

REVIEW PANEL

The review panel was composed of individuals nominated by supporting organisations (listed in alphabetical order):

- ◆ Dr David Bogod (Obstetric Anaesthetists Association)
 - ◆ Dr Iain Christie (Association of Anaesthetists of Great Britain and Ireland)
 - ◆ Dr David Counsell (National Confidential Acute Pain Critical Incident Audit)
 - ◆ Dr Max Damian (Association of British Neurologists)
 - ◆ Dr Barrie Fischer (European Society of Regional Anaesthesia, Great Britain and Ireland Section)
 - ◆ Dr Richard Howard (Association of Paediatric Anaesthetists)
 - ◆ Professor Ravi Mahajan (Royal College of Anaesthetists)
 - ◆ Dr Angelique Mastihi (Medical Protection Society)
 - ◆ Mrs Anne Murray (Patient Liaison Group, Royal College of Anaesthetists)
 - ◆ Mrs Joan Russell (National Patient Safety Agency)
 - ◆ Dr Nick Scott (European Society of Regional Anaesthesia, Great Britain and Ireland Section)
 - ◆ Dr Andrew Vickers (British Pain Society)
 - ◆ Professor Tony Wildsmith (Royal College of Anaesthetists)
- ◆ The panel was chaired by Dr Tim Cook (Project Lead, Royal College of Anaesthetists).

Additional expertise, as needed, was acquired by the chair, from individuals nominated by specialist radiological organisations or microbiologists. Several panel members also brought medico-legal expertise to the review panel.

Publication in the British Journal of Anaesthesia

A paper documenting the methods and quantitative results of this project is published by the *British Journal of Anaesthesia*. It will appear in the February edition of the journal (*British Journal of Anaesthesia* 2009:102) and will be available through 'advance access' on the BJA website at <http://bj.oxfordjournals.org> from 12th January 2009.

ACKNOWLEDGMENTS

First, our thanks go to the network of local reporters who collected the data for this project and supplied the detailed clinical reports, as well as the other individuals who notified us of cases.

The following organisations were represented at a preliminary meeting and their unanimous support contributed to the development and success of the project: Association of Anaesthetists of Great Britain and Ireland (Professor Mike Harmer), British Pain Society (Dr Beverley Collett, Dr Andrew Vickers), European Society of Regional Anaesthesia, Great Britain and Ireland Section (Dr Barrie Fischer), National Confidential Acute Pain Critical Incident Audit (Dr David Counsell), Patient Liaison Group of the Royal College of Anaesthetists (Mrs Anne Murray), Acute Pain Nurses (Ms Sharon Kitkatt), National Patient Safety Agency (Mrs Joan Russell), Council of the Royal College of Anaesthetists (Dr Anne May, Professor Tony Wildsmith).

The following individuals are thanked for the use of photographs in this report: Dr Matthew Checketts, Dr Sarah Meisner, Mr Maurice Paterson, Dr Andrew Vickers, Dr Tim Cook.

NCAPCIA was developed by Dr David Counsell and fellow members of the British Pain Society Acute Pain Interest Group.

We are also indebted to the President, Council and the Head of Professional Standards (Mr Charlie McLaughlan) and Ms Edwina Jones at the Royal College of Anaesthetists. We would also like to acknowledge the advice of Mrs Karen Thomson, Patient Information Advisory Group at the Department of Health and Ms Alexandra Cronberg, statistician at the National Patient Safety Agency

Finally special thanks go to the chief administrator for the project at the Royal College of Anaesthetists, Ms Shirani Nadarajah.

We are grateful to the editors and publishers of *Anaesthesia* and the *British Journal of Anaesthesia* for allowing us to use material also published in those journals.

CONTENTS

FOREWORD	3
ABOUT THIS REPORT	5
EXECUTIVE SUMMARY	7
<u>SECTION 1</u>	
1 INTRODUCTION	13
2 POTENTIAL BENEFITS OF CENTRAL NEURAXIAL BLOCK	17
3 PROJECT METHODS	27
<i>Quantitative analysis</i>	
4 RESULTS	31
5 DISCUSSION	39
<u>SECTION 2</u>	
CLINICAL REVIEWS	
<i>Clinical review by complication type</i>	
6 SPINAL CORD ISCHAEMIA	49
7 VERTEBRAL CANAL HAEMATOMA	55
8 VERTEBRAL CANAL ABSCESS	63
9 INFECTIVE MENINGITIS	71
10 OTHER NERVE AND SPINAL CORD INJURY	77
11 WRONG ROUTE ADMINISTRATION	85
12 CARDIOVASCULAR COLLAPSE	91
13 MISCELLANEOUS COMPLICATIONS	97

NAP 3

Report and findings of the 3rd National Audit
Project of the Royal College of Anaesthetists

Clinical review by indication

14	COMPLICATIONS AFTER PERIOPERATIVE CNB	101
15	MANAGEMENT OF DENSE MOTOR BLOCK FOLLOWING CNB OR DURING CONTINUOUS EPIDURAL ANALGESIA	113
16	COMPLICATIONS AFTER OBSTETRIC CNB	117
17	COMPLICATIONS AFTER CNB FOR CHRONIC PAIN	125
18	COMPLICATIONS AFTER CNB IN CHILDREN	131

APPENDICES

1	WRONG ROUTE ADMINISTRATION Comment from the National Patient Safety Agency	137
2	EXAMPLE DISCHARGE ADVICE FOR PATIENTS WHO HAVE RECEIVED CNB (Wrexham Maelor Hospital)	139
3	MANAGEMENT OF WEAK LEGS DURING CNB: EXAMPLE ALGORITHMS FOR RECOVERY AND ON THE WARDS (Derriford Hospital, Plymouth)	140
4	FULL RESULTS	143

FOREWORD

From the President



The 3rd National Audit Project of the Royal College of Anaesthetists (NAP3) must be considered a success. The major complications of central neuraxial blocks (CNB) have long been uncertain and therefore of concern to anaesthetists and patients.

It seems NAP3 has captured the enthusiasm of the profession throughout the UK. For the first time every one of more than 300 UK hospitals who were invited to take part in the project agreed to do so and delivered results. I would say that this project is a credit to the entire body of UK anaesthetists.

Thanks must go to those clinicians who took the time to report, in detail, relevant complications that they encountered and followed the progress of the patients affected by them. This cannot always have been an easy process for those clinicians reporting, but it seems to have been done with genuine openness, honesty and sensitivity. Without this the project would have failed. A key factor which contributed to the success of the reporting of individual cases was the personal drive of Dr David Counsell in Wrexham, in the provision of a secure and confidential mechanism for reporting each event through the website of the National Confidential Acute Pain Critical Incident Audit (NCAPCIA). The expert review panel that analysed the reports are particularly thanked for their time and dedication in providing specialist

opinion, and specific recognition must be given to Professor Tony Wildsmith for his expert opinion and wise guidance.

Thanks must go to the army of Local Reporters who managed the project at a local level, initially raising awareness of the project, then conducting the census of CNBs performed, and finally co-ordinating reporting of cases when they arose.

The project is also indebted to the numerous specialist anaesthetic societies and those of other medical specialties as well as the Chief Medical Officers of England, Northern Ireland, Scotland and Wales who added their support.

Finally thanks must go to the staff at the Royal College of Anaesthetists; Charlie McLaughlan and his team in the Professional Standards department, and in particular Shirani Nadarajah who did much of the 'leg-work'.

The result of the endeavours of so many people is the first very large prospective study of complications of CNB to be published.

The project census identified an estimated 700,000 CNBs performed in the NHS in the UK each year, in itself new and important knowledge for our profession. The strength of the census is that returns were received from all NHS hospitals in the UK. The second phase of the project sought to identify all major complications arising from this cohort of

NAP 3

Report and findings of the 3rd National Audit
Project of the Royal College of Anaesthetists

procedures and the evidence suggests that this too has been highly successful. An anonymous report of each notified case was reviewed by an expert panel in sufficient detail to determine the extent of injury and its causation. Each case of major injury was then followed up for at least six months to allow the evolution of these major complications to be determined. In these days of data protection, exporting and managing such data was another hurdle for the project: thankfully cleared.

I will leave you to read the results of the project but as you will understand it is the result of considerable work, not only by those directly recognised in the report itself but many, many others.

The quantitative aspects of the project are published both in this report and simultaneously in the British Journal of Anaesthesia. In addition, this report discusses clinical complications and clinical settings in which complications arose in considerably more detail and with learning points added to each chapter.

I hope that many will read the report in its entirety, but that all will read those parts of the report that are relevant to their practice. It contains much that I believe will be of use to all anaesthetists and their patients alike.

I'd like to add my personal thanks to Tim Cook and to congratulate anaesthetists on such a comprehensive piece of work.



Dr Judith Hulf,
President, Royal College of Anaesthetists

THE ROLE OF THIS REPORT

Dr Tim Cook

The primary role of the project was to determine, as accurately as possible, the incidence of complications of Central Nerve Block (CNB) leading to permanent patient harm. This, the quantitative section of this report, is the topic of *Section 1*. The rationale and methodology are described in *Chapters 1–3* and the results in *Chapters 4 and 5*.

Section 2 is a clinical review of the cases reported to the project, first classified by complication (*Chapters 6–13*) and then by indication for CNB (*Chapters 14–18*). Each chapter is presented to offer maximum information on the topic and the cases reported to the project while maintaining patient and clinician anonymity. Clinical vignettes are used to describe cases which are either typical or illustrative. In these, clinical detail is necessarily presented, but identifying information is removed as much as possible.

Each clinical chapter is set out as follows.

- ◆ **Headline:** a summary of the key contents of the chapter.
- ◆ **What we know already:** describing, in a brief literature review, the relevant current knowledge and areas of particular interest.
- ◆ **Case review:** summarising the demographics, indications, presentation and prognosis of the reported cases. All reported cases of interest, whether meeting criteria for audit inclusion or not, are included here.

- ◆ **Quantitative aspects:** enumerating cases relevant to the chapter topic that were included in incidence calculations.
- ◆ **Comment:** indicating how the review of cases further informs what is known already about the chapter topic.
- ◆ **Learning points:** garnered from both the literature review and further informed by the case review.
- ◆ **References.**

Each chapter stands alone, but there are many issues which are relevant to several others and these are cross referenced as necessary.

The learning points aim to indicate where the project has identified new information or reinforced existing knowledge. The chapter authors and editors have taken as broad a view as possible in producing these learning points in an attempt to maximise the value of the report. As such they represent a combination of literature interpretation, case review and expert opinion.

The report is neither a primer nor textbook of CNB. It is not positioned either to support or condemn the use of CNB. The report does not make recommendations, but does indicate areas where current recommendations are not adhered to or where new recommendations could usefully be developed.

NAP 3

Report and findings of the 3rd National Audit
Project of the Royal College of Anaesthetists

EXECUTIVE SUMMARY

MAJOR COMPLICATIONS OF CENTRAL NEURAXIAL BLOCKS: THE 3RD NATIONAL AUDIT PROJECT OF THE ROYAL COLLEGE OF ANAESTHETISTS

Dr Tim Cook

WHY?

Central neuraxial blocks (CNB) are a group of anaesthetic techniques which include epidurals, spinals and combined spinal epidurals (CSE). All are invasive techniques involving injection of pain relieving drugs into the vertebral (spinal) canal and requiring a needle to be placed close to the central nervous system. CNB has the potential to provide patients with optimal pain relief, but can also lead to patient harm.

Use of CNB for surgery may mean that general anaesthesia and its complications are avoided. Alternatively, CNB may be used in addition to general anaesthesia and as a method of providing high quality prolonged pain relief after surgery. The techniques are also used widely in the management of acute and chronic pain states, particularly in obstetrics both during labour and for delivery.

The number of CNB performed in the United Kingdom (UK) was previously unknown. It is recognised that major complications may occur as a consequence of CNB and these include damage to the nervous system, important infections and even death. The frequency with which CNB leads to harm to the patient was not known either.

WHAT?

The 3rd National Audit Project of the Royal College of Anaesthetists was designed to answer the questions:

- ◆ What types of CNB are used in the UK, and how often?

- ◆ How often do major complications, leading to permanent harm, occur in association with CNB?
- ◆ What happens to the patients experiencing these complications?

Phase one of the project used a novel process to identify the number of CNB performed in the UK's National Health Service during a defined period. These data were then used to estimate the number of such procedures performed annually.

Phase two sought to identify all cases of major complications of CNB occurring in the same population as in phase one. Each reported case was reviewed by an expert panel and this analysis enabled calculation of the incidence of complications leading to permanent patient harm after CNB.

The methodology was designed to ensure that those being notified of cases (at the Royal College of Anaesthetists) and those receiving detailed reports of cases (at the National Confidential Acute Pain Critical Incident Audit) were unable to access the other's data thereby preserving patient, hospital and clinician anonymity.

WHO?

The project required collaboration of anaesthetists throughout the UK and was supported by many specialist organisations whose members might be in a position to identify and report complications after CNB. These groups included members of acute pain teams, neurologists, radiologists, spinal and neurosurgeons.

CAVEATS

The project invited reports of all the major complications of CNB to ensure maximum reporting. However, the primary aim of the project was to identify the incidence of permanent harm due to CNB. Therefore the report does not provide information on the incidence of minor complications or major complications without permanent harm.

RESULTS

The response of the profession to this project has been unprecedented with every invited UK NHS hospital agreeing to contribute and then later returning data.

Clinical uncertainty in the reported cases, particularly regarding final clinical outcome, means that it is appropriate to report results with the incidence of permanent harm interpreted both pessimistically and optimistically.

- ◆ The census phase produced a denominator of a little over 700,000 CNB. Of these 46% were spinal and 41% epidurals, and 45% were performed for obstetric indications and 44% perioperative.
- ◆ Eighty four major complications were reported in the year of data collection, with 52 meeting all of the audit inclusion criteria. With the data interpreted 'pessimistically' there were 30 permanent injuries, and 'optimistically' 14.
- ◆ The incidence of permanent injury due to CNB (expressed per 100,000 cases) was 'pessimistically' 4.2 (95% confidence interval 2.9-6.1) and 'optimistically' 2.0 (1.1-3.3). These are equivalent to 1 in 24,000 and 1 in 54,000, respectively.
- ◆ 'Pessimistically' there were 13 deaths or paraplegias, 'optimistically' five. The incidence of paraplegia or death was 'pessimistically' 1.8 per 100,000 (1.0-3.1) or 1 in 50,000 and 'optimistically' 0.7 (0-1.6) or 1 in 140,000.

- ◆ In the 30 patients with permanent harm (judged 'pessimistically') 60% occurred after epidural block, 23% spinal anaesthesia and 13% a CSE. More than 80% of these patients had a CNB placed for perioperative analgesia.
- ◆ Two-thirds of injuries judged initially as severe resolved fully.

INTERPRETATION OF RESULTS

The results indicate that the incidence of the complications of CNB in the UK is considerably lower than some previous reports (based on much smaller surveys) have suggested. This is very reassuring for clinicians and patients.

The review panel identified many circumstances where care of patients was timely and of high quality. However, as is inevitable in a report examining cases in which patients experienced harm, there were instances of sub-optimal and even occasionally poor management. The report emphasises some of these in the hope lessons can be learnt.

The reported cases encompass almost all of the major complications of CNB previously reported and no new ones. The failures of recommended practice were identified and are commented on below and in individual chapters.

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.

EXECUTIVE SUMMARY

- 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.

NAP 3

Report and findings of the 3rd National Audit
Project of the Royal College of Anaesthetists