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CLINICAL PRACTICE GUIDELINES

# The recognition and assessment of acute pain in children

*Update of full guideline*

SEPTEMBER 2009



THE BRITISH PAIN SOCIETY



Royal College of Paediatrics and Child Health



Royal College  
of Nursing

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# Quick reference guide

## Introduction

The Royal College of Nursing (RCN) has previously produced a guideline on the *Assessment of acute pain in children* (2000). This guideline examined when pain in children should be assessed and by whom, and the use of scales and other tools that can be used to facilitate the assessment of children's pain.

The evidence-based sections of this report have been revised and updated, ensuring that descriptions of the tools used to assess acute pain in children and the associated recommendations provided are based on a systematic assessment of the published evidence as of the search date (October 2008).

In addition, a new section has been developed that examines the evidence on assessing acute pain in children with cognitive impairments.

The updated reviews have been put to external consultation with clinical experts in the project's guideline development group (GDG), and a series of updated recommendations and good practice points produced. A guide to the appropriate use of validated pain measurement tools is provided in an algorithm diagram. The RCN has developed a website to accompany this guideline: [www.rcn.org.uk/childrenspainguideline](http://www.rcn.org.uk/childrenspainguideline)

## Guideline aims

The guideline is aimed at a range of professional groups, patients and carers who may be involved in the assessment and management of children's pain. The primary aims of this guideline are to:

- identify reliable and valid measures of pain intensity appropriate for neonates and preverbal infants, and verbal and non-verbal children, through a systematic search and appraisal of the literature
- describe these tools to help practitioners select from these in different clinical settings
- make recommendations regarding timing and triggers for formal pain assessment.

## Recommendations

### Recommendation 1:

Be vigilant for any indication of pain; pain should be anticipated in neonates and children at all times.

### Recommendation 2:

Children's self-report of their pain, where possible, is the preferred approach. For children who are unable to self-report an appropriate behavioural or composite tool should be used.

### Recommendation 3:

If pain is suspected or anticipated, use a validated pain assessment tool; do not rely on isolated indicators to assess pain. Examples of signs that may indicate pain may include changes in children's behaviour, appearance, activity level and vital signs.

No individual tool can be broadly recommended for pain assessment in all children and across all contexts.

### Recommendation 4:

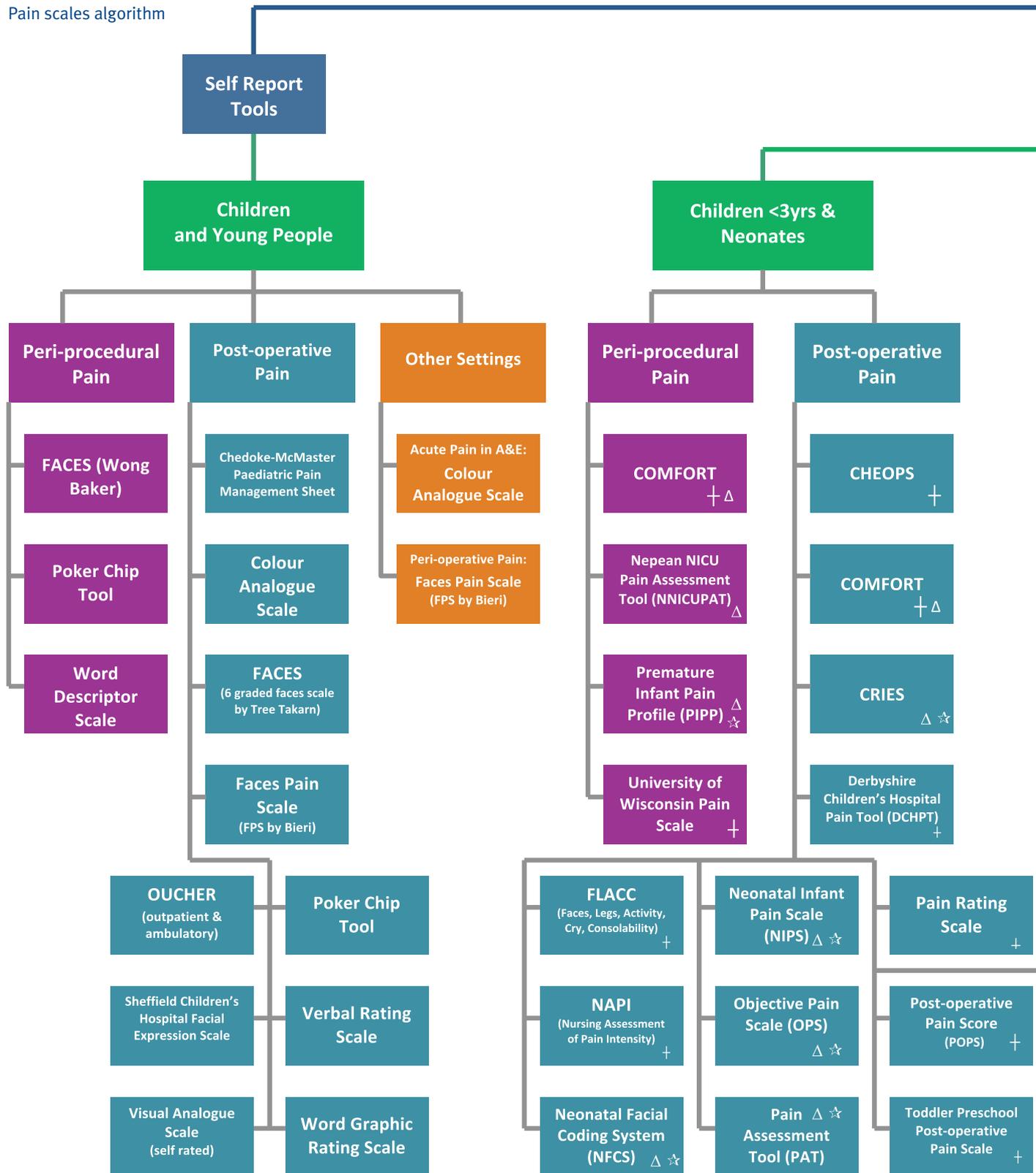
Assess, record, and re-evaluate pain at regular intervals; the frequency of assessment should be determined according to the individual needs of the child and setting.

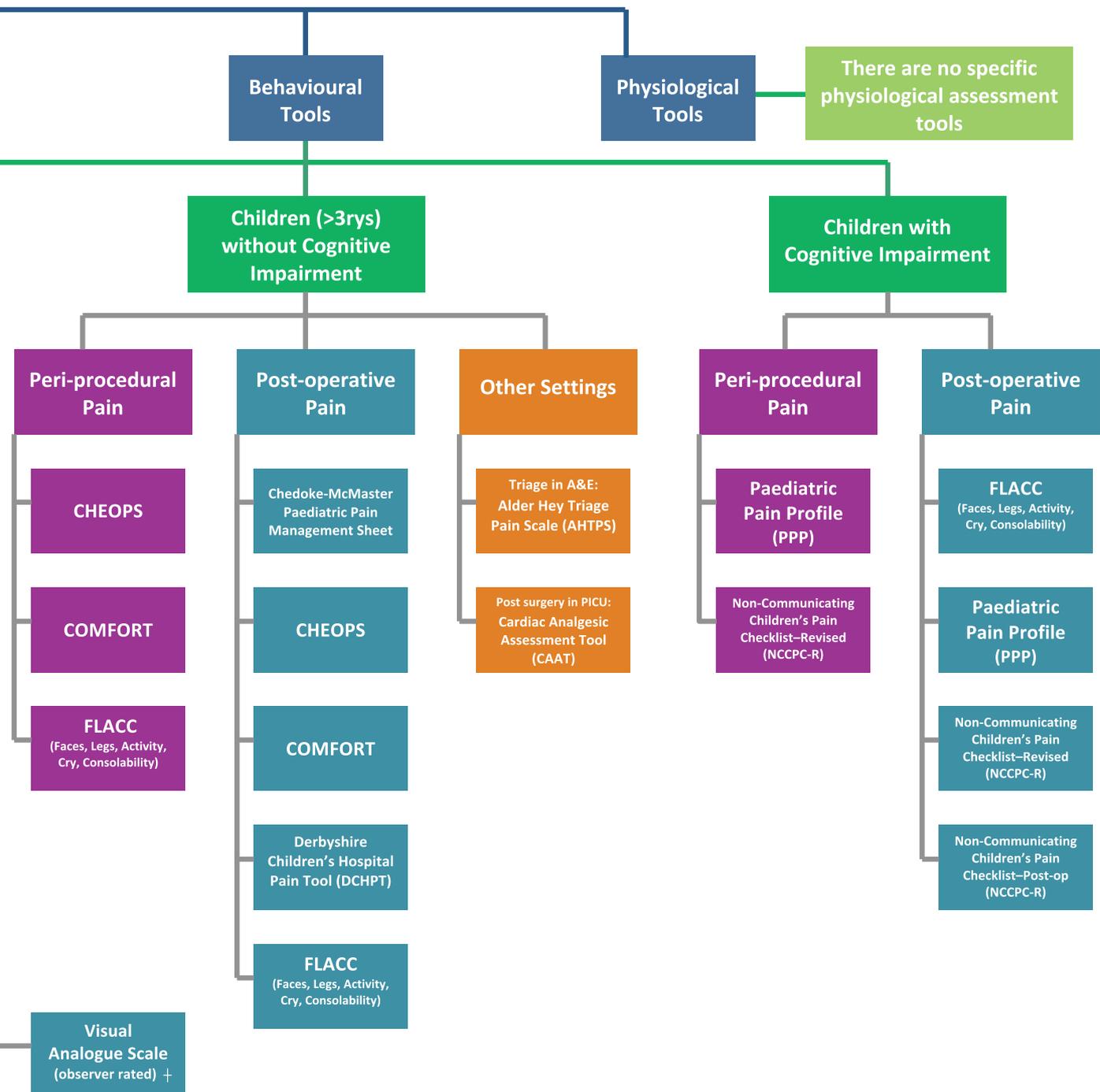
Be aware that language, ethnicity and cultural factors may influence the expression and assessment of pain.

## Good practice points

1. Acknowledging pain makes pain visible. Pain assessment should be incorporated into routine observations (as the fifth vital sign or 'TPRP' – temperature, pulse, respiration and pain).
2. Pain assessment is not an isolated element; it is an ongoing and integral part of total pain management. The other elements include implementation of appropriate interventions, evaluation and reassessment.
3. The child's pain assessment tool, written information and advice on pain assessment and treatment should be given to parents/carers on discharge for continued use at home/other care settings.
4. Parents/carers may benefit from being taught to use pain assessment tools as part of the management of their child's pain.
5. Each organisation should appoint a dedicated lead facilitator to promote and support the implementation of pain assessment for all children, including those with cognitive impairment.

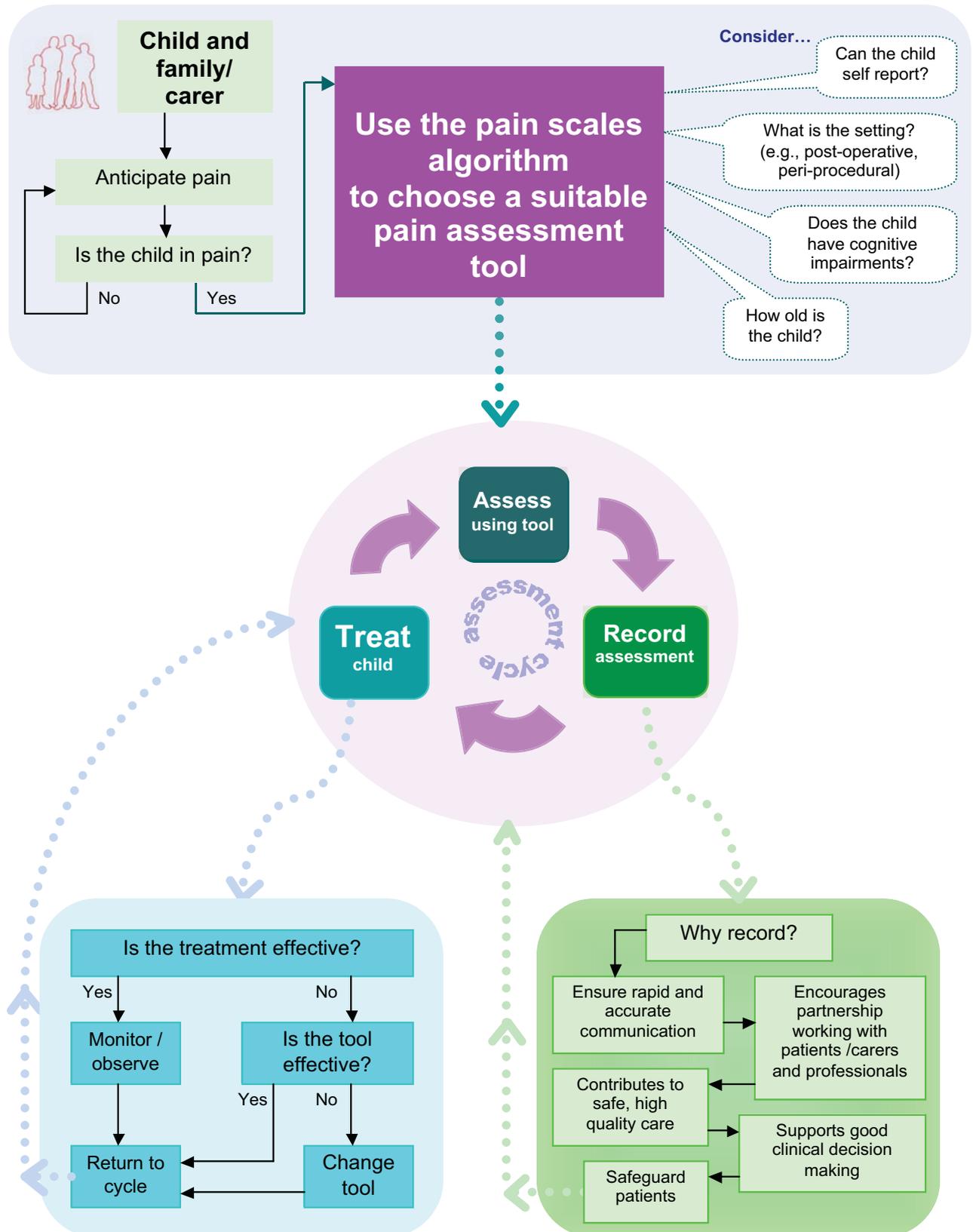
Pain scales algorithm





† Suitable for children <3yrs (excluding neonates)  
 △ Suitable for neonates  
 ☆ Suitable for preterm neonates

Pain recognition and assessment cycle



# Clinical practice guidelines: the recognition and assessment of acute pain in children

## Full guideline

### GDG membership and acknowledgements

Guideline development group (GDG) membership was initially based on the stakeholder organisations involved in the previous guideline. These stakeholders suggested other organisations that should be represented in the development of these guidelines.

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#### Disclaimer

This guidance represents the view of the Royal College of Nursing, which was arrived at after careful consideration of the evidence available. Health care professionals are strongly encouraged to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of health care professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

## Abbreviations

### General abbreviations

CI	Cognitive impairment
GDG	Guideline development group
IV	Intravenous
NICE	National Institute for Health and Clinical Excellence
NICU	Neonatal intensive care unit
PICU	Paediatric intensive care unit
RCN	Royal College of Nursing
RCT	Randomised controlled trial
SIGN	Scottish Intercollegiate Guidelines Network

### Pain scale abbreviations

AHTPS	Alder Hey Triage Pain Scale
CAAT	Cardiac Analgesic Assessment Tool
CHEOPS	Children's Hospital of Eastern Ontario Pain Scale
DCHPT	Derbyshire Children's Hospital Pain Tool
FLACC	Face, Legs, Arms, Cry, Consolability
FPS	Faces Pain Scale (by Bieri)
NAPI	Nursing Assessment of Pain Intensity
NFCS	Neonatal Facial Coding System
NNICUPAT	Nepean NICU Pain Assessment Tool
NIPS	Neonatal Infant Pain Scale
OPS	Objective Pain Scale
PAT	Pain Assessment Tool
PIPP	Premature Infant Pain Profile
POPS	Post-operative Pain Score
TPPPS	Toddler Preschool Post-operative Pain Scale
VAS	Visual Analog Scale

## Glossary

### Acute pain

Acute pain may be defined as pain that subsides as healing takes place, that is to say, is of a limited duration and has a predictable end.

### Adolescent

Child undergoing adolescence; i.e. the transitional phase of development between childhood and adulthood which incorporates the biological changes of puberty.

### Child/children

For the purposes of the guideline child/children refers to every person below the age of 19 years.

### Cross-sectional study

Examination of the relationship between disease and other variables of interest as they exist in a defined population assessed at a particular time.

### Gold standard test

A diagnostic test or procedure that is widely accepted as being the best possible available.

### Infant

Child under one year of age.

### Neonate

An infant up to four weeks old.

### Preterm neonate

Baby born at any time before the 37th week of gestation.

### Preverbal child

Working definition of this term in this report is a child under the age of three years old.

### Reliability

A measure of the reproducibility of results of a test; inter-rater reliability refers to the correlation between results from different raters assessing the same child with the same scale at the same time; test-retest reliability refers to the correlation between results on a test applied to the same child some time apart.

### Validity

A measure of the capacity of a tool to measure correctly what it is designed to measure; criterion validity refers to the correlation between scores on the new scale and on a gold standard measure; construct validity refers to the measure of the tool's ability to measure the theoretical construct under consideration.

### Venepuncture

Needle puncture of a vein for the drawing of blood.

# 1 Background and scope

## 1.1 Background to the updating process

In 2000, the Royal College of Nursing (RCN) published a guideline on the *Assessment of acute pain in children* (Royal College of Nursing, 2000). In 2006, the RCN committed to fully updating the guideline.

Bazian, a specialist evidence-based analysis firm, was commissioned to revise and update the evidence-based sections of the report, continuing to focus on the assessment of acute pain (with the exception of burns and dental pain) in children without cognitive impairments. Bazian made major revisions to the evidence-based sections of the guideline, to ensure that descriptions of tools and associated recommendations were (a) robustly based on a systematic assessment of the published evidence, and (b) up to date as of the search date (April 2006).

Following Bazian's work, a further analysis of the available evidence was conducted by RCN staff, bringing the search date of this guideline to October 2008 (this search date is used throughout the guideline). In addition, a new section was developed by RCN staff that examines the evidence on assessing acute pain in children with cognitive impairments.

A guideline development group (GDG) made up of stakeholders, including clinical experts and people working in the field of paediatrics, was established for the project. Most members of the GDG were involved in the development of the original guideline in 2000. All aspects of the revising and updating of the guideline were put to external consultation with the experts in the GDG.

## 1.2 Clinical need for the guideline

The goal of pain assessment is to ensure that effective procedures and processes are instituted to prevent or minimise pain. Paediatric pain management has been recognised as inadequate. A contributing factor is children's difficulty in expressing their pain to those taking care of them – health professionals and parents – in a way

that is recognised and clearly understood. There can be particular difficulties in inferring the sensory and emotional experience of pain in children, especially in neonates and young children. Even in adults, pain cannot be measured directly and must be inferred from self-report.

The aim of this guideline is to improve the way in which health professionals recognise and assess pain in children. It is hoped that the guideline will also provide useful strategies for parents and for children during their experiences of health care.

Children vary greatly in their cognitive and emotional development, medical condition, response to painful interventions and to the experience of pain, as well as in their personal preferences for care. Health professionals and parents have a responsibility to learn the language of child pain expression, to listen carefully to children's self-reports of pain and to attend to behavioural cues. The detection of children's pain can be improved by strategies to facilitate their expression of pain in ways that are appropriate to their cognitive development, and that can be understood by the adults caring for them.

Most hospitalised children undergo procedures. These may range from venepunctures and insertions of intravenous catheters to more stressful procedures such as lumbar punctures, bone marrow aspirates and biopsies, chest tube insertions, cardiac catheterisations, operations, and dressing changes. Infants, children and adolescents can, and do, experience pain and often describe procedures and their associated anticipatory anxiety as the most distressing aspect of disease or hospitalisation (Broome, 1994; Jay et al., 1983).

Outside of hospital settings, on a day-to-day basis children with cognitive impairments appear to be more likely to experience significant pain on a regular basis than unimpaired children (Breau et al., 2003). The particular demographic, medical and physical characteristics of these children are associated with them experiencing particular types of pain, such as musculoskeletal pain, infection pain or gastrointestinal pain (Breau et al., 2004a).

Unrecognised pain can become established, severe and difficult to control (McQuay, 1989; Wall, 1988; Woolf and Wall, 1986). Unrelieved pain has negative physical and

psychological consequences (Taddio et al., 1997) and may lead to extended lengths of hospitalised stay with resultant service and cost implications. In children with cognitive impairment, pain can reduce the ability to function in a number of domains, including communication, daily living skills, socialisation and motor skills (Breau et al., 2007). In particular, the intensity of pain rather than the duration can cause greater reductions in ability (Breau et al., 2007), which underlines the importance of recognising, assessing and managing acute pain at the earliest opportunity.

## 1.3 Aims of the guideline

### 1.3.1 Primary aims

The primary aims of this guideline are to:

- identify reliable and valid measures of pain intensity appropriate for neonates, preverbal infants, and verbal and non-verbal children, through systematic search and appraisal of the literature
- describe these tools to help practitioners select among them in different clinical settings
- make recommendations regarding timing and triggers for formal pain assessment.

### 1.3.2 Who the guideline is for

The guideline is aimed at a range of professional groups, patients and carers who may be involved in the assessment and management of children's pain. For the purposes of the guideline, child/children refers to every person below the age of 19 years.

### 1.3.3 What is covered by the guideline

The guideline covers the following key areas:

- when pain should be assessed
- indicators of pain
- individual differences
- who should assess pain in children
- role of parents/carers and other family members
- role of nurses and other practitioners
- role of self-report by children
- the use of scales and other tools to assess children's pain
- assessment of pain in neonates and infants

- assessment of pain in children
- assessment of pain in adolescents and older children.

### 1.3.4 What is not covered by the guideline

The guideline does **not** cover the following areas:

- management/treatment of pain
- assessment of chronic pain
- assessment of burns or dental pain (although the recommendations may be useful for these)
- pain in palliative care
- assessment of pain other than pain intensity
- service delivery issues related to the management of pain
- education of practitioners about techniques of pain management.

Management of pain is not covered in this guideline, as this subject is covered by the Association of Paediatric Anaesthetists guideline, *Good practice in postoperative and procedural pain* (APA, 2008). The guideline is available online at [www.apagbi.org.uk](http://www.apagbi.org.uk)

### 1.3.5 Health care setting

Studies were all undertaken in primary and/or secondary medical facilities: either in-patient settings such as A&E departments or surgical wards, or outpatient settings such as medical centres or clinics.

## 2 Principles of practice

The following principles describe the ideal context in which to implement the recommendations contained in this guideline. These reflect original research and development work undertaken by the RCN to produce the previous guideline (Royal College of Nursing, 2000) and enable health professionals using evidence-based guidance to contextualise and understand the importance of preparation and planning, prior to implementation.

Children, parents and carers should be made aware of the guideline and its recommendations, referring to the *Information for children and parents/carers* version, available from [www.rcn.org.uk/childrenspainguideline](http://www.rcn.org.uk/childrenspainguideline)

### 2.1 Patient-centred care

- Children are listened to and believed.
- Parents/carers are listened to and their views respected (*Respecting the role of the parent is a significant part of providing services to children and young people*; National Service Framework Standards for Hospital Services, 2.17).
- At first contact services should identify children and families who require extra support; for example, those who need interpreters or advocates and children in need including disabled children (National Service Framework Standards for Hospital Services, 3.2).
- Children and their families/carers are viewed as partners in care.
- Children and their families/carers are involved in shared decision-making about individualised pain assessment and have the opportunity to ask questions.
- Children and their families/carers are informed of any potential risks and/or complications associated with pain assessment.
- Training is provided in the use of tools for parents/carers.

### 2.2 A collaborative interdisciplinary approach to care

- All members of the interdisciplinary team are aware of the guidelines and all care should be documented in children's health care records.
- A collaborative, multi-disciplinary approach should be provided by appropriately trained professionals.
- The roles of children, parents/carers and health professionals in implementing the guideline recommendations should be sensitively negotiated and take into account children's views.

### 2.3 Organisational issues

- There should be an integrated approach to the recognition and assessment of acute pain in children, with a clear strategy and policy supported by management.
- Care should be delivered in a context of continuous quality improvement, where improvements to care following guideline implementation are the subject of regular feedback and audit.
- The health care team should have received appropriate training and have demonstrated their competence in the recognition and assessment of acute pain in children. This should link in with appraisal/performance management and development of e-portfolios.
- Commitment to and availability of education and training are required to ensure that all people working in paediatric pain management are given the opportunity to update their knowledge, and are able to implement the guideline recommendations.
- Staffing levels and skill mix should reflect the needs of the children and families/carers, and are paramount to providing high quality services for children who require pain assessment.

## 3 Methodology

### 3.1 Summary of guideline revision

The guideline has been carried out within the scope of the original technical report of the RCN guideline (Royal College of Nursing, 2000). The evidence-based sections of the report have been revised, and a draft report developed for external consultation with the project's GDG. Figure 1 illustrates the guideline revision process.

As in the original, the guideline continues to focus on the assessment of acute pain (except burns and dental pain) in children. Tools to assess children with cognitive impairments (CI) were not included in the original guideline as not enough relevant research existed at the time. However, since the original guideline was produced the research base has grown, and several tools for assessing pain in cognitively impaired, non-verbal children have been developed and tested. These tools were reviewed for the purpose of this updated guideline, and details are provided here of the methodology used for reviewing both non-CI (Section 3.2) and CI (Section 3.3) literature.

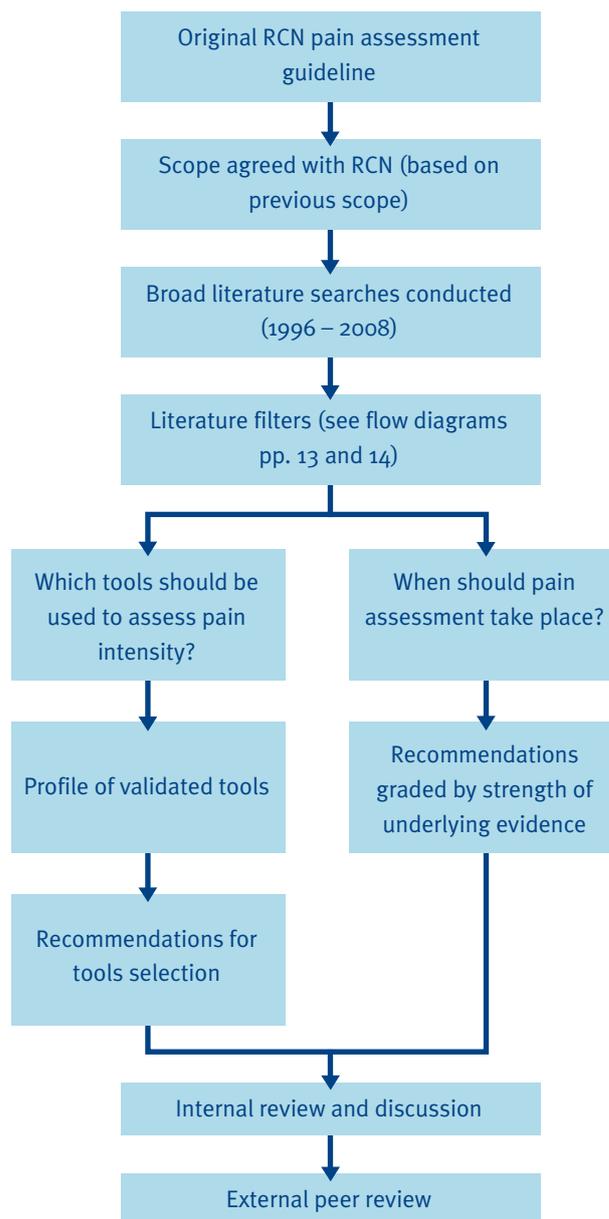
It was found that major revisions were required in the evidence-based sections of the guideline, in order that descriptions of tools and associated recommendations be (a) robustly based on a systematic assessment of the published evidence, and (b) up-to-date as of the search date (October 2008).

### 3.2 Updated search – tools for assessing pain in children without cognitive impairment

#### 3.2.1 Rationale for an evidence-based method

Nurses are faced with a wide choice of pain assessment tools for children of all ages. Criteria such as the clinical setting, available resources, and a child's characteristics and experience of pain should guide tool selection. It is important that tools for measuring pain severity are reliable and valid (Box 1, page 13) in order that nurses and

Figure 1: Guideline revision process



other carers can be confident that their tools describe the intensity of a child's pain accurately and reproducibly.

A rigorous method to search and appraise the psychometric testing literature for assessing pain severity in children was developed and applied. Only those tools that met stipulated validity and reliability criteria (Box 1, page 13) were selected and presented. These criteria were

developed based on reviews that profiled the reliability and validity of published and unpublished tools for assessing pain in infants and neonates (Duhn & Medves, 2004; Abu-Saad et al., 1998; Franck & Miaskowski, 1997).

Key features common to these scales were described to assist selection of tools, and the same inclusion criteria were applied in the case of tools for assessing pain in children with cognitive impairments.

#### Box 1: Reliability and validity – an overview of theoretical concepts

There are a number of tools for assessing the intensity of pain. It is important to determine whether these measure pain intensity and not some other construct, and that tools give sufficiently similar results when re-applied for a given severity of pain. The features of assessment tools are their validity and reliability.

#### Reliability

A reliable assessment tool is one that yields similar results when applied to the same individual experiencing the same level of pain at different times (test-retest reliability) and when applied by different raters (inter-rater reliability). Reliability measures the ratio of true variance in the test to total variance. In a perfect test, true and total variance are the same, and the ratio will be 1 (Jerosch-Herold, 2005).

#### Validity

Validity assesses a tool's capacity to measure the construct it is designed to measure. Validity can be divided broadly into three concepts:

- face and content validity – a judgement (not assessed empirically) that the tool is assessing what it purports to; assessed subjectively
- criterion-related/concurrent validity – correlation of results of the tool compared with an existing gold standard test; without a gold standard, this form of validity cannot be established
- construct validity – a tool's capacity objectively to assess the construct that it sets out to assess. This can be established by determining whether the tool can distinguish between a group known to have pain and one that does not. It can also be established by examining whether the tool yields results that vary appropriately according to changes in pain intensity, for example as a result of treatment (Agency for Health Care Policy and Research, 1992).

### 3.2.2 Search

Specialist information scientists accessed published literature from 1966 to October 2008 by searching for systematic reviews and studies looking at pain assessment

in the Medline, Embase, Cinahl, PsycINFO, British Nursing Index, Cochrane Library, SIGLE, DARE and HTA databases. This search incorporated guidelines produced in the UK or USA. For the section on assessing pain in children with cognitive impairment the same process was followed using the same databases from 1950 onwards (with the exception of the SIGLE database, which has been closed).

Search strategies, including key words and literature filters, can be found in Appendix A (page 42).

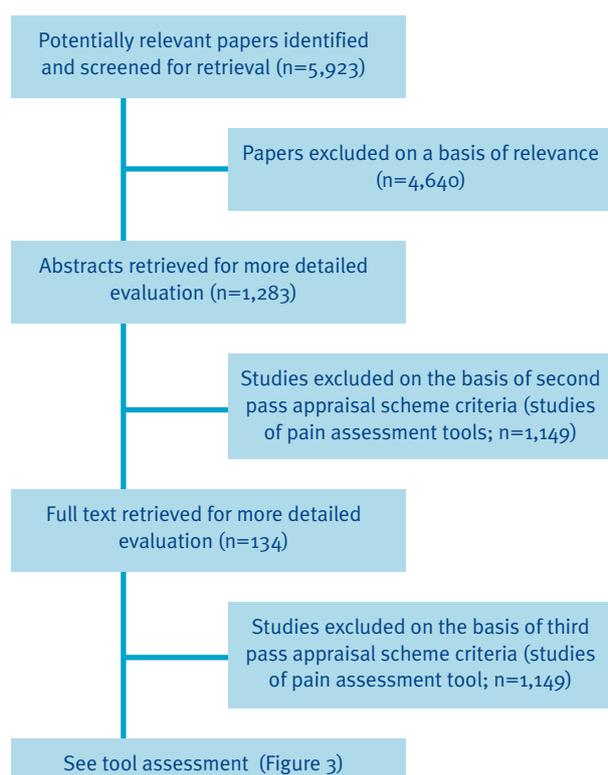
### 3.2.3 Appraising the research

The literature was appraised at two broad levels: that of the individual study and that of the pain assessment scale. A specialist evidence-based reviewer filtered and appraised all retrieved literature, and a second independent reviewer checked a random sample of inclusions and exclusions (25%). Any conflict was resolved through discussion. Any changes or modifications to the inclusion/exclusion criteria or data extraction process were then applied to all included studies to ensure a consistent approach. Individual studies that satisfied the inclusion criteria were appraised at tool level; the final tool guide discusses only those tools meeting the inclusion criteria.

#### 3.2.3.1 Study level appraisal

Details of the appraisal process can be found in Figure 2. The only studies that were included were the ones set up

Figure 2: Flow diagram of appraisal process for single studies



explicitly to validate or cross-compare pain assessment tools in children. Studies were not included in which pain was assessed as an outcome in a therapeutic study, unless this was explicitly to validate the tools used. Studies were not included that validated tools for constructs distinct from pain, such as ‘distress’, ‘coping’ or ‘anticipation’. Some studies that were included examined tools that may have been originally designed to measure something other than pain, but were now being examined in the context of assessing pain.

The same process was followed for studies examining the assessment of pain in children with cognitive impairment.

**3.2.3.2 Tool level appraisal**

Included studies were grouped according to the pain assessment tools that these examined. Figure 3 shows this process in more detail.

The most important feature of each tool was its ability to correctly identify the presence or absence of pain

(construct validity). Therefore, only tools with established construct validity were retained.

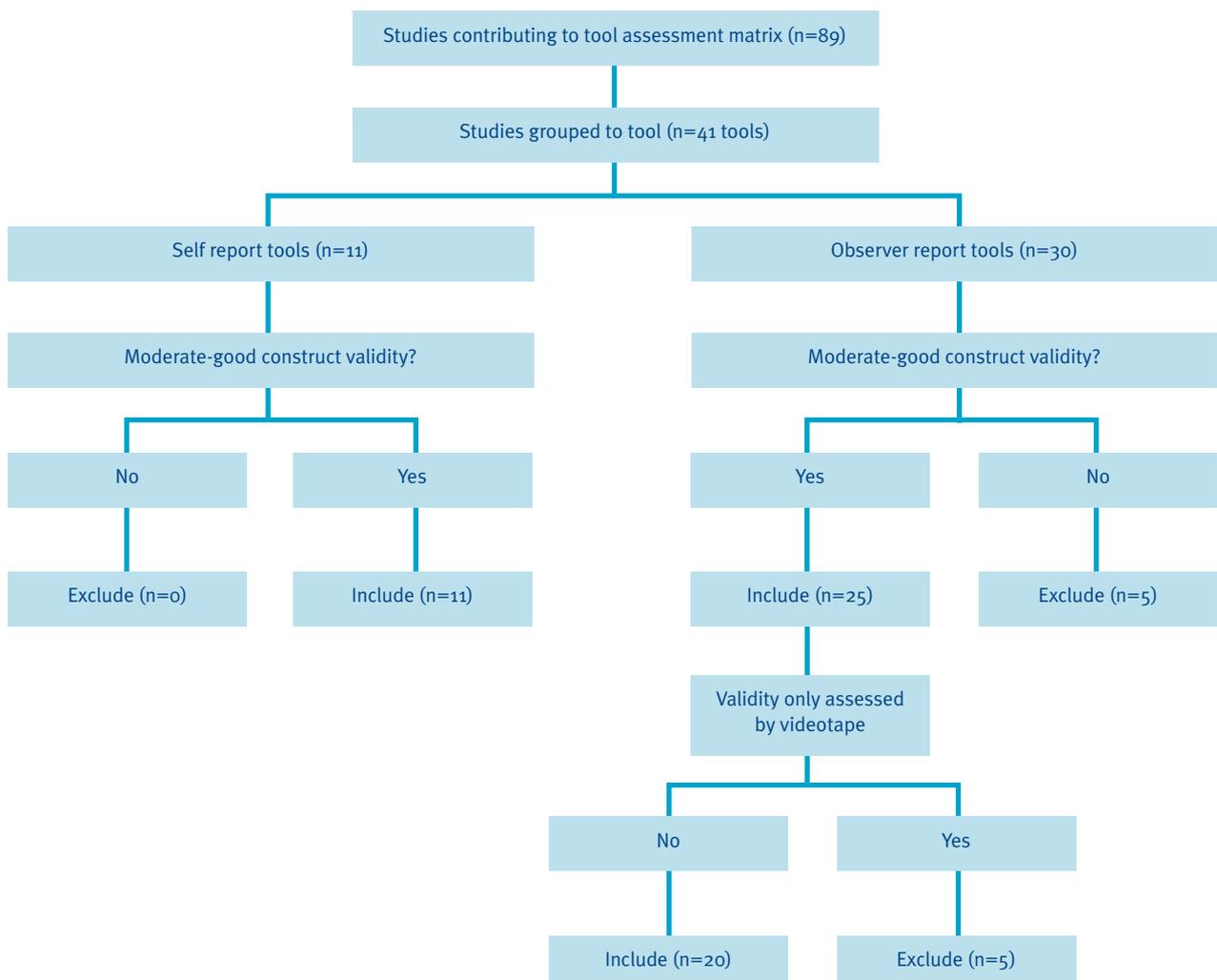
As there is no gold standard with which other tools can be compared, tools were not included if reported to be valid only because they compared well with other tools.

For observer-rated scales, it was considered that a clinically useful tool should yield consistent results when applied by different raters to the same subject. Therefore, only observer-rated tools with acceptable inter-rater reliability were included. For self-report tools, inter-rater reliability is not applicable, so its absence was not used to exclude self-report tools. The view was taken that a self-report tool with established construct validity would be reliable in the clinical context.

Tools for children with cognitive impairment were all observer-rated as this population is unable to self-report, and all of the included tools were tested for inter-rater reliability.

A number of studies examined test-retest reliability (the agreement between ratings in the same individual at

Figure 3: **Flow diagram of assessment process for tools**



different times). This is often cited as a component of self-report tools' validity. However, self-report tools for which the only type of reliability established was test-retest reliability were excluded. Test-retest reliability is likely to be confounded by changes in the intensity of acute pain over the period of assessment.

### 3.2.4 Study quality

Criteria and guidelines exist to assist the critical appraisal of diagnostic test studies. However, the search carried out for the purpose of this guideline (and queries raised with experts in evidence-based medicine through the evidence-based health email list) found few references to help set quality thresholds for excluding reliability and validity studies (Jerosch-Herold, 2005). There was limited discussion in the literature on accepted quality criteria for including or excluding reliability or validity studies during systematic review. It is also unclear how to apply these quality cut-offs to studies of a construct such as acute pain, where certain elements of reliability and validity may not apply. Rather than exclude studies on methodological grounds, the data extraction tables describe their key methodological shortcomings, according to the framework established by Jerosch-Herold (2005).

In summary, included studies were commonly limited by:

- small sample sizes
- convenience (rather than random) samples
- unblinded raters (raters who either knew whether the child had recently experienced painful stimuli, or were not blinded to analgesia or other raters' assessments)
- no control group or non-random allocation to pain or pain free situations
- less reliable analysis – intra-class correlation coefficient or Cohen's kappa are more conservative measures of inter-rater reliability. Pearson's correlation coefficient is considered a less reliable measure of correlation (Streiner and Norman, 1995).

Overall, the following were considered to be features of high quality studies:

- ideally, randomisation to pain or pain-free conditions (this was rare)
- sample size determined by power calculations (this was rare)
- in the absence of power calculations, more than 20 children or observations (depending on the unit of analysis)
- consecutive or random samples instead of convenience samples
- observers blinded to each others' ratings and to the administration of any analgesia

- appropriate statistical analyses
- results presented with confidence intervals where relevant.

### 3.2.5 Validation with video tapes

The use of video-recording of children in pain clearly provides an opportunity to analyse their responses to nociceptive stimuli very closely. However, it was felt that tools whose reliability or validity has been established solely through videotaped observations are likely to perform differently when applied in real-time clinical settings without video recording. Additionally, there is currently a lack of robust studies that demonstrate that video-only evidence is as good as clinical practice validity evidence. Such tools were therefore excluded, on the assumption that videotaped assessments are probably impractical in clinical settings.

## 3.3 Updated search – tools for assessing pain in children with cognitive impairment

The same criteria, as described in Section 3.2 above, was used for searching and reviewing studies of tools for assessing pain in children with cognitive impairment.

One exception is the use of videotaped observations. Some studies did use videotape as a means of blinding observers to the administration of analgesia, for example, in order to decrease bias. Any measures of inter-rater reliability derived under these conditions should be interpreted in the context that videotape observation cannot be considered equivalent to real world application.

Only studies that were set up explicitly to validate or cross-compare pain assessment tools in children with CI were included. A number of studies were excluded because they dealt with different aspects of the assessment of pain in this population and were not validation studies of individual tools. For example a number of studies explored caregivers' attitudes towards pain in children with CI, or tried to establish whether these children experience pain in the same way as unimpaired children.

## 3.4 Which tools should be used to assess pain intensity?

Recommendations 4 to 8 in the original guideline discussed the types of tools that should be used and other practical considerations in the assessment of pain in children. These recommendations have been replaced with an overview of the most reliable and valid pain assessment tools currently available. The purpose was to provide evidence-based answers to the following questions:

- which tools may confidently be used in clinical practice?
- under what clinical circumstances – in particular in which age groups – may each tool be used, and under what circumstances are they inappropriate?
- who may administer each tool?
- which are the most salient clinical features to include in any locally adapted or created tool?

The practicality of using these tools in a clinical setting has not been examined. Instead, the GDG examined the practical merits or weaknesses of the tools that have been identified. Tables of validated tools are presented for both the non-CI (Section 4.3, Tables 2 and 3) and CI (Section 5.3, Table 4) settings.

### 3.5 How should these tools be used?

Recommendations 1 to 3 in the original report, which dealt with issues around when children's pain should be assessed, were systematically updated. The search was repeated and the literature reappraised for the recommendations relating to the timing of, and triggers for, pain assessment (Royal College of Nursing, 2000). Overall, little high quality research was found, and most was of poor quality or consisted of expert opinion. The recommendations are, therefore, supported by a body of expert opinion, and extrapolated from the results of observational studies. The recommendations are augmented by the consensual interpretation of the evidence by the GDG, drawing on members' combined clinical experience.

In addition to the recommendations, the GDG has also included good practice points relating to the assessment of pain in children. These points, which complement the evidence-based recommendations, are suggestions for best practice based on the GDG membership's combined clinical experience. Consensual decisions for including the good practice points were made using a nominal group consensus method.

#### 3.5.1 Presentation of recommendations

Recommendations were not graded, as it was determined that a grading process would give undue weight to the recommendations. This is in line with the standard methodology as laid out in the *NICE guidelines manual* (NICE, 2009), and is an appropriate approach to presenting recommendations given the nature of the studies under review.

Studies have been attributed a level of evidence using the widely accepted SIGN system (SIGN, 2008), and Table 1 illustrates the levels of evidence according to this system. This level of evidence does not reflect the importance of the

resulting recommendations, but rather indicates the strength of the evidence according to the SIGN system, and in particular the power of the studies' designs to achieve the desired outcome if the recommendation is implemented. The SIGN system assigns greater predictive power to studies using trial methodologies. In this case the majority of the included studies were not conducted according to trial methodology, as this would not have answered the questions posed in the studies. However, the methodologies that were used were appropriate and the studies were well conducted. As such, although the evidence received a lower level of evidence according to SIGN methodology, the quality of the evidence should not be assumed to be poor, and should be considered in the appropriate context.

Table 1 SIGN Levels of Evidence

Levels of Evidence	
1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High quality systematic reviews of case-control or cohort studies High quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies (for example, case reports, case series)
4	Expert opinion
Good practice points	
✓	Guideline development group

This table is developed from Annex B of *SIGN 50: A guideline developer's handbook* (SIGN, 2008).

### 3.6 Review and updating

The guideline will be reviewed two years from publication date, in line with National Institute of Health and Clinical Excellence guidelines.

## 4 Assessing pain intensity in children without cognitive impairments

### 4.1 Background

This section of the guideline concerns assessing acute pain intensity in children without cognitive impairments, and is an update of the previous RCN guideline (Royal College of Nursing, 2000).

### 4.2 Search results

The process for appraising and filtering studies is described in Section 3.2 (page 12).

After filtering the papers identified through initial searches, 89 papers were selected for review. The papers examined 41 separate tools, of which 11 were self-report tools and 30 were observer-rated tools. All 11 self-report tools were included in the guidelines but 10 observer-rated tools were excluded; five due to poor construct validity and inter-rater reliability and five due to assessments of the tool being made by videotape observation only.

#### 4.2.1 Types of studies

The types of studies included in this review were mainly repeated cross-sectional studies, with some randomised controlled trials.

#### 4.2.2 Types of participants

The population considered was, broadly, children aged 0 – 18 years experiencing or expected to experience acute pain, most often as a result of surgery or other medical procedures such as, for example, immunisation or IV catheter insertion. Sample groups were all identified through medical facilities including medical centres or clinics, emergency departments and NICUs.

The majority of studies focused either on neonates (age given as gestational age in weeks) or children (age given in weeks, months or years), and the summary of validated tools differentiates between these populations.

#### 4.2.3 Types of tool

Validated tools for measuring pain intensity in children without cognitive impairments were all either self- or observer-rated, with some also requiring physiological

measures such as blood pressure and heart rate. Each tool has a particular clinical setting and age group to which it can be confidently applied. The features of each tool are detailed in Table 2 and Table 3 on pages 18 and 19.

#### 4.2.4 Study design

Full details about each reviewed study are provided in the tables of included studies in Appendix B (page 49). These tables present the levels of evidence attributed, the study design, the age and population in which the studies are validated, information about inter-rater reliability and known groups validity, and a brief discussion of any practicality and quality issues.

The majority of included studies were cross-sectional or repeated cross-sectional study designs, with a few randomised controlled studies also included.

Studies were all undertaken in medical facilities: either in-patient settings such as A&E departments or surgical wards, or outpatient settings such as medical centres or clinics throughout the world. Studies that were not written in English were excluded, as there was no access to translation services.

The number of participants in each study varied, although all sample sizes were greater than 20, which was the minimum criterion for a good quality study.

#### 4.2.5 Methodological quality

The tables of included studies in Appendix B (page 49) describe the key methodological shortcomings of the studies included, according to the framework established by Jerosch-Herold (2005). In summary, included studies were commonly limited by:

- small sample sizes
- convenience (rather than random) samples
- unblinded raters (raters who either knew whether the child had recently experienced painful stimuli, or were not blinded to analgesia or other raters' assessments)
- no control group or non-random allocation to pain or pain free situations
- less reliable analysis – intra-class correlation coefficient or Cohen's kappa are more conservative

measures of inter-rater reliability. Pearson’s correlation coefficient is considered a less reliable measure of correlation (Streiner and Norman, 1995).

### 4.3 Summary of assessment tools for children without cognitive impairments

Tables 2 and 3 present a guide to the valid and reliable tools for measuring pain intensity in children without cognitive impairments. For each tool, the table summarises whether the tools are self- or observer-rated, whether they require physiological measures such as blood pressure and heart rate, and the clinical setting and age group in which they can be confidently applied.

Key	
	Observer rated tool
	Training necessary
	Tool includes physiological measures (e.g. blood pressure, heart rate)
	Indicates groups for which the tool is suitable
	Indicates groups for which the tool has not been validated

Table 2: Guide to selection of pain scales for neonates

Tool name	Features	Suitable for setting:	Suitable for (gestational age):	
			Pre-term neonates	Term neonates
COMFORT	  	Post-operative and peri-procedural pain		
CRIS	  	Post-operative pain		
Neonatal Facial Coding System (NFCS)	 	Post-operative pain		
Nepean NICU Pain Assessment Tool (NNICUPAT)	 	Peri-procedural pain		
Neonatal Infant Pain Scale (NIPS; developed from CHEOPS for neonates)	 	Post-operative pain		
Objective Pain Scale (OPS)	  	Post-operative pain		
Pain Assessment Tool (PAT)	  	Post-operative pain		
Premature Infant Pain Profile (PIPP)	  	Peri-procedural pain		

Table 3: Guide to selection of pain scales for infants and verbal children

Tool name	Features	Suitable for setting:	Suitable for (age [years]):												
			<3*	3	4	5	6	7	8	9	10	11	12	12+	
Alder Hey Triage Pain Scale (AHTPS)	 	During triage in A&E	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Cardiac Analgesic Assessment Tool (CAAT)	 	Routine care in paediatric intensive care unit after surgery	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Chedoke-McMaster Paediatric Pain Management Sheet <sup>3</sup>	  	Post-operative pain	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Colour Analogue Scale <sup>4</sup>	 	Post-operative pain and acute pain in the emergency department				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Children's Hospital of Eastern Ontario Pain Scale (CHEOPS)		Post-operative and peri-procedural pain	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
COMFORT <sup>5</sup>	  	Post-operative and peri-procedural pain	✓	✓											
Derbyshire Children's Hospital Pain Tool (DCHPT)	 	Post-operative pain	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
FACES scale (Wong-Baker) <sup>6</sup>	 	Peri-procedural pain		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

\* Age <3 excludes neonates (for neonatal tools, see table 1), but includes other preverbal infants and children

2 For self report tools, evidence for validity is usually based on starting with a pain free patient, rather than observed responses or reports of alleviation of pain

3 The Chedoke-McMaster Paediatric Pain Management Sheet is a tool which combines self and observer report using VAS and the CHEOPS observational scale. We found one randomised controlled trial (RCT) that assessed the clinical and process effects of this tool in managing post-operative pain in children aged 18 months – 12 years (Stevens, 1990). The RCT found that children being assessed using this tool experienced less pain, were assessed more frequently and received more analgesia than those in the 'usual care' group. We have included this tool here because the use of this tool directly improved outcomes for children, even though we found no studies assessing validity and reliability.

4 One study validating CAS was in Thai children aged 5-12 years (Suraseranivongse et al., 2005)

5 Construct validity of a version of the COMFORT scale which includes only the behavioural items, i.e. COMFORT-B has been shown (Hartrick and Kovan, 2002), however we found no studies assessing inter-rater reliability of this tool so it is not discussed further.

6 Although the original instructions for the Wong-Baker FACES pain rating scale was specific about explanations required for children, it is not clear from the studies whether the tool was delivered in this way. We have indicated with the 'training' icon that these instructions are likely to be important.

7 The FPS has been revised with one less face (Spagrud et al., 2003), though this adaptation has been cross validated with other tools (Miro et al., 2004; Hicks et al., 2001) we do not discuss it here as we did not find studies assessing its construct validity.

Key	
	Self-report tool <sup>2</sup>
	Observer rated tool
	Training necessary
	Tool includes physiological measures (e.g. blood pressure, heart rate)
✓	Indicates groups for which the tool is suitable
	Indicates groups for which the tool has not been validated

8 Correlation between large and small versions of Caucasian, African-American and Hispanic OUCHER was high in 3 to 12 year olds, supporting use of a smaller version.<sup>60</sup> Another study found that a reduced version of the OUCHER poster (i.e. 8.5 x 11") was significantly correlated with the usual-sized version (11 x 16") (Jordan-Marsh et al., 1994).

Tool name	Features	Suitable for setting:	Suitable for (age [years]):												
			<3*	3	4	5	6	7	8	9	10	11	12	12+	
FACES scale (a six-graded faces scale by Tree Takarn)		Post-operative pain			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Faces Pain Scale (FPS; by Bieri) <sup>7</sup>		Peri-operative pain				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Face, Legs, Arms, Cry, Consolability (FLACC)		Post-operative and peri-procedural pain	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Nursing Assessment of Pain Intensity (NAPI; a modification of CHEOPS)		Post-operative pain	✓												
OUCHER <sup>8</sup>		Post-operative pain (outpatient and ambulatory)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Poker Chip Tool		Post-operative and peri-procedural pain		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Post-operative Pain Score (POPS)		Post-operative pain	✓												
Pain Rating Scale		Post-operative pain	✓												
Sheffield Children's Hospital Facial Expression Scale		Post-operative pain				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Toddler Preschool Post-operative Pain Scale (TPPPS)		Post-operative pain	✓	✓	✓	✓	✓								
University of Wisconsin Pain Scale		Peri-procedural pain	✓												
Visual Analogue Scale (self rated)		Post-operative pain		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Visual Analogue Scale (observer rated)		Post-operative pain	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Verbal Rating Scale		Post-operative pain				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Word Descriptor Scale		Peri-procedural pain		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Word Graphic Rating Scale		Post-operative pain							✓	✓	✓	✓	✓	✓	✓

### 4.3.1 Tool selection

Selection of an appropriate tool is influenced by:

- age groups in which the tool has been validated
- clinical circumstances (such as post-operative settings) in which the tool has been validated
- cultural appropriateness and language of the tool
- whether the tool is designed for use by the child, by a health care professional, or by parents
- resources required to deliver the tool
- training and educational requirements required to deliver the tool.

Tools for neonates:

- all are observer-rated
- all require familiarisation and training
- most include a measure of facial response to painful stimuli
- most require a measure of physiological response
- most have been validated in post-operative settings
- some have been validated following procedures such as routine heelstick, catheter insertion and endotracheal intubation.

Tools for older children:

- for preverbal children, observer-rated tools have been validated
- several valid self-report tools are available for use in children who can talk, including the faces pain scale, OUCHER, poker chip tool, visual analogue scales and Wong-Baker FACES
- some observer-rated tools have also been validated in older children (e.g. CAAT, CHEOPS, COMFORT, DCHPT, FLACC, TPPPS, VAS)
- all observer-rated scales, except the simple VAS, are likely to require raters to be trained in their use. It is unclear whether DCHPT and CAAT require training; each was only validated in one study that was not explicit about training requirements. We have assumed that training will be needed
- OUCHER consists of two scales – one photographic and one numeric. Only children who can count to 100 should use the numeric OUCHER scale (Peden et al., 2001). Others should use the photographic scale. Both scales have been validated.

### 4.3.2 Practical considerations

Thirty-one tools were identified that are both reliable and valid according to the predefined inclusion criteria. However, practical considerations might limit a tool's usefulness, as the context in which assessment takes place may impact the implementation process. For example, factors that influence practicality might include: the equipment needed for tools that include physiological measures such as blood pressure and heart rate; the tool's cost; the time taken to complete the assessment (tools needing a long time may be less appropriate in emergencies); or the tool's format (some tools may be in chart, poster or poker chip format, raising issues relating to storage, durability, ease of use and infection control). Issues of this nature should be incorporated into the quality cycle through evaluation and audit.

### 4.3.3 Nature of tools

Aside from the above considerations, the following additional factors should also help to guide selection of tools for different clinical situations:

- as neonates cannot self-report, tools for use in this age group should ideally include a composite of measures (for example, behavioural and physiological)
- for verbal children, self-report is considered to be the most valid measure of pain intensity. However, we identified a number of valid tools for verbal children that did not require self-report. These may be useful when a child is non-verbal or has cognitive impairments
- faces scales (such as OUCHER, Wong-Baker FACES and the Faces Pain Scale) are cognitively appropriate for children who are still unable to quantify abstract phenomena (typically aged 3-7 years) (Loy, 2002)
- observer-rated tools enhance a child's self report, or may be useful for children who are unable or unwilling to report their pain.

### 4.3.4 Validation profile

Tools should only be used in situations for which they have been validated.

- Clinical setting
  - All neonatal pain scales identified by the systematic search have been validated in neonates experiencing acute pain as a result of surgery or minor invasive procedures (such as routine heelstick, catheter insertion and endotracheal intubation). These scales may not apply outside such settings.
  - For triage in A&E only one tool was identified – AHTPS – as being suitable for use in children aged 0-15 years old.

- Age group
  - Tools should be selected depending on whether they are valid for the age group under study, as indicated in Tables 2 and 3 (pages 18 and 19).
  - Term and preterm neonates respond to pain differently (Holsti et al., 2004; Grunau et al., 2001). It should not be assumed that tools validated only for term neonates are also suitable for preterm neonates.
  - The OUCHER tool has specific instructions, and children should use either the photographic or the numeric subscale depending on their cognitive abilities. Children should use the numerical scale only if they can count to 100.
- Culture and language
  - It cannot be assumed that a tool that is clinically useful and valid in one language and culture will be valid in a different language or culture.
  - For most tools, trans-lingual validity is unclear. However, there are some exceptions where robust translations of tools have been validated in languages other than English:
    - for neonates:
      - COMFORT has been validated in Dutch
      - PIPP has been validated in Icelandic
    - for verbal children:
      - COMFORT has been validated in Dutch
      - CAS, CHEOPS, FLACC, PCT, VRS and Sheffield Facial Expression Scale have been validated in Thai.
  - Similarly, trans-cultural validity is not clear, although there have been some studies of this:
    - three ethnic versions of the OUCHER tool have been validated: African-American, Caucasian and Hispanic
    - DOLLS, an adaptation of Wong-Baker FACES, has been validated in Lebanese children (Badr et al., 2006)
    - one study (Gharaibeh et al., 2002) found correlations between the Wong-Baker FACES, Poker Chip Tool and Word Description Scales in Jordanian Children. Children suggested they had some preference for the Poker Chip Tool.
- Rater:
  - As a rule of thumb, tools designed to be observer-rated should not be used as self-report tools, and vice versa. Some studies that compare children's

scores on a self-report scale to observer-rating with the same tool find that professionals consistently record lower pain than children (Schneider and LoBiondo-Wood, 1992; Maciocia et al., 2003; LaMontagne et al., 1991), while parents' scores correlate well with their children's (Schneider and LoBiondo-Wood, 1992; Maciocia et al., 2003; Kelly et al., 2002; Miller, 1996). By contrast, one study found that parents rated their children's post-procedural pain higher than the child themselves (Chambers et al., 1999).

#### 4.3.5 Clinical context

A child's clinical circumstances may preclude the use of some tools. For instance:

- tools that assess facial features are not appropriate if the face is fully or partially obscured (for example, ventilated with a face mask), or in those who are paralysed; this constraint applies to most of the identified neonatal tools
- tools relying on the assessment of body movements are inappropriate for heavily sedated, paralysed or otherwise immobilised children.

#### 4.3.6 Training requirements

It should be assumed that, for all but the simplest observer rated tools, users will need training in how and when to apply them, and how to interpret and document their results. Training requirements must be considered when selecting tools and developing pain assessment protocols.

#### 4.3.7 Techniques for using tools

There have been a number of studies that have investigated alternative techniques for using tools, including printing the Wong-Baker FACES scale on to dolls for children to interact with (Badr et al., 2006) and using temporary tattoos of the FACES scale on children's arms (Franck et al., 2007). Both of these studies have notable findings, although further work is needed to investigate the validity and reliability of such adaptations.

## 5 Assessing pain in children with cognitive impairment

### 5.1 Background

There is evidence to suggest that children with cognitive impairment (CI) experience significant pain on a more regular basis than children without CI. A study by Breau et al. (2003) found that cognitively impaired children experienced pain with greater frequency than unimpaired children, that the pain was significant in nature and quite long in duration. It appears that this population is at greater risk of experiencing pain mainly due to their more numerous medical conditions, illnesses or chronic painful conditions (Breau et al., 2003).

There is a substantial body of evidence to show that clinicians often have difficulty in assessing pain in non-verbal populations such as children with CI. As a result, this population often receives less effective pain treatment. For example, Stallard et al. (2001), in their study of the everyday occurrence of pain in non-communicating children with CI, found that “while pain in (these) children is more common than within the normal population, verbally non-communicating children are less likely to receive active pain management” (p.461). Oberlander and O’Donnell (2001) found that, while many health care professionals did recognise that pain was a common experience of children with CI, these professionals felt that “pain was not easily assessed or thought to be adequately managed even when it was recognised” (p.139).

Evidence that children with CI receive sub-optimal pain management relative to cognitively intact children may be explained by continued beliefs that this group is insensitive or indifferent to pain, or that these children’s pain behaviours are too idiosyncratic to inform observers about their pain. Even where professionals believe that children with CI do experience pain in the same way as unimpaired children, their approach to treatment may still differ for this group. Breau et al. (2004b) found in their study that “it is possible that [health care] professionals hold beliefs about pain treatment that directly impact upon treatment decisions, regardless of pain assessment.” It is likely, however, that the lack of valid, reliable tools for assessing pain in this population is also a factor contributing to inadequate pain management.

Normally self-report is the gold standard for pain assessment. However, children with CI who are non-verbal

are unable to self-report reliably. It was previously believed that behaviours in this group were too idiosyncratic to be used as reliable indicators of pain, but research over the past few years has suggested that children in this population do in fact display predictable, observable behaviours that can be used to detect the presence and degree of pain. In fact, some studies have shown that patients with CI experiencing pain exhibit more pain behaviours than patients without CI. This knowledge has led to the development of observer-rated behavioural pain assessment tools specifically for use with children with CI.

### 5.2 Search results

The process for appraising and filtering studies is described in Section 3.2 (page 12).

The literature search for this section yielded significantly fewer studies than the search for non CI related literature (256 papers versus 5,923 papers). As a result the process for appraising the research was less involved.

In brief, three tools for use specifically with non-verbal children with CI are recommended:

- Face, Legs, Activity, Cry, Consolability (FLACC) tool (including a revised version of the FLACC tool)
- Paediatric Pain Profile (PPP)
- Non-communicating Children’s Pain Checklist (NCCPC).

#### 5.2.1 Types of studies

Given the aims of the included studies, which in each case was to establish the reliability and validity of a given pain assessment tool, randomised control trial methodology was not appropriate. The studies in question each aimed to establish the validity and reliability of a single tool, rather than to find any cause-and-effect relationship in a clinical intervention. As such, Randomised Controlled Trial methodology was not an appropriate study design. Instead, validation study designs were used.

#### 5.2.2 Types of participants

Participants in the included studies ranged in age from

one to 19 years, and varied in the degree and cause of their cognitive impairments. Each study included children with a variety of impairments so all could be generalised well to the wider population, rather than focusing on a single cause of impairment such as cerebral palsy, as some other studies have done.

In general participants were unable to communicate verbally or through the use of communication aides and so were unable to use self-report tools, apart from some participants in the FLACC studies. In the Voepel-Lewis (2002) study, some of the children had verbal abilities and were found to be capable of self-report. However, during the trial itself no usable self-report data were gathered and only the observer data were used.

This guideline deals with the assessment of acute pain in children. Although many children with CI may experience chronic pain as a result of their conditions, in the included studies only incidences of acute pain were examined. While these incidences of pain may not have been unusual for the children, these were individual episodes with defined onset and ending. In addition, episodes normally had an identifiable source such as accidental injury, surgery, headache, a medical procedure or treatment such as needle stick or physical therapy.

### 5.2.3 Types of tool

The features of each validated tool for measuring pain intensity in children with cognitive impairments are detailed in Section 5.3.

### 5.2.4 Study design

All of the included studies were cross-sectional studies in which a single group of participants was used to gather data, either through surveys or with observers utilising one of the tools once or several times over a set period to compare pain and non-pain situations. For the FLACC tool two studies were included (Voepel-Lewis et al., 2002; Malviya et al., 2006), for the PPP two studies were included (Hunt et al., 2004; Hunt et al., 2007) and for the NCCPC two studies were included (Breau et al., 2002a and 2002b).

Studies were undertaken either in hospital settings or in the children's normal day-to-day care setting (for example, at home). This depended to some extent on whether the tool was designed for use in hospital or at home; for example, the NCCPC-PV is specifically a tool for post-operative use, so naturally it was tested in a hospital setting.

All of the studies were undertaken in English-speaking environments but in different countries. Two studies were from the United States (Voepel-Lewis et al., 2002; Malviya et al., 2006); two were from the United Kingdom (Hunt et

al., 2004 and 2007); and two were from Canada (Breau et al., 2002a and 2002b).

The number of participants in each study varied, although all sample sizes were greater than 20, which was also a minimum criterion for a good quality study in the non-CI related review.

### 5.2.5 Methodological quality

None of the included studies used a randomised controlled trial study design so randomisation was not part of the methodology. Key criteria for assessing methodological quality were:

- sample size and sampling methodology
- sample demographics and generalisability
- potential for bias.

Three studies used convenience sampling and both based sample sizes on priori power calculations (Voepel-Lewis et al., 2002; Hunt et al., 2004; Malviya et al., 2006). One study used a purposive sample taken from a larger convenience sample that had already been selected for an earlier study by the same authors (Hunt et al., 2007). In two studies sample populations were made up of participants who had already been recruited for larger, longitudinal studies by the same authors. However, details of how the samples were selected from these larger populations were not given (Breau et al., 2002a; Breau et al., 2002b).

Five studies reported sample demographics that supported good generalisability to the wider populations concerned, with samples showing a good mix of gender, age, cause of cognitive impairment and source of pain (Voepel-Lewis et al., 2002; Hunt et al., 2004; Malviya et al., 2006; Breau et al., 2002a; Breau et al., 2002b). The study that used purposive sampling did not give information about sample demographics (Hunt et al., 2007).

In two studies where withdrawals were reported none of these was as a result of the study – either participants' carers were no longer available to participate or, in one case, a participant's behaviour was adversely affected prior to the study by factors unrelated to the study (Breau et al., 2002b; Breau et al., 2002a). One study reported a single withdrawal but reasons for this were not explained (Voepel-Lewis et al., 2002).

Three studies used videotape to blind one set of observers to the administration of analgesia for the purposes of testing inter-rater reliability (Voepel-Lewis et al., 2002; Hunt et al., 2004; Malviya et al., 2006). Observer reports may have been unnaturally affected in the Hunt et al. (2004) study as observers had the facility to rewind tapes to check behaviours, which would not be possible under normal circumstances using the tool.

One study did not test inter-rater reliability, and each child was rated by the same observer using the tool and another pain measure – this increased the possibility of bias in the scores (Breau et al., 2002b).

The validity of all three tools has only been tested through rated comparison, due to the lack of more objective measures available in this population. While this issue will be the same for any tool developed for non-verbal, cognitively impaired children, the test of validity is less robust than if it could be measured against — for example, self-report or physiological measures.

All three tools were tested for construct validity and inter-rater reliability, and produced good results on these tests. The NCCPC-R (Breau et al., 2002b) was not specifically tested for inter-rater reliability but its checklist items are all the same as on earlier versions of the NCCPC as well as on the NCCPC-PV, and inter-rater reliability was tested on these versions.

### 5.3 Summary of assessment tools for children with cognitive impairment

This review yielded preliminary evidence to suggest that three tools are valid and reliable for measuring the presence and intensity of pain in children with CI (Table 4). Although all three tools would benefit from further studies into their validity and reliability, the evidence that is available so far is promising. All three tools are observer-rated since children in this population are non-verbal and so unable to self-report. None can be used with physiological measures since there are no such measures that have been demonstrated to be consistent indicators of pain within this population.

#### 5.3.1 Nature of tools

The FLACC is a behavioural pain scale designed to be used by clinicians at the bedside, to aid in assessing the presence of pain. The tool comprises five behaviour categories, each with three possible types of behaviour to select from, which are scored from 0 to 2. A score of 0 indicates relaxed position, normal behaviour or lack of the expected pain behaviour, with scores of 1 and 2 indicating increased presence of the pain behaviour for that category. Overall, the minimum possible score is 0 for a child showing no pain behaviours, and the maximum possible score is 10, indicative of high levels of pain behaviour in each category.

The tool asks users to indicate whether a particular type of behaviour is present based on the descriptions given. The current studies did not indicate a score at which point pain management intervention is recommended, although results of the tool assessments suggest that nurses' FLACC scores were linked to the amount of pain relief that was later administered.

In the Maliviya (2006) study, the FLACC tool is revised to include additional specific descriptors most consistently associated with pain in children with CI. In addition, open-ended fields allowed the further addition of parent-identified unique pain behaviours for individual children. The study suggests these additions may improve the reliability of pain assessment in children with CI using the revised FLACC tool, and allow the tool to be augmented according to behaviour of individual children.

The Paediatric Pain Profile (PPP) is a behaviour rating scale designed to assist in assessing and monitoring pain in children with severe to profound neurological impairment. It is intended to be used as a parent-held record that can be referred to in all of the child's care settings.

The PPP uses a four-point ordinal scale to record the extent to which each of 20 items (behaviours) occurs

Table 4: Guide to selection of pain tools for non-verbal children with cognitive impairment

Tool name	Suitable for setting:	Suitable for (gestational age):
FLACC (Face, Legs, Activity, Cry, Consolability)	Post-operative pain	4 – 18 years
PPP (Paediatric Pain Profile)	All settings	1 – 18 years
NCCPC – R (Non-communicating Children's Pain Checklist – Revised)	All settings	3 – 19 years
NCCPC-PV (Non-communicating Children's Pain Checklist – Post-operative Version)	Post-operative pain	3 – 19 years

References and details of individual studies contributing to this assessment can be found in Appendix B (page 49).

within a given time period – the scale ranges from 0 (not at all) to 3 (a great deal). Overall, the minimum possible score is 0 for a child showing no pain behaviours within the time period, and the maximum possible score is 60 for a child showing all 20 pain behaviours ‘a great deal’. Scores of 0, however, could also indicate that the observer is ‘unable to assess’ the behaviour.

Although the authors do not specify a time period for observations in this paper they do mention that it should take no more than two to three minutes to complete the scale, and one observation period during the study lasted five minutes, suggesting that that is sufficient time.

Similarly no point for PPP scores is indicated at which pain should be considered to be serious and require intervention. However, in the 2004 study the authors suggest that scores above 14 are indicative of significant pain. They also state that individual children are likely to have different patterns of pain behaviour and that carers who use the PPP would come to learn the individual child’s cut-off point and apply it to their pain management.

As the accuracy of the scale depends on the quality of observations, this tool would best be used by observers who are familiar with both the scale and with an individual child’s pain cues. As the scale has been designed to be used repeatedly by parents, through continued use they should develop the necessary level of expertise to use the scale accurately.

The NCCPC is an observational tool for assessing pain in children with cognitive impairment who are unable to communicate verbally. It is intended to be usable by any person involved in a child’s care, whether they are familiar with the individual child or not. The usefulness of the tool in a clinical setting has been considered, such as whether its length makes it a practical tool for clinicians and whether it performs well when used by carers unfamiliar with the child.

Two versions of the NCCPC have been derived from the original checklist: the post-operative version (NCCPC-PV) and a revised general version (NCCPC-R). The two versions are identical except that the NCCPC-PV does not include one of the checklist items (eating/sleeping subscale), as those behaviours may be unnaturally affected by analgesia and so forth in post-operative setting, and may require more time to assess than is available in a clinical setting.

The NCCPC-R and NCCPC-PV are 30-item and 27-item checklists respectively, with higher scores indicating greater pain. Items are scored on a 0 – 3 scale based on how often each item occurred (0 = not at all, 3 = very often). Scores for items are then summed to create a total score. Each checklist takes up to two minutes to complete.

### 5.3.2 Validation profile

#### FLACC

Currently the tool has only been validated within a hospital setting. In terms of usefulness, results suggest that, although the tool can be used by clinicians, it is more effective with parent input to provide a description of ‘baseline’ behaviour. This is supported by the findings of the Malviya (2006) study, which suggested that the addition of unique descriptors allowed parents to augment the tool with individual behaviours unique to their children. Revisions were reviewed by experts (physicians and advanced practice nurses with expertise in pain assessment and treatment in children with CI) to confirm content validity.

Whether or not the tool could be used just as effectively by clinicians without involvement of parents is an area for further exploration.

#### PPP

The PPP showed better intra-rater reliability than inter-rater, which suggests that it is more consistent when used by the same observer over time. As it was designed to be a parent-held document, this is in line with its intended use.

This tool was validated in a number of care settings, including home, residential care facilities and hospital (post-operative setting) for children with severe CI.

#### NCCPC-PV

The Post-operative Version of the NCCPC tool was validated for use in a hospital setting. Results suggest that familiarity with the individual child is not necessary and that it can be administered over a brief period of observation. These are important findings in terms of the tool’s usefulness in the post-operative, clinical setting.

#### NCCPC-R

The revised version of the NCCPC was validated for use in day-to-day care settings.

## 6 Recommendations and good practice points

### 6.1 Recommendations

For each of the recommendations presented in this section, a summary of the evidence is presented together with full references to the research studies. The evidence of each study has been attributed a level of evidence using SIGN system (SIGN, 2008). This is followed by evidence statements based on the reviewed research and a brief overview of the GDG discussion and interpretation of the evidence.

#### RECOMMENDATION 1:

Be vigilant for any indication of pain.

Pain should be anticipated in neonates and children at all times.

#### Summary of the evidence

There has been a traditional view that neonates, particularly preterm neonates, are less able to experience and interpret pain than older children and adults. The evidence does not support this view. The physiological and biochemical prerequisites for nociception are developed in utero, so from birth neonates are able to demonstrate physiological and behavioural responses to pain; this is supported by evidence from observational studies (Mathew and Mathew, 2003; Stevens and Franck, 2001; Duhn and Medves, 2004; Abu-Saad et al., 1998; Stevens and Koren, 1998; Franck and Miaskowski, 1997; Morison et al., 2001; Walden et al., 2001; Johnston et al., 1995). Like adults, responses to pain appear proportionate to pain severity (Porter et al., 1999), though this may not be the case with very preterm, sick, or exhausted neonates (Van Dijk et al., 2004). Surveys suggest that nurses use different cues to assess pain in preterm neonates and term babies. This might lead them to miss more subtle indicators of pain in preterm neonates, and so underestimate pain intensity in this group (Shapiro, 1993; Reyes, 2003). Immature motor capabilities, behavioural state, and clinical status may further complicate pain assessment in preterm babies (Duhn and Medves, 2004; Craig et al., 1993). These factors, combined with outdated views that neonates do not feel pain and a reluctance to prescribe and administer analgesia, may result in insufficient pain management in neonates (Shapiro, 1993; Purcell-Jones et al., 1988).

All studies cited are repeated cross-sectional studies (considered non-analytic studies) and have been attributed level of evidence 3 (SIGN, 2008).

#### Evidence statements

- A foetus acquires the physiological and biochemical prerequisites for nociception in utero. Following birth therefore, preterm neonates have the prerequisites for nociception. Observational studies have demonstrated physiological and behavioural responses to pain in all neonates.
- Repeated cross sectional studies before and after a painful event show that children and neonates experience pain in the same situations as adults.

#### GDG discussion

Given the evidence that neonates demonstrate physiological and behavioural responses to pain and that children and neonates experience pain in the same situations as adults, the GDG agreed that a fundamental principle for assessing pain in children is that practitioners should anticipate pain in any situation that an adult would consider painful. The GDG felt that it was important to recognise that pain should be anticipated at all times, especially (but not only) when painful situations occur.

#### RECOMMENDATION 2:

Children's self-report of their pain, where possible, is the preferred approach.

For children who are unable to self-report, an appropriate behavioural or composite tool should be used.

#### Summary of the evidence

Children with CI who are non-verbal are unable to self-report reliably. Recent studies suggest that children with CI display predictable, observable behaviours that can be used to detect the presence and degree of pain. This has led to the development of observer-rated behavioural pain assessment tools specifically for use with children with CI (Breau et al., 2002a; Breau et al., 2002b; Voepel-Lewis et al., 2002; Hunt et al., 2004; Malviya et al., 2006; Hunt et al., 2007).

All studies cited are repeated cross-sectional studies (considered non-analytic studies) and have been attributed level of evidence 3 (SIGN, 2008).

### Evidence statements

- The limited evidence available to date shows that, contrary to previous beliefs, children with cognitive impairment do demonstrate consistent, measurable patterns of pain behaviour, which allow for the use of standardised pain assessment tools.
- Evidence for pain assessment tools designed specifically for children with cognitive impairment shows that they are effective and reliable in a number of care contexts.

### GDG discussion

The GDG recognised that children's self-report of their pain is considered the gold standard, where this is possible. As shown by the review of tools designed specifically for non-verbal children with CI, valid, reliable tools do exist for this population. The GDG agreed with this, while recognising that expertise needs to continue to be developed in this area. An important finding of this review was that children with CI display clear, measurable pain behaviours around which these specific assessment tools have been structured. The GDG also highlighted that there are other reasons why children are unable to self-report; for example, as they may be ventilated. Although self-report may not be possible in these cases, pain assessment should still be carried out.

#### RECOMMENDATION 3:

If pain is suspected or anticipated, use a validated pain assessment tool; do not rely on isolated indicators to assess pain.

Examples of signs that may indicate pain include changes in children's behaviour, appearance, activity level and vital signs.

No individual tool can be broadly recommended for pain assessment in all children and across all contexts.

### Summary of the evidence

Both term and preterm neonates vary greatly in their physiological, biochemical and behavioural responses to pain (Franck and Miaskowski, 1997). Older children also show inconsistent behavioural and verbal responses that may be related to contextual and cultural factors (Stanford et al., 2005). Certain responses may be indicators of pain, though these responses should not be used in isolation and should cue formal assessment with valid, often composite, scales.

### Biochemical and physiological responses

Studies have shown variable, undefined biochemical responses (for example, plasma or salivary cortisol and plasma catecholamine levels) to painful stimuli in neonates (Franck and Miaskowski, 1997). Similarly, although most studies in neonates show that heart rate increases and oxygen saturation decreases in response to procedures that are likely to be painful (Holsti et al., 2004; Grunau et al., 2001; Porter et al., 1999; Craig et al., 1993; Morison et al., 2003; Holsti et al., 2005; Gorduysus et al., 2002; Stevens and Johnston, 1994; Schwartz and Jeffries, 1990; Lindh et al., 1999) this is not always the case (Grunau et al., 2000; McIntosh et al., 1993). Gestational age, intensity and invasiveness of the pain stimulus (Porter et al., 1999), prior pain exposure (Grunau et al., 2001) and medical condition can all affect physiological response. In children aged 8 to 17 years, heart rate may not be a sensitive indicator of pain (Foster et al., 2003).

### Behavioural responses

Many studies in term and preterm infants show increased frequency of limb flexion and finger splay in response to procedures that are likely to be painful (Holsti et al., 2004; Walden et al., 2001; Morison et al., 2003; Holsti et al., 2005; Grunau et al., 2000; Taddio et al., 2002; Stevens et al., 1993). But this is not always so. Startles and twitching do not seem to be useful indicators of pain (Grunau et al., 2000). Gestational age may affect the nature of behavioural response, though this is unpredictable. Some studies suggest that infants with a lower gestational age at birth respond more to pain (Holsti et al., 2004), while others suggest a dampened response (Grunau et al., 2001; Oberlander et al., 2000). Previous pain exposure may also affect behavioural response (Taddio et al., 1997; Taddio et al., 2002).

### Facial expression and cry

Most studies assessing facial response to pain in neonates suggest that acute pain increases overall facial activity (Holsti et al., 2004; Craig et al., 1993; Grunau et al., 1990), in particular the brow-bulge, eye-squeeze, nasolabial furrow features and open mouth (Holsti et al., 2004; Holsti et al., 2005; Grunau et al., 1990; Rushforth and Levene, 1994). One repeated cross-sectional study suggests that newborn girls were more facially expressive than newborn boys in response to capillary puncture (Guinsburg et al., 2000). Again, these responses are variable and may be difficult to assess in some children. Another study found that, in some cases, no facial expression was observed although infants still mounted a cortical haemodynamic response, suggesting cortical response to painful stimulation may occur in the absence of facial expression (Slater et al., 2008). Short latency to cry and longer

duration of first cry may be typical responses to acute pain (Grunau et al., 1990), but one cross-sectional study suggests that cry features are not a sensitive indicator of pain intensity in preterm neonates (Johnston et al., 1999). Relying on cry features to assess pain is inappropriate if all or some of the face is obscured, for example, in ventilated neonates, neonates with facial tapes, or eye patches (Van Dijk et al., 2004).

Research primarily in neonates suggests that neither physiological nor behavioural indicators of pain are highly sensitive. Studies demonstrating concordance between these cues lend support to a recommendation for the use of validated, multi-dimensional scales when assessing pain (Morison et al., 2001; National Association of Neonatal Nurses, 2001).

All studies cited are repeated cross-sectional studies (considered non-analytic studies) and having been attributed level of evidence 3 (SIGN, 2008).

### Evidence statements

- Neonates, both term and preterm, and older children vary greatly in their responses to pain, be they biochemical, physiological, behavioural or verbal.
- Certain responses may be indicators of pain, but they should not be used in isolation to assess pain intensity.
- Studies demonstrate concordance between physiological and behavioural indicators of pain in neonates, which lends support to a recommendation for the use of validated, multi-dimensional scales when assessing pain.

### GDG discussion

Principles given in these recommendations should be applied to all neonates and children, with or without CI, or critically ill children who are intubated and ventilated. All tools for all children should be chosen for the context in question and applied by appropriately trained people.

#### RECOMMENDATION 4:

Assess, record, and re-evaluate pain at regular intervals; the frequency of assessment should be determined according to the individual needs of the child and setting.

Be aware that language, ethnicity and cultural factors may influence the expression and assessment of pain.

### Summary of the evidence

Evidence of the best time to assess pain is limited and based largely on expert opinion. Some experts recommend assessments and documentation of pain at least every four to six hours (Royal College of Nursing, 2002; Van Dijk et

al., 2004; Anand, 2001; Agency for Health Care Policy and Research, 1992). An increase in pain severity, lack of response to pain management or worsening of a child's clinical condition may warrant more frequent assessment (Royal College of Nursing, 2002; Anand, 2001; Agency for Health Care Policy and Research, 1992). Pain assessments should also be used to evaluate the efficacy of management strategies (Anand, 2001). One RCT found that management within a framework including more regular pain assessments (every four hours compared with every six hours) in the 24 hours after surgery reduced the severity of post-operative pain and increased the use of post-operative analgesia (Stevens, 1990). One retrospective comparative study found that assessment every four hours using a self-report tool had no effect on analgesia, pain report, length of hospital stay or time and progress of ambulation when compared with chart review of children having no formal pain assessment (Boughton et al., 1998).

All studies cited are a body of expert opinion (level of evidence 3) with the exception of one randomised controlled trial (Stevens 1990; level of evidence 1-) and one case series with a retrospective control (Boughton et al., 1998; level of evidence 3).

### Evidence statements

- Regular assessment of pain in a systematic framework improves outcomes for children.
- An increase in pain severity, a lack of response to a pain management intervention or a worsening of a child's clinical condition may warrant more frequent assessment.
- Both term and preterm neonates vary greatly in their physiological, biochemical and behavioural responses to pain.
- Older children also show inconsistent behavioural and verbal responses that may be related to contextual and cultural factors.

### GDG discussion

The GDG agreed that a fundamental principle for assessing pain in children is that practitioners should anticipate pain in any situation that an adult would consider painful, and should be prepared to formally assess and manage pain using an appropriate tool. This principle applies to all children. The selection of an assessment tool, however, should be guided by the individual child's condition and circumstances to ensure that the most effective tool is chosen. For example, tool selection may be influenced by whether a child presents in acute pain or is pain free at the time of assessment and explanation of the tool. Cultural factors should be taken

into consideration as necessary in the selection of an assessment tool. Pain assessment should not be seen as a one off, but rather as part of a cycle of assessment, management and reassessment. If a selected tool is not working, another appropriate tool should be selected in its place.

## 6.2 Good practice points

These good practice points are suggestions for best practice, based on GDG expertise in the absence of evidence. In terms of providing a complete, practical guideline, the good practice points are as important as the recommendations. These complement the evidence-based recommendations and are based on GDG members' clinical expertise, providing important guidance on the practice of assessing pain in children.

1. Acknowledging pain makes pain visible. Pain assessment should be incorporated into routine observations (as the fifth vital sign or 'TPRP' – temperature, pulse, respiration and pain).
2. Pain assessment is not an isolated element; it is an ongoing and integral part of total pain management. The other elements include implementation of appropriate interventions, evaluation and reassessment.
3. The child's pain assessment tool, written information and advice on pain assessment and treatment should be given to parents/carers as part of their preparation for discharge for continued use at home/other care settings.
4. Parents/carers may benefit from being taught to use pain assessment tools as part of the management of their child's pain.
5. Each organisation should appoint a dedicated lead facilitator to promote and support the implementation of pain assessment for all children, including those with cognitive impairment.

## 7 Recommendations for further research

### 7.1 Research recommendations – making things more child-friendly

Further research is required to address gaps in the guideline to cover areas of poor or lack of evidence, or where the GDG has been unable to make recommendations for that reason.

Some of the research questions that have emerged through the development of this guideline are:

- does the use of colour in pain assessment tools impact on the management of pain?
- what are the implications in the validation and use of electronic pain assessment tools?
- what are the implications for validating and using tools in different cultural settings?
- how does the style and nature of nursing communication impact on the assessment of pain?
- what value is placed on the talk/discourse that surrounds the use of objective pain assessment tools?
- what other aspects of acute pain should be assessed and recorded apart from intensity?

### 7.2 Other relevant studies

Several studies emerged from the systematic review of the literature that, while not falling under the inclusion requirements of this guideline, did highlight some key areas for subsequent further research.

A study based at the Phoenix Children's Hospital in Phoenix, US (McConahay et al., 2006) used the Color Analog Scale to calculate the degree of change in pain severity required to achieve a clinically significant improvement in pain levels. The main outcome of the study was to quantify the smallest change required for a child to state that their pain was improved. Further research of this nature into the measurement of clinically significant change in pain for children would be beneficial.

Another study examined the relations between Neonatal Facial Coding System (NFCS) scores and spectral analysis measures of infant crying during pain procedure (Lehr et al., 2007). Further research into the relationships of pain measurement scales against other indicators of pain could further increase the validity and reliability of pain scales. Such research could be particularly valuable in assessing pain scales that are appropriate for measuring pain in non-verbal or pre-verbal children.

New scales are also being developed. The MAPS: Multidimensional Assessment of Pain Scale (Ramelet et al., 2007a, Ramelet et al., 2007b) is used to measure post-operative pain in critically ill preverbal children. The scale has been tested for content, convergent and concurrent validity, inter-rater reliability, and its clinical utility evaluated. Further work is currently being carried out to establish construct validity for the MAPS.

## 8 Implementation of the guideline

A range of tools to support the implementation of validated pain assessment will complement the publication of this guideline. The RCN is currently consulting with other organisations (including patient groups and the Association of Paediatric Anaesthetists) to develop both implementation and audit materials. The tools will set out practical ways in which pain assessment tools can be evaluated, adopted and audited, and will be made available through the RCN website: [www.rcn.org.uk/childrenspainguideline](http://www.rcn.org.uk/childrenspainguideline)

There is no single successful strategy to overcoming barriers to implementation. Overall, a clear, collaborative and concentrated approach is crucial. It is important to find the key areas of change and develop and employ strategies to support these areas. Use of resources may be varied, and resources may need to be used in a combination that is tailored to specific needs.

### 8.1 Barriers to implementation

Several factors may impact on the implementation of guidelines that need consideration. Barriers may be on both an organisational and personal level, and these barriers need to be addressed if any implementation strategy is to be successful.

All stakeholders need a sound understanding of guidelines and the application of these in relation to their situation. Both individuals and groups need to be motivated to make use of the guidelines, and accept and have confidence in the findings. Engagement with stakeholders at an early stage is paramount, and stakeholders must feel involved in any implementation process. There needs to be adequate assessment of the practicalities involved in implementing guideline recommendations.

Barriers should be identified by talking to key people and engaging with people at a local and organisational level. It is important to identify who would be affected by change, and enlist help from champions and experts in order to address concerns and promote uptake. Identifying barriers can also be achieved by observing practice, examining current reports, and through the use of audit cycles and quality indicators. For example, audit cycles might look at current activity ('where are we now?'), desired activity ('where do we want to be?'), the changes required to achieve this ('how do we get there?') and the indicators of success ('how do we know when we've got there?').

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## Appendix A

# Search strategies and searched databases

The search strategies employed for the original guideline were used as the foundation for the search strategy for these new guidelines. The journal articles cited in the original guidelines were all retrieved and two searches were performed; one for systematic reviews, and another for studies on pain assessment in children. Owing to the poor sensitivity of limiting searches for validity/diagnostic studies by study design, a broad search was made for papers on pain assessment in children, without limiting the search by using keywords for study design. Potentially relevant papers were identified during a first pass critical appraisal.

English language literature published from 1966 (or the database origin) to October 2008 was searched using

Medline, Embase, Cinahl, PsycINFO, British Nursing Index, Cochrane Library, SIGLE (where available), DARE and HTA databases. A search was also made for guidelines produced in the UK or USA. Search strategies are published below.

A separate search was conducted for papers addressing the assessment of acute pain in children with cognitive impairment. The searches documented in the original work were used as a basis for this search, with the addition of a cognitive impairment 'filter'. All the same databases searched for the original guideline (with the exception of SIGLE, which has been closed) were searched again for this new section.

Table 5: Search assessment form – non-CI update

Search date: 5 May 2006		
Databases searched	Systematic reviews	Pain assessment studies
Medline 1966-date	92	3620
Embase 1988-date	18	1604
Cinahl 1982-date		1746
PsycINFO 1985-date		1597
British Nursing Index 1994-date		375
Cochrane 2006 issue 2	0	241
SIGLE 1980-2005/03		14
CRD		
• DARE		–
• HTA		–
• NHS Economic Evaluation Database (NHSEED)		2
		9199 (before de-duplication)
<b>Total retrieved</b>	<b>110</b>	<b>5923</b>

### Guidelines

#### NELH Guidelines finder: UK

Guidelines for good practice – recognition and assessment of acute pain in children, Royal College of Paediatrics and Child Health, 2001

Guideline for management of pain in children, British Association for Accident and Emergency Medicine, 2004

Pain management in children – implementation guide, Royal College of Nursing, 2001

The recognition and assessment of acute pain in children – technical report, Royal College of Nursing, 2000

#### National Guidelines Clearinghouse USA

Management of postoperative and procedural pain in infants, children, and adolescents, Agency for Health Care Policy and Research, 1992

Chronic abdominal pain in children, American Academy of Pediatrics, 2005

The assessment and management of acute pain in infants, children, and adolescents, American Academy of Pediatrics, Committee on Psychosocial Aspects of Child and Family Health, Task Force on Pain in Infants CaA, 2001

Assessment and management of acute pain, Institute for Clinical Systems Improvement (ICS), 2006

## Search strategies

### Database: Ovid MEDLINE(R) <1966 to October Week 1 2008>

- 1 exp review/
- 2 (scisearch or psychinfo or psycinfo or medlars or embase or psychlit or psyclit or cinahl or pubmed or medline).ti,ab,sh.
- 3 ((hand adj2 search\$) or (manual\$ adj2 search\$)).ti,ab,sh.
- 4 ((electronic or bibliographic or computeri?ed or online) adj4 database\$).ti,ab.
- 5 (pooling or pooled or mantel haenszel).ti,ab,sh.
- 6 (peto or dersimonian or der simonian or fixed effect).ti,ab,sh.
- 7 or/2-6
- 8 1 and 7
- 9 Meta Analysis/
- 10 (meta-analys\$ or meta analys\$ or metaanalys\$).ti,ab,sh.
- 11 ((systematic\$ or quantitativ\$ or methodologic\$) adj5 (review\$ or overview\$ or synthesis\$)).ti,ab,sh.
- 12 (integrative research review\$ or research integration).ti,ab,sh.
- 13 or/9-12
- 14 8 or 13
- 15 clinical trials, phase iv/ or clinical trials, phase iii/ or randomized controlled trials/ or multicenter studies/
- 16 (random\$ or placebo\$ or ((singl\$ or double\$ or triple\$ or treble\$) and (blind\$ or mask\$))).ti,ab,sh.
- 17 15 or 16
- 18 (animal\$ not human\$).sh.
- 19 17 not 18
- 20 19 and 14
- 21 pain measurement/ (
- 22 exp Pain/cl, di, is [Classification, Diagnosis, Instrumentation]
- 23 Pain, Postoperative/cl, di [Classification, Diagnosis]
- 24 ((pain\$ or distress\$) and (measur\$ or assess\$ or scale\$ or recogni\$ or score\$ or evaluat\$ or rating or observ\$ or validat\$ or perception\$ or response\$ or respond\$ or behav\$)).ti.
- 25 exp Nursing Assessment/
- 26 exp pain/ and 25
- 27 or/21-24,26
- 28 limit 27 to "all child (0 to 18 years)"
- 29 (child\$ or infan\$ or adolesc\$ or newborn\$ or pediatri\$ or paediatr\$ or neonat\$ or baby or babies or toddler\$ or teenag\$).ti,ab.
- 30 29 and 27
- 31 28 or 30
- 32 31 and 14
- 33 \*Pain Measurement/
- 34 pain measurement/
- 35 exp Child Behavior/ or "Attitude of Health Personnel"/ or parents/
- 36 Facial Expression/ or Nursing Assessment/
- 37 35 or 36
- 38 34 and 37
- 39 ((pain\$ or distress\$) and (measur\$ or assess\$ or scale\$ or recogni\$ or score\$ or evaluat\$ or rating or observ\$ or validat\$ or perception\$ or response\$ or respond\$ or behav\$)).ti.
- 40 33 or 38 or 39
- 41 CRIES.ti,ab.
- 42 "children's hospital of eastern ontario pain scale".ti,ab.
- 43 cheops.ti,ab.
- 44 "liverpool infant distress".ti,ab.
- 45 "premature infant pain profile".ti,ab.
- 46 "neonatal infant pain scale".ti,ab.
- 47 "neonatal facial coding system".ti,ab.
- 48 tpps.ti,ab.
- 49 "post?operative pain tool".ti,ab.
- 50 Toddler Preschool Postoperative Pain.ti,ab.
- 51 "objective pain scale".ti,ab.
- 52 "objective pain score".ti,ab.
- 53 flacc.ti,ab.
- 54 "n-pass".ti,ab.
- 55 "pain faces scale".ti,ab.
- 56 "faces scale".ti,ab.
- 57 ("pain intensity scale" or "pain intensity score").ti,ab.
- 58 "memorial pain assessment card".ti,ab.
- 59 "brief pain inventor".ti,ab.
- 60 ("pain distress scale" or "pain distress score").ti,ab.
- 61 "Nurses Assessment of Pain Inventory".ti,ab.
- 62 "Assessment of Pain Inventory".ti,ab.
- 63 ("behavioral pain score" or "behavioral pain scale").ti,ab.
- 64 ("behavioural pain score" or "behavioural pain scale").ti,ab.

- 65 "riley infant pain".ti,ab.  
66 "Nursing Assessment of Pain Intensity".ti,ab.  
67 or/41-66  
68 40 or 67  
69 limit 68 to "all child (0 to 18 years)"  
70 (child\$ or infan\$ or adolesc\$ or newborn\$ or pediater\$ or paediatr\$ or neonat\$ or baby or babies or toddler\$ or teenag\$).ti,ab.  
71 68 and 70  
72 69 or 71  
73 limit 72 to english language  
74 73 not 32
- Database: EMBASE <1988 to 2008 Week 40>**
- 1 exp review/  
2 (scisearch or psychinfo or psycinfo or medlars or embase or psychlit or psyclit or cinahl or pubmed or medline).ti,ab,sh.  
3 ((hand adj2 search\$) or (manual\$ adj2 search\$)).ti,ab,sh.  
4 ((electronic or bibliographic or computerized or online) adj4 database\$).ti,ab.  
5 (pooling or pooled or mantel haenszel).ti,ab,sh.  
6 (peto or dersimonian or der simonian or fixed effect).ti,ab,sh.  
7 or/2-6  
8 1 and 7  
9 Meta Analysis/  
10 (meta-analys\$ or meta analys\$ or metaanalys\$).ti,ab,sh.  
11 ((systematic\$ or quantitativ\$ or methodologic\$) adj5 (review\$ or overview\$ or synthesis\$)).ti,ab,sh.  
12 (integrative research review\$ or research integration).ti,ab,sh.  
13 or/9-12  
14 8 or 13  
15 clinical trials, phase iv/ or clinical trials, phase iii/ or randomized controlled trials/ or multicenter studies/  
16 (random\$ or placebo\$ or ((singl\$ or double\$ or triple\$ or treble\$) and (blind\$ or mask\$))).ti,ab,sh.  
17 15 or 16  
18 (animal\$ not human\$).sh.  
19 17 not 18  
20 19 and 14  
21 ((pain\$ or distress\$) and (measur\$ or assess\$ or scale\$ or recogni\$ or score\$ or evaluat\$ or rating\$ or observ\$ or validat\$ or perception\$ or response\$ or respond\$ or behav\$)).ti.  
22 CRIES.ti,ab.  
23 "children's hospital of eastern ontario pain scale".ti,ab  
24 cheops.ti,ab.  
25 "liverpool infant distress".ti,ab.  
26 "premature infant pain profile\$.ti,ab.  
27 "neonatal infant pain scale\$.ti,ab.  
28 "neonatal facial coding system\$.ti,ab.  
29 tpps.ti,ab.  
30 "postoperative pain tool".ti,ab.  
31 Toddler Preschool Postoperative Pain.ti,ab.  
32 "objective pain scale\$.ti,ab.  
33 "objective pain score\$.ti,ab.  
34 flacc.ti,ab.  
35 "n-pass".ti,ab.  
36 "pain faces scale".ti,ab.  
37 "faces scale".ti,ab.  
38 ("pain intensity scale\$ or "pain intensity score\$").ti,ab.  
39 "memorial pain assessment card\$.ti,ab.  
40 "brief pain inventor\$.ti,ab.  
41 ("pain distress scale\$ or "pain distress score\$").ti,ab.  
42 "Nurses Assessment of Pain Inventory".ti,ab.  
43 "Assessment of Pain Inventory".ti,ab.  
44 ("behavioral pain score" or "behavioral pain scale").ti,ab.  
45 ("behavioural pain score" or "behavioural pain scale").ti,ab.  
46 "riley infant pain".ti,ab.  
47 "Nursing Assessment of Pain Intensity".ti,ab.  
48 \*pain assessment/  
49 or/21-48  
50 (child\$ or infan\$ or adolesc\$ or newborn\$ or pediater\$ or paediatr\$ or neonat\$ or baby or babies or toddler\$ or teenag\$).ti,ab.  
51 limit 49 to (infant <to one year> or child <unspecified age> or preschool child <1 to 6 years> or school child <7 to 12 years> or adolescent <13 to 17 years>)  
52 49 and 50  
53 51 or 52  
54 53 and 14  
55 53 not 54  
56 limit 55 to english language

**Database: CINAHL – Cumulative Index to Nursing, Allied Health Literature <1982 to October Week 1 2008>**

- 1 Pain Measurement/
- 2 ((pain\$ or distress\$) and (measur\$ or assess\$ or scale\$ or recogni\$ or score\$ or evaluat\$ or rating or observ\$ or validat\$ or perception\$ or response\$ or respond\$ or behav\$)).ti.
- 3 \*Pain Measurement/
- 4 \*Instrument Validation/
- 5 cheops.ti,ab,it.
- 6 CRIES.ti,ab,it.
- 7 "children's hospital of eastern ontario pain scale".ti,ab,it.
- 8 "liverpool infant distress".ti,ab,it.
- 9 "premature infant pain profile".ti,ab,it.
- 10 "neonatal infant pain scale".ti,ab,it.
- 11 "neonatal facial coding system".ti,ab,it.
- 12 tpps.ti,ab,it.
- 13 "post?operative pain tool".ti,ab,it.
- 14 Toddler Preschool Postoperative Pain.ti,ab,it.
- 15 "objective pain scale".ti,ab,it.
- 16 "objective pain score".ti,ab,it.
- 17 flacc.ti,ab,it.
- 18 "n-pass".ti,ab,it.
- 19 "pain faces scale".ti,ab,it.
- 20 "faces scale".ti,ab,it.
- 21 ("pain intensity scale\$ or "pain intensity score\$").ti,ab,it.
- 22 "memorial pain assessment card\$.ti,ab,it.
- 23 "brief pain inventor\$.ti,ab,it.
- 24 ("pain distress scale\$ or "pain distress score\$").ti,ab,it.
- 25 "Nurses Assessment of Pain Inventory".ti,ab,it.
- 26 "Assessment of Pain Inventory".ti,ab,it.
- 27 ("behavioral pain score" or "behavioral pain scale").ti,ab,it.
- 28 ("behavioural pain score" or "behavioural pain scale").ti,ab,it.
- 29 "riley infant pain".ti,ab,it.
- 30 "Nursing Assessment of Pain Intensity".ti,ab,it.
- 31 pain\$.it.
- 32 1 and 4
- 33 2 or 3
- 34 33 or 32
- 35 or/5-31

- 36 35 or 33
- 37 (child\$ or infan\$ or adolesc\$ or newborn\$ or pediatri\$ or paediatr\$ or neonat\$ or baby or babies or toddler\$ or teenag\$).ti,ab.
- 38 limit 36 to (newborn infant <birth to 1 month> or infant <1 to 23 months> or preschool child <2 to 5 years> or child <6 to 12 years> or adolescence <13 to 18 years>)
- 39 36 and 37
- 40 38 or 39
- 41 limit 40 to english

**Database: PsycINFO <1985 to October Week 1 2008>**

- 1 pain measurement/
- 2 pain\$.tm.
- 3 ((pain\$ or distress\$) and (measur\$ or assess\$ or scale\$ or recogni\$ or score\$ or evaluat\$ or rating or observ\$ or validat\$ or perception\$ or response\$ or respond\$ or behav\$)).ti.
- 4 cheops.ti,ab,tm.
- 5 CRIES.ti,ab,tm.
- 6 "children's hospital of eastern ontario pain scale".ti,ab,tm.
- 7 "liverpool infant distress".ti,ab,tm.
- 8 "premature infant pain profile".ti,ab,tm.
- 9 "neonatal infant pain scale".ti,ab,tm.
- 10 "neonatal facial coding system".ti,ab,tm.
- 11 tpps.ti,ab,tm.
- 12 "post?operative pain tool".ti,ab,tm.
- 13 Toddler Preschool Postoperative Pain.ti,ab,tm.
- 14 "objective pain scale".ti,ab,tm.
- 15 "objective pain score".ti,ab,tm.
- 16 flacc.ti,ab,tm.
- 17 "n-pass".ti,ab,tm. (
- 18 "pain faces scale".ti,ab,tm.
- 19 "faces scale".ti,ab,tm.
- 20 ("pain intensity scale\$ or "pain intensity score\$").ti,ab,tm.
- 21 "memorial pain assessment card\$.ti,ab,tm.
- 22 "brief pain inventor\$.ti,ab,tm.
- 23 ("pain distress scale\$ or "pain distress score\$").ti,ab,tm.
- 24 "Nurses Assessment of Pain Inventory".ti,ab,tm.
- 25 "Assessment of Pain Inventory".ti,ab,tm.
- 26 ("behavioral pain score" or "behavioral pain scale").ti,ab,tm.

- 27 "riley infant pain".ti,ab,tm.
- 28 "Nursing Assessment of Pain Intensity".ti,ab,tm.
- 29 or/1-28
- 30 \*distress/
- 31 exp \*pain/
- 32 30 or 31
- 33 exp measurement/
- 34 32 and 33
- 35 34 or 29
- 36 (child\$ or infan\$ or adolesc\$ or newborn\$ or pediatr\$ or paediatr\$ or neonat\$ or baby or babies or toddler\$ or teenag\$).ti,ab.
- 37 limit 35 to (100 childhood <birth to age 12 yrs> or 120 neonatal <birth to age 1 mo> or 140 infancy <age 2 to 23 mo> or 160 preschool age <age 2 to 5 yrs> or 180 school age <age 6 to 12 yrs> or 200 adolescence <age 13 to 17 yrs>)
- 38 35 and 36
- 39 37 or 38

Table 6: Search assessment form – child pain assessment in cognitive impairment (CI)

Searches from beginning of database			
Databases	Searched from	Date of search	Results
Medline	1950	13 April 2007	85
Embase	1980	17 April 2007	49
Cinahl	1982	17 April 2007	40
PsycINFO	1985	18 April 2007	63
British Nursing Index	1994	18 April 2007	11
Cochrane 2007 (2)		19 April 2007	105
SIGLE	1980	n/a	n/a
CRD (NHSEED, DARE, HTA)	–	18 April 2007	0
		<b>Total =</b>	<b>353</b>
		<b>After de-duplication =</b>	<b>256</b>

**Database: Medline**

No.	Search terms	Results
1	<b>Child pain assessment filter (limited to eng. language)</b>	3047
2	exp communication disorders/	39990
3	exp mental retardation/	65518
4	((sever\$ or profound\$ or significant\$) adj2 (cognition or cognitive\$ or intellectual\$ or neurological\$ or disabilit\$ or disable\$)).ti,ab.	11700
5	((cognition or cognitive\$ or intellectual\$ or neurological\$) adj2 (impair\$ or problem\$)).ti,ab.	18480
6	nervous system diseases/	26052
7	exp cognition disorders/	31232
8	special needs.mp.	1776
8	or/2-7	177991
9	1 and 8	85

**Database: Embase**

No.	Search terms	Results
1	Child pain assessment filter (limited to eng. Language)	1412
2	exp Communication Disorder/	17387
3	exp Mental Deficiency/	48507
4	Cognitive Defect/	30166
5	Neurologic Disease/	35373
6	((sever\$ or profound\$ or significant\$) adj2 (cognition or cognitive\$ or intellectual\$ or neurological\$ or isability\$ or disable\$)).ti,ab.	11005
7	((cognition or cognitive\$ or intellectual\$ or neurological\$) adj2 (impair\$ or problem\$)).ti,ab.	18573
8	special needs.mp.	1098
9	exp Intellectual Impairment/	140126
10	or/2-9	217548
11	1 and 10	49

**Database: Cinahl**

No.	Search terms	Results
1	Child pain assessment filter (limited to eng. language)	1432
2	((sever\$ or profound\$ or significant\$) adj2 (cognition or cognitive\$ or intellectual\$ or neurological\$ or disabilit\$ or disable\$)).ti,ab.	1997
3	((cognition or cognitive\$ or intellectual\$ or neurological\$) adj2 (impair\$ or problem\$)).ti,ab.	3284
4	exp Communicative Disorders/	8264
5	exp Cognition Disorders/	3885
6	exp Mental Retardation/	6241
7	Nervous System Diseases/	903
8	special needs.mp.	1444
9	or/1-8	23615
10	1 and 9	40

**Database: Psycinfo**

No.	Search terms	Results
1	Child pain assessment filter	1170
2	((sever\$ or profound\$ or significant\$) adj2 (cognition or cognitive\$ or intellectual\$ or neurological\$ or disabilit\$ or disable\$)).ti,ab.	6028
3	((cognition or cognitive\$ or intellectual\$ or neurological\$) adj2 (impair\$ or problem\$)).ti,ab.	12161
4	special needs.mp.	3427
5	exp cognitive impairment/	6516
6	exp communication disorders/	22741
7	exp Nervous System Disorders/	87604
8	exp special needs/	1483
9	exp mental retardation/	18259
10	or/2-9	131895
11	1 and 10	67
12	limit 11 to english language	63

**Database: British Nursing Index**

No.	Search terms	Results
1	Child pain assessment filter	407
2	((sever\$ or profound\$ or significant\$) adj2 (cognition or cognitive\$ or intellectual\$ or neurological\$ or disabilit\$ or disable\$)).ti,ab.	154
3	((cognition or cognitive\$ or intellectual\$ or neurological\$) adj2 (impair\$ or problem\$)).ti,ab.	180
4	special needs.mp.	107
5	exp learning disabilities/	1932

No.	Search terms	Results
6	((cognition or cognitive) adj2 (disorder\$ or defect\$)).ti,ab.	8
7	(communicat\$ adj2 (disorder\$ or problem\$ or unable or inabilit\$ or limit\$ or abilit\$)).ti,ab.	70
8	or/2-7	2336
9	1 and 8	
11		

**Database: Cochrane 2007**

No.	Search terms	Results
#1	((pain* or distress*) and (measur* or assess* or scale* or recogni* or score* or evaluat* or rating or observ* or validat* or perception* or response* or respond* or behav*)):ti	1816
#2	(CRIES):ti,ab,kw	484
#3	("children's hospital of eastern ontario pain scale"):ti,ab,kw	43
#4	(cheops):ti,ab,kw	51
#5	("liverpool infant distress"):ti,ab,kw	0
#6	("premature infant pain profile*"):ti,ab,kw	35
#7	("neonatal infant pain scale*"):ti,ab,kw	14
#8	("neonatal facial coding system*"):ti,ab,kw	16
#9	(tpps):ti,ab,kw	1
#10	("post*operative pain tool"):ti,ab,kw	0
#11	(toddler preschool postoperative pain):ti,ab,kw	0
#12	("objective pain scale*"):ti,ab,kw	44
#13	("objective pain score*"):ti,ab,kw	27
#14	(flacc):ti,ab,kw	7
#15	("n-pass"):ti,ab,kw	0
#16	("pain faces scale"):ti,ab,kw	0
#17	("faces scale"):ti,ab,kw	25
#18	((("pain intensity scale*" or "pain intensity score*")):ti,ab,kw	86
#19	("memorial pain assessment card*"):ti,ab,kw	7
#20	("brief pain inventor*"):ti,ab,kw	0
#21	((("pain distress scale*" or "pain distress score*")):ti,ab,kw	0
#22	("nurses assessment of pain inventory"):ti,ab,kw	0
#23	("assessment of pain inventory"):ti,ab,kw	0
#24	((("behavioral pain score" or "behavioral pain scale")):ti,ab,kw	18
#25	((("behavioural pain score" or "behavioural pain scale")):ti,ab,kw	5
#26	("riley infant pain"):ti,ab,kw	0
#27	("nursing assessment of pain intensity"):ti,ab,kw	0

No.	Search terms	Results	No.	Search terms	Results
#28	((child* or infant* or adolesc* or newborn* or pediatr* or paediatr* or neonat* or baby or babies or toddler* or teenag*)):ti,ab,kw	101494	7	(( cognition OR cognitive ) AND (disorder* OR defect* ))	468
#29	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27)	2535	8	(communicat* AND ( disorder* OR problem* OR unable OR inabilit* OR limit* OR abilit* ))	409
#30	(#28 AND #29)	1002	9	learning AND disorder*	83
#31	((sever* OR profound* OR significant*) AND (cognition OR cognitive* OR intellectual* OR neurological* OR disabilit* OR disable*)):ti,ab,kw	10708	10	learning AND disabilit*	68
#32	((cognition OR cognitive* OR intellectual* OR neurological*) AND (impair* OR problem)):ti,ab,kw	3355	11	mental AND retard*	82
#33	special AND needs:ti,ab,kw	749	12	#4 or #5 or #6 or #7 or #8 or #9 or #10 or #11	2199
#34	((cognition OR cognitive) AND (disorder* OR defect*)):ti,ab,kw	4151	13	#3 and #12	73
#35	(communicat* AND (disorder* OR problem* OR unable OR inabilit* OR limit* OR abilit*)):ti,ab,kw	852			
#36	(learning AND disorder*):ti,ab,kw	861			
#37	(learning AND disabilit*):ti,ab,kw	302			
#38	(mental AND retard*):ti,ab,kw	743			
#39	(#31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38)	15868			
#40	(#30 AND #39)	51			
#41	MeSH descriptor Pain Measurement explode all trees	7839			
#42	(pain and measure*):kw	8046			
#43	(#41 OR #42)	8046			
#44	(#29 OR #43)	9883			
#45	(#28 AND #44)	2762			
#46	(#39 AND #45)	107			

### Database: CRD

1	pain	2995
2	child* OR infant* OR adolesc* OR newborn* OR pediatr* OR paediatr* OR neonat* OR baby OR babies OR toddler* OR teenag*	7725
3	#1 AND #2	510
4	(( sever* OR profound* OR significant*) AND ( cognition OR cognitive* OR intellectual* OR neurological* OR disabilit* OR disable* ))	1581
5	(( cognition OR cognitive* OR intellectual* OR neurological*) AND ( impair* OR problem ))	355
6	special AND needs	52

# Tables of included studies

## Appendix B

### Included studies: pain assessment tools for children without cognitive impairment

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
AHTPS (Alder Hey Triage Pain Scale) Observer rated scale	Stewart et al 2004	3	Repeated X sectional study at triage in A&E setting	0-15yrs (only 2% under 1yrs); n=575	Children presenting to A&E department	k=0.84 (between investigator and triage nurse, n=575)	Correlation with discharge diagnostic group (as determined by experience) was poor: r=0.57 Significant difference before and after analgesia/intervention: p<0.001	All triage nursing staff had been trained in the use of the tool	
CAS (Colour Analogue Scale) See footnote <sup>1</sup>	Suraserani-vongse et al 2005	3	Repeated X sectional, before and after surgery	5-12 yrs; n=87	Undergoing general anaesthesia and surgery	Not relevant	Significant difference before and after surgery: p<0.0001	CAS 19.5% preferred on ward (not assessed in PACU)	
CAAT (Cardiac Analgesic Assessment Tool) Observer rated scale	Bullock and Tenenbein 2002 Suominen et al 2004	3 3	Repeated X sectional before and after analgesia Repeated X sectional before and after application of a stimulus	5-16 yrs; n=30 with pain 0-16 yrs; n=69 (two separate studies)	Admissions to emergency department at urban children's hospital 2 separate studies – 1st (n=32) children admitted to PICU after cardiac surgery with sternotomy incision	Four concurrent observers (n=32): r=0.97 (by Lin's concordance correlation coefficient)	Before and after analgesia: p<0.001  'Statistical difference' between mean CAAS scores before and after IV morphine was administered (n=37) (significance not reported)		

<sup>1</sup> One study (Bailey et al., 2007) compared the CAS, VAS and Wong-Baker FACES and found that VAS and CAS measured well against one another. However, although this study does raise some valid points about further research into the comparison of scales, it does have a number of limitations. These include concerns about ethics relating to the methodology, inadequate sample size calculation, concerns regarding the order in which scales were assessed and overstated conclusions.

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
CMPPMS (Chedoke-McMaster Paediatric Pain Management Sheet) Observer rated scale	Stevens 1990	1-	Randomised controlled trial	18mo-12yrs; n=43	Postoperative children	Not assessed	Not assessed		This study was not a validity study but uniquely used a robust design to show that outcomes in children were improved by use of this tool. We have included this study and discuss it separately.
CHEOPS (Children's Hospital Eastern Ontario Pain Scale) Observer rated scale	Suraserani-vongse et al 2001	3	Repeated X sectional before and after surgery	1-5.5 yrs; n=167	Videotapes of children in Thailand undergoing general anaesthesia and surgery in tertiary care hospitals	r=0.92 (n=30 pain behaviours) (by intra-class correlation)	Significant difference before and after surgery: p<0.001	Observers were trained in use of rating scales	Significance assessments not performed
	Tyler et al 1993	3	Repeated X sectional before and after surgery and after analgesia	6mo-12 yrs; n=43	Undergoing elective surgery	Not assessed	Significant quadratic trend analysis: p<0.001		
	Fradet et al 1990	3	Repeated X sectional before, during and after venepuncture	3-17 yrs; n=171	Undergoing venepuncture	k=0.71 overall (n=47 children)	Significant difference between during venepuncture and just before: p<0.001	Training required	

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
CHEOPS	McGrath et al 1985	3	Repeated X sectional before and after analgesia	1-7 yrs; n=20	Following circumcision	Not assessed	Score changed in response to analgesia (significance assessments not performed)		
CHEOPS modifications:									
NAPI Observer rated scale See footnote <sup>2</sup>	Joyce et al 1994	3	Reported X sectional study before and after surgery	<36 months; n=98	Post-operative children	(p<0.0001)	Significant difference between before and after analgesia scores (p<0.0001)	Convenience sample	
BOPS	Hesselgard et al 2007	3	Repeated X sectional	1 – 7yrs (4.5±1.8); n=76	Children following elective surgery	kw=0.93 (89% percentage agreement)	Significant difference before and after analgesia (p<0.001 Friedman's test). Differences between time intervals significant between before analgesia and at 15mins, 30mins and 60mins after analgesic administration (p<0.01 Wilcoxon's signed-rank test)	Nurses trained in use of CHEOPS and BOPS	Nurses not blinded to administration of analgesics. Scale uses CHEOPS as gold standard; BOPS and CHEOPS had positive correlation (rs=0.871, p<0.001). BOPS is also adapted from Princess Margaret Hospital Pain Assessment Tool (not included in this guideline), and so requires further investigation

2. One study of a modified version of the NAPI demonstrated inter-rater reliability and construct validity, although the population was a mix of children with and without cerebral palsy (Schade et al, 1996); results are not discussed here.

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
COMFORT Observer rated scale See footnote <sup>3</sup>	Van Dijk 2000	3	Repeated X sectional before and after surgery	At least 35wk ga and infants up to 3 years old; n=158	Neonates and toddlers undergoing major abdominal or thoracic surgery	k=0.70	Not assessed	Raters were trained in use of COMFORT (2hr session with videotapes and in vivo practice)	
	Blauer and Gerstmann 1998	3	Repeated X sectional before, during and after procedure	24-40wk ga neonates; post-natal age 0-214 days; n=33	Neonates undergoing endotracheal intubation, IV catheter insertion, ET suctioning and diaper changes	Not assessed	Significant increase in pain scores from before to during intubation: p<0.001; no significant difference in before v after; significant increase in pain scores from before to during IV insertion: p<0.001; no significant difference in before v after; significant increase in pain scores from before to during suction: p<0.001; no significant difference in before v after significant increase in pain scores from before to during diaper change: p<0.001; no significant difference in before v after		Results were analysed by procedure i.e. 33 neonates underwent 68 procedures giving 14,000+ observations; subgroup analyses showed larger babies and those given analgesia or sedatives had sustained higher scores

<sup>3</sup> The first study here assessed inter-rater reliability of COMFORT, while the second study assessed construct validity. Although the second study included preterm neonates, it did not assess inter-rater reliability in this age group. Our interpretation here is that this tool is valid in the age group in which these studies overlap, i.e. in term neonates. COMFORT-B (only behavioural items); other internal reliability studies suggest that this tool is an appropriate modification to the tool (Van et al, 2000; Ista et al, 2005) Construct validity of a version of the COMFORT scale which includes only the behavioural items, i.e. COMFORT-B has been shown (Hartrick and Kovan, 2002), however we found no studies assessing inter-rater reliability of this tool so it is not discussed further. One study (Bear et al, 2006) examined the inter-rater reliability of the COMFORT scale in older children (Pearson r=0.71, p<0.005). However, this study did not determine construct validity and is therefore excluded under the criteria of this guideline.

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
CRIES Observer rated scale See footnote <sup>4</sup>	Suraserani-vongse 2006	3	Repeated X sectional before, during and after surgery	Median age 1 day (range 1-23 days); n=22	Neonates before and during major surgery	ICC (95% CI) r=0.98 (0.98 – 0.98)	Significant difference in pain scores before and during surgery; Wilcoxon matched pair signed-rank test, p<0.001	Study assessed nurse preference of tools; 20% preferred CRIES and 65% preferred NIPS (n=20)	Observers not blinded to painful/pain-free situations; convenience sample Study also measured CRIES and CHIPPS. CHIPPS previously excluded from this guideline, but this study supports usefulness of NIPS and CRIES
	McNair et al 2004	3	Repeated X sectional after surgery	Neonates within 30 days of life (n=51)	Neonates having surgery in NICU in Canada	r=0.90 – 0.95	Not assessed		Raters not blinded to administration of analgesics; inter-rater reliability not fully explained Study does demonstrate both scales (CRIES and PIP) may be useful in assessing post-operative pain, although further work is needed to investigate why correlations were more divergent 24+hrs after surgery
	Krechel & Bildner 1995	3	Repeated X sectional before and after analgesia	32-60wks; n=24	Infants admitted to neonatal intensive care unit or PICU following surgery	r=0.72, p<0.0001; (n=680) (by Spearman rank)	Significant difference before and after analgesia: p<0.0001 (n=74)	Assessed nurse preference: 73% preferred CRIES	All children entering NICU or PICU after surgery

<sup>4</sup> Internal reliability studies suggest that this tool is an appropriate modification to the tool (Van et al, 2000; Ista et al, 2005) Construct validity of a version of the COMFORT scale which includes only the behavioural items, i.e. COMFORT-B has been shown (Hartrick and Kovan, 2002), however we found no studies assessing inter-rater reliability of this tool so it is not discussed further. One study (Bear et al, 2006) examined the inter-rater reliability of the COMFORT scale in older children (Pearson r=0.71, p<0.005). However, this study did not determine construct validity and is therefore excluded under the criteria of this guideline.

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
Derbyshire Children's Hospital pain tool Observer rated scale	Peden et al 2003	3	Repeated X sectional before and after surgery and before and after analgesia	1-5 yrs; n=40	Children undergoing minor or intermediate surgery	r=0.81 (Spearman rank)	Significant difference between pre-and post-analgesia scores in 19 children who needed analgesia, p<0.001 (student's t-test)		Small sample size; minor/intermediate surgery; research observer was blind to nurse ratings
Wong-Baker FACES See footnote <sup>5</sup>	Peden et al 2005 Keck et al 1996	3	Repeated X sectional before and after surgery Repeated X sectional before and after painful procedure	6-12 yrs; n=60 3-18 yrs (divided into 3 groups; 3-7yrs, 8-12, 13-18); n=118	Children undergoing various minor or intermediate surgeries Children with haematology or oncology diagnoses undergoing painful procedures, or venepuncture in phlebotomy lab	k=0.57-1 (n=248/371 observations, 8 time points) Test-retest: r=0.90, p<0.001	Significant difference between pre-and post-analgesia scores (n=32 children): p<0.001 Significant difference between pre- and post-procedural scores, p<0.001 for all children analysed together	No significant difference between numbers saying they preferred FACES v WDS	Test-retest methodology, assessed pain immediately and then 15 mins after pain event
DOLLS (adapted from Wong-Baker FACES) See footnote <sup>6</sup>	Badr et al 2006	3	Repeated X sectional before and after PAC access	4 – 10yrs; n=45	Children with cancer undergoing invasive procedures (PAC access) in Children's Cancer Centre, Beirut, Lebanon	Not relevant	Significant difference before and after procedure; t=12.45, p<0.01.	Strong correlation between ratings of DOLLS and Wong-Baker FACES in: self report (r=0.90, p<0.01); parents (r=0.73 – 0.81, p<0.01); nurses (r=0.78 – 0.82, p<0.01).	

<sup>5</sup> One study compared the reports of pain at triage between children, professionals and parents using Wong-Baker FACES. It found that professionals recorded lower pain than either children or parents (p<0.001) but found no difference between parent and children's report (p>0.05) (Maciocia et al, 2003). One study in children aged 5-12 undergoing venepuncture found very low correlation between child and parents ratings (r=0.21) finding that parents scored significantly higher than their children (p<0.001) (Chambers et al, 1999). One study found no difference (p=0.26, Mann-Whitney U-test) in the number of analgesics administered to children in two parent groups using or not using Wong-Baker FACES to measure pain in children's post operative pain at home (Unsworth et al, 2007). One study (Gharaibeh et al, 2002) compared FACES, PCT, and WDS in Jordanian children aged 3-14yrs (n=95), finding strong test-retest correlation in all three tools (FACES r=0.84, p<0.01). Children expressed a preference for the PCT tool (55.8%, n=53), although boys preferred FACES (46.8%, n=22).

<sup>6</sup> A further adaptation of Wong-Baker FACES (Franck et al, 2007) was the Temporary Tattoo Pain Scale. This RCT study examined the technique of using this scale rather than assessing its validity or reliability. The study compared the use of the paper version of the scale with the use of a temporary tattoo of the FACES pain intensity scale applied to children's arms.

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
A 6-graded faces scale (Tree-Takarn)	Bosenberg et al 2003	3	Repeated X sectional after surgery	4-12 yrs; n=110	Children undergoing inguinal surgery in two South African hospitals (all received caudal block before surgery)	Not relevant	Significant difference at treatment v after treatment: $p<0.0001$	Children were shown the scale before their surgery	
Faces Pain Scale See footnote <sup>7</sup>	Bullock and Tenenbein 2002	3	Repeated X sectional before and after analgesia	5-16 yrs; n=30 with pain	Admissions to emergency department at urban children's hospital	Not relevant	Before-after analgesia: $p<0.001$		There was a control no-pain group in whom scores were found to be 0
	Keck et al 1996	3	Repeated X sectional before and after surgery and before and after analgesia after surgery	7-12 yrs; n=75 (study 1) and n=28 (study 2)	Undergoing surgery at a paediatric hospital	Not relevant	Before-after surgery (study 1): $p<0.001$ Before-after analgesia (study 2): $p<0.05$ for 4/6 measurements		Not all before-after analgesia t-tests showed significant difference
	Chambers et al 2003	3	Repeated X sectional on two days post-op	7-12 yrs; n=110	Children undergoing day surgery rated as high pain, moderate pain or low pain (see quality comments) and their parents	Not relevant	Significant difference in score between children undergoing low/moderate pain operations and those undergoing high pain for both age groups: $p<0.05$ (see quality column) Significant difference in scores from day 1 to day 2: $p<0.0001$ Significant difference in scores on both days between high or moderate pain and low pain class (ANOVA): $p<0.0001$ , but not between high and moderate class		Determination of whether children underwent low/moderate- or high-pain minor surgery was determined by categorisation assessed in a study in 1996 by asking parent to rate post-operative pain on a VAS

<sup>7</sup> FPS: one study in children aged 5-12 years undergoing venepuncture found very low correlation between child and parents ratings ( $r=0.21$ ) finding that parents scored significantly higher than their children ( $p<0.001$ ) (Chambers et al, 1999). The FPS has been revised (with one less face) (Spagrud et al, 2003), though this adaptation has been cross validated with other tools (Miro et al, 2004; Hicks et al, 2001) we do not discuss it here as we did not find studies assessing its construct validity. One study compared the ability of the FPS to discriminate between pain intensity and unpleasantness (Goodenough et al, 1999).

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
FLACC (Face, Legs, Activity, Cry, Consolability) See footnote <sup>8</sup> Observer rated scale	Nilsson and Finnstrom 2008	3	Repeated X sectional before and after procedure	5-16yrs; n=80 (analysed in two groups: 5-10 yrs, n=40; 1-16yrs, n=40)	Children having procedural peripheral venous cannulation or percutaneous puncture of a venous port	K=0.85, p<0.001	Significant difference before and after procedure (p<0.001)	Observers familiar with FLACC	Observers not blinded to procedure; convenience sample. Correlation coefficient slightly lower in older children group (r=0.50, p<0.05) than younger children group (r=0.59, p<0.05), but still usable. Further work needed to determine whether specific studies are needed for older children.
	Suraseranivongse et al 2001	3	Repeated X sectional before and after surgery	1-5.5 yrs; n=167	Children in Thailand undergoing general anaesthesia and surgery in tertiary care hospitals	r=0.95 (n=30 pain behaviours) (by intra-class correlation)	Significant difference before and after surgery: p<0.001	Assessed practicality (time taken, asked nurses about feasibility, ease of use, general satisfaction etc): CHEOPS and FLACC scored highest; CHEOPS took slightly longer to complete	Videotapes of behaviours used for coding
	Willis et al 2003	3	Repeated X sectional, approx. 20 hrs after surgery	3-7 yrs; n=30	Post-op inpatients in children's hospital having undergone a variety of surgeries	k=1 (n=6 [17%] of sample)	Not assessed	Observations were made by nurse researcher who was familiar with use of FLACC	Convenience sample
	Manworren and Hynan 2003	3	Repeated X sectional before and after analgesia	under 3 yrs; n=147	Children in speciality units in a children's medical centre experiencing pain – as determined by clinical judgement of nurse	Assessed but through inappropriate method	Significant effect of time in one-way ANOVA (p<0.001)	Observers were trained in use of FLACC	Convenience sample

<sup>8</sup> FLACC: although one study included 'children under three years old', this was unlikely to have included any neonates (Willis et al., 2003). One study compared results reported by parents and nurses (both trained) and found no significant difference between ratings (p=0.166) (Suraseranivongse et al., 2002).

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
FLACC (Face, Legs, Activity, Cry, Consolability)	Merkel et al 1997	3	Repeated X sectional before and after analgesia	2mo-7 yrs; n=89 (three separate parts)	Children having undergone a variety of surgical procedures and now recovering in PACU	k=0.52-0.82 across categories (n=30/87 observations)	Significant decrease in FLACC scores from pre- to all three post-analgesia observations (n=29), p<0.001	Observers were trained in use of FLACC	Observers not blinded to analgesia; sedative analgesia may have affected behaviour
	Hartrick and Kovan 2002	3	Repeated X sectional before and after analgesia	1.1-5.1 yrs; n=12	Children having undergone myringotomy, tonsillectomy or adenoidectomy or simple diagnostic radiographic procedures	Not assessed for FLACC in this study	Significant difference before-after opioid analgesia (n=14): p<0.0002	Observers were experienced in use of tools for pain assessment	Reporting of numbers of people in each part of this study is inconsistent
NFCS (Neonatal Facial Coding System) See footnote <sup>9</sup> Observer rated scale	Pereira et al 1999	1-	Randomised controlled study (venous puncture or swab friction), measurements of pain before, during and after event	Gestation at age 37-41wks; n=70	Neonates randomised to venous puncture (VP) or alcohol swab friction; real time observations	Not assessed	Median VP scores significantly higher than swab during and at one and three mins after event: p<0.00001, p<0.00001 and p=0.006 respectively, but not at five and ten minutes after Greater proportion of neonates considered to be in pain (NFCS>2) during, at T=1 and T=3mins than before, T=5 and T=10mins	Allocation to painful and pain-free situation was random	

<sup>9</sup> NFCS has been adapted for preschool aged children to create the Child Facial Coding System. We found no assessment of inter-rater reliability for this derived tool (Gilbert et al, 1999).

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
NFCS	Craig et al 1994	3	Repeated X sectional before and after procedure	Gestation at age 32wks within a week of birth; n=56	Neonates videotaped undergoing routine heel lancing	89% agreement: (n=25% of infants)	Significant difference between baseline, swab and lance: p<0.0001 (MANOVA); all behaviours significantly more at lance v baseline: p<0.0001	Coders of NFCS were trained beforehand and practiced using practice observations until they achieved good agreement with experienced coders	Coded observations were 10secs prior to any contact, 10secs just after swabbing and 10secs just after lancing; IRR was determined by %agreement (method is criticised); Sample for assessing IRR was randomly selected
	Peters et al 2003	3	Repeated X sectional at various time points after surgery	Gestation at age >=35wk; postnatal age 0-18 mo; n=37	Infants and neonates having undergone major abdominal surgery, videotaped at 3-hourly assessments for up to 24 hours post-op; arterial blood was collected immediately after surgery, at 6, 12, and 24 hrs post-op	Cohen's k: >0.84 for all behaviours	Not assessed		Video recordings were made at the same time as nurses assessed child with COMFORT and VAS; IRR measured in raters assessing video recordings in which slow-motion, freeze-frame was possible
	Grunau et al 1998	3	Repeated X sectional before, during and after needlestick	Gestation at age 32 wks; n=40	Neonates undergoing routine heelstick; real time observations at six time points	r = (n=33% or 15 using FACS reliability formula – see above) for total NFCS:0.86	Significant difference between times: p<0.0001; pair-wise: no significant difference between baseline and unwrap, unwrap and swab; significant difference between swab and lance (p<0.0001) and lance and squeeze (p<0.0001)	Coders were trained beforehand using videotapes and practice coding at the bedside	

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
NIPS (Neonatal Infant Pain Scale) Observer rated scale	Suraserani-vongse 2006	3	Repeated X sectional before, during and after surgery	Median age 1 day (range 1-23 days); n=22	Neonates before and during major surgery	ICC (95% CI) r=0.98 (0.98-0.98)	Significant difference in pain scores before and during surgery; Wilcoxon matched pair signed-rank test, p<0.001	Study assessed nurse preference of tools; 65% preferred NIPS (n=20)	Observers not blinded to painful/pain-free situations; convenience sample Study also measured CRIES and CHIPPS. CHIPPS previously excluded from this guideline, but this study supports usefulness of NIPS and CRIES
	Pereira et al 1999	1-	Randomised controlled study (venous puncture or swab friction), measurements of pain before, during and after event	Gestation at age 37-41wks; n=70	Neonates randomised to venous puncture (VP) or alcohol swab friction	Not assessed	Median VP scores significantly higher than swab during and one min after event: p<0.00001, p<0.00001 respectively, but not at 3, 5 and 10 mins after Greater proportion of neonates considered to be in pain (NIPS>3) during, at T=1 and T=3mins than before, T=5 and T=10mins	Mentions that although NIPS was easier to use than COMFORT or SUN, but had the highest coefficient of variation (ratio of standard deviation to the mean; i.e. measure of dispersion of results)	Real-time evaluation of validity

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
NIPS (Neonatal Infant Pain Scale)	Blauer and Gerstmann 1998	3	Repeated X sectional before, during and after procedure	Gestational age: 24-40wk; postnatal age 0-214 days; n=33	Neonates undergoing endotracheal intubation, IV catheter insertion, ET suctioning and diaper changes	Not assessed	Significant increase in pain scores from before to during intubation: $p < 0.001$ ; no significant difference in before v after Significant increase in pain scores from before to during IV insertion: or $p < 0.001$ ; no significant difference in before v after Significant increase in pain scores from before to during suction: $p < 0.001$ ; no significant difference in before v after Significant increase in pain scores from before to during diaper change: $p < 0.001$ ; no significant difference in before v after Diaper changes had lowest change in score on NIPS, intubations had highest		Results were analysed by procedure i.e. 33 neonates underwent 68 procedures giving 1400+ observations; also analysed effect of size and use of medication on scores – larger babies and those given analgesia or sedatives had sustained higher scores; real-time observation of validity; wide spread of chronological age
	Lawrence et al 1993	3	Repeated X sectional before, during and after punctures for blood	Term and preterm neonates; n=38	Neonates undergoing routine blood sampling, videotaped for observation	$r = 0.92-0.97$ (n=20 procedures; at times before, during and after procedure)	SD in mean scores over time (ANOVA): $p < 0.001$		Videotaped assessments
NNICUPAT (Nepean NICU Pain Assessment Tool) Observer rated scale	Marceau 2003	3	X sectional before and after painful procedure (venepuncture, lumbar puncture, etc) in ventilated infants	25-36wks; n=30	Ventilated neonates in NICU before and after painful procedure	$r = 0.88$ before and during procedure, but $r = 0.48$ after procedure	Significant difference before v after procedure; $p < 0.01$		

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
OPS (Objective Pain Scale) Observer rated scale	Krechel and Bildner 1995	3	Repeated X sectional after surgery	32-60wks; n=24	Infants admitted to neonatal intensive care unit or PICU following surgery	r=0.73, p<0.0001; (n=659)	Significant difference before v after analgesia: p<0.0001 (n=77)	Assessed nurse preference: 73% preferred CRIES	All children entering NICU or PICU after surgery
OUCHER (photographic and numeric)	Beyer and Aradine 1987	3	X sectional before and after surgery	3-12 yrs; n=95	Hospitalised children undergoing surgery	Not relevant	Expected increase on first postoperative day and then reduction (no significance assessments performed)	Convenience sample	
	Aradine et al 1998	3	X sectional before and after analgesia	3-12.4 yrs; n=25	Hospitalised children (for traumatic injury or surgery)	Not relevant	Significant difference before and after analgesia, p<0.01 Subgroup analysis found similar result for numeric OUCHER (p<0.01), though sample using photographic was too small to allow statistical comparison	Children were appropriately assessed for use of either photographic or numeric OUCHER scale	
Asian Photographic OUCHER See footnote <sup>10</sup>	Yeh 2005	3	Repeated X sectional before and after two time points after surgery	3-10 yrs; n=111	Children in Taiwan admitted for outpatient surgery at Taiwanese medical centre	Not relevant	Significant difference between baseline and during surgery and baseline and after surgery: p<0.001 (study 3)	Studies 1 and 2 in this paper developed and assessed content validity of Asian OUCHER	

<sup>10</sup> Photographic OUCHER has been cross validated for parents v child v nurse. No significant difference between parent- and child rated; significant difference between nurse and child (p=0.008). No significant difference between nurse and parent. This study was in children undergoing routine immunisation (Schneider and LoBiondo-Wood, 1992). Correlation between large and small versions of Caucasian, African-American and Hispanic OUCHER was high in 3-12yr, supporting use of a smaller version (Beyer et al., 2005); one study found that a reduced version of the OUCHER poster (i.e. 8.5 x 11") was significantly correlated with the usual-sized version (11 x 16") (Jordan-Marsh et al, 1994).

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
African-American and Hispanic OUCHER OUCHER See footnote <sup>11</sup>	Beyer and Knott 1998	3	Repeated X sectional before and after surgery	3-12 yrs; n=104 (52 African-American/ 52 Hispanic)	African-American and Hispanic children admitted for various types of ambulatory surgery	Not relevant	Significant difference between pre- and post-surgical scores for Hispanic children with numeric: p=0.001; and for African-American children with numeric: p<0.001; overall result using photographic: p=0.01 (p=0.068 for photographic groups by ethnicity [n=4 and n=7])		Appropriate use of OUCHER, i.e. only children who could count to 100 used numerical scale; convenience sample; randomised order of presentation of tools in X-validation; 52 African American (26 young, using photographic, 26 older using numeric) and 52 Hispanic (26 young, using photographic, 26 older using numeric)
PAT (Hodgkinson) Observer rated scale	Beyer and Aradine 1987  Spence et al 2005	3  3	Repeated X sectional before and after surgery  X sectional in neonates on NICU	3-12 yrs; n=95  Mean gestational age: 36wks; n=144	Post-operative hospitalised children  Term and preterm infants in NICUs in Australia some undergoing surgery, some not, some ventilated and some not	Not relevant  Intra-class correlation=0.85	Reports that pattern of pre- and post- surgical scores were as expected (no significance assessments performed)  Used Levene's test to compare variance between groups (i.e. surgical v nonsurgical, term v preterm, ventilator v not) – similar measurement error (significance assessment not performed)		Seems correctly powered for subgroup analysis
	Hodgkinson et al 1994	3	X sectional in neonates in ward after surgery	Gestational age: 27 weeks to full term	Post-op term and preterm neonates	Not assessed	Found that in 2 of the 8 neonates who received a morphine infusion and were given a bolus dose, their scores fell more quickly than the other six who were infused – (no significance assessments)		Small convenience sample (n=20)

<sup>11</sup> PCT: one study found a high correlation between the PCT and a multi-size PCT in children undergoing routine immunisation; moderate correlation between parent and children's report using both HPCT and multi-size PCT (St-Laurent-Gagnon et al, 1999). One study (Gharaibeh et al, 2002) compared FACES, PCT and WDS in Jordanian children aged 3-14yrs (n=95), finding strong test-retest correlation in all three tools (PCT r=0.83, p<0.01). Children expressed a preference for the PCT tool (55.8%, n=53), although boys preferred FACES (46.8%, n=22).

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
Icelandic PIPP	Jonsdottir and Kristiansdottir 2005	3	Repeated X sectional before and after heelstick	24-42 wks gestational age; postnatal age <28days; n=24	Children in Iceland undergoing routine heelstick in NICU	r=0.96, p<0.0001 for pain event, r=0.89, p<0.0001 for non-pain, r=0.90, p<0.0001 for baseline	Significantly lower PIPP scores at pain event (p<0.0001) v non-pain; significantly higher PIPP scores at non-pain v baseline (p<0.0001)		Convenience sample; real-time observations
PIPP Observer rated scale See footnote <sup>12</sup>	McNair et al 2004	3	Repeated X sectional after surgery	Neonates within 30 days of life (n=51)	Neonates having surgery in NICU in Canada	r=0.90 – 0.95	Not assessed		Raters not blinded to administration of analgesics; inter-rater reliability not fully explained  Study does demonstrate both scales (CRIES and PIP) may be useful in assessing post-operative pain, although further work is needed to investigate why correlations were more divergent 24+hrs after surgery
POPS Observer rated scale	Ballantyne et al 1999	3	Randomised crossover study (baseline, non-pain, pain event)	Neonates; n=43	Neonates undergoing baseline, non-pain and painful event (tissue-damaging); videotaped and real time observation	r=0.93-0.96 for individual score events	Significant difference between non-pain and baseline events (ANOVA): p=0.0001		Convenience sample; real-time and videotaped observations
PRS Observer rated scale	Joyce et al 1994	3	X sectional	36 mo; n=98	Post-op	k=0.80 at T1 and 0.85 at T2	before-after analgesia: p<0.0001		
PRS Observer rated scale	Joyce et al 1994	3	X sectional	36 mo; n=98	Post-op	k=0.78 at T1 and 0.73 at T2	before-after analgesia: p<0.0001		

12 One study (Slater et al, 2008) compared PIPP with measurements of cortical haemodynamic activity in infants aged 25-43wks (n=12, 33 test occasions). PIPP and the cortical haemodynamic activity were strongly correlated (regression coefficient =0.72, 95% CI=0.32 to 1.11, p<0.001, correlation coefficient=0.566), although there was stronger correlation with facial components (regression coefficient=1.26, 95% CI=0.84 to 1.67, p<0.0001, correlation coefficient=0.744) than with physiological components (regression coefficient=0.98, 95% CI=0.05 to 1.92, p<0.004, correlation coefficient=0.398). This study did not assess construct validity. Another study of the Anderson Behavioural State Scoring System (Ahn, 2006) – excluded here as it did not assess construct validity – found a positive correlation between PIPP and CRIES (r=0.447, p=0.000) during NICU procedures on 54 infants, further supporting the use of these scales.

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
Sheffield Children's Hospital facial expression scale	Joyce et al 1994	3	X sectional, before and after surgery	5-12 yrs; n=87	Undergoing general anaesthesia and surgery	Not relevant	before and after surgery: p<0.0001	Sheffield faces scale was preferred on ward (58.4%). However, not assessed in PACU	
TPPPS Observer rated scale	Suraserani-vongse et al 2001	3	X sectional before and after surgery	1-5.5 yrs; n=167 Thai children	Undergoing general anaesthesia and surgery in tertiary care hospitals	r=0.97 (n=30 pain behaviours)	Significant difference before and after surgery: p<0.001	Assessed practicality (time taken, asked nurses about feasibility, ease of use, general satisfaction etc): CHEOPS and FLACC scored highest, except CHEOPS took slightly longer to complete	Unclear whether convenience or consecutive sample
	Hartrick and Kovan 2002	3	X sectional, post-op, before and after analgesia	1.1-5.1 yrs; n=51 (three separate parts to study)	Children having undergone myringotomy, tonsillectomy or adenoidectomy or simple diagnostic radiographic procedures	r=0.84 (n=20 children)	Significant difference before and after opioid (n=12 for combined adenoidectomy and tonsillectomy): p<0.002	Observers were described as experienced in the use of behavioural pain assessment tools	Although this study says that it cross compares tools, it actually looks at pre- and post-analgesia scores for all tools (FLACC, TPPPS and COMFORT) and then makes a comment that all changed; reporting of numbers of people in each part of this study is inconsistent
	Tarbell et al 1992	3	X sectional post-op, before and after analgesia	12-74 mo; n=74	Following minor surgery (inguinal hernia or hydrocele repair)	k=0.67 [mean for all behaviours] (n=28 [38%] of children)	Significant difference before and after analgesia (n=25 children): p<0.0001		Consecutively selected (not random) sample; observers not blind to admin of postoperative medication

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
University of Wisconsin Children's Hosp Pain Scale Observer rated scale	Soetenga et al 1999	3	X sectional, during procedure, before and after analgesia	< 3yrs; n=74	Children admitted to hospital or clinics likely to be experiencing procedural pain	r=0.92, p<0.001 (n=58)	Significant difference pre-and post-analgesia p<0.001	Raters had been 'oriented' to the proposed scale	
VAS See footnote <sup>13</sup>	Tyler et al 1993	3	X sectional before and after elective surgery	6-12 yrs; n=43	Children undergoing elective surgery	Not relevant	Significant quadratic trends for all tools in all age groups over time: p<0.001		Children were appropriately assessed for use of either photographic or numeric OUCHER scale
	Yeh 2005	3	X before and at two time points after surgery	3-10 yrs; n=111	Children in Taiwan admitted for outpatient surgery at medical centre	Not relevant	Significant difference between baseline and during surgery and base line and after surgery: p<0.001		
	Aradine et al 1988	3	X sectional before and after analgesia	3-12.4 yrs; n=25	Hospitalised children (for traumatic injury or surgery)	Not relevant	Significant difference before and after analgesia, p<0.01		

<sup>13</sup> One study compared the reports of pain at triage between children, professionals and parents using a linear scale (VAS). It found that professionals recorded lower pain than either children or parents (p<0.001) but found no difference between parent and children's report (p>0.05) (Maciocia et al, 2003); a second study compared parent v child report in children seeking treatment for painful conditions and found moderate correlation between the reports (Kelly et al, 2002); one study compared children's ratings on VAS to nurse and physician ratings and found that nurses and physicians under-rated pain (LaMontagne et al, 1991); a study in adolescents after surgery found moderate correlation between nurse and self-report and found that correlation was lower for inexperienced nurses (r=0.48) compared with more experienced nurses (r=0.74) (Favaloro and Touzel, 1990); another study compared parent v self v nurse reports in post-operative children using VAS, it found low to moderate correlation between child or mother and nurses, and moderate to high correlation between child and parent (Miller, 1996).

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
VAS (observer)	Romsing et al 1996a Romsing et al 1996b	3	X sectional post-operatively before and after analgesia	3-15 yrs; n=100	Children in Denmark undergoing tonsillectomy, nurses rating on VAS	r=0.52-0.60, p<0.001 (Spearman rank for nurse results)	Change from before-after analgesia nurse ratings: 53-58% lower after – no significance assessment		
	Suominen et al 2004	3	X sectional before and after application of a stimuli	0-16 yrs; n=69 (two separate studies)	Two separate studies – 1st (n=32) children admitted to PICU after cardiac surgery with sternotomy incision (nurse rating on VAS)	Two nurse observers (n=32): Lin's concordance correlation coefficient: 0.61	Not assessed		
	Suraserani-vongse et al 2005	3	X sectional, before and after surgery	5-12 yrs; n=87	Undergoing general anaesthesia and surgery	Not assessed	SD before and after surgery: p<0.0001	VRS 2.6% preferred on ward (not assessed on PACU)	
VRS	Suraserani-vongse et al 2005	3	X sectional, before and after surgery	5-12 yrs; n=87	Undergoing general anaesthesia and surgery	Not assessed	Significant difference before and after surgery: p<0.0001	VRS 2.6% preferred on ward (not assessed on PACU)	
WDS (Word Descriptor Scale) See footnote <sup>14</sup>	Keck et al 1996	3	X sectional before and after painful procedure	3-18 yrs (divided into 3 groups; 3-7yrs, 8-12, 13-18); n=118	Children with haematology or oncology diagnoses undergoing painful procedures	Test-retest: r=0.90, p<0.001	Significant difference between pre- and post-procedural scores, p<0.001	No significant difference between numbers saying they preferred FACES v WDS	
Word Graphic Rating Scale See footnote <sup>15</sup>	Tesler et al 1991	3	Repeated X sectional study after surgery	8-17 yrs; n=55	Children after surgery (neurological, thoracic, orthopaedic, urological, abdominal)	Not relevant	Significant time effect – i.e. pain decreased in days following surgery; p=0.002		Convenience sample

14 A similar 10cm scale ranging from no pain to severe pain (which formed part of the Abu-Saad Paediatric Pain Assessment Tool) was validated in Dutch school-age children to assess the severity of their post-operative pain (Abu-Saad et al, 1994); known-groups validation in this study was not partitioned by age group (Abu-Saad et al 1994). One study (Gharabeh et al, 2002) compared FACES, PCT and WDS in Jordanian children aged 3-14yrs (n=95), finding strong test-retest correlation in all three tools (WDS r=0.82, p<0.01). Children expressed a preference for the PCT tool (55.8%, n=53), with only 7.4% (n=7) preferring WDS.

15 The WGRS forms part of the adolescent paediatric pain tool (a tool designed to measure pain intensity, location and affect). We do not discuss this tool here as it is not exclusively measuring pain intensity (Savendra et al, 1993).

### Included studies: pain assessment tools for children with cognitive impairment

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
NCCPC-PV (Non-communicating Children's Pain Checklist – Post-operative Version)	Breau et al 2002a	3	x-sectional	3.7 – 19.6 years; n=25	Children with cognitive impairment undergoing surgery	ICC: 0.82 before surgery, 0.78 after	Caregiver and researcher scores were significantly greater after surgery (paired t-tests: $p=0.003$ & $p=0.01$ )	Nurses did not use NCCPC in this trial	Limited sampling methodology information
NCCPC-R (Revised version)	Breau et al 2002b	3	x-sectional	3 – 18 years; n=71	Children with cognitive impairments experiencing non-surgical pain	None	Significant difference between situation (ANOVA x 2): $p < 0.001$ for no-pain episode 1 vs. pain episode 1 $P < 0.001$ for no-pain episode 2 vs. pain episode 2	Care givers were briefly trained in using the tool but did not score results themselves	No inter-rater reliability test; limited sampling methodology information; not tested for clinical situations
PPP (Paediatric Pain Profile)	Hunt et al 2004	3	x-sectional	1 – 18 years; n=140	Children with severe cognitive impairment using health centre services	ICC: 0.74 ICC analgesic subgroup: 0.89	PPP vs. VRS score (ANOVA): $p < 0.001$ Significant difference in scores pre- and post-analgesia ( $p < 0.001$ )	<ul style="list-style-type: none"> <li>health care staff were given training</li> <li>parents were facilitated by a researcher</li> <li>the 1st section should ideally be completed during a discussion between parent/s and clinician</li> <li>designed for repeated use by one carer (for optimum performance)</li> </ul>	Data from the analgesic group was complicated by the variety and number of analgesia given
	Hunt et al 2007	3	x-sectional	9.6 ± 5.8 years; n=29	Children with severe cognitive impairment using hospices, care centres or hospital	ICC: 0.62	Significant differences in scores between high pain and low pain groups for each rater ( $p = 0.023 - 0.009$ )		

Tool name	Study references	Level of evidence	Study design	Validated in age:	Validated in population:	Inter-rater reliability (for observer rated tools)	Known groups validity	Practicality issues	Quality issues
FLACC (Face, Legs, Activity, Cry, Consolability)	Voepel-Lewis et al 2002	3	x-sectional	4 – 18 years; n=79	Children with varying degrees of cognitive impairment admitted for orthopaedic or general surgery	$r \leq 0.651$ for each observer	Decrease in FLACC scores after administration of analgesics $p < 0.001$	Certain categories appear to require knowledge of 'baseline' behaviour to work best	
FLACC (revised tool)	Malviya and Voepel-Lewis 2006	3	x-sectional	$11.3 \pm 4.7$ years; n=52	Children with cognitive impairment experiencing postoperative pain	ICC=0.90 (CI 0.87-0.92); k=(0.44-0.57)	Decrease in FLACC scores after administration of analgesics for both bedside nurse observers (n=20; $6.1 \pm 2.5$ vs $2.2 \pm 2.4$ ; $p < 0.001$ ) and blinded video observers' scores (n=20; $6.1 \pm 2.6$ vs $1.9 \pm 2.7$ ; $p < 0.001$ )	Additional individualised descriptors may need preoperative parent interview to establish baseline	

## Appendix C

# Tables of excluded studies

### Excluded studies: pain assessment tools for children without cognitive impairment

Tool name	Study	Reason for exclusion
NFCS modifications: NFISS	Chen et al 2005	Excluded from the final analysis as studies relied on videotaped analyses
LIDS (Liverpool Infant Distress Scale)	Horgan et al 2002 Horgan et al 1996	Excluded from the final analysis as studies relied on videotaped analyses
FACS (Facial Action Coding System – with adaptations for coding infants)	Craig et al 1994	Excluded from the final analysis as studies relied on videotaped analyses
CHEOPS modifications: Modified Behavioural Pain Scale (mBPS)	McClellan et al 2003	Excluded from the final analysis as studies relied on videotaped analyses
BPSN (Bernese Pain Scale for Neonates) <sup>117</sup>	Cignacco et al 2004	Excluded from the final analysis as studies relied on videotaped analyses

### Excluded studies: pain assessment tools for children with cognitive impairment

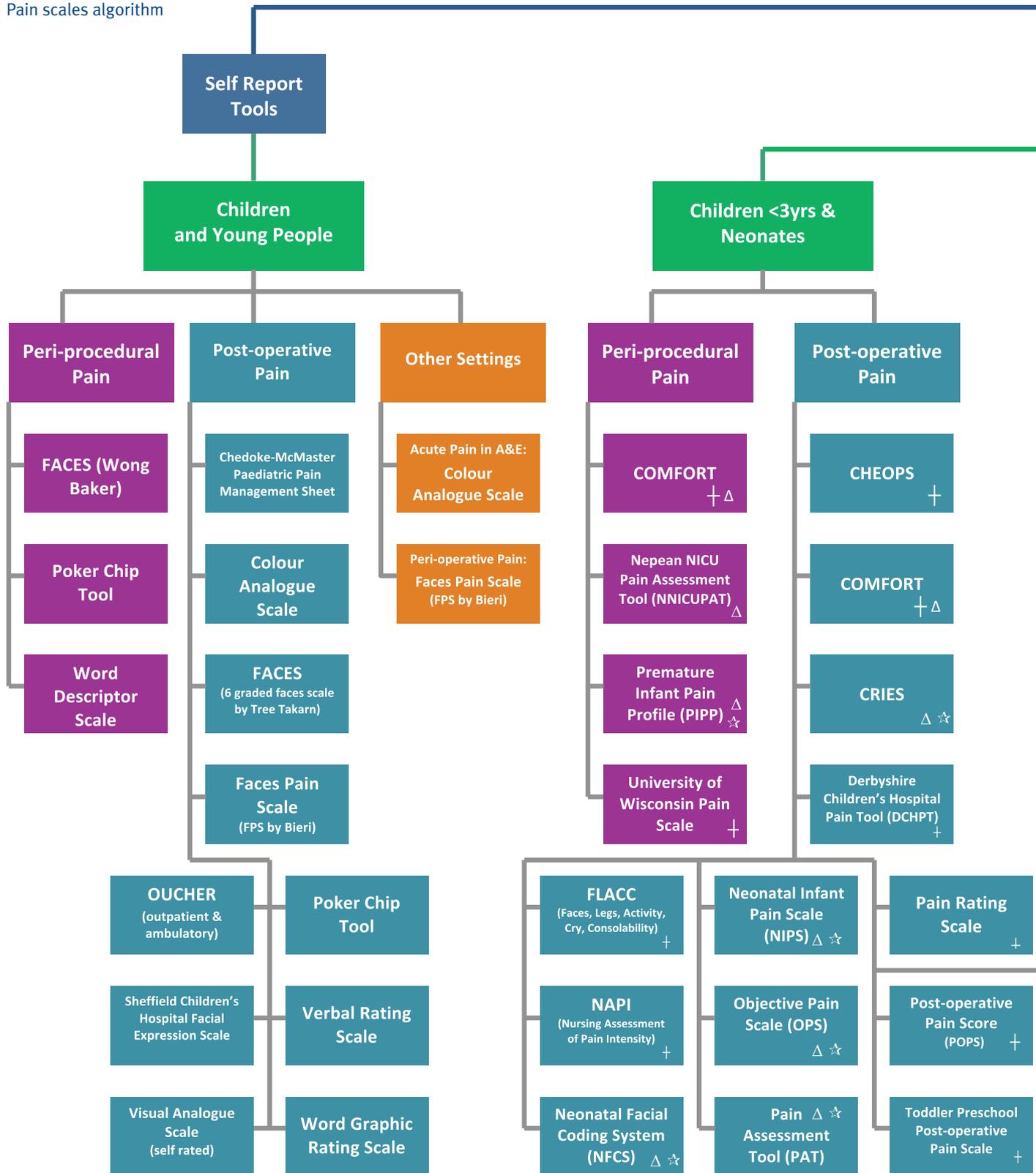
Study	Reason for exclusion
Fanurik et al 1998	Not an assessment of a tool
Fanurik et al 1999	Not an assessment of a tool
Oberlander 2001	Not an assessment of a tool
Oberlander and O'Donnell 2001	Not an assessment of a tool
Stallard et al 2001	Not an assessment of a tool
Carter et al 2002	Not an assessment of a tool
Stallard et al 2002	Not an assessment of a tool
Hadden and von Baeyer 2005	Comparison of various tools
Hunt et al 2003(b)	Not an assessment of a tool
Breau 2003	Not an assessment of a tool
Breau et al 2003	Not an assessment of a tool
Solodiuk and Curley 2003	Not an assessment of a tool
Breau et al 2004(a)	Not an assessment of a tool
Dowling 2004	Not an assessment of a tool
Breau et al 2004(b)	Not an assessment of a tool
Stevens et al 2006	Not an assessment of a tool
Breau et al 2007	Not an assessment of a tool
Defrin et al 2006	Not an assessment of a tool

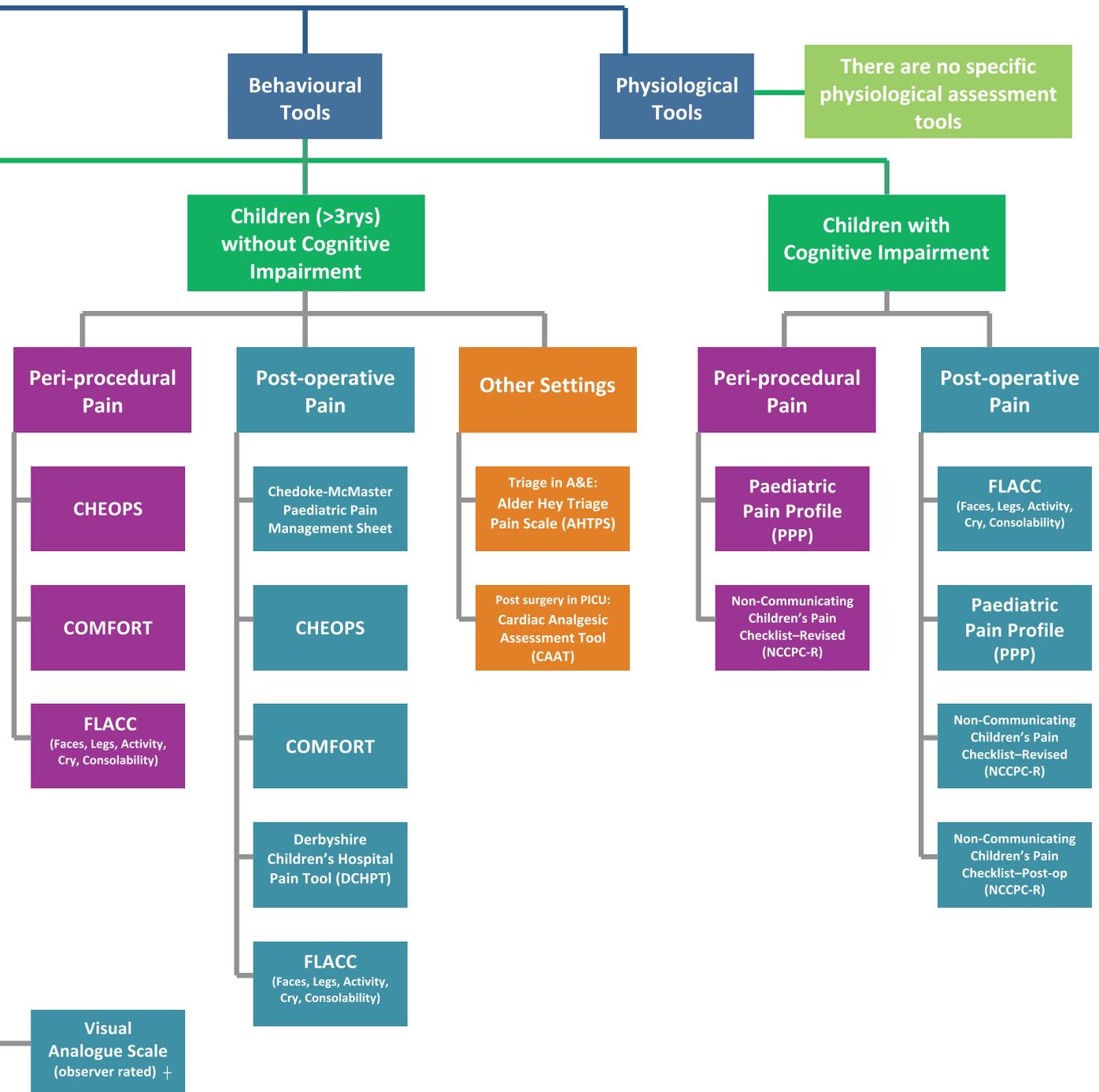
Study	Reason for exclusion
Duivendoorden et al 2006	Main objective was not to validate tool – did not test inter-rater reliability
Stevens et al 2007	Not an assessment of a tool
Breau et al 2001	Not an assessment of a tool
McGrath et al 1998	Not an assessment of a tool
Breau et al 2000	Preliminary validation – did not test inter-rater reliability
Voepel-Lewis et al 2005	Not an assessment of a tool

# Appendix D

## Diagrams

Pain scales algorithm



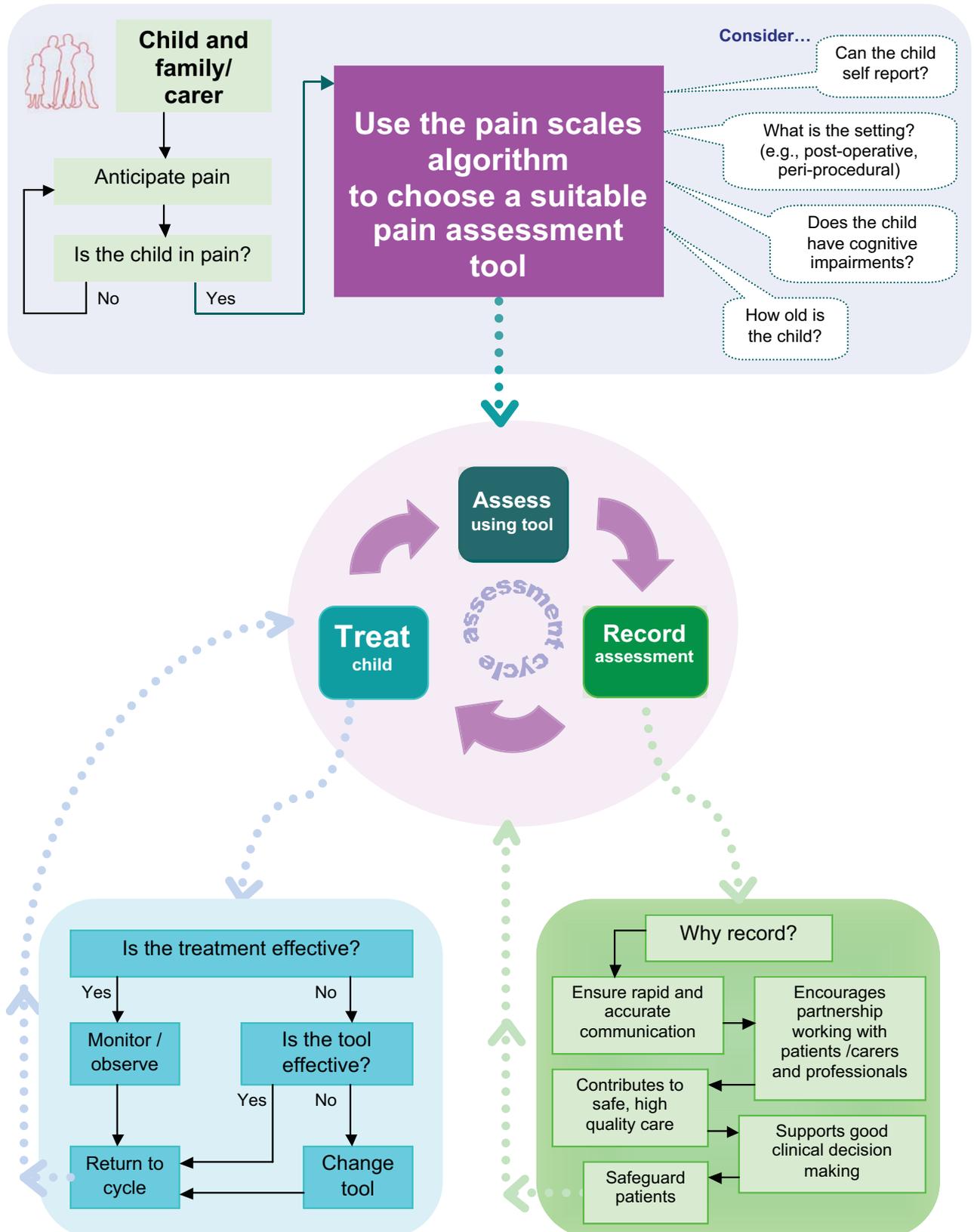


† Suitable for children <3yrs (excluding neonates)  
 Δ Suitable for neonates  
 ☆ Suitable for preterm neonates

# Appendix D

## Diagrams

Pain recognition and assessment cycle



## Appendix E

# Declarations of interests

There are no declarations of interest.

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