

Deaths following Surgery in Children
Study protocol

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Introduction

The delivery of surgical services for children has changed in the last 20 years. This followed recommendations made by NCEPOD and others about standards for the surgical and anaesthetic care for children^{1,2}. There have also been many other influences in this time period with both direct and indirect effects on the totality of care for children in the health service and include a National Service Framework for children³, the Every Child Matters programme⁴ the Healthcare Commissions, 'Improving Services for Children in Hospital'⁵, The Children's Plan⁶, the reports of the Children's Surgical Forum^{7,8} the NHS Next Stage Review⁹, and latterly the joint DCSF/DH strategy for children and young people¹⁰. As a result there has been both clinical and organisational change to health care provision for children. These include specialisation and centralisation of children's services, and modifications of staff training. There is direct evidence that children's surgery is now less likely to be delivered in district general hospitals¹¹. However the majority of operations are still undertaken in this setting.

It is 20 years since the first NCEPOD study which reviewed deaths in children within 30 days of surgery¹. This study showed that there were deficiencies in the skills of healthcare professional who cared for surgical children and in the facilities available. This was thought to be especially so in district general and single speciality hospitals. Recommendations were made that surgeons and anaesthetists should not undertake occasional paediatric practice and that consultants who have responsibility for children need to maintain their competence in the management of children. The subsequent 1999 NCEPOD report, Extremes of Age, recommended a regional approach to the organisation of paediatric surgical services². These recommendations along with others have resulted in considerable debate on the best model for children's surgery in the UK both in terms of skills of healthcare professional and the appropriate facilities^{12,13}.

There has been a decline in the number of children who have surgery performed in district general hospitals from more than 410,000 children under 18 years in 1994/1995 to 325,000 in 2004/2005¹⁴. This is a complex situation and some of this reduction reflects changes in practice (e.g. general reduction in minor ENT procedures). However, there has been a parallel increase in referrals to tertiary centres among neonates and the very young, particularly in the areas of general surgery and orthopaedics, without any shift of resources¹⁴. While in principle this may encourage greater paediatric specialisation and concentration of expertise there is a perception amongst clinicians and anecdotal evidence that this has been to the detriment to children's surgical services in District General Hospitals (DGHs)¹¹. There is a concern regarding the deskilling of surgeons and anaesthetists in DGHs who care for children which may limit their ability to manage critically ill children who present at their hospital^{15,16}.

The development of networks of paediatric surgical and anaesthetic care has been recommended as a solution to this problem^{16,17}. However, although encouraged during recent health services reforms⁷ there has been no clear national initiative and change has been extremely slow to be implemented with only a handful of functional networks for children's surgery in the UK¹⁸. There is a risk of reaching a tipping point in the care of children in DGHs and several professional bodies have been calling for an urgent national review of paediatric surgical and anaesthetic services^{17,19}.

Congenital Cardiac Surgery

Following the Kennedy inquiry (<http://www.bristol-inquiry.org.uk/>), which reviewed the care of children receiving complex cardiac surgery at the Bristol Royal Infirmary

between 1984 and 1995, there has been considerable concern regarding the care of children with congenital cardiac disease²⁰. A review of congenital cardiac services in the UK made proposals on how the recommendations from the Kennedy inquiry can be put in to practice, (<http://www.dh.gov.uk/ab/Archive/PCCSRG/index.htm>)²¹. A series of standards were proposed which included development of regional team working, systematic clinical accountability and national audit, child centred care, clinical assessment and consent, and medical and surgical care. However, since then there has been little further review or audit of congenital cardiac services to determine if any of these recommendations have been implemented.

Analysis of the results for surgery for congenital heart defects (CHD) is problematic: the number of types of surgical procedures is large (149 under the international nomenclature) with small numbers being performed in each unit per year in each category in the UK. This makes statistical analysis difficult. Furthermore there is no accepted method of risk stratification so that comparison of outcomes between patient groups is not meaningful.

At present, Central Cardiac Audit Database (CCAD) collects data from each of the 13 paediatric cardiothoracic units in the UK to monitor performance and to work towards improving quality of care (<http://www.ccad.org.uk/congenital>)²². Outcomes (survival) are calculated for 36 more commonly performed surgical procedures, and 12 cardiology interventional procedures, held in the database. Statistical confidence limits are wide making identification of "best practice" difficult. Many of the deaths that occur after surgery do not come into this analysis as they occur after uncommon procedures not included in the data base.

Information from CCAD has shown that in 2005-2006, 3999 children (up to age 16) had surgery for a CHD (2871 with cardiopulmonary bypass and 1128 non bypass)²². The mortality was 4% (160 deaths per year).

Successful cardiac surgery for congenital heart defects requires not only a high level of technical skill but also good organisational care and teamwork. These factors are difficult to measure using traditional quantitative data analysis. A qualitative approach using peer review as used by NCEPOD will provide an insight into the processes of care.

Thus this study will provide valuable data on the current state of paediatric surgical and anaesthetic practice which can be used to inform and provide recommendations for those planning the future direction of paediatric surgical and anaesthetic services.

Aims and Objectives

Overall Aim

The aim of this study is to explore remediable factors in processes of care of children less than 18 years of age, including neonates who die within 30 days of emergency or elective surgery on the same admission.

The questions that this study would help to answer are:

1. What impact have the changes in practice had on the quality of care of children who require surgery?
2. What is the best organisational model for delivering paediatric surgical care in the UK?

The results will enable a comparison with data from both the 1989 and 1999 NCEPOD reports and will add to the body of information on paediatric surgical and anaesthetic services thus guiding future service development.

Overall Objectives

The study will explore the following areas of care:

1. Preoperative care and admission
2. Inter-hospital transfer
3. Networks of care
4. The seniority of clinicians
5. Multidisciplinary team working (involvement of paediatric medicine)
6. Delays in surgery
7. Anaesthetic and surgical techniques
8. Acute Pain Management
9. Critical Care
10. Co-morbidities
11. Consent

Method

Design

Peer review will be undertaken to identify possible remediable factors in the organisation of care using the indicators identified above. Clinical and organisational questionnaires will also be used to obtain quantitative data and clinician views.

Population

Inclusion criteria:

- all patients aged less than 18 years of age
- who died within 30 days following an emergency or elective procedure who died between 1st April 2008 and 31st March 2010
- under general or regional anaesthesia for any interventional procedure including radiological imaging

Estimated sample size 500-700 deaths

Exclusions

Any patient undergoing surgery without the use of general or regional anaesthesia.

Sites

All hospitals that admit children less than 18 years of age for surgery (both emergency and elective) in the National Health Service and Independent sector in England, Wales and Northern Ireland, and public hospitals in the Isle of Man, Jersey and Guernsey, will be included in the study.

Case Identification

Cases will be identified via the recording of the use of general or local anaesthesia, or using OPCS codes.

An NCEPOD Local Reporter in each hospital will be asked to identify all patients, less than 18 years of age who were admitted to hospital and underwent surgery, and died between 1st April 2008 and 31st March 2010 and input that data into the spreadsheet provided by NCEPOD.

Once patients are identified, a questionnaire will be sent to the surgeon and anaesthetist involved in the case. Casenote extracts will also be requested. The questionnaires and associated casenote extracts will then be reviewed by a multidisciplinary group of clinicians and aggregated data analysed quantitatively.

Comparisons may also be made from ONS and HES data

Data Collection

Three questionnaires will be used in this study:

- Organisational Questionnaire

For the purpose of this study, 'organisation' will be defined as a hospital/centre not a Trust. This will give a clearer picture of the facilities and care received by the patient at that particular site rather than by the Trust as a whole. An organisational questionnaire will be sent to the Medical Director for each site. The questionnaire is designed to collect data on topics such as hospital/site facilities, staff numbers and clinical protocols. Lead Clinician for paediatric surgery and anaesthesia will be asked to complete specific questions.

- Surgical Questionnaire

A questionnaire will be sent to the surgeon who carried out the primary procedure of the final admission.

- Anaesthetic Questionnaire

A questionnaire will be sent to the anaesthetist responsible for the patient during the primary procedure on the final admission.

- Casenote extracts

Copied extracts of the casenotes will be requested to be returned alongside the questionnaires. These will include;

- Inpatient and outpatient annotations from pre-admission (birth) to death
- Integrated care pathways
- Nursing notes
- Drug charts
- Imaging reports
- PICU / SCBU charts
- Fluid balance charts
- Operation notes

- Notes from MDT meetings
- Consent forms
- Pathology results
- Haematology (FBC), biochemistry results (LFT, U&E),
- Incident report form and details of outcome
- Post mortem report
- Discharge summary
- Operation notes
- Anaesthetic charts
- Pre-anaesthetic or pre-admission protocols/checklists
- Recovery room records
- DNAR documentation

An assessment form will be developed. NCEPOD staff will complete data fields based on the patients casenotes. The notes will be made anonymous and sections of the assessment form left blank for a panel of advisors to complete. They will be asked to give their expert opinion on the care the patient received during that admission.

Analysis and Review of Data

Advisors

A multidisciplinary advisory group will review the data collected and provide expert opinion on the process of care and management of children undergoing emergency and elective surgery. Advisors will be from:

Both tertiary centres and District General Hospitals

Paediatric general / urology surgery

Orthopaedic surgery

ENT surgery/ Oral & Maxillofacial surgery

Paediatric Cardiac surgery

Paediatric cardiology

Paediatric Neurosurgery

Paediatric Anaesthesia

Paediatric Pathology

Emergency Medicine

Paediatric Medicine

Paediatric Critical Care Medicine

Children's Nursing

All identifiable information will be removed prior to review by the advisors, i.e. all data will be anonymised (see below).

Confidentiality and Data Protection

Once the data have been extracted by the NCEPOD researchers, the questionnaires and case notes will be anonymised to remove patient, clinician and hospital identifiers prior to review by the Advisory Group.

All electronic data are held in password protected files and all paper documents in locked filing cabinets. As soon as possible after receipt of data NCEPOD will encrypt electronic identifiers and anonymise paper documents. Section 60 approval has been obtained to perform this study without obtaining patient consent.

Approval for the study methods of all NCEPOD studies is granted by the Patient Information Advisory Group (PIAG) during an annual review.

Dissemination

On completion of the study a report will be published and widely disseminated.

Timescale

| | Date |
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| <i>Data collection</i> | <i>July 2009</i> |
| <i>Questionnaires sent</i> | <i>October 2009</i> |
| <i>Advisory Groups</i> | <i>December 2009</i> |
| <i>Data Analysis</i> | <i>August 2010</i> |
| <i>Publish Report</i> | <i>Spring 2011</i> |

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