

# **Peri-Operative Care Study**

**Protocol : November 2009**

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## **Introduction:**

Rough estimates indicate that 160,000 high risk surgical procedures are performed annually in the UK. This group of patients has a mortality rate of 12% and accounts for over 80% of post-operative deaths, despite being a relatively small sub section of all surgical procedures (12.5%). Furthermore, 62% will go on to develop complications and in particular, hospital acquired infections. A national study has suggested fewer than 15% of high-risk patients are admitted to ICU<sup>1</sup>. In contrast, cardiac surgical patients, whose care pathway includes being routinely admitted to critical care, have a noticeably lower mortality rate (as low as 2%). In a study in a Trust in the UK, there was no critical care admission for more than 50% of the high-risk patients who died. Recent developments in peri-operative care may significantly improve outcomes for high-risk non-cardiac patients but unless suitable critical care facilities are available, patients may not be able to benefit from these advances in therapeutic approaches.

However, admitting patients to critical care, is just one area to improve surgical outcomes. Another study indicated a mortality rate of approximately 42% for patients who had a pre-operative assessment score of ASA 3 or less<sup>2</sup>. This may suggest that the surgeon had not fully taken on board the severity of the illness and mortality risk in the subjective assessment. This and other areas will be covered in the following themes to be addressed in this study:

1. Patient factors
2. Pre-operative assessment
3. Anaesthetic factors
4. Surgical factors
5. Post operative care
6. Complications

Overall, this study would be the first national study to establish what the current standards of peri-operative care in the UK are, outline any variations in the use of patient care pathways and level of care, and identify any remediable factors in the process of care.

## **Aims and objectives:**

*Primary aim:* to carry out a national study on the peri-operative care of patients undergoing specific inpatient surgery (both elective and emergency).

The primary aim would be met by addressing the following factors: patient factors, pre-operative assessment, anaesthetic factors, surgical factors, post operative care, and lastly, complications.

**Sample size:**

The estimated sample size is 30,000 patients who undergo surgery per week. This number comprises patients who we will exclude such as cardiac patients (see Exclusions below). From this, we would sample to obtain approximately 2000 cases with casenote extracts.

**Method:**

All patients who undergo inpatient surgery, both elective and emergency, during the study period and meet the study criteria, will be included. Data collection will take part in two stages. Firstly, basic data will be collected at the time the patient is operated on, to allow prompt identification of patients undergoing surgery during a given week. These forms will be completed by the anaesthetist involved in the case. If the patient goes to a recovery room, a small section of the form will also be completed by the recovery room staff. This method will ensure that data are collected accurately with regard to patient location and movements at the time of surgery, details that are often not clear from the casenotes and hard to obtain clearly retrospectively.

The second stage of data collection will use the standard NCEPOD method and we will ask NCEPOD Local Reporters to identify all patients retrospectively who underwent surgery in the given time period via the hospital PAS/local system. This will 'double-check' that all patients were captured in the first identification of cases and will also allow us to identify the consultant at the time of discharge. NCEPOD will then request photocopied case note extracts for a selection of these cases for the standard peer review process. Outcome at 6 months post surgery, will also be determined via the Office for National Statistics (ONS). NCEPOD plans to obtain data on post operative location including level 2 or 3 critical care, from local reporters via their PAS/local system.

***Population:***

All patients aged 16 years or over, who underwent inpatient surgery within the timeframe.

***Exclusions:***

Cases that are day case, obstetric, cardiac, transplant and neurosurgery.

***Timeframe:***

The study period of data collection will be determined from the pilot study.

***Data Collection:*****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 NCEPOD Local Reporter/study contact for each site. The questionnaire is designed to collect data on topics such as hospital/site facilities, staffing and clinical protocols.

Clinical form:

A form will be completed prospectively by an anaesthetist, for each patient undergoing surgery.

Photocopied Casenote Extracts:

Photocopied casenote extracts will be requested for a selection of cases.

**Sites:**

All hospitals that perform surgery 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.

**Analysis and Review of Data:**

**Advisors:**

A multidisciplinary advisory group will review the data collected and provide expert opinion on the peri-operative care of this group of surgical patients.

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 forms and casenotes 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 251 (of the NHS Act 2006) approval has been obtained to perform this study without obtaining patient consent. The reason for obtaining this approval is because a high proportion of patients in this study will be admitted as emergency patients and go straight to theatre. As this is a national one day snapshot of activity if we can only include patients who consent then our sample will be meaningless. To ensure that data are reported accurately in this study we need to have true denominator data.

Approval for the study methods of all NCEPOD studies is granted by the National Information Governance Board for Health and Social Care (NIGB) during an annual review.

**Dissemination:**

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

**Timescale:**

Main Event	Date
Pilot study	December 2009
Data collection	March 2010
Advisor meetings	July 2010-February 2011
Data Analysis	May 2011
Publication	November/December 2011

**Ethical considerations:**

As the study methodology would be similar to previous NCEPOD studies, there would be no specific ethical considerations.

**References:**

1. Pearse, R.M., Harrison, D.A., James, P., Watson, D., Hinds, C., Rhodes, A., Grounds, R. M., and Bennett, E. D. Identification and characterisation of the high-risk surgical population in the United Kingdom. *Critical Care* 2006; 10:R81.
2. Williams, N.S., Roberts, D. Critical Care: appropriate elective surgical admissions, improving surgical outcomes. National Public Health Service for Wales, 2009.