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## Assessment and measurement of pain and pain treatment

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## **2.1 | Assessment**

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## **2.2 | Measurement**

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## **2.3 | Outcome measures in acute pain management**

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## 2.0 | Assessment and measurement of pain and pain treatment

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Reliable and accurate assessment of acute pain is necessary to ensure safe and effective pain management and to provide effective research outcome data. The assessment and measurement of pain is fundamental to the process of assisting in the diagnosis of the cause of a patient's pain, selecting an appropriate analgesic therapy and evaluating then modifying that therapy according to the individual patient's response. Pain should be assessed within a sociopsychobiomedical model that recognises that physiological, psychological and environmental factors influence the overall pain experience. Likewise, the decision regarding the appropriate intervention following assessment needs to be made with regard to a number of factors, including recent therapy, potential risks and side effects, any management plan for the particular patient and the patient's own preferences. A given pain 'rating' should not automatically trigger a specific intervention without such considerations being undertaken (van Dijk 2012a **Level IV**, n=2,674; van Dijk 2012b **Level IV**, n=10,434). Care must be undertaken with pain assessment to avoid the process of assessment itself acting as a placebo (see Section 1.3).

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### 2.1 | Assessment

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The assessment of acute pain should include a thorough general medical history and physical examination, a specific "pain history" (see Table 2.1) and an evaluation of associated functional impairment (see Section 2.3). In acute pain management, assessment must be undertaken at appropriate frequent intervals. At these times, evaluation of pain intensity, functional impact and adverse effects of treatment must be undertaken and recorded using tools and scales that are consistent, valid and reliable (Scott 2008 **NR**). In addition, pain assessment must lead to changes in management and re-evaluation of the patient to ensure improvements in the quality of care (Gordon 2005 **GL**).

Although not always possible in an acute setting, a complete pain history provides important diagnostic information that may help distinguish different underlying pain states such as nociceptive (somatic and visceral) or neuropathic pain (Victor 2008 **Level III-2**, n=823). Somatic pain may be described as sharp, hot or stinging, is generally well localised and is associated with local and surrounding tenderness. By contrast, visceral pain may be described as dull, cramping or colicky, is often poorly localised and may be associated with tenderness locally or in the area of referred pain, or with symptoms such as nausea, sweating and cardiovascular changes (Scott 2008 **NR**).

While nociceptive pain typically predominates in the acute pain setting, neuropathic pain may also be present (Guastella 2011 **Level IV**, n=54) (see also Section 1.1 and 8.1.4). Features in the pain history that may suggest a diagnosis of neuropathic pain include (Dworkin 2007 **Level III-2**, n=618; Haanpaa 2011 **GL**; Gray 2008 **NR**):

- Clinical circumstances associated with a high risk of nerve injury (eg thoracic or chest wall procedures, amputations or hernia repairs);
- Pain descriptors such as burning, shooting and stabbing;
- The paroxysmal or spontaneous nature of the pain which may have no clear precipitating factors;
- The presence of dysaesthesias (spontaneous or evoked unpleasant abnormal sensations), hyperalgesia (increased response to a normally painful stimulus), allodynia (pain due to a stimulus that does not normally evoke pain such as light touch) or areas of hypoaesthesia; and

- Regional autonomic features (changes in colour, temperature and sweating) and phantom phenomena.

The IASP definition of neuropathic pain is “*pain caused by a lesion or disease of the somatosensory system*” (IASP 2019 **GL**; Jensen 2011 **NR**). This has been subdivided into ‘central’ and ‘peripheral’ neuropathic pain (IASP 2019 **GL**). Symptoms consistent with neuropathic pain may occur without nerve injury (nociplastic pain) (IASP 2019 **GL**; Kosek 2016 **NR**). To determine if pain is neuropathic, further quantitative sensory testing (QST) may be needed (Haanpaa 2011 **GL**; Garcia-Larrea 2012 **NR**).

It is useful to draw the distinction between the different types of pain because the likely duration of the pain and the response to analgesic strategies may vary. The concept of “*mechanism-based pain diagnosis*” has been promoted (Woolf 2001 **NR**) and although the correlation between symptoms, mechanisms and response to therapy is not fully defined, specific therapy targeted at, for example neuropathic pain, may be of benefit (Gray 2008 **NR**).

**Table 2.1** | Fundamentals of a pain history (not necessarily applicable to all settings of acute pain)

<b>1 Site of pain</b>
<ul style="list-style-type: none"> <li>a. primary location: description ± body map diagram</li> <li>b. radiation</li> </ul>
<b>2 Circumstances associated with pain onset</b>
including details of trauma or surgical procedures
<b>3 Character of pain</b>
<ul style="list-style-type: none"> <li>a. sensory descriptors eg sharp, throbbing, aching (Victor 2008)</li> <li>b. McGill Pain Questionnaire: includes sensory and affective descriptors (Melzack 1987)</li> <li>c. neuropathic pain characteristics (eg NPQ; DN4; LANSS; PainDETECT; ID Pain)</li> </ul>
<b>4 Intensity of pain</b>
<ul style="list-style-type: none"> <li>a. at rest</li> <li>b. on movement</li> <li>c. temporal factors               <ul style="list-style-type: none"> <li>i duration</li> <li>ii current pain, during last week, highest and lowest level</li> <li>iii continuous or intermittent</li> </ul> </li> <li>d. aggravating or relieving factors</li> </ul>
<b>5 Associated symptoms (eg nausea)</b>
<b>6 Effect of pain on activities and sleep</b>
<ul style="list-style-type: none"> <li>a. Functional assessment tools               <ul style="list-style-type: none"> <li>i Acute (eg Functional Activity Scale)</li> <li>ii Recent (eg Brief Pain Inventory – Short Form (BPI-SF))</li> </ul> </li> </ul>
<b>7 Treatment</b>
<ul style="list-style-type: none"> <li>a. current and previous medications — dose, frequency of use, efficacy, adverse effects</li> <li>b. other treatment eg transcutaneous electrical nerve stimulation</li> <li>c. health professionals consulted</li> </ul>

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## 8 Relevant medical history

- a. prior or coexisting pain conditions and treatment outcomes
- b. prior or coexisting medical conditions

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## 9 Factors influencing the patient's symptomatic treatment

- a. belief concerning the causes of pain
- b. knowledge, expectations and preferences for pain management
- c. expectations of outcome of pain treatment
- d. reduction in pain required for patient satisfaction or to resume "reasonable activities"
- e. typical coping response for stress or pain, including presence of anxiety or psychiatric disorders (eg depression or psychosis)
- f. family/cultural expectations and beliefs about pain, stress and postoperative course

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Notes: NPQ - Neuropathic Pain Questionnaire; DN4 - Douleur Neuropathique en 4; LANSS - Leeds Assessment of Neuropathic Symptoms and Signs.

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## 2.2 | Measurement

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The definition of pain underlies the complexity of its measurement. As described in Chapter 1, pain is an individual and subjective experience modulated by physiological, psychological and environmental factors such as previous events, culture, prognosis, coping strategies, fear and anxiety. Therefore, most measures of pain are based on self-report. These measures lead to sensitive and consistent results if administered properly (Moore 2003 **NR**). Self-report measures may be influenced by mood, sleep disturbance and medications (Scott 2008 **NR**).

In some instances, it may not be possible to obtain reliable self-reports of pain eg patients with impaired consciousness or cognitive impairment, young children (see Section 10.3), elderly patients (see Section 9.2) or where there are failures of communication due to language difficulties, inability to understand the measures, unwillingness to cooperate or severe anxiety. In these circumstances, other methods of pain assessment will be needed.

There are no objective measures of "pain" but associated factors such as hyperalgesia (eg mechanical withdrawal threshold), the stress response (eg plasma cortisol concentrations), behavioural responses (eg facial expression), functional impairment (eg coughing, ambulation) or physiological responses (eg changes in heart rate) may provide additional information. Analgesic requirements (eg patient-controlled opioid doses delivered) are commonly used as *post hoc* measures of pain experienced (Moore 2003 **NR**).

Regular and repeated measurements of pain and its impact should be made to assess ongoing adequacy of analgesic therapy. An appropriate frequency of reassessment will be determined by the duration and severity of the pain, patient needs and response, and the type of medicine or intervention (Gordon 2005 **GL**). Such measurements should incorporate different components of pain, and assessment for analgesic side effects, especially sedation (Macintyre 2011 **NR**). For example, in the postoperative patient this should include assessments of static (rest) and dynamic (on sitting, coughing or moving the affected part) pain. Whereas static measures may relate to the patient's ability to sleep, dynamic measures can provide a simple test for mechanical hyperalgesia and determine whether analgesia is adequate for recovery of function (Breivik 2008 **NR**).

Recording pain intensity as "*the fifth vital sign*" was a program advocated by the USA Department of Veteran Affairs, which aimed to increase awareness and utilisation of pain

assessment (Mularski 2006 **Level III-3**, n=600), with the intention of leading to improved acute pain management (Gould 1992 **Level III-3**, n=2,035). However, an over-reliance on sometimes unrealistic aims (such as “pain free”) and an excessive use of opioids is leading to a more moderate and balanced approach to intervention (Levy 2018 **NR**).

Aiming to reduce suffering and improve function rather than targeting ‘zero pain’ is more in keeping with patient expectations (Lee 2016 **NR**). In 2018, the USA Joint Commission (JCAHO) implemented new and revised pain assessment and management standards for accredited hospitals, emphasising patient engagement, multimodal therapy and improving pain assessment by concentrating more on how pain affects patients’ physical function (JCAHO 2017 **GL**).

Uncontrollable or escalating pain should always trigger a reassessment of the diagnosis and consideration of alternatives such as developing surgical or other complications, or the presence of neuropathic pain. Review by an acute pain service (APS) or other specialist group should be considered.

## 2.2.1 | Unidimensional measures of pain

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A number of scales are available that measure either pain intensity or the degree of pain relief following an intervention. Pain relief scales, although less commonly used, have some advantage when comparing the response to different treatments as all patients start with the same baseline “relief” score (zero), whereas they may have differing levels of baseline pain intensity (Breivik 2008 **NR**; Moore 2003 **NR**).

### 2.2.1.1 | Categorical scales

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Categorical scales use words to describe the magnitude of pain or the degree of pain relief (Moore 2003 **NR**). The verbal descriptor scale (VDS) is the most common example (eg using terms such as none, mild, moderate, severe and excruciating or agonising) typically using four or five graded descriptors.

These terms can then be converted to numeric scores (eg 0, 2, 5, 8, 10) for charting and easy comparison over time. There is a good correlation between descriptive verbal categories and visual analogue scales (VAS) (Banos 1989 **Level III-2**, n=212), but the VDS is a less sensitive measure of pain treatment outcome than the VAS (Jensen 2002 **Level IV**, n=247). Pain “relief” may also be graded as none, mild, moderate or complete using a VDS.

Categorical scales have the advantage of being quick and simple and may be useful in the elderly or visually impaired patient and in some children. However, the limited number of choices in categorical compared with numerical scales may make it more difficult to detect differences between treatments (Breivik 2000 **Level III-2**). Other limitations include personal, cultural or linguistic differences in interpretation of the specific words chosen as descriptors both between patients and between patients and their clinicians.

### 2.2.1.2 | Numerical rating scales

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Numerical rating scales (NRS) have both written and verbal forms. Patients rate their pain intensity on the scale of zero to ten where zero represents “no pain” and ten represents “worst pain imaginable”. The Verbal NRS (VNRS) is typically administered using a phrase such as: “On a scale of zero to ten, with zero being no pain at all and ten being the worst pain you could imagine, where would you rate the pain you are experiencing right now?”. VNRS are often preferred because they are simpler to administer, give consistent results and correlate well with the VAS (Karcioglu 2018 **Level I**, 19 RCTs, n=853; Hjermstad 2011 **Level IV SR**, 54 studies, n unspecified; Safikhani 2018 **NR**). Recall of pain intensity using the VNRS over the previous 24 h was a reasonable

indicator of average pain experienced by the patient during that time (Jensen 2008 **Level III-2**). VNRS may reflect pain interference as well as pain intensity (Thong 2018 **Level III-3**, n=101; Jensen 2017 **Level IV**, n=807).

It is important that scales are consistent, and it is recommended that the “no pain” point be represented as zero rather than one (Scott 2008 **NR**). Pain relief may be measured in the reverse direction with zero representing “no relief” to ten representing “complete relief”. A visual form of the 11-point NRS with tick marks on a line or boxes with numbers may also be used (Breivik 2008 **NR**). Although NRS are widely used, some patients have difficulty representing their pain in numerical terms and are better suited to a categorical scale. A value of four or more is often used as a threshold to guide clinical intervention (Hartrick 2003 **Level IV**, n=222).

### 2.2.1.3 | Visual analogue scales

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Visual analogue scales (VAS) consist of a 100 mm horizontal line with verbal anchors at both ends and no tick marks. The patient is asked to mark the line and the “score” is the distance in millimetres from the left side of the scale to the mark. VAS are the most commonly used scales for rating pain intensity in research, with the words “no pain” at the left end and “worst pain imaginable” at the right. Pictorial versions also exist. VAS can also be used to measure other aspects of the pain experience (eg affective components, patient satisfaction, adverse effects).

Assessment of pain immediately after surgery can be more difficult and lead to greater interpatient variability in pain scores because of transient anaesthetic-related cognitive impairment and decreases in visual acuity. A “pain meter” (PAULA), which used five coloured emoticon faces on the front of a ruler and corresponding VAS scores on the back and allowed patients to move a slider to mark the pain they were experiencing, resulted in less variance than pain scores obtained from a standard VAS (Machata 2009 **Level III-2**, n=48).

VAS ratings  $\geq 70$  mm are indicative of “severe pain” (Aubrun 2003 **Level IV**, n=3,045; Jensen 2003 **Level IV**, n=248) and 0–5 mm “no pain”, 5–44 mm “mild pain” and 45–69 mm “moderate pain” (Aubrun 2003 **Level IV**, n=3,045). A reduction in pain intensity by 30–35% has been rated as clinically meaningful by patients with postoperative pain (Cepeda 2003 **Level IV**, n=700; Jensen 2003 **Level IV**, n=248), acute pain in the emergency department (ED) (Lee 2003 **Level IV**, n=143), breakthrough cancer pain (Farrar 2000 **Level IV**, n=1,268 [episodes of breakthrough pain]) and chronic pain (Farrar 2001 **Level IV**, n=2,724).

These scales have the advantage of being simple and quick to use, allow for a wide choice of ratings and avoid imprecise descriptive terms (Scott 2008 **NR**). However, the scales require concentration and coordination, need physical devices, are unsuitable for children aged  $<5$  y and may be unsuitable in up to 26% of adult patients (Cook 1999 **NR**).

The VAS has been shown to be a linear scale for patients with postoperative pain of mild to moderate intensity (Myles 1999 **Level IV**, n=52) and severe pain (Myles 2005 **Level IV**, n=22). Therefore, results are equally distributed across the scale, such that the difference in pain between each successive increment is equal.

## 2.2.2 | Functional impact of acute pain

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Analgesia should be titrated to achieve both decreased pain intensity and the ability to undertake appropriate functional activity (Breivik 2008 **NR**). This will enable analgesia to optimise recovery. Most tools for measuring the functional impact of pain are based on chronic pain assessment and therefore are not routinely applicable to the acute pain environment.

Measurement of pain intensity scores on movement or with coughing is a useful guide; however, this reflects the subjective pain experience and not the capacity to undertake the

specific activity. The Functional Activity Scale (FAS) score is a simple three-level ranked categorical score designed to be applied at the point of care (Scott 2008 **NR**). Its fundamental purpose is to assess whether the patient can undertake appropriate activity at their current level of pain control and to act as a trigger for intervention should this not be the case. The patient is asked to perform the activity or is taken through the activity in the case of structured physiotherapy (eg joint mobilisation) or nurse-assisted care (eg ambulation, turned in bed). The ability to complete the activity is then assessed using the FAS as:

- |                            |  |
|----------------------------|--|
| A — no limitation          | the patient is able to undertake the activity without limitation due to pain (pain intensity score is typically zero to three);              |
| B — mild limitation        | the patient is able to undertake the activity but experiences moderate to severe pain (pain intensity score is typically four to ten); and   |
| C — significant limitation | the patient is unable to complete the activity due to pain, or pain treatment-related adverse effects, independent of pain intensity scores. |

This score is then used to track effectiveness of analgesia on function and trigger interventions if required. Disadvantages of the FAS score are that it has not been independently validated and clinical staff need to be educated in its application.

A four-level scale (no interference, interference with some vs most activities vs unable to do any activity) has been evaluated against NRS in a pilot study and identified a correlation with NRS in cognitively intact but not impaired patients (Halm 2019 **Level III-2**, n=68).

### 2.2.3 | Multidimensional measures of pain

Rather than assessing only pain intensity, multidimensional tools provide further information about the characteristics of the pain and its impact on the individual. Examples include the Brief Pain Inventory (BPI), which assesses pain intensity and associated disability (Daut 1983 **Level IV**), and the McGill Pain Questionnaire (MPQ), which assesses the sensory, affective and evaluative dimensions of pain (Melzack 1987 **NR**). The MPQ also exists in a 15-item short-form (SF-MPQ), which is well validated and has a VAS item for pain intensity and a VRS for rating the overall pain experience. The role of the McGill Pain questionnaire (and its Short Form variants) has been reviewed; with a conclusion that, while still useful, it provides little information regarding mechanism, nor the broader social and functional impact of the pain and so should not be used as a single measure to guide research or therapy (Main 2016 **NR**). The BPI also exists in a short form (BPI-SF and -SF2) which includes functional impact of the pain over the previous 24 h (Dworkin 2009 **Level IV**, n=1,008).

#### 2.2.3.1 | Neuropathic Pain

Neuropathic pain is not easily identified using unidimensional tools such as the VAS (Haanpaa 2011 **GL**). Specific scales have been developed that identify (and/or quantify) descriptive factors specific for neuropathic pain (Dworkin 2007 **Level III-2**, n=618; Bouhassira 2005 **Level III-2**, n=160; Bouhassira 2004 **Level IV**, n=176; Cruccu 2004 **GL**; Freynhagen 2006 **NR**) and may also include sensory examination (Bouhassira 2005 **Level III-2**, n=160; Cruccu 2004 **GL**) and allow evaluation of response to treatment (Bouhassira 2004 **Level IV**, n=176).



Screening tools in common use for identifying neuropathic pain include:

- Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) has five symptom items and two clinical assessment items — a subjective-only form also exists (Bennett 2001 **Level III-3**, n=100);
- Douleur Neuropathique en 4 (DN4) has ten items — seven symptomatic and three from clinical examination (Bouhassira 2005 **Level III-3**, n=160);
- Pain DETECT has nine self-reported items that do not require a clinical examination and gives a likelihood scoring for neuropathic pain (Freyenhagen 2006 **NR**); its use has been reviewed in over 300,000 patients (Freyenhagen 2016 **NR**);
- Neuropathic Pain Questionnaire (NPQ) comprises twelve items and can be self-reported — a three-item short-form also exists (Krause 2003 **Level III-2**, n=528; Backonja 2003 **NR**);
- ID Pain has six self-reported items (Portenoy 2006 **Level IV**, n=586).

These scales have similar specificity and sensitivity (except for the ID Pain, which has lower values than the others), have mostly been validated and are often available in validated translations in many languages (Haanpaa 2011 **GL**). In assessing the criterion validity and reliability of the above screening questionnaires, the DN4 and NPQ were found to be most suitable for clinical use overall, noting that cross-cultural adaptations had less evidence than the original versions (Mathieson 2015 **Level IV SR**, 37 studies, n unspecified).

Clinical questionnaires for neuropathic pain show that subjective pain assessments are essential for diagnosis and assessment of neuropathic pain, with screening questionnaires being effective at leading to more formal diagnosis (aided by assessment questionnaires), and also are valuable in research (Attal 2018 **NR**).

### 2.2.3.2 | Global scales and satisfaction

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Global scales are designed to measure the effectiveness of overall treatment (see Section 2.3.1). They are more suited to outcome evaluation at the end of treatment than to modifying treatment in the acute stage (Moore 2003 **NR**). Questions such as “*How effective do you think the treatment was?*” recognise that unimodal measures of pain intensity cannot adequately represent all aspects of pain perception.

Satisfaction is often used as a global indicator of outcome; however, patients may report high levels of satisfaction even if they have moderate to severe acute pain (Svensson 2001 **Level IV**, n=191). Satisfaction may also be influenced by preoperative expectations of pain, effectiveness of pain relief, the patient–provider relationship (eg communication by medical and nursing staff), interference with function due to pain and number of opioid-related adverse effects (Jensen 2004 **Level IV**, n=191; Carlson 2003 **Level IV**, n=787; Svensson 2001 **Level IV**, n=191). Although complete absence of pain is not required for patients to report high levels of satisfaction, moderate pain (VAS >50/100) has been associated with dissatisfaction (Jensen 2005 **Level III-2**, n=207).

### 2.2.4 | Patients with special needs

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Validated tools are available for measuring pain in neonates, infants and children but must be both age and developmentally appropriate (see Section 10.3). These include behavioural assessments, pictorial scales (eg faces) and response to treatment. Adult patients who have difficulty communicating their pain (eg patients with cognitive impairment or who are critically unwell in the ED or intensive care unit [ICU]) require special attention as do patients whose language or cultural background differs significantly from that of their health care team. Communication aids and behavioural scales such as the modified Faces, Legs, Activity, Cry and

Consolability (FLACC) scale (Erdek 2004 **Level III-3**) can be particularly useful in these situations (see Section 9.2.3).

NRS are considered the best tool for measurement of pain intensity for adult ICU patients who may be non-verbal, sedated or ventilated. If they are not feasible, then the Behavioural Pain Scale (BPS) or Critical-Care Pain Observation Tool (CPOT) should be used (Varndell 2017 **Level III-3 SR**, 26 studies, n unspecified; Barr 2013 **GL**; Azevedo-Santos 2018 **NR**; Gelinas 2013 **NR**). The CPOT has been validated in neurosurgical patients (Echegaray-Benites 2014 **Level III-3**, n=43) and in different countries (Rijkenberg 2015 **Level III-3**, n=68; Li 2014 **Level III-3**, n=63). The CPOT appears to be more specific for pain than the BPS (Rijkenberg 2015 **Level III-3**, n=68).

In patients with dementia, similar challenges often require the use of non-verbal tools. Overall, in assessing reviews of multiple tools there is limited evidence about the reliability, validity and clinical utility of any specific tool (Lichtner 2014 **Level IV SR**, 23 reviews [28 tools]).

A systematic review of the effect of the use of pain assessment tools in critically ill patients on patient outcomes concluded that it improves pain management, but evidence was too heterogeneous to draw firm conclusions regarding outcomes such as length of mechanical ventilation or ICU stay (Georgiou 2015 **SR Level III-2**, 10 studies, n unspecified)

Surveys in the UK and Netherlands show that pain assessment tools were underutilised in many ICUs (Kemp 2017 **Level IV**, n=750 [patients assessed by 362 UK physicians]; van der Woude 2016 **Level IV**, n=107 [adult ICUs in the Netherlands]) (see also Section 8.10).

## KEY MESSAGES

1. There is good correlation between the visual analogue and verbal numerical rating scales (**S**) (**Level I**).
2. Regular assessment of pain leads to improved acute pain management (**U**) (**Level III-3**).
3. Appropriate assessments (including screening tools) are required to determine the presence of neuropathic pain (**N**) (**Level III-2**).

The following tick boxes represent conclusions based on clinical experience and expert opinion:

- Functional outcomes rather than pain scores alone should be used to guide acute pain management, including non-pharmacological approaches (**N**).
- Self-reporting of pain should be used whenever appropriate as pain is by definition a subjective experience (**U**).
- The pain measurement tool chosen should be appropriate to the individual patient and the clinical context (eg intensive care, ward, community). Developmental, cognitive, emotional, language and cultural factors should be considered (**U**).
- Scoring should incorporate different components of pain including the functional capacity of the patient. In the postoperative patient, this should include static (rest) and dynamic (eg pain on sitting, coughing) pain (**U**).
- Uncontrolled or unexpected pain requires a reassessment of the diagnosis and consideration of alternative causes for the pain (eg new surgical/ medical diagnosis, neuropathic pain) (**U**).

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## 2.3 | Outcome measures in acute pain management

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What follows is a brief guide to some of the outcome measures used particularly in the acute pain literature. A comprehensive review is beyond the scope of this document and more detail may be found elsewhere (Breivik 2008 **NR**). Concerns have been raised regarding trial design limitations resulting in type II errors (failure to identify a difference when one truly exists) and recommendations have been made for the design of chronic pain RCTs that include patient numbers, study site and outcome measurements to reduce this problem (Dworkin 2012 **GL**). Similar issues are of relevance to studies in acute pain interventions.

### 2.3.1 | Outcome measures

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#### 2.3.1.1 | Pain

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The aim of many clinical trials is to determine whether a medicine or intervention provides adequate pain relief for the majority of participants or is equivalent or noninferior to an existing accepted treatment. This can be achieved by repeated single measures at fixed time points, which may encompass only a proportion of the total illness. When comparison is made with a placebo, a statistically significant result can be achieved with a relatively small number of patients (eg n=40) (Collins 2001 **Level I**, 11 SRs [151 RCTs], n unspecified). The primary outcome is chosen by the researcher and may not be of direct importance to the individual patient, particularly if it relates to only a proportion of the total time he/she was in pain. It is also important to consider that statistically significant differences in pain scores may not reflect clinically significant differences, although these are harder to define (see above).

Data derived from categorical and VAS of pain intensity or relief produce a range of summary outcomes that can be used to assess (Moore 2003 **NR**):

- the degree of analgesic effect:
  - difference between the baseline and post-intervention score of pain intensity or pain relief (summed pain intensity difference [SPID]);
  - the area under the time-analgesic effect curve for a given time (total pain relief [TOTPAR]);
  - dose of rescue analgesic consumption required in a given time period (eg PCA use);
- the time to analgesic effect:
  - the time to onset of analgesic effect;
  - time to maximum reduction in pain intensity or to peak relief;
- the duration of effect:
  - time for pain to return to at least 50% of baseline;
  - time for pain intensity to return to baseline or for pain relief to fall to zero; and
  - time to re-medication/rescue analgesia.

A widely used method of describing the effectiveness of an analgesic intervention is the number needed to treat (NNT). In this setting it is commonly defined as the number of patients that need to be treated to achieve at least 50% pain relief (eg at least 50% maximum TOTPAR) in one patient compared with a placebo over a 4–6 h treatment period (Moore 2003 **NR**). Analysis at other cut-off points (30–70% max TOTPAR) has shown the same relative efficacy of different treatments (McQuay 2003 **NR**).

In acute pain research, using TOTPAR to assess pain relief may be more sensitive to treatment effects than SPID which is assessing intensity (Singla 2015 **Level I** [PRISMA], 45 RCTs, n unspecified).

The validity of this approach as a true method of comparison may be questioned as there is no standardisation of the acute pain model or patient and only single doses of the analgesic agents are used. However, it may sometimes be reasonable to extrapolate estimates of analgesic efficacy from one pain model to another (Barden 2004 **Level I**, 160 RCTs, n=14,410).

The use of supplemental analgesic consumption as an outcome measure has been questioned in situations where pain scores are not similar (McQuay 2008 **Level I**, 18 RCTs, n=1,217).

### 2.3.1.2 | Physical functioning

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Measures of physical functioning quantify many aspects of a patient's life including their ability to sleep, eat, think, deep breathe, cough, mobilise, perform activities of self-care and daily living, undertake their usual vocation and to enjoy leisure activities and sport (Williams 1999 **NR**). In acute pain, this may be measured by pain intensity scores with movement or other functional activity scores (see above).

Global or multidimensional measures of function attempt to combine various abilities or disabilities to derive a summary measure. Scales that employ a large number of items might be comprehensive but risk patient exhaustion or error, while scales with fewer items might be patient friendly but risk becoming insensitive to state or change (Williams 1999 **NR**). These scales have been used in some studies of acute spinal pain and cancer-related pain:

- *Disability scales* — generic scales include the Short Form 36 of Medical Outcomes Study (SF-36), the Sickness Impact Profile (SIP) and Roland & Morris Short SIP (Williams 1999 **NR**);
- *Quality of life (QOL) measures* — these measures are not widely used in acute pain studies, but have relevance for chronic or cancer-related pain (Higginson 1997 **NR**).

Disease-specific measures quantify the impact of a specific pain problem on function and can be used to track changes after an intervention (eg ability to cough after thoracotomy, ability to lift a baby after Caesarean section) (Garratt 2001 **Level IV**, n=187). Generic measures facilitate comparisons among the functional limitations of different conditions and treatments and may have advantages for audit of an APS that includes patients with a range of conditions (Patrick 1989 **NR**).

### 2.3.1.3 | Emotional functioning

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Acute pain is an unpleasant sensory and emotional experience. The unpleasantness of the experience and its meaning for the individual may have short term (anxiety, depression, irritability) and long term (lost confidence or self-efficacy or post-traumatic stress disorder) consequences for the individual's emotional functioning.

### 2.3.1.4 | Adverse effects

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In trials of efficacy, adverse effects are usually considered to be of secondary importance and inadequate reporting has been found in as many as half of randomised trials reviewed (Ioannidis 2001 **Level I**, 192 RCTs, n=130,074; Edwards 1999 **Level I**, 52 RCTs, n unspecified). If adverse effects are sufficiently common (eg nausea with opioids), they may be quantifiable in trials of efficacy and specifically measured using dichotomous (present or absent), categorical (none, mild, moderate, severe) or interval (analogue or Likert) scales. Analogous to NNTs, the number needed to harm (NNH) may be used to describe the incidence of adverse effects.

Most efficacy trials will have inadequate power to detect rare adverse effects and therefore they are also absent from systematic reviews. Large clinical trials specifically designed to detect adverse effects are required (eg the Vioxx Gastrointestinal Outcomes Research [VIGOR] study

investigated gastrointestinal toxicity of NSAIDs) (Bombardier 2000 **Level II**, n=8,076, JS 5). Case reports and post-marketing epidemiological research and surveillance (eg the Australian Adverse Drug Reactions Advisory Committee) remain important for detection of delayed effects occurring after the initial trial period. Results from comprehensive large prospective audits and database reviews have provided a sufficiently reliable denominator for incidence and risk factor evaluation in rare but serious adverse effects in acute pain management (Wijeysundera 2008b **Level IV**, n=259,037; Cameron 2007 **Level IV**, n=8,210; Wijeysundera 2008a **NR**).

Besides the adverse effects attributed to acute pain management interventions, another area of interest is whether the adverse effects of trauma and surgery might be prevented by effective acute pain management. Outcomes such as mortality, morbidity due to derangements of the cardiovascular, respiratory, gastrointestinal and coagulation systems and progression to chronic pain have also been reported (see Chapter 1).

### KEY MESSAGE

1. Assessment of pain relief (with total pain relief [TOTPAR]) may be more sensitive to treatment effects than assessment of intensity (with summed pain intensity difference [SPID]) (**N**) (**Level I** [PRISMA]).

The following tick box represents conclusions based on clinical experience and expert opinion:

- Multiple outcome measures are required to adequately capture the complexity of the pain experience and how it may be modified by pain management interventions (**U**).

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