



Oxford Radcliffe Hospitals NHS Trust

**Progress following the publication of the Healthcare
Commission's investigation report in March 2007**

September 2008

Background

In March 2007, the Healthcare Commission published its report of the investigation into the care and treatment of patients undergoing cardiac surgery at the Oxford Radcliffe Hospitals NHS Trust.

The focus of the investigation was on the adult cardiothoracic services provided by the trust and the data collected on their outcomes following cardiac surgery. There were concerns raised about the rates of mortality for adults undergoing the most common cardiac surgical procedure at the trust. These concerns were against a background of a number of critical reviews of the cardiothoracic unit over previous years. The investigation focused on:

- The way in which the trust had responded to previous reviews.
- Data on rates of mortality.
- The quality of the service provided to adult patients undergoing cardiac surgery in the trust's cardiothoracic unit.

At the time of the original investigation, the analysis of data in the Central Cardiac Audit Database (CCAD) by the Healthcare Commission showed that the trust bordered on the 99.8% control limit, based on the UK rates of mortality for coronary artery bypass graft (CABG) current at that time. In preparation for this visit, the CCAD data were analysed again and it was found that the trust's rates of mortality were within acceptable limits. Currently, there are no concerns relating to operative mortality rates at the trust.

In our report, we made 13 recommendations relating to the adult cardiothoracic services and to the trust's clinical governance arrangements:

Consent and information

- 1 The trust must ensure that staff in the cardiothoracic surgical unit obtain the consent of all patients to treatment in accordance with the Department of Health's guidelines, *Good practice in consent implementation guide: consent to examination or treatment* (2001), and guidance issued by the Health Service Ombudsman and the Society for Cardiothoracic Surgery, *Consent in cardiac surgery: a good practice guide to agreeing and recording consent*.

Management of patients assessed as high-risk

- 2 The trust must ensure that staff in the cardiothoracic surgical unit assess and meet the needs of patients categorised as high-risk in an agreed and consistent way. This must include assessing and planning the care and treatment provided prior to, during and following surgery. The system must be effectively monitored and evaluated.

Clinical governance and leadership: the cardiothoracic surgical service

- 3 The staff in the cardiothoracic unit must define the core objectives of the unit and agree how these fit in with the objectives of the trust as a whole and with the aspirations of the individual surgeons.
- 4 The chief executive and medical director must manage the consultant cardiac surgeons more effectively and ensure that appraisals result in a full assessment of individual performance and any developmental needs.
- 5 The model for the provision of care for patients in the cardiothoracic critical care unit must be reviewed to ensure that it provides continuity of care for patients and is in line with best practice in other cardiac units. The implementation of a new model of care must be supported by a policy, which must be monitored and evaluated with input from the multidisciplinary team. It must include clarity of roles and accountability.
- 6 The trust must review the effectiveness of the cardiothoracic mortality and morbidity meetings. In particular, the trust must be able to demonstrate that the multidisciplinary team considers the care and treatment given to patients that lessons are learned from outcomes of surgery, and that developments and improvements to care and treatment result.
- 7 The trust should reactivate the involvement of the Society for Cardiothoracic Surgery to help ensure that the necessary improvements are made in relation to the care and treatment of high-risk patients and that the trust uses its own data to help drive improvement.

Clinical governance and leadership: the trust

- 8 The trust must continue to develop its arrangements for clinical governance and ensure that these arrangements are rigorously monitored, assessed and evaluated.
- 9 The trust must ensure that healthcare professionals have access to the necessary time, facilities, advice and expertise in order to conduct clinical audits effectively.
- 10 The trust must ensure that it has a robust system for reviewing, updating and distributing its policies and procedures. The implementation of policies and procedures must be monitored.
- 11 The trust's board must ensure that the data on outcomes following CABG are closely monitored and that action is taken wherever necessary.

Collection and use of data on the outcomes following cardiac surgery

- 12 The trust must ensure that the cardiothoracic consultants work with the staff responsible for coding for the patient administration system (PAS), to ensure that the data fed to HES are accurate. Regular and rigorous cross checks between the PAS and the cardiothoracic unit's own data collection system must be put in place.

13 The trust must introduce rigorous systems for internally validating cardiac data against patients' medical records. The trust must use its cardiac data to inform clinical practice in the unit and improve the quality of care for patients.

The review and assessment process

On completion of the investigation, the trust drew up an action plan that outlined how it aimed to address each of the recommendations. The trust, the South Central Strategic Health Authority (the SHA) and the Healthcare Commission all agreed the action plan. Over the past year, progress against the action plan has been assessed generally through meetings between the trust and South Central SHA and with regional Healthcare Commission staff.

A year after publication of the original report, between March and May 2008, the Healthcare Commission undertook an assessment of progress against the action plan. Details of the assessment team are provided in Appendix A.

A range of data and trust documents, including trust strategies, policies and minutes of meetings were also analysed by the Healthcare Commission's assessment team.

A scheduled visit was conducted at Oxford Radcliffe Hospitals NHS trust on the 6 May and 7 May 2008 to assess progress against the 13 recommendations outlined in the original investigation report.

A tour of the cardiothoracic unit was followed by interviews with a range of directors and staff including managers, chairs, clinicians and nursing staff. See appendix B for a full list of interviewees.

The trust's progress against each of the 13 recommendations is detailed below.

Consent and information

Recommendation 1

The trust must ensure that staff in the cardiothoracic surgical unit obtain the consent of all patients to treatment in accordance with the Department of Health's guidelines, *Good practice in consent implementation guide: consent to examination or treatment* (2001), and guidance issued by the Health Service Ombudsman and the Society for Cardiothoracic Surgery, *Consent in cardiac surgery: a good practice guide to agreeing and recording consent*.

Obtaining the consent of patients to treatment is now a shared process and starts with the cardiologist before referral to the cardiothoracic surgical team. The consent process is outlined in the trust's policy document *Model Policy for Consent for Cardiothoracic Surgery* (June 2007), which refers to the Department of Health guidelines and refers to a two or three-stage consent process. The policy includes information on the sharing of information and describes who is responsible for obtaining consent. There are two directorate documents that support the policy – *the Consent Process Policy of the Cardiothoracic Surgery Unit* (March 2007) and the *Consent Patient Pathway* (November 2007), both of which further define the roles of different individuals in obtaining informed consent from patients.

The consent policy states that senior house officers (SHOs) undertake specific training on consent in their local induction programme. It also covers staff's competence to obtain consent from patients. It states that it is a health professional's own responsibility to ensure that when they require colleagues to seek consent on their behalf, they are confident that the colleague is competent to do so; and that individuals are to work within their own competence and not to agree to perform tasks which exceed that competence. As such, health professionals should not be obtaining consent for a procedure if they do not have the required knowledge base.

All new medical staff are required to attend an induction session that, according to the programme, includes a 30-minute session on consent. Senior medical staff and registrars reported that medical staff also learn about the patient pathway as part of their induction, and visit outpatient clinics where the majority of patients are seen by a consultant. In the clinics, new medical staff observe how the consent process is carried out, including sharing information with the patient about the procedure and its benefits and risks.

The trust's policy states that the consultants are required to discuss with the patient the benefits and the risks of the procedure to be undertaken, as well as the procedure itself. Staff commented that all discussions are documented in the patient's health care record. As part of the patient's consent pathway, discussion also takes place with the pre-admission nurse. Patients are given written information that includes:

1. The Oxford Heart Book (also known as the Blue Book), which covers details of the surgery, the ward, cardiothoracic critical care unit (CTCC), staff,

information about the recovery period, healthy eating, what to bring to the hospital, visiting hours and phone numbers for relatives and friends.

2. A leaflet specific to the surgery (for example, valve or bypass surgery), the risks involved, why surgery is necessary, alternatives to surgery, and trust contact details.
3. Department of Health guidelines on consent and the consent form itself.
4. British Heart Foundation booklets as appropriate.
5. A booklet from the College of Anaesthetists on anaesthetics.
6. A leaflet on risk from the Society of Cardiothoracic Surgeons and Parliamentary and Health Service Ombudsman (called *Surgery and risk*).

Nursing staff from the pre-admission clinic told us that, if patients are unable to attend, they are telephoned at home and the patient information leaflets are posted to them. Patients on the inpatient ward will also be visited if they have not received the information.

An audit conducted in February 2008 indicated that four out of the five consultants were documenting involvement in the consent process. For the fifth consultant, their specialist registrar had been documenting information on benefits and risks the day before surgery.

The audit also showed that patients receive written patient information leaflets and that signed consent is obtained, although only 37.5% of patients had received a copy of the completed consent form. The same audit found that all the medical staff involved in taking consent had undertaken training in the consent process.

The consent policy states that nursing staff may re-confirm the consent of a patient on admission if the consent form has been completed in advance. However, senior nursing staff said that, currently, this is undertaken by the medical staff and that this will continue until the nursing staff have the required skill and knowledge base.

No direct reference is made in any of the documents reviewed to the guide published by the Health Service Ombudsman and the Society for Cardiothoracic Surgery, *Consent in cardiac surgery: a good practice guide to agreeing and recording consent*, although the consent policy does state that health professionals must also be aware of any guidance on consent issued by their own regulatory bodies. The key principles of this document – including that professionals should share a wide range of information with patients, that discussions should be documented and that patients should receive written information – are all covered as part of the process on the CCTC unit.

Summary

The trust has made good progress on compliance with the consent process. Information and guidelines from both internal and external sources are made

available to patients and obtaining consent is now a shared process. However, the trust needs to ensure that all patients receive copies of their consent forms and that all stages of the consent process are documented clearly in the medical notes for all patients.

Management of patients assessed as high-risk

Recommendation 2

The trust must ensure that staff in the cardiothoracic surgical unit assess and meet the needs of patients categorised as high-risk in an agreed and consistent way. This must include assessing and planning the care and treatment provided prior to, during and following surgery. The system must be effectively monitored and evaluated.

Weekly meetings are held between the cardiologists and the cardiothoracic surgeons where patients referred as urgent or high-risk are discussed, enabling all of the consultants to have a say and to decide which consultant will take the referral. The minutes of these meetings indicate that patient history, care management and surgery processes are discussed. Some cases are further discussed at the monthly mortality and morbidity meetings, which are multidisciplinary. This meeting aims to promote learning from the management of high-risk patients who survive and those who die. Patients' pre and post-operative care is also discussed at these meetings.

The registrars reported that the structured consent process now in place helps to identify actual or potential risk factors earlier than in the past. High-risk patients are usually identified at first by the consultant cardiothoracic surgeons and the cardiologists. Patients are then followed up by junior staff and there are further detailed discussions before surgery.

The cardiologists and the surgeons make joint decisions on the prioritising of outpatient appointments with the surgeon. The pre-admission clinic nursing staff report that they discuss patients with the consultants at the end of the outpatient clinics and receive copies of letters dictated by the consultants. This is to ensure that they know if patients have priority for surgery, and that ward staff are aware of any issues before admission.

A completed patient care pathway is held in the pre-admission clinic in readiness for the patient's admission. The content of this is reviewed by the nursing staff prior to admission. The nurse may then visit the ward and speak to the ward co-ordinator for that day, to discuss patients due for admission to ensure that the nursing staff are informed of any identified risks or specific care needs. Where appropriate, they will also visit the CTCC unit to provide information to staff about the patients who will be arriving after their operations.

In terms of the management of high-risk patients, the Integrated Care Pathway (ICP) is reported to concentrate predominantly on pre-admission clinic issues and on cardiology and surgical outpatients. Staff stated that the ICP is being reviewed for further development, to include the whole patient journey. Medical staff told us that the post-operative management of unstable inpatients is discussed on an individual basis, as it has been recognised that one ICP would not be able to take account of the variety of conditions and circumstances for

such a patient. Other specialities such as the vascular team and the renal team are asked for their input when appropriate.

The lead consultant for the cardiothoracic unit reported that unit specific protocols have been developed to assist in the management of high-risk patients and improve the consistency of care. The deputy matron said that time is made for the review of current evidence and benchmarking, to ensure that protocols have a solid evidence base. However, only one of the documents seen contained any references. The protocols presented as evidence had all been reviewed in June or July 2007 and were:

- Cardiothoracic Surgery Practice Guidelines Fluid challenge protocol (2)
- Cardiothoracic Surgery Practice Guidelines Guideline for taking CO studies by thermodilution (2)
- Cardiothoracic Surgery Practice Guidelines Haemofiltration guidelines
- Cardiothoracic Surgery Practice Guidelines Inotrope Administration
- Guideline for double pumping Inotropes
- Cardiothoracic Surgery Practice Guidelines Potassium Chloride Administration (2)
- Cardiothoracic Surgery Practice Guidelines Ventilator care bundles
- Removing Endo tracheal tube.

These have been developed by nurses and anaesthetic staff, with the surgeons having input prior to final agreement. There is some evidence that support in the development of these guidelines has been sought from the local cardiac network and that they were scheduled for discussion at a meeting in January, but no evidence of the outcome has been provided.

The minutes of the governance committee meeting held in April 2007 show that continuity of care was identified as a key issue for the management of high-risk patients and for promoting more effective patient care. While it is acknowledged that high-risk patients have very individual needs and requirements, some high-risk patients do require a multidisciplinary approach and support may be required from other specialties.

The two-firm system, introduced recently to replace the single consultant firm system, has been said to be good for training and continuity of patient care. The new model of care introduced in the CTCC has improved the lines of communication and the change in the anaesthetic cover to blocks of days instead of single days has improved the continuity of care. Nursing staff in the CTCC reported that the decision-making process is much clearer and nursing staff are no longer getting conflicting messages from different medical staff.

Summary

The trust has made progress in implementing a structured process for the identification and management of high-risk patients. The regular meetings to discuss the profiles of patients and their care have created an opportunity to discuss aspects of care and surgical treatment in an open forum. These meetings are well attended by consultant staff within the directorate. Staff stated that this has led to greater consistency in the treatment of high-risk patients. Monitoring of patient care takes place at the monthly mortality and morbidity meetings. However, no formal evaluation of the management of high-risk patients has been undertaken to date.

Clinical governance and leadership

Recommendation 3

The staff in the cardiothoracic unit must define the core objectives of the unit and agree how these fit in with the objectives of the trust as a whole and with the aspirations of the individual surgeons.

The directorate manager described the system for objectives and stated that objectives are usually referred to as “improvements” and that unit specific objectives are embedded in trust-wide documents.

There is a system of coding of objectives that links the cardiac service improvements with the trust-wide objectives. This ensures that everything is cross-referenced between trust and local documents. It was stated that the objectives are developed throughout the whole directorate system and these are then aligned with the trust plans.

Within the cardiothoracic unit, there appeared to be some confusion with terminology. While some used the term objectives, others referred to the trust’s business plan. This appears to be the same thing. The trust’s business plan clearly defines objectives, two of which relate directly to cardiology and cardiac services. These are to deliver the new cardiac centre within service and financial parameters and to complete the action plan arising from the Healthcare Commission’s report on the trust’s cardiac services.

There is a business plan in place for the cardiac directorate and, although not dated, identified timescales that refer to the 2007/08 period. There are 21 targets set for the directorate relating to national targets, local targets, management of healthcare-associated infection, business development, staff development, training, audit and risk management. Some are clearly set targets while others are objectives. Cross-referencing to the trust objectives is evident.

The matron reported that nursing staff have done a lot of work in relation to the thoracic business case, and the congenital work and heart failure service, mainly around expansion and patient flows. The main challenges for the nursing staff are around work flow and skill mix. It was stated that the workforce is discussed at matron level and at ward level. On the cardiothoracic critical care (CTCC) unit, the challenge is to make sure that the right number of appropriately trained staff are in the right place at the right time. At ward level, work is being done on the integrated care pathway, with training identified as part of this process. The pre-admission nurse, while not aware of any objectives as such, reported that they had been involved in the business plan, particularly for the new build unit.

The consultant surgeons have divided some responsibilities, with one being involved in contributing to plans for the new build and another having responsibility to repatriate the thoracic team so that thoracic work is done in

Oxford rather than out of the county. A business case has been made for this. A business case has also been approved for the employment of an intensivist, who will also take on the role of lead for the CTCC unit. Staff are aware of both these business cases. One consultant is the clinical director of the unit, one has primary responsibility for training and one has responsibility for thoracic surgery, one for paediatric surgery and one for academic matters. The consultants' job plans do not make any reference to objectives.

Nursing staff reported that there is now more dialogue between the three specialties (nursing, intensivist/anaesthetists and medical) than before. There are two groups, the cardiothoracic surgical unit and the CTCC user group meeting, where issues relating to the operation and management of the cardiothoracic unit are discussed. The first is a directorate level meeting, while the second group is focused on the CTCC unit and is between medical and nursing staff.

Summary

Trust and directorate objectives have been agreed and are clearly linked. Nursing and medical staff have had involvement in the development of the unit's business plan, which contains the unit's objectives. All consultant surgeons have a clear role to play in the progression of the department and are involved in contributing to and achieving the unit's business plan. Other staff have also been consulted and involved in this.

Recommendation 4

The chief executive and medical director must manage the consultant cardiac surgeons more effectively and ensure that appraisals result in a full assessment of individual performance and any developmental needs.

A review of the management structure within the cardiothoracic unit has been undertaken with input from the trust's chief executive officer (CEO). It was stated that some relationship issues had been affecting the unit, of which the CEO had not been fully aware. Following a process involving staff interviews to ascertain the root of the problems, these issues have since been resolved.

One of the cardiothoracic surgeons has been identified as the clinical director for the cardiothoracic surgical unit and support has been provided to develop his management and leadership skills. He is also acting as the lead for the CTCC unit until the vacancy is filled. The CEO said that the unit is now being more effectively managed within limits that have been set and agreed between himself and the lead consultant. Interviews with medical staff clearly demonstrated that there is more open communication. The trust's medical director stated that the consultants now more readily come to him with any concerns. Any identified issues are reported through the directorate to the operational director or directorate chair and on to the CEO.

The CEO, the medical director and the divisional and directorate chairs have all been involved in discussions about appraisals. The directorate chair and manager have reviewed the job plans for all the consultants and these are said to be used to inform the appraisal process, along with business plan requirements. The divisional director of operations stated that central records of appraisals are now being held.

It is trust policy that all staff should have an appraisal at least once a year. At the time of the visit, four of the five consultants had received an appraisal and the final one had been scheduled for the end of their first consultant year. Consultants are still able to choose who carries out their appraisal, in line with national guidelines. However, performance reports are reviewed by the divisional chair and the medical director. This is done separately to the appraisal. The medical director has reviewed the appraisals for the consultants and assured the CEO that they have been completed in their entirety. However, no completed appraisals were provided as evidence due to the confidential nature of these documents.

The appraisal process continues to be reviewed and some members of staff from the cardiac services directorate are taking part in a 360-degree assessment process as a pilot.

Summary

The trust's senior management has taken an active role in resolving issues relating to the appraisals for the consultant cardiothoracic surgeons. A system for appraisals is in place, although performance reviews are conducted separately. The current appraisal process is under further review by the trust, with the possibility of 360-degree feedback becoming part of the appraisal process. The appraisals for four of the consultant cardiothoracic surgeons have been completed. The CEO has reviewed the leadership structure within the cardiothoracic unit and one of the consultants has taken on the lead role. It is clear that there is now more effective leadership in the cardiothoracic unit.

Recommendation 5

The model for the provision of care for patients in the cardiothoracic critical care unit must be reviewed to ensure that it provides continuity of care for patients and is in line with best practice in other cardiac units. The implementation of a new model of care must be supported by a policy, which must be monitored and evaluated with input from the multidisciplinary team. It must include clarity of roles and accountability.

The current cardiothoracic critical care unit was originally formed as a cardiac recovery unit (CRU) as the majority of patients could be extubated rapidly ('fast-tracked') and thereafter could be regarded as high-dependency rather than intensive care patients. CRU differed from a conventional intensive care unit in that the surgeons retained clinical control of their patients and much of the care and decision-making was devolved to the nursing staff.

As the patient group changed, so did their care needs. The CRU structured as a high-dependency unit, is said to have evolved more slowly. Anaesthetic sessions were increased to a level compatible with the proper delivery of intensive care and new techniques for organ support (primarily haemofiltration) were introduced successfully. The name of the unit was changed to cardiothoracic critical care (CTCC), but this change was not accompanied by a change in unit philosophy or management structure.

The assistant director of governance stated that changes to the structure, clinical leadership and improved multidisciplinary team working in the cardiothoracic unit have made a significant difference

Following the original report, there has been a review and changes made to the model of care in the CTCC unit. These changes are supported by the trust's *Operational Policy for Cardiothoracic Critical Care* (November 2007), complemented by the document *Cardiothoracic Critical Care: Medical Roles and Responsibilities* (December 2007). In the past, the five consultants worked independently with their own team rather than in multi consultant teams. Now a two-firm system has been introduced. Two consultants lead one team and three consultants lead the other, with a team of medical staff to support them. It is believed that, as each firm is fully versed in each patient's condition throughout their time in hospital, the care of patients will be enhanced.

These changes were agreed at the consultants' meeting in December 2007. Minutes for the CTCC users' group show that these changes were discussed before their implementation and are now being monitored by this group.

There is now greater clarity in relation to the different roles and responsibilities that staff have for the care of patients. The care of patients on the CTCC unit is now consultant-led, multi professional (across professional groups) and multidisciplinary (across specialty groups). The consultant surgeons take overall clinical responsibility for patients during their stay on the CTCC unit. The trust's

Operational Policy for Cardiothoracic Critical Care (November 2007), clearly states that clinical decision-making is shared between surgeons and intensivists, depending on the clinical needs of each patient and the duration of their stay on the CTCC unit. Staff reported that there is now a collaborative model of care and joint decision-making.

Previously, intensivist cover used to involve a different person each day, which did not provide effective continuity of care. This has also been reviewed and now one person covers Monday to Thursday and another Friday to Sunday. This is said to have improved continuity and is better for long-term patients. After hours, individual surgeons will manage their own patients, in conjunction with the on-call consultant anaesthetist when necessary.

Senior trust staff acknowledged that they still need to recruit an intensivist who is also to be the CTCC lead. The funding and the job description have been agreed for this role. In the interim, a consultant intensivist from the adult intensive care unit is supporting the anaesthetists who cover the CTCC unit.

The intensivist from the adult intensive care unit, who has been working with the unit, reported that there are three intensive care units in the hospital and they all have slightly different models of care due to the patient type, and therefore their care needs. However, there are similarities between them all. In the cardiac intensive care unit, the surgeons have a greater involvement and are involved in decision-making.

To improve the daily continuity of patient care, one designated doctor is identified each day to act as the single channel of communication of instructions relating to patient care. Previously there had been many people making decisions, with little or no coordination. During the day, this is a senior anaesthetic registrar and at night this is a senior surgical registrar. The purpose of this role is to ensure more effective communication about, and coordination of, patient care.

The purpose and function of ward rounds has also been reviewed. There are now three formal multi professional ward rounds, with defined functions at set times each day.

1. Surgical 'Business Round' (07:30 to 08:00)

A rapid surgeon-led, multi professional business round attended by night and day surgical registrars, night and day anaesthetic registrars, night and day senior house officers (SHOs), nurse coordinator and bedside nurse.

- Identify/confirm patients who can be transferred routinely to the cardiothoracic unit.
- 'Flag-up' patients who need more detailed review at the next ward round.
- Allow all members of the night-shift team to fully appraise the day staff (particularly the medical coordinator) of issues overnight, and to relay plans in progress.

2. Intensivist Round (e.g. 09:00-10:30)

Led by a consultant intensivist and attended by day surgical registrar, day anaesthetic registrar, day SHO, nurse coordinator and bedside nurse

- Review of fast-tracked patients from the 07:30 ward round.
- Detailed review of the 'flagged' and the 'complex' patients.
- Teaching of presentation and clinical skills when appropriate.

3. Intensivist 'Business Round' (e.g. 17:00-18:00)

Led by a consultant intensivist and attended by day surgical registrar, day anaesthetic registrar, day SHO, nurse coordinator and bedside nurse.

- Review of all patients including the day's surgical patients.
- Preparation of plans for the on-call team.

Nursing staff reported that, after some initial issues that have been addressed, the present system now works well. The decision-making process is much clearer and nursing staff are no longer getting conflicting messages from different medical staff. Nursing staff said that having an anaesthetist as the medical co-ordinator by day worked better, as they are always available. A surgeon is the medical co-ordinator at night.

The registrars commented that the changes to the model of care in the CTCC unit have meant that there is more control. Patients requiring a longer stay continue to be managed on the CTCC by the clinical team instead of having to be transferred to the adult intensive care unit. The medical co-ordinator role is said to have improved the communication between different groups of staff.

Summary

The trust has reviewed the model of care for the provision of patient care in the CTCC unit. There is now a collaborative model of care with joint decision-making. This is supported by a policy that outlines clear roles and responsibilities for all relevant staff. There are now clearer lines of communication regarding clinical decision-making and processes have been put in place to ensure greater continuity of care. This includes new ward round systems and processes to simplify lines of communication between staff. Staff were positive about these changes, although no formal evaluation has been conducted. The trust acknowledges it needs to recruit an intensivist who will also take on the role of CTCC lead. The trust has taken direct action to improve the management of these patients.

Recommendation 6

The trust must review the effectiveness of the cardiothoracic mortality and morbidity meetings. In particular, the trust must be able to demonstrate that the multidisciplinary team considers the care and treatment given to patients, that lessons are learned from outcomes of surgery, and that developments and improvements to care and treatment result.

Mortality and morbidity meetings are considered an integral and essential part of the team's function and the review of services. The meetings are held monthly and are multidisciplinary. At each meeting, data showing the cumulative operational risks and outcomes for the previous month are presented, including comparisons with national figures. A selection of case histories about morbidity or mortality is presented by the medical staff. Discussions take place around what went well and what did not.

While some staff commented that the meetings are fast paced and it is therefore difficult to take minutes, notes are made and distributed by one of the consultant's secretaries. These include notes on discussions about the audit presentation and data management, and discussions on the cases presented.

The trust is now trialling the use of a 'wider learning form' to facilitate trust-wide learning from all the mortality and morbidity meetings held across the trust

There is a general feeling throughout the directorate that the mortality and morbidity meetings have a clear purpose and are more focused. While the meetings are attended by a range of clinical staff, some commented that the discussion is dominated by the doctors. Some staff suggested that the meetings could be improved by greater involvement from other disciplines. Others felt that the meetings were too big.

The assistant director of governance stated that these meetings were essential and that their effectiveness would be monitored through the governance committee, who present their findings to the trust board.

Summary

The mortality and morbidity meetings now have a clear focus and structure, enabling the sharing of information and learning. However, consideration needs to be given to the numbers attending these meetings and how it can be ensured that all disciplines contribute to the discussion. The limited note taking means that it is difficult to demonstrate that learning from discussions is documented and used to inform further practise. The trust is, however, trying to further develop learning from these meetings through the use of the wider learning form.

Recommendation 7

The trust should reactivate the involvement of the Society for Cardiothoracic Surgery to help ensure that the necessary improvements are made in relation to the care and treatment of high-risk patients and that the trust uses its own data to help drive improvement.

All of the consultant surgeons are members of the Society for Cardiothoracic Surgery in Great Britain and Ireland. The clinical director is on the audit committee of the society and one surgeon is the president-elect. Efforts have been made by the trust to follow up with the society following its first approach in September 2007. The clinical director has followed up with letters and phone calls.

The trust received a letter from the society in April 2008 confirming that there is positive interaction between the surgeons in Oxford and the society. As demonstrated by the unit submitting data regularly to the national database, the unit is represented at the audit leads meeting, one of the consultants is the president-elect of the society and therefore sits on the executive, and at the annual meeting in March the unit made a number of presentations.

Summary

The consultants are involved with the society and therefore indirectly support is being given to the unit.

Recommendation 8

The trust must continue to develop its arrangements for clinical governance and ensure that these arrangements are rigorously monitored, assessed and evaluated.

Recommendation 9

The trust must ensure that healthcare professionals have access to the necessary time, facilities, advice and expertise in order to conduct clinical audits effectively.

Recommendations 8 and 9 are considered together.

The trust has made changes to the clinical governance systems and processes, with improvements in incident reporting, risk management, handling of complaints and audits.

The trust's risk management strategy has been revised and is now the governance, quality and risk framework. The assistant director of quality and care has trust-wide responsibility for clinical governance, quality, risk, investigations of serious untoward incidents, and reporting. The appointment of a director of operations for Division A, which includes the cardiac directorate, has been instrumental in refocusing clinical governance. There are several different elements to the governance process. These include the management of serious untoward incidents, risk registers, clinical indicators, complaints and audits.

Risk management

The trust's risk assessment policy and guidance dated May 2007 outlines organisational responsibilities and arrangements for risk assessment, which includes reporting and monitoring, and the principles of risk assessment.

The trust's policy states that local risk registers are maintained by the ward/department manager and should be reviewed quarterly, with a report sent to the directorate boards. Divisional/directorate risk registers and associated risk reduction plans should be maintained continuously by the divisional and directorate teams and form part of the quality and risk assurance report to the governance committee. The corporate risk team maintain the trust's risk register.

Risk registers provided by the trust demonstrate the escalation of risk from one level to the next. The Division A quarterly quality and risk report for June 2007 shows that the divisional risk register was reviewed. This report also states that the cardiac directorate holds a monthly cardiac risk management meeting which covers the clinical governance agenda – reviewing incidents, complaints and

claims data, and reviewing and updating their risk register. Minutes of these meetings show that risk management and the risk register are discussed. The minutes of the trust's executive board meetings show that the trust's risk register is discussed in this forum. The division's clinical governance co-ordinator reported that they have had a role in assisting units in the development of their risk registers.

Incident reporting

The trust has focused on improving the risk management processes. The trust's *Incident Reporting Policy*, dated August 2007, states that in managing incidents, staff and local managers must have ownership of an incident. Local solutions aim to be identified as quickly as possible and must include feedback to staff. The corporate risk team follows up only the most serious incidents. The reporting process and grading system used by the trust is outlined in the policy. Incidents regarded as low grade risks are dealt with locally, medium grade at directorate level and high-risk or serious untoward incidents (SUIs) at trust level.

A three-stage process is in place to monitor all reported SUIs. The incidents, claims and complaints committee review all SUIs; this is supported by the minutes of the meetings. They agree formal closure of the investigation and action plan. The health and safety committee and the clinical risk committee receive the final report for formal closure and cascade learning from the incident throughout the trust. The governance committee receives summary reports on new and current SUIs to provide assurance that they are being managed appropriately and according to trust procedure. In addition, the quality and risk department provide quarterly summaries to divisions, directorates, the clinical risk management committee, the health and safety committee and the governance committee.

Complaints

High-level complaints are reported to the incident, claims and complaints committee; this is reflected in the minutes. If a complaints investigation has shown the need for a policy change or for further work to be undertaken by the trust, these are monitored by the complaints department. The management of complaints is said to have improved with the recruitment of a full-time permanent member of staff in the complaints department and the use of IT systems to monitor complaints. Minutes of meetings held at all levels in the trust show that complaints are discussed and monitored. It is the responsibility of the division's associate directors of nursing to ensure that complaints are being discussed and acted on properly. They are supported in this by the clinical governance co-ordinator and other members of staff from the directorates and divisions.

Audit

Trust level:

While there is evidence that audits are conducted throughout the trust, there is no established system for co-ordinating or recording audits at trust-wide level. Staff commented that while compliance with NICE guidance and national service frameworks (NSFs) are monitored, this is not undertaken robustly in all areas of the trust. A business case has been approved for the development of an audit team that will consist of the clinical audit lead, the patient information and survey lead, the NSF lead, three audit facilitators and administrative backup. At the time of the visit, this team had not yet been established. Across the trust, matrons are required to produce a monthly report around infection control and other issues. There are also 11 nursing standards that are audited across the trust.

Cardiac directorate:

The cardiac directorate has a multidisciplinary audit group that meets quarterly. Anaesthetists are managed by a different directorate – although they do have an involvement in audit, they are not part of this audit group. The group has developed a risk management toolkit to help staff prioritise risks. This group has also helped the directorate prioritise audits according to national initiatives and local issues. An audit plan has been developed and there are plans to appoint an administrator who will support the audit group and the audit process generally. Currently, the appointment to this role is not reflected throughout the trust.

The results of audits are presented to the audit group and at the directorate risk management meetings, with results being put on the cardiac unit's internal website. The cardiac directorate also holds an audit meeting every four months where all staff are given the opportunity to present audits. Anaesthetic audits are also presented here and at the anaesthetic audit meetings. The annual report of the cardiac directorate includes details of performance against the standards within the NSFs for coronary heart disease.

All staff groups reported that they were involved in audit. Anaesthetists lead anaesthetic audit projects in the cardiac speciality, and the surgical registrars conduct several collaborative audits with senior house officers and nurses, including audits of hand-cleaning, follow-up of consent practice, and other prescribed audits. All matrons are actively involved in audit, including monthly audits such as saving lives and hand hygiene. All matrons are also required to produce a monthly report for the trust around infection control and other issues. There are also 11 nursing standards that are audited and patient surveys are used to evaluate the pre-admission service.

Clinical indicators

Using clinical indicators, key areas of risk are reported with a dashboard system, a colour coded system used to demonstrate results. Since December 2007, the trust has had access to information from Dr Foster Intelligence, which

includes comparative information on a range of quality and clinical indicators measured against all other trusts in England. This will enable the trust to monitor and identify in good time those areas where the trust is not performing as expected against national benchmarks. The assistant director of quality and risk and the clinical governance coordinator stated that, as part of their role, they review Dr Foster Intelligence information.

Clinical governance reporting processes

The clinical governance co-ordinators in each division produce the quarterly quality and risk reports, which are presented to the divisional boards and to directorates. The reports cover all aspects of governance, quality and risk including SUIs and learning, comments and complaints, audits, core standards and other relevant issues. Divisions present their governance reports to the trust's clinical governance committee, a committee of the trust board, which is chaired by a non-executive director. Senior staff commented that, currently, these reports are said to be too operationally-focused and need to develop to be more focused on assurance. Information from this committee is used to assure the trust board. They also commented that, at divisional level, while staff are now good at identifying risks, there is a need to improve how they filter the masses of information.

Summary

The trust has made good progress in developing a clinical governance framework. There is ownership of risk registers at all levels of the trust structure, with evidence of escalation from one level to the next. Management of incidents is clearly defined and monitored at all levels. Audits are conducted, although trust-wide co-ordination of audits and the sharing of audit outcomes need to be developed. A review of compliance with national service frameworks also needs to become a standard part of the trust's clinical governance processes. The trust has identified audit as an area in need of improvement and recruitment to key posts has taken place. The clinical governance reporting structure is still developing and needs to become more focused on assurance.

Recommendation 10

The trust must ensure that it has a robust system for reviewing, updating and distributing its policies and procedures. The implementation of policies and procedures must be monitored.

There is a list of the key policies and procedures within the trust that have recently been collated and are accessible via the trust's intranet system. Senior staff provided assurance that they had reviewed the policies and procedures on the database and had found them all to be accessible and current.

The policies and procedures guide states that a set of policies should be held in a central place within each division. Directorates and departments should decide on how best to ensure easy access by all members of staff. Policies, procedures and protocols specific to the cardiac directorate are available on the cardiac server and are accessible by all staff.

There is trust guidance, reviewed in 2007, on the *Development and Approval for Policies and Procedures*. The trust's policies and procedures group ratifies trust-wide policies. The policies and procedure guide states that every policy must have an implementation and monitoring plan agreed by the lead director before being submitted for formal approval. The guide also outlines who has responsibility to ensure that appropriate means of distribution are agreed and that policies and procedures should be distributed appropriately within each area of the hospital. Guidelines and protocols are ratified through the divisional risk management group and need to include the author, version, date and review date. Minutes of the risk management meetings of the cardiac directorate include discussion on policies, procedures and protocols.

In September 2007, the trust achieved Level 1 of the NHS Litigation Authority's (NHSLA) risk management standards for acute trusts, which includes standards relating to policies. The trust is now working towards Level 2. However, the NHSLA report points out throughout the need to reference within documents the tool by which the processes described within the policy can be monitored for effectiveness. Nursing staff from the cardiothoracic unit were not aware of how compliance with policies is monitored. The clinical governance coordinator stated that policies and procedures would be audited through an evaluation process and ratified through the risk management committee.

There is an agreement within the cardiac directorate that the content of policies and protocols are reviewed annually in April. Matrons have a responsibility to ensure this is followed through. Nursing staff reported that draft policies are circulated via email and can be discussed.

While there is trust level guidance on how policies and procedure should be developed and implemented, no evidence has been provided to show how compliance with this process is monitored.

Summary

The trust has a policy in place on the development and approval of policies and procedures, which clearly sets out managerial responsibility. The evidence shows that there are several different systems for the approval of policies and procedures, depending on the level of impact within the trust. Trust policies and procedures are accessible on the trust's computer system. No evidence has been provided on how the implementation of the policy *Development and Approval for Policies and Procedures* is being monitored and there was no assurance that adherence to policies and procedures is being monitored.

Recommendation 11

The trust's board must ensure that the data on outcomes following CABG are closely monitored and that action is taken wherever necessary.

Notes from key meetings within the cardiac unit show that data from cardiothoracic audits and outcomes from surgical procedures are analysed and discussed. These sessions provide opportunities for knowledge to be shared and lessons learned among peers.

A quarterly presentation relating to coronary artery bypass graft (CABG) information is made to the trust board using data from cardiothoracic clinical information system DataCam. The presentation is undertaken by the directorate chair, who is able to give an explanation of the data and any evidence found.

Minutes of the trust's board and governance meetings provide evidence that the board is receiving information and is assured that the data is being monitored. However, until there is an improved completeness of morbidity data, the only data used is for mortality. From the information provided, it has not been possible to establish what, if any, action has been taken as a result of monitoring this data.

Summary

Data from cardiothoracic audits and outcomes from surgical procedures are analysed and discussed. Currently, this information is derived mainly from mortality data.

Collection and use of data on the outcomes following cardiac surgery

Recommendation 12

The trust must ensure that the cardiothoracic surgeons work with the staff responsible for coding the patient administration system (PAS), to ensure that the data fed to Hospital Episode Statistics (HES) are accurate. Regular and rigorous cross-checks between the PAS and the cardiothoracic unit's own data collection system must be put in place.

The trust has been working on improving coding processes as evidenced in their action plans. However, neither the consultant cardiac surgeon nor the clinical coding supervisors were aware of what discussions had taken place, or if changes had been made as a result.

The clinical staff have a role in ensuring that information is put into the cardiothoracic clinical information system (DataCam). This is initiated by pre-admission nurses for elective cases and is added to in theatre by the anaesthetist, surgeons and perfusionists. Post-operatively, the data inputting is undertaken by the registrars and the nursing staff. This process is supported by the document *Cardiothoracic Adult Surgery Data Entry and Validation Procedures*, written by the cardiac information manager and dated December 2007. The document makes reference to data entry, cross-checking and validation of data for the DataCam system.

The coders who input the information on to the Oxford patient administration system (OxPAS) use the patient notes to obtain the required information. Trust staff reported that DataCam can be used by the coders, who use the case notes, to check if the case notes are not clear, but there is a difference with timing. The procedure and diagnostic coding on the OxPAS needs to be completed within five working days, while the registrars have an additional month to complete the data on DataCam. It was reported that there is no formal set up for consultants to work with coders. One of the consultant cardiac surgeons has informally offered to help any coders, but this offer has not been taken up. The same consultant uses the DataCam to write discharge letters, a facility not currently used by the other consultants.

Interviews with relevant staff indicated that some checks are conducted between OxPAS and DataCam. This is reported to be undertaken by the cardiac information manager who uses OPCS-coded episode data from OxPAS and reconciles it with information from DataCam. Any identified discrepancies can then be investigated. The cardiac information manager had sole responsibility for the validation checks while staff recruitment was undertaken. Staffing issues are reported to have had an impact on the recording of the validation checks.

There is a one-directional feed from OxPAS to DataCam for patient demographics. This interface is triggered whenever a patient record is accessed

on DataCam, ensuring that the demographics on DataCam are kept up to date and in line with OxPAS, which is the primary source for patient demographics.

Mortality data are either entered directly onto OxPAS, or updated on OxPAS by a feed of mortality data from the general practitioners' systems. Mortalities are kept up to date on DataCam by an overnight batch update that brings DataCam in line with the latest mortality information on OxPAS

All reports given at the monthly mortality and morbidity meeting relate to the data on DataCam. No consultant is personally checking data on OxPAS. However, the lead consultant said they would all guarantee the data on DataCam.

The directorate managers are said to receive downloads from the commissioning system to enable checking for missing codes on OxPAS, and that this was reported at individual consultant level. The lead consultant reported that the consultants do not look at this report.

The cardiac information manager has joined the data quality board. The issues raised within this committee include why the trust has not met its targets in some areas. It also acknowledges that the national service framework (NSF) cardiac report indicates that overall all targets have been met. However, in relation to the NSF report 2007/08, data completeness figures are derived directly from the local data held on the cardiothoracic clinical information system DataCam. The report does not relate to data held on OxPAS, and hence on the HES dataset. This information is not intended to be used as assurance checks on OxPAS data.

The director of planning and information said that routine and rigorous checking between OxPAS and DataCam is through the cardiac information manager and the commissioning route. A consultant stated that they "believed" that there are people within the directorate who cross-check the data. The directorate manager talked about using tools and wanting the data correct for commissioning and benchmarking purposes, but did not describe any routine and rigorous processes that occur.

Summary

There is no evidence that clinicians are working with the staff responsible for coding the patient administration system to ensure that data fed into HES is accurate. While evidence was provided of the monthly process for checking OxPAS and DataCam, there was no documentary support or evidence of actions as a result of checking. There is a rigorous system in place for the checking of information on DataCam.

Recommendation 13

The trust must introduce rigorous systems for internally validating cardiac data against patients' medical records. The trust must use its cardiac data to inform clinical practice in the unit and improve the quality of care for patients.

Each month, one of the research registrars looks at 20-25% of case notes to check that DataCam is a true reflection of the notes. PAS coders use the notes to enter clinical coding data into the PAS system.

From December 2007, the trust has had access to information from Dr Foster Intelligence. This includes comparative information on a range of quality and clinical indicators measured against all other trusts in England. The assistant director of quality and risk said that Dr Foster is monitored for "red bells", the alert system used, and where these occur data is reviewed. The directorate business plan for 2007/08 sets out an objective for improving data quality and its validation, ensuring that data returns are submitted to national organisations complete and in a timely manner and having remedial measures in place to resolve any anomalies. The trust risk register presented to the governance committee in December 2007 identifies the following as risks:

- Poor data quality which will adversely impact on provision of high quality clinical care, the planning and management of services and the recording and capture of income.
- The standard of the content of the health record and its availability, which will not be high enough to support the requirements of safe quality clinical care or the demands of the NHSLA for Level 2.

The quarterly NSF reports show that data quality for DataCam is monitored and reported.

Data is collected and presented at the monthly mortality and morbidity meetings, and a quarterly report relating to the cardiac national service framework is produced. There is also a separate CABG mortality report presented to the executive board by the directorate chair. Reports on surgical outcome data derived from mortality data for CABG and aortic valve replacement are provided to the governance committee and the trust board.

The monthly reports for the mortality and morbidity meeting include a cumulative mortality CUSUM and funnel plot by unit and consultant. Reports also consider the EuroSCORE where, for the last three years, the trends for mortality rates have been steady. Files of all patients who die are kept and, if the trend for an individual consultant or the unit moves outside the expected levels, the files are re-audited and discussed at the mortality and morbidity meeting. In addition, there has been work on more process measures – for example length of stay, reducing cancellations, and waiting times for emergency surgery.

Further work is reported to be being undertaken on the morbidity fields. It is hoped that by the end of this year there should be the same confidence in the morbidity data as in mortality data. That data could then be used by the trust to look at the care of patients. Until that time, the trust is said to be using information from additional sources to inform practice. These include, for example, benchmarking, surgical reporting activity, and information about length of stay and bed occupancy.

Summary

The trust has introduced some internal validation processes. Internal validation of cardiac data against patients' medical records is undertaken but only with regard to DataCam which is used to check OxpAS data, but not all OxpAS data is on DataCam, for example diagnostic information. There is no work to validate patients' records directly against the OxpAS data. However, validating against Dr Foster data, which is derived from HES, would substitute where this is carried out. The work that is undertaken is based mostly around mortality and EuroSCORE, which are discussed at the monthly mortality and morbidity meetings. There is some work on processes but, until the morbidity data is available at the end of the year, no further types of analysis are available to inform clinical practice and improve the quality of care for patients. Work being undertaken on the morbidity information being collected should ensure that the data can be used in addition to other available information to look at the care of patients.

Conclusion

It is clear that the trust has put considerable effort and resource into making improvements within the unit and, where indicated, the wider organisation. The unit has a vibrant atmosphere with medical staff having clearly designated roles and responsibilities. There has been strong support and leadership from senior staff within the organisation as part of this improvement process, and staff reported effective leadership within the unit itself.

The new roles in the intensive care area, the improved management of the many high-risk patients the unit takes on, and the strengthened audit and clinical governance structures are all to be commended. The new model of care has led to improved communication and will enable greater consistency and continuity of patient care. To ensure that this is achieved, it needs to be fully evaluated. The unit is also developing new roles and there are major new developments about to take place with the new build and increased surgical procedures to be added to the existing ones.

At the time of the original investigation, the analysis of data in the Central Cardiac Audit Database (CCAD) by the Healthcare Commission showed that the trust bordered on the 99.8% control limit, based on the UK rates of mortality for coronary artery bypass graft (CABG) current at that time. In preparation for this visit, the CCAD data were analysed again, and it was found that the trust's rates of mortality were within acceptable limits. Currently, there are no concerns relating to operative mortality rates at the trust.

In summary, good progress has been made in the following areas:

- Improving how staff obtain patient consent.
- Agreeing and implementing a structured process for the identification and management of high-risk patients.
- Core objectives have been defined within the cardiothoracic unit and have been linked with the wider trust objectives. Business plans are in place and have been developed with staff involvement.
- A system for consultant appraisal is in place and four of the five consultants have received a full appraisal. The trust's senior management has taken an active role in resolving issues about consultant appraisals and the management of the unit.
- The trust has reviewed the model of care for the provision of patient care in the CTCC unit. There is now a collaborative model of care with joint decision-making. The model of care is supported by a policy that outlines clear roles and responsibilities for all relevant staff. Staff report that the leadership arrangements are effective and these arrangements have been fully supported by senior staff within the trust.
- The mortality and morbidity meetings now have a clear focus and structure, enabling the sharing of information and learning.

- The trust has made substantial progress in developing a clinical governance framework and has acknowledged the need to further develop support for audit and audit processes.
- Work for internally validating cardiac data against patients' medical records is undertaken, but only with regard to DataCam which is used to check OxPAS.

The following areas need to be addressed:

- The trust needs to ensure that all patients receive copies of their consent forms and that all stages of the consent process are documented clearly in the medical notes for all patients.
- The trust needs to ensure that a formal evaluation of the management of high-risk patients is conducted to demonstrate that changes have led to improved and more consistent management.
- An appraisal needs to be conducted with the remaining consultant who, at the time of the follow-up, had not completed their appraisal.
- The trust needs to evaluate the reviewed model of care for the provision of patient care in the CTCC unit.
- The planned developments for the resourcing and support of audit work need to be completed.
- While progress has been made in developing a clinical governance framework, the reporting structure is still developing and needs to become more assurance-focused.
- The trust needs to demonstrate that there is effective monitoring of the implementation of policies and procedures.
- The trust needs to improve the system used to ensure the accuracy of coding, including creating better links between clinicians and the staff responsible for coding the PAS system.
- Further work with Dr Foster Intelligence will help to ensure that HES data is accurate.

Appendix A: The assessment team

The assessment team consisted of:

- Andrew Brand – Assessor, Healthcare Commission
- Lisa Cook – Assessor, Healthcare Commission and Investigation Follow-up Lead
- Mr Paul Jankowiak – Associate Director (Information) Buckinghamshire Hospitals NHS Trust
- Dr Alison Loftus-Hills – Assessor, Healthcare Commission
- Mr Danny Keenan – Consultant Cardiac Surgeon and Healthcare Commission Advisor
- Claire Roberts – Investigation team, Healthcare Commission
- Duncan Simpson – Senior Analytic Advisor, Healthcare Commission
- Benjamin Young – Investigations Analyst, Healthcare Commission

Appendix B: Staff interviewed for follow-up against the action plan (by role)

- Chief Executive Officer
- Chairman
- Medical Director
- Director of Planning and Information
- Assistant Director of Quality and Risk
- Assistant Director of Governance
- Director of Operations, Division A
- Chair, Division A
- Directorate Manager, Cardiac Services
- Consultant Cardiologist and Directorate Chairman, Cardiac Services
- Associate Director of Nursing, Division A
- Clinical Governance Coordinator, Division A
- Consultant Intensivist and lead for adult intensive care
- Consultant Anesthetist and lead consultant for cardiac anesthesia
- Two consultants from the cardiothoracic unit, including the Clinical Director for Cardiothoracic Surgery
- Five senior nurses from the cardiothoracic critical care unit and cardiothoracic unit
- Matron
- Deputy Matron
- Senior Sister, Cardiac Theatres
- Two PAC and Discharge Liaison Nurse
- Practice Development Nurse
- Cardiac Information Manager
- Two clinical coding supervisors