Evidence to Decision Frameworks: Pain Assessment and Treatment

Clinical question What are accurate and effective methods to assess pressure injury pain?

Recommendation 11.1 **Conduct a comprehensive pain assessment for individuals with a pressure injury**

Option: Conducting a comprehensive pain assessment
Comparison: Not conducting a comprehensive pain assessment

Background: Pressure injuries are painful. Individuals with pressure injuries experience pain that can be quantified and differentiated from other pain. Data gathered during a pain assessment measures pressure injury pain presence, quality and quantity, and informs the development of a pain management plan.

BENEFITS & HARMS OF THE RECOMMENDED PRACTICE

CRITERIA	JUDGEMENTS
What is the overall certainty of the evidence of effectiveness?	*N/A* [X] | *Very low* [ ] | *Low* [ ] | *Moderate* [ ] | *High* [ ]
Is there important uncertainty about how much people value the main outcomes?	*N/A* [X] | *Possibly important uncertainty or variability* [ ] | *Probably no important uncertainty or variability* [ ] | *No important uncertainty or variability* [ ] | *No known undesirable outcomes* [ ]
How substantial are the desirable anticipated effects?	*N/A* [X] | *Not substantial* [ ] | *Probably not substantial* [ ] | *Probably substantial* [ ] | *Substantial* [ ]
How substantial are the undesirable anticipated effects?	*N/A* [X] | *Not substantial* [ ] | *Probably not substantial* [ ] | *Probably substantial* [ ] | *Substanital* [ ]
Do the desirable effects outweigh the undesirable effects?	*No* [ ] | *Probably No* [ ] | *Uncertain* [ ] | *Probably Yes* [ ] | *Yes* [ ] | *N/A* [X]

RESEARCH EVIDENCE

Evidence for complete pressure injury healing
Not available

Evidence for that a conducting a pain assessment identifies pressure injury pain
Assessing pressure injury pain with a Visual Analog Scale (VAS)

- In adults with at least one pressure injury (n=132), pressure injury pain was significantly and moderately correlated with generalized pain intensity on a VAS (r=0.59, p<0.01)[1,2] *(Level 1 diagnostic, high quality)*
- In hospitalized adults (n=2,507), the VAS identified more pain in individuals with a pressure injury than for individuals without a pressure injury (Mean difference –23.9 (95% CI –48.56 to 0.95, p= 0.06).[3] (*Level 5 diagnostic, low quality*)

Assessing pressure injury pain with Wong-Baker FACES® Pain Rating Scale (FRS)

- In adults with at least one pressure injury (n=132), pressure injury pain was significantly and moderately correlated with generalized pain intensity on the FRS (r=0.53, p<0.01).[1,2] *(Level 1 diagnostic, high quality)*

Assessing pressure injury pain with the McGill's Pain Questionnaire (MPQ)

- In older adults with a Category/Stage II or greater pressure injury (n=19), the total MPG score for pressure injury pain was significantly and moderately correlated with Global Severity Index (r=0.62, p<0.05).[4] *(Level 3 diagnostic, low quality)*
- In adults with a Category/Stage II or greater pressure injury (n=47), the Present Pain Index subscale of the MPQ identifying 'severe pressure injury pain' was associated with having a pressure injury of longer duration (F=9.56, p<0.05).[5] *(Level 5 diagnostic, moderate quality)*
- In adults with a Category/Stage II or greater pressure injury (n=32), pain was identified with the MPQ in 92% of individuals with a Category/Stage II pressure injury, 100% of individuals with a Category/Stage III pressure injury and 75% of individuals with a Category/Stage IV pressure injury.[6] *(Level 5 diagnostic, moderate quality)*

Strength of Evidence: B1 - Level 1 studies of moderate or low quality providing direct evidence

ADDITIONAL CONSIDERATIONS

- The MPQ is a valid and reliable tool for assessing different types of pain.[5]
- The FRS-R is a valid and reliable tool for assessing different types of pain.[5]

	CRITERIA	JUDGEMENTS	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
RESOURCE USE	**How substantial are the resource requirements?**	*Not clear* ☐ *Not sub-stantial* ☐ *Probably not sub-stantial* ☒ *Probably sub-stantial* ☐ *Sub-stanital* ☐ *Varies* ☐	• There is no evidence available on the resources associated with conducting a pain assessment (*Expert opinion*). • Some well-established pain assessment tools (e.g. MPQ, VAS and FRS) are available for free (*Expert opinion*).	
PRIORITY AND ACCEPTABILITY	**Is the option acceptable to key stakeholders?**	*No* ☐ *Probably No* ☐ *Uncertain* ☒ *Probably Yes* ☐ *Yes* ☐ *Varies* ☐	No evidence available.	
	Is the option a priority for key stakeholders?	*No* ☐ *Probably No* ☐ *Uncertain* ☐ *Probably Yes* ☐ *Yes* ☒ *Varies* ☐	In the consumer survey, pain management was ranked as one of the three primary care goals for 43% of people who identified as having had a pressure injury or having been assessed as being at risk of a pressure injury. It is likely that patient consumers would consider a pain assessment to be a priority.[7,8] (*Indirect evidence*)	
FEASIBILITY	**Is the option feasible to implement?**	*No* ☐ *Probably No* ☐ *Uncertain* ☐ *Probably Yes* ☐ *Yes* ☒ *Varies* ☐	In most clinical settings, conducting a comprehensive pain assessment is feasible; however, health professionals require appropriate training. (*Expert opinion*).	

Balance of consequences	Undesirable consequences *clearly outweigh* desirable consequences in most settings	Undesirable consequences *probably outweigh* desirable consequences in most settings	The balance between desirable and undesirable consequences *is closely balanced or uncertain*	Desirable consequences *probably outweigh* undesirable consequences in most settings	Desirable consequences *clearly outweigh* undesirable consequences in most settings
	☐	☐	☐	☐	☒
Strength of recommendation	Strong negative recommendation: Definitely don't it	Weak negative recommendation: Probably don't do it	No specific recommendation	Weak positive recommendation: Probably do it	Strong positive recommendation: Definitely do it
	☐	☐	☐	☐	☒
Justification	Managing pain is a priority for people with pressure injury pain. In the US it is mandated that people in hospitals receive regular, ongoing pain assessment.[9] No evidence was identified indicating that conducting a pain assessment contributes to pressure injury healing or management of pressure injury pain. However one high quality Level 1 diagnostic study[1,2] established that pressure injury pain can be identified using two well-established pain assessment tools, a VAS and FRS. A low quality Level 3 diagnostic study[4] and two Level 5 diagnostic studies[5,6] suggested that pressure injury pain can be identified using the well-established pain assessment tool, the McGill Pain Questionnaire (MPQ). A range of pain assessment tools are easily accessible and feasible to implement in most clinical settings.				

Clinical question	What are effective non-pharmacological interventions for reducing pressure injury pain?
Good practice statement 11.2	**Use non-pharmacological pain management strategies as a first line strategy and adjuvant therapy to reduce pain associated with pressure injuries.**

Background: Non-pharmacological interventions are well-acknowledged as important in controlling pain.

SUPPORTING EVIDENCE, WHEN AVAILABLE	
Evidence to support the opinion (when available)	This statement is based on expert opinion.
Justification	Using non-pharmacological pain management strategies to reduce pain associated with pressure injuries reflects good practice. There is no direct evidence from literature search on the effectiveness of non-pharmacological pain management strategies for treating pain associated with pressure injuries; however, non-pharmacological pain management strategies are well-acknowledged as being useful in pain management.

Clinical question	What are effective non-pharmacological interventions for reducing pressure injury pain?
Good practice statement 11.3	**Use repositioning techniques and equipment with consideration to preventing and managing pressure injury pain.**
GOOD PRACTICE STATEMENT	***Background:*** Pressure injuries are caused, at least in part, by unrelieved pressure and the resulting ischemia of tissues that occurs between an external surface and underlying bone. Therefore, repositioning is essential.
	SUPPORTING EVIDENCE, WHEN AVAILABLE
Evidence to support the opinion (when available)	In a general hospital population without pressure injuries (n = 1,395) mean pain score on an 11-point numerical rating scale during repositioning was 4.9 ± 3.1.[10] (*Indirect evidence*). People with multiple sclerosis and pressure injuries, described their experience of pain during movement and related to use of repositioning equipment.[11] (*Indirect evidence).*
Justification	There is indirect evidence that repositioning and turning can cause both generalized pain and pressure injury pain,[10,11] especially in individuals with chronic pain, limited cognitive ability or receiving end-of-life care.

Clinical question	What are effective non-pharmacological interventions for reducing pressure injury pain?
Good practice statement 11.4	**Use the principles of moist wound healing to reduce pressure injury pain.**
GOOD PRACTICE STATEMENT	***Background:*** Wounds re-epithelialize more quickly in the presence of moist wound healing.[12] Pressure injury pain can be minimized by keeping the wound bed moist and covered.[13].
SUPPORTING EVIDENCE, WHEN AVAILABLE	
Evidence to support the opinion (when available)	This statement is based on expert opinion.
Justification	Wounds re-epithelialize more quickly in the presence of moist wound healing.[12] Pressure injury pain can be minimized by keeping the wound bed moist and covered.[13]

Clinical question What are effective pharmacological interventions for reducing pressure injury pain?

Recommendation 11.5 **Consider applying a topical opioid to manage acute pressure injury pain, if required and when there are no contraindications.**

Option: Use topical opioid-based analgesia to reduce pressure injury pain
Comparison: No use of topical analgesia (i.e. use alternative pain management interventions or a placebo)

Background: Pressure injuries are painful. Individuals with pressure injury pain can experience pain differentiated from other pain. Pressure ulcer pain can occur at rest, when no procedures are being performed,[6,14-17] and may be acute (including hyperalgesia), chronic, or neuropathic. Topical diamorphine acts on nociceptors in superficial skin.[18] Data gathered using pain assessment tools to assess the efficacy of topical analgesia can inform choices for pain management.

BENEFITS & HARMS OF THE RECOMMENDED PRACTICE

CRITERIA	JUDGEMENTS	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
What is the overall certainty of the evidence of effectiveness?	*No included studies* ☐ | *Very low* ☐ | *Low* ☒ | *Moderate* ☐ | *High* ☐	**Evidence pressure injury pain reduction** • In individuals in end-of -life care (n=5), 100% of individuals with painful sacral pressure injuries treated with 10mg topical morpine sulphate had lower pain scored on a visual analog scale (VAS) compared to when the same pressure injuries were treated with a topical placebo gel.[19] (*Level 1, low quality*) • In individuals in end-of-life care with Category/Stage II and II pressure injuries (n=7), treatment with topical diamorphine gel applied daily was associated with statsitically significant improvements in pain scores measuresd on a 5-point VAS at one hour after application (p=0.003) and 12 hours after application (p=0.005). The mean score improvement was not reported. Statsitical comparison to the control group receiving a hydrogel was not reported.[20] (*Level 1, low quality*) • In individuals in end-of-life care with Category/Stage II pressure injuries (n=17), 70.5% reported improvement in pain by ≥4 points on a 10-point VAS over five days when topical 5-10mg diamorphine gel was applied 12-24 hourly (mean score 9.4 versus 4.6, p<0.02).[18] (*Level 4, low quality*) • In individuals with chronic wounds, treatment with 0.5% or 0.15% morphine gel was associated with substanital pain relief for 77.69% of people.[21] (*Level 5)* **Possible adverse effects** In individuals in end-of-life care with Category/Stage II and II pressure injuries (n=7), side-effects of using a topical diamorphine gel included skin irritation, nausea and vomiting, drowsiness ahd hallucinations/nightmares, but these effects were not attributed to the topical treatment.[20] (*Level 1, low quality*) **Strength of Evidence: B1 —Level 1 studies of moderate or low quality providing direct evidence , most studies have consistent outcomes and inconsistencies can be explained**	
Is there important uncertainty about how much people value the main outcomes?	*Important uncertainty or variability* ☐ | *Possibly important uncertainty or variability* ☐ | *Probably no important uncertainty or variability* ☐ | *No important uncertainty or variability* ☒ | *No known undesirable outcomes* ☐		
How substantial are the desirable anticipated effects?	*Unclear* ☐ | *Not substantial* ☐ | *Probably not substantial* ☐ | *Probably substantial* ☒ | *Substantial* ☐		
How substantial are the undesirable anticipated effects?	*Unclear* ☒ | *Not substantial* ☐ | *Probably not substantial* ☐ | *Probably substantial* ☐ | *Substanital* ☐		
Do the desirable effects outweigh the undesirable effects?	*No* ☐ | *Probably No* ☐ | *Uncertain* ☒ | *Probably Yes* ☐ | *Yes* ☐ | *Varies* ☐		

	CRITERIA	JUDGEMENTS	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
RESOURCE USE	**How substantial are the resource requirements?**	*Not clear* ☒ *Not sub-stantial* ☐ *Probably not sub-stantial* ☐ *Probably sub-stantial* ☐ *Sub-stanital* ☐ *Varies* ☐	No evidence available.	
PRIORITY AND ACCEPTABILITY	**Is the option acceptable to key stakeholders?**	*No* ☐ *Probably No* ☐ *Uncertain* ☒ *Probably Yes* ☐ *Yes* ☐ *Varies* ☐	No evidence available.	
	Is the option a priority for key stakeholders?	*No* ☐ *Probably No* ☐ *Uncertain* ☐ *Probably Yes* ☐ *Yes* ☒ *Varies* ☐	In the consumer survey, 43% of people pain who identified as having had a pressure injury or having been assessed as being at risk of a pressure injury ranked pain management as one of their three most important care goals.[7] (*Indirect evidence*)	
FEASIBILITY	**Is the option feasible to implement?**	*No* ☐ *Probably No* ☐ *Uncertain* ☐ *Probably Yes* ☐ *Yes* ☐ *Varies* ☒	• Topical opioid-based analgesics may not be available in all geographic regions (*Expert opinion*). • Topical opoiods require a prescription from a licensed health professional in some geopgraphic regions (*Expert opinion*).	

Balance of consequences	Undesirable consequences *clearly outweigh* desirable consequences in most settings ☐	Undesirable consequences *probably outweigh* desirable consequences in most settings ☐	The balance between desirable and undesirable consequences *is closely balanced or uncertain* ☒	Desirable consequences *probably outweigh* undesirable consequences in most settings ☐	Desirable consequences *clearly outweigh* undesirable consequences in most settings ☐
Strength of recommendation	Strong negative recommendation: Definitely don't it ☐	Weak negative recommendation: Probably don't do it ☐	No specific recommendation ☐	Weak positive recommendation: Probably do it ☐	Strong positive recommendation: Definitely do it ☐
Justification	There is evidence from small Level 1 studies[19,20] and lower levels of evidence[18,21] that use of a topical opioid can decrease pressure injury pain by at least four points on a VAS at five days,[18] which is likely to be a clinically significant reduction in pain for most individuals. There was insufficient evidence to make recommendations on other topical products that are used to manage wound-related pressure injury pain (e.g., anti-inflammatory preparations and anaesthetics).				

Clinical question	What are effective non-pharmacological interventions for reducing pressure injury pain?
Good practice statement 11.6	**Use non-pharmacological pain management strategies as a first line strategy and adjuvant therapy to reduce pain associated with pressure injuries.**
	Background: Non-pharmacological interventions are well-acknowledged as important in controlling pain.
SUPPORTING EVIDENCE, WHEN AVAILABLE	
Evidence to support the opinion (when available)	This statement is based on expert opinion.
Justification	Using non-pharmacological pain management strategies to reduce pain associated with pressure injuries reflects good practice. There is no direct evidence from literature search on the effectiveness of non-pharmacological pain management strategies for treating pain associated with pressure injuries; however, non-pharmacological pain management strategies are well-acknowledged as being useful in pain management.

Clinical question	What are effective pharmacological interventions for reducing pressure injury pain?

Applying a topical anti-inflammatory gel or wound dressing to relieve procedural pain

Option: use topical anti-inflammatroy to reduce pressure injury pain
Comparison: not use topical anti-inflammatory to reduce pressure injury pain (i.e. use alternative pain management interventions or a placebo)

Background: Pressure injuries are painful. Individuals with pressure injury pain can experience pain differentitated from other pain. Pressure ulcer pain can occur at rest, when no procedures are being performed,[6,14-17] and may be acute (including hyperalgesia), chronic, or neuropathic.

	CRITERIA	JUDGEMENTS	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
BENEFITS & HARMS OF THE PRACTICE	**What is the overall certainty of the evidence?**	*No included studies* ☐ | *Very low* ☐ | *Low* ☒ | *Moderate* ☐ | *High* ☐	**Direct evidence for reducing pain** • Topical 3% benzydamine hydrochloride cream applied to to intact peri-wound skin surrounding unstaged pressure injuries was not associated with any greater reduction in pressure injury pain compared to placebo gel (mean VAS reduction 23.5mm±22.5 versus 15.8±22.5mm, p=0.41).[22] (*Level 1*)	
	Is there important uncertainty about how much people value the main outcomes?	*Important uncertainty or variability* ☐ | *Possibly important uncertainty or variability* ☐ | *Probably no important uncertainty or variability* ☐ | *No important uncertainty or variability* ☒ | *No known undesirable outcomes* ☐		
	How substantial are the desirable anticipated effects?	*Unclear* ☐ | *Not substantial* ☒ | *Probably not substantial* ☐ | *Probably substantial* ☐ | *Substantial* ☐		
	How substantial are the undesirable anticipated effects?	*Unclear* ☒ | *Not substantial* ☐ | *Probably not substantial* ☐ | *Probably substantial* ☐ | *Substanital* ☐		
	Do the desirable effects outweigh the undesirable effects?	*No* ☐ | *Probably No* ☐ | *Uncertain* ☒ | *Probably Yes* ☐ | *Yes* ☐ | *Varies* ☐		

	CRITERIA	JUDGEMENTS	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
RESOURCE USE	**How substantial are the resource requirements?**	*Not clear* ☒ | *Not sub-stantial* ☐ | *Probably not sub-stantial* ☐ | *Probably sub-stantial* ☐ | *Sub-stanital* ☐ | *Varies* ☐	No evidence avialable	
PRIORITY AND ACCEPTABILITY	**Is the option acceptable to key stakeholders?**	*No* ☐ | *Probably No* ☐ | *Uncertain* ☒ | *Probably Yes* ☐ | *Yes* ☐ | *Varies* ☐	No evidence avialable	
PRIORITY AND ACCEPTABILITY	**Is the option a priority for key stakeholders?**	*No* ☐ | *Probably No* ☐ | *Uncertain* ☐ | *Probably Yes* ☒ | *Yes* ☐ | *Varies* ☐	In the consumer survey, 43% of people pain who identified as having had a pressure injury or having been assessed as being at risk of a pressure injury ranked pain management as one of their three most important care goals.[7] (*Level 5*)	
FEASIBILITY	**Is the option feasible to implement?**	*No* ☐ | *Probably No* ☐ | *Uncertain* ☐ | *Probably Yes* ☐ | *Yes* ☐ | *Varies* ☐	• Topical anti-inflammatory preparations, including ibuprofen-releasing wound dressings, may not be available in all geographic regions. (*Expert opinion*)	

Balance of consequences	Undesirable consequences *clearly outweigh* desirable consequences in most settings	Undesirable consequences *probably outweigh* desirable consequences in most settings	The balance between desirable and undesirable consequences *is closely balanced or uncertain*	Desirable consequences *probably outweigh* undesirable consequences in most settings	Desirable consequences *clearly outweigh* undesirable consequences in most settings
	☐	☐	☒	☐	☐
Strength of recommendation	Strong negative recommendation: Definitely don't it	Weak negative recommendation: Probably don't do it	No specific recommendation	Weak positive recommendation: Probably do it	Strong positive recommendation: Definitely do it
	☐	☐	☐	☐	☐
Recommendation (text)	**No recommendation**				
Justification	The available evidence indicated that there is no clinical benefit above using a placebo gel for anti-inflammatory preparations applied to peri-wound skin.				

References

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