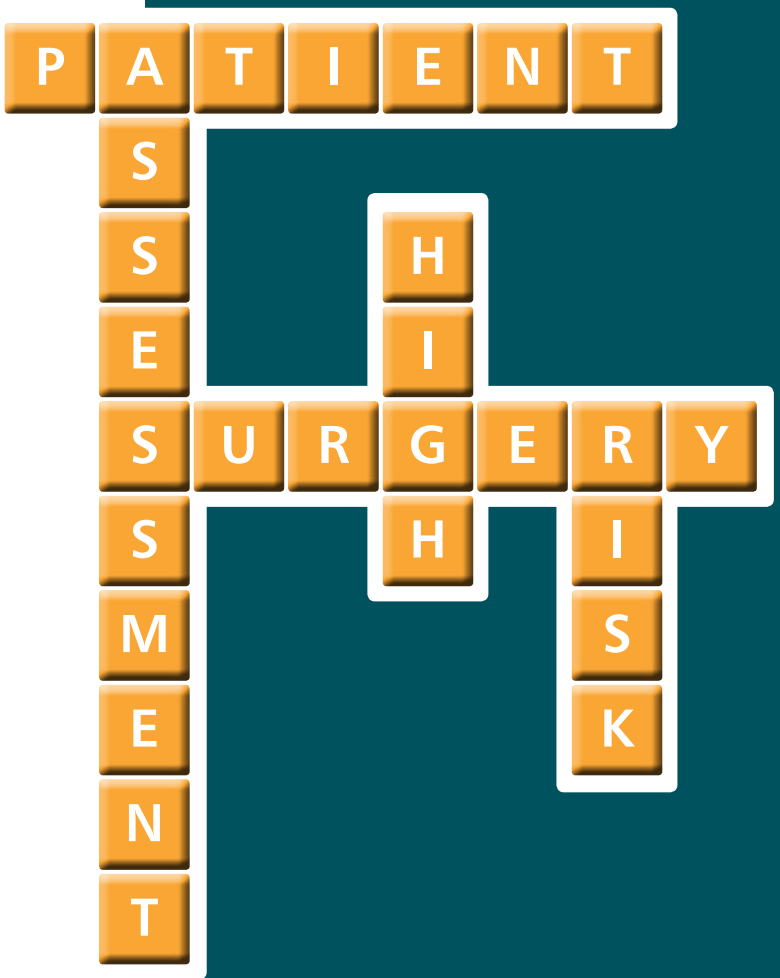
Knowing the Risk

A review of the peri-operative care of surgical patients



NCEPOD

SUMMARY

Full report available to download at www.ncepod.org.uk

Knowing the Risk

A review of the peri-operative care of surgical patients
A report by the National Confidential Enquiry into Patient Outcome and Death (2011)

Written by:
G P Findlay FRCA FFICM
NCEPOD Clinical Co-ordinator
University Hospital of Wales, Cardiff and Vale University Health Board

A P L Goodwin FRCA FFICM
NCEPOD Clinical Co-ordinator
Royal United Hospital Bath NHS Trust

K Protopapa BSc - Researcher

N C E Smith PhD - Clinical Researcher and Deputy Chief Executive

M Mason PhD - Chief Executive

The authors and Trustees of NCEPOD would particularly like to thank the NCEPOD staff for their work in collecting and analysing the data for this study: Robert Alleway, Aysha Butt, Donna Ellis, Heather Freeth, Kathryn Kelly, Dolores Jarman, Sherin Joy, Waqaar Majid, Sabah Mayet, Eva Nwosu and Hannah Shotton.

Special thanks are given to Professor Martin Utley and Professor Steve Gallivan from the Clinical Operational Research Unit at University College London, for their scientific advice.

Designed and published by Dave Terrey
dave.terrey@greysquirrel.co.uk

Contents

Introduction

Advances in surgical and patient care continue to deliver overall good patient outcomes despite an aging population, increasing comorbidities and ever expanding surgical therapies. Risk of death and major complications after surgery in the general surgical patient population are low: less than 1% of all patients undergoing surgery die during the same hospital admission[1].

Despite this overall low death rate, mortality in some groups of patients can be surprisingly high. It is estimated that around 20000 - 25000 deaths per year occur in hospital after a surgical procedure, across the UK. Of these deaths approximately 80% occur in a small population of patients. This population is known by the term 'high risk patients'. High risk patients are estimated to make up approximately 10% of the overall inpatient surgical workload and are a major source of not only mortality but also morbidity and resource utilisation. This population of high risk patients has a hospital mortality rate of approximately 10-15%[2].

There are concerns that UK outcomes may be less good than outcomes in other countries. It appears that the NHS as a whole has poorer outcomes compared with centres in similar sized hospitals and patient populations in the United States of America (USA)[3,4].

The data below show that UK mortality appears to be noticeably greater than US mortality – eight fold in the predicted risk of death group 0-5% to three fold in the predicted risk of death group 11-20%.

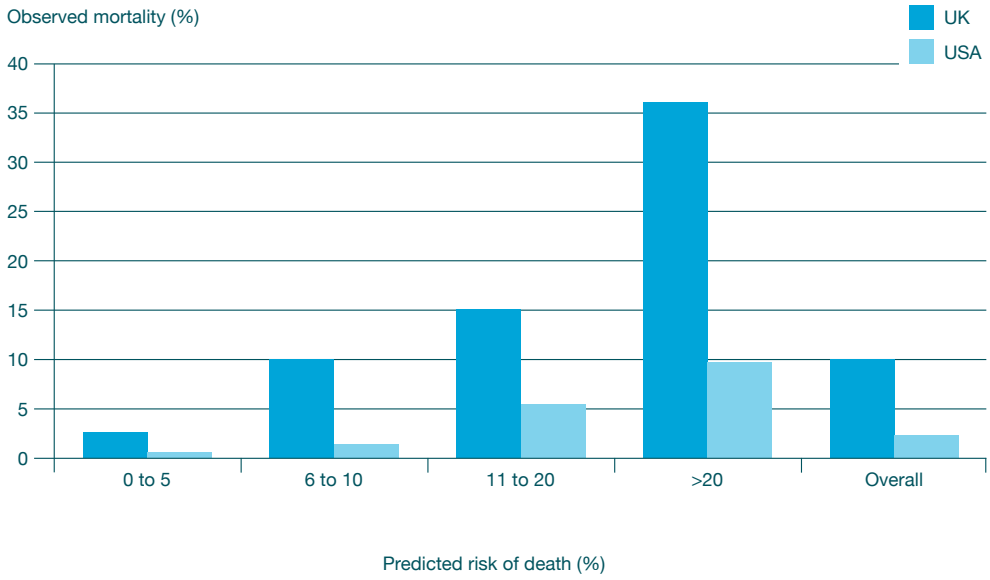


Figure 1. Observed deaths for case-mix adjusted patients undergoing major, non-cardiac surgery in UK and USA cohorts over the same time period and in comparable hospitals.[3]

There are several steps to addressing this problem.

1. Identification of the high risk group

The first challenge is to reliably and accurately identify the patient group that is at high risk of mortality and morbidity. Whilst this might seem obvious, the literature is full of differing descriptions, scoring systems and tests to meet this aim. They are largely based on assessment of comorbidities alone or combined with a classification of surgical intervention. Tests of organ function and more recently of physiological reserve are also used to try to address this issue.

2. Improved pre-operative assessment, triage and preparation

Measures to improve fitness for surgery can be targeted and applied if the identification of these high risk patients can be performed in a suitable timescale. Usually this process is thought of as having started once the patient has been accepted for surgery but more recent developments identify primary care as a key partner in identifying fitness for surgery. As well as specific optimisation of comorbidities it is important to manage volaemic status and nutritional status. Recently there has been interest in improving physiological reserve, using exercise regimens, where appropriate. There is also the opportunity to consider if surgical intervention is the best course of action due to the risk of adverse outcomes.

3. Improved intra-operative care

Once this high risk patient group can be reliably identified the next challenge, if a surgical pathway is the proposed treatment, is to improve the process of care. This will potentially improve survival, reduce morbidity and as a consequence potentially consume less health care resources. There is substantial evidence to help us meet these aims for our patients. Use of cardiac output monitoring and fluid optimisation has been studied in many groups of patients including colorectal, trauma and vascular patients. Most results support the use of peri-operative optimisation in high risk patients undergoing major surgery. Pre-optimisation before and during surgery[5-10] in a protocolised manner improves patient outcomes in high risk surgical patients. Meta-analysis, including all available studies, confirms an improvement in mortality[11]. More recent work has confirmed that these benefits are realisable in everyday practice[12]. In addition, the National Institute for Health and Clinical Excellence (NICE) has issued guidance to support this area[13].

4. Improved use of postoperative resources

In many other countries, patients undergoing major surgery routinely receive a higher level of postoperative care than is delivered in the UK to NHS patients. In part this may be due to resources allocated to critical care. The proportion of hospital beds allocated to critical care in the UK is lower than comparable countries. In addition the UK has a pattern of critical care beds that may not be maximally efficient, with high numbers of units operating with fewer than six beds. The challenge faced is to ensure that patients receive the level of postoperative care they require to achieve optimal outcomes, recognising that a vast increase in critical care beds is not likely.

It can be seen that there are significant challenges regarding the identification and care pathway of high risk surgical patients. However, much of the data are pieced together from institutional studies and extrapolated or gained from databases for which the initial purpose was not to study this group. Whereas the study described in this report was undertaken specifically to provide an overview of current care for all surgical patients with a particular focus on the high risk group and to provide a baseline assessment of the current status of care, what remediable factors are evident and what needs to be done to improve the care of such patients.

Principal Recommendations

There is a need to introduce a UK wide system that allows rapid and easy identification of patients who are at high risk of postoperative mortality and morbidity. *(Departments of Health in England, Wales & Northern Ireland)*

All elective high risk patients should be seen and fully investigated in pre-assessment clinics. Arrangements should be in place to ensure more urgent surgical patients have the same robust work up. *(Clinical Directors and Consultants)*

An assessment of mortality risk should be made explicit to the patient and recorded clearly on the consent form and in the medical record. *(Consultants)*

The postoperative care of the high risk surgical patient needs to be improved. Each Trust must make provision for sufficient critical care beds or pathways of care to provide appropriate support in the postoperative period. *(Medical Directors)*

To aid planning for provision of facilities for high risk patients, each Trust should analyse the volume of work considered to be high risk and quantify the critical care requirements of this cohort. This assessment and plan should be reported to the Trust Board on an annual basis. *(Medical Directors)*

Method and Data Returns

Study aim

To carry out a national review of the peri-operative care of patients undergoing inpatient surgery.

Expert group

An Expert Group was formed to steer this study and determine the objectives of the work. This comprised a multidisciplinary group of consultants from intensive care medicine, anaesthesia, surgery (including upper gastrointestinal, vascular and colorectal), critical care nursing, a representative from ICNARC, and scientific Advisors, who all contributed to the design of the study, and reviewed the findings.

Objectives

The Expert Group identified six main objectives that would address the primary aim of the study, and these will be addressed throughout the following chapters:

- Patient factors
- Pre-operative assessment
- Anaesthetic factors
- Surgical factors
- Postoperative care
- Complications

Hospital participation

National Health Service hospitals in England, Wales and Northern Ireland were expected to participate, as well as hospitals in the independent sector and public hospitals in the Isle of Man, Guernsey and Jersey.

Within each hospital, a named contact, referred to as the NCEPOD Local Reporter, acted as a link between NCEPOD and the hospital staff, facilitating dissemination of questionnaires and data collation.

Study population

All patients aged 16 or over were eligible for inclusion in the prospective element of the study if they underwent specific inpatient surgery between 1st and 7th March 2010 inclusive.

To be included in the peer review aspect of the study the patients had to have been described as high risk by the anaesthetist completing the prospective form.

Exclusions

Patients were excluded from the study if they had day surgery with no planned overnight stay, or were obstetric, cardiac, transplant or neurosurgery cases.

Method

All patients who underwent inpatient surgery, both elective and emergency, during the study period and met the study criteria, were included. Data collection took place in two stages. Firstly, prospective data were collected at the time the patient was operated on, to allow prompt identification of patients undergoing surgery during the defined sample week. The second stage of data collection used the standard NCEPOD method of case review by asking NCEPOD Local Reporters to identify all patients retrospectively who underwent surgery in the same given time period via the hospital patient administration systems. This was to allow cross checking to ensure the captured prospective sample was representative and to allow identification of the consultant

at the time of discharge and the outcome of the patient. From this data a group of patients, defined as high risk, were randomly selected for detailed peer review.

Organisational questionnaire

To assess the facilities available at each site performing surgery an organisational questionnaire was sent to the NCEPOD Local Reporter for completion in collaboration with relevant specialty input. A letter outlining the request was also sent to the Medical Director. The information requested in this questionnaire included information on operating facilities, theatre availability, special care areas, and pre-operative assessment facilities.

Definition of risk

As the purpose of this study was to examine the care of high risk patients it is important to describe how patients were classified as high risk or low risk. The stratification of risk could have been based on patient comorbidities, age, urgency of surgery and procedure performed. However, for the purpose of this study we asked the anaesthetist, who filled out the prospective data collection form, whether they considered the patient to be high risk. No definition of what constituted a high risk patient was provided and this classification was therefore shaped by the anaesthetists' knowledge of the high risk surgical literature and their own perception of risk in the context of their own institution. This pragmatic definition was used for several reasons:

1. Classification of risk was determined prospectively, with no knowledge of outcome.
2. Where patients were classified as high risk it is reasonable to expect that processes would be in place to treat the patient according to the perception of risk, as this was decided by the treating physician within their own organisation.
3. Clinician stratification of risk could be compared during analysis to established systems using factors such as patient comorbidities, age, urgency of surgery and procedure performed to determine agreement.

Patients who were not classified as high risk will be referred to as low risk in this report to allow the two groups to be easily differentiated.

Case ascertainment – prospective data

Patients undergoing inpatient surgery were identified by anaesthetists who completed a clinical form prospectively at the time of surgery. The information requested included ASA class, comorbidities, urgency of surgery, postoperative location (preferred and actual), and whether they considered the patient to be a high risk patient. If the patient went to a recovery room, a small section of the form was also completed by the recovery room staff. This method ensured that data were collected accurately with regard to patient location and movements at the time of surgery, details that are often not clear from the case notes and hard to obtain retrospectively.

Case ascertainment – retrospective case data

Local reporters retrospectively used patient identifiers from the forms to link to 30 day outcome data including identifying patients who were admitted to level 2 or 3 critical care. These data were sent to NCEPOD on password protected spreadsheets and imported to a secure database.

Case ascertainment – peer review data

From those patients who had both a clinical form and outcome data, up to six high risk patients per hospital were selected at random by NCEPOD and included in the case note review by Advisors.

Photocopied case note extracts were requested for each case that was to be peer reviewed which included:

- Inpatient annotations, including the pre-operative assessment, admission clerking notes and notes for the first consultant ward round
- Nursing notes
- Level 2/Level 3 notes
- Nutrition notes
- Anaesthetic record
- Any operating notes
- Biochemistry results
- Haematology results
- Drug charts (including parenteral nutrition prescription chart)
- Fluid balance charts
- Observation charts
- Discharge summary
- Post mortem report, if applicable

These were anonymised upon receipt at NCEPOD.

Advisor group

A multidisciplinary group of Advisors was recruited to review the case notes and associated clinical form of each patient selected. The group of Advisors comprised consultants, associate specialists, nurses and trainees, from the following specialties: anaesthesia, intensive care medicine, critical care and surgery.

Clinical forms and case notes were anonymised by the non-clinical staff at NCEPOD. All patient, clinician and hospital identifiers were removed. Neither Clinical Co-ordinators at NCEPOD, nor the Advisors, had access to identifiable information.

After being anonymised, each case was reviewed by one Advisor within a multidisciplinary group. At regular intervals throughout the meeting, the Chair allowed a period of discussion for each Advisor to summarise their case and ask for opinions from other specialties or raise aspects of the case for discussion.

The grading system below was used by the Advisors to grade the overall care each patient received:

Good practice: A standard that you would accept from yourself, your trainees and your institution.
Room for improvement: Aspects of **clinical** care that could have been better.
Room for improvement: Aspects of **organisational** care that could have been better.
Room for improvement: Aspects of both **clinical and organisational** care that could have been better.
Less than satisfactory: Several aspects of clinical and/or organisational care that were well below that you would accept from yourself, your trainees and your institution.
Insufficient data: Insufficient information submitted to NCEPOD to assess the quality of care.

Quality and confidentiality

Each case was given a unique NCEPOD number so that cases could not be easily linked to a hospital.

The data from all questionnaires received were electronically scanned into a preset database. Prior to any analysis taking place, the data were cleaned to ensure that there were no duplicate records and that erroneous data had not been entered during scanning. Any fields that contained spurious data that could not be validated were removed.

Data analysis

Following cleaning of the quantitative data, descriptive data summaries were produced and the qualitative data collected from the Advisors' opinions were coded, where applicable, according to content to allow quantitative analysis. The data were reviewed by NCEPOD Clinical Co-ordinators, a Researcher, and a Clinical Researcher, to identify the nature and frequency of recurring themes.

Case studies

Case studies have been used through the peer review section of this report to illustrate particular themes.

All data were analysed using Microsoft Access and Excel by the research staff at NCEPOD and the findings of the report were reviewed by the Expert Group, Advisors and the NCEPOD Steering Group prior to publication.

Data returns

Organisational questionnaire
There were 301 questionnaires returned.

19,097 clinical forms were included in the analysis of prospective data and a sample were also used by the Advisors during the peer review. In total, 829 cases were assessed by the Advisors. The remainder of the returned case note extracts were either too incomplete for assessment or were returned after the final deadline and last Advisor meeting.

Prospective forms and case notes for review

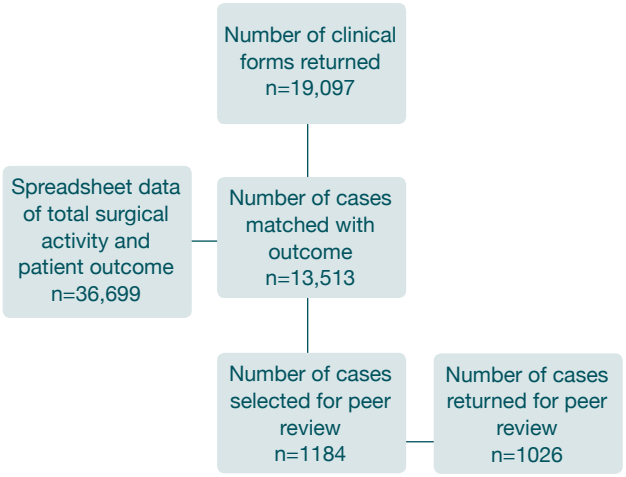


Figure 1.2 Data returned

Overall quality of care

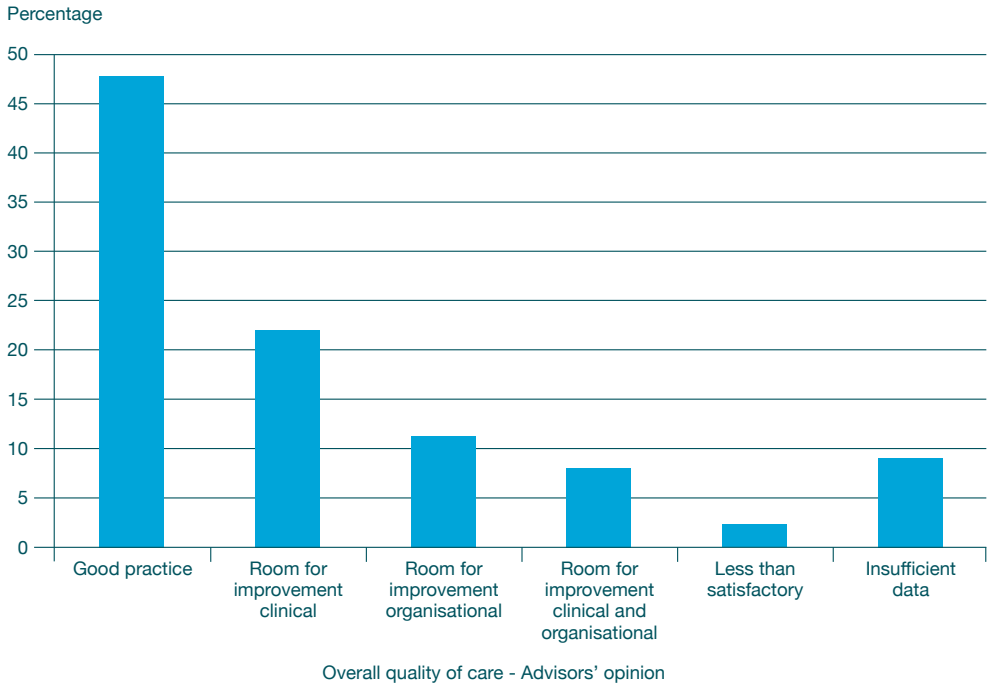


Figure 4.2 Advisors' overall assessment of the standard of care received

Summary of the Findings

This study is very important for NCEPOD for two main reasons. Firstly it is a change to the usual study method. Secondly it has revealed that there are many remediable factors in the peri-operative care pathway of high risk surgical patients.

This is the first time that NCEPOD has collected data prospectively. Data was collected on all eligible surgical procedures over a one week period. This allowed us to gather a large data set and fully describe the characteristics of this group of patients and pathways of current care. This provided us with denominator data and ensured that our findings were not skewed by a biased sample group. This has long been a criticism of NCEPOD – when we focus on a group with adverse outcomes (e.g. death) it is unsurprising that many remediable factors are found but it is often questioned if these findings can be extrapolated to the whole population. To complement this robust prospective dataset we looked deeper into the care of a group of high risk patients. This relied on peer review of medical notes and other documentation by a group of Advisors. The peer review process allowed opinion to be formed about aspects of patient care and this qualitative assessment supports and enriches the quantitative data from the prospective dataset.

The two sections of the study provide a complete story of the care of high risk surgical patients and highlight the areas of concern.

There are difficulties in identifying high risk patients. However somewhere between 1 in 10 and 1 in 20 of surgical cases should be considered high risk. This is a very significant volume of patients.

There are deficiencies in pre-operative assessment. Management of patients prior to surgery was a concern, particularly in non-elective patients, and fluid management was a common problem.

- Intra-operative monitoring for high risk patients rarely included cardiac output monitoring despite the evidence base.
- Critical care was the post operative location for 1 in 5 high risk patients. Most high risk patients return to ward care.
- The high risk group 30 day mortality was almost 7% and this encompassed three quarters of the postoperative deaths.
- Advisors' opinion was that care was good in less than half the cases.

These points highlight that there are major deficiencies in how high risk surgical patients are cared for. As a result, the high risk surgical group has poor outcomes (death and morbidity) and the resultant health care resource utilisation is significant. This study provides some recommendations to remedy this situation and supports the conclusions of the report published by the Royal College of Surgeons of England on the higher risk general surgical patent. Improvement will require both a change in thinking from health professionals about the need of this group and support from health service managers to provide the resources to do so. The returns could be significant – less postoperative death and morbidity, quicker return to health and independent living, more efficient care and less cost to the NHS.

Key Findings and Recommendations

Key Findings – Organisational data

158/218 (72.5%) of NHS hospitals had availability of dedicated emergency theatres 08.00-17.59 during Monday to Friday.

289/293 hospitals had a post anaesthetic recovery area. Of these hospitals only 192 sites (67%) have twenty four hours per day, seven days per week provision.

203 hospitals responding stated that they could provide ventilatory support and ongoing management in the post anaesthetic recovery area. 59 hospitals (23%) could not provide this level of support.

Most hospitals (127/200 – 64%) could only provide ventilatory support and ongoing management in the post anaesthetic recovery room for short periods (up to 6 hours).

27/232 hospitals (12%) did not have a formal policy in line with NICE Clinical Guideline 50 for the recognition and initial response to acutely unwell patients.

87/253 hospitals (34%) did not have a critical care outreach team.

44/283 hospitals (16%) did not provide pre-admission anaesthetic assessment clinics.

48/283 hospitals (17%) did not provide pre-admission surgical assessment clinics.

Only 117/291 hospitals (40%) had the facility to undertake cardiopulmonary exercise testing on their patients.

97/288 hospitals (34%) did not have a policy for the prevention of peri-operative hypothermia.

Key Findings - Prospective data

Anaesthetists involved in the surgery identified 3734/18565 patients as high risk (20%).

79% of the deaths were in the high risk group (165/208).

Urgency of surgery did not correlate well with risk category – half of the high risk patients were elective procedures.

Higher ASA grades had a higher proportion of high risk patients – however there were still substantial numbers of high risk patients in ASA grades 1-2.

Almost 1 in 5 elective high risk patients were not seen in a pre-assessment clinic. Within this study, elective patients not seen in a pre-admission assessment clinic had a higher 30 day mortality than those who were seen (4.8% v 0.7%).

Arterial lines, central lines and cardiac output monitoring were only used in 27%, 14% and 5% of the high risk group. This is despite the considerable evidence that peri-operative haemodynamic monitoring can improve patient outcomes.

Overall mortality at 30 days was 1.6%. The mortality in the high risk group was 6.2% and in the low risk group was 0.4%.

Degree of surgical urgency in high risk patients was closely linked to mortality. 1 in 4 high risk, immediate patients were deceased at 30 days. The figure for urgent and expedited high risk patients was 1 in 8 and 1 in 16 respectively.

1167/17295 (6.7%) of patients were cared for in a critical care unit immediately after theatre/recovery. In the high risk group this figure was 736/3323 (22.1%), returning almost 4 out of 5 of the high risk population to ward level care.

There were concerns over postoperative location (from theatre/recovery) in 353 cases. These cases had a 30 day mortality rate of 5.0 % compared to 1.4% where there were no concerns.

48% of high risk patients who died never went to a critical care facility (80/165).

14/26 elective and 99/158 non-elective patients who died never accessed critical care facilities.

Recommendations - Prospective data

There is a need to introduce a UK wide system that allows rapid and easy identification of patients who are at high risk of postoperative mortality and morbidity. *(Departments of Health in England, Wales & Northern Ireland)*

The decision to operate on high risk patients (particularly non-elective) should be made at consultant level, involving surgeons and those who will provide intra and postoperative care. *(Clinical Directors and Consultants)*

An assessment of mortality risk should be made explicit to the patient and recorded clearly on the consent form and in the medical record. *(Consultants)*

Once a decision to operate has been made there is a need to provide a package of full supportive care. This may include critical care admission or support, for the higher risk patients. If critical care admission is not possible then the decision to operate is being made without provision of an appropriate package of care: this should be communicated to the patient as part of the consent procedure. *(Clinical Directors and Consultants)*

Better intra-operative monitoring for high risk patients is required. The evidence base supports the use of peri-operative optimisation and this relies on extended haemodynamic monitoring. NICE Medical Technology Guidance 3 relating to cardiac output monitoring should be applied. *(Clinical Directors)*

The postoperative care of the high risk surgical patient needs to be improved. Each Trust must make provision for sufficient critical care beds or pathways of care to provide appropriate support in the postoperative period. *(Medical Directors)*

To aid planning for provision of facilities for high risk patients, each Trust should analyse the volume of work considered to be high risk and quantify the critical care requirements of this cohort. This assessment and plan should be reported to the Trust Board on an annual basis. *(Medical Directors)*

Key Findings - Peer review data

Overall the care of patients was good in only 48% of high risk patients.

The review of the high risk cases by the NCEPOD Advisors uncovered a lack of consensus as to what constitutes high peri-operative risk.

67% of these high risk patients were overweight.

In only 37/496 patients was any mention of mortality made on the consent forms.

Only 6.1% of patients had a documented plan to improve their pre-operative nutritional status.

For those patients in the non-elective group 95.7% had a timely initial assessment and 98.8% had a documented management plan.

98% of high risk elective patients received appropriately timed surgery. In comparison 80% of non-elective patients received timely surgery. One in five non-elective high risk patients were delayed going to theatre.

The 30 day mortality in those patients in whom the Advisors considered there to have been inadequate pre-operative fluid management was 20.5% compared to 4.7% mortality in those with adequate pre-operative fluid therapy. This reinforces previous evidence outlining the beneficial effects on outcome of optimisation of fluid status prior to surgery.

Patients who suffered intra-operative complications had a 30 day mortality of 13.2% compared to 5.7% in those without.

Cardiac output monitoring was rarely used in high risk patients.

Inadequate intra-operative monitoring was associated with a three fold increase in mortality.

In only 19/550 elective patients was there any record of entrance into any form of enhanced recovery programme.

For those high risk patients not discharged to a higher care level area 360/489 (74%) had records of being in an early warning scoring system or track and trigger system for the detection of a deterioration in their physiological status.

8.3% of high risk patients who should have gone to a higher care level area postoperatively did not do so.

The Advisors considered that postoperative complications had affected outcome in 56/213 (26%) of cases.

Recommendations - Peer review data

All elective high risk patients should be seen and fully investigated in pre-assessment clinics. Arrangements should be in place to ensure more urgent surgical patients have the same robust work up. *(Clinical Directors and Consultants)*

Greater assessment of nutritional status and its correction should be employed in high risk patients. *(Consultants)*

High risk patients should have fluid optimisation in a higher care level area pre-operatively, if it is to be adequate and contribute to better outcomes. *(Consultants)*

The adoption of enhanced recovery pathways for high risk elective patients should be promoted. *(Clinical Directors)*

Given the high incidence of postoperative complications demonstrated in the review of high risk patients, and the impact this has on outcome there is an urgent need to address postoperative care; this supports the prospective data.* *(Clinical Directors)*

***Recommendation from page 14**
The postoperative care of the high risk surgical patient needs to be improved. Each Trust must make provision for sufficient critical care beds or pathways of care to provide appropriate support in the postoperative period. *(Medical Directors)*

Published December 2011
by the National Confidential Enquiry
into Patient Outcome and Death

5th Floor
125 Wood Street
London
EC2V 7AN

T 0207 600 1893
F 0207 600 9013
E info@ncepod.org.uk
w www.ncepod.org.uk

ISBN 978-0-9560882-6-0

A company limited by guarantee Company no. 3019382
Registered charity no. 1075588