3rd National Audit Project of the Royal College of Anaesthetists (NAP3): major complications of central neuraxial block.

Results

Prepared by Dr Tim Cook
College Project lead
Rationale

Very rare serious complications, life-changing

Unknown prevalence and incidence

Relevance to risk/benefit analysis, informed consent
Aims

Primary aim
To determine the incidence of permanent harm (ie persisting at 6 months) after CNB
Aims

Primary aim
To determine the incidence of permanent harm (ie persisting at 6 months) after CNB

Secondary Aim
To study those cases for learning points
An epidural (or spinal) is.....

“a complex amalgam of clinical judgment, technical skills, materials and equipment, drug delivery systems, patient supervision and care pathways. In addition to inherent complications in the procedure, each of these facets has the potential to generate patient harm through a combination of patient characteristics, human error or shortfalls in performance, equipment dysfunction and broader system failures. As a consequence, an enormous number of injuries can result”.

3 sections
i Methods and quantitative results
ii Clinical review: by complication type
iii Clinical review: by indication
Clinical chapters

Each set out as……
– Headline
– What we already know
– Case review
– Quantitative aspects
– Comment
– Learning points
– References
Major complications of central neuraxial block: report on the Third National Audit Project of the Royal College of Anaesthetists

T. M. Cook¹*, D. Counsell² and J. A. W. Wildsmith³ On behalf of the Royal College of Anaesthetists Third National Audit Project

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Background. Serious complications of central neuraxial block (CNB) are rare. Limited information on their incidence and impact impedes clinical decision-making and patient consent. The Royal College of Anaesthetists Third National Audit Project was designed to inform this situation.

Methods. A 2 week national census estimated the number of CNB procedures performed annually in the UK National Health Service. All major complications of CNBs performed over 1 yr (vertebral canal abscess or haematoma, meningitis, nerve injury, spinal cord ischaemia, fatal cardiovascular collapse, and wrong route errors) were reported. Each case was reviewed by an expert panel to assess causation, severity, and outcome. ‘Permanent’ injury was defined as symptoms persisting for more than 6 months. Efforts were made to validate numerator (procedures performed) and denominator (complications) data through national databases.

Results. The census phase produced a denominator of 707 455 CNB. Eighty-four major complications were reported, of which 52 met the inclusion criteria at the time they were reported. Data were interpreted ‘pessimistically’ and ‘optimistically’. ‘Pessimistically’ there were
Acknowledgements: at the college

Project idea and inception
Prof Tony Wildsmith (College Council)
Dr Anne May (College Council)
Sir Peter Simpson, Dr Judith Hulf (Two College Presidents)
Dr David Counsell (NCAPCIA)

Hard graft!
Mr Charlie McLaughlan (Professional standards)
Ms Shirani Nadarajah (Professional standards)
Ms Edwina Jones (RCOA publications inc)
Acknowledgements: nationally

All local reporters

Raising awareness of NAP3
Performing snapshot survey
Identifying, chasing and reporting cases
Partners 1

Association of Anaesthetists of GB&I
British Pain Society
Association of Paediatric Anaesthetists
Obstetric Anaesthetists Association
European Society of Regional Anaesthesia GB&I
Partners 2

British Association of Spinal Surgeons
Society of British Neurological Surgeons
Association of British Neurologists
Royal College of Radiologists
Association of Neuroradiologists
Endorsers

| National Patient Safety Agency         |
| Patient Information Advisory Group of DH |
| Chief Medical Officer England         |
| Chief Medical Officer Scotland        |
| Chief Medical Officer Wales           |
| Chief Medical Officer Northern Ireland|
| Medical Protection Society            |
| Medical Defence Union                 |
Procedures included

Epidurals
Subarachnoid block
Combined spinal epidurals
Caudal blocks

NOT
LPs, Blood patches (As logistically impossible
Failures so data would be unreliable)
Indications included

Peri-operative
Obstetric
Pain clinic
Paediatrics
Non-anaesthetists

NHS only
Complications included

**Spinal infections** (eg vertebral canal abscess, meningitis)

**Spinal bleeding** (eg vertebral canal haematoma)

**Major nerve damage** (eg paraplegia, spinal cord damage, spinal cord infarction, major neuropathy)

**Death** (where the anaesthetic/analgesic procedure is causal)

**Wrong route errors** (iv drugs given epidurally/ intrathecally or vice versa)
Incidence and prevalence

Numerator __________________________

Denominator __________________________

Complications in 1 year __________________________

Cases in 1 year __________________________
Incidence and prevalence

Numerator

Denominator

Complications in 1 year

Cases in 1 year

Important to ensure numerator and denominator are from same population: ie NHS only
Process

Network of local reporters
All NHS hospitals ‘invited’ to participate

March 2006
310 hospitals identified
Sept 2006
100% agreed
Denominator

2-week snapshot audit.

September 2006: ‘census’ to identify
number of procedures in 12 months in UK NHS
Numerator

Local Reporters to provide comprehensive reports on EVERY case for 12 months.

complications arising from procedures performed 1st September 2006 and 31st August 2007

(Reporting window left open until March 2008)
Process of reporting

What?
Name of reporter, contact details
Name of hospital reported from
Name of hospital where anaesthetic performed

NO PATIENT DETAILS
Process of reporting

– RCA contacts Local Reporter of relevant hospital
– Local reporter creates report
– *Anonymous report* uploaded to NCAPCIA
– NCAPCIA generates report and summary to RCoA audit team
NAP3 and NCAPCIA

www.ncapcia.org.uk

A secure password protected website
NCAPCIA frontpage: password protected

NCAPCIA

National Confidential Acute Pain Critical Incident Audit

Introduction

Royal College of Anaesthetists
British Pain Society
Association of Anaesthetists of Great Britain & Ireland

This web page is not available to the general public. It is for professional use by UK doctors and nurses interested in the complications associated with techniques used to relieve pain. If you are one of that group and think that this website is of interest to you or that you may wish to contribute to the project please click here to contact the Administrators. If you are looking for information on pain management or anaesthesia you may wish to try some of our links above.
NCAPCIA pages, including surveys

National Confidential Acute Pain Critical Incident Audit (NCAPCIA)

Objectives of the NCAPCIA Project

1. To identify acute pain therapy related critical incidents in UK practice.
2. To communicate these incidents or to inform changes in current practice.
3. To facilitate networking in the resolution of litigation claims arising as a result of these incidents.

These objectives were initially aimed specifically at acute pain management related incidents but have been expanded at the request of the RCOA to include obstetric and chronic pain neuraxial interventions. In addition the site now also allows the reporting of spontaneous events, such as epidural haematoma or abscess that are commonly but not necessarily associated with neuraxial blocks.
NCAPCIA: the start of 70-odd questions with freetext......

Reported Critical Incidents

Critical Incident Categories: View All: Incident No 115

Next Incident

1) Please summarise the incident in 200 letters
2) Age
3) Sex
4) Did this patient have an operation
5) Type of Surgery or Department
6) Site of Incision or pain
7) Was the patient suffering from any of the following problems

- [ ] IHD
- [ ] CVA
- [ ] COPD/Asthma
- [ ] History of bleeding problems/coagulopathy
- [ ] Platelet dysfunction
- [ ] Diabetes
- [ ] Malignancy
- [ ] Other peripheral vascular disease
- [ ] PET/HELP Syndrome
- [ ] Obesity/Sleep Apnoea
- [ ] Neurological disorder
- [ ] Liver Impairment
- [ ] Immunosuppression
- [ ] Inflammatory Bowel Disease
NCAPCIA access for review team

### Reported Critical Incidents

**Critical Incident Categories: All Reported Incidents**

<table>
<thead>
<tr>
<th>Incident No</th>
<th>Category</th>
<th>Modification Date</th>
<th>Creation Date</th>
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<td>105</td>
<td>Epidural Abscess</td>
<td>31/10/2006</td>
<td>31/10/2006</td>
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<td>113</td>
<td>Epidural Haematoma</td>
<td>16/01/2007</td>
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<td>Epidural Haematoma</td>
<td>12/01/2007</td>
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<tr>
<td>102</td>
<td>Epidural Haematoma</td>
<td>30/10/2006</td>
<td>05/10/2006</td>
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<td>110</td>
<td>Miscellaneous Major Incidents</td>
<td>21/12/2006</td>
<td>21/12/2006</td>
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<td>109</td>
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<td>26/10/2006</td>
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<td>116</td>
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<td>27/02/2007</td>
<td>27/02/2007</td>
</tr>
<tr>
<td>111</td>
<td>Minor Neurological Injury</td>
<td>05/01/2007</td>
<td>05/01/2007</td>
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<tr>
<td>114</td>
<td>Meningitis</td>
<td>19/01/2007</td>
<td>19/01/2007</td>
</tr>
</tbody>
</table>
Review of numerator cases

Duplication excluded
Inappropriate cases excluded

Peer review of cases
Calculation of prevalence and incidence
Quantitative analysis
(how many of what)

Qualitative analysis
(what’s happening)
Review process

CONFIDENTIAL

Analytical and fair without being judgemental

Not a witch-hunt
Aware of

**Outcome bias**: knowledge of poor outcome leading to ‘harsh judgement’

**Hindsight bias**: exaggerated belief that a poor outcome would have been predicted
Review Team
NAP 3
The 3rd National Audit Project of The Royal College of Anaesthetists

Major complications of central neuraxial block in the United Kingdom

Report and findings
January 2009
Report writing team
Quantitative analysis (how many of what)

Qualitative analysis (what’s happening)
Snapshot replies

100%
Accurate vs Estimates

>92% accurate
Sums

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Obstetric</td>
<td>45%</td>
</tr>
<tr>
<td>Peri-operative</td>
<td>44%</td>
</tr>
<tr>
<td>Pain</td>
<td>6%</td>
</tr>
<tr>
<td>Paediatric</td>
<td>3%</td>
</tr>
<tr>
<td>Non-anaesthetist</td>
<td>2%</td>
</tr>
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</table>
## Sums

<table>
<thead>
<tr>
<th>Method</th>
<th>Percentage</th>
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<tr>
<td>Epidural</td>
<td>41%</td>
</tr>
<tr>
<td>Spinal</td>
<td>46%</td>
</tr>
<tr>
<td>CSE</td>
<td>6%</td>
</tr>
<tr>
<td>Caudal</td>
<td>7%</td>
</tr>
</tbody>
</table>
Denominators

*based on 25 x 2 weeks
Multiplier used was from annualised data from RUH Bath

707,000 blocks per yr*

325,000 spinals (46%)
293,000 epidurals (41%)
42,000 CSEs (6%)
48,000 caudals (7%)
Reports

84 reviewed by panel

23 cases excluded prior to review
Validation.....we approached

<table>
<thead>
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<td>NJR</td>
<td>-</td>
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<tr>
<td>NOAD</td>
<td>-</td>
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<tr>
<td>HES</td>
<td>-</td>
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<td>-</td>
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<tr>
<td>NHSLA</td>
<td>1 ?new case</td>
</tr>
<tr>
<td>MPS</td>
<td>-</td>
</tr>
<tr>
<td>MDU</td>
<td>-</td>
</tr>
</tbody>
</table>

Overall not much additional information was gained
Overall results
Indicative reports...how the reported cases were reviewed and reduced

**Vertebral Canal Abscess**

20 cases reported and reviewed

- Panel reviewed 20
- Panel agreed diagnosis 17
- Consensus: important harm 15
- Permanent harm pessimistically interpreted 8
- Permanent harm optimistically interpreted 3
- Paraplegia pessimistically interpreted 3
- Paraplegia optimistically interpreted 0
Clinical uncertainty

Statistical uncertainty
Clinical uncertainty
pessimistic and optimistic incidence
Statistical uncertainty
confidence intervals
Cases with Permanent harm

Pessimistic  30
Optimistic  14

‘pessimistic’
4.2 per 100 000 (95% CI 2.9–6.1)
1 in 23 500

‘optimistic’
2.0 per 100 000 (95% CI 1.1–3.3)
1 in 50 500
Paraplegia and death

Pessimistic 13
Optimistic 5

‘pessimistically’
1.8 per 100 000 (95% CI 1.0–3.1)
1 in 54 500

‘optimistically’
0.7 in 100 000 (95% CI 0–1.6)
1 in 141 500
Death

Pessimistic  6
Optimistic  3

‘pessimistic’ 0.8 per 100 000 (95% CI 0–1.8)
<1 in 100 000

‘optimistic’ 0.4 per 100 000 (95% CI 0–1.2).
<1 in 200 000

Four of the deaths were considered to be directly associated with CNB and two indirectly.
## Injury types

<table>
<thead>
<tr>
<th>Category</th>
<th>Total</th>
<th>Excluded from incidence calculation: full recovery</th>
<th>Included: pessimistic incidence calculation</th>
<th>Included: Optimistic incidence calculations</th>
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</thead>
<tbody>
<tr>
<td>Epidural Abscess</td>
<td>20</td>
<td>7</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Meningitis</td>
<td>6</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Vertebral canal haematoma</td>
<td>8</td>
<td>1</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Nerve injury</td>
<td>18</td>
<td>7</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Spinal cord ischaemia</td>
<td>6</td>
<td>0</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Wrong route error</td>
<td>11</td>
<td>8</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Cardiovascular collapse</td>
<td>6</td>
<td>3</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>9</td>
<td>1</td>
<td>2</td>
<td>1</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td><strong>84</strong></td>
<td><strong>30</strong></td>
<td><strong>30</strong></td>
<td><strong>14</strong></td>
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</table>
## Indicative reports

**84 Cases reported (permanent harm)**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Pessimistic</th>
<th>Optimistic</th>
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<tbody>
<tr>
<td>Abscesses (20)</td>
<td>8....3</td>
<td></td>
</tr>
<tr>
<td>Haematomas (8)</td>
<td>5...4</td>
<td></td>
</tr>
<tr>
<td>Nerve injuries (18)</td>
<td>7...3</td>
<td></td>
</tr>
<tr>
<td>Meningitis (6)</td>
<td>3...0</td>
<td></td>
</tr>
<tr>
<td>CVS collapse (6)</td>
<td>3...2</td>
<td></td>
</tr>
<tr>
<td>Wrong route (11)</td>
<td>1...1</td>
<td></td>
</tr>
<tr>
<td>Cord infarctions (6)</td>
<td>4...0</td>
<td></td>
</tr>
<tr>
<td>Miscellaneous (9)</td>
<td>2...1</td>
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## Block types

<table>
<thead>
<tr>
<th></th>
<th>Cases</th>
<th>Epidural / Spinal / CSE / Caudal</th>
<th>Perioperative / Obstetric / Chronic pain / paediatrics / non-anaesthetist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epidural Abscess</td>
<td>8</td>
<td>5 / 2 / 0 / 1</td>
<td>6 / 1 / 1 / 0 / 0</td>
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<tr>
<td>Meningitis</td>
<td>0</td>
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<tr>
<td>Vertebral canal haematoma</td>
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<td>5 / 0 / 0 / 0 / 0</td>
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<tr>
<td>Nerve injury</td>
<td>7</td>
<td>3 / 3 / 1 / 0</td>
<td>5 / 2 / 0 / 0 / 0</td>
</tr>
<tr>
<td>Spinal cord infarction</td>
<td>4</td>
<td>4 / 0 / 0 / 0</td>
<td>4 / 0 / 0 / 0 / 0</td>
</tr>
<tr>
<td>Wrong route</td>
<td>1</td>
<td>0 / 0 / 1 / 0</td>
<td>1 / 0 / 0 / 0 / 0</td>
</tr>
<tr>
<td>Cardiovascular collapse</td>
<td>3</td>
<td>0 / 2 / 1 / 0</td>
<td>3 / 0 / 0 / 0 / 0</td>
</tr>
<tr>
<td>Miscellaneous</td>
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<td>1 / 0 / 1 / 0</td>
<td>1 / 1 / 0 / 0 / 0</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>30</td>
<td>18 / 7 / 4 / 1</td>
<td>25 / 4 / 1 / 0 / 0</td>
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# Reports of harm

30 (pessimistic) included

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<tr>
<td>Peri-operative adult</td>
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<tr>
<td>Obstetric</td>
<td>4</td>
</tr>
<tr>
<td>Chronic</td>
<td>1</td>
</tr>
<tr>
<td>Paediatric</td>
<td>0</td>
</tr>
<tr>
<td>Non anaes</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epidural</td>
<td>18</td>
</tr>
<tr>
<td>Spinal</td>
<td>7</td>
</tr>
<tr>
<td>CSE</td>
<td>4</td>
</tr>
<tr>
<td>Caudal</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Cases included n=52</td>
</tr>
<tr>
<td>--------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Female : male</td>
<td>33 : 19</td>
</tr>
<tr>
<td><strong>Age in years</strong></td>
<td></td>
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<tr>
<td>&lt;16</td>
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</tr>
<tr>
<td>16–50</td>
<td>16</td>
</tr>
<tr>
<td>51–70</td>
<td>17</td>
</tr>
<tr>
<td>&gt;70</td>
<td>19</td>
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<tr>
<td><strong>ASA grade</strong>*</td>
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</tr>
<tr>
<td>1–2</td>
<td>33</td>
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<tr>
<td>3–4</td>
<td>17</td>
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<tr>
<td>Not assessed</td>
<td>2</td>
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<tr>
<td><strong>Surgery</strong></td>
<td></td>
</tr>
<tr>
<td>Elective : emergency (total operations)</td>
<td>33 : 11 (44)</td>
</tr>
<tr>
<td>Site of nursing:</td>
<td>Cases included (n=52)</td>
</tr>
<tr>
<td>-----------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Ward : ICU: died in theatre</td>
<td>11 : 34 : 2</td>
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<tr>
<td>Not recorded</td>
<td>5</td>
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</table>

**Operator for procedure**

<table>
<thead>
<tr>
<th></th>
<th>Cases included (n=52)</th>
<th>Cases with permanent injury (pessimistic interpretation), n=30</th>
<th>Cases with permanent injury (optimistic interpretation), n=14</th>
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<tbody>
<tr>
<td>Consultant</td>
<td>27</td>
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<td>Non-consultant-career grade</td>
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<tr>
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</table>
Matching subgroup numerator with denominators allows subgroup incidence calculation

<table>
<thead>
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<th>Peri-op</th>
<th>Chronic</th>
<th>Obstetric</th>
<th>Paeds</th>
<th>non-anaes</th>
<th>Sum</th>
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<tr>
<td><strong>Sum</strong></td>
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<table>
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<td>189000</td>
<td>1325</td>
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<td>325</td>
<td>775</td>
<td>324950</td>
</tr>
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<td>CSE</td>
<td>16525</td>
<td>0</td>
<td>25350</td>
<td>0</td>
<td>0</td>
<td>41875</td>
</tr>
<tr>
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<td>9000</td>
<td>11375</td>
<td>0</td>
<td>18050</td>
<td>9125</td>
<td>47550</td>
</tr>
<tr>
<td><strong>Sum</strong></td>
<td><strong>312450</strong></td>
<td><strong>40675</strong></td>
<td><strong>320425</strong></td>
<td><strong>21500</strong></td>
<td><strong>12375</strong></td>
<td><strong>707425</strong></td>
</tr>
</tbody>
</table>
Indication and block type: pessimistic incidences

<table>
<thead>
<tr>
<th></th>
<th>Perioperative</th>
<th>Obstetric</th>
<th>Chronic pain</th>
<th>Paediatric</th>
<th>Non-anaesthetists</th>
<th>Sum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epidural</td>
<td>17.4 (7.2–27.8)</td>
<td>0.6 (0–3.4)</td>
<td>0 (0–10.7)</td>
<td>0 (0–95.9)</td>
<td>0 (0–121.1)</td>
<td>6.1 (3.6–9.7)</td>
</tr>
<tr>
<td>Spinal</td>
<td>2.6 (1.0–6.2)</td>
<td>1.5 (1.0–5.4)</td>
<td>0 (0–226.1)</td>
<td>0 (0–921.8)</td>
<td>0 (0–386.6)</td>
<td>2.2 (1.0–4.4)</td>
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<tr>
<td>CSE</td>
<td>18.2 (3.7–53.0)</td>
<td>3.9 (1.0–22.0)</td>
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<td>n/a</td>
<td>n/a</td>
<td>9.6 (2.6–24.5)</td>
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<tr>
<td>Caudal</td>
<td>0 (0–33.3)</td>
<td>n/a</td>
<td>8.8 (1.0–49.0)</td>
<td>0 (0–16.6)</td>
<td>0 (0–32.8)</td>
<td>2.1 (1.0–11.7)</td>
</tr>
<tr>
<td>Total</td>
<td>8.0 (5.2–11.8)</td>
<td>1.2 (1.0–3.2)</td>
<td>2.5 (1.0–13.7)</td>
<td>0 (0–13.9)</td>
<td>0 (0–24.2)</td>
<td>4.2 (2.9–6.1)</td>
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</tbody>
</table>
## Indication and block type: optimistic incidences

<table>
<thead>
<tr>
<th>Block Type</th>
<th>Perioperative</th>
<th>Obstetric</th>
<th>Chronic pain</th>
<th>Paediatric</th>
<th>Non-anaesthetists</th>
<th>Sum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epidural</td>
<td>8.2 (3.5–16.1)</td>
<td>0.6 (0–3.4)</td>
<td>0 (0–10.7)</td>
<td>0 (0–95.9)</td>
<td>0 (0–121.1)</td>
<td>3.1 (1.4–5.8)</td>
</tr>
<tr>
<td>Spinal</td>
<td>1.6 (1.0–4.6)</td>
<td>0 (0–2.2)</td>
<td>0 (0–226.1)</td>
<td>0 (0–921.8)</td>
<td>0 (0–386.6)</td>
<td>0.9 (0–2.7)</td>
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<tr>
<td>CSE</td>
<td>12.1 (1.5–43.7)</td>
<td>0 (0–11.8)</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>4.8 (1.0–17.3)</td>
</tr>
<tr>
<td>Caudal</td>
<td>0 (0–33.3)</td>
<td>n/a</td>
<td>0 (0–26.3)</td>
<td>0 (0–16.6)</td>
<td>0 (0–32.8)</td>
<td>0 (0–6.3)</td>
</tr>
<tr>
<td>Total</td>
<td>4.2 (2.2–7.1)</td>
<td>0.3 (0–1.7)</td>
<td>0 (0–7.4)</td>
<td>0 (0–13.9)</td>
<td>0 (0–24.2)</td>
<td>2.0 (1.1–3.3)</td>
</tr>
</tbody>
</table>
## Progress (over 6 months) of those initially reported with nerve injury

<table>
<thead>
<tr>
<th></th>
<th>Cases reported with initial neurological impairment</th>
<th>Major improvement</th>
<th>No or minimal improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ischaemia</td>
<td>5</td>
<td>0 (0)</td>
<td>5 (100)</td>
</tr>
<tr>
<td>Abscess</td>
<td>12</td>
<td>7 (58)</td>
<td>5 (42)</td>
</tr>
<tr>
<td>Nerve injury</td>
<td>13</td>
<td>9 (69)</td>
<td>4 (31)</td>
</tr>
<tr>
<td>Meningitis</td>
<td>3</td>
<td>3 (100)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Vertebral canal haematoma</td>
<td>8</td>
<td>6 (75)</td>
<td>2 (25)</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>41</strong></td>
<td><strong>25 (61)</strong></td>
<td><strong>16 (39)</strong></td>
</tr>
</tbody>
</table>
Reports
Natural history

Of 84 cases

<table>
<thead>
<tr>
<th>Neurological injury with known progress</th>
<th>41</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full or almost complete recovery</td>
<td>25</td>
</tr>
<tr>
<td>None or partial recovery</td>
<td>16</td>
</tr>
</tbody>
</table>
Quantitative analysis (how many of what)

Qualitative analysis (what’s happening)
Comments

− Many of the patients in whom problems arise are highly complex
− The same predictable problems were seen as in previous reports
− System errors (e.g., wrong routes)
− Variation in practice (lack of protocols)
Good practice

Lots of…..

– generally good practice
– APS involvement rule rather than exception
– Patient review generally good
– Clear explanation of problems to patients
not so good….

Some….

– Incomplete aseptic technique (consultants)
– Indwelling catheters >5-7d for questionable reasons
– Lack of evidence of risk-assessments
– Delays in senior review when problems
– Delays in seeking neurological review
– Delays in getting neurological review
– Lack of urgency when complications considered
Sections 2 and 3

ii Clinical review: by complication type

iii Clinical review: by indication
Spinal cord Ischaemia

5 relevant cases (4 meet audit criteria)
All elderly frail patients
All peri-operative epidurals
All did notably poorly

Risk factors rarely present
Hypotension not common
Delays in diagnosis
?Causative
Vertebral canal Haematoma

8 cases notified (5 meet audit criteria)
7/8 elderly peri-operative patients
Unfit
All elective
All epidurals (most thoracic)

Few traumatic procedures
50% at time catheter removed
Vertebral canal Haematoma

Standard anticoags (mostly)
Weak legs
Sometimes unilateral

Avoidable delays in diagnosis
Avoidable delays in treatment

All but one did badly
Abscess

20 notified (17 were abscesses!, 15 in audit)

Most had risk factors
- Immunocompromise
- Prolonged catheterisation

7 definitely recovered
- 8 pessimistically harmed
- 3 optimistically
Abscess

14/17 epidurals
  – 10/14 thoracic
2 spinal
1 caudal

13/15 peri-operative

Several very late presentations (weeks)
Abscess

*Staph aureus* commonest organism

7 of 15: infected at time of CNB, but different organism in 6!

Presentation with no local signs common

Apparent improved prognosis if external signs noted

Conservative management frequent
Meningitis

6 cases notified

3 confirmed and included

All 3 (indeed all 6) made full rapid recoveries
Nerve and spinal cord injury

18 notifications
  - 4 excluded
  - for lack of anaesthetic causation, out-with the reporting period

13 judged: physical injury (from needle or catheter)
  - 7 made a documented full recovery within six months
  - 6 harmed pessimistically, 3 optimistically

One patient developed paraplegia from arachnoiditis.

Generally younger group than other injuries (random ages)
No patterns
Nerve and spinal cord injury

Paraesthesia: when.....

prolonged/persisting severe bilateral

...should not be ignored!
A nurse died two hours after giving birth when an epidural anaesthetic was injected into her arm instead of her spine, an inquest heard yesterday.

And in a cruel twist Mayra Cabrera's husband is facing deportation - because his wife is no longer working.

Mrs Cabrera, 30, moved from the Philippines in 2002, to begin work as a theatre nurse at the Great Western Hospital in Swindon.

Her husband Arnel followed a year later and found work at the same hospital.

He was granted a visa until February this year on the condition of his wife's work.

The couple were thrilled to discover Mrs Cabrera was pregnant.

But when she went into labour on May 11, 2004, something went terribly wrong.

Mrs Cabrera was given an epidural anaesthetic, but the drip was wrongly connected to a line into her right arm, intended for a painkiller or saline solution, the inquest heard.

Her baby, Zac, was delivered with forceps at 8.14am. But by 9am Mrs Cabrera was feeling dizzy.

She began to fit and had heart attack, dying hours later.

Coroner David Masters said: "In the early stages of the resuscitation a bag of Bupivacaine for epidural was found to have been set up and attached to the patient's right hand.

"Dr Benedict Maxwell directed that the bag be detached immediately.

"He did not consider at that time that this was relevant to the death but the present diagnosis was an amniotic fluid embolism."
NPSA strategy
PASA report
Focus on connectors
Fail-safe solutions
Wrong route

NAP3
Estimated 365,000 spinals per annum

No inadvertent wrong spinal drugs errors
CVS collapse

6 Notified

3 Deaths
   All spinals
   All peri-operative

Non deaths
Uneventful caudal (? Vasovagal)
Thoracic epidural + test then GA
   (total spinal)
LSCS after EFL (high block)
Miscellany

Subdural bleed (2)

one following an obstetric spinal
one following dural tap during a failed epidural

?permanent harm
Learning points

- Subdural haematoma is a recognised complication of CNB, due to CSF loss.
- Multiple attempts at dural puncture may increase the CSF leak.
- Aspiration of CSF after accidental dural puncture is unnecessary and ill advised.
- Atypical or persistent headache after CNB should lead to investigation to exclude subdural haematoma.
Peri-operative

44% of all blocks
83% of cases of harm

Incidence of harm after peri-operative CNB
(pessimistic) 8.0 in 100,000
(95% confidence interval 5.2–11.8) or 1 in 12,500
(optimistic) 4.2 in 100,000
(95% confidence interval 2–7) or 1 in 24,000
Peri-operative Epidurals
1 in 7 of CNB
1 in 2 of cases of harm

Incidence of harm after peri-operative CNB
(pessimistic) 17 in 100,000 (95% confidence interval 10–28) or 1 in 5,800
(optimistic) 8 in 100,000 (95% confidence interval 4-16) or 1 in 12,000
Peri-operative

This *does not* equate to peri-operative CNB being more dangerous

- Case mix
- Benefits
- Risks of other omission
- Risks of alternatives
Permanent harm (peri-op)
pessimistically 1 in 5,500 cases (18 in 100,000, 95% CI 3.7–53)
optimistically 1 in 8,300 (12 in 100,000, 95% CI 1–44).

CSE

<6% of blocks

>13-14% of major complications

15–40% of cases of paraplegia/death

2 deaths
Obstetrics

Low incidence of permanent harm

45% of all UK CNB
<14% of cases of harm

1 abscess, 2 nerve injuries, 1 subdural
Obstetrics

permanent harm

pessimistically
4 in 320,425 CNB (1 in 80,000)
(1.24 in 100,000, 95% CI 1–3.2)

optimistically
1 in 320,425
(0.2 in 100,000, 95% CI 0–1.7)
Obstetrics

Wrong route is a big issue
Direct nerve injury
Don’t forget subdurals
Neuraxial infections

No ischaemia
no haematomas

Young fit patients!!
Chronic pain

3 cases reported
Only one included (pessimistic)

Vertebral canal abscess
Following a caudal

1 case of neurological deficit (?) following a single shot lumbar epidural (full recovery)

1 case CVS collapse/cardiac arrest followed a lumbar epidural (full recovery)
Paediatrics

>80% of CNB were caudals

No permanent harm

One deep abscess (not reaching canal)

Consistent with recent 10,000 patient UK epidural study
Evidence of avoidable harm
Comments

Incomplete asepsis
Failure to follow recommended practices
Catheters in unnecessarily long
Delays in diagnosis
WEAK LEGS
Recommendations

Good practice in the management of continuous epidural analgesia in the hospital setting

November 2004

63

2004
Patient safety alert

Safer practice with epidural injections and infusions

The National Patient Safety Agency (NPSA) has identified actions that can make administering epidural injections and infusions safer.

Between 2000 and 2004, three patient deaths were reported following the administration of epidural bupivacaine infusions by the intravenous route.

A review of reports made to the NPSA between 1 January 2005 and 31 May 2005 reveals that there were 346 incidents reported that involved epidural injections and infusions.

Most of those resulted in no or low harm, and included six incidents where epidural medicines had been administered by the intravenous route. The others included wrong route errors where intravenous medicines had been administered by the epidural route and the wrong product selected, resulting in the wrong drug or dose being administered.

These incidents highlight a number of risks related to epidural injections and infusions, including how the medicines and devices are labelled, stored and used. Managing these risks successfully will make patient care safer.

Action for the NHS and the independent sector

The NPSA recommends all NHS and independent sector organisations in England and Wales take the following steps to minimise risk when administering epidural injections and infusions:

1. Clearly label infusion bags and syringes for epidural therapy (whether purchased commercially, manufactured by the hospital pharmacy or prepared in clinical areas) with "For Epidural Use Only" in a large font. Make judicious use of colour and design to differentiate these products from those for administration by intravenous and other routes.

2. Minimise the likelihood of confusion between different types and strengths of epidural injections and infusions:

   a. Rationise the range of epidural injections and infusions available, and introduce procedures for preparing and administering these products. Undertake an annual audit to ensure epidural practices adhere to the agreed range of products and procedures.

   b. Maximise the use of ready-to-administer epidural infusions to help reduce the need for complex calculations and preparations.

For response by:
- All NHS and independent sector organisations in England and Wales

For action by:
- The chief pharmacist/pharmaceautical advisor should lead the response to this alert, supported by the chief executive, medical director, nursing director and clinical governance lead/manager.

For the NPSA has informed:
- Chief executives of acute trusts, primary care trusts, ambulance trusts, mental health trusts and local health boards in England and Wales.
- Chief executive/regional directors and clinical governance leads of strategic health authorities (England) and regional offices (Wales).
- Healthcare Commission.
- Healthcare Inspectorate Wales.
- Welsh Assembly.

Products, regulatory agency:
- NHS Purchasing and Supply Agency.
- Business Services Centre (Wales).
- Welsh Health Supplies.
- Royal Colleges and societies.
- NHS Direct.
- Relevant patient organisations and community health councils in Wales.
- Relevant education providers.
- Independent Healthcare Advisory Services.
- Commission for Social Care Inspection.

Ref: NPSA/2007/21

Immediate action
Action ✓
Update
Information request
Late presentations

weeks or months
to others
delayed diagnosis
A letter for those who have had a CNB

See report Appendix 1

**Trust ADDRESS**

**Post Epidural Infusion / Injection Patient Instruction Leaflet / Discharge Instructions**

**Introduction**
Serious complications from epidural analgesia are rare (1 in 10,000). Because the epidural space is close to the spinal cord, a collection of pus, or a blood clot can cause pressure on the spinal cord. In the unlikely event that there is pressure on the spinal cord, it is crucial to diagnose and treat it as quickly as possible; this must be done by expert hospital doctors to prevent delays in treatment and long-lasting damage. This leaflet tells you what to look for and what action to take if you think that you have a problem.

**Assessment before the removal of epidural catheter**
At the end of treatment with your epidural infusion, the team of doctors and nurses caring for you will examine you to ensure that you do not have any residual numbness or weakness of your legs from the action of the drugs in your epidural infusion. They will ask you to move your legs and examine you to make sure that the sensation in your legs is as it was before the operation. It is important to remember that some operations can cause altered sensation in the legs, therefore any changes experienced may be as a result of the surgery and not the epidural. If you do have altered sensation when the epidural is removed, the attending team can discuss this with you.

If you experience any of the listed signs and symptoms (see list below) as a new problem, after your epidural infusion has been stopped as an inpatient, ask the nurse in charge of the ward to contact the Pain Team or on-call anaesthetist immediately.

If you have been discharged it is important that you contact the on-call anaesthetist at the hospital immediately (Telephone XXXX XXXXXX) and ask the switchboard operator to bleep XXXX). After speaking to the on-call Anaesthetist they will arrange to see you in the Accident and Emergency department in order to examine you.

**Signs and symptoms**
- Redness, pus, tenderness, or pain at the epidural wound site
- Feeling generally unwell despite the fact that all seems to be well with the surgical wound
- High temperature, neck stiffness
- Numbness and or weakness in your legs / inability to weight bear
- Difficulty passing water / incontinence of faeces

**Further Information**
For further information on this subject, please contact: Pain Nurse Specialist on Ext XXXX or Bleep XXXX.
Weak legs
....a problem
see chapter 15

Issues
Not identified as abnormal
Ignored when found
Infusions restarted
Poor outcomes.....
**Red flags**

The following can be considered as ‘red flags’: these routinely require immediate referral to an appropriate anaesthetist and consideration of neuroimaging

- Significant motor block with a thoracic epidural
- Unexpectedly dense motor block, including unilateral block
- Markedly increasing motor block during epidural infusion
- Motor block that does not regress when an epidural is stopped.
- Recurrent unexpected motor block after restarting an epidural infusion that was stopped because of motor block
Flowcharts for management of weak legs

See report Appendix 3
Flowcharts for management of weak legs

See report Appendix 3

Management of leg weakness with epidural analgesia

All patients receiving epidural analgesia must have leg strength assessed regularly using the leg strength score that appear on the epidural observation form. Thoracic epidural analgesia should not cause profound leg weakness. Increasing leg weakness usually means the infusion rate is too high. However it may mean that the patient is developing an epidural haematoma. If not diagnosed and treated promptly, this will lead to paraplegia. Use this algorithm to help differentiate.

- Increasing leg weakness? Leg strength score 3 or 4?
  - YES: Recommend epidural infusion
  - YES: Reassess leg strength every 30 minutes
  - YES: Patient comfortable?
    - NO: Contact the Acute Pain Team to reassess the patient’s analgesia
    - YES: Leg strength improving?
      - NO: More than 4 hours since stopping epidural infusion?
        - NO: Suspect an epidural haematoma. Proceed as follows
          - YES: Contact the Acute Pain Team and inform them of the situation

During weekday office hours contact a member of the Acute Pain Team (XXXX or bleep YYYY) who will arrange an urgent spinal MRI scan through the neuroradiology department and contact the neurosurgical team on take. After hours and weekends contact the Anaesthetist on call (bleep ZZZ) who will arrange an urgent spinal MRI scan through the on call radiologist and neurosurgical teams. An epidural haematoma has to be evacuated within 8 hours of the onset of symptoms for your patient to have the best chance of recovery of neurological function. Do not delay.
The Bromage scale was graded as set out in the table below.\textsuperscript{1} A modification of the scale has also been described by Breen et al.\textsuperscript{2}

<table>
<thead>
<tr>
<th>Grade</th>
<th>Criteria</th>
<th>Degree of block</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Free movement of legs and feet</td>
<td>Nil (0%)</td>
</tr>
<tr>
<td>2</td>
<td>Just able to flex knees with free movement of feet</td>
<td>Partial (33%)</td>
</tr>
<tr>
<td>3</td>
<td>Unable to flex knees, but with free movement</td>
<td>Almost complete (66%)</td>
</tr>
<tr>
<td>4</td>
<td>Unable to move legs or feet</td>
<td>Complete (100%)</td>
</tr>
</tbody>
</table>

References

Project weaknesses

- Excludes independent sector
- Known unknowns
- Unknown unknowns (Rumsfeld factor)
- Focus only on adverse effects of blocks
- Focus only on severe adverse events
Summing up

Project demanding but largely successful

Quantitative: Incidence (early minimum estimates)
  – lower than feared by some

Qualitative review at least as useful
Executive Summary

Major complications of central neuraxial blocks:
The 3rd National Audit Project of the Royal College of Anaesthetists
SUMMARY

1. This project achieved widespread awareness within the specialty. There was a universal response to the census phase and attempts at validation did not identify cases which had not been notified to or identified by the project. This suggests that the project has achieved its goals. As such the estimates of incidence are likely to be robust, certainly as robust as is achievable.

2. The incidence of permanent harm following CNB in this series, in all groups considered, is lower than reported in some smaller studies and this is reassuring. The incidence of permanent harm based on an optimistic interpretation of the reported cases reported is approximately half that if all cases are judged pessimistically.
3 Two thirds of patients with complications reported to the project made a full recovery. However patients with vertebral canal haematoma and spinal cord ischaemia had a poor prognosis, with most patients being left with significant disability after these complications.

4 Most complications leading to harm occurred following CNB performed in the perioperative setting. The incidence of complications in children, and after CNB for chronic pain or obstetric indications seems to be extremely low.

5 The majority of complications after perioperative CNB occurred after epidurals. Perioperative epidurals represent approximately 1 in 7 of all CNB, but accounted for more than half of complications leading to harm. The data do not clarify whether this is because perioperative epidurals are intrinsically unsafe or because these patients have particularly high risk.
6 Considering the relatively small number of combined spinal epidurals performed (<6% of all CNB) the number of associated reports of harm (>13%) is concerning.

7 Failure to follow published recommendations is a recurring issue in some of the reported complications.

8 Several reported cases illustrate that failure to identify and understand the relevance of inappropriately weak legs (including unilateral weakness) after CNB or during continuous postoperative CNB can lead to avoidable harm.
9 Organisational deficiencies contributed to delays in diagnosis and intervention in several cases and led to avoidable harm. Delays included failure to monitor, poor understanding of abnormal findings (by nurses and doctors), poor interdepartmental referral processes, scanning equipment which was routinely unavailable out of hours or broken, and lack of availability of beds in tertiary referral centres for patients requiring specialised emergency surgery.

10 A care bundle for CNB might usefully be developed. On the basis of this report its most useful application would be in the management of perioperative epidurals. Such a care bundle might usefully include aspects such as balancing risk/benefit before insertion, optimal choice of the vertebral level for CNB, use of a full aseptic technique, management of difficult procedures, patient monitoring and daily assessment of the risk/benefit of continued use. If such a care bundle were to be developed audit of its implementation would be appropriate.
3 messages

NAP3 data is notably reassuring

CNB can lead to complications with and without good practice

Progress in patient safety will be made not by doing new things, but doing better the things we already do (Gawande)
3rd National Anaesthesia Audit

tcook@rcoa.ac.uk

as good as you made it
Obstetrics

Learning points

• Obstetric CNB appears acceptably safe
• Infrequent complications are probably due to maternal health and brief epidural catheterisation.
• Nerve injuries: consider obstetric causes. Neurology opinion and good electrophysiological studies are indicated
• Multiple attempts at CNB, especially with bleeding, may increase infection risk
• Headache is common but remember meningitis and subdural haematoma
• Block height is unpredictable after multiple blocks
• Wrong route errors are notably more common in obstetrics. This merits specific consideration
Abscess

Learning points

• Presentation may be varied, including simply sepsis
• Delay in diagnosis is commoner than delay in treatment
• Still evidence of anaesthetists not using full aseptic technique for CNB.
• Epidural analgesia used patients with risk factors for an abscess should prompt particularly close monitoring…..
• ….especially when epidural catheterisation is beyond 48 hours.
• Abscesses may present well after discharge from hospital, (even weeks or months later) a letter indicating CNB has been performed may be suggested
Vertebral canal Haematoma

Learning points

• Incidence is low
• All occurred during post-op epidural infusions and most in elderly high risk patients after major surgery
• All except one had drugs interfering with coagulation
• Back pain was rare: weak legs were universal and often missed as a ‘red flag’
• Using strategies that minimise weak legs may increase the chance of early recognition
• Prognosis was poor. Rapid speed of onset and limited time for effective intervention make this a very high risk complication.
Spinal cord Ischaemia

Learning points

• The incidence of spinal cord ischaemia is low
• Elderly, infirm patients undergoing major surgery were affected.
• It is not clear if CNB caused spinal ischaemia or was co-incident
• Hypotension is likely to be causative/contributory and should be prevented, diagnosed early and treated promptly
• The prognosis of patients with spinal cord ischaemia was universally poor.
Spinal cord Ischaemia

Learning points 2

- Epidural infusion can complicate early diagnosis
- Inappropriately dense motor and/or sensory loss in the legs was universal.
- Weak legs during thoracic epidural block should be considered a warning sign
- Where spinal cord ischaemia is considered a senior opinion should be sought with a view to urgent MRI (and exclusion of treatable causes of spinal cord injury)
- MRI scans, particularly early, may show no changes
Learning points

- Meningitis is a rare after CNB
- Prompt treatment led to full resolution
- Multiple attempts at spinal anaesthesia require scrupulously asepsis
- Presentation may be atypical and may be difficult to differentiate from post dural puncture headache.
- Suspicion requires prompt diagnostic LP and full examination of CSF
- Meningitis may occur after epidurals too
- Chlorhexidine in alcohol is the skin preparation of choice for CNB
- In patients with systemic sepsis antibiotics should be administered before CNB.
Nerve and spinal cord injury

Learning points

• When significant severe or sustained paraesthesiae occur during CNB for elective surgery, it is unwise to continue with surgery.

• Serious consideration should be given to postponing surgery so that the consequences of the adverse event can be monitored and investigated more rapidly

• Previous failure or difficulty with CNB should be regarded as a risk factor for future problems.

• Current data is inadequate to be certain whether a distinction can be drawn between localised, non painful paraesthesiae and paraesthesiae which radiate along a nerve distribution and/or are painful but several permanent injuries were associated with the latter.
Learning points

• There were no episodes of the wrong intrathecal drug

• IV administration of LA intended for epidural use was the commonest wrong route error
• Many cases have benign outcomes but there is potential for serious morbidity or death
• Physical segregation and dissimilar drugs/equipment are important but not 100% effective.
• The mantra ‘read the label’ is not the whole solution, but is worth repeating!
• Technical solutions, (eg non-interchangeable connections) must encompass the whole delivery system and should only be introduced after thorough evaluation (including the potential for ‘unintended consequences’.)
• ‘lipid rescue’ is increasingly supported in addition to standard LA toxicity management.

• Treatment for epidural-induced hypotension involves IV drugs and/or plasma expanders, often with some degree of urgency. This series suggests this may be a high risk period for wrong route errors.
CVS collapse

Learning points
• CVS collapse after CNB is often multifactorial
• Changes in CVS status are expected during CNB but may be unexpectedly severe particularly in the elderly and unfit.
• Active management of the circulation can prevent further cardiovascular deterioration and other complications such as spinal cord ischaemia
• Appropriate training in CVS management is a necessity for all anaesthetists
• CNB should only be performed where circulatory support with IV fluid and vasopressors is readily achieved
• Continuous CNB used on wards requires the same standards of care.
• Monitoring of all patients after CNB should be frequent and performed by those with the knowledge and authority to ensure abnormalities are acted upon promptly
• When CNB techniques do not go entirely to plan, the risk of complications is likely to increase. Clear communication and increased surveillance are necessary.
Learning points

• Subdural haematoma is a recognised complication of CNB due to CSF loss

• Multiple attempts at dural puncture may increase the CSF leak

• Aspiration of CSF after accidental dural puncture is unnecessary and ill advised

• Atypical or persistent headache after CNB should lead to investigation to exclude subdural haematoma
Peri-operative

Learning points 1

• More complications, and harm, were reported after peri-operative CNB than for other indications.
• Whether this is a result of increased risk or different case mix is unknown. The benefits of peri-operative CNB will also differ from other indications.
• The risk is lower than previous estimates.
• Epidural and CSE were associated with most reports of harm.
• Vertebral canal haematoma, vertebral canal abscess and spinal cord ischaemia were the main causes of permanent neurological harm after perioperative CNB. Haematoma and cord ischaemia occurred only in elderly peri-operative patients.
Peri-operative

Learning points 2

- Delays in identification, review and diagnosis of inappropriately weak legs after CNB led to avoidable harm
- Full asepsis is mandatory for all perioperative CNBs.
- Continuous CNB on the wards mandates training, monitoring and support services complying with previously published multidisciplinary recommendations and NPSA guidance
- The potential for late complications mean written patient information describing possible late neurological/infective complications is sensible
Paediatrics

Learning points

• The majority of paediatric CNB are caudals
• There were no cases of permanent harm reported
• The incidence of major complications, and harm, following CNB in children appears to be very low

• Clinical suspicion and vigilant monitoring offer the best chance of early identification of infection during continuous CNB. Prompt treatment is justified while further investigation is targeted at determining the organism and the nature and extent of the infection.
Chronic pain

Learning points

• Major complication after chronic pain CNB was rare
• Abscess may present atypically, after discharge from hospital and to other clinicians. Consider a letter..
• Radicular pain, during CNB should lead to re-siting of needle or catheter. While harm is rare, consider following-up to exclude nerve injury
• Even single-shot CNB may precipitate cardiovascular collapse. Be ready to resuscitate
• Discussion of risks of CNB is part of the informed consent process.