

# NCEPOD audit pack

Death following a first time, isolated coronary artery bypass graft

## The heart of the matter

A report of the National Confidential Enquiry into Patient Outcome and Death (2008)



## What is clinical audit

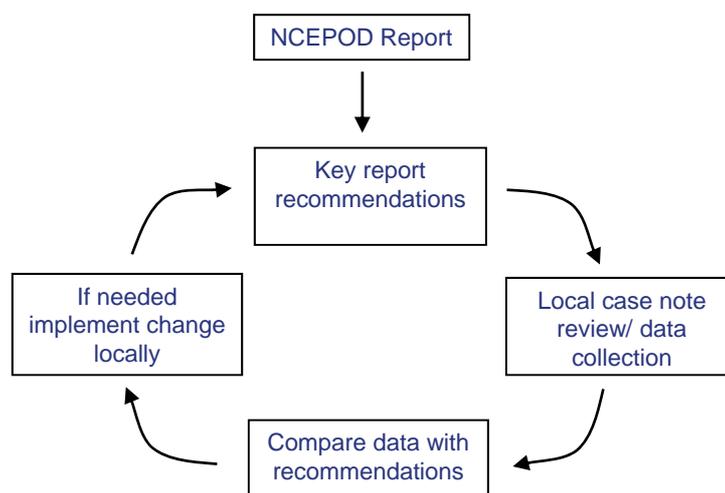
The National Institute for Clinical Excellence (NICE) endorsed definition of clinical audit is: 'A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery'. Please refer to the Health Quality Improvement Partnership (HQIP) [www.hqip.org.uk](http://www.hqip.org.uk) for more details.

**NCEPOD** – “Improving the quality of medical and surgical care”.

The overall aim of NCEPOD is to assist in maintaining and improving standards of medical and surgical care.

This is achieved by undertaking confidential questionnaire and peer review based studies, the findings of which are disseminated back to the medical profession and wider audience in the form of a report. Each NCEPOD report makes a number of key recommendations related to both clinical and organisational aspects of care. It is only when these recommendations are implemented that NCEPOD realises its function and overall aim.

The purpose of the NCEPOD audit pack is to provide clinicians with a tool to carry out local audits based on the findings of specific NCEPOD reports. Where appropriate report recommendations have been adapted to become more relevant to front line clinicians and case note review.



## Introduction

Coronary artery bypass grafting (CABG) must be the most thoroughly researched operation in the history of surgery. This single operation has dominated the work of most adult cardiac surgical units and represents over 80% or even 90% of the work in many busy cardiac surgery services. While there has been much research performed to identify clinical risk factors associated with outcome there has been limited research conducted on the impact of organisational factors. In this sample of cases associated with CABG we have found half of operations were performed as urgent procedures. That is to say, amongst these were patients with clinical manifestations of cardiac ischaemia, processed through the stages of invasive diagnostic procedures and scheduled for percutaneous or surgical interventions. This is a considerable feat of organisation requiring excellent team work and communication if it is to routinely go well. It is this process which is the subject of this NCEPOD report.

CABG is a technically demanding but commonly performed surgical procedure. A recent meta-analysis estimated there to be 800,000 procedures worldwide each year<sup>1</sup>. Surgeons accepting a greater proportion of patients at increased risk of peri-operative death may have a higher mortality rate but these are the very patients who stand to gain the most from having surgery. Unless mortality rates are adjusted for risk on a case by case basis they may give a false picture of the performance of a surgeon and the surgical unit. Proper use of risk prediction also helps to reduce avoidance of the very deserving but high risk patients.

A great deal of work has been done and much is known about the patient-related risks. The system used throughout the era of this study is the European System for Cardiac Operative Risk Evaluation

(EuroSCORE)<sup>2</sup>. This is the most established and tested international risk stratification system. With greater public awareness of performance there needs to be transparent and open systems in place, that acknowledge strengths and weaknesses of the methods used for risk stratification of patients, especially with respect to high-risk patients<sup>3</sup>.

A good understanding and meticulous implementation of systems to make fair comparisons is imperative. It is likely that as older patients with more morbidity are operated upon there will be a commensurate rise in mortality rates. So far this has not been demonstrated in UK data from the Society for Cardiothoracic Surgery in Great Britain and Ireland (SCTS). Data published in 2003 showed that while the number of procedures performed over the previous five years had remained relatively stable at around 25,000 per annum, the associated mortality rate has also remained stable at about 2%<sup>4</sup>. Since then, and within the time frame of the NCEPOD study, the number of CABG procedures performed annually has in fact decreased. In 2004/2005 just under 23,000 bypass procedures were carried out, for the period 2005/2006 this dropped to 20,773 bypass operations, of which 98.4% patients survived the procedure<sup>5, 6</sup> and in 2006/2007 this further reduced to 19,444<sup>7</sup>.

What is clear is that elective waiting times have come down and more operations are being performed in less stable patients at almost certainly increased risk. There remains an anxiety that in a modern era of transparency and accessible data, surgical teams may want to avoid high risk cases unless increasing risk and the organisational factors in caring for more acute cases are fully appreciated.

Cardiothoracic surgeons have been under increasing

## Introduction

pressure to publish surgeon-specific mortality rates to enable the public and the profession to make comparisons between surgeons and units, but it is recognised that simple outcome data are open to misinterpretation. In 2003, the SCTS approached the National Confidential Enquiry into Patient Outcome and Death (NCEPOD), to carry out a study to investigate the impact of organisational factors on outcome following first time isolated CABG. By determining areas of care that influence patient outcome, other than just the surgical procedure, factors that lie behind surgical mortality rates may be more clearly understood and defined; this is an essential step in refining systems of care for these patient groups. In this study NCEPOD aimed to review all in-hospital deaths following first time isolated CABG surgery to identify the effect of such organisational factors on patient outcome.

## Method

### Study aim

The aim of the study was to examine whether there are identifiable changes in care processes, including the functioning of cardiac teams, that impact on patient outcome following a first time isolated coronary artery bypass graft (CABG).

### Consensus method

Prior to the start of the study, the expert group and CORU undertook a consensus exercise, the aim of which was to identify which factors of care should be examined in the study. An initial postal survey of the expert group identified 95 potential topics, from which a list of 27 topics related to remediable features of the care process was identified. A meeting was held during which the expert group discussed and amended this list of topics before ranking them in priority order. The top 13 topics (below) were then chosen to form the basis of the study. Full details of the consensus process used can be found in Utley et al, 2007<sup>8</sup>.

1. To what extent does variation in referral and admission process affect outcome?
2. To what extent do institutional approaches to retrospective multidisciplinary case review and audit vary?
3. To what extent does the scheduling of operations affect outcome?
4. To what extent does the in-hospital process for reviewing unstable cases affect outcome?
5. Was the operation performed appropriate for the patient and the circumstances?
6. To what extent does variation in the anaesthetic process affect outcome?
7. To what extent does variation in multidisciplinary case planning affect outcome?
8. To what extent does variation in the patient investigation process affect outcome?

9. To what extent does variation in the patient investigation process affect outcome?
10. To what extent does the identification and management of peri-operative complications affect outcome?
11. To what extent does variation in medical or interventional management pre-operatively affect outcome?
12. Is continuity of care and communication a factor that affects outcome?
13. Are there identifiable changes in care processes that could reduce the influence of comorbidities on outcome?

### Sample size

Cases were identified via a nominated main point of contact in each unit; this could have been the cardiothoracic audit lead, the cardiothoracic database manager or the NCEPOD Local Reporter (a local contact who supplies NCEPOD with data for most of their studies). The patients were identified either by the Office of Population Census and Surveys (OPCS) codes (bleow), or by defining the operation as CABG only as defined in the minimum data set of the Society for Cardiothoracic Surgery in Great Britain and Ireland (SCTS)<sup>4</sup>.

### OPCS codes

- K40 – Saphenous vein graft replacement of coronary artery
  - K41 – Other autograft replacement of coronary artery
  - K42 – Allograft replacement of coronary artery
  - K43 – Prosthetic replacement of coronary artery
  - K44 – Other replacement of coronary artery
  - K45 – Correction of thoracic artery to coronary artery
- Excluding codes K44.2, K45.6 and those with an ICD10 code of Z95.1

# Method

## Questionnaires

### Surgical questionnaire

A surgical questionnaire was sent to the consultant cardiothoracic surgeon involved in each patient's care.

### Anaesthetic questionnaire

An anaesthetic questionnaire was sent to the consultant anaesthetist responsible for the care of each patient.

### Organisational questionnaire

Each site was required to complete an organisational questionnaire for the first year and third year of the study. In the second year of the study sites were simply requested to inform NCEPOD if there had been any changes in organisational facilities. Where new sites were participating in the second or third year they were asked to complete the whole questionnaire.

### Casenotes

Alongside the completed questionnaires NCEPOD also asked that copied extracts of the casenotes be returned. These included admission notes; EuroSCORE scoring sheet; medical casenotes for the duration of the hospital stay (admission to death or discharge); records of multidisciplinary team (MDT) decisions; any separate notes/charts relating to the surgical procedure; any separate anaesthetic records; consent form; copy of autopsy report if performed; any relevant minutes of mortality audit meetings relating to this case (for deceased patients); discharge summary (for surviving patients). NCEPOD also requested data to be sent back to accompany the organisational questionnaire where applicable; this included copies of any written policies for clinical review of unstable, urgent, in-hospital cardiothoracic

patients; records of attendance for/minutes of MDT case planning meetings; patient information sheets for cardiac surgery; records of attendance for/minutes of MDT review and audit meetings.

### Advisor groups

A multidisciplinary group of advisors was recruited to review the casenotes and associated questionnaires. This group comprised cardiothoracic surgeons, cardiothoracic anaesthetists and cardiologists. For each case an assessment form was completed by both NCEPOD researchers and the advisors. NCEPOD researchers extracted information from the casenotes with regard to dates of referral, admission and review, the mode of admission and the consenting process. Advisors gave their expert opinion on the timeliness of the admission and review process, transfers, the scheduling of the operation, patient investigations, peri-operative management and the appropriateness of surgery.

All questionnaires and casenotes were anonymised by non-clinical staff at NCEPOD. All patient, clinician and hospital identifiers were removed. Neither clinical staff at NCEPOD, nor the advisor group had access to any information that would enable patients or clinicians to be identified. 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 cases and ask for opinions from other specialties or raise aspects of a case for discussion.

# Key findings and recommendations

## Referral and admission process

### Key findings

Written protocols for referral of patients were available in 28/58 of cardiothoracic units. However there were discrepancies in the use of protocols as described by surgeons and those reported to be present in each unit.

99% of patients were referred by a cardiologist. Of these, 86% were referred by a consultant.

Of the sample of patients included in the study, in 272/821 (33%) integrated care pathways were used. Variation in the quality of proforma and integrated care pathways documentation was found. Furthermore there was lack of clarity on the purpose of these documents and how they contributed to patient care pathways.

In the opinion of the advisors for 57/821 (7%) of cases there was a delay from referral to the first cardiothoracic review and in 33 of these patients outcome was adversely affected.

In (80/820) 10% of patients the initial cardiothoracic assessment was poor or unacceptable in the advisors' opinions.

It was difficult to assess, from the casenotes, whether patients deteriorated during transfer. However, of the 405 patients transferred to a cardiothoracic unit 27 (7%) were judged by the advisors to have deteriorated during the transfer.

### Recommendations

Cardiothoracic units need to adhere to the requirement of the National Service Framework for Coronary Artery Disease and use protocols for referrals to their unit. These protocols should be standardised nationally for patients who require coronary artery bypass graft surgery. The degree of urgency of referral should be emphasised within these protocols (Clinical Directors).

Cardiothoracic units need to ensure that monitoring systems are in place to record nationally agreed audit data on referrals and the decision to operate. These systems need to identify patients who are in danger of breaching national agreed waiting times so that surgery can be expedited (Clinical Directors).

If cardiothoracic units use integrated care pathways (ICPs) for patients requiring CABG surgery these should be fit for purpose. A standard minimum data set of information that should be included in these ICPs needs to be developed (Clinical Directors).

Pre-admission clinics have an important place in assessing and determining patient requirements for surgery. Cardiothoracic units need to review the function of these clinics to ensure that they meet nationally agreed requirements (Clinical Directors).

Patients who have acute myocardial ischaemia and require CABG require special attention. Many of these patients are intra or inter-hospital transfers. This group of patients should have surgery performed as soon as their clinical condition permits based on appropriate investigation and pre-operative therapeutic optimisation (Clinical Directors).

## Key findings and recommendations

### Scheduling of operations

#### Key findings

Less than 10% of cases were operated upon outside normal hours.

Consultant involvement in out of hours cases was higher than during normal working hours.

Patients operated upon out of hours were judged to have received an overall standard of care rated as “good practice” more frequently than those operated upon during normal hours.

The scheduling of operations does not appear to have had any clinically significant detrimental impact on the quality of care. Out of hours facilities and availability of senior clinicians were at least as good as availability during normal hours.

#### Recommendations

## Key findings and recommendations

### Multidisciplinary case planning

#### Key findings

Only four of the 58 units had a protocol for multidisciplinary case planning for patients undergoing intervention as a result of coronary artery disease.

Only 21 of the 58 units held pre-operative MDT meetings.

Most MDT meetings were attended by cardiologists (19/21 units) and cardiothoracic surgeons (17/21 units). Anaesthetists were rarely involved in MDT meetings (1/21 units).

Documentation of participation in MDT meetings was poor and only recorded in 7/21 units.

Only one in four patients in this study were discussed at a pre-operative MDT meeting.

Patients who were discussed at a pre-operative MDT meeting were more likely to have a clear written operative plan

#### Recommendations

Each unit undertaking coronary artery bypass grafting should hold regular pre-operative MDT meetings to discuss appropriate cases. Core membership should be agreed and a regular audit of attendance should be performed (Clinical Directors).

Each unit should have a clear policy for which cases should be discussed at pre-operative MDT meetings (Clinical Directors).

There should be a clear protocol for deciding on best treatment strategy (surgery v PCI) that involves both cardiologists and surgeons (Clinical Directors).

A clear written plan should be made pre-operatively for all patients (with the exception of salvage cases) (Clinical Directors).

Trusts and consultants should identify time within the agreed job plan to allow participation in MDT meetings (Clinical Directors).

## Key findings and recommendations

### Patient investigations

#### Key findings

Almost one in ten patients did not receive appropriate pre-operative investigations.

In half of the patients that did not receive appropriate pre-operative investigations, the outcome was judged to have been adversely affected.

The use of a written protocol for patient investigations was associated with a higher percentage of cases judged to have received an overall standard of care which was good.

#### Recommendations

There should be a written protocol available for the preoperative investigation of all patients (Clinical Directors).

Pre-operative investigations should be contemporaneous; where delay has occurred between assessment and surgery consideration should be given to repeating investigations (Clinical Directors).

There must be a system in place to ensure that preoperative investigations are reviewed by a senior clinician and acted upon (Clinical Directors).

### Medical management

#### Key findings

While the majority of patients continued on beta blockers, potassium channel inhibitors and calcium antagonists, a substantial number of patients stopped these drugs prior to surgery.

The majority of patients stopped anticoagulant therapy prior to surgery with the exception of LMW heparin where equal numbers of patients stopped or continued the drug.

Whilst the majority of patients stopped clopidogrel or anticoagulant therapy a substantial number of patients continued and these patients had a higher rate of postoperative bleeding complications including tamponade.

#### Recommendations

Further studies should be undertaken to establish the risks and benefits of continuing pre-operative medication. Guidelines should be produced based upon sound evidence (Society for Cardiothoracic Surgery in Great Britain and Ireland/NICE).

NCEPOD supports the guidance of the American College of Cardiology and the American Heart Association that clopidogrel should be stopped prior to surgery wherever practicable.

## Key findings and recommendations

### Non-elective, urgent, in-hospital cases

#### Key findings

304 patients were defined as urgent, in-hospital.

Only 39% of these patients received a standard of care defined as good practice.

208/300 patients (69%) were inpatients for three or more days prior to surgery.

Three out of four hospitals did not have a policy to ensure timely and appropriate review of these urgent, in-hospital patients.

Medical management of these patients was inappropriate in 37 cases (12%).

Investigations were not appropriate in 26 cases (9%) and it was felt that outcome was affected by this deficit in appropriate investigations in 15 cases.

Peer review identified cases where surgery was inappropriately performed in the presence of an acute myocardial infarct and also inappropriately not performed when patients were clearly unstable despite medical therapy.

#### Recommendations

There should be a protocol to ensure timely and appropriate review of unstable cases that involves both cardiologists and cardiac surgeons (Clinical Directors).

The senior surgeon needs to be aware of any change in clinical status in the pre-operative period to ensure that surgery is still appropriate (Consultant Cardiothoracic Surgeons).

Given the high mortality when operating soon after an acute infarct more use should be made of strategies to optimise clinical condition, provide symptom relief and allow surgery to be performed at a later date (IABP and PCI) (Clinical Directors).

A "track and trigger" system should be used to provide early recognition of clinical deterioration and early involvement of consultant staff (Clinical Directors).

## Key findings and recommendations

### Comorbidities

#### Key findings

Neither height and/or weight nor body mass index (BMI) were recorded in almost a quarter of cases.

More than half of the patients were overweight or obese.

There was a high level of comorbidity in this group of patients. The majority had their comorbidity managed reasonably, but in a number of cases there was room for improvement particularly in the management of renal disease.

There were discrepancies between surgeons and anaesthetists in the grading of LV function.

#### Recommendations

All patients should have height, weight and a BMI recorded on admission, unless their clinical condition precludes this (Medical Directors).

Where pre-operative comorbidity exists, there should be a clear written management plan which is followed in order to optimise the physical status of the patient prior to surgery, and identify the need for specific postoperative support to be available (Clinical Directors).

There should be clear guidance about how to estimate LV function, and at what point in the patient journey this should be ascertained and recorded. Units should audit discrepancies in recorded LV function from surgeons and anaesthetists and where there are significant differences ensure that systems are in place to address this (Clinical Directors and Audit Leads).

### Anaesthetic process

#### Key findings

901/923 (98%) patients were assessed by an anaesthetist prior to surgery, 79% of the anaesthetists were consultants.

In 899/923 (97%) cases a consultant was the most senior anaesthetist at induction.

## Key findings and recommendations

### Peri-operative management and post operative care

#### Key findings

The majority of patients underwent elective or urgent operations.

All patients received an appropriate level of care immediately postoperatively.

A small number of patients were transferred to a lower level of care sooner than their clinical condition dictated (10 cases).

There was a high incidence of postoperative complications (94%).

There was delay in detecting complications in 5% of cases.

Pre- and postoperative complications were felt to be inadequately managed in 127/811 cases.

Of these 127 cases it was felt that inadequate management of the complications may have led to death in 95 patients.

Advisors raised concern over the role of cardiac ICU and general ICU in the management of patients with a complicated postoperative course.

Critical incidents were more frequently observed in the absence of a clear written operative plan.

#### Recommendations

Patients who have a more complicated postoperative period are difficult to manage. Any interaction between different medical specialities about patient management should be at consultant-to-consultant level, in particular for patients with suspected intra-abdominal pathology (Consultants).

Cardiac recovery areas/critical care units are best suited to managing the majority of patients who recover uneventfully. Patients who are developing critical illness and additional organ failure should be managed in an environment with sufficient throughput of such patients to have the resources and experience to provide optimum outcomes (General Critical Care Units).

Cardiac critical care units should have the facility to provide renal replacement therapy (Cardiac Critical Care Units).

Senior clinicians should be readily available throughout the peri-operative period in order to ensure that complications (which occur commonly) are recognised without delay and managed appropriately (Clinical Directors and Consultants).

## Key findings and recommendations

### Appropriateness of surgery

#### Key findings

Overall 84% of cases received an appropriate operation.

A clear written operative plan was available in 83% of cases.

Consultant anaesthetists were involved in most (97%) cases.

When operating out of hours nearly all procedures were performed by a consultant surgeon.

#### Recommendations

A clear written operative plan should be available. This should include contingency arrangements where the findings at surgery dictate an alternative approach (back planning) (Clinical Directors and Consultant Cardiothoracic Surgeons).

Where unexpected events occur during surgery, surgeons should have an adaptable approach, and modify the operation to suit the circumstances of the case (Cardiothoracic Surgeons).

A clear description of the extent of the disease should be recorded (Cardiothoracic Surgeons).

Where an operation performed deviates from the operation planned, the reason for this should be clearly documented. (Cardiothoracic Surgeons).

# Key findings and recommendations

## Communication, consent and continuity of care

### Key findings

Only 16 out of 58 cardiothoracic units had a protocol for handover between clinical teams.

18 out of 58 cardiothoracic units had no standard handover documentation from theatre to recovery/critical care.

13 out of 58 cardiothoracic units had no standard handover documentation from recover/critical care to the ward.

Independent sector hospitals had more protocols for handover between clinical teams and standard handover documents from theatre to recovery/critical care and from recovery/critical care to the ward than NHS hospitals.

7 out of 57 units did not provide written information sheets about coronary artery bypass grafting to patients.

The consenting process for patients undergoing coronary artery bypass grafting is poor. Consultant involvement in the consent process was low, almost one third of patients were consented by SHOs and no risk of death could be found in 384 cases (47%).

### Recommendations

Protocols must exist for handover between clinical teams and patient locations to ensure effective communication and continuity of care (Clinical Directors).

All patients should receive an information sheet describing the proposed operation (Consultant Cardiothoracic Surgeons).

A consultant should obtain consent for coronary artery bypass grafting (Consultant Cardiothoracic Surgeons).

Potential complications must be recorded on the consent form. This should detail the likely complications and the incidence of these complications based on local data (Clinical Directors and Consultant Cardiothoracic Surgeons).

An accurate risk of death must be quoted on the consent form. This should take into account the proposed procedure and clinical status of the patient (Clinical Directors and Consultant Cardiothoracic Surgeons).

# Key findings and recommendations

## Multidisciplinary review and audit

### Key findings

43/58 cardiothoracic units held regular morbidity and mortality audit meetings, of which 38/43 of these held meetings monthly or more frequently.

Only 7/43 cardiothoracic units graded quality of patient care at morbidity and mortality audit meetings.

Procedures for providing feedback from morbidity and mortality audit meetings varied between cardiothoracic units often without clear identifiable systems being in place.

822/907 (91%) of cases were reviewed at a morbidity and mortality audit meeting.

An anaesthetist attended a morbidity and mortality audit meeting for 396/910 (44%) of cases.

369/910 (41%) of cases were known to have had an autopsy, 85% of these were coronial.

The total number of autopsies fell from year 1 (172, 46%) to (87, 34%) in year 3 of the study.

798/910 (88%) of cases were referred to the coroner, of these the proportion that had coronial autopsies was 141 (44%), 100 (40%) and 73 (32%) respectively for each year of the study.

### Recommendations

Morbidity and mortality audit meetings should be held in all cardiothoracic units. The majority of units should hold meetings at least monthly. If the numbers of cases performed in a unit are small, alternative arrangements should be made to incorporate these cases in other surgical audit meetings (Clinical Directors and Audit Leads).

The personnel present at morbidity and mortality audit meetings should reflect the composition of the multidisciplinary cardiothoracic team (The Cardiac Team and Clinical Directors).

A clear record should be kept of morbidity and mortality audit meeting which should comply with national guidelines (Audit Leads).

A common system for grading of quality of care of patients should be employed for all patients discussed in morbidity and mortality audit meetings. The peer review scale used by NCEPOD provides such a system (Clinical Directors).

There should be robust systems in place to learn from the findings of morbidity and mortality meetings. The cardiothoracic audit leads should be responsible for managing this process (Audit Leads).

The decline in the number of autopsies performed following deaths from first time coronary artery bypass grafting needs to be reversed. To achieve an increase in the autopsy rate will require a substantial change to both the coronial system and hospital autopsy service (Chief Executives, Medical Directors and Clinical Directors).

## References

- 1 Nalysnyk L, Fahrbach K, Reynolds M W, et al. (2003). *Adverse events in coronary artery bypass graft (CABG) trials: a systematic review and analysis*. *Heart*; 89; 767-772.
- 2 Nashef S A M, Roques F, Michel P, et al. (1999). *European system for cardiac operative risk evaluation (EuroSCORE)*. *European Journal of Cardiothoracic Surgery*.; 16; 9-13.
- 3 Bridgewater B, Grayson A D, Jackson M, et al. (2003). *Surgeon specific mortality in adult cardiac surgery: comparison between crude and risk stratified data*. *British Medical Journal*.
- 4 Keogh B, Kinsman R. (2004). *Fifth national adult cardiac surgical database report 2003*. London: Society of Cardiothoracic Surgeons of Great Britain and Ireland.
- 5 Hospital Episode Statistics. (2005). *Hospital Episode Statistics: Main operations. NHS hospitals. England 2004-05*. The Information Centre.
- 6 Health Care Commission. (2007). *Latest survival rates for heart surgery published*. [http://www.healthcarecommission.co.uk/newsandevents/pressreleases.cfm?cit\\_id=5624&FAArea1=customWidgets.content.view.1&usecache=false](http://www.healthcarecommission.co.uk/newsandevents/pressreleases.cfm?cit_id=5624&FAArea1=customWidgets.content.view.1&usecache=false). Published 8th August 2007.
- 7 Society for Cardiothoracic Surgery in Great Britain and Ireland. *Sixth national adult cardiac surgical database report. 2008*. In press.
- 8 Utley M, Gallivan S, Mills M, et al. *A consensus process for identifying a prioritised list of study questions*, *Health Care Management Science*, 2007; 10:105-110.