Evidenced-based clinical practice guideline for management of newborn pain

Kaye Spence, David Henderson-Smart, Karen New, Cheryl Evans, Jan Whitelaw, Rowena Woolnough and the Australian and New Zealand Neonatal Network

Centre for Perinatal Health Services Research, University of Sydney, Sydney, New South Wales, Australia

Aim: To facilitate the uptake of evidence and to reduce the evidence practice gap for management of newborn pain through the development of a clinical practice guideline.

Method: An audit of practice and an appraisal of clinical practice guidelines were undertaken to establish current practices and guideline availability for the management of newborn pain in 23 hospitals in Australia. Guidelines were appraised using the Appraisal of Guidelines for Research and Evaluation instrument. A literature search was undertaken to acquire the evidence for best practice for management of newborn pain.

Results: Neonatal units in 17 hospitals had clinical practice guidelines. Each was peer reviewed and assessed according to the domains of the Appraisal of Guidelines for Research and Evaluation instrument. There was lack of consistency across the guidelines. As a result, a best practice guideline was developed based on current best evidence and the Royal Australian College of Physicians recommendations. To facilitate an ongoing compliance with the guideline, an audit tool was included together with algorithms for procedural pain and pain assessment.

Conclusion: The clinical practice guideline can be used by clinicians in varying settings such as the neonatal intensive care and special care unit. The document can be used to support existing practices or challenge clinicians to close the evidence practice gap for the management of newborn pain.

Key words: Assessment; clinical practice guideline; management; newborn pain; procedural pain.

Pain management in newborn infants is an emotive issue for clinicians in the neonatal intensive care and special care units. Despite an overwhelming amount of evolving evidence on the short-term and long-term consequences of pain in newborns, the use of this evidence in practice remains variable. There is an increasing volume of scientific evidence1,2 to support the assessment,3–8 management9–14 and guidance for procedural pain15–20 and short-term and long-term effects1,2 of pain in neonates. In addition, there have been several consensus statements,21,22 guideline statements23–25 and policy directives26 at a national and international level. Despite this volume of evidence, there remains a wide practice gap between what is known and what occurs in practice.27,28

A national project, involving 23 hospitals of the Australian and New Zealand Neonatal Network, was undertaken with the aim of closing the evidence practice gap for newborn pain management. As part of this project, it became clear that a practical clinical guideline that could be adapted to each hospital’s practice was necessary to facilitate the uptake of best available evidence. The Royal Australian College of Physicians (RACP) had published their guideline statement on management of procedure-related pain in neonates.21 This statement says that guidelines need to be further developed to take into consideration local contexts. Thus, the project team identified a need within the current situation for a practical clinical practice guideline for the assessment and management of newborn pain in all hospital contexts where care is provided to newborn infants.

The aim was to develop a clinical practice guideline for newborn pain that can be adapted to specific hospital contexts, to include a dissemination strategy and tools on the use of the guidelines and to enable practice for newborn pain to be evaluated.

Key Points

1 A clinical practice guideline can be used by clinicians to provide evidence for practice.
2 The Appraisal of Guidelines for Research and Evaluation criteria are a useful tool for the assessment and development of clinical practice guidelines.
3 The management of newborn pain based on current evidence is supported by the use of a clinical practice guideline.

Correspondence: A. Prof Kaye Spence, Grace Centre for Newborn Care, The Children’s Hospital at Westmead, Locked Bag 4001, Westmead, NSW 2145, Australia. Fax: +02 9845 2251; email: kaye@chw.edu.au

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Methods

Appraisal of existing guidelines

Baseline data on current practices in relation to pain assessment and management, and the availability of a practice guideline were collected from each participating neonatal intensive care unit of the Australian and New Zealand Neonatal Network. If available, a paper copy of each guideline was collected and any identifying information was removed. Each guideline was scored using the Appraisal of Guidelines for Research and Evaluation (AGREE) criteria by two clinicians. The AGREE consists of 23 key items organised in six domains. Each domain is intended to capture a separate dimension of guideline quality. The scores were combined and averaged as recommended by the tool, and results were presented as a percentage of compliance. This appraisal revealed that there was a lack of consistency with the documents in terms of content and applicability, and it was felt that a national guideline would be beneficial. Written clinical practice guidelines were available from 17 (74%) units. Overall, 19 guidelines were appraised (two units had more than one guideline). The domains of assessment are listed in Table 1. The numbers indicate the overall percentage that met each criterion.

The overall assessment requires the appraiser to make a judgement of ‘strongly recommend’, ‘recommend (with provisos or alterations)’, ‘would not recommend’ and ‘unsure’ in terms of the quality of the guideline, taking each of the appraisal criteria into account. Following appraisal, four guidelines were ‘strongly recommended’, with a further six requiring some alterations. The remaining nine could not be recommended for further use. As a result of the review, it was agreed by the project team that the development of a document of ‘best’ practice guidelines for pain management in neonates would be required for the project. This was based on the recommendations from the RACP guideline statement, and the guideline was to be expanded to include pain assessment, the use of a pain assessment tool and narcotic withdrawal, which were not included in the RACP statement.

Development of the Clinical Practice Guideline

The development of the guideline aimed at identifying interventions that will ensure the best possible outcomes for newborn infants who experience pain from a variety of causes and interventions. The process was consistent with the National Health and Medical Research Council recommendations and was based on the best available evidence that included a statement about the strength of recommendations with the strongest applicability.

The guideline was to be comprehensive and include an easy appendix on how to use a pain assessment tool (Table 5), a list of painful procedures (Table 2) and an audit tool (Fig. 1) for ongoing audits at a local level to enable improvement in practice to occur, and two algorithms (Figs 2,3) as a guide for pain assessment and procedural pain management.

Search strategy

The search strategy to identify additional sources covering pain assessment scoring, narcotic withdrawal and family participation included searches of electronic databases for both published and unpublished studies, including, but not limited to, systematic reviews, randomised control trials, clinical trials, policy statements and clinical guidelines: CINAHL (1982–2008),...
**Audit Tool**

This tool can be used as an audit to be undertaken in each clinical area (NICU, SCN, post natal ward). The charts of all the infants discharged over a 1-month period maybe part of the audit. The results are collated and the percentage of the responses fed back to the clinical staff. Strategies to improve or sustain the assessment and management of newborn pain can be developed for each context.

1. **What is the baby’s main food source?**
   - [ ] Breast
   - [ ] Artificial formula
   - [ ] Other - please state .................................................................

2. **What painful procedures has baby experienced during hospitalisation?**
   - [ ] Heel stab
   - [ ] Intramuscular injection
   - [ ] Venepuncture
   - [ ] Other (refer to list in Table 2 of this document) – please state
     ........................................................................................................

3. **Were comfort measures instituted prior to, during or after the painful procedure?**
   - [ ] Yes
   - [ ] No

4. **Which comfort measures were used?**
   - [ ] Swaddling (wrapping in bunny rug/sheet/muslin wrap)
   - [ ] Containment (holding/cuddling)
   - [ ] Non-nutritive sucking (dummy/pacifier)
   - [ ] Other .................
   - [ ] None used

5. **Was breastfeeding offered as analgesia for painful procedures?**
   - [ ] Always
   - [ ] Mostly
   - [ ] No
   - [ ] Unsure
   - Comments:..........................................................................................

6. **Sucrose Use**
   - [ ] Yes
   - [ ] No

7. **Was sucrose administered as an analgesic?**
   - [ ] Yes
   - [ ] No

8. **Does sucrose order appear on the medication chart?**
   - [ ] Yes
   - [ ] No

9. **Is sucrose available as a standing order?**
   - [ ] Yes
   - [ ] No

**Clinical Practice Guidelines (or Policy)**

These questions need to be asked of the staff caring for the infant during the audit period.

10. **Is there a clinical practice guideline available for the management of procedural pain available in your service?**
    - [ ] Yes
    - [ ] No

11. **Is the clinical midwife/nurse (who was caring for the infant being audited) aware of the specific components of the guideline?**
    - [ ] Yes
    - [ ] No

12. **Is the registrar (that was caring for the infant being audited) aware of the specific components of the guideline?**
    - [ ] Yes
    - [ ] No

13. **Was the family (of the infant being audited) aware of the use of breastfeeding or sucrose for procedural pain?**
    - [ ] Yes
    - [ ] No

14. **Did the parent/s receive a brochure informing them of the use of breastfeeding/sucrose for procedural pain?**
    - [ ] Yes
    - [ ] No

**NICU – Ventilated infants**

15. **Was analgesia used during mechanical ventilation**
    - [ ] Yes
    - [ ] No

16. **Was a pain assessment tool/score used**
    - [ ] Yes
    - [ ] No

17. **Was the pain assessment score documented every 4 h**
    - [ ] Yes
    - [ ] No

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**Fig. 1** Sample newborn pain audit tool.

In addition, searches of the electronic databases were based on the following search terms: the MeSH terms ‘infant, newborn’ OR ‘neonate’ OR ‘nurser’, hospital’ OR ‘intensive care units, neonatal’ AND the MeSH terms ‘pain’ OR ‘pain measurement’ OR ‘pain management’ OR the text word ‘diagnostic pain’ OR ‘therapeutic pain’ OR ‘post-operative pain’ OR ‘procedure’ pain’ OR ‘pain assessment’ AND the MeSH terms ‘guideline statement’ OR ‘analgesia’ OR the text word ‘opioid’ OR ‘sucrose’ OR ‘glucose’ OR ‘breastfeeding’ OR ‘breast milk’ OR ‘expressed breast milk’ OR ‘EBM’ OR ‘comfort measures’ OR ‘swaddling’ OR ‘non-nutritive sucking’ OR ‘positioning’.

Scope and purpose

The RACP Guidelines for Newborn Pain recommends that clinical units providing health care to neonates should develop written guidelines and protocols for the management of neonatal pain. This document has been produced to assist clinicians to develop written guidelines for their clinical unit and to enable them to benchmark any existing guidelines on this topic. The document has been developed according to the AGREE domains and a search of the current best available evidence.

Newborn infants may experience pain as a result of undergoing a single or repeated procedure for diagnostic or therapeutic and/or surgical reasons (Table 2). This is true for neonates of all gestational ages in all hospital settings. Additionally, mechanically ventilated neonates are subjected to multiple invasive and procedural interventions that may be particularly painful. Sedation alone does not alleviate pain.

Guideline Recommendations

The recommendations in this guideline are based on the level of quality, relevance and strength of the evidence, which has been applied to each recommendation. The designation of levels of evidence used and quality of evidence are according to the National Health and Medical Research Council:

I – evidence obtained from a systematic review of all relevant randomised controlled trials.

II – evidence obtained from at least one properly designed randomised controlled trial.

III-1 – evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).

III-2 – evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case control studies or interrupted time series with a control group.

III-3 – evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.

IV – evidence obtained from case series, either post-test or pre-test, and post-test.

Quality of evidence – methods used to minimise bias.
High – intervention concealed from investigator, blind or double blind, complete follow-up.

Moderate – clear methods used to select subjects, comparability of treatment, use of controls, methods for measuring outcomes, follow-up.

Consensus – lack of clear evidence but acknowledged consensus from expert panels, working groups or professional organisations (Table 3).

Recommended dose and administration of sucrose

The use of sucrose is a common practice in neonatal units across Australia, and the administration and dosing requires careful consideration (Table 4).

Technique

- Two minutes prior to the painful procedure (see Table 2), administer a small amount of the dose, about one drop, onto the neonate’s tongue using a pacifier or syringe. If necessary, repeat giving a drop of sucrose onto the infant’s tongue during the procedure.
- Use the smallest amount of sucrose to provide pain relief, and if necessary, administer in small drops until the maximum recommended volume is achieved.
- Sucrose is more effective if given in conjunction with non-nutritive sucking using a pacifier.
- Intubated infants can be given oral sucrose using a syringe and placing a drop on the tongue, caution is taken to avoid gagging or choking, use one drop at a time.
- Comfort measures, such as facilitated tucking, rocking, skin-to-skin care and swaddling, may be used in conjunction with the sucrose during the procedure.

Implementation strategy

In order for the guidelines to be implemented into clinical practice, a strategy needs to be used to ensure that all stakeholders are informed and aware of the contents of the guidelines. There needs to be a commitment from the organisation that the guidelines are part of the institution’s guideline development and quality improvement initiatives. Active support from key stakeholders such as neonatologists, nursing management and clinical educators will ensure that the guidelines are accepted practice. There needs to be a recognition of the importance of change and having evidenced-based guidelines to inform practice.

Choosing a credible change agent from the unit staff who has a commitment to the guidelines and outcomes of practice will assist in the dissemination to the clinical staff. Face-to-face
Table 3  Recommendations for pain assessment and management

<table>
<thead>
<tr>
<th>Key strategies</th>
<th>NHMRC levels of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consideration of the least painful method of undertaking specific procedures is important.</td>
<td>Consensus</td>
</tr>
<tr>
<td>Provide information to parents about strategies they can use to assist their infant in coping with pain, stress and discomfort in the intensive care, special care nursery, post-natal wards and other areas of the hospital where they are cared for.</td>
<td>Lack of empirical evidence – descriptive survey design (quality of evidence – high)</td>
</tr>
<tr>
<td>Provide information to the parents that emphasises that breastfeeding or oral sucrose is effective for short duration procedures and the administration may be repeated for subsequent procedures.</td>
<td>Consensus statement</td>
</tr>
<tr>
<td>Comfort measures such as: • positioning, swaddling, containment; • a quiet environment; • pacifiers; and • a familiar odour reduce the effects of extraneous stimuli and are effective strategies for pain management.</td>
<td>III-3</td>
</tr>
<tr>
<td>Painful or stressful procedures should be minimised and when appropriate, coordinated with other aspects of the neonate’s care. Special consideration is required for infants less than 30 weeks gestation as they may not tolerate clustered cares following a stressful intervention.</td>
<td>II</td>
</tr>
<tr>
<td>A sweet-tasting solution, such as a breastfeed or sucrose, is given prior to painful procedures.</td>
<td>Quality of evidence – moderate</td>
</tr>
<tr>
<td>The use of opioid for infants with ongoing pain or post-operative pain is recommended and weaned as soon as possible to avoid narcotic dependence and withdrawal, and pain assessments should be undertaken regularly.</td>
<td>II</td>
</tr>
<tr>
<td>Premature infants, specifically those less than 28 weeks gestation, require particular attention as opioids can be harmful and their behavioural responses can be altered.</td>
<td>CII</td>
</tr>
<tr>
<td>Breastfeeds or sucrose for procedural pain</td>
<td>IV</td>
</tr>
<tr>
<td>Neonatal responses to short-duration, single-event procedures indicate that they experience considerable pain and this is often undertreated.</td>
<td>I</td>
</tr>
<tr>
<td>Breastfeeds</td>
<td>Consensus</td>
</tr>
<tr>
<td>Infants who are able to safely suckle are placed on the breast to suck for 2 min prior to and, if possible, during a painful procedure such as a heel lance.</td>
<td>Consensus statement</td>
</tr>
<tr>
<td>Breast milk</td>
<td>Consensus</td>
</tr>
<tr>
<td>Small amounts of mother’s EBM, if available, have been found to be effective for painful procedure management in newborns unable to suckle at the breast. A small amount of EBM is placed on the tongue prior to and during a painful procedure. The effectiveness of repeated doses over time has not been evaluated as yet.</td>
<td>Consensus statement</td>
</tr>
<tr>
<td>Sucrose</td>
<td>Consensus</td>
</tr>
<tr>
<td>When breastfeeding is not possible, oral sucrose has been found to be effective for repeated painful procedures during an infant’s hospitalisation in term and preterm neonates.</td>
<td>Consensus statement</td>
</tr>
<tr>
<td>Small amounts of sweet solutions placed onto the neonate’s tongue have been shown to mediate an increase in endogenous opioid release, reduce procedural pain and minimise crying following the procedure.</td>
<td>Consensus statement</td>
</tr>
<tr>
<td>The oral administration of sucrose is a safe and effective form of analgesia for short-duration procedures and may be given for repeated procedures.</td>
<td>Consensus statement</td>
</tr>
<tr>
<td>It is recommended that sucrose be ordered on the medication chart or as a standing order. This may be as a nurse-initiated medication. Document each dose with a precautionary maximum dose for every 24 h.</td>
<td>Consensus statement</td>
</tr>
<tr>
<td>The recommended sucrose concentration is a 24% solution.</td>
<td>Consensus statement</td>
</tr>
<tr>
<td>The long-term effects of sucrose use for short-duration procedures are unknown; therefore, sucrose should be used with caution for neonates hospitalised for a prolonged period of time, in particular, neonates of less than 32 weeks gestation.</td>
<td>Consensus statement</td>
</tr>
<tr>
<td>Infants of methadone-addicted mothers have altered endogenous opiate systems and the analgesic effects of oral sucrose may not be as effective.</td>
<td>Consensus statement</td>
</tr>
<tr>
<td>Sucrose has been found to be effective for immunisations in infants up to 4 months of age.</td>
<td>Consensus statement</td>
</tr>
<tr>
<td>The effect of sucrose on pain is mediated via its gustatory effect (taste), and therefore, doses are given onto the tongue (buccal). No benefit has been demonstrated when administered via a gastric tube.</td>
<td>Consensus statement</td>
</tr>
<tr>
<td>Two minutes prior to the painful procedure, administering a small amount of the dose onto the neonate’s tongue using a syringe or pacifier have a lesser risk of poor developmental outcomes in one small study.</td>
<td>Consensus statement</td>
</tr>
<tr>
<td>Pain assessment</td>
<td>Consensus</td>
</tr>
<tr>
<td>Pain assessments should be carried out by health professionals at least once per shift for all neonates following surgery, those receiving mechanical ventilation and those in intensive or special care nurseries who are subjected to painful procedures.</td>
<td>Consensus statement</td>
</tr>
<tr>
<td>A lack of behavioural responses (including crying and movement) does not necessarily indicate a lack of pain.</td>
<td>Consensus statement</td>
</tr>
<tr>
<td>Infants at risk of neurological impairment also respond to painful stimuli.</td>
<td>Consensus statement</td>
</tr>
<tr>
<td>Assessment of pain and distress in ventilated preterm infants presents special challenges.</td>
<td>Consensus statement</td>
</tr>
</tbody>
</table>
Contact with clinicians helps to promote enthusiasm, ensuring that the targeted staff have ownership of the guideline and are empowered to change. Using a selection of the clinical staff from all levels and roles may be helpful in ensuring that the best practice occurs as a result of implementing the guideline. Compliance with the guideline may be measured by the key performance indicators as listed below.

It is recommended that this guideline be reviewed every 3 years because of the current research that is in progress for newborn pain. Several tools have been included with this guideline as part of the implementation strategy. These include a guide for the use of pain assessment (Table 5), an audit tool (Fig. 1) and algorithms for the management of procedural pain (Fig. 2) and pain assessment (Fig. 3).

**Key performance indicators**

- Invasive painful procedures are performed only when necessary.
- The use of behavioural modifications and comfort measures (including repositioning, containment, swaddling, diminishing environmental noise and lighting) are implemented prior to all painful procedures.
- A sweet-tasting solution (breastfeed or sucrose) is used as analgesia before all heel lances and venepuncture for hospitalised neonates.
- Pain assessment scores are recorded at least once per shift for all ventilated neonates.

**Endorsement**

The guideline has been endorsed by:
1. Australian College of Neonatal Nurses Inc.
2. Australian College of Midwives Inc.
3. Australian and New Zealand Neonatal Network.

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**Table 3** Continued

<table>
<thead>
<tr>
<th>Key strategies</th>
<th>NHMRC levels of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Useful indicators of persistent pain in ventilated preterm infants may include facial expression, varied activity, poor response to routine care and poor ventilator synchrony.4</td>
<td>II</td>
</tr>
<tr>
<td>Pain should be assessed as frequently as other vital signs.42</td>
<td>Consensus</td>
</tr>
<tr>
<td>All neonates who undergo a surgical procedure should have their pain scores measured every 4 h for at least 48 h or until narcotics have been ceased for 48 h.12,13</td>
<td>I and IV</td>
</tr>
</tbody>
</table>

**Analgesia**

Continuous infusions of opioid are used for post-operative or post-procedural pain, and for the treatment of painful medical conditions.12

When continuous infusions of morphine are used, the addition of extra morphine is ineffective for the management of pain in additional procedures.45

Use infusions for administering synthetic opioid, such as fentanyl, as bolus doses can cause glottic and chest wall rigidity, and are not recommended.12

For the duration that the neonate requires treatment for pain, use a validated assessment tool to assess pain in a consistent way and document the assessment.6,8

Opioid infusions are used at the lowest effective dose and minimum duration based on clinical assessment.13

Neonates aged 7 days or younger may require lower doses of morphine in the post-operative period than neonates who are over a week of age.8

When opioid or other sedating medications are administered for a prolonged period, physical dependence and tolerance may develop. This means that higher opioid or sedative doses are required in order to maintain patient comfort.12

Opioid infusions administered for greater than 4 days should be weaned over a period of days at the rate of 10% of the prescribed dose per day based on the clinical assessment of the neonate.24 Close observation is required as withdrawal symptoms may appear after 3 days of weaning.13

Opioid antagonists must be used with caution in neonates who have received opioid for greater than 4 days as the antagonist may precipitate acute opioid withdrawal.14,21

Regional anaesthesia techniques (such as epidural) can be used to provide anaesthesia and analgesia for procedures on the trunk or limbs as an adjunct to general anaesthesia and for post-operative analgesia.22

**Table 4** Sucrose dose for procedural pain

<table>
<thead>
<tr>
<th>Gestational age</th>
<th>Sucrose concentration</th>
<th>Dose</th>
<th>Volume per dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Term and preterm</td>
<td>24%</td>
<td>0.012–0.12 g</td>
<td>0.05–0.5 mL</td>
</tr>
</tbody>
</table>

EBM, expressed breast milk; NHMRC, National Health and Medical Research Council.
Table 5  Guide for how to use a pain assessment tool

Getting started
• Familiarise yourself with the components of the assessment tool and the recommended actions from the score obtained.
• Stand where you can clearly see the neonate’s face and all of the body.
• Note the gestational age of the neonate.
• Observe the neonate’s behavioural state for 15–30 s.
• At conclusion of the observation, gently touch neonate’s limb to determine muscle tone/tension.
• Complete the physiological and behavioural parameters.

During the score consider

Physiological conditions that may influence the score. For example, neonates with cyanotic heart disease would score their colour as normal unless there is a change in the intensity of the cyanosis or dullness in response to pain.
• Medications the neonate is receiving or has recently received that may affect behaviour or physiological responses.
• Other environmental issues that may contribute to an elicited response from the neonate. For example, sudden bright lights, noise, activity around the bedspace.
• Document these potential distracters on the chart or in the notes at the time of the score.

When to do the assessment and score
• At the commencement of your shift – think of pain assessment as a vital sign and a priority in assessment.
• Prior to and at the completion of a painful intervention
• At least once per nursing shift (every 4–6 h) and continue as long as analgesia is being used for pain relief.
• When analgesia is being weaned, continue to score when the analgesia has been completed for a further 48 h.

Action to be taken on the results of the pain assessment score
• Depending on the assessment tool being used and the recommended thresholds, institute comfort measures or analgesia when the score is above baseline.
• Re-assess after 1–2 h after administering analgesia or comfort measures.
• If the score continues to rise, then consider increasing the dose of analgesia.
• Re-assess after 1–2 h.
• If score is constantly at 0 and analgesia is maintained, consider reducing the analgesia according to the guidelines.

Ensuring the reliability of staff in using a pain assessment score
• Each clinician needs to be able to demonstrate their reliability in their assessment of a neonate’s pain using a pain score.
• To assess the reliability of all staff and to teach new staff the following criteria for pain assessment skill, it is recommended:

 Clinicians in groups of two or three observe the neonate as described above and each clinician scores the neonate’s pain separately.

 Compare scores and see where differences occur.

 Re-observe neonate or a different neonate until consensus is reached for each.

 Parameter of the assessment tool.

 This test and retest should occur on a regular basis for all staff.

Adapted from Pain Management In Newborn Infants Practice Guideline I/C/06:0028-10:00 The Children’s Hospital at Westmead.

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References


