Guideline for the management of a child aged 0-18 years with a decreased conscious level

Appendix B

Contains;
- Methodology

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The Royal College of Paediatrics and Child Health (RCPCH) is a registered charity in England and Wales (1057744) and in Scotland (SC038299).
Methodology for the 2005 Guideline

This section outlines the methodology that was used in the development of the 2005 Guideline and applies only to those parts of the Guideline that were developed in 2005.

A grant from the National Reye’s Syndrome Foundation UK commissioned a clinical guideline for the management of children presenting with a decreased conscious level to hospital. The project began in November 2003.

Developers and conflicts of interest

A Guideline Development Group (GDG) was assembled for the project in November 2003. Potential members were ascertained from individual stakeholder groups. The members were then selected by personal invitation with an agreement on their part to contribute to the guideline development process over two years.

GDG meetings took place every 3 months with minutes kept for reference. None of the GDG stated any conflict of interest during the development process.

Literature search strategy

A list of 75 review questions were drawn up from the scope. The questions were based around themes of defining decreased conscious level, assessing children with a decreased conscious level, identifying the cause of the decreased conscious level and initial treatment strategies for the causes of decreased conscious level.

All searches were conducted on core databases Cochrane Library, Medline (1966 onwards), Embase (1980 onwards), CINAHL (1982 onwards), British Nursing Index (1985 onwards), AMED (1985 onwards). A hand search of five peer-reviewed journals Acta Paediatrica, Journal of Pediatrics, Journal of Neurology, Neurosurgery & Psychiatry Neurology Pediatrics was performed for the previous 12 months. This was to ensure that an important article, which had been recently published but not yet indexed in the electronic databases, was not missed. The references of all the selected papers were reviewed and those relevant to the clinical question were also retrieved. Criteria for selecting papers were drawn up before the searches took place. Papers were selected for review by a clinical research fellow trained in evidence-based medicine and electronic literature searching. All the searches were performed between March 2004 and July 2005.

Synthesis of evidence

Retrieved papers were reviewed by a clinical research fellow trained in evidence appraisal. Papers were selected against review questions inclusion criteria and each selected paper was summarised and entered into an evidence table. The papers were appraised on their methodological quality with the aid of Scottish Intercollegiate Guideline Network critical appraisal checklists. Each paper was given a level of evidence according to the criteria developed by the Oxford Centre for Evidence-Based Medicine. A number of the papers, which contributed to the Grade A and B recommendations, were appraised by a second member of the Guideline Development Group to ensure validity of the appraisal methodology.

Delphi Consensus Process

For subject areas in the guideline where no evidence was found a three round Delphi consensus process was carried out. A large multi-professional Delphi panel was convened for the Delphi
Consensus process (Appendix H). In the Delphi consensus process performed as part of this Guideline, the defining rules were as follows:

- The panel must be multidisciplinary and include patient/parent representatives.
- The panel should be reasonably large (i.e. 30 - 50 participants) and at least 7 panellists must respond to each statement.
- A nine-point Likert scale will be used for panellists to provide their responses to statements.
- A “Don't know” option will be provided for panellists to select for a statement regarding a field of medicine in which they have no experience.
- “Consensus agrees” will be defined as 75% of panellists selecting 7, 8 or 9 on the Likert scale for a statement.
- “Consensus disagrees” will be defined as 75% of panellists selecting 1, 2 or 3 on the Likert scale for a statement.
- Those answering “Don't know” will not be included in the statistical analysis of consensus.
- There will be no literature sent out to participants as any evidence sent out could bias the responses.
- Feedback will be provided by the statistical analysis of the group's responses and by the comments from the group anonymised.
- There will be three rounds in total.
- Any statements which fail to reach consensus will be made explicit in the final guideline.

A total of 39 panellists participated in forming over 100 statements. These statements were used to form the recommendations in areas where there was limited published evidence.

Developing Recommendations

The GDG met to agree recommendations using the evidence tables or the Delphi consensus results if no evidence was available. Any disagreements on the wording of the recommendations within the group, which could not be settled by discussion, were settled by consultation with Stakeholder Groups. After a period of consultation with the Stakeholder groups, the GDG reassessed the recommendations based on the comments received.

The final recommendations were translated into an algorithm for easy use on a Paediatric Assessment Unit or in the Emergency Department setting.

Stakeholder involvement

Stakeholders were invited to make comments throughout the guideline development process. Draft versions of the recommendations were reviewed before the final version was drawn up. Patient groups were represented as stakeholders in this project, and participated fully in the discussions.

Economic Evaluation

Economic evidence was included whenever it was available. Specific searches were performed to look for economic data regarding the core investigations recommended by the Guideline. The economic search strategy was based on the work by the NHS Centre for Reviews and Dissemination for the National Institute for Clinical Excellence. As well as the electronic databases used for clinical trials, the economic databases of the NHS Health Technology Assessment Programme and the NHS Economic Evaluation Database were also searched.

No economic evaluations were found for the topic of using the core investigations as the initial screening tests in the Guideline target population.
Economic modelling

One of the key recommendations made in the Guideline is to perform the core investigations in a child with decreased consciousness. Current practice of investigating this group of patients varies widely between professionals. Performing a cost-effectiveness analysis was beyond the scope of the guideline.

A cost-comparison analysis of performing the core investigations in children with a decreased conscious level compared with the sorts of tests performed currently on these patients has been performed (see table 1). As the number of children to whom the guideline will apply is small, the changes in investigation practices will not require the establishment of a new laboratory service. Therefore, the analysis has used the marginal costs of the laboratory consumables (blood bottles, reagents and other consumables). The costs incurred by equipment purchase, phlebotomy, staffing and other laboratory overheads have not been included as these are also incurred by current practice.

The data of laboratory consumable costs have been provided by a teaching hospital laboratory (Queen’s Medical Centre, Nottingham and therefore may represent an underestimate for smaller units.

**Table 1: Cost-comparison of the incurred marginal costs associated with sending the recommended core investigations**

<table>
<thead>
<tr>
<th>Recommended Core Investigations</th>
<th>Estimated Current Investigations</th>
<th>Extra cost (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capillary glucose</td>
<td>Capillary glucose</td>
<td>0</td>
</tr>
<tr>
<td>Blood gas (arterial or capillary or venous)</td>
<td>Blood gas (arterial or capillary or venous)</td>
<td>0</td>
</tr>
<tr>
<td>Urinalysis (dipstick at bedside)</td>
<td>Urinalysis (dipstick at bedside)</td>
<td>0</td>
</tr>
<tr>
<td>Laboratory blood glucose</td>
<td>Urea and electrolytes</td>
<td>0.22</td>
</tr>
<tr>
<td>Urea and electrolytes</td>
<td>Urea and electrolytes</td>
<td>0</td>
</tr>
<tr>
<td>Liver function tests</td>
<td></td>
<td>0.15</td>
</tr>
<tr>
<td>Plasma ammonia</td>
<td></td>
<td>0.29</td>
</tr>
<tr>
<td>Full blood count and film</td>
<td>Full blood count and film</td>
<td>0</td>
</tr>
<tr>
<td>Blood culture</td>
<td>Blood culture</td>
<td>0</td>
</tr>
<tr>
<td>1-2ml of plasma (separated, frozen and saved for later analysis if required)</td>
<td></td>
<td>0.09</td>
</tr>
<tr>
<td>1-2 ml of plain serum (frozen and saved for later analysis if required)</td>
<td></td>
<td>0.09</td>
</tr>
<tr>
<td>10ml of urine (saved for later analysis)</td>
<td></td>
<td>0.07</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>Total</strong></td>
<td><strong>£1.01</strong></td>
</tr>
</tbody>
</table>

From this basic cost-comparison study, an extra £1.01 would be needed to investigate each child presenting with a decreased level of consciousness. However, as individual laboratories use different consumables and have different purchasing agreements, this is a very rough estimate.

A cost-comparison analysis is not the gold standard economic evaluation for an evidence-based guideline. A cost-effectiveness analysis of this issue has been proposed as a research question.
Good Practice Points

Good practice points are recommendations about important issues which are highlighted by the guideline, but for which there is not, nor is there likely to be, any research evidence. This typically involves issues of communication and documentation. The Guideline Development Group used patient testimonies and the Delphi consensus process to form the Good Practice Points.

Guideline consultation process

The draft guideline was reviewed by all the Stakeholder Groups in August 2005. A public open day was held in October 2005. This event was nationally advertised by the Royal College of Paediatrics and Child Health, and personal invitations were sent to the Stakeholder Groups, the Delphi panellists and end-user groups. The open day provided a forum for the Stakeholders, parents and end-users of the guideline to discuss the recommendations. Any potential barriers to the implementation of the recommendations were identified at this meeting. The final recommendations were signed off by the Guideline Development Group after this meeting.