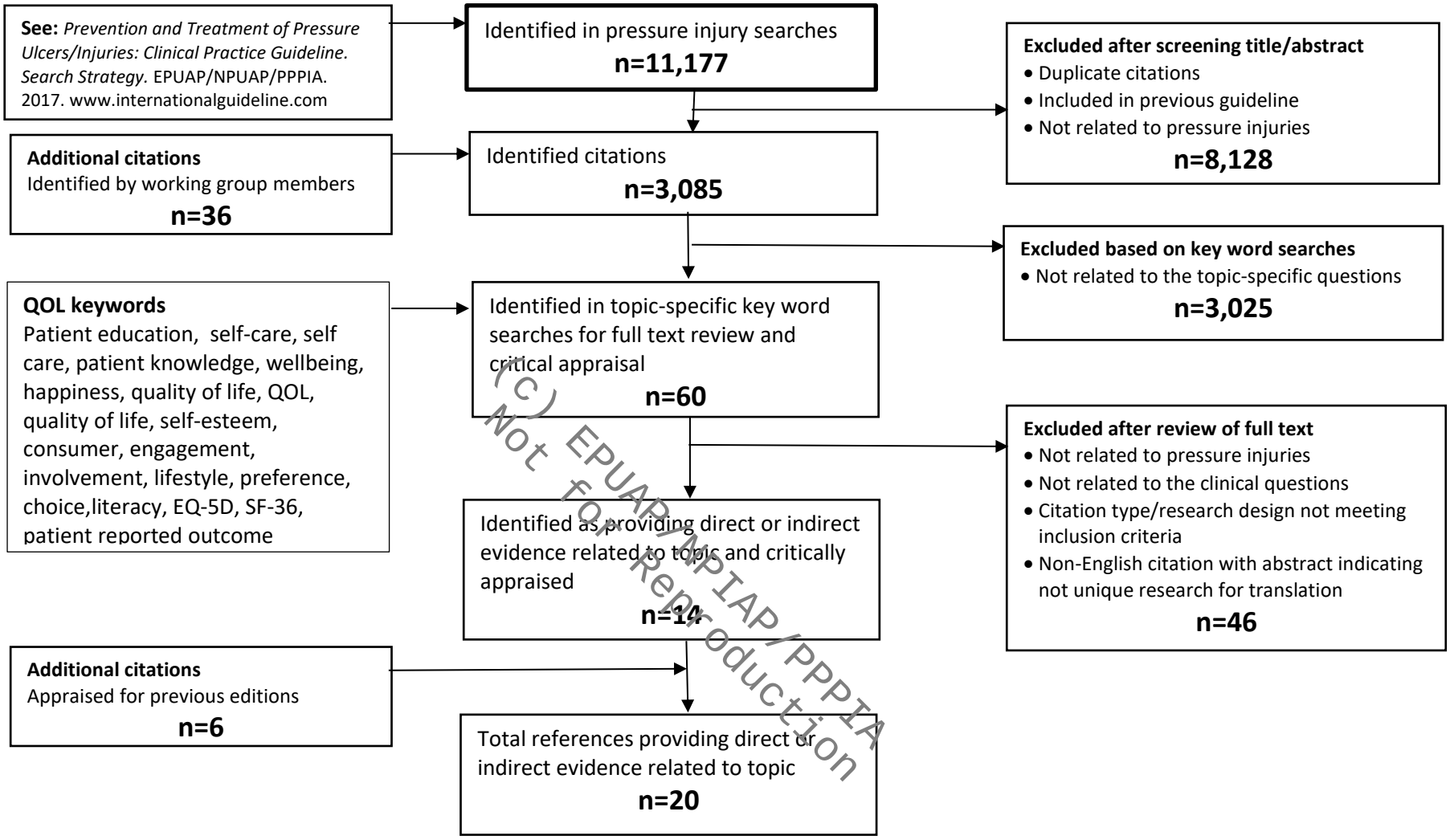
Search results for 2019 International Pressure Injury Guideline: Biophysical agents



European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Emily Haesler (Ed.). EPUAP/NPIAP/PPPIA; 2019

Articles Reviewed for International Pressure Injury Guideline

The research has been reviewed across three editions of the guideline. The terms pressure ulcer and pressure injury are used interchangeably in this document and abbreviated to PU/PI. Tables have not been professionally edited. Tables include papers with relevant direct and indirect evidence that were considered for inclusion in the guideline. The tables are provided as a background resources and are not for reproduction.

European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Emily Haesler (Ed.). EPUAP/NPIAP/PPPIA; 2019

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Measurement tools							
Rutherford et al., 2018	Psychometric study evaluating a tool for measuring patient reported outcomes	Participants were a sub-group of another pressure injury study in UK (n=617) Recruited in secodnray care hospitals	N/A	PU-QOL contains 10 scales for measuring: symptoms, physical functioning, psychological well-being and social participation specific to pressure ulcers. nine PU-specific outcomes: three symptom and six function scales	Internal consistency (Cronbach's alpha values ranging 0.795 - 0.97		**Level of Evidence: 4** **Quality: N/A Psychometric study**
C. Gorecki et al., 2013	Psychometric study evaluating a tool for measuring patient reported outcomes	Participants recruited in England and Scotland NHS community trusts (n=229 for final psychometric analysis) Inclusion: Aged over 18 years	N/A	• Patient-reported outcome tool, PU-QOL • PU-QOL contains 10 scales for measuring: symptoms, physical functioning, psychological well-being and social participation specific to pressure ulcers. • patients rate the amount of "bother" attributed during the	• Reliability: (Cronbach's alpha values ranging 0.89 - 0.97) • validity: correlation between PU-QOL and SF-12 scores (r >0.30) and PU-QOL scales and sociodemographic variables (r <0.30) were consistent with predictions). **Author conclusion: PU-QOL instrument provides a standardized method for assessing PROs**	• Participants purposively sampled base on PU Category/Stage, PU location, setting, age and gender	**Level of Evidence: 4** **Quality: N/A Psychometric study**

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				past week on a 3-point response scale			
Chaboyer et al., 2017	The aim of this study was to develop the Patient Participation in Pressure injury prevention (PPPIP) scale as well as undertake initial testing of some of its psychometric properties.	Participants recritied in 8 hospitals in Australia (1598 eligible, n=1332 responding to the PPPIP scale). • Inclusion criteria • 18 years or older, • expected hospital stay > 48 hours • at risk of PI as measured by limited mobility • able to read English and consent. Exclusion criteria: • Admitted to the hospital for > 36 hours prior to recruitment • maternity, pediatrics, mental health, dialysis, day surgery, ICU, emergency department, • previous trial participants • receiving end of life care. • Participant characteristics and any baseline differences	Phase 1: PPPIP scale development Phase 2 Psychometric testing: The PPPIP scale was administered by a research assistant when patients developed a PI, was D/C'd from hospital, or reached 28 days in the study – whichever of these came first. Their responses were entered directly into the trial database	Outcome measure: Patient Participation in Pressure Injury Prevention Scale items (PPPIP). Patient participation in pressure injury prevention scale items included 7 items on knowledge, decision making and family engagement	Outcome 1 Internal consistency reliability: Subsample A × = 0.86 Subsample B × - 0.86 Internal consistency reliability reported Summary of psychometric testing: **The EFA and CFA suggest that the seven items in the PPPIP reflect a unidimensional measure that focuses on PIP, with high scores reflecting high-patient participation in PIP and low scores reflecting low-patient participation in PIP.**	• 83.4% of participants completed PPPIP. of those 51.7% completed every item in the scale • Force-choice response • PPPIP was administered by research assistant, so not known if the scale could in a self-report form. • Sample reflected limits the generalizabilty of the current scale. • Measure of patient participation, distinctions between concepts such as participation, engagement and involvement are not clear.	**Level of Evidence: 4** **Quality:** **N/A Psychometric study**
de Laat, de Munter, van der	Cross sectional study	Recruited in 2 rehabilitation centers in Netherlands	N/A	• Questionnaire on demographics. Paraplegia	• mean PAM-score was 54 (±8.1) indicating a low level of health activation	Investigates patient engagement in care	**Level of Evidence: 4**

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Burg, Ulrich, & Kloeters, 2017	exploring self management behavior of paraplegic individuals	(n=441 eligible, n=170 included, n=162 analyzed) Inclusion: Aged > 18 years Paraplegia Participant characteristics: • 26.2% had one comorbidity and 16.5% had two comorbidities • 35% engaged in pressure injury prevention activities less than weekly • 54% had a past history of pressure injuries • 35% had previously had surgery		information, information about PU history, general health • Quality of life on EQ5D-3L and the VAS • Patient Activation Measure (PAM-score) used to measure extent of health activation. (0-100)	• Level of education (OR 2.2, p =0.017) and degree of paraplegia (OR 2.8, p = 0.036). were significantly associated with health activation • Pressure injury history and level of paraplegia not related to health activation	Peripherally related to pressure injuries Limited to paraplegic individuals	**High quality**
Kisala, Tulsky, Choi, & Kirshblum, 2015	Validation of self-reported HRQOL tool for individuals with SCI and pressure ulcers	N=189 adults with traumatic SCI who experienced a pressure injury	Not applicable	• 30 items related to pressure injuries	• 12-item SCI-QOL Pressure Ulcers scale • Test re-test for 7-item version (n=245 participants) r=0.79, ICC (2,1) = 0.79 (95% CI 0.74 to 0.84) **SCI-QOL PrU scale is a psychometrically sound measurement tool, which can reliably estimate HRQOL effects of PrUs in a traumatic SCI population.**	Scale may be administered in its entirety or as a 7-item "short form"	**Level of Evidence: 4**
Lourenco, Blanes, Salomé, & Ferreira, 2014	Cohort study comparing HRQOL in individuals with SCI who do and do not have pressure injuries	Participants recruited in Brazilian outpatient clinic, rehab center, sports associate (n=120 total, n=60 with pressure injuries) Inclusion:	Not applicable	Brazilian-Portuguese version of the Self-Esteem Rosenberg Scale (RSE/UNIFESP-EPM)20 Includes eight subscales: physical functioning, role physical, bodily pain,	Pressure injury cohort had significantly lower scores (worse health status) on all SF-36 subscales (p≤0.0013) except for general health (p=0.109). The RSE/UNIFESP-EMP scale total score was significantly higher in the study group than in the control group (p<0.001), indicating that patients with	• Self-esteem can be defined as the perception of self-worth and value, or in other words, the evaluation that the individual makes regarding himself.	**Level of evidence: 3** **Quality: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Traumatic SCI for > 1 year • Aged 18-60 years • Category/Stage II or greater PI for > 6 months (except in control group, no PI for past 12 months) Exclusion: • Surgery within 12 months Characteristics: • Mean age 38 in PU group and 30 in non-PU group (p=0.001) • Individual with PU more likely to be on social security (p<0.0001)		general health, vitality, social functioning, role emotional, mental health Cronbach's alpha values for the SF-36 and EPM/UNIFESP scale were 0.790 and 0.745, respectively	pressure ulcers had lower selfesteem than controls **The self-esteem and HRQoL of individuals with SCI are negatively affected because of loss of control over bodily functions and inability to perform self-care. Participants with pressure ulcers have negative experiences related to social and emotional Therefore, routinely assess risk of developing PUs and HRQoL and self-esteem**		
Gélis 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	**Level of Evidence: 4** **Quality of evidence: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Clinical Question 2: What are effective strategies for engaging individuals in pressure injury prevention and treatment?							
Lane, Selleck, Chen, & Tang, 2016	Retrospective cohort study investigating efficacy of **smoking cessation in individuals with SCI**	Groups recruited through electronic record review at an outpatient wound clinic in the US Inclusion criteria: Quadriplegic or paraplegic due to SCI Aged ≥ 18 years Exclusion criteria: Pregnant Mental impairment Wards of the state/prisoners Participant characteristics: • No significant difference between groups for demographics • Mena age 44 years • Approx 47% participants black • Approx 80% male • Approx 50% smokers at baseline	• Smoking cessation program initiated at the wound clinic and based on US national guidelines using the 5As program • Controls- seen in the 6-months prior to the smoking cessation program (n=83) • Cases– seen in the 6-months after the smoking cessation program was introduced (n=75)	• Chart review	**Impact of smoking cessation on smoking status** There was a statistically significant increase in the number of participants who stopped smoking during the period of observation (44% vs 21%) ($\chi 2$= 4.45, p=0.03) **Impact of smoking cessation on choice to have PU surgery** There was no statistically significant difference in percent of participants who desired and underwent surgery (45% control versus 35% case, p=0.35) **Impact of smoking cessation on PU healing** • More smokers than non-smokers had a PU (smokers 24.1% versus non-smokers 10.8%, p=0.03) • Smokers had higher decrease in number of wounds (65.2% versus 33.3%, p=0.03) • Smokers experienced significant increase in total wound size compared to non-smokers and smokers who stopped smoking (17.8cm^3 versus -14.2cm^3 versus -170.3cm^3, F=5.6, p=0.004)	• Factors that could influence success of smoking cessation program (e.g. baseline number, social factors such as other smokers in family) were not collected • Relied on report of patient re smoking status • Small sample size • Relied on data base entries • Full extent of intervention was not reported (e.g. how many sessions per patient) • Sustainability not demonstrated • Unclear who assessed wounds and what strategies used for same	**Level of evidence: 3** **Quality: low**
Schoeps, Tallberg, & Gunningberg, 2017	Pretest-post test to improve **knowledge of**	Convenience sample of individuals undergoing surgery (n=31)	Patient information sheet left on bed	• Non-validated questionnaire • Data collected 2 days after pamphlet left	• There was a significant increase in patients receiving information about PU risks (13% vs 28%, p=0.013)	Non-validated data collection Self reported (including pressure injuries)	**Indirect evidence (PU not an outcome)**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	pressure injuries for individuals undergoing surgery using written material	92% did not have a pressure injury, 7% (n=4) had a pressure injury	Patient information sheet was developed by EPUAP based on guidelines		• There was a significant increase in patients receiving information about PU causes (13% vs 48%, p=0.001) • There was a significant increase in patients receiving information about PU prevention (14% vs 47%, p=0.001) • Participation in care • 46% of post-pamphlet group reported engaging in PU prevention including moving in the bed, moving feet and changing position	No evidence the pamphlet decreased PU	**Quality of evidence: low**
Houlihan et al., 2013; Mercier, Ni, Houlihan, & Jette, 2015	RCT comparing a self-efficacy telephone intervention	Participants recruited in the community US (n=142) Inclusion: MS or SCI Using wheelchair > 6 hours/day Private residents with phone access Health insurance Exclusion Category/Stage II or greater pressure injury Severe depression Bipolar disorder Characteristics: 38% female Mean age 48 years 46.5% history of pressure injuries	Randomized to receive: "CareCall" which is an automated telephone-based voice response system. Intervention provides education, cognitive behavioral interventions, screening, referrals and alerts a nurse for follow-up. (n=71) Usual care consisting of a resource book (n=71)	• PUSH scale • Patient Health Questionnaire—9 depression scale • Cornell Services Index • Craig Hospital Inventory of Environmental Factors-Short Form Question 5	**Pressure injuries** • Intervention did not have an overall positive impact on reducing the number of pressure ulcers at 6 months, controlling for baseline number of pressure ulcers, age and gender. • In women receiving intervention • there were no pressure ulcers at the 6-month visit (p = 0.04) Feasibility and acceptability • 22% of intervention group were non-adherent (missing 3 or more calls in a row, 3 separate times over 6 months • Average call length 12.6 minutes(see Mercier et al 2015) • Described as most useful by 70% of participants (see Mercier et al 2015) • Written support was described as useful by 10% of individuals with SCI and 6.3% of MS. (see Mercier et al 2015)	• Significant in females, who are not reflective of the usual individual with SCI • Potential cost savings noted as a benefit but no analysis • Depression outcomes were significantly improved	**Level of evidence: 1** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Carlson et al., 2017	To test the efficacy of a **lifestyle-based intervention** designed to reduce incidence of Medically serious pressure injuries (MSPrIs) in adults with SCI.	Participants recruited in rehabilitation facility in US (n=170 plus 62 non-randomized controlled) Inclusion criteria: • Aged ≥ 18 years • SCI • ≥ one Category/Stage III or IV PI in past 5 yrs • Using RLANRC services • Medical chart available • English or Spanish • contactable by telephone • cognitively intact • willing to undertake lifestyle changes Exclusion criteria: • Ambulatory • < 6 months post-injury • unstable or worsening Category/Stage III or any Category/Stage IV Participant characteristics: • Treatment groups were balanced	Randomized to either: • The Pressure Ulcer Prevention Program (PUPP) consisted of six modules. Lifestyle-based intervention, knowledge on prevention. and application to a person's circumstances, information, activities, and exercises. Ongoing and intensive exposure to PUPP content (n=83) • Control group: no intervention (n=87) Standard care included clinic visits to undergo skin checks and receive necessary medical treatment and advice when a PI was present.	• Blinded assessments of annualized MSPrI incidence rates at 12 and 24 months, based on: skin checks, quarterly phone interviews with participants, and review of medical charts and billing records. • Secondary outcomes included number of surgeries and various quality-of-life measures	**Annualized MSPrI rates** • No significant difference • 12 months: 0.56 intervention versus 0.48 controls • 24 months: 0.44 intervention versus 0.39 control • Rate ratio for serious MSPrIs at 12 months in intervention group was 1.15 (95% CI 0.76 to 1.76, p=NS) • Rate ratio for serious MSPrIs at 24 months in intervention group was 1.14 (95% CI 0.72 to 1.82, p =NS) Both groups improved significantly on: • physical functioning (effect size (ES =0.40 for intervention, 0.50 for control) • physical role limitations (ES=0.72 for intervention and 0.32 for control) • emotional role limitations (ES=0.31 for intervention and 0.38 for control) • social functioning (ES=0.28 for intervention and 0.38 for control) • pain (ES=0.41 for intervention and 0.33 for control) • depression (ES=-0.36 for intervention and -0.33 for control). **Author conclusions: Evidence for intervention efficacy was inconclusive**	• Limited generalizability • Participants had higher MSPrI rate, require a more intensive intervention, and sustain greater PI risk even with intervention services. Results of this study may not be directly applicable to more typical SCI populations	**Level of evidence: 1** **Quality: high**
Hossain et al., 2017	And home visit care program compared to standard treatment	Community-based individuals with SCI in Bangladesh (n=30)	Intervention: telephone support (fortnightly for one year, monthly for second year) and home visit (3 times over 24 months) providing education and support; small financial	• SF-12 • Pressure injury incidence • Beck Depression scale	**Pressure injury incidence** a telephone support and home visit education program was associated with no significant difference in pressure injury incidence compared to standard care (20% vs 13.3.%, p = not reported)	• Small sample size, failed to reach statistical power but was designed to test sample sizes for a future study	**Level of evidence: 1** **Quality: moderate**

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			support for equipment (n=15 randomized, n = 14 completed) Control group (n=15 randomized, n = 14 completed) Intervention delivered by a trained physiotherapist		**Feasibility** 87% of phone calls and 100% home visits were delivered	• No inter-group analysis	
Arora et al., 2017	To determine the effectiveness of telephone-based management of pressure ulcers in people with spinal cord injury in low- and middle-income countries	Participants were recruited in community settings in Bangladesh and India (n=120) • Inclusion criteria: • >18 years • SCI >3 months • 1 PU or more sacrum, ischial tuberosity or greater trochanter • unlikely to be admitted to hospital in 12 weeks • community living • speak Hindi or Bengali • access to a phone • potential to benefit • Exclusion criteria: • Cognitive or verbal impairments • Clinically significant medical condition • Unlikely to be assessed at 12 weeks Participant characteristics: • Mean age 35 years	Participants were randomized to: Intervention group: (n=60) • Pamphlet with information about PU management • free to seek any help or medical assistant • Weekly phone calls from a trained health-care professional/ nurse or physiotherapist) for 12 weeks. • reinforcing self-help strategies, minimizing psychological stress and enhancing engagement with life. • Participants and families received education and advice about appropriate seating, bed overlays, cushions, equipment, diet, nutrition and wound dressings. Advise about techniques to relieve pressure and when to seek further medical or nursing attention. Some were advised to remain on strict bed rest. Advise to minimize dampness associated with incontinence,	• Three trained, blinded assessors. • Time of healing • Primary outcome: size of PU at 12 weeks (length and width expressed as cm^2) • Secondary outcomes: ○ PUSH ○ depth of PU ○ Undermining ○ Braden scale ○ HADS ○ Participation items (WHODAS), Utility score (EQ-5D-5L), ○ Self-rated health (EQ-5D-VAS), ○ Participants' impression of PU status, ○ Participants' confidence to manage PU, ○ Clinician's impression of PU status, ○ Participants' satisfaction,	**Size of pressure injury** The mean between-group difference for the size of the PU at 12 weeks, adjusted by baseline size , was 2.3cm^2 favoring the intervention group (95% CI -0.3 to 4.9; P=0.008). **Confidence in managing pressure injury (10-point NRS)** Between group difference of 1.7 (1.0 to 2.3; P<0.001) favoring intervention group QoL rating (EQ-5D 100-point VAS) Improvements in quality of lfie were superior in intervention group (mean between-group difference on EQ-5D VAS, 10.5, 95% CI 4.5 to 16.6; p=0.001) **The results of our primary outcome (size of PU) do not provide conclusive evidence that people with SCI can be supported at home to manage their Pus through regular telephone-based advice.**	• Unblinded assessor collected data in PU healing by phone (self reported data) • A samples size of 120 people was selected on the basis of available resources. The minimally worthwhile treatment effect was set a priori as equivalent to 10% of the mean initial size of participants´ PU at baseline	**Level of evidence: 1** **Quality: high**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Mean time since injury 7 years • Mix of complete and incomplete SCI • PU Category/Stage II (n=35); III (n=83) and IV (n=2) • The groups were similar at baseline	• Each week goals were negotiated and were reviewed at the nest phone call. Control group: (n=60) • Pamphlet with information about PU management and were free to seek any help or medical assistant that they deemed appropriate	○ Self-reported time for PU resolution • Follow up period 12 weeks			
Hilgart et al., 2015	Observational study investigating utility of an online education package for people with SCI	Participants with SCI were recruited from a rehabilitation in the US (n=8, 7 completed study) Inclusion criteria: • Aged 18 years or over • Medical diagnosis of traumatic spinal cord lesion • Paraplegia or tetraplegia • Regular internet access • Identified health provider to follow care Exclusion criteria: • Paralysis from other causes • Previous history of category/Stage 3 or 4 PU Characteristics: • 71.4% female	Internet-delivered interactive education program developed by a range of health professionals. Includes 3 Cores (overview and personal risk; PUs in real life; and healthy skin behaviors), modules, follow-up activities, printable education and calendars and diary entries. Participants were given access to the program for 6 weeks	**Program usage** Measured through login numbers, completion of cores, use of diaries, follow-ups and modules. **Internet delivered evaluation questionnaire** (15 Likert scales questions and 3 open ended response questions) covering experiences and perceptions	**Study completion** 1/8 participants did not complete the evaluation **Usage** • Program accessed mean 14.86±10.75 unique times over 6 weeks (range 7 to 38) • Mean diary entries 19.57±13.21 (range 5 to 42) • Mean module completion 6.86±4.45 **Evaluation** • 86% found program helpful in behavioral support for skin care activities • 71% rated program as mostly or very effective for themselves • 71% rated diaries as mostly or very helpful in tracking daily skin care • 86% stated they were able to follow program • 86% rated program as somewhat, mostly or very helpful in promoting confidence in skin care	• 12.5% drop out • Very small sample size • Participants not representative of SCI population, which is primarily male • Potential sample bias • Participants paid to participate	**Indirect evidence: PU not an outcome measure**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Mean age: 36.14 years • Mean education: 13.29 years • Mean duration of injury: 10.43 years • Primarily daily internet/email users					
Guihan et al., 2014	To compare a multicomponent motivational interviewing self-management intervention with a multicomponent education intervention to improve skin-protective behaviors and prevent skin worsening	Participants recruited in SCI centers in the US (n=143) Inclusion criteria: • Aged ≥18 years • Category/Stage III or IV pelvic pressure injury • SCI > 6 months prior Exclusion criteria: • terminal diagnosis • severe psychiatric comorbidities or cognitive impairments • severe hearing loss • wound not expected to heal • discharged to nursing home Participant characteristics: • mean age 59.3±11.5 • 97.2% male • white 68.5%, black 26.6%, Hispanic American 4.2%, other 0.7%	• Participants randomized to intervention or control **Regimen for intervention group** • 7 conference calls 45-60mins covering self-management, skin education, problem solving, self-monitoring skills, community resource utilization, relaxation, stress management, improving provider relationships, development of action plans • Phone call reminders • study materials sent by mail • Participants received motivational interviewing 8 times over 24 weeks to elicit talk of change in behavior related to improving skin care **Regimen for comparison group** Same number of audiotaped calls and same schedule but providing education and advice only plus the written SCI education guide. Group leaders received training in chronic disease self-management and were	• Recorded number of guideline recommended skin care behaviors-using a self-administered skin care behavior check list over previous week • skin status by digital photography and planimetry • health care utilization • Skin related visits using international classification of diseases • self-reported days of bedrest resulting from skin problems • self-management assessment using self-efficacy scales • the pressure ulcer knowledge test • patient health questionnaire	**Skin care behaviors** Possible self-reported skin care behaviors being conducted (%) Change over time was not significant for either group at 6 months (p=0.45) There was a non-significant greater improvement in intervention vs control from admission at 3 months (mean 83.5%±17.5 vs 79.5%±19.6 P=0.21) and at 6 months (mean 85.0%±15.2 vs 83.0%±14.6 P=0.41). **Skin status:** 52.8% experienced worsening not significant between groups. SM+MI 35(49.3%) vs 39(54.2%) P=0.51. within 0-3 months SM+MI 26(36.6%) vs 28(38.9%) and 4-6months 9(12.7%) vs 11(15.3%) P=0.86. **VA health utilization** no difference between groups **Skin related visits** no difference between groups **Feasibility** Intervention group, 81% received minimum of 4 calls vs education control 86% received of 4 minimum calls	• Underpowered • High attrition rate • Inadequate dose of SM+MI and control treatment (especially group calls) • Poor reliability between site coordinators • Behavior checklist not validated • Healing and worsening captured in only largest pressure injury • Several people involved in interventions without mention of reliability • Not enough information on other patient factors	**Level of evidence: 1** **Quality: moderate quality**

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		• 51% some college education, 31.5% high school or lower • mean duration SCI: 24.0±15.8(0.5-61.3) years • mean PU risk scores: 9.5±2.8(4-18) • mean number prior PU: 2.41±3.27(0-25) • history PU: 78.3% • mean number current PU: 1.4±0.8 (1-5)	supervised by clinical psychologist	• Follow up period 3 and 6 months	**Author conclusion: Self-Management + Motivational interviews Intervention did not improve skin protective behavior or pressure injury outcomes**		
Kim & Cho, 2017	To develop a self-efficacy enhancement program and evaluated its effects on the self-care behaviors, self-care knowledge, and self-efficacy regarding pressure ulcer prevention in patients with a spinal cord injury.	Participants recruited in 6 hospitals in Korea (n=47) Inclusion criteria: spinal cord injury undergoing rehabilitation after receiving acute treatment. ≥20 years old; Able to use a wheelchair independent self-care >6 months post-spinal cord injury diagnosis no cognitive impairment, psychiatric history, or pressure ulcer history; Internet access at home	The experimental group participated in the 8 week self-efficacy enhancement program that consisted of small group face-to-face intervention (education and skills training), education with computer animation, phone counseling, face-to-face counseling, and self-management records. (n=24) The control group participants did not receive training in, or demonstrations of, selfcare skills and were only given information with a booklet (n=23).	The pretest data were collected in both the experimental and the control groups including the demographic characteristics, clinical characteristics, self-care knowledge, self-efficacy, self-care behaviors, and skin condition. The post-test data on self-care knowledge, self-efficacy, self-care behaviors, and skin condition	Eight week outcomes The experimental group showed a significantly greater improvement in self-care knowledge, self-efficacy, and self-care behaviors for pressure ulcer prevention than did the control group. Pressure ulcer outcomes One participant in the control group developed a pressure ulcer, none of the participants in the experimental group developed a pressure ulcer (p>0.05)	Limitation Some measurement instruments needing testing for reliability and validity. follow-up period in this study might have been insufficient to accurately evaluate the effectiveness of a self-efficacy enhancement Small sample size	**Level of evidence: 1** **Quality: high quality**
Rottkamp, 1976	To determine the effectiveness of a body positioning	Participants were recruited in a SCI service (n=10) Inclusion:	Randomized to receive: Intervention	• Nurses observed position changes • Short term, 24 hour follow up	• Frequency of position changes increased significantly in experimental groups vs control (p=0.016) • Use of prone position unchanged	• Very small study • Subjective outcome measures • Minimal methods reported	**Level of evidence: 1** **Quality: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	education program	Sensory impairment in positioning Upper body mobility No plans for discharge or surgery Can tell the time, differentiate direction and read Characteristics: Mean age 41 years (range 34 to 72) Mean hospital duration: 18.6 weeks	• body-positioning training sessions of 10to 60 mins duration, 6 to 12 times/week • Verbal encouragement from nurses • Written steps and illustrations provided • Skills demonstration and practice • Written positioning schedule Control • Usual care		• Frequency of intervals of prolonged skin pressure were significantly fewer in experimental group (p=0.004)		
Brace & 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:	• 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.	**Indirect evidence Quality of evidence: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• 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 American • 57.9% had a current PU 47.4% had experienced a previous PU					
J. Schubart, 2012	Case series **reporting on a patient education e-learning package for individuals with SCI**	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	• 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. Participants evaluated the program	• Assessment of e-learning program using validated tools with Likert scales: • Internet Evaluation and Utility (ease of use, convenience, engagement, enjoyment, layout, privacy, satisfaction and acceptability) • Internet Impact and Effectiveness Questionnaire (usefulness, comprehension, credibility, likelihood of returning, mode of delivery and helpfulness)	**Participant assessment of e-learning package** • The program scored very favourably on all items related to potential access barriers and favourably for items related to utility, impact and effectiveness. **Knowledge** • 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**	• 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 • PU not an outcome • Non-validated assessment tools • No statistical analysis • Details of program not reported •	**Level 4** **Quality of evidence: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• 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		• Internet Adherence Questionnaire (barriers to 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 • Skin Care Knowledge and Practice Questionnaire • Assessments via phone interview 6 month followup	**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**		
Garber, Rintala, Holmes, Rodriguez, & Friedman, 2002 (note, methods reported in Rintala et al. 2008)	Quasi-experiment comparing a multi-faceted education program to no education	Veterans with SCI recruited in US Post-surgery for a Category/Stage III or IV PU	Four one-hour sessions that included: Didactic, written, training of family, knowledge test (n=20) No intervention (n=21)	Knowledge on a non-validated knowledge test Locus of control	there was a main effect of time (admission versus discharge, $F = 37.23$, $p < 0.0001$), no main effect of group (intervention group versus control group, $F = 1.22$, $p < 0.28$), and an interaction effect (time by group, $F = 4.72$, $p < 0.04$). both groups gained some knowledge during their hospitalization, but the enhanced education group gained more (20 versus 10 percentage points gained).	• No PU outcomes • Non-validated tools Recruitment poorly reported	**Level of evidence: 1** **Quality of evidence: low**
Rintala, Garber, Friedman, & Holmes, 2008	Randomized controlled trial **investigating an education**	Participants were individuals with SCI recruited from a veterans affairs medical center in US (n=41)	• All participants received standard care pre and post surgery. • Participants were randomized to receive:	• 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)	• Small sample size • Inappropriate randomization method and	**Level of evidence: 1**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
(note, other outcomes reported in Garber et al. 2002)	**program post-surgery to reduce PU recurrence rates**	Post-surgery for a Category/Stage III or IV PU 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)	○ 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** 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** 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.	• Pressure Ulcer Knowledge Test (non-validated • Skin status was assessed through phone interview • Follow up was 2 years (or until recurrence)	• 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	allocation concealment • Study did not reach sample size required for statistical power • Groups 1 and 2 participated in another study concurrently • Non-equivalent groups at baseline • Self-assessed outcomes • Two participants had MS, both assigned to group 1 • Knowledge outcomes not reported •	**Quality of evidence: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Hartigan, Murphy, & Hickey, 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 • 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.	• 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	**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 PU.**	• 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: 2** **Quality of evidence: low**
Quality of Life background							

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Jackson et al., 2017	Qualitative research exploring patient experiences with PI in home setting	12 participants with pressure injuries living in UK 11 living at home (5 with carers), 1 in hospital Age range 31-92 years	None	Semi structured interviews	Themes: • Loss of mobility and independence associated with pressure injury (unable to perform home chores, feeling handicapped and dependent) • Loss of privacy and dignity (requiring physical help, odor and leakage) • Loss of social engagement and ability to perform preferred activities (Housebound, odor, sense of loss for preferred activities) • Loss of personal control and autonomy	• 12 participants only in one area of UK •	**Level of evidence: 5 (qualitative)** **Quality: high**
Latimer, Chaboyer, & Gillespie, 2014	Qualitative research exploring patient experiences with PI prevention	Participants were recruited in Australian hospitals (n=20) Inclusion: Aged > 18 years In hospital more than 3 days before recruitment Able to ambulate 65% female Age range 24-80 years 35% had previously had a PI and 15% a current PI and 35% had family members experience a PI	None	Semi structured interviews	Themes: • Experiencing PI (many emotions, enduring pain, relieving pressure, smelling odor) • Participating in PIP (Enabling, knowing about PI, involving in care decisions • Self determining • Resourcing PIP and treatment (costly, trying to access information, struggling to get help, prolonging healing) **Current healthcare processes and facility ability to provided PIP resources make it difficult for patients participation** **Nurses have a tendency not to engage patients as partners in their PIP care.** **Patients want and are willing a to participate in PIP care; but poorly defined roles are a barrier**	• Small sample, some participants were not Pi patients	**Level of evidence: 5 (qualitative)** **Quality: high**
Degenholtz, Rosen, Castle, Mittal, & Liu, 2008	Cross-sectional and Longitudinal study	Participants recruited two non-profit nursing homes in USA in a 4 year	None	Resident interviews Dependent Variable : • Resident self-reported QOL in 11	**Longitudinal multivariate analysis (n=140)** • Having ≥one PU stage II or higher for two-consecutive 6-month periods was	• Observed association does not imply causation	**Level of evidence: 3**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		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 Characteristics: • mean age 85.09±7.16 • 73.62% female • 14.01% black • mean duration in facility: 5.81±6.88 mths • 15.64% had a PU stage I to IV		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	associated with significant declines in three domains of QOL: ○ autonomy (p=0.047), ○ security (p=not reported), and ○ 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**.	• 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.	**Quality of evidence: moderate**
Dunn, Carlson, Jackson, &	Qualitative cross-case secondary analysis	Case profiles from a previous qualitative study conducted in a US	None	• Re-analysis of previous original research to establish differences and	• Eight themes of response to PU stages I to II identified within the 46 events	• Ethnically diverse group whose demographics may have skewed results	**Level of evidence: 5 (qualitative)**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Clark, 2009		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		similarities in experiences of people with • stage I or II PUs • Initial data collected through participant observation and interviews 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	○ 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 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.**	(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	**Quality of evidence: moderate**
C. Gorecki, Nixon, Madill, Firth, & Brown, 2012	Qualitative study	Participants recruited from hospital and community settings in England and Northern Ireland (n=30) Inclusion: • A purposive sampling method considering	None	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	• 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, ○ hospitalization, ○ inconsistencies,	• Limited to a population with PU • Further areas of research were identified	**Level of evidence: 5 (qualitative)** **Quality of evidence: high**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		age, PU severity, 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.		categories and the data framework analyzed to produce a taxonomy of contributing factors affecting pressure ulcer-related HRQL . • Interrelationships between factors based on views of adults with pressure ulcers Interrater reliability established the extent of agreement between two independent raters.	○ 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**		
Galhardo, Magalhaes, Blanes, Juliano, & Ferreira, 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 Analyzed in two groups: • PU present (n=21)	None	Participants were visited in their home and interviewed. PU measurement: • PU presence confirmed by examination • PU classification according to NPUAP staging system HRQOL measurement:	• 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.	• 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**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• No PU present (n=21) 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		• 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 •	• 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.**		
Yarkin, Tamer, Gamze, Irem, & Huseyin, 2009	Cohort 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	• None	• 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	• 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)	• 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)	**Level of evidence: 3** **Quality of evidence: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		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		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 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 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.**	• 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.	
Thein, Gomes, Krahn, & Wodchis, 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 Stage II PU or higher.	• None	• Records analysis of MDS scores over 5 years. • If any participant had > 1 MDS completed in timeframe, one randomly selected. • Initial data collected by trained assessors, 68% including patient participation, 27% including family participation	• 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	• 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	**Level of evidence: 3** **Quality of evidence: high**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• No significant difference in age, length of stay, marital status between participants with and without a PU • Significantly more with PU than those without PU were males (34% versus 30%, p=0.001) • Participants with PU had a significantly lower BMI • 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 significantly more likely to have incontinence, reduced mobility requiring turning, polypharmacy and regular use of restraint (all p<0.001).		• Minimum Data Set-Health Status Index (MDS-HIS) derived from mapping MDS scores for cognition, self-care, mobility, sensation, emotion, pain onto Canadian Health Utilities Index 2 (HUI2). • The MDS-HIS score used to calculate 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)	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.**	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	
Essex, Clark, Sims, Warriner, & Cullum, 2009	Multicenter cohort study **exploring impact of health related quality of life**	Multicenter study in the 4 hospitals in UK between 1996 to 1998 with recruitment stratified by specialty (n=218 participants with PU and n=2,289 without PU)	• None	• A multi center study investigated HRQOL using the Short Form -36 (SF-36) • Follow-up pilot study included a survey with structured	**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	• Small sample size impeded control for comorbities • Accuracy of information on comorbities in both studies relied on the	**Level of evidence: 3** **Quality of evidence: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	(HRQOL) of 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) • PU participants more likely to have diabetes, PVD, cancer 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) conducted in one UK district hospital in 2007 Inclusion: • age ≥16 years • able to give consent able to take part interview Characteristics: • People with PU had a significantly higher consent rate (80% versus 35%)		interview using SF-36, EQ-5 D and pain VAS to investigate HRQOL 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	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) **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**	completeness of the medical records available • Potential participants with severe co-morbidities were less likely to consent, and many of these people had PU	

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• No significant difference in age, mean age approx. 80 years • Participants with PUs had PU stage II or higher					
C. Gorecki et al., 2010	Prospective mixed methods study with emphasis on qualitative research **Investigating HRQOL**	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) 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	None	• Data analysis using both inductive and deductive processes. • Single interviews conducted at the patient's home or clinical setting lasting a mean of 42 minutes.	• Four domains identified: symptoms, physical functioning, psychological well-being, and social functioning. **Symptoms** pain and discomfort commonly reported as interrupting sleep and daily activity. Exudate and odour 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 identified. PUs reported to have negative impact on physical functioning. **Psychological well-being** Negative psychological well-being that categorised as mood, anxiety and worry, self-efficacy and dependence, appearance and self-consciousness. **Social functioning** disrupted or limited, participants felt isolated, lonely and left out. No major differences could be attributed by age, gender, PU severity or location.	• Limited to English-speaking British nationals • Researcher identified power of study, attrition rates, design flaws, reliability & validity • 10% of interviews and transcripts reviewed by a second researcher for quality assurance.	**Level of evidence: 5 (qualitative)** **Quality of evidence: high**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• 17 in hospital or community, 13 in community settings			**Study conclusions: for patients of all age and PU severity, impact of PU on HRQOL influences 4 domains: symptoms, physical functioning, psychological well-being, and social functioning**		
Background – Self Care Skills							
Ghaisas, Pyatak, Blanche, Blanchard, & Clark, 2015	Retrospective analysis of outcomes of one cohort in trial **to identify associations between PU status and lifestyle change**	Retrospective secondary analysis of outcomes for the treatment group in a previously conducted trial. All participants who completed 12 months of the intervention were eligible for inclusion (n=47 eligible, n=17 included) Inclusion criteria: • SCI • Completed 12 months of the intervention with sufficient participation • Experienced PU during intervention period Exclusion criteria: • Experience no PU • Poor adherence to lifestyle changes	None	• Participants were classified as having achieved lifestyle changes vs no changes • Treatment note review to categorize participants based on making lifestyle changes • Participants were classified as having improved or worsening PU status •	1,922 notes were reviewed (mean 40.9/participant) Four patterns identified: • Positive lifestyle change and positive PU status change (n=19) • Positive lifestyle change and no change or worsening in PU status (n=3) • Minor or no lifestyle change and positive PU change (n=1) • Minor or no lifestyle change and no change or worsening in PU status (n=2) Four case studies are presented to represent each pattern. Discussion of factors: • People with positive lifestyle change were motivated, had identifiable goals and had support • People with no lifestyle change lacked a sense of urgency, had knowledge gaps regarding skin health, prioritized other issues	• Analysis was limited to treatment arm of a trial (i.e. bias sample) with no control • Participants who did not adhere to lifestyle changes were excluded but reasons were not clear (others were included and described as making minor or no lifestyle change) • Unclear how PU status was assessed and whether recurrence was considered • Subjective outcome measures • Does not state how PU status assessed	**Level of evidence: 3** **Quality: low**
Hug et al., 2017	To investigate whether persons with greater levels of general self-efficacy	• Participants were recruited from community settings in Switzerland between 2011 and 2013 (n=511 included, n=52	No intervention	• Main Outcome Measurements: Self-efficacy was assessed by the GSE scale comprising 10 items	General self-efficacy was not related to PU prevention activities without other interacting factors When adding interacting factors of sociodemographic, lesion-related, and lifestyle-related confounders to the	• Self-reported data could have been biased by social desirability and the real values might be	**Indirect evidence (No PU outcomes)**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	are more likely to perform skin-care strategies for PU prevention regularly.	excluded no to incomplete data, n=456 included) Inclusion criteria: • traumatic or non-traumatic SCI • aged > 16 years Exclusion criteria: • Guillain-Barre syndrome, palliative care, Participant characteristics: • 72% male • Mean age 53 years (SD 14.6) 76% receiving home support, 41% employed		(higher score equals higher self efficacy). • PU preventive behavior was operationalized using 5 items of an adapted version of the Spinal Cord Injury Lifestyle scale" (SCILS). • Both measurements were components of a self-administered questionnaire. • Associations between GSE and PU prevention behavior were analyzed by multivariate proportional odds regression models	model general self efficacy was associated with PU activities at night (OR 1.16, 95%CI 1.13 to 1.20, p<0.001), daily skin checks (OR 1.17, 95%CI 1.12 to 1.23, p<0.001), and control of pressure injury prevention devices (OR 1.09, 95%CI 1.05 to 1.14, p<0.001) **Although scientific evidence showing self efficacy is a relevant factor for improving health related outcomes in general chronic diseases, but was not related to skin care prevention behavior for individuals with SCI**	somewhat lower than indicated. • Participants recruited through SCI-rehabilitation centers • Does not measure pressure injury incidence • The sample sizes for analyses with two dependent variables were smaller than for the first three PU prevention items which may diminish the generalizability of the results. • No measure of change able to investigate potential changes in GSE levels or PU prevention during the time course after SCI and causality cannot be determined.	
Background: Knowledge Levels and Education Needs							
McInnes, Chaboyer, Murray, Allen, & Jones, 2014	To survey hospitalized patients' views on a) their perceived roles in PIP and, b) factors that enable or	Participants recruited in orthopaedic and neurology wards in Australia (n=51) • Inclusion criteria • 18 years and older, • admitted to hospital > 24 hours		Data collection through interviews using a study specific questionnaire. Took 10-15 minutes to administer. 5 demographic questions	**Strategies participants identified for patient participation in PIP** Themes: Keep the skin healthy, Listen to your body, Looking after the inside **Participant nominated strategies to facilitate patient participation in PIP** Manage pain and discomfort, Work together, Ongoing PI education	Small convenience sample	**Indirect evidence: 5** **High quality**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	inhibit patient participation in PIP strategies	• Exclusion criteria • Not verbal in English • Participant characteristics: • Mean age 65 years (range 19-93) • 55% female 74% surgical admissions		18 fixed or multiple-choice questions 5 open ended questions Content analyses	**Author conclusions: To ensure successful participation in PIP, patients require education throughout admission, management of pain and discomfort and a supportive and collaborative relationship with health care staff. Health professionals should identify patient ability and motivation to prevent PI, work in partnership with patients to adhere to PIP, and ensure that PIP actions are facilitated with appropriate pain relief.**		
Thietje 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	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	• Participants had initial poor level of knowledge (KBS) and functional ability (SCIM-II score) in every day care that significantly ($p<0.001$) improved 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 ($p<0.001$), 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**	• 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	**Indirect evidence (PU not an outcome)** **Quality of evidence: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• 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.		based on KBS score. Outcome measures at admission, 1 and 3 months post-admission, and after discharge at 6, 18, and 30 months	• rehabilitation physician most important source of information (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 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.**		
J. R. Schubart, Hilgart, & Lyder, 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:	• 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.	**Perception of risk** 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 limited to initial post-injury care period. • Education had been fear-oriented for older patients.	• 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 (qualitative)** **Quality of evidence: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• 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	•		• Opportunity for education limited to time when had a PU requiring care. • Preferred face-to-face education from other SCI patient or health professional, (less frequently, Internet) • Some participants believed education is delivered too early, when in shock or denial, and this was ineffective. • Family members also need education. **Environmental considerations** • home environment and available equipment influenced ability to implement PU prevention. **Access to appropriate care** • limited access to service after acute care and had frustration dealing with health systems and insurance. Education needs were prioritised as: • SCI learners and caregivers need to be aware that SCI poses lifelong risk for PU that may be serious and/or life threatening. • SCI learners need to take charge of own skin care and to feel empowered to partner with health care providers. • SCI learners need PU prevention strategies that fit with their level of functioning and activity and can be 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. •	

Table 1: Level of Evidence for Intervention Studies

Level 1	**Experimental Designs** • Randomized trial
Level 2	**Quasi-experimental design** • Prospectively controlled study design • Pre-test post-test or historic/retrospective control group study
Level 3	**Observational-analytical designs** • Cohort study with or without control group • Case-controlled study
Level 4	**Observational-descriptive studies (no control)** • Observational study with no control group • Cross-sectional study • Case series (n=10+)
Level 5	**Indirect evidence**: studies in normal human subjects, human subjects with other types of chronic wounds, laboratory studies using animals, or computational models

Table 2: Levels of evidence for diagnostic studies in the EPUAP-NPUAP-PPPIA guideline update

Level 1	Individual high quality (cross sectional) studies according to the quality assessment tools with consistently applied reference standard and blinding among consecutive persons.
Level 2	Non-consecutive studies or studies without consistently applied reference standards.
Level 3	Case-control studies or poor or non-independent reference standard.
Level 4	Mechanism-based reasoning, study of diagnostic yield (no reference standard).

Table 3: Levels of evidence for prognostic studies in the EPUAP-NPUAP-PPPIA guideline update

Level 1	A prospective cohort study.
Level 2	Analysis of prognostic factors amongst persons in a single arm of a randomized controlled trial.
Level 3	Case-series or case-control studies, or low quality prognostic cohort study, or retrospective cohort study.

APPRAISAL FOR STUDIES PROVIDING DIRECT EVIDENCE (i.e. ELIGIBLE FOR SUPPORTING AN EVIDENCE-BASED RECOMMENDATIONS

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

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

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Endnote ID	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 measure	% drop out in study arms is reported and acceptable	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Level of evidence	Quality
14241	Arora et al., 2017	Y	Y	Y	N	Y	Y	Y	Y	Y	U	Y	Y	1	High
3045	Guihan et al., 2014	Y	Y	U	N	Y	Y	N	N	Y	Y	Y	Y	1	Moderate
14584	Kim & Cho, 2017	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	1	High
18261	Hossain et al., 2017	Y	Y	N	N	Y	Y	Y	Y	Y	U	Y	Y	1	Moderate

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES/OBSERVATIONAL/PSYCHOMETRIC

Endnote ID	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	Level of evidence	Quality
14534	Chaboyer et al., 2017	Y	Y	Y	Y	Y	Y	NA	Y	Y	Y	4	NA (psychometric)
18265	Rutherford et al., 2018	Y	Y	Y	Y	Y	Y	NA	Y	Y	Y	4	NA (psychometric)
71	C. Gorecki et al., 2013	Y	Y	Y	Y	Y	Y	NA	Y	Y	Y	4	NA (psychometric)
14620	de Laat et al., 2017	Y	Y	Y	N	Y	Y	NA	Y	Y	Y	4	High
9200	Kisala et al., 2015	Y	Y	Y	Y	Y	NA	NA	Y	Y	Y	4	NA (psychometric)

QUALITATIVE STUDIES

Endnote ID	Author/year	Clear statement of aims	Qualitative method is appropriate	Appropriate research design	Recruitment appropriate to research and sample justified	Clear, explicit and appropriate methods for data collection	Researcher's role in data collection and analysis and potential bias addressed	Ethics clearance	In-depth description of analysis technique indicates rigorous process	Clear findings stated	Research contributes to the existing knowledge	Level of evidence	Quality
15738	Jackson et al., 2017	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	5	High
1404	Latimer et al., 2014	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	5	High
6271	McInnes et al., 2014	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	5	High

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 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	Level of evidence	Quality
2942	Lourenco et al., 2014	Y	N	Y	Y	N	N	Y	U	Y	N	N	N	Y	Y	3	Low
13701	Lane et al., 2016	Y	Y	N	N	N	N	Y	U	U	N	N	N	Y	Y	3	Low
6709	Ghaisas et al., 2015	Y	Na	N	U	NA	NA	Y	U	N	N	N	N	Y	Y	3	Low

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