty; Spec'ty; PPV; NPV; AUC** Braden 14 92.5% 69.8% 40.6% 97.6% 0.881 Song and Choi 21 95.0% 69.2% 40.8% 98.4% 0.890 Cubbin and Jackson 28 95.0% 81.5% 53.5% 98.6% 0.902 The optimal cut‐off points, as determined by the ROC curve, are: 14 for Braden scale, 21 for Song and Choi scale and 28 for the Cubbin and Jackson scale.	• Researchers not blind to risk score • No report of order of scale completion, therefore risk of order effect.	Quality: Moderate
(Kumari, Sharma et al., 2012)	Prospective cohort study comparing the the predictive validity of three PU risk scales—the Norton scale, the Braden scale, and the Waterlow scale—and to	Participants recruited from general surgical wards of tertiary care hospitals in New Delhi (n=100 patients) Inclusion: • Postoperative admission to surgical ward within the last 24hrs • Aged >14yrs	Not reported	Outcome definition: development of new ≥Stage 1 PU NPUAP staging. Skin inspected for PU daily (morning) • mean length and range of follow-up not reported Risk tool evaluated: the Norton Plus, Braden, and Waterlow scales Patients assessed by 3 independent assessors from the research team	N=23 developed PUs • PU stages not reported No. in final: n=100/100 assumed **Cutoff; Sen'ty; Spec'ty; PPV; NPV** Norton 15 82.61% 98.70% 48.72% 95% Norton+ 10 52.17% 100% 50% 87.5% Braden 16 86.96% 93.51% 44.44% 96%	• Excluded pts with baseline PU • Inter-assessor blinding; assuming ward staff were blind to scores	Quality: High

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Sensitivity, specificity, positive and/or negative predictive value, likelihood ratio, area under receiver operating curve (ROC)	Limitations	
	choose the most appropriate calculator for predicting PU risk in surgical wards of India.	• Informed consent • No preexisting PUs at study enrolment Exclusion: • Active skin disease that would interfere with PU assessment • Hospital stay of <72 hrs • Physical constraints to skin assessment Characteristics: • Patient sample characteristics not reported • n=0 lost to follow-up • Sample without PUs at baseline		(not by nurse involved in direct patient care). Assessment was done within 24 hrs postoperatively for patients who underwent surgery or who were on conservative treatments. Scoring by different scales was carried out independently at separate times, and the assessors were blinded to each other's scores. Statistical methods: Sensitivity, specificity, PPV and NPV. These parameters were then used for evaluating the predictive validity of each assessment scale. Cohen's kappa was calculated to assess inter-scale agreement.	Waterlow 10 95.65% 74.02% 34.38% 98.28% The ROC curve shows that the Norton scale can provide the highest sensitivity without compromising specificity. Cohen's kappa values indicate the Norton and Braden scales have a higher agreement among each other than with the Waterlow scale (0.80 vs. 0.46 and 0.47).		
(Webster, Coleman et al., 2011)	A RCT evaluating the effectiveness of two PU screening tools against clinical judgement in preventing PU.	Participants recruited from one hospital (n=1231 non-surgical patients from internal medicine and oncology) Inclusion: • All patients admitted to medical or oncology ward from A&E or out-patients Exclusion: • Expected length of hospital stay <3 days • In hospital for >24 hrs before baseline assessment Characteristics: • n=619 males; n=612 females	Allocation to treatment was concealed to the investigator and patient until after randomisation. The patient and the outcome assessor were blinded to group assignment. Staff in participating wards used only the instrument found in the chart. No other changes to routine care. Identified PUs were documented and reported to the nurse assigned to that patient's care for appropriate management. On day 3 after hospital	Outcome definition: development of new ≥Stage 1 PU, or any increase in the stage of existing ulcer, NPUAP staging system Skin inspected daily (except weekends) for PU development • length of follow-up duration not reported Risk tool evaluated: Waterlow and Ramstadius tools. Patients were randomised to Waterlow, Ramstadius or clinical judgement groups using a phone randomisation method. Statistical methods: Calculated OR and their 95% CIs for the proportion of patients with PUs in each group.	N=81 developed 81 PUs (PU grade not reported) No. in final: 984/1231 When compared with the Waterlow group, the clinical judgement group had a non-significant 10% reduction in the incidence of PUs (OR 0.90; 95% CI 0.53-1.53) and the Ramstadius group a non-significant reduction of 30% (OR 0.70; 95% CI 0.40-1.22).	• Included pts with and without PUs at baseline • Did not do appropriate analysis • Incidence lower than sample size; not considered power • Not discussed contamination bw groups	Quality: High

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Sensitivity, specificity, positive and/or negative predictive value, likelihood ratio, area under receiver operating curve (ROC)	Limitations	
		• mean age 62.6 yrs; range 18-100 yrs • n=0 lost to follow-up (i.e. intention-to-treat) • Sample with and without PUs at baseline ; n=71 with baseline PU (n=26 stage 1 ; n=28 stage 2 ; n=6 stage 3 ; n=5 stage 4 ; n=6 unstageable)	admission, the data collector observed whether the participant was nursed on a special mattress, if they had a documented pressure care plan (e.g. regular turning schedule), and whether been reviewed by the specialist skin integrity nursing service or reviewed by a dietician.				
Saleh et al (2009)	Pre and post comparison study (ward cluster trial; 3 groups) to determine whether use of RAS reduces nosocomial PUs	Participants recruited from the Riyadh Military hospital (n=xxx patients; 9 wards) Inclusion: • Braden score ≤18 Exclusion: • Patients discharged within 8 wks were excluded from analysis Characteristics: • Patient sample characteristics not reported • n=198 excluded from analysis (i.e. not intention-to-treat) • Not reported whether sample free of baseline PUs	Each patient was monitored for protective measures, including: (1) Protective mattresses (e.g. standard hospital bed mattress, alternating pressure relief system, gel overlay or air fluidised bed); (2) Creams and skin barriers; (3) Vitamin supplements and special nutritional formulas; (4) Patients' turning (positioning) schedules every two, three to four, or six hours.	Outcome definition: development of new ≥Stage 2 PU NPUAP staging system Frequency of skin inspection not reported • Patients followed-up for 8 wks Risk tool evaluated: Three groups tested: (A) Braden scale (training in application; implement scale post-training); (B) Training group (training but not implement scale); (C) Clinical judgement (received mandatory training (not about scales); used clinical judgment rating scale 1-5 Statistical: Chi-square test for significant difference between groups.To test the effect of group allocation, all significant factors plus age and PU on admission were entered into a logistic regression analysis with incidence as the outcome variable using forward conditional method of entry and entry criterion p = 0.05, removal p = 0.1.	PU incidence not reported No. in. pretest: 265 No. in posttest: 256 No. excluded: 198 No significant differences between the three groups (A, B and C) for PU incidence or PU grade 2–4 in the pre- or post-intervention (chi square p = 0.90 and p = 0.38 respectively). Differences between groups that could have affected PU incidence, including medical diagnoses, protective measures, referral to the wound care team (19.2% were referred), use of barrier creams (46.8% received barrier creams) and vitamin therapy (39.9% received vitamins). Factors that remained in the regression equation were Braden score, age, referral to the wound care team, and use of the Atmosair mattress. However, group allocation was not significant.	• No a priori sample size • Not ITT • No detail about randomisation procedure • Analysis methods limited; not appropriate • Sample size small; excluded n=198 pts • Differential sample sizes in groups • Not reported number in each group • Differences between groups that could have affected outcomes (not adjusted analysis)	Quality: Low

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Sensitivity, specificity, positive and/or negative predictive value, likelihood ratio, area under receiver operating curve (ROC)	Limitations	
(Kosmidis & Koutsouki, 2008)	Non-experimental prospective study comparing the predictive validity of two PU risk scales: the Jackson/ Cubbin and the Braden scales in an ICU setting in a general hospital.	Participants recruited from one general hospital ICU (n=71 ICU patients) Inclusion: • Aged ≥16 yrs • Admitted to ICU • ≥24hr hospital stay • without existing PU on admission Characteristics: • n=55 (77.5%) males; n=16 females • mean age 53.62±19.7 • n=0 lost to follow-up • Sample without PUs at baseline		Outcome definition: PU appearance (≥stage II EPUAP classification) Skin inspected for PU daily until ulcer occurrence or termination of ICU stay • mean length of follow-up 11.3 days (range 3-90 days) Risk tool evaluated: All subjects who met inclusion criteria were assessed with Jackson/ Cubbin and Braden scales within the first 24-36hrs of admission (T1), 72hrs after admission (T2) and every 3 days after until ulcer occurrence (T3) or discharge from ICU/death. Statistical methods: Sensitivity (Se), specificity (Sp), positive predictive value (PPV) and negative predictive value (NPV), and area under the curve (AUC).	N=24 (33.8%) developed PUs No. in final: n=71/71 Braden Scale T1: optimum cut-off point ≤11, AUC 0.608 T2: optimum cut-off point ≤17, AUC 0.511 T3: optimum cut-off point ≤14, AUC 0.633 Jackson/Cubbin T1: optimum cut-off point ≤27, AUC 0.739 T2: optimum cut-off point ≤28, AUC 0.698 T3: optimum cut-off point ≤34, AUC 0.766	How the data was collected and from whom is not stated in the paper. No follow-up was performed after discharge from ICU. Small sample size.	Quality:

References

Bååth, C., M.-L. Hall-Lord, E. Idvall, K. Wiberg-Hedman, B. Wilde Larsson. (2008). "Interrater reliability using Modified Norton Scale, Pressure Ulcer Card, Short Form-Mini Nutritional Assessment by registered and enrolled nurses in clinical practice." Journal of Clinical Nursing **17**(5): 618-26.

Chan, W., S. Pang, E. Kwong. (2009). "Assessing predictive validity of the modified Braden scale for prediction of pressure ulcer risk of orthopaedic patients in an acute care setting." Journal of Clinical Nursing **18**(11): 1565-73.

de Souza, D., V. Santos, H. Iri, M. Sadasue Oguri. (2010). "Predictive validity of the Braden Scale for Pressure Ulcer Risk in elderly residents of long-term care facilities." Geriatric Nursing **31**(2): 95-104.

Eun-Kyung, K., et al. (2009). "Comparison of the predictive validity among pressure ulcer risk assessment scales for surgical ICU patients. ." Australian Journal of Advanced Nursing **27**(4): 87-94.

Fossum, M., O. Olle Söderhamn, C. Cliffordson, U. Söderhamn. (2012). "Translation and testing of the Risk Assessment Pressure Ulcer Sore scale used among residents in Norwegian nursing homes." BMJ Open 2:e001575 doi:10.1136/bmjopen-2012-001575.

González-Ruiz, J. M., et al. (2008). "Validity study of the current risk assessment scale of PUs in intensive care." Enferm Intensiva **19**(3): 123-31.

Kosmidis, D., S. Koutsouki. (2008). "Pressure ulcers risk assessment scales in ICU patients: validity comparison of Jackson/Cubbin (revised) and Braden scales." Nosileftiki **47**(1): 86-95.

Kottner, J., T. Dassen. (2008). "An interrater reliability study of the Braden scale in two nursing homes. ." International Journal Of Nursing Studies **45**(10): 1501-11.

Kottner, J., T. Dassen. (2010). "Pressure ulcer risk assessment in critical care: interrater reliability and validity studies of the Braden and Waterlow scales and subjective ratings in two intensive care units." International Journal of Nursing Studies **47**(6): 671-77.

Kottner, J., R. Halfens, T. Dassen. (2009). "An interrater reliability study of the assessment of pressure ulcer risk using the Braden scale and the classification of pressure ulcers in a home care setting." International Journal of Nursing Studies **46**(10): 1307-12.

Kumari, S., D. Sharma, A. Rana, R. Pathak, R. Lal, A. Kumar, et al. (2012). "Risk assessment tool for pressure ulcer development in Indian surgical wards." Indian Journal of Surgery **Dec**: 1-7.

Moura De Araújo, T. M., M. F. Moura De Araújo, C. da Silva Cavalcane, G. M. Barborsa J, J. A. Caetano. (2011). "Accuracy of two pressure ulcer risk scales for patients within critical condition." Rev enferm **19**(3): 381-5.

Rogenski, N. M. B., P. Kurcgant. (2012). "Measuring interrater reliability in application of the Braden Scale." Acta Paulista de Enfermagem **25**(1): 24-8.

Serpa, L. F., et al. (2011). "Predictive validity of the Braden scale for pressure ulcer risk in critical care patients." Revista Latino-Americana de Enfermagem **19**(1): 50-7.

Simão, C., M,, M. Caliri, H,L, , C. Dos Santos, B. (2013). "Agreement between nurses regarding patients' risk for developing pressure ulcer." Acta Paulista de Enfermagem **26**(1): 30-5.

Suriadi, H. Sanada, J. Sugama, B. Thigpen, M. Subuh. (2008). "Development of a new risk assessment scale for predicting pressure ulcers in an intensive care unit." Nursing in Critical Care **13**(1): 34.

Webster, J., K. Coleman, A. Mudge, L. Marquart, G. Gardner, M. Stankiewicz, et al. (2011). "Pressure ulcers: effectiveness of risk-assessment tools. A randomised controlled trial (the ULCER trial)." British Medical Journal Quality & Safety **20**(4): 297-306.

SKIN AND TISSUE ASSESSMENT

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
Skin assessment technological strategies							
(Farid, Winkelman et al., 2012)	Observational retrospective study **investigating relationship between temperature at a pressure-impacted skin site versus intact skin site**	Records were reviewed from eligible participants admitted in an 18 month period to one university hospital (n= 85) Inclusion: • admitted to med/surg, ventilator, critical care units • record of directly observable pressure-impacted skin at least 4cm^2 • hospitalized at least 6 days Exclusion criteria: • lower extremity pressure-impacted skin area together with history of peripheral vascular disease • blistered or disrupted skin over pressure-impacted area • potential diabetic foot ulcer as determined by history	• Data from all acute care hospital patients with an observed pressure-related intact discolored areas of skin (PRIDAS) who received a skin integrity consult, including a skin temperature measurement with a handheld thermographic device	• Skin temperature • Presence or absence of capillary refill • Initial assessment and follow-up 7 to 14 days later Correlated temperatures with the development of skin necrosis after 7 to 14 days Examine the effect of additional patient variables on the progression or resolution of a PRIDAS.	• 55 participants (65%) had a lower temperature at baseline in the pressure-impacted region compared with than adjacent skin. Of these, 29 participants progressed to necrosis compared to one of 30 with a higher temperature in pressure impacted region than adjacent skin. • At 7 day follow up, having a cooler PRIDAS was 31.8 times more likely to progress to necrosis than the warm PRIDAS (OR 31.8, 95% CI 3.8 to 263.1, p=0.001) • Skin tone (white, dark) showed a trend towards significant relationship with skin necrosis (OR 7.7, 95% CI 0.8 to 70.8, p=0.07) • 0% of 26 patients who had blanching and a warm PRIDAS developed skin necrosis • **Study conclusions: skin temperature measures and comparison to intact normal skin may provide an indicator for likelihood of skin necrosis and possible indication of STI rather than stage 1 PU**	• Use of a single device to measure temperature • Very wide confidence intervals, suggesting uncertainty with findings	**Level of evidence: 4 (prognostic) Quality: moderate**
(Hagblad, Lindberg et al., 2010)	Observational laboratory study **to validate a probe to measure blood flow at different depths**	Participants were healthy volunteers (n=11) No demographics provided.	• Measurements were performed at room temperature firstly in a sitting position, then in an exercise phase and in a post-exercise sitting position	• Changes in blood flow measured using photoplethysmogram (PPG) and laser doppler flowmetry (LDF)	• **Study conclusions: In clinical situations without pressure present, the probe appears to measure changes in blood flow related to exercise accurately.**	• Probe was used only in situations without applied pressure	**Indirect evidence Quality: low**
(Hagblad, Folke et al., 2012)	Observational laboratory study **investigating changes in temperature and skin blood flow**	Participants were healthy volunteers (n=20) No demographics provided.	• The measurement procedure was preceded by a 15 min resting period to control for any confounding factors • Measurements for all participants were taken using a sensor on the	• Changes in temperature measured using a temperature sensor • Changes in blood flow measured using photoplethysmogram (PPG) and laser doppler flowmetry (LDF)	• There is a statistically significant ($p < 0.001$) rise in temperature in all subjects from baseline to one hour, from baseline to 20 minutes, from 20 minutes to 45 minutes and from 45 minutes to 60 minutes. • There were significant increases in blood flow measured via PPG and LDF from baseline to 60 minutes, from 20 minutes to	• Does not state the type of support surface • No demographics provided for the participants • Potential morbidity was not identified e.g.	**Indirect evidence Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
	during supine lying		participant's back and with the participant in supine position and on both the participant's sides.	• Measures were taken continuously for half the participants and intermittently every 15 minutes for the other half of participants.	45 minutes and from 45 minutes to 60 minutes.	unknown if any of these volunteers had underlying disease, but low mean age • No visual assessment of skin condition	
(Kim, Wang et al., 2012)	Observational laboratory study **investigating relationship between interface pressure and tissue blood oxygen**	Participants were healthy volunteers (n=20) Characteristics: • 50% sample female • Mean weight 69 kgs (SD 17) • Mean age 24 years	Measurements were performed for every participant in supine on a standard hospital mattress and sitting positions • Measurement of tissue blood oxygen • Measurement of interface pressure	Tissue oxygen using a radiometer calibrated to room air temperature that (maintained at 25°C SD 2°C throughout study) and electrodes placed on bony prominences Interface pressure measured using a pressure mat Data was collected at 5-minute intervals over 20 minute period for each position	**Supine position** • No significant difference in transcutaneous tissue oxygen or interface pressure for right ischial tuberosity. • Significant increase in in transcutaneous tissue oxygen at sacrum between baseline and 15 minutes ($p<0.05$) but no significant difference in interface pressure. • For left ischial tuberosity there was a statistically significant increase in interface pressure over time between baseline and 15 minutes ($p<0.01$) and 20 minutes ($p<0.001$) and a significant increase in interface pressure between 5 minutes and 20 minutes ($p<0.10$) **Sitting position** • No significant differences in in transcutaneous tissue oxygen at any time point. **Conclusions: Relationship between transcutaneous tissue oxygen and interface pressure showed no statistically significant correlation. Able bodied individuals appear asymmetric.**	• Small study with healthy volunteers – results may not be generalizable to populations at risk of PU • Potential morbidity was not identified e.g. unknown if any of these volunteers had underlying disease, but low mean age • No visual assessment of skin condition	**Indirect evidence Quality: moderate**
Assessing erythema							
(Kottner, Dassen et al., 2009)	Quasi experimental **comparing a transparent disc to a finger method for assessing erythema (stage I PU)**	The study was conducted as part of an annual prevalence survey in 39 hospitals and 29 nursing homes in Germany (n=9752) (intervention = 4657; control = 5095) Characteristics: • 76.6% were hospital patients ($p<0.001$ between groups, significantly more in control group) • Mean age approx. 68 years	• prior to data collection all participating nurses were trained • For all facilities, skin examinations were conducted by a team of 2 nurses – both nurses had to agree on the presence or absence of a PU • Facilities were randomly assigned to either: o Application of a transparent disc to	• Skin assessment conducted by two nurses simultaneously • grade I PU point prevalence • Braden score	• grade I PU prevalence was significantly higher in the control group versus the intervention group (7.1% versus 3.9%, $p<0.001$) • OR of having a PU identified via the disc method versus finger method was 1.80 (95% CI 1.49 to 2.18, $p<0.001$) i.e. chance of identifying a grade 1 PU increased by 80% when the finger method was used. • **Study conclusion: more grade I PUs are identified using the finger method; however, it is unclear why this is the case or if this accurately reflects PU prevalence.**	• study design was inappropriate for exploring the reasons why grade 1 PU prevalence was much higher when the finger method was applied • assumed the two comparison groups were identical • potential selection bias	**Level of evidence: 4 (diagnostic) Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		• Mean BMI approx. 25	reddened skin so assessment of blanching could be made at the same time as pressure was applied (n=4657) ○ Finger method depressing skin to assess blanching (n=5095)			• no intention to treat analysis • potential for attrition • no interrater reliability	
(Vanderwee, Grypdonck et al., 2006)	Observational study investigating **interrater reliability in assessing blanching and non-blanching erythema**	Participants were recruited consecutively in an acute geriatric ward over 20 days (n=265) Inclusion criteria: • erythema observed by researcher Characteristics of patient participants: • 57.8% participants were female • mean age 88 years • median Braden score 17 • No participants had dark skin Characteristics of nurses (n=16): • Average age 32 years • 37.5% Level 1 nurses, 43.7% level 2 nurses	• All assessors received pre-trial training • researcher assessed all patients on ward during morning shift • Any patients with erythema were entered into study and both researcher and nurse used finger method and transparent disk to assess erythema (order of assessment methods was randomized) • Assessors conducted assessments within 30 minutes	• Skin assessments using finger press and transparent disk • Assessments made within 30 minutes of each other • Assessments conducted at sacrum, heels, hips	**Finger method** • κ = 0.69 between nurses and researchers for all body locations, 73.1% sensitivity, 95.5% specificity • κ = 0.78 between nurses and researchers for sacrum, 86.3% sensitivity, 93.9% specificity • κ = 0.63between nurses and researchers for heels, 65.3% sensitivity, 95.8% specificity **Transparent disk method** • κ = 0.72 between nurses and researchers for all body locations, 74.5% sensitivity, 95.6% specificity • κ = 0.79 between nurses and researchers for sacrum, 86.1% sensitivity, 93.4% specificity • κ = 0.67 between nurses and researchers for heels, 67.2% sensitivity, 96.1% specificity **Agreement between two methods** • κ = 0.88 all locations, all assessors • κ = 0.83 sacrum, all assessors • κ = 0.90 heels, all assessors • Agreement increased with increase in nurses experience and education levels	• Assessors were aware of their assessment results using different methods so possible contamination of assessments • Only conducted in one ward	**Level of evidence: 2 (diagnostic) Quality: high**
(Sterner, Lindholm et al., 2011)	Prospective cohort study **interrater reliability in assessing blanching and non-blanching erythema**	Participants were consecutively recruited in an emergency room in a hospital in Sweden (n =78) Inclusion criteria: • aged over 65 years • admitted to orthopedic ward with hip fracture • Exclusion criteria: • Pre-existing skin disease • Sacral PU Category/Stage II or greater	• The sacral area of each participant was visually assessed by 2 blinded assessors • Skin assessment included a visual inspection and a finger press test •	• Blanching/nonblanching erythema • Pressure ulcer prevalence • Risk assessment • Assessments were made daily for up to 5 days or until discharge/death • Kappa statistics were used for analysis	**Finger press test** • κ = 0.44 (95% CI 0.21 to 0.67) on day 1, decreasing to κ=0.20 on day 5 (95% IC –0.06 to 0.46) **Visual inspection** • κ = 0.67 (95% CI 0.53 to 0.82) on day 1, increasing to κ=0.76 on day 5 (95% IC 0.61 to 0.91) • **Study conclusion: Finger-press tests and visual observation alone were not reliable methods to discriminate between blanching and non-blanching erythema**	• High rate of PU compared with other prevalence studies, potentially due to selection bias • Several different assessors were used, specific levels of experience not reported • Experience and education of assessors not reported	**Level of evidence: 4 (diagnostic) Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		Characteristics: • Mean age 82 years for women (n=64) and 74 years for men (n=14) • 58.7% (n=34) had no PU at discharge from orthopedic ward, 45.2% (n=34) had a Category /Stage I PU and 13.3% (n=10) had a Category /Stage II PU				• Blinded assessors had access to previous assessment results • Missing data	
Assessing PU in Different Skin tones							
(Bates-Jensen, McCreath et al., 2009)	Descriptive cohort study	Participants were recruited in 4 U.S. nursing homes (NH) (n = 66) Inclusion: • Long stay NH resident • participating in a concurrent nutrition trial and consented for this additional study Characteristics: • light skin tone (n=55) and dark skin tone (n=11) • n=56 completed the study, n=6 deceased, n=2 discharged, n=3 withdrew	• Braden scale assessments conducted monthly • Skin assessment conducted by trained staff weekly for 20 weeks • Erythema and stage I PU categories • subepidermal moisture (SEM) obtained at the right and left buttocks and sacrum weekly for 20 weeks	• SEM moisture was measured with a surface electrical capacitance dermal phase meter and reported as dermal phase units • Visual assessment was rated as normal, erythema/stage I PU or stage II + PU • Discoloration was graded as: minimal, moderate or severe	• There were significant differences in SEM values according to level of skin damage detected by visual assessment • The SEM values for persons with dark skin tones compared to persons with light skin tones were: o lower for sacral sites o lower for normal skin assessment conditions o SEM pattern of scores was similar in both groups • Among persons with dark skin tones, SEM values detected the incidence of stage II or greater PU I week later (OR 1.02 per 1 dermal phase units, 95% CI 1.001 to 1.01; OR = 1.15 per 100 DPU) • SEM identified local tissue edema related to inflammatory changes that occur from 3 to 10 days prior to visual skin breakdown • **Study conclusion: Visual assessment to detect early PU breakdown is difficult in darker skin tones. A handheld dermal phase meter to measure subepidermal moisture may have clinical value to detect early PU in darker skins.**	• Recruitment is not clearly reported • Study was not designed or powered to measure the objectives reported • Interrater agreement was established prior to study	**Level of evidence: 4 (prognostic) Quality: moderate**
(Bates-Jensen, McCreath et al., 2008)	Descriptive cohort study	Participants were recruited in 2 U.S. nursing homes (NH) (n = 31) Inclusion: • Long stay NH resident • participating in a concurrent trial and consented for this additional study	• Braden scale assessments conducted monthly • Skin assessment conducted by trained staff weekly for 20 weeks • Erythema and stage I PU categories • subepidermal moisture	• SEM moisture was measured with a surface electrical capacitance dermal phase meter and reported as dermal phase units • Visual assessment was rated as normal, erythema/stage I	• There was higher concurrent SEM with higher skin damage assessed by visual assessment • SEM was 104 DPU for normal skin, 185 DPU for erythema, 264 DPU for stage I PU, 727DPU for stage II PU • SEM was responsive to changes in visual skin assessment over time	• Recruitment is not clearly reported • Study was not designed or powered to measure the objectives reported • Interrater agreement was established prior	**Level of evidence: 4 (prognostic) Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		Characteristics: • 72% light skin tone • Mean age 84.14 years • n=28 completed the study, n=2 deceased, n=1 discharged	(SEM) obtained at the right and left buttocks and sacrum weekly for 20 weeks	PU or stage II + PU • Discoloration was graded as: minimal, moderate or severe	• **A handheld dermal phase meter to measure subepidermal moisture may have clinical value to differentiate between erythema and stage I PU**	to study	

References

Bates-Jensen, B.M., H.E. McCreath and V. Pongquan. (2009). "Subepidermal moisture is associated with early pressure ulcer damage in nursing home residents with dark skin tones: pilot findings." Journal of Wound, Ostomy, and Continence Nursing **36**(3):277-84.

Bates-Jensen, B.M., H.E. McCreath, V. Pongquan, et al. (2008). "Subepidermal moisture differentiates erythema and stage I pressure ulcers in nursing home residents." Wound Repair And Regeneration **16**(2):189-97.

Farid, K., C. Winkelman, A. Rizkala, et al. (2012). "Using temperature of pressure-related intact discolored areas of skin to detect deep tissue injury: an observational, retrospective, correlational study." Ostomy WoundManage **58**(8):20-31.

Hagblad, J., M. Folke and M. Linden. (2012). "Long term monitoring of blood flow at multiple depths - observations of changes." Studies in Health Technology and Informatics **177**:107-12.

Hagblad, J., L.G. Lindberg, A. Kaisdotter Andersson, et al. (2010). "A technique based on laser Doppler flowmetry and photoplethysmography for simultaneously monitoring blood flow at different tissue depths." Medical & Biological Engineering & Computing **48**(5):415-22.

Kim, J.T., X. Wang, C. Ho, et al. (2012). "Physiological measurements of tissue health; implications for clinical practice." Int Wound Journal **9**(6):656-64.

Kottner, J., T. Dassen and N. Lahmann. (2009). "Comparison of two skin examination methods for grade 1 pressure ulcers." Journal of Clinical Nursing **18**(17):2464-9.

Sterner, E., C. Lindholm, E. Berg, et al. (2011). "Category I pressure ulcers: how reliable is clinical assessment?" Orthopaedic Nursing **30**(3):194-205.

Vanderwee, K., M. Grypdonck, D. Bacquer, et al. (2006). "The reliability of two observation methods of nonblanchable erythema, Grade 1 pressure ulcer." Applied Nursing Research **19**:156–62.

PREVENTIVE SKIN CARE

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(Houwing, van der Zwet et al., 2008)	Double blind, randomized, multicenter, placebo-controlled study	Participants were recruited from 8 nursing homes in the Netherlands (n=79) Inclusion: • pressure reliving support surface available • At risk of PU using Braden score of 20 as cut-off point Exclusion: • being treated with another topical cream • surgery within the previous 2 weeks of about to undergo surgery • existing PU • dark skin Characteristics: • Mean age between 80 and 85 years for the three groups • >50% participants were always incontinent of urine	Participants were randomly assigned to: • control group with no topical application receiving regular repositioning (n=18) • placebo Vaseline cream massaged into buttocks and heels/ankles every 6 hours for 4 weeks (n=32) • 5% DMSO cream massaged into buttocks and heels/ankles every 6 hours for 4 weeks (n=29)	Incidence of PU evaluated by 2 external observers every 2 days and categorized using EPUAP staging	• No difference between the control group and the placebo treatment group therefore massage had no influence on PU incidence • Massage with a 5% DMSO cream demonstrated a higher incidence of PU development compared to the control and to the placebo groups (OR of PU at heal or ankle 8.80 95% CI 2.61 to 29.6)	• Methods of randomization and allocation concealment not reported	**Level of evidence: 2** **Quality: moderate**
(Verdú & Soldevilla, 2012)	Prospective, multi-centre, double-blind, placebo-controlled, RCT investigating **the effect of IPARZINE-4A-SKR topical preparation in preventing PU**	Participants recruited from hospitals and social health care centres in Spain (n=194) Inclusion: • Aged over 18 years • Braden score ≤ 15 indicating medium, high or very high risk of PU • No current PU Exclusion: • Terminal illness • Active PU • Peripheral vasculopathy • Allergies to ingredients in study products	All participants had standard PU prevention programs and 12 hourly skin checks. Participants received either: • The product (IPARZINE-4A-SKR) applied topically 12 hourly to the sacrum, trochanters and heels with gentle massage until absorbed (n=99) • A placebo topical product applied as hourly to the sacrum, trochanters and heels (n=95) The intervention product is referred to as a galenic formula	Primary Endpoint • PU incidence Secondary Outcome • tolerance	• PU incidence was 6.1% in intervention group and 7.4% in the control group (z=0.08,p=0.94) • Relative risk was 0.82 (95% CI 0.29 to 2.36, p=not significant) **Study conclusions: The topical hyperoxygenated fatty acids preparation IPARZINE-4A-SKR is no more effective than a placebo topical preparation at reducing the risk of PU over 14 days.**	• Sample did not meet apriori size calculation • The study was only 14 days in length, which may not be sufficient for a prevention trial in which comprehensive PU preventative strategies were also used.	**Level of evidence: 2** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Vasopressor or chemotherapy treatment • Been in a clinical trial in previous month Characteristics: • No significant difference at baseline for age, gender or Braden score. • Mean age approx. 78 years (range 29 to 101) • Mean Braden score approx. 12 (range 8 to 15)	(i.e. compounded medicine) and contains hyperoxygenated fatty acids (actual ingredients not listed in English).				
(Pittman, Beeson et al., 2012)	RCT comparing three bowel management programs for preventing development of PU	Participants were recruited from a critical care unit (n=56) (n=59 for analysis) Inclusion: aged >17 years incontinent of at least 2 stools/24 hours no contraindications to internal bowel management devices Characteristics: 60% of sample was female mean age 59.9 ± 12 years mean BMI 33.2 mean baseline IAD score 11.7 ± 10.1 BMS group had significantly lower Braden score at baseline 18/56 participants had a PU at entry	Participants were randomized to: a) Bowel management system (BMS) catheter (n=21) b) Rectal trumpet (RT) utilized as a rectal fecal incontinence device (n=20) c) Usual care consisting of barrier creams and/or a fecal pouch collector (n=18)	Skin status measured using Incontinence Associated Dermatitis and Its Severity Instrument (IAD score) PU measured using NPUAP staging Clinician satisfaction (measured using a Likert survey) Follow up was until device failure (>3 stools incontinence/24 hours, complications or discharge from critical care)	• Three PUs developed during the study and three resolved during the study, but it was not reported to which groups these participants were assigned. • There was no significant difference between the groups on the presence of PUs at any time in the study (BMS 42.9% vs RT 35% vs usual care 27.8%, p=0.63). • Clinicians preferred the RT (82%) over the BMS (78%) and usual care (0%). • Usual care group experienced greatest reduction in IAD. • Withdrawal from the study due to complications (including rectal bleeding) or failure of device was higher in RT group. **Conclusions: use of a BMS or RT was not associated with a significant decrease in PUs, but was preferred by clinical staff**	• Insufficient participants to meet power calculation • Most participants had short entry period in the study • Some participants (n=3) enrolled in the study twice • Mean duration in study ranged from 2 days to 60 days.	**Level of evidence: 2** **Quality: low**
(Shannon, Coombs et al., 2009)	Quality improvement study investigating a silicon based emollient cream for preventing PU in incontinent patients	The study was conducted in a medical care ward in a US hospital	Hospital ran a refresher training course on patient care. WOC nurses analyzed the product use in the ward and developed a protocol for product use, including introduction of a silicon based dermal nourishing emollient. Full description of the product use was not reported.	Braden scale	• Risk of a PU was significantly reduced in the period following introduction of the emollient cream (χ^2 =7.09, p= 0.008) • PUs in the pre-intervention period peaked at 31% dropping to an average of 7% in the post-intervention period	• Full use of product not reported • No raw PU data reported • Confounding issues not addressed	**Level of evidence: 4** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(Cooper & Gray, 2001)	RCT comparing sopa and water to a foam cleanser for preventing PU	Participants were randomly selected at 5 nursing home and a hospital sites providing long term care. Inclusion criteria: • Some form of incontinence or catheterization • Consenting Characteristics: • Average age 79 to 85 tears • Mean length of stay between 0.38 yrs (soap group) and 1.72 years (foam cleanser group).	Randomized to: • standard hospital soap and water: 1% aqueous solution with a pH of 9.5-10.5 (n=49) or • foam no-rinse cleanser: combination of emollient, water-repellant deodorant and water-repellant barrier with a pH of 5.5 (n=44)	Skin assessed using Stirling Pressure Severity Scale and classified as: • broken skin (Category/Stage II pressure ulcer or above) • erythematous (Category/Stage I pressure ulcer) or • healthy (no alterations to skin integrity) Follow up 14 days.	• Skin condition maintained or improved for more participants receiving the cleanser compared with the soap and water (66% versus 37%, p = 0.05) • Participants classified with healthy skin at commencement experienced more erythema (30.3% versus 15.1%) and more broken skin (12.1% versus 0%) when using soap and water	• No blinding • Mean LOS was significantly different between groups, but skin condition was similar at start • No analysis per facility • Potential participants did not receive care to which they were assigned at one facility • Unclear if nutrition and comorbidities similar between participants.	**Level of evidence: 2** **Quality: moderate**

References

Cooper, P., D. Gray. (2001). "Comparison of two skin care regimes for incontinence." British Journal of Nursing **10**(6): S6-S20.

Houwing, R., W. van der Zwet, S. van Asbeck, R. Halfens, J. W. Arends. (2008). "An unexpected detrimental effect on the incidence of heel pressure ulcers after local 5% DMSO cream application: a randomized, double-blind study in patients at risk for pressure ulcers." Wounds: A Compendium of Clinical Research & Practice **20**(4): 84-8.

Pittman, J., T. Beeson, C. Terry, W. Kessler, L. Kirk. (2012). "Methods of bowel management in critical care." Journal of Wound Ostomy and Continence Nursing **39**(6): 633-39.

Shannon, R. J., M. Coombs, D. Chakravarthy. (2009). "Reducing hospital-acquired pressure ulcers with a silicone-based dermal nourishing emollient-associated skincare regimen." Advances in Skin & Wound Care **22**(10): 461-7.

Verdú, J., J. Soldevilla. (2012). "IPARZINE-SKR study: Randomized, double-blind clinical trial of a new topical product versus placebo to prevent pressure ulcers." International Wound Journal **9**(5): 557-65.

EMERGING THERAPIES FOR PRESSURE ULCER PREVENTION

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Electrical stimulation							
(Janssen, de Koning et al., 2010)	Cross over RCT **investigating the effect of electrically stimulated (ES) muscle activation on sitting pressure distributions**	Five participants Selection, setting and inclusion/exclusion criteria are not reported. Characteristics: • Incomplete SCI • All male • Mean age 41 ±13yrs • Mean weight 83 ±15kgs	All participants completed two protocols of ES (50 HZ, 70 to 80 mA, 2 ch neuro-stimulator administered for a 3 hour session via custom clothing to the gluteal and hamstring muscles) in a randomised order • 3 minutes stimulation in a 1sec on:1 sec off protocol followed by 17 min rest • 3 minutes stimulation in a 1sec on:4 sec off protocol followed by 17 min rest	• Seated pressure value before protocol commenced then at 1 hour, 22 hour and 3 hour • Measured during the 3 minute stimulation and the last minute before stimulation	Peak pressure significantly decreased ($p<0.05$) from • Protocol A: 183±13mmHg at rest to 168±17mmHg during stimulation • Protocol B: 179±14mmHg at rest to 147±24mmHg during stimulation Within the stimulation period muscle fatigue was apparent in protocol A but not protocol B **Study conclusions: for patients with SCI, an ES regimen of 3 minutes stimulation in a 1sec on:1 sec off followed by 17 minutes reset achieves reduction in interface pressure without muscle fatigue**	• Small trial, participant selection not reported • Short study duration, unclear if results would be sustained over longer than 3 hour periods • Unclear of a clinically significant effect, PU development was not an outcome measure	**Indirect evidence Quality: low**
(Smit, Haverkamp et al., 2012)	Comparative study **investigating the effect of electrically stimulated (ES) muscle activation on sitting pressure distributions**	Ten participants Inclusion • Complete or incomplete upper motor neuron lesion • Intact gluteal and hamstring muscles **Exclusion:** • PU of buttocks • Flaccid paralysis, intolerance to electrical stimulation • History of severe autonomic dysreflexia • Severe cognitive or communication problems **Characteristics:** • Mean age 33.7±8.9 years • Mean body mass 76.0±13.5kg • Primarily C3 to C8 injuries	All participants completed two 1-hour protocols of ES using electrical stimulation garments applied over normal garments. All participants all used their own wheelchair with a regular cushion **Protocols** • Both protocols: four blocks of 3-min stimulation (1 sec on, 4 sec off) and 17 min of rest in between blocks • Protocol A: gluteal (g) muscles were stimulated • Protocol B: gluteal + hamstring (g + h) muscles were stimulated • There was a 30 min rest period in between protocols	Interface (IT) pressures recorded during the 3 min of stimulation and during the last minute of the preceding rest period using a pressure mapping device	• In all participants, both protocols caused a decrease in IT pressure • Protocol B provided significantly greater pressure release than Protocol A (mean pressure relief (37.8mmHg±23.2mmHg versus 11.8±11.7mmHg) • Protocol B achieved a significant reduction over time in IT pressure from 44mmHg at commencement to 28.5mmHg at cycle end ($p=0.01$) **Study conclusions: ES of muscles in participants with SCI reduces interface pressure in seated position. Stimulation of gluteal and hamstring muscles appears to be more effective than stimulating only the gluteal muscles.**	• Unclear if the washout period of 30 minutes is suitable	**Indirect evidence Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Low friction textiles							
(Smith & Ingram, 2010)	Cohort comparative study **investigating effectiveness of low friction fabrics in preventing PU**	Participants were recruited from 2 medical wards and an orthopaedic ward in a UK hospital (n=650) Inclusion: • Waterlow score ≥15 (high or very high risk of PU) • Unable to reposition independently • With or without PU Exclusion: • Waterlow <15 • PU in location other than sacrum or heel Characteristics: • Demographics (e.g. age, morbidity) not reproted	Participants were in two consecutive cohorts. All patients were cared for on pressure relieving mattresses. All care and nutrition was identical except: • Cohort 1: regular hospital garments (n=204 included cases) • cohort 2 participants at high risk of sacrum or heel/ankle breakdown wore the low friction fabric Parafricta® undergarments or bootees (n=165 included cases)	• PU incidence and grading (scale not reported) • PU outcome at discharge reported as deteriorating, the same or improving.	• From participants who had no PU on admission, the incidence of hospital-acquired PU was significantly less in cohort 2 (25% versus 41%, 16% difference, p=0.02) • From participants who had a PU on admission, there was no difference in the incidence of hospital acquired PU (17% in cohort 2 versus 26% in cohort 1, p=0.184) • From participants admitted with PU, there was a lower rate of PU deterioration in cohort 2 (6% versus 27%, 21% difference, p=0.001) **Study conclusions: The use of low friction garments was associated with a reduced incidence of PU in patients presenting without a PU who had a high risk. In patients who did acquire a PU, the low friction undergarments were associated with fewer PUs deteriorating in condition.**	• Demographics of participants not reported so comparison is unknown • Prevalence of PU in each cohort was determined by auditing approx. 20% of cases. • No blinding • Drop out rate, number of participants in his cohort at commencement were not reported • Wound management was not reported	**Level of evidence: 3** **Quality: low**
(Smith, McNichol et al., 2013)	Retrospective cohort study (record review)	Participants were recruited from telemetry, urology and ICU in a US hospital. control time period (n= 659) intervention time period (n= 768) Inclusion: • Admitted or transferred to the study units during the study period for at least 48 hours Exclusion criteria: • Bed that required specialized manufacturer bedding	• All participants received the same standard pressure ulcer care including daily skin assessment, incontinence management, regular repositioning, nutritional management and moist wound healing strategies for existing PU • Control period: conventional cotton-blend linen including a fitted bottom sheet, underpad and a patient gown • Intervention period: Synthetic silk-like hospital linen and gown, including an underpad that was identical	• Record review to determine development of Stage I to IV PU during the 3 month time frame for each group	• The control group experienced significantly greater Stage I PUs than the intervention group (5.6% versus 2.3%, p<0.001) • The control group experienced significantly greater Stage II or greater PUs (5.95 versus 0.8%, p<0.001). • At discharge, significantly more control participants had a PU (13.45 versus 6.8%, p<0.001) • **Study conclusions: The use of low friction garments was associated with a reduced incidence of PU compared with conventional cotton-blend linen.**	• Record review relies on accurate documentation • Control time frame included Christmas and New Year, which may have increase in casual staff members (a known institutional factor in PU risk)	**Level of evidence: 4** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Participant characteristics: • The control group was statistically significantly older (mean 695 years vs mean 66.4 years, p=0.01) • Co morbidities included hypertension (68.7% of participants), pulmonary disease (37.4%), diabetes (36.1%) • Average mean Braden score 17.1 & 17.3 (p=0.10 between groups) • 9.9% (control) and 8.7% (intervention) had PU in admission (p=0.23 between groups)	to the control underpad except the top layer was silk-like. • All data was retrieved from record reviews				
(Coladonato, Smith et al., 2012)	Prospective, non-randomized controlled trial investigating **the effectiveness of silk-like fabrics in preventing PU**	Participants were recruited in a medical renal unit (n=307) and a surgical ICU (n=275) Inclusion: • Admitted to the unit for a minimum of 2 consecutive days • Not nursed on a pressure-relieving surface or bariatric bed Exclusion: • Hospital stay overlapped the control and intervention periods Medical renal unit characteristics: • No significant difference in weight, age (mean approx. 63 yrs), albumin levels, Braden scores (mean approx. 17) or PU on admission (13.6% control, 17% intervention). • Intervention group had	• All participants received standard pressure care including repositioning, nutritional management, moist wound dressings and continence management. • Control period: In both units there was an 8 week control period, with all participants nursed on cotton-blend linen. Control period was repeated after the intervention period. • Intervention period: An 8 week intervention period in which silk-like linen was used was introduced after the control period. • In the surgical ICU in the control period, participants assessed as having early signs of a PU were nursed directly on a mattress overlay without sheeting.	Primary endpoint was the development of a new PU	**Medical Renal Unit** • Incidence of new PUs was significantly less in the intervention period (4.6% versus 12.3%, p=0.01) • Average length of stay was significantly shorter in the intervention period (5.31 days versus 5.97 days, p=0.07) • 36.8% fewer participants were discharged with a PU during the intervention period (p=0.05) **Surgical ICU** • Incidence of new PUs significantly lower in the intervention period (0% versus 7.5%, p=0.01) • Average length of stay was not significantly different (4.33 days in intervention period versus 4.5 days in the control period, p=0.33) • **Study conclusions: the silk-like linen was associated with a lower incidence of PU in medical and surgical units compared with cotton-blend linen. Hospital stays**	• Intervention items were easily distinguishable from the control (i.e. no blinding) • No randomization	**Level of evidence: 3** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		lower prevalence of anaemia (51% versus 65.6%, p=0.005), higher prevalence of drugs/alcohol use (16.3% versus 9.1%, p=0.03) and higher prevalence of dementia (11.1% versus 5.2%, p=0.03) Surgical ICU characteristics: • No significant difference in weight, age (mean approx. 65 years), albumin levels, or PU on admission (6% control, 2.6% intervention). • Significantly less intervention participants had anemia (p=0.05) and more had pulmonary comorbidity (p=0.002) • No difference in PU on admission (9.1% control, 5.3% intervention, p=0.50)			**were shorter for medical patients nursed on silk-like linen.**		
(Yusuf, Okuwa et al., 2013)	**See data entry under microclimate**						
Microclimate							
(Angelidis, Lidman et al., 2009)	Observational experimental design **investigating the effect of pressure on skin temperature of buttocks during sitting**	Healthy volunteers acting as own controls (n=12) Characteristics: • Health and able-bodied • Mean age 22.7±1.6 years • Mean BMI 22.3±1.5 • 50% sample was female	• A special chair was constructed with a seat molded in plastic as a rounded shape with a 20 x16 cm opening in the center, leaving the area of skin and underlying tissue with the ischial tuberosities bare. • Participants were subjected to an increase in pressure of the tissues overlaying the left ischial tuberosity up to 320 mmHg. • The skin temperature was measured on the loaded left buttock half and on the unloaded right buttock half	• Skin temperature taken every 5 minutes during pressure loading and continuing after loading ceased, until peak temperature was reached	• Skin temperature increased significantly 2.7±0.4°C (men) and 2.7±0.6°C (women) on the loaded left side (p<0.001 for both groups) • When pressure was relieved, a period of hyperemia followed, this increased the temperature further significantly by 2.0±1.0°C for men (p<0.01) and 1.3±0.6°C for women 9p<0.05). • During hyperemia, maximum temperature was reached after 366±257 seconds (women) and 266±88 seconds (men). • Both men and women exhibited an increase in skin temperature for each increment in pressure	• Small sample size of young, healthy participants • Unclear if the study methods of loading on one buttock would influence pressure on alternate buttock. • No confidence intervals, no blinding, no randomisation	**Indirect evidence Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
			for control		loading during the loading period. This increase was statistically significantly higher on the loaded left side compared to the unloaded right side. **Study conclusions: buttock temperature increases as a result of external pressure alone.**		
(Posada-Moreno, Losa Iglesias et al., 2011)	Quasi-experimental study **investigating the effect of different mattress coverings on skin surface temperature**	Participants were healthy volunteers. Participants acted as own controls. (n=31) Characteristics: • Not taking medications • No known pathology or illicit drug use • Mean age 24.83±2.38 yrs (range 19 to 29) • 55% sample female	• Temperature of examination room controlled between 22 and 25°C • Participants lay without motion in the supine position in contact with three different mattress surfaces • The same standard foam cushion was used and the surface cover was varied: ○ Cover 1: conventional cotton cover ○ Cover 2: conventional cotton cover with small plastic film underneath ○ Cover 3: plastic protective case	• Baseline temperature measured at axilla • Skin temperature measured at 7 areas (sacrum, right and left scapula, right and left elbow, right and left calcaneus) • Temperature measurements were taken every minute for the first 15 min, followed by a measurement at 30 min, 45 min and then every minute until 60 minutes.	• Skin temperature dropped at most thermometer points for all types of cover compared with baseline ($p<0.001$ for most body points and covers) • Plastic covering produced a larger increase in local temperature at all extremities	• Small sample of young adults with no pathology • Baseline temperature was taken at axilla and study measures were taken at extremities, therefore drops in temperature from baseline should be expected	**Indirect evidence Quality: low**
(Källman, Bergstrand et al., 2013)	Descriptive comparative design investigating **the effect of positioning on tissue blood flow and skin temperature**	Convenience sample recruited from hospital wards in Sweden. Participants acted as their own controls. (n=20) Inclusion: • aged 65 years and older • able to lie in study positions Exclusion: • history of PU, or an existing PU, or skin damage to the sacrum, trochanter or gluteus maximus • with fever (>37.5°C) Characteristics: • Mean age 84±7.5 years • Mean BMI 23±3.5 • Mean body temperature	Participants were place in six positions for measurement of blood flow and skin temperature. • In all positions a 14cm thick pressure reducing cold foam mattress with a 65+50kg/m^3 density and covered with a soft elastic, vapor permeable overlay was used. The mattress was covered with a cotton sheet. • All patients were dressed in a hospital gown and covered with a blanket during measurements • Six positions were used: in the same order for each	• Superficial and deep tissue blood flow measured over bony prominences and in gluteus muscle using a photoplethysmography (PPG)instrument and probe • skin temperature measured over bony prominences and in gluteus muscle using a single sensor optical probe • measurements were taken after 25 minutes in position	**Tissue blood flow** • The median relative change in superficial blood flow over bony prominences increased in all supine positions and decreased in the lateral positions. • The blood flow over the bony prominence areas was most changed in superficial skin and was decreased most in the 30° lateral position ($p<0.05$ compared with supine positions) • Mean arterial pressure was significantly correlated with superficial blood flow over bony prominences ($p=0.039$) • There were significant individual differences in blood flow responses but no common trend	• Participant movements may influence readings • Skin temperature increased during the procedure due to heat accumulation between the patient and the bed • Study was contradictory to previous findings that skin oxygenation is lowest in lateral 90° position	**Indirect evidence Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		36.5±0.5°C • Mean arterial pressure 76±3mmHg • Participants were taking a range of cardiac medications, analgesia and other systemic medications	participant: ○ Supine tilt 30° ○ Supine 0° ○ Semi-fowler 30° ○ Semi-fowler 30-30° ○ Lateral 30° ○ Lateral 90°		**Skin temperature** • Skin temperature was significantly correlated with overall relative change in superficial blood flow (r=0.23, p= 0.007) • No relationship was found between skin temperature and relative changes in deep blood flow **Study conclusions: lying position influences superficial skin blood flow in different ways.**		
(Jan, Liao et al., 2013)	Quasi-experiment investigating the **effect of lowering the skin temperature on metabolic rate of skin and muscles**	Convenience (?) sample of healthy participants (n=10) and participants with SCI (n=10) in the US. Inclusion for SCI participants: • Wheelchair user • SCI level C4 to T5 • At least 6 months post-injury Exclusion: • Existing sacral PU • Cardiopulmonary disease, diabetes or medication influencing cardiovascular function Characteristics: Mean age 27.5 years healthy volunteers, 35.8 years SCI Mean injury duration 9.7 years Mean BMI 23.3 SCI, 25.8 healthy volunteers	• Participants acclimatized for 30 mins prior to study commencement in the 24±2°C heated laboratory. • Each participant underwent three protocols with 10 min baseline periods and a wash out period after each: • 20 min loading with 60mmHg applied to the sacral skin surface • 20 min loading with 60mmHg applied to the sacral skin surface while temperature was reduced by 10°C • 20 min loading with 60mmHg applied to the sacral skin surface while temperature was increased by 10°C	• Skin temperature and skin blood flow at sacrum during each protocol	• No significant differences in skin temperature were noted between healthy volunteers and SCI participants • Mean skin blood flow in the three protocols was not significantly different between groups. • Peak and total hyperemia was significantly lower when pressure was applied with cooling (p<0.17 compared with no temperature change and compared with heating) • Recovery was shorter in the cooling protocol compared with heating (p<0.17) **Study conclusions: skin cooling appears to lead to reduced hyperemia in response to pressure.**	• Small sample size • Difference in ages between SCI and healthy volunteers (but did not reach significance)	**Indirect evidence**
(Yusuf, Okuwa et al., 2013)	Prospective cohort study **investigating the relationship between PU development and microclimate**	Participants were recruited in an Indonesian hospital (n=86, 71 completed study) Inclusion: • Braden score of 18 or lower • Aged ≥ 18 years • No history of PU	• Standard care in the facility. Influences on microclimate and pressure ulcer prevention: ○ Dry season in Indonesia (high humidity) ○ Average room temperature 30°C ○ Foam mattress with	• Microclimate measured at the sacrum and periumbilicum (skin temperature, skin moisture (only from 8am until midnight) • Room temperature • Daily skin inspections and EPUAP staging system	• 28% participants developed PU or superficial skin changes, primarily Stage II PU • There was no significant difference in skin temperature at the sacrum between those who did and did not develop PU (p=0.07) • Multivariate analysis found the	• High humidity of ward environment decreases reliability of skin temperature measures • Exclusion criteria were not established apriori • No randomization (unclear how many patients received synthetic sheets)	**Level of evidence: 3** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Exclusion: • Pain, pre-existing PU or skin maceration • Critical health condition	synthetic fiber or 100% cotton sheets	• All observations by a single observer	type of sheet (cotton versus synthetic fiber) and total Braden score were significant factors in the development of PU o Sheet (more likely with cotton sheets): p=0.053, OR 0.11, 95% CI 0.012 to 1.032 o Braden score: p=0.00, OR 0.347, 95% CI 0.206 to 0.585 • **Study conclusions: Although the authors conclude that skin temperature could be used to detect increased risk of PU in patients with dark skin tones, the temperature of skin was not significant in development of PU. The authors also conclude that the sheets changed the microclimate, however there is no data on relationship between sheets and sacral temperature.**	• Non-blinded	
Prophylactic wound dressings							
(Walsh, Blanck et al., 2012)	Case series exploring the influence of a **silicone border foam dressing in reducing incidence of sacral PU**	Sample of participants recruited in a US ICU (n=62) Selection criteria included: • Cardiac arrest or vasopressors for > 48 hours • Surgery for > 8 hours • Shock, SIR, MODS • > 5 PU risk factors Participant characteristics: • Mean age 66 years • Mean Braden score 12	For participants meeting the selection criteria, a silicone border foam dressing was applied to the sacrum every 3 days while in the ICU	• Skin/dressing assessed daily • NPUAP PU staging system • Follow up period is not reported	• 4.8% of patients with the silicone border foam dressing experienced a sacral PU	• Selection of participants into study is not reported • No control group • Combination of change in interventions, therefore cannot clearly indicate outcome is associated with a dressing	**Level of evidence: 5** **Quality: low**
(Santamaria, Gerdtz et al., 2013)	RCT investigating the influence of a soft **silicone multi-layer foam dressing in reducing incidence of heel and sacral PU**	Participants recruited in acute hospital and admitted to ICU in Australia (n=440) Inclusion: • Emergency dept. with ICU admission • Aged ≥ 18 years	Participants were randomized to receive: • Control group: normal PU care • Intervention group: silicone border foam dressing applied to heels (retained with net stocking) and sacrum. Dressings were	• Skin assessed every 2 to 4 hours by researcher • All researchers underwent inter-rater reliability in staging PU (AWMA staging system) prior to the study commencement	• There was significantly less PUs in the intervention group (4.3% versus 17.8%, p=0.002) • There was significantly less heel PUs in the intervention group (3.1% vs 12.5%, p=0.002) • There was significantly less sacral PUs in the intervention group (1.2% versus 5.2%, p=0.05)	• Patients who did not have first skin assessment after dressing applied were excluded • Non-blinded assessment and analysis • Inconsistency in reporting (Table 2	**Level of evidence: 2** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Exclusion: • Suspected/actual spinal injury precluding repositioning • Pre-existing sacral /heel PU • Trauma to sacrum or heels Participant characteristics: • Mean age 54 to 56 years • Primarily admitted due to critical illness • Mean stay in ED was 6 hours, mean time in OR was 4 hours, mean time in ICU 86 to 91 hours • Mean Braden score 12	applied in ED and changed every 3 days unless soiled/dislodged		• Number need to treat = 10	reports 2 different % of PU incidence) • No confidence intervals reported • Category/Stage not reported	
(Torra I Bou, Rueda López et al., 2009)	Multi-center RCT **comparing a protective bandage to a hydrocellular foam dressing for preventing PU**	Participants recruited from 3 long term care facilities and 3 home care programs in Spain (n=130 recruited, 111 completed trial) Inclusion: • At risk of PU according to Braden score • Able to consent Exclusion: • Existing heel PU • Diabetes • Using a preventative support surface • Using local device for offloading heel pressure Characteristics: • Groups were comparable at baseline • Mean age approx. 85 years • Primarily female participants • Mean Braden score 13.4±3 • Mean time spent in bed each day was approx. 14.5	All participants treated according to the standard PU prevention care in the facilities including skin inspections and regular repositioning. Participants were randomly allocated to either: • Bandage group: protective bandage of the heel (covering ankle articulation) • Dressing group: polyurethane foam hydrocellular dressing applied to heel and fixed with a net bandage Study duration was 8 weeks	• PU development at 8 weeks determined according to skin assessments • Relative risk of developing a PU	• The dressing group had a significantly lower incidence of heel PU at 8 weeks (3.3% versus 44%, p<0.001) • Bandage group required replacement of bandages significantly more often than dressings required replacement (2.04±1.1 times/week versus 0.58±0.48 times/ week, p<0.001) • Relative risk of developing a PU was 13.42 (95% CI: 3.31 to 54.3) for the bandage group compared to the dressing group • **Study conclusions: A preventative hydrocellular foam dressing is associated with a lower incidence of PU in older adults at high risk compared with a non-standard protective bandaging intervention.**	• Minimal reporting of methods • Co-morbidities and risk factors not reported (e.g. nutritional status) • Protective bandaging is not considered a standard preventative strategy for heel PU therefore was not a reasonable comparison	**Level of evidence: 2** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		hours, with repositioning approx. every 3 to 4 hours.					
(Brindle & Wegelin, 2012)	RCT investigating the **effectiveness of a silicon border foam dressing in preventing sacral PU**	Participants were admitted to a cardiac ICU in USA. Beds in the unit were randomised as control or intervention beds, participants entered the group assigned to their bed (n=100 included participants, n=85 participants completed study and analysed). Inclusion: Participant considered to have high risk of PU based on: • Surgery duration >6 hours • Cardiac arrest during admission • Vasopressors > 48 hours • Presence of shock, systemic inflammatory response syndrome, multiple organ dysfunction • Presence of at least 5 common risk factors for PU Exclusion: • Existing PU greater than stage I on admission • Aged less than 18 years • Pregnant female • Not meeting inclusion criteria Characteristics: • No significant difference in demographic characteristics, • Mean age 61.8±13.2 yeears, • 66% sample male • Mean Braden score 11.2±2.12 • Mean time in OR approx.	• Staff members in ICU were provided with education on PU prevention for 3 weeks prior to the study. • All participants received low air loss mattress, repositioning, hydration, dietitian referral, regular skin checks. • All participants had prophylactic dressing in place during surgery. • Participants were assigned to either: o Control group received only standard preventative care and barrier cream at least twice daily(n=35) o Dressing group received standard preventive care plus application of the silicone border foam dressing covering sacrum and changed every 3 days or as required (n=50)	• Incidence of PU	• 9 PUs of stage II or greater developed during the course of the study. • No patient developed a PU until at least 6 days after the operative procedure. • 8 PUs developed in 4 participants in the control group (11.7%) versus 1 PU (2.0%) in the intervention group (p=NS between groups). • The unadjusted hazard ratio obtained was 4.4 (95% CI 0.49 to 39.4, p=0.19). • After adjustment by propensity score the hazard ratio was 3.6 (95% CI 0.32 to 40.7, p=0.30) i.e. those in standard care group experience a risk 3.6 times greater than the dressing group, but this is not significantly different. **Study conclusions: in patients in the ICU at high risk of PU, preventative sacral foam dressings are no more or less effective in preventing PU incidence than comprehensive standard PU prevention programs coupled with staff education.**	• Overall incidence of PU was less than expected or reported in other studies • Study was insufficiently powered to test for clinical significant results • Randomisation by bed instead of participant, no blinding, no intention to treat analysis.	**Level of evidence: 3** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		7.70 hours • Primarily on bed rest • 32 to 37% with diabetes mellitus, 2% with malnutrition, 2 to 3% with incontinence •					
Device-related pressure ulcers							
(Forni, Loro et al., 2011)	Historical controlled clinical trial **investigating effectiveness of polyurethane foam applied inside a foot plaster cast for reducing device-related heel PU**	Participants recruited from an orthopaedic ward in Italy (n=158, 156 completed study). Study used an historical control group. Inclusion: • Orthopaedic disease requiring plaster cast on lower limb and foot, including heel • Sore skin (stage I PU) on presentation OR undergoing chemotherapy Exclusion: • Cast not including foot • PU > stage I • Not having a risk factor of sore skin or chemotherapy Characteristics: • No significant difference in demographics at baseline • Mean age 28 to 30 years • Primarily quick setting plaster cast including spica casts, above the knee casts and below the knee casts	• Study group: received sterile polyurethane foam pad measuring 10 x 10 cm in contact with the skin of the heel before applying the cast (n=71). Treated 2007 to 2009. • Control group: retrospective participants with the same risk factors but not administered the foam prior to cast application (n=85). Treated 2005 to 2006.	• Presence/absence of PU in the treated limb using NPUAP staging	**Participants with stage I PU (sore skin) as a risk** (n=56 in study group, n=49 in control group) • Significantly less participants in the experimental dressing group who presented with stage I PU experienced PU of the heel on cast removal (3.6% versus 42.9%, p < 0.0005 • The relative risk of heel PU on cast removal was 0.08 (95% CI 0.02 to 0.33) equating to a 92% (95% CI 58% to 97%) reduction in risk of a heel PU associated with the foam heel dressing. • Number needed to treat (NNT) was 3 (95% CI 2 to 4). **Participants with chemotherapy as a risk factor** (n=24 in study group, 54 in control group) • From participants undergoing chemotherapy, the study group had significantly less PU (4.2% versus 33.3%, p=0.005) **Study conclusions: application of a polyurethane foam in contact with the skin prior to applying a plaster cast covering the foot is associated with a lower rate of heel PU in patients presenting with risk factors of existing stage I PU or undergoing chemotherapy**	• Historical control • Length of plaster cast insitu is not reported and may be significantly different • Other management strategies (e.g. patient education) were not reported and may vary between groups	**Level of evidence: 4** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(Weng, 2008)	Quasi-experiment investigating **effect of tegaderm and tegarsorb in preventing device-related PU**	Participants recruited from a medical ICU and a cardiac ICU in Taiwan (n=90) Inclusion: • Diagnosed with respiratory failure • Using and tolerating with non-invasive face mask • No facial skin breakdown Exclusion: • Not reported Characteristics: • No significant differences between groups at commencement for any demographics including BP and bloods • Primarily classified as having adequate nutrition and no sensory impairment • Majority had no sweating observed • Mean age approx. 75years	Participants were assigned to one of three groups: • Control group with no dressing (n=30) • Tegasorb group (n=30) • Tegaderm group (n=30) The materials were used to cover the nasal bridge and patients were observed for PU formation	• Formation of PU assessed as being one of four grades (grading system not reported, Grade I defined as reddened area lasting more than 30 mins after change of position). • Time until PU formed in minutes	• Incidence of grade I PU was lower in the tegaderm group compared with control group (53.3% versus 96.7%, p<0.01) • Incidence of grade I PU was lower in the tegasorb group compared with control group (40%% versus 96.7%, p<0.01) • PUs formed significantly faster in control group (1111±2169 mins) versus the tegaderm (2628±1655mins) or tegasorb groups (3272±2566 mins, p=0.0) • There were no statistical significant difference in occurrence duration and time between the tegasorb and tegaderm group • Tegaderm adhered less effectively than tegasorb • **Study conclusions: A protective dressing was associated with decreased incidence of grade I PU in older adults wearing non-invasive face masks**	• Small number of subjects • No blinding, no power calculations • Several factors may influence the findings (e.g. skin colour precluding accurate assessment of PU formation) • Facial formation may influence PU formation • No reporting of skin breaks/damage associated with dressing removal	**Level of evidence: 3** **Quality: moderate**

References

Angelidis, I., D. Lidman, F. Sjaberg. (2009). "Decubitus ulcer development: pressure alone increases tissue temperature." European Journal of Plastic Surgery **32**(5): 241-4.

Brindle, C. T., J. A. Wegelin. (2012). "Prophylactic dressing application to reduce pressure ulcer formation in cardiac surgery patients." Journal of Wound, Ostomy and Continence Nursing **39**(2): 133-42.

Coladonato, J., A. Smith, N. Watson, A. T. Brown, L. McNichol, A. Clegg, et al. (2012). " Prospective, Nonrandomized Controlled Trials to Compare the Effect of a Silk-Like Fabric to Standard Hospital Linens on the Rate of Hospital-acquired Pressure Ulcers." Ostomy/Wound Management **58**(10): 14-31.

Forni, C., L. Loro, M. Tremosini, S. Mini, E. Pignotti, O. Bigoni, et al. (2011). "Use of polyurethane foam inside plaster casts to prevent the onset of heel sores in the population at risk. A controlled clinical study." Journal of Clinical Nursing **20**(5/6): 675-80.

Jan, Y. K., F. Liao, L. A. Rice, J. A. Woods. (2013). "Using Reactive Hyperemia to Assess the Efficacy of Local Cooling on Reducing Sacral Skin Ischemia Under Surface Pressure in People With Spinal Cord Injury: A Preliminary Report." Archives of Physical Medicine and Rehabilitation.

Janssen, T., A. de Koning, K. Legemate, C. Smit. (2010). "Electrical stimulation-induced Gluteal and Hamstring muscle activation can reduce sitting pressure in individuals with a spinal cord injury, ." Assistive Technology Research Series: 332-4.

Källman, U., S. Bergstrand, A. C. Ek, M. Engström, L. G. Lindberg, M. Lindgren. (2013). "Different lying positions and their effects on tissue blood flow and skin temperature in older adult patients." Journal of Advanced Nursing **69**(1): 133-44.

Posada-Moreno, P., M. E. Losa Iglesias, R. Becerro de Bengoa Vallejo, I. O. Soriano, I. Zaragoza-García, C. Martínez-Rincón. (2011). "Influence of different bed support surface covers on skin temperature." Contemporary Nurse **39**(2): 206-20.

Santamaria, N., M. Gerdtz, S. Sage, J. McCann, A. Freeman, T. Vassiliou, et al. (2013). "A randomised controlled trial of the effectiveness of soft silicone multi-layered foam dressings in the prevention of sacral and heel pressure ulcers in trauma and critically ill patients: the border trial." Int Wound J. Epub 2013/05/29.

Smit, C., G. Haverkamp, S. de Groot, J. Stolwijk-Swuste, T. Janssen. (2012). "Effects of electrical stimulation-induced gluteal versus gluteal and hamstring muscles activation on sitting pressure distribution in persons with a spinal cord injury." Spinal Cord **50**(8): 590-4.

Smith, A., L. L. McNichol, M. A. Amos, G. Mueller, T. Griffin, J. Davis, et al. (2013). "A retrospective, nonrandomized, beforeand- after study of the effect of linens constructed of synthetic silk-like fabric on pressure ulcer incidence." Ostomy WoundManage **59**(4): 28-30, 2--4. Epub 2013/04/09.

Smith, G., A. Ingram. (2010). "Clinical and cost effectiveness evaluation of low friction and shear garments." Journal of Wound Care **19**(12): 535-42.

Torra I Bou, J. E., J. Rueda López, G. Camañes, E. Herrero Narváez, J. Blanco Blanco, J. Ballesté Torralba, et al. (2009). "Preventing pressure ulcers on the heel: a Canadian cost study." Dermatology Nursing **21**(5): 268.

Walsh, N. S., A. Blanck, L. Smith, M. Cross, L. Andersson, C. Polito. (2012). "Use of a sacral silicone border foam dressing as one component of a pressure ulcer prevention program in an intensive care unit setting." Journal of Wound, Ostomy and Continence Nursing **39**(2): 146-9.

Weng, M. (2008). "The effect of protective treatment in reducing pressure ulcers for non-invasive ventilation patients." Intensive & Critical Care Nursing: The Official Journal Of The British Association Of Critical Care Nurses **24**(5): 295-9.

Yusuf, S., M. Okuwa, Y. Shigeta, M. Dai, T. Iuchi, R. Sulaiman, et al. (2013). "Microclimate and development of pressure ulcers and superficial skin changes." International Wound Journal.

Prevention and Treatment of Pressure Ulcers

NUTRITION IN THE PREVENTION AND TREATMENT OF PRESSURE ULCERS

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
Nutritional interventions for treatment of PUs – multidisciplinary nutritional guideline							
(Meijers, Schols et al., 2008)	Cross-sectional study investigating **whether a facility-wide nutritional guideline improved assessment and management of patients with PU**	n=363 organizations in Netherlands, Germany and UK (from 1,087 invited to participate) Each facility delegated one person to respond to survey Characteristics: • 46.9% hospital-setting • 25.8% nursing home 21.6% home care • n=240 (66%) had a nutritional guideline • 58.8% respondents were nurses, 17.8% were dietitians, 85% were on a PU committee	Investigation into differences in daily practice regarding nutritional care in patients with PU and possible barriers in providing patients nutritional support Data collected via standardized questionnaire	Daily practice regarding nutritional care in patients with PU and possible barriers in providing patients nutritional support	• Facilities with a guideline were more likely ($p<0.05$) than those without to: ○ always conduct nutritional screening for a patient with PU ○ conduct nutritional assessment at regular intervals ○ record weight gain , development of PU and improvement in PU healing as outcomes for success or failure of a nutritional intervention ○ Use BMI, clinical judgement or nutritional screening tools in conducting a nutritional assessment • There was no significant difference in the types of nutritional interventions used in facilities with or without a nutritional guideline • Facilities with a guideline were less likely ($p=0.001$) to have no barriers to care. • Knowledge and skills was the most important ($p<0.006$) care barrier in facilities with and without guidelines • Facilities without guideline other significant factors were no specific guidance ($p=0.001$), reimbursement restrictions ($p=0.001$) • In facilities with guidelines, barriers were lack of resources ($p=0.001$). • **Conclusions: Having a nutritional guideline contributes to conducting of nutritional screening on a regular basis in daily practice and reduces barriers to providing nutritional support**	• Unclear if responding facilities were reflective of overall facilities invited • Reported (not observed) practice, may have been biased by survey respondents perception, interest in PU and exposure to daily care within the facility • No independent analysis based on duration of guideline use in facility	**Level of evidence: N/A Quality: moderate**
Nutritional interventions for treatment of PUs – disease specific or individualised diet							
(Cereda, Gini et al., 2009)	Single blinded RCT investigating **disease-specific nutritional**	Participants were residents in 4 LTC facilities in Italy (n=28) Inclusion: • Aged ≥ 65 yrs	• All participants had similar general PU care. • All participants received 30 kcal/kg of body weight. • Participants were	Primary outcomes were: PU healing assessed using • Pressure Ulcer Scale for Healing (PUSH; 0=complete healing and	**Change in biochemical parameters over 12 weeks** • weight gain: mean 1.8±2.7 kg treatment, 0.7±2.6 kg control, p=ns • total protein changes: mean 3.3±7.0g/L	• Small sample size • absence of a control group supplemented only with protein • orally and tube-fed	**Level of evidence: 2 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
	approach as a strategy to promote PU healing	• Stage II, III & IV PUs on NPUAP staging system Exclusion: • Acute illness • Chronic disease including diabetes mellitus, PVD • Lack of adherence to diet • Immunosuppressant Characteristics: • Primarily female, mean age approx. 82 years. • 64.3% were tube fed (p=ns between groups) • Control group had significantly more PUs of lesser severity (p=0.03) • No significant differences in BMI (20.8±3.2 treatment group versus 23.1±5.0 control group)	randomised to receive either: ○ Standard hospital diet with additional 400 mL oral supplement containing 500 kcal, 34 g protein, 6 g arginine, 500 mg vit C, 18 mg zinc OR if tube fed 1,000mL high protein formula (20% energy from protein enriched with arginine, zinc, vit C) infused with isocaloric formula to reach energy requirements (intervention group, n=15 but 2 deceased, analysis was n=13) ○ Standard hospital diets (16% energy from protein) OR standard enteral formula (control group, n=15)	17=greatest severity) and • Lesion area measurements (mm^2 and % healed) 12-week follow-up	treatment, 2.2±4.5g/L control, p=ns • Albumin, transferrin, lymphocytes and haemoglobin all p=ns between groups **PU healing over 12 weeks** • Both groups had significant improvement in PU healing (p<0.001 for both groups) • PUSH score became statistically significantly different between groups at Week 12 (favoured treatment, p<0.05) and ulcer area was significant by week 8 (favoured treatment, p<0.05) • **Conclusions: Rate of PU healing in older adults appears to accelerate when a nutrition formula enriched with protein, arginine, zinc and vitamin C is administered for at least 8 weeks**	subjects were analyzed together • no intention-to-treat analysis was performed • Excluded any co-morbidities so results are not generalizable (from 371 potential participants, only 39 met inclusion criteria) • Control group had significantly less severe PUs at baseline • Superior healing only evident after 8 to 12 weeks of treatment	
(Ohura, Nakajo et al., 2011)	RCT investigating effectiveness of **nutritional intervention that uses calorie calculation according to Basal Energy Expenditure (BEE) in promoting PU healing**	n=60 older Japanese patients Inclusion: • Tube fed • Sacral, coccygeal, trochanter or calcaneal stage III or IV PUs according to NPUAP classification • albumin of 2.5 to 3.5g/dL • Braden scale score of 9 to 17 Exclusion: • Liver or renal disease, severe diabetes mellitus, arteriosclerosis, malignancy • >20% necrotic tissue or 2cm depth of PU or multiple PUs Characteristics: • No significant differences between groups at baseline • Mean age approx. 81 years	All participants were managed according to local PU guidelines including pressure mattress and 2 hourly repositioning. Participants were randomised to either: • Same number of calories as before participating in this trial (control group, n=29) • calories according to the range of Basal Energy Expenditure x active factor 1.1 x stress factor 1.3 to 1.5 (treatment group, n=21) 4 week protocol	• Mean daily caloric intake • Changes over time in nutritional state • Changes over time in PUs using DESIGN scale • Risk for development of PU • Adverse events Follow-up at 12 weeks	• Mean daily calories administered during the intervention period were 1,092.1 ± 161.8 kcal in the control group and 1,383.7 ± 156.5 kcal in intervention group • Statistically significant increases were noted for the intervention group over the control group for weight (p<0.001), waist circumference (p<0.001), supra-iliac skinfold thickness (p<0.005) and thigh circumference (p<0.005). • PUs healed within 12 weeks for four subjects in the control group and seven subjects in the intervention group. • PU depth decreased more steadily in intervention group (p< 005) • No significant changes over time for each parameter of the DESIGN scale • No significant changes over time for each parameter of the Braden scale • **Conclusions: a nutritional intervention calculated on Basal Energy Expenditure x active factor 1.1 x stress factor 1.3 to 1.5**	Small sample size	**Level of evidence: 2 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		(range 58 to 95) • Mean BMI 18			**may be related to increased PU healing in older adults being tube fed**		
Nutritional interventions for treatment of PUs – arginine supplementation							
(Leigh, Desneves et al., 2012)	RCT **comparing different doses of arginine for healing PUs**	Participants were recruited from acute inpatient and rehabilitation wards from an Australian hospital (n=23) Inclusion: • Category II, III or IV PUs showing no sign of healing • Oral diet without arginine supplement Exclusion: • Acute GIT surgery • Sepsis • Dialysis • Receiving hydroxyurea or >10mg daily prednisolone or 1.5mg daily dexamethasone Characteristics: • No significant differences in characteristics between groups at baseline • Mean age 67 to 69 yrs • Mean BMI approx 26.8 • Primarily category II PUs • Baseline PUSH scores for the two groups similar 8.9 ± 0.7 (4.5g) versus 8.1 ± 1.0; (9g), p=0.507	All participants had standard PU care throughout study. Participants were randomized to receive either: • Standard hospital diet plus 4.5 g arginine daily for 3 weeks (n=12) or • Standard hospital diet plus 9g arginine daily for 3 weeks (n=11) Patients who were discharged before the end of the study were given the appropriate number of arginine supplements and reviewed at the nearest wound clinic at the end of the study period	• Healing rate of PU size and severity assessed weekly using by PUSH tool • Nutritional status assessed on Subjective Global Assessment Follow up at 3 weeks	• There was a significant decrease in PU severity over time (p<0.001) with no evidence of difference in healing rate between the two arginine dosages (p=0.991) • Based on expected healing time, patients in both treatment groups were estimated to achieve an almost 2-fold improvement compared with the historical control group • Participants categorized as malnourished showed clinically significant impaired healing rates compared with well-nourished patients (p=0.057) although this was unaffected by arginine dosage (p=0.727) • There was no significant difference in healing rates based on arginine dosage (p=0.393) • Concordance was 92% of participants, with no difference between groups • **Conclusions: Arginine was associated with increased healing compared with historical controls, with no difference noted between a 4.5g daily and a 9g daily dose of supplementation.**	• No active control group and • No stratification or monitoring of arginine levels • There were no differences in healing rates of PU with arginine doses however it is a valid question would be if such healing rates differed from the normal rate of healing of PUs • Healing rate was monitored over a 3 week period rather than as time-to-healing data • No wound measurement or digital planimetry to objectively assess healing	**Level of evidence: 4** **Quality: low**
(Brewer, Desneves et al., 2010)	Historical control study investigating **the effect of arginine supplementation in promoting healing of PU in community SCI patients**	Participants were recruited from through a SCI community support group in Australia (n=18) and database from spinal nurse of same group was used to attain control group (n=17) Inclusion: • SCI	Intervention group (n=18): Consumed x2 sachets daily of supplement containing 4.5g arginine, 4g carbohydrate, 155mg vitamin C, 50mg vitamin E. Sachets consumed in 200 to 250 ml water. All other care was according to recommended guidelines.	• PU size and severity assessed using PUSH tool • Nutritional status assessed on Subjective Global Assessment	• The intervention group showed superior healing with respect to time to complete healing compared to the control group (10.5±1.3 wks versus21.1±3.7 wks, p=0.006) • There was no significant difference in healing rates between participants with and without diabetes in the intervention group (p=0.894) or between participants with and without diabetes in the historical control group (p=0.994)	• Relied on database information for control group • Nutritional status of control group was unavailable • Small sample size	**Level of evidence: 5** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		• Aged ≥ 18 years • Category II, III or IV PU Exclusion: • Phenylketonuria • Sepsis • Chronic renal failure • Metabolic disease • Diabetic foot ulcer • Suspected osteomyelitis • Receiving hydroxyurea or >10mg daily prednisolone or 1.5mg daily dexamethasone Characteristics: • Participants were matched for age, gender, level of SCI injury, baseline PUSH, baseline PU area • Baseline PU area was 4.5 to 6.7 cm2 • Mean age was 49.9 to 52.2			• All participants n intervention group consumed at least 85% of supplement doses until full healing was achieved. • **Conclusions: arginine supplementation of 9g daily may be associated with faster PU healing in patients with SCI with and without diabetes**		
(Chapman, Mills et al., 2011)	Observational study **investigating PU healing in SCI patients receiving arginine supplements**	Participants were recruited from inpatient and outpatient services in Australia (n=34) Inclusion: • Over 18 years age • At least one PU of at least stage II severity • Able to receive oral nutritional support Characteristics: • Age range 18 to 71 years • Primarily admitted for management of PU • Primarily stage III PUs	In addition to standard diet, all participants were prescribed 237 mL x 2 daily of a supplement containing 18 g protein, 9 g arginine, 30mg zinc and 500 mg vitamin C. All participants received nutritional counselling and dietitian review weekly and if supplementation was < 75% prescribed dose for 3 consecutive days, participant was offered an alternative high protein without micronutrients.	• Nutritional status classified as well-nourished or undernourished based on BMI, weight and diet history, clinical factors and impacting nutrition) • PU healing assessed via measurement and classification according to EPUAP classification criteria • PU condition assessed using PUSH Scale for Healing tool • Wound assessments conducted weekly	• 41% of participants ceased the supplement prior to full healing, there was no significant difference in demographics between participants who ceased or completed supplementation • No difference in time to healing of grade III PUs between those who ceased treatment (mean 14.3±7.3 wks) and those who completed (11.4±2.0 wks, p=ns) • No difference in time to healing of grade IV PUs between those who ceased treatment (mean 31.3±13.6 wks) and those who completed (11.4±2.0 wks, p=ns) • A 2.5 fold greater rate of healing was observed in those who completed supplementation until full healing compared with those who ceased taking the supplement when healing of grade III and IV PUs was combined (8.5±1.1 wks vs. 20.9±7.0 wks, p=0.04) • **Conclusions: an arginine supplement (9 g daily) may be associated with improved PU healing rates in SCI patients with grade III**	• Small study with no control group • Co-morbidities that may influence healing were not reported • 41% of participants did not tolerate supplement • Non-blinded assessment of PU healing • Concurrent management not reported • Multi-site study that did not report comparisons by site	**Level of evidence:5 Quality:low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
					and IV PUs		
Nutritional interventions for treatment of PUs – Fish oil supplementation							
(Theilla, Schwartz et al., 2012)	Prospective RCT **investigating the impact of fish oil enriched diet on healing of PUs**	Participants were recruited from an ICU in Israel. (n=40) Inclusion: • Requiring nutritional support for ≥ 5 days • Grade II or more severe PU according to NPUAP classification Exclusion: • Immuno-impairment (e.g. AIDS, autoimmune diseases) • Immunosupressives Characteristics: • No significant between group differences in age, gender, BMI, duration in ICU, diagnostic category. • Mean age 49 to 53 years • Mean BMI 28 to 32 • Primarily medical and trauma patients • 1/20 in treatment group and 2/20 in control group had a pre-existing PU on admission to ICU and remaining PUs developed after a mean of 6 days (no difference between groups) • No significant difference in PU severity at baseline (primarily grade II, p=0.02)	Participants received enteral nutrition, or if this was not tolerated, parenteral nutrition. Quantity of formula was based on non-fasting resting energy requirements. Randomised to receive either: • fish oil and micronutrient-enriched formula (EN was enriched with vitamins A, C, E, zinc, manganese, copper, protein) (study group, n=20) or • an isonitrogenous formula (control group, n=20) Parenteral nutrition formulas taken by study and control group participants were not different with respect to micronutrients (but were different for fatty acids).	• PU state measured at baseline then weekly for 4 weeks using PUSH tool with 0=healed and 17=worst score • Acute inflammation as assessed through serum C-reactive protein (CRP) measured weekly	• There was no significant difference in protein intake between the two groups. Fatty acids intake was significantly higher in the study group ($p<0.001$) • Severity of PUs as indicated by PUSH score increased significantly over time for the control group ($p=0.02$) but not for the study group. • The study group had significantly greater decrease in CRP concentrations than the control group ($p=0.02$). • **Conclusions: a fish oil and micronutrient-enriched formula may prevent worsening PUs**	• Small sample size • No objective measurement of PUs to indicate % wound healing or time to complete healing • Person assessing PU severity was not blinded	**Level of evidence: 2 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
Nutritional interventions for treatment of PUs – high protein supplement							
(van Anholt, Sobotka et al., 2010)	double-blind RCT investigating a **high protein, arginine and micro-nutrient rich supplement to improved PU healing in adults of normal nourishment**	Participants recruited from 8 health care centres, hospitals, and long term care facilities in 4 European countries (n=43) Inclusion: • Aged 18 to 90 years • At least one stage III or IV PU according to EPUAP classification • Receiving standard care and diet without supplements for at least 2 weeks Exclusion: • Malnourished (BMI <18.5kg/m^2 if aged 18 to 70 or 21kg/m^2 if aged over 70 years • Medical condition that would influence healing • Ulcer of different aetiology • Palliative care • Protein restricted diet • Corticosteroids Characteristics: • No significant difference in baseline characteristics between groups • Mean age 73 to 76 years • Mean BMI 23.7 to 25.8 • Primarily bed or chair bound with very limited mobility • Primarily stage III PUs • Baseline PU size approx. 11cm^2	Participants were randomly allocated to either: • High energy oral nutrition supplement enriched with protein (20 g) arginine (3 g), antioxidants, vitamins A, E and C, zinc (9 mg), copper (1.35 mg), selenium (64 µg) and folic acid (200 µg) of 200ml x3 daily between meals for 8 weeks (ONS group, n=22) or • Non-caloric flavoured placebo 200ml x3 daily between meals for 8 weeks (control group, n=21)	• PU healing assessed by the change in surface area over 8 weeks (measured with ruler weekly) • PUSH tool score change over 8 weeks (recorded weekly)	• At 8 weeks there was a statistically significant difference in decrease in PU size between groups (p=0.006 treatment by time, p=0.016 treatment by time^2, repeated-measures mixed models [RMMM]) • PUs in ONS group were significantly smaller compared with baseline by week 3 (p=0.019, ANOVA) and continued to be improved (p≤0.012, ANOVA) • PUs in control group showed significant improvement compared with baseline from week 5 (p=0.019) and continued to show improvements (p≤0.008) • ONS group had significant improvement in PUSH score compared with control group (p=0.033, treatment by time^2, RMMM) • **Conclusions: a nutritional supplement with high protein, arginine and micronutrients may be associated with improved PU healing in older adults who do not have pre-existing malnourishment**	• Concurrent management strategies are not reported and it is unclear if this is consistent between 4 countries • Comparison of results by site is not reported	**Level of evidence: 2 Quality: moderate**
Nutritional interventions for treatment of PUs – ornithine alphaketoglutarate supplement							
(Meaume, Kerihuel et al., 2009)	Double blind RCT investigating effectiveness of ornithine alphaketoglutar	Participants were recruited from 67 European centres. (n=160) Exclusion: Bed-bound prior to PU	All participants received wound care according to French guidelines, heel offloading, pain management, protein intake of 1.2 to 1.5 g/kg/day. Participants were	• Heel PU area reduction assessed via clinical description, acetate tracings and measurement of length/width	**Participants with baseline PU ≤8cm^2** • mean decrease in PU area at week 6 was significantly greater in OKG group versus placebo group (–2.3±4.2cm^2 versus –1.7±1.7cm^2, p=0.006) • closure rate at week 6 was significantly higher	• Uneven distribution of PU severity between groups at baseline leading to analysis by sub group based on 8cm^2 cut-off	**Level of evidence: 1 Quality: high**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
	ate (OKG) in promoting healing of heel PUs in older adults	• PU entirely covered by necrosis or fibrin, or infected • Poorly controlled diabetes • Dialysis • Neoplasm • Parenteral nutrition • Serum albumin <22g/L • Advanced peripheral arterial disease Characteristics: • OKG group had significantly more females than control, otherwise the groups were matched for age (mean 80.8±8.8 yrs), BMI (mean 26.9±6.2 kg/m^2) Braden score (mean 17.82±3.2) • Placebo group had higher proportion of smaller PUs (52% versus 25.9% with area ≤4cm2, p=0.044)	randomised to receive either: • 10g sachet of OKG administered once daily in 200ml water during or after lunch (n=85) • Placebo sachet administered once daily in 200ml water during or after lunch (n=75) No participants had concurrent vitamin C, high dose zinc, amino acids or omega-3 fatty acids during the study. Treatment was for 6 weeks	• Braden score • Mini nutritional assessment scale • Laboratory values	in OKG group versus placebo group (–0.07±0.11cm^2/day versus –0.04±0.08cm^2/day, p=0.007) • Difference in closure rate was attributed to higher closure rates in first 2 weeks of study **Participants with PU area > 8cm2** • no difference between groups in mean decrease in PU area. • no difference between groups closure rate. **Clinically relevant adverse effects** Higher incidence of GIT complaints including diarrhoea, vomiting or nausea in OKG group versus placebo (7 considered to be related to treatment, none considered to be severe) • **Conclusion: The results suggest that OKG supplementation in older adults may contribute to faster healing rates in smaller PUs, particularly in the first 2 weeks of therapy.**	to create homogenous groups • No reporting of difference between sites, however care was standardized •	
Nutritional interventions for prevention of PUs – post operative supplementation							
(Gunnarsson, Lönn et al., 2009)	Non-randomised pre/post-test investigating **effectiveness of nutritional intervention on postoperative complications including PU**	n = 100 consecutive hip fracture patients at a Swedish orthopaedic ward Exclusion: • Dialysis or kidney disease requiring low protein diet or liquid restrictions • Severe liver disease Characteristics: • 71% female • Mean age 81yrs • Mean time before surgery was 24 hrs • Intervention group had significantly (p=0.048) higher weight on admission • Approximately 8% in each	Aim for all patients was to achieve 33% of daily need (30kcal/kg) on postop day 1, 50% of daily need on post op day 2 and 75% daily need by day 3. Where aim was not achieved, nasogastric feeding and glucose infusion for 12 hours. • Control group received (n=50 assigned, 23 did not participate): ○ Glucose infusion preoperatively (1,00ml, 50mg/ml) ○ Standard hospital diet postoperatively • Intervention group received	All data collected daily for one pre-operative period and five days postoperatively: • Risk of PU on Modified Norton Scale (MNS) with score ≤ considered at risk • Presence of PU based on EPUAP classification • Weight • Nosocomial infections • Cognitive ability (short portable mental status questionnaire) • Walking assistance • Functional ability on Katz index	• Significantly fewer (p=0.043) patients in the intervention group n=9 (18%) had PUs five days postoperatively compared with the control group n=18 (36%) • Incidence of newly occurring PU was lower in intervention group (18% versus 28%) • Nutrient and liquid intake (compliance with intervention) was significantly higher (p < 0.001) in the intervention group • Median length of stay was significantly less in intervention group (7 days versus 9 days, p=0.137) • Nosocomial infections significantly decreased (18 % versus 8.7% , p=0.137) • Predictors of developing PU: ○ PU on admission OR=30.55, 95% CI 2.8 to 338.6, p<0.005 ○ Nutritional intervention OR=0.31, 95% CI 0.1 to 1.0, p=0.049	○ No randomization ○ High level of non-participation ○ Short study period	**Level of evidence: 3 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		group had PU on admission • Risk of PrU on Modified Norton Scale : control group 15.9 ± 3.5 (10-26); intervention group 16.6 ± 3.5 (10-24) p=0.398	(n=50 assigned, 35 did not participate): ○ Glucose infusion (3,00ml, 50mg/ml) and carbohydrate drink (800ml) pre operatively ○ Drinking supplement (520 ml) and standard hospital diet postoperatively		○ Preoperative length of stay OR=2.41, 95% CI 1.3 to 4.4, p=0.004 • **Conclusions: regular skin inspection, assessment of PU risk and early nutritional supplementation may contribute to a reduced incidence of PU in elderly hip fracture patients**		
Nutritional interventions for prevention of PUs – fluid supplementation							
(Stotts, Hopf et al., 2009)	Prospective RCT investigating **effectiveness of supplemental fluid in preventing PUs in older adults**	Participants recruited from 5 nursing homes in US (n=53) Inclusion: • Nursing home resident • Braden Scale ≤18 • BMI 20 to 29.5 kg/m^2 • WBC ≥ 2,000/nm^3 Exclusion: • Heart failure, kidney disease, tobacco use, acute illness, immunosuppressive medication, • Implantable defibrillator • Known or suspected dehydration Characteristics: • Mean age 79.3±8.79 • Mean BMI 25.2±2.56 • Mean Braden score 14.0±2.31 • Three PUs present at baseline, all in treatment group	Participants randomised to: • Usual prescribed fluid prescribed by dietician (control group, n=27) • Supplemental fluid with target volume of fluid prescribed by dietician plus 10 mL/kg body weight administered daily for 5 days, the target volume was divided into 3 doses given orally or NGT (n=26)	Potential to heal assessed through measurement of: • collagen deposition was measured with Hyp form ePTFE tubes • Subcutaneous tissue oxygen • Estimated total body water Pain measured on Present Pain Intensity Scale of the McGill Pain Questionnaire Fluid overload (measured through lung auscultation)	• few participants in this study had PUs and so the effect of supplemental fluid on skin oxygen levels adjacent to the ulcer could not be determined • PU prevalence was 5.6% of participants • participants potential to heal as measured with Hyp (Collagen) was low at baseline when they took fluids freely and did not increase significantly during the treatment (additional fluid systematically provided) • the additional fluid did not result in adverse outcomes including change in lung sounds, extra heart sounds or result in emergency department visits or hospitalization • fluid administered based on PsqO2 values resulted in greater fluid being administered to those with low PsqO2 and subsequent work shower greater fluid administered resulted in higher Hyp (collagen) levels;	• Strict inclusion criteria lead to over 2,00 participants not meeting inclusion criteria	**Level of evidence: 1** **Quality: High**
Nutritional interventions for prevention of PUs – enteral feeding							
(Arinzon, Peisakh et al., 2008)	Prospective, observational cohort **reporting effectiveness of enteral**	Participants recruited from psychogeriatric wards for patients with terminal diagnoses in Israel (n=167) Inclusion:	Two groups were followed: • Enteral nutrition group (ENG) receiving EN primarily for weight loss (40%) stroke with impaired oral intake (32%), vegetative state	• BMI – 21kg/m^2 was considered marker of malnutrition • PU presence – used staging but did not state the scale	• ENG had significant differences in laboratory values compared with CG. • ENG experienced more major complications or symptoms related to nutrition (61% versus 34%, p<0.01) including pneumonia, weight changes,	• Groups were significantly different at baseline for primary outcome measures of nutritional state and	**Level of evidence: 5** **Quality: Low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
	nutrition (EN) in reducing prevalence of PUs in elderly patients with terminal diagnoses	• Admitted to one of 3 wards participating in the study • Randomised to be included Characteristics: • Mean age approx. 80 yrs, primarily female (p=ns between groups for age/gender) • Approx 70% had CV disease, 21-30% had diabetes mellitus (p=ns between groups for co-morbidities) • BMI <21kg/m^2 more frequent in ENG (30% versus 16%, p=0.043) • Presence of PU at baseline more frequent in ENG (26% versus 12%, p=0.017) • ENG participants had higher levels of dehydration at baseline (26% versus 13%, p=0.028) • Significant differences between groups in albumin, transferrin, CRP, BUN/Cr, sodium, potassium, urea nitrogen at baseline	(12%), end-stage Parkinson's disease (9%), and malignancy (5%). 74% had NGT, 26% PEG. Most frequent diet was 1800 to 2000 calories, 2 to 3 g sodium and 80 g protein delivered through Osmolite® HN (81% participants). (n=57) • Control group (CG) taking a regular oral diet. However, 76% of the group had nutritional supplementation for >2 months during the observation period, usually Ensure®. (n=110)	• PU risk – Norton scale • Laboratory values including serum proteins, renal function, cholesterol, iron, folic acid	death. **PU prevalence** • ENG had high prevalence of stage III to IV PUs at completion of study (14% versus 2%, p=0.005). • No significant difference in stage I to II PUs (16% ENG versus 12% CG, p>0.05) • Prevalence of PUs overall appears to be 24% CG versus 30% ENG, however analysis compared with baseline differences is not reported. • Difference between ENG and CG in mean PU risk assessed on Norton scale was significant at baseline and at the conclusion of study. • **Conclusions: An EN regimen in older adults with malnutrition and terminal disease states does not appear to influence prevalence of PU or PU risk significantly compared with an oral diet.**	PU • Unclear how PU staging was done • Large number of dropouts, primarily due to death (42% in ENG, 27% in CG) • No reporting of concurrent management strategies e.g. pressure relieving surfaces. • Pollution of control group, 76% of whom also took supplementation for at least 2 months.	
Nutritional interventions for prevention of PUs – multidisciplinary nutritional protocol							
(Allen, 2013)	Pre/post quasi experimental design investigating the **effect of a comprehensive multidisciplinary nutritional protocol on PU healing in adults over 60 years**	Participants were recruited from an acute long term care USA hospital, retrospective control group from record analysis (n=100) Inclusion: • Aged ≥60 yrs • Stage II or II PU Exclusion: • Medical conditions prohibiting vitamin, zinc or iron intake	• Control group received standard care (diet according to physician orders) and were matched for experiment group participants on age, gender, PU stage, Braden scale(all data collected from record analysis, n=50) • Experimental group (n=50) received a comprehensive nutritional protocol that included: ○ Admission and weekly	• PU risk assessed using Braden scale • PU wound healing using Bates-Jensen Wound Assessment Tool with a PU considered to be resolved when 100% granulation tissue and at least 75% reduction in size.	• There was a significant difference between groups in tissue health by week 2 (38% versus 2%, p<0.005) and in week 3 (37% versus 23.4%, p<0.05) but no significant differences in weeks 4 and 5 • **Conclusions: a multidisciplinary nutritional intervention that includes protein and vitamin/mineral supplementation may contribute to increased PU healing (assessed as % tissue regeneration) in older adults**	• No co-morbidities that may influence nutrition or healing are reported • Drop outs were not considered in the analysis and were not equivalent between groups • Relied on chart reviews for control group • No blinding of assessor and used a	**Level of evidence: 4 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		Characteristics: • 28% had stage II PUs and 72% had stage III PUs, primarily sacrum and coccyx • Mean age79.42±9 yrs • Mean BWAT 32±8.1 (range 16 to 52, p=ns between groups) • No co-morbidity reported	albumin/pre-albumin levels to determine level of nutritional support ○ OT, dietitian, speech therapist review ○ Protein supplement for all people with PU and increased protein supplementation for those with moderate or severe malnutrition ○ Vitamin A, Z, zinc, iron supplementation Experimental group received intervention until discharge or PU had a 75% reduction in size.			subjective Likert-scale wound assessment tool	
(Teno, Gozalo et al., 2012)	Cohort study investigating **the effectiveness of tube feeding in preventing PU or promoting healing**	Data was collected from the Minimum Data Set (MDS) from 1999 to 2007 (n=3170) Inclusion: • Nursing home resident hospitalised at least once in first year of entry to cohort • Advanced dementia Exclusion: • Death within 2 weeks of baseline MDS • Evidence PEG within 6 months preceding baseline MDS • Existing PU (for prevention analysis) Characteristics: • No significant differences in the following demographics between those with/without PU and those with/without PEG: • Age (mean approx. 82 yrs) • Wight loss (22 to 30%) • Diabetes, CAD,CHF, COPD, cancer, hip fracture	• Matched cohort analysis with each participant who had a PEG tube matched to 3 participants without a PEG • Used a fixed-effects model to determine if PEG was related to prevention or healing of PU	• Number and stage of stage II or greater PUs recorded quarterly and annually in MDS • PEG insertion during hospitalization	• 461 participants had a PU and a PEG inserted • Risk of new PU stage II or greater when a PEG was present was OR=2.27, 95% CI 1.95 to 2.65 • Risk of a new stage IV PU when a feeding tube was present was OR=3.31 (95% CI 2.14 to 4.89) • Of those who had a PEG inserted, 27.2% of Pus improved compared with 34.6% improving in participants with no PEG (OR=0.66, 95% CI 0.45 to 0.97) • Researchers suggest increased risk may relate to increased diarrhea or increased immobility, but this was not investigated. • **Conclusions: Feeding tubes (PEG) are not beneficial and may be associated with increased risk of PU**	• Relied on completed MDS, unclear how assessments of PU was made • Assumed PEG was inserted in an acute care facility	**Level of evidence: 4 Quality: moderate**

References

Allen, B. (2013). "Effects of a comprehensive nutritional program on pressure ulcer healing, length of hospital stay, and charges to patients." Clinical Nursing Research **22**(2):186-205.

Arinzon, Z., A. Peisakh and Y.N. Berner. (2008). "Evaluation of the benefits of enteral nutrition in long-term care elderly patients." J Am Med Dir Assoc **9**(9):657-62.

Banks, M., J. Bauer, N. Graves, et al. (2010). "Malnutrition and pressure ulcer risk in adults in Australian health care facilities." Nutrition in Clinical Practice **26**(9):896-901.

Brewer, S., K. Desneves, L. Pearce, et al. (2010). "Effect of an arginine-containing nutritional supplement on pressure ulcer healing in community spinal patients." Journal of Wound Care **19**(7):311-6.

Cereda, E., A. Gini, C. Pedrolli, et al. (2009). "Disease-specific, versus standard, nutritional support for the treatment of pressure ulcers in institutionalized older adults: a randomized controlled trial." Journal of the American Geriatrics Society **57**(8):1395-402.

Chapman, B.R., K.J. Mills, L.M. Pearce, et al. (2011). "Use of an arginine-enriched oral nutrition supplement in the healing of pressure ulcers in patients with spinal cord injuries: An observational study." Nutrition & Dietetics **68**(3):208-13.

Gunnarsson, A.-K., K. Lönn and L. Gunningberg. (2009). "Does nutritional intervention for patients with hip fractures reduce postoperative complications and improve rehabilitation?" Journal of Clinical Nursing **18**(9):1325-33.

Iizaka, S., M. Okuwa, J. Sugama, et al. (2010). "The impact of malnutrition and nutrition-related factors on the development and severity of pressure ulcers in older patients receiving home care." Clin Nutr **29**(1):47-53.

Leigh, B., K. Desneves, J. Rafferty, et al. (2012). "The effect of different doses of an arginine-containing supplement on the healing of pressure ulcers." Journal of Wound Care **21**(3):150-6.

Meaume, S., J.C. Kerihuel, T. Constans, et al. (2009). "Efficacy and safety of ornithine alpha-ketoglutarate in heel pressure ulcers in elderly patients: results of a randomized controlled trial." The Journal of Nutrition, Health & Aging **13**(7):623-30.

Meijers, J.M.M., J.M.G.A. Schols, P.A. Jackson, et al. (2008). "Differences in nutritional care in pressure ulcer patients whether or not using nutritional guidelines." Nutrition (Burbank, Los Angeles County, Calif) **24**(2):127-32.

Morello, M., M.L. Marcon, A. Laviano, et al. (2009). "Enteral nutrition in nursing home residents: a 5-year (2001-2005) epidemiological analysis." Nutrition in Clinical Practice **24**(5):635-41.

Ohura, T., T. Nakajo, S. Okada, et al. (2011). "Evaluation of effects of nutrition intervention on healing of pressure ulcers and nutritional states (randomized controlled trial)." Wound Repair & Regeneration **19**(3):330-6.

Stotts, N.A., H.W. Hopf, J. Kayser-Jones, et al. (2009). "Increased fluid intake does not augment capacity to lay down new collagen in nursing home residents at risk for pressure ulcers: a randomized, controlled clinical trial." Wound Repair and Regeneration: Official Publication of the Wound Healing Society [and] the European Tissue Repair Society **17**(6):780-8.

Teno, J., P. Gozalo, S. Mitchell, et al. (2012). "Feeding tubes and the prevention or healing of pressure ulcers. Natural history of feeding-tube use in nursing home residents with advanced dementia." Archives of Internal Medicine **172**(9):697-701.

Theilla, M., B. Schwartz, J. Cohen, et al. (2012). "Impact of a nutritional formula enriched in fish oil and micronutrients on pressure ulcers in critical care patients." American Journal of Critical Care **21**(4):e102-e9.

van Anholt, R., L. Sobotka, E. Meijer, et al. (2010). "Specific nutritional support accelerates pressure ulcer healing and reduces wound care intensity in non-malnourished patients." Nutrition **26**(9):867-72.

Verbrugghe, M., D. Beeckman, A. Van Hecke, et al. (2013). "Malnutrition and associated factors in nursing home residents: A cross-sectional, multi-centre study." Clin Nutr **32**(3):438-43.

Wojcik, A., M. Atkins and D.R. Mager. (2011). "Dietary intake in clients with chronic wounds." Canadian Journal of Dietetic Practice and Research **72**(2):77-82.

Yamamoto, T., Fujioka, R. Kitamura, et al. (2009). "Evaluation of nutrition in the healing of pressure ulcers: are the EPUAP nutritional guidelines sufficient to heal wounds?." Wounds: A Compendium of Clinical Research & Practice **21**(6):153-7.

REPOSITIONING (INCLUDING HEELS) AND EARLY MOBILIZATION

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Prone positioning							
(Grisell & Place, 2008)	Blinded RCT **comparing different facial pillows for prevention of PU in the OR setting**	Participants were consecutive patients admitted for elective surgery requiring prone position at a surgery in the USA (n=66) Inclusion: • elective thoracic and/or lumbar surgery requiring prone positioning • aged 18 to 65 yrs Exclusion: • existing facial ailment including redness, inflammation, rash, graze, bruising • history of increased intraocular pressure or glaucoma • major language not English Characteristics: • surgery times varied from 1 to 12 hours and not reported • no demographic data reported	• All participants were positioned using standard prone positioning. • Patients were randomized to receive different facial pillows: ○ Orthopedic Systems Inc (OSI) disposable polyurethane foam positioner (n=22) ○ Dupaco Prone View® Protective Helmet System disposable polyurethane foam head positioner (n=22) ○ ROHO Group neoprene air filled bladder dry flotation device (n=22)	• Facial tissue pressures were measured at the patient's forehead and chin at time 0, 5, 15, and 60 minutes of positioning • The integrity of skin was recorded and classified using NPUAP system staging at the end of surgery	• 10 patients positioned on the OSI positioner developed PUs (eight stage I PUs and two stage II PUs) • No patients from the other two groups showed any evidence of PUs • The pressure measurements for the Dupaco Prone View® were lower at all of the time points for both the forehead and the chin in comparison to the OSI and the ROHO ($p<0.05$) • Forehead pressures were significantly less for the ROHO compared with the OSI ($p<0.05$)	• Patients were not stratified by age, race, or gender and existing risk factors for PU not reported • Risk of PU on entry to study not reported • Length of time in position not recorded (procedures last from 1 to 12 hours)	**Level of evidence: 2 Quality: low**
(Romero, Cornejo et al., 2009)	Case series **investigating the effect of prone positioning ventilation and reporting PU as an adverse effect of positioning**	Participants were recruited from an ICU in Chile (n=15) Inclusion: • aged over 18 years • severe Acute Respiratory Distress Syndrome (ARDS) • ventilation >72hrs Exclusion: • contraindications to prone positioning ventilation • hemodynamic disorders • chronic respiratory insufficiency • likelihood of death within 24hrs	Prone position ventilation for 48 hours or until the oxygenation index was 10 or less (extended PPV)	Primary: • Barotraumas and/or monobronchial incursion of the orotracheal tube • Arterial and venous blood gas results Secondary: • Development of a new PU as assessed using NPUAP staging	• Prone position ventilation was continuously maintained for 55 ± 7 hours • Two patients (13%) developed grade II PUs (nasal septum, cheek) • All patients experienced facial edema • No patients experienced ventilation complications in prone position	• No control group • Only 20% of the individuals were older than 60 years	**Level: 5 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Characteristics: • Mean age 46±17 years (range 19 to 69) • Mean time for mechanical ventilation 19±9 days (rang 4 to 64) • 40% died in UC • PU risk factors not reported					
(McMichael & Place, 2008)	Cross-over quasi-experiment investigating face pillow effectiveness in reducing interface pressure in the prone position for use in the OR setting	n=15 healthy conscious subjects	• Subjects tested 3 prone face positioners: ○ a disposable polyurethane foam prone head positioner ○ a face plate and mirror with a disposable foam prone head positioner ○ a neoprene "dry flotation" device	• Face-pillow interface pressures for the forehead and chin were recorded at baseline, 1 minute, 5 minutes and 15 minutes • Measurement device not reported	• At all of the time points for the forehead and chin, the face plate and mirror positioner and the neoprene "dry flotation" device demonstrated significantly lower (p≤0.05) face-pillow interface pressures than the disposable polyurethane foam prone head positioner • No complications from the different face positioners • Volunteers rated the face plate and mirror with disposable foam prone head positioner as most comfortable	• Neoprene "dry flotation" device requires inflation using a manual pump • Participants predominantly young male healthy volunteers	**Indirect evidence Quality: low**
Heel positioning							
(Bales, 2012)	quasi-experimental clinical trial **comparing IV bags to pressure relieving boots for preventing PU**	Participants were recruited in a USA orthopaedic unit (n=30) Inclusion: • hip or knee surgery • aged 55 to 70 years • Normal ambulatory level prior to admission • Normal albumin level • No diagnosis of diabetes or peripheral vascular disease • No pre-existing PU heel or Achilles area Characteristics: • Average age 60.97 years • 70% knee surgery, 30% hip surgery	• Participants received either: ○ intravenous (IV) bags used to offload heel pressure (n=15) ○ commercial heel suspension foam boot designed to offload the foot (Heelift®) (n=15) • Devices were used for the duration of hospital stay (duration unreported)	• Daily skin assessment of heels and Achilles tendon area for redness, warmth, coolness and pain • Daily assessment via visualization and palpation to assess pain, skin condition and non-blanchable erythema and PU staging using NPUAP classification • Nurse opinion on design, texture, ease of use and preventative characteristics of interventions	• Significantly less participants using the pressure relieving boot showed signs or symptoms of pressure (blanchable erythema and warmth) compared with the IV bag group (0 versus 6, p=0.006) • Significant correlation between nurses' opinions on design and ease (r=0.569, p=0.043); design and texture (r=0.786, p=0.001) and design and prevention (r=0.788, p=0.001).	• Small convenience sample size without *a priori* power calculation • Duration of care not reported • Unclear how similar participants co-morbidity and PU risk factors were at start of trial • Other pressure relieving interventions including level of mobility not reported	**Level: 3 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(Donnelly, Winder et al., 2011)	RCT **comparing complete offloading to standard care for prevention of heel PUs**	Participants were recruited from a fracture trauma unit in Ireland (n=239, n=227 completed study) Inclusion: • Aged 65+ years • Fractured hip in previous 48 hours Exclusion: • Existing heel pressure damage • History of previous PU • Considered unsuitable by research team or no consent Characteristics: • Mean age 81 yrs • Mean Braden score 15 • low prevalence of peripheral vascular disease and diabetes • Approximately 1/3 sample were at moderate to high risk of malnutrition • No differences between groups in types of injury or time taken to get to hospital • Significantly more of the control group waited >72 hours between injury and surgery (p=0.0009) • Significantly more of the heel elevation group had surgery of > 2 hrs duration (p=0.034)	• Participants were randomized to receive either: ○ heel elevation achieved using a commercial device (Heelift® Suspension Boot) plus pressure-redistributing support surface (n=120, 9 withdrew) ○ standard care that included a pressure-redistributing support surface (n=119, 3 withdrew) • Pressure redistribution support surfaces included cut foam mattresses, alternating mattresses and mattress overlays selected according to individual needs.	Primary outcome: • Number of new category 1 or greater PUs on heels or other sites assessed daily for signs of tissue discoloration or ulceration (skin temperature, induration, oedema, pain, itching) with all skin damage photographed and confirmed by a blinded skin viability nurse who categorized damage on NPUAP scale Secondary outcomes: • Participant opinion assessed via questionnaire • Concordance with an offloading device	**Effectiveness in preventing PU** • Significantly fewer PUs in any body location in heel elevation group (7% versus 26%, p<0.001) • Significantly fewer patients in the heel elevation group developed a PU on ankles, feet or heels (0 versus 29, p<0.001) • Control group more likely (p=0.001) to suffer pressure damage at all time points. **Acceptability and concordance** • The heel elevation device was rated: ○ comfortable by 59% participants ○ interfering with sleep by 32% participants ○ adversely affecting movement in bed by 41% participants • Reasons for poor concordance included weight and bulk (36%), heat (31%) and discomfort (24%). **Adverse events** 45 adverse events (no significant association between the groups and adverse events, p=0.691)	• Potential observer bias due to non-blinding; however, all pressure damage was confirmed by a blinded assessor • Half of the subjects had support surface upgraded by nursing staff (protocol violations) • Duration of time spent in bed/days treatment was not reported • Study failed to recruit *a pirori* sample size	**Level: 2 Quality: moderate**
(Meyers, 2010)	Case series investigating **the effectiveness of a heel protection device in prevention and treatment of PUs**	Participants were recruited from an ICU in the USA (n=53) inclusion: • aged ≥ 18 years • sedated • ICU for ≥5 days • Braden Scale score of ≤16 on admission to ICU Exclusion: • aged < 18 years	• All participants had the heel protector device (Prevalon™ Pressure-Relieving Heel Protector) applied to both heels. • The device maintained foot in neutral position and floated heel off the bed. • Heel protector device was removed every shift for skin assessment and range of movement exercise	Primary: • Development of a new heel PU or worsening of a preexisting heel PU as assessed using the Braden Scale and defined using NPUAP classification scale. Secondary: • Development of a new plantar flexion contracture or worsening or a preexisting plantar flexion contracture	• There was a 55% reduction in the number of abnormal heels between admission and discharge (from 21% on admission to 9% on discharge) • No new heel PUs developed during admissions • Patients with normal heels had significantly (p=0.0136) higher Braden Scale scores compared to those with abnormal heels (stage 1 to 4 PUs)	• Absence of a control group • Lack of standardized skin assessment • Unclear what other interventions were used e.g. support surface, PUs dressings • Unclear over what timeframe the	**Level: 5 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Medical condition contraindicating use of heel protection device • Not deemed at high risk of heel PU Characteristics on admission: • 21% of participants (16 heels) had at least one abnormal heel (PU stage I to IV)	• Participants with existing PU had a hydrocolloid dressing applied to heels changed as ordered by treating physician.	measured using goniometer measurements second daily Measurements continued until patient transferred; heel protector was discontinued or Braden Score >16	• No patients developed plantar flexion contractures	intervention was delivered to each participant • No reporting of comorbidity or other risk factors for PU • Severity and duration of PU on admission not reported	
(Malkoun, Huber et al., 2012)	Cross-over quasi-experiment **investigating interface pressure at the heel and Achilles tendon of different offload devices <u>in the OR setting</u>**	Consecutive subjects were recruited from an outpatient vascular laboratory (n=116) Characteristics: • mean age 56yrs ±18.3 • mean weight 78.1kg±14.5 • mean BMI 27.3±4.7	• Comparison of interface pressures for: ○ Action® Heel Support ○ Oasis Elite viscous elastic gel (VEG) heel block ○ Action® Overlay VEG mat ○ Prototype leg elevation device, Viater® Medical ○ Regular theatre table	• Interface pressure reading at four anatomical sites using XSensor® X3 pressure mapping system • Measurements were taken 2 minutes after the device was put into place • Measurements were taken at the heel, Achilles tendon, lateral malleolus, and calf	• Offloading devices (Oasis block and prototype) generated significantly ($p<0.0001$) less pressure at heel compared to the other devices/surfaces. • Prototype device and Oasis block median pressure 0 mmHg at heels • Theatre table and the Action® VEG mat median pressure 0 mmHg at Achilles tendon but 193.2 mmHg and 174.8 mmHg respectively at heel • Prototype device applied significantly ($p<0.0001$) less pressure to the Achilles tendon than the Action® heel support or Oasis block • Prototype device significantly ($p<0.0001$) less pressure at lateral malleolus than Oasis block or Action	• No blinding	**Indirect evidence Quality: low**
Sitting							
(Smit, Haverkamp et al., 2012)	Comparative study **investigating the effect of electrically stimulated (ES) muscle activation on sitting pressure distributions**	Ten participants Inclusion • Complete or incomplete upper motor neuron lesion • Intact gluteal and hamstring muscles Exclusion: • PU of buttocks	All participants completed two 1-hour protocols of ES using electrical stimulation garments applied over normal garments. All participants all used their own wheelchair with a regular cushion **Protocols** • Both protocols: four blocks of 3-	Interface (IT) pressures recorded during the 3 min of stimulation and during the last minute of the preceding rest period using a pressure mapping device	• In all participants, both protocols caused a decrease in IT pressure • Protocol B provided significantly greater pressure release than Protocol A (mean pressure relief (37.8mmHg±23.2mmHg versus 11.8±11.7mmHg) • Protocol B achieved a significant reduction over time in IT pressure from 44mmHg at	○ Unclear if the washout period of 30 minutes is suitable	**Indirect evidence Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Flaccid paralysis, intolerance to electrical stimulation • History of severe autonomic dysreflexia • Severe cognitive or communication problems Characteristics: • Mean age 33.7±8.9 years • Mean body mass 76.0±13.5kg • Primarily C3 to C8 injuries	min stimulation (1 sec on, 4 sec off) and 17 min of rest in between blocks • Protocol A: gluteal (g) muscles were stimulated • Protocol B: gluteal + hamstring (g + h) muscles were stimulated • There was a 30 min rest period in between protocols		commencement to 28.5mmHg at cycle end (p=0.01) • **Study conclusions: ES of muscles in participants with SCI reduces interface pressure in seated position. Stimulation of gluteal and hamstring muscles appears to be more effective than stimulating only the gluteal muscles.**		
(Giesbrecht, Ethans et al., 2011)	Repeated measures observational study **measuring reduction in interface pressure associated with tilted seating positions**	Participants were recruited from an outpatient SCI clinic in Canada. (n=18) Inclusion: • aged 18 to 65 yrs • SCI with American Spinal Injury Association (ASIA) A or B level of injury Exclusion: • Substantive scoliosis or deformity preventing central alignment in sitting Characteristics: • 94% sample was male • Mean age 42.6 yrs (SD 8.3 yrs) • Mean weight 74.7 kgs (SD 12.7kgs)	Using a standardized protocol participants seating was tilted in 10° increments between 0° and 50°	Relative pressure reduction from baseline was calculated and compared between tilt angles using interface pressure (IP) readings obtained at the ischial tuberosities (IT) and sacrum using pressure mapping technology	• No significant difference between IP at left and tight IT • Tilt angles above 20° significantly reduced IP at the ITs F(4,17)=165.1 to 202.7, p=0.000 with each successive tilt producing greater relative IP reduction • Tilt angles above 30° significantly reduced sacral IP (p=0.000 to 0.002), with slight increase in IP at 10° tilt • Pressure reductions were not significantly different between tetraplegic and paraplegic participants • A minimum tilt of 30° is required to initiate unloading the sacrum and to achieve a clinically significant reduction in pressure at the IT	• Sitting tolerance and the potential for changes in pelvic positioning not considered, IP readings taken after 1 minute • Use of the participants' own seating products may reflect true effects of tilt • Randomizing the application of tilt angle and obtaining multiple measures for test-retest reliability would have been optimal • Most participants were male	**Indirect evidence: indirect outcome measure Quality: moderate**
(Best, Desharnais et al., 2012)	RCT evaluating **the effect of a trunk release manoeuvre (TRM) on interface pressure for sitting in bed**	Participants were a convenience sample of healthy, community-dwelling adults (n=117) Inclusion: • aged over 60 yrs • MMSE ≥ 22 Exclusion: • moderate to high risk of PU ≤14 on Braden scale	• All participants were on the same bed with a visco-elastic foam mattress with a fitted sheet. • Participants were randomly assigned to either: o low-tech TRM consisting of a manual handling technique that involved pulling the trunk forward and away from the support surface of the bed without lifting the	Primary outcome: • Interface pressure measured as peak pressure index (PPI) Secondary outcomes: • trunk displacement (proxy measure for shear) defined as change in distance between top edge of mattress to top of participant's shoulder • perceived discomfort using	• The TRM group had a significantly lower mean PPI value post-intervention compared to the control group 59.6 (SD 30.7) mmHg versus 79.9 (36.5) mmHg, p=0.002 • There was a significant trunk displacement between the TRM group and the control group +3.2mm versus –5.8 mm, p=0.005	• Generalizability of the results • Crude indicator of trunk entrapment to capture displacement of the trunk • Intervention group had significantly more co-morbidities	**Indirect evidence: indirect outcome in healthy volunteers Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Characteristics: • mean age 67.4 yrs (SD 6.7 yrs) • 27% male • mean BMI 24.8 (SD 4.5)	○ buttock (n=59) ○ control group in standard high Fowler's position (n=58)	either a horizontal numerical scale(0 to 10) or the Wong-Baker Faces scale • location of discomfort using a body map	• There were no significant differences in perceived discomfort between the groups	• IP at points other than the sacrum was not measured	
(Shabshin, Ougortsin et al., 2010)	Experimental investigation investigating **thickness of fat layer in different seating tilts**	n=10 healthy volunteers	• Subjects underwent sitting MRI in six postures including neutral with/without weight-bearing, 10° and 20° lateral-tilts and 20° and 40° anterior lifts	• Thickness of tissues between the skin and the lowest point of the ischial tuberosity, of fat between the skin and the gluteus muscle and of muscle between the ischial tuberosity and fat • Measurements in weight-bearing positions were compared to the non-weight bearing for calculation of compressive tissue deformations in each trunk tilt	• Muscle and soft tissue compressive deformations from highest and lowest were 20° lateral tilt (87%, 72%), lateral 10° (85%m 70%), anterior 20 (79%, 67%), anterior 40° (74%, 64%) and neutral (72%, 59%) • For the fat highest was anterior tilts (42%), followed by lateral 20° tilt (41%), lateral 10° (39%) and neutral (35%)	• Small sample size of healthy subjects • Did not address potential effects of gender on tissue deformations • Datasets of muscle and fat deformations at the tilted postures were not independent of the neutral-posture data which does not conform the statistical theory of pairwise comparisons in full	**Indirect evidence**
(Karatas, Tosun et al., 2008)	Observational study **investigating the displacement in center of pressure influencing dynamic sitting stability of people with spinal cord injury (SCI)**	n = 34 (16 with SCI, 18 healthy volunteers)	• Participants were seated on an 45 x 45 cm hard chair of appropriate height, without a backrest • Feet were supported in wooden blocks and the height of the foot support was adjusted to each individual to keep the hip, knee and ankles at 90° degrees • Participants were asked to maintain a static position with their hands resting on their thighs without support as a starting position	• Center of pressure displacements measured using a seat sensor placed underneath buttocks	• Center of pressure displacements in all directions in spinal injured patients were smaller than healthy volunteers ($p< 0.05$) • Center of pressure displacements for high and low thoracic spinal cord injured participants were not significantly different (p=ns) • Mean center-of-pressure displacement during forward leaning and backward leaning were smaller in participants with PU history (p=0.04 and p=0.03, respectively) • This study suggests that impaired dynamic sitting stability may be associated with PU development due to impaired ability to weight shift in the seated position	• Small number of participants • PU development was not a direct outcome	**Indirect evidence**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(Kobara K, Fujita D et al., 2013)	Experimental study **investigating the mechanism of the fluctuation in shear force applied to the buttocks**	Participants were healthy male participants without leg or trunk diseases (n=11) Characteristics: • Mean age 22±5.2 yrs • Mean height 171.1±5.9 cm • Mean body weight 66.1±6.6 kg	• All participants were seated in an experimental chair with an electrical function for reclining the back support • The experimental back support was reclined at increasing angles beginning in a full upright position of 10° from the vertical upright position, proceeding to a fully reclined position	• The amount of force applied to the buttocks was measured using a force plate and a pressure and shear force sensor	• The average shear force applied to the buttocks was: ○ 9.4 ± 2.4 (%BW) in the initial upright position (IUP) ○ 9.3 ± 1.2 (%BW) in the fully reclined position (FRP) ○ 15.0 ± 2.9 (%BW) in the returning to an upright position (RUP) • The average normal force on the buttocks was: ○ 78.0 ± 5.0 in the IUP ○ 66.0 ± 8.2 in the FRP ○ 87.0 ± 6.9 in the RUP	• Healthy subjects • PUs were not a direct outcome measure	**Indirect evidence**
(van Geffen, Reenalda et al., 2008)	Experimental design	n=8 healthy male subjects	• A simulator chair was developed that adjusts sitting posture in the sagittal plane	• The authors investigated the influence of seat inclination on: 1) pelvis rotation; 2) and chair recline on 3) buttock load	• A combination of independent pelvis rotation and seat inclination is effective to regulate the net buttock shear force and the sacral interface pressure in healthy subjects • No significant relations were found for Δcp and ΔP_s • The influence of chair recline shows strong significant relations were found for Δcp, ΔF_8 and ΔF_n	• Not discussed	**Indirect evidence**
Positioning in bed							
(Moore, Cowman et al., 2011)	RCT **investigating 3 hourly turning and 30° tilt positioning for prevention of PUs**	Participants were older adults in 12 aged care facilities that were identified for the study (n=213) (99 in the experimental group and 114 in the control) participants, aged 80 and older from 12 study sites Inclusion: • geriatric hospital inpatient • Aged ≥ 65 years • At risk of PU development as assessed on Braden Scale • No existing PU • No medical condition	• Facilities were randomized as control or experimental facilities to reduce the chance of contamination. • Facilities were either; ○ Experimental: participants were repositioned every 3 hours at night using the 30° tilt (left side, back, right side back) between 8pm and 8am (n=10 facilities, 99 participants) ○ Control: participants received routine repositioning every 6 hours using a 90° lateral rotation between 8pm and 8am (2 facilities, 114	Primary outcome: • Incidence of stage I to IV PU as assessed using EPUAP classification system and assessed on every turning of participant. Identified PUs were confirmed by second assessor. Follow up was 4 weeks	• Significantly less participants in the experimental group developed any PU (3% versus 11%, (p=0.03, intracluster correlation [ICC] =0.001) • Incidence rate ratio 0.27 (95% CI 0.08 to 0.93, p=0.038, ICC 0.001) • OR of PU in experimental group was 0.2343 (95% CI 0.067 to 0.879, p=0.034) • All PUs were grade I (44%) or grade II (56%) • Mobility and activity were the highest predictors of PU development (multiple	• Final sample size did not reach *a priori* target of 389 participants in each arm • Variance in the sizes of the clusters • No reporting of positioning in the day time and duration of time spent in bed. • Control care was 6 hourly repositioning,	**Level: 2 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		precluding repositioning Characteristics: • 79% of participants were female • 66% aged ≥ 81 years • 70% considered to have low risk of malnutrition as assessed using MUST • 87% were chair-bound and 77% had limited activity • 99% used a pressure relieving device in a chair • 86% control and 96% experimental had pressure relieving device on bed • No statistically significant difference btw groups for age, gender or Braden score • Significantly more in experimental group were bed-fast (20 versus 8, p<0.005)	participants) • Both groups received education on PU grading system, the study purpose and data collection. The experimental facilities received education on 30° tilt. • Day time care remained "routine" for all facilities.		regression analysis, β=0.246, 95% CI –0.319 to –0.066; p=0.003 and β=0.227, 95% CI 0.041 to 0.246; p=0.006)	which may not be considered standard care elsewhere. • Increased frequency of turning and use of the tilt position were assessed as a single intervention. • Control facilities had more participants which may have made maintaining adequate repositioning regimens more difficult for staff members.	
(Chung, Lau et al., 2012)	Descriptive comparative design investigating **the effect of head of bed elevation angle on sacral and tuberosity peak pressures**	Participants were recruited from long term care in Hong Kong (n =42) Inclusion criteria: • Impaired bed mobility • Bed bound Exclusion: • Independent bed mobility • Agitated or uncooperative • Unstable medical condition • Existing sacral or tuberosity PU • Contraindications to recumbent position Characteristics: • 50% sample female • Mean age 58.8 yrs (range 24 to 95)	Participants were positioned on standard mattresses wearing hospital gowns Participant was in each position for 6 minutes before pressure readings commenced Participants were positioned flat and in 15°, 30°, 45° and 60° head elevation	• Interface pressure measured using a sensor pressure map • In each position, 5 pressure recordings were taken and the mean value recorded	**Sacral peak interface pressure** • Mean peak interface pressure was significantly greater (all p< 0.001) than in a flat position(38.6±2.5 mmHg) at 30° (50.4±3.6 mmHg); 45° (74.3±5.3 mmHg) and 60° (98.5±7.4) elevations **Tuberosities peak interface pressure** • Mean peak interface pressure was significantly greater (all p< 0.001) than in a flat position(29.8±1.0 mmHg) at 30° (41.8±1.6 mmHg); 45° (60.1±4.1 mmHg) and 60° (87.1±6.6) elevations	• The pressure-time curve values extrapolated from the study and presented in the discussion are not based on clinical evidence (i.e. there was no examination of how long the patient could withstand each position before developing a PU)	**Indirect evidence Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Mean weight 51.3± 11.4 kg range (30.3 to 80 kg) • Mean BMI 22.3±4.0 (range 12.5 to 29.2) • 57% stroke patients,$14% cerebral palsy, 7% multiple sclerosis					
(Källman, Bergstrand et al., 2013)	Descriptive comparative design investigating **the effect of positioning on tissue blood flow and skin temperature in lying positions**	Convenience sample recruited from hospital wards in Sweden. Participants acted as their own controls. (n=20) Inclusion: • aged 65 years and older • able to lie in study positions Exclusion: • history of PU, or an existing PU, or skin damage to the sacrum, trochanter or gluteus maximus • with fever (>37.5°C) Characteristics: • Mean age 84±7.5 years • Mean BMI 23±3.5 • Mean body temperature 36.5±0.5°C • Mean arterial pressure 76±3mmHg • Participants were taking a range of cardiac medications, analgesia and other systemic medications	Participants were place in six positions for measurement of blood flow and skin temperature. • In all positions a 14cm thick pressure reducing cold foam mattress with a 65+50kg/m^3 density and covered with a soft elastic, vapor permeable overlay was used. The mattress was covered with a cotton sheet. • All patients were dressed in a hospital gown and covered with a blanket during measurements • Six positions were used: in the same order for each participant: ○ Supine tilt 30° ○ Supine 0° ○ Semi-fowler with elevated head 30° ○ Semi-fowler with head and legs elevated 30° ○ Lateral 30° ○ Lateral 90°	• Superficial and deep tissue blood flow measured over bony prominences and in gluteus muscle using a photoplethysmography (PPG)instrument and probe • skin temperature measured over bony prominences and in gluteus muscle using a single sensor optical probe • measurements were taken after 25 minutes in position	**Tissue blood flow** • The median relative change in superficial blood flow over bony prominences increased in all supine positions and decreased in the lateral positions. • The blood flow over the bony prominence areas was most changed in superficial skin and was decreased most in the 30° lateral position ($p<0.05$ compared with supine positions) • Mean arterial pressure was significantly correlated with superficial blood flow over bony prominences ($p=0.039$) • There were significant individual differences in blood flow responses but no common trend **Skin temperature** • Skin temperature was significantly correlated with overall relative change in superficial blood flow ($r=0.23$, $p= 0.007$) • No relationship was found between skin temperature and relative changes in deep blood flow • **Study conclusions: lying positions influences superficial skin blood flow in different ways.**	• Participant movements may influence readings • Skin temperature increased during the procedure due to heat accumulation between the patient and the bed • Study was contradictory to previous findings that skin oxygenation is lowest in lateral 90° position	**Indirect evidence Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Foot positioning							
(Hosono, Shuichi et al., 2012)	Pilot Study **Could be indirect evidence for the contribution of movement: passive motion system for toe joints will be effective in preventing ulcer formation on the foot.**	n = 5 healthy subjects in their 20s to 50s (Group 1) n = 10 healthy subjects in their 20s to 80s (Group 2) n = 10 healthy subjects in their 20s to 60s (Group 3)	• Group 1: participated in experiments to measure blood flow during active exercise • Group 2: participated in an experiment to measure blood flow during passive motion of their right toe during use of a continuous passive motion device • Group 3: participated in an experiment to measure the flexion and extension angles and the force of their right toe joints	• Measured lower extremity blood flow in the foot during active and passive motion of the tow joints were measured • Also the flexion and extension angles and the force of the toe joints were measured to determine appropriate specifications for the systems	• Increases in blood flow were observed at the external malleolus during movement • Flexion and extension angles and the force of the toe joints were found to differ significantly among participants • Toe joint passive motion system can be effective in preventing PUs	• Not listed	**Indirect evidence**
Frequency of repositioning							
(Pompeo, 2013)	Observational study investigating the **influence of a pressure map in increasing frequency of repositioning**	Study conducted in a 55-bed long term acute care facility in US (n = 43 in each phase) Characteristics: High risk of PU (Braden score ≤ 12)	• Intervention was a pressure mapping device that sent visual display of anatomical locations reaching high interface pressures. An alarm system was pre-set to sound 2 hours after patient repositioning. • Phase 1: all patients placed on pressure map device and no monitor or alarm used • Phase 2: monitor and alarm were turned on, staff received in-service training on system use • Phase 3: monitor and alarm were turned on, staff attended mandatory meetings with senior staff to discuss system use	• Mean time to patient repositioning measured by automated pressure map system	• In Phase 1 mean time to reposition was 240 minutes • In Phase 2 mean time to reposition was 325 minutes • In Phase 3 mean time to reposition was 164 minutes • **Conclusions: pressure mapping system with visual interface pressure map and pre-set alarm reduced average time to patient repositioning. Mandatory staff meetings further decreased time to patient repositioning.**	• Did report measure PU rates • Pressure system was reported to reduced airflow around the skin which may influence PU risk	**Indirect evidence Quality: low**
(Still, Cross et al., 2013)	Observational study (quality improvement initiative) investigating **influence of a turn team on rate of PUs**	Study conducted in a surgical intensive care unit in US (n = 20 beds) Characteristics: Routine population includes general surgery, implant patients, ENT, urology Nurse:patient ratio 2:1 with	• Prior to intervention introduction nursing staff received an online education intervention on PU prevention, Braden scale scoring • PCAs received training in turn mechanics • Turn team initiative required the turn team (2 PCAs) to turn every	• Prevalence surveys conducted over 2 year period, with frequency of data collection ranging from every 3 months to biweekly over the course of the project • Clinical nurse specialist used NPUAP staging system to	• **Baseline (15 audits over 2 years)** Average 2.8 PUs per audit 42 PUs in 278 patients Primarily stage II sacral/buttock PU 4 patients had 2 PUs • **After intervention (15 audits over 15 weeks)** 12 patients in 229 patients	• Unclear if other changes were made in the ward over the 2 year period • Data was collected more frequently after intervention was introduced,	

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		additional 2 patient care attendants (PCAs)	haemodynamically stable patient every 2 hours, unless the nurse identified contraindications.	determine prevalence of PU on audit days. •	Average of 0.87 PUs per audit (p<0.0001 compared with baseline) • Patients who were ventilated or who had longer stays were more likely to have PU	possible Hawthorne effect • If a patient was present for more than one audit, patient was included in only one audit and assigned his/her worst state. Exclusion of patients from previous audits if their PU progressed would reduce the prevalence rate in the earlier audit.	
(Rich, Margolis et al., 2011)	Analysis of a larger cohort study **investigating association between repositioning and PU incidence**	Participants were recruited between 2004 and 2007 from nine hospitals in the USA (n=269) Inclusion: • Aged ≥65 years • Hip fracture surgery • Bed-bound at index study visits during first 5 days of hospitalization Exclusion: • No study visit on first 5 days of hospitalization • Not bed-bound for at least one visit day according to Braden scale activity item Characteristics: • 51.7% participants aged ≥ 85 yrs • 98.5% White race • 43.9% had Braden scale ≤ 16 • 14.2% had PU at baseline	• Information about repositioning frequency for the first 5 days of hospitalization was collected from patient charts, including number of times manual repositioning performed • Study nurses performed skin assessments and Braden scale score at baseline and on alternating days for 21 days	• Primary outcome: development of stage 2 or greater PUs as defined on a scale on which stage II was partial thickness dermal loss or serum filled blister. • The association between frequent manual repositioning and PU incidence was estimated adjusting for PU risk factors using generalized estimating equations and weighted estimating equations • Frequent repositioning was defined as ≥12 manual repositions per hospital day •	• Patients were repositioned frequently on 53% (187/354) of index visit days • The incidence of PUs per person-day did not differ between the two groups (incidence rate ratio 1.12, 95% CI 0.52 to 2.42) • Patients repositioned frequently were more likely to have a PU at baseline (p=0.006), more likely to have high risk of nutrition-related complications (p=0.006) and more likely to have a lower mean Braden score (p=0.07) • For participants with a high PU risk based on Braden score. There was a lower incidence of PUs among those who were frequently turned (IRR 0.39, 95% CI 0.08 to 1.84) • Although no association was found between frequent repositioning of bed-bound patients and lower PU incidence, there was an effect in patients at high risk of PU	• Limited adherence to repositioning recommendations • Observational design • Relied on medical records data, turning frequency was not verified	**Level: 3 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(Gucer, Gaitens et al., 2013)	Cross-sectional survey investigating **relationship between availability of powered mechanical lifting (PML) aids for manual handling/ repositioning and PU incidence in long term care (LTC) facilities**	Directors of Nursing (DONs) from 656 Medicare/Medicaid certified LTC facilities in USA were invited to participate (n=271 participant facilities, 41% response rate) Characteristics: • Facilities averaged between 77 to 80 filled beds • 54% were owned by for-profit organizations • 59% were located in Middle America • Mean number of full PMLs increased over the 2 year survey time frame to 3.35 per 100 residents • Mean number of sit-stand PMLs over the 2 year survey time frame to 2.65 per 100 residents	• DONs were surveyed on availability of PMLs and the lifting policy of the facility for the years 2005 to 2007 • To this information the authors linked data on mobility-related resident outcomes from the Centers for Medicare and Medicaid Serviced Minimum Data Set Quality Indicators data over 3 years	• The authors explored the relationship between resident quality indicators of well-being (including PU incidence while at high risk) and: ○ safe lifting policies and procedures ○ availability of different kinds of PMLs (full lift vs. sit-stand)	• Significantly more residents at high risk had PUs in facilities with 0-4 PMLs of any sort versus facilities with >8 PMLs of any sort (14.94% versus 9.74%, p=0.000) • Significantly more residents were bed-bound in facilities with 0-4 PMLs of any sort versus facilities with >8 PMLs of any sort (3.44% versus 1.72%, p=0.013) • There was no significant difference in residents with PUs when comparing number of full PMLs in facilities (p=0.866) • There was significantly more residents at high risk had PUs in facilities with 0-1 sit-stand PMLs versus facilities with >3 sit-stand PMLs (16.10% versus 9.62%, p=0.000)	• Based upon recall • Based upon self-report (availability of aids) and database review (incidence of PU) • Modest self-selected response rate • Sample may over-represented singly owned and underrepresented large chain facilities • Associations were formed but definitive causality cannot be assigned	**Level: 5 Quality: moderate**
Early mobilization interventions							
(Dammeyer, Dickinson et al., 2013; Dickinson, Tschannen et al., 2013; Knoblauch, Bettis et al., 2013)	Retrospective, descriptive study **investigating an early mobilization protocol in an ICU setting** **nb:** Dickinson, Tschannen et al. (2013)reports the study Dammeyer, Dickinson et al. (2013) describes the intervention Knoblauch, Bettis et al. (2013) reports cost-effectiveness	• Conducted in a surgical ICU in the US • (pre-implementation phase n=555; post-implementation phase n=557) Inclusion for protocol: • fractional inspired oxygen saturation less than 605 • positive end-expiratory pressure less than 10cm H_20. • receiving low dose catecholamine drips Exclusion for protocol: • hypoxia, • hemodynamic instability, intercranial pressure monitoring, • unstable cardiac rhythm, or • new cardiac arrhythmia	• Mobility intervention for patients at least 3 times per day • Early mobility protocol included three separate phases: 0, 1, and 2. • All patients started in phase 0 after physiological stabilization and progress as tolerated • Phase 0: range of motion (active and passive), continuous lateral rotation, HOB at 30 to 45° • Phase 1includes Phase 0 interventions plus chair position or out of bed and dangling (all 3 times daily) • Phase 2 includes phase 1 interventions plus standing, bearing own weight and walking. • The intervention required employment of a nursing tech for 12 hours/day to assist RNs to deliver the intervention.	• Incidence of pressure ulcers unstated how these were assessed but appears to be a document review. • PUs were classified according to NPUAP staging system	• Pre-implementation group had a significantly shorted mean hospital length of stay (13.78 days vs 16.58 days, p=0.002) and mean unit LOS 4.02 days vs.. 6.16 days, p<0.001) • Pre implementation group: 20 patients (3.6%) developed unit acquired PU compared with 41 patients (7.4%) in post implementation group • Pre implementation group 30 patients (5.4%) developed unit acquired PU compared with 34 patients (6.1%) in post implementation group • In consideration of extra time spent in the unit, there was a significant increase in PUs associated with the intervention (p=0.009)	• Not targeting the intervention to specific populations deemed at risk • Acuity differences between pre and post implementation groups • Staff compliance to the early mobility protocol • Limited variety of exercise	**Level of evidence: 3 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Characteristics: • post-implementation group had a significantly higher risk of PU based on Braden score (15.24 vs 15.66, p<0.001) • No significant difference in APACHE scores	• Medical staff and family education was implemented				

References

Bales, I. (2012). "A Comparison between the Use of Intravenous Bags and the Heelift Suspension Boot to Prevent Pressure Ulcers in Orthopedic Patients." Advances in Skin & Wound Care **25**(3): 125-31.

Best, K., G. Desharnais, J. Boily, W. Miller, P. Camp. (2012). "The effect of a trunk release maneuver on Peak Pressure Index, trunk displacement and perceived discomfort in older adults seated in a high Fowler's position: a randomized controlled trial." BMC Geriatr **12**(1): 72.

Chung, C. H. K., M. C. H. Lau, T. Y. C. Leung, K. Y. S. Yui, S. H. S. Chan, S. L. S. Chan, et al. (2012). "Effect of head elevation on sacral and ischial tuberosities pressure in infirmary patients." Asian J Gerontol Geriatr **7**(2): 101-6.

Dammeyer, J., S. Dickinson, D. Packard, N. Baldwin, C. Ricklemann. (2013). "Building a protocol to guide mobility in the ICU." Critical Care Nursing Quarterly **36**(1): 37-49.

Dickinson, S., D. Tschannen, L. L. Shever. (2013). "Can the use of an early mobility program reduce the incidence of pressure ulcers in a surgical critical care unit?" Critical Care Nursing Quarterly **36**(1): 127-40.

Donnelly, J., J. Winder, W. G. Kernohan, M. Stevenson. (2011). "An RCT to determine the effect of a heel elevation device in pressure ulcer prevention post-hip fracture." Journal of Wound Care **20**(7): 309.

Giesbrecht, E. M., K. D. Ethans, D. Staley. (2011). "Measuring the effect of incremental angles of wheelchair tilt on interface pressure among individuals with spinal cord injury." Spinal Cord: The Official Journal Of The International Medical Society Of Paraplegia **49**(7): 827-31.

Grisell, M., H. M. Place. (2008). "Face tissue pressure in prone positioning: a comparison of three face pillows while in the prone position for spinal surgery." Spine **33**(26): 2938-41.

Gucer, P. W., J. Gaitens, M. Oliver, M. A. McDiarmid. (2013). "Sit-stand powered mechanical lifts in long-term care and resident quality indicators." Journal of Occupational and Environmental Medicine **55**(1): 36-44.

Hosono, M., I. Shuichi, M. Sato, K. Yamashita, T. Izumi. (2012). "A system utilizing metal hydride actuators to achieve passive motion of toe joints for prevention of pressure ulcers: a pilot study. ." Rehabilitation research and practice **article 541383**.

Källman, U., S. Bergstrand, A. C. Ek, M. Engström, L. G. Lindberg, M. Lindgren. (2013). "Different lying positions and their effects on tissue blood flow and skin temperature in older adult patients." Journal of Advanced Nursing **69**(1): 133-44.

Karatas, G. K., A. Tosun, U. Kanatl. (2008). "Center-of-pressure displacement during postural changes in relation to pressure ulcers in spinal cord-injured patients." American Journal Of Physical Medicine & Rehabilitation **87**(3): 177-82.

Knoblauch, D. J., M. A. Bettis, F. Lundy, C. Meldrum. (2013). "Financial implications of starting a mobility protocol in a surgical Intensive Care Unit." Critical Care Nursing Quarterly **36**(1): 120-6.

Kobara K, Fujita D, Osaka H, Ito T, Yoshimura Y, Ishida H, et al. (2013). "Mechanism of fluctuation in shear force applied to buttocks during reclining of back support on wheelchair." Disabil Rehabil Assist Technol **8**(3): 220-4.

Malkoun, M., J. Huber, D. Huber. (2012). "A comparative assessment of interface pressures generated by four surgical theatre heel pressure ulcer prophylactics." International Wound Journal **9**(3): 259-63.

McMichael, J. C., H. M. Place. (2008). "Face tissue pressures in prone positioning: a comparison of 3 pillows." J Spinal Disord Tech **21**(7): 508-13.

Meyers, T. R. (2010). "Preventing heel pressure ulcers and plantar flexion contractures in high-risk sedated patients." Journal of Wound, Ostomy and Continence Nursing **37**(4): 372-8.

Moore, Z., S. Cowman, R. M. Conroy. (2011). "A randomised controlled clinical trial of repositioning, using the 30° tilt, for the prevention of pressure ulcers." Journal of Clinical Nursing **20**(17/18): 2633-44.

Pompeo, M. (2013). "Pressure Map Technology for Pressure Ulcer Patients: Can We Handle the Truth?" Wounds: A Compendium of Clinical Research & Practice **25**(2): 34-40.

Rich, S. E., D. Margolis, M. Shardell, W. G. Hawkes, R. R. Miller, S. Amr, et al. (2011). "Frequent manual repositioning and incidence of pressure ulcers among bed-bound elderly hip fracture patients." Wound Repair and Regeneration **19**(1): 10-8.

Romero, C. M., R. A. Cornejo, L. R. Galvez, O. P. Llanos, E. A. Tobar, M. Berasain, et al. (2009). "Extended prone position ventilation in severe acute respiratory distress syndrome: A pilot feasibility study." Journal of Critical Care **24**(1): 81-8.

Shabshin, N., V. Ougortsin, G. Zoizner, G. A. (2010). "Evaluation of the effect of trunk tilt on compressive soft tissue deformations under the ischial tuberosities using weight-bearing MRI." Clinical Biomechanics, **25**(5): 402-8.

Smit, C., G. Haverkamp, S. de Groot, J. Stolwijk-Swuste, T. Janssen. (2012). "Effects of electrical stimulation-induced gluteal versus gluteal and hamstring muscles activation on sitting pressure distribution in persons with a spinal cord injury." Spinal Cord **50**(8): 590-4.

Still, M. D., L. C. Cross, M. Dunlap, R. Rencher, E. R. Larkins, D. L. Carpenter, et al. (2013). "The Turn Team: A Novel Strategy for Reducing Pressure Ulcers in the Surgical Intensive Care Unit." J Am Coll Surg. Epub 2013/01/15.

van Geffen, P., J. Reenalda, P. H. Veltink, B. F. Koopman. (2008). "Effects of sagittal postural adjustments on seat reaction load." Journal Of Biomechanics **41**(10): 2237-45.

SUPPORT SURFACES

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Low air loss support surfaces							
(Pemberton, Turner et al., 2009) (prevention and treatment)	Observational pilot study **investigating incidence of PU for a low air loss continuous later bariatric bed**	n= 21 consecutively admitted patients Inclusion: • BMI > 35 • minimum 3 day stay on support mattress (max 7 days) Participant characteristics: • mean BMI 51.4 (±10.3) • mean age 51.7 years (±14, range 32 to 76) • 28% (n=6) had existing PU • 57% diabetes mellitus • 57% urinary incontinence • 43% faecal incontinence • 43% neurological impairment	Low-air-loss, continuous lateral rotation bariatric bed with advanced microclimate technology (TotalCare® Bariatric Plus Therapy System) Participants spent an average of 4.8±2.5 days (range 2 to 8) on the bed surface.	• PU incidence • PU stage (NPUAP criteria) and size (measurement strategy not reported) • employee satisfaction on a 4-point Likert scale • patient comfort rating (multiple choice questionnaire where 1 = very uncomfortable and 4 = very comfortable) • Final outcome measures at day 7.	• No new PUs developed • PUs (primarily category I) decreased from an average size of 5.2 cm^2 (±5.2) to 2.6cm^2 (±5.0) • 5 PUs (primarily category I) completely healed, but 3 PUs had no change • Mean caregiver satisfaction rating was 3.6 • Mean patient comfort rating 3.9 • **Study conclusion: In patients with a BMI above 35kg/m^2, a low air loss, continuous rotation bariatric bed was associated with no new PUs and a decrease in PU size for existing PUs after a maximum of 7 days.**	• Small, non-randomised study • No statistical significance reported • No comparison group • No long term follow up (patients stayed on bed for between 2 and 7 days)	**Level of evidence: 5** **Quality: low**

(Johnson, Peterson et al., 2011a; Johnson, Peterson et al., 2011b)
 	
(prevention)
	Prospective comparative study **investigating the prevalence of HAPU in patients cared for on low air loss beds**	Participants recruited from 4 units in a community hospital (n=297)
		
		Inclusion:
		• Inpatient on observation days in 2008
		
		Characteristics:
		• first comparison (cardiac renal and medical telemetry units)
		  ○ no significant difference in demographics
		  ○ mean age 64 to 65 years
		  ○ mean length of stay 4 to 6 days
		  ○ mean Braden score approx. 18
		• Second comparison: (general surgical versus pulmonary unit)
		  ○ Patients on low air loss beds had significantly higher Braden scores (18.96±3.1 versus 17.79±2.9, p=0.013)
		  ○ Patients on low air loss beds had significantly longer length of stay
			164 patients were included in survey, of which 133 were allocated to low air loss device
			
			The same care staff worked across both unit s in each of the comparisons
			
			Two comparisons:
			• Cardiac renal unit with standard beds(n=75) versus medical telemetry with low air loss beds (n=53)
			• general surgical with low air loss bed (n=80) versus pulmonary unit with standard bed (n=89)
				• Pressure ulcer prevalence observed in four units on three occasions
				• Use of NPUAP staging system
				• Skin assessments conducted by skin nurses and interrater reliability established prior to survey
					PU prevalence did not differ significantly between groups
					
					Comparison one: cardiac renal (standard) versus medical telemetry (low air loss)
					Cardiac unit had lower prevalence HAPU but difference was not significant (1.3% versus 3.8%, p>0.05)
					
					Comparison two: medical pulmonary (standard) versus general surgical (low air loss)
					Medical pulmonary had lower prevalence of HAPU but difference was not significant (3.4% versus 6.3%, p>0.05)
						• No incidences were measured, only prevalence figures
						• Not controlled for differences in patient characteristics
						• No randomization
							Level of evidence: 3
							Quality: low

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		○ (6.01±7.0 days versus 4.21±3.7, p=0.036) ○ Mean age 64 to 67 years					
(Black, Berke et al., 2012) (prevention)	Quasi experiment **comparing a low air loss bed with microclimate management to an integrated power air redistribution bed for preventing PU**	Participants were recruited from a cardiovascular surgical unit in USA (n=52) Inclusion: • Likely to be ICU for three days • Not receiving palliative care • No pulmonary or wound issues requiring special beds Characteristics: • No significant differences in demographics at baseline • Mean length of stay 7 days, mean length of data collection was 5 days • Mean age 59.1 years • Mean admitting Braden score 11.2 (range 7 to 20)	• Staff training occurred prior to study commencement. • Participants received similar regimens for repositioning and skin care. Participants received either: ○ loss bed with microclimate management (n=31) ○ integrated power air redistribution bed (n=21)	• PU incidence determined through skin assessment every three days • Mean follow up period was 5.7 days	• Participants on a low air loss bed had significantly less PUs (0% versus 18%, p=0.046)	• No randomization, blinding, study power calculation • Limited baseline demographics • Concurrent management unclear • Short study period • No interrater reliability	**Level of evidence: 3** **Quality: low**
(Korniewicz, Siegel et al., 2011) (prevention)	Open label quasi-experimental trial **investigating a low air loss surface with advanced microclimate technology**	Participants recruited from a surgical ward and undergoing elective orthopaedic or neurological surgery in USA (n=99) Inclusion: • Weigh >70lb and <500lb • Admitted for surgical procedure • Remain in bed for at least 2 days Exclusion: • Traction • Mechanical ventilation • Spinal injuries • Existing stage IV PU • Terminal condition Characteristics: • No significant differences in baseline demographics • Mean age 59.55±14.96 years • 51.5% Hispanic, 10% White, 38% Black • 61.6% had a previous history of PU	• Hill-Rom (company providing beds) representative conducted training sessions in the ward prior to study • Participants were randomly assigned to either: ○ Control group: VersaCare AIR (n=38) ○ Study group: VersaCare P500 with advanced microclimate technology that manages heat and moisture (n=61)	• Prevention of pressure ulcers (?) • Braden score changes • Data was collected daily from the patient's electronic medical record	• Clinical effectiveness parameter not reported • Study group had significantly longer bed confinement 6.44±3.23 versus 5.26±2.13 days, p=0.028) • Multivariate analysis indicated that the VersaCare P500 bed accounted for 24.5% of variance in Braden scores	• Open-label design • Data was retrieved from electronic medical records • Study did not directly measure the influence of the mattresses on Pus • Braden scale scores limited outcome parameter	**Indirect evidence** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• 17.2% diabetics • 67% had a Braden score indicating at risk of PU					
Alternating pressure air mattresses							
(Ward, Fenton et al., 2010) (treatment)	Case series investigating **a semi-automated alternating air pressure mattress for treatment of PU**	Convenience sample considered at high risk located in 5 hospital wards in Malta (n=60) Inclusion and exclusion not reported Characteristics: • 58% sample female • Mean weight 71kgs (range 30 to 110 kgs) • 26.6% considered "vulnerable to" PU and 73.3% considered to be at "elevated risk" • 65% had existing PU, 75% of which were stage I PU or superficial skin loss.	• Participants were nursed on the Alpha Response™ System that comprises a mattress replacement, mattress overlay or seat cushion operated from same pump. • System can be operated as a reactive constant low air mattress, but for this investigation it was operated as an active (alternating) air pump that periodically redistributed pressure by inflating/ deflating beneath the body every 10 minutes	• PU clinical outcomes with PU defined as "improved" or "deteriorated"	• Of the participants who had PU at commencement (n=39), follow-up data for discharge was available for 74% (n=29) • In these participants 69% (n=20) showed improvement in PU at discharge (including 4 participants with stage III and IV PU). • Mean treatment period 19 days. • One wound was reported to deteriorate during the evaluation	• "High risk" was not specified • No randomization and no control group • No interrater checks were performed • Unclear who performed skin observations • Other management of PU was not reported	**Level of evidence: 5** **Quality: low**
(Demarré, Beeckman et al., 2012) (prevention)	Multicenter Randomized controlled trial **comparing alternating low pressure air mattresses with different inflation/ deflation cycles**	Participants were recruited via convenience sample in 25 hospital wards in Belgium. (n=610) Inclusion: • Aged ≥ 18 years • At risk of PU as determined by Braden scale score <17 Exclusion: • Incomplete Braden score • Not at risk of PU • PU stage I to IV on admission • Expected admission <3 days • Do not resuscitate • Weighing < 30 kgs or > 160 kgs • No informed consent Characteristics: • Approximately 60% sample female • Mean age 76.3±14.0 years • Approx. 50% incontinent • Median Braden score 14.0	• Participants were randomly allocated to either: ○ Experimental group: alternating low pressure air mattress with multi-stage inflation and deflation cycle (between 10 and 12 minutes) of the air cells with a sensor at the sacral zone measuring the applied pressure of the body on the mattress (n=298) ○ Control group: alternative low pressure air mattress with a standard single stage inflation cycle (10 min) and deflation cycle of the air cells (n=312) • Both mattresses were covered with an identical mattress cover • No standard repositioning protocol was used in bed	• Daily skin observations and risk assessments • Cumulative PU incidence (stage II to IV) • Inter-rater reliability in classification of PU and Braden scoring was established	• There was no significant difference in cumulative PU incidence between groups (5.7% in experimental group versus 5.8% in control group, p=0.97) • Median time to develop PU was not significantly different between groups: (5.0 days [IQR 3.0 to 8.5] in experimental group versus 8 days [IQR 3.0 to 8.5] in the control group, p=0.182). • An equal number of patients developed a PU Grade II to IV at the pelvic area (hip and sacral) in the experimental group (3.7%) compared to the control group (3.5%) • No significant difference in PU incidence at the heel/ankle between the experimental (1.3%) and the control group (1.9%) • **Study conclusions: an alternating low pressure air mattress with**	• Lack of a blinded outcome • Limited predictive value of the Braden Scale to assess risk for PU development	**Level of evidence: 1** **Quality: high**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• 15.4% participants in each group had PU grade I on admission (p=0.99 between groups) • Mean BMI 23.8±4.65 • Approx 27% participants were bed-bound and 61.3% were chair bound.			**multi-stage inflation/deflation of air cells has no benefit over a standard cycle alternating low pressure air mattress in preventing PUs.**		
Mattress overlays							
(Cassino, Ippolito et al., 2013)	RCT comparing a **gel overlay to a three dimensional, multi-layer macro-porous polyester overlay**	Participants were recruited from 8 long term care facilities in Italy (n=72) Inclusion: • aged > 18 years • Braden score between 6 and 14 • Norton score between 5 and 12 • Category/stage I to IV PU Exclusion: • No existing PU • Infection • allergy to overlays, needing additional aids • immunosuppressants, antiblastic therapy, AIDS, HCV, pregnancy, terminal diagnosis Characteristics: no significant difference in gender, age (mean approx. 85 years) or PU risk scale scores at baseline The 3D overlay group had more PUs of category IV (22.22% versus 6.81%, p =not reported)	Participants were randomly assigned to receive either: • 3D overlay (n=35) • Gel overlay (n=37)	• Unclear how wounds were measured and surface area calculated • Outcome appears to be reduction in percent surface area • Outcome of improved, worsened or resolved is reported, but unclear how wounds were categorized • Follow up 12 weeks, reports outcome measures at 4, 8 and 12 weeks.	• No significant difference between overlays for % wounds unchanged/worsened (45% for 3D, 59.5% for gel p = ns) • Approximately 1/3 participants in both groups were suspended from trial, primarily due to worsening of PU • No significant difference in wounds resolved in 12 weeks (8.57% for 3D, 13.5% for gel, p =ns) • 3D overlay had greater percent reduction in wound surface area (p<0.05) • No significant difference in rating for comfort (rating of good or excellent was 40% for 3D overlay and 19% for gel, p =ns) • Ease of use (e.g. bed-making) was significantly greater for 3D (p<0.001)	• No power calculation • Does not report methods of randomization • Large drop out, unclear if included in analysis for % surface area • Method of wound assessment and categorization is not reported	**Level of evidence: 2 Quality: low**
(van Leen, Hovius et al., 2011) (prevention)	Single center prospective controlled trial **comparing polyether foam to static air mattress overlay**	Participants were recruited from a geriatric long term care facility in the Netherlands (n=83) Inclusion: • Aged > 65 years • Norton scale between 5 and 12 • No existing PU at commencement Exclusion:	• All participants received standardized pressure reduction in sitting position by using a static air cushion • No participants received repositioning before development of a stage II PU • Participants were randomised to receive either: ○ 15cm cold foam mattress	• Primary outcome measure was development of stage II, III or IV PUs at the heel or in the sacral region • Participants were checked weekly for PUs by an independent nurse • Follow-up was at 6 months	• Less participants on the air mattress overlay developed a stage II or greater PU but the difference was not significant (4.8% versus 17.1%, p=0.088) • There was no difference regarding PU incidence between patients with a high risk (Norton 5-8) and patients with a medium risk (Norton 9-12) • 71% of participants who developed	• Comorbidities influencing healing are not reported (e.g. nutrition) • No blinding methods not reported • PU healing protocol is not	**Level of evidence: 2 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• PU in previous 6 months Characteristics: • More participants in the static air mattress group had lower Norton scores (p=not reported, unclear if significant difference) • Mean age approx. 81 to 83 years • About 75% of participants had dementia	made of polyether foam (n=42) ○ a static air overlay on top of a 15cm cold foam mattress made of polyether foam (n=41)		a PU on the control foam mattress showed no healing using the standard PU protocol versus 100% of participants on the air mattress overlay showing healing	reported • ITT analysis is unclear • Length of time before PU development not reported	
(Turnage-Carrier, McLane et al., 2008)	Quasi-experimental **investigating interface pressure between occiput and different support surfaces in children**	Participants were recruited from an inpatient level II hospital nursery (n=13, n=11 completed study) Inclusion: • healthy premature infants of post-menstrual age (PMA) 35 to 37 weeks • feeding and gaining weight • in an open crib • within 1 to 3 weeks of discharge • no history or diagnosis of a skin disorder Exclusion: • Supplemental oxygen • Apnea, bradycardia, active infection, cardiopulmonary disease, congenital abnormality, skin disorder, trauma, hydrocephaly, cephalohematoma, caput succedaneum or birth injury of head/neck. Characteristics: • Mean age 30.2 gestational weeks, mean PMA 36.1 weeks • Mean weight 2556.9g	• All participants were positioned on 5 different support surfaces in a random order for 3 to 5 minutes. • The 5 bed surfaces were: ○ Standard crib mattress with 2.75" foam overlay ○ Standard crib mattress without foam overlay ○ Gel pillow ○ Gel mattress ○ Water pillow – 288mL water • Crib blanket was placed over the standard crib mattress, the gel mattress and the foam overlay and a new disposable cover was placed over the gel pillow.	• Interface pressures obtained under the occiput using an interface (IF) pressure evaluator and recorded in mmHg • Three measurements were taken on each surface	• No significant differences between the readings for participants • A significant difference in the mean of the IF pressures between each mattress and the standard crib mattress was established ($p<0.001$) • Mattress with foam overlay had the lowest IF pressure (mean 31mmHg) and standard mattress had the highest IF pressure (86.9mmHg) • **Study conclusions: A foam mattress overlay is associated with lower occipital IF pressure in babies**	• Infant movement could alter interface pressures • Observable differences in head shape could have influenced the IF pressures	**Indirect evidence Quality: low**
Continuous, reactive low pressure support surfaces							
(García-Molina, Balaguer-López et al., 2012)	survey investigating **incidence of HAPU in a children**	Participants were admitted over a 2 year period to the 5 bed Paediatric ICU in a Spanish hospital (n=30 children) Inclusion: aged 1 day to 10 years	• All participants received standard PU prevention including application of hyperoxygenated fatty acid oil to skin 8 hourly, and protective	• Presence of PU determined by daily skin assessment	• 63.3% participants did not receive any repositioning due to their clinical condition • There was a significantly lower incidence of non-device related	• Small sample size • Comparison cohort was not described and reported as an	**Level of evidence: 4 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(prevention)	**nursed on continuous and reactive low pressure mattresses**	• Admitted for > 24 hours • Braden score indicating at risk of developing PU (Braden–Q ≤ 16, Neonatal Skin Risk Assessment Scale≤13) Exclusion: • Admitted <24 hours • Aged > 10 years • No consent • Not received the pressure mattress support surface PMSS Characteristics: • Primarily aged from 1 month to 3 years (73.3%, n=22) • Average Braden score for those aged >1 month 10.4±2.4 • Average Braden score for those aged < month 13.2±3.03 • About half participants were sedated and had vasoactive medication (n=15) • 33.3% had a PU on admission to study	hydrocellular dressings) • Participants of interest to survey were nursed on one of two mattresses provided in the unit for children at risk for PU • Both mattresses classified as continuous and reactive low-pressure special surfaces consisting of double air-cell construction that reacts to pressure in three different compartments (head, body, trunk) but maintains same level of support in each section (i.e. not alternating pressure). ○ First mattress (Cartio Neo®): designed for children weighing 500g to 6kg (n=4) ○ Second mattress(Cartio Juve®): designed for children weighing ≥6 Kg (n=26) • Participants were placed on the study mattresses for a mean of 7±7 days days (range 1 to 25 days)		HAPU in the study participants compared with the estimated incidence in the previous year (3.3% versus 20%, 95% CI 0.08% to 17.2%, p=0.021) • 66.6% of participants admitted with a PU healed before discharge from the PICU • **Study conclusions: the continuous and reactive low-pressure support surface was associated with a lower incidence of new PU in children in the absence of regular repositioning**	estimated incidence • Severity of PUs prior to admission not reported • Participating nurses were trained informally • Concurrent use of several local pressure-management devices in certain high-risk anatomical locations •	
Mattress coverings							
(Posada-Moreno, Losa Iglesias et al., 2011) (micro climate)	Quasi-experimental study **investigating the effect of different mattress coverings on skin surface temperature**	Participants were healthy volunteers. Participants acted as own controls. (n=31) Characteristics: • Not taking medications • No known pathology or illicit drug use • Mean age 24.83±2.38 yrs (range 19 to 29) • 55% sample female	• Temperature of examination room controlled between 22 and 25°C • Participants lay without motion in the supine position in contact with three different mattress surfaces • The same standard foam cushion was used and the surface cover was varied: ○ Cover 1: conventional cotton cover ○ Cover 2: conventional cotton cover with small	• Baseline temperature measured at axilla • Skin temperature measured at 7 areas (sacrum, right and left scapula, right and left elbow, right and left calcaneus) • Temperature measurements were taken every minute for the first 15 min, followed by a measurement at 30 min, 45 min and then every minute	• Skin temperature dropped at most thermometer points for all types of cover compared with baseline (p<0.001 for most body points and covers) • Plastic covering produced a larger increase in local temperature at all extremities	• Small sample of young adults with no pathology • Baseline temperature was taken at axilla and study measures were taken at extremities, therefore drops in temperature from baseline should be expected	**Indirect evidence Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
			plastic film underneath ○ Cover 3: plastic protective case	until 60 minutes.			
Lateral rotation beds							
(Futamura, Sugama et al., 2008) (potential adverse effects)	Quasi-experimental investigating **impact of an automated turning ability in a low air-cell mattress on heart rate**	n= 10 bedridden women with verbal communication difficulties	• Participants were nursed on the NEO® air cell mattress. • The air cell mattress has an automatic turning function in which two inflation cells aligned parallel to the patient at either side of the bed alternatively inflate to incline the body. • Participants acted as own controls for two study periods: ○ Control period: 1-week in which air cell mattress was used without the automated turning function and repositioning was performed by staff ○ Experimental period: 1-week during which the automated turning function of the air-cell mattress was applied at night	• Degree of comfort • High frequency(HF) components of heart rate (parasympathetic activity) variability measured via insitu electrodes providing measures overnight	• No significant differences in the HF component associated with automated turning were observed in 5 of the participants • Significant increases in the HF component were observed in 3 participants associated with the automated turning • 2 participants with the lowest body mass index values exhibited a significant reduction in the HF component during the automated time period • **Study conclusions: automated tilting bed does not appear to significantly influence HF components of heart rate in most participants.**	• The relationship between HF heart rate and comfort is not established • The relationship between HF heart rate and PU risk is not established	**Indirect evidence Quality: low**
Seating cushions and pads							
(Makhsous, Lin et al., 2009) (treatment)	Randomized controlled study **evaluating wheelchair cyclic pressure relief seating**	Participants were in and outpatients recruited from a rehabilitation centre in USA (n=44) Inclusion: • SCI • Existing stage II or stage III PU of the sacral or ischial region • Able to independently use a manual or powered wheelchair • Sitting tolerance of 4 hours Exclusion: • Degenerative spinal disorder	• All participants received PU treatment by a physician or a trained nurse practitioner. • PU wound care was varied according to individual wound requirements and included silver antimicrobial dressings and NPWT. • Participants were randomized to receive either: • Study group: wheelchairs equipped with an individually adjusted automated seat that provided cyclic pressure relief	• Wound characteristics were assessed using the PUSH tool twice weekly • Wound dimensions were recorded with digital photography twice a week • Median healing time for a 30% healing relative to initial measurements • The percentage reduction in wound area • Percentage improvement in PUSH score achieved at the end of the trial	• There was no significant difference in overall wound area between groups at the trial end ($p>0.05$) • The treatment group achieved 30% PU closure significantly faster than the compared with the control group (median 25±2.9 days versus >30 days, $p=0.007$) • The percentage improvement in PU area was greater in study group (45.0±21% versus 10.2±34.9%, $p<0.001$) • The percentage improvement in PUSH score was greater in study	• Trial short duration • Small sample size • Randomisation and blinding not reported • Unclear of difference on pressure-relief behavior for the participants (e.g. when not in the wheelchair) • Non-equivalent	**Level of evidence: 2 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Injury or surgery to pelvis, hip joint, thigh • Hip contractures • Severe pain, spasms • Concerns regarding concordance Characteristics: • No significant difference between groups for demographics • Mean age approv 42 to 44 years • Mean BMI 25.2 • Mean years since SCI injury approx. 3.9 to 6.1 • PU area at commencement: study group1745.8 ± 1324.9 mm² versus control 1586.8 ± 1865.0 mm², p>0.05 • PUs were not significantly different for duration at entry to study	using a protocol of alternating 10 minutes on normal sitting and 10 minutes on off-loading sitting (n=22) • control group: standard wheelchair and participants instructed to perform arm push-ups every 20 to 30 minutes for pressure relief • All subjects sat in wheelchairs for a minimum of 4 hours per day for 30 days		group (21.9±24.6% versus 5.8±9.2%, p=0.003) • wound closure rate (mm²/day) was significantly faster in study group (21.7±14.6 versus2.3 ± 20.4, p<0.001)	wound care (some participants had moist dressings, others had silver dressing or NPWT) • Nonequivalent PU at baseline – treatment group larger PU therefore favoured for 30% healed outcome	
(Brienza, Kelsey et al., 2010) (prevention)	Randomized clinical trial **comparing wheelchair cushions for prevention of PU**	Participants recruited from 12 nursing homes in USA (n=232 included, 180 completed study) Inclusion: • Aged ≥65 years • Wheelchair use for ≥6hrs daily • Braden score of ≤18 • combined Braden activity and mobility score of ≤5 • No pre-existing PU of ischial area Exclusion: • Body weight ≥113kgs or hip width ≥51cm • Requiring wheelchair head support • Severe orthopedic deformity requiring chair adaption • Current use of seating cushion Characteristics: • Only significant difference at baseline was more participants in the SP group having ability to walk more than 3	All participants received a seating assessment at study commencement by a seating specialist and provided with a fitted wheelchair. All participants received a skin and risk assessment by a blinded nurse on a weekly basis. Participants were assigned either: • SP group: skin protection (n=113) receiving an air, viscous fluid and foam or gel and foam cushion (n=113) • Foam group: received a 7.6 cm crosscut segmented foam cushion (n=119)	• PU incidence over 6 months for PUs near the ischial tuberosities (IT) assessed using NPUAP staging • Secondary analysis was performed on combined IT PUs and PUs over the sacrum and coccyx • Follow up was 6 months or until PU incidence	• The foam group experienced a significantly greater incidence of IT PUs (6.7% versus 0.9%, p=0.04) • There was no significant difference in incidence of combined IT and sacral PUs (17.6% versus 10.6%, p=0.14) that included 29 stage II PUs and 2 stage III PUs • Kaplan Meier methods did not demonstrate statistically significant differences in the cumulative incidence of PUs between groups	• The study did not control for conditions that may influence PU risk while participants were not in wheelchair • Staff awareness of residents' participation in the study may have affected the PU incidence rate • Sample was primarily female and white	**Level of evidence: 2** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		metres (p=0.03) • Mean age approx. 86 years • >80% sample female; > 90% White • Mean BMI approx. 24 to 25 • Mean Braden score 15.5 • Over 85% were incontinent					
Thorne et al, 2009 (prevention)	Observation survey investigating **the impact of a gel pad on interface pressure when in supine position**	Participants were recruited from medical and surgical wards in a Canadian hospital (n=60) Inclusion: • Aged ≥ 18 years • Low to moderate risk of PU based on Braden score of 10 to 18 • Able to sit in 30º supine position • 75 to 120 lb body weight Exclusion: • Agitation or need for restraint • Incontinence • Palliative care • Cellulitis or dermatological condition of buttocks, lower back or upper thigh • Existing PU • Chest tubes, nephrostomy tubes or NGT • Unable to sit in required position Characteristics: • 57% sample male • Mean age 72.6 years • Mean BMI 25.68±5.80 for men and 24.53±5.81 for women	• .Participants acted as own comparison unit between first and second sessions with 2 hour rest period between sessions • For both sessions participants were in supine position with 30º bed head elevation Comparison conditions: • First session: no gel mat • Second session: 18x18x1 inch gel pad between mattress and pressure mapping mat	• Participants had IF pressure mapping mat placed underneath the buttock region and pressure readings taken at 5 minute intervals for 20 minutes • Mean value of the 4 readings was used for analysis • Skin assessment was conducted before and after each session	• For the majority of participants (n=55) there was no significant increase or decrease in the interface pressure between no gel mat and gel mat present. • For 3 participants there was a significant reduction in interface pressure (more than –73.55mmHg) associated with the gel pad. • For 2 participants there was a significant increase in interface pressure (more than 68.77mmHg) • There was no significant difference in skin assessments before and after using the gel pad. • **Study conclusions: the benefit of using a gel pad while in a 30º supine position in bed is uncertain as there is no significant difference observed in interface pressure.**	• Indirect outcome measure • Participants did not have high risk of PU • Not blinded • Unclear whether the gel pad was covered (i.e. micro climate) • Participants were positioned for only 20 minutes so it is unclear if skin assessments would have been different over longer period of time •	**Indicate evidence Quality: moderate**
(Williams, Leslie et al., 2011)	Quasi-experimental (cross-over design in two phases) investigating interface pressure between	Participants were recruited from an ICU (22-bed ICU on a closed unit in tertiary-referral hospital in Australia (phase 1 n=18, phase 2 n=20) Inclusion: • impaired mobility • scheduled to be sitting out of bed in the regular	Phase 1: • All participants were positioned on 3 different seating surfaces (non-random because of availability of surfaces) for at least 30 minutes (except for one patient who had to put back in bed within minutes after	• Interface pressures at the buttock-seat interface (excessive pressures (≥200 mm Hg)) • A Force Sensing Array (FSA version 4.0) pressure mapping system (Vista Medical Ltd, Winnipeg, Canada) with a single	Phase 1 • In participants with pressure maps showing excessive pressures (≥200 mm Hg): 46% of pressures recorded for the regular chair were higher than pressures for the gel chair, and on 11% of maps, the pressures were similar for the regular and gel seating surfaces (z = 2.0, P = .04)	• Not clear how drop-out was handled in analyses (patients were measurements could not be completed (phase 1: n=1 -reason	**Indirect evidence Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	buttock and different seating surfaces in ICU patients	ICU chair Exclusion: • unsuitable for sitting out of bed • severe diarrhea • able to bear weight (could sit on a regular high-back chair) Characteristics: Phase 1 • Median age 66 (59-73), female participants (28%), mean BMI 27 (5), worst APACHE II score in first 24h 17 (16-19), mean Braden score 12 (2), median number of days in ICU 14 (8-24) Phase 2 • Median age 62 (51-75), female participants (55%), mean BMI 27 (6), worst APACHE II score in first 24h 20 (17-23), mean Braden score 12 (2), median number of days in ICU 17 (12-30)	starting. • Phase 1: three seat surfaces were: ○ Regular chair with single cushion (TotaLift-II trolley chair, Wy'East, Clackamas, Oregon) ○ Alternative chair with 4 separate cushions (Hausted APC, SterisCorp, Mentor, Ohio) ○ Regular chair with gel overlay • Phase 2: two seating surfaces were: ○ Regular chair with single cushion(TotaLift-II trolley chair, Wy'East, Clackamas, Oregon) ○ Alternative chair consisting of three cushions (back rest, cushion under buttocks , and cushion under legs) made from combination of high and low-density foam	standard 45x45-cm pressure map • The period of 5 to 29 minutes of sitting out of bed was used • System was calibrated with an autocalibrator specific to the system • Seating protocol was used	• Participants in alternative chair had significantly fewer excessive seating interface pressures compared with the regular chair • Participants in the alternative chair had significantly fewer excessive pressures when compared with the gel overlay • alternative chair lacked the practical utility of the regular chair (difficult to transfer participants and limited adjustment options for supporting the patient) • Gel overlay did not reduce interface pressures Phase 2 • 55% (n=11) of the patients had seating interface pressures of 200 mm Hg or greater, and of these 10 participants (93%) had fewer episodes of excessive pressures on the new surface ($P < .001$). • The remaining 9 participants, seating interface pressures were lower than 200 mm Hg. Among patients who had pressures of 150 to less than 200 mm Hg, 40% had fewer episodes of higher interface pressure with the new surface than with the regular surface ($P < .001$).	hypotension; phase 2)+ some participants (number not reported) were too tall to be seated in alternative chair • Outcome measures were not clearly described • Competitors not always clearly described • Materials of seating surfaces (foam) not clearly described	
(Gil-Agudo, De la Peña-González et al., 2009) (prevention)	Biomechanical study investigating **the impact of different seating cushions on interface pressure**	Unclear from where participants were recruited. Appears to be a Spanish trial (n=48) Inclusion: • Aged 18 to 65 years • Complete cervical or thoracic SCI • No PU in preceding month • No surgical resection of pelvis or femur • Passive hip flexion range of at least 90º	• All cushions were covered with their own cover with a protective non-skid, flameproof inner layer and a breathable, elastic outer layer • All participants acted as own controls and were seated on the following cushions for 15 minutes in wheelchairs. Washout period between cushions was not reported. • Seating cushions: • Cushion 1: single	• Participants had IF pressure mapping mat placed underneath the buttock region and pressure readings taken at 1.5 minute intervals for 15 minutes • Mean value of readings was used for analysis	• Cushion 3 (dual compartment cushion with two chambers simulating ergonomic seating base) had the lowest mean interface pressure distribution (34.9 mmHg versus 38.5 to 41.9mmHg for other three cushions, $p<0.05$) • Cushion 4 (gel and firm foam) had the highest interface pressure distribution • **Study conclusions: a dual compartment cushion with two chambers simulating ergonomic**	• Indirect outcome measure • Participants did not have high risk of PU • No skin assessments	**Indicate evidence Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Characteristics: • 79% sample male • Mean age 42±17 years • Mean weight 67.6±18.6 kgs • Mean BMI 23.3±6.0 • Mean Braden scale 13.0±2.4	compartment low profile cushion • Cushion 2: single compartment high profile cushion • Cushion 3: dual compartment cushion with two chambers simulating ergonomic seating base • Cushion 4: gel and firm foam cushion		**seating base has the most favorable profile when considering interface pressure over 15 minutes sitting time.**		
Air mattresses and air mattress overlay							
(Vermette, Reeves et al., 2012) (prevention)	RCT – prospective study **comparing efficacy of inflated static overlay to a micro-fluid static overlay**	Participants recruited from medical, surgical, ICU and geriatric wards. Country not stated. (n=110) Inclusion: • Aged ≥ 18 years • Without existing PU on visual inspection • Weigh <300lb • Informed consent • Moderate to high risk of PU with a Braden score ≤ 14 Characteristics: • No statistical differences between groups at baseline • Mean Braden score 11 to 12 • Mean age approx. 77 yrs • More participants in study group had BMI <18 and more in control groups had BMI >25 (p=0.0241) • More study group participants had diabetes (unclear if statistical due to conflicting data in paper) • Matched for bed-ridden/chair ridden status	• Both groups had identical protocols with repositioning and device check every 2 hrs, sacral moisturizer, minimal raising of bed head, pillow supports. • Participants were randomized to receive either: ○ Study surface: inflated static overlay (n=55) ○ Control surfaces: micro-fluid static overlay for participants <200lb (n=50) or low-air-loss dynamic mattress with pulsation for participants 200 to 300lb or who required edema management (n=5)	• PU incidence within the study period of 2 weeks determined by head to toe assessments performed 3 times a week with PUs classified on NPUAP scale • Comfort level rated by participants on a 5 point Likert scale	• No significant difference in PU incidence was found between the control and study groups (11% versus 4%, p=0.2706) • No significant difference in comfort (90% for control versus 85% for study, p=0.7129) • There was a significant difference in total cost with the ISO was less expensive ($13606 versus $3364, p≤0.001)	• Experiment was not blinded • Cost analysis was limited to the rental or the purchasing of surfaces	**Level of evidence: 1 Quality: high**
(Manzano, Pérez et al., 2013)	Quasi experiment comparing **alternating**	participants were retrospectively recruited over 5 months in 2001 (overlays) and 2006 (mattresses) in an ICU in Spain (n=221)	Participants received either: • small-cell alternating overlay (maximum cell height: 6.5 cm and cell cycle time: 6 minutes,	Incidence of pressure ulcers grade II to IV	Multivariate analyses: risk for developing a pressure ulcer was 0.44 (95% CI: 0.21–0.92), indicating a significantly lower risk for developing a	• No information on preventive measures when seated.	**Level of evidence: 3 Quality:**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	pressure mattress to alternating pressure air overlay for preventing PU in ICU patients	Inclusion: • aged over 18 years • invasive or non-invasive mechanical ventilations for at least 24 hours In ICU • within 24/48h after initiating invasive or non-invasive MV Exclusion: • Existing PU • Body weight > 140 kgs Characteristics:	standardized protocol for turning every 4 hours using following schedule: semi-Fowler 30°, right-side lateral position 30°, semi-Fowler 30°, and left-side lateral position 30°) • alternating replacement mattress: Alternating modus of the Total Duo2®, Hill-Rom Corporate, Bastesville, IN, USA (maximum cell height: 13.5 cm, turning protocol similar as in intervention 1 group)		pressure ulcer (cat II-IV) on the replacement mattress compared to the small-cell overlay mattress (p=0.038).	• time lag between two interventions is 5 years. • no correction possible for unknown differences between two groups • Not clear how multivariate analyses was conducted • no information on non-blachable erythema and possible baseline differences	**moderate**
(Valente, Greenough III et al., 2012) (prevention and treatment)	Retrospective analysis comparing a **gel-foam mattress with a power air mattress overlay**	Participants were inpatients at a geriatric hospital in USA during the retrospective study period. (n=122) Inclusion: • Placed on study mattress for at least 10 days during retrospective study time period Exclusion: • admission or time on mattress of interest <10 days Characteristics: • All participants on one of the two support surfaces of interest were at high risk of PU (Braden<16) Participants on a gel mattress had significantly (p<0.03) more health problems (9.3±2.2 versus 8.3±2.7) • Mean Braden score 12.9 to 13.5 • Length of stay was significantly greater for those on the air mattress overlay 83±13.5 days versus 133±16.7 days)	• On admission patients were assessed using the Braden Score risk assessment tool • Each participant was assigned to either (decision by physician or nurse and not related to this study): • Gel-foam mattress (n=55) • Power Air mattress overlay (n=67)	• PU rates determined by skin assessment • PU healing determined by weekly skin assessment The size of each ulcer (length and width) was assessed using paper tape measurements	• There was no significant difference in PU incidence between those on the gel-foam mattress and those on the air mattress overlay (25% versus 40%, p=0.118). • In the gel-foam mattress group (n=55) there were 63 PUs: 36 on admission, and 27 that developed during stay. • In the air mattress overlay group (n=67) there were 110 PUs: 54 on admission and 56 developing during stay • A larger percentage of PUs healed in the air mattress overlay group (42% versus 27%) • Overall, of the pressure ulcers that showed healing, the lesions healed at simultaneous rates between groups (mean rate of 31.9 ± 15.4 cm2/week on the gel mattress and 31.3 ± cm2/week on the air overlay) • **Study conclusions: when controlling for the total amount of time each group spent on the respective**	• Retrospective • No randomization • Patients were on the gel mattress for longer than the on the power air overlay • Assumed no PU would develop in less than 7 to 10 days so exclude these patients	**Level of evidence: 5 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Mean age 65 to 69 years • Primarily Caucasian			**mattresses, the efficacy of the gel-foam mattress preventing new PUs equaled or outweighed the benefit of the Power Air overlay**		
Water mattress							
(Nwadinigwe, Anyaehie et al., 2012) (prevention)	Retrospective review **investigating a static water mattress for preventing PU**	Participants were consecutive patients admitted to a spinal unit in Nigeria (n=99) in 2005 to 2006 (foam group) or in 2007 to 2008 (water group) Inclusion: • complete traumatic SCI Exclusion: • Missing record data • PU on admission • Incomplete SCI Characteristics: • All males • Water mattress group were significantly older (41.5±3.2 versus 39.0±4.6, p=0.002) • No significant difference in length of hospital stay • Significant differences in cause of SCI	• All participants received 4 hourly turning, IDC and structured care programs. Participants received either: ○ foam mattresses were unbranded, 6" thick made from conventional firm foam and covered with a waterproof plastic canvas (n=35) ○ water mattress is a static device that reduces pressure by spreading the weight of the body over the larger area (n=64)	• Incidence of PUs through staging based on NPUAP classification	• There were significantly less PUs in participants treated with a water mattress (p=0.003) • PUs in water mattress group were all stage II or less and less likely to require a flap cover (p=0.001) but no difference in rate of split-skin grafts (p=0.307)	• Retrospective control • Data base reviews • Insufficient data on concurrent treatments • Frequency of PU assessment unclear • Follow-up only 40 to 50% of cases in each group • Analyses not controlled for differences in baseline characteristics	**Level of evidence: 4** **Quality: low**
Many different support surface comparisons							
(McInnes, Jammali-Blasi et al., 2012; McInnes, Jammali-Blasi et al., 2011) (prevention)	Systematic review and meta-analysis **investigating the effectiveness of a large range of products in preventing PU**	N = 53 eligible trials were identified with a total of 16,285 study participants	• **Comparison of a wide range of pressure relieving support surfaces – see results**	• PU incidence	**Foam alternative pressure support surfaces/overlays** • Foam alternative pressure support surfaces were associated with a decreased risk of PU compared with a standard hospital mattress (n=5 trials, RR 0.40, 95% CI 0.21 to 0.74, p=0.004). • No significant differences between silicone or foam overlays and alternating pressure devices (n=4 studies) **Alternating pressure devices** • A two layer large cell ripple alternating pressure device was more	• The risk of bias in the included trials was high due to many methodological flaws • there was a small sample size in many studies • failure to report on PU status on study entry • many trials did not provide	**Level of evidence: 1** **Quality: high**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					effective in preventing PUs compared with another alternating pressure device (16% vs. 34%, p>0.05) **seat cushions** • No significant differences were found in the2 trials that compared slab and contoured foal cushions • No differences found between a pressure redistribution set cushion compared with a standard cushion **Australian standard medical sheepskins** • Sheepskins were associated with a decrease in PU compared to standard care (RR 0.48, 95% CI 0.31 to 0.74)	information about co-interventions • many of the published trials had received funding from manufacturers	
Other relevant topics							
(Williamson, Lachenbruch et al., 2013)	Laboratory study **comparing interface pressure associated with excess bed linen/pads**	A pelvic indentor model was used.	The pelvic indentor was placed on the following beds with combinations of the following linen, including different head of bed (HOB) elevation (30° and 45°): **Beds** • High specification foam mattress with standard fitted sheet • Low air Loss bed with standard fitted sheet **Linen** • disposable pad • repositioning sheet • quilted pad with plastic back • bath blanket • flat sheeted folder in quarters Moisture effect was also tested by soaking the incontinence linen.	• Peak sacral interface pressure (IFP) measured using pressure map	• For the low air loss bed all linen combinations had higher peak sacral IFP compared to fitted sheet alone (increase ranged from 19.2% to 63.5%, p <0.01) • On the low air loss bed disposable pad without plastic had higher peak sacral IFP than the pad with plastic back • For the foam bed all linen combinations had higher peak sacral IFP compared to fitted sheet alone (increase ranged from 5.6% to 31.6%, p <0.01) • When moisture was added, peak sacral IFP did not change, or was lowered compared to dry incontinence pads. • **Study conclusions: additional layers on the bed are associated with increased sacral IFP**.	• Laboratory model study	**Indirect evidence**

References

Black, J., C. Berke and G. Urzendowski. (2012). "Pressure ulcer incidence and progression in critically ill subjects : influence of low air loss mattress versus a powered air pressure redistribution mattress." Journal of Wound, Ostomy and Continence Nursing **39**(3):267-73.

Brienza, D., S. Kelsey, P. Karg, et al. (2010). "A randomized clinical trial on preventing pressure ulcers with wheelchair seat cushions." Journal of the American Geriatrics Society **58**(12):2308-14.

Cassino, R., A.M. Ippolito, C. Cuffaro, et al. (2013). "A controlled, randomised study on the efficacy of two overlays in the treatment of decubitus ulcers." Minerva chirurgica **68**(1):105-16.

Demarré, L., D. Beeckman, K. Vanderwee, et al. (2012). "Multi-stage versus single-stage inflation and deflation cycle for alternating low pressure air mattresses to prevent pressure ulcers in hospitalised patients: A randomised-controlled clinical trial." International Journal of Nursing Studies **49**(4):416-26.

Futamura, M., J. Sugama, M. Okuwa, et al. (2008). "Evaluation of comfort in bedridden older adults using an air-cell mattress with an automated turning function: measurement of parasympathetic activity during night sleep." Journal Of Gerontological Nursing **34**(12):20-6.

García-Molina, P., E. Balaguer-López, J.E. Torra I Bou, et al. (2012). "A prospective, longitudinal study to assess use of continuous and reactive low-pressure mattresses to reduce pressure ulcer incidence in a pediatric intensive care unit." Ostomy Wound Management **58**(7):32-9.

Gil-Agudo, A., A. De la Peña-González, A. Del Ama-Espinosa, et al. (2009). "Comparative study of pressure distribution at the user-cushion interface with different cushions in a population with spinal cord injury." Clin Biomech **24**(7):558-63.

Johnson, J., D. Peterson, B. Campbell, et al. (2011a). "Hospital-acquired pressure ulcer prevalence--evaluating low-air-loss beds SEE ERRATUM." Journal of Wound, Ostomy, and Continence Nursing **38**(1):55-60.

Johnson, J., D. Peterson, B. Campbell, et al. (2011b). "Correction: hospital-acquired pressure ulcer prevalence-evaluating low-air-loss beds." Journal of Wound, Ostomy, and Continence Nursing: Official Publication of the Wound, Ostomy and Continence Nurses Society / WOCN **38**(4):347-.

Korniewicz, D.M., J. Siegel, V. Fajardo, et al. (2011). "Evaluation of the incidence of pressure ulcers using hill-rom versacare surfaces." Advances In Skin & Wound Care **24**(4):160-6.

Makhsous, M., F. Lin, E. Knaus, et al. (2009). "Promote pressure ulcer healing in individuals with spinal cord injury using an individualized cyclic pressure-relief protocol." Advances in Skin & Wound Care **22**(11):514-21.

Manzano, F., A.M. Pérez, M. Colmenero, et al. (2013). "Comparison of alternating pressure mattresses and overlays for prevention of pressure ulcers in ventilated intensive care patients: A quasi-experimental study." Journal of Advanced Nursing **0**.

McInnes, E., A. Jammali-Blasi, S. Bell-Syer, et al. (2012). "Preventing pressure ulcers—Are pressure-redistributing support surfaces effective? A Cochrane systematic review and meta-analysis." International Journal of Nursing Studies **49**(3):345-59.

McInnes, E., A. Jammali-Blasi, S.E. Bell-Syer, et al. (2011). "Support surfaces for pressure ulcer prevention." Cochrane Database Of Systematic Reviews (Online) **4**:CD001735.

Nwadinigwe, C.U., U.E. Anyaehie and E.C. Onyegbule. (2012). "The impact of water mattresses on incidence of PUs in patients with spinal cord injuries in Nigeria." Journal of Wound Care **21**(4):184-9.

Pemberton, V., V. Turner and C. VanGilder. (2009). "The effect of using a low-air-loss surface on the skin integrity of obese patients: results of a pilot study." Ostomy/Wound Management **55**(2):44-8.

Posada-Moreno, P., M.E. Losa Iglesias, R. Becerro de Bengoa Vallejo, et al. (2011). "Influence of different bed support surface covers on skin temperature." Contemporary Nurse **39**(2):206-20.

Turnage-Carrier, C., K.M. McLane and M.A. Gregurich. (2008). "Interface pressure comparison of healthy premature infants with various neonatal bed surfaces." Advances in Neonatal Care **8**(3):176-84.

Valente, S.A., W.B. Greenough III, S.L. DeMarco, et al. (2012). "More expensive surfaces are not always better." Kuwait Medical Journal **44**(1):40-5.

van Leen, M., S. Hovius, J. Neyens, et al. (2011). "Pressure relief, cold foam or static air? A single center, prospective, controlled randomized clinical trial in a Dutch nursing home." Journal of Tissue Viability **20**(1):30-4.

Vermette, S., I. Reeves and J. Lemaire. (2012). "Cost effectiveness of an air-inflated static overlay for pressure ulcer prevention: A randomized, controlled trial." Wounds: A Compendium of Clinical Research & Practice **24**(8):207-14.

Ward, L., K. Fenton and L. Maher. (2010). "The high impact actions for nursing and midwifery 4: your skin matters... fifth in a series." Nursing Times **106**(30):14-5.

Williams, T.A., G.D. Leslie, R. Bingham, et al. (2011). "Optimizing seating in the intensive care unit for patients with impaired mobility." American Journal of Critical Care **20**(1):e19-e27.

Williamson, R., C. Lachenbruch and C. Vangilder. (2013). "The effect of multiple layers of linens on surface interface pressure: results of a laboratory study." Ostomy WoundManage **59**(6):38-48.

MEDICAL DEVICE RELATED PRESSURE ULCERS

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
Interventions to prevent device-related pressure ulcers							
(Forni, Loro et al., 2011)	Historical controlled clinical trial **investigating effectiveness of polyurethane foam applied inside a foot plaster cast for reducing device-related heel PU**	Participants recruited from an orthopaedic ward in Italy (n=158, 156 completed study). Study used an historical control group. Inclusion: • Orthopaedic disease requiring plaster cast on lower limb and foot, including heel • Sore skin (stage I PU) on presentation OR undergoing chemotherapy Exclusion: • Cast not including foot • PU > stage I • Not having a risk factor of sore skin or chemotherapy Characteristics: No significant difference in demographics at baseline Mean age 28 to 30 years Primarily quick setting plaster cast including spica casts, above the knee casts and below the knee casts	• Study group: received sterile polyurethane foam pad measuring 10 x 10 cm in contact with the skin of the heel before applying the cast (n=71). Treated 2007 to 2009. • Control group: retrospective participants with the same risk factors but not administered the foam prior to cast application (n=85). Treated 2005 to 2006.	• Presence/absence of PU in the treated limb using NPUAP staging	**Participants with stage I PU (sore skin) as a risk** (n=56 in study group, n=49 in control group) • Significantly less participants in the experimental dressing group who presented with stage I PU experienced PU of the heel on cast removal (3.6% versus 42.9%, p < 0.0005 • The relative risk of heel PU on cast removal was 0.08 (95% CI 0.02 to 0.33) equating to a 92% (95% CI 58% to 97%) reduction in risk of a heel PU associated with the foam heel dressing. • Number needed to treat (NNT) was 3 (95% CI 2 to 4). **Participants with chemotherapy as a risk factor** (n=24 in study group, 54 in control group) • From participants undergoing chemotherapy, the study group had significantly less PU (4.2% versus 33.3%, p=0.005) • **Study conclusions: application of a polyurethane foam in contact with the skin prior to applying a plaster cast covering the foot is associated with a lower rate of heel PU in patients presenting with risk factors of existing stage I PU or undergoing chemotherapy**	• Historical control • Length of plaster cast insitu is not reported and may be significantly different • Other management strategies (e.g. patient education) were not reported and may vary between groups	**Level of evidence: 4 Quality: moderate**
(Weng, 2008)	Quasi-experiment investigating **effect of tegaderm and tegarsorb in preventing device-related PU of the nasal bridge from**	Participants recruited from a medical ICU and a cardiac ICU in Taiwan (n=90) Inclusion: • Diagnosed with respiratory failure	Participants were assigned to one of three groups: • Control group with no dressing (n=30) • Tegasorb group (n=30) • Tegaderm group	• Formation of PU assessed as being one of four grades (grading system not reported, Grade I defined as reddened area lasting more than 30 mins after	• Incidence of grade I PU was lower in the tegaderm group compared with control group (53.3% versus 96.7%, p<0.01) • Incidence of grade I PU was lower in the tegasorb group compared with control group (40%% versus 96.7%,	• Small number of subjects • No blinding, no power calculations • Several factors may influence the findings (e.g. skin colour precluding accurate	**Level of evidence: 3 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
	oxygen masks	• Using and tolerating with non-invasive face mask • No facial skin breakdown Exclusion: • Not reported Characteristics: • No significant differences between groups at commencement for any demographics including BP and bloods • Primarily classified as having adequate nutrition and no sensory impairment • Majority had no sweating observed • Mean age approx. 75years	(n=30) The materials were used to cover the nasal bridge and patients were observed for PU formation	change of position). • Time until PU formed in minutes	p<0.01) • PUs formed significantly faster in control group (1111±2169 mins) versus the tegaderm (2628±1655mins) or tegasorb groups (3272±2566 mins, p=0.0) • There were no statistical significant difference in occurrence duration and time between the tegasorb and tegaderm group • Tegaderm adhered less effectively than tegasorb • **Study conclusions: A protective dressing was associated with decreased incidence of grade I PU in older adults wearing non-invasive face masks**	assessment of PU formation) • Facial formation may influence PU formation • No reporting of skin breaks/damage associated with dressing removal	
(Huang, Tseng et al., 2009)	Quasi experiment investigating **the effectiveness of Duoderm® and Soft Liner in preventing nasal PU in nasal intubation**	A sample of participants was recruited in China (n = 18) Inclusion: • Nasal intubation • head/neck surgery for squamous cell carcinoma Characteristics: • No significant difference between groups for age, length surgery, diameter of endotracheal tube length of tube inserting or operative time • Mean age 60 to 62 years • Mean surgery length 9.8 to 10.4 hours	• Participants were managed with either: • Duoderm and Soft Liner used for a custom-made cushioning	• PU area (strategy for measuring area was not reported)	• Mean pressure sore surface area was less in participants who had protection with DuoDerm and Soft Liner (8.0±9.0 mm^2 versus 35.2±27.5mm^2,p=not reported) • Few participants who had protection with DuoDerm and Soft Liner experienced nasal PU (60% versus 100%, p = not reported) • **Study conclusion: Protective dressing was associated with lower incidence of nasal PU**	• Recruitment of participants not reported • No statistical analysis • Small sample size • Unclear how outcomes were measured	**Level of evidence: 3** **Quality: low**
(Zaratkiewicz, Whitney et al., 2010)	Quality improvement report/ retrospective review of electronic records **to describe change in oral PU rates associated with**	Participants were those who had been critical care patients at a level I trauma center in the US • Pre-intervention: March - July 2007 n=1571 • Post-Intervention Aug – Dec 2007 n=1522	• In July 2007 the unit was using two ET tubes, Hollister™ ETAD and B&B Medical Universal Bite Block™ • In December 2007 months the ETAD was discontinued and a new device the	• PUs rates associated with ET tubes • Analysis of the number of PUs on the lips, mouth, gums, and tongue of orally intubated patients pre-intervention (phase 1)	**Pre-intervention (March – July 2007)** • Total n=1517 (ventilator days: 7175) Oral/lip PUs: 19 **Post intervention (Aug – Dec 2007)** • Total n=1522 (ventilator days: 7592) Oral/lip PUs: 2	• No statistical analysis • Patient demographics not reported • Method of identifying a PU was not reported • Unclear if other practices also changed	**Level of evidence: 4** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
	practice changes	• Follow up post Intervention Jan – Dec 2009 n=3010 Inclusion: Mechanical ventilation and intubation with an oral endotracheal (ET) tube Exclusion: Aged ≤ 17 years Facial burns Prone positioning PU on admission or ulcer unrelated to pressure	Hollister™ Anchor Fast was introduced.	group compared to post-intervention (phases 2 and 3) groups • No staging was conducted in line with the NPUPAP policy for mucosal PU	**Follow up Jan – Dec 2009** • Total n=3010 (ventilator days: 14328) Oral/lip PUs: 2 • **Study conclusion: change in ET tube model was associated with a reduction in PU incidence**		
Paediatric populations – prevalence and interventions							
(Limpaphayom, Skaggs et al., 2009)	Retrospective case series **reporting on complications associated with Halo use in children**	Participants were those treated in a children's hospital in USA from 1996 to 2005. (n=97 eligible, n=68 with complete medical records included) Inclusion: • Treatment with halo Exclusion: • Incomplete medical record Characteristics: • Mean age was 10 years (range 1 to 20 years) • 54% sample male	Halo used for immobilization (n=37), halo traction (n=12) or halo traction followed by halo vest (n=19). Mean duration of treatment was 12 weeks when used for immobilization and 3 weeks when used for traction.	Development of pressure ulcers as a complication. Frequency of assessment, assessment methods or staging are not reported.	• Incidence of pressure ulcers was 7.3% (severity not reported) • In no cases did development of a pressure sore require cessation of halo use or surgical intervention. • The authors suggest that "cutting off the offending portion of the halo vest" may reduce discomfort. (expert opinion) • The authors recommend routine skin checks by parents at home and during clinic visits, but do not detail frequency or assessment strategies. (expert opinion) • **Study conclusions: The report highlights the potential complications associated with medical device use in children**	• retrospective review • small sample size • 30% eligible records were not reviewed due to being incomplete, which leads to an unreliable indication of PU incidence • Insufficient detail of PU preventative strategies used, duration of treatments, participant characteristics, severity and duration of PU or management of PU while halo in use were provided in this study.	**Level of evidence: 5** **Quality: low**
(Boesch, Myers et al., 2012)	Qualitative Plan Do Study Act (PDSA) investigating a multi-faceted intervention in reducing tracheostomy-related pressure ulcers(TRPU) in	Conducted in a academic children's hospital in the US (490 beds) Results included 834 tracheostomy patients and 10,132 tracheostomy patient days.	**Professional intervention** PDSA cycle frame to implement a bundle that included: • Pressure ulcer risk (Braden scale) and skin assessment • Moisture free device interface	TPRU rate	**Mean TRPU rate** • Pre-intervention ranged from approx. 3.8% to 16% over 6 months (mean rate 8.1%) • During bundle development and implementation ranged from 0% to 12% over 12 months (mean rate 2.6%) • Post-intervention ranged from 0% to 3% over 10 months (mean 0.3%)	• The study is limited to a single hospital unit design and was not a randomized controlled trial • Measurement periods were different for pre-during and post-intervention which	**Level of evidence: 4** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
	children	Patient characteristics: • Mean age 2yr 8 mo • 87% ventilator dependent	• Pressure free device interface • Hydrophilic polyurethane foam dressing (Mepilex Lite®) used under tracheostomy tube to wick the moisture away from the stoma and skin surface • Use of extended tracheostomy tube design • Online education on risk and skin assessment for all nurses **Organizational intervention** • Patient information brochures • Engagement with tracheostomy tube manufacturer to develop and deliver extended tracheostomy tube design • Real time reporting of TRPU • Incorporation of TRPU interventions into electronic record nursing workflow		• Statistical analysis on effect of extended tracheostomy tube design found a significant reduction in number of TPRUs (p=0.007) and number of days with TPRU (p<0.0001)	influences mean rates	
(Jatana, Oplatek et al., 2010)	Cross-sectional study investigating **effect of nasal continuous positive airway pressure (CPAP) and cannula use in neonates** ***Nb: Mucosal membrane PU***	Participants were a consecutive sample enrolled in NICU over a one year period (n=100, n=200 nasal cavities) Inclusion: • younger than 12 months in age • at least 7 days of CPAP or cannula use Excluded: • Pyriform aperture stenosis • choanal atresia • cleft lip/palate • previous nasotracheal	• External nasal examinations and anterior nasal endoscopy (0° telescope) and digital photographic documentation	• Incidence and characteristics of internal and external nasal finings categorized as ulceration, granulation or vestibular stenosis • Vestibular stenosis graded as mild, moderate or severe	• Nasal complications were seen in 12 of the 91 patients (13.2%) • Nasal complications from CPAP were associated with lower Apgar scores at one minute (p=0.02) and 5 minutes (p=0.06) and no association with gestational age, birth weight, CPAP setting or CPAP duration **Internal examination** • Ulceration in 3.3% of nasal cavities • Granulation in 1.6% cavities • Vestibular stenosis in 2.2% nasal cavities • All abnormalities located wt the top of the CPAP nasal prong and occurring as early as 8 days after administration of	• Unclear how often endoscopies were performed or duration of therapy at time endoscopy performed	**Level of evidence: N/A** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		intubation or nasal surgery Characteristics: • Nasal CPAP use (n=182 nasal cavities), • Nasal cannula (n=18 nasal cavities)			CPAP **External examination** 5.5% of participants who used CPAP had columellar necrosis occurring 5 to 25 days after exposure		
(Wilbrand, Wilbrand et al., 2012)	Retrospective observational study **reporting rates of adverse events including PU associated with helmet therapy**	Participant group for record review, location and selection of records was not reported (n = 410 children) Exclusion: • records without adequate follow up Characteristics: Children categorized as plgiocephaly (n=230_, brachycephaly (n = 32) or both (n148)	• All records were analyzed for adverse effects	• Complications: ○ Pressure sores ○ Local ethanol erythema ○ Skin infection ○ Bacterial abscess ○ Helmet fitting issues ○ Failure to achieve therapeutic success • Did not state how often or by whom the participants were inspected	• Complications were seen 22.4% of the cohort. • PUs were found in 43 cases (10.5%) • Local ethanol related erythema found in 26 cases (6.3%) • Deficient fitting of the helmet was noted in 24 cases (5.9%) • PU primarily seen in initial phase of therapy • In the discussion the researchers provided expert opinion that firm manual pressure applied to the inner surface of the helmet at the site of PU for several minutes each day helps resolve the PU (this was not investigated in the research)	• Categorization of adverse events was unclear e.g. a deficit fitting of the helmet could lead to PU • Did not report PU stages • Did not report how differentiation was made between local erythema and stage I PU • Unclear how cases were selected	**Level of evidence: N/A Quality: moderate**
(Chidini, Calderini et al., 2010)	Quasi experiment **comparing a CPAP delivery devices (face mask versus helmet) and reporting on complications including PUs**	Participants were recruited from a PICU in Italy and experimental participants were matched to controls for age, organ failure, $PaCo_2$ and PaO_2:$F10_2$ (n=40) Inclusion: • PaO_2:$F10_2 \leq 300$ • bilateral lung infiltrates on chest xray • Venturi mask for 15 minutes provided no significant improvement in function • absence of other organ failure Exclusion: • endotracheal tube or tracheostomy prior to PICU • facial deformities	Participants had CPAP delivered via either: • facial mask chosen to provide optimal fit to the contour of the child's face, with nasal masks used as facial masks In the smallest children. Colloid dressing was applied to facial pressure points to reduce risk of pressure injury. (n=20) • helmet: an infant helmet made of transparent latex-free polyvinyl chloride secured to a soft collar that adheres to the child's neck (n=20)	Primary outcome was improvement in gas exchange Secondary outcome included PUs assessed on a four point scale of severity	• There was significantly more stage 1 PUs associated with the facial mask compared with the helmet (75% versus 0%, p=0.002) • Participants with facial mask CPAP delivery had significantly less hours wearing the delivery device compared with the helmet group (6.4±1.8 versus 10.8±2.0 hours, p=0.001) • CPAP delivered via both the helmet and the mask led to significant improvements in gas exchange, with no difference between the groups. • Other adverse events (CPAP associated outcomes and eye irritation, gastric distension) were equivalent between the groups • Intolerance of the device leading to sedation was higher in the facial mask group (70% versus 5%, p=0.001)	• Small sample size • Of 97 potential participants, only 20 met the selection criteria to use the helmet • Non-blinded, non-randomised study	**Level of evidence: 3 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		• wide range of respiratory system exclusion criteria upper airway obstruction Characteristics: • Age range 3 to 11 months • Primarily requiring CPAP due to community-acquired pneumonia or post-operatively • No significant differences between groups in oxygen/respiratory variables, weight, age, body temperature			• **Study conclusions: The report highlights the potential of stage 1 PUs associated with oxygen delivery medical devices in children, despite the use of hydrocolloid preventative dressing.**		
(Kuo, Wootten et al., 2013)	Retrospective record review investigating **effectiveness of a preventative dressing under tracheostomy ties**	Participants were children with tracheostomies receiving care in a 6 year period in a US hospital (n = 134) Inclusion: • tracheostomy within retrospective review period Characteristics: • Age: 2 weeks to 16 years • mean age was 3.3 years in no dressing cohort vs 3.9 years in dressing cohort	Mepilex Ag was applied underneath tracheostomy ties for the last 15 months of the retrospective review period. (n=41) Prior to that, no dressing was applied under tracheostomy ties (n=93) All participants had the same tracheostomy rube	No stated	• No dressing cohort: 11/93(11.8%) developed some degree of skin breakdown Average time to skin breakdown was 5 days • Dressing cohort: 0/41 (0%) had skin breakdown	• Other care interventions/changes in routine in the ward over the 6 year period may have influenced findings • Unclear if there were significant differences between groups at baseline • Methods of assessing skin not stated • Relied on documentation f	**Level of evidence: 4** **Quality: low**
(Günlemez, Isken et al., 2010)	RCT investigating **effectiveness of silicon gel in preventing nasal PU in neonates**	Participants recruited in a NICU in India over 2 years (n = 179) Inclusion: • premature infant • nasal CPAP Exclusion: • term gestation • nasal deformity • shock • coagulant defect	Participants were randomized to receive: • 1.8mm thick silicon gel sheeting applied to nares surface during ventilation (n=92) • No sheeting (n=87)	Nasal injuries including: bleeding, crusting, excoriation, columella necrosis assessed daily by the same plastics surgeon 1 month follow up	• Nasal injury incidence was significantly greater in the group that did not have prophylactic gel sheeting (4.3% versus 14.9%, OR 3.43, 95% CI 1.1 to 10.1, p<0.05) • Columella necrosis was significantly greater in the group that did not have prophylactic gel sheeting (6.8% versus 1.08%, OR 6.34, 95% CI 0.78 to 51.6, p<0.05) • Infants with nasal injury had a significantly longer duration of ventilation (19.6 ± 10.6 days) vs those	• Minimal reporting of randomization, allocation concealment and blinding • Duration of therapy confounded results • Included no PU in the outcome measure • Unclear how assessment was performed • No apriori power calculation	**Level of evidence: 2** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		Characteristics: • mean birth weight approx. 1760 g • Mean age 32 gestational weeks • Mean ventilation: 5-6 days			without injury (4 ± 3.3 days) • Nasal injury developed significantly slower in those without gel sheeting (10.8 ±3.1 days vs 16.2 ±3.2 days, p <0.05)		
Prevalence and background data for adults							
(Black, Cuddigan et al., 2010)	Secondary analysis of incidence and prevalence study data	Prevalence rates measured in a subset of participants at one US hospital (n=2079) Exclusion: • psychiatric and obstetric patients with length of stay < 3 days • Patients not available due to surgery, medical tests • declined consent • aged < 17 years • PU on admission to hospital Inclusion: • ICU, medical, surgical and step down wards	• No intervention, prevalence survey	• HAPU determined by identifying if a PU was documented on admission report • Wound nurse confirmed PU	• The overall rate of HAPU was 5.3% • Medical device related HAPU 1.3% • Proportion of HAPU that were related to medical devices was 34.5% **Risk with a medical device** • Patients with a medical device were significantly more likely to develop a PU (p = 0.008). • Patients with a medical device were 2.4 times more likely to develop PU of any kind (95% CI 1.2 to 4.8, p = 0.10) **Types of medical device HAPU** • Stage I – 35% of HAPU • Stage III – 3% of HAPU • Unstageable – 24% of HAPU • 43% of HAPU were on head (primarily ears)	• Specific medical devices were not recorded • Procedures for performing survey were not reported	**Level of evidence: N/A** **Quality: low**
(Turjanica, Clark et al., 2011)	Descriptive correlational design **reporting characteristics associated with development of ear PU**	Convenience sample recruited from a medical-surgical unit in the US (n=100) Inclusion: • receiving oxygen via nasal cannula during hospital admission Exclusion: • non- English-speaking Characteristics: • Not reported	• A graduate student and the patient's staff nurse jointly assessed the skin condition around the patient's ears • If skin breakdown was present the nurses appropriately staged and documented the lesions on the Turjanica Pressure Ulcer of the Ear Data Collection Tool	• Skin assessment aided by the Turjanica PU of the Ear Data Collection Tool used to assess skin, patient discomforts at the ears, length of time using oxygen, eyeglasses, skin diagnoses that may influence skin condition	• The incidence of skin breakdown was 37% (range 28 to 47%) • Only one patient exhibited ear PU on admission • Predominately Stage I PU, no stage III or IV PU • No statistically significant associations existed between skin integrity and patient demographics (use of glasses, fever, other skin conditions, Braden scale • Lack of oxygen use at home predicted the presence of ear PUs ($\chi^2 = 6.113$, p = 0.013)	• Used a non-validated data collection tool • No multivariate analysis • Unclear how PU was assessed and staged	**Level of evidence: N/A** **Quality: low**
Prevalence and background data for children							

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
(Jaryszak, Shah et al., 2011)	Retrospective case series **reporting on wound complications associated with tracheostomy in children**	Participants were those identified from the Children's National Medical Center database in the USA as being coded for tracheostomy over a 15 month period (2008 to 2009) (n=65). Inclusion: • Coded for tracheostomy • Electronic medical record in audit period Characteristics: • Mean age at time of tracheostomy was 45±8.7 months • Most common indication was pulmonary disease (36.9%)	Tracheostomy	Number of participants developing wound complications as assessed using the NPUAP PU staging system Type of tracheostomy tube Wound cultures conducted from 2 weeks before until 2 weeks after tracheostomy	• 19/65 (29.2%) participants developed a post-operative wound complication • There was no significant difference in age between those with and without wound complications (mean age 39.3 versus 47.4 months, p=0.068) • There was a higher rate of wound complications in participants aged less than 1 year compared with those aged over 1 year (39% versus 17%, p=0.04) • Use of extended mechanical ventilation) (p=0.58), weight (p=0.55), positive preoperative wound culture (p=0.06), positive postoperative wound culture (p=0.28) and maturation of stoma at time of surgery (p=0.14) were not associated with wound complications. • Type of tracheostomy tube was associated with wound complications (p=0.02) with a Bivona® Flex-Tend™ predicting wound complications (likelihood ration 4.9, p=0.03) compared with a Standard Bivona® or a Shiley™. • Wound complications were not associated with increased hospital length of stay or readmission. • As a result of wound complication rates the facility instituted a specialty trained tracheostomy nurse, use of barrier protection between tube flanges and the skin and aggressive wound care to early wound complications to prevent progression. The success of these interventions is not reported. • **Study conclusions: The report highlights the potential of wound complications associated with medical device use in children**	• Retrospective review • Small sample size • Records may be unreliable • Insufficient detail of PU preventative strategies used, duration of treatments, participant characteristics, severity and duration of PU or management of PU were provided in this study.	**Level of evidence: 5 Quality: low**
(Schluer, Halfens et al., 2012)	Cross-sectional clinical	**Clinical site** 14 paediatric hospitals	Clinical audit of PU	Classification using EPUAP staging	• Overall PU prevalence 35% • The prevalence of PUs for patients	Category 1 PUs may be over- or underdiagnosed in	**Level of evidence:**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		including paediatric intensive care units (PICU), neonatal intensive care units (NICU), surgical, medical and rehabilitation (Switzerland) **Sample** • n= 412 • Inclusion: hospitalised children (ages 24 hours to 18 years) in 14 paediatric in 24 hour period in June 2009. • Inclusion: hospitalised for at least 1 day • Exclusion: psychiatric wards, no consent or refusal			with an external device (tubes, IVs, continuous positive airways pressure, splints, and other installations) was 40%	this study remains unclear, although the interrater reliability suggest the scores are reliable.	**N/A** **Quality: moderate**
(Fujii, Sugama et al., 2010)	Prospective cohort study	Survey of seven NICUs in Japan in 2006 (n=81) Inclusion: • Neonate in an incubator • No pre-existing skin breakdown • Consent given Characteristics: 51.9% sample female low birth weight most common reason for admission (74.1%) Mean age 32.5 weeks gestation (range 24 to 41) mean birth weight 1745 g (range 478 to 4122)	Clinical audit of PU	• Skin was assessed daily by nurses and researchers • Skin texture was assessed using Dubowitz neonatal maturity assessment scale	• 86% of PUs were associated with CPAP or DPAP **Risk factors associated with PU** (p<0.05): • endotracheal intubation **Multivariate analysis risk factors:** • endotracheal intubation OR 4.0 (95% CI 1.04 to 15.42, p=0.047)	• High level of non-consent (61.8%) led to high exclusion • Most neonates were not extremely underweight (<500g) • Potential Hawthorne effect as researcher visited hospitals to directly assess and observe •	**Level of evidence: 4** **Quality: moderate**
(Schindler, Mikhailov et al., 2011)	Retrospective database study	Survey of nine PICUs in trauma centers in USA All patients in the center between March 2006 and December 2007 were included. (n=5346)	Clinical audit of PU		**Multivariate analysis risk factors:** • bilevel or CPAP OR 2.004 (95% CI 1.509 to 2.661, p<0.001) • mechanical ventilation OR 1.334 (95% CI 1.031 to 1.726, p=0.03) • high frequency oscillatory ventilation OR 2.057 (95% CI 1.208 to 5.134, p=0.01) • extracorporeal membrane oxygenation OR 2.490 (95% CI 1.208 to 5.134,	• Did not reach sample size based on power calculation (15 sites) • Site may have influenced risk factor analysis as there was differing use of support surfaces between facilities • Inter-rater reliability not	**Level of evidence: 4** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
					p=0.01)	established • Does not report PU classification scale used	

References

Black, J.M., J.E. Cuddigan, M.A. Walko, et al. (2010). "Medical device related pressure ulcers in hospitalized patients." International Wound Journal **7**(5):358-65.

Boesch, R.P., C. Myers, T. Garrett, et al. (2012). "Prevention of tracheostomy-related pressure ulcers in children." Pediatrics **129**(3):e792-e7.

Chidini, G., E. Calderini and P. Pelosi. (2010). "Treatment of acute hypoxemic respiratory failure with continuous positive airway pressure delivered by a new pediatric helmet in comparison with a standard full face mask: A prospective pilot study." Pediatric Critical Care Medicine **11**(4):502-8.

Forni, C., L. Loro, M. Tremosini, et al. (2011). "Use of polyurethane foam inside plaster casts to prevent the onset of heel sores in the population at risk. A controlled clinical study." Journal of Clinical Nursing **20**(5/6):675-80.

Fujii, K., J. Sugama, M. Okuwa, et al. (2010). "Incidence and risk factors of pressure ulcers in seven neonatal intensive care units in Japan: a multisite prospective cohort study." International Wound Journal **7**(5):323-8.

Günlemez, A., T. Isken, A. Gökalp, et al. (2010). "Effect of silicon gel sheeting in nasal injury associated with nasal CPAP in preterm infants." Indian Pediatrics **47**:265-7.

Huang, T.T., C.E. Tseng, T.M. Lee, et al. (2009). "Preventing pressure sores of the nasal ala after nasotracheal tube intubation: from animal model to clinical application." Journal of Oral & Maxillofacial Surgery **67**(3):543-51.

Jaryszak, E.M., R.K. Shah, J. Amling, et al. (2011). "Pediatric tracheotomy wound complications: Incidence and significance." Archives of Otolaryngology **137**(4):363-6.

Jatana, K.R., A. Oplatek, M. Stein, et al. (2010). "Effects of nasal continuous positive airway pressure and cannula use in the neonatal intensive care unit setting." Archives of Otolaryngology **136**(3):287-91.

Kuo, C., C.T. Wootten, D. Tylor, et al. (2013). "Prevention of pressure ulcers after pediatric tracheostomy using a Mepilex Ag dressing." The Laryngoscope: doi:10.1002/lary.24094.

Limpaphayom, N., D.L. Skaggs, G. McComb, et al. (2009). "Complications of halo use in children." Spine **34**(8):779-84.

Schindler, C.A., T.A. Mikhailov, E.M. Kuhn, et al. (2011). "Protecting fragile skin: nursing interventions to decrease development of pressure ulcers in pediatric intensive care. ." American Journal of Critical Care **20**(1):26-35.

Schluer, A.B., R.J. Halfens and J.G.A. Schols. (2012). " Pediatric pressure ulcer prevalence: A multicenter, cross-sectional, point prevalence study in Switzerland." Ostomy Wound Management **58**(7):18-31.

Turjanica, M.A., L. Clark, C. Martini, et al. (2011). "Incidence, Correlates, And Interventions Used For Pressure Ulcers of the Ear." Medsurg Nursing **20**(5):241-7.

Weng, M. (2008). "The effect of protective treatment in reducing pressure ulcers for non-invasive ventilation patients." Intensive & Critical Care Nursing: The Official Journal Of The British Association Of Critical Care Nurses **24**(5):295-9.

Wilbrand, J.F., M. Wilbrand, C.Y. Malik, et al. (2012). "Complications in helmet therapy." Journal of Cranio-Maxillofacial Surgery **40**(4):341-6.

Zaratkiewicz, S., J.D. Whitney, J.R. Lowe, et al. (2010). "Development and implementation of a hospital-acquired pressure ulcer incidence tracking system and algorithm." Journal For Healthcare Quality: Official Publication Of The National Association For Healthcare Quality **32**(6):44-51.

Treatment of Pressure Ulcers

CLASSIFICATION OF PRESSURE ULCERS

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
Pressure Ulcer Characteristics							
(Mizokami, Furuta et al., 2012)	Observational study **investigating the properties of sacral and foot PUs**	Participants with foot and sacral PU were recruited in Japan using undescribed methods (n=93) Exclusion crit eria: • Soft tissue infection Characteristics: • Foot PUs (n=48) • Sacrum PUs(n=45) • Mean age was 79.6 years	• No intervention	• The size of each wound, including the undermined area measured and photographed at least one a week • The wound deformity, the diameter of the wound was measured before and after applying force • Wound mobility was examined by forcing surrounding skin in an upward direction	• Sacrum PUs were more likely to exhibit mobility than foot PUs (p<0.001 for grade II, III and IV PUs) • Sacrum grade IV PUs were more likely than grade IV foot PUs to exhibit deformity, (p<0.001), there was no differences noted in grade II and III PUs • **The researchers propose that physical factors of surrounding tissues influence the characteristics of a PU shape**	• No interrater reliability • No validated method for assessing mobility and deformity • Selection criteria and participant characteristics not reported • Combined heel and ankle PUs together, but noted variation exists	**Level of evidence: N/A** **Quality: low**
(Kottner, Dassen et al., 2010)	Cross-sectional studies **investigating prevalence and characteristic of suspected DTI**	Two studies conducted in 2008 (n=6919) and 2009 (n=8451) in nursing homes and hospitals Inclusion: • voluntary participation by facility • inpatients and residents from all wards of the participating hospitals & nursing homes aged 17 years or older;	• Data collectors received training prior to data collection • Data collection occurred on a specific day during a specified week in spring 2008 & 2009 • Assessment results were documented on written data & collection forms	Trained nurses conducted full skin assessments and collected demographic data based on written data collection forms; the Braden scale was used to measure PU risk; the nurses collecting data classified PUs in 4 grades in accordance with the European Pressure Ulcer Advisory Panel	**Prevalence** • PU prevalence (including grades 1 to 4 and DTIs) ranged from 4.3% in nursing homes to 7.1% in hospitals • DTI prevalence was 0.3 to 0.5% in hospitals and 0 to 0.1% in nursing homes **Characteristics of DTIs** • DTIs are more common in hospitals than nursing homes • heels are more prone to DTI than other body sites • prevalence of DTI was related to periods of long unrelieved pressure forces (e.g. unconscious, pronged lying prior to admission, anaesthesia) • DTIs were most commonly assessed as being present for 1 to 2 weeks. • DTI prevalence in nursing homes was very low compared to previous reports e.g. VanGilder 2007, 2009 reported 3% in US health facilities) - nurses may be unfamiliar with the category	• Data may be influenced by selection & non-response bias • Those at a higher PU risk may have been underrepresented • DTI prevalence may be underestimated; samples were not truly randomized the interpretation of the prevalence estimated no formal interrater reliability conducted on DTI diagnosis	**Level of evidence: N/A** **Quality: high**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
(Nanjo, Nakagami et al., 2011)	Observational study investigating **relationship between PU shapes and qualities and etiological factors in ICU patients**	Participants were recruited in an ICU in Japan over a 3 year period (n=30) Inclusion: • aged > 19 years • no PU on admission to ICU • developed a PU after > 48 hours in ICU Exclusion: • medical device PU • use of kinetic bed • insufficient documentation	• No intervention	• Details of individual PUs were described by sketching the PU photograph and categorized to characterize the morphology of PUs • After identification of characteristics the developmental process was evaluated by in-depth review of medical records • One on one semi-structured interviews were conducted with 5 nurses who cared for patients in the study	• Morphological characteristics were divided into 4 categories: 1) location 2) shape 3) type of skin lesion and 4 periwound skin • Novel morphological characteristics included rhombic oval, PU wrinkles and outside of PU wrinkles • Possible etiologic factors for the specific PUs were divided into 4 categories: o The occurrence of PU risk episodes o Failure of the peripheral circulation o Period of critical immobility o Position change techniques inducing skin deformation	• Small ICU sample • Selection of sample is poorly reported • Positioning techniques may influence the development of PU • No interrater reliability established for assessment purposes • Confounding factors given little consideration	**Level of evidence: N/A** **Quality: low**
Classifying Pressure Ulcers using digital sources							
(Baumgarten, Margolis et al., 2009)	Diagnostic study **comparing digitized photography was compared with real time assessment as a strategy for staging PU**	Participants were selected from a medical center in the US by the wound care specialist making assessments (n=48, 1 excluded due to technical problems with photo) **Inclusion and exclusion criteria:** • Not reported **Participant characteristics:** • 28/48 had white skin, 20/48 had dark skin	• A wound care specialist assessed each PU • Photographs were taken at the same time of the PU (up close and distance) and a reference skin point on the participant	• A wound care specialist viewed the PU in real time and made a diagnosis of positive or negative for PU greater than stage II using NPUAP/EPUAP staging. • A blinded dermatologist/wound care specialist viewed paired photos of each PU and the paired reference site PUs and made a diagnosis of positive or negative for PU greater than stage II using NPUAP/EPUAP staging. • Sensitivity and specificity were calculated.	• Of 33 PUs diagnosed in real time, 32 were rated correctly from the photographs: Sensitivity: 97%, 95% CI 91 to 100% • 62 cases where there was no PU of stage II or greater present, 60 were correctly diagnosed by photo: Specificity: 97%, 95% CI 92% to 100% • In dark skin patients, sensitivity was 92% ((5% CI 75 to 100%) and specificity was 93% (95% CI was 82 to 100%) • **Study conclusions: Use of photographic images to assess the presence or absence of a PU stage II or higher has a high degree of validity.**	• Validity of the photographic assessment evaluated in relation to a standard assessment that itself may not be perfectly valid. • Only one reviewer rated the photographs (inter-rater reliability not established) • Only one assessment of photos (no intra-rater reliability established)	**Level of evidence: 3 (diagnostic)** **Quality: moderate**
(Mahoney, Rozenboom et al., 2011)	Survey **investigating nurse skills in classifying wounds via photos**	Respondents were wound care nurses invited to participate through the WOCN Society forum and email (n = 100)	• Respondents viewed 9 unique would photos (gluteal cleft or buttocks) to determine diagnosis wound etiology (pressure vs moisture vs incontinence-associated dermatitis or skin tear) • Survey delivered online	• Consensus in the classification of lesions • Consistency	• The overall *K* coefficient for 9 photos was 0.1708 (99% CI 0.1630 to 0.1786) equivalent to "slight agreement" between participants • Only 3 photos achieved agreement greater than 75% • **Study conclusion: there is a lack of consensus for intergluteal cleft and fleshy buttock wounds**	• No demographic information incl education levels, clinical experience or certification • Possible that respondents replied to survey multiple times • No accepted classification system	**Level of evidence: 4 (diagnostic)** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
			with multiple choice responses			for wounds of unclear or mixed etiology • Survey was not designed to measure respondents' accuracy in wound classification but rather to determine the level of consensus	
(Sarhan, 2010)	Retrospective review of the digital images to **determine whether image qualities are satisfactory for clinical decision making regarding PUstaging**	A sample was recruited over 12 months from a PU outpatient clinic in the US (n=50) Inclusion: spinal cord injury receiving rehabilitation aged ≥ 18 years PU diagnosed by a trained nurse and assessment documented Sample of 10 nurses assessed digital photos Inclusion and characteristics: no details provided	• Ten nurses independently assessed one image from each patient • Assessment forms used were based upon the EPUAP framework	• Assessment variables: o PU location o Stage of the PU o State of PU bed (slough, necrosis, granulation, epithelialization) o Characteristics of PU edge (maceration, edema, induration) o Surrounding skin condition (eczema, inflammations/infection) • TIME variables assessed: o Tissue o Infection or Inflammation o Moisture Imbalance o Edges non-advancing • Nurse assessment of barriers to digital photography	• Overall 83% response rate. 79% of the images were rated as being of very good quality. • The average agreement about the stage and location of the ulcers was 85% o Highest agreement was for stages 1 and 2 (100%) o Lowest agreement was for stage 4 (77%) • The overall agreement declined as the stage of the ulcer increased • The average agreement regarding the wound descriptors was: necrosis = 85%; granulation tissue = 81%; ischaemia = 83%; cellulitis/infection = 69%; erythema = 68% • **Study conclusion: nurses have high interrater agreement when staging PUs in good quality digital images, however it was not established that these assessments were in agreement with the in-person wound assessment.**	• Period of study and type of digital photography is not reported • Selection of and experience of nurses performing assessments was not reported • Unclear if digital assessment was made blinded to case notes • No comparison between digital assessment and the documented case notes/in-person assessment was made	**Level of evidence: 4 (diagnostic) Quality: low**
Interrater Reliability of Pressure Ulcer Staging							
(Bååth, Hall-Lord et al., 2008)	Cross sectional study **investigating the interrater reliability of classification assessments between and among registered and enrolled nurses**	• Rater participants were recruited from three hospitals in Sweden by unreported methods (n = 111) • Patient participants were recruited consecutively (n = 114) Inclusion of patients: • aged 65 years or over Characteristics of raters:	• All participants received training on use of assessment tools at commencement of study • Assessments of each patient were conducted by RN and EN (work pair) as part of normal care within one hour of each other. Each patient was assessed by two work pairs /day with no greater than 2 hours	• Assessment of patient skin using 5 grade system (grade 0 = intact skin) detailed on Pressure Ulcer Card that included descriptions and color illustrations.	• κ co-efficient was reported for each anatomical location (i.e. no overall reporting of interrater reliability) • Amongst the RNs (n=114 assessments) κ ranged from 0.364 to 0.637 (primarily moderate agreement) • Amongst the ENs(n=114 assessments) κ ranged from 0.322 to 0.607 (primarily moderate agreement) • Between RNs and ENs (n=228 assessments), κ ranged from 0.394 to 0.755 (primarily moderate agreement) • Agreement was greater for sacral assessments	• Does not state number of PUs in each Category/Stage, but reports primarily intact skin and grade 1 PU • Unclear recruitment of staff to make assessments • Does not report overall reliability, only by anatomical site • Unclear why agreement was higher	**Level of evidence: 4 (diagnostic) Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		• 50 registered nurses (RNs) and 61 enrolled nurses (ENs) • RNs: mean age 41.2 years, mean work experience 16.2 years • ENs: mean age 45.8 years, mean work experience 19.8 years	between work pair assessments. • Assessments were made on days 3 or 4 of patient admission		than all other anatomical sites. • Only a few pressure ulcers above grade 1 occurred in the study	for sacrum (possibly less PU at this location?) • Time frame of up to 2 hours between assessments may have altered skin conditions	
(Bergquist-Beringer, Gajewski et al., 2011)	Descriptive study with a triangulation approach **comparing direct observation with photograph assessment for staging PUs using the National Database of Nursing Quality Indicators (NDNQI) staging system**	• Participants (n=180) were teams of health professionals considered to be experienced in PU staging recruited with 31 NDNQI participating hospitals in the US. • Each team consisted of up to 10 team members Characteristics: • hospital size ranged from 100 to 500 beds • 180 raters completed study • 46.3% raters had a bachelor degree, 24.1% were certified in wound ostomy and continence, 24.7% were the hospital/skin nurse • 21% had completed the NDNQI tutorial, 66.7% had received other previous training in staging	• Each team was assessed pressure ulcers in the same bedside round • Team members were asked to inspect each pressure ulcer, stage the ulcer and record the stage on a data collection form • Team members were blinded to each other's' staging • Team members were anonymous – data analysis was on a hospital level. • Team members completed a web-based staging program within 48 hours of the bedside staging • Web program consisted of photos of PUs for a) identification as PU or other wound and b) staging • Team members were randomized to receive either: ○ a) basic web based program consisting of photos ○ b) advanced program that included photos	• Direct observation • Web-based testing with and without accompanying wound descriptions	• A total of 591 ulcers were evaluated and staged: ○ Stage I – 27.2% ○ Stage II – 43.5% ○ Stage III – 10.9% ○ Stage IV – 6.5% ○ Unstageable – 11.9% • 58.5% were on the coccyx, sacrum, buttock/ischial tuberosity or trochanter • 28.3% were on the heel **Staging reliability** • Direct observation stage I to IV PU: Average *K* coefficient 0.60 (SD 0.29) • Direct observation stage II to IV and unstageable PU: Average *K* coefficient 0.61 (SD 0.31) • Web-based photos (overall): Average *K* coefficient 0.69 (SD 0.20) • Web-based photos with accompanying short description: Average *K* coefficient 0.81 (SD 0.16) • Web-based photos without accompanying short description: Average *K* coefficient 0.59 (SD 0.18) **Hierarchical linear modeling** (controlled for participant and hospital characteristics) Direct observation: • Team led by a certified nurse had significantly higher *K* coefficient (*K* coefficient = 0.68 vs 0.57, p=0.027) • Team with a wound/skin care nurse had significantly higher *K* coefficient (*K* coefficient 0.76 vs 0.54, p = 0.003) Web-based staging: • participants who received photos PUs that	• Convenience sample • Magnet hospital overrepresentation • Variations in viewing technology for web based program • Randomization processes for web based programs not reported	**Level of evidence: 2** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
			plus short descriptions		included short narrative descriptions had significantly higher *K* coefficient values (P ≤ 0.001) than participants who received only the photos • Certification was significantly associated with higher *K* coefficient values		
Systems to Support Staging of Pressure Ulcers							
(Young, Estocado et al., 2011)	Validation of **a tool designed to assist in staging**	Participants were a convenience sample of health professionals and students (n=101) Inclusion and exclusion criteria not reported Characteristics: • primarily working in urban acute care hospital (n=58) • 53% had less than one year experience in wound care • Student participants had received training on PU pathology and staging	N.E. One Can Stage (NEOCS) tool contains descriptions from NPUAP criteria and representative photos. Clinician can take a photo of the wound and if correctly aligned, calculate wound margins, wound is staged and documentation of process is possible. The tool was renamed NE1 Wound Assessment Tool in 2012.	• Test contained 10 photos that participants were asked to stage (8 wounds were PUs and 2 were other wound types) • Participants took the test 4 times, 3 times on one day and one time 4 weeks later. • First administration they received no training or tool, 2nd test they received the NEOCS tool, 3rd test they received training on NEOCS tool, fourth time they received NEOCS without the instructions.	**Test results on test one (pre-education and tool)** Test one all clinicians: 34.7% All students: 26% **Test results on test two (with tool)** All clinicians: 63.5% All students: 52.3% **Test results on test three (after education and tool)** All clinicians: 70.7% (p < 0.005 vs test one) All students: 67% (p < 0.005 vs test one) **Test-retest reliability compared test 3 and test 4** • Intraclass coefficient (ICC) = 0.793 (95% CI 0.697 to 0.862) • Correct responses on test 3 ranged from 63% to 79.4% between different health professional classes (physios, RNs, LPNs and students) • Correct responses on test 4 ranged from 58.3% to 77.5% between different health professional classes (physios, RNs, LPNs and students) • **The researchers concluded that the tool was cost effective, reliable and valid.**	• No random selection for inclusion • Used photos rather than actual PUs • Tool was not used in the way intended (i.e. for the clinician to take a picture of the PU aligned with the measures) • Tool was not developed based on the EPUAP-NPUAP combined classification scale • Clinician perceptions of ease of use not assessed • No inter-rater reliability performed	**Level of evidence: 3 (diagnostic)** **Quality: low**
(Alvey, Hennen et al., 2012)	To investigate **the accuracy of staging when a computerized clinical decision support (CCDS) program is used**	• Convenience sample of student nurses and nurse technicians working in one medical center in US (n=31) Inclusion and exclusion criteria were not reported Characteristics: 74% aged > 40 years with >	• The CCDS program includes description information provided by a nurse with the NPUAP classification criteria to assign a PU stage • User describes location, depth characteristics and color of the PU using a drop down menu	• Participants received description and training	• Software was unable to correctly render stage II PUs, so all stage II PUs were excluded (leaving only 4 test photos) • Nurses accurately staged 64% of the time by either accepting the CCDS suggestion or over-riding the suggestion and manually staging • Nurses agreed with the CDDS only 55% of the time • All over-ride decisions were staged accurately • In the 36% of failed staging, nurses used an incorrect sequence of descriptors and were	• Did not include stage IV PUs in the trial due to potential problems assessing depth from a photo • Tool was not used in the way intended (i.e. for the clinician to take a picture of the PU aligned with the measures)	**Level of evidence: 5** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		10 years' experience 52% of RNs had a BN			given a possibility of 3 stages by the CCDS. • **Study conclusions: Further testing of CCDS is required, but it may be a useful strategy to improving PU staging**	• Tool was not developed based on the EPUAP-NPUAP combined classification scale • Participants received incentives to participate	

References

Alvey, B., N. Hennen, H. Heard. (2012). "Improving accuracy of pressure ulcer staging and documentation using a computerized clinical decision support system. ." Journal Of Wound, Ostomy, And Continence Nursing **39**(6): 607-12.

Bååth, C., M.-L. Hall-Lord, E. Idvall, K. Wiberg-Hedman, B. Wilde Larsson. (2008). "Interrater reliability using Modified Norton Scale, Pressure Ulcer Card, Short Form-Mini Nutritional Assessment by registered and enrolled nurses in clinical practice." Journal Of Clinical Nursing **17**(5): 618-26.

Baumgarten, M., D. J. Margolis, J. L. Selekof, N. Moye, P. S. Jones, M. Shardell. (2009). "Validity of pressure ulcer diagnosis using digital photography." Wound Repair and Regeneration **17**(2): 287-90.

Bergquist-Beringer, S., B. Gajewski, N. Dunton, S. Klaus. (2011). "The reliability of the National Database of Nursing Quality Indicators pressure ulcer indicator: a triangulation approach." Journal of Nursing Care Quality **26**(4): 292-301.

Kottner, J., T. Dassen, N. Lahmann. (2010). "Prevalence of deep tissue injuries in hospitals and nursing homes. Two cross-sectional studies." International Journal of Nursing Studies **47**(6): 665-70.

Mahoney, M., B. Rozenboom, D. Doughty, H. Smith. (2011). "Issues related to accurate classification of buttocks wounds." Journal of Wound, Ostomy, and Continence Nursing **38**(6): 635-42.

Mizokami, F., K. Furuta, A. Utani, Z. Isogai. (2012). "Definitions of the physical properties of pressure ulcers and characterisation of their regional variance." International Wound Journal **Epub 2012 Jul 11**.

Nanjo, Y., G. Nakagami, T. Kaitani, A. Naito, K. Takehara, J. Lijuan, et al. (2011). "Relationship between morphological characteristics and etiology of pressure ulcers in intensive care unit patients." Journal of Wound, Ostomy, and Continence Nursing **38**(4): 404-12.

Sarhan, F. (2010). "Use of digital images in the assessment and treatment of pressure ulcers in patients with spinal injuries in community settings." Journal of Telemedicine and Telecare **16**(4): 207-10.

Young, D. L., N. Estocado, M. R. Landers, J. Black. (2011). "A pilot study providing evidence for the validity of a new tool to improve assignment of national pressure ulcer advisory panel stage to pressure ulcers." Advances in Skin & Wound Care **24**(4): 168-75.

ASSESSMENT OF PRESSURE ULCERS AND MONITORING OF HEALING

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Assessment and monitoring of PUs							
(Andersen and Karlsmark 2008)	Non-experimental observation study evaluating **four non-invasive techniques of wound assessment**	Participants were recruited at a wound center in Denmark (n=11 with n=15 PUs) **Inclusion criteria:** • aged ≥ 18 years • ≤ 10 mg corticosteroid daily **Exclusion criteria:** • Pregnancy, breastfeeding	• A nurse with extensive experience with PUs staged and photographed all PUs. • Wound treatments followed the guidelines for the Copenhagen Wound Healing Center. • Assessment of various wound characteristics at o location of ulceration o 5cm distance from ulcer o reference point on symmetrical body location **Redness** • handheld Derma Spectrometer measuring erythema at 3 points **Temperature** • skin temperature measured using DermaTemp **Ultrasound** • 20MHz B-mode scanner • Cross sectional images **Elasticity** • Dermalab USB	Four non-invasive techniques were used to measure: redness index; skin temperature; skin elasticity and ultrasound scanning.	• Redness index was higher at the PU site than at the reference skin • Temperature measurements showed wide variation • Ultrasound scans showed a hypo-echogenic sub epidermal layer at all PUs • No correlation was found between the stage of the PU and the temperature, redness index, sup epidermal layer thickness or retraction time. • Confounding factors included age, position and presence of general edema. • Study conclusion: Ultrasound is the most promising assessment strategy to characterize PUs, however confounding factors suggest that comparisons be made to reference site on the patient rather than to other patients/PUs • **Overall conclusion: The study is does not clarify the benefits of these technologies.**	• Small sample size • Patient characteristics not reported, including age and comorbidity • No reporting of influence of comorbidity on findings • Large variation in results limits clinical application • Closed and open PU results were combined. Unclear if infection ruled out for these patients.	**Level of evidence: 5** **Quality: low**
(Davis, Nishimura et al. 2013)	Observational study investigating **reliability and validity of 3D wound imaging for monitoring wound progress**	Participants were recruited from an SCI unit in US (n = 10 with n = 13 PUs) Inclusion: • aged ≥ 18 years • chronic PU (not defined) • not scheduled for surgery for wound closure Characteristics: • primarily pelvic region PUs	• Wounds were assessed by 2 wound experts and 2 RNs on a weekly basis • All observers received training in the use of the 3D photography equipment	• Two observers independently assessed each PU weekly for 6 weeks using 3D photography, standard wound measurement and a 3 point scale (improving, no change, deteriorating) for wound characteristics • Observers rated the acceptability of the 3D equipment on a 17 item questionnaire	• Expert wound assessors attained 3D images at 83% of assessment times and 89% were readable Non-expert observers attained images on 69% of assessments and 81% were readable. • No significant difference between expert and non expert for any readings • 3D imaging differentiated between improving and static wounds (all $p<0.05$) for wound perimeter, wound volume, minimum depth, maximum depth and length. • No significant difference between linear measurements and 3D measurements for width and surface area (both $p<0.01$) • **Study conclusions: 3D photography provides a reliable estimate of wound progress and is acceptable to observers,**	• There was low concordance between readable images for each time point for direct comparison. • Small sample size • No validation of true wound measurement • Only chronic PUs (not defined)	**Level of evidence: N/A** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					but attainment of a useable image is important and achieved in only about half the assessments.		
(Grubbs, Ludwig et al. 2009)	Randomized study comparing **a physical examination to high frequency ultrasound for early identification of stage I PU**	Participants at high risk of PU were recruited from a long-term facility (n=27) Inclusion: • Braden score ≤16 Exclusion: • study refusal Characteristics: • Mean age 43 years (range 39 to 99 years)	• All participants were repositioned every 2 hours while in bed or 30 mins while seated, mobilization promoted. • All participants positioned with head of bed at 30º angle • All participants had heel, elbow protectors and repositioning devices • All participants received skin care, including emollients. • Participants were randomized to receive either: o Chart review at beginning and end of study (control group, n=6); or o History, physical exam and care recommendations conducted by students weekly (student intervention group) o Heel and sacrum scanned each week with high frequency ultrasound (ultrasound group) o Clinical exam and high frequency ultrasounds weekly (Student and ultrasound group)	PU incidence	• There was no statistical significance for the interaction of student examination and ultrasound (p=0.142) • There was no statistical significant difference between the three study groups in the treatment modalities of the patients (p=0.551) • 18% (n=2) of the ultrasound only group experienced category 1 PU and 9% (n=1) experienced category II PU • 1 patient in the student only group developed a new onset stage II heel • **Conclusions: This study failed to show that using high frequency ultrasound in addition to physical assessment and conducting Braden scores is more effective in preventing development or progression of PUs of heel and sacrum.**	• Does not report randomization methods or allocation concealment • No blinding • Small sample size • Unclear how many patients in each group (19 were exposed to ultrasound intervention) • Poor reporting of participant characteristics.	**Level of evidence: 2 Quality: moderate**
(Edsberg, Wyffels et al. 2012)	Longitudinal, observational repeated measures study **investigating protein as a biomarker for wound healing**	Participants were recruited from a long term care facility (n=32 with 42 PUs) They are a sub-set of an initial selection of participants. **Exclusion criteria:** • Current treatment with negative pressure wound therapy, enzymatic debridement, topical growth factors, protein dressing.	• Study participants were seen every day for 10 days then weekly until study end (day 42 day) • At each visit wounds digitally photographed and analyzed • Participants were categorized as healed (decrease in area of 81 to 100%), moderately healed (decrease in wound area of 40 to 80%) or delayed healing (wound area decrease < 40%) • Wound fluid protein concentrations measured using	• Wound size • Wound protein concentration • Antibody screening assays • Isobaric tags for relative and absolute quantitation with mass spectrometry and multiplexed microassays were used to characterize wound fluid • Evaluation occurred over 6 weeks	• There was significant difference (all p<0.00) between healed and chronic wounds in 21 proteins • 19 proteins were differentially expressed between the interior and periphery of the wounds • Pyruvate kinase isozymes M1/M2, profilm – 1, Ig lambda – 1 chain C regions and Ig gamma-1 chain C region) were present in lower levels for periphery samples • al 6A, keratin, type I cytoskeletal 14, S100 calcium binding proteins A7, alpha – 1 – antitrypsin precursor, hemoglobin subunit alpha and hemoglobin subunit beta were	• Sample selection is not reported • Confounding factors is not reported	**Level of evidence: 4 (prognostic) Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Participant characteristics: • 69% of participants were female • Mean age was 72.8 years • 54.8% had diabetes, 54.8% had hypertension and 28.6% had coronary artery disease • 29% stage II PU, 24% stage III PU and 48% stage IV PU	standard technique		present in higher levels in periphery samples • **Study conclusions: a full understanding of the best position within the wound to measure protein levels is essential for use of protein as a marker of healing**		
(Edsberg, Wyffels et al. 2011)	Longitudinal, observational repeated measures study **investigating strategies to predict wound healing**	Participants were recruited in a long term care facility in US (n = 27 with 31 PUs) **Inclusion criteria:** • PU for a minimum of 4 weeks **Exclusion criteria:** • Current treatment with negative pressure wound therapy, enzymatic debridement, topical growth factors, protein dressing. **Participant characteristics:** • 74% of PUs were stage III and 24% were stage IV at commencement • 48.4% participants had diabetes, 58.1% hypertension, 22.6% coronary artery disease • Average area ranged from 0.62 to 24.54 cm^2	• Wound length, width and perimeter were measured at 15 time points or until healing • Study participants were seen every day for 10 days then weekly until study end (day 42 day) • At each visit wounds were digitally photographed and analyzed using stereophotogrammetry • Participants were categorized as healed (decrease in area of 81 to 100%), moderately healed (decrease in wound area of 40 to 80%) or delayed healing (wound area decrease < 40%)	• The following healing parameters were calculated: ○ Absolute area (cm^2) ○ Percent area reduction ○ Mean percent area reduction ○ Trajectory (change in area compared to baseline) ○ Three variations of the linear healing parameter (baseline, weekly and mean adjusted) • Duration of the study was 6 weeks	• 8 participants withdrew during the study • Two subjects achieved total closure before 42 days • 10 PUs healed, 5 moderately healed and 16 delayed healing. • Ulcer size at day 0 was a significant predictor of time to heal (p =0.0231) with smaller wound taking less time to heal • Initial size did not influence wound outcome (p= 0.3537) • Average daily healing was positively correlated with initial wound size (p<0.000) • Among ulcers classified as healed, the initial linear healing rate (4 weeks) was 0.16 ± 0.02 cm/week • Change in wound size after 4 weeks is a predictor of healing stage III and stage IV PUs • **Study conclusion: Percent area measurements are easiest to determine but sensitive to initial wound size. Linear healing rate is a reliable indication of healing. A 4-week response time with regular recording of validated wound measurement achieves a reliable indication of response to care.**	• Not all ulcers included in the temporal evaluation of wound healing parameters because of small initial wound size and study participant discontinuation • Small sample size, underpowered for analysis • Measurement was at a PU level, participant factors may influence healing • Small number of PUs reached 100% closure due to timeframe of study	**Level of evidence: 4 (prognostic) Quality: moderate**
Predictors of PU prognosis							
(Aoi, Yoshimura et	Descriptive diagnostic	Participants were recruited at a hospital in Tokyo. From	Intermediate frequency (10-MHz) ultrasound was performed to	• Patients were checked periodically (almost	• The stage of ulcer worsened in 6 of 12 cases and healed in the remaining 6.	• Small sample size, method of selection is	**Level of evidence: 4**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
al. 2009)	study to **examine the use of ultrasound to predict progression of PUs**	242 patients who were identified with PU, ultrasound was performed on 144 to detect DTI. 63 patients were followed until the PU reached final stage. Participants were selected from this group (n=12) **Inclusion and exclusion criteria:** • Not reported **Patient characteristics:** • 9/12 males • age range from 16 years to 92 years • 6 patients had a healed PU and 6 had a stage IV PU at final examination	evaluate deep tissue injury.	weekly) and the grade of PU was evaluated with visual inspection according to the NPUAP classification. • Ultrasound images were read and evaluated by 3 persons (1 non-blinded and 2 blinded). • Patients were followed until the pressure ulcer reached the final stage.	• **Unclear layer structure on ultrasound** positive predictive value for PU progression (PPV) 50%, specificity for PU progression 0%, sensitivity for PU progression 100% • **Hypoechoic lesion on ultrasound** PPV 40%, specificity 0%, sensitivity 66.7% • **Discontinued fascia on ultrasound** PPV 85.7%, specificity 83.3%, sensitivity 100% • **Heterogeneous hypoechoic area on ultrasound** PPV 100%, specificity 100%, sensitivity 83.3% • **Study conclusion: Discontinued fascia and heterogeneous hypoechoic area on ultrasound appear to be reliable predictors of future progression of PUs**	not reported. • Potential confounding factors (e.g. age, comorbidity, hydration) are not reported.	**(prognostic) Quality: low**
(Higashino, Nakagami et al. 2012)	Retrospective record review to **examine early stage PU features that may indicate presence of deep tissue injury**	Participants in a Japanese university hospital selected for record reviews (n=21 with 28 PUs) Inclusion: • received PU team interventions within an 11 month record review period Characteristics: • Average age 66.4 years (range 20 years to 98 years) • 14.3% stage I PU; 85.7% stage II PU • 50% sacral, 32.1% greater trochanter, 7.1% coccyx, 7.1% iliac crest, 3.6% back	• All participants received pressure relieving mattress and regular repositioning • PUs were assessed after dressing removals	• Thermographic imaging using infrared thermography that compared wound temperature, categorizing as low, equal or high versus surrounding skin. • Ultrasound 10mHz was performed • Japanese PU staging system	• From 28 PUs, 2 were diagnosed as having deep tissue injury (category II or IV PUs) • 13 PUs with lower temperature than surrounding skin. Of these, 3 had unclear layer structure and 2 had hypoechoic lesion on ultrasound. 0 progressed to deep tissue injury • 3 PUs had temperature equivalent to surrounding skin. Of these, 1 had unclear layer structure and 0 progressed to deep tissue injury. • 12 had wound temperature higher than surrounding skin. Of these, 6 had unclear layer structure, 2 had heterogeneous hypoechoic area and 1 had discontinued fascia. 2 progressed to deep tissue injury. • Deep tissue injury cases both had high wound temperature and heterogeneous hypoechoic area • **Study conclusion: thermographic detection of high PU temperature and ultrasound detection of heterogeneous hypoechoic area were features of early PUs that progressed to deep tissue injury.**	• Small sample size • No statistical analysis • Unclear when and how often assessments were conducted • Unclear who performed assessments and their experience/ reliability with ultrasound reading	**Level of evidence: 4 (prognostic) Quality: low**
(Nakagami, Sanada et al.	Prospective cohort study	participants were recruited in a hospital in Japan (n = 35,	• All patients underwent thermographic assessment	• PUs were classified depending on whether	• 21 PUs classified as having a low temperature wound and 14 PUs	• Small sample size • Short follow up	**Level of evidence: 2**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
2010)	**investigating thermography to predict PU healing**	2 excluded, final n =33) Inclusion: • Stage II to IV trunk PU Exclusion: • severe medical conditions (e.g. terminal condition, circulatory shock) • PU on extremity • PU with black eschar • Infection at baseline Characteristics: • Mean age 65 to 68 years, no significant difference between high and low temp wound groups • No significant difference in DESIGN-R score between high and low temperature wounds at baseline • No significant difference in wound size at baseline	on discovery of their PU • Thermography was performed immediately after dressing removal • Intrarater (0.93) and interrater reliability (0.94) for temperature scaning was high	or not the wound site temperature was lower or higher than the periwound skin • Wound surface area measured weekly via planimetry and wound reduction rate calculated using standard formula • Wound severity classified using DESIGN-R performed blinded to the thermography assessment • Follow-up was at least 3 weeks • PUs classified as healing if 30% or greater reduction in wound surface area after 3 weeks.	classified as having a high temperature wound. Two PUs excluded due to infection at baseline. • 22 PUs healed normally (wound area reduced by 30% or more within 3 weeks) • 16 did not heal • Relative risk for delayed healing in high temperature cases was 2.25 (95% CI; 1.13 to 4.47, p = 0.021) • Sensitivity was 0.56; specificity was 0.82; positive predictive value was 0.75 and negative predictive value was 0.67 • **Study conclusion: Thermography to classify PUs according to temperature could be a useful predictor of healing at 3 weeks – the higher temperature in the wound site may imply the presence of critical colonization or other factors which disturb the wound healing**	period	**(prognostic) Quality: moderate**
(Yabunaka, Iizaka et al. 2009)	Retrospective case series describing **ultrasound findings for trochanter Pus of various stages**	Participants were consecutive cases identified in the database records for a hospital in Japan (n=11) Inclusion: • trochanter PU • assessed using ultrasound	• Retrospective analysis of records.	• Wounds were classified using DESIGN (5 different stages of PU) • Ultrasound examination was made of the PU region and the contralateral region.	• Comparison of normal versus contralateral PU side showed presence edema in subcutaneous fat, PU has an unclear layer structure, compared to absence of edema and a clear layer structure (n = 3) • Comparison of PU at stage I and stage II, both over time showed initial edema and unclear layer structure that reduced and became clearer as the PU healed (n =2) • Superficial vs full thickness PU comparison showed heterogeneous hypoecholic lesions in subcutaneous fat in full thickness PU. Edema was identified on all PUs **Study conclusions: difference in ultrasound presentation could be used as a prognostic tool**	• Unclear who performed assessments and their experience/ reliability with ultrasound reading • Small sample size • Descriptive findings, this study does not use the findings to as a diagnostic or prognostic tool	**Level of evidence: N/A (descriptive) Quality: moderate**
(Nakagami, Sanada et al. 2011)	Retrospective record review investigating **the reliability of ultrasound combined**	Participants were recruited from a Japanese hospital (n=37) Inclusion: • Treatment during record	• PU severity assessed using DESIGH-R (a 7-item scale including depth, exudate, size, inflammation/infection, granulation and necrosis) which has a score of 0 to 66 (higher	• Wounds were classified as healing if wound area reduction was >20% • Wound bed temperature equal to or greater than surrounding skin indicated	• 13 PUs totally healed, 11 were in the process of healing and 13 showed deterioration/delayed healing **Ultrasound** • Comparison of healing outcome with positive/negative findings on ultrasound	• Unclear who performed assessments and their experience/ reliability with ultrasound reading	**Level of evidence: 4 (prognostic) Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	with thermography to predict prognosis of PUs	review period of 51 months • Stage I or II PU on the trunk • treated for at least 3 weeks or until PU healed Exclusion: • Severe medical condition • Terminal condition • PU located on extremity Participant characteristics: • mean age 67.3±12.4 years (range 20 to 98 years) • 54.1% males • 10 participants had stage I PU, 27 had stage II PU	score is more severe). • Wound reduction rate as a % was calculated (baseline area – area week 2)/baseline area x 100 • Ultrasound performed • Thermographic images of wound bed and surrounding skin	a temperature increase in the wound bed	showed only unclear layer structure had a potential to predict PU prognosis: ○ hypoechoic lesion p= p=0.716 ○ unclear layer structure p =0.072 ○ heterogeneous hypoechoic area = p=1.0 ○ discontinued fascia p =1.0 **Thermography** • Comparison of healing outcome with positive/negative findings on of increased wound bed temperature was not significant p=0.109 **Combined ultrasound and thermography** • Positive ultrasound together with increased wound temperature were significant predictors of delayed healing (OR 6.85, 95% CI 1.11 to 42.13, p=0.038, sensitivity 0.69, specificity 0.71, positive predictive value 0.56, negative predictive value 0.81) • **Study conclusion: thermographic detection of high PU temperature and positive findings on ultrasound can be considered together as a predictor of early PUs that are likely to progress to deep tissue injury.**	• Short follow up duration of 2 weeks • Small sample size	
(Wyffels and Edsberg 2011)	Observational study investigating **the relationship between amount of granulation tissue and PU prognosis**	A sample was recruited from long term inpatient facilities in the US (n=47 participants with n=31 PU) Inclusion: PU present at least 4 weeks Exclusion: • negative pressure wound therapy, enzymatic debridement, topical growth factors, protein dressings Characteristics: • 45% PUs were stage IV, 23% were stage III and 32% were stage II • Average age 72.3 years	• Study participants were seen on days 0, 1, 2, 3, 4, 7, 8, 9, 10, 11, 14, 21, 28, 35 and 42; • Wounds were digitally photographed with a 3 cm^2 calibration target; • Images were analyzed using Vev MD and Adobe Photoshop CS3 Extended • Granulation tissue type was selected by either manual or automated selection using the imaging software	• Change in wound size calculated as percentage of day 0 area • Classification as: ○ healed (decrease of 81 to 100% area) ○ moderate healing (decrease 40 to 80%) ○ delayed healing/chronic (less than 40%) • Tissue type analysis (only PU with 14 days or more data) • Granulation tissue expressed as a percent of wound area	• There was no relationship between the amount of granulation tissue expressed as a percentage of the total PU area and wound outcome • There was no relationship between temporal trends of the percentage of granulation tissue present in a wound and it's outcome • Healed wounds (n=10) closed an average 94.6% of their day 0 area and moderately healing wounds (n=5) closed 51.2% of their day 0 area • Chronic wound (n= 6) area changes ranged from a 37% decrease to 362% increase as compared with day 0 with an average of 41.25% • Automatic classification of granulation tissue was incorrectly assigned for 5%±10% of the manually selected tissue • **Study conclusions: automated selection of granulation tissue in digital images is an acceptable strategy. There was no**	• Only 10 PU healed, so analysis of relationship of granulation tissue to healing is based on a very small sample • Classification of granulation tissue in digital images has not been validated • Manual selection of granulation tissue in images was tedious and not practical for clinical use • Limited to chronic PU which do not show normal wound healing stages • Since stage II PUs are partial thickness loss of dermis, it is not supposed to have	**Level of evidence: 2 (prognostic) Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					correlation between change in granulation tissue and healing prognosis in chronic PU; however, the study was not sufficiently large to measure a relationship.	granulation tissue.	
Digital assessments and telehealth (e.g. digital photography)							
(Terris, Woo et al. 2011)	Observational study **determining reliability of digital photography**	Participants were recruited from an inpatient SCI center in the US (n=15 participants with n=31 PUs) Inclusion: • PU stage III or IV in pelvic region or lower limb • Able to be motionless for photography Participant characteristics: • Mean age 65.5±8.5 years • All male participants • Wide range of anatomical locations for PUs	• One nurse did all in-person assessments and another did all digital assessments. With a third taking digital photos. • A descriptive text of PUs accompanied all the photos • Assessment and photos done after dressing removal and cleansing, with removed dressing placed next to PU in photo and a 14cm ruler placed adjacent • All in person assessments occurred within 24 hours of photography	A standard wound assessment form was used for clinical evaluation contained 39 wound descriptions including: • length, width and depth • wound drainage (6-point scale) • exudate type and color (8 categories) • wound bed (11 categories) • periwound tissue(11 categories) • Random sample of 10 wounds repeated for intra-rater reliability	**Interrater comparison (inperson:digital n=31)** • Interrater agreement was observed for 50% of the wound description categories • No significant agreement for length and width • Characteristics with moderate or better agreement(κ >0.5) were: o Exudate type: green κ=0.635, p<0.001 o Wound bed description: eschar κ=0.763, p<0.001) o Wound bed description: undermining κ=0.853, p<0.001 o Wound bed description: other κ=0.652, p<0.001 **Intrarater (same nurse using both methods n=10)** • Characteristics with moderate or better agreement(κ>0.5) were: o Exudate type: Seroanguinous κ=0.898 (p<0.001) o Wound bed description: yellow tissue and slough κ=0.519, p=0.004 o Wound bed description: Brown tissue with slough κ=0.773, p=0.001 o Wound bed description: undermining κ=0.571, p=0.005 o Periwound tissue color: within normal limits κ=0.634, p=0.001 **Intramethod (different nurses using same methods)** • Only 38.5% evaluated description categories had any correlation • **Study conclusions: There is difference in subjective assessments of wound characteristics both in-person and in digital assessments, and thus the use of digital assessment is an acceptable but labor intensive strategy.**	• Small sample size, some analysis used on 10 assessments for 39 wound characteristics • potential that nurse performing digital assessment had real-life exposure to the wound • Assessment of depth not possible via digital photography • Only included stage II and IV PUs	**Level of evidence: 3 (diagnostic) Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(Bhedi, Saxena et al. 2013)	Observational study to determine **correlation between digital photography and other wound size measurement strategies**	• Sample was recruited from a surgical wound in India (n=40) Inclusion criteria: • Clean or infected wounds following trauma, debridement, PU, VLUS, surgical abscess drainage wounds.	• Wounds were measured using three methods simultaneously on alternate days commencing on day wound started. • Measurements were taken on days 1,3,5,7,9.	• Transparency method: Wound traced onto a transparency film using a permanent marker and surface area calculated using square centimeter planimetry • Photographic method: digital camera used at 1.5ft from wound exactly 90° above center of wound with a 16x zoom. Images transferred using a frame grabber and the wound margin was delineated using the mouse and surface area calculated automatically using AutoCAD 2004 software. • Linear method: maximum length and width of wound using measure tape, with surface area determined by multiplying length and width	• The introduction highlights problems with wound volume assessment by any volumetric measure as including: (expert opinion) ○ subjective judgment on wound boundary ○ wound flexibility due to slight movements make give rise to changes in appearance ○ natural curvature of body makes surface area difficult to assess ○ extensive undermining may change based on patient positioning ○ wounds in areas with thick soft tissue may maintain a cavity appearance • There was no significant difference between mean transparency method versus photographic method for any of the five measurements. (p=0.32 to 0.59) • The difference between linear method and photographic method was significant on each of the five measurement days (p=0.0004 to p=0.005) On day 1: mean transparency was 51.78cm^2 and mean photography was 83.02cm^2 (p=0.0004) Differences were similar for the other • The difference between linear method and transparency method was significant on each of the five measurement days (p=0.0004 to p=0.001). On day 1: mean transparency was 47.40cm^2 and mean photography was 83.02cm^2 (p=0.001) **Study conclusions: no significant difference between measurement of wound size using photographic or the transparency methods. The linear method gives significantly different (larger) wound surface area results compared with both other methods.**	• Small sample, unclear if wound assessment was conducted by blinded assessors • Unclear who completed the assessments and if it was the same person each time • It is possible that findings for a small number of wounds may have influenced the overall mean, thereby overestimating the significance of findings.	**Indirect evidence (mixed etiology) Quality: moderate**
(Iizaka, Kaitani et al. 2013)	Observational study reporting the **use of granulation tissue color on digitized images as a predictor of**	Participants were recruited from 24 different facilities in Japan (n=91, n =64 completed study). The participants were involved in both arms of a treatment RCT. Exclusion:	• Photographs were digitally calibrated to determine a granulation red index (GRI) – a measure of the redness of granulation tissue	• Participants were assessed weekly for 3 weeks using the DESIGN tool • Wounds were photographed weekly with a commercially available color chart with nine calibrated colors placed	• PUs at the extremity had significantly lower GRI values	• Large drop out (> 25%) • No validation of GRI against vascular perfusion or tissue oxygenation • Interater reliability in this study was not	**Indirect evidence Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	wound healing	• PU completely covered with necrotic tissue • Bleeding or tunnelling making assessment difficult • poor quality photo Characteristics: • Mean age 77.6±15.7 years • 64.8% were in a community hospital • 28.6% had cerebrovascular disease, 40.7% had infection, 18.7% had diabetes • Mean Braden score 11.8±3.0		beside the wound		established • Some wounds were subjected to debridement, vibration therapy that promoted skin perfusion. This may influence tissue color • GRI varies by wound location	
(Iizaka, Sugama et al. 2011)	Cross-sectional study investigating assessment of **granulation tissue using digital photography**	Sample recruited over a 3 yearS from 10 institutions in Japan (n=47 with 55 PUs) Inclusion: • aged > 60 years • > one full-thickness PU Exclusion: • PU with necrotic tissue, bleeding or difficult to evaluate due to tunneling Characteristics: • 63% sample female • Mean BMI 18.4±3.7 • Mean hemoglobin 9.8±1.9g/dL • 23.4% diabetes	• All PUs photographed by one of two researchers using a digital camera and with the reference color chart (9 colors) adjacent to PU	• Clinical red color in granulation was measured by a tristimulus colorimetric instrument and reported as a granulation red index (GRI) and image analysis color (a*) and calibrated image analysis color (â*). • Healthy granulation tissue was evaluated by visual assessment using the subscale of the DESIGN tool • Hydroxyproline (OHP) level in wound fluid measured as a marker for collagen content of the wound • Hemaglobin levels	• 52.4% of the PUs were classified as D4 on the DESIGN tool indicating depth into muscle tissue. • Primarily sacral PU (58%) • The were no significant differences between GRI and â* for sacral PUs (p=0.78) and for other PU sites (p=0.925) • a* was significantly correlated with the GRI (p=0.007) and with â*(p<0.001) • There was strong intra (ICC=0.97) and interrater reliability (ICC=0.93) for measuring GRI and â*. • **Study conclusions: study suggests a correlation between different digital measures of wound redness, but did not indicate how this correlates with non-digital visual assessment, wound condition or wound progress. Indirect evidence on wound assessment.**	• Only evaluated the concurrent validity for color indicators by image analysis but did not evaluate the predictive validity for PU healing • Recruited only older patients • The feasibility of implementing the methods in realistic clinical setting is uncertain	**Indirect evidence Quality: low**
(Hill, Cronkite et al. 2009)	Observational study determining **the reliability of telephone and video wound assessment**	Patient participants were recruited from a spinal cord injury (SCI) treatment center in the US (n= 42 with n = 67 PUs) Assessors were physical therapists (n=3) Exclusion: Primary physician would not	• All participants were assessed in a home-like environment • Pilot study to assess interrater reliability found kappa ≥ 0.80 could not be achieved between the three assessors and a SCI clinician despite additional training. • Assessors were randomized to perform one of three	Skin was assessed using a 0 to 4 staging scale from AHCPR where 0 = no PU and 4 = stage IV PU. Other aspects (tunnelling, pain, erythema, types of exudate etc) were assessed as present, absent, cannot assess or N/A	Telephone consultation • There was moderate correlation (κ=0.47) for PU stage between telephone and in person assessment. • Correlation was poor for assessment of exudate eschar and surrounding tissue (κ<0.20); good for assessment of pain (κ=0.70); moderate for assessment of sinus tract (κ=0.48). Video consultation	• The three assessors could not achieve a very good correlation in their in person assessments in the pilot study despite training • Only three assessors used, no intrarater reliability assessment	**Level of evidence: 3 (diagnostic) Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		approve travel to study site Patient participant characteristics Mean age 58 years 95% sample male 77% sample white skin 62% paraplegia 74% facility inpatient	assessments on each patient • Assessment via: • In person evaluation • Telephone consultation • Low bandwidth video conference • Measuring guide was placed beside wound for the video consult		• There was moderate correlation (κ=0.54) for PU stage between video conference and in person assessment. • Correlation ranged from poor to moderate for assessment of different exudate types (κ=0.20 to 0.56); fair for eschar (κ=0.32); and fair for surrounding tissue (κ<0.42); good for assessment of pain (κ=0.75); good for assessment of sinus tract (κ=0.61). • Wound sizes and volumes tended to be measured as larger in telephone and video consultation than in person assessments. • **Study conclusions: Correlation for assessment of presence of a PU was lower in video and telephone assessments than an in person assessment.**	• Research assistant told assessors the area of skin they should assess • Insufficient stage I PUs in study to assess reliability in their identification	
(Sprigle, Nemeth et al. 2011)	Observational study **reporting reliability of a digital photography wound assessment strategy**	n=19 PU images Characteristics: • training and experience of assessors is not reported	• Wound Measurement Device consisted of a protype platform on a smartphone that used a digital camera and a software interface (WoundSuite) • Photos were taken at a range of distances and skew angles (7 heights and 3 skew per PU) • Each clinician traced the wound boundaries of 19 PUs using a touch screen stylus • Clinicians took digital photos and then measured the wound using a ruler based method.	• Accuracy • Clinical utility • The reliability of area measurements was determined using multiple evaluators who manually circumscribed a cohort of wound images	• At a skew 0°, the average error between the calculated and known area for the square and oval shapes was 1.90% (error range 0.4% to 3.55%) • At a 5° skew the average error was 1.76% (range -0.4% to 4.6%) • With a 10° skew angle the average error was 4.28% (range f2.14% to 5.62%) • The intrarater reliability for wound tracing was 0.975 • The interrater reliability for wound tracing was 0.966 for one trial and 0.978 for other trial • **Study conclusions: digital photography accuracy varies depending upon angle skew.**	• Ruler based method is not reported in detail • Assessor training and experience is not reported • Rater reliability for manual method is not reported	**Level of evidence: N/A** **Quality: low**
Assessing exudate							
(Iizaka, Sanada et al. 2011)	Cross sectional study **aiming to develop an equation to estimate wound exudate volume**	Participants were recruited over a 2.5 year period from 10 hospitals and nursing homes in Japan (n=41 with 58 PUs) Inclusion: • aged ≥ 60 years • at least one full thickness PU	• Exudate was collected by covering each wound with a transparent occlusive dressing • Exudate retained within the film was withdrawn a number of hours later (mean 2.5 hrs) using a pipette • Accumulated volume was used to estimate volume per day	• DESIGN-R wound assessment scale: ○ Depth (score 0-6) ○ Exudate (score 0-6) ○ Size (score 0-15) ○ Inflammation/infection (score 0-9) ○ Ganulation (score 0-6) ○ Necrosis (score0-6) ○ Pocketing (score 0-24)	• Mean wound exudate was 6.0±10.3ml/day (range 0.0 – 47.0 ml/day) • Mean PU surface area 25.9±17.8cm^2 • Mean depth 1.0±0.8cm • Mean wound volume 12.1±17.4cm^3 • Mean total DESIGN –R score 25.9±27.0 **Univariate analysis** • The following factors were significantly associated with wound volume: ○ age r = –0.30. p=0.057 (negative	• Small sample size • Limited number of outliers • Multicollinearity may have influenced the accuracy of each estimated coefficient • Other properties of exudate may influence the absorbency of	**Level of evidence: N/A** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Exclusion: • negative pressure wound therapy Participant characteristics: • mean age 80.8±9.3 years • Mean Charlson comorbidity score 3.4±2.6		• DESIGN-R conducted by 2 specialist wound researchers. • Wound tracings and planimetry • Wound depth using cotton swab	correlation) ○ DESIGN-R total score r=0.73, p<0.001 ○ DESIGN-R depth score r=0.28, p=0.036 ○ DESIGN-R exudate score r=0.76, p<0.001 ○ DESIGN-R size score r=0.60, p<0.001 ○ DESIGN-R inflammation score r=0.37, p=0.004 ○ DESIGN-R pocketing scorer=0.62, p<0.001 ○ Wound surface area r=0.49, p=0.002 ○ Wound depth r=0.59, p<0.001 ○ Wound volume r=0.64, p<0.001 • DESIGN-R granulation score and necrotic score, blood nitrogen ura/creatinine, haemoglobin, serum C-reactive protein, serum albumin were all not significantly related to exudate volume **Exudate equation** • A model with continuous parameters was developed: exudate volume per day (ml/day) = exp ([0.86 x exudate score] + [0.21 x size score] + [0.12 x total score] – [0.013 x size score x total score] – [0.04 x age] – 3.60) • R^2 =0.77 for equation suggesting approx. 20% error • **Study conclusion: elements of the DESIGN-R tool can be used within an equation to more accurately estimate wound exudate**	dressings • Only one measure was taken for wound exudate for each participant • Use of a transparent film dressing may influence the volume of exudate collected • Different time frames used for exudate collection • In a clinical setting, the type of dressing used may influence exudate score • Timely and practical use of scale in clinical practice is questionable	
Assessing erythema							
(Kottner, Dassen et al. 2009)	Quasi experimental **comparing a transparent disc to a finger method for assessing erythema (stage I PU)**	The study was conducted as part of an annual prevalence survey in 39 hospitals and 29 nursing homes in Germany (n=9752) (intervention = 4657; control = 5095) Characteristics: • 76.6% were hospital patients (p<0.001 between groups,	• prior to data collection all participating nurses were trained • For all facilities, skin examinations were conducted by a team of 2 nurses – both nurses had to agree on the presence or absence of a PU • Facilities were randomly assigned to either: ○ Application of a transparent disc to reddened skin so assessment of blanching could	• Skin assessment conducted by two nurses simultaneously • grade I PU point prevalence • Braden score	• grade I PU prevalence was significantly higher in the control group versus the intervention group (7.1% versus 3.9%, p<0.001) • OR of having a PU identified via the disc method versus finger method was 1.80 (95% CI 1.49 to 2.18, p<0.001) i.e. chance of identifying a grade 1 PU increased by 80% when the finger method was used. • **Study conclusion: more grade I PUs are identified using the finger method; however, it is unclear why this is the case**	• study design was inappropriate for exploring the reasons why grade 1 PU prevalence was much higher when the finger method was applied • assumed the two comparison groups were identical • potential selection	**Level of evidence: 5 (diagnostic) Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		significantly more in control group) • Mean age approx. 68 years • Mean BMI approx. 25	be made at the same time as pressure was applied (n=4657) ○ Skin inspection using the finger method of depressing skin to assess blanching (n=5095)		**or if this accurately reflects PU prevalence.**	bias • no intention to treat analysis • potential for attrition • no interrater reliability	
Factors influencing healing							
(Bergstrom, Smout et al. 2008)	Retrospective cohort study investigating **patient characteristics that influence with wound healing**	Nursing homes in the US (n=102 facilities, n=774 residents) **Inclusion criteria:** • Admission of ≥14 days • stage 2 PU either facility acquired or prior to admission **Participant characteristics:** • 65% sample female • Mean age 79 years • 38.6% required assistance with ≥ 7 ADLs • Mean 1.6 PUs per resident	• Medical records and other written records were reviewed retrospectively • Reliability of data collection through inter-rater comparison	• Resident characteristics • PU characteristics • Records reviewed for 4 weeks prior to PU identification until 8 weeks following identification (total 12 weeks) • Follow up ranged from 14 to 96 days	• 563 (45.4%) healed • Median time to heal was 46 days • There was a significant difference in healing rates between facilities **Factors significantly associated with faster healing (n=1,241 PUs)** • Smaller PU size (p<0.001) • BMI in normal range (p=0.03) • Resident experiences agitation (p<0.001, OR=1.64) • Resident experiences eating problem (p<0.001, OR=1.7695% CI 1.36 to 2.27) • Larger initial PU **Factors significantly associated with slower healing(n=1,241 PUs)** • Transferred from facility temporarily (p<0.001, OR=0.26, 95% CI 0.16 to 0.43) • PU on extremity (p<0.001, OR=0.69, 95% CI 0.55 to 0.88) • Requiring assistance with ≥ 7 ADLs (OR-0.72, 95% CI 0.55 to 0.92)	• Limited to stage 2 PU • Convenience sampling • Analysis at a PU level for resident factors may have influenced results (e.g. one resident with an eating problem and multiple PUs that heal fast could influence the overall results)	**Level of evidence: 4 (prognostic) Quality: moderate**
Studies reporting on PUSH tool							
(Günes 2009)	Prospective descriptive study	Participants were a convenience sample recruited from a Turkish university hospital (n=72 persons with 86 PUs) **Inclusion criteria:** • stage II or greater PU • > 2 months life expectancy • > 18 years age **Participant characteristics:** • mean age 66.9±12.8 years	• Pressure ulcers were staged according to NPUAP classification system. • An investigator utilized the PUSH tool 3.0 to make wound assessments weekly • Wound area in all ulcers was measured with a digital planimetry system.	• Each patient was assessed weekly until healing or until 8 weeks whichever came first. • Repeated measure ANOVA to compare PUSH scores in healed and unhealed PUs	• 8 PUs healed in the time frame • PUSH scores decreased significantly over the 8 week study period (F=365.9, df=7, p<0.001) • There was a significant difference between PUSH scores in healed and unhealed PUs (F= 214.1, df=1, p<0.001) • Mean PUSH scores decreased significantly over 8 weeks for healed PUs (F=117.4, df=7, p<0.001) • PU size decreased significantly from weeks 1 through 8 in healed PUs (F=114.8, df=7, p<0.001) but was only significantly	• Small study size with insufficient power • No interrater/intrarater reliability established • influence of dressing type on exudate level observation was not considered	**Level of evidence: N/A Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• 71% sample was male • 49% stage II PUs, 49% stage III PUs, 4% stage IV PUs • 77% sacral PUs • 55.8% PUs duration > 4 weeks • 39% participants had > 1 PU (all tracked individually)			different in week 1 and 8 comparison for unhealed PUs. Thus a significant decrease in PUSH total score was seen on each weekly score for healed PUs, but only between week 1 and 8 for unhealed PUs. • There was no significant difference in tissue type and exudate amount scores (p>0.05) • **Study conclusions: This study demonstrates that the PUSH tool 3.0 total score is sensitive to change over time and differentiates healing and non-healing PUs. Two subscales of the tool (exudate and tissue type) did not significantly differentiate healing. The researchers recommend including assessment of wound volume on the PUSH tool.**		
(George-Saintilus, Tommasulo et al. 2009)	Retrospective chart review comparing **PUSH to traditional observation as a means to assess PUs**	Participants were recruited a long term care facility in US (n=100 but 52 excluded due to only stage I PU, 21 had healed PU and 9 had incomplete data; therefore n=48 participants with n=370 recorded PU observations) **Inclusion criteria:** long term care stay between Jan 2004 and Dec 2006 stage II to IV PU at least 8 consecutive weekly observations were present in the chart aged ≥ 65 years only one PU/patient included **Participant characteristics:** None additional reported	• The 3 parameters in the PUSH tool (length by width, exudate amount, and tissue type) were tabulated based on clinical observations documented by the nurses. • PUSH score was calculated by the principal investigator • Comparison was made between PUSH score and nurses' documented assessment of the PU as deteriorated, unchanged or improved.	• Agreement between nurse documentation and conclusions and PUSH score using kappa statistics	There was agreement between PUSH score and nurse conclusion (improved, unchanged, deteriorated) in 43% of observations For stage II PUs, level of agreement was low (kappa=0.132, p=0.029) For stage III PUs, level of agreement was low (kappa=0.129, p=0.04) For stage IV PUs, level of agreement was low (kappa=0.111, p=0.029) **Study conclusion: The PUSH score has poor correlation with traditional nursing observation; however, it is unclear which is more reliable and valid.**	• Stage I PU excluded as PUSH not designed for its assessment • Validity and reliability of neither method is determined • Experience of nurses is not reported; number of nurses not reported • Retrospective documentation of PUSH may not be reliable • Scores were not compared to the actual and known outcome of the PU	**Level of evidence: N/A** **Quality: low**
(Hon, Lagden et al. 2010)	Prospective descriptive study **to evaluate PUSH tool's validity compared to acetate tracing and**	Convenience sample of participants recruited over 10 months from acute care, outpatients and community settings (n=105, 98 completed study, n=47 with PU) Inclusion:	• Exudate estimated • All wounds irrigated and debridement as required • length and width taken • Tissue type • PUSH score calculated • Wound tracing conducted and digital tablet used to calculate	• PUSH score and acetate surface wound tracings conducted by the same assessor at baseline and 4 weeks (or patient's next appointment, whichever earlier). • Assessors received training	**Wound tracings** • For all PUs, there was a statistically significant difference between baseline size (mean) and followup (mean 25.4±5.6 days) size (mean 9.2±12.3cm^2 versus 6.2±10.8cm^2, p=0.0001) • For all chronic wounds there was a statistically significant difference between	• Very large wound excluded due to difficulty conducting wound tracings • No interrater/intrarater reliability conducted • Lengthy of time to	**Level of evidence: 4** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	ability to detect change over time	• Wound with potential to heal with correctable underlying cause • Stage II to IV PU, venous leg ulcer [VLU] or diabetic foot ulcer Exclusion: • Non-viable wound bed • Advanced active infection • Arterial wounds or unknown etiology • Malignancy • Unable to perform 4 week follow up Characteristics: • 47 PUs (15 stage II, 16 stage III, 16 stage IV) • 23 VLUs, 28 diabetic foot ulcers. • Mean baseline surface area for PUs 9.2cm^2	surface area	before commencement • Mean follow up time 31.7 days	baseline size (mean) and followup (mean 31.7±20.1 days) size (mean 7.1±10.1cm^2 versus 4.7±9.1cm^2, p=0.0001) **PUSH scores** • For PUs, there was a statistically significant change in mean score from baseline to follow up (mean score 12.1±2.8 versus 9.4±4.2, effect size [ES] 0.97, p=0.0001). • Change in PUSH score was statistically significant (all p=0.01) for Stage II PUs (ES 1.4), stage III PUs (ES 1.0) and stage IV PUs (ES 0.86) • For all chronic wounds, there was a statistically significant change in mean score from baseline to follow up (mean score 11.0±3.1 versus 8.0±4.5, ES 0.97, p=0.0001) • There was a statistically significant change (all p=0.0001) in each component of the PUSH tool i.e. size using disposable ruler (ES 0.74), exudate amount (ES -.71 and tissue type (ES 1.29) • Change in PUSH scores for healing wounds were statistically significant (ES 1.3, p=0.0001) but change was not statistically significant in non-healing wounds (ES –0.16, p=0.2) **Correlation wound tracing and PUSH** • Relationship between wound tracing and PUSH score was good for PUs (Pearson's r =0.63, p=0.01) and all chronic wounds (r=0..66, p=0.01) • **Study conclusions: The PUSH score has a strong responsiveness to change in PU sizes and correlates well with wound tracings.**	follow-up was much longer than in clinical application of PUSH	
Studies reporting on DESIGN-R tool							
(Zhong, Nagase et al. 2013)	Observational validation study **investigating validity and reliability of the Chinese version of**	Participants were nursing and medical staff at a Chinese hospital (n = 44 RNs, n= 11 medical staff) Characteristics: • Staff experience varied • Experienced medical staff had significantly more	• DESIGN-R was translated into Chinese using a back-translation method • Each assessor used the DESIGN-R to assess 8 photos of wounds in isolation from other assessors • 3 staff members re-conducted assessments after 1 month for	• See intervention	• There was a high correlation between raters (intraclass correlation coefficient [ICC] = 0.960, 95% CI 0.912 to 0.990 for the total score • ICC for individual items on the DESIGN-R ranged from 0.570 to 1.0 • There was significant correlation between DEISGN-R and BWAT for all raters (r =	• Insufficient sample size for intrarater reliability and criterion validity • Use of photos for assessments may have influenced the results	**Level of evidence: 4 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	DESIGN-R	years' experience than general medical staff • Majority of staff saw 1 to 5 wounds per month	intra-rater reliability • 8 staff members used an English version of the BWAT for criterion validity		0.807 to 0.939, p<0.001) • Only 27.3% of raters believed the DEISGN-R was easy to use in the clinical setting	• Self-selected participants • One participant was also a tool translator	
(Iizaka, Sanada et al. 2012)	multicenter cohort study **investigating the predictive value of the DESIGN-R score in PU monitoring over time**	All sample was compiled of all people in facilities affiliated with the Japan PU Society in a 2 month period who had a PU (n=761 cases followed) Week 1: n = 411 Week 2: n = 286 Week 3: n = 224 Week 4: n=170 Inclusion: documented PU with a baseline DESIGN-R score Exclusion: each week, PUs that had healed or been surgically repaired were excluded from the ongoing analysis Multiple PUs Missing DESIGN-R data Characteristics: median age was 79 to 80 years over the 4 weeks primarily sacral PUs (about 33%)	• Wound severity was evaluated by the DESIGN-R tool every week and the score change was calculated weekly for 4 weeks	• PU severity measured on DESIGN-R Score (score 0 to 66 worst) assessed weekly • PUs were followed for 4 weeks or until healed (whichever shorter) • Same assessor performed DESIGN-R each time	• Median change in DESIGN-R score from baseline to week 1 was 0, week 2 was 0, week3 was 1 and week 4 was 1. • For superficial PUs, a one-point improvement in the DESIGN-R score over any period was positively associated with healing within the next 30 days independent of initial wound severity . Hazard ratio was 1.16 (95% CI 1.07 to 1.26, p<0.001) for score change over 2 weeks and 1.33 (95% CI 1.18 to 1.48, p<0.001) for score change over 3 weeks. • For deep ulcers, a one-point improvement in the DESIGN-R score over any period was positively associated with healing within the next 30 days independent of initial wound severity. Hazard ratio was 1.21 (95% CI 1.10 to 1.35, p<0.001) for score change over 3 weeks and 1.27 (95% CI 1.12 to 1.44, p<0.001) for score change over 4 weeks. • Higher DESIGN-R score at baseline was negatively associated with healing for both superficial and deep PUs (p < 0.05) **Cut off points** • For a superficial PU over 1 week, a change in score of -1/0: sensitivity of 86.8; specificity of 38.9 • For a deep PU over 1 week, a change in score of 1/2: sensitivity of 60.9; specificity of 66.4 for deep PUs • For a superficial PU over 2 weeks a score change of -2/-1: sensitivity 87.5, specificity 45 • For a deep PU over 2 weeks, a score change of 1/2: sensitivity 73.9; specificity 29.3 • For a superficial PU over 4 weeks a change in score of -3/-2: sensitivity 96, specificity 43.3 • For a deep PU over 4 weeks a change in score of 2/3, sensitivity 93.8, specificity 62.7	• Did not adjust the treatments or the systemic risk factors for PU development • Large number of participants had surgical repair and were excluded • Not considered appropriate for post-operative healing	**Level of evidence: 2 (prognostic) Quality: moderate**

References

Andersen, E. S. and T. Karlsmark (2008). "Evaluation of four non-invasive methods for examination and characterization of pressure ulcers." Skin Research And Technology **14**(3): 270-276.

Aoi, N., K. Yoshimura, et al. (2009). "Ultrasound assessment of deep tissue injury in pressure ulcers: possible prediction of pressure ulcer progression." Plastic and Reconstructive Surgery **124**(2): 540-550.

Bergstrom, N., R. Smout, et al. (2008). "Stage 2 pressure ulcer healing in nursing homes." Journal of the American Geriatrics Society **56**(7): 1252-1258.

Bhedi, A., A. K. Saxena, et al. (2013). "Digital Photography and Transparency-Based Methods for Measuring Wound Surface Area." Indian Journal of Surgery **75**(2): 111-114.

Davis, A. J., J. Nishimura, et al. (2013). "Repeatability and clinical utility in stereophotogrammetric measurements of wounds." Journal of Wound Care **22**(2): 90-97.

Edsberg, L. E., J. T. Wyffels, et al. (2012). "Analysis of the proteomic profile of chronic pressure ulcers." Wound Repair and Regeneration **20**(3): 378-401.

Edsberg, L. E., J. T. Wyffels, et al. (2011). "Longitudinal Study of Stage III and Stage IV Pressure Ulcer Area and Perimeter as Healing Parameters to Predict Wound Closure." Ostomy Wound Management **57**(10): 50-62.

George-Saintilus, E., B. Tommasulo, et al. (2009). "Pressure ulcer PUSH score and traditional nursing assessment in nursing home residents: do they correlate?" Journal of the American Medical Directors Association **10**(2): 141-144.

Grubbs, S., M. Ludwig, et al. (2009). "The effect of high frequency ultrasound on the prevention of pressure ulcers in long-term care patients." Internet Journal of Academic Physician Assistants **7**(1): 3-3.

Günes, U. Y. (2009). "A prospective study evaluating the Pressure Ulcer Scale for Healing (PUSH Tool) to assess Stage II, Stage III, and Stage IV pressure ulcers." Ostomy Wound Management **55**(5): 48-52.

Higashino, T., G. Nakagami, et al. (2012). "Combination of thermographic and ultrasonographic assessments for early detection of deep tissue injury." Int Wound J: e-publication.

Hill, M. L., R. C. Cronkite, et al. (2009). "Validation of home telehealth for pressure ulcer assessment: a study in patients with spinal cord injury." Journal of Telemedicine and Telecare **15**(4): 196-202.

Hon, J., K. Lagden, et al. (2010). "A prospective, multicenter study to validate use of the Pressure Ulcer Scale for Healing (PUSH©) in patients with diabetic, venous, and pressure ulcers." Ostomy Wound Management **56**(2): 26.

Iizaka, S., T. Kaitani, et al. (2013). "Predictive validity of granulation tissue color measured by digital image analysis for deep pressure ulcer healing: A multicenter prospective cohort study." Wound Repair and Regeneration **21**(1): 25-34.

Iizaka, S., H. Sanada, et al. (2012). "Predictive validity of weekly monitoring of wound status using DESIGN-R score change for pressure ulcer healing: a multicenter prospective cohort study." Wound Repair and Regeneration **20**(4): 473-481.

Iizaka, S., H. Sanada, et al. (2011). "Quantitative estimation of exudate volume for full-thickness pressure ulcers: the ESTimation method." Journal of Wound Care **20**(10): 453.

Iizaka, S., J. Sugama, et al. (2011). "Concurrent validation and reliability of digital image analysis of granulation tissue color for clinical pressure ulcers." Wound Repair and Regeneration **19**(4): 455-463.

Kottner, J., T. Dassen, et al. (2009). "Comparison of two skin examination methods for grade 1 pressure ulcers." Journal of Clinical Nursing **18**(17): 2464-2469.

Nakagami, G., H. Sanada, et al. (2011). "Combination of Ultrasonographic and Thermographic Assessments for Predicting Partial-thickness Pressure Ulcer Healing." Wounds-a Compendium of Clinical Research and Practice **23**(9): 285-292.

Nakagami, G., H. Sanada, et al. (2010). "Predicting delayed pressure ulcer healing using thermography: a prospective cohort study." Journal of Wound Care **19**(11): 465-472.

Sprigle, S., M. Nemeth, et al. (2011). "Iterative design and testing of a hand-held, non-contact wound measurement device." Journal of Tissue Viability.

Terris, D. D., C. Woo, et al. (2011). "Comparison of in-person and digital photograph assessment of stage III and IV pressure ulcers among veterans with spinal cord injuries." Journal of Rehabilitation Research & Development **48**(3): 215-224.

Wyffels, J. T. and L. E. Edsberg (2011). "Granulation tissue of chronic pressure ulcers as a predictive indicator of wound closure." Advances in Skin & Wound Care **24**(10): 464-473.

Yabunaka, K., S. Iizaka, et al. (2009). "Can ultrasonographic evaluation of subcutaneous fat predict pressure ulceration?" Journal of Wound Care **18**(5): 192, 194, 196 passim.

Zhong, X., T. Nagase, et al. (2013). "Reliability and Validity of the Chinese Version of DESIGN-R, an Assessment Instrument for Pressure Ulcers." Ostomy Wound Management **59**(2): 36-43.

PAIN ASSESSMENT AND TREATMENT

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
Pain mangement							
(Paris, Horvath et al., 2008)	Randomized, crossover, multicenter, prospective, open-label, pilot study **comparing morphine to nitrous oxide for PU pain management**	n=34 (33 completed study) Inclusion: • 8 days inpatient stay • PU causing pain during care Exclusion: • Aged <18 years • Pregnancy or desire to be pregnant within 12 months • Intracranial hypertension • Pneumothorax, chronic resp failure • Middle ear or sinus surgery • Alcohol intoxication or delirium tremens • Bullous emphysema gaseous abdominal distention • Facial fracture Median age 84 82% had a PU, 18% varicose ulcer	Crossover protocol requiring each participant to receive three different protocols over six days (every second day) in a randomised order: **Arm 1** morphine subcutaneous 30 mins prior to care at 1mg/10kg body weight or 10% of daily dose if already receiving morphine **Arm 2** nitrous oxide-oxygen mixture inhaled 5 mins before care and throughout procedure at an individualized dose **Arm 3** morphine plus nitrous oxide oxygen mixture both of above	Level of pain following procedure assessed after and before care using: • Evaluation of Pain in Non-communicating Elderly (ECPA) • global hetero-evaluation scale (GHES) • DOLOPLUS-2 scale • This scale measures both out-of-care and in-care observations During all procedures pulse, arterial pressure and pO2 saturation Duration of care	• Duration of care was significantly shorter for arms 2 and 3 than arm 1 ($p<0.001$) • ECPA average difference after and before care: Arm 1: 5.2 ± 8.6, $p<0.001$ Arm 2: -0.3 ± 8, $p<0.001$ Arm 3: -0.6 ± 7.4, $p<0.001$ Significant difference between arms 1 and 2 ($p<0.001$) and arms 1 and 3 ($p<0.001$) but not arms 2 and 3 ($p=0.971$) • GHES and DOLOPLUS-2: • Similar significant differences (both tests in all arms $p<0.01$) Significant difference ($p<0.001$) between arms 1 and 2 and arms 1 and 3, but not arms 2 and 3 ($p=0.17$) • No differences were found with regard to safety or tolerability • **Conclusions: the study found that nitrous oxide – oxygen mixture was superior to morphine for analgesia when attending PU care in patients aged over 65 years**	• Bias in pain evaluation • Small study	**Level of evidence: 2 Quality: moderate**
Pain experience							
(Gunes, 2008)	Descriptive study reporting **the pain experience of PUs**	n=47 participants recruited from a university hospital in Turkey Inclusion: • ≥18 yrs of age • Stage II, III or IV PU • Ability to sense and report pain • Able to complete McGill Pain Questionnaire (MPQ) and Faces Rating Scale Revised (FRS-R)	Completion of FRS-R by selecting the face reflecting degree of pain felt at PU site Completion of 4 parts of MPQ: • mark the location of pain on a line drawing • choose most	• PU stage, location and cause of pain • Pain descriptors • Pain intensity • Pain occurrence	44 participants reported experiencing pain 6 participants received pain medication Pain experience by PU stage: • Stage II – 3 of 6 • Stage III – 32 of 32 • Stage IV – 9 of 9 Time of pain occurrence: • 41 participants reported no typical time for occurrence	• Size of the study • Dressing type, administration of pain medication and air mattress were not standardised	**Level of evidence: 5 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		Exclusion: • Sensory-motor deficits • Peripheral neuropathy Primarily men (62%) Aged 38 to 72 years (mean 60.1 ±8.23) Primarily neurological disorders 74% had only one PU Primarily stage II PUs of sacrum	appropriate from 78 pain descriptors • select description that best applies • assess present pain intensity based on a 0 to 5 scale		• 32 participants dressing change aggravated pain • 9 participants movement of the afflicted area aggravated pain • 3 participants had pain at rest Word descriptors: • 13 words were used to describe PU pain • Participants with stage IV ulcers chose three times as many word descriptors as those with stage II PU and 1.5 times as many as those with stage III PU Pain intensity: • Stage II PU: 3 of 6 rated their pain as "discomforting" • Stage III PU: all 32 rated pain as "distressing" • Stage IV PU: all 9 rated pain as "horrible" Mean FRS-R pain intensity score 6.04 ± 2.78 corresponding to a moderate pain rating		
(Kapp & Annells, 2010)	Hermeneutic qualitative pilot study reporting **themes associated with living with a PU**	7 participants • 4 men and 3 women • No cognitive impairment • All were receiving home-based care for a PU • Mean age 73 yrs	• unstructured in-depth interviews averaging 50 minutes duration were conducted by the same researcher • All interviews were audio-taped and then transcribed verbatim by the researcher who conducted the interviews	Interview questions: • Tell me what it is like having a PU and to be living at home? • How do you feel about that? • Can you tell me more about that? Thematic analysis process suggested by van Manen (1990) guided interpretation of data	**Themes** • To live with discomfort: Participants spoke about the soreness and pain they experienced • To live with differing interests: living with a PU at home required involvement from more than one community-based health professional • To live with restrictions: living with a PU meant that adaptation may be required to accommodate physical restrictions imposed by wound • To place trust and have faith in the nurse: all participants trusted the home nurses and had faith in their wound management skills	• Generalizability of small sample • Patient selection not detailed • Justification of the method very limited • Unclear if informed consent required • Potential for researcher bias not discussed • Statements suggest evidence of researcher bias	**Level of evidence: 5** **Quality: low**
(Essex, Clark et al., 2009)	Cohort study and pilot study	**cohort study** • n=2,507, including 218 participants with PUs • Participants with PU were significantly older (p<0.001, mean age 75.8) than those without (mean age 64.3) • Primarily PU grade I or II **Pilot study** Inclusion: • Inpatient in elderly or surgical ward and identified by tissue	**cohort study** questionnaires designed to be self-completed, however, a structured interview method addressed the problem that many patients could not complete the questionnaires. **Pilot study** Health-related Quality of	**cohort study** information collected included age, sex, reason for admission, co-morbidities and PU grade; short-form SF-36 (including pain). **Pilot study** • comparison of the findings of measures: EQ-5D, SF-36 and Pain	**cohort study** SF-36 pain • Participants with PUs mean 28.41 (SD 17.00) median 31.0 (IQR 30.0) Score of 0=17 (12.3%) • Participants without PUs mean 32.79 (SD 17.36), median 41.0 (IQR 28.0), score of 0=226 (11.6%) **Pilot study** SF-36 pain (any cause) • Participants with PUs (n=5) mean 46.6 (SD 31.2) • Participants without PUs mean 55.6 (SD 34.51)	**Overall** This paper does not report PU pain, rather general pain experienced by the patient with a PU. **Cohort study** • Unclear when HRQOL and pain assessments were undertaken (on admission or during hospital stay) • Described as a cohort study but conducted as a	Level of evidence: 5 Quality: low

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		viability nurse • ≥65 years Exclusion: • Physical or mental incapacity to complete survey Mean age 79 to 80 yrs Primarily grade II PU	Life (HRQoL) tool designed to be self-completed; however, supplemented by a structured interview	VAS • information collected included demographics; main co-morbidities; PU grade and HRQoL	mean difference 9.0 (95% CI 27.7 to 45.7, p= 0.61) Pain VAS (anywhere on the body) • Participants with PUs (n=6) mean 48.6 (SD 22.1) • Participants without PUs mean 24.8 (SD 23.4) • Mean difference –23.9 (95% CI –48.56 to 0.95, p= 0.06)	cross-sectional study **Pilot study** • Non-completion of SF-36 • Participant identification and selection process not described • Small sample size with low statistical power represents only a small subset of the population	
(Faigeles, Howie-Esquivel et al., 2013)	Observational study **investigating strategies used to manage pain during turning**	Participants were a convenience sample selected in 169 US hospitals (n=1,395) Inclusion: • Aged ≥ 18 years • Able to understand and communicate Exclusion: • Blind or deaf • Receiving neuromuscular blocking medication • Disease/injury that impaired sensory transmission proximal to the procedure site (e.g. peripheral neuropathy) Characteristics: • 86.3% sample were White • Mean age 63.5±3.1 years • 65.9% in a critical care unit • 70.4% were surgical patients	Participant was repositioned once as required by the care team and rated pain during the repositioning.	• Pain associated with turning measured during the turn procedure using a numerical rating scale (0 to 10) • Survey (participant , family and nurse) after the turn procedure regarding use of pain relief interventions during the procedure	• Overall mean pain was 4.9±3.1 during turning. • Participants were primarily turned using a draw sheet (53.6%) • Most participants (69.4%) were given assistance to turn • 12% were premedicated with an opioid prior to turning • The three most used non-pharmacological interventions were a calming voice, providing information and encouraging deep breathing. • Surgical patients more likely than medical to receive information (OR 1.73, 95% CI 1.25 to 2.38) and deep breathing (OR 2.33, 955 CI 1.62 to 3.34)	• Participants did not have PU • Did not evaluate effectiveness of the interventions	**Indirect evidence**
(Lukas, Mayer et al., 2013)	Cross sectional study investigating **characteristics of the pain experience in older adults in care**	Participants were older adults recruited from long term care facilities in 8 countries (primarily in EU) (n=3926 residents, 1900 with pain) Characteristics: • mean age 83.6 ± 9.3 years • 73.3% of sample were female • 48.4% participants reported pain	Pain assessment conducted at baseline and at 6 months.	• New assessment tool inter-RAI instrument for Long Term Care Facilities that is derived from the Minimum Data Set. • Nurses received training on comprehensive assessment and used direct observation, interviews and clinical records to make assessments	• Patients in pain were significantly more likely to have a PU than these who did not have pain (13.7% vs 7.5%, p<0.001) • Presence of a serious pressure ulcer was significantly correlated (p<0.01) with having pain OR 2.03 (95% CI 1.51 to 2.72) • Presence of severe PU significantly correlated (p<0.01) with insufficiently controlled pain intensity in previous 3 days (OR 1.45 to 1.01 to 2.08)	• Estimation of pain in participants with dementia may be unreliable • Validation of tool is not reported, interrater reliability is not reported.	**Level of evidence: N/A** **Quality: low**

References

Essex, H. N., M. Clark, J. Sims, A. Warriner, N. Cullum. (2009). "Health-related quality of life in hospital inpatients with pressure ulceration: assessment using generic health-related quality of life measures." Wound Repair and Regeneration: Official Publication of the Wound Healing Society [and] the European Tissue Repair Society **17**(6): 797-805.

Faigeles, B., J. Howie-Esquivel, C. Miaskowski, J. Stanik-Hutt, C. Thompson, C. White, et al. (2013). "Predictors and Use of Nonpharmacologic Interventions for Procedural Pain Associated with Turning among Hospitalized Adults." Pain management nursing : official journal of the American Society of Pain Management Nurses **14**(2): 85-93. Epub 2013/05/22.

Gunes, U. Y. (2008). "A descriptive study of pressure ulcer pain." Ostomy/Wound Management **54**(2): 56-61.

Kapp, S., M. Annells. (2010). "Pressure ulcers: home-based nursing." British Journal of Community Nursing **15**(12): 6-13.

Lukas, A., B. Mayer, D. Fialova, E. Topinkova, J. Gindin, G. Onder, et al. (2013). "Pain Characteristics and Pain Control in European Nursing Homes: Cross-sectional and Longitudinal Results From the Services and Health for Elderly in Long TERm care (SHELTER) Study." J Am Med Dir Assoc. Epub 2013/02/05.

Paris, A., R. Horvath, P. Basset, S. Thiery, P. Couturier, A. Franco, et al. (2008). "Nitrous Oxide-Oxygen Mixture During Care of Bedsores and Painful Ulcers in the Elderly: A Randomized, Crossover, Open-Label Pilot Study." Journal of Pain and Symptom Management **35**(2): 171-6.

WOUND CARE: CLEANSING AND DEBRIDEMENT

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Wound cleansing							
(Fernandez & Griffiths, 2008)	Systematic review with meta-analysis **investigating the effectiveness of potable tap water for wound (primarily lacerations) cleansing**	11 RCTs and quasi-RCTs were included Participants in the trials ranged from 2 years to 95 years. Two trials were on paediatric samples. In no trials were the wounds PU. In 5 trials the wounds were lacerations, one trial was in open fractures, one in chronic wounds and 4 in surgical wounds. The majority of trials were set in emergency wards.	The trials investigated: Tap water (8 trials) Cooled boiled water (1 trial) Distilled water (1 trial) Normal saline (1 trial)	• The primary outcome of interest was wound infection measured • objectively by bacterial counts, wound cultures, wound biopsy and/or by subjective indicators of wound infection. • Other outcomes were: proportion of wounds that healed; the rate of wound healing expressed as percentage or absolute change in wound area; costs; pain and discomfort; patient satisfaction; staff satisfaction.	• Meta-analysis results : **Tap water versus no cleansing** ○ No difference in infection rate (3 RCTs, RR 1.06, 95% CI 0.07 to 16.50) ○ No difference in wound healing (2 RCTs, RR 1.26, 95% CI 0.18 to 8.66) • **Review conclusions: There is no evidence that using tap water to cleanse acute wounds (primarily lacerations) in adults increases infection. However, there is not strong evidence that cleansing wounds per se increases healing or reduces infection. In the absence of potable tap water, boiled and cooled water as well as distilled water can be used as wound cleansing agents.**	• Primarily lacerations were treated, only one trial included chronic wounds • Individual trials generally low quality or had inadequate reporting	**Indirect evidence: mixed wounds Quality: High**
(Ho, Bensitel et al., 2012)	Double blind prospective RCT **investigating pulsatile lavage for PU cleansing**	Participants recruited from an inpatient facility (n=28) Inclusion: • aged > 18 yrs with SCI • stage III and IV pelvic PUs, presenting as clean with no odor, necrosis, minimal exudate, no tunnelling or fistula, no cellulitis, no erythema of surrounding tissue • PU maximum diameter of 3 to 15cm at baseline • No antibiotics within preceding 7 days • no malignancy or vascular disease associated with PU • no diabetes, heart disease or renal failure Characteristics: • Primarily ischial PUs • No significant	All participants received standard care according to clinical guidelines. Participants were randomised to receive either: • Daily low-pulsatile lavage treatment with 1 litre of normal saline at 11 psi applied over 10 to 20 mins using a device designed for the procedure (n=14) or • Sham treatment in which no lavage was administered directly to the PU but participants were given the impression it had been (n=14) Dressings were removed before the commencement of	• Length, width and depth of PU obtained weekly for 3 weeks • PU depth using saline injection method • PU healing rate over the 3-week study period	• Random-coefficient models for analysis of linear and volume measurements revealed improvements over time for both groups • Time trend analysis revealed greater measurement decreases for the treatment groups • Differences in rates of change over time (95% CI) for treatment and control groups respectively ($p<0.001$): ○ Depth: –0.24 (0.09 to –0.58) cm/wk ○ Width: –0.16 (0.06 to –0.39) cm/wk ○ Length: –0.47 (0.18 to –1.12) cm/wk ○ Volume: –0.33 (0.13 to –0.80) cm^3/wk All 95% CIs span the null value, decreasing confidence in the significance of the results.	• Small number of participants and underpowered • Strict exclusion criteria excluded 221 participants • All 95% CIs span the null value, decreasing confidence in the significance of the results.	Level of Evidence: 2 Quality: moderate

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		demographic differences • Mean age 55 to 57 years	treatment and replaced at the completion of treatment				
Topical therapies							
(Mizokami, Murasawa et al., 2012)	Retrospective **observational study comparing iodoform gauze to povidone-iodine and sugar or sulfadiazine cream** (only data from clinical study is summarised)	Retrospective records analysis of participants with PU treated at geriatric centre in Japan between 2008 and 2010 (n=53 participants with 60 PUs) Inclusion: • All participants with PUs were systematically recorded during a 2-year period and included in the study Characteristics: • Mean age approx. 80 yrs • Participants treated with iodoform gauze had significantly lower albumin (2.8±0.5g/dL versus 3.2±0.6 g/dL, p<0.007) • Participants treated with iodoform gauze had significantly larger wound surface area (17.6±19.6cm^2 versus 7.7±8.2cm^2, p=0.004) • Participants treated with iodoform gauze had more PUs stage IV (83.3% versus 57%, p=0.009) •	There was no indication as to how treatment was selected for each participant. Participants were treated with either: • iodoform gauze was applied with a polyurethane top-dressing • The conventional treatment used as a comparison was either silver sulfadiazine cream or povidone-iodine and sugar	Primary outcome was wound-cleaning capacity determined by the % of wound surface area covered in necrotic tissue. The area of necrotic tissue was blindly determined using digitalized images.	• Treatment period was significantly shorter for participants who were treated with iodoform gauze (14.1±9.7 versus 29.0±24.5, p=0.002) • There was significantly greater PUs treated with iodoform gauze classified as having necrotic tissue completely removed after 2 weeks of treatment compared to conventional treatments (60% versus 10%, p<0.001) • By 4 weeks, 80% of PUs treated with iodoform gauze had necrotic tissue completed removed (versus 30%, p<0.001) • **Study conclusion: Iodoform gauze is effective in preparing the PU wound bed for healing, but there is no evidence from this study that this leads to complete healing or faster healing**	• Indirect evidence: no relationship between debridement and wound healing outcomes was presented • No randomization, pre-defined outcome measures or clear participant selection • Non-equivalent participants at baseline • Various comparison treatments • Concurrent management strategies not reported	**Indirect evidence** **Quality: low**
(Felzani, Spoletini et al., 2011)	Double-blind RCT **comparing lysine hyaluronate cream to sodium hyaluronate cream for managing PUs**	Participants recruited from a hospital in Italy (n=50) Inclusion: • >18yrs of age • Stage I to III PU using EPUAP staging system • Mean age approx. 65 years • 18% of participants had diabetes	• All PUs were initially cleaned with saline and debrided as required. • Participants were stratified by PU stage. Randomized to receive either: ○ lysine hyaluronate cream (Lys-HA, n=25) or	• Wound size • Time to reach 50% reduction in wound size • Photographs and planometry were taken before the treatment and then every 3 days and at the end of the study	• PU reduction was greater and faster in the Lys-HA groups than SH groups. **Stage I PU results** (n=20, 10 each group) • The Lys-HA had significantly greater total PU healing over 15 days (90% versus 70%, p< 0.05) • Time to reach 50% reduction in wound size was faster in Lys-HA group (9 versus 15 days, p<0.05) **Stage II PUs** (n=20, 10 each group) • The Lys-HA group had significantly greater total PU healing over 15 days (70% versus 40%, p< 0.02) • Time to reach 50% reduction in wound size was	• Small study and overall results are not reported (only stratified by PU severity) therefore unclear if adequately powered • Lack of inclusion of patients with stage IV PU • Wound size and condition and co-morbidity at commencement not reported	**Level of evidence: 2** **Quality: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
			○ sodium hyaluronate (SH, n=25) • For all PUs, the topical hyaluronate was applied as a thin layer across the ulcer surface and overed with fat gauze then sterile gauze. • Dressing changes were daily during the first week and every other day the second week. • Duration of active treatment of 15 days		faster in Lys-HA group (9.5 versus 15 days, p<0.05) **Stage III PU** (n=10 participants with 14 PUs, 7 PUs in each group) • Time to reach 50% reduction in wound size was faster in Lys-HA group (12.9 versus 19.2 days, p<0.05) • **Study conclusions: This small, underpowered study without a placebo control found lysine hyaluronate cream was associated with faster healing over 15 days compared with sodium hyaluronate for stage I to III PUs. The study is of a weak quality and provides insufficient support for use of this product.**	• No reporting of effect overall (i.e. not by stratified groups) • Participants who dropped out (approx. 18%) not included in analysis • Wound size not reported • No placebo control • No definition of standard care and how this relates to intervention tested.	
(Biglari, Vd Linden et al., 2012)	observational case series **reporting on Medihoney for stage III and IV PUs**	Participants were recruited from 9 trauma centres in Germany (n=20) Inclusion/exclusion: • SCI patients with chronic PUs • No other criteria reported Characteristics: • PUs were at least 12 weeks in duration at entry to study • 65% sample male • Mean age 48.7 years (range 30 to 79) • 5/20 had stage IV PU • 15/20 had stage III PU	• All of the participants were treated with Medihoney approx. 3mm thickness applied once daily after cleansing with Ringer's solution • Surrounding skin was disinfected with a range of anti-microbial preparations • Treatment was continued for more than 6 weeks	• Weekly photographs, measurement and cultured (methods not reported) • PUs were documented at 3-week intervals	• After 1 week of therapy all swabs were void of bacterial growth • 90% of participants showed complete wound healing after 4 weeks • No negative effects were noted from the treatment	• Objective measurement strategy not reported • Peri-ulcer skin was treated with different antimicrobials that may have influenced culture findings • PU size and condition at entry not reported • Co-morbidity not reported • **Nb: This paper is reported in the Infection section of the guideline**	**Level of evidence: 5** **Quality: low**
(Sipponen, Jokinen et al., 2008)	Prospective, multicentre RCT investigating **effectiveness of resin salves (*Picea abies*) in PU care**	Participants recruited from 11 primary care hospitals in Finland between 2005 and 2007 (n=37, n=22 completed and analysed) Inclusion: • grade II to IV PU • not requiring surgical management of PU • with or without clinical	Details of concurrent management strategies were limited. Approximately 22% of control group and 8% of treatment group were managed on a pressure mattress. Participants were randomly assigned to either:	• Primary outcome measure was complete healing of the ulcer within 6 months • Secondary outcome measures included eradication of bacterial strains cultured from ulcers at the study entry • Bacterial cultures were obtained from all PUs at baseline and 1 month, but	• The resin salve group achieved a higher rate of complete healing at 6 months (92% versus 44%, p=0.003) • The speed of PU healing was significantly faster in the resin than in the control group (p=0.013) • Bacterial cultures from the PU area more often became negative within 1 month in the resin group • 100% of PUs in treatment group were rated fully healed or significantly improved versus 91% in the control group (p=0.003)	• No blinding or intention to treat analysis • Over 40% drop out of study. Although there was no significant difference in baseline characteristics between drop outs in each group, more treatment participants dropped out due to deteriorating PUs	**Level of evidence: 2** **Quality: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		wound infection Exclusion: • Life expectancy < 6 months • Advanced malignant disease Characteristics: • No significant between group difference on baseline demographics or wound characteristics • Mean age approximately 74 to 80 years • Mean BMI 21.8, mean P-albumin 28.3 to 31.4 gL^{-1} • Primarily bedridden participants • Primarily non-smokers • Primarily stage II and III PUs	• resin salve applied at 1mm thickness between gauze layers with dressing changed third daily or daily for heavily exudating PUs (n=13 with 18 PUs) • sodium caboxymethylcellulose hydrocolloid polymer dressing (Aquacel®) or for clinically infected PUs, hydrocolloid dressing with ionic silver (Aquacel Ag®). Dressing changed third daily, or daily for heavily exudating PU. (n=9 with 11 PUs) • Some participants in both groups received concurrent antibiotics	thereafter only as clinically indicated. • PU size measured by digital photography and planimetry	• Drop outs in intervention included participants who required surgical intervention (n=2) and allergic reaction to the product (n=1). Drop outs were not significantly different between groups.	and had these cases been included in analysis there may not have been statistically significant effect. • Study failed to recruit and maintain sufficient numbers to reach a-priori sample size calculations. • Bacterial eradication analysis is complicated by the concurrent use of antibiotics for some participants	
(Chuangsuwanich, Charnsanti et al., 2011)	Prospective randomized clinical trial **comparing silver sulfadiazine cream to a silver dressing**	Participants were recruited from an in and outpatient clinic in Thailand (n=40) Inclusion: PU stage III or IV Characteristics: • Mean age 62.6 to 69.1 years • No significant difference for blood results at baseline, including albumin levels <3.5 in both groups suggesting possible malnutrition • SSD cream group had significantly larger PU at commencement of study (12.17 versus 22.82cm^2)	• All PUs were debrided if required. • Participants were randomly assigned to receive: o wound beds covered with silver sulfadiazine (SSD) cream applied daily (n=20) o silver mesh dressings applied every 3 days (n=20) • Treatment was for 8 weeks	Data collected at the beginning of the study and every two weeks thereafter: • Wound size (planimetry) • Wound photography • PUSH score • Bacterial wound culture Study period was eight weeks for each participant	• Silver mesh dressing was superior to SSD cream for reduction in wound area at 8 weeks (18.22 versus 7.96 and cm^2, p=0.093) • There was no significant difference between groups for PU healing rate after 8 weeks (36.95% in the mesh group and 25.06% in the SSD group, p=0.507) • The means of PUSH score were 11.4 (mesh) and 13.4 (SSD cream) at commencement and 7.55 (mesh) and 9.6 (SSD cream) after 8 weeks. • **Study conclusions: considering the significant difference in wound size at commencement of this study, there appears to be no significant difference between a silver dressing and topical SSD cream for healing in PU. There is no placebo group to assess the overall benefit of silver in managing PUs.**	• Small trial, no power study • No placebo control • No blinding • Groups not comparable at baseline • Unclear treatment (e.g. dressing applied over SSD cream?) • Non comparable management (dressing changes at different frequency) • Unclear co-morbidities • **Nb: This paper is reported in the Dressings section of the guideline**	**Level of evidence: 2** **Quality: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(Golinko, Clark et al., 2009)	Retrospective survey **of pathology reports for debrided PUs**	Participants were consecutive patients undergoing wound debridement in a tertiary hospital (n=98 patients, 139 debrided PUs) Inclusion: • Undergoing PU debridement Characteristics: • Participant and PU characteristics are not reported	Chronic wound biopsies of the skin edge, wound bed and bone were obtained.	Participant data for each debrided wound was recorded, with pathological findings reported at the level: • epidermis • dermis • subcutaneous • fascia • tendon • muscle • bone	**Epidermal pathology reports (n=107**) • 31% showed hyperkeratosis • 9% showed parakeratosis • 6% showed acanthosis • 4% showed gangrene **Dermal pathology reports (n=105)** • 60% showed granulation tissue • 66% showed inflammation • 30% showed fibrosis • 24% showed necrosis • 4% showed gangrene **Subcutaneous tissue pathology reports (n=87)** • 38% showed granulation tissue • 51% showed inflammation • 32% showed fibrosis • 55% showed necrosis • 11% showed gangrene **Fascial pathology reports (n=14)** • 57% showed granulation tissue • 71% showed inflammation • 21% showed fibrosis • 29% showed gangrene **Tendon pathology reports (n=7)** • 43% showed inflammation • 43% showed necrosis • 14% showed gangrene **Bone pathology reports (n=70)** 20% showed granulation tissue 33% showed acute osteomyelitis 20% showed chronic osteomyelitis 21% showed reactive bone **Study conclusions:** • surgeons should debride a wound until there is an absence of hyperkeratosis in the epidermis and an absence of fibrosis in the dermis • deep debridement of infected bone in the case of osteomyelitis is rarely associated with inhibition of soft tissue growth	• No standardisation regarding PU duration or previous management • Debridement was not necessarily first debridement • Findings are based on researcher opinion rather than directly associated with the survey findings • Retrospective design • Indirect evidence: no relationship between debridement width or depth and wound healing outcomes was presented	**Indirect evidence Quality: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(Waycaster & Milne, 2013)	Two phase RCT	Participants were recruited in one long term care facility (n=27) Inclusion: Stage III and IV PUs ≥ 85% necrotic tissue	• Participants were randomized to receive either: ○ Hydrogel dressing (n=13) ○ Collagenase with semi-occlusive dressing (n=14) • No sharp debridement performed • All PUs irrigated, cleaned and dressed daily or more frequently	• Complete debridement within 42 days (Phase I) • Complete wound healing by 84 days (Phase II)	• Significantly more PUs managed with collagenase achieved complete debridement by 42 days compared with hydrogel (approx. 85% vs 29%, p<0.03) • Significantly more PUs managed with collagenase achieved complete wound healing by 84 days compared with hydrogel(69% vs 21%, p=0.02)	• Randomization, allocation concealment not reported • Participant characteristics not reported • No blinding	**Level of evidence: 2** **Quality: low**
(Shannon, 2013)	Retrospective record review	Records in a nursing home in the US were reviewed to identify patients who had heel PU (n=179)	Heel PUs were defined as: • having entire eschar coverage (67.8% of sample)or • having blister coverage (31.8% of sample)	155 PUs were followed to completion	• 154 of the wounds (99.3%) healed. • 100% of wounds healed with an average healing time of 11 weeks (range 2 to 50 weeks). • Complications included one patient who developed osteomyelitis (with eventual healing) and two cases of cellulitis and one eventual amputation in a patient with blister coverage of the ulcer	• Unclear how assessments were performed • Patient characteristics not reported • Other care not reported • No control group	**Level of evidence: 5** **Quality: low**

References

Biglari, B., P. H. Vd Linden, A. Simon, S. Aytac, H. J. Gerner, A. Moghaddam. (2012). "Use of Medihoney as a non-surgical therapy for chronic pressure ulcers in patients with spinal cord injury." Spinal Cord: The Official Journal Of The International Medical Society Of Paraplegia **50**(2): 165-9.

Chuangsuwanich, A., O. Charnsanti, V. Lohsiriwat, C. Kangwanpoom, N. Thong-In. (2011). "The efficacy of silver mesh dressing compared with silver sulfadiazine cream for the treatment of pressure ulcers." Journal of the Medical Association of Thailand **94**(5): 559-65.

Felzani, G., I. Spoletini, A. Convento, B. Di Lorenzo, P. Rossi, M. Miceli, et al. (2011). "Effect of lysine hyaluronate on the healing of decubitus ulcers in rehabilitation patients." Advances In Therapy **28**(5): 439-45.

Fernandez, R., R. Griffiths. (2008). "Water for wound cleansing." Cochrane Database of Systematic Reviews (1).

Golinko, M. S., S. Clark, R. Rennert, F. A., A. J. Boulton. (2009). "Wound emergencies: the importance of assessment, documentation, and early treatment using a wound electronic medical record." Ostomy WoundManage **55**(5): 54-61.

Ho, C. H., T. Bensitel, X. Wang, K. M. Bogie. (2012). "Pulsatile lavage for the enhancement of pressure ulcer healing: a randomized controlled trial." Physical Therapy **92**(1): 38-48.

Mizokami, F., Y. Murasawa, K. Furuta, Z. Isogai. (2012). "Iodoform gauze removes necrotic tissue from pressure ulcer wounds by fibrinolytic activity." Biol Pharm Bull **35**(7): 1048-53.

Shannon, M. M. (2013). "A retrospective descriptive study of nursing home residents with heel eschar or blisters." Ostomy WoundManage **59**(1): 20-7. Epub 2013/01/12.

Sipponen, A., J. J. Jokinen, P. Sipponen, A. Papp, S. Sarna, J. Lohi. (2008). "Beneficial effect of resin salve in treatment of severe pressure ulcers: a prospective, randomized and controlled multicentre trial." The British Journal of Dermatology **158**(5): 1055-62.

Waycaster, C., C. T. Milne. (2013). "Clinical and Economic Benefit of Enzymatic Debridement of Pressure Ulcers Compared to Autolytic Debridement with a Hydrogel Dressing." Journal of medical economics. Epub 2013/05/25.

ASSESSMENT AND TREATMENT OF INFECTION AND BIOFILMS

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Managing infection							
(Wild, Bruckner et al., 2012)	Prospective RCT **comparing PHMB swabbing to a cellulose dressing impregnated with polyhexa-methylene biguanide (PHMB) in eradicating MRSA from PUs**	Participants were recruited from in and out patients clinics in Switzerland (n= 30) Inclusion: • MRSA contaminated PU stages II to IV according to EPUAP classification • PU with MRSA colonization that has been unresponsive to several disinfection attempts during a 2-week wash out period Characteristics: • Groups comparable at baseline • 50% sample female • Mean age 66.5 to 70.9 years • Mean wound area study group 47.67±22.75cm2 and control group 35.80±13.47cm2 • In both groups 7/15 PUs were stage IV sacral PUs	• Participants were randomly assigned to: ○ Control group: cleansing performed with PHMB swabs for 20 minutes after which a foam dressing was applied (n=15) ○ Study group: cleansed with normal saline and received a PHMB impregnated cellulose dressing with the foam dressing applied as a secondary dressing (n=15) • In both groups, zinc cream was applied to peri-wound skin and dressings were changed second daily for 14 days	Primary outcome was MRSA eradication assessed on days 7, 14 and for 3 consecutive days after the treatment period via wound swab and culture Secondary outcome was per cent of non-vital and granulation tissue assessed via wounds photography and planimetry performed weekly	MRSA eradication • At day 7 more PUs in the study group had been eradicated of MRSA (40% versus 86.67%) • At day 14 significantly more PUs in the study group had been eradicated of MRSA 66.67% versus100%, p<0.05)	• Outcomes for formation of granulation tissue were not reported in detail • Results for sustained eradication on days 14 to 17 not reported	**Level of evidence: 2 Quality: moderate**
(Beele, Meuleneire et al., 2010)	Prospective RCT **comparing a silver alginate dressing to silver-free alginate dressing**	Participants were recruited from three centres in Belgium and the Netherlands (n=36 participants, of which n=12 had PUs) Inclusion: • aged over 18 years • chronic wound suitable for treatment (i.e. of size no more than 2cm x 20cm for PUs) • at risk of infection assessed as having at least two characteristics on mASEPSIS tool Exclusion: • target wound showing general or systemic infection based on clinical signs	Participants were randomized to receive either: • Study group: an ionic silver alginate/ carboxymethylcellulose (SACMC) dressing • control group: a non-sliver calcium alginate fibre (AF) dressing Treatment continued for up to 4 weeks. Concurrent treatments not reported.	The primary study endpoints were: • Prevention of infection (assessed as progress of wound to or away from infection based on mASEPSIS score for wound pain, presence of erythema, oedema, warmth, moderate to heavy exudate, slough, discoloured granulation, pocketing at wound base, malodour, necrosis) • Progression to wound healing based on wound surface area The efficacy was evaluated	Wound healing • There was a statistically significant difference in the overall wound surface area reduction over time for the treatment wounds (p=0.017) • There was no significant difference at 4 weeks in change in mean surface area from baseline between the two groups (+4.5cm2 control group versus –2.4cm2 study group, p=ns) Prevention of infection • The study dressing was associated with a significantly greater reduction in signs/symptoms associated with infection as rated by mASEPSIS score than the control group (p=0.013) • over the 4-week follow-up period one adverse event (wound maceration) was reported in the study group and five were	• sensitive to different definitions of critical colonization • low sample size	**Indirect evidence (mixed aetiology) Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• requiring or already taking systemic antibiotics • known condition or physical/medical state affecting wound healing • systemic corticosteroids, immunosuppressants, radiation or chemotherapy • poor life expectancy Characteristics: • mean age 73.4 to 73.5 years • mean BMI 27.1 to 30.5 • difference in baseline mean wound surface area 20.1cm^2 for study group and 14.2cm^2 for control group • difference in wound duration 15.5 months for study group and 10.2 months		over a 4-week period	reported in the control group (two cases of wound infection, one serious sticking of dressing, on rehospitalisation for further wound care).		
(Sipponen, Jokinen et al., 2008)	Prospective, multicentre RCT investigating **effectiveness of resin salves (*Picea abies*) in PU care**	Participants recruited from 11 primary care hospitals in Finland between 2005 and 2007 (n=37, n=22 completed and analysed) Inclusion: • grade II to IV PU • not requiring surgical management of PU • with or without clinical wound infection Exclusion: • Life expectancy < 6 months • Advanced malignant disease Characteristics: • No significant between group difference on baseline demographics or wound characteristics • Mean age approximately 74 to 80 years • Mean BMI 21.8, mean P-albumin 28.3 to 31.4 gL^{-1} • Primarily bedridden participants	Details of concurrent management strategies were limited. Approximately 22% of control group and 8% of treatment group were managed on a pressure mattress. Participants were randomly assigned to either: • resin salve applied at 1mm thickness between gauze layers with dressing changed third daily or daily for heavily exudating PUs (n=13 with 18 PUs) • sodium caboxymethylcellulose hydrocolloid polymer dressing (Aquacel®) or for clinically infected PUs, hydrocolloid dressing with ionic silver (Aquacel Ag®). Dressing changed third daily, or	• Primary outcome measure was complete healing of the ulcer within 6 months • Secondary outcome measures included eradication of bacterial strains cultured from ulcers at the study entry • Bacterial cultures were obtained from all PUs at baseline and 1 month, but thereafter only as clinically indicated. • PU size measured by digital photography and planimetry	• The resin salve group achieved a higher rate of complete healing at 6 months (92% versus 44%, p=0.003) • The speed of PU healing was significantly faster in the resin than in the control group (p=0.013) • Bacterial cultures from the PU area more often became negative within 1 month in the resin group • 100% of PUs in treatment group were rated fully healed or significantly improved versus 91% in the control group (p=0.003) • Drop outs in intervention included participants who required surgical intervention (n=2) and allergic reaction to the product (n=1). Drop outs were not significantly different between groups.	• No blinding or intention to treat analysis • Over 40% drop out of study. Although there was no significant difference in baseline characteristics between drop outs in each group, more treatment participants dropped out due to deteriorating PUs and had these cases been included in analysis there may not have been statistically significant effect. • Study failed to recruit and	**Level of evidence: 2** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Primarily non-smokers • Primarily stage II and III PUs	daily for heavily exudating PU. (n=9 with 11 PUs) • Some participants in both groups received concurrent antibiotics			maintain sufficient numbers to reach a-priori sample size calculations. • Bacterial eradication analysis is complicated by the concurrent use of antibiotics for some participants	
(Trial, Darbas et al., 2010)	Prospective RCT **comparing anti-microbial effectiveness of an ionic silver alginate dressing to a silver-free alginate dressing**	Participants were recruited over 18 months from a wound clinic and inpatient service at a hospital in France (n=42, n=24 with PU) Inclusion: • One or more symptoms of local infection including local heat, peri-wound erythema, persistent pain, oedema, malodour, fever, pus and heavy exudate. Exclusion: • Allergy to dressing components • Burn patients • Ulcers associated with infectious disease • Taking anticoagulants • < 18 years or over 80 years Characteristics of PU participants: • Mean age of females 80.9±9.0 and mean age of men 65.5±17.7 • NS between baseline mean clinical infection score (8.7±2.8 treatment group versus 7.9±3.6 control group) • 63% sacral PUs • 46% of PUs were described as having "superficial tissue damage with pus exuding blisters", 33% had "tissue damage not extending to the	• Participants were randomly assigned to receive either: ○ Study product: An ionic silver alginate matrix dressing that is described as providing controlled, sustained delivery of silver ions over 72 hours (Askina® Calgitrol® Ag; n = 20, n=11 with PU) ○ Active control product: A standard alginate dressing (Algosteril® ; n = 22, n=13 with PU) • Treatment was for 15 days. • Concurrent management strategies were not reported	• Assessments on days 1, 8 and 15. • Primary outcome measure was progression or regression of local infection assessed by: ○ an 18-point scale based on presence and intensity of clinical signs (fever, local heat, persistent pain between dressing change, peri-lesion erythema, oedema, pus, exudate) ○ a blinded assessment my a microbiologist categorising wound as deteriorated, unchanged or improved based on bacteriological status • Additional outcomes on 5-point scale were usefulness and acceptance; ease of application and removal; reduction of malodour; reduction of persistent pain; improvement of the periwound skin; dressing comfort; cleansing effect; absorption properties; adherence to the wound.	Participants with PUs (direct evidence) • The study group (p=0.005) and the control group (p=0.008) both had statistically significant improvements in clinical infection scores between baseline and day 15 • There was no significant difference between the two groups on the clinical infection score at day 15 (3.3±3.1 study group versus 3.2±3.2 control group, p=ns) All participants (mixed aetiology, indirect evidence) • There was no significant difference between the two groups on the clinical infection score at day 15 (3.8±2.9 study group versus 3.8±3.4 control group, p=ns) • Results for the two microbiologists' assessments were not combined. Both microbiologists rated 45% of wounds tested with the study dressing and 27% of positive-control wounds as having improved in biological status (p=ns for both microbiologists) • There was no significant difference between groups for any of the items for acceptability and usefulness except for "adherence to wound for PUs", for which the study product showed greater per cent of good/excellent ratings (100% versus 38%, p=0.04) **Study conclusions: The results of this small study indicated that the test dressing appeared to improve the blindly rated bacteriological status of clinically infected wounds over 15 days, but there was no**	A priori calculation for sample size was established for the overall study i.e. the findings for PU participants were underpowered.	**Level of evidence: 2 (also some indirect evidence) Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		bone" • 79% graded ≥10 on Norton scale and 38% graded ≥ 15 on Norton scale		• Bacteriological status rated as deteriorated, unchanged or improved independently by 2 blinded microbiologists • Adverse events	**statistically significant difference from the positive control dressing performance.**		
(Robicsek, Beaumont et al., 2009)	Two retrospective cohort studies **investigating the impact of decolonization therapy on MRSA** **Study 1) evaluating the impact of decolonization therapy in patients who were carrying MRSA and were later readmitted** **Study 2) evaluating the impact of decolonization therapy in patients who were carrying MRSA but did not have clinical infection**	Participants were recruited within three acute care hospitals operated by an organization in the USA. For both studies, retrospective records analysis for all non-neonate patients admitted overnight in a one year period Nov 2006 to Dec 2007 and followed through to March 2008 Study 1) (n=407) Inclusion: • MRSA surveillance testing performed at time of admission • surveillance test or clinical culture performed within 2 days of admission was positive for MRSA • subsequent readmission in the study period Exclusion: • discharged after first admission with script for mupirocin or chlorhexadine Characteristics: • 69% ≥ 70 years of age • 91% admitted to internal medicine • 41% had diabetes mellitus Study 2) (n=933) Inclusion: • MRSA surveillance testing performed • no clinical culture indicative of MRSA within 30 days prior or 3	• Three hospitals with universal surveillance for MRSA colonized patient who could be treated with a 5-day course of nasal mupirocin calcium 2% twice daily plus chlorhexidine gluconate 4% every second day • MRSA carriers were later retested for colonization or followed up for development of an MRSA infection	• MRSA cultures reviewed by microbiology laboratory according to standardized criteria.	**Study 1)** • patients were readmitted for a mean of 76.5±77.2 days after first admission • There was significantly less rate of colonization at readmission in patients who received any dose of mupirocin compared with those who did not receive mupirocin (47.8% versus 63.2%, p=0.007) • In multivariate analysis, independent dependent risk factors for sustained colonization included having PU (OR 2.31, 95%CI 1.22 to 4.35, p=0.010) • Mupirocin at any dose decreased the risk colonization on readmission, particularly during the 30 to 60 day period after therapy (OR 0.48 to 0.56) **Study 2)** • patients were followed for a mean of 271.7±132 days after first admission • 7.4% participants developed MRSA infection during follow-up. • In multivariate analysis, having a PU was not a risk factor for developing a clinical infection. • Receipt of mupirocin did not affect the risk of infection, although there was a trend toward delayed infection among patients receiving mupirocin **Study conclusions: having a PU is an independent risk factor for MRSA colonization. Treatment of MRSA colonization with a mupirocin-based decolonization regimen leads to only a small reduction in colonization and does not reduce infection rate.**	• Nonrandomized treatment, with patients with a higher risk of infection more likely to receive treatment than those with low risk of infection • Participants who received mupirocin generally 92.4% also received chlorhexadine • Only performed routine nasal swab surveillance (no wound swabs)	**Indirect evidence: mixed infections Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		days after surveillance testing Exclusion: • discharged after first admission with script for mupirocin or chlorhexadine					
(Biglari, Vd Linden et al., 2012)	Observational case series **reporting on Medihoney® for stage III and IV PUs**	Participants were recruited from 9 trauma centres in Germany (n=20) Inclusion/exclusion: • SCI patients with chronic PUs • No other criteria reported Characteristics: • PUs were at least 12 weeks in duration at entry to study • 65% sample male • Mean age 48.7 years (range 30 to 79) • 5/20 had stage IV PU • 15/20 had stage III PU	• All of the participants were treated with Medihoney® approx. 3mm thickness applied once daily after cleansing with Ringer's solution • Surrounding skin was disinfected with a range of anti-microbial preparations • Treatment was continued for more than 6 weeks	• Weekly photographs, measurement and cultured (methods not reported) • PUs were documented at 3-week intervals	• After 1 week of therapy all swabs were void of bacterial growth • 90% of participants showed complete wound healing after 4 weeks • No negative effects were noted from the treatment	• Objective measurement strategy not reported • Peri-ulcer skin was treated with different antimicrobials that may have influenced culture findings • PU size and condition at entry not reported • Co-morbidity not reported	**Level of evidence: 5 Quality: low**
(Jull, Walker et al., 2013)	Cochrane review including one RCT (Weheida, Nagubib et al., 1991 honey in PUs	Participants were recruited in a hospital in Egypt (n=40) Inclusion: • Orthopaedic patients • Ulcers ≥ 2cm diameter • No baseline infection • Stage I and II PUs Exclusion: • Debilitant co-morbidity	• Participants were randomized to receive: ○ medical-grade honey (n=20) or ○ saline-soaked gauze (n=20) • All participants were restricted to bed or wheelchair for at least 2 weeks • All patients received treatment for 10 days	• Mean time to healing • Follow up 3 months	• Mean time to healing was faster with honey compared with saline-soaked gauze (mean 8.20±9.93 days versus 9.93±0.27 days)	• Methods of randomization, allocation concealment and blinding not stated • Unclear if there was drop outs or intention-to-treat analysis performed	**Level of evidence: 2 Quality: low**
Prevalence studies							
(James, Swogger et al., 2008)	Descriptive study reporting **prevalence of biofilm in acute and chronic wounds**	Participants were recruited from a wound care centre in USA. (n= 93 wound specimens) Inclusion: • ≥ 18 years • Requiring sharp wound debridement (chronic wounds) or consenting to wound biopsy	Wound specimens were obtained from chronic wounds during the debridement process and from acute wounds via wound biopsy	Presence of biofilms	• Significantly more chronic wounds (30/50) than acute wounds (1/16) were characterised via microscopy as containing biofilm (60% versus 0.6%, p<0.001) • Most common isolates in both chronic and acute wounds were: ○ *Staphylooccus* (65% chronic wounds, 60% acute wound) ○ *Enterococcus* (62% chronic wounds, 80%	Duration and previous treatment of wounds, including previous use of antibiotics, was not reported	**Indirect evidence: mixed wounds Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		(acute wounds) • Characteristics: • 77 subjects with chronic wounds including PUs, diabetic foot ulcers, venous leg ulcers and other (surgical site infections and traumatic wounds) • 16 subjects acute wounds including blisters and skin tears			acute wound) and ○ *Pseudomonas* (35% chronic wounds, 20% acute wounds) • **Study conclusions: Biofilms are prevalent in chronic wounds and rare in acute wounds**		
(Manzur, Gavalda et al., 2008)	Cross-sectional prevalence study **to determine the incidence of MRSA in PUs in long term care facilities**	Participants were recruited from nine long term care facilities with in Spain. Prevalence study was undertaken for all residents present on the day of the study (n=1377 participants) Characteristics: • Comorbidities included dementia (39.8%), diabetes mellitus (23.3%), chronic obstructive pulmonary disease (2315%), solid tumor (14.1%) and hemiplegia (12.3%) • primarily female sample (all facilities have >65% female) • mean age in facilities varied from 76.1 years to 83.9 years • Stay ≥ 6 months varied between facilities from 54.9% to 94.4% • Prior MRSA colonization ranged between facilities from 0 to 21.8% • Prior antibiotic therapy ranged between facilities from 10.3% to 44% • Use of invasive devices ranged between facilities from 0% to 27.6%	Nasal swabs (n=1337) and 82 decubitus ulcers swabs (n=82)	Microbiological screening for *S. aureus* showing methicillin resistance	• Prevalence of MRSA colonization was 16.8% (95% CI 14.9 to 18.8%) • Prevalence of MRSA colonization varied between facilities from 6.7% to 35.8% (p<0.001) • 59% of PUs were colonized with MRSA (63% of these participants also had a positive nasal swab) • Independent factors significantly associated with MRSA colonization: ○ age ≥85 years OR 1.56 (95% CI 1.13 to 2.19, p=0.009) ○ Having a PU OR 2.92 (95% CI 1.73 to 4.93, p<0.001) ○ Previously taking antibiotics OR 2.20 (95% CI 1.56 to 3.13, p<0.001) ○ Medical devices OR 3.05 (95% CI 1.56 to 5.97, p<0.001) • Stay ≥ 6 months was not significantly related to MRSA colonization • **Study conclusions: Prevalence of MRSA colonization in PUs in long term care in Spain was 59%**	• Only aged care setting in Spain, might not be generalizable • wide range of prevalence between different facilities	**Level of evidence: N/A Quality: low**
(Buck, Goucher et al., 2012)	A retrospective review study **investigating prevalence of MRSA in PUs**	Participants were from a consecutive sample encountered by a single surgeon in USA from 2007 to 2009 (n=56 patients with 115 PUs) Inclusion: • PU	Demographic data, medical records, culture and laboratory results, and operative details were recorded, and outcomes assessed.	The incidence of MRSA	• 4% of PUs had clinical signs of infection including cellulitis • Seven patients (13%) were positive for MRSA colonization. • Twelve PUs (10%) were positive for MRSA by sterile bedside wound culture • 102 (89%) PUs underwent operative debridement and /or bone biopsy.	• Unclear if the MRSA cases identified during surgery were the same cases as identified by bedside culture • One site study,	**Level of evidence: N/A Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Consulting plastic surgery regarding "wound infection" Characteristics: • 82% sample male • Mean age 41.8±14.2 yrs • average of 2.1PUs per patient • 89% participants had SCI • PUs primarily sacral or ischial • 90% of PUs were classified as stage IV (classification system not reported) • 96% participants had used antibiotics within prior 1 to 2 weeks and 29% were still actively taking antibiotic • 89% presented from a rehabilitation or long term care facility			Intraoperative culture results from these procedures were positive for organism growth in 45 (44%) cases (primarily polymicrobial) including 9 MRSA cases. • **Study conclusions: Rates of antibiotic use may contribute to the incidence of MRSA observed in this single-site study; however confounding factors were not addressed.**	may not be generalizable; however patients were commenced on antibiotic therapy prior to screening at this service. • Antibiotics commenced in the previous 2 weeks may have influenced the low rate of clinical signs of infection	
(Nery Silva Pirett, Braga et al., 2012)	Prevalence and prognostic retrospective cohort studies **investigating the prevalence of MRSA colonization in PUs and estimating the risk of MRSA-associated bacteraemia**	Participants were recruited over a 9 month period from a teaching hospital in Brazil for two concurrent cohort studies. Study a): determining the prevalence of MRSA in stage II or greater PUs Study b): in participants detected as having MRSA-colonzied PUs, estimating the risk of MRSA-bacteraemia Data was collected through medical record analysis (n=145). Inclusion: • Stage II or greater PU Characteristics: • 57.2% sample were male • Average age 612±18.4 yrs (range 20 to 101 yrs) • Mean hospital stay 69.6±66.7 days • primarily admitted due to clinical cause (60.1%); 4.1% admitted due to PU infection • 56.5% had used at least 2 classes	• Following cleansing, a sterile swab moistened with saline solution was rotated over a 1-cm square of granulation tissue with sufficient pressure to force fluid from the wound tissue • The swab was inoculated in Mannitol salt agar and the S. aureus strain was identified as coagulase-positive	• Estimate the prevalence of MRSA colonization • Identify risk factors for colonization of these wounds • Ascertain whether MRSA colonization of PU increases the risk of MRSA bacteremia	• Of the 145 PU participants, 63 (43.5%) had a MRSA colonized PU • 40 (27.6%) participants had presence of infected PU • 12 (8.3%) participants had MRSA bacteremia • There was no statistically significant association between age, gender, cause of admission, length of hospital stay, underlying disease, presence of invasive devices or surgical procedures and having a PU colonized with MRSA • Among the patients with positive blood cultures and MRSA colonized PU: ○ odds ratio for MRSA bacteremia was 19.0 (95% CI 2.4 to 151.1, p< 0.001) ○ odds ratio for bacteremia and mortality was 21.9 (95% CI 1.23 to 391.5, p=0.002) • Independent risk factors for MRSA bacteremia were: ○ ≥2 underlying diseases (OR 6.26, 95% CI 1.01 to 39.1, p=0.04) ○ prior MRSA infected PU (OR 12.75, 95% CI 1.22 to 132.9, p=0.03)	• Only hospitalized patients, lacks generalizability • Management of the condition and severity of the underlying illness was unavailable • Small sample size • Unclear the duration of PU at time of admission and the prior management techniques • May lack generalizability doe to location	**Level of evidence: 4 (prognostic)** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		of antibiotics in the past 30 days • 70.3% had at least 2 invasive devices (e.g. mechanical ventilation, IDC, CVC, gastric catheter, endotracheal catheter) • Overall mortality 42.1%					
(Cataldo, Bonura et al., 2011)	Prevalence study **investigating multidrug-resistant organisms (MDRO) in PUs**	Participants were recruited as a consecutive convenience sample of older adults enrolled in a home care service in Italy in a 3-month period in 2010 (n=32) Characteristics: • It appears that 100% of the patients enrolled in the service over a 3-month period had a PU of at least stage III. • 65.6% sample female • stage III or greater PU • aged 60 to 97 years • PUs ranging from 1 to 6 months duration (mean 3.6 months)	Samples for culture were obtained from stage III or greater PUs ulcers by swabbing sterile cotton-tipped applicator sticks	• Colonization as determined by swab and culture • Environmental cultures	• Risk factors for MDRO colonization: ○ 37.5% of participants were on antibiotic therapy ○ 37.5% of participants had taken antibiotic therapy in the preceding 90 days ○ 15.6% of participants had been admitted to hospital for ≥72 hours in the preceding 12 months • Prevalence of MDRO in PUs: ○ Vancomycin-resistant *Enterococcus* (VRE) was found in 1 patient (3%) ○ Methicillin-resistant *Staphylococcus aureus* (MRSA) was found in 5 patients (15%) ○ MDR gram-negative bacilli was identified in 53% patients • Environmental cultures identified 2 MRSA isolates and 8 MDR gram-negative bacilli isolates from bedroom furniture • **Study conclusions: the authors suggested that PUs in home care patients could play a role in bringing MDROs in to the community setting; however, there was no confirmation through screening caregivers and family members**	• Very small sample size from one service • Duration and severity of the PUs was heterogeneous • Treatment strategies were not reported beyond antibiotic use • Causation was not established	**Level of evidence: N/A Quality: low**
(Smith, Snow et al., 2010)	Comparative survey **reporting on the biodiversity of bacterial infection in PUs**	Samples from 49 PUs. Origin of PU samples was not reported.	• Samples were taken from PU wound bed via sharp debridement • Bacterial tag-encoded FLX amplicon pyro sequencing (bTEFAP), a universal bacterial identification method, was used to identify bacterial populations	• Bacteria classified at appropriate taxonomic levels using BLASTn derived sequence identity	• There was considerably large diversity of microflora in PUs(228 genera and 487 species over 49 PU samples) • Majority of organisms were most closely related to *Staphylococcus, Enterococcus, Serratia, Pseudomonas, Streptococcus* and *Corynbacterium* • Most PUs contained >10^5 bacteria per mg debridement • The diversity in bacteria in PUs negated global recommendations for targeting microburden in PUs. • **Study conclusions: PUs exhibit a diverse range of bacteria. As each PU is unique in the range of bioflora treatment of bioburden in PUs should be individualized.**	• Unclear from where patients were recruited, their clinical background or their previous treatment (particularly antimicrobial) although this data was collected • Although the researchers report that patient factors (e.g. gender) influence	**Level of evidence: N/A Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
						diversity of microflora these characteristics are not reported.	
(Dowd, Delton Hanson et al., 2011)	Retrospective study **investigating the prevalence and diversity of fungal and yeast infection in mixed wound types**	Record review of participants over a 4-month period with a chronic wound (n=609 participants, 915 specimens)	• Samples were obtained by sharp debridement as per standard care • Diagnosis using level I (finite panel of most commonly occurring bacteria and genetic antibiotic resistance factors in chronic wounds) and level II (comprehensive diagnostic list of bacteria and fungi with capability of >95% sequence identity) wound pathogen diagnostics	• Correlation analysis and ANOVA to determine if there were any significant relationships between bacterial and fungal genera and patient demographics	• Of the 915 clinical specimens, 208 (23%) were positive for fungal species • 11.05% of chronic wounds positive for fungal species were PUs (n=23) • The most abundant fungi were yeasts in the genus *Candida* • A notable bacterial/fungal negative correlation was found to be apparent between *Staphylococcus* and *Candida* • *Candida albicans* was the fungi most observed in PUs	• Single site study, potentially site-related factors were associated with the prevalence of fungal infection • Does not report the duration of wounds or previous management strategies (e.g. have these participants received treatment for wound colonization)	**Indirect evidence: mixed wounds Quality: moderate**
Diagnosis of osteomyelitis							
(De Heredia, Hauptfleisch et al., 2012; Hauptfleisch, Meagher et al., 2013; Luis, Hauptfleisch et al., 2012)	Retrospective record review diagnostic study **investigating inter-rater reliability of MRI scans for identifying osteomyelitis associated with PU**	Participant records from those attending a service in the UK between 2007 and 2011 (n= 37, n= 41 MRI scans) Inclusion: • Adult patients • Diagnosed with SCI • Indication of PU Characteristics: • Primarily male patients (70.2%) • Mean age 52 years (range 22 to 83yrs) • 70.2% of PUs were located in greater trochanter	Analysis of MRI examinations and clinical records collected over a four year period Images were independently assessed by two experiences radiologists for osteomyelitis	Inter-observer agreement for indicative MRI signs of osteomyelitis in complex PUs based on: • Muscle inflammatory change • Deep fluid collection • Corticol bone erosion • Bone marrow oedema • Hip effusion • Heterotopic ossification • Presence of sinus tract	• There was significant association between an intermediate and high probability of osteomyelitis and cortical bone erosion (sensitivity and specificity 90%, Pearson's *r*=0.84) • There was significant association between an intermediate and high probability of osteomyelitis and abnormal bone marrow oedema (sensitivity of 81%, Pearson's *r*=0.82) • There was an 88% agreement on likelihood of osteomyelitis (kappa 0.92, 95% CI 0.84 to 1.01, p<0.0001) • There was a lack of agreement on presence of sinus tract (possibly related to unclear definition of when a PU becomes a sinus) • **Study conclusions: there was strong inter-rater agreement in identification of MRI scan signs that may indicate osteomyelitis; however, no comparison was made to a reference standard (e.g. histological confirmation).**	• Retrospective nature of the study • Unclear sample selection • Lack of reference standard including histological confirmation • Raters were given access to the patient's full clinical file to assist in diagnosis	**Level of evidence: 5 (diagnostic) Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(Larson, Gilstrap et al., 2011)	Retrospective record review diagnostic study **investigating comparing the reliability of x-ray compared with bone biopsy for identifying osteomyelitis associated with PU**	Participant records were recruited from a department of plastic surgery in the USA between 2004 and 2008 (n=44) Inclusion: • Stage IV PU according to NPUAP classification as identified on billing information • Treated with surgical debridement • Bone culture performed after radiologic study of underlying bone • Multiple PUs analysed as separate PUs where at least 6 months passed between treatment Exclusion: • Lacking x-ray imaging or intraoperative bone culture • PU not treated with surgical debridement	• All included participants were treated with surgical debridement of stage IV PUs accompanied by a bone culture, after having prior radiographic imaging of the underlying bone were included • Participants were treated in a standard manner preoperatively, intraoperatively and postoperatively	• Abstracted data included: o location of ulcer o radiographic imaging obtained before operation o data and description of operation o results of intraoperative bone biopsy o antibiotic received before and after surgical intervention o follow-up • Radiographic studies were interpreted by a single musculoskeletal radiologist - who was blind to operative findings	• Sensitivity: percentage of cases with biopsy-proven osteomyelitis identified with imaging was 50% using a computed tomography (CT) scan and 88% using a plain film of the bony area of involvement (overall sensitivity of radiological studies was 61%) • Specificity: percentage of cases without osteomyelitis identified as not having the condition by imaging was 85% for CT scan and 32% for plain film (overall specificity of radiologic studies was 69%) • **Study conclusions: Preoperative radiologic studies for osteomyelitis in PU are far from definitive and might only be of value in defining the extent of disease for surgical planning purpose.**	• Small retrospective study • Radiologic studies may or may not have been performed due to indications for local osteomyelitis • Radiographic imaging done up to 3 months prior to bone cultures • None of the patients had the complete spectrum of radiologic studies	Level of evidence: 4 Quality: low
(Daniali, Keys et al., 2011)	Retrospective case-controlled study **comparing pre-operative management and post-operative outcomes between pre-operative MRI diagnosis of osteomyelitis and intra-operative bone biopsy**	Participants were recruited from a spinal cord center in the USA between 1996 and 2008 (n=65 had flap reconstruction had osteomyelitis and n=47 had either MRI or bone culture diagnosis). Characteristics: • Mean age 56.2 to 58.7 years • Primarily males with SCI • The preoperative MRI group had a greater percentage of participants with stable PUs of unchanging size win comparison to the bone culture group (46.2% versus 23.8%, p =0.04) • MRI group had a greater number of patients with a history of peripheral vascular disease (14.3% versus 0%, p=0.05)	• Data were collected from patient electronic medical records including operative reports, admit notes, daily progress notes and consult and weekly wound care team notes • Participants received either: o pre-operative MRI diagnosis of osteomyelitis (n=26) o post-operative bone culture diagnosis of osteomyelitis (n=21)	• Recurrence of PU at the same anatomic site • Suture line dehiscence • Significant suture line dehiscence and • Time until mobilization by physical therapy	• Patients with a diagnostic preoperative MRI did not differ significantly in rates of pre-operative antibiotic administration compared to those without pre-operative MRI (26.9% versus 23.8% OR 1.2, p=0.81) • There was no significant difference in PU recurrence rates post-surgery between those with osteomyelitis diagnosed by MRI had and those with osteomyelitis diagnosed by bone culture (39% versus 29%,OR 2.4, p=0.22) • There was no significant difference in infection rates post-surgery between those with osteomyelitis diagnosed by MRI had and those with osteomyelitis diagnosed by bone culture (7.7% versus 14.3%,OR 0.50, p=0.44) • **Study conclusions: the study concluded that there was no evidence that a preoperative MRI diagnosis of osteomyelitis significantly alters clinical or surgical management or patient outcomes**	● Retrospective chart review subject to Inaccuracies of data recording ● Study cohorts were small potentially limiting the study generalizability.	**Level of evidence: 5 (diagnostic) Quality: moderate**

References

Beele, H., F. Meuleneire, M. Nahuys, S. L. Percival. (2010). "A prospective randomised open label study to evaluate the potential of a new silver alginate /carboxymethylcellulose antimicrobial wound dressing to promote wound healing." International Wound Journal **7**(4): 262-70.

Biglari, B., P. H. Vd Linden, A. Simon, S. Aytac, H. J. Gerner, A. Moghaddam. (2012). "Use of Medihoney as a non-surgical therapy for chronic pressure ulcers in patients with spinal cord injury." Spinal Cord: The Official Journal Of The International Medical Society Of Paraplegia **50**(2): 165-9.

Buck, D. W., J. H. Goucher, J. V. L. Lewis. (2012). "The Incidence of Methicillin-Resistant Staphylococcus aureus in Pressure Ulcers." Advances in Skin & Wound Care **25**(11): 509-12.

Cataldo, M. C., C. Bonura, G. Caputo, A. Aleo, G. Rizzo, D. M. Geraci, et al. (2011). "Colonization of pressure ulcers by multidrug-resistant microorganisms in patients receiving home care." Scandinavian Journal of Infectious Diseases **43**(11-12): 947-52.

Daniali, L. N., K. Keys, D. Katz, D. W. Mathes. (2011). "Effect of preoperative magnetic resonance imaging diagnosis of osteomyelitis on the surgical management and outcomes of pressure ulcers." Annals of Plastic Surgery **67**(5): 520-5.

De Heredia, L., J. Hauptfleisch, R. Hughes, A. Graham, T. Meagher. (2012). "Magnetic resonance imaging of pressure sores in spinal cord injured patients: Accuracy in predicting osteomyelitis." Topics in Spinal Cord Injury Rehabilitation **18**(2): 146-8.

Dowd, S. E., J. Delton Hanson, E. Rees, R. D. Wolcott, A. M. Zischau, Y. Sun, et al. (2011). "Survey of fungi and yeast in polymicrobial infections in chronic wounds." Journal of Wound Care **20**(1): 40-7.

Hauptfleisch, J., T. M. Meagher, R. J. Hughes, J. P. Singh, A. Graham, L. Lopez de Heredia. (2013). "Interobserver Agreement of Magnetic Resonance Imaging Signs of Osteomyelitis in Pelvic Pressure Ulcers in Patients With Spinal Cord Injury." Archives of Physical Medicine and Rehabilitation.

James, G. A., E. Swogger, R. Wolcott, E. d. Pulcini, P. Secor, J. Sestrich, et al. (2008). "Biofilms in chronic wounds." Wound Repair and Regeneration: Official Publication of the Wound Healing Society [and] The European Tissue Repair Society **16**(1): 37-44.

Jull, A. B., N. Walker, S. Deshpande. (2013). "Honey as a topical treatment for wounds." Cochrane database of systematic reviews (Online) **2**: CD005083.

Larson, D. L., J. Gilstrap, K. Simonelic, G. F. Carrera. (2011). "Is there a simple, definitive, and cost-effective way to diagnose osteomyelitis in the pressure ulcer patient?" Plastic and Reconstructive Surgery **127**(2): 670-6.

Luis, J. Hauptfleisch, R. Hughes, A. Graham, T. M. M. Meagher. (2012). "Magnetic Resonance Imaging of Pressure Sores in Spinal Cord Injured Patients: Accuracy in Predicting Osteomyelitis." Topics in Spinal Cord Injury Rehabilitation **18**(2): 146-8.

Manzur, A., L. Gavalda, E. Ruiz de Gopegui, D. Mariscal, M. A. Dominguez, J. L. Perez, et al. (2008). "Prevalence of methicillin-resistant Staphylococcus aureus and factors associated with colonization among residents in community long-term-care facilities in Spain." Clinical Microbiology and Infection **14**(9): 867-72.

Nery Silva Pirett, C. C., I. A. Braga, R. M. Ribas, P. P. Gontijo Filho, A. D. Filho. (2012). "Pressure ulcers colonized by MRSA as a reservoir and risk for MRSA bacteremia in patients at a Brazilian university hospital." Wounds: A Compendium of Clinical Research & Practice **24**(3): 67-75.

Robicsek, A., J. L. Beaumont, R. B. Thomson, Jr., G. Govindarajan, L. R. Peterson. (2009). "Topical therapy for methicillin-resistant Staphylococcus aureus colonization: impact on infection risk." Infection Control and Hospital Epidemiology: The Official Journal of The Society of Hospital Epidemiologists of America **30**(7): 623-32.

Sipponen, A., J. J. Jokinen, P. Sipponen, A. Papp, S. Sarna, J. Lohi. (2008). "Beneficial effect of resin salve in treatment of severe pressure ulcers: a prospective, randomized and controlled multicentre trial." The British Journal of Dermatology **158**(5): 1055-62.

Smith, D. M., D. E. Snow, E. Rees, A. M. Zischkau, J. D. Hanson, R. D. Wolcott, et al. (2010). "Evaluation of the bacterial diversity of pressure ulcers using bTEFAP pyrosequencing." BMC Medical Genomics **3**(1): 41-.

Trial, C., H. Darbas, J. P. Lavigne, A. Sotto, G. Simoneau, Y. Tillet, et al. (2010). "Assessment of the antimicrobial effectiveness of a new silver alginate wound dressing: a RCT." Journal of Wound Care **19**(1): 20-6.

Wild, T., M. Bruckner, M. Payrich, C. Schwarz, T. Eberlein, A. Andriessen. (2012). "Eradication of methicillin-resistant Staphylococcus aureus in pressure ulcers comparing a polyhexanide-containing cellulose dressing with polyhexanide swabs in a prospective randomized study." Advances in Skin & Wound Care **25**(1): 17-22.

WOUND DRESSINGS FOR TREATMENT OF PRESSURE ULCERS

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(Kerihuel, 2010)	Open-label RCT **comparing activated charcoal dressing without silver with hydrocolloid dressing for managing chronic PUs**	Participants were recruited from 6 hospitals and outpatient departments in N = 120 (60 in each study) Inclusion: • PU area from 5 to 100cm^2 • PU <3 months duration • PU grade IIc to IV on Yarkoni classification scale (i.e. full thickness but not extending to bone) • considered by assessors to have ≥50% necrotic/slough wound surface area Exclusion: • unable to consent in writing • severe illness • PU requiring surgical debridement or 100% coverage with necrotic tissue • requiring systemic antibiotics • previous use of investigation product • allergy to investigation products Characteristics: • Baseline patient demographic and PU characteristics comparable between groups • Mean age 78.5±16.5 (control) and 83.2±13.2 (treatment) • Primarily heel PUs (66% to 76%) • 50% >1 month duration, 10 to 13% > 3 months duration • 13.3% necrotic tissue (control) and 17.2% necrotic tissue (treatment)	• All participants received standard PU prevention including repositioning and use of pressure-redistribution surfaces • All PUs received sharp debridement at study commencement • Participants were randomly assigned to received either: ○ saline cleanse and activated charcoal dressing (Actisorb®) impregnated with saline, covered with gauze and secured with non-compression bandage and changed 2 to 3 times weekly (n=29) ○ Hydrocolloid dressing (Duoderm®) impregnated with saline and managed the same as the study treatment (n=30)	Wounds were assessed at weekly intervals using photography and wound tracings with follow-up was at 4 weeks Outcome measures: • reduction in wound area • relative reduction in wound area compared to baseline • percentage reduction of debrided tissue	• 23.7% participants withdrew, equivalent between groups • Differences in reduction in mean wound surface area at week one favoured the treatment group (–2.5cm^2 versus 0, p=0.255) but were not significant. • Differences in percentage reduction in wound size compared to baseline were not significant between groups • More participants in the control group reported local adverse events (6.9% versus 23.3%) • **Study conclusions: There was no significant difference in healing between PUs treated with an activated charcoal dressing compared with a hydrocolloid dressing over 4 weeks.**	• The statistical tests used (Mann Whitney) were not appropriate to adjust for institution/ site (multivariate analysis) • No a priori power calculation, small sample size, no blinding of analysis • Products do not perform the same function in wound management so comparison is questionable	**Level of evidence: 2** **Quality: low**
(Davis, Johannigman et al., 2001)	Case series study **investigating a glucose oxidase dressing**	Participants were recruited from 27 wound clinics in multiple European countries (n=100, n=13 with PU, 8/13 withdrew but results were reported) Inclusion:	• The test dressing was applied directly to the cleansed wound in accordance with the manufacturer's instruction • Dressing change	• Measurements (size, depth) derived from digital photographs • Condition of wound margins • Condition of wound bed	• 8/13 participants with PU withdrew from the study prior to 6 week conclusion. Reasons for withdrawal were: ○ 2/8 infection requiring removal from study	• Lack of a control group • Differences in 'best practice' procedures at the various clinics • Inter-clinician	**Level of evidence: 5** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Aged ≥ 18 years • Non-cavity chronic hard-to-heal wound with a static or deteriorating condition in the previous 4 weeks Exclusion: • Wound infection based on clinical signs • Sensitivity to iodine • Thyroid disorders • Pregnancy/breast feeding • Taking lithium • Characteristics of PU participants: • Mean age 73.4years (range 52 to 93) • All participants had PU stage III to IV (EPUAP grading) • Mean PU duration 12 months (range 3 to 24 months)	frequency was based on the wound status and local practice • The dressing was used for the duration of 6 weeks	and peri-wound skin • Exudate type and amount • Patient-rated satisfaction with the test dressing	○ 3/8 maceration or increase in PU size ○ 2/8 not-related to dressing ○ 1/8 undisclosed reason relating to dressing • Mean percentage in wound area reduction over 6 weeks was 13.1% for PUs • 9 PUs improved in condition, 3 remained static and 1 deteriorated (note that these results do not match the reasons for withdrawal which imply at least 5/8 PUs had a deteriorated condition) • **Conclusions: the glucose oxidase dressing was associated with complications requiring its cessation in more than half the patients, including development of PU infection and increase in PU size.**	variability in the wound assessments many were subjective • High drop out rate, 38% of the entire population and 62% of participants with PU	
(Parish, Dryjski et al., 2008)	Prospective non-comparative quasi-experiment **investigating an ahesive gelling foam wound dressing (GFD-A) for promoting PU healing**	Participants were recruited from 6 US centres and 1 Canadian centre (n=23, n=16 completed 28 days) Inclusion: • Stage II PU ≥2 cm^2 or stage II or IV PU Exclusion: • Stage I PU • Stage II PU < 2cm^2 or stage II PU of size greater than 11.6cm x 15.5cm (maximum dimensions of dressing product Characteristics: • Co-morbidities not reported • Mean age 57.6±20.8 years (range 18 to 97) • 61% sample males • Mean PU duration 1.0±1.8 years (range 0 to 8) • Mean PU size 10.6±16.4cm2 (range 0.8 to 62.5) • Mean PU depth 5.7±8.8mm (range	• All participants used appropriate pressure relieving devices • Wounds were debrided using the sharp method and cleansed at commencement of study. • All participants' PU's were treated with: ○ An adhesive gelling foam wound dressing (AQUACEL® Hydrofiber) in either a ribbon or dressing size. • Concurrent skin barrier creams and securing aids/bandages varied according to clinician preference. • Dressing changes were done at least once every 7 days.	• Primary outcome was safety • Secondary outcomes: ○ Exudate management assessed as excellent, good, fair or poor ○ Pain and comfort assessed using 11-point visual analog scale ○ Clinical improvement assessed as ulcer condition, appearance and depth (photography, acetate tracings and cotton bud depth) • Subjects were followed until healing or up to 28 days or patient withdrawal.	• The hydrofiber dressing was primarily used as a wound filler (50% of all dressing changes) although this is not its primary intended use. • 30% (n=7) participants experienced adverse events related to dressing including clinical infection (n=1), wound enlargement (n=1), erythema (n=1), dressing-related maceration (n=3) and blister (n=1) • At final visit or 28 days, PU were described as: Healed (4%) Marked improvement (30%) Mild improvement (26%) No change 26% Mild deterioration 4% Marker deterioration (9%) • Between baseline and final visit there was no significant difference in mean per cent of PUs described as epithelium (p=0.14) slough (p=0.089) or fibrin (p=0.145) and there was a significant decrease in mean per cent of ulcer bed with granulation (p=0.01)	• Small sample; high attrition rate. • >20% non-response on subjective measures of dressing performance by participants • Supported by a grant from company supplying product	**Level of evidence: 5** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		0 to 40) • 305 sacral, 22% heel, 4% ischial, 4%trochanter, 39% other location • Exudate: 52% moderate, 39% minimal, 9% heavy • 9% clinically infected			• 65% of participants had peri-skin described as healed, mild improvement or marked improvement; 22% had no change in surrounding skin, 13% had deteriorated condition of surrounding skin. • The dressing was described as comfortable (80% participants), soothing (64%) and cushioning (70%)		
(Kordestani, Shahrezaee et al., 2008)	Randomized controlled trial **comparing wound healing rates between a bioactive dressing and gauze.**	Participants were recruited from 5 major teaching hospitals in Iran (n= 85 participants with 98 wounds, 51 participants with 60 wounds completed the study and included in analysis) Inclusion: • wound regardless of etiology, size or depth Exclusion: • Pregnancy • addiction to alcohol, narcotics or tobacco • Immunocompromising conditions Characteristics: • Co-morbidities not reported • Mixed aetiology wounds, approximately 50% PUs in both groups • mean age 43.42±5.08 years • Mean wound length 14.13±2.3cm • Mean wound width 8.24±1.92cm • Mean wound duration 21.5±6.2 days	• Wounds debrided at commencement as required. • No concurrent use of pressure relief products or offloading . • All wounds irrigated with normal saline and treated for 21 days with either: ○ Study group: a bioactive advanced wound dressing containing chitosan (derived from sea crustacean) and polysaccharide alginate that was available in various forms including transparent film, gel, impregnated pads and a powder. Dressings were changed every 2 to 4 days. (n=33 randomized, n=32 completed and analysed, of these 16 were PUs) ○ Control group: covered with gauze secured with a bandage and adhesive tape. (n=52 randomized, n=22 completed and analysed of these 12 were PUs)	Recorded at every dressing change: • Wound size by photography and planimetry • Stage (where appropriate) using NPUAP staging classification • Presence of infection using wound swab and culture for wounds showing clinical signs of infection Follow-up: 3 month post-treatment	At 21 days, there was significantly greater number of PUs that achieved complete healing (68.75% versus 25%, p<0.05) Control group PUs • 4 PUs healed (3 stage I and one stage II) • 8 PUs deteriorated in condition by day 21 based on NPUAP staging • 75% of wounds required antibiotic therapy for clinical infection • 3 month follow up findings are not reported Treatment group PUs • 11/16 PUs healed completed • 2 stage IV PUs “reduced slightly in size” • All PUs were healed by 3 month follow up • 0% wounds required antibiotics • Remaining 5 wounds healed during follow-up	• 1200 participants were screened for inclusion but 1115 did not meet criteria or did not consent • High dropout (>30%) that was not equivalent between groups (3% in study group, 57.6% in control) • Unclear of stage of PUs was equivalent between groups • Poor randomization and blinding methods, no intention-to-treat analysis, unclear comparability of results between sites • Long follow up (3 months) after short treatment period (21 days) • Control group received only gauze dressings • Although it was a double blind study, some participants already observed that the bioactive dressing benefits them prior to the entry of study.	**Level of evidence: 2** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(Chuangsuwanich, Charnsanti et al., 2011)	Prospective randomized clinical trial **comparing a silver dressing to silver sulfadiazine cream**	Participants were recruited from an in and outpatient clinic in Thailand (n=40) Inclusion: PU stage III or IV Characteristics: • Mean age 62.6 to 69.1 years • No significant difference for blood results at baseline, including albumin levels <3.5 in both groups suggesting possible malnutrition • SSD cream group had significantly larger PU at commencement of study (12.17 versus 22.82cm^2)	• All PUs were debrided if required. • Participants were randomly assigned to receive: ○ wound beds covered with silver sulfadiazine (SSD) cream applied daily (n=20) ○ silver mesh dressings applied every 3 days (n=20) • Treatment was for 8 weeks	Data collected at the beginning of the study and every two weeks thereafter: • Wound size (planimetry) • Wound photography • PUSH score • Bacterial wound culture Study period was eight weeks for each participant	• Silver mesh dressing was superior to SSD cream for reduction in wound area at 8 weeks (18.22 versus 7.96 and cm², p=0.093) • There was no significant difference between groups for PU healing rate after 8 weeks (36.95% in the mesh group and 25.06% in the SSD group, p=0.507) • The means of PUSH score were 11.4 (mesh) and 13.4 (SSD cream) at commencement and 7.55 (mesh) and 9.6 (SSD cream) after 8 weeks. • **Study conclusions: considering the significant difference in wound size at commencement of this study, there appears to be no significant difference between a silver dressing and topical SSD cream for healing in PU. There is no placebo group to assess the overall benefit of silver in managing PUs.**	• Small trial, no power study • No placebo control • No blinding • Groups not comparable at baseline • Unclear treatment (e.g. dressing applied over SSD cream?) • Non comparable management (dressing changes at different frequency) • Unclear co-morbidities	**Level of evidence: 2 Quality: low**
(Trial, Darbas et al., 2010)	prospective RCT **comparing anti-microbial effectiveness of an ionic silver alginate dressing to a silver-free alginate dressing**	Participants were recruited over 18 months from a wound clinic and inpatient service at a hospital in France (n=42, n=24 with PU) Inclusion: • One or more symptoms of local infection including local heat, peri-wound erythema, persistent pain, oedema, malodour, fever, pus and heavy exudate. Exclusion: • Allergy to dressing components • Burn patients • Ulcers associated with infectious disease • Taking anticoagulants • < 18 years or over 80 years Characteristics of PU participants: • Mean age of females 80.9±9.0 and	• Participants were randomly assigned to receive either: ○ Study product: An ionic silver alginate matrix dressing that is described as providing controlled, sustained delivery of silver ions over 72 hours (Askina® Calgitrol® Ag; n = 20, n=11 with PU) ○ Active control product: A standard alginate dressing (Algosteril® ; n = 22, n=13 with PU) • Treatment was for 15 days. • Concurrent management strategies were not reported	• Assessments on days 1, 8 and 15. • Primary outcome measure was progression or regression of local infection assessed by: ○ an 18-point scale based on presence and intensity of clinical signs (fever, local heat, persistent pain between dressing change, peri-lesion erythema, oedema, pus, exudate) ○ a blinded assessment my a microbiologist categorising wound as deteriorated, unchanged or improved based on bacteriological status • Additional outcomes on 5-point scale were usefulness and	Participants with PUs • The study group (p=0.005) and the control group (p=0.008) both had statistically significant improvements in clinical infection scores between baseline and day 15 • There was no significant difference between the two groups on the clinical infection score at day 15 (3.3±3.1 study group versus 3.2±3.2 control group, p=ns) All participants (mixed aetiology, indirect evidence) • There was no significant difference between the two groups on the clinical infection score at day 15 (3.8±2.9 study group versus 3.8±3.4 control group, p=ns) • There was no significant difference between groups for any of the items for acceptability and usefulness except for "adherence to wound for PUs", for which the study product showed	A priori calculation for sample size was established for the overall study i.e. the findings for PU participants were underpowered.	**Level of evidence: 2 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		mean age of men 65.5±17.7 • NS between baseline mean clinical infection score (8.7±2.8 treatment group versus 7.9±3.6 control group) • 63% sacral PUs • 46% of PUs were described as having "superficial tissue damage with pus exuding blisters", 33% had "tissue damage not extending to the bone" • 79% graded ≥10 on Norton scale and 38% graded ≥ 15 on Norton scale		acceptance; ease of application and removal; reduction of malodour; reduction of persistent pain; improvement of the periwound skin; dressing comfort; cleansing effect; absorption properties; adherence to the wound. • Adverse events	greater per cent of good/excellent ratings (100% versus 38%, p=0.04)		
(Wild, Bruckner et al., 2012)	Prospective RCT **comparing PHMB swabbing to a cellulose dressing impregnated with polyhexa-methylene biguanide (PHMB) in eradicating MRSA from PUs**	Participants were recruited from in and out patients clinics in Switzerland (n= 30) Inclusion: • MRSA contaminated PU stages II to IV according to EPUAP classification • PU with MRSA colonization that has been unresponsive to several disinfection attempts during a 2-week wash out period Characteristics: • Groups comparable at baseline • 50% sample female • Mean age 66.5 to 70.9 years • Mean wound area study group 47.67±22.75cm2 and control group 35.80±13.47cm2 • In both groups 7/15 PUs were stage IV sacral PUs	• Participants were randomly assigned to: ○ Control group: cleansing performed with PHMB swabs for 20 minutes after which a foam dressing was applied (n=15) ○ Study group: cleansed with normal saline and received a PHMB impregnated cellulose dressing with the foam dressing applied as a secondary dressing (n=15) • In both groups, zinc cream was applied to peri-wound skin and dressings were changed second daily for 14 days	Primary outcome was MRSA eradication assessed on days 7, 14 and for 3 consecutive days after the treatment period via wound swab and culture Secondary outcome was per cent of non-vital and granulation tissue assessed via wounds photography and planimetry performed weekly	MRSA eradication • At day 7 more PUs in the study group had been eradicated of MRSA 40% versus 86.67%) • At day 14 significantly more PUs in the study group had been eradicated of MRSA 66.67% versus100%, p<0.05)	• Outcomes for formation of granulation tissue were not reported in detail • Results for sustained eradication on days 14 to 17 not reported	**Level of evidence: 2 Quality: moderate**
(Beele, Meuleneire et al., 2010)	Prospective RCT **comparing a silver alginate dressing to silver-free alginate dressing**	Participants were recruited from three centres in Belgium and the Netherlands (n=36 participants, of which n=12 had PUs) Inclusion: • aged over 18 years • chronic wound suitable for treatment (i.e. of size no more than 2cm x 20cm for PUs)	Participants were randomized to receive either: • Study group: an ionic silver alginate/ carboxymethylcellulose (SACMC) dressing • control group: a non-sliver calcium alginate fiber (AF) dressing	The primary study endpoints were: • Prevention of infection (assessed as progress of wound to or away from infection based on mASEPSIS score for wound pain, presence of erythema, edema, warmth, moderate to	Wound healing • There was a statistically significant difference in the overall wound surface area reduction over time for the treatment wounds (p=0.017) • There was no significant difference at 4 weeks in change in mean surface area from baseline between the two groups (+4.5cm2 control group versus –2.4cm2 study group, p=ns)	• sensitive to different definitions of critical colonization • low sample size	**Indirect evidence (mixed aetiology) Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• at risk of infection assessed as having at least two characteristics on mASEPSIS tool Exclusion: • target wound showing general or systemic infection based on clinical signs • requiring or already taking systemic antibiotics • known condition or physical/medical state affecting wound healing • systemic corticosteroids, immunosuppressants, radiation or chemotherapy • poor life expectancy Characteristics: • mean age 73.4 to 73.5 years • mean BMI 27.1 to 30.5 • difference in baseline mean wound surface area 20.1cm^2 for study group and 14.2cm^2 for control group • difference in wound duration 15.5 months for study group and 10.2 months	Treatment continued for up to 4 weeks. Concurrent treatments not reported.	heavy exudate, slough, discolored granulation, pocketing at wound base, malodor, necrosis) • Progression to wound healing based on wound surface area The efficacy was evaluated over a 4-week period	Prevention of infection • The study dressing was associated with a significantly greater reduction in signs/symptoms associated with infection as rated by mASEPSIS score than the control group (p=0.013) • over the 4-week follow-up period one adverse event (wound maceration) was reported in the study group and five were reported in the control group (two cases of wound infection, one serious sticking of dressing, on rehospitalization for further wound care).		
(Mizokami, Murasawa et al., 2012)	Retrospective **observational study comparing iodoform gauze to povidone-iodine and sugar or sulfadiazine cream** (only data from clinical study is summarised)	Retrospective records analysis of participants with PU treated at geriatric centre in Japan between 2008 and 2010 (n=53 participants with 60 PUs) Inclusion: • All participants with PUs were systematically recorded during a 2-year period and included in the study Characteristics: • Mean age approx. 80 yrs • Participants treated with iodoform gauze had significantly lower albumin (2.8±0.5g/dL versus 3.2±0.6 g/dL, p<0.007)	There was no indication as to how treatment was selected for each participant. Participants were treated with either: • iodoform gauze was applied with a polyurethane top-dressing • The conventional treatment used as a comparison was either silver sulfadiazine cream or povidone-iodine and sugar	Primary outcome was wound-cleaning capacity determined by the % of wound surface area covered in necrotic tissue. The area of necrotic tissue was blindly determined using digitalized images.	• Treatment period was significantly shorter for participants who were treated with iodoform gauze (14.1±9.7 versus 29.0±24.5, p=0.002) • There was significantly greater PUs treated with iodoform gauze classified as having necrotic tissue completely removed after 2 weeks of treatment compared to conventional treatments (60% versus 10%, p<0.001) • By 4 weeks, 80% of PUs treated with iodoform gauze had necrotic tissue completed removed (versus 30%, p<0.001) • **Study conclusion: Iodoform gauze is effective in preparing the PU wound bed for healing, but there is no evidence from this study that this leads**	• Indirect evidence: no relationship between debridement and wound healing outcomes was presented • No randomization, pre-defined outcome measures or clear participant selection • Non-equivalent participants at baseline • Various comparison treatments • Concurrent management strategies not	**Indirect evidence** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Participants treated with iodoform gauze had significantly larger wound surface area (17.6±19.6cm^2 versus 7.7±8.2cm^2, p=0.004) • Participants treated with iodoform gauze had more PUs stage IV (83.3% versus 57%, p=0.009)			**to complete healing or faster healing**	reported	

References

Beele, H., F. Meuleneire, M. Nahuys, S. L. Percival. (2010). "A prospective randomised open label study to evaluate the potential of a new silver alginate/carboxymethylcellulose antimicrobial wound dressing to promote wound healing." International Wound Journal **7**(4): 262-70.

Chuangsuwanich, A., O. Charnsanti, V. Lohsiriwat, C. Kangwanpoom, N. Thong-In. (2011). "The efficacy of silver mesh dressing compared with silver sulfadiazine cream for the treatment of pressure ulcers." Journal of the Medical Association of Thailand **94**(5): 559-65.

Davis, K., Jr., J. A. Johannigman, R. S. Campbell, A. Marraccini, F. A. Luchette, S. B. Frame, et al. (2001). "The acute effects of body position strategies and respiratory therapy in paralyzed patients with acute lung injury." Critical Care (London, England) **5**(2): 81-7.

Kerihuel, J. C. (2010). "Effect of activated charcoal dressings on healing outcomes of chronic wounds." Journal of Wound Care **19**(5): 208.

Kordestani, S., M. Shahrezaee, M. N. Tahmasebi, H. Hajimahmodi, D. H. Ghasemali, M. S. Abyaneh. (2008). "A randomised controlled trial on the effectiveness of an advanced wound dressing used in Iran." Journal of Wound Care **17**(7): 323-7.

Mizokami, F., Y. Murasawa, K. Furuta, Z. Isogai. (2012). "Iodoform gauze removes necrotic tissue from pressure ulcer wounds by fibrinolytic activity." Biol Pharm Bull **35**(7): 1048-53.

Parish, L. C., M. Dryjski, S. Cadden. (2008). "Prospective clinical study of a new adhesive gelling foam dressing in pressure ulcers." International Wound Journal **5**(1): 60-7.

Trial, C., H. Darbas, J. P. Lavigne, A. Sotto, G. Simoneau, Y. Tillet, et al. (2010). "Assessment of the antimicrobial effectiveness of a new silver alginate wound dressing: a RCT." Journal of Wound Care **19**(1): 20-6.

Wild, T., M. Bruckner, M. Payrich, C. Schwarz, T. Eberlein, A. Andriessen. (2012). "Eradication of methicillin-resistant Staphylococcus aureus in pressure ulcers comparing a polyhexanide-containing cellulose dressing with polyhexanide swabs in a prospective randomized study." Advances in Skin & Wound Care **25**(1): 17-22.

BIOLOGICAL DRESSINGS AND GROWTH FACTORS

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Biological dressings							
(Caravaggi, Grigoletto et al., 2011)	Multicentre, prospective, observational study **investigating a hyaluronic acid matrix dermal substitute for development of healthy dermal tissue at wound edges**	Participants were recruited from 70 Italian centers (n=262) I Inclusion: • chronic wound • undergone conventional treatment for at least 2 months previously that proved ineffective • medication known to interfere with healing were not excluded Exclusion: • signs of infection Characteristics: • Mean age 70 years (range 53 to 103) • 46% wounds were vascular, 25% diabetic foot ulcers, 12% trauma wounds, 2% PUs (i.e. 5 PUs) • 25% wounds were >50cm^2, 30% of PUs were >50cm^2 • 31% wounds were <15cm^2, 35% PUs were <15cm^2 • 64% of wounds were partial thickness not involving tendons or joints	• Standard wound bed preparation including debridement of necrotic, non-vital tissue and hemostasis. • Hyalomatrix PA® (HPA), a non-woven pad of hyaluronic acid derivative coupled and a layer of medical grade silicone, was applied directly to the clean ulcer. • A non-adherent dressing was placed in contact with the HPA as a secondary dressing and left undisturbed for at least 1 week • Participants with peripheral vascular disease underwent revascularization. • Offloading was recommended for patients with neuropathic planter foot ulcer	• Epithelial (edge) advancement of 10% • Secondary outcome was pain assessment • Weekly follow up and at 60 days	• Re-epithelialization of 10% was achieved in 217 (83%) of the ulcers in a mean time of 16 days • The endpoint of at least 10% or re-epithelialization within 60 days of follow-up was observed in 88% of patients affected by ulcers with onset ≤1year, while the same end point was achieved by 73% of patients affected by ulcers with onset >1 year ($p<0.05$) • 26% of wounds achieved at least 75% re-epithelialization within 60 days of the follow up period after treatment with HPA only • Pain intensity was reduced almost 3-fold within 30 days after the initial treatment with HPA	• The study was not randomized or controlled • Unclear if participants with PVD underwent revascularization before or during treatment in accordance with criteria established by Inter-Society for the Management of Peripheral Vascular Disease (TASD II)	**Indirect evidence: wounds of mixed aetiology Quality: low**
(Piatkowski, Ulrich et al., 2012)	Prospective, randomized, controlled pilot study investigating **effectiveness of a collagen dressings for healing Category III ulcers**	Participants were recruited from a plastic surgery department in Germany (n=10) Inclusion: • Stagnating PU of at least 4 weeks' duration • Wound had to be granulating and had to be free of necrotic tissue and slough • No clinical signs of infection Characteristics:	• Patients were randomized to receive either: ○ foam dressing as a primary dressing (n=5) or ○ combination of a collagen dressing covered with the same foam dressing (n=5) • Dressing changes were performed every second day • All participants had foam mattress and 3 hour repositioning	**Primary outcome** • Level and expression of matrix metalloproteinases (MMPs) MMP-2 and MMP-9 and tissue inhibitors of metalloproteinases (TIMPs) TIMP-1 and TIMP-2, elastase and angiogenesis • Wound fluid was collected and evaluated prior to treatment (day 0) and on days 3, 7, 14 and 21 (study end) **Secondary Outcomes** • Time to ulcer healing and	• On day 3 collagen dressing was associated with significantly decreased MMP-2 levels by compared with foam dressing ($p<0.05$) but by day 14 collagen group had higher MMP-2 levels than foam group. • MMP-9 concentrations showed a faster and higher reduction in collagen group compared to foam group and the difference was significant by day 7 ($p<0.04$) • In the collagen group TIMP-1 and	• Small number of patients in pilot study resulted in the study lacking power • No blinding • 2/5 patients withdrew in collagen foam group due to early healing but included in analysis	**Level of evidence: 2 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Mean age 63±0.62 in foam group and in 67±0.62 collagen foam group • 60% sample diabetes in both groups • All ulcers category III • Mean ulcer diameter 8.3cm in foam group and 11.4cm in collagen foam group		reduction in ulcer area measured with digital photography, wound tracings and planimetry • Safety of treatment • Patient-reported ulcer pain • Comfort of the dressing regimen	TIMP-2 increased faster and levels were higher than in group A. • Collagen dressing was associated with a significant positive effect on angiogenesis compared with foam group ($p<0.05$) • On day 14, 40% of the ulcers (n=2) in collagen group had healed compared to 0% in foam group • On day 21, all 100% of the ulcers healed in collagen group compared to 80% (4/5) of foam group.		
(Karr, 2008)	Case series reporting **the benefits of a living bilayered cell therapy**	Recruitment of participants is not reported (n=10) Characteristics: • Age range 39yrs to 78yrs 80% were diabetic foot ulcers , 20% venous ulcers • All ulcers located on heels • Ulcers ranged in size from 1.0cm^2 to 18.0cm^2 • 20% participants had osteomyelitis • Ulcer duration prior to treatment was a mean of 161.3 days	• All ulcers were debrided then treated with: ○ Apligraf®, a living bilayered cell therapy. ○ 60% of participants had only one application ○ For 40% with > one application, minimum time between applications was 4 weeks. • All participants had pressure offloading.	Days to closure – standardised wound assessment is not reported	• Average days to complete healing was 44 days (range 13 to 80 days) • Average days to complete healing in participants without osteomyelitis (20% sample) was 49.5 days • Average days to complete healing in participants with osteomyelitis (80% sample) was 44 days • Average days to complete healing in non-smokers (80% sample) was 39.9 days • Average days to complete healing in smokers (20% sample) was 60.5 days	• No randomization, blinding or control • Small sample size • Selection criteria is not reported	**Indirect evidence: wounds of mixed aetiology** **Quality: low**
Growth factors							
(Ohura, Nakajo et al., 2011)	Case-control study **investigating fibroblast growth factor for PU healing**	Participants were recruited from 14 institutions in Japan (n=29 pairs were enrolled , 23 pairs were analysed) Participants were paired for PU risk factors, levels of PU care and total scores on Pressure Ulcer Healing Process-Ohura (PUHP-Ohura) Inclusion: • Level B or C on Standard of Functional Independence Measure (Japanese Ministry of Health, Labor and Welfare • coding)	• All study matched pairs had equivalent alternating pressure-relief air mattress and regular repositioning 2 to 3 hourly • Surgical debridement was carried out at least 7 days prior to study period For all participants: • PUs were washed with saline solution • Foam and hydrocellular dressings were used in combination with polyurethane films for all dressings.	Wound condition changes assessed weekly for 8 weeks using PUHP-Ohura and photographs. Validation and reliability of this scale is not reported. The scale included assessment of: • Exudate volume • Necrotic tissue • Ulcer depth • Granulation formation • Wound edge • Epithelialization • Undermining • Surface area of the ulcer • Total score of PUHP-Ohura	• bFGF group showed a significantly greater decrease in exudate volume compared with control group after 4 weeks of treatment ($p<0.001$) • The bFGF group showed significantly greater decrease in ulcer depth score compared with control group on and after week 5 of the treatment ($p< 0.001$) • The change in granulation formation in group x time was not significant ($p=0.858$) and the main effects were significant ($p=0.019$) • Change in wound edge the group x time interaction was not significant ($p=0.495$) and the main effects of the group and time were significant	• Small study • Participant characteristics are not reported • Non validated assessment tool • No randomization or blinding of assessors or statisticians is reported • No confidence intervals reported	**Level of evidence: 3** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• PU Category III or IV (NPUAP classification) • Stayed in hospital for "a long time" and rejected surgical management Exclusion: • signs of infection Characteristics: • not reported	For the study group (bFGF group): • Basic fibroblast growth factor (bFGF) spray was sprayed on the wound daily (at a dose of 1μg/cm^2) prior to applying dressing. • Study period was 8 weeks		(p=0.017) • Change in epithelialization the group x time interaction was significant ($p < 0.001$); the bFGF group showed a significantly greater decrease in epithelialization compared with control group at and after week 3 of the treatment ($p<0.001$) • Total score PUHP-Ohura the group x time interaction was significant ($p<0.001$) the bFGF group showed significantly greater decrease in total PUHP-Ohura score compared with the control group at and after week 4 of treatment ($p<0.006$)		
(Sarasúa, López et al., 2011)	Report of preliminary data on **bone marrow mononuclear cells infusion for healing PUs**	Participants with SCI were recruited in Spain (n=22) Inclusion: • SCI • PU not responded to 4 months topical treatment • PU size 5 to 6 cms • Free from necrotic tissue and local infection • Medical condition compatible with surgery Characteristics: • Mean age 56.4 yrs (range 29 to 79) • Stage IV PUs: ischial (4), sacral-ischial (3) ischial-trchanter (1), plantar (1). • 13/22 participants had • Had undergone prior surgery on PU and antibiotic treatment	All PUs were surgically debrided and treated with bone marrow mononuclear cells (BM-MNCs) in the OR Participants were required to lie prone for 3 weeks following surgery 5/22 participants received a second infusion	• Healing rate • Mean follow up was 19 months (range 7 to 38 months) • Follow-up sessions were conducted at 1, 3, 6 months and 1 year after cell therapy	• 5/22 participants experienced suture dehiscence and required a second surgical procedure • In 17 participants the PUs fully healed after a mean time of 21 days	• The variation among the 27 extracts in the number of isolated MNCs that was patient dependent • Small sample size • No control group, no randomization, no standard assessment methods • Unclear how participants were selected	**Level of evidence: 5 Quality: low**
(Scevola, Nicoletti et al., 2010)	Prospective randomized controlled open clinical pilot trial investigating **effectiveness of allogenic platelet gel**	Participants with SCI were recruited from a neuro-rehabilitation ward in Italy (n=13 with 16 PUs) Inclusion: • SCI • grade III and IV PUs • no signs of necrosis or infection nutritional status stable	• All patients used pressure-relieving devices followed their 2 hour postural change protocol • PUs were randomized to be either: ○ study group receiving allogenic platelet gel applied directly to	• Every two weeks the ulcer dimensions, colour and bleeding of the granulation tissue (at the instant of scraping) were checked and photographs were collected • Ulcer volume	• At the end of the study 15 out of 16 ulcers clinically improved • No statistically significant difference was demonstrated in volume reduction between the two groups • A statistically significant difference was demonstrated in the onset time of granulation tissue proliferation – the wounds treated with platelet gel	• Small sample size for which baseline demographics were not reported • Does not report randomization or allocation concealment methods • PU was unit of analysis	**Level of evidence: 2 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	for healing PUs	Exclusion: • metabolic, endocrine and collagen pathologies • ischaemic cardiopathy • corticosteroid or immune-suppressive therapy • obesity • malignancies • organ failure Characteristics: • 10 sacral PUs, 6 ischial PUs	wound bed then covered with polyurethane sponge and semi-permeable film dressing system ○ control group receiving saline cleanse, packing with iodoform-impregnated gauze, sodium alginate foam or cadexomer iodine powder or vacuum assisted closure with zinc oxide paste or silver sulfadiazine applied to peri-ulcer skin • PUs treated twice weekly for 8 weeks		the healing process was triggered earlier • Platelet gel is mostly effective within the first 2 weeks of treatment while a prolonged treatment does not provide any significant advantage • Semi-quantitative data (colour and bleeding of granulation tissue) did not show significant differences between the two groups.	(multiple PUs per participant) • Control treatments included a range of different management strategies that are not considered standard PU care	
(Rappl, 2011)	Case series **reporting use of platelet-rich plasma gel for healing chronic wounds including PUs**	Participants with SCI were recruited from 11 long term care facilities, 2 outpatient wound clinics, 1 home care agency and 1 wound care equipment and service supplier in USA (n=20, 18 of the 20 wounds were PUs) Inclusion criteria: • patients with SCI • open, cutaneous wound not progressing in healing • wounds that could have a majority clean wound bed just prior to application of product • without clinical signs and symptoms of active infection Exclusion criteria: • malignancy in the wound bed • concurrent chemotherapy • active untreated wound infection Characteristics: • Mean age 49.2yrs (range 27 to 75 yrs) • Mean wound duration 79.4	All wounds were treated with 1.3 x platelet-rich plasma (PRP gel)	Wounds were assessed using different techniques all locations, but were possible the same person performed repeat measures. Outcomes included: • Mean per cent change from baseline of wound area • mean per cent change from baseline of wound volume • Improvement in sinus tracts and undermining • Number of treatments • Number of weeks	• Wounds closed on average of 47.9% in area and 56% in volume in a mean of 4.0 treatments over 3.4 weeks • Undermining closed on 31.4% using 3.5 treatments over 2.6 weeks • Sinus tracts and tunnels closed on an average of 26.1% after 2.3 treatments over 1.5 weeks • In area and volume, 90% of subjects responded positively with an average reduction of 53.8% and 67.3% respectively • Of the four subjects with undermining 75% closed 47% on average • Of the three sinus tracts and tunnels 100% closed 26.1% on average	• Diversity of sites prevented standardized measurement techniques and treatment across the 14 sites of care	**Level of evidence: 5** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		weeks (range 8 to 416 weeks) • 14/20 wounds were <1cm in depth, 7/20 wounds were, 2cm in depth • Mean wound area 25.6cm^2 • Mean wound volume 53.4cm^3					
(de Leon, Driver et al., 2011)	Case series **reporting use of platelet-rich plasma gel for healing chronic wounds including PUs**	Participants were recruited from 39 long term care centers, outpatient clinics, home health agency, long term acute care and an equipment supplier (n=200 with 285 wounds of which 142 were PUs) Inclusion: • open, cutaneous wound that has failed to respond to standard wound care per each facility protocol • wound has a mostly clean wound bed just before product application • no clinical signs and symptoms of active infection Exclusion: • Malignancy in the wound bed • current use of chemotherapy • allergy to bovine products Characteristics: • Mean baseline area 26.0cm^2±50.40 • Mean baseline depth 1.40cm±1.54 • 49.8% wounds were PU, 14.3% were diabetic ulcers, 11.2% were venous ulcers	• All participants received appropriate offloading devices. • The wound bed was cleaned thoroughly and debrided before treatment. • All participants were treated with: o moisture barrier preparation on intact peri-wound skin o Preparation of autologous platelet-rich plasma (PRP) gel from a sample of ≤20ml of the participant's blood o As soon as it was ready the PRP gel was applied topically to the wound and covered with a non-absorbent contact layer dressing • PRP gel was reapplied 1 to 2 times weekly according to clinical judgment.	• Wound measurements taken weekly using disposable tape measure and cotton bud probe with the deepest part of wound taken as depth measurement. • Mean wound area • Wound volume • Length of treatment time	• Of the 285 wounds, in a mean of 2.2 weeks (range: 0.4 to 11) with 2.8 PRP gel treatment (range 1 to 7) 86.3% of the wounds responded with a reduction of 47.5% in area, and 90.5% of the wounds responded with a reduction of 63.6% in volume • 63 (22.9%) wounds had undermining at baseline. In a mean of 1.8 weeks (range 0.4 to 9) with mean 2.5 PRP gel treatments (range: 1 to 8), 89.4% of the wounds responded with a 71.9% reduction in undermining • 28 wounds (10.2%) had sinus tracking at baseline. In a mean of 1.8 weeks (range: 0.4 to 3.1) with 2.5 PRP gel treatment (range: 1 to 4), 85.7 % of these wounds responded with a 49.3% reduction in sinus tract/tunneling. • 10 wounds failed to respond as a measure by reduction in area, volume, undermining, or tunneling reduction. • Percent change of area and depth between baseline and the final PRP gel post-treatment assessment were compared the mean volume area was reduced by 40.8%±36.16% and mean wound depth by 38.5%±47.17%	• **A sub-set population is reported in Frykberg et al, 2010** • missing data for certain variables and lack of specific comorbid patient factors that could be used to explain some of the results, but did not negatively affect the study analysis • no randomization, control or blinding of assessment • no clear explanation of recruitment strategy/patient selection	**Indirect evidence: wounds of mixed aetiology Quality: moderate**
(Frykberg, Driver et al., 2011)	Prospective case series **reporting use of platelet-rich autologous plasma gel for healing chronic**	A convenience sample of participants from 8 long term care facilities and 3 outpatient foot clinics in USA were recruited (n =49, with 65 wounds, 21 of which were PUs) Inclusion: • open, cutaneous wound	• All participants received appropriate offloading devices. • The wound bed was cleaned thoroughly and debrided before treatment. • All participants were treated with: o moisture barrier	• Wound measurements taken weekly using disposable tape measure and cotton bud probe with the deepest part of wound taken as depth measurement. • Mean wound area • Wound volume • Length of treatment time	Results for participants with PUs: • Mean wound volume decrease was 58%± 29.6% • Mean wound area reduction was 49%±29.1% • Mean undermining reduction 67.7%±32.8% • Mean decrease in sinus tract/tunneling was 38.9%±36.7%	• **this is a sub-set of the participants reported in de Leon et al 2011** • No randomization or control, no a priori power calculation • Results reported in the text are different from results in the tables,	**Level of evidence: 5 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	wounds including PUs	determined to be not progressing toward healing • wound with mostly clean wound bed • no clinical signs and symptoms of active infection Exclusion: • malignancy in the wound bed • current chemotherapy Characteristics of all participants (n =49, with 65 wounds): • Mean age 52.9±14.2 years • Mean wound duration 48.3weeks • Mean baseline area 21.0cm^2±18.1 • Mean baseline volume63.5cm^3±79.3 weeks • Albumin 3.3g/dL, prealbumin 21.5g/dL Characteristics of participants with chronic wound **(indirect evidence):** • 32.2% PU, 24.6% venous ulcers, 21.5% diabetic ulcers • Mean age 60.6±14.7 years • Mean wound duration 47.8weeks • Mean baseline area 19.0cm^2±29.4 • Mean baseline volume36.2cm^3±77.7 • Albumin 3.2g/dL, prealbumin 24g/dL	preparation on intact peri-wound skin ○ Preparation of autologous platelet-rich plasma (PRP) gel from a sample of ≤20ml of the participant's blood ○ As soon as it was ready the PRP gel was applied topically to the wound and covered with a non-absorbent contact layer dressing • PRP gel was reapplied 1 to 2 times weekly according to clinical judgment.		• No systemic or wound site side effects were noted Results for all participants **(indirect evidence):** • Mean duration of treatment as of 2.8± 2.4 weeks • Mean number of PRP applications was with 3.2± 2.2 • 97% wounds showed improvement • Mean undermining reduction 77.8%±28.9% • Mean decrease in sinus tract/tunneling was 45.8%±40.2% • No systemic or wound site side effects were noted	reducing clarity and confidence in the findings • Patients were not available for ongoing follow-up to the endpoint of complete healing • Clinicians determined treatment and dressing change frequency • Did not use gold standard wound measurement strategies	

References

Caravaggi, C., F. Grigoletto and N. Scuderi. (2011). "Wound Bed Preparation With a Dermal Substitute (Hyalomatrix (R) PA) Facilitates Re-epithelialization and Healing: Results of a Multicenter, Prospective, Observational Study on Complex Chronic Ulcers (The FAST Study)." Wounds-a Compendium of Clinical Research and Practice **23**(8):228-35.

de Leon, J.M., V.R. Driver, C.P. Fylling, et al. (2011). "The Clinical Relevance of Treating Chronic Wounds with an Enhanced Near-Physiological Concentration of Platelet-Rich Plasma Gel." Advances in Skin & Wound Care **24**(8):357-68.

Frykberg, R.G., V.R. Driver, L.A. Lavery, et al. (2011). "The use of pulsed radio frequency energy therapy in treating lower extremity wounds: Results of a retrospective study of a wound registry." Ostomy Wound Management **57**(3):22-9.

Karr, J. (2008). "Utilization of Living Bilayered Cell Therapy (Apligraf) for Heel Ulcers." Advances in Skin & Wound Care **21**(6):270-4.

Ohura, T., T. Nakajo, T. Moriguchi, et al. (2011). "Clinical efficacy of basic fibroblast growth factor on pressure ulcers: Case-control pairing study using a new evaluation method." Wound Repair and Regeneration **19**(5):542-51.

Piatkowski, A., D. Ulrich, D. Seidel, et al. (2012). "Randomised, controlled pilot to compare collagen and foam in stagnating pressure ulcers." J Wound Care **21**(10):505-11.

Rappl, L.M. (2011). "Effect of platelet rich plasma gel in a physiologically relevant platelet concentration on wounds in persons with spinal cord injury." International Wound Journal **8**(2):187-95.

Sarasúa, J.G., S.P. López, M.Á. Viejo, et al. (2011). "Treatment of pressure ulcers with autologous bone marrow nuclear cells in patients with spinal cord injury." Journal of Spinal Cord Medicine **34**(3):301-7.

Scevola, S., G. Nicoletti, F. Brenta, et al. (2010). "Allogenic platelet gel in the treatment of pressure sores: a pilot study." International Wound Journal **7**(3):184-90.

BIOPHYSICAL AGENTS FOR TREATMENT

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	Level, quality, type evidence
Negative pressure wound therapy							
(Wild, Stremitzer et al., 2008)	RCT	Recruited from nursing home, n=10 Inclusion: • PU stage III or IV Exclusion: • Palliative care Mean age 78 to 83 years	NPWT with either: • V.A.C.® system (n=5) with dressings changed x3 weekly • Redon surgical drain bottles (n=5) delivering pressure between –900mmHg and 0mmHg, but pressure level is uncontrolled. Dressings changed as required. All wounds surgically debrided and all patients received appropriate nutritional support.	• Absolute and relative proportion of wound area consisting of granulation tissue, fibrin and necrosis assessed by an independent observer using Wound Healing Analyzing Tool (WHAT) • Frequency of dressing change Mean follow-up of 8.5 days	Dressing changes: • Significantly more frequently for Redon group (3 times daily versus 0.5 times daily, p<0.05) Healing: • Mean change in granulation tissue favored V.A.C.® system (54% versus –7.1%, p=0.01) • Mean change in fibrin favored V.A.C.® system (–27% versus 21.8%, p=0.035) • Mean change in necrotic tissue favored V.A.C.® system but there was no statistically significant differences (p=0.598) Redon system: • Seal checked two hourly • Bottles reapplied when vacuum insufficient • Bottles changed up to 10 times daily • Leakage and suction of stool • Complaints of pain from participants	• Unable to recruit sufficient participants to meet apriori power calculation • Study ceased early • Ethics not obtained (states not required in country research performed)	**Level of evidence: 2 Quality: low**
(de Laat, van den Boogaard et al., 2011)	Prospective RCT (Nb: the RCT included two study arms – PUs and surgical wounds. Only data from PUs included in evidence table)	n= 12 patients with 16 PUs Inclusion: Spinal cord injury patient with PU grade IV Mean age approx. 48 years, mean BMI approximately 23.9kg/m^2	All wounds debrided, all SCI patients managed in hospital. Random assignment to either: • Patients were assigned to either treatment with NPWT using VAC® system (n=6 patients with 9 PUs) : foam dressing changed x3 weekly • sodium hypochlorite wound dressings (n=6 patients with 7 PUs): wet to moist dressings changed x3 daily	• Time to reach 50% reduction in wound volume • Maximum follow-up was 6 weeks	Only 14 PUs reached 50% healing within 6 weeks. Median treatment time to 50% reduction of would volume: • NPWT group 2.0 weeks (interquartile range [IQR]=1 to 2) versus sodium hypochlorite group 3.0 weeks (IQR = 3 to 4, p=0.001 • Unadjusted hazard rate ratio (HRR) 0.188 (p=0.014) and HRR adjusted for baseline wound volume and smoking status was 0.833 (p=0.021) Complications associated with NPWT included clinical infection (2 wound) and 1 patient had an arterial bleed requiring surgical repair.	• Used wound as a point of analysis rather than patient • Used non-conventional comparative treatment that may favor NPWT • Excluded patients who did not reach 50% healing within 6 weeks from analysis	**Level of evidence: 2 Quality: moderate**
(Ubbink, Westerbos et al., 2008)	Cochrane review	Two RCTs (n=47) considered participants with PU Both these trials are reported to be of low methodological quality Indirect evidence from an	NPWT versus moist gauze dressings (n=12) (Wanner 2003) NPWT versus wound gel products including papain-urea	Days to reach 50% of initial wound volume (Wanner 2003) Complete healing within 6 weeks (Ford 2002)	• Mean time to reach 50% wound volume No significant difference between NPWT (27 days ± 10) versus moist gauze dressing (28 days ± 7, p=0.9) • Complete healing within 6 weeks No statistically significant difference	• Two trials on PUs were of low methodological quality • No pooling of results as different	**Level of evidence: 2 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	Level, quality, type evidence
		additional 5 RCTs on NPWT for managing wounds of mixed aetiology (n=158)	ointments and hydrophilic beads containing 0.9% cadexomer iodine (n=35 full thickness PUs) (Ford 2002)	Reduction in wound volume (Ford 2002) Pain Quality of life (EuroQol and McGill Pain Questionnaire) Cost Complications	between wound gel products (13% complete healing) over NPWT (10% complete healing; RR 0.75, 95% CI 0.12 to 4.73) • Reduction in mean wound volume • No significant difference between wound gel products (51.8%) and NPWT (42.1%, p=0.46) • Findings from RCTs with mixed wound etiology supported the findings of the PU RCTs • Findings from trials with mixed wound etiology suggested no significant difference in pain, quality of life or complications between NPWT and conventional management but NPWT was significantly cheaper (p=0.001) in one RCT set in the US in 2006.	outcome measures used	
(Wallin, Bostrom et al., 2011)	Retrospective record analysis (Nb: Included patients with wounds of other aetiology. Only data from PUs included in evidence table)	Consecutive selection of patients treated with NPWT in one general hospital between 2005 to 2007. n=14 patients with PUs	NPWT using VAC® device with continuous sub atmospheric pressure of 125 mm Hg. Dressings changed x2 to 3 weekly or more frequently depending on exudate	Patient demographic Comorbidities Clinical infection Wound complications Treatment outcome: • successful: wound much improved and/or left to heal by secondary granulation; wound healed; wound bed improved and skin graft performed, • unsuccessful: wound not improved, wound bed larger or worse, treatment discontinued due to complications. Follow up ranged from 24 to 48 months.	• 86% wounds treated with NPWT had positive wound swab, primarily *E.Coli, Pseudomonas, Streptococci, Enterococci* and *Bacteroides* • 50% (n=7) cases classified as successful • Median treatment time was not significantly different (p=0.48) between cases that were successful (median 28 days ± 71 days, range 8 to 210) and those that were unsuccessful (median 23 days ± 23 days, range 4 to 75 • Patients with infectious, postoperative, and traumatic wounds had greater treatment success than those with PU (p=0.001). • In the full sample (n=87) there were complications in 10 patients including infection (n=5), breakdown of surrounding skin (n=3) and hematoma (n=2).	• Retrospective chart review • No controls • Small number of patients	**Level of evidence: 5 Quality: moderate**
(Ho, Powell et al., 2010)	Observational study	Participants (n=86) with SCI recruited from 10 Veterans Affairs medical centres Inclusion: • stage III or IV PU in the pelvic region (sacral, coccygeal, ischial, buttock • age ≥ 18 years age	All patients received low air loss mattress, regular turning, wound debridement, hydrotherapy, routine wound cleansing and dressing changes. At discretion of physician patients received either:	Change in wound surface area Digital planimetry on day 1, during weeks 2 and 3 and on day 28 Laboratory data (serum albumin) was collected on	• No significant difference in number of patients classified as healing between NPWT group (70%) versus standard care group (67%, p=ns) • In patients who were classified as healing, there was no significant difference in size of wound surface area decreased amount between the NPWT group (–43% ± 22%) versus standard care group (–50% ± 26%,	• Wound depth, which is a consideration in selection of NPWT, was not measured • Prealbumin, which is a better indicator of nutritional status, was not	**Level of evidence: 5 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	Level, quality, type evidence
		Exclusion: • reconstructive flap surgery • unresolved osteomyelitis • palliative care • coronary artery disease, vascular disease, congestive heart failure • malignant disease Characteristics: • Mean age 55 years • Primarily male patients (96 to 100%)	• NPWT (n=33) • standard wound care alone (n=53)	day 1 and 28 (± 2 days) PUs were classified as healing (wound surface area decreasing) or non-healing (wound surface area increasing	p=ns) • In the NPWT group there was a significant difference in serum albumin levels between patients classified as healing versus non-healing (2.9 ± 0.4 vs. 3.3 ± 0.5 mg/dL, p<0.05) • In the standard care group there was no significant difference in serum albumin levels between patients classified as healing versus non-healing (3.2 ± 0.3 vs. 3.2 ± 0.3 mg/dL)	measured	
Electrical stimulation							
(Franek, Kostur et al., 2012)	RCT	n=57 (7 did not complete treatment and not considered in analysis) Inclusion: • Physician's discretion Exclusion: • Diabetes mellitus • ABPI < 0.9 • cancer Characteristics: • All PUs on lower extremities • Mean age 56 to 59 yrs • Primarily stage II PU • Mean PU area 3.97 to 4.54cm^2 • Mean PU duration 2 to 3 months	All participants received standard care: Range of wound dressings (e.g. non-adhesive, hydrogels, moist gauze), topical treatments, pressure relieving surface if required. Participants received either: • Only standard care (n=24) • High-Voltage Electrical Stimulation (HVES) at 100V;100 µs; 100 Hz for 50 minutes once daily five times a week (n=26)	• Wounds photographed on weekly basis and digital planimetry to determine wound area • Wound area measured using calipers at deepest point • Patient were followed until healing for a maximum of 6 weeks	• Mean PU areas decreased significantly in both groups • Mean PU area was statistically significantly different from week 3 (p=0.008) • Average granulation area increase was statistically significantly superior in treatment group only in week 5 (p=0.02) • Week 6 surface area change was 88.9% (SD=14) in the treatment group and 44.4% (SD= 63.1) in the control group (p=0.00003) • Correlation coefficients between changes in wound surface area, longest length and longest width were R=0.96 and R=0.98 in the treatment and R=0.94 and R=0.89 in the control	• Study length of 4 years • No blinding • Lower extremity PU only • Variety of other treatments may not have been consistent between groups	**Level of evidence: 2** **Quality: moderate**
(Franek, Kostur et al., 2011)	RCT	n = 58 participants Inclusion: • Stage I, II or III PU Exclusion: • SCI or paralysis • ABPI <0.9 • Diabetes mellitus • Arrhythmias • Post-steroid therapy Characteristics:	All patients received standard care: local bath of potassium permanganate, compresses of fibrolan, colistin, iruxol, and wet dressings containing 10% sodium chloride Participants received either: • Standard care only (n=29) • Monophasic pulsed current generator high voltage monophasic stimulation (HVMS) at 100 µs, 100 Hz, 100 V once daily, five times a	• Per cent change in wound surface area • Per cent change in wound depth • Per cent change in wound volume • Per cent change in wound length	• Both groups had statistically significant reduction in (p≤0.0001) wound surface area, wound volume, wound depth, wound length and pus covered area • In HVMS group 8/29 PUs healed versus 4/29 PUs in control group • Relative changes : o total surface area: 85.38% in HVMS group versus 40.08% in control group) o Length: 71.22% in HVMS group versus 30.38% in control group o Width: 76.09% in HVMS group versus 32.48% in control group o volume 20.69% in HVMS group versus	• Non-blinded study • Wide variety in participants and PU characteristics • Authors unable to confirm the mechanism by which HVMS influences healing	**Level of evidence: 2** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	Level, quality, type evidence
		• Mean age 59 to 60 yrs • Primarily leg PU • Mean PU duration 2 to 3 mths • Mean PU area 4.5 to 5cm^2 • Mean PU volume 0.04cm^3 • About 50% participants were smokers	week for 6 weeks (n=29)		9.39% in control group • The Gilman Index (0.64 cm in HVMS group versus 0.28 cm in control group) indicated a difference in favor of group A (p≤0.001) • More efficient decrease of pus and greater granulation growth were observed in group A but difference was not statistically significant (p=0.07) • In HVMS group the correlation between change of total area and length of ulcers was 0.85 (p=0.002), total area and width was 0.84 (p=0.002), and total area and volume was 0.66 (p=0.01). • In control group the correlation between change of total area and length of ulcers was 0.55 (p=0.02), total area and width was 0.54 (p=0.02), total area and volume was 0.49 (p=0.04).		
(Houghton, Campbell et al., 2010)	Single-blind RCT	Participants (n=67 screened, n=34included) with SCI living in the community Inclusion: • Stage II to IV PU between 1 and 20cm^2 of at least 3 month duration Exclusion: • Serious comorbidity • Contraindications to electrical stimulation therapy (e.g. pacemaker) • Deep tunneling PU • Three or more abnormal blood values Characteristics: • Mean age 50 years • primarily stage IV PUs • mean wound duration 1.2 to 3 years	Patients were stratified based upon wound severity and duration to four groups prior to randomisation. All participants received standard wound care of nutritional assessment and program, activity program, blood analysis, customised wound care, seating cushion. Participants received either: • Standard wound care (SWC) • Electrical stimulation therapy (EST): - Silver dressing regimen to facilitate therapy - 2 to 30 30 minute education sessions - Individualised electrical stimulation (generally single electrode placed directly over wound with larger dispersive electrode placed 20cm away from wound), twin-peak monophasic pulsed current with 50µs pulse duration at 50 to 150V	Percentage decrease in wound surface area over 3 months assessed by digital planimetry Proportion of wounds achieving at least 50% reduction in wound surface area Wound appearance assessed using a photographic wound assessment tool Assessed monthly over 3 months then followed for 4 months to assess recurrence.	• Percentage decrease in wound surface area over 3 months significantly greater in EST group (70% ± 25% versus 36% ± 61%, p=0.048) • All stage II PUs healed in both groups • Proportion of wounds achieving at least 50% reduction in wound surface area significantly greater in EST group (80% versus 36%, p=0.02) • photographic wound assessment tool score was improved in more PUs in the EST group (75% versus 44%, p=0.07) • Adverse reactions included red itchy skin beneath dispersive electrode (resolved within 24 hours)., one patient acquired a burn. • Mean treatment time was 3.0±1.5 hrs per day (lower than recommended time) • 8 subjects in each treatment group had recurrent or new PUs develop within 4 months of closure	• Small single-blinded study sample size • EST treatments were applied in combination with silver dressings • High PU recurrence rate	**Level of evidence: 2 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	Level, quality, type evidence
			intensity. 40 minutes therapy followed by 20 minutes with no therapy for an 8 hour cycle daily.				
Pulsed electromagnetic therapy							
(Gupta, Taly et al., 2009)	Double-blind RCT	Participants (n=12) with neurological disorders A total of 24 PUs were included (13 stage IV PUs and 11 stage III PUs) Inclusion: • Stage III or IV PU Excluded: • Osteomyelitis • Non-ischaemic PU Characteristics: • Mean age 27 to 28 years • Mean duration of PU 103.75±113.70 days	All PUs debrided and treated with antibiotics as required prior to study. Both groups were given standard PU care including daily dressing changes. Participants randomised either: • PEMT (n=6, 13 PUs) administered in 'Pulsatron' delivering low frequency PEMT (1Hz frequency sine waves with 30 miliampere current intensity). • Sham therapy (n=6, 11 PUs) in 'Pulsatron' without machine switched on Therapy was administered for 30 sessions, 5 days a week for 6 weeks, for 45 minutes/session.	Wound healing assessed based on Bates-Jensen wound assessment (BJWAT) tool score Ulcer stage assessed on NPUAP criteria	• Significant improvement in BJWAT scores in both PEMT group (p=0.001) and sham group (p=0.003) but no significant difference between the two groups (p=0.361) • Both groups achieved significant healing of PUs assessed on NPUAP staging criteria (PEMF group p=0.008 and sham group p=0.014) but no significant difference between the two groups (p=0.649)	• Small sample size • Non-standard assessment of healing outcomes	**Level of evidence: 2** **Quality: low**
Aziz et al, 2012.	Cochrane review	Two RCTs (n=60) considered participants with PU Both these trials are reported to be of low methodological quality	The application of PEMT was compared with sham PEMT in two RCTS (Comorosan, 1993, Salzberg, 1995) One of the RCTs included an arm receiving standard care (Comorosan, 1993)	Proportion of ulcers healed	Proportion of ulcers healed: • PEMT group 85% healed versus 0% in sham therapy group and 0% in standard care group (risk ratio [RR] 10.0, 95%CI 0.70 to 143.06, p=ns) (Comorosan, 1993) • PEMT group 60% of stage III PUs healed in seven days versus 0% in sham PEMT group (RR 7.00, 95% CI 0.97 to 50.38, p=ns)	• Two small RCTs with significant methodological shortcomings. • Both these studies have been previously reported in 2009 guideline	**Level of Evidence: 2** **Quality: low**
(Ho, Bensitel et al., 2012)	Double blind prospective RCT	Participants recruited from an inpatient facility (n=28) Inclusion: • aged > 18 yrs with SCI • stage III and IV pelvic PUs, presenting as clean with no odor, necrosis, minimal exudate, no tunneling or fistula, no cellulitis, no erythema of surrounding	All participants received standard care according to clinical guidelines. Participants were randomised to receive either: • Daily low-pulsatile lavage treatment with 1 liter of normal saline at 11 psi applied over 10 to 20 mins using a device designed for	• Length, width and depth of PU obtained weekly for 3 weeks • PU depth using saline injection method • PU healing rate over the 3-week study period	• Random-coefficient models for analysis of linear and volume measurements revealed improvements over time for both groups • Time trend analysis revealed greater measurement decreases for the treatment groups • Differences in rates of change over time (95% CI) for treatment and control groups respectively (p<0.001): o Depth: –0.24 (0.09 to –0.58) cm/wk	• Small number of participants and underpowered • Strict exclusion criteria excluded 221 participants • All 95% CIs span the null value, decreasing confidence in the	**Level of Evidence: 2** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	Level, quality, type evidence
		tissue • PU maximum diameter of 3 to 15cm at baseline • No antibiotics within preceding 7 days • no malignancy or vascular disease associated with PU • no diabetes, heart disease or renal failure Characteristics: • Primarily ischial PUs • No significant demographic differences • Mean age 55 to 57 years	the procedure (n=14) or • Sham treatment in which no lavage was administered directly to the PU but participants were given the impression it had been (n=14) Dressings were removed before the commencement of treatment and replaced at the completion of treatment		o Width: –0.16 (0.06 to –0.39) cm/wk o Length: –0.47 (0.18 to –1.12) cm/wk o Volume: –0.33 (0.13 to –0.80) cm^3/wk All 95% CIs span the null value, decreasing confidence in the significance of the results.	significance of the results.	
Pulsed radio frequency energy and acoustic ultrasound							
(Frykberg, Driver et al., 2011)	Retrospective case series	Database review of records of patients treated with PRFE (n=413) from 100 facilities in USA. Inclusion: (n=28 patients with 34 PU) • Wound duration ≥ 4 weeks • PREF treatment for ≥ 4 weeks • Mean age 71±14 yrs, 91% male • PU duration 9±10 mths • PU size 15±24.4 cm^2 (range 0.4 to 115.2) • Chronic PUs non-responsive to debridement, NPWT, moist wound healing, offloading, growth factors, bioengineered skin equivalents.	• Pulsed radio frequency energy administered 30 mins, x2 daily • By placing applicator adjacent to wound dressing • Administered by patients (community-based) or staff (facility-based) • Frequency not reported.	• Per cent reduction in wound area at 4 weeks • Wound healing trajectory at 4 weeks ([initial wound area-final wound area]/number days treatment) • Proportion of wounds achieving ≥ 50% reduction in size at 4 weeks	• Mean per reduction cent wound surface area at 4 weeks 49% ± 6% (range 100% to –386%, p<0.0001) • 59% PUs achieved ≥ 50% reduction in size at 4 weeks • Wound healing trajectory at 4 weeks: 0.34 ±0.60 cm^2 per day	• Selection bias favoured severe wounds • Assumed reliable database entries • Compliance with therapy regimen is known as self-administered for patients in the community	**Level of Evidence: 5 Quality: low**
(Conner-Kerr and Isenberg, 2012)	Retrospective record case series analysis	Data was taken from a device manufacturer's registry consisting of cases from 99 different facilities in USA. (n=89 participants, 110 PUs) Inclusion: • PU of at least 1 month duration • At least 4 wks of outcome data Characteristics: • Treated with PRFE due to failure of other treatments and primarily	Wound and additional PU care was as per individual institution standards PRFE performed by carer or participant All facilities had been instructed to use Provant Therapy System by placing applicator over wound dressings for 30 minutes twice daily	• Median wound surface area reduction at 4 weeks • Per cent of wound achieving 50% reduction or greater in wound surface area • Rate of healing • Method of assessing the outcome measures is not reported	• Median wound surface area was 9.8cm^2 at baseline and 4.5cm^2 at 4 weeks • Median wound surface area reduction at 4 weeks was 44%±54%, mean 51%, range 100% to –386% (i.e. increased) • 51% of wound achieving 50% reduction or greater in wound surface area at 4 weeks • Wound healing trajectory at 4 weeks was 0.36±0.63cm^2/day (mean 0.13, range 3.06 to –1.29) • Greatest reduction in wound size was seen in Stage II PUs (median wound surface area reduction of 82%)	• No control group • Database records • Excluded all cases without 4 weeks of outcome data, thereby favouring treatment • Adherence to instructions for administration is not checked • Method of assessing the	**Level of Evidence: 5 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	Level, quality, type evidence
		following surgical intervention. • Median age 69 yrs (range 28 to 75) • 82% participants had only one PU • 89% treated in inpatient facilities • PUs ranged from 1 to 82 mths duration (median 6 mths) • 43% stage IV, 20% stage III, 19% stage II, 18% unstaged.				outcome measures is not reported and may differ between facilities	
(Arashi, Sugama et al., 2010)	Non-randomised blinded trial investigating vibration for accelerating PU healing	Participants recruited from a hospital facility. (n=31 participants with 41 PUs) Inclusion: • Aged > 65 years • Stage I PU defined as moderate to severe skin discoloration with non-blanching. Exclusion: • Considered unsuitable by medical practitioner • Marker contractures • PU located above shoulders Characteristics: • Mean age 80 years • Primarily bedridden • Mean BMI 15 to 16 kg/m^2 • Primarily cared for on an alternating air mattress • Mean Braden score 10.6 to 12.7 • Primarily sacral PU	All participants received standard care according to the PU care guidelines. • Experimental group (n=16 participants, n=20 PUs) received vibration therapy in which a vibrator (RelaWave) was used to apply vibration (frequency: 47 Hz; time 10 seconds; amplitude modulation cycle: 15 seconds) for 15 minutes 3 times a day for up to 7 days • Control group (n=15 participants, n=21 PUs) received only standard care	Primary outcomes: • Healing Rate • Healing Period Secondary Outcomes: • Ulcer areas • Intensity of redness	• More PUs in experimental group healed compared to control group (40% versus 9.5%, p=0.033) • Mean relative change per day of wound area was superior in the experimental group (20.4±27.2% versus 6.4±6.9%, p=0.007) • The healing rate during the study was significantly higher in the experimental group than in the control group (P = .018, log rank test) • The hazard ratio adjusted for baseline risk factors was 0.031 (95% CI 0.002 to 0.594, p=0.021) • No participants experienced physical discomfort from vibration	• Non blinded, non randomised study • Groups followed at different time periods and authors suggest seasonal conditions may have influenced microclimate • Interrater reliability for evaluating healing was not assessed • Difficult to measure real intensity of vibration level reaching/impacting on the skin was hard to assess – used a method of– main method of checking was placing hand under patient to feel the vibration	**Level of Evidence: 3 Quality: moderate**
Light therapy							
(Nussbaum, Flett et al., 2013)	Double-blind RCT investigating ultraviolet C light therapy	Participants recruited from two inpatient facilities Inclusion: SCI Stage 2 to 4 PU according to American Spinal Injury Impairment Scale	All participants received standard pressure relieving measures. Wound care regimen not reported. Assigned to receive either: • Placebo UVC attained using regular light bulb and	• Weekly wound area as per cent of baseline • Mean per cent wound area change between consecutive weeks • Weeks to wound closure Assessed weekly by wound	• 13 PUs in UVC group and 12 in placebo group closed during treatment time (p=ns overall or by subgroup) • At any weekly time point, number of PUs closed was similar between groups (p=ns) • 5 PUs reopened within 1 month (p=ns between groups) • 15 PUs were unhealed after 12 months	• Homogeneity between PU location and severity was considered responsible for lack of significant results.	**Level of Evidence: 2 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	Level, quality, type evidence
		Exclusion: NPWT Surgical repair in previous 3 months Neoplasm Primarily buttock and lower extremity PUs Mean age 54 to 55yrs Mean PU size stage 2 PUs 2.44 to 4.22cm2 PU duration primarily 1-8 wks in both groups, UVC group had more PUs of 9-52 wks than placebo group and placebo group had more PUs >52 wks than UVC group.	regimen as per treatment group (n=28) • Ultraviolet C light therapy (UVC) applied x3 weekly (wound edges and peri-wound irradiated for 15 seconds at ~15mW/cm^2 then PU irradiated on a regimen based on PU severity (n=30) Therapy until 100% PU closure or discharge from facility	photography and imaging software to calculate area Subgroup analysis for stage 2 and stage 3-4 PUs	(p=ns between groups) • Stage 2 PUs showed significant healing at some weekly time points (weeks 3, 5 and 7) with respect to per cent of baseline size for UVC group versus placebo group (p<0.03 to 0.05).	• Large drop out not included in analysis	
(Durovic, Maric et al., 2008)	Prospective randomized single-blind study investigating polarised light therapy	Participants (n=40) Inclusion: • stage I to III PUs according to PU Classification System • no contraindications for polarized light • no deterioration of a common disease or development of a new disease Exclusion: • Intended skin graft within 7 days • Previous PU study participation • Albumin levels < 3.0g/dL • Local or general infection including pilonidal sinus or osteomyelitis • Steroids, immunosuppressants, antineoplastics or anticoagulants. Characteristics: • Mean age 61.86 to 68.65 yrs • Mean PU surface area 15.10 to 19.15 • More PUs in experimental group had light (50%) or moderate (25%) exudate and more in control group had no exudate (65%) p=0.04 • More PUs in control group were “closed” or epithelialized at	All participants received standard wound cleaning and dressings. Participants randomised to receive either: • Polarized light therapy (experimental group, n=20) • No additional therapy (control group, n=20)	• Surface of PU measured using calipers • Rank of PU (this outcome is not described) • PUSH score	There were significant differences between the groups at the end of the treatment regarding: • The surface of PU (experimental group 10.80 ±19.18 versus control group 22.97±15.69, p=0.00005); however, 50% of the PUs in control group were described as “closed” at baseline • Rank of PU (experimental group 5.95±2.48 versus control group 8.6±1.05, p =0.0005) • Total PUSH score (experimental group 7.35±3.17 versus control group 11.85±2.35, p=0.00003)	• Non-blinded and poorly described randomisation and inclusion criteria. • Outcome measure of “rank of PU) not described • Did not address if an individual assessor was involved in assessing the results • Did not use gold standard for PU assessment (wound tracings and/or digital planimetry) • Control PUs were less severe at baseline therefore less opportunity for improvements	**Level of Evidence: 2 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	Level, quality, type evidence
		baseline (75% versus 65%, p=0.01)					
(Onigbinde, Olafimihan et al., 2010)	Non-randomised controlled study with participants serving as own controls	Participants were bed ridden patients at a teaching hospital in Nigeria (n=10) Inclusion: • Bilateral PU on lower limbs • Stable medication regimen including ciproflaxin • Aged 35 to 55 years Exclusion: • Diabetes • Malnutrition • Dermatitis • Metallic implants Characteristics: • Mean age 45.3±18.3 yrs • Mean PU surface area 76.5±63.7cm^2 for experimental PUs and 43.8±32cm^2 for control PUs • Mean PU volume at baseline was 34.9±34.2ml for experimental PUs and 26.1±25.5ml in control PUs	All PUs were dressed with Ringer's solution dressings. • Left limbs were radiated with ultraviolet radiation type B (UVR – B) every, 3 days for 6 weeks with gradual increase in session duration for ¾ to 5 minutes • The right limbs only received the normal wound dressing for 6 weeks	• Mean surface area using wound tracings • Mean wound volume measured by lining the wound with foil • Bacterial growth assessed by Likert score (0 being no growth and 5 being very heavy growth)	• 78.9% decrease in the mean surface area of the experimental group limb (initial = 76.5 cm^2; final 16.6 cm^2) compared with 37.4% decrease in the control group (initial = 43.8 cm^2; final 27.4 cm^2, p=not reported) • 74.7% decrease in the mean volume of the experimental group (initial = 34.9 ml; final 8.2 ml) versus 46.3% decrease in the control group (initial = 26.1 ml; final 14.0 ml, p=not reported) • Significant decrease in the growth of bacteria (X^2 = 37.01, p<0.00)	• Experimental PUs had larger baseline size therefore had greater opportunity for improvement • oral ciprofloxacin confounded results • Volumetric measurements for depth lined the wound with "foil" but usual gold standard is to cover with a film and then gently fill cavity with normal saline until full giving • Assessed bacteria growth by a non-standard method (Likert scoring by laboratory scientists) • Unclear if positioning side-side was equivalent	**Level of Evidence: 3 Quality: low**
Ultrasound							
(Serena, Lee et al., 2009)	Case series and animal study	Participants were recruited from 3 centers (n = 13, n = 11 completed study) Inclusion: • Category III PU • Bacterial burden at baseline (i.e. > 10^5 bacterial count)	• All wounds received debridement at baseline • Noncontact low frequency ultrasound (NC-LFUS) applied for a mean duration of 4 minutes for daily for 6 days.	• Per-protocol analysis • Wound biopsy at baseline and 2 weeks for wound culture	• Mean reduction in bacterial bioburden from 4 x 10^7 to 2 x 10^7, p not reported • 26% reduction in mean wound area (p not reported) • 20% mean wound volume (p not reported) • Increase in *S. aureus* in animal arm	• Analysis excluded drop outs • No analysis by center • No control • No blinding • Small sample size • Unclear how wound size was assessed • No statistical analysis	**Level of Evidence: 5 Quality: low**
(Honaker, Forston et al., 2013)	Retrospective case review	Retrospective record review (n = 127 cases of SDTI) Characteristics:	• Records were reviewed as either cases or controls • All patients received standard pressure ulcer prevention	• Development of a new assessment tool to assess SDTI, validity and reliability not	• NC-LFUS group achieved significant reduction in severity score at follow up compared to the control group (t = 5.67, p < 0.000)	• Assessment of wound color using digital photography requires a validated	**Level of Evidence: 5 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	Level, quality, type evidence
		• Control group had larger wound surface area at baseline but significance was not reported • No difference in severity score at baseline (p<0.913)	• Cases received NC-LFUS daily for 5 days then every second day (mean number of treatments = 10)	reported • Tool used three scales on which total surface area, skin integrity and wound color were assessed from photos in patient records • Severity score was assigned based on three scales (score 3-18 with higher score = greater severity)	• 18% of SDTI in NC-LFUS resolved spontaneously versus 2% in control group	photographic strategy – unclear if this was used. • Non blinded • Relies on documentation • Underpowered study	

References

Arashi, M., J. Sugama, H. Sanada, et al. (2010). "Vibration therapy accelerates healing of stage I pressure ulcers in older adult patients." Advances in Skin & Wound Care **23**(7):321.

Aziz Z, Flemming K. Electromagnetic therapy for treating pressure ulcers. Cochrane Database of Systematic Reviews. 2012;12:CD002930.

Conner-Kerr, T. and R.A. Isenberg. (2012). "Retrospective analysis of pulsed radiofrequency energy therapy use in the treatment of chronic pressure ulcers." Advances in Skin & Wound Care **25**(6):253-60.

de Laat, E.H.E.W., M.H.W.A. van den Boogaard, P.H.M. Spauwen, et al. (2011). "Faster Wound Healing With Topical Negative Pressure Therapy in Difficult-to-Heal Wounds: A Prospective Randomized Controlled Trial." Annals of Plastic Surgery **67**(6):626-31.

Durovic, A., D. Maric, Z. Brdareski, et al. (2008). "The effects of polarized light therapy in pressure ulcer healing." VojnosanitPregl **65**(12):906.

Franek, A., R. Kostur, A. Polak, et al. (2012). "Using high-voltage electrical stimulation in the treatment of recalcitrant pressure ulcers: Results of a randomized, controlled clinical study." Ostomy Wound Management **58**(3):30-44.

Franek, A., R. Kostur, J. Taradaj, et al. (2011). "Effect of high voltage monophasic stimulation on pressure ulcer healing: results from a randomized controlled trial." Wounds: A Compendium of Clinical Research & Practice **23**(1):15-23.

Frykberg, R.G., V.R. Driver, L.A. Lavery, et al. (2011). "The use of pulsed radio frequency energy therapy in treating lower extremity wounds: Results of a retrospective study of a wound registry." Ostomy Wound Management **57**(3):22-9.

Gupta, A., A.B. Taly, A. Srivastava, et al. (2009). "Efficacy of pulsed electromagnetic field therapy in healing of pressure ulcers: A randomized control trial." NeurolIndia **57**(5):622.

Ho, C.H., T. Bensitel, X. Wang, et al. (2012). "Pulsatile lavage for the enhancement of pressure ulcer healing: a randomized controlled trial." Physical Therapy **92**(1):38-48.

Ho, C.H., H.L. Powell, J.F. Collins, et al. (2010). "Poor nutrition is a relative contraindication to negative pressure wound therapy for pressure ulcers: preliminary observations in patients with spinal cord injury." Advances in Skin & Wound Care **23**(11):508-16.

Honaker, J.S., M.R. Forston, E.A. Davis, et al. (2013). "Effects of non contact low-frequency ultrasound on healing of suspected deep tissue injury: A retrospective analysis." International Wound Journal **10**(1):65-72.

Houghton, P.E., K.E. Campbell, C.H. Fraser, et al. (2010). "Electrical stimulation therapy increases rate of healing of pressure ulcers in community-dwelling people with spinal cord injury." Archives of Physical Medicine and Rehabilitation **91**(5):669-78.

Nussbaum, E., H. Flett, S. Hitzig, et al. (2013). "Ultraviolet-C irradiation in the management of pressure ulcers in people with spinal cord injury: A randomized, placebo-controlled trial." Arch Phys Med Rehabil **94**(4):650-9.

Onigbinde, A.T., K.F. Olafimihan, A. Ojoawo, et al. (2010). "The effect of ultraviolet radiation (type B) on decubitus ulcers." Internet Journal of Allied Health Sciences & Practice **8**(1):1-6.

Serena, T., S.K. Lee, K. Lam, et al. (2009). "The impact of noncontact, nonthermal, low-frequency ultrasound on bacterial counts in experimental and chronic wounds." Ostomy/Wound Management **55**(1):22-30.

Ubbink, D.T., S.J.l. Westerbos, D. Evans, et al. (2008). "Topical negative pressure for treating chronic wounds." Cochrane Database Of Systematic Reviews (Online) (3):CD001898.

Wallin, A.-M., L. Bostrom, J. Ulfvarson, et al. (2011). "Negative pressure wound therapy - a descriptive study." Ostomy/Wound Management **57**(6):22-9.

Wild, T., S. Stremitzer, A. Budzanowski, et al. (2008). "Definition of efficiency in vacuum therapy--a randomised controlled trial comparing with V.A.C. Therapy." International Wound Journal **5**(5):641-7.

SURGERY FOR PRESSURE ULCERS

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Diagnosing and managing osteomyelitis							
(Daniali, Keys et al., 2011)	Retrospective case-controlled study **comparing pre-operative management and post-operative outcomes between pre-operative MRI diagnosis of osteomyelitis and intra-operative bone biopsy**	Participants were recruited from a spinal cord center in the USA between 1996 and 2008 (n=65 had flap reconstruction had osteomyelitis and n=47 had either MRI or bone culture diagnosis). Characteristics: • Mean age 56.2 to 58.7 years • Primarily males with SCI • The preoperative MRI group had a greater percentage of participants with stable PUs of unchanging size win comparison to the bone culture group (46.2% versus 23.8%, p =0.04) • MRI group had a greater number of patients with a history of peripheral vascular disease (14.3% versus 0%, p=0.05)	• Data were collected from patient electronic medical records including operative reports, admit notes, daily progress notes and consult and weekly wound care team notes • Participants received either: ○ pre-operative MRI diagnosis of osteomyelitis (n=26) ○ post-operative bone culture diagnosis of osteomyelitis (n=21)	• Recurrence of PU at the same anatomic site • Suture line dehiscence • Significant suture line dehiscence and • Time until mobilization by physical therapy	• Patients with a diagnostic preoperative MRI did not differ significantly in rates of pre-operative antibiotic administration compared to those without pre-operative MRI (26.9% versus 23.8% OR 1.2, p=0.81) • There was no significant difference in PU recurrence rates post-surgery between those with osteomyelitis diagnosed by MRI had and those with osteomyelitis diagnosed by bone culture (39% versus 29%,OR 2.4, p=0.22) • There was no significant difference in infection rates post-surgery between those with osteomyelitis diagnosed by MRI had and those with osteomyelitis diagnosed by bone culture (7.7% versus 14.3%,OR 0.50, p=0.44) • **Study conclusions: the study concluded that there was no evidence that a preoperative MRI diagnosis of osteomyelitis significantly alters clinical or surgical management or patient outcomes**	• Retrospective chart review subject to Inaccuracies of data recording • Study cohorts were small potentially limiting the study generalizability. • Inherent bias as patients undergoing MRI are usually more stable.	**Level of evidence: 5 (diagnostic) Quality: moderate**
Surgical outcomes							
(Ahluwalia, Martin et al., 2009)	Retrospective medical record review **investigating complications of wound reconstruction by flap site**	Sample was a consecutive cohort of patients undergoing surgery in a 10 year period in one Canadian hospital (n=78 with n=93 PUs) Inclusion: surgical reconstruction of a stage III or IV PU Characteristics: 72/93 PUs were ischial mean age 43 years (range 15 to 71) 94% had SCI 63 fasciocutaneous flaps and 41	• All participants had a similar surgical regimen including wound cultures, antimicrobial therapy, wound drainage, pressure relief, postop care for 4 to 5 days in hospital and 5 weeks of bed rest followed by gradual weight bearing, high protein, high calorie diet. • Records were reviewed for complications and recurrence rates	• Demographics; location of sores; methods of reconstruction; flap selection; complications and recurrences • "Complication" was not defined	• Overall flap complication rate of 16% (17/104) was observed in flap • Complication rate for ischial flaps by site ○ Posterior medial thigh flap: 17% ○ Biceps femoris muscle combined with posterior medial thigh flap: 14% ○ Gluteus myocutanous flap: 12% ○ Gluteus fascio flap: 33% • Recurrence rate 7% • **Study conclusion: authors recommend that for ischial PU**	• No control to suggest whether overall effect is due to study intervention • All surgery performed by the same surgeon in a single hospital • No statistical analysis to determine if results were significant • No reporting of relevant demographics to ensure comparison is appropriate	**Level of evidence: 5 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		musculcutaneous flaps			**reconstruction, a combination posterior medial thigh fasciocutaneous flap with a bicep femoris muscle flap is the preferred strategy. However, there is no statistical analysis to support this and the sample were surgeries performed by a single surgeon.**	• Relied on accurate records for data base review • Unclear what was considered to be a "complication" and how this was assessed	
(Thiessen, Andrades et al., 2011)	Retrospective clinical comparing **outcomes for muscle and non-muscle flaps**	Participants were a consecutive sample undergoing PU surgery over a 6 year period in Belgium (n=94) Exclusion: • trochanter PU Characteristics: • Mean age 45.99±17.9yrs • 77% had some level of paralysis • 43% were non-hospitalized • 47% were chronic (>3 mths) PU • 100% PU were stage IV	**Pre-operative** 69% participants had pre-operative antibiotics **Operative phase** 61% fasciocutaneous or perforator flap 39% musculocutaneous flap	Mean follow up 3.10 ± 1.8 years	**Outcomes for musculocutaneous versus fasciocutaneous flaps** • No significant difference in hospital stay duration (75.45±52.2 days vs 64.76±75.5 days, p=0.059) • No significant difference in wound dehiscence (47% vs, 44%, p=0.835) • No significant difference in infection (35% vs, 51%, p=0.135) • No significant difference in hematoma/seroma (22% vs, 27%, p=0.628) • No significant difference in flap necrosis (8% vs, 11%, p=0.735) • No significant difference in need for secondary procedure (34% vs, 39%, p=0.668) • No significant difference in recurrence (32% vs, 26%, p=0.648) **Post-operative outcomes risk (multivariate analysis)** • Non-paralyic patients had decreased risk of post-operative complications (OR 0.081, 95% CI 0.009 to 0.706, p=0.023) • Developing PU in a non-hospital environment had decreased risk of post-operative complications (OR 0.108, 95% CI 0.0021 to 0.563, p=0.008) • No relationship between type of flap and risk of complication **Study conclusions: there is no significant difference in outcomes between different flap types and selection should be based on quality of available tissue**	• Four surgical teams • The retrospective study design is subject to chart completeness and data collection errors • May not be adequate sample size for statistical power •	**Level of evidence: 3 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(Estrella and Lee, 2010)	retrospective chart review to **investigate outcomes for nonambulatory patients with hypoalbuminemia who undergo sacral PU surgery**	Participants were a sample of patients have flap reconstruction over a 6 year period at a tertiary hospital in Phillipines (n=16) Inclusion: • nonambulatory • stage III to IV sacral PU • moderate to severe hypoalbuminemia preoperatively (serum albumin <35g/L) • minimum of 3 month's post surgery follow up documented in record Exclusion: • ambulatory • serum albumin >35g/L • previous history of flap surgery Characteristics: • Mean age 54 years • 14/16 PU were stage IV and 2/16 were stage II PU • 5/16 had additional PU in another anatomical location • All participants were dependent on others for bed mobility • Average serum albumin 21g/L ± 5.7g/L • Co morbidity included CVA and diabetes	**Pre surgery** • At time of referral all participants received high protein, high calorie diet for 3 weeks prior to surgery • All participants were managed on a regular hospital mattress with 3 to 4 hour repositioning • All PUs received moist gauze packs **Surgery** • All participants underwent a V-Y advancement flap coverage for the sacral PU with radical debridement of necrosis, padding of bony prominences, dead space management, negative suction drain, tension free closure **Post surgery** • Prone positioning with lateral position 3 to 4 hours for 1 to 2 weeks or until wound healed • Where prone was not tolerated, doughnut air cushion was used • Sitting initiated at 3 to 4 weeks • Wound cleaned daily (some wound managed with wet to dry gauze).	• Outcomes measured included the number of surgeries needed for coverage and complications encountered • Average follow up 11.25 months after surgical closure	• Wound related complication rate 37.5% (n=6) including corner necrosis, delayed healing. • Recurrence rate was 12.5% (n=2) • No association was established between complications and number of surgeries for eventual closure (r=0.516) • More complications occurred in younger age group (< 54 years; p=0.039) • There was no correlation between wound complications and having a comorbidity (p=0.458) • **The study provides some evidence on rate of complications for surgery. The facility implemented PU prevention and management strategies that are no longer recommended.**	• No control group • Relied upon accurate records and data extraction • Many of the care initiatives pre and post surgery do not reflect best practice (e.g. no specialized surfaces, use of doughnut pillow following surgery, moist gauze packs only). • Surgery in only one hospital • Unclear if sample is consecutive • Minimal characteristics of participants reported • "complication" is not defined and its assessment is not reported	**Level of evidence: 5 Quality: low**
(Laing, Ekpete et al., 2010)	Retrospective analysis reporting **outcomes for PU surgery**	Records for all participants receiving surgery for PU between 2001 and 2007 in one facility in Ireland (n=41 with n=58 PU) Inclusion: • Surgery for PU Characteristics: • mean age 52.1 yrs (range 36 to 79) • 80%sample were male	• All patients underwent initial surgical debridement followed by application of negative pressure wound therapy using the vacuum-assisted closure 24 to 48 hours following surgery	• Requirement for reconstruction following surgical debridement • Time from presentation to complete wound healing • Complications • Mean follow-up was 18 months	• Following debridement, surgical reconstruction procedures were required for approximately 50% of patients (n=20 patients, n=23 procedures) • Mean time from debridement to definitive reconstruction was 4.3 weeks • Reconstructive procedures: o Primary closure (n=1) o Split-thickness graft (n=5) o Local fasciocutaneous flap	• Relied on medical record accuracy • One facility and possibly only one surgical team	**Level of evidence: N/A Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• 50% had grade IV PU, 43% had grade II PU, 7% had grade II PU • 29% had associated osteomyelitis and 41% were MRSA positive • 41% ischial PU, 29% sacral PU, 16% trochanter PU, 12% heel PU • 36.6% participants had a co-morbidity, primarily chronic respiratory disease, diabetes or cardiac failure			(n=4) o Musculcutaneous flap (n=11) • Post-reconstructive complications occurred in 25% (n=10) • Complications: o Bleeding requiring transfusion, all occurring post debridement (n=5) o Partial flap necrosis (n=3) o Ulcer recurrence (n=0) • The mean time to complete wound healing from initial presentation was 12.4 weeks (range 6 to 22 weeks) • **The authors propose that a two stage process (debridement followed by reconstruction if required) prevents the flap concealing bleeding, allows for antibiotic management based on biopsy and allows for assessment of patient compliance. However, there is no comparison to support this interpretation of the data.**		
(Keys, Daniali et al., 2010)	Retrospective record review reporting **outcomes for PU surgery**	Records were reviewed in one US hospital for all patients who underwent flap surgery over a 15 year period (1993 to 2008). (n=135, flap surgeries = 227) Inclusion: • all patients undergoing flap surgery Exclusion: • Death within 6 mths of surgery • primary closure, skin grafts Characteristics • Most flaps were ischial (54%) followed by sacral (27%), and trochanter (18%) • Primarily male patients, median age 54 yrs • 45% of flaps were repeat flaps	All patients underwent flap surgery. This was a retrospective review of outcomes and multivariate analysis of predictors for return to operating room.	• N/A	**Wound dehiscence** • Total: 48.5% (n=110) • Requiring surgical revision 15.5% (n=36) **Recurrence** • Total 38.8% • Early recurrence 18.5%, late recurrence 20.3% **Multivariate analysis predictors for dehiscence** • Age < 45 years (OR 4.9, 95% CI 1.2 to 20.1) • History of same site failure (OR 3.8, 95% CI 1.2 to 11.9) • Poor diabetes control (OR 15.9, 95% CI 2.0 to 127) **Multivariate analysis predictors for recurrence** • Ischial wound location (OR 2.87, 95% CI 1.5 to 5.6) • Previous same site flap failure (OR 3.3, 95% CI 1.4 to 7.6)	• Single site audit, unclear if it is a single surgical team • Strategy of identifying long term complications is unknown (e.g. ongoing clinical reviews, patient reports) • Unclear if there was consideration of patients who may be reviewed by other facilities after surgery (e.g. may have had complications managed elsewhere).	**Level of evidence: 4** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(Kim, Kim et al., 2013)	Retrospective cohort study **comparing outcomes for different types of flap surgery**	Participants were all recruited at surgical center in Korea. conventional flap group was recruited from 1998 to 2002 (n=17) and perforator based flaps group recruited 2002 to 2007 (n=21 with n=23 PU) Inclusion: • trochanter PU requiring surgery Characteristics: • mean age 56.6 yrs • grade III or IV PU • mean PU size 90cm2 • Mean flap size 108cm2 • No significant differences in characteristics between groups	Participants received either: • Conventional tensor fascia lata (TFL) flap (n=17) • tensor fascia lata perforator-based island flap(TFL-PBIF)	• recurrence rates • Complications • Mean follow up was 9.6 months	• There was no significant difference in recurrence rates between groups (1 case in each group, p=1.00) • Complications were not significantly different between groups (TFL vs TFL-PBIF): o Hematoma (11.7% vs 4%, p=0.565) o Seroma (5.8% vs 4%, p=1.00) o Graft ulceration (11.7% vs 0%, p=0.174) o Wound dehiscence (11.7% vs 4%, p=0.565) o Partial necrosis (0% vs 4%, p=1.00) o Total complications (41.2% vs 17.4%, p=0.153)	• Selection of participants is not clear • Single surgeon • Short follow up period	**Level of evidence: 4 Quality: moderate**
Reports on different pre, intra and post-operative management							
(Larson, Hudak et al., 2012)	5-year retrospective study **reporting outcomes of a standardized clinical pathway**	Participants were a consecutive sample of patients undergoing PU surgery at one center over a 5 year period (n=101 with 179 PU) Inclusion: • All surgical patients in facility Characteristics: • Mean age 49.4 yrs • PU locations: Ischial-49.7%, sacral-26.8%, trochanteric- 19% • 87.7% of PU were stage 4 • 33% smokers, 21% renal disease	• All patients were treated at the same institution under the same plastic surgeon using the same postoperative protocol • All patients underwent surgery with immediate reconstruction – this included sharp debridement of the bony base using the VersaJet	Data abstracted included: • Demographics, • Comorbidities • Location and stage of ulcers • Treatment history with outcomes • Laboratory data Mean follow-up was 629 days	• Primary closure was performed on 45.8% and remaining 53.2% underwent flap closure • There was no correlation between positive bone cultures and recurrence or complications • The overall recurrence rate was 16.8% at a mean period of 435.9 days • New ulcer occurrence was 14.5% and the complication rate was 17.3% • Complications: o Suture line dehiscence – 27 (15%) o Infection – 4 (2.2%) o Distal flap necrosis – 1 (0.6%) • **The author concludes that the protocol that had been unchanged for 10 years had an adequate success rate.**	• Unclear how many lost to follow up (7% lost to death) • No discussion of other literature or other protocols that may be appropriate or more successful • Protocol had not changed over a 10 year period • Patients may not have returned if there was a recurrence	**Level of evidence: 5 Quality: moderate**
(Singh, Singh et al., 2013)	Prospective clinical study **outlining management strategy and outcomes**	Participants were recruited over 5 years from one tertiary facility in India (n=35 with n= 37 PU) Inclusion criteria: • Occurrence of a traumatic event in	**Pre-operative** • 2/24 posture changes with encouragement to increase prone positioning in preparation for post-operative period	• Overall outcome rated as excellent, good or poor (no indication of how this was determined) • wound dehiscence	**Type of procedure** • 19 gluteus maximus V-Y advancement flaps • 6 tensor fascia lata flaps • 2 tensor fascia lata vastus lateralis flap • 3 gluteus maximus island flaps	• Small sample size • No factors that may influence post-surgical outcomes are reported (e.g. comorbidites) • One facility and possibly	**Level of evidence: 5 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		SCI below C4 • PU stage III or IV that fails to heal with conservative treatment • Signed consent • Aged >18 yrs Exclusion: • chronic mental illness Characteristics: • Mean age 34.12 yrs (range 17 to 57) • 72.9% Sacral, 21.6% trochanter	• water or air bed • avoid bedding linen creases • clean intermittent self-catheterization • nutritious diet • daily antiseptic dressing +/- debridement as required **Intra-operative** PUs treated using classic and modified flaps with improvisations **Post-operative** • Daily inspection by surgeon, patient and/or caretaker • Avoid pressure on flap • 2/24 repositioning commenced at 2 weeks postoperative • Indwelling catheter for 2 weeks • Sitting allowed after 6 weeks • Proper wheel chair cushions	• flap necrosis and • recurrence • Follow up average duration 14.34 months	• 7 fasciocutaneous rotation flaps **Complications** • Partial flap necrosis 2.7% • PU recurrence at flap site 5.4% • Overall PU recurrence rate 11.4% **Overall outcome** • excellent in 32 (86.48%) • good in 4 (10.81%) • Poor in 1 (2.7%)	only one surgical team	
(Srivastava, Gupta et al., 2009)	Prospective study **investigating the efficacy of surgical interventions for PU in patients with spinal disorders**	Participants were those admitted in a one year period to a neurological ward in India (n=25 with n=39 ulcers) Inclusion: • stage III, IV or unstaged pressure ulcers • spinal cord disorder Characteristics: • 33.3% sacral , 23% gluteal , 20.5% trochanter, 10.2% ischial, 5% heel, 5% sole of foot , 2.5% dorsum ankle • 36sample had > one PU • 58.9% stage IV, 33.3% stage III PU • 88% participants had a high risk Braden score (<16) • Spinal injuries included tranverse myelitis, spinal tuberculosis, SCI, tumors	**Preoperative management** • nursing care • bedside sharp debridement dressing • education **Operative interventions** • based on PU stage and presence/absence of eschar • 58.9% had flap closure • 33.3% had skin grafting • 7.6% surgical debridement **Postoperative management** • continuous negative pressure for 48 to 72 hours • appropriate wound hygiene	• postoperative complications • recurrence rate • neurological (ASIA grade) • functional recovery (Barthel Index) • Mean follow up duration 15.4±7.45 months (range 12 to 21 months; 8% lost to follow up)	**Healing** 87% had total healing 17.3% recurrence (13% at the same site and 4.3% at a new site) **Surgical complications** • Complication rate 10.2% (n=2) • For split skin graft (n=13): ○ wound infection (n=2) • For flap mobilization and closures (n=23): ○ suture line dehiscence (n=2) **Length of stay** • Mean 97.36 days (range 16 to 269) • participants with a traumatic spinal pathology had a longer mean stay (180.55±65.45 days) compared with non-traumatic spinal pathology (134.71±42.34) **Barthel Index** • baseline: mean score 28.6±16.68	• Small sample size • Selection bias in in terms of age at onset, level of lesion, and pattern of paralysis • One surgical team • No statistical analysis • No factors that may influence post-surgical outcomes are reported (e.g. comorbidites)	**Level of evidence: 5 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
			• sutures removed day 10 gradual mobilization and weight bearing • rehabilitation • counseling.		(range 5 to 75) • postoperative mean score 67.0±16.95 (range 25 to 100, p=not reported) • follow up mean score 74.61±23.97 (range 25 to 100, p=not reported) **Neurological evaluation** • baseline versus postop ○ ASIA Grade A 80% vs 21.7% ○ ASIA Grade B 12% vs 4.3% ○ ASIA Grade C 8% vs 8.6% ○ ASIA Grade D 0% vs 60%		
Identify surgical site							
(Isken, Alagoz et al., 2009)	Retrospective case series **reporting detecting the position of suitable perforators**	Participants were ambulatory patients requiring surgery between 2002 to 2007 (n=26) Inclusion and exclusion criteria not reported Characteristics: • Mean age 47.7 yrs (range 7 to 77 yrs) • Mean PU size 83cm^2 • 22 sacral PU, 6 trochanter PU, 8 ischial PU • 53.8% ambulatory participants with PU following surgery	• Color Doppler ultrasonography was performed using high sensitivity and low wall filter to detect blood vessels with low flow • Pulsed repetition frequency 700 Hz and medium persistence was used • Vascular structures with arterial flow pattern with flow direction to cutaneous layers were accepted as cutaneous perforating artery • All perforators were marked on the participant the day prior to surgery	• Flap viability • Operating time • Mean follow up 15.9 months	• 36 gluteal perforator flaps were performed, • Mean flap area 166 cm^2 • Mean duration of surgery 31.9 minutes • Complications: ○ Superficial epidermolysis (n=3 participants) ○ Wound site infection (n=2) 11.5% ○ wound dehiscence (n=2) 10% ○ Partial necrosis (n=2) 10% • 100% of perforators were identified precisely • Flap viability rate was 94.4% • **Study conclusion: use of color Doppler ultrasonography to identify perforator vessels precisely prior to surgery is related to short operation time, high flap viability and low complication rates**	• Self reported surgical outcomes • No control for comparison • No comorbidities are reported • Participants inclusion/exclusion and recruitment strategy is not reported	**Level of evidence: 5 Quality: low**
Predicting surgical risk							
(Kurita, Ichioka et al., 2009)	Case control study **investigating validated measurement systems to quantify surgical risk for people with PU**	Participants were all recruited from a Plastic Surgery department in Japan (n=112) Inclusion for PU cohort: (n=50 with n=71 PU surgeries) • underwent PU surgery • followed for > 30 days Inclusion for non-PU cohort: (n=62 with n=62 surgeries)	**PU cohort** • types of surgery ○ debridement (n=29) ○ wound closure/suturing (n=5) ○ wound closure/skin graft (n=5) ○ wound closure/flap (n=32) • types of PU ○ grade III (n=7) and grade	Risk of mortality calculated using: • Physiological and Operative Severity Score for enumeration of Mortality and Morbidity (POSSUM; has previously been validated) • O-POSSUM (POSSUM developed for	• PU cohort – 8/50 patients died within 30 days; non-PU cohort 0/62 died • Patients with PU had lower haemoglobin and higher predicted mortality scores than non PU patients • O-POSSUM was significantly more likely to predict morbidity than haemoglobin levels (p<0.01) in participants with PU • O-POSSUM showed best discriminatory power with AUC of	• Cohort of PU patients had demographics that increased surgical risk that were not related to having a PU (e.g. age) • No comparative analysis of demographics • Unclear how participants were	**Level of evidence: 4 (prognostic) Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• patients undergoing non-PU surgery (but not another type of chronic wound) • aged ≥ 15 years Characteristics of PU cohort: Mean age 72.1±17.5 yrs Characteristics of non-PU cohort: Mean age 47.2±20.8 yrs	IV (n=64) PUs ○ sacral (n=54), trochanter (n=14), ischial (n=7), other (n=4) **Non PU cohort** • types of surgery ○ plastic surgery for facial disfigurement (N=17) ○ reduction of facial bone fracture (n=14) ○ resection and /or reconstruction for sift tissue malignancy (n=9) ○ reconstruction of trauma burns (n16)	orthopedic patients) • haemoglobin level • albumin level	0.83±0.08 • O-POSSUM and POSSUM were both valid predictive methods (p>0.05 for both) • **Conclusion: The study provides support for POSSUM and O-POSSUM scores being used as a predictor for risk of mortality for patients undergoing PU surgery**	selected for inclusion • Clear use of the tool is not described (e.g. how different PU surgeries were classified on an orthopedic tool) • Small cohort of deaths – may not have statistical power	
Impact of surgery on quality of life							
(Yarkin, Tamer et al., 2009)	Prospective observational study **investigating impact of PU reconstruction surgery on psychiatric state**	Participants and their caregivers were a sample of successive surgical patients recruited in Turkey (n=20 people with PU plus their caregivers, n=17 patients and n=18 caregivers completed study) Inclusion: • Reconstructive PU surgery in Jan 2006 to Jan 2008 • Spinal cord injury (SCI) Exclusion criteria: • Experienced progressive depression during the course of 6 month follow up Characteristics: • 15/17 participants were paraplegic and 2/17 were quadriplegic • 18 PUs of which all were full-thickness, 15 were sacral and 3 were trochanter • 5/17 participants had PU recurrence during 6 month follow up • 23 local fasciocutaneous flap surgeries performed in total • All participants had at least 5 years of formal education	• Participants completed the outcomes measure test tools prior to surgery and at 6 month follow up • Instructions were provided by a psychiatrist	• Psychiatric state and quality of life (QOL) measured using Beck depression inventory (BDI), trait anxiety inventory (TAI), and the short form-36(SF36) • Components reported from SF-36 included physical function, physical role difficulty, pain, general health, energy, social function, emotional role difficulty and mental health. • Self-administered tools • 6 month follow up	**Patient participants** • Prior to surgery, all SF-36 outcome measures were significantly lower than the national average (p<0.05 for all) • At 6 month follow up, all SF-36 outcome measures except physical role difficulty on SF-36 were significantly lower than the national average (p<0.05) • There was a statistically significant improvement in all SF-36 outcome measures (p<0.05 for all) between preoperative measures and 6 month follow up • There was a statistically significant improvement in BDI score between preoperative measures and 6 month follow up(17.9±5.99 preop versus 10.8±5.50 postop, p<0.05) • There was a statistically significant improvement in TAI score between preoperative measures and 6 month follow up(44.4±10.81 preop versus 29.2±5.79 postop, p<0.05) • There was a positive correlation between BDI score and PU recurrence (p<0.05) **Caregiver participants** • There was no significant difference between SF-36 outcome measures for	• Compares to a national average, but no details of the national average cohort are provided • Perioperative protocol is not reported clearly • Self-completed outcome measurement tools, subject to bias • Insufficient details provided regarding the participants and aspects of their life that may impact psychosocial scores • Excluded participants with progressive depression	**Level of evidence: 3** **Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					physical function, physical role difficulty, pain, general health or energy when compared with national average. • There was significantly lower scores for social function, emotional difficulty and mental health compared with the national average ($p<0.05$ for all). • There was a statistically significant improvement in TAI score between preoperative measures and 6 month follow up(53.0±7.78 preop versus 27.2±4.81 postop, $p<0.05$) • There was a statistically significant improvement in BDI score between preoperative measures and 6 month follow up(16.0±4.05 preop versus 10.3±1.78 postop, $p<0.05$) • There was a positive correlation between TAI score and PU recurrence ($p<0.05$) • **The study provides evidence that people with PU and their caregivers have more depression and lower QOL than average and that surgery may improve this' however the small study sample and insufficient participant characteristics prevent any generalization of the study results.**		
Patient education surgery							
(Rintala, Garber et al., 2008)	Randomized controlled trial **investigating an education program post-surgery to reduce PU recurrence rates**	Participants were recruited from a veterans affairs medical center in US (n=41) Inclusion/exclusion not stated Characteristics • Mean age 50 to 54 years • Mean time since SCI 15 to 20 years • Significant difference between groups in type of flap surgery (p=0.02) • group 3 had significantly shorter	• All participants received standard care pre and post surgery. • Participants were randomized to receive: • enhanced education and monthly structured follow up intervention for 2 years after discharge (group 1, n= 20,n=18 analyzed) • monthly contacts for up to 2 years after discharge to assess skin status, with no	• primary outcome was time to pressure ulcer recurrence • Self assessed health status • Skin status was assessed through phone interview • Follow up was 2 years (or until recurrence)	• Significantly fewer participants in group 1 had a recurrence of PU by 24 months (33% vs 60% vs 90%, p=0.007) • For group 1 odds ratio (OR) of a PU by 24 months was 0.228 (95% CI 0.080 to 0.647, p=0.003) • No significant differences between groups 2 and 3 in recurrence	• Small sample size • Inappropriate randomization method and allocation concealment • Study did not reach sample size required for statistical power • Groups 1 and 2 participated in another study concurrently • Nonequivalent groups at baseline	**Level of evidence: 2 Quality of evidence: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		time since last surgical closure (1.05 yrs vs 6.30 yrs, p=0.03)	education during or after hospitalization (group 2, n=11, n=10 analyzed) • minimal contact via mail every 3 months for up to 2 years after discharge only to assess skin status, but received, with no education during or after hospitalization (group 3, n=10, n=10 analyzed) • Standard education consisted of 1 to 2 hours of 1:1 education on prevention incl nutrition, smoking, skin inspection and care; a manual that included sections on PU prevention; training for families by phone/mail; therapist-supervised progressive sitting program and education on transfers and seating. • Enhanced education included 1 to 4 additional hours 1:1 over four sessions on etiology, prevention and pressure relieving devices; one session for families, additional education monthly for 25 minutes via phone.			• Self-assessed outcomes • Two participants had MS, both assigned to group 1	

References

Ahluwalia, R., D. Martin and J.L. Mahoney. (2009). "The operative treatment of pressure wounds: a 10-year experience in flap selection." International Wound Journal **6**(5):355-8.

Daniali, L.N., K. Keys, D. Katz, et al. (2011). "Effect of preoperative magnetic resonance imaging diagnosis of osteomyelitis on the surgical management and outcomes of pressure ulcers." Annals of Plastic Surgery **67**(5):520-5.

Estrella, E.P. and E.Y. Lee. (2010). "A retrospective, descriptive study of sacral ulcer flap coverage in nonambulatory patients with hypoalbuminemia." Ostomy Wound Manage **56**(3):52-9.

Isken, T., M.S. Alagoz, M. Onyedi, et al. (2009). "Preoperative color Doppler assessment in planning of gluteal perforator flaps." Annals of Plastic Surgery **62**(2):158-63.

Keys, K.A., L.N. Daniali, K.J. Warner, et al. (2010). "Multivariate predictors of failure after flap coverage of pressure ulcers." Plastic and Reconstructive Surgery **125**(6):1725-34.

Kim, Y.H., S.W. Kim, J.T. Kim, et al. (2013). "Tensor Fascia Lata Flap Versus Tensor Fascia Lata Perforator-Based Island Flap for the Coverage of Extensive Trochanteric Pressure Sores." Annals of Plastic Surgery.

Kurita, M., S. Ichioka, Y. Tanaka, et al. (2009). "Validity of the orthopedic POSSUM scoring system for the assessment of postoperative mortality in patients with pressure ulcers." Wound Repair And Regeneration: Official Publication Of The Wound Healing Society [And] The European Tissue Repair Society **17**(3):312-7.

Laing, T.A., N. Ekpete, S. Oon, et al. (2010). "Surgical reconstruction of pressure ulcer defects: a single- or two-stage procedure?" Journal of Wound, Ostomy, and Continence Nursing: Official Publication of the Wound, Ostomy and Continence Nurses Society / WOCN **37**(6):615-8.

Larson, D.L., K.A. Hudak, W.P. Waring, et al. (2012). "Protocol management of late-stage pressure ulcers: A 5-year retrospective study of 101 consecutive patients with 179 ulcers." Plastice and Reconstructive Surgery **129**(4):897-904.

Rintala, D.H., S.L. Garber, J.D. Friedman, et al. (2008). "Preventing recurrent pressure ulcers in veterans with spinal cord injury: impact of a structured education and follow-up intervention." Archives of Physical Medicine And Rehabilitation **89**(8):1429-41.

Singh, R., R. Singh, R.K. Rohilla, et al. (2013). "Improvisations in classic and modified techniques of flap surgery to improve the success rate for pressure ulcer healing in patients with spinal cord injury." International Wound Journal **10**(4):455-60.

Srivastava, A., A. Gupta, A.B. Taly, et al. (2009). "Surgical management of pressure ulcers during inpatient neurologic rehabilitation: outcomes for patients with spinal cord disease." JSpinal Cord Med **32**(2):125-31.

Thiessen, F.E., P. Andrades, P.N. Blondeel, et al. (2011). "Flap surgery for pressure sores: should the underlying muscle be transferred or not?" Journal of Plastic, Reconstructive & Aesthetic Surgery **64**(1):84-90.

Yarkin, O., S. Tamer, O. Gamze, et al. (2009). "Effect of surgery on psychiatric states and quality of life of paraplegics and quadriplegics with pressure sores and their primary caregivers." European Journal of Plastic Surgery **32**(4):173-6.

Special Populations

BARIATRIC INDIVIDUALS

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
(Pemberton, Turner et al. 2009)	Observational pilot study	Participants were a convenience sample of consecutively admitted patients (n=21) Inclusion: • BMI > 35 • Weight 250 to 500lbs • minimum 3 day stay on support mattress (max 7 days) Exclusion: • Using only one turning position Participant characteristics: • mean BMI 51.4 (±10.3) • mean age 51.7 years (±14, range 32 to 76) • 28% (n=6) had existing PU • 62% had COPD • 63% had hypertension • 57% diabetes mellitus • 57% urinary incontinence • 43% faecal incontinence • 43% neurological impairment	Low-air-loss, continuous lateral rotation bariatric bed with advanced microclimate technology (TotalCare® Bariatric Plus Therapy System) Participants spent an average of 4.8±2.5 days (range 2 to 8) on the bed surface.	• PU incidence • PU stage (NPUAP criteria) and size • employee satisfaction on a 4-point Likert scale • patient comfort rating (multiple choice questionnaire where 1 = very uncomfortable and 4 = very comfortable) • Final outcome measures at day 7.	• No new PUs developed • PUs decreased from an average size of 5.2 cm^2 (±5.2) to 2.6cm^2 (±5.0) • 5 PUs completely healed, but 3 PUs had no change • Mean caregiver satisfaction rating was 3.6 • Mean patient comfort rating 3.9 • **Study conclusion: In patients with a BMI above 35kg/m^2, a low air loss, continuous rotation bariatric bed was associated with no new PUs and a decrease in PU size for existing PUs after a maximum of 7 days.**	• Small, non-randomised study • No statistical significance reported • No comparison group • No long term follow up (patients stayed on bed for between 2 and 7 days)	**Level of evidence: 5** **Quality: low**
(Elsner and Gefen 2008)	Biomechanical modelling to determine if internal muscle tissue loads under the ischial tuberosities (IT) is elevated at high BMI	• n=5 finite element (FE) models representing the same individual at BMIs ranging from 25.5 to 40	• Biomechanical models of internal muscle tissue loads under the IT in seated positions • Models represented the same individual (i.e. same IT shape, size, distance between IT), a 28 yr old male of 1.82m height, but with different thickness of gluteal muscles and fat tissue layers for different BMI • In some models gluteal muscle atrophy of 30% was investigated to represent a patient with SCI	• Computational FE models	• Maximal principal strain, compression strain, principle tensile stress, maximum shear stress and strain energy densities all increased with an increase in BMI • Increases were of a greater magnitude for seating on a hard surface versus a soft chair • When muscle atrophy was included in models (30% atrophy and a BMI of 40) there was additional increase in tensile stress, maximum shear stress and strain energy density.	• No simulation for BMI >40 • Does not provide evidence that increased tissue loading increases PU	**Indirect evidence**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
(Sopher, Nixon et al. 2010)	Biomechanical modelling to determine if internal muscle tissue loads under the ischial tuberosities (IT) is elevated at high BMI	• n=21 finite element (FE) models representing the same individual at BMIs ranging from <16.5 to 40 • overweight (BMI 25 to 30) n=4 models • obese class I (BMI 30 to 35) n=1 model • obese class II (BMI 35 to 40) n=2 models	• Biomechanical models of internal muscle tissue loads under the IT in seated positions • Models represented the same individual (i.e. same IT shape, size, distance between IT) but with different thickness of gluteal muscles and fat tissue layers for different BMI	• Computational FE models	• Percentage volume of muscle tissue exposed to critical compression strain increased 5.7 times for an increase in BMI from 19 to 40. • Trend of progressive increase in internal tissue loading for BMI outside the range 17 to 22.	• Unclear how model differentiated gluteal muscle density versus fat and whether this would influence the findings • No simulation for BMI >40 • Does not provide evidence that increased tissue loading increases PU	**Indirect evidence**

PREVALENCE DATA

Reference	Subjects	Design/ method	Incidence & follow up	Prevalence Stage/ Category	Clinical Site	Database or clinical	Limitations
(Rimmer, Yamaki et al. 2010)	n=461 adolescents (aged 12 to 18 years) with cognitive (n=322) or physical (n=139) disability overweight (BMI ≥ 85th percentile): • 130/322 with cognitive disability • 28/139 with physical disability 67.5% males (mean age 14.8±1.9) 32.5% females (mean age 15.2±2.0)	Prospective web-based survey	N/A	• 1.8% of overweight adolescents with cognitive disability had PU versus 0.7% of healthy weight (p=0.574) 30.8% of overweight adolescents with physical disability had PU versus 14.3% of healthy weight (p=0.081)	Community based	CL	• Parent-reported web-based survey • Non-representative population – primarily higher SES • Unclear how parents differentiated PU from other wounds or if only health professional diagnosis was requested

(Rana, Michalsky et al. 2009)	n=1314 record reviews of children admitted to one paediatric hospital in USA admitted to trauma centre from Jan 2004 to July 2007. Inclusion: • Admission for a trauma injury • Documented weight and height Obese (n=294) • BMI ≥95th percentile for age • Mean BMI 29.7 (significantly higher than non-obese group, p<0.001) • No differences between groups in reason for trauma admission • Both groups primarily female (approx. 70%) Non-obese (n=1020) • BMI <95th percentile for age • Mean BMI 18.8	Retrospective record analysis cohort study	• PU occurred more often during the admission for obese population compared with non-obese population, (1% versus 0.2%, p=0.04) • Length of hospital stay did not differ between groups (2.6±5.0 days for non-obese versus 2.9±10 days for obese, p=0.50) and mortality was equivalent between groups.	N/A	Paediatric trauma hospital	DB	• Database review for which 73% of entries did not have a documented weight so were not included • Single site study • Does not state how PU was classified • Did not appear to address PU present on admission • Comorbidity on admission was not reported (e.g. other risk factors such as SCI were not controlled for)
(VanGilder, MacFarlane et al. 2009)	Facilities in the US signed up for the survey and completed data on all patients admitted or residing in the facility within the 24 hour time period • 2006 702 facilities, n=88 743 • 2007 628 facilities, n=79 193	Prospective web-based cross-sectional cohort survey with a convenience sample	N/A	Findings were very similar between 2006 data and 2007 data. Braden score was used for PU risk. **Under weight (BMI <18.5)** 5.5% of participants Mean Braden scale 16 Nosocomial PU 10.5% Stage I PU 32.8% Stage II 31.8% Stage III 7.5% Stage IV 9.4% Unstageable 13.6% DTI 4.6% **Normal (BMI 18.5 to 24.9)** 30.6% of participants Mean Braden scale 18 Nosocomial PU 7.8% Stage I PU 32.6% Stage II 36% Stage III 8% Stage IV 6.8% Unstageable 12.7% DTI 3.2% **Over weight (BMI 25 to 29.9)** 28.2% of participants Mean Braden scale 18 Nosocomial PU 5.8% Stage I PU 31.9% Stage II 37.2% Stage III 6.9%	Acute, long term care, rehabilitation and home care. Prevalence rates by facility type are reported in study (without breakdown by weight)	DB	• Facilitated and sponsored by a product manufacturer • Self reported data by facilities who chose to participate or not selection bias may have occurred as only facilities with a strong PU management ethos are likely to participate • Unclear how many incomplete records • No information about PU management in the facilities.

				Stage IV 6.8% Unstageable 11.8% DTI 3.9% **Obese (BMI 30 to 39.9)** 25.9% of participants Mean Braden scale 18 Nosocomial PU 4.9% Stage I PU 30.8% Stage II 39.8% Stage III 5.4% Stage IV 6.9% Unstageable 11.6% DTI 4.2% **Extremely obese (BMI 40 to 49.9)** 7% of participants Mean Braden scale 18 Nosocomial PU 4.9% Stage I PU 26.2% Stage II 40.4% Stage III 7.6% Stage IV 6.1% Unstageable 15% DTI 3.4% **Super obese (BMI≥50)** 2.8% of participants Mean Braden scale 18 Nosocomial PU 5% Stage I PU 18.7% Stage II 51.2% Stage III 9.4% Stage IV 3.9% Unstageable 12.3% DTI 3.9% • Participants with BMI≥40 had significantly less stage I PU (p=0.02) and significantly more stage II PU (p=0.004) than participants with BMI<40			
(Cai, Rahman et al. 2013)	Participants were newly admitted (from 2004 to 2008) nursing home residents in US followed for up to one year (n=2.217 million participants)	Prospective cohort study	Up to 12 months	Prevalence of PU as determined from MDS database information **Moderate or severe obesity (BMI ≥ 35)** (7.7% population) • PU at time of admission : 24.03% • OR of having a PU on admission from residents who stayed at least 90 days OR=1.158 (95% CI 1.142 to 1.174, p<0.001) • OR of developing a PU for residents who had no PU on admission and stayed at least 90 days OR=1.192 (95% CI 1.171 to 1.214, p<0.001) **Mild obesity (BMI 30 to 35)** (11.6% population) • PU at time of admission :18.70% • OR of having a PU on admission from residents who stayed at least 90 days OR=1.032 (95% CI 1.020 to 1.045, p<0.001)	nursing homes	DB	• Database review which may have been inaccurate • Only considered residents who are "long stayers"

				• OR of developing a PU for residents who had no PU on admission and stayed at least 90 days OR=1.032 (95% CI 1.017 to 1.047, p<0.001) **No obesity (BMI 18.5 to 30)** (80.6% population) • PU at time of admission : 18.70% **Influences on OR of PUs in obese residents:** higher level of CAN staffing associated with lower level of PUs			

References

Cai, S., M. Rahman and O. Intrator (2013). "Obesity and pressure ulcers among nursing home residents." Med Care **51**(6): 478-486.

Elsner, J. J. and A. Gefen (2008). "Is obesity a risk factor for deep tissue injury in patients with spinal cord injury?" Journal of Biomechanics **41**(16): 3322-3331.

Pemberton, V., V. Turner and C. VanGilder (2009). "The effect of using a low-air-loss surface on the skin integrity of obese patients: results of a pilot study." Ostomy/Wound Management **55**(2): 44-48.

Rana, A. R., M. P. Michalsky, S. Teich, J. I. Groner, D. A. Caniano and D. P. Schuster (2009). "Childhood obesity: a risk factor for injuries observed at a level-1 trauma center." Journal Of Pediatric Surgery **44**(8): 1601-1605.

Rimmer, J. H., K. Yamaki, B. M. D. Lowry, E. Wang and L. C. Vogel (2010). "Obesity and obesity-related secondary conditions in adolescents with intellectual/developmental disabilities." Journal of Intellectual Disability Research **54**(9): 787-794.

Sopher, R., J. Nixon, C. Gorecki and A. Gefen (2010). "Exposure to internal muscle tissue loads under the ischial tuberosities during sitting is elevated at abnormally high or low body mass indices." Journal of Biomechanics **43**(2): 280-286.

VanGilder, C., G. MacFarlane, S. Meyer and C. Lachenbruch (2009). "Body mass index, weight, and pressure ulcer prevalence: an analysis of the 2006-2007 International Pressure Ulcer Prevalence Surveys." Journal Of Nursing Care Quality **24**(2): 127-135.

CRITICALLY ILL INDIVIDUALS

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
Wound care							
(Weng 2008)	Quasi-experiment investigating **effect of tegaderm and tegarsorb in preventing PU in patients with oxygen masks**	Participants recruited from a medical ICU and a cardiac ICU in Taiwan (n=90) Inclusion: • Diagnosed with respiratory failure • Using and tolerating with non-invasive face mask • No facial skin breakdown Exclusion: • Not reported Characteristics: • No significant differences between groups at commencement for any demographics including BP and bloods • Primarily classified as having adequate nutrition and no sensory impairment • Majority had no sweating observed • Mean age approx. 75years	Participants were assigned to one of three groups: • Control group with no dressing (n=30) • Tegasorb group (n=30) • Tegaderm group (n=30) The materials were used to cover the nasal bridge and patients were observed for PU formation	• Formation of PU assessed as being one of four grades (grading system not reported, Grade I defined as reddened area lasting more than 30 mins after change of position). • Time until PU formed in minutes	• Incidence of grade I PU was lower in the tegaderm group compared with control group (53.3% versus 96.7%, p<0.01) • Incidence of grade I PU was lower in the tegasorb group compared with control group (40%% versus 96.7%, p<0.01) • PUs formed significantly faster in control group (1111±2169 mins) versus the tegaderm (2628±1655mins) or tegasorb groups (3272±2566 mins, p=0.0) • There were no statistical significant difference in occurrence duration and time between the tegasorb and tegaderm group • Tegaderm adhered less effectively than tegasorb • **Study conclusions: A protective dressing was associated with decreased incidence of grade I PU in older adults wearing non-invasive face masks**	• Small number of subjects • No blinding, no power calculations • Several factors may influence the findings (e.g. skin colour precluding accurate assessment of PU formation) • Facial formation may influence PU formation • No reporting of skin breaks/damage associated with dressing removal	**Level of evidence: 3 Quality: moderate**
(Brindle and Wegelin 2012)	RCT investigating the **effectiveness of a silicon border foam dressing in preventing sacral PU in ICU patients**	Participants were admitted to a cardiac ICU in USA. Beds in the unit were randomised as control or intervention beds, participants entered the group assigned to their bed (n=100 included participants, n=85 participants completed study and analysed). Inclusion: Participant considered to have high risk of PU based on: • Surgery duration >6 hours • Cardiac arrest during	• Staff members in ICU were provided with education on PU prevention for 3 weeks prior to the study. • All participants received low air loss mattress, repositioning, hydration, dietitian referral, regular skin checks. • All participants had prophylactic dressing in place during surgery. • Participants were assigned to either: ○ Control group	• Incidence of PU	• 9 PUs of stage II or greater developed during the course of the study. • No patient developed a PU until at least 6 days after the operative procedure. • 8 PUs developed in 4 participants in the control group (11.7%) versus 1 PU (2.0%) in the intervention group (p=NS between groups). • The unadjusted hazard ratio obtained was 4.4 (95% CI 0.49 to 39.4, p=0.19). • After adjustment by propensity score the hazard ratio was 3.6 (95% CI 0.32 to 40.7, p=0.30) i.e. those in standard care group experience a risk 3.6 times greater than the dressing group, but this is not	• Overall incidence of PU was less than expected or reported in other studies • Study was insufficiently powered to test for clinical significant results • Randomisation by bed instead of participant, no blinding, no intention to treat	**Level of evidence: 3 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
		admission • Vasopressors > 48 hours • Presence of shock, systemic inflammatory response syndrome, multiple organ dysfunction • Presence of at least 5 common risk factors for PU Exclusion: • Existing PU greater than stage I on admission • Aged less than 18 years • Pregnant female • Not meeting inclusion criteria Characteristics: • No significant difference in demographic characteristics, including comorbidities. • Mean age 61.8±13.2 years, • 66% sample male • Mean Braden score 11.2±2.12 • Mean time in OR approx. 7.70 hours • Primarily on bed rest • 32 to 37% with diabetes mellitus, 2% with malnutrition, 2 to 3% with incontinence	received only standard preventative care and barrier cream at least twice daily(n=35) ○ Dressing group received standard preventive care plus application of the silicone border foam dressing covering sacrum and changed every 3 days or as required (n=50)		significantly different. • **Study conclusions: in patients in the ICU at high risk of PU, preventative sacral foam dressings are no more or less effective in preventing PU incidence than comprehensive standard PU prevention programs coupled with staff education.**	analysis.	
Nutritional interventions							
(Theilla, Schwartz et al. 2011; Theilla, Schwartz et al. 2012)	Prospective RCT **investigating the impact of fish oil enriched diet on healing of PUs in ICU patients**	Participants were recruited from an ICU in Israel. (n=40) Inclusion: • Requiring nutritional support for ≥ 5 days • Grade II or more severe PU according to NPUAP classification	Participants received enteral nutrition, or if this was not tolerated, parenteral nutrition. Quantity of formula was based on non-fasting resting energy requirements. Randomised to receive either:	• PU state measured at baseline then weekly for 4 weeks using PUSH tool with 0=healed and 17=worst score • Acute inflammation as assessed through serum C-reactive protein (CRP) measured weekly	• There was no significant difference in protein intake between the two groups. Fatty acids intake was significantly higher in the study group (p<0.001) • Severity of PUs as indicated by PUSH score increased significantly over time for the control group (p=0.02) but not for the study group. • The study group had significantly greater decrease in CRP concentrations than the	• Small sample size • No objective measurement of PUs to indicate % wound healing or time to complete healing • Person assessing PU severity was not blinded	**Level of evidence: 2 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
		Exclusion: • Immuno-impairment (e.g. AIDS, autoimmune diseases) • Immunosupressives Characteristics: • No significant between group differences in age, gender, BMI, duration in ICU, diagnostic category. • Mean age 49 to 53 years • Mean BMI 28 to 32 • Primarily medical and trauma patients • 1/20 in treatment group and 2/20 in control group had a pre-existing PU on admission to ICU and remaining PUs developed after a mean of 6 days (no difference between groups) • No significant difference in PU severity at baseline (primarily grade II, p=0.02)	• fish oil and micronutrient-enriched formula (EN was enriched with vitamins A, C, E, zinc, manganese, copper, protein) (study group, n=20) or • an isonitrogenous formula (control group, n=20) Parenteral nutrition formulas taken by study and control group participants were not different with respect to micronutrients (but were different for fatty acids).		control group (p=0.02). • **Conclusions: a fish oil and micronutrient-enriched formula may prevent worsening PUs**		
Support surfaces							
(Williams, Leslie et al. 2011)	Quasi-experimental (cross-over design in two phases) **investigating interface pressure between buttock and different seating surfaces in ICU patients**	Participants were recruited from an ICU (22-bed ICU on a closed unit in tertiary- referral hospital in Australia (phase 1 n=18, phase 2 n=20) Inclusion: • impaired mobility • scheduled to be sitting out of bed in the regular ICU chair Exclusion: • unsuitable for sitting out of bed • severe diarrhea • able to bear weight (could sit on a regular high-back chair)	Phase 1: • All participants were positioned on 3 different seating surfaces (non-random because of availability of surfaces) for at least 30 minutes (except for one patient who had to put back in bed within minutes after starting. • Phase 1: three seat surfaces were: ○ Regular chair with single cushion (TotaLift-II trolley chair, Wy'East, Clackamas, Oregon) ○ Alternative chair with 4 separate cushions	• Interface pressures at the buttock-seat interface (excessive pressures (≥200 mm Hg)) • A Force Sensing Array (FSA version 4.0) pressure mapping system (Vista Medical Ltd, Winnipeg, Canada) with a single standard 45x45-cm pressure map • The period of 5 to 29 minutes of sitting out of bed was used • System was calibrated with an autocalibrator specific to the system • Seating protocol was used	Phase 1 • In participants with pressure maps showing excessive pressures (≥200 mm Hg): 46% of pressures recorded for the regular chair were higher than pressures for the gel chair, and on 11% of maps, the pressures were similar for the regular and gel seating surfaces (z = 2.0, P = .04) • Participants in alternative chair had significantly fewer excessive seating interface pressures compared with the regular chair • Participants in the alternative chair had significantly fewer excessive pressures when compared with the gel overlay • alternative chair lacked the practical utility of the regular chair (difficult to transfer participants and limited	• Not clear how drop-out was handled in analyses (patients were measurements could not be completed (phase 1: n=1 - reason hypotension; phase 2)+ some participants (number not reported) were too tall to be seated in alternative chair • Outcome measures were	**Indirect evidence Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
		Characteristics: Phase 1 • Median age 66 (59-73), female participants (28%), mean BMI 27 (5), worst APACHE II score in first 24h 17 (16-19), mean Braden score 12 (2), median number of days in ICU 14 (8-24) Phase 2 • Median age 62 (51-75), female participants (55%), mean BMI 27 (6), worst APACHE II score in first 24h 20 (17-23), mean Braden score 12 (2), median number of days in ICU 17 (12-30)	(Hausted APC, SterisCorp, Mentor, Ohio) ○ Regular chair with gel overlay • Phase 2: two seating surfaces were: ○ Regular chair with single cushion(TotaLift-II trolley chair, Wy'East, Clackamas, Oregon) ○ Alternative chair consisting of three cushions (back rest, cushion under buttocks , and cushion under legs) made from combination of high and low-density foam		adjustment options for supporting the patient) • Gel overlay did not reduce interface pressures Phase 2 • 55% (n=11) of the patients had seating interface pressures of 200 mm Hg or greater, and of these 10 participants (93%) had fewer episodes of excessive pressures on the new surface ($P < .001$). • The remaining 9 participants, seating interface pressures were lower than 200 mm Hg. Among patients who had pressures of 150 to less than 200 mm Hg, 40% had fewer episodes of higher interface pressure with the new surface than with the regular surface ($P < .001$).	not clearly described • Competitors not always clearly described • Materials of seating surfaces (foam) not clearly described	
(Black, Berke et al. 2012) (prevention)	Quasi experiment **comparing a low air loss bed with microclimate management to an integrated power air redistribution bed for preventing PU in a cardiovascular ICU unit**	Participants were recruited from a cardiovascular surgical ICU in USA (n=52) Inclusion: • Likely to be ICU for three days • Not receiving palliative care • No pulmonary or wound issues requiring special beds Characteristics: • No significant differences in demographics at baseline • Mean length of stay 7 days, mean length of data collection was 5 days • Mean age 59.1 years • Mean admitting Braden score 11.2 (range 7 to 20)	• Staff training occurred prior to study commencement. • Participants received similar regimens for repositioning and skin care. Participants received either: ○ loss bed with microclimate management (n=31) ○ integrated power air redistribution bed (n=21)	• PU incidence determined through skin assessment every three days • Mean follow up period was 5.7 days	• Participants on a low air loss bed had significantly less PUs (0% versus 18%, p=0.046)	• No randomization, blinding, study power calculation • Limited baseline demographics • Concurrent management unclear • Short study period • No interrater reliability	**Level of evidence: 3 Quality: low**
Positioning							
(Romero, Cornejo et al. 2009)	Case series **investigating the effect of**	Participants were recruited from an ICU in Chile (n=15)	Prone position ventilation for 48 hours or until the oxygenation index was 10 or	Primary: • Barotraumas and/or monobronchial incursion of the	• Prone position ventilation was continuously maintained for 55 ± 7 hours	• No control group • Only 20% of the individuals were	**Level: 5 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
	prone positioning ventilation and reporting PU as an adverse effect of positioning	inclusion: • aged over 18 years • severe Acute Respiratory Distress Syndrome (ARDS) • ventilation >72hrs exclusion: • contraindications to prone positioning ventilation • hemodynamic disorders • chronic respiratory insufficiency • likelihood of death within 24hrs Characteristics: • Mean age 46±17 years (range 19 to 69) • Mean time for mechanical ventilation 19±9 days (rang 4 to 64) • 40% died in UC • PU risk factors not reported	less (extended PPV)	orotracheal tube • Arterial and venous blood gas results Secondary: • Development of a new PU as assessed using NPUAP staging	• Two patients (13%) developed grade II PUs (nasal septum, cheek) • All patients experienced facial edema • No patients experienced ventilation complications in prone position	older than 60 years	
Critical care nurses' knowledge and education							
(Tweed and Tweed 2008)	Longitudinal repeated measures design **investigating effectiveness of an education program in improving knowledge of ICU nurses**	Participants recruited from a 12-bed ICU in a teaching hospital in New Zealand (n=62) Inclusion: all nursing staff in unit Baseline characteristics: • 27% RN2 level, 4% RN4 (most senior and 1% RN1 (most junior) • 39% graduated in 1990s • 55% had a nursing diploma or degree, 10% had postgraduate qualifications • Mean time in ICU 83 months • 53% no additional education on PU	• Educations program based on the Australian Wound Management Association guidelines for prediction and prevention of PU ○ Delivered in small groups over 2 week period ○ Interactive format based on oral presentation with 112 slides ○ 3 hours session ○ Key areas include guideline methods, PU epidemiology, aetiology, pathophysiology, risk factors, risk assessment, staging, equipment for prevention,	Knowledge level at baseline, within 2 weeks of an educational program and at 20 weeks.	• Mean score at baseline (n=62) 84% • Mean score at 2 weeks (n=38) 89%, (p=0.003 versus baseline). • mean score 20 week (n=29) 85% (p=ns versus baseline) • No association between years of qualification, length of time in the ICU or self-reported additional PU education and test scores at any time point • **Study conclusions: ICU had a strong baseline knowledge of PUs and this improved for a short period after a structured PU education session. Improvements in knowledge were not sustained at 5 months post-education.**	• Use of 3 different tests may have accounted for differences in the scores. • Baseline tests were observed while the participant was taking the test, but not the 2 or 20 week tests • Use of nurses drawn from a single ICU • Possible that knowledge improvement only occurred in those who	**Indirect evidence: no association made between knowledge and PU outcomes Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
			documentation • Knowledge test designed with input from EUPAP members using a modified Delphi technique consisting of 11 multiple choice and short answer questions piloted in a step-down unit			already had a high knowledge • No	
(Strand and Lindgren 2010)	Descriptive, cross-sectional study **investigating knowledge toward PU care in ICU** (also investigated attitudes and practice, see "Workplace practice" below)	Participants were nursing staff in four ICUs in a Swedish University Hospital (n=315 received survey, n=146 returned survey) Characteristics: • 56.2% worked full time • Mean age 38.8±7.4 years for RNs and 43.5±9.7 for ENs (p=0.001)	• Questionnaire developed from other previously questionnaires. • Pilot testing of instrument prior to distribution.	• nurse attitudes • nurse knowledge • nurse perceived barriers and opportunities towards PU prevention in the ICU setting.	Knowledge • RNs were able to correctly categorize PU more frequently than ENs (p=0.019) • Significant differences in agreement between RN and EN on the following risk factors ○ poor sensory perception (p=0.029) ○ shearing forces (p=0.016) ○ poor nutritional status (p=0.012) • **Study conclusions: PU knowledge levels were higher in RNs than ENs in this sample of ICU nurses.**	• Response rate was low at 46% (according to the authors) may be due to the length of the questionnaire • No validation of practice in the ICUs • Self-selected response may be from ICU nurses with more interest in area of PU	**Indirect evidence: no association made between knowledge and PU outcomes Quality: moderate**
(Cox, Roche et al. 2011)	Pre/post-test study **comparing didactic learning to computer-based learning for retention of PU knowledge**	A convenience sample of staff nurses (RN) in a teaching hospital in USA (n=60, n=32 were in ICU) Characteristics: • 57% aged > 40 years • 95% sample female • 53% White, 35% Asian/Pacific • 68% highest degree was Bachelor's , 20% had a diploma • 28% had less than 6 years' experience and 55% had greater than 10 years' experience • 75% preferred a lecture learning environment	Participants were randomly assigned to: • traditional class teaching: 1 hour long sessions presented by a wound ostomy nurse using oral presentation and slides. Sessions had defined learning objectives. Sessions were run over a two week period to allow all staff to attend (n=20) • computer based learning: self-learning module developed by the wound ostomy nurse based on the same learning objectives as the class room teaching and containing the same	• Nurses were administered the Pieper Pressure Ulcer Knowledge Test (47 items) for which previous validation is reported • Measures at baseline, post-test, 3 months and 6 months	Pre-test knowledge • No significant difference in three groups at pre-test knowledge measure (p=0.537) Post-test knowledge • Significant differences between three groups from pretest to posttest (p=0.00) • Lecture group had significantly greater increase in scores than the computer group (p=0.043) 3 month knowledge • Significant differences between three groups from posttest to 3-month test (p=0.00) • No significant difference between mean improvements for lecture versus computer groups (p=0.717) 6 month knowledge • No significant differences for any group	• Hawthorne effect is a potential limitation • Self-selection may limit findings as may be a highly motivated group • Independent learning may influence findings	**Indirect evidence: no association made between knowledge and attitudes and PU outcomes Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
		• 52% reported being visual learners • 82% reported being unaware of PU clinical guidelines • 37% had most recent PU knowledge > 4 years ago	slides. Nurses had two weeks to do the module. (n=20) • control: no education (n=20)		between 3- month and 6-month scores (p=0.405) • Study conclusions: computer-based learning is a viable learning option and has greater flexibility. Increased knowledge of PU management was sustained over 6 months, with greatest knowledge loss in the first 3 months following education.		
(Iranmanesh, Rafiei et al. 2011)	Descriptive study	Nurses recruited from ICU settings in 5 hospitals in Iran (n=126) nb: approx. 300 total ICU nurses in Iran Inclusion: • all qualified ICU nurses invited to participate Characteristics: • Mean age 30.23±5.97 • Mean years' experience 6.07±5.29 • 88.1% sample female	• Nurses were administered an adapted Pieper Pressure Ulcer Knowledge Test (translated into Farsi using forward-backward procedure) • Tool was pilot tested and content validity and test-retest coefficients are reported	• Knowledge scores using percent of correct responses on test items	• Test scores ○ Overall correct response rate was 55.75% ○ PU evaluation section: 83.35% correct responses (individual questions in the section ranged from 73% to 93.7%) ○ PU prevention section (33 items): 73.41% correct responses range (individual questions in the section ranged 2.4% to 100%) • There was no correlation between nurse age and performance on test (p>0.05) • **Study conclusions: ICU nurses in Iran who self-select to participate in a knowledge test on PU management demonstrate "almost high" scores, with no correlation between age and performance**	• Predominantly female • Convenience sampling • Selection bias • Self-reported questionnaire use may have contributed to overestimation of some findings (test conditions unclear) • No re-test to determine sustained knowledge • Unclear when last training was conducted	**Indirect evidence: no association made between knowledge and attitudes and PU outcomes Quality: low**
Quality improvement initiatives							
(Kelleher, Moorer et al. 2012)	Quality improvement project **investigating PU bedside rounds to decrease PU incidence**	Carried out in a 17 bed surgical ICU (total n=180) Average number of patients per quarterly prevalence survey was 15	• Nurse-led quality improvement program • Pre-intervention stage all nurses received a pocket sized education resource on PUs. • Main intervention: ○ Weekly bedside rounds conducted by nurse managers and WOCNs aimed at engaging nurses in discussion on PU risk factors, application of Braden score subscales and	• Quarterly HAPU rates were tracked from January 2008-December 2010 • Prevention measures in use commenced in Q6 • Validation of PU/staging systems not reported	• HAPU rate: 10.6% overall • Pre-intervention HAPU rate (over 5 quarters, 1 to 5): 0% to 26.7% • Post-intervention HAPU rate (over 7 quarters, 6 to 12) ranged from 0% to 27.1% • From quarters 9 to 12, the highest prevalence was 6.3% • Observations of the following prevention strategies improved with 100% compliance observed from Q 9 to Q 12: ○ Use of a prevention surface ○ Repositioning ○ Nutrition ○ Moisture Management	• Introduction of specialty beds/mattresses and wicking under-pads during the study period may have affected the HAPU rate • Small number of patients per quarter	**Level: 4 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
			development of appropriate, related PU prevention plans ○ Bed side rounds used a question format to guide discussion (included in article) and focused on patient-specific issues				
(Gray-Siracusa and Schrier 2011)	Descriptive study reporting on **a multifaceted QI intervention**	QI project in a 27-bed cardiovascular and coronary care ICU in USA Participants in pre-QI intervention stage (2007 to 2008)(n=554) Mean age 69.3±21.97 61.9% sample male Participants in post-QI intervention stage (2008 to 2009) (n=645) Mean age 66.8±19.10 56.4% sample male	• Introduced a pressure ulcer bundle (PUB) including: ○ Risk assessment conducted every 12 hours ○ Mobility – lighting and chimes every 2 hours to indicate repositioning time ○ Minimal head of bed elevation ○ Heel elevation ○ Nutritional screening on admission and daily ○ Skin assessment using NPUAP staging ○ Sacral cleanse and moisturize	• HAPU identified through skin assessments and using EPUAP staging system	• No significant difference between pre-PUB and post-PUB for HAPU rates (p=0.11) • Comparison of quarterly rates showed decreasing trend: ○ Pre-PUB quarterly HAPU rates: QI 5.7% Q2 0% Q3 5.2% Q4 0% ○ Post-PUB quarterly HAPU rates: QI 0% Q2 ~0.8% Q3 0% Q4 0%	• Small number of participants each quarter • Only one site	
(Dibsie 2008)	Descriptive study reporting on **a QI project aimed at standardising skin and wound care products**	QI project commenced in the adult surgical ICU and expanded to multisite (2) academic medical centers	• Nurse driven protocol to improve skin and wound care within a Standardization of all products related to the prevention of skin breakdown and care of partial-thickness wounds based on nurse recommendations Consistent and correct completion of order sets, education provided on new products and skin care, prevention of PU, identification and staging of PU, assessment and	Prevalence of pressure ulcers quarterly over 2 years PUs validated by wound care nurses	Prevalence data reflect steady decreases in the rate of hospital-acquired stage 2 or greater pressure ulcer. Data from surgical ICU showed: • ~16.5% at baseline (Q4 2005) • ~ 6% at second measure (Q4 2006) • ~ 12.5% at third measure (Q1 2007) • ~ 6.5% at fourth measure (Q2 2007) • ~6% by fifth measure (Q3 2007)	• Interventions might be specific to organizational structure and culture of study site, and might not be generalizable. • No statistical analysis • No reporting of baseline education level, experience of nursing staff	**Level: 4 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
			treatment. • Electronic reporting of all skin issues and PUs • Daily reminder systems for use of reporting system • Weekly evaluation of wounds and skin by clinical specialists • Management support and funding for the project • Organizational support including financial reward associated with strategic goals				
Workplace practice and PU prevention							
(Strand and Lindgren 2010)	Descriptive, cross-sectional study **investigating attitudes toward PU care in ICU** (also investigated knowledge, see "Nurse knowledge and education" above)	Participants were nursing staff in four ICUs in a Swedish University Hospital (n=315 received survey, n=146 returned survey) Characteristics: • 56.2% worked full time • Mean age 38.8±7.4 years for RNs and 43.5±9.7 for ENs (p=0.001)	• Questionnaire developed from other previously questionnaires. • Pilot testing of instrument prior to distribution.	• nurse attitudes • nurse perceived barriers and opportunities towards PU prevention in the ICU setting.	Current practice in ICU • 67.6% reported no routines existed for PU risk assessment in their ICU • 97% reported use of pressure relief • 38% reported use of nutritional support Attitudes • no difference between RN and ENs • Nurses with more education agreed with the statement "all patients are at risk for PU" more often (p=0.014) • Nurses with more education disagreed with the statement "I am less interested in PU prevention than in other aspects of care" more often (p=0.009) Barriers to PU prevention • 57.8% mentioned lack of time • 28.9% mentioned severely ill patients Opportunities • 38% mentioned knowledge • 35.5% mentioned access to pressure relieving equipment • **Study conclusions: PU prevention was considered important but lack of time and severe morbidity of patients impacted on ability to implement PU care.**	• Response rate was low at 46% (according to the authors) may be due to the length of the questionnaire • No validation of practice in the ICUs • Self-selected response may be from ICU nurses with more interest in area of PU	**Indirect evidence: no association made between attitudes and PU outcomes Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
(Ozdemir and Karadag 2008)	Descriptive, observational study **investigating nurse practice in an ICU with respect to PU prevention**	Stratified random sampling methodology to recruit nurses working in three ICUs (coronary, cardiovascular, gastroenterology) in Turkey. (n=126 total nurse, n=30 participated in study) Characteristics: • 80% had completed LPN program, 6% had an undergraduate program • 73% had 2 to 4 years work experience • 83.3% had not completed additional training on PU • 60% self-evaluated their PU management as "partly adequate", 26.7% rated their behaviour as "not adequate" and 13.3% rated as "adequate"	• All patients prior to the observations of the nursing care were rated by the researcher using the Braden scale. Included were patients with a BS of 18 or less. ○ Data were collected using the following: ○ ICU evaluation form used to record intervention used by each ICU to prevent PU ○ Demographic questionnaire of nurses involved in the study. ○ Braden Scale score ○ Observation record used by the researchers to record interventions provided by the nurses.	• Data were collected over a 4 month time period. Nurses were followed 3 times for observation rounds, for a total of 90 observations. • If preventative measure provided; recorded as observed, if not, recorded as not observed. If intervention was considered unnecessary, NA was recorded. • Intervention needed to be performed > 50% to be considered provided.	In 100% of all 3 observation periods observation was that nurses: • Did not use risk assessment scales • Did not record risk assessment on any observation • Did not teach the patient who is capable to shift weight every 15 minutes in chair • Did not relieve pressure points every hour if patient is not capable of independent movement while in a chair. • Did not use a support surfaces in a chair. • Did not give information on PU prevention to auxiliary personnel • Did not give information to relatives on PU prevention Most frequently observed interventions: • Avoiding hot water when bathing (83 to 90%) • Avoiding placement on the trochanter in side-lying position (70%) • Avoidance of donut devices (96 to100%) • Use of pressure redistribution surfaces (86.7%) Least used interventions: • Skin protectant (60 to 70%) • Protecting skin from friction/shear during transfers (80%) • Moisturizing agents (30%) • Documentation of nursing interventions (76.7%) • **Study conclusions: inadequate PU preventative care was observed among ICU nurses.**	• No limitations reported by the authors • Number of observations (3 observations for 30 nurses) • Potential influence of Hawthorne effect • Descriptive statistics only • Study did not provide analysis of education levels or other demographics and work practices	**Indirect evidence: no association made between practice and PU outcomes Quality: low**
(Cho, Park et al. 2011)	Descriptive retrospective review **focussed on nursing document-ation of PU care in the ICU**	Retrospective review of ICU patient notes from those admitted during 2007 to a teaching hospital in Korea (n=427) Inclusion: • Aged ≥ 18 yrs • no PU on admission • hospitalised ≤ 4 days prior to	• Review of nursing notes in case records integrating daily skin assessment records with the nursing care data • Participants identified as having PU or at risk of PU based on skin assessment items in Nursing Assessment Checklist	Computerised patient records were reviewed to determine: • Incidence of PU • Preventive interventions documented by ICU nurses	• Incidence of PU was 14.98% (n=64 participants with PU) • There was significantly more documentation of skin care (0.26±0.60 interventions/day versus 0.18±0.51, p<0.0001) and nutritional care (0.04±0.26 interventions per day versus 0.007±0.12, p<0.0001) for the group of participants considered at-risk of PU compared with those who developed a PU but no	• Nurses reported that PU prevention is implemented routinely without documentation i.e. documentation may not be reliable reflection	**Indirect evidence: no association made between documentation and PU outcomes**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
		transfer to ICU • stayed in ICU ≥ 3 days Exclusion: • More than one ICU admission in hospitalized period Characteristics: • those with PUs were significantly older (mean age 64.11±15.91 versus 59.08±16.63, p=0.0253) • those with PUs had significantly greater hospital LOS (63.47±49.63 days versus 29.14±26.81, p<0.0001) • those with PUs had significantly greater ICU LOS (15.72±19.85 days versus 5.55±5.29, p=0.0001)			difference in documented rate of sensory/mobility care, positioning changes or use of pressure relieving devices • Nurses who were younger (p=0.03), had higher education (p=0.04) had fewer months experience has a nurse (p=0.02) and who had more months experience in ICU (p<0.001) performed more nursing interventions per month • **Study conclusions: the computerized data record indicated that ICU staff documented a lower number of PU prevention interventions in patients who developed a PU; however, there was no validation as to whether less PU prevention interventions were actually delivered by nursing staff.**	of care provided • Nursing characteristics may influence frequency of computerized data entry (or any documentation) rather than actual number of nursing interventions performed • No consideration of PU severity	**Quality: low**

PREVALENCE DATA

Reference	Subject	Design/method	Incidence & Follow up	Prevalence	Stage/category	database or clinical	Limitations and comments	
(Kottner, Wilborn et al. 2009)	• 225 hospitals participated (majority of the hospitals participated only once or twice) • Participants recruited from all units in the hospital, n=1920 for ICU • For entire sample: ○ included adults ≥ 18yrs ○ mean age 65.3 years ○ 56% sample female ○ 11.2% had a Braden score ≤ 14	Prevalence survey cross-sectional, longitudinal over seven years (2001-2007)		• Overall prevalence in ICU • Stage I to IV PUs 24.5% Stage II to IV PUs 14.3%	• Braden scale used for risk assessment • EPUAP PU classification for staging	CL	• Non-response bias/proportions of non-responders increased annually from 14.6% to 33.3.% • ICU patients consisted of only 4.8% of total study population	**Level: N/A Quality: low**
(Shahin, Dassen et al. 2009)	• 169 participants admitted into ICU in 18 German hospitals • Data collected on one day in April 2007	Cross sectional point prevalence survey		• Overall prevalence 27.2% • Prevalence in surgical ICU 39% • Prevalence in surgical ICU 28.9%	• Braden Scale risk factors • APACHE II score • EPUAP classification (but PU stages not	CL	• Small number of PUs reported in the study time period • Excluded unconscious patients	**Level: N/A Quality: high**

	Inclusion: • ≥18 years age • ICU patients Exclusion: • < 18 years of age Characteristics: • 83% had a Braden score ≤20 • mean age 66.9±14.8 yrs PU strategies in use: • Skin inspection 81.8% • Mobilization 56.6% • Massage with cream 80.5% • Nutrition 68.6% • Pressure mattress 36.5% • Repositioning 41.5% • Patient education 40.3%			• Prevalence in interdisciplinary ICU 18.8%	reported)			

References

Black, J., C. Berke, et al. (2012). "Pressure ulcer incidence and progression in critically ill subjects : influence of low air loss mattress versus a powered air pressure redistribution mattress." Journal of Wound, Ostomy and Continence Nursing **39**(3): 267-273.

Brindle, C. T. and J. A. Wegelin (2012). "Prophylactic dressing application to reduce pressure ulcer formation in cardiac surgery patients." Journal of Wound, Ostomy and Continence Nursing **39**(2): 133-142.

Cho, I., H. Park, et al. (2011). "Exploring practice variation in preventive pressure-ulcer care using data from a clinical data repository." International Journal of Medical Informatics **80**(1): 47-55.

Cox, J., S. Roche, et al. (2011). "The effects of various instructional methods on retention of knowledge about pressure ulcers among critical care and medical-surgical nurses." Journal of Continuing Education in Nursing **42**(2): 71-78.

Dibsie, L. G. (2008). "Implementing evidence-based practice to prevent skin breakdown." Critical Care Nursing Quarterly **31**(2): 140-149.

Gray-Siracusa, K. and L. Schrier (2011). "Use of an intervention bundle to eliminate pressure ulcers in critical care." Journal of Nursing Care Quality **26**(3): 216-225.

Iranmanesh, S., H. Rafiei, et al. (2011). "Critical care nurses' knowledge about pressure ulcer in southeast of Iran." International Wound Journal **8**(5): 459-464.

Kelleher, A. D., A. Moorer, et al. (2012). "Peer-to-peer nursing rounds and hospital-acquired pressure ulcer prevalence in a surgical intensive care unit: A quality improvement project." Journal of Wound, Ostomy and Continence Nursing **39**(2): 152-157.

Kottner, J., D. Wilborn, et al. (2009). "The trend of pressure ulcer prevalence rates in German hospitals: results of seven cross-sectional studies." Journal of Tissue Viability **18**(2): 36-46.

Ozdemir, H. and A. Karadag (2008). "Prevention of pressure ulcers: a descriptive study in 3 intensive care units in Turkey." Journal of Wound, Ostomy, and Continence Nursing: Official Publication of the Wound, Ostomy and Continence Nurses Society / WOCN **35**(3): 293-300.

Romero, C. M., R. A. Cornejo, et al. (2009). "Extended prone position ventilation in severe acute respiratory distress syndrome: A pilot feasibility study." Journal of Critical Care **24**(1): 81-88.

Shahin, E. S. M., T. Dassen, et al. (2009). "Pressure ulcer prevention in intensive care patients: guidelines and practice." Journal of Evaluation In Clinical Practice **15**(2): 370-374.

Strand, T. and M. Lindgren (2010). "Knowledge, attitudes and barriers towards prevention of pressure ulcers in intensive care units: a descriptive cross-sectional study." Intensive & Critical Care Nursing: The Official Journal of the British Association of Critical Care Nurses **26**(6): 335-342.

Theilla, M., B. Schwartz, et al. (2012). "Impact of a nutritional formula enriched in fish oil and micronutrients on pressure ulcers in critical care patients." American Journal of Critical Care **21**(4): e102-e109.

Theilla, M., B. Schwartz, et al. (2011). "Enteral n-3 fatty acids and micronutrients enhance percentage of positive neutrophil and lymphocyte adhesion molecules: a potential mediator of pressure ulcer healing in critically ill patients." British Journal of Nutrition: 1-6.

Tweed, C. and M. Tweed (2008). "Intensive care nurses' knowledge of pressure ulcers: development of an assessment tool and effect of an educational program." American Journal of Critical Care **17**(4): 338.

Weng, M. (2008). "The effect of protective treatment in reducing pressure ulcers for non-invasive ventilation patients." Intensive & Critical Care Nursing: The Official Journal Of The British Association Of Critical Care Nurses **24**(5): 295-299.

Williams, T. A., G. D. Leslie, et al. (2011). "Optimizing seating in the intensive care unit for patients with impaired mobility." American Journal of Critical Care **20**(1): e19-e27.

OLDER ADULTS

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
Nutritional interventions							
(Arinzon, Peisakh et al., 2008)	Prospective, observational cohort **reporting effectiveness of enteral nutrition (EN) in reducing prevalence of PUs in elderly patients with terminal diagnoses**	Participants recruited from psychogeriatric wards for patients with terminal diagnoses in Israel (n=167) Inclusion: • Admitted to one of 3 wards participating in the study • Randomised to be included Characteristics: • Mean age approx. 80 yrs, primarily female (p=ns between groups for age/gender) • Approx 70% had CV disease, 21-30% had diabetes mellitus (p=ns between groups for co-morbidities) • BMI <21kg/m^2 more frequent in ENG (30% versus 16%, p=0.043) • Presence of PU at baseline more frequent in ENG (26% versus 12%, p=0.017) • ENG participants had higher levels of dehydration at baseline (26% versus 13%, p=0.028) • Significant differences between groups in albumin, transferrin, CRP, BUN/Cr, sodium, potassium, urea nitrogen at baseline	Two groups were followed: • Enteral nutrition group (ENG) receiving EN primarily for weight loss (40%) stroke with impaired oral intake (32%), vegetative state (12%), end-stage Parkinson's disease (9%), and malignancy (5%). 74% had NGT, 26% PEG. Most frequent diet was 1800 to 2000 calories, 2 to 3 g sodium and 80 g protein delivered through Osmolite® HN (81% participants). (n=57) • Control group (CG) taking a regular oral diet. However, 76% of the group had nutritional supplementation for >2 months during the observation period, usually Ensure®. (n=110)	• BMI – 21kg/m^2 was considered marker of malnutrition • PU presence – used staging but did not state the scale • PU risk – Norton scale • Laboratory values including serum proteins, renal function, cholesterol, iron, folic acid	• ENG had significant differences in laboratory values compared with CG. • ENG experienced more major complications or symptoms related to nutrition (61% versus 34%, p<0.01) including pneumonia, weight changes, death. **PU prevalence** • ENG had high prevalence of stage III to IV PUs at completion of study (14% versus 2%, p=0.005). • No significant difference in stage I to II PUs (16% ENG versus 12% CG, p>0.05) • Prevalence of PUs overall appears to be 24% CG versus 30% ENG, however analysis compared with baseline differences is not reported. • Difference between ENG and CG in mean PU risk assessed on Norton scale was significant at baseline and at the conclusion of study. • **Conclusions: An EN regimen in older adults with malnutrition and terminal disease states does not appear to influence prevalence of PU or PU risk significantly compared with an oral diet.**	• Groups were significantly different at baseline for primary outcome measures of nutritional state and PU • Unclear how PU staging was done • Large number of dropouts, primarily due to death (42% in ENG, 27% in CG) • No reporting of concurrent management strategies e.g. pressure relieving surfaces. • Pollution of control group, 76% of whom also took supplementation for at least 2 months. • **Nb: This paper is reported in the nutrition section of the guideline**	**Level of evidence: 5 Quality: Low**
(Cereda, Gini et al., 2009)	Single blinded RCT investigating **disease-specific nutritional approach as**	Participants were residents in 4 LTC facilities in Italy (n=28) Inclusion: • Aged ≥ 65 yrs • Stage II, III & IV PUs on NPUAP staging system	• All participants had similar general PU care. • All participants received 30 kcal/kg of body weight. • Participants were randomised to receive either:	Primary outcomes were: PU healing assessed using • Pressure Ulcer Scale for Healing (PUSH; 0=complete healing and 17=greatest severity) and	**Change in biochemical parameters over 12 weeks** • weight gain: mean 1.8±2.7 kg treatment, 0.7±2.6 kg control, p=ns • total protein changes: mean 3.3±7.0g/L treatment, 2.2±4.5g/L control, p=ns • Albumin, transferrin, lymphocytes and	• Small sample size • absence of a control group supplemented only with protein • orally and tube-fed subjects were analyzed together • no intention-to-treat	**Level of evidence: 2 Quality: moderate**

	a strategy to promote PU healing	Exclusion: • Acute illness • Chronic disease including diabetes mellitus, PVD • Lack of adherence to diet • Immunosuppressant Characteristics: • Primarily female, mean age approx. 82 years. • 64.3% were tube fed (p=ns between groups) • Control group had significantly more PUs of lesser severity (p=0.03) • No significant differences in BMI (20.8±3.2 treatment group versus 23.1±5.0 control group)	○ Standard hospital diet with additional 400 mL oral supplement containing 500 kcal, 34 g protein, 6 g arginine, 500 mg vit C, 18 mg zinc OR if tube fed 1,000mL high protein formula (20% energy from protein enriched with arginine, zinc, vit C) infused with isocaloric formula to reach energy requirements (intervention group, n=15 but 2 deceased, analysis was n=13) ○ Standard hospital diets (16% energy from protein) OR standard enteral formula (control group, n=15)	• Lesion area measurements (mm^2 and % healed) 12-week follow-up	haemoglobin all p=ns between groups **PU healing over 12 weeks** • Both groups had significant improvement in PU healing (p<0.001 for both groups) • PUSH score became statistically significantly different between groups at Week 12 (favoured treatment, p<0.05) and ulcer area was significant by week 8 (favoured treatment, p<0.05) • **Conclusions: Rate of PU healing in older adults appears to accelerate when a nutrition formula enriched with protein, arginine, zinc and vitamin C is administered for at least 8 weeks**	analysis was performed • Excluded any co-morbidities so results are not generalizable (from 371 potential participants, only 39 met inclusion criteria) • Control group had significantly less severe PUs at baseline • Superior healing only evident after 8 to 12 weeks of treatment • **Nb: This paper is reported in the nutrition section of the guideline**	
(Morello, Marcon et al., 2009)	5-year epidemiological analysis investigating **demographics of patients receiving enteral nutrition (EN) in nursing homes**	n=482 nursing home residents in Italy recruited 2001 to 2005 Characteristics: • Mean age 81±13 yrs • Primarily females over 76 yrs • Mean weight 54.1±12 kgs • Mean BMI 20.7±3.9 kg/m^2 • 42.3% had PUs	• Data was collected at the initiation of EN including: ○ age and gender ○ underlying disease ○ Karnofsky index ○ type of enteral access device ○ presence of PUs ○ weight and BMI ○ daily enteral intake	• Patient survival • Duration of therapy	• An average of 6.6% nursing home residents received EN • Almost all participants receiving EN had a Karnofsky index ≤ 50 • Median duration of EN was 296 days and median survival was 411 days • Direct relationship observed between severity of PU and age p<0.01 at baseline. • **Conclusions: 42.3% of older adults commenced on enteral nutrition had a pre-existing PU that was significantly more likely (p<0.01) to be more severe as age increased.**	• Clinical monitoring is not analyzed • PU status not an outcome measure. • Does not state how PU presence and severity was assessed • **Nb: This paper is reported in the nutrition section of the guideline**	**Indirect evidence Quality: low**
(Meaume, Kerihuel et al., 2009)	Double blind RCT investigating effectiveness of ornithine alphaketoglutarate (OKG) in promoting healing of heel PUs in older adults	Participants were recruited from 67 European centres. (n=160) Exclusion: Bed-bound prior to PU • PU entirely covered by necrosis or fibrin, or infected • Poorly controlled diabetes • Dialysis • Neoplasm • Parenteral nutrition • Serum albumin <22g/L • Advanced peripheral arterial disease	All participants received wound care according to French guidelines, heel offloading, pain management, protein intake of 1.2 to 1.5 g/kg/day. Participants were randomised to receive either: • 10g sachet of OKG administered once daily in 200ml water during or after lunch (n=85) • Placebo sachet	• Heel PU area reduction assessed via clinical description, acetate tracings and measurement of length/width • Braden score • Mini nutritional assessment scale • Laboratory values	**Participants with baseline PU ≤8cm²** • mean decrease in PU area at week 6 was significantly greater in OKG group versus placebo group (–2.3±4.2cm^2 versus –1.7±1.7cm^2, p=0.006) • closure rate at week 6 was significantly higher in OKG group versus placebo group (–0.07±0.11cm^2/day versus –0.04±0.08cm^2/day, p=0.007) • Difference in closure rate was attributed to higher closure rates in first 2 weeks of study **Participants with PU area > 8cm2**	• Uneven distribution of PU severity between groups at baseline leading to analysis by sub group based on 8cm^2 cut-off to create homogenous groups • No reporting of difference between sites, however care was standardized • **Nb: This paper was appraised and included by the nutrition SWG, but not included in the section as there was insufficient**	**Level of evidence: 1 Quality: high**

		Characteristics: • OKG group had significantly more females than control, otherwise the groups were matched for age (mean 80.8±8.8 yrs), BMI (mean 26.9±6.2 kg/m^2) Braden score (mean 17.82±3.2) • Placebo group had higher proportion of smaller PUs (52% versus 25.9% with area ≤4cm2, p=0.044)	administered once daily in 200ml water during or after lunch (n=75) No participants had concurrent vitamin C, high dose zinc, amino acids or omega-3 fatty acids during the study. Treatment was for 6 weeks		• no difference between groups in mean decrease in PU area. • no difference between groups closure rate. **Clinically relevant adverse effects** Higher incidence of GIT complaints including diarrhoea, vomiting or nausea in OKG group versus placebo (7 considered to be related to treatment, none considered to be severe) • **Conclusion: The results suggest that OKG supplementation in older adults may contribute to faster healing rates in smaller PUs, particularly in the first 2 weeks of therapy.**	**evidence to make comment on the intervention**	
(Volkert, Pauly et al., 2011)	Cross-sectional prospective prevalence study **comparing PU rates in tube fed older adults to orally fed older adults**	Participants were recruited from 3 municipal nursing homes in Germany (n=350) Inclusion: • aged ≥65 years • in long term care • not in terminal state as judged by nurse Exclusion: • terminal illness • aged < 65 years • short term/respite care • refusal Characteristics: • Median length stay 2.7 years • mean age 84.8±8.0 years 7.7% (n=15) receiving PEG	• Standardised interviews with responsible nurse • Nutritional screening • Dietary intake monitoring (documentation and observed food intake)	Malnutrition measured using: • Mini Nutritional Assessment (MNA) • BMI • midarm and calf circumference PU measured through nurse interview	• Malnutrition (MNA <17) was significantly more prevalent in tube-fed participants (57.7% vs 24.1%, p<0.001) • There was no significant different between groups in risk of malnutrition (MNA 17 to 23.5) (tube fed 42.3% vs oral 53.7%) • There was no significant difference in PU prevalence between tube fed and oral fed participants (18.5% vs 2.5%, p=ns) • Malnourished participants were significantly more likely than at-risk participants and well- nourished participants to experience PU (p<0.001)	• Critical measurements relied on nurse judgment without inter-rater reliability reporting. • No standardised scale used for pressure sore, no pressure sore grading severity. • Confounding factors such as underlying disease were not considered	**Level of evidence: N/A Quality: low**
Background prevalence studies							
(Baumgarten, Margolis et al., 2009)	Prospective observational prevalence study **comparing facility acquired PU incidence in different clinical settings in**	Participants were recruited from nine hospitals in a US hip studies network and 105 post acute facilities participants were admitted to thereafter (n=658) Inclusion: • aged ≥ 65 years • surgery for hip fracture • consent	• Second daily skin assessments commencing as soon as possible after admission • Follow up of 10 days post-acute setting	Facility acquired PU assessed using a standard assessment strategy by trained nurses with photographs for interrater validation	Participants who developed a PU had significantly worse RAND Sickness at Admission scores (p<0.001), significantly lower MMSE scores (p<0.001), significantly higher nutritional risk (p<0.001), had lower mobility (p<0.0) and longer length of stay (p<0.001) compared with those who did not develop a PU Facility acquired PU incidence in the full sample was 31.6%		**Level of evidence: N/A Quality: High**

	older hip fracture patients	Exclusion: • hip fracture occurring during an admission Characteristics: • mean age 83.2± 6.6 years • 46.5% participants were aged > 85 years • mean BMI was 23.8±5.1 • mean length of stay was 5.9±3.2 days			88.4% were stage II PU 0.8% stage III PU 0.8% PU were unstageable 47.3% occurred at sacrum, 19.4% at heels. 12% at ischium		
(Cadigan, Grabowski et al., 2012)	Longitudinal data	323 nursing home residents with advanced dementia living in 22 Boston-area facilities.	Aim was to examine the association between residence in an special care units (SCU) and the quality of end-of-life care for nursing home residents with advanced dementia.	analyzed the association between residence in an SCU and measures of quality of end-of-life care including: treatment of pain and dyspnea, prevalence of pressure ulcers, hospitalization, tube feeding, antipsychotic drug use, advance care planning, and health care proxy (HCP) satisfaction with care.	A total of 43.7% residents were cared for in an SCU. After multivariate adjustment, residents in SCUs were more likely to receive treatment for dyspnea, had fewer hospitalizations, were less likely to be tube fed, and more likely to have a do-not-hospitalize order, compared with non-SCU residents. However, non-SCU residents were more likely to be treated for pain, **had fewer pressure ulcers**, and less frequent use of antipsychotic drugs than SCU residents. HCPs of SCU residents reported greater satisfaction with care than HCPs of non-SCU residents. **Residence in an SCU is associated with some, but not all, markers of better quality end-of-life care among nursing home residents with advanced dementia.**	1) Included residents of nursing homes in the greater Boston area, the geographic and socioeconomic homogeneity of which may restrict the external validity of the results. 2) Additional unobserved variables may have influenced SCU admission. 3) May be differences between facilities in terms of size, ownership status, and chain membership, all potentially contributing to bias in our results. 4) Only stage II pressure ulcers were tracked. Identifies the potential of improved PU outcomes (i.e. fewer ulcers) with specialized resources	**Level of evidence: N/A Quality: low**
(Rodriguez-Fernandez, Adarraga-Cansino et al., 2011)	Retrospective case control study	• Two groups of patients with hip fractures. • First group (n = 109) had been exposed to an average delay in receiving surgical treatment of more than 1 week. • Second group (n = 79) were operated on within 48 hours or as soon as condition permitted.	•	Clinical audit	PU prevalence • group 1 = 19 (17.4%) • group 2 5 (6.3%), p=0.02	No information about definition of PU and category of PU. **Nb: This is reported in the prevalence section of the guideline**	**Level of evidence: N/A Quality: moderate**

Risk factors and risk assessment							
(Baumgarten, Rich et al., 2012)	Prospective cohort study investigating care-related risk factors for hospital-acquired PU in elderly adults with hip fractures	Participants recruited from 9 acute care hospitals (n=658 surgical patients) Inclusion: • Elderly adults aged ≥65 yrs; had surgery for hip fracture Characteristics: • n=152 males; n=506 females • mean age 83.2 yrs; range not reported • n=0 lost to follow-up • N=19 (3%) with baseline PU – no grade provided	Not reported	Outcome definition: development of ≥1 new Stage 2 or higher hospital-acquired PU. Skin inspected for PU at baseline and alternating days until hospital discharge (11 assessments) • mean length of follow-up 3 days (range 0.5 to 21 days) PU definition for regression: ≥Stage 2 NPUAP staging system Statistical methods: Poisson regression model with log link function. Two groups of care factors were considered and a modelling strategy applied.	N=96 (14.6%) developed 121 hospital-acquired PUs • 88% PUs were stage 2; remainder unstageable **Incidence of PU** • Incidence of PU over 90 days was 39.4% (n =37) • Incidence of PU was20.2% in the first month of study, 11.7% in second month and 7.4% in third month • Patients with PU history were more likely to develop a PU than those without a history (odds ratio 2.76, 95% CI 1.06 to 7.20) • Incidence varied between the four facilities from 21.4% to 56.3% **PU stage** • Stage I PU n=26 patients • Stage II PU n=11 patients • Stage III, IV, unstageable PU n=0 patients **Location of PU** • 27.1% PU occurred on malleolus 25% PU occurred on the ischium No in final: 560 – 643/658 (sample varies for factors); fully adjusted n=456 N=16 risk factors entered into MV analysis (13 covariates + 3 care-related factors (group 1 or 2): • Co-variates: MMSE score; history of chronic deficit; risk of nutrition-related complications; BMI; activity level; preexisting PU; Rand sickness admission score; age; sex; preadmission residence; albumin level; no. orientations at baseline; admission hospital • Group 1 factors: timing (day) of transport to hospital; type of transport to hospital; length of stay in ED • Group 2 factors: time between inpatient admission and surgery; surgery duration; type of anesthesia N=3 risk factors from final model:	• Not clear how variables categorized • Only presented partial model (i.e. data for all RFs explored not presented) • Insufficient number of events • Data dependent • **Nb: This paper is reported in the risk assessment section**	**Level of evidence: N/A Quality: low**

					Group 1 Length of stay (hrs) in ED *Group2* Time (hrs) from admission to surgery General anesthesia **P values, OR, CI** >4-6 hrs: 0.03; 0.68; 0.48-0.96 >6 hrs: 0.047; 0.68; 0.46-0.99 ≥24 hrs: <.001; 1.62; 1.24-2.11 0.005; 0.66; 0.49-0.88		
(de Souza and de Gouveia, 2010; de Souza, Santos et al., 2010)	Prospective cohort study investigating associations between PU occurrence and socio-demographic and clinical factors.	Participants recruited from 4 long-term care facilities (n=94 elderly care, non-surgical patients) Inclusion: • Elderly adults aged ≥60 yrs • Braden Scale score ≥18 Characteristics: • n=37.2% males; n=62.8% females • mean age 79.1 yrs; range 60-103 yrs • n=0 lost to follow-up • N=27 with baseline PU – no grade provided • Mean BMI 20.9±4.9 • 28.7% (n=27) history of PU	Facilities had similar professional and physical resources; none had a specific protocol to assess PU risk and prevent or treat PU. Empiric treatment was initiated when a ≥stage II PU was detected. All facility patients entered in the study had full skin assessment three times a week until PU formed Participants who were discharged and readmitted were re-entered into the study as a new case	Outcome definition: development of Stage 1 or higher PU. Skin inspected for PU 3-times weekly on alternate days • follow-up for 90 days PU definition for regression: ≥Stage 1 NPUAP staging system Statistical methods: Stepwise logistic regression.	N=37 developed 48 PUs • n=26 patients developed stage 1 PU; n=11 stage 2; no stage 3 or 4 PU developed during study period No. in final: 94 (assumed) N=12 risk factors entered into MV analysis: • Age; BMI; Total Braden score; Gender; previous PU; regular use of neuroleptic or psychotropic medications; Braden subscale moisture; Braden subscale nutrition; Braden subscale friction and shear; time residing in long term care facility; smoking; presence of a number of comorbidities N=2 risk factors from final model: Female gender Previous PU **P values, OR, CI** 0.012; 3.46; 1.32-9.09 0.038; 2.76; 1.06-7.20	• No interrater reliability established • Only included high risk patients • sample number unclear • Only assessed patients 3 times per week • Wide variation in incidence rate between facilities may be due to assessment technique or interventions • Some participants entered study more than once • Insufficient number of events • **Nb: This paper is reported in the risk assessment section**	**Level of evidence: N/A Quality: low**
Individuals with Dementia							
(Aminoff, 2012)	Cohort study **investigating 6-month outcomes for patients with end-stage dementia and PU**	Participants were recruited over a 3 year period from a geriatric centre in Israel (n=200) Inclusion: • Severe, end-stage dementia (of difference origins) • Communication difficulties • Complete dependency in ADLs and functional movement	• Comparison of two cohorts: ○ Cohort one : no PU on admission (n=80) ○ Cohort two: PU on admission (n=120)	• Mini-Suffering State Examination (MSSE, validated tool) that assesses for presence of conditions associated with suffering, of which PU is one. • Presence of PU (Stages I to IV) unclear how this was assessed	• On admission participants with PU had a higher rate of: ○ male gender (p<0.009) ○ malnutrition (low albumin; p<0.0001) ○ high cholesterol (p<0.0001) ○ antidepressants (10.8% vs. 2.5%, p=0.028) ○ analgesia (23.8% vs. 11.7%, p<0.032) • Participants with PU had a significantly higher 6-month mortality rate compared	• Unclear how outcome measures e.g. presence of PU was assessed • It is unclear whether the overall significant difference in MSSE score is attributable to presence of PU being one question on the MSSE • **Nb: This paper is reported in the palliative care section**	**Level of evidence: N/A Quality: low**

		Characteristics: 102 males, 98 females Mean age 80.9±8.1 years (range 50 to 100)		Follow-up period of 6 month	with those without PU (71.3% vs. 45.8%, p<0.0001) • Participants with PU had a higher significantly higher MSSE score than those without PU (5.49±2.17 vs. 3.48± 222, p<0.0001) • On the MSSE, participants with PU had no significant differences for being not calm, screaming, pain, eating disorder, of suffering according to family opinion. • On the MSSE, participants with PU were more likely to have malnutrition, invasive actions, suffering according to medical opinion and unstable medical conditions. • **Study conclusions: People with end-stage dementia that have concurrent PU have a high 6-month mortality rate. It is unclear if PUs arise from their multiple medical conditions or contribute toward them.**		
Assessment							
(Grubbs, Ludwig et al., 2009)	Randomized study comparing **a physical examination to high frequency ultrasound for identifying stage I PU**	Participants at high risk of PU were recruited from a long-term facility (n=27) Inclusion: • Braden score ≤16 Exclusion: • study refusal Characteristics: • Mean age 43 years (range 39 to 99 years)	• All participants were repositioned every 2 hours while in bed or 30 mins while seated, mobilization promoted. • All participants positioned with head of bed at 30º angle • All participants had heel, elbow protectors and repositioning devices • All participants received skin care, including emollients. • Participants were randomized to receive either: o Chart review at beginning and end of study (control group, n=6); or o History, physical exam and care recommendations conducted by students weekly (student	PU incidence	• There was no statistical significance for the interaction of student examination and ultrasound (p=0.142) • There was no statistical significant difference between the three study groups in the treatment modalities of the patients (p=0.551) • 18% (n=2) of the ultrasound only group experienced category 1 PU and 9% (n=1) experienced category II PU • 1 patient in the student only group developed a new onset stage II heel • **Conclusions: This study failed to show that using high frequency ultrasound in addition to physical assessment and conducting Braden scores is more effective in preventing development or progression of PUs of heel and sacrum.**	• Does not report randomization methods or allocation concealment • No blinding • Small sample size • Unclear how many patients in each group (19 were exposed to ultrasound intervention) • Poor reporting of participant characteristics. • **Nb: this study is reported in the Assessment section of the guideline**	**Level of evidence: 2 Quality: moderate**

			intervention group) ○ Heel and sacrum scanned each week with high frequency ultrasound (ultrasound group) ○ Clinical exam and high frequency ultrasounds weekly (Student and ultrasound group)				
Repositioning							
(Urasaki, Nakagami et al., 2011)	Descriptive observational study	Elderly participant recruited from a geriatric hospital (n = 107) Inclusion: Aged over 65 years (group A - house-bound = 37; group B- chair-bound = 34; Group C – bed-bound = 36 and 36 able-bodied – limited information on classification into each category. Comparison group of able body people with mean age of 32.6 years (n=36)	• Interface pressure distribution was measured using a Tekscan pressure measurement system attached to the seat support	• Maximum pressure • Total support area • Distance from backrest to coccyx and • Sitting pattern	• Maximum pressure was significantly lower for able-bodies than groups B and C ($p < 0.01$ and $p = 0.024$) • Total support area was significantly larger for able-bodies than each elderly group (group A $p = 0.014$, group B $p = 0.021$ and group C $p < 0.001$ • Distance from backrest to coccyx was significantly longer for group C than able-bodies ($p < 0.001$) • The occurrence of proper sitting pattern significantly decreased as the degree of independence reduced ($p < 0.001$) • The proportion of people with the proper sitting pattern was 30/36, 20/37, 10/34 and 8/36 for able-bodies, group A, group B and group C	• Small and specific regions samples were enrolled • The measurement time of sitting in wheelchair was for a short time (3 min) • Used a basic study wheelchair • Did not consider the impact of existing wounds or disability on sitting pattern	**Indirect evidence Quality: low**
(Rich, Margolis et al., 2011)	Analysis of a larger cohort study **investigating association between repositioning and PU incidence**	Participants were recruited between 2004 and 2007 from nine hospitals in the USA (n=269) Inclusion: • Aged ≥65 years • Hip fracture surgery • Bed-bound at index study visits during first 5 days of hospitalization Exclusion: • No study visit on first 5 days of hospitalization • Not bed-bound for at least one visit day according to Braden scale activity item	• Information about repositioning frequency for the first 5 days of hospitalization was collected from patient charts, including number of times manual repositioning performed • Study nurses performed skin assessments and Braden scale score at baseline and on alternating days for 21 days	• Primary outcome: development of stage 2 or greater PUs as defined on a scale on which stage II was partial thickness dermal loss or serum filled blister. • The association between frequent manual repositioning and PU incidence was estimated adjusting for PU risk factors using generalized estimating equations and weighted estimating equations • Frequent repositioning was defined as ≥12	• Patients were repositioned frequently on 53% (187/354) of index visit days • The incidence of PUs per person-day did not differ between the two groups (incidence rate ratio 1.12, 95% CI 0.52 to 2.42) • Patients repositioned frequently were more likely to have a PU at baseline ($p=0.006$), more likely to have high risk of nutrition-related complications ($p=0.006$) and more likely to have a lower mean Braden score ($p=0.07$) • For participants with a high PU risk based on Braden score. There was a lower incidence of PUs among those who were frequently turned (IRR 0.39, 95% CI 0.08 to 1.84) • Although no association was found between frequent repositioning of bed-bound patients and lower PU incidence, there was	• Limited adherence to repositioning recommendations • Observational design • Relied on medical records data, turning frequency was not verified • **Nb: this study is reported in the Repositioning section of the guideline**	**Level of evidence: 3 Quality: moderate**

		Characteristics: • 51.7% participants aged ≥ 85 yrs • 98.5% White race • 43.9% had Braden scale ≤ 16 • 14.2% had PU at baseline		manual repositions per hospital day	an effect in patients at high risk of PU		
Staffing models and issues							
(Yamamoto, Hayashino et al., 2010)	Cross sectional survey investigating the **association between caregiver burden and development of PU in older adults**	Participants were recruited from 10 home care services in Japan (n=137) Inclusion: • aged ≥ 40years • limited activity & mobility (Braden scale 1 or 2) Exclusion: • attempted suicide Characteristics: • Mean age participants 80.9 years • Mean duration of caregiving 6.58 years • 83.8% (n=115) participants were free from PU	Survey and record review	Assessed PU presence and status from medical records. Caregiver burden assessed from Burden Index of Caregivers (BIC) & Japanese short version of Zarit Burden Interview.	Multivariate analysis found the following factors were significantly associated with Burden Index of Caregivers score: • patient from PU (β coefficient 3.18, 95% CI 1.42 to 4.95, p=0.003) The following factors were not significantly associated with BIC: • patient age (p=0.72) • caregiver age (p=0.98) • family relationship (p=0.54) • daily time spent caregiving (p=0.54) • dementia (p=0.44) In patients free from PU (n=115) multivariate analysis found the following factors were significantly associated with BIC: • use of a pressure relieving airmat (β coefficient 3.52, 95% CI 1.10 to 5.95, p=0.01) • having severest grade of national index of long term care need (β coefficient –3.42, 95% CI –5.96 to –0.88, p=0.002)	• Details of PU only from medical records, does not state how PU was identified • No discussion of burden of wound care • Not generalizable to other countries where different support surfaces may be used	**Level of evidence: N/A** **Quality: moderate**
(Mangaco-Borja, 2011)	Quality improvement project and prevalence study **investigating the impact of a work assignment intervention in aged care on PU rates**	A 100-bed long term care skilled nursing facility in US. Participants were residents and 30 nursing assistants.	• Nursing assistants were assigned to a permanent schedule of patients for whom they provided daily care (defined as the same nursing assistant cares for the same group of patients for at least 85% of the assistants shift). • Consistent education was also provided to new staff throughout the project.	Outcome was the quarterly pressure ulcer rate per 1000 patient days (however annual rates were reported in the paper). Data for four years was presented	The overall rate of pressure ulcers decreased from 2.48/1000patient days in 2007 to 0.4/1000patient days in 2010	No indication of who assessed pressure ulcer incidence. No indication of pressure ulcer staging Not clear if patients were at similar risk of PU at each time collection point No reporting of compliance with intervention **Nb: this study is reported in the Strategy section of the guideline**	**Level of evidence: N/A** **Quality: low**
(Pérez-Zepeda, Gutiérez-Robledo et al., 2012)	Prospective matched cohort design investigating **effectiveness**	210 acute care patients 70 of which were on geriatric services (Group 1) and 140 on internal medicine unit (Group 2).	Determine the effectiveness of a geriatrics evaluation management in prevention or treatment of functional decline, falls, pressure ulcers	During initial nurse interview measured: • Functional status: Barthel Index and	Non-statistically significant differences between groups were observed for poly-pharmacy before hospitalization and presence of pressure ulcers at admission with both having a higher prevalence in	Stated Limitations: 1. Can only be generalized to a fraction of all hospitalized elderly 2. Study time frame limited to	**Level of evidence: 3** **Quality: high**

	of a geriatric evaluation and management in preventing adverse events including PU	Patients aged 60≥ were recruited over a 2 year period. Eligibility: Have at least 1 frequent geriatric problem (falls, slow walking speed, tiredness, sorrow, depression, memory deficit, difficulty with ADLs, and bathing). Exclusion: altered consciousness or not able to communicate, under mechanical ventilation or parenteral nutrition.	and in-hospital mortality when compared to usual care. Group 1: patient assessed, diagnosis established, tailored intervention Group 2: patient received usual care Matching: By age, gender, main diagnosis group. For each Group 1 patient there were 2 Group 2 patients entered.	Lawton ADL Scale • Mood: Yesavage's Geriatric Depression Scale • Cognitive /status: Minimental State Examination • Delirium: Confusion Assessment Method • Quality of Life: Visual analog scale of EuroQoL • Presence of pressure ulcers (irrespective of severity) During final nurse interview measured: • Functional status: Barthel Index • Delirium: Confusion Assessment Method • Quality of Life: Visual analog scale of EuroQoL • Falls • Presence of pressure ulcers (irrespective of severity)	Group 1. Group 1 showed a statistically significant lower combined frequency (a 73% reduction in odds) of functional decline, delirium, pressure ulcers, and death than Group 2.	hospitalization without evaluating geriatric outcomes after hospitalization Reviewer identified limitations: 1. Matching did not included race, ethnicity, or BMI 2. Pus reported without staging or severity noted 3. PU assessment not included in daily visits and weekly data entry—only assessed at initial and final interview. Adds support for existing evidence. Findings regarding functional decline and a lower frequency in delirium and pressure ulcers in geriatric evaluation management are consistent with earlier studies.	

Background etiology studies							
(Sopher and Gefen, 2011)	Experimental analysis of biomechanical model	Aged skin	Finite element models of skin were developed and analysis was done via simulation.	Effects of skin wrinkling were studied independently or while coupled with age-related mechanical property changes.	-Deeper wrinkles caused elevated loads in the stratum corneum consistently for all outcome measures and independently of the age factor -Thinning and/or stiffening the stratum corneum increased both the surface and internal stratum corneum stresses. -theoretically, wetness, skin aging, and or skin wrinkling are all risk factors	• Small sample • Not generalizable • Classified as Relevant and new by etiology group but not included in etiology section	This etiology information can be used for introduction
(Stojadinovic, Minkiewicz et al., 2012)	Experimental analysis of biomechanical model	human skin specimens from three young (32.5) and three aged (57.5) caucasian female patients.	Newly-developed bio-mechanical model for human skin specimens were subjected to confined compression load for 0.5, 1, 2, 4 hours	Mechanical load affect on inflammasome activation and contribution to inhibit healing	Aging contributes to the degree of morphological change and decrease in inflammasome activation seen in response to load, suggesting that the elderly have a decline in the innate inflammatory response.	Classified as Relevant and new by etiology group but not included in etiology section	This etiology information can be used for introduction
(Takahashi, Chandra et al., 2008)	Case control	612 cognitively intact ambulatory community dwelling persons aged 60	Endothelial function measured via peripheral artery tonometry.	Tonometry scores in cases (those with Hx of pressure ulcer in last 5 years)	Seven individual identified as having pressure ulcer within period of interest. Average tonometry score significantly worse than	• Sample size small. • Community ambulatory population, so may not	This etiology information

		and over.		compared to controls	controls p=0.04, & all 7 cases met score criterion for endothelial dysfunction.	be generalizable to other populations. • Classified as Relevant and new by etiology group but not included in etiology section	can be used for introduction
(Jan, Struck et al., 2009)	Quasi-experimental	20 healthy older adults (10 aged 65-75 years, 10 aged 75-85 years)	Testing the ageing effect on microvascular function, by measuring vasodilation and skin blood flow in the presence of local heating of the sacrum.	Wavelet spectrum analysis skin blood flow response to fast heating protocol	Using wavelet – based spectrum analysis of skin blood flow in response to heating this study showed indirect evidence that 0.01 Hz frequency to be associated with endothelial nitric oxide activity. The endothelial related frequency(0.01Hz) has had attention due to potential impact on early detection of endothelial dysfunction & relationship to pressure ulcers.	• Identified by authors. • Small sample size. • Classified as Relevant and new by etiology group but not included in etiology section	This etiology information can be used for introduction
(Fromy, Sigaudo-Roussel et al., 2010)	Compared PIV in nonneuropathic and neuropathic older subjects	Aged 60-75 years were compared to aged 20-35 years		Laser Doppler flowmetry was used to evaluate the cutaneous responses to local pressure application, acetylcholine, and local heating. Quantitative sensory tests were used to evaluate sensory-nerve-fiber function.	The nonneuropathic older subjects had an impaired PIV (12±7% increase in blood flow with pressure) compared with young subjects (62±4%, Po0.001). In the presence of peripheral neuropathy, the older subjects were totally deprived of PIV, leading to early pressure-induced cutaneous ischemia (31±10%, Po0.001). This inability of the skin to adapt to localized pressure in older subjects is related to the severity of the sensory-fiber dysfunction rather than to endothelial dysfunction, which was comparable between the non-neuropathic (141±19% increased blood flow with acetylcholine, Po0.05) and neuropathic older subjects (145±28% increase, Po0.05) compared with young subjects (234±25% increase).	Potential limitation of the study is the possible involvement of thinning of the skin due to aging in the PIV reduction observed in older subjects as compared with young subjects. The sensory neuropathy reported in this study was not as severe as that induced by total denervation, which reduced the thickness of the epidermis changes in skin blood flow are not expressed as a percentage from the maximal value, since responses to local heating were not performed to obtain the maximal skin blood flow values in this study. Classified as Relevant and new by etiology group but not included in etiology section	This etiology information can be used for introduction

References

Aminoff, B.Z. (2012). "End-stage dementia: Aminoff suffering syndrome and decubitus ulcers." Dementia **11**(4):473-81.

Arinzon, Z., A. Peisakh and Y.N. Berner. (2008). "Evaluation of the benefits of enteral nutrition in long-term care elderly patients." J Am Med Dir Assoc **9**(9):657-62.

Baumgarten, M., D.J. Margolis, D.L. Orwig, et al. (2009). "Pressure ulcers in elderly patients with hip fracture across the continuum of care." Journal of the American Geriatrics Society **57**(5):863-70.

Baumgarten, M., S.E. Rich, M.D. Shardell, et al. (2012). "Care-related risk factors for hospital-acquired pressure ulcers in elderly adults with hip fracture." Journal of the American Geriatrics Society **60**(2):277-83.

Cadigan, R., D. Grabowski, J. Givens, et al. (2012). "The quality of advanced dementia care in the nursing home: the role of special care units." Medical care **50**(10):856-62.

Cereda, E., A. Gini, C. Pedrolli, et al. (2009). "Disease-specific, versus standard, nutritional support for the treatment of pressure ulcers in institutionalized older adults: a randomized controlled trial." Journal of the American Geriatrics Society **57**(8):1395-402.

de Souza, D. and S.V. de Gouveia. (2010). "Incidence of pressure ulcers in the institutionalized elderly." Journal of Wound, Ostomy, and Continence Nursing: Official Publication of the Wound, Ostomy and Continence Nurses Society / WOCN **37**(3):272-6.

de Souza, D., V. Santos, H. Iri, et al. (2010). "Predictive validity of the Braden Scale for Pressure Ulcer Risk in elderly residents of long-term care facilities." Geriatric Nursing (New York, NY) **31**(2):95-104.

Fromy, B., D. Sigaudo-Roussel, M. Gaubert-Dahan, et al. (2010). "Aging-associated sensory neuropathy alters pressure-induced vasodilation in humans." The Journal of Investigative Dermatology **130**(3):849-55.

Grubbs, S., M. Ludwig, E. McHale, et al. (2009). "The effect of high frequency ultrasound on the prevention of pressure ulcers in long-term care patients." Internet Journal of Academic Physician Assistants **7**(1):3-.

Jan, Y.-K., B.D. Struck, R.D. Foreman, et al. (2009). "Wavelet analysis of sacral skin blood flow oscillations to assess soft tissue viability in older adults." Microvascular Research **78**(2):162-8.

Mangaco-Borja, E. (2011). "The significance of introducing permanent assignments for nursing assistants at a long-term care setting on the incidence rate of facility-acquired pressure ulcers among elderly patients." Journal of the American College of Certified Wound Specialists **3**(1):13-5.

Meaume, S., J.C. Kerihuel, T. Constans, et al. (2009). "Efficacy and safety of ornithine alpha-ketoglutarate in heel pressure ulcers in elderly patients: results of a randomized controlled trial." The Journal of Nutrition, Health & Aging **13**(7):623-30.

Morello, M., M.L. Marcon, A. Laviano, et al. (2009). "Enteral nutrition in nursing home residents: a 5-year (2001-2005) epidemiological analysis." Nutrition in Clinical Practice **24**(5):635-41.

Pérez-Zepeda, M., L. Gutiérez-Robledo, S. Sánchez-Garcia, et al. (2012). "Comparison of a geriatric unit with a general ward in Mexican elders." Archives of Gerontology and Geriatrics **54**(3):e370-e5.

Rich, S.E., D. Margolis, M. Shardell, et al. (2011). "Frequent manual repositioning and incidence of pressure ulcers among bed-bound elderly hip fracture patients." Wound Repair and Regeneration **19**(1):10-8.

Rodriguez-Fernandez, P., D. Adarraga-Cansino and P. Carpintero. (2011). "Effects of delayed hip fracture surgery on mortality and morbidity in elderly patients." Clinical Orthopaedics and Related Research **469**(11):3218-21.

Sopher, R. and A. Gefen. (2011). "Effects of skin wrinkles, age and wetness on mechanical loads in the stratum corneum as related to skin lesions." Medical and Biological Engineering and Computing **49**(1):97-105.

Stojadinovic, O., J. Minkiewicz, A. Sawaya, et al. (2012). "Differential activation of the inflammasome in loaded skin of young and elderly individuals." Journal of Investigative Dermatology **132**:S12.

Takahashi, P., A. Chandra, C. Caldwell, et al. (2008). "The association between pressure ulcers and endothelial dysfunction in a cohort of community elderly." Wounds: A Compendium of Clinical Research & Practice **20**(11):290-1.

Urasaki, M., G. Nakagami, H. Sanada, et al. (2011). "Interface pressure distribution of elderly Japanese people in the sitting position." Disability and Rehabilitation Assistive Technology **6**(1):38-46.

Volkert, D., L. Pauly, P. Stehle, et al. (2011). "Prevalence of malnutrition in orally and tube-fed elderly nursing home residents in germany and its relation to health complaints and dietary intake." Gastroenterology Research and Practice.

Yamamoto, Y., Y. Hayashino, T. Higashi, et al. (2010). "Keeping vulnerable elderly patients free from pressure ulcer is associated with high caregiver burden in informal caregivers." Journal of Evaluation in Clinical Practice **16**(3):585-9.

INDIVIDUALS IN THE OPERATING ROOM

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Preventing heel PUs							
(Donnelly, Winder et al., 2011)	RCT **comparing complete offloading to standard care for prevention of heel PUs in post-operative patients**	Participants were recruited from a fracture trauma unit in Ireland (n=239, n=227 completed study) inclusion: • Aged > 65 years • Fractured hip in previous 48 hours Exclusion: • Existing heel pressure damage • History of previous PU • Considered unsuitable by research team or no consent Characteristics: • Mean age 80 yrs • Mean Braden score 15 • low prevalence of peripheral vascular disease and diabetes • Approximately 1/3 sample were at moderate to high risk of malnutrition • No differences between groups in types of injury or time taken to get to hospital • Significantly more of the control group waited >72 hours between injury and surgery (p=0.0009) • Significantly more of the heel elevation group had surgery of > 2 hrs duration (p=0.034)	• Participants were randomized to receive either: ○ heel elevation achieved using a commercial device (Heelift® Suspension Boot) plus pressure-redistributing support surface (n=120, 9 withdrew) ○ standard care that included a pressure-redistributing support surface (n=119, 3 withdrew) • Pressure redistribution support surfaces included cut foam mattresses, alternating mattresses and mattress overlays selected according to individual needs.	Primary outcome: • Number of new category 1 or greater PUs on heels or other sites assessed daily for signs of tissue discoloration or ulceration (skin temperature, induration, oedema, pain, itching) with all skin damage photographed and confirmed by a blinded skin viability nurse who categorized damage on NPUAP scale Secondary outcomes: • Participant opinion assessed via questionnaire • Concordance with an offloading device	**Effectiveness in preventing PU** • Significantly fewer PUs in any anatomical location in heel elevation group (7% versus 26%, p<0.001) • Significantly fewer patients in the heel elevation group developed a PU on ankles, feet or heels (0 versus 29, p<0.001) • Control group more likely (p=0.001) to suffer pressure damage at all time points. **Acceptability and concordance** • The heel elevation device was rated: ○ comfortable by 59% participants ○ interfering with sleep by 32% participants ○ adversely affecting movement in bed by 41% participants • Reasons for poor concordance included weight and bulk (36%), heat (31%) and discomfort (24%). **Adverse events** 45 adverse events (no significant association between the groups and adverse events, p=0.691)	• Potential observer bias due to non-blinding; however, all pressure damage was confirmed by a blinded assessor • Half of the subjects had support surface upgraded by nursing staff (protocol violations) • Duration of time spent in bed/days treatment was not reported • Study failed to recruit *a pirori* sample size for clinical significance	**Level: 2 Quality: moderate**
(Malkoun, Huber et al., 2012)	Cross-over quasi-experiment **investigating interface pressure at the heel and Achilles tendon of**	Consecutive subjects were recruited from an outpatient vascular laboratory (n=116) Characteristics: • mean age 56yrs ±18.3 • mean weight 78.1kg±14.5 • mean BMI 27.3±4.7	• Comparison of interface pressures for: ○ Action® Heel Support ○ Oasis Elite viscous elastic gel (VEG) heel block ○ Action® Overlay VEG mat ○ Prototype leg elevation device, Viater® Medical ○ Regular theatre table	• Interface pressure reading at four anatomical sites using XSensor® X3 pressure mapping system • Measurements were taken 2 minutes after the device was put into place • Measurements were	• Offloading devices (Oasis block and prototype) generated significantly (p<0.0001) less pressure at heel compared to the other devices/surfaces. • Prototype device and Oasis block median pressure 0 mmHg at heels • Theatre table and the Action® VEG mat median pressure 0 mmHg at	• No blinding	**Indirect evidence Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	different offload devices in the OR setting			taken at the heel, Achilles tendon, lateral malleolus, and calf	Achilles tendon but 193.2 mmHg and 174.8 mmHg respectively at heel • Prototype device applied significantly ($p<0.0001$) less pressure to the Achilles tendon than the Action® heel support or Oasis block • Prototype device significantly ($p<0.0001$) less pressure at lateral malleolus than Oasis block or Action		
Preventing PUs in prone position							
(Wu, Wang et al., 2011)	Observational study	Participants were recruited in a spinal unit in Taiwan (n=30) Inclusion: • spinal surgery • expected surgery duration ≥ 3 hrs • prone positioning Exclusion: • emergency surgery • vascular disease • diabetes • Braden score <18 Characteristics: • Mean age 57.2±19.6 years • Mean weight 62.3±10.5kgs • 6.7% had BMI <18, 26.7% had BMI 18 to 24, 53.3% participants had BMI of 24 to 29, 13.3% had BMI >30 • Mean Braden scale 20.8±1.2 • Mean operative time 285.4±73.4 mins	Participants received either: • 10cm thick high density foam (HDF) • 2cm thick viscoelastic pads(VP) Each participant had VP on the left side of the chest and iliac crest and HDF padding on the right side	• Interface measurement prior to starting surgery • Presence of PU as defined by NPUAP classification observed 30mins following surgery and if PU present then again in 24hrs and 48hrs	• Immediately after surgery 75% of participants had nonblanchable skin redness on iliac and chest pressure points (73% of VP pressure points, 77% of HDF pressure points). • At 30mins post-operative overall incidence of PU was higher in HDF group, but not difference was not significant (10% versus 5%, OR=0.47, 95% CI 0.11 to 1.99, $p>0.05$) • One stage II PU in VP group after 48 hrs • Interface pressure was significantly lower ($p<0.001$) with VP pad • Univariate analysis of risk factors for PU at 30mins ○ Female gender(OR=0.04, 95% CI 0 to 0.79, $p<0.05$) ○ BMI < 18 (OR=21.40, 95% CI 4.11 to 111.51, $p<0.05$) ○ Body weight <50kgs (OR=18.57, 95% CI 4.06 to 85.03, $p<0.05$)	• 48 hours follow up • small sample size • Side that the pad was placed not randomized • Blinding of assessor and statistician not reported • Not designed for the null hypothesis	**Level of Evidence: 3 Quality: moderate**
(Grisell and Place, 2008)	Blinded RCT **comparing different facial pillows for prevention of PU <u>in the OR setting</u>**	Participants were consecutive patients admitted for elective surgery requiring prone position at a surgery in the USA (n=66) Inclusion: • elective thoracic and/or lumbar surgery requiring prone positioning • aged 18 to 65 yrs	• All participants were positioned using standard prone positioning. • Patients were randomized to receive different facial pillows: ○ Orthopedic Systems Inc (OSI) disposable polyurethane foam positioner (n=22)	• Facial tissue pressures were measured at the patient's forehead and chin at time 0, 5, 15, and 60 minutes of positioning • The integrity of skin was recorded and classified using NPUAP system staging at the end of	• 10 patients positioned on the OSI positioner developed PUs (eight stage I PUs and two stage II PUs) • No patients from the other two groups showed any evidence of PUs • The pressure measurements for the Dupaco Prone View® were lower at all of the time points for both the forehead and the chin in comparison to the OSI and the ROHO ($p<0.05$)	• Patients were not stratified by age, race, or gender and existing risk factors for PU not reported • Risk of PU on entry to study not reported • Length of time in position not recorded (procedures last from 1	**Level of evidence: 2 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Exclusion: • existing facial ailment including redness, inflammation, rash, graze, bruising • history of increased intraocular pressure or glaucoma • major language not English Characteristics: • surgery times varied from 1 to 12 hours and not reported • no demographic data reported	○ Dupaco Prone View® Protective Helmet System disposable polyurethane foam head positioner (n=22) ○ ROHO Group neoprene air filled bladder dry flotation device (n=22)	surgery	• Forehead pressures were significantly less for the ROHO compared with the OSI ($p<0.05$)	to 12 hours)	
Time to surgery							
(Al-Ani, Samuelsson et al., 2008)	Prospective cohort study **comparing the incidence of PU in those who had delayed surgery to those who had surgery within 24 hours**	Participants were recruited from two hospitals in Sweden (n=850, n=744 met inclusion) Inclusion: • undergoing surgery for hip fractures Exclusion: • arrived at hospital <24 hrs after fracture occurred Characteristics: • Mean age 81 years • 73% sample were female • 28% of sample had dementia • 49% cervical fracture, 43% trochanter fracture, 8% subtrochanter fracture • Demographics were not significantly different between time-to-surgery groups	Time to surgery defined as hours from admission to the ER to the time of operation.	Classification of PUs conducted by a specialist nurse according to EPUAP 1998 guidelines. Analysis included only grade II, III and IV PUs	**Time to surgery** • Median wait time to surgery was 24hrs (range 2.8 to 331 hrs) • 48% had surgery within 24 hours • 74% had surgery within 36 hours • 87% had surgery within 48 hours **Incidence of PU** • Participants who had a >24 hr wait for surgery were more likely to develop a PU (21/359, 6% versus 40/385, 10%, $p<0.05$) • Participants who had a >36 hr wait for surgery were more likely to develop a PU (31/550, 6% versus 30/194, 15%, $p<0.001$) • Participants who had a >48 hr wait for surgery were more likely to develop a PU (41/646, 6% versus 20/98, 20%, $p<0.001$) • After adjusting for age, ASA score, pre-fracture mobility, dementia and duration of surgery, adjusted OR of developing a PU: ○ Delay of >24 hrs OR=2.19 (95% CI 1.21 to 3.96, $p<0.01$) ○ Delay of >36 hrs OR=3.42 (95% CI 1.94 to 6.04, $p<0.001$) ○ Delay of >48 hrs OR=4.34 (95% CI 2.34 to 8.04, $p<0.001$)	• Presence of PU on admission to ER was not reported on considered • Unclear when PU classification was conducted and if there was repeat assessment • Unclear if PU assessments were conducted by nurses blinded to surgery time • Small numbers in the group who waited longer for surgery	**Level of evidence: 2 (prognosis) Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(Stahel, Vanderheiden et al., 2013)	Cohort study **comparing an early spinal surgery protocol versus delayed surgery**	Participants were those undergoing spinal surgery in a US hospital (n=112) Inclusion: • aged > 18 years • unstable thoracic or lumbar fracture Characteristics: • Mean age 34 to 36 years • Mean time to surgery significantly (ESG 8.9 hrs, DSG 98.7 hrs) different between groups	• Early spinal surgery group (ESG, n=42): surgery performed within 24 hours • Delayed surgery group (DSG, n=70): surgery for spinal fixation delayed by at least 24 hours, (protocol defined patients for whom delayed surgery was more appropriate)	• Method and frequency of assessment of PU was not reported. • Grade/stage of PU was not reported	• Pressure uclers occured less frequently in the participants ho had early surgey (2.4% versus 8.6%, p<0.05)	• Does not report method or frequency of assessment of PU • Other factors that may have influenced findings (e.g. duration of surgery) were not included in a correlational analysis • No confidence intervals	**Level of evidence: 5 Quality: low**
(Smektala, Endres et al., 2008)	Prospective cohort study **investigating impact of delayed surgery in older adults with hip fracture**	Participants were recruited from 2002 to 2003 in 268 acute care hospitals in Germany (n=2,916) Inclusion criteria: • aged ≥ 65 • proximal femoral fracture • first fracture event • surgical treatment acute-care admission Exclusion: • multitrauma or comatose • malignancy • incomplete medical records Characteristics: • 79.7% sample female • Mean age from 81.5 yrs to 82.4 yrs with participants waiting >36 hours significant younger (p=0.009) • >50% participants had ADA score of III, with those in the lingers surgery wait group being more likely to have higher ASA score	Time to surgery classified as hours from time of fracture event to the time of operation. • 27.5% sample had surgery within 12 hours of fracture • 40.8% had surgery within 12 to 36 hours • 31.7% waited > 36 hours	• The occurrence of a post-operative complication or patient death with one year follow up, of which pressure ulcer was one complication reported • Assessment or classification of PU is not reported	• Incidence of PU was 1.4% • In all patients multi-variate adjusted hazard ratio for PU was 2.08 (95% CI 1.20 to 3.58, p=0.009) • Time to surgery was not significantly associated with PU developed: Multivariate-adjusted OR as a function of time-to-surgery OR=1.33 (95% CI 0.96 to 2.05, p=0.201)	• Only patients with comprehensive records maintained for 12 months were included • Method and timing of PU assessment not reported • PU prevention strategies in OP and postoperative are not reported • Does not report identification of PU on admission	**Level of evidence: 2 (prognosis) Quality: moderate**
(Lefaivre, Macadam et al., 2009)	Retrospective cohort study investigating **effect of delay to surgery on incidence of**	Participants were admitted to trauma unit in Canada between 1998 and 2001 (n=607) Inclusion: Aged > 65 years Isolated fracture of proximal femur	Time to surgery defined as hours from admission to the ER to the time of operation.	Method and timing of assessing is not reported. Categories/staging of PU is not reported Delay in surgery was categorised as:	• Incidence of PU was 13.5% (82/607) • Delay of 24 to 40 hours was not associated with a significant increase in risk of PU (OR 1.23. 95% CI 0.71 to 2.12, p=0.47) • Delay >48 hours prior to surgery was associated with an increased risk of PU	• Determination of time of discharge was a limitation • Method of PU assessment and classification is not reported	**Level of evidence: 2 (prognosis) Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	PUs	Exclusion: Incomplete medical record Characteristics: • Mean age 83.3 years (range 66 to 111) • 79% sample female • 55% trochanter or subtrochanter fracture, 45% femoral neck • Mean time to surgery 33.6±26.18 hrs • Morbidity was 7.9%		• < 24 hours • 24 to 48 hours • > 48 hours	(OR 2.29, 95% CI 1.19 to 4.40, p=0.0128)	• Repeat assessment of PU presence not reported • Blinded assessment is not reported or discussed	
(Nilsson, 2013)	Descriptive study **reporting on association between post-operative pain and PU**	Consecutive elective surgery patients at a hospital in Sweden (n=86) Inclusion: • supine position during surgery • aged ≥ 18 years • ASA status I or II • elective surgery under general anesthesia Exclusion: • pre-existing PU • peripheral neuropathy. PVD, paralysis, muscular diseases • BMI < 19 or > 34 Characteristics: • Mean age 48 years (range 18 to 87) • average surgery duration 151 minutes (range 60 to 560) • 27% of participants experienced preoperative pain	• None	• Pain located on heels, arms or overall, assessed in the post-anesthetic care unit (PACU) on a numerical rating scale (0 to 10) • Heel skin inspection and grading using four grades, conducted in the PACU by the nurse if the patient suffered heel pain	• 85% participants had a Tempur mattress and 15% had an air mattress • Four participants experienced heel pain (range 2 to 5 on NRS). 100% of these participants had a Tempur mattress. • 50% of participants experiencing heel pain had stage I heel PU.	• Skin assessment was only conducted on participants experiencing pain in PACU, therefore prevalence of heel PU is not accurate	**Level of evidence: N/A Quality: low**
(Primiano, Friend et al., 2011)	Prospective cohort observational study investigating **risk factors associated with development**	Participants were admitted to a trauma academic medical center in from June 2009 to Feb 2010 (n=258) Inclusion: • Aged ≥ 18yrs • same day admission for surgery • expected surgery duration >3hrs • expected inpatient stay ≥24hrs	• Duration of surgery • Observation of multiple intrinsic and extrinsic factors	• Presence of a new PU within 72 hours of surgery • Assessment preoperatively, intraoperatively and postoperatively using NPUAP classification system and daily Braden	• Incidence of new PU was 8.1% • Variables significantly associated with PU development in chi-square analysis: ○ type of positioning device used in OR (χ^2=7.897, p=0.048) ○ table surface used in OR (χ^2=15.848, p=0.000) ○ postanaesthetic care unit skin	• single site • confidence intervals not reported • only included surgical • procedures of > 3hr duration • Location of PU not stated • Selection of sample is	**Level of evidence: 2 (prognosis) Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	of PU post-operatively	Exclusion: • Pregnancy • Pre-existent PU • 73.3% sample aged between 46 and 75 yrs • 57% sample female • 58% sample White • 97.2% had ASA score of 2 or 3 • 65% surgery lasted 3 to 5 hours • 70% participants has no positioning device, 19.8% had pillow under knees, 8.1% had elevated heels, 2% had wedge foam • Foam table pads with valves were used for 63% participants and 48% had heated gel pads		scales scores • Preoperative factors analysed: ○ Age ○ Weight ○ Surgical procedure ○ Incontinence ○ ASA score ○ Nutritional status ○ Blood levels ○ Skin integrity including previous breakdown ○ Alterations in sensation • Intraoperative factors analysed: ○ type of anaesthesia ○ patient temperature ○ temperature devices in OR ○ length surgery ○ type of surgical pad/overlay ○ hypotension, hypoxia ○ medications	assessment score (χ^2=41.652, p=0.000) ○ female gender (χ^2=6.984, p=0.030) • Variables significantly predicting PU development logistic regression multivariate analysis: ○ use of a foam pad on OR table (OR=14.740, p=0.024) ○ Braden score on day 1postoperative (OR=0.783, p=0.003) • 23% of participants who developed a PU (suggests primarily sacral) had their heels elevated (p=ns) • Closed cell foam pad was used for 29% of participants who developed a PU	not reported • Rater reliability and blinding of assessment is not reported	

References

Al-Ani, A.N., B. Samuelsson, J. Tidermark, et al. (2008). "Early operation on patients with a hip fracture improved the ability to return to independent living. A prospective study of 850 patients." The Journal Of Bone And Joint Surgery American Volume **90**(7):1436-42.

Bry, K.E., D. Buescher and M. Sandrik. (2012). "Never say never: a descriptive study of hospital-acquired pressure ulcers in a hospital setting." Journal of Wound, Ostomy and Continence Nursing **39**(3):274-81.

Bulfone, G., I. Marzolil, R. Wuattrin, et al. (2012). "A longitudinal study of the incidence of pressure sores and the associated risks and strategies adopted in Italian operating theatres." Journal of Perioperative Practice **22**(2):50-6.

Donnelly, J., J. Winder, W.G. Kernohan, et al. (2011). "An RCT to determine the effect of a heel elevation device in pressure ulcer prevention post-hip fracture." Journal of Wound Care **20**(7):309.

Grisell, M. and H.M. Place. (2008). "Face tissue pressure in prone positioning: a comparison of three face pillows while in the prone position for spinal surgery." Spine **33**(26):2938-41.

Haleem, S., G. Heinert and M.J. Parker. (2008). "Pressure sores and hip fractures." Injury **39**(2):219-23.

Lefaivre, K.A., S.A. Macadam, D.J. Davidson, et al. (2009). "Length of stay, mortality, morbidity and delay to surgery in hip fractures." The Journal of Bone and Joint Surgery British Volume **91**(7):922-7.

Malkoun, M., J. Huber and D. Huber. (2012). "A comparative assessment of interface pressures generated by four surgical theatre heel pressure ulcer prophylactics." International Wound Journal **9**(3):259-63.

Nilsson, U.G. (2013). "Intraoperative positioning of patients under general anesthesia and the risk of postoperative pain and pressure ulcers." Journal of perianesthesia nursing : official journal of the American Society of PeriAnesthesia Nurses / American Society of PeriAnesthesia Nurses **28**(3):137-43.

Primiano, M., M. Friend, C. McClure, et al. (2011). "Pressure ulcer prevalence and risk factors during prolonged surgical procedures." AORN Journal **94**(6):555-66.

Smektala, R., H.G. Endres, B. Dasch, et al. (2008). "The effect of time-to-surgery on outcome in elderly patients with proximal femoral fractures." BMC MusculoskeletDisord **9**:17 doi:0.1186/471-2474-9-171.

Stahel, P.F., T. Vanderheiden, M.A. Flierl, et al. (2013). "The impact of a standardized "spine damage-control" protocol for unstable thoracic and lumbar spine fractures in severely injured patients: A prospective cohort study." The journal of trauma and acute care surgery **74**(2):590-6.

Wu, T., S.T. Wang, P.C. Lin, et al. (2011). "Effects of using a high-density foam pad versus a viscoelastic polymer pad on the incidence of pressure ulcer development during spinal surgery." Biological Research For Nursing **13**(4):419-24.

INDIVIDUALS IN PALLIATIVE CARE

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
Prevalence data							
(Aminoff, 2012)	Cohort study **investigating 6-month outcomes for patients with end-stage dementia and PU**	Participants were recruited over a 3 year period from a geriatric centre in Israel (n=200) Inclusion: • Severe, end-stage dementia (of difference origins) • Communication difficulties • Complete dependency in ADLs and functional movement Characteristics: 102 males, 98 females Mean age 80.9±8.1 years (range 50 to 100)	• Comparison of two cohorts: ○ Cohort one : no PU on admission (n=80) ○ Cohort two: PU on admission (n=120)	• Mini-Suffering State Examination (MSSE, validated tool) that assesses for presence of conditions associated with suffering, of which PU is one. • Presence of PU (Stages I to IV) unclear how this was assessed Follow-up period of 6 month	• On admission participants with PU had a higher rate of: ○ male gender (p<0.009) ○ malnutrition (low albumin; p<0.0001) ○ high cholesterol (p<0.0001) ○ antidepressants (10.8% vs. 2.5%, p=0.028) ○ analgesia (23.8% vs. 11.7%, p<0.032) • Participants with PU had a significantly higher 6-month mortality rate compared with those without PU (71.3% vs. 45.8%, p<0.0001) • Participants with PU had a higher significantly higher MSSE score than those without PU (5.49±2.17 vs. 3.48± 222, p<0.0001) • On the MSSE, participants with PU had no significant differences for being not calm, screaming, pain, eating disorder, of suffering according to family opinion. • On the MSSE, participants with PU were more likely to have malnutrition, invasive actions, suffering according to medical opinion and unstable medical conditions. • **Study conclusions: People with end-stage dementia that have concurrent PU have a high 6-month mortality rate. It is unclear if PUs arise from their multiple medical conditions or contribute toward them.**	• Unclear how outcome measures e.g. presence of PU was assessed • It is unclear whether the overall significant difference in MSSE score is attributable to presence of PU being one question on the MSSE	**Level of evidence: N/A** **Quality: low**
(Hendrichova, Castelli et al., 2010)	Retrospective records **analysis of PU prevalence in cancer patients**	Records were analysed from patients with cancer admitted within a 6-month in 2008 to a palliative care service in Italy (n= 414) Characteristics: • It is a requirement of admission to service that patients have a Karnofsky Performance Scale (KPS) index lower than 50% indicating a high risk of PU	Individualized prevention strategies were used for all participants including: • higher specification foam mattress • an active support surface for patients with highest risk • regular turning and repositioning • observed skin regularly • used skin emollients	• Presence of PUs determined using European staging system	• Prevalence of PUs of 22.9% • Incidence of PUs of 6.7% • Karnofsky Performance Scale (KPS) Index scores, age and length of stay were significantly related to the pressure sore development (p<0.001) • Patients who developed PUs were significantly older than those who did not develop them (79.9±6.8 versus 73.4±11.5 days) • Patients who developed PUs were cared for a significantly greater number of days (57.2 versus 37.4 days, p=0.027)	• Retrospective design • Single site study • Lacks generalizability	Level of evidence: N/A Quality:

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
		• Mean age 74 years • 65% admitted from home and 35% from another palliative service	to hydrate dry skin and reduce the risk of skin damage				
(Maida, Ennis et al., 2012)	Prospective observational sequential case series cohort comparison **of PU incidence in palliative care patients**	Participants were sequential patients referred from a community and hospital based palliative care program in Canada (n=593 with 1036 wounds were assessed) Characteristics: • 70% of participants had a cancer diagnosis • Mean age was significantly older for non-cancer patients (80.5±11.1 versus 72.4±13.2 years, p<0.001) • Primarily Caucasian • Mean Braden score was significantly lower for non-cancer patients (10.1±2.9 versus 15.8±3.8, p<0.001) • Non-cancer patients had more comorbidities (9.1±3.1 versus8.3±3.3, p=0.01)	• Participants were followed by serial clinical assessments every 24-48 hours throughout their palliative trajectory • Performance status was measured at baseline and then weekly until death • Risk was measured using the Braden Scale	Observational period spanned 24 months PUs were classified according to the National Pressure Ulcer Advisory Panel (NPUAP)	• During the 24 month assessment period 891 new wounds developed • PUs accounted for 60.6% of all wounds • Most common anatomical site for wounds was the coccyx/sacrum • non-cancer patients experienced a higher prevalence of PUs • cancer patients had a higher point prevalence of malignant wounds and iatrogenic wounds • **Study conclusions: palliative care patients have a high rate of wound development, with PUs accounting for 60.6% of wounds and the most common site being the sacrum/coccyx region. Non-cancer patients have a higher risk of PU, with a lower mean Braden score and higher level of co-morbidity.**	• Participants all were recruited from a single health care organization in a single country • Reassessment occurs at 24 and 48 hour intervals resulting in some degree of error in assessing the onset date of particular wounds	**Level of evidence: N/A Quality: moderate**
(Maida, Ennis et al., 2009)	Cohort study investigating the **association between wounds and survival in cancer patients**	Participants were cancer patients (n=418) of which 90% were followed to their death) Characteristics: • Mean age 73±13 years • Primarily Caucasian (86.1%)	• Assessment on admission to study	• Cancer type classified per body system • Wound types were classified within 24 hours of admission	• Participants with wounds were less likely to have gastrointestinal cancer than those without wounds (37.4% versus 62.6%, p<0.0001) • PUs were the most common wound class observed (22.7%) • Participants with wounds at referral had a significantly worse prognosis (23 days versus 43 days, p<0.0001) • **Study conclusions: there was a statistically significant increase in risk of death for female patients with PUs (HR 2.00, p=0.0002)**	• Participants all were recruited from a single health care organization in a single country • Reassessment occurs at 24 and 48 hour intervals resulting in some degree of error in assessing the onset date of particular wounds	**Level of evidence: N/A Quality: moderate**
(Maida, Ennis et al., 2012)	Prospective case series **assessing**	Participants were recruited from a palliative care program in Canada.	• All patients were examined within 24 hours of the initial	• Complete wound healing	• Proportions of patients showing complete healing prior to death: ○ 18.9% for stage I PUs	• Lack of standardization for wound assessment • Use of referral date as	**Level of evidence: 5 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
	potential for complete wound healing in in patients with advanced illness.	(n = 282 with 823 wounds of mixed aetiology) Characteristics: • patients with cancer (n=148) and non-cancer (n=134) • Mean Braden score 12.2 (range 6 to 22) • Wounds were primarily PU: ○ Stage I n=218 ○ Stage II n=239 ○ Stage III n=21 ○ Stage IV n=28 ○ Unstageable n=55	referral • Risk for developing PUs was measured using the Braden Scale • All wounds were managed by a specialist wound management team with intet to heal • All patients with a stage IV or stage US PU were also placed on support surfaces within 48 hours of baseline.		○ 10.4% for stage II PUs ○ 7.7% for stage III PU ○ 0% for stage IV PU and unstageable PU • **Study conclusions: for patients with advanced disease who develop PUs, the likelihood of complete wound healing before death is low for most PU stages, particularly for patients with less than 7 days to live.**	baseline • Since many wounds had incomplete data pertaining to wound dimensions the validated Pressure Ulcer Scale for Healing guidelines were not employed • Participants lived for between 7 and 182 days with majority not surviving beyond 7 days	
(Bonaldi, Parazzini et al., 2009)	multicentre-observational study **providing information on PU epidemiology across a range of people receiving palliative care**	Participants recruited from seven publically funded palliative care centres in Milan. (n=1081) Inclusion: • Diagnosis of end-stage cancer where no curative treatment available • Did not require admission for intensive care • Not expected to live longer than 90 days.	MD completed a 2-part questionnaire: • socio-demographic characteristics clinical data including • information regarding presence and severity of PU	• Presence of pressure ulcers (AHCPR classification tool all stages reported I through IV) • Self-evaluated pain ad self-reported dyspnea using VAS with both outcomes assessed as moderate-to- severe where the VAS score was greater than 5. • Assessments twice weekly • Patients followed until death or withdrawal from the study	1081 patients followed: • 687 died at home (63.6%) • 178 (16.5%) died in a palliative care unit • 140 (13%) died in hospital • 67 withdrew from the study. PU prevalence: • 10.5% reported to have PU • mean PU/ participant 1.5±1.2 • 1.3% reported stage III or IV PU • 9.6% males had PU • 11.4% females had PU Pressure ulcers by cancer location: • Breast 9% • Lung 11.6% • Colon 10.8% • Gastric cancer 12.1% • Gynaecological cancer 11.6% • Prostate 10.8% • CNS cancer 8.7% • Other cancers 9.2%	• Patient sub-groups often small precluding detailed analysis of PU by cancer type and location at time of death • Local variation in palliative care services across Italy perhaps limiting generalisation from the data to services in Italy and beyond.	**Level of evidence: N/A Quality: low**
Factors influencing PU development in palliative care							
(Kayser-Jones, Kris et al., 2008)	prospective, anthropological study **reporting on the**	A purposive sample of residents receiving end-of-life care in two nursing homes in USA (n=117, n=64 with PU)	Records review for quantitative descriptive statistics Interviews, events analysis for qualitative data	Data were collected during a 30-month period spent in the research settings observing daily activities, asking appropriate	• 81.3% of residents with PU at time of study still had a PU at time of death. • 47.3% of the PUs were on lower extremities. • Healed PU occurred in: ○ 17% stage I PU	Limitations include the small sample and that data were collected in only two nursing homes. This study was not initially	**Level of evidence: 5 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
	experience of terminally ill residents admitted with or acquiring PUs in a nursing home	Characteristics: • Of residents with PU, 37.5% had acquired PU whilst in facility and 59.4% had acquired them at home before admission. • Mean age of residents with PU was significantly higher than those without PU (81 vs. 76 yrs, p=0.033) • Mean length of stay was longer for residents with PU (112 vs.52 days, p=0.0033) • Residents with PU had higher requirement for ADL support (p=0.022) and were less likely to have cancer (p=0.01). • 64 residents had a total of 171 PU.	(primarily a qualitative study)	questions, identifying and interviewing key informants, and taking detailed field notes.	○ 29.8% stage II PU ○ 20% stage III PU ○ 0% stage IV PU ○ 29.4% of all PUs • A significant finding was that the residents with PUs had a mean weight loss of 30 pounds, whereas those without PUs had a mean weight loss of 6.9 pounds. • Qualitative interviews identified organizational factors that led to the development of PU: • Inadequate staffing and lack of supervision led to inadequate assistance with meals, infrequent repositioning and inadequate incontinence care. These factors led to weight loss, unrelieved pressure and moist, irritated skin. As a result a high rate of resident who were dying developed PUs. • Absence of family advocates and inability to speak English were factors that contributed to the above model of PU development in residential aged care.	designed as an investigation of PUs, thus the data are not comprehensive for the PU experience.	
(Gozalo, Teno et al., 2011)	Retrospective study **investigating association between burdensome health care transition and outcomes indicating of poor quality in end-of – life care**	Participants were retrospective record reviews of Medicare Minimum Data Set and claims from files 2000 to 2007 for deceased nursing home residents in USA (n= 474,829) Inclusion: • Nursing home resident before death Characteristics: • Mean age 85.7±7.6 years • 78% females • 83% White race • 73% had a DNR order • 54% had swallowing problems • 43% had unstable cognitive or ADL status	Authors examined whether there was an association between regional rates of burdensome transition and the likelihood of presence of a stage IV PU and hospice enrolment in the last 3 days of life	• Burdensome transition defined as: ○ Transfer in last 3 days life ○ Lack of continuity of nursing home facilities before and after hospitalization in last 90 days life ○ Multiple hospitalizations in last 90 days life	• 19% of participants had at least one burdensome health care transition (range 2.1% to 37.5% between regions) • 5,176 (13.6%) had a stage IV decubitus ulcer • Adjusted risk ratio for a stage IV PU in last 30 days of life ranged from 1.48(95% CI 1.31 to 1.66) in the region with the lowest quintile for burdensome transitions to 2.28 (95% CI 2.04 to 2.54) in regions in the highest quintile of burdensome transitions • **Study conclusions: a burdensome health care transition may be associated with indicators of poor end-of-life care, including PUs.**	• Retrospective design relying on record entries • No information regarding patient preferences for care or transfer • Large variability between USA states reduces generalizability within and between countries	**Level of evidence: N/A Quality: moderate**
(Searle & McInerney,	Interpretative description	Participants were nurses with recent experience in	• Semi-structured interviews were used to	Outcomes not assessed with qualitative design – looking	Themes that emerged: • Moral agency	• Focuses on nurses in one setting	**Level of evidence:**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
2008)	qualitative study	providing end-of-life care (n=12 nurses)	collect data • Interviews were audio-taped, transcribed verbatim and imported into the software NVivo	for themes to emerge and data saturation	• Disagreements about best care between nurses • Disagreement between nurse, patient and family members about best care at the end of life • Disagreements about best care between nurses on difference shifts or wards • Moral distress	• Restriction to health service • Small sample size with minimal contradictory data sought out of presented	**N/A** **Quality: moderate**
Assessment of PUs in palliative care patients							
(Maida, Ennis et al., 2009)	observational case series **for development of Toronto Wound Assessment System for Wounds (TSAS-W)**	Participants were all new referrals to a palliative care program in Canada between 2005 and 2006 Inclusion: • Referral to the palliative care program • Cancer or noncancer advanced disease • Presenting with wounds or developing wounds during followup period Exclusion: • Lack of English proficiency Phase 1: n=531 patients with 2,102 wounds Phase 2: n=83 patients with 103 wounds, 21 participants with PU	Phase 1: All patients were examined within 24 hours Phase 2: TSAS-W scores were assessed at referral and 1 week later	Phase 1: • wound class • % of patients who reported each symptom at least once at any assessment Phase 2: • TSAS-W global wound symptom distress score Phase 1 and observational period spanned 24 months TSAS-W included an 11 point numerical rating scale for: • Pain • Exudate • Cosmetic appearance • Odor • Itchiness • Bleeding • Mass effect (swelling or edema around wound, bulk effect from wound, bulk effect from dressing) • Crusting • Restricted movement Findings were combined to give a mean global wound symptom distress scale (GWSDS)	• The most prevalent wound-related symptoms included: pain, exudation, odor, itching, bleeding, aesthetic concern, swelling and mass and bulk effects from the wound and associated dressings • In Phase 2 (n=121 participants with PU) Mean GWSDS for participants with PU was 33.10 at baseline and 25.24 at 7 day followup **Completion of tool** • 78.6% of assessments were carried out by participant alone • 14.6% of assessments were carried out by participant with caregiver • 6.8% carried out by the caregiver alone	• Single setting • Pilot testing was of limited duration • TSAS-W needs to be validated in a number of clinical settings	Primarily indirect evidence from mixed wound etiology Level of evidence (black text): 5 Quality: low

References

Aminoff, B. Z. (2012). "End-stage dementia: Aminoff suffering syndrome and decubitus ulcers." Dementia **11**(4): 473-81.

Bonaldi, A., F. Parazzini, O. Corli, L. Lodetti. (2009). "Palliative care at home in cancer patients in Milan." European Journal of Palliative Care **16**(1): 40-2.

Gozalo, P., J. M. Teno, S. L. Mitchell, J. Skinner, J. Bynum, D. Tyler, et al. (2011). "End-of-life transitions among nursing home residents with cognitive issues." The New England Journal of Medicine **365**(13): 1212-21.

Hendrichova, I., M. Castelli, C. Mastroianni, M. Piredda, F. Mirabella, L. Surdo, et al. (2010). "Pressure ulcers in cancer palliative care patients." Palliative Medicine **24**(7): 669-73.

Kayser-Jones, J., A. E. Kris, K. Lim, R. I. Walent, E. Halifax, S. M. Paul. (2008). "Pressure ulcers among terminally ill nursing home residents." Research in Gerontological Nursing **1**(1): 14-24.

Maida, V., M. Ennis, J. Corban. (2012). "Wound outcomes in patients with advanced illness." International Wound Journal.

Maida, V., M. Ennis, C. Kuziemsky. (2009). "The Toronto Symptom Assessment System for Wounds: a new clinical and research tool." Advances in Skin & Wound Care **22**(10): 468.

Maida, V., M. Ennis, C. Kuziemsky, J. Corban. (2009). "Wounds and survival in cancer patients." European Journal Of Cancer (Oxford, England: 1990) **45**(18): 3237-44.

Searle, C., F. McInerney. (2008). "Creating comfort: nurses' perspectives on pressure care management in the last 48 hours of life." Contemporary Nurse **29**(2): 147-58.

PEDIATRIC INDIVIDUALS

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Support surfaces and positioning							
(Turnage-Carrier, McLane et al., 2008)	Quasi-experimental **investigating interface pressure between occiput and different support surfaces in children**	Participants were recruited from an inpatient level II hospital nursery (n=13, n=11 completed study) Inclusion: • healthy premature infants of post-menstrual age (PMA) 35 to 37 weeks • feeding and gaining weight • in an open crib • within 1 to 3 weeks of discharge • no history or diagnosis of a skin disorder Exclusion: • Supplemental oxygen • Apnea, bradycardia, active infection, cardiopulmonary disease, congenital abnormality, skin disorder, trauma, hydrocephaly, cephalohematoma, caput succedaneum or birth injury of head/neck. Characteristics: • Mean age 30.2 gestational weeks, mean PMA 36.1 weeks • Mean weight 2556.9g	• All participants were positioned on 5 different support surfaces in a random order for 3 to 5 minutes. • The 5 bed surfaces were: ○ Standard crib mattress with 2.75" foam overlay ○ Standard crib mattress without foam overlay ○ Gel pillow ○ Gel mattress ○ Water pillow – 288mL water • Crib blanket was placed over the standard crib mattress, the gel mattress and the foam overlay and a new disposable cover was placed over the gel pillow.	• Interface pressures obtained under the occiput using an interface (IF) pressure evaluator and recorded in mmHg • Three measurements were taken on each surface	• No significant differences between the readings for participants • A significant difference in the mean of the IF pressures between each mattress and the standard crib mattress was established ($p<0.001$) • Mattress with foam overlay had the lowest IF pressure (mean 31mmHg) and standard mattress had the highest IF pressure (86.9mmHg) • **Study conclusions: A foam mattress overlay is associated with lower occipital IF pressure in babies**	• Infant movement could alter interface pressures • Observable differences in head shape could have influenced the IF pressures	**Indirect evidence: indirect outcome measure Quality: low**
(García-Molina, Balaguer-López et al., 2012)	survey investigating **incidence of HAPU in a children nursed on continuous and reactive low pressure mattresses**	Participants were admitted over a 2 year period to the 5 bed Paediatric ICU in a Spanish hospital (n=30 children) Inclusion: aged 1 day to 10 years • Admitted for > 24 hours	• All participants received standard PU prevention including application of hyperoxygenated fatty acid oil to skin 8 hourly, and protective hydrocellular dressings) • Participants of interest to	• Presence of PU determined by daily skin assessment	• 63.3% participants did not receive any repositioning due to their clinical condition • There was a significantly lower incidence of non-device related HAPU in the study participants compared with the estimated incidence in the previous year (3.3% versus 20%, 95% CI 0.08% to 17.2%,	• Small sample size • Comparison cohort was not described and reported as an estimated incidence • Severity of PUs prior to admission not reported • Participating nurses	**Level of evidence: 4 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Braden score indicating at risk of developing PU (Braden–Q ≤ 16, Neonatal Skin Risk Assessment Scale≤13) Exclusion: • Admitted <24 hours • Aged > 10 years • No consent • Not received the pressure mattress support surface PMSS Characteristics: • Primarily aged from 1 month to 3 years (73.3%, n=22) • Average Braden score for those aged >1 month 10.4±2.4 • Average Braden score for those aged < month 13.2±3.03 • About half participants were sedated and had vasoactive medication (n=15) • 33.3% had a PU on admission to study	survey were nursed on one of two mattresses provided in the unit for children at risk for PU • Both mattresses classified as continuous and reactive low-pressure special surfaces consisting of double air-cell construction that reacts to pressure in three different compartments (head, body, trunk) but maintains same level of support in each section (i.e. not alternating pressure). ○ First mattress (Cartio Neo®): designed for children weighing 500g to 6kg (n=4) ○ Second mattress(Cartio Juve®): designed for children weighing ≥6 Kg (n=26) • Participants were placed on the study mattresses for a mean of 7±7 days days (range 1 to 25 days)		p=0.021) • 66.6% of participants admitted with a PU healed before discharge from the PICU • **Study conclusions: the continuous and reactive low-pressure support surface was associated with a lower incidence of new PU in children in the absence of regular repositioning**	were trained informally • Concurrent use of several local pressure-management devices in certain high-risk anatomical locations	
(De Raeve, Vercruysse et al., 2001)	Randomized trial **comparing ability of neonates to maintain their body temperature on a visco-elastic foam compared to a gel mattress , also reports PU**	Participants were recruited over a one year period at a NICU in Brussels (n = 72) Characteristics: • gestational age 24 to 41 weeks (mean 32±3.7 weeks) • weight 535g to 3,600g (mean 1,692±741g) • 78% low-birth weight, 16% respiratory distress syndrome • babies with cold stress were considered a subgroup	• babies were admitted on a radiant warmer and transferred to the incubator with support surface when stabilized • randomized to receive either: ○ viscoelastic polyurethane foam mattress (Tempur®) (n=41) ○ 43% on a gel mattress (Premat®) (n=31)	• Settings of air flow systems • Settings of humidifiers • PU – does not state how this was measured, or how often assessed • 8 month study period	• Hyperthermia occurred more frequently than hypothermia • Mode of ventilation and temperature of the environment had an influence on hypothermia • Temperature setting in the humidifier was lower when babies were on a viscoelastic mattress, suggesting they could better regulate body temperature • There was no PU in the time of the study	• Methods of randomization and allocation concealment are poorly described • Outcome measures were poorly described • Unclear how PU was assessed • No statistical analysis for PU outcome • Unclear if sample size was sufficient	**Level of evidence: 2 Quality: low**
(Solis, Krouskop et al., 1988)	Observational study **comparing interface**	Participants were healthy volunteers (n =13) Characteristics:	• Participants lay on a standard hospital mattress and a hospital mattress with a 2" or 4"	• Interface pressure (IP) was measured at the occiput, scapula and sacrum	• There was significant differences in IP between occiput and sacrum (p < 0.001) ○ Age 0 to 2: mean occiput IP was 45.7 mmHg, mean sacral IP 17 mmHg	• Healthy volunteers, indirect outcome measures	**Indirect evidence: indirect outcome**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	pressure between a standard mattress and a foam overlay	• age range 10 weeks to 13.5 years	foam overlay		○ Age 2 to 10 years mean occiput IP was 54.3 mmHg ○ Aged > 10 yrs: mean occiput IP was 78 mmHg; mean sacral IP 34 mmHg • There was a significant reduction in mean IP with the foam overlay compared with a standard mattress alone at the occiput ○ aged 0 to 2 years, 22.3 mmHg versus 45.7 mmHg ○ aged 2 to 10 years, 30.5 mmHg versus 54.3 mmHg ○ 10 to 14 years, 42.4mmHg versus 78mmHg		**measure**
(McLane, Krouskop et al., 2002)	Observational study **comparing interface pressure between a standard mattress and a foam overlay, gel pillow and low air loss bed**	Participants were healthy volunteers (n = 54) Characteristics: 0 to <2yrs (n=13) 2 to <6 yrs (n=8) 6 to < 10yrs (n=16) 10 to <14yrs (n=10) 14 to 16 yrs (n=7)	• Participants lay on: • Neonates (n = 13) ○ standard crib mattress ○ crib mattress were a 2.75" foam overlay ○ crib mattress with a gel pillow ○ crib mattress with 2.75" foam overlay and a donut pillow ○ low-air-loss bed • aged >2 years (n=41) ○ low air loss bed ○ standard mattress ○ standard mattress with 3.5" foam overlay ○ standard mattress with gel pillow ○ standard mattress with 3.5" foam overlay and gel pillow	• Interface pressure (IP) was measured at the occiput, coccyx and heel (occiput only in < 6 yrs)	**Neonates (n =13) occiput IP** • all 4 modified surface types had lower occiput IP than crib mattress (61±19mmHg) (p<0.001) • foam overlay had lower occiput IP than the gel pillow (mean 26±6mmHg vs 32±10 mmHg, p = 0.018) and the low air loss bed (mean 26±6mmHg vs 32 ±13mmHg, p=0.059) • no significant difference between foam and foam + gel pillow (mean 26±6mmHg vs 26±9 mmHg, p =0.834) **2 to 16 years (n = 41) occiput IP** • age had no effect on IP • all 4 modified surface types had lower occiput IP than standard mattress (53±27mmHg) (p=0.00) • gel pillow had significantly lower IP than low air loss bed (24±10mmHg vs. 32±17mmHg p=0.12) • gel pillow + overlay had significantly lower IP than low air loss bed (26±12mmHg vs. 32±17mmHg p=0.032) • no significant difference between foam overlay and low air loss bed (28±14mmHg vs. 32±17mmHg p=0.78) • no differences between foam overlay, gel pillow or gel pillow + overlay. **6 to 16 years (n = 33) coccyx IP** no significant difference between standard mattress, delta foam overlay and low air loss	• Healthy volunteers, indirect outcome measures • No description of standard mattress	**Indirect evidence: indirect outcome measure**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					bed (p=0.159) **6 to 16 years (n = 33) heel IP** delta foam overlay had significantly lower IP than standard mattress (71±17mmHg vs. 81±22mmHg p=0.014) low air loss bed had significantly lower IP than standard mattress (66±20mmHg vs. 81±22mmHg p=0.014) no significant difference between foam overlay and low air loss bed.		
Pressure ulcers associated with medical devices							
(Limpaphayom, Skaggs et al., 2009)	Retrospective case series **reporting on complications associated with Halo use in children**	Participants were those treated in a children's hospital in USA from 1996 to 2005. (n=97 eligible, n=68 with complete medical records included) Inclusion: • Treatment with halo Exclusion: • Incomplete medical record Characteristics: • Mean age was 10 years (range 1 to 20 years) • 54% sample male	Halo used for immobilization (n=37), halo traction (n=12) or halo traction followed by halo vest (n=19). Mean duration of treatment was 12 weeks when used for immobilization and 3 weeks when used for traction.	Development of pressure ulcers as a complication. Frequency of assessment, assessment methods or staging are not reported.	• Incidence of pressure ulcers was 7.3% (severity not reported) • In no cases did development of a pressure sore require cessation of halo use or surgical intervention. • The authors suggest that "cutting off the offending portion of the halo vest" may reduce discomfort. (expert opinion) • The authors recommend routine skin checks by parents at home and during clinic visits, but do not detail frequency or assessment strategies. (expert opinion) • **Study conclusions: The report highlights the potential complications associated with medical device use in children**	• retrospective review • small sample size • 30% eligible records were not reviewed due to being incomplete, which leads to an unreliable indication of PU incidence • Insufficient detail of PU preventive strategies, duration treatments, participant characteristics, severity and duration of PU or management of PU while halo in use.	**Level of evidence: 5 Quality: low**
(Jaryszak, Shah et al., 2011)	Retrospective case series **reporting on wound complications associated with tracheostomy in children**	Participants were those identified from the Children's National Medical Center database in the USA as being coded for tracheostomy over a 15 month period (2008 to 2009) (n=65). Inclusion: • Coded for tracheostomy • Electronic medical record in audit period Characteristics: • Mean age at time of	Tracheostomy	Number of participants developing wound complications as assessed using the NPUAP PU staging system Type of tracheostomy tube Wound cultures conducted from 2 weeks before until 2 weeks after tracheostomy	• 19/65 (29.2%) participants developed a post-operative wound complication • There was no significant difference in age between those with and without wound complications (mean age 39.3 versus 47.4 months, p=0.068) • There was a higher rate of wound complications in participants aged less than 1 year compared with those aged over 1 year (39% versus 17%, p=0.04) • Use of extended mechanical ventilation) (p=0.58), weight (p=0.55), positive preoperative wound culture (p=0.06), positive postoperative wound culture (p=0.28) and maturation of stoma at time	• Retrospective review • Small sample size • Records may be unreliable • Insufficient detail of PU preventative strategies used, duration of treatments, participant characteristics, severity and duration of PU or management of PU were provided in this study.	**Level of evidence: 5 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		tracheostomy was 45±8.7 months • Most common indication was pulmonary disease (36.9%)			of surgery (p=0.14) were not associated with wound complications. • Type of tracheostomy tube was associated with wound complications (p=0.02) with a Bivona® Flex-Tend™ predicting wound complications (likelihood ration 4.9, p=0.03) compared with a Standard Bivona® or a Shiley™. • Wound complications were not associated with increased hospital length of stay or readmission. • As a result of wound complication rates the facility instituted a specialty trained tracheostomy nurse, use of barrier protection between tube flanges and the skin and aggressive wound care to early wound complications to prevent progression. The success of these interventions is not reported. • **Study conclusions: The report highlights the potential of wound complications associated with medical device use in children**		
(Chidini, Calderini et al., 2010)	Quasi experiment **comparing a CPAP delivery devices (face mask versus helmet) and reporting on complications including PUs**	Participants were recruited from a PICU in Italy and experimental participants were matched to controls for age, organ failure, $PaCo_2$ and PaO_2:$F10_2$ (n=40) Inclusion: • PaO_2:$F10_2 \leq 300$ • bilateral lung infiltrates on chest xray • Venturi mask for 15 minutes provided no significant improvement in function • absence of other organ failure Exclusion: • endotracheal tube or tracheostomy prior to PICU • facial deformities	Participants had CPAP delivered via either: • facial mask chosen to provide optimal fit to the contour of the child's face, with nasal masks used as facial masks In the smallest children. Colloid dressing was applied to facial pressure points to reduce risk of pressure injury. (n=20) • helmet: an infant helmet made of transparent latex-free polyvinyl chloride secured to a soft collar that adheres to the child's neck (n=20)	Primary outcome was improvement in gas exchange Secondary outcome included PUs assessed on a four point scale of severity	• There was significantly more stage 1 PUs associated with the facial mask compared with the helmet (75% versus 0%, p=0.002) • Participants with facial mask CPAP delivery had significantly less hours wearing the delivery device compared with the helmet group (6.4±1.8 versus 10.8±2.0 hours, p=0.001) • CPAP delivered via both the helmet and the mask led to significant improvements in gas exchange, with no difference between the groups. • Other adverse events (CPAP associated outcomes and eye irritation, gastric distension) were equivalent between the groups • Intolerance of the device leading to sedation was higher in the facial mask group (70% versus 5%, p=0.001) • **Study conclusions: The report highlights the potential of stage 1 PUs associated**	• Small sample size • Of 97 potential participants, only 20 met the selection criteria to use the helmet • Non-blinded, non-randomised study	**Level of evidence: 3 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• wide range of respiratory system exclusion criteria upper airway obstruction Characteristics: • Age range 3 to 11 months • Primarily requiring CPAP due to community-acquired pneumonia or post-operatively • No significant differences between groups in oxygen/respiratory variables, weight, age, body temperature			**with oxygen delivery medical devices in children, despite the use of hydrocolloid preventative dressing.**		
Risk assessment							
(Anthony, Willock et al., 2010)	Cross sectional study **comparing the predictive validity of Glamorgan scale to the Braden Q and Galvin scales**	Convenience sample of participants were recruited from 11 pediatric hospitals (n=71, primarily with PU) and from a 12th pediatric hospital (n=165, primarily without PU). Inclusion: unclear Exclusion: unclear Characteristics: • Age, gender, diagnoses and co-morbidities were not reported • PU status: ○ No PU n=175 ○ Stage 1 n=15 ○ Stage 2 n=28 ○ Stage 3 n=13 ○ Stage 4 n=5 • PU location: ○ Heel n=17 ○ Ear n=11 ○ Sacrum n=11 ○ Occipital n=10 ○ Ischial tuberosity n=9 ○ Other n=27	Three risk assessment scales were administered on all participants by a special interest group of nurses. • Glamorgan scale: scale with 10 sub-scores developed through literature review, statistical analysis of patient data and expert opinion • Braden Q: modification of the adult Braden scale and validated for use in ages 21 days to 8 years • Garvin scale: scale with four risk factors (mobility, sensory perception, nutrition and moisture) with four risk categories	Chi-square, Mann-Whitney and logistic regression to determine statistically significant risk factors. Receiver operating characteristic (ROC) curves were used to produce area under curve (AUC). It is unclear how many times the risk scales were applied or when they were applied in the sequence of care and PU development.	• Glamorgan sub-score The following sub-scores were significant when comparing those with and without PU at p<0.001: anaemia, equipment pressing, mobility, poor peripheral perfusion, pyrexia, serum albumin, surgery in past 4 weeks The following sub scales were not significant: weight < 10th centile, (p=0.105) continence (p=0.628) , nutrition (p=0.960) The following sub-scales were significant by logistic regression: equipment pressing, continence, mobility, pyrexia and serum albumin • Braden Q scale The following sub-scores were significant when comparing those with and without PU: activity (p<0.001), mobility (p<0.001), sensory perception (p<0.001), tissue perfusion (p=0.009), friction-shear (p=0.014) The following sub scales were not significant: moisture (p=0.112). nutrition (p=0.890) The following sub-scales were significant by	• Cross-sectional design, not prospective • Characteristics of the population (particularly age) not defined • Unclear whether the risk assessments were performed blind to each other and PU status • Inter-rater/intra-rater reliability is unclear • No sample size calculation for establishing clinically relevant difference	**Level of evidence: 3 (diagnostic) Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					logistic regression: mobility, moisture, tissue perfusion • Garvin scale The following sub-scores were significant when comparing those with and without PU at p<0.001: mobility, sensory perception The following sub scales were not significant: moisture (p=0.139), nutrition (p=0.652) The following sub-scales were significant by logistic regression: mobility, moisture • Area under curve Glamorgan total scale AUC 0.912, standard error 0.017, p<0.001, lower bound 0.878, upper bound 0.946 Garvin total scale AUC 0.641, standard error 0.036, p=0.001, lower bound 0.570, upper bound 0.712 Braden Q total scale AUC 0.694, standard error 0.034, p<0.001, lower bound 0.627, upper bound 0.762		
(Willock, Anthony et al., 2008)	Study reporting the **interrater reliability of the Glamorgan risk assessment scale**	Raters: Self-selected sample of 15 nurses working in 7 pediatric wards in a tertiary hospital in Wales (n=35 invited, n=15 participated) Sample: children in 7 pediatric wards in a tertiary hospital in Wales (n=15) Inclusion: self-selected Exclusion: not reported Characteristics: • Experience, age, training of nurses is not reported • All nurses had used the Glamorgan scale previously in clinical practice • Nurses worked in a range of specialties including medical (n=4), high dependency (n=4), NICU (n=3), oncology (n=2), PICU (n=1) and surgical (n=1).	Each nurse assessed one child (selection not clear) using the scale. A second assessment was conducted on the same child by a researcher blinded to the first assessment within 10 minutes of the first assessment.	Paired score analysis with SPSS analysis	• There was 100% agreement on 9 of 10 Glamorgan sub-scales: mobility, equipment, anaemia, pyrexia, poor perfusion, low albumin, low weight, inappropriate incontinence (κ=1.0 for all) • There was good agreement for the 10th subscale: nutrition (κ=0.63, p<0.001) • On most of the sub-scales (excepting equipment and mobility), a dichotomous score is allocated (1 if present, 0 if absent) • Agreement for overall Glamorgan score was not reported • **Conclusions: There was good agreement between nurses on the scale in a population of children with low PU risk**	• Small sample of 15 nurses • Self-selection may favour those who are more confident using the tool • Selection of children was those who primarily had low risk of PU • Characteristics of nurses and children is not reported • Confidence intervals not reported • No sample size calculation for establishing clinically relevant difference	**Level of evidence: 3 (diagnostic) Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(Kottner, Kenzler et al., 2012)	Study reporting the **interrater reliability of the Glamorgan risk assessment scale**	Raters: Participants were all nurses in one unit of a university hospital in Germany (n=27) Sample: convenience sample of children in the ward (n=30) Inclusion: all nurses in the ward Characteristics of nurses: • Median work experience 14 years • Median time in this unit 3.5 years Characteristics of children: • Median age 5.5 years • Median weight 19.9 kgs • Median VAS score 15.3 (IQR 11.3 to 23.7) • Median Glamorgan scale score 4.8 (IQR 0.3 to 11.0)	Three nurses assessed one child simultaneously but without consultation with each other using: • Glamorgan scale • 100mm VAS for pressure ulcer risk labelled one end ' no risk' and other end 'maximum risk' Each nurse rated approximately 3 children resulting in 90 observations	Interrater agreement calculated by per cent. Interrater reliability calculated using kappa and intraclass coefficient (ICC) Construct validity by scatter plots and Pearsons'r	• Agreement for Glamorgan scale was 48% and interrater reliability was ICC=0.34 (95% CI 0.12 to 0.57) • Subscales interrater agreement: Mobility 82%, κ=0.15 (95% CI –0.19 to 0.48) Equipment 91% κ=0.47 (95% CI 0.10 to 0.82) Anaemia 100% Pyrexia 98% κ=0.31 (95% CI –0.78 to 1.00) Poor peripheral perfusion 93% κ=0.49 (95% CI 0.05 to 0.95) Nutrition 94% κ=0.58 (95% CI 0.13 to 1.00) Serum albumin 99% κ=–0.01 (95% CI –1.00 to 1.00) Weight < 10^{th} percentile 97% κ=0.63 (95% CI 0.04 to 1.00) Incontinence 94% κ=0.31 (95% CI –0.32 to 0.95 • Interrater reliability for VAS was ICC=0.25 (95% CI 0.03 to 0.49) • Correlation between VAS and Glamorgan scale was r=0.68 (r^2=0.46) • **Conclusion: Interrater agreement for Glamorgan scale (strong agreement between nurses) was high but interrater reliability was low (poor differentiation between children), likely due to the low overall PU risk observed in the sample.**	• Most children had a low risk of PU	**Level of evidence: 2 Quality: high**
(Kottner, Schroer et al., 2012)	Study reporting the **interrater reliability of the Glamorgan risk assessment scale**	Raters: Participants were nurses in one PICU unit of a university hospital in Germany (n=20) Sample: convenience sample of children in the ward (n=20) Inclusion: 24 of 30 nurses Characteristics of nurses: • Mean work experience 15.5 years • Mean time in this PICU 8.5 years Characteristics of children:	Three nurses assessed one child simultaneously but without consultation with each other using: • Glamorgan scale • 100mm VAS for pressure ulcer risk labelled one end ' no risk' and other end 'maximum risk' Each nurse rated approximately 3 children resulting in 60 observations	Interrater agreement calculated by per cent. Interrater reliability calculated using kappa and intraclass coefficient (ICC) Construct validity by scatter plots and Pearsons'r	• Interrater reliability for Glamorgan scale was ICC=0.43 (95% CI 0.16 to 0.69) • Subscales interrater agreement: Mobility 63%, κ=0.21 (95% CI –0.21 to 0.35) Equipment 97%, κ=-0.03 (95% CI -0.28 to 0.22) Anaemia 92% , κ=0.35 (95% CI -0.09 to 0.59) Pyrexia 95% κ=0.52 (95% CI –0.26 to 0.77) Poor peripheral perfusion 92% κ=0.35 (95% CI 0.09 to 0.59) Nutrition 88% κ=0.53 (95% CI 0.27 to 0,78) Serum albumin 98% κ=0.48 (95% CI 0.23 to 0.73) Weight < 10^{th} percentile 92% κ=0.56 (95% CI 0.30 to 0.80)	• Most children had a high risk of PU	**Level of evidence: 2 Quality: high**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Median age 1 years • Median weight 19.9 kgs • Median VAS score 10 (IQR 6.2 to 14.4) • Median Glamorgan scale score 27.6			Incontinence 95% κ=0.69 (95% CI 0.43 to 0.94) • Interrater reliability for VAS was ICC=0.34 (95% CI 0.01 to 0.67) • Correlation between VAS and Glamorgan scale was r=0.78 (r^2=0.61) • **Conclusion: Interrater agreement for Glamorgan scale (strong agreement between nurses) was high but interrater reliability was low (poor differentiation between children), likely due to the high overall PU risk observed in the sample.**		
(Fujii, Sugama et al., 2010)	Prospective cohort study	Survey of seven NICUs in Japan in 2006 (n=81) Inclusion: • Neonate in an incubator • No pre-existing skin breakdown • Consent given Characteristics: 51.9% sample female low birth weight most common reason for admission (74.1%) Mean age 32.5 weeks gestation (range 24 to 41) mean birth weight 1745 g (range 478 to 4122)	• Skin was assessed daily by nurses and researchers	• Skin texture was assessed using Dubowitz neonatal maturity assessment scale	• Cumulative incidence of PU was 16% • 62% PUs occurred in patients aged <33 weeks gestation • Stage I PU 21.4%; Stage II PU 78.6% **Body sites:** • 86% of PUs were associated with CPAP or DPAP • 50% PU nose • 28% PU labrum and dorsal foot • 7.1% PUs occipital **Risk factors associated with PU** (p<0.05): • birth weight • skin texture • incubator temperature • incubator humidity • support surface • limited position changes • endotracheal intubation **Multivariate analysis risk factors:** • skin texture immaturity odds ratio (OR) 7.6 (95% CI 1.58 to 36.71, p=0.012) • endotracheal intubation OR 4.0 (95% CI 1.04 to 15.42, p=0.047)	• High level of non-consent (61.8%) led to high exclusion • Most neonates were not extremely underweight (<500g) • No congenital heart disease or exacerbated circulation • Potential Hawthorne effect as researcher visited hospitals to directly assess and observe • Does not report PU classification scale used	**Level of evidence: 2** **Quality: moderate**
(Schindler, Mikhailov et al., 2011)	Retrospective – sectional database review	Survey of nine PICUs in trauma centers in USA All patients in the center between March 2006 and December 2007 were included. (n=5346)	•	•	• Aggregate incidence 10.2% (rage 0.8% to 17.5% by PICU site) • Aggregate incidence per 10000 patient days was 24.35 (range 2.47 to 57.10 by PICU site) **Stages** Stage I PUs 63% Stage II PUs 32% Stage III PUs 4% Stage IV PUs 1% **Multivariate analysis risk factors:**	• Did not reach sample size based on power calculation (15 sites) • Site may have influenced risk factor analysis as there was differing use of support surfaces between facilities • Inter-rater reliability not	**Level of evidence: 4** **Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					• stay ≥ 4 days OR 5.68 (95% CI 4.481 to 7.21, p<0.001) • bilevel or CPAP OR 2.004 (95% CI 1.509 to 2.661, p<0.001) • mechanical ventilation OR 1.334 (95% CI 1.031 to 1.726, p=0.03) • high frequency oscillatory ventilation OR 2.057 (95% CI 1.208 to 5.134, p=0.01) • extracorporeal membrane oxygenation OR 2.490 (95% CI 1.208 to 5.134, p=0.01) • Pediatric Index of Mortality 2 score OR 1.132 (95% CI 1.055 to 1.215, p<0.001) Body sites: • 17% buttocks • 10% neck • 6% perineum • 6% occipital • 6% sacrum • 5% shoulders • 4% forehead • 4% back	established • Does not report PU classification scale used	
(McCord, McElvain et al., 2004)	Prospective ase control study **investigating PU risk factors in children**	Participants were recruited over a 10 ponth period from a 30-bed PICU in US (n = 118) Inclusion: • Child included in PU group when a PU was identified Characteristics: • 48% sample male • aged from less than 1 year to greater than 14 years	• Risk factor assessment	• Risk assessment tool was based on Braden scale and included 45 indicators (content validity and interrater reliability is reported). • Braden scale • Assessment and staging using NPUAP system.	• Skin breakdown related to medical devices occurred. • 36% PU occurred in aged < 1 years, 30% in 1-3 yrs, 9% in aged 3-8 years, 18% in 8-14 years, 7% in > 14 years • Significant risk factors: (0.002 < p < 0.05 was considered significant): o Edema (p =0.0016) o Length of stay , 96 hrs (p=0.0011) o Increasing positive end expiratory pressure (p=0.002) o Nut turning/turned by low air loss bed (p=0.0001) o Weight loss (p<0.0001)	• Does not indicate how controls were selected and assessed • Unclear if ongoing assessments were conducted • Demographics and similarities of groups not reported • Participants were not weight-matched • No confidence intervals are reported	**Level of evidence: 4 Quality: low**

PREVALENCE AND RISK FACTOR DATA

Reference	Subject	Design/ method	Incidence & Follow up Risk factors	Prevalence Risk factors	Stage/category	Clinical site	Database or Clinical	Limitations and comments
(Schluer, Cignacco et al., 2009)	• Convenience sample • n=155 including n=51 medical unit, n=33 surgical unit, n=30 rehab unit, n=41 neonates • Ages: 24 hrs to 17 yrs • Inclusion: hospitalized at least 24 hours, consent • Exclusion: psychiatric unit	Point prevalence study		• Overall PU prevalence 27.7% (43/155) • 78% HAPU • Body sites: 26% heel or ankle 10% ear 2% occipital 43% "other" including medical device related	Assessment was systematically conducted by rater pairs using Bours et al (1999) PU prevalence registration form and Braden risk assessment Stage I PUs 84% Stage II to IV PUs 4.5%	4 acute paediatric hospitals including surgical, medical, rehab and neonates	CL	• Did not use Braden Q as not validated in aged < 8 years and no German version • Included both pre-existing and HAPU
(Schluer, Halfens et al., 2012)	• n= 412 • Inclusion: hospitalised children (ages 24 hours to 18 years) in 14 paediatric in 24 hour period in June 2009. • Inclusion: hospitalised for at least 1 day • Exclusion: psychiatric wards, no consent or refusal	Cross-sectional		• Overall PU prevalence 35% • Most patients with PUs (80%) had category 1 ulcers. • Prevalence rate highest in the paediatric intensive care unit (16/36, 44%) and neonatology (47/109, 43%). • The prevalence of PUs for patients with an external device (tubes, IVs, continuous positive airways pressure, splints, and other installations) was 40%	EPUAP classification	14 paediatric hospitals including paediatric intensive care units (PICU), neonatal intensive care units (NICU), surgical, medical and rehabilitation (Switzerland)	CL	Category 1 PUs may be over- or underdiagnosed in this study remains unclear, although the interrater reliability suggest the scores are reliable.
(Rana, Michalsky et al., 2009)	n=1314 record reviews of children admitted to one paediatric hospital in USA admitted to trauma centre from Jan 2004 to July 2007. Inclusion: • Admission for a trauma injury • Documented weight and height Obese (n=294) • BMI ≥95th percentile for age • Mean BMI 29.7	Retrospective record analysis cohort study	• PU occurred more often during the admission for obese population compared with non-obese population, (1% versus 0.2%, p=0.04) • Length of hospital stay did not differ between groups (2.6±5.0 days for non-obese versus 2.9±10 days for obese, p=0.50) and mortality was equivalent between groups.	N/A	N/A	Paediatric trauma hospital	DB	• Database review for which 73% of entries did not have a documented weight so were not included • Single site study • Does not state how PU was classified • Did not appear to address PU present on admission • Comorbidity on admission was not reported (e.g. other risk factors such as SCI were not controlled for)

	(significantly higher than non-obese group, p<0.001) • No differences between groups in reason for trauma admission • Both groups primarily female (approx. 70%) Non-obese (n=1020) • BMI <95th percentile for age • Mean BMI 18.8							

References

Anthony, D., J. Willock and M. Baharestani. (2010). "A comparison of Braden Q, Garvin and Glamorgan risk assessment scales in paediatrics." Journal Of Tissue Viability **19**(3):98-105.

Chidini, G., E. Calderini and P. Pelosi. (2010). "Treatment of acute hypoxemic respiratory failure with continuous positive airway pressure delivered by a new pediatric helmet in comparison with a standard full face mask: A prospective pilot study." Pediatric Critical Care Medicine **11**(4):502-8.

De Raeve, P., R. Vercruysse, T. Waterschoot, et al. (2001). "Two mattresses for neonates compared for cost and quality of nursing care." Critical Care Nursing in Europe **1**(1):5-10.

Fujii, K., J. Sugama, M. Okuwa, et al. (2010). "Incidence and risk factors of pressure ulcers in seven neonatal intensive care units in Japan: a multisite prospective cohort study." International Wound Journal **7**(5):323-8.

García-Molina, P., E. Balaguer-López, J.E. Torra I Bou, et al. (2012). "A prospective, longitudinal study to assess use of continuous and reactive low-pressure mattresses to reduce pressure ulcer incidence in a pediatric intensive care unit." Ostomy Wound Management **58**(7):32-9.

Jaryszak, E.M., R.K. Shah, J. Amling, et al. (2011). "Pediatric tracheotomy wound complications: Incidence and significance." Archives of Otolaryngology - Head and Neck Surgery **137**(4):363-6.

Kottner, J., M. Kenzler and D. Wilborn. (2012). "Interrater agreement, reliability and validity of the Glamorgan Paediatric Pressure Ulcer Risk Assessment Scale." J Clin Nurs:pre-pub.

Kottner, J., F. Schroer and T. A. (2012). "[Evaluation of the Glamorgan Scale in a paediatric intensive care unit: agreement and reliability]." Pflege Zeitschrift **25**(6):459-67.

Limpaphayom, N., D.L. Skaggs, G. McComb, et al. (2009). "Complications of halo use in children." Spine **34**(8):779-84.

McCord, S., V. McElvain, R. Sachdeva, et al. (2004). "Risk factors associated with pressure ulcers i na pediatric intensive care unit." Journal of Wound Ostomy and Continence Nursing **July**:179-83.

McLane, K., T.A. Krouskop, S. McCord, et al. (2002). "Comparison of interface pressures in the pediatric population among various support surfaces." Journal of Wound, Ostomy and Continence Nursing **28**:242-51.

Rana, A.R., M.P. Michalsky, S. Teich, et al. (2009). "Childhood obesity: a risk factor for injuries observed at a level-1 trauma center." Journal Of Pediatric Surgery **44**(8):1601-5.

Schindler, C.A., T.A. Mikhailov, E.M. Kuhn, et al. (2011). "Protecting fragile skin: nursing interventions to decrease development of pressure ulcers in pediatric intensive care. ." American Journal of Critical Care **20**(1):26-35.

Schluer, A.B., E. Cignacco, M. Muller, et al. (2009). "The prevalence of pressure ulcers in four paediatric institutions." Journal of clinical nursing **18**(23):3244.

Schluer, A.B., R.J. Halfens and J.G.A. Schols. (2012). " Pediatric pressure ulcer prevalence: A multicenter, cross-sectional, point prevalence study in Switzerland." Ostomy Wound Management **58**(7):18-31.

Solis, I., T.A. Krouskop, N. Trainer, et al. (1988). "Supine interface pressure in children." Arch Phys Med Rehabil **69**(7):524-6.

Turnage-Carrier, C., K.M. McLane and M.A. Gregurich. (2008). "Interface pressure comparison of healthy premature infants with various neonatal bed surfaces." Advances in Neonatal Care **8**(3):176-84.

Willock, J., D. Anthony and J. Richardson. (2008). "Inter-rater reliability of Glamorgan Paediatric Pressure Ulcer Risk Assessment Scale." Paediatric Nursing **20**(7):14-9.

INDIVIDUALS WITH SPINAL CORD INJURY

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Patient education							
(Gélis, Daures et al., 2011)	Psychometric study on a **self-administered patient checklist on knowledge and prevention**	Participants for the reliability study were recruited from 6 centers in France (n=138) Characteristics: mean age 45.9±14.9 years 75% sample male 60% had complete injury (ASIA-A) 66% had no Pus, 25% had one PU of Pus present, 65% were grade III=IV	revised-Skin Management Needs Assessment Checklist (SMnac) self-administered, 12 question Likert score survey covering skin checks, preventing PU and preventing wounds.	• Psychometric properties	• Previously, English language psychometric properties have been tested: o Internal consistency (Cronbach's alpha: 0.85); test-retest reliability (ICC=0.90) In this study, French version was tested: **Feasibility and acceptability** (n=12) • Patients found the survey and its easy to use **Reliability** (n=138) • Intraclass coefficient (ICC) = 0.899 (95% CI 0.862 to 0.927)	• Participants were all recent SCI patients, or had been recently hospitalized so may have had recent education • Self-administered tool, unclear on conditions for administration	**Indirect evidence Quality of evidence: low**
(Brace and Schubart, 2010)	Case series reporting **effectiveness of an e-learning program for people with PU and SCI**	Participants recruited from two sites, a trauma hospital and an outpatient rehabilitation Center in the USA. (n=27 met inclusion, n=16 completed study) Inclusion: • SCI at any level • aged ≥18 years and of any ethnic group • with our without current PU or PU history • medically stable • transferred to an acute rehabilitation facility Exclusion: • non-English speaking • medically unstable Characteristics: • Mean age 49 yrs, minimum 23 yrs • Time since PU injury ranged from 3.5 weeks to 27 years • 63% of sample were male	E-learning program on PU prevention and management in adults (see also Schubart, 2012)	• Pre-and post-test assessment using 20 multiple choice questions addressing the primary focus of the E-learning program. The questionnaire was validated in a population of 12 nurses.	• Median pre-test score was 65% (range 25% to 100%). Median post test score was 92.5% (range 75% to 100%) • 15/16 participants achieved improved scores on post-test compared to pre-test. • PU staging questions were more frequently answered incorrectly. **Study conclusions: an E-learning program is associated with increased knowledge regarding PU staging, prevention and support services in patients with SCI.**	• Indirect evidence, PU occurrence is not an outcome measure • Sample size small • No statistical analysis so unclear if the findings are significant • Broad ethnic and age groups selected but no analysis to indicate if the program was equally effective for all demographics. • Sample had a high education level at commencement with almost 50% having attended tertiary or greater education. • Nb: reported in Consumers section of the guideline	**Indirect evidence Quality of evidence: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• 42% had completed high school, 47% had education to a higher level • 52.6% Caucasian, 42.1% African American • 57.9% had a current PU • 47.4% had experienced a previous PU					
(Schubart, Hilgart et al., 2008)	Qualitative study using needs assessment methodology **to explore education needs on PU for SCI patients**	Purposive sampling to recruit participants from a US rehabilitation (n=16 SCI individuals) Inclusion: • SCI • Would provide an 'information rich cases' Characteristics: • Aged 20 to 59 years with wide spread • Primarily Caucasian, 2 African Americans • Most had been injured more than 10 years • 50% had experienced several PU, 37.5% had never experienced a PU	• An initial review of an evidence-based guideline was used to determine recommended PU prevention education needs. • Participants completed an interview and a survey regarding what they considered their education needs were and their feelings about PU prevention.	• Thematic analysis using NVivo software.	Four themes identified: • **Perception of risk**: awareness of PU risk was varied. People who considered themselves at risk had usually experienced a PU in the past. Those who had not experienced a PU considered themselves at low risk and practiced less preventative actions. • **PU education:** previous education was generally limited to initial post-injury care period. Education had been fear-oriented for older patients. Opportunity for further education was generally limited to that time when they had a PU requiring care. Participants preferred face-to-face education from another SCI patient or a health professional and less frequently, the Internet. Some participants believed that education is delivered too early, when they were in shock or denial, and this was ineffective. • Environmental considerations: the home environment and available equipment influenced ability to implement PU prevention. Family members also need education. • Access to appropriate care: participants had limited access to service after acute care and had frustration dealing with health systems and insurance. From the data education needs were prioritised as: • SCI learners and their caregivers need to be aware that SCI poses lifelong risk for developing PU that may be serious and/or life threatening.	• Unclear how the guideline were used or how interviews were synthesised into themes and recommendations. Recommendations seemed contrary to some information in the interviews (e.g. fear) • Small sample, although saturation was reached. • May not be generalizable to other countries. • Nb: reported in Consumers section of the guideline	**Indirect evidence Quality of evidence: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					• SCI learners need to take charge of their own skin care regimen and to feel empowered to partner with their health care providers. • SCI learners need PU prevention strategies that fit with their level of functioning and activity and can be consistently maintained and updated as risk changes. • SCI learners need strategies for coordinating social supports for both family and paid caregiving situations.		
(Thietje, Giese et al., 2011)	Prospective cohort study investigating **acquisition of knowledge of SCI patients about SCI-complications**	Consecutive admissions to a German hospital between 2005 and 2008 of patients with a traumatic or non-traumatic SCI (n=214 completed knowledge tests) Inclusion: • aged ≥18 years • patient's first admission to hospital • minimum duration of admission of 3 months Exclusion: • incomplete database record • severe cognitive impairment • cranio-cerebral injury or malignancies with short life expectancy • Characteristics: • All patients discharged 3 to 6 months following admission • Approximately 4% participants were 18 to 20years, 24% were aged 20 to 34 years, 28% were aged 35 to 49 years, 27% were aged 50 to 64 and 17% aged over 65 years.	Development of knowledge about PUs and bladder management in SCI patients throughout a first hospital admission of 3 to 6 months duration for SCI	**Functional ability** • Ability to perform everyday tasks and overall impact of disability measured using SCIM-II (validated tool) consisting of scales for self-care, respiration and sphincter management and mobility. **Knowledge of SCI-related topics** • Knowledge tested using Knowledge Boberg Score (un-validated tool) including PUs and bladder management. • Knowledge was classified as poor, average or good based on KBS score. Outcome measures at admission, 1 and 3 months post-admission, and after discharge at 6, 18, and 30 months	• Participants had an initial poor level of knowledge (KBS) and functional ability (SCIM-II score) in every day care that showed significant (p<0.001) improvement by discharge. **Knowledge** • At discharge 22.4% participants had poor knowledge, 30.4% had average knowledge and 47.2% had good knowledge of SCI-related topics. • Mean total KBS increased from 5.44 to 11.24 at discharge (p<0.001). However, after 30 months mean score decreased to 10.8. • Patients aged ≥65 years achieved lower knowledge scores by discharge compared with younger patients (p<0.001). **Functional ability** • Mean total SCIM-II score increased from 26.84 on admission to 58.32 at discharge (p<0.001) and continued to improve, peaking at 66.65 after 18 months. **Information sources** • Participants identified rehabilitation physician as an important source of information most often (77.6% identified at discharge, 68.5% identified at 30 months). • At discharge other important information sources were physiotherapist (66.5%), in-hospital SCI course (48.4%), nurse (47%), general	• Knowledge score has not validated • Education levels were not reported • Content of information courses is not reported therefore replicability is limited • Personal factors may be involved in the relative importance of different health professionals as an information source • Nb: reported in Consumers section of the guideline	**Indirect evidence Quality of evidence: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					practitioner or other physician (44.6%), other patients (28.9%) family (23.8%). • At 30 months, general practitioner or other physician (55.3%) and the internet (39%) had higher ratings than prior to discharge. • Support groups and friends were not important sources for information either before or after discharge. **Study conclusions: While in hospital, SCI patients improve their knowledge of PU prevention and increase their ability to self-care. Knowledge declines somewhat after discharge. Health professionals are a primary source of information before and after discharge. An inpatient SCI course is considered important by just under half of patients with SCI. Support groups are not considered important for information, however other individual patients are valued during an admission. The internet is used as a primary source of information by almost 40% of participants after discharge.**		
(Schubart, 2012)	Case series **reporting on a patient education e-learning package**	Participants recruited from an outpatient rehabilitation Center in the USA. (n=15, n=14 completed) Inclusion: • SCI at any level • aged ≥18 years • ability to access the Internet Exclusion: • non-English speaking • medically unstable Characteristics: • Median age 37 years • 66% of sample were male • Median 72 months since injury (range 6 to 360) • Primarily Caucasian • About 50% had high school education and 50% had higher	• E-learning program on PU prevention and management in adults (also pilot - tested in earlier study Brace 2010) • Program allowed participants to complete the learning package in multiple sittings over a two week timeframe.	• Assessment of the e-learning program was made using three validated tools containing Likert scales. ○ Internet Evaluation and Utility Questionnaire includes ease of use, convenience, engagement, enjoyment, layout, privacy, satisfaction and acceptability. ○ Internet Impact and Effectiveness Questionnaire includes usefulness, comprehension, credibility, likelihood of returning, mode of delivery and helpfulness. ○ Internet Adherence	• The program scored very favourably on all items related to potential access barriers and favourably for items related to utility, impact and effectiveness. • The median score for pre-program knowledge and skin care management practice was 96 (possible score: 0 to 120; range 70–100). Post-program use median score was 107 (range 97–114). • The greatest improvement was in the responses to knowledge and practice questions about skin checks and preventing skin problems ($p<0.005$). **Study conclusions: People with an SCI who have at least high school level education rated an e-learning package highly with respect to utility, impact and effectiveness and perceived that their knowledge had increased after using it; however, there was no objective assessment conducted that may support this perception.**	• Small sample size from limited ethnic background • Questions assess perceived knowledge and their perceived ability to perform preventive actions. No real insight in the objective knowledge or practice of the participants • Nb: reported in Consumers section of the guideline	**Indirect evidence Quality of evidence: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		level of education • 20% had a current PU and 27% had ever had a PU		Questionnaire includes barriers to program use. • Assessment of effectiveness of program was made using Needs Assessment Checklist, a non-validated structured tool to assess self-perceived knowledge and self-perceived care ability • Assessments was made via phone interview			
(Dunn, Carlson et al., 2009)	Qualitative cross-case secondary analysis	Case profiles from a previous qualitative study conducted in a US rehabilitation center were analyzed (n=19) Inclusion: • Included in the parent study (n=20) • Community dwelling adults with SCI • Personal profiles selected with adequate information about one or more responses to a low-grade ulcer Exclusion: • Did not develop a PU (n=1) Characteristics: • There were 46 PU events reported by 19 participants. • 19 participants had SCI and 1 had transverse myelitis • Described as "ethnically diverse" • No demographic characteristics e.g. age, gender, co-morbidities, duration of disease, duration of PU was reported	• Re-analysis of previous original research to establish differences and similarities in experiences of people with PU • Initial data collected through participant observation and interviews.	• Researchers analyzed previous data and identified responses to stage I or II PUs • Responses were categorized according to types and confirmed by 2 researchers • One randomly selected PU event for each participant was analyzed in-depth to enhance vigor	• Eight themes of response to PU stages I to II identified within the 46 events o Lacking adequate knowledge: overlooking a PU or underestimating danger o Procrastinating: delaying action on the basis of emotion, negating consciously o Experiencing cognitive dysfunction o Diverting attention: attending to comorbidities, desiring activity, attending to external exigencies o Avoiding social discomfort o Being thwarted from receiving adequate medical help o Relying on self or caregiver help o Adhering to medical recommendations **Study conclusions: rehabilitation professionals need to provide education about early PU detection and recognition, potential severity of PU and the importance of early treatment. Patients with PU need to support to effectively self-advocate for proper medical care and to balance preventative measures with lifestyle concerns. Wound care clinics and consumer support groups can serve as valuable ongoing community-based resources.**	• Ethnically diverse group whose demographics may have skewed results (but demographics not reported) • Based on self-report and recall of events, memory lapses or misrepresentation of history may limit findings • Methodology could have allowed researchers to categorize differently • No opportunity to pursue follow-up for more complete responses	
(Rintala, Garber et al., 2008)	Randomized controlled trial **investigating an education**	Participants were recruited from a veterans affairs medical center in US (n=41)	• All participants received standard care pre and post surgery. • Participants were	• primary outcome was time to pressure ulcer recurrence • Self assessed health status	• Significantly fewer participants in group 1 had a recurrence of PU by 24 months (33% vs 60% vs 90%, p=0.007) • For group 1 odds ratio (OR) of a PU by	• Small sample size • Inappropriate randomization method and allocation	**Level of evidence: 2 Quality of**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	program post-surgery to reduce PU recurrence rates	Inclusion/exclusion not stated Characteristics • Mean age 50 to 54 years • Mean time since SCI 15 to 20 years • Significant difference between groups in type of flap surgery (p=0.02) • group 3 had significantly shorter time since last surgical closure (1.05 yrs vs 6.30 yrs, p=0.03)	randomized to receive: • enhanced education and monthly structured follow up intervention for 2 years after discharge (group 1, n= 20,n=18 analyzed) • monthly contacts for up to 2 years after discharge to assess skin status, with no education during or after hospitalization (group 2, n=11, n=10 analyzed) • minimal contact via mail every 3 months for up to 2 years after discharge only to assess skin status, but received, with no education during or after hospitalization (group 3, n=10, n=10 analyzed) • Standard education consisted of 1 to 2 hours of 1:1 education on prevention incl nutrition, smoking, skin inspection and care; a manual that included sections on PU prevention; training for families by phone/mail; therapist-supervised progressive sitting program and education on transfers and seating. • Enhanced education included 1 to 4 additional hours 1:1 over four sessions on etiology, prevention and pressure relieving devices; one session for families, additional education monthly for 25 minutes via phone.	• Skin status was assessed through phone interview • Follow up was 2 years (or until recurrence)	24 months was 0.228 (95% CI 0.080 to 0.647, p=0.003) • No significant differences between groups 2 and 3 in recurrence	concealment • Study did not reach sample size required for statistical power • Groups 1 and 2 participated in another study concurrently • Nonequivalent groups at baseline • Self-assessed outcomes • Two participants had MS, both assigned to group 1 • Nb: reported in Surgery section of the guideline	**evidence: low**
Positioning and support surfaces							
(Gil-Agudo, De la Peña-	Biomechanical study	Unclear from where participants were recruited. Appears to be a	• All cushions were covered with their own cover with a	• Participants had IF pressure mapping mat	• Cushion 3 (dual compartment cushion with two chambers simulating	• Indirect outcome measure	**Indicate evidence**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
González et al., 2009)	investigating **the impact of different seating cushions on interface pressure**	Spanish trial (n=48) Inclusion: • Aged 18 to 65 years • Complete cervical or thoracic SCI • No PU in preceding month • No surgical resection of pelvis or femur • Passive hip flexion range of at least 90º Characteristics: • 79% sample male • Mean age 42±17 years • Mean weight 67.6±18.6 kgs • Mean BMI 23.3±6.0 • Mean Braden scale 13.0±2.4	protective non-skid, flameproof inner layer and a breathable, elastic outer layer • All participants acted as own controls and were seated on the following cushions for 15 minutes in wheelchairs. Washout period between cushions was not reported. • Seating cushions: • Cushion 1: single compartment low profile cushion • Cushion 2: single compartment high profile cushion • Cushion 3: dual compartment cushion with two chambers simulating ergonomic seating base • Cushion 4: gel and firm foam cushion	placed underneath the buttock region and pressure readings taken at 1.5 minute intervals for 15 minutes • Mean value of readings was used for analysis	ergonomic seating base) had the lowest mean interface pressure distribution (34.9 mmHg versus 38.5 to 41.9mmHg for other three cushions, p<0.05) • Cushion 4 (gel and firm foam) had the highest interface pressure distribution **Study conclusions: a dual compartment cushion with two chambers simulating ergonomic seating base has the most favorable profile when considering interface pressure over 15 minutes sitting time.**	• Participants did not have high risk of PU • No skin assessments	**Quality: moderate**
(Karatas, Tosun et al., 2008)	Observational study **investigating the displacement in center of pressure influencing dynamic sitting stability of people with spinal cord injury (SCI)**	n = 34 (16 with SCI, 18 healthy volunteers)	• Participants were seated on an 45 x 45 cm hard chair of appropriate height, without a backrest • Feet were supported in wooden blocks and the height of the foot support was adjusted to each individual to keep the hip, knee and ankles at 90° degrees • Participants were asked to maintain a static position with their hands resting on their thighs without support as a starting position	• Center of pressure displacements measured using a seat sensor placed underneath buttocks	• Center of pressure displacements in all directions in spinal injured patients were smaller than healthy volunteers (p< 0.05) • Center of pressure displacements for high and low thoracic spinal cord injured participants were not significantly different (p=ns) • Mean center-of-pressure displacement during forward leaning and backward leaning were smaller in participants with PU history (p=0.04 and p=0.03, respectively) • This study suggests that impaired dynamic sitting stability may be associated with PU development due to impaired ability to weight shift in the seated position	• Small number of participants • PU development was not a direct outcome	**Indirect evidence Quality: not appraised**
Prevalence							

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(Ploumis, Kolli et al., 2011)	Retrospective study reporting PU prevalence rates	Patients admitted to rehabilitation from level 1 SCI trauma center (n = 78) and admitted from non-SCI level 1 trauma centers (n = 131) from 2005 to 200 Total n= 209	• Database review	• Pressure ulcers were graded as per NPUAP classification.	**Point prevalence on admission** More patients from non-SCI centres (n = 44, 34%) than SCI centres (n = 24, 12%) had PUs (p=0.001) Percentage of patients with grade III and IV pressure ulcers (6% SCI, 11% non-SCI)	• Relied on database entries to be correct • No interrater reliability • Incomplete discharge notes from the acute care hospital were excluded.	**Level of evidence: N/A Quality: moderate**
(Wilson, Arnold et al., 2012)	Prospective cohort study **reporting all complications in SCI patients**	411 patients in 6 US trauma centers over a 7- year period (n=411) Inclusion: • aged > 16 years • AIS Grade A_D • cervical level injury • documented neurological exam within 24 hours of injury • followup until acute discharge	No intervention	•	• Mean length of stay (LOS) was 34.3±54.6 days • Any complication was related to significant increase in LOS, p<0.001 • 39% experienced at least one complication • PU account for 4.6% of complications (which is equivalent to approx. 2.6% of people, assuming only 1 PU per person)	• Unclear how PU was defined and identified	**Level of evidence: N/A Quality: moderate**
(Mathew, Samuelkamaleshkumar et al., 2013)	Cross sectional study investigating **relationship between practices and PU development in people with SCI**	Participants were a sample from an Indian rehabilitation center (n = 108) Inclusion: • T2 or below lesion Characteristics: • Age range 16 to 65 years • 9% had no education, 20% had college level education • 55% had SCI lesion < 10 years • 68% complete injury (ASIA-A) • 76% were working	participants completed a survey with primarily closed questions regarding their work and leisure history, preventative practice and history of PU	• Demographics and PU history	• 82% of respondents had experienced a PU • 65% of PUs that formed were primarily related to poor pressure relief practice, 15% were related to accidents, 12% were related to lack of education • There was no significant relationship between work history, leisure activity and self-care and PU history • There was no significant correlation between level of injury and PU development • Participants with complete injury were more likely to experience a PU (p=0.001) • Participants working in manual work were more likely to have a PU than those in home based or office occupations (p=0.04)	• Unclear how cause of PU was determined • Self-reported data, unclear how the diagnosis of PU was made (classified as mild-severe) • Unclear how participants were selected for inclusion • Single site in developing nation	**Level of evidence: N/A Quality: low**
(Wu, Ning et al., 2013)	Retrospective cross sectional study **investigating factors related to increase hospital length of stay**	Participants were recruited from 17 hospitals in one city in China over a four year period (n=631) Inclusion: • SCI • aged > 14 years • not deceased during length of stay • complete records Characteristics:	No intervention	• Demographics and medical history	• Any medical complication was related to an increased acute care length of stay • Pressure ulcer was related to an increased length of stay in acute care (incidence 2.7%, p=0.000)	• Unclear how PU was defined and identified	**Level of evidence: N/A Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		85% participants male					
Wound management							
(Rappl, 2011)	Case series **reporting use of platelet-rich plasma gel for healing chronic wounds including PUs**	Participants with SCI were recruited from 11 long term care facilities, 2 outpatient wound clinics, 1 home care agency and 1 wound care equipment and service supplier in USA (n=20, 18 of the 20 wounds were PUs) Inclusion criteria: • patients with SCI • open, cutaneous wound not progressing in healing • wounds that could have a majority clean wound bed just prior to application of product • without clinical signs and symptoms of active infection Exclusion criteria: • malignancy in the wound bed • concurrent chemotherapy • active untreated wound infection Characteristics: • Mean age 49.2yrs (range 27 to 75 yrs) • Mean wound duration 79.4 weeks (range 8 to 416 weeks) • 14/20 wounds were <1cm in depth, 7/20 wounds were, 2cm in depth • Mean wound area 25.6cm^2 • Mean wound volume 53.4cm^3	All wounds were treated with 1.3 x platelet-rich plasma (PRP gel)	Wounds were assessed using different techniques all locations, but were possible the same person performed repeat measures. Outcomes included: • Mean per cent change from baseline of wound area • mean per cent change from baseline of wound volume • Improvement in sinus tracts and undermining • Number of treatments • Number of weeks	• Wounds closed on average of 47.9% in area and 56% in volume in a mean of 4.0 treatments over 3.4 weeks • Undermining closed on 31.4% using 3.5 treatments over 2.6 weeks • Sinus tracts and tunnels closed on an average of 26.1% after 2.3 treatments over 1.5 weeks • In area and volume, 90% of subjects responded positively with an average reduction of 53.8% and 67.3% respectively • Of the four subjects with undermining 75% closed 47% on average • Of the three sinus tracts and tunnels 100% closed 26.1% on average	• Diversity of sites prevented standardized measurement techniques and treatment across the 14 sites of care • Nb: this is reported in the Biological dressings section	**Level of evidence: 5 Quality: moderate**
(Sarasúa, López et al., 2011)	Report of preliminary data on **bone marrow mononuclear cells infusion for healing PUs**	Participants with SCI were recruited in Spain (n=22) Inclusion: • SCI • PU not responded to 4 months topical treatment • PU size 5 to 6 cms • Free from necrotic tissue and local	All PUs were surgically debrided and treated with bone marrow mononuclear cells (BM-MNCs) in the OR Participants were required to lie prone for 3 weeks following surgery	• Healing rate • Mean follow up was 19 months (range 7 to 38 months) • Follow-up sessions were conducted at 1, 3, 6 months and 1 year after cell therapy	• 5/22 participants experienced suture dehiscence and required a second surgical procedure • In 17 participants the PUs fully healed after a mean time of 21 days	• The variation among the 27 extracts in the number of isolated MNCs that was patient dependent • Small sample size • No control group, no randomization, no	**Level of evidence: 5 Quality: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		infection • Medical condition compatible with surgery Characteristics: • Mean age 56.4 yrs (range 29 to 79) • Stage IV PUs: ischial (4), sacral-ischial (3) ischial-trchanter (1), plantar (1). • 13/22 participants had • Had undergone prior surgery on PU and antibiotic treatment	5/22 participants received a second infusion			standard assessment methods • Unclear how participants were selected • Nb: this is reported in the Biological dressings section	
(Scevola, Nicoletti et al., 2010)	Prospective randomized controlled open clinical pilot trial investigating **effectiveness of allogenic platelet gel for healing PUs**	Participants with SCI were recruited from a neuro-rehabilitation ward in Italy (n=13 with 16 PUs) Inclusion: • SCI • grade III and IV PUs • no signs of necrosis or infection nutritional status stable Exclusion: • metabolic, endocrine and collagen pathologies • ischaemic cardiopathy • corticosteroid or immune-suppressive therapy • obesity • malignancies • organ failure Characteristics: • 10 sacral PUs, 6 ischial PUs	• All patients used pressure-relieving devices followed their 2 hour postural change protocol • PUs were randomized to be either: ○ study group receiving allogenic platelet gel applied directly to wound bed then covered with polyurethane sponge and semi-permeable film dressing system ○ control group receiving saline cleanse, packing with iodoform-impregnated gauze, sodium alginate foam or cadexomer iodine powder or vacuum assisted closure with zinc oxide paste or silver sulfadiazine applied to peri-ulcer skin • PUs treated twice weekly for 8 weeks	• Every two weeks the ulcer dimensions, colour and bleeding of the granulation tissue (at the instant of scraping) were checked and photographs were collected • Ulcer volume	• At the end of the study 15 out of 16 ulcers clinically improved • No statistically significant difference was demonstrated in volume reduction between the two groups • A statistically significant difference was demonstrated in the onset time of granulation tissue proliferation – the wounds treated with platelet gel the healing process was triggered earlier • Platelet gel is mostly effective within the first 2 weeks of treatment while a prolonged treatment does not provide any significant advantage • Semi-quantitative data (colour and bleeding of granulation tissue) did not show significant differences between the two groups.	• Small sample size for which baseline demographics were not reported • Does not report randomization or allocation concealment methods • PU was unit of analysis (multiple PUs per participant) • Control treatments included a range of different management strategies that are not considered standard PU care • Nb: this is reported in the Biological dressings section •	**Level of evidence: 2 Quality: low**
(Ho, Powell et al., 2010)	Observational study	Participants (n=86) with SCI recruited from 10 Veterans Affairs medical centres Inclusion: • stage III or IV PU in the pelvic region (sacral, coccygeal, ischial, buttock	All patients received low air loss mattress, regular turning, wound debridement, hydrotherapy, routine wound cleansing and dressing changes.	Change in wound surface area Digital planimetry on day 1, during weeks 2 and 3 and on day 28	• No significant difference in number of patients classified as healing between NPWT group (70%) versus standard care group (67%, p=ns) • In patients who were classified as healing, there was no significant difference in size of wound surface	• Wound depth, which is a consideration in selection of NPWT, was not measured • Prealbumin, which is a better indicator of nutritional status, was not	Level of evidence: 5 Quality: low

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• age ≥ 18 years age Exclusion: • reconstructive flap surgery • unresolved osteomyelitis • palliative care • coronary artery disease, vascular disease, congestive heart failure • malignant disease Characteristics: • Mean age 55 years • Primarily male patients (96 to 100%)	At discretion of physician patients received either: • NPWT (n=33) • standard wound care alone (n=53)	Laboratory data (serum albumin) was collected on day 1 and 28 (± 2 days) PUs were classified as healing (wound surface area decreasing) or non-healing (wound surface area increasing	area decreased amount between the NPWT group (–43% ± 22%) versus standard care group (–50% ± 26%, p=ns) • In the NPWT group there was a significant difference in serum albumin levels between patients classified as healing versus non-healing (2.9 ± 0.4 vs. 3.3 ± 0.5 mg/dL, p<0.05) • In the standard care group there was no significant difference in serum albumin levels between patients classified as healing versus non-healing (3.2 ± 0.3 vs. 3.2 ± 0.3 mg/dL)	measured • Nb: this is reported in the Biophysical Agents section	
Electrical stimulation for treating PUs							
(Houghton, Campbell et al., 2010)	Single-blind RCT **investigating electrical stimulation therapy**	Participants (n=67 screened, n=34included) with SCI living in the community Inclusion: • Stage II to IV PU between 1 and 20cm^2 of at least 3 month duration Exclusion: • Serious comorbidity • Contraindications to electrical stimulation therapy (e.g. pacemaker) • Deep tunneling PU • Three or more abnormal blood values Characteristics: • Mean age 50 years • primarily stage IV PUs • mean wound duration 1.2 to 3 years	Patients were stratified based upon wound severity and duration to four groups prior to randomisation. All participants received standard wound care of nutritional assessment and program, activity program, blood analysis, customised wound care, seating cushion. Participants received either: • Standard wound care (SWC) • Electrical stimulation therapy (EST): - Silver dressing regimen to facilitate therapy - 2 to 30 30 minute education sessions - Individualised electrical stimulation (generally single electrode placed directly over wound with larger dispersive electrode placed 20cm away from wound), twin-peak monophasic pulsed current with 50µs pulse duration at 50 to 150V intensity. 40 minutes	Percentage decrease in wound surface area over 3 months assessed by digital planimetry Proportion of wounds achieving at least 50% reduction in wound surface area Wound appearance assessed using a photographic wound assessment tool Assessed monthly over 3 months then followed for 4 months to assess recurrence.	• Percentage decrease in wound surface area over 3 months significantly greater in EST group (70% ± 25% versus 36% ± 61%, p=0.048) • All stage II PUs healed in both groups • Proportion of wounds achieving at least 50% reduction in wound surface area significantly greater in EST group (80% versus 36%, p=0.02) • photographic wound assessment tool score was improved in more PUs in the EST group (75% versus 44%, p=0.07) • Adverse reactions included red itchy skin beneath dispersive electrode (resolved within 24 hours)., one patient acquired a burn. • Mean treatment time was 3.0±1.5 hrs per day (lower than recommended time) • 8 subjects in each treatment group had recurrent or new PUs develop within 4 months of closure	• Small single-blinded study sample size • EST treatments were applied in combination with silver dressings • High PU recurrence rate • Nb: reported in Biophysical Agents section of the guideline	**Level of evidence: 2 Quality: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
			therapy followed by 20 minutes with no therapy for an 8 hour cycle daily.				
Patient experiences in daily life							
(Jackson, Carlson et al., 2010)	Qualitative study investigating the ways in which PU risk influences the life of a person with SCI	Participants were recruited from the database from a rehabilitation center in US (n=20) Inclusion: • representation based on gender, age, ethnicity and level of injury. • age > 18 years • paraplegic or tetraplegic • previous history of stage III or IV PU Characteristics: • represented 4 ethnicities (Caucasian, Asian-American, Latino, African-American) • From low, medium and high socio-economic status groups • aged 28 to 77 years • 14 males, 6 females	Interview with thematic and narrative analysis	Each participant had an average of 11.5 interviews over approx. 14 months	Seven themes were determined: **Perpetual danger** • The threat of PU is continuous **Change/disruption of routine** • Change in life routine or personal PU prevention habits can often cause a PU **Decay of prevention behaviors** • Over time, PU prevention habits decline either intentionally or unintentionally **Lifestyle risk ratio** • PU risk relates to overall ration of risk:buffers within the individual's life **Individualization** • lifestyle considerations that influence PU risk are individual **Simultaneous presence of awareness and motivation** • Having an awareness, knowledge and motivation to prevent PU is crucial **Lifestyle trade-off** • there is often tension between living a full life and avoiding conditions that might increase risk of PU **Access to needed care, services and supports** • Inability of service or health providers to adequately meet the individual's needs influences PU risk	• Limited sample, unclear if a large range of lifestyles is represented • Ethics approval is not reported • Generalizability is not established	**Indirect evidence**

References

Brace, J.A. and J.R. Schubart. (2010). "A prospective evaluation of a pressure ulcer prevention and management e-learning program for adults with spinal cord injury." Ostomy Wound Management **56**(8):40-50.

Dunn, C.A., M. Carlson, J.M. Jackson, et al. (2009). "Response factors surrounding progression of pressure ulcers in community-residing adults with spinal cord injury." American Journal of Occupational Therapy **63**(3):301-9.

Gélis, A., J.P. Daures, C. Benaim, et al. (2011). "Evaluating self-reported pressure ulcer prevention measures in persons with spinal cord injury using the revised Skin Management Needs Assessment Checklist: reliability study." Spinal Cord: The Official Journal Of The International Medical Society Of Paraplegia **49**(5):653-8.

Gil-Agudo, A., A. De la Peña-González, A. Del Ama-Espinosa, et al. (2009). "Comparative study of pressure distribution at the user-cushion interface with different cushions in a population with spinal cord injury." Clin Biomech **24**(7):558-63.

Ho, C.H., H.L. Powell, J.F. Collins, et al. (2010). "Poor nutrition is a relative contraindication to negative pressure wound therapy for pressure ulcers: preliminary observations in patients with spinal cord injury." Advances in Skin & Wound Care **23**(11):508-16.

Houghton, P.E., K.E. Campbell, C.H. Fraser, et al. (2010). "Electrical stimulation therapy increases rate of healing of pressure ulcers in community-dwelling people with spinal cord injury." Archives of Physical Medicine and Rehabilitation **91**(5):669-78.

Jackson, J., M. Carlson, S. Rubayi, et al. (2010). "Qualitative study of principles pertaining to lifestyle and pressure ulcer risk in adults with spinal cord injury." Disability & Rehabilitation **32**(7):567-78.

Karatas, G.K., A. Tosun and U. Kanatl. (2008). "Center-of-pressure displacement during postural changes in relation to pressure ulcers in spinal cord-injured patients." American Journal of Physical Medicine and Rehabilitation **87**(3):177-82.

Mathew, A., S. Samuelkamaleshkumar, S. Radhika, et al. (2013). "Engagement in occupational activities and pressure ulcer development in rehabilitated South Indian persons with spinal cord injury." Spinal Cord **51**(2):150-5.

Ploumis, A., S. Kolli, M. Patrick, et al. (2011). "Length of stay and medical stability for spinal cord-injured patients on admission to an inpatient rehabilitation hospital: a comparison between a model SCI trauma center and non-SCI trauma center." Spinal Cord: The Official Journal Of The International Medical Society Of Paraplegia **49**(3):411-5.

Rappl, L.M. (2011). "Effect of platelet rich plasma gel in a physiologically relevant platelet concentration on wounds in persons with spinal cord injury." International Wound Journal **8**(2):187-95.

Rintala, D.H., S.L. Garber, J.D. Friedman, et al. (2008). "Preventing recurrent pressure ulcers in veterans with spinal cord injury: impact of a structured education and follow-up intervention." Archives of Physical Medicine And Rehabilitation **89**(8):1429-41.

Sarasúa, J.G., S.P. López, M.Á. Viejo, et al. (2011). "Treatment of pressure ulcers with autologous bone marrow nuclear cells in patients with spinal cord injury." Journal of Spinal Cord Medicine **34**(3):301-7.

Scevola, S., G. Nicoletti, F. Brenta, et al. (2010). "Allogenic platelet gel in the treatment of pressure sores: a pilot study." International Wound Journal **7**(3):184-90.

Schubart, J. (2012). "An e-learning program to prevent pressure ulcers in adults with spinal cord injury: a pre- and post- pilot test among rehabilitation patients following discharge to home." Ostomy Wound Management **58**(10):38-49.

Schubart, J.R., M. Hilgart and C. Lyder. (2008). "Pressure ulcer prevention and management in spinal cord-injured adults: analysis of educational needs." Advances in Skin & Wound Care **21**(7):322-9.

Thietje, R., R. Giese, M. Pouw, et al. (2011). "How does knowledge about spinal cord injury-related complications develop in subjects with spinal cord injury? A descriptive analysis in 214 patients." Spinal Cord **49**(1):43-8.

Wilson, J., P. Arnold, A. Singh, et al. (2012). "Clinical prediction model for acute inpatient complications after traumatic cervical spinal cord injury: a subanalysis from the Surgical Timing in Acute Spinal Cord Injury Study." J Neurosurg Spine **17**(1):46-51.

Wu, Q., G.Z. Ning, Y.L. Li, et al. (2013). "Factors affecting the length of stay of patients with traumatic spinal cord injury in Tianjin, China." Journal of Spinal Cord Medicine **36**(3):237-42.

Implementing the Guideline

FACILITATORS, BARRIERS AND IMPLEMENTATION STRATEGY

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
National level quality improvement							
(Lahmann, Halfens et al., 2010)	Cross-sectional retrospective study investigating guideline use on a nationwide level	National level in Germany Conducted in 60 nursing homes (n=7377 residents) and 82 acute-care hospitals (n = 28,102 patients)	No intervention Conducted annual nationwide pressure ulcer surveys investigating guideline use; risk assessment; use of preventive devices and measures; and overall prevalence and nosocomial prevalence Individual facilities participated 1 to 3 times	Percentage of institutions using guidelines and risk assessment tools (structures) The use of prevention devices and measures (processes). Prevalence and nosocomial prevalence of pressure ulcers (outcomes).	Repeated survey participation associated with statistically significant increase in use of guideline and Braden scale and preventive measures/devices Nursing homes Those participating in survey twice significant reduction in prevalence of stage I to IV PU by 4.3% and reduction in grade II to IV PU of 1.5% (p=ns). Prevalence of nosocomial PU decreased for participation 2 and 3 times (p=ns). Hospitals Participation in survey twice associated with significant decrease in grade I to IV PU by 4.9% and nosocomial PU by 3.6%; reduction in grade II to IV of 3.9% overall (p=ns) and significant 2.3% reduction in nosocomial ulcers. Participation in survey thrice (n = 11) showed statistically significant reductions in grade I to IV PU by 7.5% in the second year and another 9.7% in the third year. Similarly, grade II to IV PU significantly decreased by 2.5% in the second year and another 2.8% in the third year. Participation in 3 surveys prevalence of nosocomial grade I to IV PU dropped significantly from 26.3% to 11.3% in the third year and prevalence of grade II to IV PU dropped significantly from 10.2% to 5.2% in the third year.		**Level of evidence: 4** **Quality: moderate**

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
Facility level quality improvement programs							
(Ackerman, 2011)	Quasi-experimental design	Organization-level with no control group Conducted in hospital	Professional intervention Treatment protocol Treatment record: nurse documentation of skin care Physician sticker: notify of skin breakdown Radar screen: nurse worksheet serves as a tracking mechanism to alert nurses to patients at high risk Dietary collaboration: patients with stage III to IV PU Use of appropriate bed surface Care plan: potential for and actual skin breakdown Organizational intervention Dietary collaboration: patients with stage III to IV PU Skin Care Nurse: visually inspecting and assessing patient with advanced skin breakdown. Skin Care Resource Nurse: assess patient skin condition weekly (implemented in January 2009)	Hospital-acquired pressure ulcer (HAPU) incidence HAPU incidence: every third Monday of the Month by the admitting nurse	HAPU incidence in January-June 2008: 11 stage I, 4 stage II, 1 stage III, and 1 unstageable HAPU incidence in July-December 2008: 10 stage I, 11 stage II, and 1 unstageable HAPU incidence in January 2009: 6 stage I, 2 stage II Study conclusions: Strategies to improved skin assessment, identification of at risk patients and appropriate dietary referral and support surface selection was associated with no change in HAPU rate. Introduction of a nurse responsible for weekly skin assessment reduced HAPU prevalence but sustained effect not demonstrated.	Historical control Hospital-level instead of patient-level analysis Drop-out, missing data not reported. No information on analysis. Descriptive no tests	**Level of evidence: 4 Quality: low**
(Asimus, Maclellan et al., 2011)	Quasi-experimental design	Organization-level with no control group Conducted in hospital	Professional intervention Provision of algorithm to guide clinicians in the appropriate selection of equipment (e.g. renting dynamic bed surfaces) Educational online program (understanding and staging PU, risk assessment, prevention plans) Successful completion recorded on staff record Structural intervention Replacement of vinyl-covered mattresses with superior high-density foam mattress (scheduled systematic replacement)	Evaluate the effectiveness of policy implementation Identify cost-effective strategies Pressure Ulcer (PU) prevalence: survey tool PU risk assessment: Waterlow risk assessment tool Use of risk assessment tool and timing: survey tool	Prevalence PU rate: 29.4% 2008; 23.8% 2009; 13.0% 2010 Prevalence HAPUs: 23.4% 2008; 17.2% 2009; 8.0% 2010 Number stage III and IV PUs: 14.9% 2008; 13.9% 2010 Prevalence PU rate after mattress replacement: significant reduction in hospital-acquired PUs Compliance to risk assessment: 78.9% 2008; 79.2% 2009; 86.8% 2010 Prescription of appropriate PU relieving devices: 44% 2008; 71.5% 2009; 90.9% 2010 Cost saving related to appropriate PU relieving devices: AUD 500 000 (first year) Study conclusion: Introduction of high specification foam mattress, a decision algorithm for support surface selection	Historical control Hospital-level instead of patient level analysis Drop-out, missing data not reported. No information on analysis. Descriptive no tests	**Level of evidence: 4 Quality: moderate**

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
					and staff education was related to increased risk assessments, appropriate PU support surface selection and sustained reduction in PU prevalence		
(Baldelli and Paciella, 2008)	Quasi-experimental design	Organization-level with no control group Conducted in hospital (ICU medical-surgical unit)	Professional intervention Pressure Ulcer Prevention Bundle: based on AHRQ and WOCN PU guidelines 'Turn' clocks as visual reminder Comprehensive PU education: 45 minute Compliance: nurse manager responsible for compliance through education and staff reinforcement. Bedside education/consultation from Certified wound ostomy continence nurses (CWOCN). Clinical nurse specialist supervising CWOCNs Organizational intervention Feedback: PU rates and unit specific rate are posted for staff	PU prevalence and incidence PU prevalence/incidence: assessed by trained nurses	Intervention vs control for PU prevalence in medical-surgical unit : 9% versus 15% Intervention vs control for PU incidence in medical-surgical unit : 12% versus 7% Intervention vs control for PU prevalence in ICU : 20% versus 20% Intervention vs control for PU incidence in ICU: 3% versus 13%	No comparison with control group (national benchmark numbers) Hospital-level instead of patient level analysis. Drop-out, missing data not reported. No information on analysis. Descriptive no tests	**Level of evidence: 4 Quality: low**
(Revello and Fields, 2012)	Pre-post quasi-experiment investigating effect of	One 30 bed mixed acute rehabilitation and medical/surgical nursing care unit. All patients in this unit with a skin assessment 40 licensed RN staff and 20 nursing assistants	Professional intervention Wound care champion to educate staff using photographs of patients Education of all patient care staff formally done with classroom and computer format and continued for new staff. Organizational intervention Tracking form used to track all patients with PU	Measure the number of nosocomial pressure ulcers on one day per quarter. -Counted every quarter for three years	Baseline prevalence was 7.1% and as high as 16.7 % in June of 2008. There was not always a steady decline in rate until after January2009 After March 2010 the facility had achieved nosocomial prevalence 0%	No information on workflow with pictures Turnover of the wound care champion When wound care champion was off the process didn't occur Skill or credential of the wound care champion was not clear	**Level of evidence: 4 Quality: low**
(Thomas, 2008)	Prospective quasi-experiment investigating standardized assessment ad management across local facilities in reducing PU prevalence	One hospital, one nursing home, and two home health agencies	Organizational intervention Regularly at least monthly meetings between staff in four local facilities to determine: Standardized terms for PU Standardized documentation of treatment Wound module for basic education on pressure ulcers Physician order sheet	Hospital PU incidence measurement strategy not reported	Distribution of interventions to all facilities and health care workers Hospital PU incidence reduced from 53% to 13% over 10 months, and sustained at 12% after a further 6 months	No data for nursing homes or home health agencies Hospital data does not provide statistical comparison between pre and post PU incidence No control group / facility, blinding, or randomization	**Level of evidence: 4 Quality: low**

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
(Milne, Trigilia et al., 2009)	Quasi-experimental interrupted time series study investigating an organization wide multi-faceted program to decrease PU prevalence	Conducted in a 108-bed long-term acute care Hospital (LTACH)	Professional intervention Formation of multidisciplinary wound care team Wound Care specialty certification for key team members standard wound assessment documentation and internal reporting Staff education (content not described) Structural interventions Review of wound care products with development of prevention and treatment algorithms Revisions to electronic medical record to facilitate risk assessment; wound prevention, assessment and treatment documentation; and nurse care planning Organizational intervention Introduction of "guideline" –based pressure ulcer policies and procedure	Point prevalence of facility-acquired PU Monthly measurement pre-intervention (3 months pre intervention, 15 months post intervention)	Reduction in the prevalence of facility-acquired pressure ulcers from 41% at baseline (pre-intervention) to an average of 4.2% during a 12 month follow up period.	No demographic information about subjects No information about residents' levels of risk.	**Level of evidence: 4 Quality: low**
(McInerney, 2008)	Time series study investigating a quality improvement initiative introduced over a three year period	Conducted in 2 acute care facilities (n=548 beds) Excluded paediatric, obstetric and mental health patients	Multifaceted interventions introduced over a 3 year period: Year 1 electronic medical record to assess and document skin care needs Automatic, electronic consults to the (WOC nurse based on Braden Scale less than 13 (tallied from documentation in the electronic medical record and routed electronically) WOC nurse –generated, evidence-based pressure care Static overlay ordered for every patient with a Braden Score less than 16. hiring another WOC nurse Year 2 Protocol introduced for application of heel protective, one-size-fits-all boot to all patients with end-stage renal disease and all ventilator patients. Year 3 Powered air beds with continuous rotation purchased for most critical care beds.	Prevalence of hospital-acquired pressure ulcers. Prevalence of hospital-acquired heel ulcers Prevalence measured every 6 months for 4.5 years.	Pre-intervention prevalence of hospital-acquired pressure ulcers was 12.8% which dropped to 5.1% within 18 months of intervention (Year 1), but still more than 50% of ulcers were heel ulcers. With additional interventions (Years 2, 3) hospital-acquired prevalence rate decreased to 2.0% with no hospital-acquired heel ulcers in July 2005, and 0.7% heel ulcers in July 2006.	Potential Hawthorne effect for Year 1 interventions	**Level of evidence: 4 Quality: low**

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
			New pressure-reducing mattresses purchased for other (non-critical) hospital beds.				
(Bales and Duvendack, 2011; Bales and Padwojski, 2009)	Quasi-experimental design	Organization-level with no control group Conducted in community hospital	Professional intervention NDNQI training of unit-based 'champions' on PU assessment and prevention (2004-2008) Mandatory education sessions (2007-2008) Computer tool for assessment and initial PU care developed by the CWOCN to provide 24-hours support (2007-2008) Music tune reminded the nurses every two hours to turn and toilet patients. (March 2008) Skin assessments for patients at risk on admission to emergency department (March 2008) CWOCN part-time (2004-2007), fulltime (2007-2008); ongoing daily monitoring and evaluation (documentation and measurements) by CWOCN (February 2008) Evidence based algorithm on PU prevention for surgical unit (August 2008) Organizational intervention 'Zero HAPU campaign' flyers (June 2008) Zero HAPU campaign': staff received a small reward in recognition. (June 2008) Purchase of PU redistributing beds (March 2008)	PU prevalence assessed by trained nurses	From Bales et al, 2008 HAPU prevalence 2004 : 12% 2005: 4% Aug 2007: 9.5% Feb 2008 : 4.2% May 2008 : 2.6% Sept 2008: 1.36% Dec 2008 : 0% From Bales et al, 2011 HAPU incidence 2008: 77 2009: 28 2010: 14 2011: 0 Study conclusions: Staff training had an initial impact on HAPU prevalence. Focus on skin assessments, reminders for repositioning and a nurse responsible for care planning lead to sustained PU prevalence reduction. Financial incentives and purchase of appropriate support surfaces further reduced PU prevalence.	Historical group Hospital-level instead of patient level analysis. Drop-out, missing data not reported. No information on analysis. Descriptive no tests.	**Level of evidence: 4** **Quality: low**
Staffing models							
(Mangaco-Borja, 2011)	Quality improvement project and prevalence study investigating the impact of a work assignment intervention in aged care on PU rates	A 100-bed long term care skilled nursing facility in US. Participants were residents and 30 nursing assistants.	Nursing assistants were assigned to a permanent schedule of patients for whom they provided daily care (defined as the same nursing assistant cares for the same group of patients for at least 85% of the assistants shift). Consistent education was also provided to new staff throughout the project.	Outcome was the quarterly pressure ulcer rate per 1000 patient days (however annual rates were reported in the paper). Data for four years was presented	The overall rate of pressure ulcers decreased from 2.48/1000patient days in 2007 to 0.4/1000patient days in 2010	No indication of who assessed pressure ulcer incidence. No indication of pressure ulcer staging Not clear if patients were at similar risk of PU at each time collection point No reporting of compliance with the intervention (although	**Level of evidence: N/A** **Quality: low**

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
						this data was collected)	
(Horn, 2008)	Retrospective cohort study investigating association between cost-benefit of levels of nurse staffing and PU development in aged care	Long-term care facilities (n=11) in US	No intervention	Cost: national database for cost; Bureau of Labor and statistics for wages; Healthcare cost and utilization project fir mean hospital charges; articles of Xakellis and Frantz (1996) for cost of PU PU development : Database designed by an expert multidisciplinary panel.	RN direct care time There was a trend or threshold decrease of residents developing PUs for each 10-minute increase in RN direct care time, with lowest complications rates for 30-40 minutes per resident per day. RN direct care time (30-40 minutes per resident per day) and PU development: OR: 0.16 Cost benefit societal benefit of $319.120 per year for a 100-bed high risk nursing home or $3,191 for 10 to30-40 minutes per resident per day (reduction in adverse event versus increased cost of nurse wages) After excluding hospitalization saving the total costs increased by $199,507 for a 100-bed high-risk nursing home	Difference in groups poorly described Number of persons asked to participate is not reported. Drop-out not reported No information on validity, reliability of measurements Main outcomes are not identified and entered in the analysis.	**Level of evidence: N/A Quality: low**
(Konetzka, Stearns et al., 2008)	Prospective cohort study effect of staffing models in aged care on pressure ulcer development	Nursing homes in the US (1,366 facilities, n=399,206 resident assessments).	No intervention	Staffing: Minimal Data Set (MDS) and Online Survey Certification (OSCAR) PU development : MDS	RN hours per resident day and PU development There was a significant relationship ($p<0.01$) when adjusting for time trends, resident level controls (e.g. age and stroke), and facility level controls (e.g. adl, medicare) There was a significant relationship ($p<0.01$) using conditional logit with tradition two-stage least square approach adjusted for time trends, resident level controls (e.g. age and stroke), and facility level controls (e.g. adl, medicare) There was a significant relationship ($p<0.01$) using conditional logit with residential-inclusion approach (adjusted for time trends, resident level controls (e.g. age and stroke), and facility level controls (e.g. adl, medicare) Skill mix and PU development there was no significant relationship	Difference in groups poorly described Number of persons asked to participate is not reported. Drop-out not reported No information on validity, reliability of measurements Confounders: time trends, resident level controls (e.g. age and stroke), and facility level controls (e.g. adl, medicare)	**Level of evidence: 3 Quality: low**

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
					(p>0.05) when adjusted for time trends, resident level controls (e.g. age and stroke), and facility level controls (e.g. adl, medicare) there was no significant relationship (p>0.05) using conditional logit with tradition two-stage least square approach (also adjusted for above factors) There was no significant relationship (p>0.05) using conditional logit with residential-inclusion approach) (adjusted for time trends, resident level controls (e.g. age and stroke), and facility level controls (e.g. adl, medicare)		
(Hart and Davis, 2011)	Cohort study investigating the association between staffing indicators and hospital-acquired pressure ulcers (HAPU)	Hospitals (n=5, n=26 nursing units) in US	No intervention	Staffing indicators: National database of nursing quality indicators (NDNQI) HAPU: NDNQI	Medical-surgical units The following factors were significantly associated with HAPU: Total nursing care hours per patient day (r=-0.485; p<0.05) RN hours per patient day (r=-0.525; p<0.05) RN hours by agency staffing (r=0.586; p=0.022) The following factors were not significantly related to HAPU: Licensed practical nurse hours per patient day (r=-0.112; p>0.05) Unlicensed assistive personnel hours per patient day (r=0.301; p>0.05) Critical care units The following factors were not significantly related to HAPU: Total nursing care hours per patient day (r=-0.119; p>0.05) RN hours per patient day (r=-0.524; p>0.05) Licensed practical nurse hours per patient day (r=0.233; p>0.05)	Difference in groups poorly described Number of persons asked to participate is not reported. Drop-out not reported No information on validity, reliability of measurements Main outcomes are not identified and entered in the analysis.	**Level of evidence: 3** **Quality: low**
(Gunninberg, Brudin et al., 2010)	Cross-sectional study investigating relationship between PU	Participants were nurse managers in hospitals in Sweden County A: non-university hospital with 565 beds (n=27	No intervention	Contextual factors: University Health Systems Consortium operational database PU prevalence: EPUAP	PU prevalence There was no significant difference in PU prevalence (grade 1 to 4) between university county hospitals and non-university county hospitals (p=0.903)	Main outcomes are not identified and entered in the analysis.	**Level of evidence: N/A** **Quality: moderate**

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
	prevalence and contextual factors in the hospital organization	nurses) County B: university hospital with 1000 beds (n=45 nurses)		Minimal Data Set	PU prevalence was significantly lower in non-university county hospitals than in university county hospitals when grade 1 PU (p=0.035) PU prevention planning No significant difference between University county hospitals and non-university county hospitals (p=0.724) No significant difference between University county hospitals and non-university county hospitals for patients with PU grade 1 without prevention plan (p=0.155) University county hospitals were significantly more likely to have PU management guidelines than non-university county hospital (p=0.025) Staffing University county hospitals had significantly more RNs responsible for PU planning than non-university county hospital (p=0.017) No significant difference between University county hospitals and non-university county hospitals for number of assistant nurses responsible for PU prevention (p=0.527)		
(Temkin-Greener, Cai et al., 2012)	Cross sectional study investigating influence of working environment on PU prevalence	Nursing homes in one US state (n=162) Direct care workers in the facilities (n=7,418) were invited to participate Facility characteristics: all facilities > 50 beds operating > 2 years no special-needs patients Mean PU prevalence 13.7±6.5% (compared with 14.6±7.1% for all facilities in the state, p=0.064) Significantly more of the facilities were not for profit compared to State statistic	No intervention	PU prevalence as ascertained from MDS database review Primary work environment outcomes were: Staff cohesion and commonality of goals consistent assignment care team models assessed through items on a 7-point Likert scale (previous validation reported)	After controlling for independent resident risk factors and facility characteristics, residents in facilities with stronger staff cohesion have significantly lower odds of PUs (OR=0.958; p =0.035) After controlling for independent resident risk factors and facility characteristics, residents in facilities with self-managed care teams had higher odds of PU (OR=1.001, p=0.001) No association between PU prevalence and formal care teams (p=0.372), nursing hours per patient per day (p=0.615) or primary assignment care model (p=0.262).	No experimental design, correlation data only 162 out of 600 and facilities had significant differences to overall possible sample, so possible response bias Relied on database evidence, may be inaccurate, unable to determine how presence of PU was initially assessed	**Level of evidence: N/A** **Quality: low**

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
		(p=0.001) Facilities had a mean LPN hours/resident/day that was significantly higher than the state mean (p=0.001) Facilities had significantly fewer Medicaid residents compared with the State mean (p=0.033) Participant characteristics: 50% CNAs, 19% LPNs, 13% RNs, 18% other including allied health					
(Decker and Castle, 2011)	Cross-sectional study investigating the relation between job tenure of NHAs and DONs in aged care with prevalence of PU	Nursing homes in the US Participants were nursing home administrators (NHA, n=787) and directors of nursing (DON, n=703)	No intervention	Job tenure NHAs and DONs: National Nursing Home Survey (NNHS) PU prevalence: Minimal Data Set (MDS)	NHAs overall there was no significant relationship between length of time NHA had been in job and PU prevalence: p=0.205 job tenure ≥10 years and PU prevalence: p=0.040 job tenure 5-9 years and PU prevalence: p=0.377 NHA job tenure 3-4 years and PU prevalence: p=0.294 DONs overall there was a significant relationship between length of time DON had been in position and prevalence of PU (p=0.008) job tenure ≥10 years and PU prevalence: p=0.026 DON job tenure 5-9 years and PU prevalence: p=0.010 DON job tenure 3-4 years and PU prevalence: p=0.709	Number of persons asked to participate is not reported. No information on validity, reliability of measurements Unclear if multiple sites are comparable Main outcomes are not identified and entered in the analysis.	**Level of evidence: N/A** **Quality: low**
Staff attitudes and culture							
(Strand and Lindgren, 2010)	Descriptive, cross-sectional study investigating	Participants were nursing staff in four ICUs in a Swedish University Hospital (n=315 received survey,	Questionnaire developed from other previously questionnaires. Pilot testing of instrument prior to distribution.	nurse attitudes nurse perceived barriers and opportunities towards PU prevention in the ICU	Current practice in ICU 67.6% reported no routines existed for PU risk assessment in their ICU 97% reported use of pressure relief	Response rate was low at 46% (according to the authors) may be due to the length	**Indirect evidence: no association**

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
	attitudes toward PU care in ICU (also investigated knowledge, see "Nurse knowledge and education" see "Education")	n=146 returned survey) Characteristics: 56.2% worked full time Mean age 38.8±7.4 years for RNs and 43.5±9.7 for ENs (p=0.001)		setting.	38% reported use of nutritional support Attitudes no difference between RN and ENs Nurses with more education agreed with the statement "all patients are at risk for PU" more often (p=0.014) Nurses with more education disagreed with the statement "I am less interested in PU prevention than in other aspects of care" more often (p=0.009) Barriers to PU prevention 57.8% mentioned lack of time 28.9% mentioned severely ill patients Opportunities 38% mentioned knowledge 35.5% mentioned access to pressure relieving equipment Study conclusions: PU prevention was considered important but lack of time and severe morbidity of patients impacted on ability to implement PU care.	of the questionnaire No validation of practice in the ICUs Self-selected response may be from ICU nurses with more interest in area of PU	**made between attitudes and PU outcomes** **Quality: moderate**
(Pekkarinen, Sinervo et al., 2008)	Cross sectional survey investigating the influence of staffing on PU prevalence in aged care	Conducted in aged care facilities in Finland that had at least 2 years of data (n=66) 724 nurses in the facilities completed surveys. Characteristics of facilities: Mean resident beds 27 (range 8 to 50) Characteristics of nurses: 23% RNs, 58% LPNs, 14% NAs, 5% head nurses Mean time in current job 9±8.6 years	No intervention	'Time pressure' and 'unfair management' determined through validated nursing staff survey with Likert scored items. PU prevalence (stages 1-4) determined from MDS (database review) and adjusted for resident dependency as measured on an Activities of Daily Living Hierarchy	Mean PU prevalence 9.7±6.7% for the year survey conducted. No significant relationship between unit size and PU prevalence. Nurse-ranked 'unit time pressure' was significantly related to an increased PU prevalence (p=0.05) No significant influence of 'perceived unfair management' on PU prevalence (p=0.259)	No comparison group Total number of eligible units not stated, so the proportion of units volunteering is unclear. Used a non-validated method to calculate PU prevalence. Unclear how PU presence was assessed initially. Database data may not be reliable.	**Level of evidence: N/A** **Quality: high**
(Beeckman, Defloor et al., 2010)	Two-phase-Prospective psychometric instrument	Conducted in hospitals (n=2) and psychiatric hospital (n=1) in Belgium and in the Netherlands	No intervention – reliability and validity testing of a psychometric tool measuring attitudes towards pressure ulcer prevention in nurses	Outcome Attitudes to pressure ulcer prevention measured using APuP	Entire APuP instrument Cronbach's α = 0.79 Intraclass coefficient (ICC) = 0.88 (95% CI 0.84 to 0.91, p<0.001)	Convenience sample Non-response-bias Not more than three items per subscale	**Level of evidence: N/A** **Quality:**

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
	validation study reporting the Attitude towards Pressure Ulcer Prevention Instrument (APuP)	Initial convenience sample (32-item APuP) of qualified nurses (n=258) and nursing students (n=291) Participant characteristics: 70% aged 25 to 50 years >50% had more than 10 years' experience in nursing 65.5% nurses had bachelors degree and 6.2% had masters degree	Original 32-item tool was tested for face value/content validity by PU experts using a Delphi process and pilot tested on 10 nurses/nursing students for clarity, ambiguity, layout and time to complete Tool reduced to 13 items (5 subscales) and tested in a convenience sample of nurses/nursing students	Test-retest procedure with 1 week interval	Personal competency to prevent PU subscale Cronbach's α = 0.81 ICC = 0.80 (95% CI 0.73 to 0.85, p<0.001) Priority of PU prevention subscale Cronbach's α = 0.75 ICC = 0.82 (95% CI 0.76 to 0.86, p<0.001) Impact of PU subscale Cronbach's α = 0.79 ICC = 0.85 (95% CI 0.80 to 0.89, p<0.001) Responsibility in PU prevention subscale Cronbach's α = 0.82 ICC = 0.83 (95% CI 0.78 to 0.87, p<0.001) Confidence in effectiveness of PU prevention subscale Cronbach's α = 0.76 ICC = 0.77 (95% CI 0.70 to 0.83, p<0.001)		**N/A**
(Bosch, Halfens et al., 2011)	Cross-sectional study investigating relationship between organization culture, team climate, and preventive PU) quality management at ward level and PU prevalence	Nursing homes (n=36) and hospitals (N=25) in the Netherlands Questionnaire completed by doctors, nurses and nursing assistants (n=460)	No intervention	Organizational culture: Competing values framework (CVF) Team climate: Team climate inventory (TCI) Quality indicators preventive quality management: checklist formulated by a team of experts based on (inter)national guidelines and expert opinion. PU prevalence: point prevalence according to the EPUAP classification	Group culture and PU prevalence: OR 1.00 (95% CI 0.98-1.02) (adjusted for age, malnutrition and type of ward) Developmental culture and PU prevalence: OR 1.02 (95% CI 0.98-1.06) (adjusted for age, malnutrition and type of ward) Hierarchical culture and PU prevalence: OR 0.99 (95% CI 0.97-1.02) (adjusted for age, malnutrition and type of ward) Rational culture and PU prevalence: OR 0.99 (95% CI 0.96-1.02) (adjusted for age, malnutrition and type of ward) Team climate: OR 0.99 (95% CI 0.96-1.02) (adjusted for age, malnutrition and type of ward) Preventive quality management and PU prevalence: OR 0.96 (95% CI 0.88-1.06) (adjusted for age, malnutrition and type of ward)	Confounders included age, malnutrition and type of ward	**Level of evidence: N/A Quality: moderate**
Organization commitment to quality							
(Goode, Blegen et al., 2011)	Retrospective cohort study comparing PU care HAPU in	ICU and general units in Magnet (n = 19) and non-Magnet (n = 35) hospitals	No intervention	HAPUs: Quality indicators software developed by AHRQ Staffing data: University	Nurse staffing Magnet hospitals had significantly more total hours of care per day than non-Magnet hospitals in general units	Difference in groups poorly described Number of persons asked to participate is	**Level of evidence: N/A Quality:**

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
	Magnet and non-Magnet hospitals			Health Systems Consortium operational database	(p<0.05) but there was no significant difference in ICU (p=ns) Magnet hospital had significantly more RN skill mix than non-Magnet hospitals in general units and ICU (both p<0.05) PU prevalence There was no significant difference in HAPU between Magnet and non-Magnet hospitals (p<0.10) When adjusting for percentage registered nurses, Magnet status, and Medicare case mix index, total hours per patient day was not significantly related to HAPU in general units or ICU or general units (p=ns) When adjusting for total hours per patient day, Magnet status, and Medicare case mix index percentage of registered nurses was significantly related to HAPU in ICU and general units (p<0.05) When adjusting for total hours per patient day, percentage registered nurses, and Medicare case mix index Magnet status was not significantly related to HAPU in ICU or general units (p=ns) When adjusting for total hours per patient day, percentage registered nurses, and Magnet status Medicare case mix index was significantly related to HAPU in ICU and general units (p<0.05)	not reported. Drop-out not reported No information on validity, reliability of measurements Confounders: total hours per patient day, percentage registered nurses, Magnet status and Medicare case mix index	**low**
Critical care-specific QI projects							
(Kelleher, Moorer et al., 2012)	Quality improvement project investigating PU bedside rounds to decrease PU incidence	Carried out in a 17 bed surgical ICU (total n=180) Average number of patients per quarterly prevalence survey was 15	Professional intervention Nurse-led quality improvement program Pre-intervention stage all nurses received a pocket sized education resource on PUs. Main intervention: Weekly bedside rounds conducted by	Quarterly HAPU rates were tracked from January 2008-December 2010 Prevention measures in use commenced in Q6 Validation of PU/staging systems not reported	HAPU rate: 10.6% overall Pre-intervention HAPU rate (over 5 quarters, 1 to 5): 0% to 26.7% Post-intervention HAPU rate (over 7 quarters, 6 to 12) ranged from 0% to 27.1% From quarters 9 to 12, the highest	Introduction of specialty beds/mattresses and wicking under-pads during the study period may have affected the HAPU	**Level: 4** **Quality: moderate**

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
			nurse managers and WOCNs aimed at engaging nurses in discussion on PU risk factors, application of Braden score subscales and development of appropriate, related PU prevention plans Bed side rounds used a question format to guide discussion (included in article) and focused on patient-specific issues		prevalence was 6.3% Observations of the following prevention strategies improved with 100% compliance observed from Q 9 to Q 12: Use of a prevention surface Repositioning Nutrition Moisture Management	rate Small number of patients per quarter	
(Dibsie, 2008)	Descriptive study reporting on a QI project aimed at standardising skin and wound care products	QI project commenced in the adult surgical ICU and expanded to multisite (2) academic medical centers	Professional intervention Education provided on new products and skin care, prevention of PU, identification and staging of PU, assessment and treatment. Weekly evaluation of wounds and skin by clinical specialists Organizational intervention Organizational support including financial reward associated with strategic goals Management support and funding for the project Daily reminder systems for use of reporting system Electronic reporting of all skin issues and PUs Standardization of all products related to the prevention of skin breakdown and care of partial-thickness wounds based on nurse recommendations Consistent and correct completion of order sets	Prevalence of pressure ulcers quarterly over 2 years PUs validated by wound care nurses	Prevalence data reflect steady decreases in the rate of hospital-acquired stage 2 or greater pressure ulcer. Data from surgical ICU showed: ~16.5% at baseline (Q4 2005) ~ 6% at second measure (Q4 2006) ~ 12.5% at third measure (Q1 2007) ~ 6.5% at fourth measure (Q2 2007) ~6% by fifth measure (Q3 2007)	Interventions might be specific to organizational structure and culture of study site, and might not be generalizable. No statistical analysis No reporting of baseline education level, experience of nursing staff	**Level: 4 Quality: moderate**
(Gray-Siracusa and Schrier, 2011)	Descriptive study reporting on a multifaceted QI intervention	QI project in a 27-bed cardiovascular and coronary care ICU in USA Participants in pre-QI intervention stage (2007 to 2008)(n=554) Mean age 69.3±21.97 61.9% sample male Participants in post-QI intervention stage (2008 to 2009) (n=645)	Professional intervention Introduced a pressure ulcer bundle (PUB) including: Risk assessment conducted every 12 hours Mobility – lighting and chimes every 2 hours to indicate repositioning time Minimal head of bed elevation Heel elevation Nutritional screening on admission and daily Skin assessment using NPUAP staging Sacral cleanse and moisturize	HAPU identified through skin assessments and using EPUAP staging system	No significant difference between pre-PUB and post-PUB for HAPU rates (p=0.11) Comparison of quarterly rates showed decreasing trend: Pre-PUB quarterly HAPU rates: QI 5.7% Q2 0% Q3 5.2% Q4 0% Post-PUB quarterly HAPU rates: QI 0% Q2 ~0.8%	Small number of participants each quarter Only one site Study conducted in a community hospital and requires more research needs to be conducted to validate its effectiveness and generalizability.	**Level of evidence: 4 Quality: moderate**

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
		Mean age 66.8±19.10 56.4% sample male	Online training given to the staff using the NDNQI pressure ulcer training modules Assessment of nurses' skills using the schematic drawings and photos of pressure ulcers by stage. Organizational intervention Data extraction by RN from administrative and outpatient areas to differentiate community and hospital, unit acquired pressure ulcers.		Q3 0% Q4 0%		
(Ballard, McCombs et al., 2008)	Pre/post intervention study investigating effectiveness of a bundle of strategies in reducing PU in an ICU unit	44-bed ICU divided into a trauma/neurosurgical/general surgery unit (26 beds) and a medical unit (18 beds).	Professional intervention increased staff awareness, implemented "turn rounds" increased PU assessments redesigned structure of the skin team, evidence-based practice as a basis for care Organizational intervention graphs for ease of understanding by staff restructured risk assessment and documentation, database to track weekly prevalence	Weekly pressure ulcer rate (continuous)	Reports data from PU prevalence reduced from a rate of 25 to 35% in the 4 quarters reports preceding introduction of the intervention to 3 to 15% in the 6 quarters after intervention introduction.	pre-post study with historical control No statistical analysis	**Level of evidence: 4** **Quality: low**
Aged care-specific QI projects							
(Beeckman, Clays et al., 2013)	Randomized controlled trial investigating the effect of an electronic clinical decision support system in reducing PUs in an aged care setting	Nursing home wards in Belgium (n = 11 wards, n = 646 residents, n = 118 health care professionals) Resident characteristics: There was no significant difference between groups for basic demographic characteristics Approx 60% residents were at risk of PU >60% were incontinent of urine Almost 50% were <55kgs	Wards were randomized to either the experimental group or control group. Experimental group: (n=6 wards, 225 residents, 65 professionals) Professional interventions Electronic decision support system Interactive education Monitoring and feed back Reminders Introduction of the key nurse role Organizational interventions Inventory, support on acquisition and support of organization of the delivery of PU preventive materials Control group: (n=5 wards, 239 residents,	Validated PU Knowledge Assessment Tool assessing professional knowledge of PU prevention Attitude towards Pressure Ulcer tool to assess attitudes toward prevention Knowledge and attitudes was only collected at baseline and 120 days after implementation PUs prevalence and classification assessed according to EPUAP/NPUAP Classification Data was collected at	PU prevalence For PUs stage I to IV, there was a significantly lower PU prevalence in the experimental group compared with the control group at the end of the study (7.1% versus 14.6%) For PUs stage II to IV, there was no significant difference in PU prevalence between the experimental group compared with the control group at the end of the study (1.8% versus 2.1%) Knowledge of PU prevention No significant difference was found between baseline and post test (F=1.98, p=0.16) Attitude towards PU	A possible Hawthorne-Effect A possible selection bias (drop out in the group of health care professionals due to additional workload) Not all healthcare workers were able to attend the educational activities	**Level of evidence: 1** **Quality: high**

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
		Health care professional characteristics: There was no significant difference between groups for basic demographic characteristics >50% aged over 35 years Between 40 to 50% were nurse assistants About 10% were Bachelor Nurses >50% had more than 11 years' experience	53 professionals) Hard copy format pressure ulcer prevention protocol No additional interventions	baseline data and five times over 4 months.	The experimental group had a significantly higher mean score after the intervention (83.5% versus 72.1%, F=15.12, p<0.001)		
(Tippet, 2009)	Prospective quasi-experimental	Single nursing home in US Facility characteristics: Average bed census was 137 per month	Professional intervention Mandatory staff education: wound fundamentals, Braden scale, wound assessment, treatment, prevention, support surfaces Evaluate support surface equipment for pressure management Organizational intervention Formation of interdisciplinary leadership team Development of protocols for prevention and treatment Simplified wound care formulary	PU incidence and prevalence tracked monthly for 2 years pre-intervention and 4 years post-intervention. PUs were identified as facility-acquired or present on admission. All PUs classified according to NPUAP guidelines.	PU prevalence There was a significant 86% reduction in PU incidence reduction (p<0.0001) and a greater than 99% PU prevalence reduction Pre-initiative average monthly PU incidence 5.18% Post-initiative average monthly PU incidence 0.73% (sustained for 4 years) Financial cost benefit analysis Costs included $27,200 for contract wound consultant, $11,000 equipment $488,000 estimated care savings in reduced PU including $9,600 savings on skin care products	Single facility, no randomization, no blinding, no control group or control intervention. PU identification method not reported Characteristics of residents and facility were not provided in detail	**Level of evidence: 4** **Quality: moderate**
(Rantz, Zwygart-Stauffacher et al., 2012)	Prospective Randomized clinical trial investigating the effect of management support of change in conjunction with research nurse support in reducing PU prevalence	The study was conducted in nursing homes in one US state. Intervention group characteristics: Bed range 36 to 300 16/29 member of chain 20/29 for profit 150% turnover of DON during study 28% turnover of nursing home administrators during study period	Professional intervention The intervention group (n=29) received the intervention that consisted of: On site consultations with a research nurse Management support of change Promotion of team decision making Focus efforts of direct care staff on a QI program promoting general care including prevention of skin breakdown. The control group (n=29) received: Monthly videotaped in services and reading materials not directly related to quality improvement strategies and a monthly visit to answer questions regarding educational	Outcome of interest to this review was pressure ulcer prevalence as reported on MDS reported quarterly Follow up period 24months	The only significant effect on resident outcomes was a reduction in PUs in the intervention group over time (p=0.053) There was a cost to facilities with more than 100% staff turnover but this was not significantly greater than the control facilities. The intervention group had a 9% increase in LPN staffing costs (significance not reported)	Regression analysis was used to present result findings but the coded table was not labelled for interpretation Very difficult to ascertain magnitude of the intervention result.	**Level of evidence: 2** **Quality: moderate**

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
		Control group characteristics: Bed range 52 to 246 15/29 member of chain 19/29 for profit 100% turnover of DON during study 72% turnover of NHA during study period	material				
(Rantz, Cheshire et al., 2009)	Prospective quasi-experiment investigating the effectiveness of providing support in MDS and quality indicator reporting and evidence based practice on a variety of resident outcomes including PU prevalence in aged care	All nursing homes in one US state were considered as participants. Group 1: at risk facilities (those identified as having poor QIs) who accepted at least one onsite consultation (n=60) Group 2: at risk facilities refusing onsite consultations (n=32) Group 3: non-at-risk facilities accepting at least one onsite consultation (n=129) Group 4: non-at-risk facilities refusing onsite consultations (n=271) Facility characteristics: Average bed size 110 71% for profit facilities	Professional intervention On site consultations with trained post-graduate gerontological nurse providing support and education on use of MDS and quality indicator reporting, evidence based practice and team development. The intervention was not specific to PU management. Ongoing support from consultant via email and phone. Opportunity for MDS coordinators to network at inter-facility support nights.	Primary outcomes were indicators of facility quality including stage 1 to 4 pressure ulcers as reported on MDS Quarterly reporting for 12 months Other outcomes included falls, depression, use of 9 or more medications, bladder or bowel incontinence, urinary tract infection, weight loss, dehydration, bedfast residents, decline in late-loss activities of daily living, and physical restraints	At risk facilities who received consultation (group 1): 22% reduction in PU prevalence overall 12% reduction in PUs in high risk patients 41% reduction in bedfast residents 4% reduction in weight loss At risk facilities who did not receive consultations (Group 2): 3% increase PU in PU prevalence overall 11% increase in PUs in high risk patients 4% increase weight loss 35% increase bedfast residents Non-at risk facilities receiving consultation (Group 3): 12% increase PU in PU prevalence overall 14% increase in PUs in high risk patients 29% increase weight loss 26% increase bedfast residents	No random facility assignment Dose of treatment not controlled Level of outcome metrics not similar in groups at baseline Unclear if intervention was effective as facilities who were not at risk had particularly bad outcomes when they engaged in support intervention	**Level of evidence: 3** **Quality: low**
(Bonner, Castle et al., 2009)	Secondary analysis from a prospective cohort study investigating association between CNA patient safety culture and PU rate in aged care	Nursing homes in US (n=240) Participants were certified nursing assistants (n=1579) Facility characteristics: 41.6% for profit 37.8% chain membership Mean PU rate 8.2±4.6% CNA characteristics: 91.9% had high school degree and 6.1% had	No intervention	CNA PSC: Hospital survey of patient safety culture (HSOPSC) total CNA patient safety culture (PSC) considered bed capacity, licensed practical nurse staffing, average cognitive performance scale, percentage of residents with Alzheimer's dementia, average number of medication per resident,	PU rates and staff factors Total CNA PSC score and PU rate: p=0.807 Licensed practical nurse staffing and PU rate: p=0.190 PU rates and facility factors Bed capacity and PU rate: p=0.000 Percentage of residents with Alzheimer's dementia and PU rate: p=0.144 Proportion of facility resident on Medicare and PU rate: p=0.029	Percentage of recruited individuals and drop-out not reported No information on difference between drop-out group and follow-up group Main outcomes are not identified and entered in the analysis, only the	**Level of evidence: N/A** **Quality: moderate**

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
		bachelors degree of higher Mean years at facility 4.6±4.5 Mean years as a CNA 7.8±6.1%		proportion of facility resident on Medicare, average ADL scale PU rate determined by Minimal Data Se (MDS) or Online Survey Certification (OSCAR) and Reporting and Area Resource File (ARF) Follow-up time: Four quarters	PU rates and patient factors Average cognitive performance scale and PU rate: p=0.010 Average number of medication per resident and PU rate: p=0.038 Average ADL scale and PU rate: p=0.000	items and total score of the CNA PSC were entered in the analysis.	
(Lyman, 2009)	Quasi-experiment pretest/ posttest design investigating multifaceted intervention influence on prevalence of heel ulcers.	Long-term healthcare facility (n=550 residents).	Professional intervention Tailored protocol related to application of heel protective device including on-off routines. Inservice education program Using an FDA approved heel protective device to off-load pressure on heels of high risk patients (i.e., Braden score of 18 or less with 1 to 7 high risk comorbidities)	Point prevalence of facility-acquired heel ulcers. monthly measurement of prevalence of facility-acquired heel ulcers 11 months pre-intervention, 20 months post-intervention)	95% reduction in facility-acquired heel ulcers from pre-intervention (range 2.1% to 5% per month) to post-intervention (range 0% to 3.2% per month)	No information on the focus or content of the education intervention.	**Level of evidence: 5 Quality: low**
(Horn, Sharkey et al., 2010)	Quasi-experiment interrupted time-series investigating effects of standardized nurse aide documentation and feedback reports on prevalence of facility-acquired PU	Conducted in 11 US long term facilities	Professional intervention Introduction of a standardized documentation form for nurse assistants with highlighted observational triggers (alerting to increased pressure ulcer risk). Organizational interventions Computer-generated weekly reports (based on NAs documentation) to alert LTC teams to identify: Completeness of documentation patients with nutrition risk patients with high-risk triggers for pressure ulcer patients with abnormal skin observations	Multiple measures to evaluate uptake of new documentation system and use of reports. Principle outcome for patients was facility-acquired pressure ulcers averaged across facilities.	Across facilities (8 out of 10) average facility-acquired PU prevalence decreased by 62% from 12.1% pre-implementation to 4.6% post-implementation.	Selection of facilities	**Level of evidence: 4 Quality: moderate**
(Baier, Butterfield et al., 2009; Baier, Butterfield et al., 2008)	Quasi-experimental design	Organization-level with no control group Conducted in nursing homes	Structural intervention Launch of a website to help nursing homes select performance goals/targets on four outcomes (pressure ulcers, restraints, pain and depression) which allows comparison between peers. Quality Improvement Organization (QIO) support (no further information) for a 15% of the nursing homes	Evaluate relative improvements among nursing homes for PU quality measures in high-risk residents PU prevalence assessed with Minimal Data Set (MDS) Relative improvement: 4-quarter average for baseline (target set) and	Comparison nursing homes which set PU targets and nursing homes which did not set PU targets for relative improvement: 7.0% versus 5.9%; p=0.0004 Comparison nursing homes which set PU targets and nursing homes which did not set PU targets for absolute improvement: 0.9% versus 0.8%; p=0.0442	Historical group Nursing home-level instead of patient level analysis Drop-out, missing data not reported. Standardization, reliability, validity of measurement unclear.	**Level of evidence: 4 Quality: low**

Ref	Type of Study	Setting of study (setting, participants)	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations, confounding factors, comments	
				remeasurement (target expired) Nursing home characteristics: Online Survey, Certification and Report (OSCAR) database	Faculty size and relative/absolute improvement for PU: facility size did not affect previously mentioned trend Membership in a multi-facility corporation and relative/absolute improvement for PU: membership in a multi-facility corporation did not affect previously mentioned trend QIO nursing homes and improvement for PU: improvement was independent of QIO program. Non-QIO nursing homes: comparison nursing homes which set PU targets and nursing homes which did not set PU targets for relative improvement: 7.4% versus 6.0%; p<0.0001		
Pediatric-specific QI projects							
(Boesch, Myers et al., 2012)	Qualitative Plan Do Study Act (PDSA) investigating a multi-faceted intervention in reducing tracheostomy-related pressure ulcers(TRPU) in children	Conducted in a academic children's hospital in the US (490 beds) Results included 834 tracheostomy patients and 10,132 tracheostomy patient days. Patient characteristics: Mean age 2yr 8 mo 87% ventilator dependent	Professional intervention PDSA cycle frame to implement a bundle that included: Pressure ulcer risk (Braden scale) and skin assessment Moisture free device interface Pressure free device interface Hydrophilic polyurethane foam dressing (Mepilex Lite®) used under tracheostomy tube to wick the moisture away from the stoma and skin surface Use of extended tracheostomy tube design Online education on risk and skin assessment for all nurses Organizational intervention Patient information brochures Engagement with tracheostomy tube manufacturer to develop and deliver extended tracheostomy tube design Real time reporting of TRPU Incorporation of TRPU interventions into electronic record nursing workflow	TPRU rate	Mean TRPU rate Pre-intervention ranged from approx. 3.8% to 16% over 6 months (mean rate 8.1%) During bundle development and implementation ranged from 0% to 12% over 12 months (mean rate 2.6%) Post-intervention ranged from o% to 3% over 10 months (mean 0.3%) Statistical analysis on effect of extended tracheostomy tube design found a significant reduction in number of TPRUs (p=0.007) and number of days with TPRU (p<0.0001)	The study is limited to a single hospital unit design and was not a randomized controlled trial Measurement periods were different for pre-during and post-intervention which influences mean rates	**Level of evidence: 4 Quality: moderate**

References

Ackerman, C.L. (2011). "'Not on my watch:' treating and preventing pressure ulcers." Medsurg Nursing: Official Journal of the Academy of Medical-Surgical Nurses **20**(2):86-93.

Asimus, M., L. Maclellan and P.I. Li. (2011). "Pressure ulcer prevention in Australia: the role of the nurse practitioner in changing practice and saving lives." International Wound Journal **8**(5):508-13.

Baier, R., K. Butterfield, G. Patry, et al. (2009). "Identifying star performers: the relationship between ambitious targets and nursing home quality improvement." Journal Of The American Geriatrics Society **57**(8):1498-503.

Baier, R.R., K. Butterfield, Y. Harris, et al. (2008). "Aiming for star performance: the relationship between setting targets and improved nursing home quality of care." J Am Med Dir Assoc **9**(8):594-8.

Baldelli, P. and M. Paciella. (2008). "Creation and implementation of a pressure ulcer prevention bundle improves patient outcomes." American Journal of Medical Quality **23**(2):136-42.

Bales, I. and T. Duvendack. (2011). "Reaching for the moon: achieving zero pressure ulcer prevalence, an update." Journal of Wound Care **20**(8):374-7.

Bales, I. and A. Padwojski. (2009). "Reaching for the moon: achieving zero pressure ulcer prevalence." Journal of Wound Care **18**(4):137-44.

Ballard, N., A. McCombs, S. Deboor, et al. (2008). "How our ICU decreased the rate of hospital-acquired pressure ulcers." Journal of nursing care quality **23**(1):92.

Beeckman, D., E. Clays, A. Van Hecke, et al. (2013). "A multi-faceted tailored strategy to implement an electronic clinical decision support system for pressure ulcer prevention in nursing homes: A two-armed randomized controlled trial." International Journal of Nursing Studies **50**(4):475-86.

Beeckman, D., T. Defloor, L. Demarre, et al. (2010). "Pressure ulcers: development and psychometric evaluation of the Attitude towards Pressure ulcer Prevention instrument (APuP)." International Journal of Nursing Studies **47**(11):1432-41.

Boesch, R.P., C. Myers, T. Garrett, et al. (2012). "Prevention of tracheostomy-related pressure ulcers in children." Pediatrics **129**(3):e792-e7.

Bonner, A.F., N.G. Castle, A. Men, et al. (2009). "Certified nursing assistants' perceptions of nursing home patient safety culture: is there a relationship to clinical outcomes?" J Am Med Dir Assoc **10**(1):11-20.

Bosch, M., R.J.G. Halfens, T. van der Weijden, et al. (2011). "Organizational culture, team climate, and quality management in an important patient safety issue: nosocomial pressure ulcers." Worldviews On Evidence-Based Nursing / Sigma Theta Tau International, Honor Society Of Nursing **8**(1):4-14.

Decker, F.H. and N.G. Castle. (2011). "Relationship of the Job Tenure of Nursing Home Top Management to the Prevalence of Pressure Ulcers, Pain, and Physical Restraint Use." Journal of Applied Gerontology **30**(5):539-61.

Dibsie, L.G. (2008). "Implementing evidence-based practice to prevent skin breakdown." Critical Care Nursing Quarterly **31**(2):140-9.

Goode, C.J., M.A. Blegen, S.H. Park, et al. (2011). "Comparison of patient outcomes in magnet® and non-magnet hospitals." The Journal Of Nursing Administration **41**(12):517-23.

Gray-Siracusa, K. and L. Schrier. (2011). "Use of an intervention bundle to eliminate pressure ulcers in critical care." Journal of Nursing Care Quality **26**(3):216-25.

Gunninberg, L., L. Brudin and E. Idvall. (2010). "Nurse Managers' prerequisite for nursing development: a survey on pressure ulcers and contextual factors in hospital organizations." Journal of Nursing Management **18**(6):757-66.

Hart, P. and N. Davis. (2011). "Effects of nursing care and staff skill mix on patient outcomes within acute care nursing units." Journal of Nursing Care Quality **26**(2):161-8.

Horn, S.D. (2008). "The business case for nursing in long-term care." Policy, Politics & Nursing Practice **9**(2):88-93.

Horn, S.D., S.S. Sharkey, S. Hudak, et al. (2010). "Pressure ulcer prevention in long-term-care facilities: a pilot study implementing standardized nurse aide documentation and feedback reports." Advances in Skin & Wound Care **23**(3):120-31.

Kelleher, A.D., A. Moorer and M.F. Makic. (2012). "Peer-to-peer nursing rounds and hospital-acquired pressure ulcer prevalence in a surgical intensive care unit: A quality improvement project." Journal of Wound, Ostomy and Continence Nursing **39**(2):152-7.

Konetzka, R.T., S.C. Stearns and J. Park. (2008). "The staffing-outcomes relationship in nursing homes." Health ServRes **43**(3):1025.

Lahmann, N.A., R.J.G. Halfens and T. Dassen. (2010). "Impact of prevention structures and processes on pressure ulcer prevalence in nursing homes and acute-care hospitals." Journal of Evaluation in Clinical Practice **16**(1):50-6.

Lyman, V. (2009). "Successful heel pressure ulcer prevention program in a long-term care setting." Journal of Wound, Ostomy, and Continence Nursing: Official Publication of the Wound, Ostomy and Continence Nurses Society / WOCN **36**(6):616-21.

Mangaco-Borja, E. (2011). "The significance of introducing permanent assignments for nursing assistants at a long-term care setting on the incidence rate of facility-acquired pressure ulcers among elderly patients." Journal of the American College of Certified Wound Specialists **3**(1):13-5.

McInerney, J.A. (2008). "Reducing hospital-acquired pressure ulcer prevalence through a focused prevention program." Advances in Skin & Wound Care **21**(2):75-8.

Milne, C.T., D. Trigilia, T.L. Houle, et al. (2009). "Reducing pressure ulcer prevalence rates in the long-term acute care setting." Ostomy/Wound Management **55**(4):50-9.

Pekkarinen, L., T. Sinervo, M. Elovainio, et al. (2008). "Drug use and pressure ulcers in long-term care units: do nurse time pressure and unfair management increase the prevalence?" Journal of Clinical Nursing **17**(22):3067-73.

Rantz, M.J., D. Cheshire, M. Flesner, et al. (2009). "Helping nursing homes "at risk" for quality problems: a statewide evaluation." Geriatric Nursing (New York, NY) **30**(4):238-49.

Rantz, M.J., M. Zwygart-Stauffacher, L. Hicks, et al. (2012). "Randomized multilevel intervention to improve outcomes of residents in nursing homes in need of improvement." J Am Med Dir Assoc **13**(1):60-8.

Revello, K. and W. Fields. (2012). "A performance improvement project to increase nursing compliance with skin assessments in a rehabilitation unit." Rehabilitation Nursing: The Official Journal Of The Association Of Rehabilitation Nurses **37**(1):37-42.

Strand, T. and M. Lindgren. (2010). "Knowledge, attitudes and barriers towards prevention of pressure ulcers in intensive care units: a descriptive cross-sectional study." Intensive & Critical Care Nursing: The Official Journal of the British Association of Critical Care Nurses **26**(6):335-42.

Temkin-Greener, H., S. Cai, N.T. Zheng, et al. (2012). "Nursing home work environment and the risk of pressure ulcers and incontinence." Health ServRes **47**(3 Pt 1):1179-200.

Thomas, M.E. (2008). "The providers' coordination of care: a model for collaboration across the continuum of care." Professional Case Management **13**(4):220-7.

Tippet, A.W. (2009). "Reducing the incidence of pressure ulcers in nursing home residents: a prospective 6-year evaluation." Ostomy Wound Management **55**(11):52-8.

HEALTH PROFESSIONAL EDUCATION

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations	
Educational interventions							
(Cox, Roche et al., 2011)	Pre/post-test study **comparing didactic learning to computer-based learning for retention of PU knowledge**	A convenience sample of staff nurses (RN) in a teaching hospital in USA (n=60, n=32 were in ICU) Characteristics: • 57% aged > 40 years • 95% sample female • 53% White, 35% Asian/Pacific • 68% highest degree was Bachelor's , 20% had a diploma • 28% had less than 6 years' experience and 55% had greater than 10 years' experience • 75% preferred a lecture learning environment • 52% reported being visual learners • 82% reported being unaware of PU clinical guidelines • 37% had most recent PU knowledge > 4 years ago	Participants were randomly assigned to: • traditional class teaching: 1 hour long sessions presented by a wound ostomy nurse using oral presentation and slides. Sessions had defined learning objectives. Sessions were run over a two week period to allow all staff to attend (n=20) • computer based learning: self-learning module developed by the wound ostomy nurse based on the same learning objectives as the class room teaching and containing the same slides. Nurses had two weeks to do the module. (n=20) • control: no education (n=20)	• Nurses were administered the Pieper Pressure Ulcer Knowledge Test (47 items) for which previous validation is reported • Measures at baseline, post-test, 3 months and 6 months	**Pre-test knowledge** • No significant difference in three groups at pre-test knowledge measure (p=0.537) **Post-test knowledge** • Significant differences between three groups from pretest to posttest (p=0.00) • Lecture group had significantly greater increase in scores than the computer group (p=0.043) **3 month knowledge** • Significant differences between three groups from posttest to 3-month test (p=0.00) • No significant difference between mean improvements for lecture versus computer groups (p=0.717) **6 month knowledge** • No significant differences for any group between 3- month and 6-month scores (p=0.405) • Study conclusions: computer-based learning is a viable learning option and has greater flexibility. Increased knowledge of PU management was sustained over 6 months, with greatest knowledge loss in the first 3 months following education.	• Hawthorne effect is a potential limitation • Self-selection may limit findings as may be a highly motivated group • Independent learning may influence findings	**Indirect evidence: no association made between knowledge and attitudes and PU outcomes**
(Tweed & Tweed, 2008)	Longitudinal repeated measures design **investigating effectiveness of an education program in improving knowledge of ICU nurses**	Participants recruited from a 12-bed ICU in a teaching hospital in New Zealand (n=62) Inclusion: all nursing staff in unit Baseline characteristics: • 27% RN2 level, 4% RN4 (most senior and 1% RN1 (most junior)	• Educations program based on the Australian Wound Management Association guidelines for prediction and prevention of PU o Delivered in small groups over 2 week period o Interactive format based on oral presentation with 112	Knowledge level at baseline, within 2 weeks of an educational program and at 20 weeks.	• Mean score at baseline (n=62) 84% • Mean score at 2 weeks (n=38) 89%, (p=0.003 versus baseline). • mean score 20 week (n=29) 85% (p=ns versus baseline) • No association between years of qualification, length of time in the ICU or self-reported additional PU education and test scores at any time point • **Study conclusions: ICU had a strong baseline knowledge of PUs and this improved for a short period after a**	• Use of 3 different tests may have accounted for differences in the scores. • Baseline tests were observed while the participant was taking the test, but not the 2 or 20 week tests • Use of nurses drawn from a single ICU • Possible that knowledge improvement only occurred in those who already had a	**Indirect evidence: no association made between knowledge and PU outcomes**

		• 39% graduated in 1990s • 55% had a nursing diploma or degree, 10% had postgraduate qualifications • Mean time in ICU 83 months • 53% no additional education on PU	slides ○ 3 hours session ○ Key areas include guideline methods, PU epidemiology, aetiology, pathophysiology, risk factors, risk assessment, staging, equipment for prevention, documentation • Knowledge test designed with input from EUPAP members using a modified Delphi technique consisting of 11 multiple choice and short answer questions piloted in a step-down unit		**structured PU education session. Improvements in knowledge were not sustained at 5 months post-education.**	high knowledge	
(Beeckman, Schoonhoven et al., 2008)	RCT **investigating the effect of a PUCLAS2 e-learning package**	Convenience sample of nursing students (n=214) and qualified nurses (n=212) from hositals, aged care, community care and a nursing school in Belgium Characteristics: • no significant difference in age (p=0.62), self-attributed expertise (p=0.82), work experience (p=0.86), wound care experience (p=0.72), work location (p=0.80) or education (p=0.98) between controls and experimental group as a whole or for nurse sub groups or for student subgroups	• Nurses and students were randomly assigned to receive either the PUCLAS2 or standard education • Experimental group received e-learning in a private computer class using PUCLAS2 • Control group received a standardized lecture using a PowerPoint that included the same content • Education for both groups was 1 hour Pressure Ulcer Classification (PUCLAS2) web education includes: • classification of PUs • differentiation between PU and moisture lesions • variations of task difficulty	• Participants classified PUs presented in digital photos • Photos had been previously validated by an expert group and had 100% agreement on PU classification • Two sets of 20 photos were alternated in the post test	**Pre-test (100% completed)** • No statistically significant difference in Interobserver reliability between experimental group and control group (35% agreement (fair) in both groups, p=0.93) **Post test one (1 month, 100% completed)** • Interobserver reliability increased compared to pretest in both groups (p=0.003) **Post test 2 (2 months, 60 to 64% completed)** • Significantly worse interobserver reliability for both groups vs first posttest (p<0.001 both groups) • Significantly better interobserver reliability vs pretest for (both groups p<0.001) **Post test 3 (3months, 57% completed)** • Significantly worse interobserver reliability for both groups vs first posttest (p<0.001 both groups) • Significantly better interobserver reliability vs pretest for (both groups p<0.001)	• Comparison between control and experimental groups is not made • Impact of self-education and work experience throughout timeframe of study is not discussed • No relationship between education and practice is explred	**Indirect evidence: no association made between knowledge and PU outcomes**

(Thomas, 2012)	pretest/post-test **investigating a focused training course for PU knowledge and documentation improvement**	Participants were a convenience sample recruited from4 units in one US long term care facility (n = 10) Characteristics: • All aged > 35 years • 7/10 had a diploma, 1 had a bachelors degree and 2 had other qualifications • 80% had >2 years' experience • 50% had >10 yeas' experience • 70% had received PU education within the preceding year	The PU education consisted of two sessions held one month apart. The sessions included evidence-based information on assessment, prevention, offloading devices, treatment options and documentation strategies. Education was delivered via PowerPoint in a 1.5 hour session.	• Knowledge assessed using 15 multiple and true/false statements. Tests administered: ○ Pre-education session 1 ○ Post education session 1 ○ Pre education session 2 ○ Post education session 2 • Audit of nursing documentation using the PUSH tool as a framework conducted: ○ Pre-education session 1 ○ 4 weeks after first education ○ 8 weeks after first education	**Pre test knowledge** • mean score 63.2 (SD 17.23) • 50 patient wounds documented **Post test 1** • mean score 80.2 (SD 8.53) • 61 patient wounds documented • documentation of wound size, exudate and tissue type improved, documentation of interventions did not improve **Pre test 2** • mean score 73.80 (SD 11.39) **Post test 2** • mean score 92.3 (SD 6.13) • Knowledge increased by 30% versus baseline • 51 patient wounds documented • documentation of wound size, exudate and tissue type improved 20% from baseline	• Smaller standard deviations indicate increase in similarity of responses that could account for the increased mean • Very small sample, unlikely to be adequately powered • Non-validated data collection tools (same test each time) • States that incidence decreased by 6.8%, but does formally report the methods and results for PU auditing	**Indirect evidence: association made between knowledge and PU outcomes is not formally measured and reported**
(Kwong, Lau et al., 2011)	pretest/post-test **investigating a focused training course for PU prevention**	Participants were recruited from a government-subsidised nursing home in Hong Kong (n=52) Inclusion/Exclusion criteria: not reported Characteristics: • Non-licensed care providers (NLCPs)(n=41) and nurses (n=11) Demographics of NLCPs: • 58.5% aged 41-50 years, 68.3% had secondary education and 4.9% had associate diploma • 36.6% had received previous PU training	The PU prevention program for nursing homes program that included training and a evidence-based prevention protocol The focused training course involved: • 2 hour lecture • 4 hours of skills training (turning, positioning, lifting, transfers, device use, skin and risk assessment • training in etiology, assessment, risk factors, risk assessment, evidence-based interventions)	• Knowledge assessment with an adapted version of the validated Pieper and Mott's knowledge test that had been translated to Chinese • Pressure ulcer rates (no description of a staging system) but all PUs reported on discovery and verified by a researcher • Data collection points: (prevalence ad incidence was measured at each point) • Before commencement (n=41, only NLCPs) • After completion of skills training (n=41) • 6 weeks post training (n=29, 71%) • 12 weeks (prevalence and incidence only)	**Knowledge and skills** • There was a significant increase in the knowledge and skills of NLCPs immediately after intervention compared with baseline ○ knowledge: χ^2=33.67, df=2, p = 001) ○ skills: (χ^2=19.517, df=2, p=0.001) • At 6 weeks, there was a significant increase in the knowledge(p<0.001) and skills (p=0.001) of NLCPs compared with baseline • Six week knowledge scores were significantly lower than those immediately after the intervention (p<0.001) **PU incidence** • baseline 2.5% • 0 to 6 weeks 2.4% • 6 to 12 weeks 0.8% **PU prevalence** • commencement of training 9% • protocol implementation 4% • 6 weeks 3.3% • 12 weeks 2.5%	• Small sample • One site • Stated that RNs and un-licensed workers were involved in training but only assessed knowledge of unlicensed workers • Unclear if matched samples were used for skill and knowledge assessments • Possible Hawthorne effect • PU rates before the intervention were unknown • Patients assessed at each time point may not have been the same	**Level of evidence: 4** **Quality: low**

Tool validation							
(Beeckman, Vanderwee et al., 2010)	Psychometric study on **development and validation of a tool for measuring attitudes to PU**	Convenience sample of nurses (n=312) and nursing students (n=296) in Belgium and Netherlands Characteristics: • Approx half the sample was aged > 35 years • More than 55% nurses had > 10 years' experience • Half the students were in first year	Development and validation of a survey tool measuring attitudes of nurses toward PUs Tool was developed based on literature review and face and content validity by 9 PU experts Final version has 26 items in 6 themes	APuP measures: • Personal competency • Priority of PU care • Impact of PU • Responsibility in PU care • Confidence	**Construct validity** Known groups technique – groups with high level of expertise had a statistically significantly higher score on APuP, as expected. **Internal consistency** Cronbach's alpha = 0.77 for overall Lowest internal consistency in 'risk assessment' (Cronbach's alpha = 0.40) Highest consistency in 'reduction of magnitude of pressure and shear' (Cronbach's alpha = 0.87) **Test-retest reliability** intraclass coefficient (ICC) = 0.88 (95% CI 0.79 to 0.93, p<0.001)	• Used known groups to test and support validation • Convenience sample that may not be representative of nurses as a group	**Indirect evidence: no association made between knowledge and PU outcomes**
(Beeckman, Defloor et al., 2010)	Psychometric study on **validation of a tool for measuring attitudes to PU**	Convenience sample of nurses (n=258) and nursing students (n=291) in Belgium Characteristics 70% aged 25 to 50 years 54% had > 10 years' experience 65% working in a hospital, 17% working in mental healthcare	Validation of a survey tool measuring attitudes of nurses toward PUs	APuP measures: • Personal competency • Priority of PU care • Impact of PU • Responsibility in PU care • Confidence	**Internal consistency** Cronbach's alpha = 0.79 **Test-retest reliability** intraclass coefficient (ICC) = 0.88 (95% CI 0.84 to 0.91, p<0.001)	• Used known groups to test and support validation • Convenience sample that may not be representative of nurses as a group	**Indirect evidence: no association made between knowledge and PU outcomes**
Studies with only two time points for data collection (no sustainability demonstrated but large sample size)							
(Magnan & Maklebust, 2008; Magnan & Maklebust, 2008; Magnan & Maklebust, 2009)	Quasi experiment **investigating the effect of web-based training on reliability of PU risk assessments**	A self-selecting cohort of registered nurses (RNs) were recruited from 2 US medical centers (n = 1391) Inclusion and exclusion: • not stated Characteristics: • Classified as either a "regular user" (1072) or "new user" (n=329) of the Braden scale based on facility policy	**RN training** • A Detroit Medical Center Braden Scale Training Module designed to train RNs to use the Braden scale correctly. • Developed by 5 WOC nurse members as part of a QI project • Delivered via a web-based platform • Included learning and testing content that	• An expert group of nurses determined decision rules and assessed patients. • 1 to 5 RNs conducted a Braden scale on the same patient within 24 hours of the expert raters assessment • Rating was conducted pre and post training intervention • Duration of study is not specified • "Reliable" was defined as	(Magnan & Maklebust, 2008; Magnan & Maklebust, 2009) • 381 Braden assessments were made (n=223 pretest; n=158 posttest) with approximately 20% of residents being assigned to each of 5 risk categories (no risk -> very high risk) in both pre and post testing. • There was no statistically significant difference between proportion of pretest and posttest that were reliable Braden scale assessments: (62% versus 65%, χ^2=0.284, df=1, p=0.594) • There was a significant increase in reliable	• Nb: There is only two data collection points, but a large sample size. • Unclear if rating was blinded to other RNs ratings • No control for nurses changing facilities • Unclear if same nurses participated in pre and post testing, or if the cohorts were equivalent for experience and previous education • No demographics of nurses	**Indirect evidence: no association made between knowledge and PU outcomes**

		• Other demographics not reported	included exemplar case studies for various patient risk levels **Braden scale assessments** A convenience sample of patient participants was recruited from 2 US medical centers (n=102) for Braden scale testing	κ≥0.549	Braden scale assessments in "new users" of the Braden scale(63% versus 84%, χ^2=8.059, df=1, p=0.005) • There was no significant increase in reliable Braden scale assessments in "regular users". (Magnan & Maklebust, 2009) • In the post-test period RN to expert agreement was highest for activity and sensory-perception subscales and lowest for moisture and nutrition subscales. (Magnan & Maklebust, 2008) • > 80% RNs achieved a pass score on case studies with no risk, high risk and very high risk patients but there was low pass for mild and moderate risk case studies	reported • No sustainability demonstrated • Unclear how long after training the post test was conducted	
Relationship of knowledge to practice							
(Claudia, Diane et al., 2010)	Descriptive correlational study **describing nurse knowledge and its relationship to practice**	A convenience sample of nurses was recruited in one university hospital in Canada (n=256) Inclusion: • Full or part time worker Exclusion criteria: • Working in emergency services, obstetrics, neonatology, pediatric or psychiatric units A randomly selected sample of patients in the units from which nurses were recruited (n=256)	No 'intervention'; this was an observational study consisting of survey of nurse demographics and PU knowledge correlated with observed behavior gathered from nurse charting.	Nurse knowledge: Adapted questionnaire based on the Pieper and Mott Pressure Ulcer Knowledge Test Chart review of patient records to identify: • Initial evaluation within 24 hours of admission • Braden scale score • Follow up of Braden Scale assessments • Application of preventative care as related to Braden score	**Knowledge** • Nurses who reported attending a 7 hour and 25 minutes continuing education session had significantly greater knowledge scores than those who had attended either a one hour training session or no additional training (p<0.0037) **Preventative care** • Despite high knowledge on prevention measures there was low performance of prevention activities • Knowledge of initial evaluation 97% but implementation was 24% • Knowledge of Braden scale score was 86% but implementation was 3% • Knowledge of support surfaces was 84% but implementation was 57% **Conclusions: despite having good to excellent knowledge of aspects of PU care, implementation of this knowledge in practice was low**	• Single site study • No interrater reliability for chart review method • No multivariate modeling used to measure the magnitude of knowledge impact on intervention performance. This lack of analysis also prevented control for other demographic characteristics. • Relied on documentation • Self-reported training	**Indirect evidence: no association made between knowledge and PU outcomes**
(Demarré, Vanderwee et al., 2012)	Observational study **exploring the relationship between**	A convenience sample of nurses (n=54) and nursing assistants (n=91) from 18 nursing home wards in Belgium	No 'intervention'; this was an observational study consisting of survey of nurse demographics and PU knowledge correlated	Nurse knowledge measured using the Pieper Pressure Ulcer Knowledge Test (PPUKT) • 26 items	**Practice** • Only 6.9% of resident at risk received fully compliant preventative care • 26.6% of residents at risk received no preventative care	• 5 nurses from each ward were used to determine the overall knowledge and attitudes of the ward. Representation of the total population is	**Indirect evidence**

	knowledge, attitudes and practice	Characteristics: • 93%sample female • 53% aged > 35 years • 60.7% received previous in-service training • 19% < 5 years' experience (higher in students 9% versus 25%) 615 nursing home residents 75% aged >80 yrs Characteristics: • 42% residents were at risk of PU according to Braden scale • > category I prevalence 6.7% • category I prevalence 14%	with observed behavior gathered from nurse charting.	• content validity 0.78 to 1.00 Nurse attitudes to PU care measured using the Attitude towards Pressure Ulcers (APuP) tool • 13 items • internal consistency reliability 0.79 • intrarater reliability 0.88 Observational environment survey conducted in nursing homes to determine adequacy of PU prevention for each resident. 2 observers for each resident and care checked against EPUAP guidelines	• PU prevention was worse for sitting out of bed (54.8% non-compliance) than when in bed (24.7% non-compliance) **Knowledge** • Mean score was 28.9% • Highest knowledge was risk assessment (57.9%) and lowest was in nutrition (9%) • No significant difference between nurses and nursing attendants (29.3% vs 28.7%, p=0.73) **Attitudes** • Mean attitude score 74.5% • Nurses had significantly higher scores than nursing assistants (78.3% vs 72.3%, p<0.001) • No significant correlation between knowledge and attitudes (p=0.84) • Knowledge was not a significant predictor of full compliance in practice • Attitude was a significant independent predictor of full compliance (p=0.015) •	unknown.	
Background information only – studies should be excluded as they have no intervention, but can be used in background							
(Smith & Waugh, 2009)	Descriptive study **investigating professional knowledge of PU**	Convenience sample of nurses in a range of US health facilities (n=96)	No intervention – knowledge survey	Pieper Pressure Ulcer Knowledge Test (PPUKT)	• Nurses who had self-reported exposure to pressure ulcer education scored significantly better	• Self-selecting sample group may favor those with more knowledge and/or confidence	**N/A**
(Chianca, Rezende et al., 2010)	Descriptive study **investigating professional knowledge of PU**	Convenience sample of nurses in one hospital in Brazil (n=106)	No intervention – knowledge survey	Pieper Pressure Ulcer Knowledge Test (PPUKT)	• Participants had greater knowledge of prevention versus assessment (mean score 79% versus 57.4%) • Recent graduates scored significantly better than nurses with longer experience (p = 0.033)	• Self-selecting sample group may favor those with more knowledge and/or confidence • Limited to one facility	**N/A**
(Iranmanesh, Rafiei et al., 2011)	Descriptive study **investigating professional knowledge of PU**	Convenience sample of critical care nurses in 5 hospitals in Iran(n=126) Characteristics: • 88.1% female, 11.9% male	No intervention – knowledge survey	Translated version of Pieper Pressure Ulcer Knowledge Test (PPUKT)	• Approximately 54.36% of questions answered correctly • Nurses scored highest on categorization/staging questions • No association between years of experience and test result • No association between knowledge of	• Self-selecting sample group may favor those with more knowledge and/or confidence	**N/A**

		• mean age 30.23 (SD 5.97) • mean years' experience 6.07 (SD 5.29)			pressure ulcers and test result		
(El Enein & Zaghloul, 2011)	Descriptive study **investigating professional knowledge of PU**	Convenience sample of nurses in one hospital in Egypt (n=122) Sample characteristics • Most nurses had less than five years' experience in nursing and had received no additional training in pressure ulcer prevention.	No intervention – knowledge survey	Questionnaire developed using Delphi technique	• Mean score (63% ± 8.6%) considered to be poor result	• Self-selecting sample group may favor those with more knowledge and/or confidence • Limited to one facility • Non-validated measurement tool	**N/A**
(Aydin & Karadağ, 2010)	Descriptive study **investigating professional knowledge of PU**	Convenience sample of nurses in 3 health facilities in Turkey (n=237)	No intervention – knowledge survey	Questionnaire developed by the researchers	• Nurses who had a Bachelor's or Masters degree scored significantly better (p=0.004) Nurses who attended post-graduation PU prevention and management training scored significantly better (p=0.012). • No association between years' experience and knowledge levels	• Self-selecting sample group may favor those with more knowledge and/or confidence • Non-validated measurement tool	**N/A**
(Zulkowski, Ayello et al., 2010)	Descriptive study **investigating professional knowledge of PU**	Convenience sample of nurses in health facilities in US (n=460)	No intervention – knowledge survey	Pieper Pressure Ulcer Knowledge Test (PPUKT)	• Nurses with wound certification scored significantly better on the test than those who did not (89% versus 76.5%, p< 0.0) • Nurses with wound certification were more likely to report attended lectures, read journal articles, sought internet information and read recent PU clinical practice guidelines	• Self-selecting sample group may favor those with more knowledge and/or confidence	**N/A**
(Gupta, Loong et al., 2012)	Descriptive study **investigating professional knowledge of PU**	Convenience sample of nurses (n=39) and registrars (n=13) working in two SCI units in Australia Characteristics: • Rehabilitation registrars had either 6 months experience (n=6)or no experience (n=7) in SCI • The majority of nurses in both units had > 10 years experience	No intervention – knowledge survey	24-item questionnaire developed by the researchers	• No significant difference in overall scores between doctors and nurses (mean 12.54 vs 12.33, p>0.05) • Nurses with > 10 years' experience had highest scores (mean 12.15) but there was no significant difference (p>0.05) • No significant difference between areas of work (both SCI areas) for prevention knowledge(p>0.05), one unit better results on management knowledge (p<0.001) • Registrars scored better in prevention questions than in management questions	• Self-selecting sample group may favor those with more knowledge and/or confidence • Non-validated measurement tool	**N/A**
(Miyazaki, Caliri et al., 2010)	Descriptive study **investigating professional knowledge of PU**	Convenience sample of nurses (n=136)and auxiliaries (n=250) recruited in an aged care hospital in Brazil. Characteristics:	No intervention – knowledge survey	Pieper Pressure Ulcer Knowledge Test (PPUKT)	• Mean scores for nurses was 79.4% (SD8.3%) • Mean score for auxiliaries was 73.6% (SD 9.8%) • Scores for auxiliaries decreased with time since previous education (p = 0.009) and with time working in the hospital (p=0.049)	• Self-selecting sample group may favor those with more knowledge and/or confidence	**N/A**

		65% nursing auxiliaries, 35% BSN nurses mean age approx. 38 years 63% had between 5 and 15 years of experience 30% had worked in the hospital less than 5 years			• No significant difference for nurses based on time since education or time in the hospital		

References

Aydin, A., A. Karadağ. (2010). "Assessment of nurses' knowledge and practice in prevention and management of deep tissue injury and stage I pressure ulcer." Journal of Wound, Ostomy, and Continence Nursing **37**(5): 487-94.

Beeckman, D., T. Defloor, L. Demarre, A. Van Hecke, K. Vanderwee. (2010). "Pressure ulcers: development and psychometric evaluation of the Attitude towards Pressure ulcer Prevention instrument (APuP)." International Journal of Nursing Studies **47**(11): 1432-41.

Beeckman, D., L. Schoonhoven, H. Boucque, G. Van Maele, T. Defloor. (2008). "Pressure ulcers: e-learning to improve classification by nurses and nursing students." Journal of Clinical Nursing **17**(13): 1697-707.

Beeckman, D., K. Vanderwee, L. Demarre, L. Paquay, A. Van Hecke, T. Defloor. (2010). "Pressure ulcer prevention: development and psychometric validation of a knowledge assessment instrument." International Journal of Nursing Studies **47**(4): 399-410.

Chianca, T., J. Rezende, E. Borges, V. Nogueira, M. Caliri. (2010). "Pressure ulcer knowledge among nurses in a Brazilian university hospital." Ostomy Wound Management **56**(10): 58-64.

Claudia, G., M. Diane, S.-G. Daphney, D. DaniÃ¨le. (2010). "Prevention and treatment of pressure ulcers in a university hospital centre: A correlational study examining nurses' knowledge and best practice." International Journal of Nursing Practice **16**(2): 183-7.

Cox, J., S. Roche, E. Van Wynen. (2011). "The effects of various instructional methods on retention of knowledge about pressure ulcers among critical care and medical-surgical nurses." Journal of Continuing Education in Nursing **42**(2): 71-8.

Demarré, L., K. Vanderwee, T. Defloor, S. Verhaeghe, L. Schoonhoven, D. Beeckman. (2012). "Pressure ulcers: knowledge and attitude of nurses and nursing assistants in Belgian nursing homes." Journal of Clinical Nursing **21**(9/10): 1425-34.

El Enein, N. Y. A., A. A. Zaghloul. (2011). "Nurses' knowledge of prevention and management of pressure ulcer at a health insurance hospital in Alexandria." International Journal of Nursing Practice **17**(3): 262-8.

Gupta, N., B. Loong, G. Leong. (2012). "Comparing and contrasting knowledge of pressure ulcer assessment, prevention and management in people with spinal cord injury among nursing staff working in two metropolitan spinal units and rehabilitation medicine training specialists in a three-way comparison." Spinal Cord **50**(2): 159-64.

Iranmanesh, S., H. Rafiei, G. Foroogh Ameri. (2011). "Critical care nurses' knowledge about pressure ulcer in southeast of Iran." International Wound Journal **8**(5): 459-64.

Kwong, E., A. Lau, R. Lee, R. Kwan. (2011). "A pressure ulcer prevention programme specially designed for nursing homes: does it work?" Journal of Clinical Nursing **20**(19/20): 2777-86.

Magnan, M. A., J. Maklebust. (2008). "The effect of Web-based Braden Scale training on the reliability and precision of Braden Scale pressure ulcer risk assessments." Journal of Wound, Ostomy and Continence Nursing **35**(2): 199.

Magnan, M. A., J. Maklebust. (2008). "Multisite Web-based training in using the Braden Scale to predict pressure sore risk." Advances In Skin & Wound Care **21**(3): 124-33.

Magnan, M. A., J. Maklebust. (2009). "The effect of Web-based Braden Scale training on the reliability of Braden Subscale ratings." Journal of Wound, Ostomy and Continence Nursing **36**(1): 51-9.

Miyazaki, M., M. Caliri, C. Santos. (2010). "Knowledge on Pressure Ulcer Prevention Among Nursing Professionals." Rev Latino-Am Enfermagem **18**(6): 1203-11.

Smith, D., S. Waugh. (2009). "Research study: an assessment of registered nurses' knowledge of pressure ulcers prevention and treatment." Kansas Nurse **84**(1): 3-5.

Thomas, A. (2012). "Assessment of nursing knowledge and wound documentation following a pressure ulcer educational program in a long-term care facility: a capstone project. ." Wound Practice and Research **20**(3): 142-55.

Tweed, C., M. Tweed. (2008). "Intensive care nurses' knowledge of pressure ulcers: development of an assessment tool and effect of an educational program." American Journal of Critical Care **17**(4): 338.

Zulkowski, K., E. A. Ayello, S. Wexler. (2010). "Certification and education: do they affect pressure ulcer knowledge in nursing?" Journal of Nursing Administration **40**(10 Suppl): S28-S32.

PATIENT CONSUMERS AND THEIR CAREGIVERS

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
Health related quality of life							
(Degenholtz, Rosen et al., 2008)	Cross-sectional and Longitudinal study	Participants recruited two non-profit nursing homes in USA in a 4 year quality-improvement study. • A nursing home n=145 • B nursing home in=139 995 residents approached over 5 study waves. Completed surveys from approx. 62% of the resident population of the two facilities (n=624 surveys; n=307 unique residents) Inclusion: • ≥65 years of age • spoke English • not in a coma or completely uncommunicative Exclude: • unable to respond comprehensibly to six consecutive questions Characteristics: • mean age 85.09±7.16 • 73.62% sample was female • 14.01% sample was black • mean length of stay in facility was 5.81±6.88 mths • 15.64% of sample had a PU stage I to IV	Resident interviews During the period of the study, no interventions were implemented that had the specific goal of modifying or improving resident QOL.	Dependent Variable : • Resident self-reported QOL in 11 dimensions (comfort, functional competence, relationships, privacy, dignity, autonomy, meaningful activity, security, individuality, spirituality, food enjoyment) measured on a previously validated scale. Independent Variables : • PUs identified as ≥one PU stage II or higher as identified on the minimum data set (MDS) • depressive symptoms • physical disability • use of physical restraints • pain Longitudinal multivariate analysis conducted for residents who completed ≥ two interviews	**Longitudinal multivariate analysis (n=140)** • Having ≥one PU stage II or higher for two-consecutive 6-month periods was associated with significant declines in three domains of QOL: o autonomy (p=0.047), o security (p=not reported), and o spiritual well-being (p=not reported). • Having depressive symptoms was the only other independent variable besides PUs that was associated with decline on 3 or more QOL domains (comfort, meaningful activities, and food enjoyment) • Residents who recovered from a PU stage II or higher maintained a statistically significant decline in functional competence (p=0.003) after their recovery. • **Study conclusions: the study found evidence that for older nursing home residents, stage II or greater PUs lasting greater than 6 months are associated with decline in self-reported autonomy, security and spiritual wellbeing and recovery for a stage II or greater PU is associated with a decline in self-reported functional competence**.	• Observed association does not imply causation • Study did not investigate potential ways to address decline in QOL associated with PU • The sample was drawn from only two nursing homes and only residents without significant cognitive impairment, limiting the generalizability of the results.	**Level of evidence: N/A Quality of evidence: moderate**
(Gorecki, Lamping et al., 2010)	Prospective mixed methods study with emphasis on qualitative	Purposive sampling to include adults of varying age, settings, PU severity, location, clinical specialty, and experience with different treatments in Northern England and Ireland (n=30)	• Single interviews conducted at the patient's home or clinical setting lasting a mean of 42 minutes.	Data analysis using both inductive and deductive processes.	• Four domains were identified: symptoms, physical functioning, psychological well-being, and social functioning. • Symptoms: pain and discomfort were commonly reported as interrupting sleep and daily activity. Exudate and odour	• Limited to English-speaking British nationals • Researcher identified power of study, attrition rates, design flaws, reliability & validity	**Level of evidence: 5 Quality of evidence: high**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
	research **Investigating HRQOL**	Exclusion: • patients with no PU • PU healed in last 3 months • unconscious, confused, cognitively impaired • unable to speak English Characteristics: • Mean age 62yrs, range 22 to 94 yrs • 56% of sample was male. • 19 participants had other chronic health problems including SCI and MS. • 15 had severe PU, 12 had superficial PU. 13 had > one PU • PU duration ranged from 1 month to 9 years • 17 in hospital or community, 13 in community settings	• 10% of interviews and transcripts reviewed by a second researcher for quality assurance.		were identified as interfering with daily life, intimacy and closeness and contributing to self-imposed isolation, emotional distress, self-consciousness. • Physical functioning: 4 sub-domains of daily activity, mobility, general malaise and sleep were identified. PUs were reported to have negative impact on physical functioning. • Psychological well-being: participants reported negative psychological well-being that categorised as mood, anxiety and worry, self-efficacy and dependence, appearance and self-consciousness. • Social functioning was reported as being disrupted or limited and participants reported feeling isolated, lonely and left out. • No major differences could be attributed by age, gender, PU severity or location. • **Study conclusions: for English-speaking patients of all age and PU severity, the impact of PU on HRQOL can be conceived as having an influence in 4 major domain: symptoms, physical functioning, psychological well-being, and social functioning**		
(Essex, Clark et al., 2009)	Multicenter cohort study **exploring impact of health related quality of life (HRQOL) of PU**	Multicenter study in the UK (n=218 participants with PU and n=2,289 without PU) Inclusion: • age ≥16 years • able to give consent Characteristics: • Participants with PU were significantly older than those without (mean age 75.8±13 versus 64.3±17.9, p<0.001) • Statistically significant differences in co-morbidities with PU participants more likely to have diabetes, PVD, cancer	This study comprised of 2 parts: • A multi center study investigated HRQOL using the Short Form -36 (SF-36) analysed data collected in 4 UK hospitals between 1996 to 1998 with recruitment stratified by specialty • A followup pilot study conducted in one UK district hospital in 2007	HRQOL tools: • SF-36 includes 8 dimensions – physical functioning, social functioning, role limitations (physical), role limitations (emotional), mental health, vitality and pain. Physical component summary (PCS) score summarizes physical dimensions of SF-36 Mental component summary (MCS) summarizes mental dimensions of SF-36 • EQ-D • pain VAS	**Multi center cohort study** • PCS score adjusted for age, gender and comorbidities was significantly lower for having a PU (coefficient –3.12, 95% CI –4.79 to –1.44, p<0.001) • PCS score adjusted only for age and gender was significantly lower for having a PU (coefficient –4.05, 95% CI –5.75 to –2.35, p<0.001) • MCS score adjusted for age, gender and comorbidities was significantly lower for having a PU (coefficient –1.50, 95% CI –2.94 to –0.05, p=0.04) • MCS score adjusted only for age and gender was significantly lower for having a PU (coefficient –1.88, 95% CI –3.31 to –0.44, p<0.001)	• Small sample size impeded control for comorbities • Accuracy of information on comorbities in both studies relied on the completeness of the medical records available • Potential participants with severe co-morbidities were less likely to consent, and many of these people had PU	**Level of evidence: 3 Quality of evidence: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		and orthopaedic or neurological diagnoses and people with PU more likely to have CVD or no comorbidity Pilot study in UK (n=6 participants with PU and n=16 without PU) Inclusion: • age ≥16 years • able to give consent able to take part interview Characteristics: • People with PU had a significantly higher consent rate to participate (80% versus 35%) • No significant difference in age, mean age approx. 80 years • Participants with PUs had PU stage II or higher	included a survey with structured interview using SF-36, EQ-5 D and pain VAS to investigate HRQOL		**Pilot study** • SF-36 scores indicated that patients with PU had significant poorer physical functioning (mean score difference 22.3, 95% CI 10.6 to 34.0, p<0.001), and role limitations due to physical problems (mean score difference 12.9, 95% CI 2.83 to 23.0, p=0.02) • No significant differences in PCS or MCS • EQ-5D showed a trend for participants with PU to have a lower score (mean difference 0.29, 95% CI –0.04 to 0.62, p=0.08). • Pain scores on the EQ-5D VAS were significantly worse for participants with PU (p=0.02) , but this was not supported by the validated pain VAS (p=0.06) • **Study conclusions: PU has a significant negative impact on both physical and mental dimensions of HRQOL above and beyond that related to comorbid conditions for older hospitalized adults**		
(Thein, Gomes et al., 2010)	Retrospective population-based study **exploring impact of HRQOL of PU**	Participants recruited from 89 LTC homes in USA (n=16 531) Inclusion: • full MDS assessment between 2004 and 2007 • Aged > 75 years Characteristics: • 9% of participants had at least one Stage II PU or higher. • No significant difference in age, length of stay, marital status between participants with and without a PU • Significantly more participants with PU than those without PU were males (34% versus 30%, p=0.001) • Participants with PU had a significantly lower BMI than those without PU (21.7±3.3	• Records analysis of MDS scores from 2004 to 2007. • If any participant had > 1 MDS completed in timeframe, one was randomly selected. • Initial data was collected by trained assessors with majority including participation from patient (68%) and some including family participation (27%).	• Minimum Data Set-Health Status Index (MDS-HIS) was derived from mapping MDS scores for cognition, self-care, mobility, sensation (vision, hearing, and speech), emotion, and pain onto the Canadian Health Utilities Index 2 (HUI2). • The MDS-HIS score was used to calculate a cardinal index of HRQOL range of –0.02 to 1.0 (with –0.02 being 'worse than dead', 0 being 'dead' and 1 being 'best possible health'). A difference of 0.03 is clinically significant. • Participants were categorized as having a PU if they have ≥PU stage II or greater (classification scale not reported)	• Factors associated with having a low MDS-HIS were having a PU, older age, being female, recent hip fracture, multiple comorbidities, changes in health, end stage disease, clinical depression, psychotropic medication and use of restraints. • Participants with a PU had significantly lower MDS-HIS than those without a PU (0.26±0.13 versus 0.36±0.17, p=0.001) • Multivariate analysis found PU to be a significant factor in lower MDS-HIS scores for participants with PU (coefficient –0.022±0.004, p<0.001) • **Study conclusions: Having a PU of stage II or greater was associated with lower HRQOL for adults in long term care, although this effect was contributed to by a range of comorbidities also associated with decreased HRQOL.**	• Limited assessment of changes in HRQOL over time • Scores may not be generalizable • Minimal knowledge about the LTC setting environments • Significant differences between participants with and without PU for factors known to impact on HRQOL including cognition, physical dependence and restraint use. • Predictors of study could only account for 38% of variability in LTC residents and were unable to adjust for facility or socioeconomic factors	**Level of evidence: N/A Quality of evidence: high**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		versus 22.7±2.8, p<0.001) • Participants with PU were more likely to need total assistance with ADLs (67% versus 34%, p<0.001) • Participants with PU were more likely to have severe cognitive impairment (38% versus 26%, p<0.001) • Participants with PU were significantly more likely to have incontinence, reduced mobility requiring turning, polypharmacy and regular use of restraint (all p<0.001).					
(Yarkin, Tamer et al., 2009)	Qualitative study **investigating the psychiatric and QOL of participants (and their caregivers) with PU**	The study included successive participants (n=20, n=17 included) scheduled for PU surgery in Turkey between 2006 and 2008 and their caregivers (n=20, n=18 included) Excluded: • Progressive depression Characteristics: • 15/17 participants were paraplegic and 2/17 were quadriplegic • 18 (15 sacral, 3 trochanteric) deep PUs with exposed bone and muscle • All participants had flap surgery, during follow-up 5 participants had recurrent PU	Subjects followed psychiatrically and surgically over 6 months to measure depression, anxiety, and QOL post-surgical repair PU	• Beck Depression Inventory (BDI) (highest score is 63, scores > 18 indicate depression) • Trait Anxiety Inventory (TAI) (increasing score indicates increasing anxiety) • SF-36 includes 8 dimensions – physical functioning, social functioning, role limitations (physical), role limitations (emotional), mental health, vitality and pain. SF-36 scores were compared to the national average.	• Participant group had mean BDI score indicative of clinical depression preoperatively, and experienced a significant worsening of depression at 6 months (17.9±5.99 versus 10.8±5.50, p<0.05) • Participant group had mean preoperative TAI score indicating mild anxiety that had significantly reduced by 6 months postoperative (44.4±10.81 versus 29.2±5.79, p<0.01) • Participant group had SF-36 scores significantly worse than the national average preoperatively for all domains (p<0.05 for all domains) • Participant group had SF-36 scores significantly worse than the national average postoperatively for all domains (p<0.05) except physical role limitations. Values on all domains increased over 6 months (unclear if this was significant) suggesting that surgery for PU is related to improvements in QOL. • Caregivers had preoperative values for social function (p<0.05), mental health (p<0.05) and emotional role limitations (p<0.05) that were significantly worse than the national average. • Caregivers had postoperative values for	• Small sample size and generalizability to other populations and countries is limited. • Data was self-reported. • No comorbidity, demographics or information regarding social settings • Incorrect reporting (e.g. Beck depression scale scoring is reported incorrectly) • Discussion is not related to the research findings (e.g. discusses influence of age on adaptation but age of participants is not reported) • No statistical comparison of pre and post values. Both are compared to national average only.	**Level of evidence: 5 Quality of evidence: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
					social function (p<0.05) and mental health (p<0.05) that were significantly worse than the national average. • **Study conclusions: people with PU requiring surgical intervention and their caregivers have QOL ratings significantly worse than the national average. Whilst these values improve within 6 months of surgery but are still below the national average.**		
(Galhardo, Magalhaes et al., 2010)	Cross-sectional study **to evaluate HRQOL and depression of older community dwelling individuals with PU**	Participants were outpatients at health centers in Brazil from 2005 to 2006 (n=42) Inclusion: • Aged ≥ 60 years • No cognitive impairment • Living in the community Characteristics: • Study and control groups similar for age, co-morbidities, income and BMI. • Mean age of participants was 76 to 79 years • Approx. 31% of study group had immobility related to CVA and approx. 24% related to femoral fracture. • 21 participants in study group had total 36 PUs . 50% were stage II PUs, most commonly of the sacrum • Most common comorbidity was diabetes	Participants were visited in their home and interviewed. Analyzed in two groups: • PU present (n=21) • No PU present (n=21)	PU measurement: • PU presence confirmed by examination • PU classification according to NPUAP staging system HRQOL measurement: • SF-36 includes 8 dimensions – physical functioning, social functioning, role limitations (physical), role limitations (emotional), mental health, vitality and pain. • Geriatric Depression Scale (GDS-15) cut off point of ≥ 6 to identify possible case of depression	• Participants with PU had significantly lower HRQOL scores than those without PU in all SF-36 domains (p ranged from <0.0001 to 0.014) • Participants with PU had the lowest SF-36 scores for physical functioning physical role limitations and emotional role limitation (p<0.0001 versus those without PU for all). • 71.4% of participants with PU rated their current health status as slightly worse or much worse that 12 months before, versus 38% of those without PU. • 80.9% of participants with PU had light or severe depression versus 19.1% of those without PU. • There was no direct relationship between degree of depression on GDS-15 and number or severity of PU • **Study conclusions: Older adults with PUs living in the community have high rates of depression and lower scores on measurements of HRQOL than those who do not have PU, despite having similar co-morbidities.**	• Small sample size • People with cognitive impairments were excluded • Participants were described as having low educational and income levels	**Level of evidence: 3 Quality of evidence: moderate**
Coping, knowledge and social burden							
(Gorecki, Nixon et al., 2012)	Qualitative study	Participants recruited from hospital and community settings in England and Northern Ireland (n=30) Inclusion: • A purposive sampling method considering age, PU severity,	Face-to-face semi structured interviews: Participants described how PU affected their lives by recounting specific relevant events.	• Events (participant reported issues) were sorted into categories and the data framework analyzed to produce a taxonomy of contributing factors affecting pressure ulcer-related HRQL .	• Identification of 16 contributory factors presented thematically in two topics: experience of care and individual patient factors • Experience of care factors included: ○ adherence versus non-adherence to treatment,	• Limited to a population with PU • Further areas of research were identified	**Level of evidence: 5 Quality of evidence: high**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		health setting, clinical specialty and experience with different PU treatments was used to reflect the range and diversity of the PU population Exclusion: • not having a PU within preceding 3 months • unconscious • confused • cognitively impaired • unable to speak English.		• Interrelationships between factors based on views of adults with pressure ulcers • Interrater reliability established the extent of agreement between two independent raters.	○ hospitalization, ○ inconsistencies, ○ time spent on wound care, ○ satisfaction versus treatment burden • Individual patients factors included: ○ coping, ○ motivation, ○ health seeking behaviours, ○ partner involvement, ○ preoccupation with PU, ○ beliefs about causation, ○ knowledge, ○ support, financial, and ○ comorbidity. • These factors all contribute to PU-related HRQOL as well as interact with each other, resulting in a complex interaction between HRQOL and contributory factors. • **Study conclusions: Adults with PUs have concerns about treatment and wound management, treatment burden, communication difficulties, ability to cope with functional limitations, poor support networks, and other health problems and co-morbidities**		
(Dunn, Carlson et al., 2009)	Qualitative cross-case secondary analysis	Case profiles from a previous qualitative study conducted in a US rehabilitation center were analyzed (n=19) Inclusion: • Included in the parent study (n=20) • Community dwelling adults with SCI • Personal profiles selected with adequate information about one or more responses to a low-grade ulcer Exclusion: • Did not develop a PU (n=1)	• Re-analysis of previous original research to establish differences and similarities in experiences of people with PU • Initial data collected through participant observation and interviews.	• Researchers analyzed previous data and identified responses to stage I or II PUs • Responses were categorized according to types and confirmed by 2 researchers • One randomly selected PU event for each participant was analyzed in-depth to enhance vigor	• Eight themes of response to PU stages I to II identified within the 46 events ○ Lacking adequate knowledge: overlooking a PU or underestimating danger ○ Procrastinating: delaying action on the basis of emotion, negating consciously ○ Experiencing cognitive dysfunction ○ Diverting attention: attending to comorbidities, desiring activity, attending to external exigencies ○ Avoiding social discomfort ○ Being thwarted from receiving adequate medical help ○ Relying on self or caregiver help ○ Adhering to medical	• Ethnically diverse group whose demographics may have skewed results (but demographics not reported) • Based on self-report and recall of events, memory lapses or misrepresentation of history may limit findings • Methodology could have allowed researchers to categorize differently • No opportunity to pursue follow-up for more complete responses	

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		Characteristics: • There were 46 PU events reported by 19 participants. • 19 participants had SCI and 1 had transverse myelitis • Described as "ethnically diverse" • No demographic characteristics e.g. age, gender, co-morbidities, duration of disease, duration of PU was reported			recommendations • **Study conclusions: rehabilitation professionals need to provide education about early PU detection and recognition, potential severity of PU and the importance of early treatment. Patients with PU need to support to effectively self-advocate for proper medical care and to balance preventative measures with lifestyle concerns. Wound care clinics and consumer support groups can serve as valuable ongoing community-based resources.**		
Hospital length of stay							
(Allen, 2013)	Pre/post quasi experimental design investigating the **effect of a comprehensive multi-disciplinary nutritional protocol on PU healing in adults over 60 years**	Participants were recruited from an acute long term care USA hospital, retrospective control group from record analysis (n=100) Inclusion: • Aged ≥60 yrs • Stage II or II PU Exclusion: • Medical conditions prohibiting vitamin, zinc or iron intake Characteristics: • 28% had stage II PUs and 72% had stage III PUs, primarily sacrum and coccyx • Mean age79.42±9 yrs • Mean BWAT 32±8.1 (range 16 to 52, p=ns between groups) • No co-morbidity reported	• Control group received standard care (diet according to physician orders) and were matched for experiment group participants on age, gender, PU stage, Braden scale(all data collected from record analysis, n=50) • Experimental group (n=50) received a comprehensive nutritional protocol that included: ○ Admission and weekly albumin/pre-albumin levels to determine level of nutritional support ○ OT, dietitian, speech therapist review	• Length of stay • PU risk assessed using Braden scale • PU wound healing using Bates-Jensen Wound Assessment Tool with a PU considered to be resolved when 100% granulation tissue and at least 75% reduction in size.	• There was significant differences between groups for length of hospital stay, with the experimental group having a significantly shorter hospital stay (mean stay 30.9±12 days versus 43.2±31.7 days, p=reported to be significant) • The experimental group had a significantly lower number of days in hospital related to PU care (mean PU days 18±5.27 days versus 25.2±5.6 days, p=reported to be significant) • There was a significant difference between groups in tissue health by week 2 (38% versus 2%, p<0.005) and in week 3 (37% versus 23.4%, p<0.05) but no significant differences in weeks 4 and 5 • **Study conclusions: a multidisciplinary nutritional intervention that includes protein and vitamin/mineral supplementation was associated with significantly shorter hospital length of stay for older adults and may contribute to increased PU healing (assessed as % tissue regeneration) .**	• No co-morbidities that may influence nutrition or healing are reported • Drop outs were not considered in the analysis and were not equivalent between groups • Relied on chart reviews for control group • No blinding of assessor and used a subjective Likert-scale wound assessment tool	**Level of evidence: 4 Quality of evidence: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
			○ Protein supplement for all people with PU and increased protein supplementation for those with moderate or severe malnutrition ○ Vitamin A, Z, zinc, iron supplementation Experimental group received intervention until discharge or PU had a 75% reduction in size.				
Patient education							
(Hartigan, Murphy et al., 2012)	A quasi-experimental case series with pre-test, post-test	Consecutive sample of community dwelling older adults attending an assessment/treatment clinic in Ireland (n=75 commenced study , n=59 completed study) Inclusion criteria: • aged ≥65 years • living in own home • referred to the centre following discharge from acute or rehabilitation hospitals • at risk of PU based on the NICE guidelines Exclusion criteria: • no informed consent • Mental test score < 7/10 Characteristics: • mean age 79.9±6.5yrs • 64% of sample was female • 92% scored 10/10 on mental test	• Patient education leaflet on preventing PU based on 2009 EPUAP/NPUAP guideline that was reviewed by experts for content and readability. The leaflet scored 5.5 on the Flesch–Kincaid Grade Level indicating the text was appropriate to a reading age of an 8–10 year old. • Participants were given one week to read the leaflet • NB: copy of leaflet is included with this reference.	**Knowledge levels** • Patients knowledge tested pre and post receiving the leaflet • Knowledge test was administered by a nurse data collector • Questionnaire was reviewed by experts and pretested for readability and ability to understand • Questionnaire consisted of 10 open ended questions and 1 multiple choice question **PU risk** Assessed by nurse data collector	**PU risk** • 7% had experienced a previous PU • 59% of participants were identified as being at low risk, 38% at medium risk and 3% at high risk of PU. **Knowledge** • In pre-test, 32% did not know what a PU was, this decreased to 9% at post-test (p=not reported) • Prior to receiving the leaflet, 77% (n=43) of participants could identify what might cause a PU versus 89% (n=50) post-test (p=not reported) • The post-test survey identified that the majority of patients could identify possible anatomical body areas where a pressure ulcer would be most likely to occur. (p=not reported) • Participants exhibited improvements in knowledge for all questions. • **Study conclusions: the PU prevention education leaflet was associated with improved knowledge of PU in older community dwelling adults at risk of**	• No statistical tests were applied to compare pre and post test results. • Only 11 questions asked, recall bias may have been present • Demographics of participants e.g. education levels were not reported	**Level of evidence: 5 Quality of evidence: moderate**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
					PU.		
(Thietje, Giese et al., 2011)	Prospective cohort study investigating acquisition of knowledge of SCI patients about SCI-complications	Consecutive admissions to a German hospital between 2005 and 2008 of patients with a traumatic or non-traumatic SCI (n=214 completed knowledge tests) Inclusion: • aged ≥18 years • patient's first admission to hospital • minimum duration of admission of 3 months Exclusion: • incomplete database record • severe cognitive impairment • cranio-cerebral injury or malignancies with short life expectancy Characteristics: • All patients discharged 3 to 6 months following admission • Approximately 4% participants were 18 to 20years, 24% were aged 20 to 34 years, 28% were aged 35 to 49 years, 27% were aged 50 to 64 and 17% aged over 65 years.	Development of knowledge about PUs and bladder management in SCI patients throughout a first hospital admission of 3 to 6 months duration for SCI	Functional ability • Ability to perform everyday tasks and overall impact of disability measured using SCIM-II (validated tool)consisting of scales for self-care, respiration and sphincter management and mobility. Knowledge of SCI-related topics • Knowledge tested using Knowledge Boberg Score (un-validated tool) including PUs and bladder management. • Knowledge was classified as poor, average or good based on KBS score. Outcome measures at admission, 1 and 3 months post-admission, and after discharge at 6, 18, and 30 months	• Participants had an initial poor level of knowledge (KBS) and functional ability (SCIM-II score) in every day care that showed significant ($p<0.001$) improvement by discharge. **Knowledge** • At discharge 22.4% participants had poor knowledge, 30.4% had average knowledge and 47.2% had good knowledge of SCI-related topics. • Mean total KBS increased from 5.44 to 11.24 at discharge ($p<0.001$). However, after 30 months mean score decreased to 10.8. • Patients aged ≥65 years achieved lower knowledge scores by discharge compared with younger patients ($p<0.001$). **Functional ability** • Mean total SCIM-II score increased from 26.84 on admission to 58.32 at discharge ($p<0.001$) and continued to improve, peaking at 66.65 after 18 months. **Information sources** • Participants identified rehabilitation physician as an important source of information most often (77.6% identified at discharge, 68.5% identified at 30 months). • At discharge other important information sources were physiotherapist (66.5%), in-hospital SCI course (48.4%), nurse (47%), general practitioner or other physician (44.6%), other patients (28.9%) family (23.8%). • At 30 months, general practitioner or other physician (55.3%) and the internet (39%) had higher ratings than prior to discharge. • Support groups and friends were not important sources for information either before or after discharge. • **Study conclusions: While in hospital, SCI**	• Knowledge score has not validated • Education levels were not reported • Content of information courses is not reported therefore replicability is limited • Personal factors may be involved in the relative importance of different health professionals as an information source	**Level of evidence: 3 Quality of evidence: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
					patients improve their knowledge of PU prevention and increase their ability to self-care. Knowledge declines somewhat after discharge. Health professionals are a primary source of information before and after discharge. An inpatient SCI course is considered important by just under half of patients with SCI. Support groups are not considered important for information, however other individual patients are valued during an admission. The internet is used as a primary source of information by almost 40% of participants after discharge.		
(Brace and Schubart, 2010)	Case series pre-post test design	Participants recruited from two sites, a trauma hospital and an outpatient rehabilitation Center in the USA. (n=27 met inclusion, n=16 completed study) Inclusion: • SCI at any level • aged ≥18 years and of any ethnic group • with our without current PU or PU history • medically stable • transferred to an acute rehabilitation facility Exclusion: • non-English speaking • medically unstable Characteristics: • Mean age 49 yrs, minimum 23 yrs • Time since PU injury ranged from 3.5 weeks to 27 years • 63% of sample were male • 42% had completed high school, 47% had education to a higher level • 52.6% Caucasian, 42.1% African	E-learning program on PU prevention and management in adults (see also Schubart, 2012)	• Pre-and post-test assessment using 20 multiple choice questions addressing the primary focus of the E-learning program. The questionnaire was validated in a population of 12 nurses.	• Median pre-test score was 65% (range 25% to 100%). Median post test score was 92.5% (range 75% to 100%) • 15/16 participants achieved improved scores on post-test compared to pre-test. • PU staging questions were more frequently answered incorrectly. • **Study conclusions: an E-learning program is associated with increased knowledge regarding PU staging, prevention and support services in patients with SCI.**	• Sample size small • No statistical analysis so unclear if the findings are significant • Broad ethnic and age groups selected but no analysis to indicate if the program was equally effective for all demographics. • Sample had a high education level at commencement with almost 50% having attended tertiary or greater education.	**Level of evidence: 5 Quality of evidence: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
		American • 57.9% had a current PU • 47.4% had experienced a previous PU					
(Schubart, 2012)	Case series	Participants recruited from an outpatient rehabilitation Center in the USA. (n=15, n=14 completed) Inclusion: • SCI at any level • aged ≥18 years • ability to access the Internet Exclusion: • non-English speaking • medically unstable Characteristics: • Median age 37 years • 66% of sample were male • Median 72 months since injury (range 6 to 360) • Primarily Caucasian • About 50% had high school education and 50% had higher level of education • 20% had a current PU and 27% had ever had a PU	• E-learning program on PU prevention and management in adults (also pilot - tested in earlier study Brace 2010) • Program allowed participants to complete the learning package in multiple sittings over a two week timeframe.	• Assessment of the e-learning program was made using three validated tools containing Likert scales. ○ Internet Evaluation and Utility Questionnaire includes ease of use, convenience, engagement, enjoyment, layout, privacy, satisfaction and acceptability. ○ Internet Impact and Effectiveness Questionnaire includes usefulness, comprehension, credibility, likelihood of returning, mode of delivery and helpfulness. ○ Internet Adherence Questionnaire includes barriers to program use. • Assessment of effectiveness of program was made using Needs Assessment Checklist, a non-validated structured tool to assess self-perceived knowledge and self-perceived care ability • Assessments was made via phone interview	• The program scored very favourably on all items related to potential access barriers and favourably for items related to utility, impact and effectiveness. • The median score for pre-program knowledge and skin care management practice was 96 (possible score: 0 to 120; range 70–100). Post-program use median score was 107 (range 97–114). • The greatest improvement was in the responses to knowledge and practice questions about skin checks and preventing skin problems ($p<0.005$). • **Study conclusions: People with an SCI who have at least high school level education rated an e-learning package highly with respect to utility, impact and effectiveness and perceived that their knowledge had increased after using it; however, there was no objective assessment conducted that may support this perception.**	• Small sample size from limited ethnic background • Questions assess perceived knowledge and their perceived ability to perform preventive actions. No real insight in the objective knowledge or practice of the participants	**Level of evidence: 5 Quality of evidence: low**
(Schubart, Hilgart et al., 2008)	Qualitative study using needs assessment methodology **to explore education needs on PU for SCI**	Purposive sampling to recruit participants from a US rehabilitation (n=16 SCI individuals) Inclusion: • SCI • Would provide an 'information rich cases'	• An initial review of an evidence-based guideline was used to determine recommended PU prevention education needs. • Participants completed an	• Thematic analysis using NVivo software.	Four themes identified: • **Perception of risk**: awareness of P risk was varied. People who considered themselves at risk had usually experienced a PU in the past. Those who had not experienced a PU considered themselves at low risk and practiced less preventative actions. • **PU education:** previous education was	Unclear how the guideline were used or how interviews were synthesised into themes and recommendations. Recommendations seemed contrary to some information in the interviews (e.g. fear)	**Level of evidence: 5 Quality of evidence: low**

Reference	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and Comments	
	patients	Characteristics: • Aged 20 to 59 years with wide spread • Primarily Caucasian, 2 African Americans • Most had been injured more than 10 years • 50% had experienced several PU, 37.5% had never experienced a PU	interview and a survey regarding what they considered their education needs were and their feelings about PU prevention.		limited to initial post-injury care period. Education Fear-oriented for older patients. Opportunity for further education generally limited to time when PU requiring care. Participants preferred face-to-face education from another SCI patient or a health professional and less frequently, the Internet. Some participants believed that education is delivered too early, when they were in shock or denial, and this was ineffective. • Environmental considerations: home and available equipment influenced ability to implement PU prevention. Family members also need education. • Access to appropriate care: limited access to after acute care and frustration dealing with health systems and insurance. From the data education needs were prioritised as: • SCI learners and their caregivers need to be aware that SCI poses lifelong risk for developing PU. • SCI learners need to take charge of their own skin care regimen and to feel empowered to partner with their health care providers. • SCI learners need PU prevention strategies that fit with their level of functioning and activity and can be consistently maintained and updated as risk changes. • SCI learners need strategies for coordinating social supports for both family and paid caregiving situations.	Small sample, although saturation was reached. May not be generalizable to other countries.	

References

Allen, B. (2013). "Effects of a comprehensive nutritional program on pressure ulcer healing, length of hospital stay, and charges to patients." Clinical Nursing Research **22**(2):186-205.

Brace, J.A. and J.R. Schubart. (2010). "A prospective evaluation of a pressure ulcer prevention and management e-learning program for adults with spinal cord injury." Ostomy Wound Management **56**(8):40-50.

Degenholtz, H., J. Rosen, N. Castle, et al. (2008). "The association between changes in health status and nursing home resident quality of life." The Gerontologist **48**(5):584-.

Dunn, C.A., M. Carlson, J.M. Jackson, et al. (2009). "Response factors surrounding progression of pressure ulcers in community-residing adults with spinal cord injury." American Journal of Occupational Therapy **63**(3):301-9.

Essex, H.N., M. Clark, J. Sims, et al. (2009). "Health-related quality of life in hospital inpatients with pressure ulceration: assessment using generic health-related quality of life measures." Wound Repair and Regeneration: Official Publication of the Wound Healing Society [and] the European Tissue Repair Society **17**(6):797-805.

Galhardo, V.A.C., M.G. Magalhaes, L. Blanes, et al. (2010). "Health-related quality of life and depression in older patients with pressure ulcers." Wounds: A Compendium of Clinical Research & Practice **22**(1):20-6.

Gorecki, C., D.L. Lamping, J.M. Brown, et al. (2010). "Development of a conceptual framework of health-related quality of life in pressure ulcers: a patient-focused approach." International Journal of Nursing Studies **47**(12):1525-34.

Gorecki, C., J. Nixon, A. Madill, et al. (2012). "What influences the impact of pressure ulcers on health-related quality of life? A qualitative patient-focused exploration of contributory factors." Journal of Tissue Viability **21**(1):3-12.

Hartigan, I., S. Murphy and M. Hickey. (2012). "Older adults' knowledge of pressure ulcer prevention: a prospective quasi-experimental study." International Journal Of Older People Nursing **7**(3):208-18.

Schubart, J. (2012). "An e-learning program to prevent pressure ulcers in adults with spinal cord injury: a pre- and post- pilot test among rehabilitation patients following discharge to home." Ostomy/Wound Management **58**(10):38-49.

Schubart, J.R., M. Hilgart and C. Lyder. (2008). "Pressure ulcer prevention and management in spinal cord-injured adults: analysis of educational needs." Advances in Skin & Wound Care **21**(7):322-9.

Thein, H.-H., T. Gomes, M.D. Krahn, et al. (2010). "Health status utilities and the impact of pressure ulcers in long-term care residents in Ontario." Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation **19**(1):81-9.

Thietje, R., R. Giese, M. Pouw, et al. (2011). "How does knowledge about spinal cord injury-related complications develop in subjects with spinal cord injury? A descriptive analysis in 214 patients." Spinal Cord **49**(1):43-8.

Yarkin, O., S. Tamer, O. Gamze, et al. (2009). "Effect of surgery on psychiatric states and quality of life of paraplegics and quadriplegics with pressure sores and their primary caregivers." European Journal of Plastic Surgery **32**(4):173-6.

Prevention and Treatment of Pressure Ulcers:

Technical Documents:

Critical AppraisalTables

EUROPEAN PRESSURE ULCER ADVISORY PANEL

NATIONAL PRESSURE ULCER ADVISORY PANEL

PAN PACIFIC Pressure Injury Alliance

2014

INTRODUCTION

This document reports the critical appraisals used in the development of the second edition of the International Pressure Ulcer Guideline (see citation below). The full development process is outlined in the *Methodology Addendum*, available at the guideline website. An abridged version of the methodology is published as an appendix in the *Clinical Practice Guideline*.

The Small Working Groups (SWGs) involved in the guideline development were responsible for reviewing potential literature for inclusion in the section of the guideline addressing the SWG area of interest; conducting critical appraisal on studies meeting the inclusion criteria; and summarizing relevant material from the studies in data extraction tables (see *Technical Documents: Data Extraction*). The tables presented within this document support the recommendations and evidence summaries presented in the *Clinical Practice Guideline.* **Users should not rely on data extraction tables alone.**

Printed copies of the English version of the *Clinical Practice Guideline* are available through links provided on the following websites:

NPUAP website:	www.npuap.org
EPUAP website:	www.epuap.org
Australian Wound Management Association (AWMA) website:	www.awma.com.au
Hong Kong Enterostomal Therapist Society website:	www.etnurse.com.hk
New Zealand Wound Care Society (NZWCS) website:	www.nzwcs.org.nz
Wound Healing Society Singapore website:	www.woundhealingsociety.org.sg
International Pressure Ulcer Guideline website:	www.internationalguideline.com

A *Quick Reference Guide* version that contains excerpts from the *Clinical Practice Guideline* is also available. The quick reference guide is intended for busy health professionals who require a quick reference in caring for individuals in the clinical setting. **Users should not rely on excerpts from the *Quick Reference Guide* alone.**

Guideline Citation:
National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline. Emily Haesler (Ed.). Cambridge Media: Osborne Park, Western Australia; 2014.

Appraisal of Methodological Quality

The methodological quality of each study was evaluated by two members of the SWGs. Where large discrepancy of opinion was noted (such that the paper's overall quality was rated differently by the two reviewers), a third reviewer evaluated the paper. The methodologist completed a quality check on a random sample of 80% of the critical appraisals for papers selected for potential appraisal, including those papers that the SWG assessed as not meeting inclusion criteria.

The methodological quality of each study was assessed by two reviewers using methodology checklists that were based on tools developed by the Scottish Intercollegiate Guidelines Network.[4] Evaluation of study quality focused on the internal and external validity of the studies. The following quality criteria was considered: internal validity of the study; clear and appropriate research question(s); selection of subjects; allocation; baseline comparability; outcomes; blinding; confounding factors; statistical analysis; overall assessment of the study; and bias.

A range of critical appraisal tools (reported in the *Methodology Addendum* available at the guideline

website) were used based on different types of study design :

- Cross-sectional/survey/prevalence studies.
- Case-control studies.
- Cohort studies.
- RCTs.
- Quasi-experimental studies.
- Diagnostic studies.
- SQUIRE guideline checklist for quality improvement papers.
- Critical Appraisal Skills Program (CASP) Qualitative Research Checklist.
- AMSTAR criteria for systematic reviews.

Each criteria on the critical appraisal forms was assessed as being fully met (++), partially met (+), not met/not reported/unclear (—), or not applicable (NA). Studies were generally described as high, moderate, or low quality using the following general criteria:

- High quality studies: fully met at least 80% of applicable criteria
- Moderate quality studies: partially or fully met at least 70% of applicable criteria
- Low quality studies: did not partially or fully met at least 70% of applicable criteria

Full description of the appraisal process is available in the *Methodology Addendum* available at the guideline website.

Table of Contents

Background

PREVALENCE AND INCIDENCE OF PRESSURE ULCERS

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number. invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Quality
(Dugaret, Videau et al., 2012 (epub))	++	N/A	N/A	++	++	++	N/A	N/A	++	++	yes	high
	++	N/A	N/A	++	++	++	N/A	N/A	++	++		
(Gunningberg, Donaldson et al., 2012)	++	N/A	N/A	++	++	++	N/A	N/A	++	++	yes	high
	++	N/A	N/A	++	++	++	N/A	N/A	++	++		
(Gunningberg, Hommel et al., 2013)	++	N/A	N/A	++	++	++	N/A	N/A	++	++	yes	high
	++	N/A	N/A	++	++	++	N/A	N/A	++	++		
(Gunningberg, Stotts et al., 2011)	++	N/A	N/A	++	++	++	N/A	N/A	++	++	yes	high
	++	N/A	N/A	++	++	++	N/A	N/A	++	++		
(Tsai, Lin et al., 2012)	++	++	+	++	++	++	+	+	+	++	yes	moderate
	++	++	+	++	++	++	+	N/A	+	++		
(Barba, Martínez et al., 2011)	++	+	+	+	+	+	+	+	+	+	yes	low
	++	+	+	+	+	+	+	+	+	+		
(Scarlatti, Michel et al., 2011)	++	++	++	++	++	++	++	+	++	++	yes	high
	++	++	++	++	++	++	++	+	++	++		
(Sato and Ichioka, 2012)	++	++	++	++	++	+	++	++	++	++	yes	high
	++	++	++	++	++	+	++	++	++	++		
(Bry, Buescher et al., 2012)	++	++	++	++	+	++	++	++	++	++	yes	moderate
	++	++	++	+	+	+	++	++	++	++		

Author/year	Focussed question	Sampling method	Representative sample	States number. invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Quality
(Bulfone, Marzolil et al., 2012)	++	++	++	++	++	++	N/A	++	++	++	yes	high
	++	++	++	++	++	++	N/A	++	++	++		
(Igarashi, Yamamoto-Mitani et al., 2013)	+	+	—	++	+	—	N/A	+	+	+	yes	low
	+	+	—	+	+	—	—	+	+	+		
(Inan and Öztunç, 2012)	+	+	—	++	+	—	N/A	—	+	+	yes	low
	+	+	+	+	+	+	N/A	—	+	+		
(Molon and Estrella, 2011)	++	—	—	++	—	—	N/A	—	+	+	yes	low
	++	—	—	++	+	+	N/A	—	—	—		
(Moore and Cowman, 2012)	++	++	++	++	++	+	++	+	+	++	yes	moderate
	++	++	+	—	++	+	—	+	+	++		
(Mulligan, Prentice et al., 2011)	++	++	++	++	+	++	+	++	++	++	yes	high

CASE CONTROL STUDIES

Author/year	Focussed question	Comparable source populations	Same exclusion cases and controls	Per cent drop out in study arms is reported	Comparison btw participants and non-participants	Cases clearly defined	Established that controls are non-cases	Knowledge of primary exposure not influence case ascertainment	Valid, reliable assessment of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Quality
(Ploumis, Kolli et al., 2011)	++	+	+	+	+	++	++	N/A	++	++	—	++	+	yes	moderate
	++	++	+	+	+	++	++	++	++	++	—	++	+		

References

Barba, R., J.M. Martínez, A. Zapatero, et al. (2011). "Mortality and complications in very old patients (90+) admitted to departments of internal medicine in Spain." European Journal of Internal Medicine **22**(1):49-52.

Bry, K.E., D. Buescher and M. Sandrik. (2012). "Never say never: a descriptive study of hospital-acquired pressure ulcers in a hospital setting." Journal of Wound, Ostomy and Continence Nursing **39**(3):274-81.

Bulfone, G., I. Marzolil, R. Wuattrin, et al. (2012). "A longitudinal study of the incidence of pressure sores and the associated risks and strategies adopted in Italian operating theatres." Journal of Perioperative Practice **22**(2):50-6.

Dugaret, E., M.N. Videau, I. Faure, et al. (2012 (epub)). "Prevalence and incidence rates of pressure ulcers in an Emergency Department." International Wound Journal.

Gunningberg, L., N. Donaldson, C. Aydin, et al. (2012). "Exploring variation in pressure ulcer prevalence in Sweden and the USA: Benchmarking in action." Journal of Evaluation in Clinical Practice **18**(4):904-10.

Gunningberg, L., A. Hommel, C. Bååth, et al. (2013). "The first national pressure ulcer prevalence survey in county council and municipality settings in Sweden." Journal of Evaluation in Clinical Practice **19**(5):862-7.

Gunningberg, L., N.A. Stotts and E. Idvall. (2011). "Hospital-acquired pressure ulcers in two Swedish County Councils: cross-sectional data as the foundation for future quality improvement." International Wound Journal **8**(5):465-73.

Igarashi, A., N. Yamamoto-Mitani, Y. Gushiken, et al. (2013). "Prevalence and incidence of pressure ulcers in Japanese long-term-care hospitals." Archives of Gerontology and Geriatrics **56**(1):220-6.

Inan, D. and G. Öztunç. (2012). "Pressure ulcer prevalence in Turkey: A sample from a university hospital." Journal of Wound, Ostomy and Continence Nursing **39**(4):409-13.

Molon, J.N.D. and E.P. Estrella. (2011). "Pressure ulcer incidence and risk factors among hospitalized orthopedic patients: Results of a prospective cohort study." Ostomy Wound Management **57**(10):64-9.

Moore, Z. and S. Cowman. (2012). "Pressure ulcer prevalence and prevention practices in care of the older person in the Republic of Ireland." Journal of Clinical Nursing **21**(3-4):362-71.

Mulligan, S., J. Prentice and L. Scott. WoundsWest Wound Prevalence Survey 2011 State-wide Overview Report. Perth, Western Australia: Ambulatory Care Services, Department of Health 2011.

Ploumis, A., S. Kolli, M. Patrick, et al. (2011). "Length of stay and medical stability for spinal cord-injured patients on admission to an inpatient rehabilitation hospital: a comparison between a model SCI trauma center and non-SCI trauma center." Spinal Cord: The Official Journal Of The International Medical Society Of Paraplegia **49**(3):411-5.

Sato, T. and S. Ichioka. (2012). "Pressure ulcer occurrence following the great East Japan earthquake: observations from a disaster medical assistance team." Ostomy Wound Management **58**(4):70-5.

Scarlatti, K.C., J.L.M. Michel, M.A. Gamba, et al. (2011). "[Pressure ulcers in surgery patients: incidence and associated factors]." Revista da Escola de Enfermagem da U S P **45**(6):1372-9.

Tsai, Y.-C., S.-Y. Lin, Y. Liu, et al. (2012). "Factors related to the development of pressure ulcers among new recipients of home care services in Taiwan: A questionnaire study." International Journal of Nursing Studies **49**(11):1383-90.

Prevention of Pressure Ulcers

RISK FACTORS

Author/year	Baseline sample adequately described	Study attrition (<20% lost to follow-up)	Clear definition of risk factors	Were continuous variables used/ appropriate cut-point	RF measure/method valid and reliable	*Adequate % sample with complete data	Method/setting of measurement same for all	Appropriate imputation method	Appropriate classification for outcome	Potential confounders accounted in study design	Potential confounders accounted in analysis	Data adequate to assess adequacy of analysis	Appropriate strategy for model building	Model adequate for design	Adequate sample size	No selective reporting	Limitation category	Limitation notes
(Almirall, Leiva et al., 2009)	Y	Y	Y	no	Y	100 %	Y	NA	y	No	No	Y	no	Y	no	Y	Very low	Insufficient number of events No confounders Inadequate strategy for model
(Baumgarten, Rich et al., 2012)	y	y	y	unk	y	72%	y	NA	y	y	y	no	y	y	no	y	low	Insufficient number of events
(Bergquist-Beringer & Gajewski, 2011)	y	y	y	NA	no	y	y	NA	y	y	y	y	y	y	no	no	low	Insufficient number of events
(Chan, Pang et al., 2009)	y	y	y	y	y	unk	y	NA	y	y	y	y	y	y	no	no	low	Insufficient number of events
(Connor, Sledge et al., 2010)	y	y	y	y	y	unk	y	NA	y	partial	partial	partial	y	y	no	no	low	Insufficient number of events
(Cremasco, Wenzel et al., 2013)	y	y	y	y	partial	unk	y	NA	y	partial	partial	y	y	y	no	no	low	Insufficient number of events
(de Souza & de Gouveia, 2010)	partial	y	y	Unk/NR	y	unk	y	NA	y	y	y	y	y	y	no	y	low	Insufficient number of events Not presented data for MV model, only significant factors
(Kwong, Pang et al., 2009)	y	y	y	NA	y	y	y	NA	y	y	y	y	y	y	no	no	low	Insufficient number of events
(Man & Au-Yeung, 2013)	y	y	y	unk	y	unk	y	NA	y	y	y	y	y	y	no	no	low	Insufficient number of events
(Manzano, Navarro et al., 2010)	y	y	y	unk	y	unk	y	NA	y	y	y	y	no	y	no	y	Very low	Insufficient number of events Time dependent co-variates used

(Roca-Biosca, Velasco-Guillen et al., 2012)	Y	Y	Y	unclear	Y	no	Y	NA	y	unclear	Y	no	unclear	no	Y	Y	Very low	Insufficient number of events Not adequate strategy for model
(Slowikowski & Funk, 2010)	y	y	y	unk	Not clear	y	y	NA	y	y	y	y	y	y	y	no	High	
(Tescher, Branda et al., 2012)	y	y	y	no	no	y	y	NA	y	y	y	y	y	y	y	no	high	
(Tschannen, Bates et al., 2012)	y	y	y	y	no	y	y	NA	y	partial	partial	y	partial	y	y	no	moderate	Not adequate strategy for model (conceptual model)
(Webster, Coleman et al., 2011)	y	y	y	y	y	y	y	NA	y	y	y	y	y	y	no	no	low	Insufficient number of events

*If not specifically, reported the % of sample with complete data an “unk” was indicated

References

Almirall, S., R. Leiva, P. Gabasa. (2009). "Apache III Score: A prognostic factor in pressure ulcer development in an intensive care unit." Enferm Intensiva **20**(3): 95-103.

Baumgarten, M., S. Rich, M. Shardell, W. Hawkes, D. Margolis, P. Langenberg, et al. (2012). "Care-related risk factors for hospital-acquired pressure ulcers in elderly adults with hip fracture." Journal of the American Geriatrics Society **60**(2): 277-83.

Bergquist-Beringer, S., B. J. Gajewski. (2011). "Outcome and assessment information set data that predict pressure ulcer development in older adult home health patients." Advances in Skin & Wound Care **24**(9): 404-14.

Chan, W., S. Pang, E. Kwong. (2009). "Assessing predictive validity of the modified Braden scale for prediction of pressure ulcer risk of orthopaedic patients in an acute care setting." Journal of Clinical Nursing **18**(11): 1565-73.

Connor, T., J. A. Sledge, L. Bryant-Wiersema, L. Stamm, P. Potter. (2010). "Identification of pre-operative and intra-operative variables predictive of pressure ulcer development in patients undergoing urologic surgical procedures." Urologic Nursing **30**(5): 289-305.

Cremasco, M., F. Wenzel, S. Zanei, I. Whitaker. (2013). "Pressure ulcers in the intensive care unit: the relationship between nursing workload, illness severity and pressure ulcer risk." Journal of Clinical Nursing **22**: 2183-91. Epub 2012.

de Souza, D., S. V. de Gouveia. (2010). "Incidence of pressure ulcers in the institutionalized elderly." Journal of Wound, Ostomy, and Continence Nursing **37**(3): 272-6.

Kwong, E. W.-y., S. M.-c. Pang, G. H. Aboo, S. S.-m. Law. (2009). "Pressure ulcer development in older residents in nursing homes: influencing factors." Journal Of Advanced Nursing **65**(12): 2608-20.

Man, S., T. Au-Yeung. (2013). "Hypotension is a risk factor for new pressure u lcer occurrence in older patients after admission to an acute hospital." J Am Med Dir Assoc.

Manzano, F., M. J. Navarro, D. Roldán, M. A. Moral, I. Leyva, C. Guerrero, et al. (2010). "Pressure ulcer incidence and risk factors in ventilated intensive care patients." Journal of Critical Care **25**(3): 469-76.

Roca-Biosca, A., M. Velasco-Guillen, L. Rubio-Rico, N. García-Grau, L. Anguera-Saperas. (2012). "[Pressure ulcers in the critical patient: detection of risk factors]." Enferm Intensiva **23**(4): 155-63.

Slowikowski, G., M. Funk. (2010). "Factors associated with pressure ulcers in patients in a surgical intensive care unit." Journal of Wound, Ostomy and Continence Nursing **37**(6): 619-26.

Tescher, A. N., M. E. Branda, T. J. Byrne, J. M. Naessens. (2012). "All At-Risk Patients Are Not Created Equal: Analysis of Braden Pressure Ulcer Risk Scores to Identify Specific Risks." Journal of Wound, Ostomy and Continence Nursing **39**(3): 282-91. Epub 2012/05/04.

Tschannen, D., O. Bates, A. Talsma, Y. Guo. (2012). "Patient-specific and surgical characteristics in the development of pressure ulcers." American Journal of Critical Care **21**(2): 116-26.

Webster, J., K. Coleman, A. Mudge, L. Marquart, G. Gardner, M. Stankiewicz, et al. (2011). "Pressure ulcers: effectiveness of risk-assessment tools. A randomised controlled trial (the ULCER trial)." British Medical Journal Quality & Safety **20**(4): 297-306.

RISK ASSESSMENT

CROSS SECTIONAL - RELIABILITY STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number invited participants	Valid reliable outcome measurement	Were the raters blind reported or discussed	Number paired assessments reported	Minimal bias	Quality
(Suriadi, Sanada et al., 2008)	—	—	—	—	++	—	—	—	Question about validity, not reliability (sub-study)
(Bååth, Hall-Lord et al., 2008)	++	++	—	—	++	++	++	++	
(Fossum, Olle Söderhamn et al., 2012)	—	—	—	—	++	++	++	+	
(Webster, Coleman et al., 2011)	—	—	—	NA	1	++	—	—	Question about validity, not reliability (sub-study) Used case studies; Assumed raters blind; Multiple use of same case study
(Kottner & Dassen, 2008)	++	++	++	++	++	++	++	++	
(Kottner & Dassen, 2010)	++	—	—	—	++	++	++	++	Not enough detail to assess sampling method (not detailed how many participants approached)
(Kottner, Halfens et al., 2009)	++	++	++	++	++	++	++	++	
(Rogenski & Kurcgant, 2012)	++	—	—	—	++	—	—	—	Not reliability (sub-study)
(Simão, Caliri et al., 2013)	+	+	+	—	++	—	+	—	Not detailed how many participants approached Researcher and ward staff appear to be blinded but this is not specified

COHORT STUDIES – Validity studies

Author/year	Focussed question	States number invited	Per cent drop out in study arms is reported	Likelihood of outcome at enrolment considered (i.e. PU baseline)	Likelihood of outcome at enrolment considered in analysis	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Measure of assessment of exposure reliable	Comprehensive analytical tests (sens, spec, AUC, PPV, NPV, LR)	Context usual care reported or discussed	Risk assessment tool directed care	Minimal bias	Reliable conclusions	Relevant to guideline population	Quality
(de Souza, Santos et al., 2010)	—	—	—	—	—	NA	+	—	++	++	+	++	+	yes	yes	No participant flowchart; Analysis strong Nursing care not directed by risk score
(Suriadi, Sanada et al., 2008)	++	—	—	++	NA	NA	++	NR	++	++	NR	NR	+	yes	yes	Excluded pts if couldn't assess skin and post-enrolement if LOS was <72hrs (selection bias) Not described standard care Not reported how ward staff assessed risk or whether blind to SS scale
(Serpa & et al., 2011)	++	—	+	++	NA	—	++	—	++	++	—	—	+	yes	yes	Only included pts with Braden ≤18 Staff not blind to risk score At-risk pts flagged to nursing staff Small sample size (n=72; n=7 dev. PU)
(Chan, Pang et al., 2009)	++	NR	—	++	NA	NA	++	+	++	+	—	++	+	yes	yes	Not reported aim Researcher unblindbut ward staff blind to scores Not described what normal care is
(Eun-Kyung, 2009)	++	NR	—	++	NA	NA	++	—	++	++	++	++	+	yes	yes	Researchers not blind to score
(Kumari, Sharma et al., 2012)	++	+	—	++	NA	NA	++	+	++	++	—	++	++	yes	yes	Excluded pts with baseline PU Inter-assessor blinding; assuming ward staff were blind to scores

RANDOMIZED CONTROLLED TRIALS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	A priori sample size	Was the analysis appropriate?	Minimal bias	Reliable conclusions	Relevant to guideline population	Quality
(Webster, Coleman et al., 2011)	++	++	++	++	++	++	++	++	++	NA	+	—	++	yes	yes	Included pts with and without PUs at baseline; Inappropriate analysis; Incidence lower than sample size; not considered power; Not discussed contamination bw groups
(Saleh, Anthony et al., 2009)	—	—	+	—	—	—	++	+	—	NA	—	—	—	no	yes	No a priori sample size; No randomisation procedure; Analysis methods limited; Sample size small; Differential sample sizes in groups

DIAGNOSTIC STUDIES – Validity studies

Author/year	Nature of test clearly defined	Test compared with gold standard	If no gold standard exists, a validated reference standard is used as comparator.	Patients for testing selected as consecutive series or randomly, from a clearly defined study population.	Test and gold standard measured independently (blind) of each other	Test and gold standard applied as close together in time as possible	Results reported for all patients that entered study	A pre-test diagnosis is made and reported	Reliable conclusions	Is the spectrum of patients assessed in this study comparable with the patient group targeted by this guideline in terms of the proportion with the disease, or the proportion with severe versus mild disease?
(Moura De Araújo, Moura De Araújo et al., 2011)	+	NA	+	—	—	++	++	NA		++
(González-Ruiz & et al., 2008)	+	NA	—	+	—	++	++	NA		++
(Kosmidis & Koutsouki, 2008)	++	NA	++	++	—	NA	++	NA		++

References

Bååth, C., M.-L. Hall-Lord, E. Idvall, K. Wiberg-Hedman, B. Wilde Larsson. (2008). "Interrater reliability using Modified Norton Scale, Pressure Ulcer Card, Short Form-Mini Nutritional Assessment by registered and enrolled nurses in clinical practice." Journal of Clinical Nursing **17**(5): 618-26.

Chan, W., S. Pang, E. Kwong. (2009). "Assessing predictive validity of the modified Braden scale for prediction of pressure ulcer risk of orthopaedic patients in an acute care setting." Journal of Clinical Nursing **18**(11): 1565-73.

de Souza, D., V. Santos, H. Iri, M. Sadasue Oguri. (2010). "Predictive validity of the Braden Scale for Pressure Ulcer Risk in elderly residents of long-term care facilities." Geriatric Nursing **31**(2): 95-104.

Eun-Kyung, K., et al. (2009). "Comparison of the predictive validity among pressure ulcer risk assessment scales for surgical ICU patients. ." Australian Journal of Advanced Nursing **27**(4): 87-94.

Fossum, M., O. Olle Söderhamn, C. Cliffordson, U. Söderhamn. (2012). "Translation and testing of the Risk Assessment Pressure Ulcer Sore scale used among residents in Norwegian nursing homes." BMJ Open **2:e001575 doi:10.1136/bmjopen-2012-001575**.

González-Ruiz, J. M., et al. (2008). "Validity study of the current risk assessment scale of PUs in intensive care." Enferm Intensiva **19**(3): 123-31.

Kosmidis, D., S. Koutsouki. (2008). "Pressure ulcers risk assessment scales in ICU patients: validity comparison of Jackson/Cubbin (revised) and Braden scales." Nosileftiki **47**(1): 86-95.

Kottner, J., T. Dassen. (2008). "An interrater reliability study of the Braden scale in two nursing homes. ." International Journal Of Nursing Studies **45**(10): 1501-11.

Kottner, J., T. Dassen. (2010). "Pressure ulcer risk assessment in critical care: interrater reliability and validity studies of the Braden and Waterlow scales and subjective ratings in two intensive care units." International Journal of Nursing Studies **47**(6): 671-77.

Kottner, J., R. Halfens, T. Dassen. (2009). "An interrater reliability study of the assessment of pressure ulcer risk using the Braden scale and the classification of pressure ulcers in a home care setting." International Journal of Nursing Studies **46**(10): 1307-12.

Kumari, S., D. Sharma, A. Rana, R. Pathak, R. Lal, A. Kumar, et al. (2012). "Risk assessment tool for pressure ulcer development in Indian surgical wards." Indian Journal of Surgery **Dec**: 1-7.

Moura De Araújo, T. M., M. F. Moura De Araújo, C. da Silva Cavalcane, G. M. Barborsa J, J. A. Caetano. (2011). "Accuracy of two pressure ulcer risk scales for patients within critical condition." Rev enferm **19**(3): 381-5.

Rogenski, N. M. B., P. Kurcgant. (2012). "Measuring interrater reliability in application of the Braden Scale." Acta Paulista de Enfermagem **25**(1): 24-8.

Saleh, M., D. Anthony, S. Parboteeah. (2009). "The impact of pressure ulcer risk assessment on patient outcomes among hospitalised patients." Journal of Clinical Nursing **18**(13): 1923-29.

Serpa, L. F., et al. (2011). "Predictive validity of the Braden scale for pressure ulcer risk in critical care patients." Revista Latino-Americana de Enfermagem **19**(1): 50-7.

Simão, C., M,, M. Caliri, H,L, , C. Dos Santos, B. (2013). "Agreement between nurses regarding patients' risk for developing pressure ulcer." Acta Paulista de Enfermagem **26**(1): 30-5.

Suriadi, H. Sanada, J. Sugama, B. Thigpen, M. Subuh. (2008). "Development of a new risk assessment scale for predicting pressure ulcers in an intensive care unit." Nursing in Critical Care **13**(1): 34.

Webster, J., K. Coleman, A. Mudge, L. Marquart, G. Gardner, M. Stankiewicz, et al. (2011). "Pressure ulcers: effectiveness of risk-assessment tools. A randomised controlled trial (the ULCER trial)." British Medical Journal Quality & Safety **20**(4): 297-306.

SKIN AND TISSUE ASSESSMENT

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number. invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Kim, Wang et al., 2012)	++	—	—	+	++	+	N/A	—	++	+	indirect evidence: healthy volunteers		moderate
(Hagblad, Folke et al., 2012)	—	—	—	—	+	++	N/A	—	+	+	indirect evidence: healthy volunteers		low
(Hagblad, Lindberg et al., 2010)	++	—	—	—	++	++	N/A	—	+	+	indirect evidence: healthy volunteers		low
(Farid, Winkelman et al., 2012)	++	+	+	++	++	++	N/A	+	++	+	yes	4	moderate
(Sterner, Lindholm et al., 2011)	+	+	—	+	—	+	—	+	—	—	yes	3	low
	+	+	—	+	—	+	N/A	+	—	—			
(Bates-Jensen, McCreath et al., 2008)	++	+	+	++	++	++	N/A	++	++	++	yes	4	moderate
	+	—	—	++	++	++	N/A	++	+	+			
(Bates-Jensen, McCreath et al., 2009)	++	—	—	++	++	+	—	+	+	++	yes	4	moderate
	+	—	—	++	++	++	N/A	++	+	+			
(Vanderwee, Grypdonck et al., 2006)	++	++	+	++	++	++	N/A	++	+	++	yes	2	moderate

QUASI EXPERIMENTAL STUDIES

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Kottner, Dassen et al., 2009)	—	+	+	N/A	—	N/A	+	+	—	—	yes	3	low
	+	+	+	+	+	N/A	++	—	—	+			

References

Bates-Jensen, B.M., H.E. McCreath and V. Pongquan. (2009). "Subepidermal moisture is associated with early pressure ulcer damage in nursing home residents with dark skin tones: pilot findings." Journal of Wound, Ostomy, and Continence Nursing **36**(3):277-84.

Bates-Jensen, B.M., H.E. McCreath, V. Pongquan, et al. (2008). "Subepidermal moisture differentiates erythema and stage I pressure ulcers in nursing home residents." Wound Repair And Regeneration **16**(2):189-97.

Farid, K., C. Winkelman, A. Rizkala, et al. (2012). "Using temperature of pressure-related intact discolored areas of skin to detect deep tissue injury: an observational, retrospective, correlational study." Ostomy WoundManage **58**(8):20-31.

Hagblad, J., M. Folke and M. Linden. (2012). "Long term monitoring of blood flow at multiple depths - observations of changes." Studies in Health Technology and Informatics **177**:107-12.

Hagblad, J., L.G. Lindberg, A. Kaisdotter Andersson, et al. (2010). "A technique based on laser Doppler flowmetry and photoplethysmography for simultaneously monitoring blood flow at different tissue depths." Medical & Biological Engineering & Computing **48**(5):415-22.

Kim, J.T., X. Wang, C. Ho, et al. (2012). "Physiological measurements of tissue health; implications for clinical practice." Int Wound Journal **9**(6):656-64.

Kottner, J., T. Dassen and N. Lahmann. (2009). "Comparison of two skin examination methods for grade 1 pressure ulcers." Journal of Clinical Nursing **18**(17):2464-9.

Sterner, E., C. Lindholm, E. Berg, et al. (2011). "Category I pressure ulcers: how reliable is clinical assessment?" Orthopaedic Nursing **30**(3):194-205.

Vanderwee, K., M. Grypdonck, D. Bacquer, et al. (2006). "The reliability of two observation methods of nonblanchable erythema, Grade 1 pressure ulcer." Applied Nursing Research **19**:156–62.

PREVENTIVE SKIN CARE

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Pittman, Beeson et al., 2012)	++	++	++	—	+	+	+	—	—	N/A	—	+	yes	2	low
(Verdú & Soldevilla, 2012)	++	++	+	++	+	+	+	++	++	+	++	++	yes	2	moderate
	++	++	+	++	+	++	+	++	++	—	++	++			
(Houwing, van der Zwet et al., 2008)	++	—	—	++	+	+	++	++	+	—	+	+	yes	2	moderate
(Cooper & Gray, 2001)	++	++	++	—	+	++	+	++	++	—	+	++	yes	2	moderate

COHORT STUDIES

Author/year	Focussed question	Comparable source populations	States number. invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Shannon, Coombs et al., 2009)	++	++	—	—	—	N/A	N/A	—	—	++	—	—	—	+	yes	4	low

QUALITY IMPROVEMENT STUDIES

Author/year	Title/abstract is accurate	Current knowledge summarised in background	Specific project aims	Ethical aspects discussed	Sufficient reporting of intervention for replication	Reports factors contributing to intervention choice reported	Clear evaluation measures	Internal and external validity addressed	Appropriate analysis	Results report elements of the setting, change sin care processes and patient outcomes	Evidence of association between change and patient outcomes	Reports limitations	Reliable interpretation of findings	Funding sources reported	Relevant to guideline population	Level of evidence	Quality
(Shannon, Coombs et al., 2009)	++	++	+	—	—	—	—	—	+	+	—	+	+	—	yes	4	Cohort study Low quality

References

Cooper, P., D. Gray. (2001). "Comparison of two skin care regimes for incontinence." British Journal of Nursing **10**(6): S6-S20.

Houwing, R., W. van der Zwet, S. van Asbeck, R. Halfens, J. W. Arends. (2008). "An unexpected detrimental effect on the incidence of heel pressure ulcers after local 5% DMSO cream application: a randomized, double-blind study in patients at risk for pressure ulcers." Wounds: A Compendium of Clinical Research & Practice **20**(4): 84-8.

Pittman, J., T. Beeson, C. Terry, W. Kessler, L. Kirk. (2012). "Methods of bowel management in critical care." Journal of Wound Ostomy and Continence Nursing **39**(6): 633-39.

Shannon, R. J., M. Coombs, D. Chakravarthy. (2009). "Reducing hospital-acquired pressure ulcers with a silicone-based dermal nourishing emollient-associated skincare regimen." Advances in Skin & Wound Care **22**(10): 461-7.

Verdú, J., J. Soldevilla. (2012). "IPARZINE-SKR study: Randomized, double-blind clinical trial of a new topical product versus placebo to prevent pressure ulcers." International Wound Journal **9**(5): 557-65.

EMERGING THERAPIES FOR PRESSURE ULCER PREVENTION

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Janssen, de Koning et al., 2010)	+	—	—	—	++	++	+	++	++	N/A	—	—	Indirect evidence PU not an outcome		low
(Torra I Bou, Rueda López et al., 2009)	+	—	—	—	+	+	+	++	—	—	—	—	yes	2	low
	++	—	—	—	+	—	+	++	—	++	++	++			
(Santamaria, Gerdtz et al., 2013)	++	++	++	—	+	+	+	+	++	N/A	+	+	yes	2	moderate
	++	++	++	—	+	+	++	+	—	N/A	—	+			

QUASI EXPERIMENTAL STUDIES

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Coladonato, Smith et al., 2012)	++	—	+	++	++	—	++	+	+	+	yes	3	moderate
	++	—	+	++	++	—	++	+	+	+			
(Posada-Moreno, Losa Iglesias et al., 2011)	+	—	+	+	+	++	++	N/A	+	+	Indirect evidence Healthy volunteers		low
	+	—	N/A	+	+	—	—	N/A	+	—			
(Angelidis, Lidman et al., 2009)	+	—	++	+	+	++	++	N/A	—	—	Indirect evidence Healthy volunteers		low
(Smith & Ingram, 2010)	++	—	+	++	++	++	++	N/A	++	++	Indirect evidence PU not an outcome		moderate
	++	—	+	++	++	++	++	N/A	++	++			
(Källman, Bergstrand et al., 2013)	++	—	+	++	++	++	++	N/A	+	+	Indirect evidence PU not an outcome Healthy volunteers		moderate

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Weng, 2008)	++	—	++	+	+	++	++	N/A	+	+	yes	3	moderate
(Forni, Loro et al., 2011)	+	—	—	+	++	++	++	N/A	+	+	yes	4	moderate
	++	—	+	+	++	++	++	N/A	++	++			
(Brindle & Wegelin, 2012)	++	+	++	++	++	++	++	+	++	++	yes	3	moderate
	++	—	++	++	++	++	—	+	++	+			
(Jan, Liao et al., 2013)	++	N/A	++	++	++	N/A	+	N/A	++	++	Indirect evidence PU not an outcome Healthy volunteers		high

References

Angelidis, I., D. Lidman, F. Sjaberg. (2009). "Decubitus ulcer development: pressure alone increases tissue temperature." European Journal of Plastic Surgery **32**(5): 241-4.

Brindle, C. T., J. A. Wegelin. (2012). "Prophylactic dressing application to reduce pressure ulcer formation in cardiac surgery patients." Journal of Wound, Ostomy and Continence Nursing **39**(2): 133-42.

Coladonato, J., A. Smith, N. Watson, A. T. Brown, L. McNichol, A. Clegg, et al. (2012). " Prospective, Nonrandomized Controlled Trials to Compare the Effect of a Silk-Like Fabric to Standard Hospital Linens on the Rate of Hospital-acquired Pressure Ulcers." Ostomy/Wound Management **58**(10): 14-31.

Forni, C., L. Loro, M. Tremosini, S. Mini, E. Pignotti, O. Bigoni, et al. (2011). "Use of polyurethane foam inside plaster casts to prevent the onset of heel sores in the population at risk. A controlled clinical study." Journal of Clinical Nursing **20**(5/6): 675-80.

Jan, Y. K., F. Liao, L. A. Rice, J. A. Woods. (2013). "Using Reactive Hyperemia to Assess the Efficacy of Local Cooling on Reducing Sacral Skin Ischemia Under Surface Pressure in People With Spinal Cord Injury: A Preliminary Report." Arch Phys Med Rehabil.

Janssen, T., A. de Koning, K. Legemate, C. Smit. (2010). "Electrical stimulation-induced Gluteal and Hamstring muscle activation can reduce sitting pressure in individuals with a spinal cord injury, ." Assistive Technology Research Series: 332-4.

Källman, U., S. Bergstrand, A. C. Ek, M. Engström, L. G. Lindberg, M. Lindgren. (2013). "Different lying positions and their effects on tissue blood flow and skin temperature in older adult patients." Journal of Advanced Nursing **69**(1): 133-44.

Posada-Moreno, P., M. E. Losa Iglesias, R. Becerro de Bengoa Vallejo, I. O. Soriano, I. Zaragoza-García, C. Martínez-Rincón. (2011). "Influence of different bed support surface covers on skin temperature." Contemporary Nurse **39**(2): 206-20.

Santamaria, N., M. Gerdtz, S. Sage, J. McCann, A. Freeman, T. Vassiliou, et al. (2013). "A randomised controlled trial of the effectiveness of soft silicone multi-layered foam dressings in the prevention of sacral and heel pressure ulcers in trauma and critically ill patients: the border trial." Int Wound J. Epub 2013/05/29.

Smith, A., L. L. McNichol, M. A. Amos, G. Mueller, T. Griffin, J. Davis, et al. (2013). "A retrospective, nonrandomized, beforeand- after study of the effect of linens constructed of synthetic silk-like fabric on pressure ulcer incidence." Ostomy WoundManage **59**(4): 28-30, 2--4. Epub 2013/04/09.

Smith, G., A. Ingram. (2010). "Clinical and cost effectiveness evaluation of low friction and shear garments." Journal of Wound Care **19**(12): 535-42.

Torra I Bou, J. E., J. Rueda López, G. Camañes, E. Herrero Narváez, J. Blanco Blanco, J. Ballesté Torralba, et al. (2009). "Preventing pressure ulcers on the heel: a Canadian cost study." Dermatology Nursing **21**(5): 268.

Walsh, N. S., A. Blanck, L. Smith, M. Cross, L. Andersson, C. Polito. (2012). "Use of a sacral silicone border foam dressing as one component of a pressure ulcer prevention program in an intensive care unit setting." Journal of Wound, Ostomy and Continence Nursing **39**(2): 146-9.

Weng, M. (2008). "The effect of protective treatment in reducing pressure ulcers for non-invasive ventilation patients." Intensive & Critical Care Nursing: The Official Journal Of The British Association Of Critical Care Nurses **24**(5): 295-9.

Yusuf, S., M. Okuwa, Y. Shigeta, M. Dai, T. Iuchi, R. Sulaiman, et al. (2013). "Microclimate and development of pressure ulcers and superficial skin changes." International Wound Journal.

Prevention and Treatment of Pressure Ulcers

NUTRITION IN THE PREVENTION AND TREATMENT OF PRESSURE ULCERS

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number. invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Meijers, Schols et al., 2008)	++	+	+	++	+	—	++	+	+	+	yes	N/A	moderate
	++	+	+	++	+	—	++	+	+	+			
(Morello, Marcon et al., 2009)	+	+	+	+	+	—	—	—	+	+	Indirect evidence	N/A	low
	+	+	+	+	+	—	—	—	+	+			
(Verbrugghe, Beeckman et al., 2013)	+	—	—	—	++	+	—	+	+	+	yes	4	low
	+	—	—	—	++	+	—	+	+	+			
(Wojcik, Atkins et al., 2011)	+	+	—	+	+	+	N/A	—	+	++	Indirect evidence	N/A	low
	+	+	—	+	+	+	N/A	—	+	++			
(Banks, Bauer et al., 2010)	++	++	++	+	++	++	+	—	+	+	yes	N/A	moderate

CASE CONTROL

Author/year	Focussed question	Comparable source populations	Same exclusion cases and controls	Per cent drop out is reported	Comparison btw participants and non-participants	Cases clearly defined	Established that controls are non-cases	Cases and controls are from comparable populations	Knowledge of primary exposure not influence case ascertainment	Valid, reliable assessment of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to population	Level of evidence	Quality
(Iizaka, Okuwa et al., 2010)	++	++	++	++	++	++	N/A	++	N/A	—	+	++	++	+	yes	4	moderate
	++	++	++	++	++	++	N/A	++	N/A	—	+	++	+	+			

COHORT STUDIES

Author/year	Focussed question	Comparable source populations	States number. invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Yamamoto, Fujioka et al., 2009)	—	—	—	+	N/A	—	—	—	—	—	—	N	—	++	yes	N/A	low
	—	—	—	+	N/A	—	—	—	—	—	—	N	—	++			
(Arinzon, Peisakh et al., 2008)	++	+	—	++	+	—	++	—	—	+	+	—	—	++	yes	5	low
	++	+	—	++	+	—	++	—	—	+	+	—	—	++			
(Teno, Gozalo et al., 2012)	++	++	++	+	N/A	N/A	++	N/A	+	++	+	++	++	++	yes	4	moderate
	++	++	++	+	N/A	N/A	++	N/A	+	++	+	++	++	++			

QUASI EXPERIMENTAL STUDIES

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Allen, 2013)	++	N/A	—	+	+	++	++	N/A	+	+	yes	4	low
	++	N/A	—	+	+	++	++	N/A	+	+			
(Gunnarsson, Lönn et al., 2009)	++	—	+	++	++	—	++	N/A	+	+	yes	3	moderate
	++	—	++	++	++	—	++	N/A	++	+			
(Brewer, Desneves et al., 2010)	+	+	—	—	+	+	+	+	—	+	yes	5	low
	+	+	—	—	+	+	+	+	—	+			
(Chapman, Mills et al., 2011)	+	—	++	+	+	—	+	N/A	—	+	yes	5	low
	+	—	++	+	+	—	+	N/A	—	+			

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Cereda, Gini et al., 2009)	++	++	—	++	—	++	+	++	—	—	+	++	yes	2	moderate
	++	++	—	++	—	++	+	++	—	—	+	++			
(Leigh, Desneves et al., 2012)	+	++	+	++	++	+	+	+	—	N/A	—	—	yes	4	low
	+	++	+	++	++	+	+	+	—	N/A	—	—			
(Meaume, Kerihuel et al., 2009)	++	++	++	++	++	++	++	++	++	—	+	++	yes	1	high
	++	++	++	++	++	++	++	++	++	—	+	++			
(Ohura, Nakajo et al., 2011)	++	+	+	—	+	++	+	++	—	—	+	+	yes	2	moderate
	++	+	+	—	+	++	+	++	—	—	+	+			
(Stotts, Hopf et al., 2009)	++	++	++	++	++	++	++	++	+	++	++	++	yes	1	high
	++	++	++	++	++	++	++	++	+	++	++	++			
(Theilla, Schwartz et al., 2012; Theilla, Schwartz et al., 2011)	++	++	—	+	++	++	+	++	++	N/A	+	—	yes	2	moderate
	++	++	—	+	++	++	+	++	++	N/A	+	—			
(van Anholt, Sobotka et al., 2010)	++	++	++	++	++	+	++	++	++	—	+	++	yes	2	moderate
	++	++	++	++	++	+	++	++	++	—	+	++			

References

Allen, B. (2013). "Effects of a comprehensive nutritional program on pressure ulcer healing, length of hospital stay, and charges to patients." Clinical Nursing Research **22**(2):186-205.

Arinzon, Z., A. Peisakh and Y.N. Berner. (2008). "Evaluation of the benefits of enteral nutrition in long-term care elderly patients." J Am Med Dir Assoc **9**(9):657-62.

Banks, M., J. Bauer, N. Graves, et al. (2010). "Malnutrition and pressure ulcer risk in adults in Australian health care facilities." Nutrition in Clinical Practice **26**(9):896-901.

Brewer, S., K. Desneves, L. Pearce, et al. (2010). "Effect of an arginine-containing nutritional supplement on pressure ulcer healing in community spinal patients." Journal of Wound Care **19**(7):311-6.

Cereda, E., A. Gini, C. Pedrolli, et al. (2009). "Disease-specific, versus standard, nutritional support for the treatment of pressure ulcers in institutionalized older adults: a randomized controlled trial." Journal of the American Geriatrics Society **57**(8):1395-402.

Chapman, B.R., K.J. Mills, L.M. Pearce, et al. (2011). "Use of an arginine-enriched oral nutrition supplement in the healing of pressure ulcers in patients with spinal cord injuries: An observational study." Nutrition & Dietetics **68**(3):208-13.

Gunnarsson, A.-K., K. Lönn and L. Gunningberg. (2009). "Does nutritional intervention for patients with hip fractures reduce postoperative complications and improve rehabilitation?" Journal of Clinical Nursing **18**(9):1325-33.

Iizaka, S., M. Okuwa, J. Sugama, et al. (2010). "The impact of malnutrition and nutrition-related factors on the development and severity of pressure ulcers in older patients receiving home care." Clin Nutr **29**(1):47-53.

Leigh, B., K. Desneves, J. Rafferty, et al. (2012). "The effect of different doses of an arginine-containing supplement on the healing of pressure ulcers." Journal of Wound Care **21**(3):150-6.

Meaume, S., J.C. Kerihuel, T. Constans, et al. (2009). "Efficacy and safety of ornithine alpha-ketoglutarate in heel pressure ulcers in elderly patients: results of a randomized controlled trial." The Journal of Nutrition, Health & Aging **13**(7):623-30.

Meijers, J.M.M., J.M.G.A. Schols, P.A. Jackson, et al. (2008). "Differences in nutritional care in pressure ulcer patients whether or not using nutritional guidelines." Nutrition (Burbank, Los Angeles County, Calif) **24**(2):127-32.

Morello, M., M.L. Marcon, A. Laviano, et al. (2009). "Enteral nutrition in nursing home residents: a 5-year (2001-2005) epidemiological analysis." Nutrition in Clinical Practice **24**(5):635-41.

Ohura, T., T. Nakajo, S. Okada, et al. (2011). "Evaluation of effects of nutrition intervention on healing of pressure ulcers and nutritional states (randomized controlled trial)." Wound Repair & Regeneration **19**(3):330-6.

Stotts, N.A., H.W. Hopf, J. Kayser-Jones, et al. (2009). "Increased fluid intake does not augment capacity to lay down new collagen in nursing home residents at risk for pressure ulcers: a randomized, controlled clinical trial." Wound Repair and Regeneration: Official Publication of the Wound Healing Society [and] the European Tissue Repair Society **17**(6):780-8.

Teno, J., P. Gozalo, S. Mitchell, et al. (2012). "Feeding tubes and the prevention or healing of pressure ulcers. Natural history of feeding-tube use in nursing home residents with advanced dementia." Archives of Internal Medicine **172**(9):697-701.

Theilla, M., B. Schwartz, J. Cohen, et al. (2012). "Impact of a nutritional formula enriched in fish oil and micronutrients on pressure ulcers in critical care patients." American Journal of Critical Care **21**(4):e102-e9.

Theilla, M., B. Schwartz, Y. Zimra, et al. (2011). "Enteral n-3 fatty acids and micronutrients enhance percentage of positive neutrophil and lymphocyte adhesion molecules: a potential mediator of pressure ulcer healing in critically ill patients." British Journal of Nutrition:1-6.

van Anholt, R., L. Sobotka, E. Meijer, et al. (2010). "Specific nutritional support accelerates pressure ulcer healing and reduces wound care intensity in non-malnourished patients." Nutrition **26**(9):867-72.

Verbrugghe, M., D. Beeckman, A. Van Hecke, et al. (2013). "Malnutrition and associated factors in nursing home residents: A cross-sectional, multi-centre study." Clin Nutr **32**(3):438-43.

Wojcik, A., M. Atkins and D.R. Mager. (2011). "Dietary intake in clients with chronic wounds." Canadian Journal of Dietetic Practice and Research **72**(2):77-82.

Yamamoto, T., Fujioka, R. Kitamura, et al. (2009). "Evaluation of nutrition in the healing of pressure ulcers: are the EPUAP nutritional guidelines sufficient to heal wounds?." Wounds: A Compendium of Clinical Research & Practice **21**(6):153-7.

REPOSITIONING (INCLUDING HEELS) AND EARLY MOBILIZATION

COHORT STUDIES

Author/year	Focussed question	Comparable source populations	States number invited	Likelihood of outcome at enrolment	Per cent drop out in study arms is	Comparison btw drop outs and	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Rich, Margolis et al., 2011)	++	+	++	+	++	N/A	+	—	—	++	+	++	+	+	yes	3	moderate
	++	+	++	+	++	N/A	+	—	—	++	+	++	+	—			
(Dickinson, Tschannen et al., 2013)	++	+		—	++	++	++	+	—	+	++	—	+	+	yes	3	moderate

CASE SERIES

Author/year	Focussed question	Participant characteristics reported	Inclusion criteria defined	Consecutive recruitment	Participants entered at same disease	Intervention clearly reported	Outcomes relevant and defined apriori	Valid, reliable outcome measurement	Per cent drop out reported	Estimates of random variability	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Meyers, 2010)	++	—	++	—	—	++	++	+	++	—	N/A	—	—	yes	5	low
	++	—	++	—	—	++	++	+	++	—	N/A	—	—			
(Romero, Cornejo et al., 2009)	++	++	++	++	—	++	++	++	++	—	N/A	+	+	yes	5	moderate
	++	—	++	++	—	++	++	++	++	—	N/A	+	+			

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Confidence in conclusion	Relevant to guideline population	Level of evidence	Quality
(Best, Desharnais et al., 2012)	++	++	++	+	+	+	+	++	++	N/A	++	+	Indirect outcomes and healthy volunteers		moderate
	++	++	++	+	+	++	+	++	++	N/A	++	+			

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Confidence in conclusion	Relevant to guideline population	Level of evidence	Quality
(Donnelly, Winder et al., 2011)	++	++	++	+	++	+	++	++	++	N/A	++	++	yes	2	moderate
	++	++	++	+	++	+	++	++	++	N/A	++	+			
(Grisell and Place, 2008)	++	++	—	+	—	—	++	++	++	N/A	—	—	yes	2	low
	++	++	—	+	—	—	++	++	++	N/A	—	—			
(Moore, Cowman et al., 2011)	++	++	—	—	+	—	+	++	++	—	—	—	yes	2	moderate
	++	++	++	—	+	—	++	++	++	++	+	+			

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

ID	Author/year	Focussed question	Sampling method	Representative sample	States number invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Pompeo, 2013)		++	+	—	++	++	+	++	++	—	+	yes	5	moderate
		++	+	++	++	++	++	++	+	—	+			

QUASI EXPERIMENTAL STUDIES

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commence-ment	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(McMichael and Place, 2008)	++	N/A	N/A	++	—	++	++	N/A	+	—	Indirect evidence		low
	++	N/A	N/A	N/A	++	++	N/A	N/A	+	—	Healthy volunteers		
(Malkoun, Huber et al., 2012)	++	—	N/A	++	—	++	++	N/A	—	—	Indirect evidence		moderate
	++	—	N/A	++	+	++	++	N/A	+	+	Healthy volunteers		
(Bales, 2012)	++	—	—	+	+	+	+	N/A	—	—	yes	3	low
	++	—	—	—	+	++	++	N/A	—	—			

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commence-ment	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Giesbrecht, Ethans et al., 2011)	++	—	N/A	N/A	++	++	N/A	N/A	+	—	Indirect evidence PU not an outcome		moderate
	++	—	N/A	++	++	++	++	N/A	+	—			
(Källman, Bergstrand et al., 2013)	++	—	N/A	++	++	++	++	—	++	++	Indirect evidence PU not an outcome Healthy volunteers		moderate
	++	—	+	++	++	++	++	N/A	+	+			
(Smit, Haverkamp et al., 2012)	++	—	+	++	++	++	++	N/A	++	++	Indirect evidence PU not an outcome		moderate
	++	—	+	++	++	++	++	N/A	++	++			
(Still, Cross et al., 2013)	++	—	—	+	+	N/A	+	N/A	+	+	yes	5	low
(Chung, Lau et al., 2012)	++	—	N/A	++	++	++	++	N/A	++	++	Indirect evidence PU not an outcome		high

QUALITY IMPROVEMENT STUDIES

Author/year	Title/abstract is accurate	Current knowledge summarised in background	Specific project aims	Ethical aspects discussed	Sufficient reporting of intervention for replication	Reports factors contributing to intervention choice reported	Clear evaluation measures	Internal and external validity addressed	Appropriate analysis	Results report elements of the setting, change sin care processes and patient outcomes	Evidence of association between change and patient outcomes	Reports limitations	Reliable interpretation of findings	Funding sources reported	Relevant to guideline population	Level of evidence	Quality
(Knoblauch, Bettis et al., 2013)	+	++	+	—	—	—	—	—	—	+	—	—	—	++	yes	5	Quasi-experiment Low quality
	+	++	+	—	—	—	—	—	—	+	—	—	—				

DIAGNOSTIC STUDIES

Author/year	Nature of test is defined	Test compared to a gold standard	Where no gold standard exists, compared with valid reference standard	Clear population from which participants selected consecutively	Independent measurement of test and standard	Test and standard measured as close in time as possible	Results for all patients reported	Pre-test diagnosis reported	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Dammeyer, Dickinson et al., 2013; Pompeo, 2013)	+	—	—	—	—	—	—	—	—	yes	N/A	low
	+	—	—	—	—	—	—	+	—			

References

Bales, I. (2012). "A Comparison between the Use of Intravenous Bags and the Heelift Suspension Boot to Prevent Pressure Ulcers in Orthopedic Patients." Advances in Skin & Wound Care **25**(3):125-31.

Best, K., G. Desharnais, J. Boily, et al. (2012). "The effect of a trunk release maneuver on Peak Pressure Index, trunk displacement and perceived discomfort in older adults seated in a high Fowler's position: a randomized controlled trial." BMC Geriatr **12**(1):72.

Chung, C.H.K., M.C.H. Lau, T.Y.C. Leung, et al. (2012). "Effect of head elevation on sacral and ischial tuberosities pressure in infirmary patients." Asian Journal of Gerontology and Geriatrics **7**(2):101-6.

Dammeyer, J., S. Dickinson, D. Packard, et al. (2013). "Building a protocol to guide mobility in the ICU." Crit Care Nurs Q **36**(1):37-49.

Dickinson, S., D. Tschannen and L.L. Shever. (2013). "Can the use of an early mobility program reduce the incidence of pressure ulcers in a surgical critical care unit?" Crit Care Nurs Q **36**(1):127-40.

Donnelly, J., J. Winder, W.G. Kernohan, et al. (2011). "An RCT to determine the effect of a heel elevation device in pressure ulcer prevention post-hip fracture." J Wound Care **20**(7):309.

Giesbrecht, E.M., K.D. Ethans and D. Staley. (2011). "Measuring the effect of incremental angles of wheelchair tilt on interface pressure among individuals with spinal cord injury." Spinal Cord: The Official Journal Of The International Medical Society Of Paraplegia **49**(7):827-31.

Grisell, M. and H.M. Place. (2008). "Face tissue pressure in prone positioning: a comparison of three face pillows while in the prone position for spinal surgery." Spine **33**(26):2938-41.

Källman, U., S. Bergstrand, A.C. Ek, et al. (2013). "Different lying positions and their effects on tissue blood flow and skin temperature in older adult patients." Journal of Advanced Nursing **69**(1):133-44.

Knoblauch, D.J., M.A. Bettis, F. Lundy, et al. (2013). "Financial implications of starting a mobility protocol in a surgical Intensive Care Unit." Crit Care Nurs Q **36**(1):120-6.

Malkoun, M., J. Huber and D. Huber. (2012). "A comparative assessment of interface pressures generated by four surgical theatre heel pressure ulcer prophylactics." International Wound Journal **9**(3):259-63.

McMichael, J.C. and H.M. Place. (2008). "Face tissue pressures in prone positioning: a comparison of 3 pillows." J Spinal Disord Tech **21**(7):508-13.

Meyers, T.R. (2010). "Preventing heel pressure ulcers and plantar flexion contractures in high-risk sedated patients." J Wound Ostomy Continence Nurs **37**(4):372-8.

Moore, Z., S. Cowman and R.M. Conroy. (2011). "A randomised controlled clinical trial of repositioning, using the 30° tilt, for the prevention of pressure ulcers." Journal of Clinical Nursing **20**(17/18):2633-44.

Pompeo, M. (2013). "Pressure Map Technology for Pressure Ulcer Patients: Can We Handle the Truth?" Wounds: A Compendium of Clinical Research & Practice **25**(2):34-40.

Rich, S.E., D. Margolis, M. Shardell, et al. (2011). "Frequent manual repositioning and incidence of pressure ulcers among bed-bound elderly hip fracture patients." Wound Repair Regen **19**(1):10-8.

Romero, C.M., R.A. Cornejo, L.R. Galvez, et al. (2009). "Extended prone position ventilation in severe acute respiratory distress syndrome: A pilot feasibility study." Journal of Critical Care **24**(1):81-8.

Smit, C., G. Haverkamp, S. de Groot, et al. (2012). "Effects of electrical stimulation-induced gluteal versus gluteal and hamstring muscles activation on sitting pressure distribution in persons with a spinal cord injury." Spinal Cord **50**(8):590-4.

Still, M.D., L.C. Cross, M. Dunlap, et al. (2013). "The Turn Team: A Novel Strategy for Reducing Pressure Ulcers in the Surgical Intensive Care Unit." J Am Coll Surg.

SUPPORT SURFACES

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representat-ive sample	States number invited participants	Clear outcome measures	Valid reliable outcome measure-ment	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Johnson, Peterson et al., 2011a; Johnson, Peterson et al., 2011b)	++	—	+	—	++	+	—	+	+	—	yes	N/A	low
	++	—	—	—	++	++	+	+	—	—			
(Thorne, Sauve et al., 2009)	++	—	+	++	+	+	N/A	+	++	+	Indirect evidence PU not an outcome		moderate
	++	—	++	++	+	+	N/A	+	++	+			
(Gil-Agudo, De la Peña-González et al., 2009)	—	+	++	—	+	+	N/A	+	+	++	Indirect evidence PU not an outcome		moderate
	—	+	+	—	+	+	N/A	+	+	++			
(García-Molina, Balaguer-López et al., 2012)	+	+	—	—	+	+	N/A	—	—	—	yes	4	low
	+	—	—	+	+	+	N/A	—	—	—			

COHORT STUDIES

Author/year	Focussed question	Comparable source populations	States number invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Valente, Greenough III et al., 2012)	++	+	—	++	N/A	N/A	+	—	+	+	—	—	—	—	yes	5	low
	++	+	—	—	N/A	N/A	+	+	+	—	—	—	—	+			

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commenceme	Only difference btw	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(van Leen, Hovius et al., 2011)	++	—	—	—	+	+	—	—	—	N/A	+	+	yes	2	low
	++	—	—	—	+	+	—	—	—	N/A	+	+			

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commenceme	Only difference btw	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Demarré, Beeckman et al., 2012)	++	++	++	++	+	++	++	++	++	N/A	+	++	yes	1	high
	++	++	++	+	++	++	++	++	++	N/A	++	++			
(Brienza, Kelsey et al., 2010)	++	++	+	+	++	+	+	++	++	—	++	++	yes	2	moderate
	++	++	+	+	++	+	++	++	++	—	++	++			
(Vermette, Reeves et al., 2012)	++	++	++	—	++	++	++	++	++	N/A	++	++	yes	1	high
(Makhsous, Lin et al., 2009)	++	—	—	—	+	—	+	++	++	N/A	—	—	yes	2	low
(Cassino, Ippolito et al., 2013)	+	—	++	—	—	+	—	+	—	—	+	+	yes	2	low

QUASI EXPERIMENTAL STUDIES

Author/year	Focussed question	Subjects and investigator blinded	Groups comparable commence ment	Only difference btw groups treatment	Valid, reliable outcome measure	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Pemberton, Turner et al., 2009)	++	N/A	+	++	+	++	++	N/A	+	++	yes	5	low
	+	—	N/A	N/A	+	++	N/A	N/A	—	—			
(Futamura, Sugama et al., 2008)	++	—	+	+	+	—	+	N/A	+	—	Indirect outcomes Measures HR associated with tilting bed		low
	+	—	+	+	+	—	+	N/A	+	—			
(Turnage-Carrier, McLane et al., 2008)	++	—	+	+	+	+	—	N/A	—	—	Indirect evidence Healthy volunteers		low
	++	—	+	+	+	+	—	N/A	—	—			
(Korniewicz, Siegel et al., 2011)	++	—	+	—	++	—	—	N/A	+	+	Indirect outcomes Braden risk		low
	++	—	+	+	++	+	+	N/A	+	+			
(Posada-Moreno, Losa Iglesias et al., 2011)	+	—	N/A	+	+	—	—	N/A	+	—	Indirect evidence Healthy volunteers		low
	+	—	+	+	+	++	++	N/A	+	+			
(Black, Berke et al., 2012)	++	—	+	+	+	—	—	N/A	—	—	yes	3	low
	++	—	—	—	+	—	—	N/A	—	—			
(Manzano, Pérez et al., 2013)	++	+	++	+	++	++	++	N/A	+	++	yes	3	moderate
	—	—	+	+	+	—	+	N/A	+	++			

SYSTEMATIC REVIEWS

Author/year	Focussed question	Description of methodology is included	Comprehensive literature search	Critical appraisal	Meta-analysis is appropriate	Minimal bias	Reliable conclusions	Relevant to guideline population	AMSTAR score or Cochrane method	Type of evidence	Level of evidence	Quality
(McInnes, Jammali-Blasi et al., 2011)	++	++	++	++	+	++	++	yes	Cochrane	Meta-analysis of moderate to low quality RCTs	1	high

CASE SERIES

Author/year	Focussed question	Participant characteristics reported	Inclusion criteria defined	Consecutive recruitment	Participants entered at same disease stage	Intervention clearly reported	Outcomes relevant and defined apriori	Valid, reliable outcome measurement	Per cent drop out reported	Estimates of random variability	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Ward, Fenton et al., 2010)	++	—	—	—	—	+	++	—	—	—	N/A	—	—	yes	5	low
	++	—	—	—	—	+	++	—	—	—	N/A	—	—			
(Nwadinigwe, Anyaehie et al., 2012)	++	+	+	+	—	—	—	+	—	—	N/A	—	—	yes	4	low
	++	—	+	++	+	—	+	—	—	+	N/A	—	—			
(Williams, Leslie et al., 2011)	+	—	+	—	—	+	—	—	—	+	N/A	—	—	Indirect evidence		low

References

Black, J., C. Berke and G. Urzendowski. (2012). "Pressure ulcer incidence and progression in critically ill subjects : influence of low air loss mattress versus a powered air pressure redistribution mattress." Journal of Wound, Ostomy and Continence Nursing **39**(3):267-73.

Brienza, D., S. Kelsey, P. Karg, et al. (2010). "A randomized clinical trial on preventing pressure ulcers with wheelchair seat cushions." Journal of the American Geriatrics Society **58**(12):2308-14.

Cassino, R., A.M. Ippolito, C. Cuffaro, et al. (2013). "A controlled, randomised study on the efficacy of two overlays in the treatment of decubitus ulcers." Minerva chirurgica **68**(1):105-16.

Demarré, L., D. Beeckman, K. Vanderwee, et al. (2012). "Multi-stage versus single-stage inflation and deflation cycle for alternating low pressure air mattresses to prevent pressure ulcers in hospitalised patients: A randomised-controlled clinical trial." International Journal of Nursing Studies **49**(4):416-26.

Futamura, M., J. Sugama, M. Okuwa, et al. (2008). "Evaluation of comfort in bedridden older adults using an air-cell mattress with an automated turning function: measurement of parasympathetic activity during night sleep." Journal Of Gerontological Nursing **34**(12):20-6.

García-Molina, P., E. Balaguer-López, J.E. Torra I Bou, et al. (2012). "A prospective, longitudinal study to assess use of continuous and reactive low-pressure mattresses to reduce pressure ulcer incidence in a pediatric intensive care unit." Ostomy Wound Management **58**(7):32-9.

Gil-Agudo, A., A. De la Peña-González, A. Del Ama-Espinosa, et al. (2009). "Comparative study of pressure distribution at the user-cushion interface with different cushions in a population with spinal cord injury." Clin Biomech **24**(7):558-63.

Johnson, J., D. Peterson, B. Campbell, et al. (2011a). "Hospital-acquired pressure ulcer prevalence--evaluating low-air-loss beds SEE ERRATUM." Journal of Wound, Ostomy, and Continence Nursing **38**(1):55-60.

Johnson, J., D. Peterson, B. Campbell, et al. (2011b). "Correction: hospital-acquired pressure ulcer prevalence-evaluating low-air-loss beds." Journal of Wound, Ostomy, and Continence Nursing: Official Publication of the Wound, Ostomy and Continence Nurses Society / WOCN **38**(4):347-.

Korniewicz, D.M., J. Siegel, V. Fajardo, et al. (2011). "Evaluation of the incidence of pressure ulcers using hill-rom versacare surfaces." Advances In Skin & Wound Care **24**(4):160-6.

Makhsous, M., F. Lin, E. Knaus, et al. (2009). "Promote pressure ulcer healing in individuals with spinal cord injury using an individualized cyclic pressure-relief protocol." Advances in Skin & Wound Care **22**(11):514-21.

Manzano, F., A.M. Pérez, M. Colmenero, et al. (2013). "Comparison of alternating pressure mattresses and overlays for prevention of pressure ulcers in ventilated intensive care patients: A quasi-experimental study." Journal of Advanced Nursing **0**.

McInnes, E., A. Jammali-Blasi, S.E. Bell-Syer, et al. (2011). "Support surfaces for pressure ulcer prevention." Cochrane Database Of Systematic Reviews (Online) **4**:CD001735.

Nwadinigwe, C.U., U.E. Anyaehie and E.C. Onyegbule. (2012). "The impact of water mattresses on incidence of PUs in patients with spinal cord injuries in Nigeria." Journal of Wound Care **21**(4):184-9.

Pemberton, V., V. Turner and C. VanGilder. (2009). "The effect of using a low-air-loss surface on the skin integrity of obese patients: results of a pilot study." Ostomy/Wound Management **55**(2):44-8.

Posada-Moreno, P., M.E. Losa Iglesias, R. Becerro de Bengoa Vallejo, et al. (2011). "Influence of different bed support surface covers on skin temperature." Contemporary Nurse **39**(2):206-20.

Thorne, S., K. Sauve, C. Yacoub, et al. (2009). "Evaluating the pressure-reducing capabilities of the gel pad in supine." Am J Occup Ther **63**(6):744-50.

Turnage-Carrier, C., K.M. McLane and M.A. Gregurich. (2008). "Interface pressure comparison of healthy premature infants with various neonatal bed surfaces." Advances in Neonatal Care **8**(3):176-84.

Valente, S.A., W.B. Greenough III, S.L. DeMarco, et al. (2012). "More expensive surfaces are not always better." Kuwait Medical Journal **44**(1):40-5.

van Leen, M., S. Hovius, J. Neyens, et al. (2011). "Pressure relief, cold foam or static air? A single center, prospective, controlled randomized clinical trial in a Dutch nursing home." Journal of Tissue Viability **20**(1):30-4.

Vermette, S., I. Reeves and J. Lemaire. (2012). "Cost effectiveness of an air-inflated static overlay for pressure ulcer prevention: A randomized, controlled trial." Wounds: A Compendium of Clinical Research & Practice **24**(8):207-14.

Ward, L., K. Fenton and L. Maher. (2010). "The high impact actions for nursing and midwifery 4: your skin matters... fifth in a series." Nursing Times **106**(30):14-5.

Williams, T.A., G.D. Leslie, R. Bingham, et al. (2011). "Optimizing seating in the intensive care unit for patients with impaired mobility." American Journal of Critical Care **20**(1):e19-e27.

MEDICAL DEVICE RELATED PRESSURE ULCERS

COHORT STUDIES

Author/year	Focussed question	Comparable source populations	States number. invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Zaratkiewicz, Whitney et al., 2010)	+	++	+	+	++	+	—	—	—	—	—	—	—	+	yes	4	low
(Fujii, Sugama et al., 2010)	++	+	++	++	++	++	+	N/A	+	++	++	++	++	+	yes	4	moderate
(Kuo, Wootten et al., 2013)	++	+	—	—	++	++	—	—	—	—	+	—	+	+	yes	4	low

QUALITY IMPROVEMENT STUDIES

Author/year	Title/abstract is accurate	Current knowledge summarised in background	Specific project aims	Ethical aspects discussed	Sufficient reporting of intervention for replication	Reports factors contributing to intervention choice reported	Clear evaluation measures	Internal and external validity addressed	Appropriate analysis	Results report elements of the setting, change sin care processes and	Evidence of association between change and patient	Reports limitations	Reliable interpretation of	Funding sources reported	Relevant to guideline population	Level of evidence	Quality
(Boesch, Myers et al., 2012)	++	+	++	—	++	+	+	—	+	++	+	+	++	++	yes	4	Observational study
	++	++	++	—	++	+	++	+	++	++	++	+	+	—			Moderate quality

CASE SERIES

Author/year	Focussed question	Participant characteristics reported	Inclusion criteria defined	Consecutive recruitment	Participants entered at same disease stage	Intervention clearly reported	Outcomes relevant and defined apriori	Valid, reliable outcome measurement	Per cent drop out reported	Estimates of random variability	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Limpaphayom, Skaggs et al., 2009)	++	++	++	+	N/A	+	—	—	N/A	—	N/A	++	+	yes	5	low
	+	—	+	+	N/A	—	+	—	N/A	—	N/A	—	—			
(Jaryszak, Shah et al., 2011)	—	+	++	++	—	N/A	—	—	N/A	N/A	N/A	++	+	yes	5	low
	—	—	+	++	N/A	+	—	—	N/A	—	N/A	—	—			

QUASI EXPERIMENTAL STUDIES

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Weng, 2008)	++	—	++	+	+	++	++	N/A	+	+	yes	3	moderate
(Forni, Loro et al., 2011)	+	—	—	+	++	++	++	N/A	+	+	yes	4	moderate
	++	—	+	+	++	++	++	N/A	++	++			
Chidini et al, 2010	++	—	++	++	+	+	++	N/A	++	++	yes	3	moderate
	++	—	++	++	+	+		N/A	++	++			
(Huang, Tseng et al., 2009)	+	—	—	+	—	N/A	+	N/A	—	+	yes	3	low

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling - method	Representat-ive sample	States number. invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Black, Cuddigan et al., 2010)	++	+	—	—	+	+	N/A	+	+	+	yes	N/A	low
(Jatana, Oplatek et al., 2010)	++	+	—	+	++	+	+	+	+	+	yes	N/A	moderate
	++	+	—	+	++	+	+	—	+	+			
(Wilbrand, Wilbrand et al., 2012)	++	—	+	—	—	—	—	+	—	+	yes	N/A	low
(Turjanica, Clark et al., 2011)	++	+	—	++	+	—	N/A	—	+	+	yes	N/A	low
(Schluer, Halfens et al., 2012)	++	++	++	++	++	++	++	++	++	++	yes	N/A	moderate
	++	++	++	++	—	—	++	++	+	+			
(Schindler, Mikhailov et al., 2011)	++	++	++	++	+	+	+	++	++	++	yes	4	moderate
	+	++	++	++	+	+	+	++	++	++			

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Günlemez, Isken et al., 2010)	++	+	—	+	++	+	—	++	++	N/A	+	+	yes	2	moderate
	++	+	—	+	++	+	+	++	+	N/A	++	+			

References

Black, J.M., J.E. Cuddigan, M.A. Walko, et al. (2010). "Medical device related pressure ulcers in hospitalized patients." International Wound Journal **7**(5):358-65.

Boesch, R.P., C. Myers, T. Garrett, et al. (2012). "Prevention of tracheostomy-related pressure ulcers in children." Pediatrics **129**(3):e792-e7.

Forni, C., L. Loro, M. Tremosini, et al. (2011). "Use of polyurethane foam inside plaster casts to prevent the onset of heel sores in the population at risk. A controlled clinical study." Journal of Clinical Nursing **20**(5/6):675-80.

Fujii, K., J. Sugama, M. Okuwa, et al. (2010). "Incidence and risk factors of pressure ulcers in seven neonatal intensive care units in Japan: a multisite prospective cohort study." International Wound Journal **7**(5):323-8.

Günlemez, A., T. Isken, A. Gökalp, et al. (2010). "Effect of silicon gel sheeting in nasal injury associated with nasal CPAP in preterm infants." Indian Pediatrics **47**:265-7.

Huang, T.T., C.E. Tseng, T.M. Lee, et al. (2009). "Preventing pressure sores of the nasal ala after nasotracheal tube intubation: from animal model to clinical application." Journal of Oral & Maxillofacial Surgery **67**(3):543-51.

Jaryszak, E.M., R.K. Shah, J. Amling, et al. (2011). "Pediatric tracheotomy wound complications: Incidence and significance." Archives of Otolaryngology **137**(4):363-6.

Jatana, K.R., A. Oplatek, M. Stein, et al. (2010). "Effects of nasal continuous positive airway pressure and cannula use in the neonatal intensive care unit setting." Archives of Otolaryngology **136**(3):287-91.

Kuo, C., C.T. Wootten, D. Tylor, et al. (2013). "Prevention of pressure ulcers after pediatric tracheostomy using a Mepilex Ag dressing." The Laryngoscope: doi:10.1002/lary.24094.

Limpaphayom, N., D.L. Skaggs, G. McComb, et al. (2009). "Complications of halo use in children." Spine **34**(8):779-84.

Schindler, C.A., T.A. Mikhailov, E.M. Kuhn, et al. (2011). "Protecting fragile skin: nursing interventions to decrease development of pressure ulcers in pediatric intensive care. ." American Journal of Critical Care **20**(1):26-35.

Schluer, A.B., R.J. Halfens and J.G.A. Schols. (2012). " Pediatric pressure ulcer prevalence: A multicenter, cross-sectional, point prevalence study in Switzerland." Ostomy Wound Management **58**(7):18-31.

Turjanica, M.A., L. Clark, C. Martini, et al. (2011). "Incidence, Correlates, And Interventions Used For Pressure Ulcers of the Ear." Medsurg Nursing **20**(5):241-7.

Weng, M. (2008). "The effect of protective treatment in reducing pressure ulcers for non-invasive ventilation patients." Intensive & Critical Care Nursing: The Official Journal Of The British Association Of Critical Care Nurses **24**(5):295-9.

Wilbrand, J.F., M. Wilbrand, C.Y. Malik, et al. (2012). "Complications in helmet therapy." Journal of Cranio-Maxillofacial Surgery **40**(4):341-6.

Zaratkiewicz, S., J.D. Whitney, J.R. Lowe, et al. (2010). "Development and implementation of a hospital-acquired pressure ulcer incidence tracking system and algorithm." Journal For Healthcare Quality: Official Publication Of The National Association For Healthcare Quality **32**(6):44-51.

Treatment of Pressure Ulcers

CLASSIFICATION OF PRESSURE ULCERS

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number. invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Mahoney, Rozenboom et al., 2011)	+	—	—	—	+	—	N/A		—	—	yes	4	low
	+	+	—	—	+	—	N/A	—	—	—			
(Mizokami, Furuta et al., 2012)	++	—	—	—	+	+	N/A	—	—	—	yes	N/A	low
	++	—	—	—	+	—	N/A	—	—	—			
(Nanjo, Nakagami et al., 2011)	+	—	—	—	+	—	N/A	—	—	—	yes	N/A	low
(Young, Estocado et al., 2011)	++	+	—	—	+	+	N/A	+	+	—	yes	4	low
(Alvey, Hennen et al., 2012)	++	+	—	—	—	+	N/A	—	+	—	yes	5	low
(Bergquist-Beringer, Gajewski et al., 2011)	++	++	++	+	+	+	+	+	+	+	yes	2	moderate
	++	++	++	+	+	+	++	+	+	+			
(Kottner, Dassen et al., 2010)	++	++	++	+	++	++	++	++	++	++	yes	N/A	high
(Bååth, Hall-Lord et al., 2008)	++	—	+	—	+	+	—	—	+	+	yes	4	low
(Sarhan, 2010)	++	—	—	—	++	+	N/A	—	—	+	yes	4	low

DIAGNOSTIC STUDIES

Author/year	Nature of test is defined	Test compared to a gold standard	Where no gold standard exists, compared with valid reference standard	Clear population from which participants selected	Independent measurement of test and standard	Test and standard measured as close in time as possible	Results for all patients reported	Pre-test diagnosis reported	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Baumgarten, Margolis et al., 2009)	++	N/A	++	—	++	++	++	N/A	+	+	yes	3	moderate

References

Alvey, B., N. Hennen, H. Heard. (2012). "Improving accuracy of pressure ulcer staging and documentation using a computerized clinical decision support system. ." Journal Of Wound, Ostomy, And Continence Nursing **39**(6): 607-12.

Bååth, C., M.-L. Hall-Lord, E. Idvall, K. Wiberg-Hedman, B. Wilde Larsson. (2008). "Interrater reliability using Modified Norton Scale, Pressure Ulcer Card, Short Form-Mini Nutritional Assessment by registered and enrolled nurses in clinical practice." Journal Of Clinical Nursing **17**(5): 618-26.

Baumgarten, M., D. J. Margolis, J. L. Selekof, N. Moye, P. S. Jones, M. Shardell. (2009). "Validity of pressure ulcer diagnosis using digital photography." Wound Repair and Regeneration **17**(2): 287-90.

Bergquist-Beringer, S., B. Gajewski, N. Dunton, S. Klaus. (2011). "The reliability of the National Database of Nursing Quality Indicators pressure ulcer indicator: a triangulation approach." Journal of Nursing Care Quality **26**(4): 292-301.

Kottner, J., T. Dassen, N. Lahmann. (2010). "Prevalence of deep tissue injuries in hospitals and nursing homes. Two cross-sectional studies." International Journal of Nursing Studies **47**(6): 665-70.

Mahoney, M., B. Rozenboom, D. Doughty, H. Smith. (2011). "Issues related to accurate classification of buttocks wounds." Journal of Wound, Ostomy, and Continence Nursing **38**(6): 635-42.

Mizokami, F., K. Furuta, A. Utani, Z. Isogai. (2012). "Definitions of the physical properties of pressure ulcers and characterisation of their regional variance." International Wound Journal **Epub 2012 Jul 11**.

Nanjo, Y., G. Nakagami, T. Kaitani, A. Naito, K. Takehara, J. Lijuan, et al. (2011). "Relationship between morphological characteristics and etiology of pressure ulcers in intensive care unit patients." Journal of Wound, Ostomy, and Continence Nursing **38**(4): 404-12.

Sarhan, F. (2010). "Use of digital images in the assessment and treatment of pressure ulcers in patients with spinal injuries in community settings." Journal of Telemedicine and Telecare **16**(4): 207-10.

Young, D. L., N. Estocado, M. R. Landers, J. Black. (2011). "A pilot study providing evidence for the validity of a new tool to improve assignment of national pressure ulcer advisory panel stage to pressure ulcers." Advances in Skin & Wound Care **24**(4): 168-75.

ASSESSMENT OF PRESSURE ULCERS AND MONITORING OF HEALING

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES/OBSERVATIONAL

Author/year	Focussed question	Sampling method	Representative sample	States number invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Aoi, Yoshimura et al. 2009)	—	—	+	—	—	+	N/A	—	+	—	yes	4	low
	—	—	—	—	+	+	N/A	+	+	+			
(Andersen and Karlsmark 2008)	++	—	—	—	+	—	—	+	+	—	yes	5	low
	—	—	—	—	+	+	N/A	—	—	—			
(Edsberg, Wyffels et al. 2011)	++	+	—	—	++	++	N/A	+	+	+	yes	4	moderate
	++	—	+	—	+	++	N/A	+	+	+			
(Edsberg, Wyffels et al. 2012)	+	—	—	—	+	++	N/A	—	+	+	yes	4	low
(George-Saintilus, Tommasulo et al. 2009)	++	+	+	—	+	+	N/A	—	—	—	yes	N/A	low
	+	+	+	+	—	+	N/A	+	+	+			
(Günes 2009)	—	+	—	—	++	+	N/A	+	++	+	yes	N/A	moderate
(Hon, Lagden et al. 2010)	++	+	+	—	++	++	N/A	—	+	+	yes	4	moderate
(Iizaka, Sanada et al. 2011)	++	—	+	—	++	++	—	—	—	+	yes	N/A	low
	—	—	+	+	+	—	+	—	+	—			
(Bhedi, Saxena et al. 2013)	++	+	—	+	++	++	N/A	+	+	+	Indirect evidence: mixed etiology		moderate
(Davis, Nishimura et al. 2013)	++	—	—	—	+	++	N/A	—	+	+	yes	N/A	low
	+	+	+	—	++	++	N/A	+	—	+			
(Zhong, Nagase et al. 2013)	++	—	+	++	++	+	N/A	+	+	+	yes	4	moderate
(Iizaka, Sugama et al. 2011)	+	—	—	++	—	—	—	+	+	—	Indirect evidence: does not directly assess PU condition		low
	—	—	+	+	+	—	+	+	+	—			
(Iizaka, Kaitani et al. 2013)	++	+	—	++	++	+	+	+	—	—	Indirect evidence: does not directly assess PU condition		moderate

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Grubbs, Ludwig et al. 2009)	+	—	—	N/A	+	+	++	++	++	N/A	+	+	yes	3	moderate
	+	—	—	N/A	+	+	++	++	++	N/A	+	+			

CASE SERIES

Author/year	Focussed question	Participant characteristics reported	Inclusion criteria defined	Consecutive recruitment	Participants entered at same disease stage	Intervention clearly reported	Outcomes relevant and defined apriori	Valid, reliable outcome measurement	Per cent drop out reported	Estimates of random variability	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Higashino, Nakagami et al. 2012)	+	+	+	—	+	++	—	+	N/A	—	N/A	—	+	yes	4	low
	++	+	+	—	+	++	+	+	N/A	—	N/A	—	+			
(Yabunaka, Iizaka et al. 2009)	+	—	+	+	+	++	+	++	+	—	N/A	+	—	yes	N/A	moderate
	+	++	+	++	+	+	++	+	+	—	N/A	—	+			

DIAGNOSTIC STUDIES

Author/year	Nature of test is defined	Test compared to a gold standard	Where no gold standard exists, compared with valid reference standard	Clear population from which participants selected consecutively	Independent measurement of test and standard	Test and standard measured as close in time as possible	Results for all patients reported	Pre-test diagnosis reported	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Terris, Woo et al. 2011)	++	++	N/A	++	+	—	++	N/A	—	+	yes	3	moderate
	++	++	N/A	++	++	+	++	++	+	++			
(Hill, Cronkite et al. 2009)	++	+	N/A	—	—	++	++	—	—	+	yes	3	low
	+	—	N/A	—	+	+	++	—	+	+			

COHORT STUDIES

Author/year	Focussed question	Comparable source populations	States number invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Bergstrom, Smout et al. 2008)	++	++	++	++	++	N/A	—	N/A	—	+	+	++	+	+	yes	4	moderate
	+	N/A	—	+	++	N/A	+	+	+	+	+	++	+	+			
(Nakagami, Sanada et al. 2011)	++	++	—	N/A	++	++	++	—	+	—	+	++	+	+	yes	4	moderate
	+	N/A	—	N/A	++	+	+	—	+	—	+	++	+	+			
(Nakagami, Sanada et al. 2010)	++	++	++	N/A	++	++	++	++	+	—	+	++	++	+	yes	2	moderate
	+	+	—	—	++	++	+	+	+	—	+	++	+	+			
(Iizaka, Sanada et al. 2012)	++	—	++	N/A	++	+	++	—	++	+	+	++	+	+	yes	2	moderate
	+	+	+	N/A	—	—	+	—	+	+	+	++	+	+			
(Wyffels and Edsberg 2011)	++	++	—	++	—	++	++	—	+	++	++	—	+	+	yes	2	moderate
	+	N/A	—	++	—	+	+	+	+	+	+	—	+	+			

QUASI EXPERIMENTAL STUDIES

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Kottner, Dassen et al. 2009)	—	+	+	N/A	—	N/A	+	+	—	—	yes	5	low
	+	+	+	+	+	N/A	++	—	—	+			

References

Andersen, E. S. and T. Karlsmark (2008). "Evaluation of four non-invasive methods for examination and characterization of pressure ulcers." Skin Research And Technology **14**(3): 270-276.

Aoi, N., K. Yoshimura, T. Kadono, G. Nakagami, S. Iizuka, T. Higashino, J. Araki, I. Koshima and H. Sanada (2009). "Ultrasound assessment of deep tissue injury in pressure ulcers: possible prediction of pressure ulcer progression." Plastic and Reconstructive Surgery **124**(2): 540-550.

Baumgarten, M., D. J. Margolis, J. L. Selekof, N. Moye, P. S. Jones and M. Shardell (2009). "Validity of pressure ulcer diagnosis using digital photography." Wound Repair and Regeneration **17**(2): 287-290.

Bergstrom, N., R. Smout, S. Horn, W. Spector, A. Hartz and M. R. Limcangco (2008). "Stage 2 pressure ulcer healing in nursing homes." Journal of the American Geriatrics Society **56**(7): 1252-1258.

Bhedi, A., A. K. Saxena, R. Gadani and R. Patel (2013). "Digital Photography and Transparency-Based Methods for Measuring Wound Surface Area." Indian Journal of Surgery **75**(2): 111-114.

Davis, A. J., J. Nishimura, J. Seton, B. L. Goodman, C. H. Ho and K. M. Bogie (2013). "Repeatability and clinical utility in stereophotogrammetric measurements of wounds." Journal of Wound Care **22**(2): 90-97.

Edsberg, L. E., J. T. Wyffels, M. S. Brogan and K. M. Fries (2012). "Analysis of the proteomic profile of chronic pressure ulcers." Wound Repair and Regeneration **20**(3): 378-401.

Edsberg, L. E., J. T. Wyffels and D. S. Ha (2011). "Longitudinal Study of Stage III and Stage IV Pressure Ulcer Area and Perimeter as Healing Parameters to Predict Wound Closure." Ostomy Wound Management **57**(10): 50-62.

George-Saintilus, E., B. Tommasulo, C. E. Cal, R. Hussain, N. Mathew, Y. Dlugacz, R. Pekmezaris and G. Wolf-Klein (2009). "Pressure ulcer PUSH score and traditional nursing assessment in nursing home residents: do they correlate?" Journal of the American Medical Directors Association **10**(2): 141-144.

Grubbs, S., M. Ludwig, E. McHale, J. Meck, E. Nayar, A. Rice, A. Sanchez, E. Schirmann, S. Wilchinski, R. Armbrust, S. Bender, C. A. Bristol, R. DeMeo, G. Morrison, S. Prislupski, A. Szenasi, S. Siano, D. Easton and D. Ghezzi (2009). "The effect of high frequency ultrasound on the prevention of pressure ulcers in long-term care patients." Internet Journal of Academic Physician Assistants **7**(1): 3-3.

Günes, U. Y. (2009). "A prospective study evaluating the Pressure Ulcer Scale for Healing (PUSH Tool) to assess Stage II, Stage III, and Stage IV pressure ulcers." Ostomy Wound Management **55**(5): 48-52.

Higashino, T., G. Nakagami, T. Kadono, Y. Ogawa, S. Iizaka, H. Koyanagi, S. Sasaki, N. Haga and H. Sanada (2012). "Combination of thermographic and ultrasonographic assessments for early detection of deep tissue injury." Int Wound J: e-publication.

Hill, M. L., R. C. Cronkite, D. T. Ota, E. C. Yao and B. J. Kiratli (2009). "Validation of home telehealth for pressure ulcer assessment: a study in patients with spinal cord injury." Journal of Telemedicine and Telecare **15**(4): 196-202.

Hon, J., K. Lagden, A. McLaren, D. O'Sullivan, L. Orr, P. E. Houghton and M. G. Woodbury (2010). "A prospective, multicenter study to validate use of the Pressure Ulcer Scale for Healing (PUSH©) in patients with diabetic, venous, and pressure ulcers." Ostomy Wound Management **56**(2): 26.

Iizaka, S., T. Kaitani, J. Sugama, G. Nakagami, A. Naito, H. Koyanagi, C. Konya and H. Sanada (2013). "Predictive validity of granulation tissue color measured by digital image analysis for deep pressure ulcer healing: A multicenter prospective cohort study." Wound Repair and Regeneration **21**(1): 25-34.

Iizaka, S., H. Sanada, Y. Matsui, M. Furue, T. Tachibana, T. Nakayama, J. Sugama, K. Furuta, M. Tachi, K. Tokunaga, Y. Miyachi and Scientific Education Committee of the Japanese Society of Pressure Ulcers (2012). "Predictive validity of weekly monitoring of wound status using DESIGN-R score change for pressure ulcer healing: a multicenter prospective cohort study." Wound Repair and Regeneration **20**(4): 473-481.

Iizaka, S., H. Sanada, G. Nakagami, H. Koyanagi, C. Konya and J. Sugama (2011). "Quantitative estimation of exudate volume for full-thickness pressure ulcers: the ESTimation method." Journal of Wound Care **20**(10): 453.

Iizaka, S., J. Sugama, G. Nakagami, T. Kaitani, A. Naito, H. Koyanagi, J. Matsuo, T. Kadono, C. Konya and H. Sanada (2011). "Concurrent validation and reliability of digital image analysis of granulation tissue color for clinical pressure ulcers." Wound Repair and Regeneration **19**(4): 455-463.

Kottner, J., T. Dassen and N. Lahmann (2009). "Comparison of two skin examination methods for grade 1 pressure ulcers." Journal of Clinical Nursing **18**(17): 2464-2469.

Nakagami, G., H. Sanada, T. Higashino, T. Kadono, G. Uchida, H. Fujita, Y. Ogawa, Y. Yamamoto, S. Iizaka, H. Koyanagi, S. Sasaki and N. Haga (2011). "Combination of Ultrasonographic and Thermographic Assessments for Predicting Partial-thickness Pressure Ulcer Healing." Wounds-a Compendium of Clinical Research and Practice **23**(9): 285-292.

Nakagami, G., H. Sanada, S. Iizaka, T. Kadono, T. Higashino, H. Koyanagi and N. Haga (2010). "Predicting delayed pressure ulcer healing using thermography: a prospective cohort study." Journal of Wound Care **19**(11): 465-472.

Terris, D. D., C. Woo, M. N. Jarczok and C. H. Ho (2011). "Comparison of in-person and digital photograph assessment of stage III and IV pressure ulcers among veterans with spinal cord injuries." Journal of Rehabilitation Research & Development **48**(3): 215-224.

Wyffels, J. T. and L. E. Edsberg (2011). "Granulation tissue of chronic pressure ulcers as a predictive indicator of wound closure." Advances in Skin & Wound Care **24**(10): 464-473.

Yabunaka, K., S. Iizaka, G. Nakagami, N. Aoi, T. Kadono, H. Koyanagi, M. Uno, M. Ohue, S. Sanada and H. Sanada (2009). "Can ultrasonographic evaluation of subcutaneous fat predict pressure ulceration?" Journal of Wound Care **18**(5): 192, 194, 196 passim.

Zhong, X., T. Nagase, L. Huang, T. Kaitani, S. Iizaka, Y. Yamamoto, T. Kanazawa and H. Sanada (2013). "Reliability and Validity of the Chinese Version of DESIGN-R, an Assessment Instrument for Pressure Ulcers." Ostomy Wound Management **59**(2): 36-43.

PAIN ASSESSMENT AND TREATMENT

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number. invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevance to guideline population	Level of evidence	Quality
(Essex, Clark et al., 2009)	++	—	—	—	+	+	N/A	++	+	—	yes	5	low
	++	+	—	—	+	+	N/A	+	+	—			

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Confidence in conclusion	Relevance to guideline population	Level of evidence	Quality
(Paris, Horvath et al., 2008)	++	+	+	—	+	—	++	++	—	++	+	++	yes	2	moderate

QUALITATIVE STUDIES

Author/year	Focussed question	Appropriate qualitative methodology	Recruitment appropriate to research and sample justified	Setting for data collection justified	Clear, explicit methods for data collection	Saturation of data	Researcher's role in data collection and analysis and potential bias addressed	Ethics clearance	In-depth description n of analysis technique	Sufficient supporting data	Contradictory data considered	Findings related to original question are stated	Discusses evidence for and against the researcher's argument	Research contributes to the existing knowledge	Relevance to guideline population	Level of evidence	Quality
(Gunes, 2008)	Y	Y	Y	Y	Y	N	N	Y	Y	Y	N	Y	N	Y	yes	5	moderate
	Y	Y	Y	Y	Y	N	N	Y	Y	Y	N	Y	Y	Y			
(Kapp & Annells, 2010)	Y	Y	N	Y	N	N	N	Y	Y	Y	N	Y	N	Y	yes	5	low
	Y	Y	N	Y	N	N	N	Y	Y	Y	N	Y	N	Y			

References

Essex, H. N., M. Clark, J. Sims, A. Warriner, N. Cullum. (2009). "Health-related quality of life in hospital inpatients with pressure ulceration: assessment using generic health-related quality of life measures." Wound Repair and Regeneration: Official Publication of the Wound Healing Society [and] the European Tissue Repair Society **17**(6): 797-805.

Gunes, U. Y. (2008). "A descriptive study of pressure ulcer pain." Ostomy/Wound Management **54**(2): 56-61.

Kapp, S., M. Annells. (2010). "Pressure ulcers: home-based nursing." British Journal of Community Nursing **15**(12): 6-13.

Paris, A., R. Horvath, P. Basset, S. Thiery, P. Couturier, A. Franco, et al. (2008). "Nitrous Oxide-Oxygen Mixture During Care of Bedsores and Painful Ulcers in the Elderly: A Randomized, Crossover, Open-Label Pilot Study." Journal of Pain and Symptom Management **35**(2): 171-6.

WOUND CARE: CLEANSING AND DEBRIDEMENT

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Golinko, Clark et al., 2009)	++	+	—	—	++	++	N/A	+	+	++	Indirect evidence PU healing not an outcome measure		low
	++	+	—	—	—	++	N/A	—	+	—			
(Shannon, 2013)	++	+	+	++	+	+	N/A	+	+	+	yes	5	low

CASE CONTROL

Author/year	Focussed question	Comparable source populations	Same exclusion cases and controls	Per cent drop out in study arms is reported	Comparison btw participants and non-participants	Cases clearly defined	Established that controls are non-cases	Knowledge of primary exposure not influence case	Valid, reliable assessment of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Mizokami, Murasawa et al., 2012)	+	—	—	N/A	+	+	—	+	+	—	—	—	—	Indirect evidence PU healing not an outcome measure		low
	+	+	—	N/A	+	+	+	+	+	—	—	+	—			

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Ho, Bensitel et al., 2012)	++	+	++	++	++	++	++	++	++	N/A	+	+	yes	2	moderate
	++	+	++	++	++	++	++	++	++	N/A	—	—			

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Felzani, Spoletini et al., 2011)	++	+	—	++	—	++	+	—	—	N/A	—	—	yes	2	low
	—	—	—	+	—	+	+	—	—	N/A	—	—			
(Chuangsuwanich, Charnsanti et al., 2011)	++	—	—	—	—	—	++	++	++	N/A	—	—	yes	2	low
	—	—	—	—	+	—	—	++	+	N/A	—	—			
(Sipponen, Jokinen et al., 2008)	+	++	++	—	++	+	+	—	—	—	—	—	yes	2	low
	+	++	++	—	++	+	+	—	—	—	—	—			
(Waycaster & Milne, 2013)	++	—	—	—	—	+	+	++	++	N/A	+	+	yes	2	low

SYSTEMATIC REVIEWS

Author/year	Focussed question	Description of	Comprehensive literature search	Critical appraisal	Meta-analysis is	Minimal bias	Reliable conclusions	Relevant to guideline population	AMSTAR score or Cochrane method	Type of evidence	Included studies included in critical appraisal and master table	Level of evidence	Quality
Fernandez and Griffiths, 2008	++	++	++	++	++	++	++	Indirect evidence mixed aetiology	Cochrane	Meta-analysis	Previous version of this review is included in 2009 guideline	N/A	high
	++	++	++	++	++	++	++						

CASE SERIES

Author/year	Focussed question	Participant characteristics reported	Inclusion criteria defined	Consecutive recruitment	Participants entered at same disease	Intervention clearly reported	Outcomes relevant and defined apriori	Valid, reliable outcome measurement	Per cent drop out reported	Estimates of random variability	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Biglari, Vd Linden et al., 2012)	+	—	—	—	—	—	—	—	++	—	—	—	—	yes	5	low
	—	+	—	—	+	+	—	+	++	—	—	+	—			

References

Biglari, B., P. H. Vd Linden, A. Simon, S. Aytac, H. J. Gerner, A. Moghaddam. (2012). "Use of Medihoney as a non-surgical therapy for chronic pressure ulcers in patients with spinal cord injury." Spinal Cord: The Official Journal Of The International Medical Society Of Paraplegia **50**(2): 165-9.

Chuangsuwanich, A., O. Charnsanti, V. Lohsiriwat, C. Kangwanpoom, N. Thong-In. (2011). "The efficacy of silver mesh dressing compared with silver sulfadiazine cream for the treatment of pressure ulcers." Journal of the Medical Association of Thailand **94**(5): 559-65.

Felzani, G., I. Spoletini, A. Convento, B. Di Lorenzo, P. Rossi, M. Miceli, et al. (2011). "Effect of lysine hyaluronate on the healing of decubitus ulcers in rehabilitation patients." Advances In Therapy **28**(5): 439-45.

Golinko, M. S., S. Clark, R. Rennert, F. A., A. J. Boulton. (2009). "Wound emergencies: the importance of assessment, documentation, and early treatment using a wound electronic medical record." Ostomy WoundManage **55**(5): 54-61.

Ho, C. H., T. Bensitel, X. Wang, K. M. Bogie. (2012). "Pulsatile lavage for the enhancement of pressure ulcer healing: a randomized controlled trial." Physical Therapy **92**(1): 38-48.

Mizokami, F., Y. Murasawa, K. Furuta, Z. Isogai. (2012). "Iodoform gauze removes necrotic tissue from pressure ulcer wounds by fibrinolytic activity." Biol Pharm Bull **35**(7): 1048-53.

Shannon, M. M. (2013). "A retrospective descriptive study of nursing home residents with heel eschar or blisters." Ostomy Wound Manage **59**(1): 20-7. Epub 2013/01/12.

Sipponen, A., J. J. Jokinen, P. Sipponen, A. Papp, S. Sarna, J. Lohi. (2008). "Beneficial effect of resin salve in treatment of severe pressure ulcers: a prospective, randomized and controlled multicentre trial." The British Journal of Dermatology **158**(5): 1055-62.

Waycaster, C., C. T. Milne. (2013). "Clinical and Economic Benefit of Enzymatic Debridement of Pressure Ulcers Compared to Autolytic Debridement with a Hydrogel Dressing." J Med Econ. Epub 2013/05/25.

ASSESSMENT AND TREATMENT OF INFECTION AND BIOFILMS

DIAGNOSTIC STUDIES

Author/year	Nature of test is defined	Test compared to a gold standard	Where no gold standard exists, compared with valid reference standard	Clear population from which participants selected	Independent measurement of test and standard	Test and standard measured as close in time as possible	Results for all patients reported	Pre-test diagnosis reported	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Larson, Gilstrap et al., 2011)	++	++	N/A	—	+	+	+	—	—	yes	4	moderate
	++	++	N/A	+	+	+	+	—	—			
(De Heredia, Hauptfleisch et al., 2012; Hauptfleisch, Meagher et al., 2013; Luis, Hauptfleisch et al., 2012)	++	—	—	—	+	—	+	—	—	yes	5	low
	+	+	—	+	+	—	—	—	—			

CASE CONTROL

Author/year	Focussed question	Comparable source populations	Same exclusion cases and controls	Per cent drop out in study arms is reported	Comparison btw participants and non-participants	Cases clearly defined	Established that controls are non-cases	Knowledge of primary exposure not influence case ascertainment	Valid, reliable assessment of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Daniali, Keys et al., 2011)	++	++	+	++	+	++	+	+	+	+	++	+	++	yes	5	moderate
	++	+	+	++	+	++	+	+	+	+	++	—	—			

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number invited	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(James, Swogger et al., 2008)	+	—	—	+	+	+	N/A	—	—	—	Prevalence study		low
	+	+	—	+	+	+	N/A	—	—	—	Indirect evidence mixed aetiology		
(Buck, Goucher et al., 2012)	+	—	—	—	+	+	N/A	—	—	—	Prevalence study		low
	+	—	—	—	+	+	N/A	—	—	—			
(Dowd, Delton Hanson et al., 2011)	++	+	+	+	+	+	N/A	—	+	+	Prevalence study		low
	++	+	+	+	+	+	N/A	—	+	+	Indirect evidence mixed aetiology		

Author/year	Focussed question	Sampling method	Representative sample	States number invited	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Manzur, Gavalda et al., 2008)	++	++	++	++	+	+	++	—	—	+	Prevalence study		moderate
	++	++	++	++	+	+	+	—	+	+			
(Dowd, Sun et al., 2008)	++	+	++	—	++	++	—	++	+	+	Indirect evidence mixed aetiology		moderate
	+	+	+	—	++	++	—	+	+	+			
(Cataldo, Bonura et al., 2011)	+	—	—	++	++	++	N/A	—	—	+	Prevalence study		low
	++	—	—	++	++	++	N/A	—	—	+			
(Smith, Snow et al., 2010)	+	—	—	—	+	++	—	—	—	+	Prevalence study		low

COHORT STUDIES

Author/year	Focussed question	Comparable source populations	States number invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Nery Silva Pirett, Braga et al., 2012)	++	—	—	—	N/A	++	++	—	+	—	—	++	—	+	yes	4	low
	++	+	++	—	N/A	++	++	—	+	—	—	++	—	++			
(Robicsek, Beaumont et al., 2009)	+	++	++	++	++	++	+	—	+	—	+	++	+	+	Indirect evidence mixed infections		moderate

CASE SERIES

Author/year	Focussed question	Participant characteristics reported	Inclusion criteria defined	Consecutive recruitment	Participants entered at same disease stage	Intervention clearly reported	Outcomes relevant and defined apriori	Valid, reliable outcome measurement	Per cent drop out reported	Estimates of random variability	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Biglari, Vd Linden et al., 2012)	+	—	—	—	—	—	—	—	++	—	—	—	—	yes	5	low
	—	+	—	—	+	+	—	+	++	—	—	+	—			

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Trial, Darbas et al., 2010)	++	++	++	—	+	+	++	++	++	—	+	+	yes	2	moderate
	++	++	++	—	+	+	++	++	++	—	+	+			
(Sipponen, Jokinen et al., 2008)	+	++	++	—	++	+	+	—	—	—	—	—	yes	2	low
	+	++	++	—	++	+	+	—	—	—	—	—			
(Beele, Meuleneire et al., 2010)	+	+	—	—	++	++	++	++	++	—	++	+	Indirect evidence Mixed aetiology		moderate
	+	++	—	—	+	—	++	++	++	—	+	+			
(Wild, Bruckner et al., 2012)	++	++	+	+	++	+	++	++	N/A	—	++	—	yes	2	moderate
	++	++	++	+	+	+	++	++	++	—	++	+			

References

Beele, H., F. Meuleneire, M. Nahuys, S. L. Percival. (2010). "A prospective randomised open label study to evaluate the potential of a new silver alginate/carboxymethylcellulose antimicrobial wound dressing to promote wound healing." International Wound Journal **7**(4): 262-70.

Biglari, B., P. H. Vd Linden, A. Simon, S. Aytac, H. J. Gerner, A. Moghaddam. (2012). "Use of Medihoney as a non-surgical therapy for chronic pressure ulcers in patients with spinal cord injury." Spinal Cord: The Official Journal Of The International Medical Society Of Paraplegia **50**(2): 165-9.

Buck, D. W., J. H. Goucher, J. V. L. Lewis. (2012). "The Incidence of Methicillin-Resistant Staphylococcus aureus in Pressure Ulcers." Advances in Skin & Wound Care **25**(11): 509-12.

Cataldo, M. C., C. Bonura, G. Caputo, A. Aleo, G. Rizzo, D. M. Geraci, et al. (2011). "Colonization of pressure ulcers by multidrug-resistant microorganisms in patients receiving home care." Scandinavian Journal of Infectious Diseases **43**(11-12): 947-52.

Daniali, L. N., K. Keys, D. Katz, D. W. Mathes. (2011). "Effect of preoperative magnetic resonance imaging diagnosis of osteomyelitis on the surgical management and outcomes of pressure ulcers." Annals of Plastic Surgery **67**(5): 520-5.

De Heredia, L., J. Hauptfleisch, R. Hughes, A. Graham, T. Meagher. (2012). "Magnetic resonance imaging of pressure sores in spinal cord injured patients: Accuracy in predicting osteomyelitis." Topics in Spinal Cord Injury Rehabilitation **18**(2): 146-8.

Dowd, S. E., J. Delton Hanson, E. Rees, R. D. Wolcott, A. M. Zischau, Y. Sun, et al. (2011). "Survey of fungi and yeast in polymicrobial infections in chronic wounds." Journal of Wound Care **20**(1): 40-7.

Dowd, S. E., Y. Sun, P. R. Secor, D. D. Rhoads, B. M. Wolcott, G. A. James, et al. (2008). "Survey of bacterial diversity in chronic wounds using pyrosequencing, DGGE, and full ribosome shotgun sequencing." BMC Microbiology **8**: 43-.

Hauptfleisch, J., T. M. Meagher, R. J. Hughes, J. P. Singh, A. Graham, L. Lopez de Heredia. (2013). "Interobserver Agreement of Magnetic Resonance Imaging Signs of Osteomyelitis in Pelvic Pressure Ulcers in Patients With Spinal Cord Injury." Archives of Physical Medicine and Rehabilitation.

James, G. A., E. Swogger, R. Wolcott, E. d. Pulcini, P. Secor, J. Sestrich, et al. (2008). "Biofilms in chronic wounds." Wound Repair and Regeneration: Official Publication of the Wound Healing Society [and] The European Tissue Repair Society **16**(1): 37-44.

Larson, D. L., J. Gilstrap, K. Simonelic, G. F. Carrera. (2011). "Is there a simple, definitive, and cost-effective way to diagnose osteomyelitis in the pressure ulcer patient?" Plastic and Reconstructive Surgery **127**(2): 670-6.

Luis, J. Hauptfleisch, R. Hughes, A. Graham, T. M. M. Meagher. (2012). "Magnetic Resonance Imaging of Pressure Sores in Spinal Cord Injured Patients: Accuracy in Predicting Osteomyelitis." Topics in Spinal Cord Injury Rehabilitation **18**(2): 146-8.

Manzur, A., L. Gavalda, E. Ruiz de Gopegui, D. Mariscal, M. A. Dominguez, J. L. Perez, et al. (2008). "Prevalence of methicillin-resistant Staphylococcus aureus and factors associated with colonization among residents in community long-term-care facilities in Spain." Clinical Microbiology and Infection **14**(9): 867-72.

Nery Silva Pirett, C. C., I. A. Braga, R. M. Ribas, P. P. Gontijo Filho, A. D. Filho. (2012). "Pressure ulcers colonized by MRSA as a reservoir and risk for MRSA bacteremia in patients at a Brazilian university hospital." Wounds: A Compendium of Clinical Research & Practice **24**(3): 67-75.

Robicsek, A., J. L. Beaumont, R. B. Thomson, Jr., G. Govindarajan, L. R. Peterson. (2009). "Topical therapy for methicillin-resistant Staphylococcus aureus colonization: impact on infection risk." Infection Control and Hospital Epidemiology: The Official Journal of The Society of Hospital Epidemiologists of America **30**(7): 623-32.

Sipponen, A., J. J. Jokinen, P. Sipponen, A. Papp, S. Sarna, J. Lohi. (2008). "Beneficial effect of resin salve in treatment of severe pressure ulcers: a prospective, randomized and controlled multicentre trial." The British Journal of Dermatology **158**(5): 1055-62.

Smith, D. M., D. E. Snow, E. Rees, A. M. Zischkau, J. D. Hanson, R. D. Wolcott, et al. (2010). "Evaluation of the bacterial diversity of pressure ulcers using bTEFAP pyrosequencing." BMC Medical Genomics **3**(1): 41-.

Trial, C., H. Darbas, J. P. Lavigne, A. Sotto, G. Simoneau, Y. Tillet, et al. (2010). "Assessment of the antimicrobial effectiveness of a new silver alginate wound dressing: a RCT." Journal of Wound Care **19**(1): 20-6.

Wild, T., M. Bruckner, M. Payrich, C. Schwarz, T. Eberlein, A. Andriessen. (2012). "Eradication of methicillin-resistant Staphylococcus aureus in pressure ulcers comparing a polyhexanide-containing cellulose dressing with polyhexanide swabs in a prospective randomized study." Advances in Skin & Wound Care **25**(1): 17-22.

WOUND DRESSINGS FOR TREATMENT OF PRESSURE ULCERS

QUASI EXPERIMENTAL STUDIES

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Parish, Dryjski et al., 2008)	++	—	N/A	N/A	+	—	++	—	—	—	yes	5	low
	++	—	N/A	N/A	++	—	++	—	—	—			

CASE SERIES

Author/year	Focussed question	Participant characteristics reported	Inclusion criteria defined	Consecutive recruitment	Participants entered at same disease stage	Intervention clearly reported	Outcomes relevant and defined apriori	Valid, reliable outcome measurement	Per cent drop out reported	Estimates of random variability	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Davis, Johannigman et al., 2001)	+	+	++	+	—	++	+	+	—	+	++	++	+	yes	5	low
	+	+	++	+	—	++	+	+	—	—	—	—	—			

CASE CONTROL

Author/year	Focussed question	Comparable source populations	Same exclusion cases and controls	Per cent drop out in study arms is reported	Comparison btw participants and non-participants	Cases clearly defined	Established that controls are non-cases	Knowledge of primary exposure not influence case ascertainment	Valid, reliable assessment of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Mizokami, Murasawa et al., 2012)	+	—	—	N/A	+	+	—	+	+	—	—	—	—	Indirect evidence PU healing not an outcome measure		low
	+	+	—	N/A	+	+	+	+	+	—	—	+	—			

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Kerihuel, 2010)	+	++	++	+	+	—	—	++	++	—	—	+	yes	2	low
	++	++	++	+	+	—	—	++	++	—	—	+			
(Kordestani, Shahrezaee et al., 2008)	+	++	++	++	—	+	++	—	++	++	+	—	yes	2	low
	+	—	+	+	—	+	++	—	—	—	—	—			
(Chuangsuwanich, Charnsanti et al., 2011)	++	—	—	—	—	—	++	++	++	N/A	—	—	yes	2	low
	—	—	—	—	+	—	—	++	+	N/A	—	—			
(Trial, Darbas et al., 2010)	++	—	++	—	+	—	++	++	++	N/A	+	—	yes	2	low
	++	—	++	—	+	—	+	++	++	N/A	+	—			
(Beele, Meuleneire et al., 2010)	+	+	—	—	++	++	++	++	++	—	++	+	Indirect evidence Mixed aetiology		moderate
	+	++	—	—	+	—	++	++	++	—	+	+			
(Wild, Bruckner et al., 2012)	++	++	+	+	++	+	++	++	N/A	—	++	—	yes	2	moderate
	++	++	++	+	+	+	++	++	++	—	++	+			

References

Beele, H., F. Meuleneire, M. Nahuys, S. L. Percival. (2010). "A prospective randomised open label study to evaluate the potential of a new silver alginate/carboxymethylcellulose antimicrobial wound dressing to promote wound healing." International Wound Journal **7**(4): 262-70.

Chuangsuwanich, A., O. Charnsanti, V. Lohsiriwat, C. Kangwanpoom, N. Thong-In. (2011). "The efficacy of silver mesh dressing compared with silver sulfadiazine cream for the treatment of pressure ulcers." Journal of the Medical Association of Thailand **94**(5): 559-65.

Davis, K., Jr., J. A. Johannigman, R. S. Campbell, A. Marraccini, F. A. Luchette, S. B. Frame, et al. (2001). "The acute effects of body position strategies and respiratory therapy in paralyzed patients with acute lung injury." Critical Care (London, England) **5**(2): 81-7.

Kerihuel, J. C. (2010). "Effect of activated charcoal dressings on healing outcomes of chronic wounds." Journal of Wound Care **19**(5): 208.

Kordestani, S., M. Shahrezaee, M. N. Tahmasebi, H. Hajimahmodi, D. H. Ghasemali, M. S. Abyaneh. (2008). "A randomised controlled trial on the effectiveness of an advanced wound dressing used in Iran." Journal of Wound Care **17**(7): 323-7.

Mizokami, F., Y. Murasawa, K. Furuta, Z. Isogai. (2012). "Iodoform gauze removes necrotic tissue from pressure ulcer wounds by fibrinolytic activity." Biol Pharm Bull **35**(7): 1048-53.

Parish, L. C., M. Dryjski, S. Cadden. (2008). "Prospective clinical study of a new adhesive gelling foam dressing in pressure ulcers." International Wound Journal **5**(1): 60-7.

Trial, C., H. Darbas, J. P. Lavigne, A. Sotto, G. Simoneau, Y. Tillet, et al. (2010). "Assessment of the antimicrobial effectiveness of a new silver alginate wound dressing: a RCT." Journal of Wound Care **19**(1): 20-6.

Wild, T., M. Bruckner, M. Payrich, C. Schwarz, T. Eberlein, A. Andriessen. (2012). "Eradication of methicillin-resistant Staphylococcus aureus in pressure ulcers comparing a polyhexanide-containing cellulose dressing with polyhexanide swabs in a prospective randomized study." Advances in Skin & Wound Care **25**(1): 17-22.

BIOLOGICAL DRESSINGS AND GROWTH FACTORS

COHORT STUDIES

Author/year	Focussed question	Comparable source populations	States number invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Caravaggi, Grigoletto et al., 2011)	+	N/A	+	+	++	N/A	+	—	+	—	—	—	—	—	Indirect evidence Mixed aetiology		low
	+	N/A	+	+	+	N/A	+	—	+	+	+	+	++	—			
(Sarasúa, López et al., 2011)	+	N/A	+	+	++	+	N/A	N/A	+	—	—	—	—	—	yes	5	low
	+	N/A	—	N/A	++	N/A	—	N/A	—	—	—	—	—	—			

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Piatkowski, Ulrich et al., 2012)	++	++	++	—	++	++	++	++	++	N/A	+	—	yes	2	moderate
	++	++	—	—	++	++	+	+	++	N/A	+	—			
(Scevola, Nicoletti et al., 2010)	+	+	—	+	+	+	+	+	+	+	+	+	yes	2	low
	++	—	—	—	—	+	+	—	+	N/A	—	—			

CASE CONTROL

Author/year	Focussed question	Comparable source populations	Same exclusion cases and controls	Per cent drop out in study arms is reported	Comparison btw participants and non-participants	Cases clearly defined	Established that controls are non-cases	Knowledge of primary exposure not influence case ascertainment	Valid, reliable assessment of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Ohura, Nakajo et al., 2011)	+	+	+	+	+	+	+	+	+	+	—	++	—	yes	3	low
	++	++	++	+	—	++	N/A	—	—	+	—	+	+			

CASE SERIES

Author/year	Focussed question	Participant characteristics reported	Inclusion criteria defined	Consecutive recruitment	Participants entered at same disease stage	Intervention clearly reported	Outcomes relevant and defined apriori	Valid, reliable outcome measurement	Per cent drop out reported	Estimates of random variability	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Karr, 2008)	+	++	—	—	—	+	—	—	—	—	N/A	—	—	Indirect evidence		low
	+	++	—	—	—	++	—	—	—	—	N/A	—	—	Mixed aetiology		
(Frykberg, Driver et al., 2010)	+	+	+	+	+	+	+	+	++	+	+	++	+	yes	5	low
	+	+	+	—	+	+	+	+	++	—	+	—	—			
(Rappl, 2011)	+	+	+	+	+	+	+	+	++	+	+	++	++	yes	5	moderate
	+	+	+	N/A	+	+	+	+	++	—	—	+	—			
(de Leon, Driver et al., 2011)	+	+	+	+	+	+	+	+	++	+	+	++	+	Indirect evidence		moderate
	+	+	+	—	+	++	+	+	++	++	—	—	—	Mixed aetiology		

References

Caravaggi, C., F. Grigoletto and N. Scuderi. (2011). "Wound Bed Preparation With a Dermal Substitute (Hyalomatrix (R) PA) Facilitates Re-epithelialization and Healing: Results of a Multicenter, Prospective, Observational Study on Complex Chronic Ulcers (The FAST Study)." Wounds-a Compendium of Clinical Research and Practice **23**(8):228-35.

de Leon, J.M., V.R. Driver, C.P. Fylling, et al. (2011). "The Clinical Relevance of Treating Chronic Wounds with an Enhanced Near-Physiological Concentration of Platelet-Rich Plasma Gel." Advances in Skin & Wound Care **24**(8):357-68.

Frykberg, R.G., V.R. Driver, D. Carman, et al. (2010). "Chronic wounds treated with a physiologically relevant concentration of platelet-rich plasma gel: a prospective case series." Ostomy Wound Management **56**(6):36.

Karr, J. (2008). "Utilization of Living Bilayered Cell Therapy (Apligraf) for Heel Ulcers." Advances in Skin & Wound Care **21**(6):270-4.

Ohura, T., T. Nakajo, T. Moriguchi, et al. (2011). "Clinical efficacy of basic fibroblast growth factor on pressure ulcers: Case-control pairing study using a new evaluation method." Wound Repair and Regeneration **19**(5):542-51.

Pertusi, G., R. Tiberio, F. Graziola, et al. (2012). "Selective release of cytokines, chemokines, and growth factors by minced skin in vitro supports the effectiveness of autologous minced micrografts technique for chronic ulcer repair." Wound Repair Regen **20**(2):178-84.

Piatkowski, A., D. Ulrich, D. Seidel, et al. (2012). "Randomised, controlled pilot to compare collagen and foam in stagnating pressure ulcers." J Wound Care **21**(10):505-11.

Rappl, L.M. (2011). "Effect of platelet rich plasma gel in a physiologically relevant platelet concentration on wounds in persons with spinal cord injury." International Wound Journal **8**(2):187-95.

Sarasúa, J.G., S.P. López, M.Á. Viejo, et al. (2011). "Treatment of pressure ulcers with autologous bone marrow nuclear cells in patients with spinal cord injury." Journal of Spinal Cord Medicine **34**(3):301-7.

Scevola, S., G. Nicoletti, F. Brenta, et al. (2010). "Allogenic platelet gel in the treatment of pressure sores: a pilot study." International Wound Journal **7**(3):184-90.

BIOPHYSICAL AGENTS FOR TREATMENT

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Franek, Kostur et al., 2012)	++	+	++	—	+	+	+	++	—	N/A	+	++	yes	2	moderate
	++	+	++	—	+	+	+	++	—	N/A	+	++			
(Franek, Kostur et al., 2011)	+	++	++	—	+	+	+	++	++	N/A	+	++	yes	2	moderate
	+	++	++	—	+	+	+	++	++	N/A	+	++			
(Houghton, Campbell et al., 2010)	++	++	++	+	++	—	+	++	++	—	+	+	yes	2	moderate
	++	++	++	+	++	—	++	++	++	—	+	+			
(Gupta, Taly et al., 2009)	+	—	—	+	—	—	+	++	+	+	—	—	yes	2	low
	++	+	—	+	—	—	+	+	+	+	—	—			
(de Laat, van den Boogaard et al., 2011)	+	+	+	+	+	+	+	++	—	N/A	+	—	yes	2	moderate
	+	—	++	+	+	++	+	++	—	N/A	+	—			
(Wild, Stremitzer et al., 2008)	—	+	—	+	+	+	—	—	+	N/A	+	—	yes	2	low
	+	++	—	+	+	+	—	—	+	N/A	+	—			
(Durovic, Maric et al., 2008)	+	—	+	—	+	++	—	++	+	N/A	+	+	yes	2	low
	+	—	+	—	+	++	—	++	+	N/A	+	+			
(Ho, Bensitel et al., 2012)	++	+	++	++	++	++	++	++	++	N/A	+	+	yes	2	moderate
	++	+	++	++	++	++	++	++	++	N/A	+	+			
(Nussbaum, Flett et al., 2013)	++	++	++	++	+	+	++	—	—	—	+	+	yes	2	moderate

QUASI EXPERMIENTAL STUDIES

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Ho, Powell et al., 2010)	+	—	+	+	+	—	+	+	+	+	yes	5	low
	+	—	+	+	+	+	++	—	+	+			
(Arashi, Sugama et al., 2010)	+	+	+	++	+	++	++	—	+	+	yes	3	moderate
	+	+	+	++	+	++	++	—	+	+			

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Onigbinde, Olafimihan et al., 2010)	—	—	—	+	+	++	++	N/A	—	—	yes	3	low
	—	—	—	+	+	++	++	N/A	—	—			

SYSTEMATIC REVIEWS

Author/year	Focussed question	Description of methodology is included	Comprehensive literature search	Critical appraisal performed	Meta-analysis is appropriate	Minimal bias	Reliable conclusions	Relevant to guideline population	AMSTAR score or Cochrane method	Type of evidence	Included studies included in critical appraisal and master table	Level of evidence	Quality
(Ubbink, Westerbos et al., 2008)	++	++	++	++	N/A	++	++	yes	Cochrane	No meta-analysis Reports 2 RCTs of low methodological quality	Included in 2009 guideline	2	low
	++	++	++	++	N/A	+	++						
(Aziz and Flemming, 2012)	++	++	++	++	N/A	++	++	yes	Cochrane	No meta-analysis Reports 2 RCTs of low methodological quality	Included in 2009 guideline	2	low
	++	++	++	++	N/A	++	++						

CASE SERIES

Author/year	Focussed question	Participant characteristics reported	Inclusion criteria defined	Consecutive recruitment	Participants entered at same disease stage	Intervention clearly reported	Outcomes relevant and defined apriori	Valid, reliable outcome measurement	Per cent drop out reported	Estimates of random variability	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Wallin, Bostrom et al., 2011)	++	+	+	++	—	++	—	—	N/A	—	N/A	—	+	yes	5	moderate
	+	+	+	++	—	++	—	+	N/A	—	N/A	—	+			
(Conner-Kerr and Isenberg, 2012)	++	++	++	++	—	+	+	+	N/A	+	—	+	+	yes	5	moderate
	++	++	++	++	—	+	+	+	N/A	+	—	+	+			
(Frykberg, Driver et al., 2011)	+	+	++	++	—	+	N/A	+	N/A	+	—	+	+	yes	5	low
	+	+	++	++	—	++	N/A	++	N/A	+	N/A	+	+			
(Serena, Lee et al., 2009)	+	+	++	—	—	++	+	—	+	—	—	—	—	yes	5	low
(Honaker, Forston et al., 2013)	+	+	+	—	—	+	N/A	—	N/A	—	—	—	—	yes	5	low
	+	+	+	—	—	+	—	—	N/A	—	—	—	—			

References

Arashi, M., J. Sugama, H. Sanada, et al. (2010). "Vibration therapy accelerates healing of stage I pressure ulcers in older adult patients." Advances in Skin & Wound Care **23**(7):321.

Aziz, Z. and K. Flemming. (2012). "Electromagnetic therapy for treating pressure ulcers." Cochrane Database of Systematic Reviews (Online) **12**:CD002930.

Conner-Kerr, T. and R.A. Isenberg. (2012). "Retrospective analysis of pulsed radiofrequency energy therapy use in the treatment of chronic pressure ulcers." Advances in Skin & Wound Care **25**(6):253-60.

de Laat, E.H.E.W., M.H.W.A. van den Boogaard, P.H.M. Spauwen, et al. (2011). "Faster Wound Healing With Topical Negative Pressure Therapy in Difficult-to-Heal Wounds: A Prospective Randomized Controlled Trial." Annals of Plastic Surgery **67**(6):626-31.

Durovic, A., D. Maric, Z. Brdareski, et al. (2008). "The effects of polarized light therapy in pressure ulcer healing." VojnosanitPregl **65**(12):906.

Franek, A., R. Kostur, A. Polak, et al. (2012). "Using high-voltage electrical stimulation in the treatment of recalcitrant pressure ulcers: Results of a randomized, controlled clinical study." Ostomy Wound Management **58**(3):30-44.

Franek, A., R. Kostur, J. Taradaj, et al. (2011). "Effect of high voltage monophasic stimulation on pressure ulcer healing: results from a randomized controlled trial." Wounds: A Compendium of Clinical Research & Practice **23**(1):15-23.

Frykberg, R.G., V.R. Driver, L.A. Lavery, et al. (2011). "The use of pulsed radio frequency energy therapy in treating lower extremity wounds: Results of a retrospective study of a wound registry." Ostomy Wound Management **57**(3):22-9.

Gupta, A., A.B. Taly, A. Srivastava, et al. (2009). "Efficacy of pulsed electromagnetic field therapy in healing of pressure ulcers: A randomized control trial." NeurolIndia **57**(5):622.

Ho, C.H., T. Bensitel, X. Wang, et al. (2012). "Pulsatile lavage for the enhancement of pressure ulcer healing: a randomized controlled trial." Physical Therapy **92**(1):38-48.

Ho, C.H., H.L. Powell, J.F. Collins, et al. (2010). "Poor nutrition is a relative contraindication to negative pressure wound therapy for pressure ulcers: preliminary observations in patients with spinal cord injury." Advances in Skin & Wound Care **23**(11):508-16.

Honaker, J.S., M.R. Forston, E.A. Davis, et al. (2013). "Effects of non contact low-frequency ultrasound on healing of suspected deep tissue injury: A retrospective analysis." International Wound Journal **10**(1):65-72.

Houghton, P.E., K.E. Campbell, C.H. Fraser, et al. (2010). "Electrical stimulation therapy increases rate of healing of pressure ulcers in community-dwelling people with spinal cord injury." Archives of Physical Medicine and Rehabilitation **91**(5):669-78.

Nussbaum, E., H. Flett, S. Hitzig, et al. (2013). "Ultraviolet-C irradiation in the management of pressure ulcers in people with spinal cord injury: A randomized, placebo-controlled trial." Arch Phys Med Rehabil **94**(4):650-9.

Onigbinde, A.T., K.F. Olafimihan, A. Ojoawo, et al. (2010). "The effect of ultraviolet radiation (type B) on decubitus ulcers." Internet Journal of Allied Health Sciences & Practice **8**(1):1-6.

Serena, T., S.K. Lee, K. Lam, et al. (2009). "The impact of noncontact, nonthermal, low-frequency ultrasound on bacterial counts in experimental and chronic wounds." Ostomy/Wound Management **55**(1):22-30.

Ubbink, D.T., S.J.l. Westerbos, D. Evans, et al. (2008). "Topical negative pressure for treating chronic wounds." Cochrane Database Of Systematic Reviews (Online) (3):CD001898.

Wallin, A.-M., L. Bostrom, J. Ulfvarson, et al. (2011). "Negative pressure wound therapy - a descriptive study." Ostomy/Wound Management **57**(6):22-9.

Wild, T., S. Stremitzer, A. Budzanowski, et al. (2008). "Definition of efficiency in vacuum therapy--a randomised controlled trial comparing with V.A.C. Therapy." International Wound Journal **5**(5):641-7.

SURGERY FOR PRESSURE ULCERS

CASE SERIES

Author/year	Focussed question	Participant characteristics reported	Inclusion criteria defined	Consecutive recruitment	Participants entered at same disease stage	Intervention clearly reported	Outcomes relevant and defined apriori	Valid, reliable outcome measurement	Per cent drop out reported	Estimates of random variability	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Larson, Hudak et al., 2012)	++	+	++	++	++	++	++	++	—	+	N/A	+	+	yes	5	moderate
	+	++	++	++	+	++	++	++	—	+	N/A	+	+			
(Isken, Alagoz et al., 2009)	++	+	+	+	—	+	+	+	N/A	—	N/A	+	—	yes	5	low
	++	+	—	—	—	+	+	+	++	—	N/A	+	—			
(Yarkin, Tamer et al., 2009)	++	—	+	—	+	++	++	++	+	++	N/A	+	—	indirect evidence		low
	++	—	—	—	+	+	+	+	+	+	N/A	—	—	PU not an outcome measure		
(Srivastava, Gupta et al., 2009)	++	+	+	—	+	++	++	++	++	+	N/A	++	+	yes	5	moderate
	++	+	+	+	+	++	++	+	++	+	N/A	++	+			
(Ahluwalia, Martin et al., 2009)	—	—	+	—	+	+	—	+	N/A	—	N/A	—	—	yes	5	low
	+	—	—	+	+	+	—	—	++	—	N/A	—	—			
(Estrella and Lee, 2010)	+	—	+	—	+	+	+	+	N/A	—	N/A	++	—	yes	5	low
	+	+	++	—	+	++	—	—	++	—	N/A	+	—			
(Thiessen, Andrades et al., 2011)	++	++	+	++	+	+	+	+	++	++	N/A	+	+	yes	3	moderate
(Singh, Singh et al., 2013)	+	—	++	+	—	+	—	—	++	—	N/A	+	+	yes	5	low

CASE CONTROL

Author/year	Focussed question	Comparable source populations	Same exclusion cases and controls	Per cent drop out in study arms is reported	Comparison btw participants	Cases clearly defined	Established that controls are non-cases	Knowledge of primary exposure not influence case ascertainment	Valid, reliable assessment of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Daniali, Keys et al., 2011)	++	++	+	++	+	++	+	+	+	+	++	+	++	yes	5	moderate
	++	+	+	++	+	++	+	+	+	+	++	—	—			
(Kurita, Ichioka et al., 2009)	++	+	—	++	N/A	+	+	N/A	—	—	++	++	+	yes	4	low
	+	—	—	++	N/A	+	+	N/A	+	+	—	—	+			
(Kim, Kim et al., 2013)	++	+	—	++	+	++	++	—	+	—	—	+	+	yes	4	moderate

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number. invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Laing, Ekpete et al., 2010)	+	—	—	+	+	—	N/A	—	++	—	yes	N/A	moderate
	+	++	+	++	+	—	N/A	—	++	+			

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Rintala, Garber et al., 2008)	+	—	—	—	—	—	—	+	—	N/A	—	—	yes	2	low
	+	—	—	—	+	—	—	++	+	N/A	—	—			

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number. invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Keys, Daniali et al., 2010)	+	++	++	++	+	+	N/A	—	++	+	yes	4	moderate

References

Ahluwalia, R., D. Martin and J.L. Mahoney. (2009). "The operative treatment of pressure wounds: a 10-year experience in flap selection." International Wound Journal **6**(5):355-8.

Daniali, L.N., K. Keys, D. Katz, et al. (2011). "Effect of preoperative magnetic resonance imaging diagnosis of osteomyelitis on the surgical management and outcomes of pressure ulcers." Annals of Plastic Surgery **67**(5):520-5.

Estrella, E.P. and E.Y. Lee. (2010). "A retrospective, descriptive study of sacral ulcer flap coverage in nonambulatory patients with hypoalbuminemia." Ostomy Wound Manage **56**(3):52-9.

Isken, T., M.S. Alagoz, M. Onyedi, et al. (2009). "Preoperative color Doppler assessment in planning of gluteal perforator flaps." Annals of Plastic Surgery **62**(2):158-63.

Keys, K.A., L.N. Daniali, K.J. Warner, et al. (2010). "Multivariate predictors of failure after flap coverage of pressure ulcers." Plastic and Reconstructive Surgery **125**(6):1725-34.

Kim, Y.H., S.W. Kim, J.T. Kim, et al. (2013). "Tensor Fascia Lata Flap Versus Tensor Fascia Lata Perforator-Based Island Flap for the Coverage of Extensive Trochanteric Pressure Sores." Annals of Plastic Surgery.

Kurita, M., S. Ichioka, Y. Tanaka, et al. (2009). "Validity of the orthopedic POSSUM scoring system for the assessment of postoperative mortality in patients with pressure ulcers." Wound Repair And Regeneration: Official Publication Of The Wound Healing Society [And] The European Tissue Repair Society **17**(3):312-7.

Laing, T.A., N. Ekpete, S. Oon, et al. (2010). "Surgical reconstruction of pressure ulcer defects: a single- or two-stage procedure?" Journal of Wound, Ostomy, and Continence Nursing: Official Publication of the Wound, Ostomy and Continence Nurses Society / WOCN **37**(6):615-8.

Larson, D.L., K.A. Hudak, W.P. Waring, et al. (2012). "Protocol management of late-stage pressure ulcers: A 5-year retrospective study of 101 consecutive patients with 179 ulcers." Plastice and Reconstructive Surgery **129**(4):897-904.

Rintala, D.H., S.L. Garber, J.D. Friedman, et al. (2008). "Preventing recurrent pressure ulcers in veterans with spinal cord injury: impact of a structured education and follow-up intervention." Archives of Physical Medicine And Rehabilitation **89**(8):1429-41.

Singh, R., R. Singh, R.K. Rohilla, et al. (2013). "Improvisations in classic and modified techniques of flap surgery to improve the success rate for pressure ulcer healing in patients with spinal cord injury." International Wound Journal **10**(4):455-60.

Srivastava, A., A. Gupta, A.B. Taly, et al. (2009). "Surgical management of pressure ulcers during inpatient neurologic rehabilitation: outcomes for patients with spinal cord disease." JSpinal Cord Med **32**(2):125-31.

Thiessen, F.E., P. Andrades, P.N. Blondeel, et al. (2011). "Flap surgery for pressure sores: should the underlying muscle be transferred or not?" Journal of Plastic, Reconstructive & Aesthetic Surgery **64**(1):84-90.

Yarkin, O., S. Tamer, O. Gamze, et al. (2009). "Effect of surgery on psychiatric states and quality of life of paraplegics and quadriplegics with pressure sores and their primary caregivers." European Journal of Plastic Surgery **32**(4):173-6.

Special Populations

BARIATRIC INDIVIDUALS

CROSS SECTIONAL SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Quality
(VanGilder, MacFarlane et al., 2009)	++	—	—	—	+	++	—	—	—	+	yes	low
	++	—	—	—	+	++	—	—	—	+		
(Rimmer, Yamaki et al., 2010)	++	+	+	—	++	+	+	++	+	+	yes pediatric	moderate
	++	+	+	—	++	+	+	++	+	+		

COHORT STUDIES

Author/year	Focussed question	Comparable source populations	States number invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Rana, Michalsky et al., 2009)	++	++	++	—	N/A	N/A	+	+	—	N/A	—	+	+	—	yes		low
	++	++	++	—	N/A	N/A	+	N/A	—	N/A	—	+	+	—	paeds		
(Cai, Rahman et al., 2013)	+	+	++	+	N/A	+	+	+	+	+	++	—	+	+			moderate
	+	++	++	+	N/A	++	+	N/A	—	+	+	—	+	—			

QUASI EXPERIMENTAL STUDIES

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Pemberton, Turner et al., 2009)	++	N/A	+	++	+	++	++	N/A	+	++	yes	5	low
	+	—	N/A	N/A	+	++	N/A	N/A	—	—			

ADDITIONAL PAPERS	
Elsner, J.J. and A. Gefen, *Is obesity a risk factor for deep tissue injury in patients with spinal cord injury?* Journal of Biomechanics, 2008. 41(16): p. 3322-3331. (Elsner & Gefen, 2008)	Indirect evidence from computational models
Sopher, R., et al., *Exposure to internal muscle tissue loads under the ischial tuberosities during sitting is elevated at abnormally high or low body mass indices.* Journal of Biomechanics, 2010. 43(2): p. 280-286. (Sopher, Nixon et al., 2010)	Indirect evidence from computational models
Moysidis, T. Niebel, W. Bartsch, K. Maier, I. Lehmann, N. Nonnemacher, M. Kroeger, K. *Prevention of pressure ulcer: Interaction of body characteristics and different mattresses* International Wound Journal 8(6) 578-584 (Moysidis, Niebel et al., 2011)	Indirect from evidence healthy volunteers

References

Cai, S., M. Rahman, O. Intrator. (2013). "Obesity and pressure ulcers among nursing home residents." Medical care **51**(6): 478-86. Epub 2013/05/15.

Elsner, J. J., A. Gefen. (2008). "Is obesity a risk factor for deep tissue injury in patients with spinal cord injury?" Journal of Biomechanics **41**(16): 3322-31.

Moysidis, T., W. Niebel, K. Bartsch, I. Maier, N. Lehmann, M. Nonnemacher, et al. (2011). "Prevention of pressure ulcer: Interaction of body characteristics and different mattresses." International Wound Journal **8**(6): 578-84.

Pemberton, V., V. Turner, C. VanGilder. (2009). "The effect of using a low-air-loss surface on the skin integrity of obese patients: results of a pilot study." Ostomy Wound Management **55**(2): 44-8.

Rana, A. R., M. P. Michalsky, S. Teich, J. I. Groner, D. A. Caniano, D. P. Schuster. (2009). "Childhood obesity: a risk factor for injuries observed at a level-1 trauma center." Journal Of Pediatric Surgery **44**(8): 1601-5.

Rimmer, J. H., K. Yamaki, B. M. D. Lowry, E. Wang, L. C. Vogel. (2010). "Obesity and obesity-related secondary conditions in adolescents with intellectual/developmental disabilities." Journal of Intellectual Disability Research **54**(9): 787-94.

Sopher, R., J. Nixon, C. Gorecki, A. Gefen. (2010). "Exposure to internal muscle tissue loads under the ischial tuberosities during sitting is elevated at abnormally high or low body mass indices." Journal of Biomechanics **43**(2): 280-6.

VanGilder, C., G. MacFarlane, S. Meyer, C. Lachenbruch. (2009). "Body mass index, weight, and pressure ulcer prevalence: an analysis of the 2006-2007 International Pressure Ulcer Prevalence Surveys." Journal of Nursing Care Quality **24**(2): 127-35.

CRITICALLY ILL INDIVIDUALS

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Strand and Lindgren 2010)	++	++	++	++	++	++	N/A	+	+	++	Indirect evidence nurse knowledge		moderate
	++	++	++	++	++	++	+	+	+	++			
(Kottner, Wilborn et al. 2009)	++	++	+	+	+	—	+	—	+	+	Prevalence in ICU patients		low
	+	+	+	N/A	+	+	+	—	+	+			
(Shahin, Dassen et al. 2009)	++	+	+	+	++	++	—	—	+	++	Prevalence in ICU patients		low
	++	+	+	++	++	—	—	—	+	+			
(Iranmanesh, Rafiei et al. 2011)	++	+	+	—	++	++	—	—	+	—	Indirect evidence nurse knowledge		low
	++	+	+	—	++	++	—	—	+	—			
(Cho, Park et al. 2011)	++	++	++	N/A	+	+	N/A	—	+	+	Indirect evidence Workplace practice		low
	++	+	+	N/A	+	+	N/A	—	+	+			

COHORT STUDIES

Author/year	Focussed question	Comparable source populations	States number invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Tweed and Tweed 2008)	++	+	++	N/A	—	—	++	+	++	++	+	—	++	+	Indirect evidence Nurse knowledge		moderate
	++	+	++	N/A	—	—	++	+	++	+	+	—	++	+			
(Ozdemir and Karadag 2008)	++	N/A	++	N/A	++	N/A	++	N/A	+	+	+	—	+	+	Indirect evidence Nurse behaviour		low
	++	N/A	++	N/A	++	N/A	++	N/A	+	+	+	N/A	+	—			

CASE SERIES

Author/year	Focussed question	Participant characteristic reported	Inclusion criteria defined	Consecutive recruitment	Participants entered at same disease stage	Intervention clearly reported	Outcomes relevant and defined apriori	Valid, reliable outcome measurement	Per cent drop out reported	Estimates of random variability	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Williams, Leslie et al. 2011)	+	—	+	—	—	+	—	—	—	+	N/A	—	—	Indirect evidence		low
(Romero, Cornejo et al. 2009)	++	++	++	++	—	++	++	++	++	—	N/A	+	+	yes	5	moderate
	++	—	++	++	—	++	++	++	++	—	N/A	+	+			

QUALITY IMPROVEMENT STUDIES

Author/year	Title/abstract is accurate	Current knowledge summarised in background	Specific project aims	Ethical aspects discussed	Sufficient reporting of intervention for replication	Reports factors contributing to intervention choice reported	Clear evaluation measures	Internal and external validity addressed	Appropriate analysis	Results report elements of the setting, change sin care processes and patient outcomes	Evidence of association between change and patient outcomes	Reports limitations	Reliable interpretation of findings	Funding sources reported	Relevant to guideline population	Level of evidence	Quality
(Dibsie 2008)	++	++	++	—	++	++	+	—	+	++	+	—	++	++	yes	4	moderate
	+	++	—	—	+	+	+	—	N/A	++	+	+	++	N/A			
(Gray-Siracusa and Schrier 2011)	++	++	++	—	++	++	+	+	+	++	+	+	++	++	yes	4	moderate
	++	++	++	++	++	++	+	—	+	++	++	++	+	++			
(Kelleher, Moorer et al. 2012)	++	++	++	—	++	+	+	—	+	++	+	+	++	+	yes	4	moderate
	++	++	++	—	++	++	++	—	++	++	++	+	++	—			

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Theilla, Schwartz et al. 2011; Theilla, Schwartz et al. 2012)	++	++	—	+	++	++	+	++	++	N/A	+	—	yes	2	moderate
	++	++	—	+	++	++	+	++	++	N/A	+	—			

QUASI EXPERIMENTAL STUDIES

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Weng 2008)	++	—	++	+	+	++	++	N/A	+	+	yes	3	moderate
(Brindle and Wegelin 2012)	++	+	++	++	++	++	++	+	++	++	yes	3	moderate
	++	—	++	++	++	++	—	+	++	+			
(Black, Berke et al. 2012)	++	—	+	+	+	—	—	N/A	—	—	yes	3	low
	++	—	—	—	+	—	—	N/A	—	—			
(Cox, Roche et al. 2011)	+	N/A	+	—	+	++	++	N/A	+	+	Indirect evidence nurse knowledge		moderate
	+	N/A	+	—	+	++	++	N/A	+	+			

References

Black, J., C. Berke, et al. (2012). "Pressure ulcer incidence and progression in critically ill subjects : influence of low air loss mattress versus a powered air pressure redistribution mattress." Journal of Wound, Ostomy and Continence Nursing **39**(3): 267-273.

Brindle, C. T. and J. A. Wegelin (2012). "Prophylactic dressing application to reduce pressure ulcer formation in cardiac surgery patients." Journal of Wound, Ostomy and Continence Nursing **39**(2): 133-142.

Cho, I., H. Park, et al. (2011). "Exploring practice variation in preventive pressure-ulcer care using data from a clinical data repository." International Journal of Medical Informatics **80**(1): 47-55.

Cox, J., S. Roche, et al. (2011). "The effects of various instructional methods on retention of knowledge about pressure ulcers among critical care and medical-surgical nurses." Journal of Continuing Education in Nursing **42**(2): 71-78.

Dibsie, L. G. (2008). "Implementing evidence-based practice to prevent skin breakdown." Critical Care Nursing Quarterly **31**(2): 140-149.

Gray-Siracusa, K. and L. Schrier (2011). "Use of an intervention bundle to eliminate pressure ulcers in critical care." Journal of Nursing Care Quality **26**(3): 216-225.

Iranmanesh, S., H. Rafiei, et al. (2011). "Critical care nurses' knowledge about pressure ulcer in southeast of Iran." International Wound Journal **8**(5): 459-464.

Kelleher, A. D., A. Moorer, et al. (2012). "Peer-to-peer nursing rounds and hospital-acquired pressure ulcer prevalence in a surgical intensive care unit: A quality improvement project." Journal of Wound, Ostomy and Continence Nursing **39**(2): 152-157.

Kottner, J., D. Wilborn, et al. (2009). "The trend of pressure ulcer prevalence rates in German hospitals: results of seven cross-sectional studies." Journal of Tissue Viability **18**(2): 36-46.

Ozdemir, H. and A. Karadag (2008). "Prevention of pressure ulcers: a descriptive study in 3 intensive care units in Turkey." Journal of Wound, Ostomy, and Continence Nursing: Official Publication of the Wound, Ostomy and Continence Nurses Society / WOCN **35**(3): 293-300.

Romero, C. M., R. A. Cornejo, et al. (2009). "Extended prone position ventilation in severe acute respiratory distress syndrome: A pilot feasibility study." Journal of Critical Care **24**(1): 81-88.

Shahin, E. S. M., T. Dassen, et al. (2009). "Pressure ulcer prevention in intensive care patients: guidelines and practice." Journal of Evaluation In Clinical Practice **15**(2): 370-374.

Strand, T. and M. Lindgren (2010). "Knowledge, attitudes and barriers towards prevention of pressure ulcers in intensive care units: a descriptive cross-sectional study." Intensive & Critical Care Nursing: The Official Journal of the British Association of Critical Care Nurses **26**(6): 335-342.

Theilla, M., B. Schwartz, et al. (2012). "Impact of a nutritional formula enriched in fish oil and micronutrients on pressure ulcers in critical care patients." American Journal of Critical Care **21**(4): e102-e109.

Theilla, M., B. Schwartz, et al. (2011). "Enteral n-3 fatty acids and micronutrients enhance percentage of positive neutrophil and lymphocyte adhesion molecules: a potential mediator of pressure ulcer healing in critically ill patients." British Journal of Nutrition: 1-6.

Tweed, C. and M. Tweed (2008). "Intensive care nurses' knowledge of pressure ulcers: development of an assessment tool and effect of an educational program." American Journal of Critical Care **17**(4): 338.

Weng, M. (2008). "The effect of protective treatment in reducing pressure ulcers for non-invasive ventilation patients." Intensive & Critical Care Nursing: The Official Journal Of The British Association Of Critical Care Nurses **24**(5): 295-299.

Williams, T. A., G. D. Leslie, et al. (2011). "Optimizing seating in the intensive care unit for patients with impaired mobility." American Journal of Critical Care **20**(1): e19-e27.

OLDER ADULTS

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number. invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Morello, Marcon et al., 2009)	+	+	+	+	+	—	—	—	+	+	Indirect evidence		low
	+	+	+	+	+	—	—	—	+	+			
(Yamamoto, Hayashino et al., 2010)	++	++	+	++	+	++	—	—	+	+	yes	N/A	moderate
	++	++	++	++	+	++	—	++	+	+			
(Volkert, Pauly et al., 2011)	++	+	++	++	—	—	—	—	—	—	yes	N/A	low
	+	—	+	+	+	—	—	—	—	—			
(Urasaki, Nakagami et al., 2011)	++	—	—	—	++	+	N/A	—	+	—	Indirect evidence		low
(Baumgarten, Margolis et al., 2009)	++	++	++	++	++	++	++	++	++	++	yes	N/A	high
	++	++	++	++	++	++	N/A	++	++	++			

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Grubbs, Ludwig et al., 2009)	+	—	—	N/A	+	+	++	++	++	N/A	+	+	yes	3	moderate
	+	—	—	N/A	+	+	++	++	++	N/A	+	+			
(Cereda, Gini et al., 2009)	++	++	—	++	—	++	+	++	—	—	+	++	yes	2	moderate
	++	++	—	++	—	++	+	++	—	—	+	++			
(Meaume, Kerihuel et al., 2009)	++	++	++	++	++	++	++	++	++	—	+	++	yes	1	high
	++	++	++	++	++	++	++	++	++	—	+	++			

CASE CONTROL

Author/year	Focussed question	Comparable source populations	Same exclusion cases and controls	Per cent drop out in study arms is reported	Comparison btw participants and non-participants	Cases clearly defined	Established that controls are non-cases	Knowledge of primary exposure not influence case ascertainment	Valid, reliable assessment of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Rodriguez-Fernandez, Adarraga-Cansino et al., 2011)	++	++	++	—	++	++	++	—	—	++	—	++	+	yes		moderate
	++	++	++	—	++	++	++	—	—	++	—	++	—			

COHORT STUDIES

Author/year	Focussed question	Comparable source populations	States number invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Arinzon, Peisakh et al., 2008)	++	+	—	++	+	—	++	—	—	+	+	—	—	++	yes	5	low
	++	+	—	++	+	—	++	—	—	+	+	—	—	++			
(Aminoff, 2012)	+	+	—	N/A	++	—	+	—	+	+	—	—	—	—	yes	N/A	low
	+	+	—	—	++	—	—	—	+	+	—	—	—	—			
(Cadigan, Grabowski et al., 2012)	++	++	—	—	—	—	++	—	++	—	+	++	+	—	yes	5	low
	++	++	—	—	—	—	++	—	++	—	+	++	+	—			
(Pérez-Zepeda, Gutiérez-Robledo et al., 2012)	++	++	++	++	—	++	++	—	++	++	++	++	++	++	yes	3	high
	++	++	++	++	—	++	++	—	++	++	++	++	++	++			
(Rich, Margolis et al., 2011)	++	+	++	+	++	N/A	+	—	—	++	+	++	+	+	yes	3	moderate
	++	+	++	+	++	N/A	+	—	—	++	+	++	+	—			

QUALITATIVE STUDIES

Author/year	Focussed question	Appropriate qualitative methodology	Recruitment appropriate to research and sample justified	Setting for data collection justified	Clear, explicit methods for data collection	Saturation of data	Researcher's role in data collection and analysis and potential bias addressed	Ethics clearance	In-depth description n of analysis technique	Sufficient supporting data	Contradictory data considered	Findings related to original question are stated	Discusses evidence for and against the researcher's argument	Research contributes to the existing knowledge	Relevance to guideline population	Level of evidence	Quality
(Mangaco-Borja, 2011)	+	—	—	—	—	+	+	—	—	+	+	—	+	N/A	yes	N/A	Cohort study Low quality

RISK STUDIES

Author/year	Baseline sample adequately described	Study attrition (<20% lost to follow-up)	Clear definition of RFs	Were continuous variables used/ appropriate cut-point	RF measure/method valid and reliable	*Adequate % sample with complete data	Method/setting of measurement same for all	Appropriate imputation method	Appropriate classification for outcome	Potential confounders accounted in study design	Potential confounders	Data adequate to assess adequacy of analysis	Appropriate strategy for model building	Model adequate for design	Adequate sample size	No selective reporting	Limitation category
(Baumgarten, Rich et al., 2012)	y	y	y	unk	y	72%	y	NA	y	y	y	no	y	y	no	y	low
(de Souza and de Gouveia, 2010; de Souza, Santos et al., 2010)	partial	y	y	Unk/NR	y	unk	y	NA	y	y	y	y	y	y	no	y	low

References

Aminoff, B.Z. (2012). "End-stage dementia: Aminoff suffering syndrome and decubitus ulcers." Dementia **11**(4):473-81.

Arinzon, Z., A. Peisakh and Y.N. Berner. (2008). "Evaluation of the benefits of enteral nutrition in long-term care elderly patients." J Am Med Dir Assoc **9**(9):657-62.

Baumgarten, M., D.J. Margolis, D.L. Orwig, et al. (2009). "Pressure ulcers in elderly patients with hip fracture across the continuum of care." Journal of the American Geriatrics Society **57**(5):863-70.

Baumgarten, M., S.E. Rich, M.D. Shardell, et al. (2012). "Care-related risk factors for hospital-acquired pressure ulcers in elderly adults with hip fracture." Journal of the American Geriatrics Society **60**(2):277-83.

Cadigan, R., D. Grabowski, J. Givens, et al. (2012). "The quality of advanced dementia care in the nursing home: the role of special care units." Medical care **50**(10):856-62.

Cereda, E., A. Gini, C. Pedrolli, et al. (2009). "Disease-specific, versus standard, nutritional support for the treatment of pressure ulcers in institutionalized older adults: a randomized controlled trial." Journal of the American Geriatrics Society **57**(8):1395-402.

de Souza, D. and S.V. de Gouveia. (2010). "Incidence of pressure ulcers in the institutionalized elderly." Journal of Wound, Ostomy, and Continence Nursing: Official Publication of the Wound, Ostomy and Continence Nurses Society / WOCN **37**(3):272-6.

de Souza, D., V. Santos, H. Iri, et al. (2010). "Predictive validity of the Braden Scale for Pressure Ulcer Risk in elderly residents of long-term care facilities." Geriatric Nursing (New York, NY) **31**(2):95-104.

Grubbs, S., M. Ludwig, E. McHale, et al. (2009). "The effect of high frequency ultrasound on the prevention of pressure ulcers in long-term care patients." Internet Journal of Academic Physician Assistants **7**(1):3-.

Mangaco-Borja, E. (2011). "The significance of introducing permanent assignments for nursing assistants at a long-term care setting on the incidence rate of facility-acquired pressure ulcers among elderly patients." Journal of the American College of Certified Wound Specialists **3**(1):13-5.

Meaume, S., J.C. Kerihuel, T. Constans, et al. (2009). "Efficacy and safety of ornithine alpha-ketoglutarate in heel pressure ulcers in elderly patients: results of a randomized controlled trial." The Journal of Nutrition, Health & Aging **13**(7):623-30.

Morello, M., M.L. Marcon, A. Laviano, et al. (2009). "Enteral nutrition in nursing home residents: a 5-year (2001-2005) epidemiological analysis." Nutrition in Clinical Practice **24**(5):635-41.

Pérez-Zepeda, M., L. Gutiérez-Robledo, S. Sánchez-Garcia, et al. (2012). "Comparison of a geriatric unit with a general ward in Mexican elders." Archives of Gerontology and Geriatrics **54**(3):e370-e5.

Rich, S.E., D. Margolis, M. Shardell, et al. (2011). "Frequent manual repositioning and incidence of pressure ulcers among bed-bound elderly hip fracture patients." Wound Repair and Regeneration **19**(1):10-8.

Rodriguez-Fernandez, P., D. Adarraga-Cansino and P. Carpintero. (2011). "Effects of delayed hip fracture surgery on mortality and morbidity in elderly patients." Clinical Orthopaedics and Related Research **469**(11):3218-21.

Urasaki, M., G. Nakagami, H. Sanada, et al. (2011). "Interface pressure distribution of elderly Japanese people in the sitting position." Disability and Rehabilitation Assistive Technology **6**(1):38-46.

Volkert, D., L. Pauly, P. Stehle, et al. (2011). "Prevalence of malnutrition in orally and tube-fed elderly nursing home residents in germany and its relation to health complaints and dietary intake." Gastroenterology Research and Practice.

Yamamoto, Y., Y. Hayashino, T. Higashi, et al. (2010). "Keeping vulnerable elderly patients free from pressure ulcer is associated with high caregiver burden in informal caregivers." Journal of Evaluation in Clinical Practice **16**(3):585-9.

INDIVIDUALS IN THE OPERATING ROOM

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number. invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Bulfone, Marzolil et al., 2012)	++	++	++	++	++	++	N/A	++	++	++	yes		high
	++	++	++	++	++	++	N/A	++	++	++			
(Bry, Buescher et al., 2012)	++	++	++	++	+	++	++	++	++	++	yes		moderate
	++	++	++	+	+	+	++	++	++	++			
(Haleem, Heinert et al., 2008)	++	++	+	++	—	—	N/A	+	+	—	yes		moderate
	+	+	++	++	+	++	N/A	+	++	—			
(Nilsson, 2013)	+	+	—	—	—	—	N/A	—	—	—	yes		low

QUASI EXPERMIENTAL STUDIES

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commence-ment	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Malkoun, Huber et al., 2012)	++	—	N/A	++	—	++	++	N/A	—	—	Indirect evidence		moderate
	++	—	N/A	++	+	++	++	N/A	+	+	Healthy volunteers		
(Wu, Wang et al., 2011)	++	—	+	+	++	++	++	N/A	+	++	yes	3	moderate
	+	—	+	N/A	+	+	+	N/A	+	N/A			

COHORT STUDIES

Author/year	Focussed question	Comparable source populations	States number invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Al-Ani, Samuelsson et al., 2008)	++	++	++	—	++	++	+	—	+	—	++	++	+	++	yes	2	moderate
(Lefaivre, Macadam et al., 2009)	+	—	—	—	—	—	+	—	+	+	—	++	+	—	yes	2	low
	+	—	—	—	—	—	—	—	—	—	—	++	+	—			
(Primiano, Friend et al., 2011)	+	+	—	—	—	—	—	—	—	—	—	—	+	—	yes	2	low
	+	+	—	++	—	—	+	—	+	+	+	—	++	++			
(Smektala, Endres et al., 2008)	+	+	—	+	—	—	+	N/A	+	—	—	++	+	+	yes	2	low
	+	+	++	—	+	+	—	—	—	—	++	++	+	—			
(Stahel, Vanderheiden et al., 2013)	+	++	++	—	—	—	—	—	—	—	—	—	+	+	yes	5	low

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Donnelly, Winder et al., 2011)	++	++	++	+	++	+	++	++	++	N/A	++	++	yes	2	moderate
	++	++	++	+	++	+	++	++	++	N/A	++	+			
(Grisell and Place, 2008)	++	++	—	+	—	—	++	++	++	N/A	—	—	yes	2	low
	++	++	—	+	—	—	++	++	++	N/A	—	—			

References

Al-Ani, A.N., B. Samuelsson, J. Tidermark, et al. (2008). "Early operation on patients with a hip fracture improved the ability to return to independent living. A prospective study of 850 patients." The Journal Of Bone And Joint Surgery American Volume **90**(7):1436-42.

Bry, K.E., D. Buescher and M. Sandrik. (2012). "Never say never: a descriptive study of hospital-acquired pressure ulcers in a hospital setting." Journal of Wound, Ostomy and Continence Nursing **39**(3):274-81.

Bulfone, G., I. Marzolil, R. Wuattrin, et al. (2012). "A longitudinal study of the incidence of pressure sores and the associated risks and strategies adopted in Italian operating theatres." Journal of Perioperative Practice **22**(2):50-6.

Donnelly, J., J. Winder, W.G. Kernohan, et al. (2011). "An RCT to determine the effect of a heel elevation device in pressure ulcer prevention post-hip fracture." Journal of Wound Care **20**(7):309.

Grisell, M. and H.M. Place. (2008). "Face tissue pressure in prone positioning: a comparison of three face pillows while in the prone position for spinal surgery." Spine **33**(26):2938-41.

Haleem, S., G. Heinert and M.J. Parker. (2008). "Pressure sores and hip fractures." Injury **39**(2):219-23.

Lefaivre, K.A., S.A. Macadam, D.J. Davidson, et al. (2009). "Length of stay, mortality, morbidity and delay to surgery in hip fractures." The Journal of Bone and Joint Surgery British Volume **91**(7):922-7.

Malkoun, M., J. Huber and D. Huber. (2012). "A comparative assessment of interface pressures generated by four surgical theatre heel pressure ulcer prophylactics." International Wound Journal **9**(3):259-63.

Nilsson, U.G. (2013). "Intraoperative positioning of patients under general anesthesia and the risk of postoperative pain and pressure ulcers." Journal of perianesthesia nursing : official journal of the American Society of PeriAnesthesia Nurses / American Society of PeriAnesthesia Nurses **28**(3):137-43.

Primiano, M., M. Friend, C. McClure, et al. (2011). "Pressure ulcer prevalence and risk factors during prolonged surgical procedures." AORN Journal **94**(6):555-66.

Smektala, R., H.G. Endres, B. Dasch, et al. (2008). "The effect of time-to-surgery on outcome in elderly patients with proximal femoral fractures." BMC MusculoskeletDisord **9**:17 doi:0.1186/471-2474-9-171.

Stahel, P.F., T. Vanderheiden, M.A. Flierl, et al. (2013). "The impact of a standardized "spine damage-control" protocol for unstable thoracic and lumbar spine fractures in severely injured patients: A prospective cohort study." The journal of trauma and acute care surgery **74**(2):590-6.

Wu, T., S.T. Wang, P.C. Lin, et al. (2011). "Effects of using a high-density foam pad versus a viscoelastic polymer pad on the incidence of pressure ulcer development during spinal surgery." Biological Research For Nursing **13**(4):419-24.

INDIVIDUALS IN PALLIATIVE CARE

DIAGNOSTIC STUDIES

Author/year	Nature of test is defined	Test compared to a gold standard	Where no gold standard exists, compared with valid reference standard	Clear population from which participants selected	Independent measurement of test and standard	Test and standard measured as close in time as possible	Results for all patients reported	Pre-test diagnosis reported	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Maida, Ennis et al., 2009)	++	—	—	++	—	—	++	++	—	Indirect evidence Mixed wounds		low

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Bonaldi, Parazzini et al., 2009)	++	++	++	—	++	+	—	—	+	+	Yes	N/A	low
(Gozalo, Teno et al., 2011)	++	++	+	+	++	+	++	+	++	++	Yes	N/A	moderate
(Hendrichova, Castelli et al., 2010)	++	++	+	N/A	++	++	N/A	+	+	+	Yes	N/A	moderate
	++	++	+	N/A	++	++	N/A	+	+	+			

CASE SERIES

Author/year	Focussed question	Participant characteristics reported	Inclusion criteria defined	Consecutive recruitment	Participants entered at same disease stage	Intervention clearly reported	Outcomes relevant and defined apriori	Valid, reliable outcome measurement	Per cent drop out reported	Estimates of random variability	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Maida, Ennis et al., 2012)	++	+	+	++	—	—	++	—	++	—	N/A	—	—	yes	5	low
	++	+	+	++	—	—	++	—	++	—	N/A	—	—			

COHORT STUDIES

Author/year	Focussed question	Comparable source populations	States number invited	Likelihood of outcome at enrolment	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Maida, Ennis et al., 2012)	++	+	++	—	++	—	++	—	++	++	—	—	+	+	yes	N/A	moderate
	++	+	++	—	++	—	++	—	++	++	—	—	+	+			
(Maida, Ennis et al., 2009)	++	+	++	—	++	—	++	—	++	++	+	—	+	+	yes	N/A	moderate
(Aminoff, 2012)	+	+	—	N/A	++	—	+	—	+	+	—	—	—	—	yes	N/A	low
	+	+	—	—	++	—	—	—	+	+	—	—	—	—			

QUALITATIVE STUDIES

Author/year	Focussed question	Appropriate qualitative methodology	Recruitment appropriate to research and sample justified	Setting for data collection justified	Clear, explicit methods for data collection	Saturation of data	Researcher's role in data collection and analysis and potential bias addressed	Ethics clearance	In-depth description n of analysis	Sufficient supporting data	Contradictory data considered	Findings related to original question are stated	Discusses evidence for and against the researcher's argument	Research contributes to the existing knowledge	Relevance to guideline population	Level of evidence	Quality
(Kayser-Jones, Kris et al., 2008)	Y	Y	Y	Y	N	N	N	Y	N	Y	N	Y	N	Y	yes	5	moderate
(Searle & McInerney, 2008)	Y	Y	Y	Y	Y	N	N	Y	N	Y	N	Y	N	Y	yes	5	moderate

References

Aminoff, B. Z. (2012). "End-stage dementia: Aminoff suffering syndrome and decubitus ulcers." Dementia **11**(4): 473-81.

Bonaldi, A., F. Parazzini, O. Corli, L. Lodetti. (2009). "Palliative care at home in cancer patients in Milan." European Journal of Palliative Care **16**(1): 40-2.

Gozalo, P., J. M. Teno, S. L. Mitchell, J. Skinner, J. Bynum, D. Tyler, et al. (2011). "End-of-life transitions among nursing home residents with cognitive issues." The New England Journal of Medicine **365**(13): 1212-21.

Hendrichova, I., M. Castelli, C. Mastroianni, M. Piredda, F. Mirabella, L. Surdo, et al. (2010). "Pressure ulcers in cancer palliative care patients." Palliative Medicine **24**(7): 669-73.

Kayser-Jones, J., A. E. Kris, K. Lim, R. I. Walent, E. Halifax, S. M. Paul. (2008). "Pressure ulcers among terminally ill nursing home residents." Research in Gerontological Nursing **1**(1): 14-24.

Maida, V., M. Ennis, J. Corban. (2012). "Wound outcomes in patients with advanced illness." International Wound Journal.

Maida, V., M. Ennis, C. Kuziemsky. (2009). "The Toronto Symptom Assessment System for Wounds: a new clinical and research tool." Advances in Skin & Wound Care **22**(10): 468.

Maida, V., M. Ennis, C. Kuziemsky, J. Corban. (2009). "Wounds and survival in cancer patients." European Journal Of Cancer (Oxford, England: 1990) **45**(18): 3237-44.

Searle, C., F. McInerney. (2008). "Creating comfort: nurses' perspectives on pressure care management in the last 48 hours of life." Contemporary Nurse **29**(2): 147-58.

PEDIATRIC INDIVIDUALS

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Schluer, Halfens et al., 2012)	++	++	++	++	++	++	++	++	++	++	yes		moderate
	++	++	++	++	—	—	++	++	+	+			
(Schluer, Cignacco et al., 2009)	++	+	—	—	+	+	—	N/A	++	+	yes		low
(García-Molina, Balaguer-López et al., 2012)	+	+	—	—	+	+	N/A	—	—	—	yes	4	low
	+	—	—	+	+	+	N/A	—	—	—			
(Schindler, Mikhailov et al., 2011)	++	++	++	++	+	+	+	++	++	++	yes	4	moderate

QUASI EXPERMIENTAL STUDIES

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Turnage-Carrier, McLane et al., 2008)	++	—	+	+	+	+	—	N/A	—	—	Indirect evidence		low
	++	—	+	+	+	+	—	N/A	—	—	Healthy volunteers		
(Chidini, Calderini et al., 2010)	++	—	++	++	+	+	++	N/A	++	++	yes	3	moderate

COHORT STUDIES

Author/year	Focussed question	Comparable source populations	States number. invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Rana, Michalsky et al., 2009)	++	++	++	—	N/A	N/A	+	+	—	N/A	—	++	+	—	prevalence study yes		low
	++	++	++	—	N/A	N/A	+	N/A	—	N/A	—	++	+	—			
(Fujii, Sugama et al., 2010)	++	+	++	++	++	++	+	N/A	+	++	++	++	++	+	yes	2	moderate

CASE SERIES

Author/year	Focussed question	Participant characteristics reported	Inclusion criteria defined	Consecutive recruitment	Participants entered at same disease stage	Intervention clearly reported	Outcomes relevant and defined apriori	Valid, reliable outcome measurement	Per cent drop out reported	Estimates of random variability	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Jaryszak, Shah et al., 2011)	—	+	++	++	—	N/A	—	—	N/A	N/A	N/A	++	+	yes	5	low
	—	—	+	++	N/A	+	—	—	N/A	—	N/A	—	—			
(Limpaphayom, Skaggs et al., 2009)	++	++	++	+	N/A	+	—	—	N/A	—	N/A	++	+	yes	5	low
	+	—	+	+	N/A	—	+	—	N/A	—	N/A	—	—			

DIAGNOSTIC STUDIES

Author/year	Nature of test is defined	Test compared to a gold standard	Where no gold standard exists, compared with valid reference standard	Clear population from which participants selected consecutively	Independent measurement of test and standard	Test and standard measured as close in time as possible	Results for all patients reported	Pre-test diagnosis reported	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Willock, Anthony et al., 2008)	++	+	N/A	++	++	+	+	N/A	++	yes	3	moderate
	++	+	N/A	++	++	++	+	N/A	—			
(Anthony, Willock et al., 2010)	++	N/A	++	—	—	—	++	N/A	—	yes	3	low

Author/year	Nature of test is defined	Test compared to a gold standard	Where no gold standard exists, compared with valid reference standard	Clear population from which participants selected consecutively	Independent measurement of test and standard	Test and standard measured as close in time as possible	Results for all patients reported	Pre-test diagnosis reported	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Kottner, Kenzler et al., 2012)	++	N/A	++	++	++	++	++	N/A	++	yes	2	high

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(De Raeve, Vercruysse et al., 2001)	+	—	—	—	+	+	—	—	—	N/A	—	—	yes	2	low

CASE CONTROL

Author/year	Focussed question	Comparable source populations	Same exclusion cases &controls	Per cent drop out in study arms is reported	Comparison btw participants and non-participants	Cases clearly defined	Established that controls are non-cases	Knowledge of primary exposure not influence case ascertainment	Valid, reliable assessment of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(McCord, McElvain et al., 2004)	++	—	—	++	—	+	—	—	++	—	—	—	+	yes	4	low

References

Anthony, D., J. Willock and M. Baharestani. (2010). "A comparison of Braden Q, Garvin and Glamorgan risk assessment scales in paediatrics." Journal Of Tissue Viability **19**(3):98-105.

Chidini, G., E. Calderini and P. Pelosi. (2010). "Treatment of acute hypoxemic respiratory failure with continuous positive airway pressure delivered by a new pediatric helmet in comparison with a standard full face mask: A prospective pilot study." Pediatric Critical Care Medicine **11**(4):502-8.

De Raeve, P., R. Vercruysse, T. Waterschoot, et al. (2001). "Two mattresses for neonates compared for cost and quality of nursing care." Critical Care Nursing in Europe **1**(1):5-10.

Fujii, K., J. Sugama, M. Okuwa, et al. (2010). "Incidence and risk factors of pressure ulcers in seven neonatal intensive care units in Japan: a multisite prospective cohort study." International Wound Journal **7**(5):323-8.

García-Molina, P., E. Balaguer-López, J.E. Torra I Bou, et al. (2012). "A prospective, longitudinal study to assess use of continuous and reactive low-pressure mattresses to reduce pressure ulcer incidence in a pediatric intensive care unit." Ostomy Wound Management **58**(7):32-9.

Jaryszak, E.M., R.K. Shah, J. Amling, et al. (2011). "Pediatric tracheotomy wound complications: Incidence and significance." Archives of Otolaryngology - Head and Neck Surgery **137**(4):363-6.

Kottner, J., M. Kenzler and D. Wilborn. (2012). "Interrater agreement, reliability and validity of the Glamorgan Paediatric Pressure Ulcer Risk Assessment Scale." J Clin Nurs:pre-pub.

Kottner, J., F. Schroer and T. A. (2012). "[Evaluation of the Glamorgan Scale in a paediatric intensive care unit: agreement and reliability]." Pflege Zeitschrift **25**(6):459-67.

Limpaphayom, N., D.L. Skaggs, G. McComb, et al. (2009). "Complications of halo use in children." Spine **34**(8):779-84.

McCord, S., V. McElvain, R. Sachdeva, et al. (2004). "Risk factors associated with pressure ulcers i na pediatric intensive care unit." Journal of Wound Ostomy and Continence Nursing **July**:179-83.

Rana, A.R., M.P. Michalsky, S. Teich, et al. (2009). "Childhood obesity: a risk factor for injuries observed at a level-1 trauma center." Journal Of Pediatric Surgery **44**(8):1601-5.

Schindler, C.A., T.A. Mikhailov, E.M. Kuhn, et al. (2011). "Protecting fragile skin: nursing interventions to decrease development of pressure ulcers in pediatric intensive care. ." American Journal of Critical Care **20**(1):26-35.

Schluer, A.B., E. Cignacco, M. Muller, et al. (2009). "The prevalence of pressure ulcers in four paediatric institutions." Journal of clinical nursing **18**(23):3244.

Schluer, A.B., R.J. Halfens and J.G.A. Schols. (2012). " Pediatric pressure ulcer prevalence: A multicenter, cross-sectional, point prevalence study in Switzerland." Ostomy Wound Management **58**(7):18-31.

Turnage-Carrier, C., K.M. McLane and M.A. Gregurich. (2008). "Interface pressure comparison of healthy premature infants with various neonatal bed surfaces." Advances in Neonatal Care **8**(3):176-84.

Willock, J., D. Anthony and J. Richardson. (2008). "Inter-rater reliability of Glamorgan Paediatric Pressure Ulcer Risk Assessment Scale." Paediatric Nursing **20**(7):14-9.

INDIVIDUALS WITH SPINAL CORD INJURY

DIAGNOSTIC STUDIES

Author/year	Nature of test is defined	Test compared to a gold standard	Where no gold standard exists, compared with valid reference standard	Clear population from which participants selected consecutively	Independent measurement of test and standard	Test and standard measured as close in time as possible	Results for all patients reported	Pre-test diagnosis reported	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Gélis, Daures et al., 2011)	+	—	++	+	++	++	++	N/A	++	Indirect evidence PU not an outcome		moderate

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number. invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Gil-Agudo, De la Peña-González et al., 2009)	—	+	++	—	+	+	N/A	+	+	++	Indirect evidence PU not an outcome		moderate
	—	+	+	—	+	+	N/A	+	+	++			
(Mathew, Samuelkamaleshkumar et al., 2013)	+	—	—	+	+	—	N/A	—	—	+	Indirect evidence PU not an outcome		low
(Wu, Ning et al., 2013)	+	++	++	++	+	+	—	+	++	++	Indirect evidence PU not an outcome		moderate
(Wilson, Arnold et al., 2012)	+	++	++	++	+	+	—	+	++	++	Indirect evidence PU not an outcome		moderate

QUASI EXPERMIENTAL STUDIES

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Ho, Powell et al., 2010)	+	—	+	+	+	—	+	+	+	+	yes	5	low
	+	—	+	+	+	+	++	—	+	+			

COHORT STUDIES

Author/year	Focussed question	Comparable source populations	States number. invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Sarasúa, López et al., 2011)	+	N/A	+	+	++	+	N/A	N/A	+	—	—	—	—	—	yes	5	low
	+	N/A	—	N/A	++	N/A	—	N/A	—	—	—	—	—	—			
(Thietje, Giese et al., 2011)	++	+	+	+	—	—	+	—	—	+	+	—	+	+	Indirect evidence PU not an outcome		low
	++	+	+	+	—	—	+	—	—	+	+	—	+	+			

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Houghton, Campbell et al., 2010)	++	++	++	+	++	—	+	++	++	—	+	+	yes	2	moderate
	++	++	++	+	++	—	++	++	++	—	+	+			
(Scevola, Nicoletti et al., 2010)	+	+	—	+	+	+	+	+	+	+	+	+	yes	2	low
	++	—	—	—	—	+	+	—	+	N/A	—	—			
(Rintala, Garber et al., 2008)	+	—	—	—	—	—	—	+	—	N/A	—	—	yes	2	low
	+	—	—	—	+	—	—	++	+	N/A	—	—			

CASE CONTROL

Author/year	Focussed question	Comparable source populations	Same exclusion cases and controls	Per cent drop out in study arms is reported	Comparison btw participants and non-participants	Cases clearly defined	Established that controls are non-cases	Knowledge of primary exposure not influence case ascertainment	Valid, reliable assessment of exposure	Confounders identified and accounted for	Provides confidence	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Ploumis, Kolli et al., 2011)	++	+	+	+	+	++	++	N/A	++	++	—	++	+	yes		moderate
	++	++	+	+	+	++	++	++	++	++	—	++	+			

CASE SERIES

Author/year	Focussed question	Participant characteristics reported	Inclusion criteria defined	Consecutive recruitment	Participants entered at same disease stage	Intervention clearly reported	Outcomes relevant and defined apriori	Valid, reliable outcome measurement	Per cent drop out reported	Estimates of random variability	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Schubart, 2012)	+	+	++	—	—	+	—	—	+	—	N/A	—	+	Indirect evidence PU not an outcome		low
	+	+	++	—	—	+	—	—	+	—	N/A	—	+			
(Brace and Schubart, 2010)	+	+	++	—	—	+	—	—	+	—	—	+	+	Indirect evidence PU not an outcome		low
	+	+	++	—	—	+	—	—	+	—	—	—	+			
(Rappl, 2011)	+	+	+	+	+	+	+	+	++	+	+	++	++	yes	5	moderate
	+	+	+	N/A	+	+	+	+	++	—	—	+	—			

QUALITATIVE STUDIES

Author/year	Focussed question	Appropriate qualitative methodology	Recruitment appropriate to research and sample justified	Setting for data collection justified	Clear, explicit methods for data collection	Saturation of data	Researcher's role in data collection and analysis and potential bias addressed	Ethics clearance	In-depth description n of analysis technique	Sufficient supporting data	Contradictory data considered	Findings related to original question are stated	Discusses evidence for and against the researcher's argument	Research contributes to the existing knowledge	Relevance to guideline population	Level of evidence	Quality
(Schubart, Hilgart et al., 2008)	Y	Y	N	N	N	N	N	Y	N	N	N	Y	N	Y	Indirect evidence PU not an outcome		low
	Y	Y	N	N	N	Y	N	Y	N	N	N	Y	N	Y			
(Jackson, Carlson et al., 2010)	Y	Y	N	Y	Y	N	N	N	Y	Y	Y	Y	Y	Y	Indirect evidence PU not an outcome		moderate

References

Brace, J.A. and J.R. Schubart. (2010). "A prospective evaluation of a pressure ulcer prevention and management e-learning program for adults with spinal cord injury." Ostomy Wound Management **56**(8):40-50.

Gélis, A., J.P. Daures, C. Benaim, et al. (2011). "Evaluating self-reported pressure ulcer prevention measures in persons with spinal cord injury using the revised Skin Management Needs Assessment Checklist: reliability study." Spinal Cord: The Official Journal Of The International Medical Society Of Paraplegia **49**(5):653-8.

Gil-Agudo, A., A. De la Peña-González, A. Del Ama-Espinosa, et al. (2009). "Comparative study of pressure distribution at the user-cushion interface with different cushions in a population with spinal cord injury." Clin Biomech **24**(7):558-63.

Ho, C.H., H.L. Powell, J.F. Collins, et al. (2010). "Poor nutrition is a relative contraindication to negative pressure wound therapy for pressure ulcers: preliminary observations in patients with spinal cord injury." Advances in Skin & Wound Care **23**(11):508-16.

Houghton, P.E., K.E. Campbell, C.H. Fraser, et al. (2010). "Electrical stimulation therapy increases rate of healing of pressure ulcers in community-dwelling people with spinal cord injury." Archives of Physical Medicine and Rehabilitation **91**(5):669-78.

Jackson, J., M. Carlson, S. Rubayi, et al. (2010). "Qualitative study of principles pertaining to lifestyle and pressure ulcer risk in adults with spinal cord injury." Disability & Rehabilitation **32**(7):567-78.

Mathew, A., S. Samuelkamaleshkumar, S. Radhika, et al. (2013). "Engagement in occupational activities and pressure ulcer development in rehabilitated South Indian persons with spinal cord injury." Spinal Cord **51**(2):150-5.

Ploumis, A., S. Kolli, M. Patrick, et al. (2011). "Length of stay and medical stability for spinal cord-injured patients on admission to an inpatient rehabilitation hospital: a comparison between a model SCI trauma center and non-SCI trauma center." Spinal Cord: The Official Journal Of The International Medical Society Of Paraplegia **49**(3):411-5.

Rappl, L.M. (2011). "Effect of platelet rich plasma gel in a physiologically relevant platelet concentration on wounds in persons with spinal cord injury." International Wound Journal **8**(2):187-95.

Rintala, D.H., S.L. Garber, J.D. Friedman, et al. (2008). "Preventing recurrent pressure ulcers in veterans with spinal cord injury: impact of a structured education and follow-up intervention." Archives Of Physical Medicine And Rehabilitation **89**(8):1429-41.

Sarasúa, J.G., S.P. López, M.Á. Viejo, et al. (2011). "Treatment of pressure ulcers with autologous bone marrow nuclear cells in patients with spinal cord injury." Journal of Spinal Cord Medicine **34**(3):301-7.

Scevola, S., G. Nicoletti, F. Brenta, et al. (2010). "Allogenic platelet gel in the treatment of pressure sores: a pilot study." International Wound Journal **7**(3):184-90.

Schubart, J. (2012). "An e-learning program to prevent pressure ulcers in adults with spinal cord injury: a pre- and post- pilot test among rehabilitation patients following discharge to home." Ostomy/Wound Management **58**(10):38-49.

Schubart, J.R., M. Hilgart and C. Lyder. (2008). "Pressure ulcer prevention and management in spinal cord-injured adults: analysis of educational needs." Advances in Skin & Wound Care **21**(7):322-9.

Thietje, R., R. Giese, M. Pouw, et al. (2011). "How does knowledge about spinal cord injury-related complications develop in subjects with spinal cord injury? A descriptive analysis in 214 patients." Spinal Cord **49**(1):43-8.

Wilson, J., P. Arnold, A. Singh, et al. (2012). "Clinical prediction model for acute inpatient complications after traumatic cervical spinal cord injury: a subanalysis from the Surgical Timing in Acute Spinal Cord Injury Study." J Neurosurg Spine **17**(1):46-51.

Wu, Q., G.Z. Ning, Y.L. Li, et al. (2013). "Factors affecting the length of stay of patients with traumatic spinal cord injury in Tianjin, China." Journal of Spinal Cord Medicine **36**(3):237-42.

Implementing the Guideline

FACILITATORS, BARRIERS AND IMPLEMENTATION STRATEGY

DIAGNOSTIC STUDIES – VALIDATION STUDIES

Author/year	Nature of test is defined	Test compared to a gold standard	Where no gold standard exists, compared with valid reference standard	Clear population from which participants selected consecutively	Independent measurement of test and standard	Test and standard (or inter rater) measured as close in time as possible	Results for all patients reported	Pre-test diagnosis reported	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Beeckman, Defloor et al., 2010)	++	N/A	N/A	+	N/A	+	++	++	++	yes	N/A	N/A
	++	N/A	N/A	+	N/A	+	++	++	++			

RCTS

Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Rantz, Zwygart-Stauffacher et al., 2012)	++	+	+	+	++	++	++	++	+	++	+	—	yes	2	moderate
	++	+	—	—	++	+	+	++	+	+	+	—			
(Beeckman, Clays et al., 2013)	+	++	N/A	N/A	++	++	++	++	++	N/A	++	++	yes	1	good
	+	++	—	N/A	++	++	++	++	++	N/A	++	++			

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Decker and Castle, 2011)	++	++	++	—	++	—	—	—	—	—	yes	N/A	low

Author/year	Focussed question	Sampling method	Representative sample	States number invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Bosch, Halfens et al., 2011)	++	++	++	—	++	++	—	+	+	+	yes	N/A	moderate
(Gunninberg, Brudin et al., 2010)	++	+	+	++	++	++	++	—	+	+	yes	N/A	moderate
(Pekkarinen, Sinervo et al., 2008)	++	++	++	++	++	+	+	++	++	++	yes	N/A	high
(Temkin-Greener, Cai et al., 2012)	++	+	+	++	++	+	—	+	+	+	yes	N/A	low
(Strand and Lindgren, 2010)	++	++	++	++	++	++	N/A	+	+	++	Indirect evidence nurse knowledge		moderate
	++	++	++	++	++	++	+	+	+	++			

COHORT STUDIES

Author/year	Focussed question	Comparable source populations	States number. invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Bonner, Castle et al., 2009)	++	++	++	N/A	—	—	+	++	++	++	—	—	+	+	yes	N/A	moderate
(Goode, Blegen et al., 2011)	+	—	—	N/A	—	—	+	++	—	—	+	—	—	—	yes	N/A	low
(Horn, 2008)	++	++	—	N/A	—	—	++	++	++	—	—	—	—	—	yes	N/A	low
(Konetzka, Stearns et al., 2008)	+	+	—	N/A	—	—	+	++	—	—	+	—	—	—	yes	N/A	low
(Hart and Davis, 2011)	+	+	—	N/A	—	—	++	++	+	++	—	—	—	—	yes	N/A	low

QUASI EXPERIMENTAL STUDIES

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Ackerman, 2011)	+	—	—	—	—	—	—	N/A	+	—	yes	4	low
(Asimus, Maclellan et al., 2011)	++	—	N/A	N/A	+	++	N/A	N/A	+	—	yes	4	moderate
(Baier, Butterfield et al., 2008)	++	—	N/A	N/A	—	—	N/A	N/A	+	—	yes	4	low
(Baier, Butterfield et al., 2009)	++	—	N/A	N/A	—	—	N/A	N/A	+	—	yes	4	low
(Baldelli and Paciella, 2008)	+	—	—	+	+	—	—	N/A	+	—	yes	4	low
(Bales and Padwojski, 2009)	—	—	—	—	+	—	N/A	N/A	+	—	yes	4	low
(Bales and Duvendack, 2011)	—	—	—	—	+	N/A	N/A	N/A	+	—	yes	4	low
(Revello and Fields, 2012)	++	—	+	+	+	N/A	+	N/A	+	—	yes	4	low
(Rantz, Cheshire et al., 2009)	++	—	+	—	+	++	++	+	—	—	yes	3	low
(Thomas, 2008)	++	—	—	—	—	—	—	—	—	—	yes	5	low
(Tippet, 2009)	++	—	+	+	++	N/A	N/A	N/A	—	—	yes	4	moderate
(Milne, Trigilia et al., 2009)	—	N/A	N/A	N/A	+	N/A	N/A	N/A	++	++	yes	4	low
	—	—	—	—	+	N/A	N/A	N/A	+	+			

QUALITY IMPROVEMENT STUDIES

Author/year	Title/abstract is accurate	Current knowledge summarised in background	Specific project aims	Ethical aspects discussed	Sufficient reporting of intervention for replication	Reports factors contributing to intervention choice reported	Clear evaluation measures	Internal and external validity	Appropriate analysis	Results report elements of the setting, change sin care processes and patient outcomes	Evidence of association between change and patient outcomes	Reports limitations	Reliable interpretation of findings	Funding sources reported	Relevant to guideline population	Level of evidence	Quality
(Ackerman, 2011)	—	—	+	—	+	+	+	—	—	—	—	—	—	—	+	4	Quasi-experiment Low quality
(Asimus, Maclellan et al., 2011)	+	++	++	++	++	++	++	+	—	—	+	—	+	++	yes	4	Quasi-experiment Moderate quality
(Baier, Butterfield et al., 2008)	++	—	+	—	+	—	—	—	—	+	—	+	+	++		4	Quasi-experiment Low quality
(Baier, Butterfield et al., 2009)	++	+	+	—	++	++	+	+	+	++	—	+	+	++	yes	4	Quasi-experiment Moderate quality
(Baldelli and Paciella, 2008)	++	++	+	—	++	++	++	+	—	—	—	—	++	—	yes	4	Quasi-experiment Low quality
(Bales and Padwojski, 2009)	—	+	—	—	+	+	+	—	—	—	—	—	+	—	yes	4	Quasi-experiment Low quality
(Bales and Duvendack, 2011)	—	+	—	—	+	+	+	—	—	—	—	—	+	—	yes	4	Quasi-experiment Low quality
(Decker and Castle, 2011)	++	+	++	—	++	++	N/A	—	++	—	—	++	+	++	yes	N/A	Cross sectional Low quality
(Bonner, Castle et al., 2009)	++	++	++	—	+	++	N/A	+	++	+	+	++	++	++	yes	N/A	Cohort study Moderate quality
(Bosch, Halfens et al., 2011)	++	++	++	+	++	++	N/A	+	++	+	—	++	++	++	yes	N/A	Cohort study Moderate quality
(Goode, Blegen et al., 2011)	++	—	+	—	+	—	N/A	—	—	—	+	+	—	++	yes	N/A	Cohort study Low quality
(Gunninberg, Brudin et al., 2010)	++	++	++	+	++	++	N/A	—	++	+	—	++	++	—	yes	N/A	Cross sectional Moderate quality
(Horn, 2008)	++	+	+	+	+	++	N/A	—	—	—	—	+	++	++	yes	3	Cohort study Low quality
(Konetzka, Stearns et al., 2008)	++	++	+	—	—	++	N/A	—	++	—	+	+	—	++	yes	N/A	Cohort study Low quality
(Hart and Davis, 2011)	—	+	+	—	—	+	N/A	—	+	—	—	—	++	—	yes	3	Cohort study Low quality

(Ballard, McCombs et al., 2008)	+	+	—	—	+	—	+	—	—	+	+	—	+	N/A	yes	5	Observational study Low quality
(Mangaco-Borja, 2011)	+	—	—	—	—	+	+	—	—	+	+	—	+	N/A	yes	N/A	Cohort study Low quality
(Revello and Fields, 2012)	++	++	++	—	+	+	+	+	+	+	+	+	+	+	yes	4	Quasi-experiment Low quality
(Thomas, 2008)	++	+	++	—	++	++	—	—	—	—	—	—	—	—	yes	5	Quasi-experiment Low quality
(Tippet, 2009)	++	++	++	++	++	++	++	++	++	++	+	++	+	N/A	yes	4	Quasi-experiment Moderate quality
(Boesch, Myers et al., 2012)	++	+	++	—	++	+	+	—	+	++	+	+	++	++	yes	4	Observational study Moderate quality
(Gray-Siracusa and Schrier, 2011)	++	++	++	—	++	++	+	+	+	++	+	+	++	++	yes	4	Observational study Moderate quality
	++	++	++	++	++	++	+	—	+	++	++	++	+	++			
(Dibsie, 2008)	++	++	++	—	++	++	+	—	+	++	+	—	++	++	yes	4	Observational study Moderate quality
	+	++	—	—	+	+	+	—	N/A	++	+	+	++	N/A			
(Kelleher, Moorer et al., 2012)	++	++	++	—	++	+	+	—	+	++	+	+	++	+	yes	4	Observational study Moderate quality
	++	++	++	—	++	++	++	—	++	++	++	+	++	—			
(Lahmann, Halfens et al., 2010)	++	++	++	++	++	+	+	++	++	++	+	++	+	—	yes	4	Cross sectional study Moderate quality
(Milne, Trigilia et al., 2009)	+	+	+	—	++	++	+	+	+	++	++	—	+	—	yes	4	Quasi-experiment Moderate quality
(Lyman, 2009)	+	—	+	—	++	+	—	—	—	—	+	—	+	+	yes	4	Quasi-experiment Low quality
(McInerney, 2008)	++	+	—	—	—	+	—	—	—	+	—	—	+	—	yes	4	Quasi-experiment Low quality
(Horn, Sharkey et al., 2010)	++	+	+	—	++	++	—	—	+	++	+	+	+	+	yes	4	Quasi-experiment Moderate quality

References

Ackerman, C.L. (2011). "'Not on my watch:' treating and preventing pressure ulcers." Medsurg Nursing: Official Journal of the Academy of Medical-Surgical Nurses **20**(2):86-93.

Asimus, M., L. Maclellan and P.I. Li. (2011). "Pressure ulcer prevention in Australia: the role of the nurse practitioner in changing practice and saving lives." International Wound Journal **8**(5):508-13.

Baier, R., K. Butterfield, G. Patry, et al. (2009). "Identifying star performers: the relationship between ambitious targets and nursing home quality improvement." Journal Of The American Geriatrics Society **57**(8):1498-503.

Baier, R.R., K. Butterfield, Y. Harris, et al. (2008). "Aiming for star performance: the relationship between setting targets and improved nursing home quality of care." J Am Med Dir Assoc **9**(8):594-8.

Baldelli, P. and M. Paciella. (2008). "Creation and implementation of a pressure ulcer prevention bundle improves patient outcomes." American Journal of Medical Quality **23**(2):136-42.

Bales, I. and T. Duvendack. (2011). "Reaching for the moon: achieving zero pressure ulcer prevalence, an update." Journal of Wound Care **20**(8):374-7.

Bales, I. and A. Padwojski. (2009). "Reaching for the moon: achieving zero pressure ulcer prevalence." Journal of Wound Care **18**(4):137-44.

Ballard, N., A. McCombs, S. Deboor, et al. (2008). "How our ICU decreased the rate of hospital-acquired pressure ulcers." Journal of nursing care quality **23**(1):92.

Beeckman, D., E. Clays, A. Van Hecke, et al. (2013). "A multi-faceted tailored strategy to implement an electronic clinical decision support system for pressure ulcer prevention in nursing homes: A two-armed randomized controlled trial." International Journal of Nursing Studies **50**(4):475-86.

Beeckman, D., T. Defloor, L. Demarre, et al. (2010). "Pressure ulcers: development and psychometric evaluation of the Attitude towards Pressure ulcer Prevention instrument (APuP)." International Journal of Nursing Studies **47**(11):1432-41.

Boesch, R.P., C. Myers, T. Garrett, et al. (2012). "Prevention of tracheostomy-related pressure ulcers in children." Pediatrics **129**(3):e792-e7.

Bonner, A.F., N.G. Castle, A. Men, et al. (2009). "Certified nursing assistants' perceptions of nursing home patient safety culture: is there a relationship to clinical outcomes?" J Am Med Dir Assoc **10**(1):11-20.

Bosch, M., R.J.G. Halfens, T. van der Weijden, et al. (2011). "Organizational culture, team climate, and quality management in an important patient safety issue: nosocomial pressure ulcers." Worldviews On Evidence-Based Nursing / Sigma Theta Tau International, Honor Society Of Nursing **8**(1):4-14.

Decker, F.H. and N.G. Castle. (2011). "Relationship of the Job Tenure of Nursing Home Top Management to the Prevalence of Pressure Ulcers, Pain, and Physical Restraint Use." Journal of Applied Gerontology **30**(5):539-61.

Dibsie, L.G. (2008). "Implementing evidence-based practice to prevent skin breakdown." Critical Care Nursing Quarterly **31**(2):140-9.

Goode, C.J., M.A. Blegen, S.H. Park, et al. (2011). "Comparison of patient outcomes in magnet® and non-magnet hospitals." The Journal Of Nursing Administration **41**(12):517-23.

Gray-Siracusa, K. and L. Schrier. (2011). "Use of an intervention bundle to eliminate pressure ulcers in critical care." Journal of Nursing Care Quality **26**(3):216-25.

Gunninberg, L., L. Brudin and E. Idvall. (2010). "Nurse Managers' prerequisite for nursing development: a survey on pressure ulcers and contextual factors in hospital organizations." Journal of Nursing Management **18**(6):757-66.

Hart, P. and N. Davis. (2011). "Effects of nursing care and staff skill mix on patient outcomes within acute care nursing units." Journal of Nursing Care Quality **26**(2):161-8.

Horn, S.D. (2008). "The business case for nursing in long-term care." Policy, Politics & Nursing Practice **9**(2):88-93.

Horn, S.D., S.S. Sharkey, S. Hudak, et al. (2010). "Pressure ulcer prevention in long-term-care facilities: a pilot study implementing standardized nurse aide documentation and feedback reports." Advances in Skin & Wound Care **23**(3):120-31.

Kelleher, A.D., A. Moorer and M.F. Makic. (2012). "Peer-to-peer nursing rounds and hospital-acquired pressure ulcer prevalence in a surgical intensive care unit: A quality improvement project." Journal of Wound, Ostomy and Continence Nursing **39**(2):152-7.

Konetzka, R.T., S.C. Stearns and J. Park. (2008). "The staffing-outcomes relationship in nursing homes." Health ServRes **43**(3):1025.

Lahmann, N.A., R.J.G. Halfens and T. Dassen. (2010). "Impact of prevention structures and processes on pressure ulcer prevalence in nursing homes and acute-care hospitals." Journal of Evaluation in Clinical Practice **16**(1):50-6.

Lyman, V. (2009). "Successful heel pressure ulcer prevention program in a long-term care setting." Journal of Wound, Ostomy, and Continence Nursing: Official Publication of the Wound, Ostomy and Continence Nurses Society / WOCN **36**(6):616-21.

Mangaco-Borja, E. (2011). "The significance of introducing permanent assignments for nursing assistants at a long-term care setting on the incidence rate of facility-acquired pressure ulcers among elderly patients." Journal of the American College of Certified Wound Specialists **3**(1):13-5.

McInerney, J.A. (2008). "Reducing hospital-acquired pressure ulcer prevalence through a focused prevention program." Advances in Skin & Wound Care **21**(2):75-8.

Milne, C.T., D. Trigilia, T.L. Houle, et al. (2009). "Reducing pressure ulcer prevalence rates in the long-term acute care setting." Ostomy/Wound Management **55**(4):50-9.

Pekkarinen, L., T. Sinervo, M. Elovainio, et al. (2008). "Drug use and pressure ulcers in long-term care units: do nurse time pressure and unfair management increase the prevalence?" Journal of Clinical Nursing **17**(22):3067-73.

Rantz, M.J., D. Cheshire, M. Flesner, et al. (2009). "Helping nursing homes "at risk" for quality problems: a statewide evaluation." Geriatric Nursing (New York, NY) **30**(4):238-49.

Rantz, M.J., M. Zwygart-Stauffacher, L. Hicks, et al. (2012). "Randomized multilevel intervention to improve outcomes of residents in nursing homes in need of improvement." J Am Med Dir Assoc **13**(1):60-8.

Revello, K. and W. Fields. (2012). "A performance improvement project to increase nursing compliance with skin assessments in a rehabilitation unit." Rehabilitation Nursing: The Official Journal Of The Association Of Rehabilitation Nurses **37**(1):37-42.

Strand, T. and M. Lindgren. (2010). "Knowledge, attitudes and barriers towards prevention of pressure ulcers in intensive care units: a descriptive cross-sectional study." Intensive & Critical Care Nursing: The Official Journal of the British Association of Critical Care Nurses **26**(6):335-42.

Temkin-Greener, H., S. Cai, N.T. Zheng, et al. (2012). "Nursing home work environment and the risk of pressure ulcers and incontinence." Health ServRes **47**(3 Pt 1):1179-200.

Thomas, M.E. (2008). "The providers' coordination of care: a model for collaboration across the continuum of care." Professional Case Management **13**(4):220-7.

Tippet, A.W. (2009). "Reducing the incidence of pressure ulcers in nursing home residents: a prospective 6-year evaluation." Ostomy Wound Management **55**(11):52-8.

HEALTH PROFESSIONAL EDUCATION

QUALITY IMPROVEMENT STUDIES

Author/year	Title/abstract is accurate	Current knowledge summarised in background	Specific project aims	Ethical aspects discussed	Sufficient reporting of intervention for replication	Reports factors contributing to intervention choice reported	Clear evaluation measures	Internal and external validity addressed	Appropriate analysis	Results report elements of the setting, change sin care processes and patient outcomes	Evidence of association between change and patient outcomes	Reports limitations	Reliable interpretation of findings	Funding sources reported	Relevant to guideline population	Level of evidence	Quality
(Kwong, Lau et al., 2011)	++	++	++	++	++	+	+	—	+	++	+	+	++	—	yes	4	Quasi-experiment low
	++	++	++	++	++	+	+	—	+	++	+	+	+	—			

QUASI EXPERIMENTAL STUDIES

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Kwong, Lau et al., 2011)	++	N/A	N/A	N/A	++	+	N/A	N/A	—	+	yes	4	low
	++	N/A	+	+	+	+	++	—	—	—			

References

Kwong, E.W.Y., A.T.Y. Lau, R.L.P. Lee, et al. (2011). "A pressure ulcer prevention programme specially designed for nursing homes: does it work?" Journal of Clinical Nursing **20**(19/20):2777-86.

PATIENT CONSUMERS AND THEIR CAREGIVERS

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES

Author/year	Focussed question	Sampling method	Representative sample	States number. invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Degenholtz, Rosen et al., 2008)	+	+	+	++	+	+	+	+	+	++	yes	N/A	moderate
	+	+	+	++	+	+	+	+	+	++			
(Thein, Gomes et al., 2010)	++	++	++	++	++	++	++	++	++	++	yes	N/A	high
	++	++	++	++	++	++	++	++	++	++			

QUASI EXPERMIENTAL STUDIES

Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Allen, 2013)	++	N/A	—	+	+	++	++	N/A	+	+	yes	4	low
	++	N/A	—	+	+	++	++	N/A	+	+			

COHORT STUDIES

Author/year	Focussed question	Comparable source populations	States number invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Essex, Clark et al., 2009)	++	+	+	+	++	N/A	++	—	++	N/A	+	++	++	++	yes	3	moderate
	++	+	+	+	++	N/A	++	—	++	N/A	+	++	++	++			

Author/year	Focussed question	Comparable source populations	States number invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Galhardo, Magalhaes et al., 2010)	++	+	+	+	++	++	+	+	+	+	+	++	++	++	yes	3	moderate
	++	+	+	+	++	++	+	—	+	+	+	++	++	++			
(Thietje, Giese et al., 2011)	++	+	+	+	—	—	+	—	—	+	+	—	+	+	yes	3	low
	++	+	+	+	—	—	+	—	—	+	+	—	+	+			

CASE SERIES

Author/year	Focussed question	Participant characteristics reported	Inclusion criteria defined	Consecutive recruitment	Participants entered at same disease stage	Intervention clearly reported	Outcomes relevant and defined apriori	Valid, reliable outcome measurement	Per cent drop out reported	Estimates of random variability	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Relevant to guideline population	Level of evidence	Quality
(Hartigan, Murphy et al., 2012)	++	+	++	++	N/A	++	+	—	+	+	N/A	+	—	yes	5	moderate
	++	+	++	++	N/A	++	+	—	+	+	N/A	+	—			
(Schubart, 2012)	+	+	++	—	—	+	—	—	+	—	N/A	—	+	yes	5	low
	+	+	++	—	—	+	—	—	+	—	N/A	—	+			
(Brace and Schubart, 2010)	+	+	++	—	—	+	—	—	+	—	—	+	+	yes	5	low
	+	+	++	—	—	+	—	—	+	—	—	—	+			

QUALITATIVE STUDIES

Author/year	Focussed question	Appropriate qualitative methodology	Recruitment appropriate to research and sample justified	Setting for data collection justified	Clear, explicit methods for data collection	Saturation of data	Researcher's role in data collection and analysis and potential bias addressed	Ethics clearance	In-depth description n of analysis technique	Sufficient supporting data	Contradictory data considered	Findings related to original question are stated	Discusses evidence for and against the researcher's argument	Research contributes to the existing knowledge	Relevance to guideline population	Level of evidence	Quality
(Gorecki, Nixon et al., 2012)	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	yes	5	high
	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	N	Y			
(Yarkin, Tamer et al., 2009)	Y	Y	N	Y	N	N	N	Y	N	N	N	Y	N	N	yes	5	low
	Y	Y	N	Y	N	N	N	Y	N	N	N	Y	N	N			
(Gorecki, Lamping et al., 2010)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	yes	5	high
Dunn et al, 2009	Y	Y	Y	Y	Y	N	Y	N	Y	Y	Y	Y	Y	Y	yes	5	high
	Y	Y	Y	N	Y	N	Y	N	Y	Y	Y	Y	Y	Y			
(Schubart, Hilgart et al., 2008)	Y	Y	N	N	N	N	N	Y	N	N	N	Y	N	Y	yes	5	low
	Y	Y	N	N	N	Y	N	Y	N	N	N	Y	N	Y			

References

Allen, B. (2013). "Effects of a comprehensive nutritional program on pressure ulcer healing, length of hospital stay, and charges to patients." Clinical Nursing Research **22**(2):186-205.

Brace, J.A. and J.R. Schubart. (2010). "A prospective evaluation of a pressure ulcer prevention and management e-learning program for adults with spinal cord injury." Ostomy Wound Management **56**(8):40-50.

Degenholtz, H., J. Rosen, N. Castle, et al. (2008). "The association between changes in health status and nursing home resident quality of life." The Gerontologist **48**(5):584-.

Essex, H.N., M. Clark, J. Sims, et al. (2009). "Health-related quality of life in hospital inpatients with pressure ulceration: assessment using generic health-related quality of life measures." Wound Repair and Regeneration: Official Publication of the Wound Healing Society [and] the European Tissue Repair Society **17**(6):797-805.

Galhardo, V.A.C., M.G. Magalhaes, L. Blanes, et al. (2010). "Health-related quality of life and depression in older patients with pressure ulcers." Wounds: A Compendium of Clinical Research & Practice **22**(1):20-6.

Gorecki, C., D.L. Lamping, J.M. Brown, et al. (2010). "Development of a conceptual framework of health-related quality of life in pressure ulcers: a patient-focused approach." International Journal of Nursing Studies **47**(12):1525-34.

Gorecki, C., J. Nixon, A. Madill, et al. (2012). "What influences the impact of pressure ulcers on health-related quality of life? A qualitative patient-focused exploration of contributory factors." Journal of Tissue Viability **21**(1):3-12.

Hartigan, I., S. Murphy and M. Hickey. (2012). "Older adults' knowledge of pressure ulcer prevention: a prospective quasi-experimental study." International Journal Of Older People Nursing **7**(3):208-18.

Schubart, J. (2012). "An e-learning program to prevent pressure ulcers in adults with spinal cord injury: a pre- and post- pilot test among rehabilitation patients following discharge to home." Ostomy/Wound Management **58**(10):38-49.

Schubart, J.R., M. Hilgart and C. Lyder. (2008). "Pressure ulcer prevention and management in spinal cord-injured adults: analysis of educational needs." Advances in Skin & Wound Care **21**(7):322-9.

Thein, H.-H., T. Gomes, M.D. Krahn, et al. (2010). "Health status utilities and the impact of pressure ulcers in long-term care residents in Ontario." Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation **19**(1):81-9.

Thietje, R., R. Giese, M. Pouw, et al. (2011). "How does knowledge about spinal cord injury-related complications develop in subjects with spinal cord injury? A descriptive analysis in 214 patients." Spinal Cord **49**(1):43-8.

Yarkin, O., S. Tamer, O. Gamze, et al. (2009). "Effect of surgery on psychiatric states and quality of life of paraplegics and quadriplegics with pressure sores and their primary caregivers." European Journal of Plastic Surgery **32**(4):173-6.

