Investigation

Investigation into Mid Staffordshire NHS Foundation Trust

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Healthcare Commission

Inspecting Informing Improving

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The Healthcare Commission

The Healthcare Commission's full name is the Commission for Healthcare Audit and Inspection. We exist to promote improvements in the quality of healthcare and public health in England. We are committed to making a real difference to the provision of healthcare and to promoting continuous improvement for the benefit of patients and the public.

The Healthcare Commission was created under the Health and Social Care (Community Health and Standards) Act 2003. We have a statutory duty to assess the performance of healthcare organisations, award annual ratings of performance for the NHS and coordinate reviews of healthcare with others.

We have created an entirely new approach to assessing and reporting on the performance of healthcare organisations. Our annual health check examines a much broader range of issues than in the past, enabling us to report on what really matters to those who receive and provide healthcare.

On 1 April 2009, the Care Quality Commission, the new independent regulator of health, mental health and adult social care, will take over the Healthcare Commission's work in England.

Investigating serious failings in healthcare

The Healthcare Commission is empowered by section 52(1) of the Health and Social Care (Community Health and Standards) Act 2003 to conduct investigations into the provision of healthcare by or for an English NHS body.

We will usually investigate when allegations of serious failings are raised, particularly when there are concerns about the safety of patients. Our criteria for deciding whether to conduct an investigation are set out in appendix A.

In investigating allegations of serious failings in healthcare, we aim to help organisations to improve the quality of care they provide, to build or restore public confidence in healthcare services, and to seek to ensure that the care provided to patients is safe throughout the NHS.

Summary

The Healthcare Commission carried out this investigation into apparently high mortality rates in patients admitted as emergencies to Mid Staffordshire NHS Foundation Trust since April 2005, and the care provided to these patients. It also considered the trust's arrangements for monitoring mortality rates and its systems for ensuring that patients were cared for safely.

Our particular focus was on emergency admissions. We looked at the pathway of care for patients admitted as emergencies: the accident and emergency (A&E) department, the emergency assessment unit, and the surgical and medical elements of emergency admissions.

The investigation was carried out between March 2008 and October 2008. Staff from the Healthcare Commission worked with a team of external expert advisers. The membership is listed in appendix B. We interviewed over 300 people, including almost 100 patients admitted as emergencies or their relatives, past and present staff at the trust, and staff at other organisations. We reviewed the case notes of more than 30 patients who were admitted as emergencies and subsequently died. We examined over 1,000 documents including policies, reports, audits and records of meetings.

Synopsis of events leading to our decision to investigate

During the summer and autumn of 2007, the Healthcare Commission became aware, through its programme of analysis of mortality in England, of a number of apparently high mortality rates for specific conditions or operations at the trust.

In our work on mortality, we recognise that some 'alerts' (that is, indications that patients may be exposed to greater than expected risk) can be due to errors in the data or to insufficient adjustment for other factors, so a team of analysts assesses each case to establish whether there are sufficient concerns to follow up with a trust. If we do follow up an alert, we will initially ask a trust to provide further information. In many cases, this is enough to satisfy us that no further action is needed. We can escalate a case if concerns about the safety of patients have not been adequately addressed, or we think these have not been properly recognised by the trust.

In this investigation, further analysis showed that the trust consistently had a high mortality rate for patients admitted as emergencies, which it could not explain.

The rate had been comparatively high for several years, but the trust had not investigated this. In April 2007, Dr Foster's Hospital Guide showed that the trust had a hospital standardised mortality ratio (HSMR) of 127 for 2005/06, in other words more deaths than expected. The trust established a group to look into mortality, but put much of its effort into attempting to establish whether the high rate was a consequence of poor recording of clinical information.

The response of the trust to our requests for information contained insufficient detail to support its claim that the alerts were due to problems with its recording of data, and not problems with the quality of care for patients. This response, and the concerns from local people about the quality of care, led the Commission to decide that a full investigation was required.

Our key findings are summarised below and set out in full in the body of the report.

The views of patients and relatives at the trust

When we announced the investigation, we had an unprecedented response. In all, 103 patients and relatives contacted us. Of these, 99 were critical of, or had had a poor experience at, the trust. The main areas of concern they raised were A&E, the emergency assessment unit and medical wards 10, 11 and 12. Concerns were also expressed about some surgical wards. A major concern expressed by patients and relatives related to poor standards of nursing care.

Although we recognise that this was not a statistically representative sample of patients and relatives, their concerns reinforced what we found through observations, reviews of case notes, complaints and interviews – disorganisation, delays in assessment and pain relief, poor recording of important bodily functions, symptoms and requests for help ignored, and poor communication with patients and families.

In the Healthcare Commission's 2007 survey of inpatients (the latest national survey available), the trust was in the worst 20% for 39 out of 62 questions. This was a poor result. The trust was in the worst 20% for overall standards of care and whether patients felt that they were treated with respect and dignity in the hospital.

Mortality rates at the trust

Through our programme to analyse mortality rates in England, we received an unprecedented 11 alerts about high mortality at the trust, four of these after the investigation was launched. Six came from the Dr Foster Research Unit at Imperial College, London, as part of its analysis of data, and five from the Commission's own internal surveillance of data from all trusts. Details of the alerts are set out in appendix E.

The alerts at the trust were wide-ranging and suggested a general problem with regard to mortality. We considered data across the trust, which showed that mortality was high as regards emergency admissions, but not for elective admissions.

Our analysis focused on patients aged 18 and over who were admitted as emergencies. The results were 'standardised' (that is, made comparable with each other by taking account of various factors) for a number of factors, including age, sex and the type of condition that they had when admitted to the hospital. Since April 2003, the trust's standardised mortality ratio (SMR) had been consistently higher than expected. If outcomes were the same as would be expected when compared with similar trusts, the SMR would be 100. For the three years from 2005/06 to 2007/08, the trust's SMR for patients admitted as emergencies aged 18 and over varied between 127 and 145.

Looking at the three financial years covered by the investigation, we conducted a statistical analysis of the SMRs to examine to what extent they could have been due to random variation. We concluded that, for the three years we examined, there was a less that 5% probability that the high mortality rates at the trust for patients admitted as emergencies aged 18 or over were due to chance.

Standardised mortality was found to be high across a range of conditions including those involving the heart, blood vessels, nervous system, lungs, blood and infectious diseases. Our full investigation, including visits to the trust, examination of documents and wide-ranging interviews, has led us to conclude that there were systemic problems across the trust's system of emergency care.

The trust's arrangements for the collection, reporting and use of clinical information

The trust had a long history of poor information about its services. The accuracy of coding of information (that is, the system for cataloguing types of surgical and other interventions) had been poor, but had improved since 2007. The log of activity in theatres had been badly maintained and it was not possible to match information between systems, such as the theatre log and the national Hospital Episode Statistics data. Individual patients' data could not be tracked or linked in these different systems.

Although Dr Foster's analysis showed that the trust had the fourth highest hospital standardised mortality ratio (HSMR) in England for the three-year period 2003-2006, the trust only began to monitor clinical outcomes after the publication of the high rate by Dr Foster in 2007. The trust established a group to consider mortality, but considered that poor coding was the likely explanation for the high rate.

We found that, when challenged, neither the trust nor individual consultants could produce an accurate record of their clinical activity or outcomes for patients. This meant that we could not analyse the volume of surgical work and its outcomes.

Management of patients requiring emergency care

A&E and the emergency assessment unit

The detailed evidence for these findings is outlined in the section in this report on the A&E department and the emergency assessment unit (EAU). It came from a wide range of sources including interviews with staff, relatives and patients, observations, reviews of case notes, complaints, trust documents and external reports.

When we visited the A&E department in May 2008, the initial evidence raised serious concerns. We held an urgent meeting with the chief executive and followed this immediately with a formal letter requiring urgent action.

The trust did not have clear protocols and pathways for the management of patients admitted as emergencies. The A&E department was understaffed and poorly equipped. There were too few nurses to carry out an immediate assessment of patients. This was left to the receptionists, who had no clinical training. The patients in the waiting room could not be seen from the reception area. The department lacked essential equipment, such as sufficient defibrillators for every resuscitation trolley.

The nurses in A&E had not had enough training and development, and leadership had been weak. Patients often waited for medication, pain relief and wound dressings. There were delays in scanning patients out of normal hours. The most senior surgical doctor in the hospital after 9pm was often junior and inexperienced.

There were too few consultants to provide on-call cover all day, every day. There were too few middle grade doctors. The junior doctors were not adequately supervised, and were often put under pressure to make decisions quickly in order to avoid breaches of the target for all patients to be seen and moved from A&E in four hours. For the same reason, patients were sometimes rushed from A&E to the EAU without proper assessment and diagnosis, or they were moved to the 'assess and treat' area, even though staff were not formally allocated to the area and patients were not properly monitored there.

The EAU was large, with a poor layout, making it difficult for nurses to see patients. It was busy and frequently chaotic. It was understaffed, and communication was often poor between nurses and patients, and nurses and doctors.

During 2007/08, the nurses had little in-service training. Not all the nursing staff had the correct skills to observe and care for the variety of patients admitted as surgical and medical emergencies. On the bays with cardiac monitors, the nurses had not been trained to read the monitors. On occasions, the equipment was turned off.

Observations of patients were not carried out as they should have been and poor records were kept of patients' intake and output of fluids and food. Patients sometimes received incorrect medication or did not get their correct medication in a timely manner, if at all. There was poor compliance with generally accepted standards of practice in the control of infection.

Patients admitted as medical emergencies

The detailed evidence for these findings is outlined in the section on medical admissions. It included interviews with staff, relatives and patients, observations, complaints, trust documents, national surveys and external reports.

For patients admitted to the medical wards, there was sometimes poor communication with, and handover from, the EAU. Care was reported to be good for patients with heart attacks on the acute coronary unit, although there were problems with the cardiac monitors. However, because of lack of beds on the coronary unit, some patients with heart attacks remained in the EAU and were nursed in a non-specialist area.

The reconfiguration of the medical beds on floor two and associated changes in nursing staff had led to the creation of clinical areas that were poorly managed and understaffed.

The care of patients was unacceptable. For example, patients and relatives told us that when patients rang the call bell because they were in pain or needed to go to the toilet, it was often not answered, or not answered in time. Families claimed that tablets or nutritional supplements were not given on time, if at all, and doses of medication were missed. Some relatives claimed that patients were left, sometimes for hours, in wet or soiled sheets, putting them at increased risk of infection and pressure sores. Wards, bathrooms and commodes were not always clean.

Nurses often failed to conduct observations and identify that the condition of a patient was deteriorating, or they did not do anything about the results.

There was only one bay, with four beds, for patients with acute stroke. This was insufficient for the number of patients. There was no facility on the respiratory ward for non-invasive ventilation. There had been a number of problems with arrangements for resuscitation, including some serious incidents involving the contents of resuscitation trolleys. The bleep system for the management of cardiac arrests did not work effectively on several occasions. Mobile phones had to be used as a contingency.

Patients admitted as surgical emergencies

The detailed evidence for these findings is outlined in the section on patients admitted in an emergency with surgical problems or traumatic injuries. It included interviews with staff, relatives and patients, observations, reviews of case notes and inquest summaries, trust documents and external reports.

Many doctors and nurses working in surgery considered that staff on the EAU and on medical wards did not have the right training and skills to look after surgical patients.

The general surgeons did not work well together and there were few agreed protocols in surgery. This meant that patients needing emergency operations out of normal hours might receive different care and a different operation to that received from 9am to 5pm, Monday to Friday.

There were not enough doctors on duty out of hours, and the most senior surgical doctor after 9pm at night could be quite inexperienced.

In line with local understanding, the ambulance service took most, but not all, patients with severe or multiple trauma to other hospitals with specialised trauma services. For this reason, there was no trauma team at the trust. However, some staff were concerned that nurses on the EAU did not have the right training to look after those patients with traumatic injuries (such as broken limbs) who were admitted to the trust. In addition, the unit did not have equipment for traction or specialist hoists. We noted that, at times, there were too few staff to open a sufficient number of critical care beds.

For patients requiring emergency surgery, there was only one list for theatre at weekends. There was no system to assign priority to cases. Often emergency caesarean sections or surgical operations (such as removing an appendix) would take priority. This meant that patients with a broken hip might have to wait from Friday to Monday or Tuesday to have their operation. This inappropriate management meant that, for several days, these patients would not be allowed to eat or drink for many hours. On some occasions, patients who were designated as 'nil by mouth' were also inadvertently not given their essential medication.

From our review of case notes, from inquests and from findings from the alerts that the Healthcare Commission received on mortality, we noted a number of cases where patients had developed clots in the deep veins of their legs or pelvis and died from these clots breaking off and blocking the blood flow to their lungs. The trust did not have effective arrangements to prevent this or comply with accepted national guidance.

The care of post-operative patients was poor, such that signs of deterioration were missed or ignored until a late stage. When things went wrong, the trust was poor at recognising errors, reporting serious incidents and learning lessons.

Review of case notes

The Healthcare Commission reviewed the case notes of 30 patients who had died. Our case reviews were undertaken on a small scale, but nevertheless threw significant light on the arrangements for clinical quality and governance prevailing in the trust. We found that, in many of the cases, at least one element of the clinical management or monitoring of their condition was unsatisfactory. Areas of concern included infrequent reviews of patients by doctors, the lack of systematic monitoring of whether the patients were recovering or deteriorating, and the failure to respond adequately to signs of deterioration. There was inadequate monitoring to identify common complications of surgery.

What were the reasons for the failings at the trust?

It is the view of the Healthcare Commission that there were deficiencies at virtually every stage of the pathway of emergency care. This can be illustrated by following the patient's pathway.

When patients arrived in A&E, they were usually assessed by reception staff with no clinical training, before waiting in an area out of sight of the staff in reception. There was no regular check by nursing staff of the patients in the waiting room. Some essential equipment, such as cardiac monitors, was missing or not working. Assessment and treatment were often delayed.

There were too few doctors and nurses, alongside poor training and supervision, and junior doctors were put under pressure to make decisions quickly without advice and support from more senior doctors. Doctors were moved from treating seriously ill patients to deal with those with more minor ailments, in order to avoid breaching the four-hour waiting time target. Patients were moved to the clinical decision unit to 'stop the clock' but were then not properly monitored, since this area was not staffed. Patients had to wait for medication, pain relief, wound dressings and antibiotics. There was only a relatively junior doctor available after 9pm to give advice on surgical patients. There was no specialist trauma team. In summary, the care and assessment of patients fell well below acceptable standards.

Sometimes patients were rushed to the emergency assessment unit (EAU) without proper assessment or discussion, and without appropriate specialist care. The EAU was a large ward with a poor layout. It was busy, noisy and sometimes chaotic with too few nurses. Many of the nurses did not understand the cardiac monitors and did not always carry out observations adequately to identify whether a patient's condition was deteriorating. There were many instances of patients not receiving the medication they needed.

There were too few beds for patients who had had a stroke, not all patients with heart attacks went to the acute coronary unit, there was no non-invasive ventilation on the respiratory ward, and critical care beds were not always available. The medical wards on floor two were seriously understaffed and there were grave concerns about the standards of nursing care.

There were too few theatre sessions at weekends and consequent delay in getting to theatre, especially for trauma patients, and some patients did not get essential

medication. Post-operative complications were not always recognised.

Surgical practice was idiosyncratic, relationships were poor and there was little multidisciplinary team work. There were concerns about the level of cover by medical staff at night and at weekends.

Across the trust, there were shortcomings in resuscitation and arrangements to avoid potentially fatal blood clots were inconsistent. There was a shortage of critical care beds and concern about access to medical advice from critical care specialists.

It is our view that all these factors would have contributed to a poor outcome for patients.

The trust's approach to its mortality rate

One of the aims of the investigation was to clarify how the trust investigated its apparently high mortality rates.

The trust assured us that its mortality outcomes group undertook reviews of samples of case notes of patients who had died in hospital during particular periods. This was to ascertain whether the deaths were expected (unavoidable) and whether there were any questions arising about the quality of care provided to the patients.

Our scrutiny of their information, however, found that the reviews had not been sufficiently objective or robust. Moreover, the case notes revealed some sub-standard practice, which should have been identified and learned from.

Arrangements for governance and risk

The chief executive inherited a structure of governance that did not function effectively. Since 2005, there had been considerable change in the structure and responsibilities relating to governance and the management of risk.

The trust's system for identifying serious untoward incidents was poor, with failures to report some incidents and opportunities to learn lessons missed. Other incidents that were reported by staff consistently highlighted problems relating to the levels of staff, poor care for patients, and poor handovers when patients were moved from one ward to another. Many of these issues required consideration and resolution at a strategic level, but were rarely considered by the board or by its governance and risk sub-committees. There was no systematic mechanism to follow up any actions required or to share lessons.

The medical and surgical divisions failed to resolve problems such as 'nil by mouth', cardiac monitors, the cardiac bleep system, portable suction, and preventing blood clots and pulmonary embolism. Often these problems were listed on the corresponding risk register, but little effective action had been taken.

There were many complaints from patients and relatives about the quality of nursing care. These primarily related to patients not being fed, call bells not being answered, patients left in soiled bedding, medication not being administered, charts not being completed, poor hygiene and general disregard for privacy and dignity. Worryingly, the trust's board appeared to be largely unaware of these. In the reports seen by the board, these complaints were grouped into, and effectively lost in, categories such as "communication" or "quality of care".

The trust reported it had made efforts to engage clinical staff, but many senior doctors whom we spoke to considered that the trust was driven by financial considerations and did not listen to their views. They gave credit for the trust having a clear direction, but said that inflexible ways of imposing change had left many feeling marginalised.

Although most non-clinical staff thought that care at the trust was good, the majority of doctors we interviewed would not have been happy for a relative to be treated at the trust. In a 2006 survey, only 27% of staff said they would be happy to be cared for at the trust, compared with 42% nationally.

The trust generally performed poorly on clinical audit. There was no one taking the lead for clinical audit for a year and the trust-

wide group did not meet at all during this period. When audits were carried out, there was no robust mechanism to ensure that changes were implemented. When re-audits were required, they were often not undertaken, even if they had been recommended by a Royal College. The trust did not participate in many of the national audits run by the specialist societies.

The trust did not have an open culture where concerns were welcomed. Overall, the system that was intended to bring clinical risk to the attention of the board did not function effectively, and the board appeared to be insulated from the reality of poor care for emergency patients.

The trust's board and outcomes for patients

The board stated that the care of patients had always been a priority. However, no information on clinical outcomes went to the board until the publication by Dr Foster of the hospital standardised mortality ratio (HSMR) in April 2007. Even then, it went only to the private part of the meeting.

No annual report on the control of infection went to the board until July 2007, and that only went to the private part of the meeting.

The routine reports on performance that went to the board were at so high a level that they did not identify the failings in care of patients. The information on complaints and incidents was often incomplete, or so summarised that it left non-executives at a disadvantage in being able to perform their role to scrutinise and challenge on issues relating to the care of patients.

Informing the public

The trust's board preferred to discuss matters in private, even those that were not confidential or commercially sensitive. It did not discuss the Dr Foster HSMR or the alerts from the Healthcare Commission in public.

An outbreak of *Clostridium difficile (C. difficile)* occurred in the spring of 2006, and rates continued to be high during that year, but the trust did not report or acknowledge in public that it had an outbreak.

The actions of the trust's board

The year 2006/07 was a challenging one for the NHS, as trusts were required to achieve financial stability. That year, the trust set itself a challenging agenda to meet national targets for cost improvement, stabilise its finances, and become an NHS foundation trust. The trust set a target of saving £10 million, including a planned surplus of £1 million. This equated to about 8% of turnover. To achieve this, over 150 posts were lost. Although the stated intention was to minimise the loss of clinical staff, the number of nurses was significantly reduced. This was in a trust that already had comparatively low levels of staff (see pages 90-93 for details) and at a time when nurses felt they were poorly supported as a profession.

The combination of the reorganisation of wards, the reduction of beds (more than 100 fewer beds between 2005 and 2008, 18% of the total) and the loss of staff meant that the care of patients was further compromised. Areas with longstanding problems, such as A&E, were not given sufficient attention by managers.

The board claimed that its top priority was the safety of patients. However, even though clinical problems were well known, and the trust declared a financial surplus in 2006/07, it did not seek to redress the staffing problem it had exacerbated by reducing the number of nurses. The evidence suggests that the top priority for the trust was the achievement of foundation trust status. The failure of the trust to resolve the problems in A&E and to invest in staff is not consistent with the trust doing its reasonable best to provide a safe and effective service for patients.

The fact that the organisation concentrated mainly on clinical coding as the explanation for poor outcomes suggests that there was a reluctance to acknowledge, or even consider, that the care of patients was poor.

It was clear from the minutes of the trust's board that it became focused on promoting itself as an organisation, with considerable attention given to marketing and public relations. It lost sight of its responsibilities to deliver acceptable standards of care to all patients admitted to its facilities. It failed to pay sufficient regard to clinical leadership and to the experience and sensibilities of patients and their families.

Developments since the investigation was announced

It is, of course, impossible to determine what actions would have been taken by the trust if there had not been an investigation. The agreement at the end of March 2008 to fund the deficit in the numbers of nurses was taken after the board knew there was going to be an investigation.

Since January 2008, there has been a net gain of 46 qualified nurses and 51 healthcare support workers. The trust has increased the number of matrons from three to 12. However, in November 2008, the trust's board noted that further recruitment had been stopped because of actual and anticipated financial pressures, although the trust was 40 nurses below the previously agreed establishment. The trust, though, has told us that the board has not stopped recruitment and will, as part of the 2009/10 business plan, revisit the review of the establishment and take a view on recruiting to the outstanding posts.

When we expressed concerns to the trust, it welcomed them, responded positively and began to take action. The trust received formal notification of our concerns about the A&E department on 23 May 2008. It immediately set up a steering group for emergency care. Significant progress has been made, but there is still a need for further improvement. Two new consultants have been appointed, but the original consultant went on long-term sick leave. The middle grade rota is now fully staffed and there is a programme of training for junior and middle grade doctors. The number of nurses increased, but many of the new staff were inexperienced and there was still only one band seven nurse. A new model of care was introduced in the autumn of 2008. Triage is in place for 12 hours a day.

Ward-based training on the use of modified early warning scores (MEWS) was introduced in the autumn of 2008. A training package was also agreed to ensure that staff were competent to use cardiac monitors. A four-bedded surgical assessment unit was opened. Two additional beds were opened on the trauma ward. The trust is reviewing the provision of emergency theatre lists at weekends. Additional sessions have been arranged at short notice when necessary.

The mortality group has become the clinical outcomes group and is chaired by the chief executive. The trust reports that it is taking action in order to ensure that changes happen following complaints. Early signs are that mortality for emergency admissions is lower than previously, although the definitive figures for 2008 are not available yet.

The trust deserves credit for the improvement in the prevention and control of infection and it was recently found to comply with the hygiene code.

Overall conclusion about the trust

This was a small trust trying to support a range of specialties. It had become a foundation trust and improved its finances. However, it did not have a grip on operational and organisational issues, with no effective system for the admission and management of patients admitted as emergencies. Nor did it have a system to monitor outcomes for patients, so it failed to identify high mortality rates among patients admitted as emergencies. This was a serious failing.

When the high rate was drawn to the attention of the trust, it mainly looked to problems with data as an explanation, rather than considering problems in the care provided. The trust's board and senior leaders did not develop an open, learning culture, inform themselves sufficiently about the quality of

care, or appear willing to challenge themselves in the light of adverse information.

The clinical management of many patients admitted as emergencies fell short of an acceptable standard in at least one aspect of basic care. Some patients, who might have been expected to make a full recovery from their condition at the time of admission, did not have their condition adequately diagnosed or treated. As late as September 2008, we found unacceptable examples of assessment and management of patients. The trust was poor at identifying and investigating such incidents.

In the trust's drive to become a foundation trust, it appears to have lost sight of its real priorities. The trust was galvanised into radical action by the imperative to save money and did not properly consider the effect of reductions in staff on the quality of care. It took a decision to significantly reduce staff without adequately assessing the consequences. Its strategic focus was on financial and business matters at a time when the quality of care of its patients admitted as emergencies was well below acceptable standards.

The trust deserves credit for progress on infection control and for responding positively to the concerns of the Healthcare Commission.

The role of external organisations

Although South Staffordshire Primary Care Trust (PCT) commissioned services from the trust, it was initially distracted by the organisational change following the merger that created the PCT in 2006, and then focused on the number of patients treated and the cost. They had few measures of the quality of care or outcomes at the trust, and relied in part on external measures such as the Healthcare Commission's annual health check. Once the concerns of a campaign group were drawn to their attention, the PCT took action to address the individual concerns of patients and relatives, and to investigate and help to improve the quality of care at the trust.

West Midlands Strategic Health Authority (SHA) had also been created in 2006 through a merger and it too suffered from the accompanying loss of organisational memory. There was nothing to alert the SHA to concerns about the quality of care until the publication by the Dr Foster unit of the high hospital standardised mortality ratio in the spring of 2007. The SHA was reassured by the trust that it was investigating mortality appropriately.

We thought that information from the coroner would be useful for the investigation. We were disappointed that he declined to provide us with any information about the number or nature of inquests involving the trust.

The national picture and lessons for other organisations

A number of the findings of this investigation in respect of acute hospital care are potentially relevant to the whole NHS. These include the need for:

- Trusts to be able to get access to timely and reliable information on comparative mortality and other outcomes, and for trusts to conduct objective and robust reviews of mortality rates and individual cases, rather than assuming errors in data.
- Trusts to identify when the quality of care provided to patients admitted as emergencies falls below acceptable standards and to ensure that a focus on elective work and targets is not to the detriment of emergency admissions. Care must be provided to an acceptable standard 24 hours a day, seven days a week.
- Trusts to ensure that a preoccupation with finances and strategic objectives does not cause insufficient focus on the quality of patients' care.
- Trusts to ensure that systems for governance that appear to be persuasive on paper actually work in practice, and information presented to boards on performance (including complaints and incidents) is not so

summarised that it fails to convey the experience of patients or enable non-executives to scrutinise and challenge on issues relating to patients' care.

- Senior clinical staff to be personally involved in the management of vulnerable patients and in the training of junior members of staff, who manage so much of the hour-by-hour care of patients.
- Trusts to identify and resolve shortcomings in the quality of nursing care relating to hygiene, provision of medication, nutrition and hydration, use of equipment, and compassion, empathy and communication.
- Good handovers when reorganisations and mergers occur in the NHS.
- PCTs to ensure that they have effective mechanisms to find out about the experience of patients and the quality of care in the services that they commission.

Recommendations

In this report, we have drawn together the different strands of numerous, wide-ranging and serious findings about the trust which, when brought together, we consider amount to significant failings in the provision of emergency healthcare and in the leadership and management of the trust.

We have therefore written to Monitor, the regulator of NHS foundation trusts, in accordance with the Health and Social Care (Community Health and Standards) Act 2003 (s53(6)), to highlight these significant failings. We had previously raised concerns with Monitor about the leadership of the trust, and we note that both the chairman and chief executive have left the trust in the two weeks leading up to the publication of this report.

Irrespective of the above, we expect the trust to consider all aspects of this report, including all our findings, which detail serious failings at different levels and across different parts of the trust's services. Here, we highlight where action is particularly important.

Action by the board

The trust's board must ensure that there is a systematic means of monitoring rates of mortality and other outcomes for patients. This information should inform the board's discussions about the quality of services at the trust, and also inform action taken to improve outcomes for patients.

More generally, the trust's board needs to reflect on its arrangements for overseeing the quality and safety of clinical care within the trust. In particular, how the trust:

- Develops and promotes an open, learning culture.
- Collects and reports information accurately, both internally and externally, and in sufficient detail.
- Identifies and mitigates risks to the safety of its patients.
- Identifies correctly, and then reports, investigates adequately and learns from serious incidents and unexpected deaths.
- Learns from, and ensures that necessary improvements are made following incidents, near misses and complaints.
- Engages clinicians and develops effective clinical audit.
- Considers and acts on the views and experiences of patients who use the trust's services.

A&E department

Recent improvements to the emergency department – confirmed by a recent unannounced visit we made to the trust – must be sustained and extended to ensure that the service is safe, that it meets the needs of patients, and that the department is adequately staffed and equipped at all times.

Staffing and capacity

The trust must continue the work it has started to recruit additional nursing and medical staff, to ensure that care provided to patients throughout the trust, including at night and at weekends, is safe and keeps to accepted standards.

The trust needs to review the training and supervision of its nursing staff and junior doctors, to ensure that they are undertaking appropriate roles, are confident and clear about the expectations placed on them, and are receiving all necessary support.

The trust must ensure adequate availability of theatre sessions to ensure that it is able to handle demand in an emergency without delay, and has an effective means of determining which cases requiring emergency surgery should receive priority.

The trust must ensure that there is adequate access for clinical staff to advice and support from medical staff in the critical care (intensive care) service, and ensure this is independent of the availability of beds in the critical care unit.

Standards of care

The trust must ensure that its medical and nursing staff deliver basic aspects of care, such as reviewing patients on a regular basis, monitoring their condition, and identifying and managing any complications that may arise. The trust must ensure that there is timely review of patients by senior doctors.

In the light of specific findings in this report, the trust needs to audit its arrangements for and, where appropriate, equipment used in relation to: medication (particularly on admission and for patients who are 'nil by mouth'); the resuscitation of patients; non-invasive ventilation; cardiac monitoring; and anticoagulation.

National recommendations

Analysis undertaken in this and other trusts shows worrying variations across the NHS in the quality of coding of clinical outcomes, and variations in the extent to which statistical information is used to monitor the quality of local services and inform decisions at a senior level within NHS trusts.

This is of concern in a modern, information-driven health service where the interpretation and use of data is a fundamental means of improving clinical care. We recommend formally that all NHS trust boards have access to comparative data on outcomes for patients, including mortality, that is accurate, complete and as up-to-date as possible.

While recognising the challenges in ensuring that mortality rates are accurate and expressed in a way that does not cause unnecessary alarm among patients, or lead to unhelpfully risk-averse behaviour among clinicians, we believe that mortality rates can be published in a meaningful way to help patients to make informed choices about the quality of clinical care.

Boards of NHS trusts need to be focused at all times on the safety and quality of the services provided to patients. This includes having information available to boards that properly captures the experience of patients, so that non-executives can scrutinise and challenge the care received by patients.

The NHS and appropriate professional and educational bodies need to examine why the experience of patients on general wards in trusts that we have investigated continues to be of a poor standard, and take urgent action to improve the quality of nursing care in these areas.

PCTs need to develop more effective mechanisms to learn about the quality of care, the actual experience of patients and the outcomes of care in services that they commission, and give more priority to this aspect of commissioning.

The NHS needs to ensure effective handovers when reorganisations and mergers occur, so that information on services is transferred effectively to the new organisation.

Introduction

The Healthcare Commission is empowered by section 52(1) of the Health and Social Care (Community Health and Standards) Act 2003 to conduct investigations into the provision of healthcare by or for an English NHS body.

The Healthcare Commission usually investigates when allegations of serious failings are raised, particularly when there are concerns that the safety of patients might be at risk. Our full criteria for deciding whether to conduct an investigation are set out in appendix A.

This investigation began in April 2008 and was undertaken following concerns about apparently high mortality rates and poor standards of care at Mid Staffordshire NHS Foundation Trust. It aimed to establish whether the mortality rates for patients admitted as emergencies were high, to assess the care provided to those patients, and to establish whether the trust's systems and processes for the identification and prevention of poor outcomes for those patients were adequate.

The Healthcare Commission routinely reviews data about mortality rates at NHS trusts and follows up with individual trusts where there is cause for concern. Initial analysis of data from Mid Staffordshire NHS Foundation Trust compared with other trusts, and subsequent discussions with the trust, caused the Healthcare Commission to be concerned about the effectiveness of the trust's own systems for monitoring mortality rates among patients.

As a result of a number of concerns about mortality for individual procedures, the poor response to information requests made to the trust, and an apparently high mortality rate for emergency admissions, a decision was made to pursue the concerns through a screening process called an initial consideration.

However, following this, a number of concerns still remained:

- The trust appeared to have a higher number of deaths than anticipated for patients admitted as emergencies.
- There were doubts about the effectiveness of the trust's own systems for monitoring mortality rates, and we were not satisfied with the trust's explanation for the high mortality.
- There was considerable local concern about the care of patients, particularly elderly patients, that was threatening public confidence in the service.
- We were unsure of the trust's willingness to cooperate and its capacity to investigate and resolve the matter.

These concerns were noted by the Healthcare Commission's investigation committee, which agreed that a full investigation was necessary.

Terms of reference

The Healthcare Commission's investigations committee agreed the terms of reference for the investigation in April 2008.

The investigation was into the circumstances surrounding the mortality rates at Mid Staffordshire NHS Foundation Trust since April 2005 and the effectiveness of the trust's own systems for monitoring mortality rates among patients. It would aim to establish whether the trust was maintaining appropriate standards in the management, provision and quality of its services.

This included an examination of:

- The trust's arrangements for the collection, reporting, analysis and use of clinical data.

- Mortality rates at the trust, and the ability of the trust's information systems to provide an accurate picture of mortality rates, so as to identify any potential problems.
- Arrangements at the trust to ensure that patients are safe and that there is a good standard of care, particularly with regard to older patients.
- The governance arrangements within the trust and in the local NHS to protect the safety of patients and scrutinise the quality of the care provided by the trust.
- Any other matters that the Healthcare Commission considers arose out of, or were connected with, the matters above.

The investigation focused on information and events since April 2005 in relation to these matters.

Key elements of the investigation

Our investigation team worked with a team of external expert advisers and the membership is listed in appendix B.

During the investigation, we:

- Made a number of scheduled and unannounced visits to the trust to interview staff in relation to the investigation, and to observe wards and clinical areas in the trust.
- Conducted over 300 face-to-face and telephone interviews with past and present staff from the trust, representatives from local organisations representing patients, people who had used services at the trust and their relatives, and members of the public (see appendix C for further details).
- Reviewed over 30 sets of individual case notes of patients who had been admitted as emergencies and who had subsequently died.
- Analysed more than 1,000 documents provided by the trust and other organisations (see appendix D for a summary of sources of information and evidence).

This report

Since the concerns about mortality in the trust involved patients admitted as emergencies, in this report we first describe emergency admissions and look at the guidance on diagnosis and care of these patients.

The report then describes the context of the trust. It looks at the information that is available nationally about outcomes of care for patients admitted as emergencies and the work of the Healthcare Commission in reviewing these outcomes. It considers outcomes for patients admitted as emergencies to the trust and how the trust monitored these. The report also reviews the care that these patients received.

We go on to look at the pathway for patients admitted as emergencies to the trust, beginning with A&E, then the emergency assessment unit, then the medical and surgical wards. We do not consider children admitted as emergencies or maternity admissions.

The report considers the factors that were associated with outcomes for patients, in clinical areas and at strategic levels. Lastly, it looks at the role of other relevant agencies.

This report makes a number of recommendations in relation to the care and management of patients admitted as emergencies, and the monitoring of data on outcomes for patients.

The Healthcare Commission is responsible for this report and for undertaking a formal review of progress against the recommendations. The action plan will be available on our website. Monitor, the regulator of foundation trusts, will be responsible for ensuring that Mid Staffordshire NHS Foundation Trust takes action in response to our investigation and will monitor progress against the action plan.

The trust's history and role

Mid Staffordshire NHS Foundation Trust (the trust) provides services for patients on two sites: Stafford Hospital and Cannock Chase Hospital. These hospitals are about 10 miles apart. Stafford Hospital opened in 1983 and in 2008 had approximately 354 inpatient beds. Cannock Chase Hospital opened in 1991 and had approximately 115 inpatient beds. There are around 3,000 employees working in the two hospitals.

Stafford Hospital is an acute hospital offering a range of non-specialist medical and surgical services, including some specialty wards and a 24-hour accident & emergency department. Cannock Hospital has orthopaedic services for planned surgery, a nurse-led minor injuries unit, elderly care services and rehabilitation facilities. There have been various structural refurbishments across both sites in the past few years including, in 2007, the A&E department.

The trust serves a population of around 320,000 people from Stafford, Cannock, Rugeley and the surrounding rural areas. It is estimated that 21% of the population are over the age of 60. The 2001 census for Staffordshire showed that life expectancy (at birth) was slightly greater than the national average, general health was better than both the national average and regional (West Midlands) average, and unemployment was lower than both the national and regional averages. Staffordshire has a lower proportion of non-white population than both the national and regional averages.

The current chief executive came to the trust as interim chief executive in August 2005 and was appointed formally to the post in February 2006. The chairman of the trust's board has been in post since October 2004. During the first 18 months after the chief executive was appointed, a number of structures and posts were changed. These included the appointment of a director of nursing, a chief operating officer and clinical heads of divisions. All the executive team changed, with the exception of the director of finance who retired in 2008. The supporting structures for the executive team were also revised.

Since October 2006, the trust has provided services commissioned by South Staffordshire Primary Care Trust (PCT). South Staffordshire PCT was created at that time by a merger of four PCTs: Burntwood, Lichfield & Tamworth, Cannock Chase, East Staffordshire and South Western Staffordshire. The PCT is responsible for organising primary care and community health services for the local population, and commissioning hospital care. The trust also provides services to other PCTs.

From July 2006, the trust has been in the area covered by the West Midlands Strategic Health Authority (SHA) following a merger involving Shropshire & Staffordshire, Birmingham & the Black Country, and West Midlands South SHAs. The role of strategic health authorities includes establishing and managing annual performance agreements with PCTs and NHS trusts.

The trust was awarded foundation trust status on 1 February 2008. NHS foundation trusts are independent public benefit corporations. Although remaining part of the NHS, they are free from central Government control and are not subject to performance management by strategic health authorities. They are free to retain any surpluses they generate and to borrow in order to support investment.

Authorised and monitored by the regulator Monitor, foundation trusts also continue to be assessed through the Healthcare Commission's annual health check. Monitor

was established in January 2004 and acts as a regulator for foundation trusts. It is responsible for approving new applications for foundation trust status, which it grants once approval criteria have been met by the applicant trust. Once a foundation trust is established, Monitor reviews the trust's activities to ensure that they comply with the requirements of their terms of authorisation.

In 2002, the Healthcare Commission's predecessor, the Commission for Health Improvement carried out a clinical governance review of the trust. Its report was published in December 2002. The key areas for action included resolving problems associated with high numbers of emergency admissions, and ensuring patients were put on appropriate wards with fewer transfers of patients between wards. The report noted that the number of nurses was a cause for concern, and that the trust needed to improve the privacy and dignity of its patients. The trust was advised to develop an open and learning culture. The report also noted that the quality of clinical data was poor.

In 2004/05, the trust was awarded one star by the Healthcare Commission in its annual performance (star) ratings. In the 2005/06 annual health check, the trust was rated by the Healthcare Commission as having "fair" quality of services and "fair" use of resources. In the following year (2006/07), the trust received fair for its quality of services and "good" for its use of resources. In the same review, the core standards score was "fully met" after having a risk-based assessment undertaken by the Commission. The trust was rated as good against the existing standards but "weak" against the new national targets score.

The most recent assessment by the Healthcare Commission, for 2007/08 and published in October 2008, noted that the trust was being investigated at the time and was therefore based largely on the trust's assessment. The trust was rated as good for quality of services and good for use of resources. In publishing this assessment, the Commission's website noted that this investigation was underway and that the assessment would be reviewed in the light of the report.

Emergency admissions

In this report, we concentrate on emergency admissions since it was for patients admitted as emergencies that the trust had a high mortality rate.

What are emergency admissions?

Emergency admissions happen when patients are admitted to hospital as a matter of urgency. They are not scheduled stays in hospital for planned or routine procedures or operations. They vary considerably in nature, but generally include the most critically ill or injured patients in the hospital. Patients may be sent in by general practitioners (GPs), they may be brought in by ambulance, or they may decide to go directly there themselves.

Patients may be suffering from traumatic injury, for example following a fall, an accident or a violent attack. Emergencies include patients with food poisoning, pneumonia, heart attacks and strokes, and patients with acute conditions requiring surgery such as appendicitis or obstruction of the bowel.

The NHS records emergency attendances and admissions as "unscheduled care".

Emergency admissions account for over a third of all admissions to hospitals. Statistics for England show that there were 4.7 million emergency admissions in 2006/07.

Over a 10-year period, admissions to hospital nationally have increased by 15% but emergency admissions have risen by nearly 20%. Nationally, the majority of emergency admissions (79%) are for medical as opposed to surgical reasons (21%).

The management of patients admitted as emergencies: national guidance and recommendations

The Royal College of Physicians, in 2004, recommended that a doctor with the appropriate skills and knowledge in acute medicine should be present at all times in a department receiving acute medical emergencies. This is because early assessment and decisions by a clinician with the appropriate skills and knowledge are a crucial part of the management of emergency patients.

In 2005, the Department of Health described the management of emergency medical and surgical admissions as consisting of two stages: assessment and admission. Early and accurate initial assessment was said to be vital to ensure that patients were admitted to the appropriate place for the appropriate treatment at the first time of asking.

In 2007, a report by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD), *Emergency Admissions – A journey in the right direction*, also recommended that initial assessment of patients admitted as an emergency should include a doctor of sufficient experience and authority to implement an action plan for the care of the patient.

Following initial assessment, a clear plan for treatment tailored to their clinical condition should be in place for every patient – a process emphasised by guidelines produced by the National Institute for Health and Clinical Excellence (NICE) in 2007. Subsequent review and observations are critical in inpatient care as the outcome for patients is affected by the adequacy of the clinical review.

Following the initial assessment and treatment of emergency admissions,

subsequent transfer of patients should be to a ward that is appropriate for their clinical condition. NCEPOD in 2007 reported that 93% of patients are generally admitted under the appropriate specialty. Transfers to inappropriate wards may lead to a delay in treatment, which is known to have a negative effect on outcomes. Excessive transfers of patients between wards should be avoided, as these are also detrimental to the care and experience of patients.

It is generally accepted that the early involvement of a senior clinician or consultant in the management of patients admitted as an emergency can improve the quality of care. In addition to the greater ability and experience of senior staff, there is concern regarding the ability of junior staff to recognise severely ill or deteriorating patients (see, for example, clinical guideline CG50 from the National Institute for Health and Clinical Excellence, 2007).

The timing of a patient's first contact with a consultant is likely to influence the quality and standard of care received. The Royal College of Physicians recommended that 90% of patients should be reviewed by a consultant within 24 hours of admission. However, due to the nature of emergency admissions, NCEPOD in 2007 recommended that the first consultant review should be within 12 hours of admission. Moreover, regular review by a consultant is important to maintain continuity of care.

Some of the most demanding cases involve patients who have suffered severe physical trauma. Trusts should ensure that a trauma team is available 24-hours a day, seven days a week. This, according to the NCEPOD report *Trauma: Who Cares?* (2007), is essential in response to serious injury. A consultant must lead a team in the management of patients who have suffered trauma. Due to the relatively low incidence of severe trauma, it is unlikely that every hospital can deliver optimum care in these circumstances. It is, therefore, essential that there is regional planning to organise the delivery of trauma services.

A patient admitted as an emergency will usually be admitted to a specialist inpatient ward or an assessment unit (medical assessment unit or emergency assessment unit). Alternatively patients could be transferred to another establishment, or remain under the operational management of the emergency department in a clinical decision unit (CDU). Clinical decision units are for patients who require further observation and assessment before a treatment plan can be developed or a decision made to discharge them. They are normally short-stay units.

Other relevant recommendations of the NCEPOD report *Emergency Admissions – A journey in the right direction* included:

- Trainee doctors need to have adequate training and experience to recognise critically ill patients and make clinical decisions. This is an issue not only of medical education but also of ensuring an appropriate balance between a training and service role, thus exposing trainees to acute clinical problems with appropriate mid-level and senior support for their decision making.
- Hospitals that admit patients as emergencies must have access to both conventional radiology and computerised tomography (CT) scanning 24-hours a day, with immediate reporting.
- Robust systems need to be in place for the handover of patients between clinical teams, with readily identifiable agreed procedures for handovers based on agreed protocols. Clinicians should be made aware of these protocols and handover mechanisms.
- A clear plan should be made to monitor each patient according to their clinical condition. This should provide details of what is to be monitored and the frequency of observations and should be made regardless of the type of ward to which the patient is transferred.

Outcomes for patients and mortality rates

General analysis of outcomes

The use of statistical tools to compare outcomes across different hospitals and different clinical conditions is a relatively recent activity. It has achieved major prominence in the NHS with the establishment of the Dr Foster Research Unit at Imperial College in London and the associated commercial enterprise, Dr Foster Intelligence. Before Dr Foster, monitoring of outcomes tended to be focused on specific clinical areas or within individual hospitals – examples in the NHS include the monitoring of cardiac surgery outcomes, begun by the Society of Cardiothoracic Surgeons of Great Britain and Ireland, and organ transplant outcomes monitored by NHS Blood and Transplant.

The ability to use data to make national comparisons has only been possible with developments in the recording and provision of information, including improved computer power, standardised coding, the NHS minimum datasets, payment by results, and other incentives for improving data quality. Nationwide Hospital Episode Statistics (see box opposite) have been collected in some form since the mid-1980s, but there have been marked improvements in their accuracy and reliability over the past 10 years.

For the data to accurately reflect hospital activity, there must be clear, accurate and timely information recorded in the patient's notes; accurate and consistent clinical coding; and clear procedures for collecting and processing the data. There also needs to be appropriate training and accreditation of staff.

Clinical coding is the process whereby the care given to a patient (usually information on diagnosis and any procedures carried out), that is recorded in the patient's notes, is translated into coded data and entered into the hospital's information system. Clinical coding therefore depends on a clear record of the care given by clinicians.

Many of the tools that are used for monitoring outcomes in the NHS are adapted from quality control methods that have been used in industrial manufacturing since the 1930s. There are major challenges in adapting these methods to healthcare: in particular, accounting for the natural variation between individuals and deciding on appropriate thresholds for triggering a concern about the safety of patients. There are also challenges due to the great number of processes being monitored and the subsequent risk of a false alert.

The Healthcare Commission has been involved with the measurement of outcomes for patients since our inception in 2004, and includes this as part of our annual health check that rates NHS trusts. Analysis that feeds into the health check includes the use of indicators to assess a trust's compliance with core standards, and the assessment of outcomes against specific national targets (for example, cancer waiting times and reductions in MRSA infection rates). We also administer the annual surveys of NHS staff and patients, and carry out specific service reviews across the NHS (such as the recent reviews of maternity services and urgent care).

The Healthcare Commission's work on high mortality rates

In 2007, we began a formal programme to identify and follow up apparently high mortality rates in NHS trusts.

Alerts about possible high mortality (also known as 'outliers') have been either generated by us from our analysis of Hospital Episode Statistics or received from other

organisations – the main external source being the Dr Foster Research Unit at Imperial College. A review of our approach to following up high mortality rates can be accessed on our website.

It is recognised that a large number of these alerts may be due to errors in the data or to insufficient adjustment for case mix, so a team of analysts assesses each case to establish whether there are sufficient concerns to follow up with the trust.

If an alert is followed up, the trust will initially be required to provide further information and explanation. In many cases, this has been enough to satisfy us that no further action is needed. Cases can be escalated if concerns about the safety of patients have not been adequately addressed or we think these have not been properly recognised by the trust.

Hospital standardised mortality ratio

The hospital standardised mortality ratio (HSMR) is a comparative measure of an acute trust's overall mortality developed by the Dr Foster Research Unit. It does not cover all admissions, but focuses on a group of diagnoses that accounts for 80% of all deaths in hospitals in England.

The HSMR accounts for the case mix of patients at the time they are admitted to the trust, adjusting for a number of factors that include the primary diagnosis, age, sex, 'co-morbidities', deprivation and method of admission. Co-morbidities are medical conditions that exist alongside the main disease or condition for which the patient is being treated.

A value for the HSMR of 100 indicates mortality that is equivalent to what would be expected, given the case mix. Values greater than 100 indicate higher than expected mortality, and values less than 100 indicate lower than expected.

In the 2007 Dr Foster Hospital Guide, the trust was classified as having high mortality, with a one-year (2005/06) HSMR of 127 and a three-year (2003-2006) HSMR of 125.

Hospital Episode Statistics

Hospital Episode Statistics is the national data set for England of the care provided to NHS patients. HES information is stored as a large collection of separate records – one for each period of care – in a secure data warehouse. Each HES record contains a wide range of information about an individual patient admitted to an NHS hospital. For example:

- Clinical information about diagnoses and operations.
- Information about the patient, such as age group, gender and ethnic category.
- Administrative information, such as time waited and date of admission.
- Geographical information on where the patient was treated and the area in which they live.

The clinical data held in HES have been translated from the information recorded by clinicians in patients' notes into diagnosis and procedure. This is done by clinical coding teams at each trust. It enables consistent comparisons to be made across all trusts in England, and across the world wherever these codes are used.

Data such as that collected in HES are a valuable source of information, but it is important that they are used in context and that their limitations are recognised.

Concerns about outcomes at the trust

Initial concerns

The initial concerns about mortality rates at the trust arose out of the Healthcare Commission's work to follow up high mortality rates as described above. Over the period July 2007 to March 2008, the Dr Foster Research Unit generated four mortality outlier alerts for the trust and a further three were generated through the mortality outlier surveillance at the Healthcare Commission. Four more alerts (two by Dr Foster and two by the Healthcare Commission) were generated between the launch of the investigation in April 2008 and November 2008. Further details on these alerts can be found in appendix E.

Each of the alerts was analysed to establish if the apparently high rates of mortality could be ruled out because of errors in coding or data quality issues, or whether concerns about quality of care remained.

In a number of the alerts, poor coding was apparent. However, the range of alerts that emerged for the trust started to suggest a more general problem with high mortality, rather than an issue isolated to one particular area or specialty. We calculated that the chance of this number of alerts, within an individual trust, all being false alarms was extremely low (probability, $p < 0.001$). We therefore considered data across the whole trust, which showed that the raised mortality was a general concern for emergency admissions, but not for elective admissions (see the next section).

We also had concerns regarding the trust's responses when we wrote to follow up these alerts. In comparison to other trusts, responses received from the trust did not contain enough detail of the investigations or analysis carried out, yet the trust assured us that the alerts were as a result of problems with coding rather than clinical care.

The trust purchased Dr Foster's real-time monitoring system in early 2006, and used this for its internal surveillance of mortality (see appendix E). The trust gave us information generated using this system for non-elective admissions for the financial year 2007/08. This showed that the trust had significantly high mortality in 10 'patient groups', and significantly lower than expected mortality outcomes in four groups. Because of the different alert thresholds used, false alarms would be more frequent under this system than under the monitoring tools used by the Healthcare Commission or, centrally, by the Dr Foster Research Unit. However, the likelihood of this many alerts within a single trust being false alarms is very small ($p < 0.001$).

Standardised in-hospital mortality rates for emergency admissions

We compared the trust's in-hospital mortality against mortality in other non-specialist acute trusts in England. We focused on patients admitted as emergencies who were aged 18 and over. Patients admitted as emergencies account for more than a third of all admissions to acute hospitals.

We adjusted (or 'standardised') the figures for a number of factors – including the age and sex of patients and their diagnoses and procedures (by Healthcare Resource Group, see box opposite) – so that we could compare the trust with the national picture.

If a trust had outcomes that were the same as would be expected in other non-specialist trusts (once they had been adjusted as mentioned above), its standardised mortality ratio (SMR) would be 100. (Note that SMR is a different measure to Dr Foster's hospital standardised mortality ratio (HSMR)). A score above 100 indicates higher than expected mortality. A score below 100 indicates lower than expected mortality.

Figure 1 shows the quarterly SMRs for emergency admissions to the trust of people aged 18 and over between April 2003 and March 2008. This is compared to the expected SMR of 100. It can be seen that the trust's SMR was consistently higher than expected over a five-year period.

Healthcare Resource Groups

For each episode of hospital care, there will be a primary diagnosis recording the main reason why the patient is in hospital and, often, a series of secondary diagnoses that may be relevant to the episode of care. Any procedures that were undertaken will also be recorded against that episode. The combination of diagnoses and procedures is then mapped to a Healthcare Resource Group (HRG) for that episode. HRGs group together cases that are clinically similar and require similar levels of resource for treatment and care. These groupings are often referred to as 'case mix'.

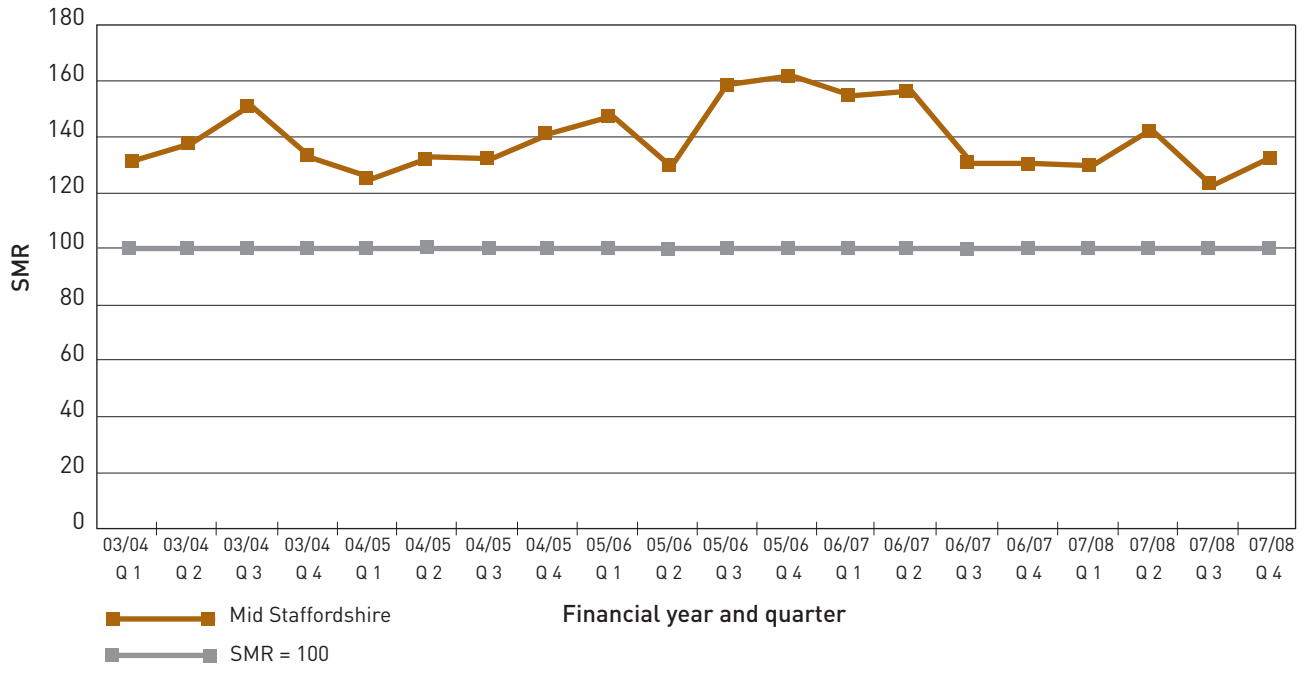
Individual HRG codes are grouped into HRG chapters. Each chapter describes the HRGs for one or more body system.

Looking at the three financial years covered by the investigation, we then conducted a statistical analysis of the SMRs to examine to what extent they could have been due to random variation. This analysis also allowed for the presence of other factors, unrelated to quality of care, such as deprivation or ethnicity. We concluded that, for the three years we examined, there was a less that 5% probability that the high mortality rates at the trust for patients admitted as emergencies aged 18 or over were due to chance. In other words, the rates were 'significantly high' (see statistical appendix E for more details).

Elective admissions

We carried out equivalent analysis of standardised mortality ratios to examine mortality outcomes for elective admissions at the trust. This analysis did not indicate any concerns about higher than expected mortality (see table 7 in appendix E for more details).

Figure 1: Quarterly standardised in-hospital mortality ratio (SMR) for Mid Staffordshire NHS Foundation Trust (emergency admissions aged 18 and over), 2003/04-2007/08



Source: Hospital Episode Statistics

Non-standardised in-hospital mortality ratios for emergency admissions

Non-standardised or 'crude' mortality ratios were examined in a similar way, comparing in-hospital mortality after an emergency admission among non-specialist acute trusts in England. This is a useful additional measure, as it removes any potential effects of differences in the accuracy of clinical coding across trusts.

Analysis of the trust's non-standardised mortality ratios has shown them to be significantly high, at the 5% level (p 0.05), for all three financial years covered by the investigation (see appendix E for more details).

Standardised HRG chapter level in-hospital mortality for emergency admissions

Having established that mortality was significantly higher than expected in overall emergency admissions for those aged 18 and over, analysis was carried out to determine whether this was concentrated in specific HRG chapters. The comparison was against other non-specialist acute trusts and case mix factors standardised for included year quarter, age, sex and admission HRG. Standardised mortality was found to be significantly high, at the 5% level ($p < 0.05$), across a range of HRG chapters.

This analysis suggests that the higher than expected mortality that we had observed at the trust was spread across a number of different groups of patients admitted as emergencies. Rather than being able to pinpoint one clinical area causing higher than expected mortality, these findings were indicative of systemic problems across the trust's emergency care system (see appendix E for more details).

Standardised HRG chapter level ONS-linked total 30-day mortality

By linking HES records with mortality data recorded by the Office for National Statistics (ONS), it is possible to get a measure of mortality within 30 days of admission to hospital, regardless of whether the patient died in hospital or after discharge. The analysis of total 30-day mortality is a useful comparison to in-hospital mortality. For example, if a trust had particular problems with being able to discharge patients due to a lack of care provision in the community, then their in-hospital mortality may look higher, whereas their overall 30-day mortality could be similar to other trusts. Conversely, a trust that routinely discharges patients earlier than others may have favourable in-hospital mortality rates, but higher than expected total 30-day mortality rates.

ONS-linked HES is currently only available until the end of 2006/07. The analysis suggests, as was seen with in-hospital mortality chapter level analysis, that there was high mortality within 30 days and it was spread across a range of groups of patients (see appendix E for more details).

Findings of fact on the trust's mortality rates

- During the period July 2007 to March 2008, Dr Foster generated four mortality outlier alerts for the trust, and a further three were generated through the surveillance of mortality outliers at the Healthcare Commission. Four more alerts (two by Dr Foster and two by the Healthcare Commission) were generated between the launch of the investigation and November 2008.
- The response of the trust to our information requests about the outliers did not contain enough detail to support the claim that the alerts were due to coding issues and not problems with quality of care.
- Analysis of Hospital Episode Statistics showed that the trust had significantly higher than expected standardised mortality for patients aged 18 and over who were admitted as emergencies. This was the case for all three financial years covered by the investigation.
- Standardised mortality ratios for elective admissions did not indicate any concerns.
- Crude mortality rates for patients aged 18 and over who were admitted as emergencies had been persistently higher than the national rates for non-specialist acute trusts over the period covered by the investigation.
- The higher than expected standardised mortality ratios at the trust were spread across a range of Healthcare Resource Group chapters, rather than being concentrated in a few groups of patients, suggesting that there were systemic problems with the trust's emergency care system.
- ONS-linked 30-day mortality analysis showed that mortality was higher than expected within 30 days and was spread across a range of conditions.

Summary

In summary, this analysis of statistics showed us that mortality rates were higher than expected in this trust, both for in-hospital deaths following an emergency admission and in relation to specific procedures, diagnoses and Healthcare Resource Groups across the pathway of emergency care. We decided that it was important on behalf of patients to seek to understand these unexplained, and consistently higher, outcomes.

We therefore contacted the trust to explore the reasons. The trust took the view that the variation was due to how procedures were coded – that is, how they were recorded and thereafter how this record was used as the basis for analysis. The trust's explanation did not satisfy our concerns, and we therefore launched this investigation.

We were particularly concerned because of the extent to which the mortality rates were higher than the norm for the whole of the five year period from 2003 to 2008. These statistics highlight differences from the norm, and they were a trigger for our investigation. They do not of themselves provide any explanation for these differences.

The trust's arrangements for the collection, reporting, analysis and use of clinical data

Sources of evidence

- Interviews with staff past and present
- Report by CHKS (Casp Healthcare Knowledge Systems) on recoding of clinical activity at the trust
- Report by the Audit Commission
- Trust documents, including minutes of the mortality outcomes group

Background

We were told by clinical staff and managers that the trust had a long history of poor quality information about its services. This was also one of the findings of the clinical governance review in 2002.

A report by CHKS was commissioned by the trust in early 2007, due to concerns about the coding of clinical data. The report identified deficiencies in the clinical coding entered in the Patient Information Management System (PIMS). This was manifested by inaccuracies in coding and under-reporting of co-morbidities (that is, patients' other health problems). The coding manager at the time had been on long-term sick leave and the rest of the team were working part-time. Contact with clinicians was also poor, with coders being reluctant to approach them about unclear notes. Clinicians had little understanding of the need to make notes clear for the coders.

The trust recruited a new coding manager in July 2007, when the previous post holder retired. More investment was put into the department and new members recruited to the team. Staff told us that the new coding manager had had a positive impact on the quality of coding. The new manager built better relationships with clinicians and motivated her staff to attend training courses and gain accreditation. Examples of positive developments included having consultants on the clinical coding and data quality group, and systems that the coders could use to cross-check information, such as radiology and pharmacy reports.

An external audit of clinical coding, undertaken in early 2008 by accredited clinical coding auditors, reviewed 300 'finished consultant episodes'. This was part of the Audit Commission's national data assurance framework in 2007/08 for payment by results. Payment by results is the system for funding the 'case mix' used to reimburse providers of acute hospital services for the majority of their activity. Case mix refers to the fact that the price paid is related not only to the volume of activity but also to the type and severity of the illness or injury being treated.

The auditors extracted all the relevant diagnostic and procedural information from the case notes and assigned the appropriate codes for a sample of 300 episodes of care that occurred between 1 July and 30 September 2007. The areas audited were trauma and orthopaedics, ear nose and throat, ophthalmology and paediatrics. In all, only 71.7% of primary diagnoses and 59.9% of secondary diagnoses were found to have been coded accurately. This meant that the trust was in the worst quarter for accurate coding of diagnoses. The accuracy of coding of procedures was also audited: 83.1% of primary and 84.3% of secondary procedures were correct. Overall, the audit found that 7% of episodes would have changed Healthcare Resource Group had the clinical coding been correct. This was lower than the national figure of 9.4%.

The coding manager told us that she still had concerns about some of the clinical input to coding. It was reported that junior doctors could present a problem because of their frequent job rotations. They were often imprecise about diagnoses, whereas the main problem encountered with senior consultants was the tendency to under-report co-morbidities.

With regard to other systems, we found that the log of activity in theatres had been badly maintained. The trust supplied the complete output of its theatre log system for the period April 2005 to June 2008. However, there were gaps when the log was compared to information the trust had submitted to Hospital Episode Statistics (HES). For example, of 13 procedures relating to the repair of abdominal aortic aneurysm that appeared in HES, only four could be found in the theatre log.

There were additional problems with matching information between systems, caused by the insufficient quality of the information to identify individual patients. This information was largely taken from the trust's previous 'korner card' surgical log system, which was a manual system used generally in the NHS. The trust had updated to an electronic system for collecting data from theatre in June 2008. This should have been more effective in linking the theatre records to the trust's central patient management system. However, there were teething problems with this system.

The trust had recognised that internal monitoring of outcomes had not been effective. There was also evidence of clinicians not wanting to be involved with monitoring. For example, in the summer of 2007, a system was introduced to enable clinicians to monitor their own performance. Despite a training programme, the system was hardly used.

The trust had a history of poor performance on mortality. The data from Dr Foster showed that the three-year HSMR for 2003-2006 was 125. This was the fourth highest ratio in England. The trust had only begun to monitor clinical outcomes after the publication of Dr Foster's Hospital Guide in 2007, and had relied on the use of the Dr Foster 'real-time monitoring tool' to identify areas of concern ('red bells'). This tool was used by the trust's lead clinician for clinical governance.

In response to its apparently high mortality rate identified by Dr Foster, the trust initially focused on the poor quality of the clinical coding of the cases involved. It also established a group to consider mortality outcomes. The group's follow-up of high mortality rates had focused on reviews of individual case notes of patients who had died. This was conducted by clinicians at the trust over a period of time. The general conclusions of the follow-up were that the deaths were predictable and that no problems with care were identified. In the next chapter and later in the report, we consider some examples of this.

The trust's responses to alerts about high mortality

In July 2007, the trust received a letter about an alert from the Dr Foster Research Unit, copied to the Healthcare Commission. This involved mortality for operations on the jejunum, a part of the small intestine. We wrote to the trust in August 2007. The chief executive replied in early September to say that the trust was reviewing this alert during September and would be happy to supply a copy of its full report once complete. We replied and confirmed we would require a copy. On 25 October, we sent another letter to the trust, requesting a copy of the report that had not been sent by the trust.

The trust gave a copy of the review they had undertaken to our local team in November 2007, and we were subsequently provided with the notes of the trust's review of four sets of case notes.

The Dr Foster Research Unit sent another letter to the trust in August 2007 about a further alert that had signalled on their system, this time regarding aortic, peripheral and visceral artery aneurysms. This was copied to the Healthcare Commission and was

considered by our panel on mortality outliers in September 2007. On 10 October 2007, we sent a letter to the trust asking for information regarding this alert. No response was received from the trust in relation to it.

Further alerts were generated internally by the Commission during the autumn of 2007, as part of the programme to identify and follow up concerns about mortality rates. Given the unprecedented number of alerts, a decision was made by the mortality outlier panel to pass all matters that it was aware of regarding the trust to our investigations team, who considered them as an initial consideration before launching this investigation.

As part of the initial consideration process, we visited the trust in March 2008. In an interview, the chief executive apologised for not responding directly to the letters about the alerts described above. In a presentation given by the trust during this visit, the trust shared an action plan titled "Patient care and safety action plan". The first section of this related to "mortality data" and the first of three actions was "engagement with HCC central team on any Dr Foster Alerts". Since that time, and the start of the investigation, there have been two further Dr Foster alerts, in July and November 2008. The trust sent us a copy of its response to Dr Foster but did not directly contact the investigation team at the Healthcare Commission about these.

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Findings of fact on the trust's arrangements for the collection, reporting, analysis and use of clinical data

- The trust had a history of poor quality data, noted in the clinical governance review in 2002. A report by CHKS in early 2007 identified deficiencies in the clinical coding.
- The quality of coding had improved, but there were still concerns about some of the clinical input to coding.
- The trust had very poor information about activity in theatres, and this could not be matched with other sources of information.
- The trust had little focus on outcomes before the publication by Dr Foster of the high hospital standardised mortality ratio in 2007.
- The trust considered that poor coding was a likely explanation for the high hospital standardised mortality ratio.
- The trust established a mortality outcomes group, which worked mainly through reviewing case notes of patients who died.
- The trust made a limited response to concerns about mortality raised by the Healthcare Commission.

Quality of care at the trust

Having looked at statistical outcomes for patients in terms of mortality, in this section we consider our analysis of case notes, the views of patients, relatives and staff, and complaints received by the trust.

Healthcare Commission's analysis of case notes

We decided to look at the case notes of some of the patients who died, to provide information on the quality of care given to these patients. We also wanted to see whether the trust had systems to identify shortcomings in care and cases that needed extra consideration, in order that lessons could be learned. These reviews were undertaken by our expert clinical advisers.

We looked at three main categories of case notes. These were the notes of:

- 10 patients who had died having suffered a stroke in the summer of 2007.
- 8 patients who died in October 2007 and whose cases had already been reviewed by the trust.
- 11 patients who died in A&E in the summer of 2008.

We also reviewed a number of individual cases drawn to our attention, for example from reports of inquests.

Patients with acute cerebro-vascular disease (stroke)

We looked at the notes for 10 patients who died during July and August 2007. All these patients had suffered a stroke, but this had not necessarily been the cause of their death. Our review looked at the quality of assessment, diagnosis and management for these patients using accepted standards from the National Sentinel Stroke Audit and the National Confidential Enquiry into Patient Outcomes and Deaths.

For patients who were in hospital for several days, it was clear that fluid charts and summaries of fluid input and output were poorly completed. Even when patients were receiving intravenous or naso-gastric fluids and had a urinary catheter in place, these charts were often incomplete. Transfers from A&E to wards and between wards were also poorly documented in the records, often with no clear handovers recorded in either medical or nursing records.

Based on the clinical records for the 10 patients, our experts considered that five deaths were predictable, in other words to be expected. In these cases, CT scans were properly performed and findings immediately noted. 'Do not resuscitate' orders were appropriately discussed with families in the light of these investigations, and this led to thoughtful and considerate care of patients in the last few days or hours of their life.

Of the other five patients, one patient who was recovering from a stroke developed rectal bleeding and died. Although the right people seemed to have been involved in the care of this patient, the patient's condition deteriorated without a clear set of decisions being documented.

A second patient suffered a brain haemorrhage while being treated with two anti-thrombotic drugs for ischaemic heart disease (that is, disease of the coronary arteries). Anti-thrombotic drugs reduce the chance of a clot (or thrombus) forming. They make it more likely that patients will bleed if a blood vessel becomes damaged. The

consultant concerned wrote to the GP and to the cardiologist who had prescribed the two anti-thrombotic drugs. The consultant asked if giving these drugs together increased the risk of stroke and whether this was an appropriate combination. No answer to these letters was available in the clinical record.

A third patient with a past history of stroke disease was admitted with a massive pulmonary embolism, which was correctly diagnosed and treated. A couple of days after thrombolysis (that is, 'clot-busting' drug treatment) was given for the pulmonary embolus, the patient suffered a stroke. The death certificate mentioned the pulmonary embolus but not the stroke.

Pulmonary embolism

A pulmonary embolism happens when a blood clot or piece of a blood clot gets stuck in one of the blood vessels in the lungs. The clot forms somewhere else in the body and is carried to the lungs in the bloodstream.

In 70% to 90% of people who get a pulmonary embolism, the blood clot comes from one of the legs. The clot usually forms in one of the deep veins that run through the centre of the leg. A blood clot in one of these veins is called deep vein thrombosis, or DVT for short.

A fourth patient came in on a Saturday with abdominal pain. Because the patient also had pains in their arms and changes on their electrocardiogram (ECG or heart tracing), they were given thrombolysis for a suspected heart attack. The patient rapidly developed signs of a brain haemorrhage and died. It later transpired that the changes on their ECG had been caused by earlier damage to the heart and did not relate to this admission.

The fifth case involved a patient who had a coronary artery bypass graft (a type of heart surgery) at another hospital and was then admitted two to three weeks later with gradual onset of weakness of the left arm and face, typical of a stroke. The patient was not given any medication to prevent the formation of a clot in the deep veins of the leg. On the fourth day after admission, the patient had a massive pulmonary embolus and died. Although the patient's stroke care was well documented and satisfactory, it would have been worth discussing the arrangements in place to consider treatment to avoid deep vein clotting and a subsequent pulmonary embolus.

For these five patients, our experts considered that they highlighted issues that could have provided opportunities to discuss, learn and improve. However, there was no indication that this had happened.

For example, the case of the third patient would have been a good case to review, because of questions about the use of thrombolysis and the risks that are attached to it, and whether patients should be given follow-up treatment for blood clots when they are known to have had a previous stroke.

Similarly, the case of the fourth patient would also have been worthy of further multidisciplinary discussion, to consider the merits of waiting for the medical records and a second opinion from a more senior physician.

Findings of fact from review of the stroke cases

- In half of the cases we reviewed, the diagnosis and care were appropriate. In the other cases, opportunities were missed to review these and potentially learn lessons.
- Problems not identified included the arrangements to prevent deep vein thromboses and use of anti-thrombotic drugs.
- Fluid charts and summaries of fluid input and output were poorly executed.
- Handovers were poorly recorded in the notes.

Patients whose care had been reviewed by the trust's mortality group

Here we looked at a sample of the notes for patients whose records had been reviewed by the trust's group responsible for considering mortality. The mortality group was established in August 2007 in response to concerns raised by Dr Foster's hospital standardised mortality ratio. The group's purpose was described as being "to investigate deaths occurring within the trust by consultant review of case notes".

The deaths that we considered occurred in a two-week period in October 2007. The spreadsheet that the trust provided following the review of deaths had information on age, a brief clinical summary, cause of death as stated on the death certificate, whether a post mortem had been performed, whether the death was thought to have been predictable and whether there were any "care issues". The spreadsheet did not record achievement or otherwise of standards or good practice, for example early assessment and regular review by a consultant. We asked to see original forms that had been completed for individual cases but were told that these had not been kept.

Of the 35 deaths in this period reviewed by the trust, 34 were said to be predictable, that is, to be expected, and one was judged to have been "unpredictable". "Care issues" were listed in five of the cases and included the use of anti-coagulation (that is, drug treatment for blood clots) and the procedure on surgical wards for ensuring that patients who were not allowed to eat or drink still received their medication. Care issues were not identified by the trust for the other 30 patients.

The primary purpose of our subsequent review was to determine whether the judgements made by the mortality group about the deaths being predictable were based on accepted standards and were reasonable; whether they had identified shortcomings in the care and management of patients; and whether any actions, such as declaring critical incidents, should have been triggered.

We reviewed eight sets of notes, which had previously been subject to review by the trust's mortality group. We chose these eight because they were all patients admitted as emergencies and were a reasonable spread of common conditions. In seven of the cases, the trust had recorded the death as "predictable". Our review of the notes suggested that only two of the deaths were predictable, and there were some concerns in all of the others.

In one case, there was a delay of three days before the patient had an operation on their fractured femur. Another patient developed *C. difficile* as a likely consequence of antibiotics prescribed in the hospital. We had concerns about management both of fluids and nutrition for this patient, and whether the patient was given the correct supplementation of potassium. Despite these notes containing details of a complaint by the relatives about nursing care, and specifically describing the patient having spent four hours in a soiled bed before the bed was changed, the trust's mortality group judged that there were no "care issues".

Another seriously ill patient appeared to have had their care managed entirely by junior doctors in the middle of the night. The only involvement of a senior clinician was a telephone consultation. Although this death may well have been unavoidable, we were concerned about the process of making decisions and the seniority of doctors involved. In another case, the majority of reviews were carried out by the most junior grade of trainee doctor, even when another healthcare professional had requested a medical review. In this set of notes, the ECG record of another patient had mistakenly been filed.

In another case, nursing staff on several occasions documented high modified early warning scores (MEWS) in the period after an operation. MEWS is a simple physiological scoring system that enables nurses to identify potential deterioration in patients and respond appropriately. Many acute hospitals use the MEWS system to monitor the clinical progress of patients. It is particularly useful to identify patients at risk of serious deterioration in a busy clinical area.

High MEWS should have triggered a clinical response, but there was no evidence of this. Our reviewers felt this case should have been the subject of a post mortem.

The trust outlined "care issues" in only three of the cases, but we considered that there were examples of substandard care in at least one area in all eight cases. In four of these, the management of fluids appeared to be poor, and in three, the management of nutrition was poor. Families had complained about the standard of nursing in two cases, but the trust's review had not identified this.

Lack of review by a senior doctor was a recurrent theme, expressly evidenced in three cases in our analysis. In one patient who became seriously ill, there was no evidence of any medical review for five days. This patient had been prescribed a mixture of antibiotics that may well have predisposed them to the development of *C. difficile* had they survived. Delays in care and lack of promptness in review were mentioned in two other cases that we considered.

Findings of fact on these cases and the decisions made by the mortality group

- The reviewers did not use criteria based on standards to judge the quality of care.
- There were no obvious criteria for designating a death as being predictable.
- Instances of poor management of fluid balance and nutritional status were identified by our reviewers but not by the trust's mortality group. Similarly, the trust's mortality group did not identify the failure to use MEWS effectively or the failure to obtain senior medical opinion early.
- Lack of review by a senior doctor was a feature in several cases.
- Opportunities were missed to learn lessons from the deaths reviewed.

Patients who died in A&E

We reviewed the casualty cards of 11 patients who died in A&E in July and August 2008.

In some cases, the documentation was quite poor. Most gave no cause for concern in terms of their clinical management, but there were some concerns in a small number of cases.

For example, a patient bought to A&E just after midnight with severe abdominal and back pain was not seen by an A&E middle grade doctor for two hours. The records supplied do not show any evidence of initial assessment on arrival or of vital signs taken on arrival. The resident surgical officer saw the patient four hours after arrival. A diagnosis of abdominal aortic aneurysm (a bulging caused by a weakened wall of the aorta as it passes through the abdomen) was agreed and an initial management plan, to admit the patient and review the following morning, was established. Before this could happen, the patient died from a ruptured aneurysm. Our reviewers thought that this death may have been inevitable, but without appropriate records it is not possible to be certain. However, there are concerns about the initial delay, lack of early assessment or monitoring, and leaving a patient with a life threatening condition for four hours before any further attempt at diagnosis with scanning or surgical intervention.

In another case, we were worried that a consultant gave an opinion to withhold treatment, having relied on a junior doctor's report and without having actually seen and assessed the patient in person.

In early September 2008, there was a dispute between doctors in A&E and the critical care unit about whether a patient should be ventilated. We asked for this case to be investigated by the trust. The review found that the arrangements for involving critical care staff in the care of patients needed to be reviewed, with clarification that the lack of a bed in critical care must not preclude involvement of the critical care team.

Other cases that we reviewed

We also reviewed three patients who had been operated on for abdominal aortic aneurysms. Two of these patients were admitted as elective cases and one was an emergency. Repairing aortic aneurysms is major surgery with a high mortality rate. We had some concerns about the decision to operate in the elective cases, as the patients had high risk factors such as severe obesity. In all these cases, we noted the failure to identify post-operative complications, something that will be considered later in the report. We were also concerned that the case notes were of poor quality, and poorly assembled and organised.

Nursing notes

A review of a range of nursing notes was also conducted. Generally, the nursing notes were poorly organised. They were seldom in chronological order. There were often gaps in care plans, in fluid balance charts and in the records of urine output. The time was not noted when intravenous fluids were commenced. The 'Waterlow' score for risk of pressure damage (that is, pressure sores) was often added up incorrectly.

Inquests

We noted that there had been a number of inquests where there had been complications of operations or missed diagnoses of serious conditions.

A review of the medical notes of one case highlighted that signs of deterioration in the patient after the operation had been missed, and this had happened more than once in the same case. The notes of the initial major operation were missing from the file and the notes were generally poorly organised. The trust had not treated this as a serious incident, the case had not been reviewed and lessons had not been learned.

The trust was able to provide us with some information about inquests. The trust's report on inquests contained summarised details of 51 deaths, of which 33 may have occurred on a surgical ward following surgery or a procedure. Twelve involved complications from a fall, orthopaedic surgery (that is hip or knee replacement) or fractured hip. Nine cases involved bowel surgery. Four cases mentioned that the patient developed a venous thrombosis, clot or pulmonary embolism. Two inquests involved complications from abdominal aortic aneurysms.

The coroner told us that he was not worried about the number of inquests involving the trust. He declined to provide us with information about the number of inquests involving the trust and the verdicts over the period covered by the investigation. The medical director told us that the coroner had informed her that the Stafford area did have more inquests than his two other areas, but the coroner did not have specific data. In a letter to the medical director, he reported that he requested postmortems in 35% of all his cases, compared with the national average of 47%. In the cases reported to him, there was no inquest and no postmortem in 62% of cases, compared with a national average of 52%.

Findings of fact

- There was a lack of timely review by a senior doctor in person in three of the deaths in A&E.
- Nursing notes were generally poorly organised.
- There were more inquests involving the trust than neighbouring trusts.
- The coroner declined to provide us with information about inquests involving the trust.

Views of patients and families on the quality of care at the trust

Sources of evidence

- Healthcare Commission national inpatient and A&E surveys
- Interviews with patients and relatives
- Complaints
- Ipsos MORI survey of patients, visitors and carers (May 2008)

National survey results

In the latest national survey available, the Healthcare Commission's survey of inpatients in 2007, the trust was in the best 20% of trusts for two questions out of 62. It was in the worst 20% for 39 questions (63%). The likelihood of this being by chance was very low ($p < 0.001$).

The trust was in the worst 20% for overall standards of care and whether patients felt they were treated with respect and dignity in the hospital.

The trust was in the top 20% for "Were you offered a choice of hospital for your first hospital appointment?" This question applies to patients admitted for elective operations, not as emergencies. It was also in the top group for "Did you have somewhere to keep your personal belongings whilst on the ward?"

Some of the specific relevant questions in which the trust was in the worst 20% on responses included:

- How long did you wait before being admitted to a bed on a ward?
- In your opinion, how clean was the hospital room or ward that you were in?
- Did you have confidence and trust in the doctors treating you?
- In your opinion, were there enough nurses on duty to care for you in hospital?
- As far as you know, did nurses wash or clean their hands between touching patients?
- How much information about your condition or treatment was given to you?
- Were you given enough privacy when being examined or treated?
- Did you think the hospital staff did everything they could to help control your pain?
- After you used the call button, how long did it usually take before you got help?

The trust's performance in the inpatient survey in 2007 had deteriorated from the position in 2006. Then, out of the 58 questions, the trust was one of the worst performing 20% of trusts for 13 questions (22%) and was one of the best performing 20% of trusts for seven items (12%). In the 2006 and 2007 surveys, the trust had been in the worst 20% on the question about whether there were enough nurses. In 2005, the trust performed better, being in the worst 20% for only three questions and in the best for 10 questions. One of the questions in 2005 on which the trust fared poorly was how long it took patients to get help when they used the call button.

The trust commissioned a survey by Ipsos MORI in May 2008. Unlike the national survey, this was carried out while patients were still in hospital through face-to-face interviews by independent contractors. It consisted of four questions rather than 62. It found a high level of overall satisfaction, with 94% of inpatients rating care as excellent, good or fairly good. The corresponding figures for visitors and carers were 88% and 93% respectively. A report to the hospital management board in June 2008 noted incorrectly that 99% of inpatients and 95% of visitors felt that patients were treated with respect and dignity. However, detailed results of the survey in the same report showed that only 76% of inpatients and 61% of visitors felt that patients were treated with respect and dignity most of the time. These results were not benchmarked against those of other trusts. The report also misquoted the results of the national NHS survey of inpatients for 2007.

The results of the national survey of emergency care were published in January 2009. These related to care provided between January and March 2008 and showed the trust to be in the worst 20% of trusts for how care was rated overall. More details are included in the chapter on A&E.

Comments from patients and relatives about general aspects of care

We had an unprecedented response from patients and relatives anxious to tell us about care at the trust. Some of the people who contacted us were members of a local group 'Cure the NHS', established because of concerns about poor standards of care at the trust. This group existed before the investigation was announced.

The cases we heard about nearly all involved patients admitted as emergencies. The overwhelming majority of the 103 relatives and patients who contacted us were not happy with the care received at the trust. These concerns occurred in the three years under investigation. The main areas that gave rise to concern were A&E, the emergency assessment unit (EAU) and wards 6, 7, 10, 11 and 12. Most, but not all, of the concerns related to older patients and to nursing care.

Some of the issues relating to nursing care on the wards included allegations that staff failed to:

- Respond promptly to call bells, to assist patients to go to the toilet or use a commode, or to help with personal hygiene.
- Respect the privacy and dignity of patients, and treat them with compassion.
- Give medication promptly and appropriately, and ensure it was taken.
- Help with feeding and drinking.
- Complete charts accurately.
- Pay attention to skin care, leading to bed sores.

Many attributed much of the poor care to the shortage of nurses. However, others talked about the poor attitude of some staff. They described instances of nurses shouting at patients, leaving them unattended for hours and not providing a proper level of care. Some felt that raising their worries led to no improvement.

Although the cases brought to us by patients and relatives occurred throughout the three-year period, we noticed clusters in the spring of 2006 and the autumn of 2007.

On 7 July 2008, we wrote to the trust's chief executive, drawing his attention to the concerns raised by patients and relatives, and asking that they be addressed. This letter is reproduced in appendix G.

Examples of concerns raised are also given in later sections of the report, in relation to particular clinical areas.

Views of the patient and public involvement forum, and of staff, on the quality of care

Sources of evidence

- Statement from, and interview with, the chairman of the patient and public involvement forum, and with a former member
- Interviews with staff past and present
- Healthcare Commission's NHS staff surveys
- Acute hospital portfolio review, 2004/05
- Formal review of complaints

The chairman of the patient and public involvement forum told us that there had been a marked improvement at the trust since the current chief executive had taken over, particularly in respect of cleanliness and hygiene, leading to an overall high standard of performance. One of the former members of the forum, however, considered that the forum had not been sufficiently robust in scrutinising standards and that in 2006 the trust had not been open about the number of patients infected with *C. difficile*.

In the national survey of NHS staff in 2006, the trust had a low response rate of 37%. The

Views of patients and relatives who contacted us, on cleanliness and hygiene at the trust

Many of the patients and relatives who contacted us were very concerned by poor cleanliness and hygiene at the trust. More than 30 drew these matters to our attention and others confirmed they had concerns when asked directly. The following are some examples; there were many more. Further examples are given later in the report.

2005

"While she was in here [EAU] for five days the chair next to her bed was covered in dried blood. This was not cleaned over the whole time she was there. Her husband also saw an instrument being dropped on the floor and then put back on the tray. She felt that the cleaners just seemed to push dirt around rather than clean."

2006

"Cleaning was poor, and excrement trodden into the floor remained for several days. Curtains were hanging off their hooks. High surfaces, the window bars and the curtains were dusty. The floors were given only a basic wiping. The cleaner missed some corners, including the toilet area."

"He was sent to the accident & emergency department and there the toilet was filthy; it was covered in blood and urine. I tried to clean up the floor of the toilet with a paper towel. He was then moved to the side room, which was not clean, with used alcohol wipes and the end of a previous infusion on the floor."

2007

"She had tried to take her mother to the toilet. It had been filthy and she had to clean it before her mother was able to use it. She explained that she had had to take off a dirty pad and there was no bin to put it into. She had then taken it outside and tried to take it to another bin, but this was overflowing. The hospital was often filthy with blood on the floors. In particular the PDU [the patient discharge unit] was filthy; the toilets and shower rooms in there were filthy."

"When he was admitted the place [A&E] was filthy; there was dried blood and rubbish on the floor."

"The ward, in hospital terms, was filthy. He described it as being nothing more than a laboratory for C. diff and MRSA cultures."

"Faeces were often splashed on the bedside, armchair, and lockers. It was not cleaned up. During the whole time that their grandmother was in the hospital they felt the ward was only cleaned about once or twice. They didn't seem to clean properly and missed huge areas."

trust featured as one of the worst 20% of trusts in 14 areas (54%) and it featured as one of the best 20% of trusts for one area (4%), with the remainder (42%) falling into the intermediate 60% of trusts.

The trust performed poorly on a question about whether staff would be happy, as a patient, with the standard of care at the trust – only 27% of staff agreed or strongly agreed with this statement. Nationally, the figure was 42%. Forty-seven per cent of staff disagreed or strongly disagreed with the statement, compared with 25% nationally. The question was removed from the following year's staff survey, so it is not possible to compare the position in 2007.

We asked 80 members of staff whether they would be happy to have a relative treated at the trust. Overall, 41 (51%) said they would be happy.

Different groups responded differently. The great majority of non-clinical staff would be

happy: 13 of 16 non-clinical staff (81.3%) said would be happy for a relative to be treated at the trust. However, the majority of doctors would not be happy: 10 out of 26 doctors (38.5%) would be happy for a relative to be treated at the trust, but 16 (61.5%) would not be happy. Nurses were in between, with 69% being happy for a relative to be treated. More junior doctors would be happy with a relative being admitted than would senior doctors. Staff in the surgical division were more likely to be unhappy about a relative being treated at the trust.

Many clinical staff told us of their concerns about the quality of care at the trust and gave specific examples. This is covered elsewhere in the report.

Complaints

The acute hospital portfolio review in 2004/05 showed the trust had a high overall number and rate of complaints. The trust was worst out of five local trusts for the number of complaints about nursing care per 10,000 occupied bed days, and the second worst out of 24 small trusts outside London.

Our analysis of complaints received by the trust during the period covered by the investigation showed that there were consistent concerns about standards of nursing care.

This can be seen in the trust's formal review of complaints for July to September 2005, where concern about basic nursing care was in the top five of complaints. Just over a year later, the report on complaints to the trust board for October to December 2006 again found frequent complaints about basic standards of nursing care (access to call buzzers, delays in obtaining assistance and delays in administrating medication). This finding was repeated during 2007.

In the trust's annual report on complaints for 2006/07, the top five themes for clinical care included infection control, medication errors and delays, the management of pain and patients falling.

We undertook an analysis of 74 complaints received by the trust between July and September 2007, relating to the divisions of surgery and medicine. In 13 cases, there were major concerns related to basic standards of nursing.

The trust's report on complaints for the first three months of 2008 noted that complaints about two medical wards, wards 10 and 11, had been of some concern over recent months. These wards were averaging two complaints a month. The general themes were basic standards of care.

Findings of fact on patients' and staff's views of services

- The trust fared poorly in the national inpatient survey, particularly for 2007 where it was in the worst 20% of trusts for 63% of questions. The trust was also rated in the worst 20% for overall standard of care.
- Almost all of the 103 patients and relatives who contacted us were dissatisfied with the quality of care, particularly nursing care. Many were also concerned about poor hygiene and the lack of cleanliness.
- In the 2006 national staff survey, 27% of staff said they would be happy with the standard of care at the trust. This compared to 42% nationally. The result was in the worst 20% of trusts.
- Of staff we interviewed, half said they would be happy for a relative to be treated at the trust. The proportion varied from 81% of non-clinical staff to 38.5% of doctors.
- In 2004/05, the trust was the second worst out of 24 small acute trusts outside London for the number of complaints about nursing, per 10,000 occupied bed days.
- Complaints received by the trust suggested longstanding concerns about the quality of nursing care.

Emergency care pathway

The emergency care pathway is a term used to describe the route or path in the trust that a patient admitted as an emergency would be expected to follow in an acute hospital. It usually starts when the patient arrives at the accident and emergency department. The next stage is often an emergency assessment or medical assessment unit, but could be a specialist unit such as critical care or coronary care. From an assessment unit, a patient might go home, transfer to a ward or specialist unit, or be taken to theatre.

Since the trust had high mortality rates for patients admitted as emergencies, the investigation team reviewed the major clinical areas involved in dealing with such emergencies and, as part of this, considered the emergency care pathway.

Accident and emergency department

Sources of evidence

- Interviews with staff past and present
- Interviews with patients and relatives
- Healthcare Commission's national inpatient surveys
- Observations carried out by members of the investigation team
- Observations by South Staffordshire Primary Care Trust during an unannounced visit
- Complaints
- Trust documents, including review of A&E, analysis of complaints, minutes of meetings and operational policies
- Review by the Heart of England NHS Foundation Trust
- Guidance from NICE, NCEPOD, the College of Emergency Medicine, the Royal College of Physicians, and the Royal College of Anaesthetists
- The trust's website
- Department of Health statistics
- Healthcare Commission's review of urgent and emergency care services

An accident and emergency (A&E) department is the front line of emergency care. The public have expectations of an emergency department that include rapid access to care and timely investigations and treatment.

The A&E department in the trust had been moved from one administrative division to another. In 2005, it was part of 'patient access' and then it was transferred to the clinical standards directorate. Since April 2006, the department has been part of the medical division.

There were 66,571 total attendances at A&E at the trust in 2007/08, according to the quarterly monitoring data set collected by the Department of Health. In line with national trends, there had been a slight but consistent increase over the past three years, with an average daily attendance of around 180 people.

The A&E department at Stafford Hospital provides most types of urgent and emergency care. It receives patients brought in by ambulance, patients referred directly by their GP, and people who decide to go straight there themselves. There are limited alternatives in the local area for people who need emergency medical attention. There is a nurse-led minor injuries unit at Cannock Chase Hospital in Cannock (about 10 miles from Stafford Hospital), an A&E department at

the University Hospital of North Staffordshire in Stoke (about 14 miles) and a walk-in clinic at Haywood Hospital in Stoke.

For historical reasons, the trust did not receive many patients with severe trauma, following the creation of trauma centres in the 1980s. Thus, patients who had suffered major trauma were usually taken by the ambulance service to other hospitals in the region, for example the University Hospital of North Staffordshire in Stoke or Selly Oak Hospital in Birmingham (about 33 miles from Stafford Hospital). Occasionally the trust received patients with multiple injuries when the ambulance crew did not realise the extent of the patient's injuries, or took a decision that it was in the patient's interests to take them to the trust. The trust did not have the capability to cope with patients with multiple trauma, since it lacked neurological and major trauma units, and did not have a trauma team.

In 2006, the trust decided to send to A&E all patients referred by GPs for admission, rather than admitting these patients directly to the emergency assessment unit.

Action taken by the Healthcare Commission during the investigation

During our visit to the A&E department in May 2008, we became very concerned about the way the service was operating and the risk that this represented to patients.

It is our practice to raise any such issues immediately, rather than waiting for the completion of the investigation. We asked for an urgent meeting with the chief executive to raise our concerns and we followed this up 24 hours later with a letter, requiring urgent action. This letter is reproduced in appendix F.

The details of our concerns are covered in this chapter. They included the low staffing levels, lack of leadership, no effective triage, lack of monitoring of one clinical area, lack of equipment and poor training. We considered that the lack of supervision and senior cover for both doctors and nurses was a risk to patients.

The trust took immediate action to address these concerns. One of the actions was to commission a specialist team from the Heart of England NHS Foundation Trust to undertake an urgent review. The findings of this review are also cited in this section.

By September 2008, the trust had made good progress in making improvements and we set this out in a statement on our website on 25 September.

The progress made in A&E is outlined later in this report, in the chapter "Developments at the trust since the start of the investigation".

Patients' views on the A&E department

In the national inpatients survey in 2007, some of the specific questions in which the trust was in the worst 20% on responses included:

- How much information about your condition did you get in the emergency department?
- Were you given enough privacy when being examined in the emergency department?
- How long did you wait before being admitted to a bed on a ward?

We have included comments made by patients and relatives in the relevant sections below.

In January 2009, we published the results of the national survey of emergency care. This was based on the views of patients who visited A&E departments in England between January and March 2008. The trust was in the intermediate 60% of trusts for 22 questions and in the worst 20% for 11 questions. It was not in the best 20% for any of the questions and was in the worst group for how care was rated overall. The trust was rated among the worst 20% of trusts for the four questions relating to waiting times and for the questions relating to the cleanliness of the department as a whole, the relief of pain, and confidence in the doctors and nurses.

The environment and the refurbishment of A&E

In March 2007, the trust began a refurbishment of the department to improve facilities for patients. It took eight months, cost over £800,000 and was undertaken while the trust continued to provide the A&E service. The majority of staff reported that they had had little opportunity to influence the changes. The trust told us that the main objective was to upgrade mechanical and engineering facilities in the department. However, the project brief in August 2006 described the objectives in terms of an improved "patient journey" and improved "patient observation". The brief noted that the changes would lead to an improved experience for patients, new models of care and better multidisciplinary standards of care.

An assessment of the workplace in A&E that took place in May 2007 was reported to the governance meeting of the trust's medical division the following month. The assessment identified risks that included maintaining a safe and secure area, and outlined actions to reduce these. In August 2007, the section on performance in the minutes of the trust's board described how the work was affecting the ability of staff to work flexibly, which in turn was having an adverse effect on the achievement of targets.

In September 2007, the members of the governance committee for the medical division discussed a series of incidents involving A&E. They acknowledged that the department was a high-risk area.

There was an increase in complaints during the period of refurbishment. As a proportion of total complaints at the trust, those about A&E rose from 32% to 42%.

As part of the investigation, the trust was asked to provide details of any serious untoward incidents that had happened in the department since April 2005. Many of these incidents (54%) occurred during the months of the refurbishment.

The refurbishment was complete by December 2007. There was a general view among most staff we interviewed that the refurbishment made the department cleaner and brighter, but that it had not helped the management of patients in A&E. The trust explained that the refurbishment was an upgrade, not a new build, and so there were limitations as to what could be achieved.

We visited the department several times during 2008 and interviewed many A&E staff. We noted difficulties with the layout of the department. In particular, it was hard for staff to see what was happening to patients in different areas.

It was apparent that patients could not easily be observed or monitored when they were in the waiting room. There were two main reasons for this. Firstly, the view from the reception desk was limited. This was a particular concern, given that the receptionists were relied on to observe the patients. Secondly, the view from the door that the staff used to enter the department was partly blocked by an interior wall. This resulted in a number of patients sitting around the corner, and therefore being out of sight.

Some staff also said that the layout made the department difficult to manage, especially during periods of increased activity. This was due to the physical separation of the different areas of the department. For example the 'assess and treat' area was out of sight of the nurses' whiteboard area and round a corner from the main department. Likewise, it was difficult to monitor from the nurses' whiteboard the assessment cubicles for patients with minor injuries, and impossible to see how busy the cubicles were from other areas of the department.

In the summer of 2008, a review of A&E was undertaken by a team from the Heart of England NHS Foundation Trust. This was at the request of the trust's chief executive, following concerns raised by the Healthcare Commission. The review commented that there were poorly designed 'traffic flows' that made little sense to the staff. For example, patients requiring admission or x-ray had to go though the area for patients with more

minor injuries and illnesses, adding to congestion and reducing effective flow.

This review also noted that problems due to geographical separation were accentuated by the lack of an IT system within the department. It was impossible to determine how busy one area of the department was without physically going there.

Equipment, and clinical and diagnostic services

The service provided by any emergency department is dependent on the availability, accessibility and quality of a range of equipment.

Many staff, including senior members of the department, criticised the lack, and quality of, the equipment. We were told that this was a longstanding problem.

Examples provided by staff of equipment that was lacking in the A&E department included trolleys, working cardiac monitors in the resuscitation bays, sufficient lighting, portable suction and tympanic thermometers (used to get a rapid and accurate assessment of temperature).

The resuscitation bays were not properly equipped. For example, there was only one defibrillator for the four resuscitation trolleys when there should have been one for each trolley. This area was frequently used to its maximum capacity, emphasising the importance of sufficient equipment. Guidelines issued by the Royal College of Anaesthetists specify the need for each resuscitation bay to have equipment capable of invasive monitoring, such as monitoring the gases in arterial blood. This was not available.

The review by the Heart of England NHS Foundation Trust noted that basic equipment in areas of the department appeared to be totally inadequate. The team was only able to locate two fully functioning infusion pumps (stored in a linen room). Most of the staff that we interviewed reported a dangerously low level of equipment for monitoring patients throughout the department, but most importantly in the areas where patients with major illnesses or trauma were being treated and in the resuscitation areas.

During our visits to the department between May and October 2008, we were told that equipment was on order, but much of it did not materialise and the situation with equipment changed little.

Access to diagnostic equipment and services is also critically important to an emergency department. Staff need 24-hour access to x-ray and computerised tomography (CT) scanning. The Royal College of Physicians noted in 2002 that the commitment of different specialties and services was essential in organising effective working practices for emergency medicine. More specifically, the College of Emergency Medicine highlighted that 24-hour access to CT scanning was a necessity for supporting an emergency department.

A review by the National Confidential Enquiry into Patient Outcomes and Deaths in 2007 stated that hospitals that admit emergency patients must have access to both conventional radiology and CT scanning 24-hours a day, with immediate reporting.

The guidance from the National Institute for Health and Clinical Excellence (NICE) on the management of head injuries suggested a CT head scan should replace a cranial x-ray and admission with observation as the first investigation. In March 2007, the hospital management board decided not to implement this element of the guidelines. The trust's medical director told us that they continued to carry out a CT scan on any patient with a head injury that was judged, after clinical assessment, to require a scan. However, senior medical staff in A&E were concerned that the guidance on scanning was not followed in full.

In April 2008, it was recorded on the medical risk register that CT scanning was only available between 9am and 5pm, Monday to Friday. Even when available, access to CT scanning was not straightforward, as requesting a scan was only possible through a consultant-to-consultant referral. We were

told that the switchboard staff were not allowed to connect a call from middle grade doctors to the consultant radiologist on call. It was raised in several interviews that, if there was no consultant present to request a scan, this led to delays. This was reported to be a common problem out of normal hours. The relationships between the emergency department and the radiology department were reported not to be good. The trust provided us with a protocol dated 23 May 2008, which stated that in exceptional circumstances a middle grade doctor could call the consultant radiologist directly to request a CT investigation. This was to be a temporary arrangement.

We were given several examples of delays in obtaining CT scans, including one that involved a patient with a subarachnoid brain haemorrhage.

Some staff told us that there were difficulties in accessing emergency diagnostic ultrasound out of normal hours, despite the fact that this is also recommended in NICE guidelines.

Findings of fact on the environment and equipment

- The department had been refurbished in 2007, improving its appearance.
- The layout of the department made it difficult for staff to see patients in the waiting room.
- The department lacked many items of equipment, including sufficient numbers of working cardiac monitors in resuscitation bays and sufficient numbers of defibrillators.
- The trust did not implement performing CT scans as the first investigation in patients with head injuries.
- Arranging CT scans out of normal hours was not straightforward and sometimes led to delays in diagnosis.

Triage

Triage is a system to rapidly place patients into categories, according to the type of treatment they need and how quickly they need it. It helps to prioritise patients who need urgent care. Triage can improve the safety of patients by reducing delays before more comprehensive assessments. In some trusts where patients are assessed by senior staff immediately or after only a short delay, triage is no longer considered necessary.

Staff trained to perform triage should monitor and assess all the patients who come to the emergency department. Their role is to immediately sort, direct, prioritise and inform patients, while also starting treatment (for example, pain relief).

During the visits we made to the department between February and October 2008, there was little evidence of effective triage in operation.

It was unclear how long the trust had been without effective triage, as there was no clear recollection of the situation among the staff that we spoke to. Some thought a triage system used to operate in the department a number of years ago, but had faded out. Staff interviewed during the visit in May 2008, including consultants, senior nurses, and managers, all reported that triage did not happen mainly because there were too few nurses available to do it.

The chief executive agreed in June 2008 that the lack of an effective system of triage was unacceptable and was a "reflection of staffing levels". In July 2008, the person responsible for running triage, a senior advanced practitioner, estimated that, for 80% of the time, it was still not possible to triage patients due to the shortage of staff in the department.

The review by the Heart of England Foundation Trust found that there were few or no consistent 'see and treat' methods in use in the department, with little or no basic triage, provision of analgesia or simple x-ray referrals, despite national guidance around the benefits of these to reduce overall waits.

Receptionists were responsible for assessing any patients who did not arrive by ambulance. This was as a consequence of having too few trained nurses to maintain consistent triage. The receptionists were relied upon to assess patients and categorise them as "major" or "minor". They had to assess, oversee the patients in the waiting room, and raise any concerns about a patient to the nursing staff. If a patient's condition was deteriorating, it was expected that the receptionists would notice this and alert a member of the nursing staff.

None of the reception staff were clinically qualified. The trust relied on administrative workers to perform a role usually filled by experienced, specifically trained nurses. A senior member of the department acknowledged that the dependency on receptionists to perform triage was unsatisfactory and unprofessional.

We were given examples by staff of instances where patients had been adversely affected by the lack of an effective system of triage. In one case, a patient with known heart problems was kept in the waiting room for 40 minutes before being assessed. Another patient with a dislocated shoulder was in the waiting room for five hours before they were assessed and given pain relief. Two patients who came to see us told us of two to three-hour waits in the waiting room, although both were subsequently found to have acute appendicitis. A senior doctor in training told us about a patient with an open fracture of the elbow who had been sitting in A&E for over four hours still covered in blood, with no pain relief, observations, dressing or antibiotics.

Findings of fact on triage

- There were too few nurses on duty to perform triage.
- A form of triage was carried out by administrative staff in reception, despite the fact that they did not have any qualifications or training to do so.
- We were given examples of patients who had been adversely affected by the lack of effective triage.

Senior leadership

In April 2005, there were three permanent A&E consultants in the department. In September 2005, there was a consultant vacancy and attempts at recruitment were unsuccessful. The department relied on two consultants until one left in March 2008. Cover from a locum consultant started on 10 May 2008 and 15 different locums were used between May and December 2008. The remaining consultant described the department as isolated. He was described by many of his medical and nursing colleagues as a poor leader.

There had been four managers of the emergency department between early 2006 and late 2007. One of these was an interim appointment; another acknowledged to us that they personally were not suited to a management role. The head of division of medicine expressed the view that it had been difficult to appoint a high-quality manager for A&E.

Medical staffing arrangements and cover

Guidance issued by the College of Emergency Medicine recommends one whole-time equivalent consultant to every 11,500 patients. The college states that a consultant should be involved in leading and managing emergency departments, including managing audit and clinical risk. Emergency departments are areas of high intensity, and therefore a senior clinician's management and teaching workload is likely to be greater than in many specialities

Due to the size of the trust's emergency department and the number of patients who attend, the College of Emergency Medicine recommendation for the trust equated to a minimum of three consultants. This recently increased to four. From September 2005 to March 2008, the department functioned with two consultants in emergency medicine, with the support of another senior doctor, an associate specialist, until October 2006. There was just one permanent A&E consultant for many months in 2008 and he was on own for two months. From May to December,

25 bookings of 15 different locums provided intermittent support. In May, only two days were covered by a locum and in June, nine.

The trust's emergency care operational policy states that "the department should have...senior medical cover on a 24-hour basis to ensure expert advice is available at all times". As a result of a redundancy of the associate specialist in October 2006, it was only possible to have consultant cover for 12 hours a day. This redundancy was part of the workforce reduction at that time.

In September 2006, a paper to the hospital management board highlighted how the one in two on-call rota, with the two consultants taking turns to cover, was not tenable. A new rota was proposed that did not include on-call duties. This prompted concerns about how the trust would respond to a major incident. The same paper was presented to the trust's board in October 2006 and it was noted that senior cover was sub-optimal in terms of hours. This issue was not mentioned again until the minutes of the hospital management board in December 2006, where concern was raised that the A&E consultants were no longer providing 24-hour cover. They had agreed to cover a major incident. The hospital management group agreed that 24-hour cover was necessary.

In the periods when the consultant was not in A&E and not on call, we were told that the clinical accountability for patients was not always clear. There were periods when the most senior person in the department was a doctor who, although experienced, had no postgraduate qualification in emergency medicine.

Following difficulties in recruiting consultants in emergency medicine, the trust took the decision to reduce the effects of the shortage of consultants in the department by the appointment of consultants in acute medicine, also called acute physicians. In July 2006, it was decided to divert the funding for an A&E consultant to fund the appointment of an acute physician. Acute physicians specialise in the management of the early stages of patients admitted as medical emergencies. They do not have the same level of expertise for other patients, such as those admitted as surgical emergencies or with traumatic injuries.

In the first instance, the trust appointed to this role an experienced senior doctor who had held a number of locum posts in the trust.

Acute physicians were responsible for the provision of initial senior clinical advice, care and treatment for medical patients admitted to the trust, either through the emergency assessment unit (EAU) or through A&E. Primarily, they had responsibility for medical care in the EAU.

The acute physicians were also expected to provide senior cover in A&E and be part of the on-call arrangements. They provided some support for the care of medical patients, but were less able to cover across the spectrum of undifferentiated illness and trauma of A&E patients. They were not trained or qualified to deal with the patients with surgical, traumatic or gynaecological problems who arrived at A&E.

Medical and nursing staff were concerned that not all the acute physicians were confident about, or prepared to deal with, medical emergencies, let alone surgical patients. During interviews, staff provided us with examples of acute physicians walking away from patients or declining to help, if they were not confident to deal with them. An example given was a stroke patient with difficulty in breathing who needed to have an endo-tracheal tube inserted. Another was a patient with ventricular tachycardia, which is a life threatening abnormal rhythm of the heart.

The review by the Heart of England NHS Foundation Trust commented: “There was a clear deficit in trained emergency medical numbers, which has been recognised by the trust. One trained and accredited consultant is obviously insufficient to provide the required level of senior cover in the department. Although there is a close working relationship with the acute medical physicians, this does not allow the department to be covered appropriately 24/7. This is a significant risk and the department would not be sanctioned nationally.”

In September 2007, the trust's submission to the Healthcare Commission's review of urgent and emergency care listed three permanent consultants in emergency medicine. At that time there were two such consultants. However, the trust included the acute physician.

Other medical cover: middle grades

Middle grade doctors in A&E are fairly experienced doctors who are sufficiently competent to be left as the senior doctor in charge of the department, particularly at night, but with cover from a consultant fully trained in the specialty. They can supervise junior doctors under these conditions. Experienced permanent doctors should be in place to staff the middle grade rota, but the trust relied heavily on locum doctors. This is not unusual in the NHS.

Throughout the period under investigation, the department did not operate with the recommended number of middle grade doctors. There should have been nine doctors in this grade. A report on medical staffing in July 2006 showed there were two permanent whole-time equivalent and 2.4 locum middle grades. The submission to the Healthcare Commission's review of urgent care in September 2007 listed three permanent middle grades, but did not give the number of locums at the time.

In May 2008, we found the department had too few middle grade doctors to provide an acceptable service. This problem was longstanding. In September 2006, a paper to the hospital management group described problems with the recruitment and retention of middle grade doctors, resulting in the regular use of locums. It noted this was also the case nationally. The staffing arrangements were reported to be a considerable risk.

The hospital management board agreed to a trial period for the first two weeks of October 2006, where there would be no middle grade cover for the seven-hour period from midnight to 7am, Monday to Thursday. This was at the time when there was no consultant cover for A&E after 9pm. At the end of the period, the trust decided that this was unworkable and unsafe, and cover by mainly locum middle grade doctors was reinstated.

Medical and nursing staff that we interviewed all reported that there were insufficient middle grade doctors to provide adequate cover. They claimed that the middle grade rota was not robust, the hours were not compliant with the European Working Time Directive and neither the middle grades nor junior doctors were able to take sufficient breaks. One long-term locum doctor only worked at night and sometimes worked a long sequence of more than 10 consecutive nights.

The report produced by the Heart of England Foundation Trust also noted that, due to staffing levels at the time of their visits, as soon as there were two patients in resuscitation, the senior medical manpower of the department was effectively exhausted.

Training and supervision of junior doctors

In 2002, the Royal College of Physicians outlined that trainees need to have adequate training and experience to recognise critically ill patients and make clinical decisions. Appropriate training included exposing trainees to real clinical problems with sufficient mid-level and senior support. The College of Emergency Medicine stated that consultants are expected to "supervise clinical care provided by others in the same environment".

A paper from the trust's chief operating officer in April 2008 stated that "the main body of medical staff in the department consists of relatively inexperienced 'foundation year two' (FY2) doctors and general practitioner trainees. These doctors require a high-level of supervision by senior staff, which can be very difficult to achieve with just two emergency medicine consultants in the department and a small number of middle grade staff". In fact, at this time there was only one consultant in emergency medicine.

From April 2008, there was only one permanent consultant, virtually no education and only limited supervision. The support from

locum consultants amounted to 11 days in total in May and June. A number of more senior staff told us that opportunities to teach within the department were further limited by managers, or senior nurses, interrupting when a doctor was attempting to provide training because of concerns over breaches of waiting times for patients.

Senior members of the department told us that there was a "non-existent culture" with regards to education and training. Additionally, several interviewees specifically mentioned that three-quarters of dedicated teaching sessions for junior doctors were cancelled, usually by managers on operational grounds.

On 25 June 2008, the dean of postgraduate medicine wrote to the trust's medical director. She expressed grave concerns regarding the training and supervision of the specialist registrar trainee in A&E. The letter pointed out that, if the training post had to be withdrawn, this would also have an effect on training for more junior staff such as foundation years one and two, and vocational trainees. The letter asked for an action plan to show what middle grade cover the trust would put in place, and for assurance that consultant cover would be provided during the day and evening shifts and that a consultant would be readily available for recall as necessary.

Findings of fact on leadership, medical cover and supervision of junior doctors

- There was a longstanding shortage of consultant medical cover.
- There was a longstanding lack of medical and general leadership.
- The trust treated as interchangeable the roles of consultant acute physicians and consultants in emergency care.
- The acute physicians were asked to cover aspects of A&E that were outside their professional competence.
- There was a longstanding shortage of middle grade doctors.
- For two weeks in October 2006, there was no consultant or middle grade cover between midnight and 7am on weekdays. The trust decided that this was unsafe and reinstated middle grade cover.
- Inadequate supervision, training and support were given to junior doctors.
- The postgraduate dean wrote to the trust in June 2008 about inadequate supervision for doctors in training.
- There was little integrated multi-professional working in the department.

Overall staffing in A&E

We looked at other groups of staff as well as doctors and senior clinicians. The majority of staff interviewed felt that the department was operating on too few staff.

We noted that staffing had been a longstanding problem for the A&E department at Stafford Hospital. Entries in a risk register report identified a number of problems with staffing as far back as September 2002. These included a number of medical vacancies in A&E that were said to "affect the morale of the staff which ultimately affects patient care and waiting times".

In April 2005, the medical division identified a risk that there would be too few staff to support the service, due to failing to replace staff who terminated their employment. This was recorded on the risk register, but no review date was provided. In July 2005, it was noted that future demands of the service may not be met due to insufficient levels of staff in the department. From these entries, it is evident that staffing levels were considered to be inadequate as far back as 2005.

Many staff that we interviewed told us that there were not enough porters, especially at night. It was explained that the number of porters had been reduced during the reduction of the overall workforce in 2006. When a member of the portering staff left they were not replaced, and financial constraints restricted the use of bank and agency staff. Certain problems were highlighted as a consequence of the reduced number of porters, including delays in transfers of patients, increased waits for diagnostic scans, and limited security presence.

Nurse staffing

The operational policy for emergency care stated that the emergency department would have cover by senior nurses on a 24-hour basis, and that nurse staffing levels and skill mix would be driven by the needs of the service. The review of skill mix by an external adviser conducted in 2007/08 showed a gap in staffing of 17.4 whole-time equivalents between the professional view of what the establishment should be (54.9) and the actual funded establishment (37.5).

Overall, the number of whole-time equivalent posts in nursing remained fairly constant from 38.0 in January 2006 to 36.3 in September 2007 and 37.9 in March 2008. The operational policy stated that the department should have cover by a senior nurse all the time. However, there have been few senior nurses (band seven) in the department in recent years.

In its submission to our review of urgent and emergency care services, the trust reported that it had seven band seven nurses. At that time, there was only one band seven nurse in A&E. The trust had in error included the clinical site managers and other band seven nurses who were part of the trust's establishment at the time of the submission.

The review by the Heart of England Foundation Trust was critical of the level of nursing supervision. The reviewers considered that the lack of band seven nurses was a considerable risk that could result in poor standards of care.

The report said that, despite the recent appointments of a matron, a band eight advanced practitioner, and a band seven post, there was still a worrying deficit of senior nurses. At the time of their visits, all but 2.5 of the nursing staff were band six or below. Because of some staff on maternity leave and 2.5 whole-time equivalent nurses released to staff the clinical decision unit, there were approximately 1,600 patients (in a year) for every trained nurse.

The review added there was a lack of senior nursing leadership and the lack of band seven nurses was a significant risk that needed addressing to prevent further episodes of poor or variable care. A number of band six nurses felt underappreciated for the role they undertook. An atmosphere of crisis management had developed and additional senior tier nurses were required to improve standards.

There was concern among most A&E staff that we interviewed about the shortage of nurses in the department. The situation was referred to in interviews with A&E nurses as "abysmal" and "horrendous", with one interviewee stating the concerns over the low number of nursing staff was the reason she was leaving the department.

Leadership, training and supervision of nurses

The review by the Heart of England NHS Foundation Trust in the summer of 2008 found that the nursing management team was struggling to cope with the situation in terms of consistently providing good quality care. This in part could be explained by lack of personnel or the relatively high reliance on junior grades of nurses. A number of band six nurses emphasised their concerns about the current lack of nursing leadership across all shifts. The nurse manager and deputy had limited clinical time or presence on a day-to-day basis, something "desperately needed to address concerns raised by staff around inadequate patient observations, monitoring, and delivery of minimum standards of care".

The majority of clinical shifts were covered by band six nurses who had to undertake a number of different roles at the same time. Through necessity, staff were taken from one clinical area of the department to another, leaving a shortfall in the first area. This was not sustainable.

Nurses in an A&E department should be able to perform skills such as taking blood, intravenous cannulation (inserting a hollow tube into a vein so that drugs and fluids can enter the bloodstream quickly) and electrocardiograms. A senior nurse estimated that fewer than two-thirds of the nurses would be able to undertake these tasks.

The recognised course offering specialised A&E education is the English National Board Course 199 in A&E nursing. For those nurses at the trust who had received training, it was generally training provided by the trust. Few nurses had undertaken any nationally recognised course in A&E nursing.

The role of an emergency nurse practitioner (ENP) should be a standardised role, transferable from one hospital to another. However, most of the ENPs at the trust had been trained in-house and were performing the role with different levels of training. The training was non-transferable. This meant that, if a nurse working as an ENP at the trust were to take up the role in another trust, their training was unlikely to be accepted.

The trust's operational policy on emergency care stated that the department would have emergency nurse practitioners whose skills would include advanced life skills, trauma care and paediatric life support.

We were told that there was no training plan or department induction for new staff, and newly qualified nurses were not routinely provided with clinical supervision. We were told that the department lacked a senior nursing presence and that there was a lack of nursing leadership.

The Heart of England NHS Foundation Trust's report noted that clinical supervision was inadequate both from a medical and nursing perspective.

These matters were being addressed by the trust and details are included in the progress section of this report.

Findings of fact on staffing, leadership and training of nurses in A&E

- Staffing problems in A&E had been prevalent for a number of years.
- The number of nurses was low and there were few band seven (senior) nurses.
- There had been little training and development of nurses.
- Leadership of nurses had been poor.
- The training for emergency nurse practitioners was provided in-house and was not transferable if staff moved to other trusts.
- The trust's submission to the review of urgent care contained some inaccuracies: the trust declared there were seven band seven nurses, but there was only one in A&E at that time.

The focus on the target for patients to wait less than four hours

The four-hour waiting time target was introduced by the Department of Health in 2004 as a minimum standard to ensure that 98% of patients should be admitted, discharged or transferred within four hours of arrival at an A&E department. The 2% cut-off refers to the small number of patients who need to remain in the department for more than four hours for clinical reasons or under observation. An important element of A&E performance relates to achieving the four-hour waiting time target and trusts are judged by their performance in respect of this.

The pressure on the department was increased in 2006 by the trust's decision to send all patients referred by GPs for admission to A&E.

Staff generally supported the aim of the target, but were concerned that the trust's focus on it could distort priorities. Some considered that the shortage of beds in the trust made it difficult to achieve, but that the trust's managers held A&E staff responsible for any failures. Nurses told us they felt they were in "the firing line" with regards to breaches of the target and, as such, were always being blamed. We heard about nurses leaving meetings in tears and being threatened that their jobs were at stake due to the number of breaches. One nurse described an average shift as "pressure, pressure, pressure".

Many staff that we interviewed volunteered their view that the approach of the trust meant that the care of patients had become secondary to achieving targets and minimising breaches. Doctors considered that the prioritisation of the patients with minor ailments led, on occasions, to a distortion of clinical priorities. Middle grade doctors told us that they were asked to work with patients in the "minor" side to push these patients through, although this was at the expense of more seriously ill or injured patients. They felt pressured to prioritise patients who were close to breaching the target rather than prioritise by clinical need.

Several doctors recounted occasions where they were asked by management to stop treating more seriously ill patients in order to see and treat patients with more minor ailments. One example was given of when a doctor was asked to work in "minors". At the time the doctor was administering thrombolysis to a patient who had suffered a heart attack. This doctor refused but was worried that a more junior doctor might have felt compelled to comply.

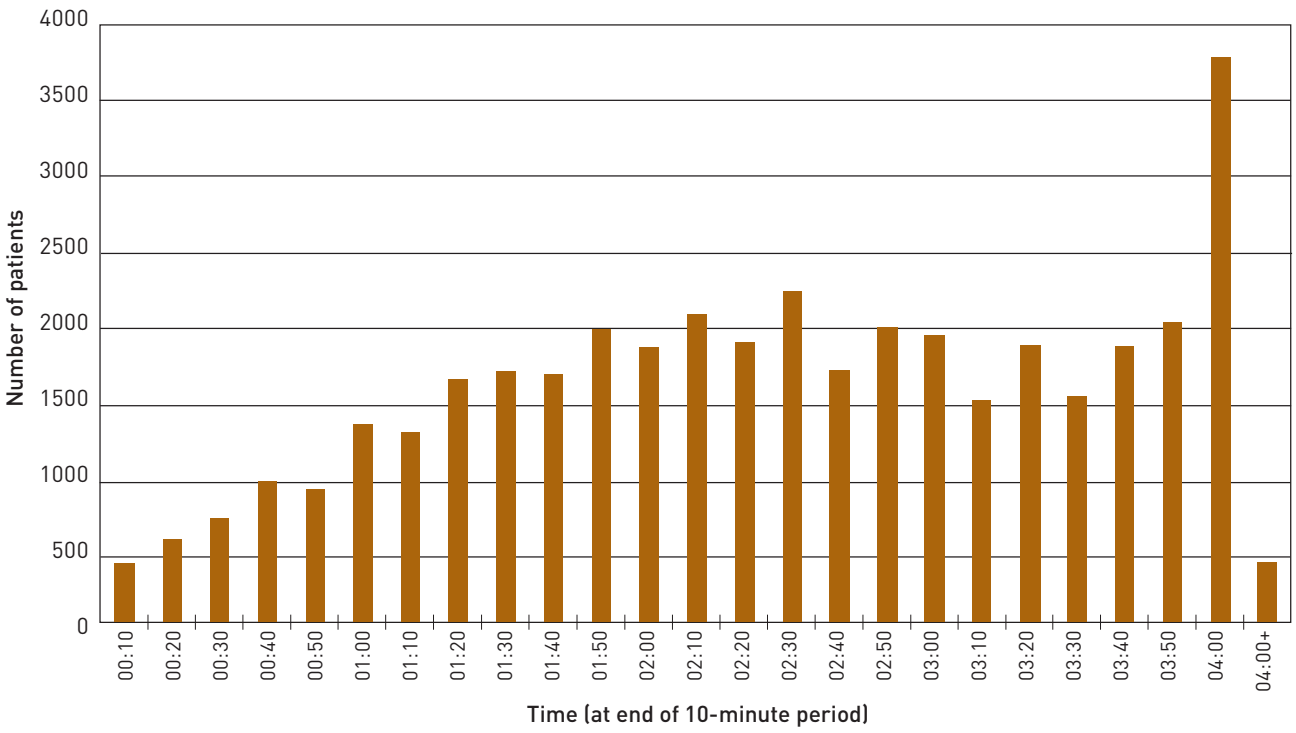
Both doctors and nurses told us that the pressure to meet the four-hour target forced doctors in training to make rapid decisions either to discharge or admit patients. In some instances, they were discharged inappropriately and, in others, they were admitted but without a proper plan of care. This resulted in a subsequent delay, for example, in patients receiving fluids and antibiotics.

A senior doctor told us how a patient who should have gone to the critical care unit was first sent to the emergency assessment unit to avoid breaching the target. Another said that patients with dislocated ankles were moved to inappropriate wards before having had X-rays, because they were going to breach the four-hour target. It could be hours after the injury before an x-ray was taken, by which time the ankle was swollen and could even be ulcerated. This was reported to be a frequent event, rather than the exception.

We analysed the total time that patients spent in A&E, breaking it down into 10-minute intervals. This was over the period from April to December 2007. This showed there was a marked drive to admit, discharge or transfer patients in the last 10 minutes before the four-hour target was breached, as can be seen in figure 2.

Patients and relatives who came to see us told us that there were several instances of patients who had been sent home from A&E who had to return soon afterwards and be admitted. We therefore analysed data from April 2007 to March 2008 in respect of patients who returned to A&E within seven days. We found 67 patients who re-attended the

Figure 2: Distribution of patient numbers by total time in A&E, April-December 2007



department within this time, 39 in the first six months and 28 in the second. From these, there were 43 cases (25 in the first six moths) where the second attendance/admission for each patient was for either the same or a very similar condition as the first. These cases could indicate instances where the patient might have been discharged sooner than appropriate.

In 25 cases (14 in the first six months), the second attendance/admission was for a condition related to, but that could be considered a deterioration or exacerbation of, the one causing the first attendance/admission. These cases could indicate instances where the patient might have been discharged inappropriately. These findings cast some doubt on the trust's submission to our review of urgent and emergency care in England, which reported only one unplanned follow-up attendance between April and September 2007.

In the private meeting of the board in March 2007, it was noted that the results against the four-hour target had been very poor in February, and it would be impossible to meet the target by the end of the year. An action plan had been sent to the SHA and the aim was to get as close to the target as possible. In April 2007, it was reported that the year-end performance had been met.

The clinical decision units

In 2005, the Department of Health outlined in a guide to emergency medicine that a clinical decision unit (CDU) should be supervised by a consultant in emergency medicine. Patients should usually be admitted for no longer than 12 to 24 hours.

The trust's policy for emergency care stated that any patient who stayed overnight, or who was admitted during the night to the CDU, must be reviewed by a senior member of the emergency department no later than 9am. The patients must either be discharged or referred to a specialty team and, should referral be appropriate, the patient must be moved out of the unit to ensure that capacity was available for that day. No patient should remain in the CDU for more than 12 hours.

When we visited in May 2008, there were two areas in the A&E department referred to as clinical decisions units. Both were located away from the rest of the department. The first area contained four beds and was generally referred to as the "assess and treat" area or, more commonly and informally, as "small CDU".

The second area contained 12 beds and opened in May 2008 when 12 beds were removed from the emergency assessment unit. It was often called "big CDU". We were told that it had been opened suddenly, without either portable or wall suction working. Suction is necessary to clear secretions from the airways during resuscitation, for example. We learned that during the refurbishment the equipment attached to the wall had not been properly connected. An incident report had to be filled out about this in order to have it remedied. The trust told us that portable suction was available at this time, but later in this report we note problems with its availability. The area of the larger CDU had previously been used as a medical assessment unit before being replaced by the emergency assessment unit in August 2004.

Many staff expressed negative views of the CDUs and were confused about their purpose. Some staff provided examples of when patients had been in the CDUs for much longer than the duration outlined in the policy for emergency care, some for three days or more.

A range of senior nurses, senior and middle grade doctors all reported that the units were being used inappropriately, in that they were used to avoid breaches of the target for patients to wait no longer than four hours. Many other interviewees also reported that the CDUs were used as a means of avoiding breaching the four-hour target. The 'assess and treat' area was described as a "dumping ground" with patients being admitted to "stop the clock". The review by the Heart of England Foundation Trust also noted that at least three staff confirmed that the 'assess and treat' area operated primarily to stop the clock on the time patients had waited in A&E.

One of the main concerns among staff we interviewed was about the staffing of the clinical decision units. The policy for emergency care stated that the staffing establishment and skill-mix had been set to reflect the number of beds and the patient's need at this stage of their care pathway.

However, most staff interviewed reported that the clinical decision units were not adequately staffed, with some pointing out that the smaller area was not actually allocated staff at all. We noted that the 'assess and treat' area was not staffed overnight because of shortage of staff. As a consequence, patients in this area were not monitored. As a nurse was not always present, coupled with confusion about which patients should be cared for on the unit, more than one member of staff thought the unit was "an unsafe environment for patients".

The review by the Heart of England NHS Foundation Trust found that there was a serious concern about the role of the 'assess and treat' unit. It was not clear what this area was used for, apart from to provide capacity in times of crisis or poor availability of beds. Patients who were quite unwell were placed in the unit without a dedicated nurse to look after them. The review recommended that the area should be closed immediately to avoid significant issues with the safety of patients. The trust acted on this recommendation.

Senior members of the department reported that experienced nurses were taken away from A&E in order to staff the 12-bed clinical decision unit.

Findings of fact on the clinical decision units and the trust's focus on the four-hour target

- The decision to admit to A&E all patients referred by GPs had increased pressure on the department.
- Staff were not clear about the purpose of the clinical decision units and the policy did not clarify the situation.
- Most staff said that the clinical decision units were used to avoid breaching the four-hour target for waiting in A&E.
- Nurses thought that much of the problem was the lack of beds in the trust, but felt that they were blamed for breaches of the target.
- The 'assess and treat' unit (the small CDU) was not staffed and was not a safe environment for patients.
- Staff considered that the trust had given higher priority to achieving the four-hour target than to providing safe care to patients.
- The focus on meeting the four-hour target put pressure on trainee doctors to make rapid decisions on patients either to discharge or admit.
- Between April and September 2007, 39 patients returned to A&E within seven days. The trust reported only one such attendance.

Governance in A&E

We were told by staff that there were few protocols and pathways in use in the department. The review of the department by the Heart of England Foundation Trust noted that there was a lack of up-to-date emergency department guidelines or evidence-based pathways available for staff in the department to use. Interviews with some medical staff referred to the West Mercia guidelines, but few were aware of these or had seen them in the department, although they were available on the trust's intranet.

The department had forms for staff to use for patients on multi-disciplinary pathways. This was commendable, but it was unclear at which point in the patient's care they were started. There was no clarity about which patients should be admitted to the clinical decision units following assessment in A&E. In August 2005, problems were identified with this pathway by an audit of the National Service Framework for Older People. This described pressure to move patients quickly, to ensure that discharge goals were achieved, and highlighted the issue of older patients transferring from A&E to the clinical decision unit where assessments used to gauge suitability were not always accurate.

There was little clinical audit in the department. What there was, was almost entirely carried out by doctors in training as part of their required programme. When audits were completed, they appear not to have been acted on, even though some results showed an unsatisfactory clinical situation (for example, the adequacy of pain relief in children). The directorate manager admitted that there were no regular audits in place, other than the monitoring of breaches of the four-hour target. The investigating team from the Heart of England Foundation Trust reported that there was no information from root cause analyses relating to the breaches. Middle grade doctors, junior doctors and nurses told us that they were not aware that the department had arrangements for clinical audit, and that audit was seldom discussed.

It was reported in the audit committee minutes in May 2007 that A&E was one of the areas in the trust where little progress had been made on audit recommendations.

There were no meetings to discuss mortality or morbidity (that is, complications or adverse consequences of treatment) within the department. There was, therefore, no systematic feedback for discussing mortality or morbidity. There was no systematic monitoring of patients who had to return to the department because their problem had not resolved or their condition had deteriorated.

We were told by all grades of doctors that, partly as a consequence of low numbers of middle grade and senior doctors, and lack of training opportunities, junior doctors rarely received feedback on their performance. One explained that they might only pick up errors that had been made by staff a number of days after they occurred, if at all, and therefore the opportunity to educate and learn from these was often missed.

An electronic incident reporting system was in use in the trust. Most members of the department reported that they did not receive any feedback after completing incident reports. A small number reported that they did not fill out incident forms as they were a "waste of time". A middle grade doctor explained how they regularly completed incident reports when they felt that pressure in the department compromised care, but said that nothing changed and referred to incident reporting as a "black hole". Nurses informed us that there was no formal feedback about complaints made by patients.

The clinical staff that we asked reported that there was no formal discussion of serious untoward incidents. A senior member of the department explained that managers received feedback on serious incidents but acknowledged that staff "on the shop floor" received limited feedback from these. This was of concern, since there had been a number of serious untoward incidents in A&E. Some of these were examples of repeated errors, such as giving penicillin to patients who were allergic to it. This happened in October 2005 and again in January 2007.

We were told that there were no regular meetings of staff in A&E. There had been attempts to introduce meetings but the staffing levels and pressure of work meant they were cancelled. Multi-disciplinary briefing meetings at the handover of shifts did not include medical staff on a regular basis.

A large number of staff reported that appraisals had not taken place for medical, nursing, reception and portering staff. Various reasons were given including there being too little time, the department was too busy, or there were insufficient senior staff. It was reported that some staff had not had appraisals for about two years, although this went back as far as five years for some staff. Two members of staff who had received appraisals, including a senior clinician, thought that the appraisal itself was not helpful in that the issues raised about the department were not addressed.

Findings of fact on governance in A&E

- There were few protocols or pathways in use.
- There were no meetings to discuss mortality and morbidity (complications of treatment).
- Junior doctors did not get feedback on their performance.
- There were no reviews of patients who had been discharged from A&E but who had to return.
- The only clinical audit was undertaken by doctors in training. When these indicated that action needed to be taken, it seldom happened.
- Staff had little confidence in the system for reporting incidents. Serious incidents were not discussed by clinical staff as part of a systematic process to learn lessons.

Emergency assessment unit

An emergency assessment unit (EAU) has been defined as an area where adult patients admitted as emergencies are assessed and inpatient hospital teams undertake initial management. It is designed to provide skilled assessment of the need for investigation, treatment or discharge. The first 48 hours are very important in producing successful outcomes for acutely ill patients.

The rationale for the use of an EAU is that such units can provide a timely service for patients in whom there is diagnostic uncertainty, and who may or may not need

admission. They can reduce both the workload of the emergency department and the length of stay in hospital for patients. The system should be designed to provide rapid assessment, diagnosis, observation and treatment dictated by clinical need. An EAU should ensure timely access to specialty care. Standards set by the Society for Acute Medicine state that there should be a designated lead clinician and a dedicated nurse or clinical manager in charge of an EAU.

The review by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) in 2007 of emergency admissions showed that the vast majority of acute trusts operated assessment units (97.7%). Fewer than 10% of the trusts reviewed had an EAU that was open to medical, surgical and trauma patients, rather than just medical patients. This was the position at the trust.

In 2003, the National Clinical Director for Emergency Care stated that an assessment unit must not be an admissions ward, a holding bay or a "dumping ground", or an extension of A&E. Instead such units should be:

- An appropriate environment for patients and staff.
- Where emergency patients are assessed, with a clear operational policy on admission, discharge, lengths of stay and clinical support.
- A catalyst for examining and developing patient pathways.
- Where total lengths of stay are limited to the period of intensive investigation and observation.
- Able to route patients to the right speciality ward for their needs.

Sources of evidence

- Interviews with staff past and present
- Interviews with patients and relatives
- Observations carried out by members of the investigation team
- Complaints
- Trust documents
- Guidance from NICE, NCEPOD, the Royal College of Physicians, and the Society of Acute Medicine

The EAU at the trust opened in August 2004. It replaced a medical assessment unit and a surgical short stay unit. Since April 2006, the unit has been part of the medical division, prior to which it was under the clinical standards directorate. The operational policy stated that the unit was introduced to improve care for adult acute patients referred by general practitioners and to ease pressure on the A&E department. The unit at the trust was in the minority, in that it took medical, surgical, trauma and gynaecological patients, rather than just medical patients.

The layout and environment of the EAU

The EAU was designed to occupy an area previously taken by two wards. The unit opened with 48 beds. This was a large unit for a hospital of this size. Twelve beds were removed in May 2008, reducing the number to 36. Beds had temporarily re-opened later in 2008 when the trust was under pressure. The trust said that additional bank and agency staff had been booked. However, staff considered there were not enough staff to look after the extra patients.

During the initial phase of deciding whether we needed to conduct this investigation, the Healthcare Commission undertook an unannounced visit one evening in February 2008. This included visiting the EAU, which at that time had 48 beds. We noted that it was a large area with a difficult layout. In particular, there was an eight-bedded area that could not be observed from the nurses' station. During our visit, there was no member of staff in this area and we had to help an elderly patient at risk of falling out of bed. We raised our concerns at the time with the nurse in charge.

These eight beds, with four others from the same end of the unit, were removed in May 2008. They had been used for patients on the unit for almost four years. Staff described

them as "secluded". A patient who came to see us told us that they had been "tucked away" in a corner away from the nurses' station.

A few senior doctors were critical of the design and layout of the unit. For example, one commented that it was easy to lose your patient in the unit. The geography of the unit was referred to as poor. We were also told there were not enough single rooms to be able to isolate patients with infections.

Doctors also told us about the lack of equipment. For example, although patients with fractures and other traumatic injuries were often admitted to the unit, there were no facilities for traction.

How the EAU operated

The current operational policy was written in August 2004 and reviewed in December 2005. It stated that the aim of the EAU was to assess patients on the unit before they were transferred to an environment appropriate to meet their need.

A number of staff, including consultants, a site manager and a ward manager, were of the opinion that the unit did not operate as a proper assessment unit, but as a ward.

In the meeting of the hospital management board in November 2005, it was noted that some patients on EAU were there for five to six days. According to the trust's policy, the maximum length of stay on the unit should have been less than 72 hours. However, a member of senior staff on the unit explained that, to be able to achieve this figure, the unit would require more than 48 beds, given the number of admissions and average lengths of stay.

The investigating team visited the unit on several occasions and noted it to be a busy, noisy area. Emergency assessment units are probably the clinically busiest areas in any hospital. Several interviewees referred to the unit as "chaotic" while others described it as "manic" or a "mad place". The director of nursing opted for "frenetic" and considered that it was comparable to other EAUs in other trusts.

Most patients and relatives who came to see us also described the EAU as "chaotic", while one described the situation as a "crisis". The nurses were reported as being extremely busy and we were told it was not uncommon for buzzers to be sounding for up to 40 minutes unanswered.

Infection control in the EAU

The trust's figures showed that there had been a rise in patients on the EAU who were confirmed as MRSA colonisation positive during the first three months of 2008. However, nearly all these infections were acquired in the community. There had been 42 such cases between January and March 2008, compared with a total of 20 cases in 2006 and 27 in 2007.

In an audit by the trust of infection control for 2007/08, the EAU was the only area that was scored as "minimal compliance" and had the lowest overall score. The audit covered hand hygiene, environment, kitchen, waste, body fluid spillages, protective equipment, sharps, specimens and decontamination. The score of 50% compliance for the unit's environment was the lowest individual score in the audit. Seventy-five per cent reflected minimal compliance.

There were six side rooms on the EAU used to isolate patients. During three visits to the unit, we found that the doors to isolation rooms had been left open. The staff justified this by saying it was to allow the staff to observe the patient, or in one case due to the patient's claustrophobia. However, the general view is that this is not appropriate unless the risk of shutting the door has been formally assessed to be greater than leaving it open.

Patients and relatives who came to see us also reported that doors to isolation rooms were commonly left open on the unit. A number of people told us about medical and nursing staff not washing their hands, using alcohol gel or wearing gloves when handling patients or moving between patients. There were several instances in which cleanliness was criticised, with examples of blood, faeces

and dust not removed. This was particularly the case for patients admitted in 2006 and 2007. There were reports of too few cleaners and cleaning staff not cleaning properly. Dirty commodes were described, as were soiled bedsheets.

Admissions to the EAU

In 2003, the National Clinical Director for Emergency Care suggested that, if a patient from A&E required an inpatient bed, they should not have to be admitted via an assessment unit but should go straight to the appropriate specialty bed. Due to the limited availability of beds and how this was managed, the majority of patients were admitted to the EAU. Some patients were admitted to the critical care unit, but most other acutely ill patients had to be admitted initially to EAU. Similarly, although some patients with heart attacks went straight to the acute coronary unit, others were admitted to the EAU.

Some staff we interviewed suggested that the pressure on the EAU to admit patients stemmed from the necessity to meet the four-hour target in A&E. Indeed, it was reported by some that this was why the unit had been established. Some interviewees, including several consultants, thought that the EAU was primarily a "holding bay" to take pressure away from A&E.

Staff from the A&E department described how patients were moved from the department to the EAU if the 'breach time' for the four-hour target was approaching. Some members of staff said that this often happened before the patient had been properly assessed in A&E. Junior and middle grade doctors explained that when patients had been waiting in the A&E department for some time, the assessment of the patient and subsequent decisions for care had to be rushed in order to avoid breaches of the target.

Several senior doctors described the situation as a culture of “admit to decide” rather than the preferred option of “decide to admit”.

It was reported to be difficult to transfer patients from the EAU to the specialist beds they required. A senior nurse said that some patients on the EAU should not have been there but could not be moved due to lack of available beds in specialist areas. This included patients who should have been in the acute coronary unit.

Several members of staff from other parts of the trust thought that surgical patients were not always well managed on the EAU. They thought this was because there were no specifically skilled surgical, trauma or orthopaedic nurses on the unit.

Doctors and nurses with particular responsibility for the care of patients with stroke considered that the EAU was not a good environment or equipped to deal with stroke patients.

A consultant in care of older patients did not think the unit was equipped appropriately for elderly patients and another questioned whether a busy, noisy unit was an appropriate environment for them to be treated in. Relatives who came to see us also raised concerns over how elderly patients were treated on the unit. For example, we were told about an elderly patient who had been left unattended on a commode and had fallen to the floor.

The trust undertook an analysis of trauma patients admitted to the trust between April and September 2008. It showed that 125 patients in this period (10%) were admitted to the EAU. The chief executive acknowledged that this resulted in unnecessary delays in patients being admitted to the trauma ward.

Patients should not move back to the EAU once they have moved to a specialty ward or to theatre. The trust's operational policy supports this. However, we were told that this did occasionally occur at the trust, both from theatre and from the critical care unit.

Findings of fact on the environment, infection control and admissions to EAU

- The environment and layout on the EAU were not good for patients or staff, particularly when 48 beds were open between 2004 and May 2008.
- The EAU was described by staff and patients as busy, chaotic and frenetic, and as a poor environment for older patients and those with strokes.
- The EAU had the lowest score, that is poorest performance, in an audit of infection control carried out by the trust in 2007/08.
- The system including EAU was not effective in sending patients to the wards most appropriate for their care.
- The capacity of EAU was not planned in relation to clinical demand and patient flow.
- Patients were often admitted to the EAU before proper assessment had taken place in A&E.
- There were concerns about the management on EAU of surgical patients and those with traumatic injuries.

Staffing levels on the EAU

The operational policy outlined that the nursing staff levels and the skill-mix would be driven by the need of the service on the unit. The policy listed a minimum number of staff for the provision of a high standard of care and service. The daily staffing level on the unit was not to fall below the minimum, as the unit would receive patients who required emergency assessment, treatment and care.

On our unannounced visit in February 2008, the staffing on the ward was slightly below the minimum figures. A senior nurse interviewed at the time told us that more staff were needed. This was because the nurse considered that the number on a shift was too few to provide appropriate care while continually receiving further emergency admissions. This was particularly the case in a large ward with poor geography and many seriously ill patients.

We were told that, when the EAU first opened, it was intended to have a staffing ratio of one qualified nurse to every six patients, on par with the recommendations of the Society of Acute Medicine. The unit opened with good staffing levels. Indeed, we were told that initially staff were taken from other wards to work on EAU. The trust's plan for cost-improvement in 2006/07 resulted in a reduction in staff numbers, as the funding for staff was cut. There was also a freeze on vacancies as part as a trust-wide reduction in the workforce. Furthermore, the manager during this period was frequently asked to cut staffing levels and review the skill-mix on the unit. At the end of 2007, we were informed that the nurse to patient ratio was closer to one qualified nurse to every 15 patients. One nurse told us she and one healthcare assistant had once been responsible for 17 acutely unwell patients. She described it as "impossible".

The staffing levels were reviewed as part of the wider review of skill mix, which was started in mid-2007 and which took account of the type and throughput of patients. Following the review of skill mix, the establishment of nurses was increased. The benefits of this increase had yet to be fully felt in mid-2008, particularly as there were five whole-time equivalent nurses on maternity leave. Those on maternity leave were said to be some of the more experienced and competent members of staff.

It was recorded in the risk register for the medical division in April 2008 that there had been a shortfall of staff in the EAU because the nursing bank was unable to fill the gaps in staffing. The entry continued that this was leading to increased complaints and was "compromising patient safety". There were concerns there would be a repeat of a previous serious untoward incident. This had involved giving an infusion of the wrong solution and is described later.

We were told that it was often hard to get bank staff to work on EAU because it was unpopular, due to the pressure on staff. The unit could not rely on agency staff as it was difficult to get staff with the required skills.

The ratio of nurses to patients improved when 12 beds were removed in May 2008. In July 2008, there was the equivalent of one qualified nurse to every 10 patients.

Although some staff told us that staffing levels were acceptable, many more described the EAU as "dreadfully understaffed" or that there were "absolutely not" enough nurses, with the 2007/08 winter period identified as "particularly stretched".

Patients and relatives of patients who had been treated on the EAU had a general impression that the unit was short-staffed. As a consequence of this, patients reported not getting basic care, such as washing and being escorted to the toilet. There was a lack of support noted for patients needing help to eat, including an elderly arthritic patient who needed help to unpack and cut up her food. One patient told us that EAU was generally chaotic, filthy and there was a lack of basic hygiene control; for example he did not see any hand washing. Weekends and late in the evenings were thought to be the worst time for staff levels.

Insufficient staffing can adversely affect communication. This was described by the staff on the unit, staff elsewhere in the hospital and the relatives of some patients. Doctors and other healthcare staff based outside the EAU blamed insufficient numbers of staff on the unit for difficulties in finding a nurse who knew about their patient. A junior doctor told us how families would often "grab" doctors as they walked by, to ask what was happening to their relative. Another complained there was not enough time to explain to patients what was happening, and this could lead to patients becoming frustrated. A manager listed communication between nursing staff and relatives as a common theme of complaints, and mentioned this was related to staffing levels. Two relatives who contacted us complained there was a lack of interaction between the nurses and the patients.

Several senior doctors told us that, due to low staffing, the nurses were generally too busy to accompany doctors on their ward rounds. This meant that essential opportunities to communicate about the condition and treatment of the patient were reduced.

We were told by patients and relatives that there had been problems with medication on the EAU. An audit by the trust in July 2006 found that 39% of prescriptions were incorrect. Some of the errors were the wrong dose, others were errors of omission. Another audit in June 2007 found that 29% of the prescriptions on the EAU had either missing or incorrect details entered on the forms. It also found that there was an average of 2.6 errors on 18 out of 53 treatment sheets.

There was a further audit of drug prescribing on the EAU in January 2008. This looked at 100 drug charts and compared them to trust policies. The main findings were that the identity of the prescriber was clear on only 24.3% of charts; allergies were not recorded on 14%; just under 10% were not legible; and 73.5% of the prescribers were junior trainee doctors.

Medical staffing on the EAU

In 2004, the Royal College of Physicians recommended that, by 2008, there should be at least three consultants with primary responsibility for acute medicine in every acute hospital. In August 2006, the clinical director for medicine acknowledged that having just one single-handed acute physician was an "immediate problem". The acute physician was an acting locum consultant. The appointments of acute physicians were considered a priority, but it took nearly two years before the EAU had a complement of three acute physicians.

By May 2008, the trust had three dedicated acute physicians, two appointed in 2008. This is to be commended, although their inclusion in the rota for covering A&E has already been identified in this report as inappropriate.

Findings of fact on how the unit operated and on staffing

- The ratio of nurses to patients by the end of 2007 was approaching one qualified nurse to 15 patients, compared to the recommended one to six. By mid-2008, it was one to 10.
- Most staff thought there were too few nurses.
- Many staff, and many patients and relatives, were concerned about poor communication. Nurses were often unable to accompany doctors on ward rounds.
- Since May 2008, there have been three consultants in acute medicine with primary responsibility for the EAU. They had additional responsibilities in A&E.

Training for nursing staff and observations of patients by nurses

The operational policy for the EAU outlined that the education of nurses in the unit was an ongoing process to meet the needs of the patient. It said that nurses would be able to demonstrate their competencies to provide care to "level two patients", in other words those patients that need monitoring and patients with severe co-morbidity (that is, other health problems in addition to their main diagnosis). The Department of Health's review of critical care in 2000 identified "level two patients" as those requiring more detailed observation and intervention.

During 2006/07, all staff on the EAU had training on immediate life support. In 2007/08, staff were released for training on basic life support during the first two months only. The training sessions were said to be at inconvenient times for staff on the unit.

In July 2008, members of staff confirmed that little training, including mandatory training, had been undertaken for the past 12 months. They expressed concern about how long it would take to bring training up to date. The main problem was said to be the difficulty in releasing staff for training due to staffing levels on the unit. It was reported in the governance meeting in July 2008 that the EAU would be depleted if staff left the unit to undertake training.

With regards to more advanced training, the operational policy for the unit specifically described advanced life support as a skill that would be available on a 24-hour basis on the unit. In July 2008, only one member of the unit had been trained in advanced life support.

There were reports from interviews with staff, qualified nurses and healthcare assistants about having to perform tasks without the necessary training. Three areas mentioned were modified early warning scores (MEWS), cardiac monitors and fluid balance charts.

The MEWS system has been described earlier in this report. It is used to monitor the clinical progress of patients and is particularly useful to identify patients at risk of serious deterioration in a busy clinical area. The investigation team observed a number of inaccuracies in MEWS scoring due to simple arithmetical errors and, on occasion, a failure to highlight clinical escalation for deteriorating patients. There were a number of patients whose scores should have triggered a referral and yet this had not happened. We raised this issue with the trust and were informed that MEWS had been identified by the trust as an area where training was necessary in order for all staff to become confident in use of the charts. It was explained that problems with the charts were due to the recruitment of newly qualified nurses who required education in order to achieve the same level of competence as the more experienced staff.

We were also told that risk scores for patients with pneumonia were not done in A&E or on the EAU.

There were 10 bed spaces set up with cardiac monitors on the EAU. We were told that the staff originally employed on the unit in 2004 had been trained to use the cardiac monitors, but since then it had been difficult to release staff for training. We learned that there had

been no training on cardiac monitors for a couple of years. When we visited in July 2008, we found that most staff working in the monitored bays had not been trained to use the monitors and did not understand them. A senior nurse from another area reported that, when she visited the unit and the alarm on the monitor sounded, the nurses did not know why this occurred. Senior nurses in the department admitted that the cardiac monitors were often turned off, or not used when necessary, because the nurses did not have the skills to use them.

One of the patients who came to see us told us about his experience in October 2007. He suffered a heart attack on a Sunday and was admitted through A&E. He was initially sent to EAU for 24 hours before being moved to the acute coronary unit on the Monday morning. While he was complimentary about the acute coronary unit, he thought EAU was "terrible" and noted there was a big disparity in care between the two areas. He was concerned that the service on Sunday was particularly poor. He reported that his condition was not monitored appropriately while in the EAU. His blood pressure had fluctuated causing the monitor to alarm, but no member of staff had come to check on this.

An audit of inpatient cardiac arrests, reported to the EAU's governance meeting in July 2008, showed that a large number of patients on the unit were succumbing to cardiac arrest.

During a visit to the unit, we found that most patients who required fluid balance charts had these in place. However, of 16 patients, only one chart had been completed to show the balance over 24 hours. A specific example was also observed of a very acutely ill patient who had been admitted late at night. This patient in the cardiac bay was on diuretics, with an infusion of intravenous fluid and hourly observations. We noted that fluid balance had not been recorded.

On another visit, we observed that nurses were not using infusion volumetric pumps to aid the administration of intravenous fluids. On one night shift, we saw that most of the intravenous drips in progress were free running and not on the pumps, which were available on the drip stands. We observed 20 intravenous infusions on patients and found only two to be running on time. The majority were running considerably behind time, and one was being infused far too quickly. In one instance, the intravenous fluid had been put up at 8.45 am to run at the rate of one litre over eight hours. However, the pump was not being used and the first litre was still running at 10pm. This patient had been admitted with dehydration as one of their problems. It appeared the nurses were not familiar with how to use the pumps.

This issue was raised with the trust and, on subsequent visits, more of the infusions that we observed were running on time.

The operational policy for the EAU stated that nurses would be able to provide care to patients who require more detailed observations and intervention. Observations are a basic element of caring for patients and include measures such as heart rate, respiratory rate and blood pressure.

Several staff that we interviewed reported problems generally with staff conducting observations. These ranged from staff saying there was a poor standard of observations, especially at night, to a consultant reporting that when he was a patient on the unit no one performed observations overnight, despite the fact he had been fitted with a chest drain. A doctor who had nearly completed their specialist training told us that they had often asked for regular observations but these had not been done to a satisfactory level, even though the patient required critical care.

One senior doctor expressed concern that there was no effective prioritisation system on the EAU and, therefore, patients were seen in a chronological order rather than according to their clinical condition. A patient who had to be moved from the EAU to the critical care unit was upset that no observations had been performed on the EAU, although they required critical care.

Additional concerns raised with us were that, at weekends, staff did not pick up abnormal blood test results. Not everyone had access to the computer, so abnormal pathology was missed.

In November 2007, a report was made to the clinical quality and effectiveness group that the unit was one of two areas across the hospital that did not comply with tissue viability audits. The audits were to establish whether there was appropriate care of vulnerable patients' skin and adequate prevention of bed sores.

In July 2008, we raised our concerns directly with the director of nursing about poor training of nurses and poor quality of observations. In September, she provided us with information on planned and actual developments in nursing. These are detailed in the chapter on developments.

Findings of fact on training of nurses and observations of patients by nurses

- Training had initially been established, but there had been limited training during 2007/08.
- When we visited in July 2008, only one member of staff on the unit was trained in advanced life support.
- Nurses were not using the modified early warning score appropriately.
- Nurses were not trained in the use of cardiac monitors. On occasions, these were turned off.
- Observations and monitoring of patients were patchy and not consistently performed to the required standard.
- On one visit, only two of 20 intravenous infusions were running on time. On subsequent visits, more were found to be running on time.

Medical admissions and the care of patients admitted as medical emergencies

We looked at what happened to patients who were admitted to a ward from the emergency assessment unit. Most patients admitted as emergencies have medical rather than surgical conditions. The proportion nationally is 79%. These conditions include heart attacks, strokes, respiratory conditions such as asthma or chronic lung disease, problems associated with diabetes, and various other disorders of glands, the stomach, bowels and so on, that do not require surgery.

The medical wards in the trust were re-organised and reconfigured into 'floors' in 2006. This is covered in more detail later in the report. Floor one at Stafford Hospital consisted of wards 1 and 2 and the acute coronary unit (ACU). The floor had 44 beds: eight of these were ACU beds and 36 were specialty beds for patients with cardiac, endocrinological and haematological conditions.

Floor two at Stafford Hospital consisted of 78 beds. The specialties covered were respiratory, gastroenterology, elderly care and stroke. It consisted of wards 10, 11 and 12. There were 38 beds on ward 10, with four of those being for patients with acute stroke; 21 beds for patients with gastroenterology problems on ward 11; and 19 beds for respiratory patients on ward 12.

Sources of evidence

- Interviews with staff past and present
- Interviews with patients and relatives
- Healthcare Commission's national inpatient surveys
- Observations carried out by members of the investigation team
- Observations by South Staffordshire Primary Care Trust during an unannounced visit
- Complaints

- Trust documents including performance monitoring reports, minutes of meetings, risk registers, SUI reports, audit results and analysis of complaints
- Statements provided by the trust
- The trust's website
- Relevant guidance on national websites
- External reports, including the Sentinel Stroke Audits in 2006 and 2008
- Absence of evidence

The reconfiguration of the medical wards

In May 2006, the proposal to change the organisation of the medical division noted, in its introduction, that the trust would be entering 2006/07 with an underlying debt of £2.158 million. However, the trust was expecting, as a minimum, to have a gap of £10 million between its income and expenditure. The trust requested the medical division to make a total saving of £580,000 as a contribution towards closing this gap. The proposal identified a potential cost saving of £325,000. Other savings were referred to but not detailed in the proposal.

The proposal also set out to alter the seniority and skill mix of the nursing workforce. Overall, there were to be 6% more staff but the proportion of senior staff (band seven) was to reduce by nearly 60%. The previous director of nursing had no recollection of being asked for advice regarding these changes to skill mix. The detail of changes to staffing at the trust is covered in another chapter.

Many consultants told us that they had opposed the reconfiguration of the wards and the reduction in nursing staff.

The environment of the medical wards

When we visited the wards, we found that they were generally clean and tidy, except on an unannounced visit in February 2008 when we were concerned about the cleanliness of the washing facilities and toilets on wards 10 and 11.

Ward 10 is a 'T shaped' ward with 38 beds and the staff are divided between three areas. Like the emergency assessment unit, it was an awkward area to nurse because of its layout. It also had very dependent patients. The problem caused by the layout of the ward was exacerbated by lack of staff. Wards 11 and 12 together constituted a large area, again with dependent and seriously ill patients, so when staff numbers were low this was also problematic.

Staffing and standards of care

As noted above, the reconfiguration of the medical wards into 'floors', as opposed to wards, led to a reduction in the number of qualified nurses, particularly more senior ward nurses. The changes took place gradually during 2006. The result was just one senior sister (band seven) for the 78 beds on floor two. Although this was meant to be offset by the appointment of more and better trained health care workers, the requirement to save money meant that overall staffing levels were in fact reduced. The previous director of nursing left in July 2006. She stated that she did not have operational responsibility for these changes and had no recollection of being asked for advice.

During most of the period covered by this investigation, there was one matron for the medical division in the trust who was the lead professional nurse, but not the line manager for the nurses in the division. Senior nursing staff, consultants, therapists and managers described the leadership of the wards on floor two as being weak. In April 2008, clinical staff from South Staffordshire Primary Care Trust (PCT) undertook an unannounced evening visit to floor two. They concluded that one sister across all three ward areas was not sufficient for leadership, team building and the culture of the team. The trust has said that the need for an additional senior nurse (band seven) was identified as part of the establishment review and support to fund this was agreed at the March board meeting.

Many staff from a range of healthcare professions expressed their concerns about staffing levels on the medical wards, especially on floor two. The review of the nurse staffing levels and skill mix in the autumn of 2007 found that the biggest shortfall was in medicine, where nearly 77 more whole-time equivalent staff were required. The director of nursing took a paper to the trust's board in March 2008 to remedy this shortfall.

Many staff told us that, on the medical wards, staff sickness was high and had been for some time. The reports in 2006 on corporate performance to the trust's board demonstrated that sickness levels were high across the whole the trust and highest in the medical division. The corporate performance monitoring reports from April 2007 also showed that staff absence due to sickness was highest in the medical division. The PCT was told this when it conducted its visit in April 2008.

The main concerns of staff, relatives and patients related to staffing levels and the effect of having a low number of nurses. This was particularly the case for the wards on floor two, consisting of wards 10, 11 and 12. When the PCT conducted its unannounced visit to wards 11 and 12, they found that the nurse staffing on the ward was below the establishment, and that staff had been too busy to communicate with patients and their relatives. One patient had been in a soiled nightdress since lunchtime.

Staff told us that they had complained or completed incident reports when they were concerned. The trust supplied information about incidents that staff had reported for wards 10, 11 and 12. This information showed that, between April 2005 and August 2008, the most frequently reported incidents related to staffing levels and lack of suitably trained or skilled staff; collectively these represented 37% of all the issues reported by staff. Ward 11 had generated as many incidents as the other two wards put together.

Patients and relatives that came to see us also expressed more concerns about nursing care on ward 11 than any other ward. One relative said that "some nights it was a war zone" and that "the family were doing lots for other patients who didn't have their relatives with them. They were helping them to go to the toilet or they were helping them to eat".

Another told us that her mother was in the far corner of a four-bedded bay on ward 11. She said: "The nurses told her to ring the buzzer, but because of her paralysis she could not use the buzzer. When someone else used it on her behalf, it often would not be answered."

A number of staff in different professions raised concerns about the lack of basic nursing care, such as poor hydration and nutrition of patients, and failure to help patients eat or drink. Some said there was a negative attitude among some of the nurses, with relatives who complained being seen as difficult.

Care was also criticised on the other medical wards on floor two. It was described as being very poor, with buzzers not being answered, privacy and dignity ignored, and patients receiving little or no help with food or drink.

There was evidence going back to 2005 of concerns about these wards. In the trust's report on complaints for July to September 2005, there was specific reference to wards 11 and 12. In a letter from the trust in June 2005 in response to a complaint, the trust noted that staffing levels had been an issue on ward 12 and that the basic standard of care could be compromised when the ward was short staffed.

In the summer of 2005, a complaint was referred to the Healthcare Commission about care on ward 11. This concerned lack of nutritional assessment and care, falls, poor communication and pressure sores. The complaint was upheld by the Commission and the initial response from the trust was considered inadequate. Another complaint referred to the Commission concerned care of a patient on ward 11 in December 2006 and

January 2007. It involved failure to assist the patient with fluids and to monitor fluid or food intake. This complaint was also upheld. The 15 recommendations included that members of staff on the ward must carry out nutritional assessments, preserve the dignity of patients and keep adequate records.

The trust's report on complaints for the first three months of 2008 noted that complaints about two medical wards, wards 10 and 11, had been of some concern over recent months. These wards were averaging two complaints per month. Basic standards of care were the general themes.

Many medical and nursing staff also described instances to us when basic nursing care had been lacking on the medical wards at Stafford Hospital. The elements of care they described as being lacking reflected those mentioned by patients and relatives. Additionally, they expressed concerns about observations and documentation not being completed, including those relating to fluid balance and to medication.

Some staff were distressed that they had been unable to deliver the level of care that they wanted to and had insufficient time to spend with relatives or to accompany doctors on their rounds. One doctor also told us that phones on the ward would not be answered for 20 minutes. We were told that, on one occasion, the phone had eventually been answered by a patient with dementia.

One bank nurse told us that some patients on ward 11 were on percutaneous gastrostomy feeds. This involves feeding by tube directly into the patients' stomach. No one had checked how much had been given and it was not clear who had put the last feed in place. The paperwork was not up to date and morning doses of medication were missing from the chart. On ward 10, there were several highly dependent patients and, on one occasion, this nurse had found some patients who had been left lying in bed in their faeces, evidently for a long time. Another nurse told us that working on ward 11 had made her ill and she would never work there again.

Staff on the critical care unit had noticed a decline in the level of care on the general medical wards and this had hampered their ability to move patients from critical care to the wards. A consultant told us that an audit on ward 12 showed that scoring of severity of illness was not being done and that over half of patients did not get antibiotics within 24 hours of them being prescribed. We noted that, in the report on incidents to the clinical quality and effectiveness group in December 2007, there had been a "catastrophic" incident on ward 12 that was due to failure to monitor a patient's condition.

A third of the patients and members of the public that came to the Healthcare Commission told us that patients did not receive the correct medication or were given the wrong medication. A related issue was that help was not always available for patients to take their medication. These issues were particularly common on the medical wards.

Although some staff said that omission of medication was uncommon, a larger number of staff, including senior doctors, told us that they had had to personally insist that patients received their correct medication, that omissions happened and that there could be delays before patients received their medication. There were no pharmacists based on these wards. A member of the pharmacy team confirmed that this was a problem.

Another concern was the development of pressure (bed) sores. Relatives informed us that patients suffered pressure sores and some showed us photographic evidence. A senior nurse told us that, although on their ward they assessed a patient's likelihood of developing pressure sores as one of the first tasks after they were admitted, this was not always the case for patients that came to them from emergency assessment unit. An audit by the trust in January 2008 of the prevalence of pressure damage found that most pressure sores occurred after patients were admitted and wards 10, 11 and 12 had among the highest rates. For example, 55% of 38 patients on ward 10 had some degree of pressure damage. Only four of these patients

had any pressure damage when they came into hospital.

For all hospitals, as patients move to different wards and areas in the hospital and as staff change shifts, it is important that appropriate information about the condition and care of patients is communicated and passed on. This is often referred to as 'handover'. Doctors in the medical division told us that, with regard to the change between shifts, handovers did not always happen, or were inadequate because of shortness of time or confusing information.

When new patients arrived on the medical wards, many nurses told us that the handover was often conducted by telephone only, and sometimes only by junior nursing staff.

Although nurses generally told us that they did receive a handover when they changed shifts, many described these as brief, short or not as effective as they could be. This we observed for ourselves when we visited ward 10 and spoke to the nurse in charge immediately following a handover.

Improvements to staffing levels are noted in the progress section of the report.

Findings of fact on nurse staffing and standards of care

- The trust's reconfiguration led to a reduction in the number of senior nurses.
- There were high sickness levels among nurses on the medical wards.
- There was a low number of nurses, particularly on floor two.
- There was a long history of poor nursing care on floor two.
- Patients, relatives and staff recounted examples of poor care.
- Some patients did not receive the correct medication.
- Handovers were often inadequate for patients, nurses and doctors.
- In January 2008, 55% of patients on ward 10 had pressure sores.

Aspects of clinical care on the medical wards

Care pathways and routes of admission

An integrated care pathway describes the care that is anticipated, in an appropriate timeframe, for a patient with a specific condition or set of symptoms. Care pathways are considered important because they help to reduce unnecessary variations in care and outcomes for patients. Care pathways can also be used as a tool to incorporate local and national guidelines into everyday practice, manage clinical risk and meet the requirements of clinical governance. They also provide benchmarks. A pathway may be varied in order to meet the specific needs of an individual patient.

We heard variable accounts from doctors and nurses as to whether care pathways were used regularly at the trust. Most staff said that a care pathway for patients admitted with a stroke was in place. There was also said to be one for patients with chest pain or cardiac symptoms, but many staff said that it was not initiated for individual patients as early as it should have been.

Some staff told us there were general pathways for medical and surgical admissions and that pathways were being developed. However, many staff, including senior clinicians, told us that care pathways did not exist or were not used. In a letter to the Healthcare Commission in October 2008, the trust acknowledged that, while they had some pathways in place, it was an area that would benefit from further development.

We were told there were fewer medical patients now on surgical wards than had been the case three or four years ago, but many senior staff told us that many patients still ended up on the "wrong" ward. For example, a

patient with chronic lung disease could be moved from the emergency assessment unit to the ward for patients with heart problems. They would then be looked after by a heart specialist, not a lung physician.

The great majority of patients were not admitted directly to their specialty ward, but admitted first to the emergency assessment unit. If there were surgical beds available, patients would sometimes be admitted direct to these, but this did not apply in the medical division, other than for some of those requiring the acute coronary unit.

Members of the team who specialised in caring for patients with stroke told us that patients with stroke were not always in the right place in the hospital and were not admitted directly to the beds specifically for them on ward 10.

Acute coronary unit

The acute coronary unit (ACU) had eight beds and was part of floor one of the medical division. We were told by senior staff that thrombolysis was provided but, although they did angiograms (a procedure for looking inside coronary arteries), patients that required angioplasty (a technique for improving the flow of blood to the heart by unblocking coronary arteries) had to go to the University Hospital of North Staffordshire.

Patients were generally complimentary about the ACU and staff told us that they thought the service and care provided by the unit was good. They described the environment as clean and said that handovers between nursing shifts always occurred.

Although some patients were admitted directly from A&E, many staff told us that patients were not always admitted directly to the unit. Beds in the ACU were often full, resulting in patients having to be cared for in other areas, often the emergency assessment unit (EAU). Senior nurses in the unit told us that not all staff in the EAU were able to interpret the monitors correctly and patients were not always started on the appropriate pathway of care. Some patients who came to see us told the same story.

Nursing staff on the ACU were generally appreciative about the support they received in terms of having regular team or unit meetings and having access to training. However, nurses did not feel that they consistently had enough staff and sometimes, when they did, their healthcare support workers would have to go and help out on other wards. In the past, they had triaged cardiac patients on the EAU to identify those in most need of transferring to the ACU. However, this had not been the case for a couple of years.

There had been a long-standing problem with the cardiac monitors on the ACU. At the meeting of the governance committee for the medical division in July 2007, it was noted that the machines for monitoring on the ACU were "breaking down". They were to go back on the corporate risk register as a high clinical risk. It was recorded on the risk register for the medical division in April 2008 as "failure to deliver a coronary care service due to lack of monitors for inpatient care".

Findings of fact for routes of admission, and the acute coronary unit

- Patients were not always located in the correct specialty area.
- There were problems with the monitors on the acute coronary unit.

Inpatient services for patients with stroke

The unit for clinical effectiveness and clinical evaluation at the Royal College of Physicians conducted the first National Sentinel Stroke Audit in 1998. There have been several subsequent national audits. The objective of the Sentinel Audit is to assess the quality of care for people who have had a stroke and to help trusts use audit as a means of improving the quality of their services. The audit uses evidence-based standards for the organisation of services and process of care.

In 2004, the Royal College of Physicians recommended that imaging of the brain should be undertaken as soon as possible in

all patients, at least within 24 hours of onset (unless there were good clinical reasons for not doing so).

In July 2008, the National Institute for Health and Clinical Excellence (NICE) published clinical guidelines for the diagnosis and management of acute stroke. These included that all people with suspected stroke should be admitted directly to a specialist acute stroke unit, following initial assessment, either in the community or from the A&E department.

An acute stroke unit is a discrete area in a hospital that is staffed by a multidisciplinary team specialising in stroke care. It has access to equipment for monitoring and rehabilitating patients, and regular multidisciplinary team meetings. The guidelines also recommend that, on admission, people with acute stroke should have their swallowing screened by an appropriately trained healthcare professional before being given any oral food, fluid or medication.

At the trust, four of the 38 beds on ward 10 at Stafford Hospital were for stroke patients. Fairoak ward at Cannock Hospital was also used to accommodate patients who had had a stroke, mainly after the acute phase of the illness.

In the 2006 Sentinel Audit, the trust reported an average wait of five to 24 hours for a CT scan on weekdays, longer than 48 hours at weekends, and a wait of longer than 48 hours for an MRI scan at any time. Against 12 clinical audit indicators that aim to assess the quality of care for people that have had a stroke, the trust scored 55% against a regional average of 63% and a national average of 65%.

In the partly released results of the 2008 Sentinel Audit, the trust reported the same waiting time for a CT scan on weekdays and 25-48 hours for a CT scan at weekends. For MRI scans, there was an average wait of between 25-48 hours on weekdays and greater than 48 hours on weekends. These results show that the trust was not meeting the guidance of the Royal College of Physicians for imaging of the brain to be undertaken at least within 24 hours of onset.

The 2006 Sentinel Audit reported that the trust met the criteria for an acute unit for stroke patients. However, the subsequent audit in 2008 said it did not. This was confirmed to us by staff that we spoke to. Staff also described the facilities (four beds) available on ward 10 as being insufficient to deal with all the stroke patients that were admitted to the hospital. They confirmed that patients with stroke were not admitted directly to the four-bedded unit, but had to come via the EAU. They might remain on EAU for up to four days without adequate intervention from therapy services.

Staff told us that access to thrombolysis was limited to between 9am and 5pm on weekdays only. The national target is that 10% of stroke patients should receive thrombolysis, but the figure for the trust was 3%-5%. Patients who received it were looked after on the acute coronary unit.

Care of stroke patients and outcomes of care

In the later stages of the investigation, the Healthcare Commission's surveillance generated an alert about high mortality related to patients who had suffered a stroke. The alert involved mortality in the period between January and March 2008. It followed two successive quarters when mortality data had been higher than expected. This was considered by the decision panel in the Commission that deals with such matters. A letter was sent to the trust in December 2008 containing our analysis and asking them to comment on the findings. The trust replied in January 2009, stating that, among other things, it had reviewed a number of the cases and had decided on a range of actions for improvement. However, we have asked the trust for further information in order to consider the matter further.

We were provided with information from the trust that the mortality from stroke was 18%, above the European average of 15%.

There were mixed views about the use of the stroke care pathway. Most staff said it existed and was in use. However, we were also told that some health professionals involved in

looking after stroke patients had to write notes in multiple places. This suggested that the care pathway was not truly multi-disciplinary and was not used as the single record of care. We were told that files were often lost or not compiled properly with loose sheets. There were also variable methods of case-note completion, some with the most recent first and some the other way round.

While some staff said that the care of patients that had suffered a stroke was good, more said it could be improved. We have already identified concerns about stroke patients being admitted first to the EAU. We were also told about the inappropriate discharge of patients to their home or transfer to Cannock Chase Hospital, resulting in re-admission within a week. Some staff thought that decisions about discharge were made on the basis of needing the bed, rather than on the basis of what was right for the patient.

We were told about poor communication within the multidisciplinary team especially between doctors and nurses. For example, it might not be clear that an individual had been placed on a special pathway for dying patients. This resulted in mixed messages between staff and family members.

In the 2006 Sentinel Audit of stroke, the trust scored 65% for patients being screened for swallowing disorders within 24 hours of admission, which was higher than the average for local trusts under the same SHA (62%) and almost the same as the national average (66%). However, a consultant told us that more staff were needed to identify swallowing difficulties. The stroke nurse was generally complimentary about the service provided by the speech and language therapists, who were employed by South Staffordshire PCT. However, she told us that patients had to wait to be seen by speech and language therapists.

The speech and language therapists had instructed nurses how to carry out assessments of swallowing, but nurses were reluctant to do them if the consultant requested an assessment, since they felt consultants preferred them to be conducted by a speech and language therapist.

The speech and language therapists reported that there had been problems in communication with ward staff. When therapists made recommendations for patients, these were not always followed up. This was attributed in part to the shortage of staff. Examples of shortcomings included poor care of patients' mouths, resulting in food debris in their mouths and their tongues being coated in "matter", recommended diets not adhered to, staff not consistently providing the correct diet, and drinks not thickened when they should be or thickened to the wrong consistency.

Non-invasive ventilation

Non-invasive ventilation is an important element of the clinical management of patients with certain types of lung disease and those who have problems with breathing. It is a means of supporting breathing through the patient's upper airway, using a mask or similar device. Although a variety of ventilator units are available, most centres now use bi-level positive airways pressure (BiPAP) units and there is a guideline that refers specifically to this form of ventilatory support. It has been produced for clinicians caring for patients with chronic obstructive pulmonary disease (COPD) in the emergency and ward areas of acute hospitals.

The National Institute for Health and Clinical Excellence (NICE) recommends that non-invasive ventilation be available in all hospitals admitting patients with COPD. This has led to a rapid expansion in the provision of non-invasive ventilation services, with over 90% of acute hospitals in the UK offering this intervention. The trust did not have it. Senior clinicians in the medical division told us that non-invasive ventilation was not available to patients but that there were plans to introduce it. The lack of non-invasive ventilation meant that doctors had to refer patients to the critical care unit. As the critical care unit often had no space, and on occasions there were no beds available in University Hospital of North Staffordshire NHS Trust, some patients did not get this service.

An audit that was part of a national audit on chronic obstructive airways disease found that five out of 30 patients could have benefited from non-invasive ventilation but did not receive it.

We were also told that, even on the ward for patients with respiratory problems, because of inadequate training many of the nurses did not understand about basic elements of patients' clinical conditions, such as their oxygen saturation levels.

Findings of fact about aspects of care of medical patients, including those with stroke

- There were four dedicated stroke beds, which was too few for the number of admissions.
- Patients were not admitted direct to the stroke beds.
- The trust had no specialist facility for the care of patients with acute stroke and did not meet the criteria for an acute stroke unit.
- The trust did not meet the guidance for all patients with stroke to have imaging of the brain within 24 hours.
- Even when care pathways existed, they were not always used or used to best effect.
- There was no facility for non-invasive ventilation on the respiratory ward.
- Some patients who needed non-invasive ventilation did not get it.

Resuscitation

Resuscitation of patients who have suffered an arrest of the function of their heart or lungs is not confined to medical patients but we have included it here, since a higher proportion of emergency admissions have medical problems.

At the meeting of the hospital management board in May 2005, it was reported that audits of resuscitation trolleys sometimes had worrying findings, with missing equipment and drugs.

There was a serious untoward incident on the EAU in September 2006 that involved the accidental infusion of lignocaine (a drug used to suppress fast heart rhythms and for pain relief). This happened when trying to resuscitate an extremely ill patient. The lignocaine should not have been on the resuscitation trolley.

The hospital management board in October 2006 noted that the trust did not have an officer for resuscitation. One was recruited in May 2007. There was only one resuscitation officer for the trust.

Problems with a lack of portable equipment for suction were identified at the medical division governance meeting in July 2007. In February 2008, the clinical quality and effectiveness group noted that there was no or only limited portable suction available for patients who had suffered an arrest. The risk register for the medical division in April 2008 stated that there were no portable suction machines at the trust, as the existing equipment had been condemned, and that handheld devices were to be introduced while different systems were reviewed. In May, it was noted that funding had been found through the capital programme, but the timescale for provision was not specified.

The trust had four different types of resuscitation trolley, rather than a single standardised type as is generally considered preferable.

We noted during our unannounced visit in February 2008 that a resuscitation trolley on ward 10 had not been checked since July

2007, was missing some items and contained some medication and solutions that were out of date. The trust explained that this was not the resuscitation trolley used on the ward. However, this could have been confusing, particularly to an agency nurse. The trust took immediate action to remove the trolley. The other trolley, that was meant to be the one in use, had not been checked for 10 days. Subsequently, we found that the checklists on the trolleys were generally up to date.

The minutes of the clinical quality and effectiveness group in July 2007 recorded that the bleep system for cardiac arrests was to be put on the risk register. It was noted that, if the system failed to work, there were difficulties getting hold of the crash team and there was no contingency plan. In a later meeting, it was confirmed that this had been added to the risk register.

In September 2007, the clinical quality and effectiveness group was informed that the cardiac arrest bleep system had failed on a number of occasions at both Stafford and Cannock Chase hospitals. As this was a clinical risk, a contingency plan of using mobile phones was adopted.

In April 2008, the risk register for the medical division recorded that the bleep system could be unreliable and had been temporarily unavailable on a number of occasions. This "would result in the resuscitation team being unaware of a cardiac arrest and so would be unable to respond". The register noted that a daily resuscitation bleep test was performed by the switchboard staff and any problems were reported to the resuscitation officer.

We were told by a junior doctor of an occasion, some months earlier, when the doctor received a bleep in the middle of the night to say that a patient was not breathing. The doctor arrived on the ward about 10 minutes later and was shocked to find that they were the first person there. The nurse had not called in a crash team and the doctor was concerned that the nurse had not received proper training, since her first action should have been to call the crash team.

Findings of fact about resuscitation

- There had been a serious incident in 2006 involving an inappropriate infusion on a resuscitation trolley.
- Our spot check on a ward in early 2008 revealed a trolley that was out of commission but that had not been checked since July 2007 and contained some items that were out of date.
- The malfunctioning of the bleep system for cardiac arrests was recorded on the risk register in 2007 and 2008. The problem continued and mobile phones had to be used.
- There were problems with the availability of portable equipment for suction.

Governance in the medical division

We have already considered specific issues to do with governance in A&E and the emergency assessment unit, both parts of the medical division, and considered complaints and incidents.

From April 2007, there were monthly meetings of the governance committee of the medical division, chaired by the head of division. These were generally well attended by consultants. Complaints and incidents were standing items at each meeting, but the amount of detail provided was unclear. The discussion on complaints was around numbers and response times, not the issues raised. The group identified clinical risks, many of which were then put on the divisional or corporate risk register. An example would be the monitors on the acute coronary unit mentioned above. In July 2007, it appeared these had previously been on the register and were to be reinstated as risks. However, over a year later, the situation had still not been resolved.

Similarly in October 2007, one of the top five risks on the register was the failure to deliver adequate and timely care to patients in A&E. In November 2007, the division had assessed

as serious the risk posed by the lack of staffing for the clinical decision unit in A&E. However, in May 2008, the situation was so worrying in A&E that we had to ask the chief executive to take immediate action on this and related issues.

There were no meetings in the medical division to discuss mortality and morbidity. There was an educational session on Friday afternoons at which interesting cases or topics were presented, but minutes were not taken.

Although there was evidence elsewhere in the division that audits had been performed, for example relating to stroke, cancer, chronic obstructive pulmonary disease, cardiac and chest pain, we were told by many senior staff that there was not an appropriate forum in which to discuss audit findings.

In July 2007, NICE produced guidance on the management of acutely ill patients. The trust had not carried out any audits of performance against the recommendations.

Findings of fact on governance in the medical division

- The governance meetings for the division began in April 2007.
- There was little, if any, learning from complaints and incidents.
- Problems were entered on the risk register but not resolved in a timely fashion.
- There were no records of meetings to review mortality and morbidity.

Patients admitted as emergencies with surgical problems or traumatic injuries

We have considered in the previous section patients admitted as emergencies with acute medical problems. A smaller proportion of emergencies consist of patients taken to hospital with traumatic injuries or conditions needing emergency surgical operations. These patients are equally important and need rapid, accurate diagnosis by experienced staff and speedy resolution of their problems.

We covered much of the relevant guidance in the introductory section to the report. Guidance from the National Confidential Enquiry into Patient Outcomes and Deaths states that there should be sufficient, fully-staffed, daytime theatre and recovery facilities to ensure that no patient requiring an urgent operation waits for more than 24 hours once ready for surgery. This includes weekends.

Sources of evidence

- Interviews with staff past and present
- Interviews with patients and relatives
- Trust documents, including reports of serious untoward incidents, operational policies, theatre utilisation reports, audit results and minutes of meetings
- External reports, for example a review by the Royal College of Surgeons
- Statements provided by the trust
- Nursing skill mix review
- Guidance from the Royal College of Physicians
- Operational protocol on medical review of fractured neck of femur (hip)
- Case notes and inquest reports
- Department of Health statistics and trust data on surgical volume

The trust provides surgical services at both Cannock Chase Hospital and Stafford Hospital. In 2003, elective orthopaedic surgery was moved to Cannock Chase. Trauma and

emergency surgical operations are performed at Stafford. Other surgical services provided at the site include breast surgery, general surgery, colorectal surgery, vascular surgery and day case surgery.

Protocols used in surgery

At the request of the trust, the Royal College of Surgeons of England conducted a review of the general surgery service (specifically colorectal surgery and laparoscopic cholecystectomy) in June 2007. The report noted that there were no departmental protocols on bowel preparation, use of antibiotics and post-operative management.

We were also told by some nurses and managers that there were few agreed protocols for the management of specific conditions. Care was not generally provided in line with protocols and individual consultants could behave in an idiosyncratic way. A policy on introducing new clinical techniques had been agreed in September 2007, but staff still had concerns that some new procedures in surgery had been introduced in an ad hoc way.

Others said that while protocols might exist for some conditions or circumstances, staff were often not aware of their existence. An example was whether there was a protocol for reporting incidents if a patient was moved out of hours, contrary to NICE guidelines. Instead, staff relied on what they had been told verbally.

Process of admission and location of surgical patients

Several members of staff told us that before the opening of the EAU in 2004, surgical patients would go directly to a surgical bed, cared for by surgical nurses, although they might have had to wait for such a bed to become available. This changed so that patients subsequently had to go to the EAU. This and the reduction of trauma and orthopaedic beds from 36 to 22, meant that there were more surgical patients on medical wards and that surgical patients often spent a long time on EAU, often up to the actual time of surgery.

When the EAU opened, about half the nurses who staffed it originally worked in surgery and the other half worked in medicine. However, over time, the nurses on EAU predominantly had medical backgrounds and expertise.

There was a difference of opinion about the frequency with which patients with traumatic injuries spent a significant length of time on the EAU. There is a reference earlier in the report to an audit showing that 10% of these patients were admitted to the EAU. This resulted in unnecessary delays in patients being admitted to the trauma ward.

We also noted in a previous section that there were concerns about the standard of observations by nurses of patients on the EAU.

On occasions, surgical and trauma patients could be moved from the EAU to the medical wards. Staff, particularly in trauma and orthopaedics, considered that staff on non-surgical wards had little knowledge of surgical conditions or serious injuries. Staff on non-surgical wards had less appreciation of what was needed in terms of providing care to trauma and orthopaedic patients. It was also reported that, when surgical patients were on non-surgical wards, it was difficult to monitor their care and implement pathways. Ward rounds could take a long time as the patients were spread around the hospital.

There was particular concern about the period when the reconfiguration of the surgical floors meant that the beds for patients with traumatic injuries were located next to wards 6 and 7. There were different accounts of how long this 'boarding out' had lasted, ranging from six months to two years. It appeared that the service moved three or four times during the reconfiguration programme. The trauma service finally moved to ward 3 in August 2007.

The area used for this temporary arrangement was on occasion described by staff as a "no man's land". When it was initially set up, there was no ward station, no reception, no access to computer and no phone. Facilities such as the sluice and store room were located on the adjoining wards. The layout also meant that there were some beds that could not be

observed. Cleanliness was said to be a further concern, as was the risk of infection due to the proximity of the toilets.

It was in this area that, in April 2007, a serious untoward incident occurred. The subsequent investigation report stated that "it was an unpleasant place to work and would be an unpleasant place to be a patient". The report also pointed out that the staffing levels and the skill mix on the ward were poor, while the level of nursing input that the patients required was high.

Several patients and relatives were concerned about the lack of information in this area, the difficulty in contacting doctors and the overall standard of care.

As an example, a patient "was admitted overnight to a four-bed bay on ward 7, adjacent to the orthopaedic ward. She was never transferred to the orthopaedic ward, however, after four days she was moved to the other wall in the bay, which was adjacent to the orthopaedic ward, but not in view of the orthopaedic nursing station. There were several occasions where her friend had to call a nurse because the patient was hanging out of the bed or in a soiled bed or because of the lack of observations. Her friend challenged the nurses regarding the soiled bed and also about leaving soiled things for hours within two feet of her bed. It was agony for her to be changed and on one occasion a nurse made an unpleasant remark about her being difficult. Her friend was not confident that she had adequate pain relief".

Ward 7 was where patients with colorectal and vascular surgery were cared for. We observed that it was a very busy ward, again with a layout that made nursing difficult. Both colorectal and vascular surgery are 'heavy' specialties requiring specialty nursing skills. Two separate teams nursed these patients.

Surgical cover at night and at weekends

The resident surgical officer (RSO) out of hours covered both general surgery and orthopaedics. This meant that the workload was high and sufficient experience was required to cover both. This was not always the case for some of the junior doctors who worked as the RSO on shifts. RSOs at night often had to take responsibility for completing tasks that were left over from the day, as well as undertake the workload for the night. The RSO not only had to admit as many as 15 to 20 patients, they might have to go to theatre or be called to A&E, and they had to provide back-up to the junior doctor covering all the surgical wards. Out of normal hours, there was just one foundation year one doctor (the most recently qualified) responsible for covering all the surgical beds.

In trauma and orthopaedics, there was also a specialist registrar on call, and these doctors lived in the hospital or nearby. For general surgery, however, there was no registrar after 9pm, so the only other person on call was the consultant. Although the consultants said they were happy to be called, some of the doctors in training admitted they had left some patients to the morning rather than call the consultant in the middle of the night. One consultant also thought this was a concern.

Several members of staff told us that the RSOs were quite varied in the level of experience they had. Some had a lot of surgical experience, while others had not. For example, one RSO had only had four months of surgical experience as a foundation year trainee, the most junior level of doctor. Senior doctors in A&E were concerned that, when they needed a surgical opinion on a patient out of normal hours, they might get someone with limited experience. We identified through our reviews of case notes that these situations occurred.

Short stay surgical unit

This unit, as its name suggests, was for patients coming for planned operations that needed only a short stay. It was intended to be open from Monday morning to 3pm on Saturday.

Several staff told us that the short stay unit often remained open at the weekends and was staffed by bank staff during that time. Staff

from wards 7 and 8 were expected to oversee or help out on the unit. This was not always allowed for in the staff rota. One senior nurse said that they have some medical patients there and that it was sometimes unsafe at weekends.

In February 2008, the surgical division drew to the attention of the clinical quality and effectiveness group their concerns about the standards of care on the unit when it was open as an escalation area. They reported that it was on their risk register.

The review of the nursing establishment found that the short stay unit had a gap of three whole-time equivalents between the professional view and the funded establishment.

Findings of fact on surgical protocols and admissions, cover and the short stay unit

- There were few protocols in use in surgery.
- When on wards other than surgical or trauma, patients with surgical conditions and severe trauma were not always cared for by nurses who understood their conditions.
- For a considerable period of time, when located between wards 6 and 7, the environment and management of patients with traumatic injuries were not acceptable.
- Ward 7 had a difficult environment and layout for the combination of colorectal and vascular patients cared for on this ward.
- There were concerns about the use of the short stay unit as an overflow ward at weekends.
- There was inadequate medical cover for surgical patients after 9pm.

Time to operation

There is evidence to suggest that there has been a steady increase nationally over the last 10 years in waiting times for emergency surgery. A longer wait is more harmful for some conditions than others. For example, the natural course of appendicitis is the rupture of the appendix and life threatening peritonitis. For other conditions, the risk may be less immediate but it is still worrying and uncomfortable for patients, and potentially harmful.

One of the most common emergencies encountered, particularly among older patients, is that of a broken hip (more specifically, a fractured neck of femur). The guidance from the Royal College of Physicians is that patients with this condition should have an operation to repair it within 24 hours. On occasions, this will not be possible because the patient has a medical condition, such as an abnormal heart rhythm, which must be treated first. Delay in operation not only causes discomfort, but can lead to other problems such as chest infections and pressure injuries.

We heard from many staff that there was concern about delays in operations, especially for trauma patients and, in particular, patients with a fractured hip. The operational policy for the theatres at Stafford Hospital noted that the trauma theatre was operational every weekday from 1pm to 5pm, except on Tuesdays when it ran from 9am to 5pm. At the weekends, there was no dedicated trauma list and all cases, trauma or otherwise, were put on the emergency theatre list.

There was no system to prioritise cases for the emergency theatre list at the weekend. This meant that trauma cases were often delayed further, as priority was given to general surgical or obstetric emergencies. We heard of many examples where patients with fractured hips had their operations cancelled several times. In some instances, this meant that they were not operated on for three or four days. This was contrary to the guidance.

Figure 3 shows the results of an ongoing audit, conducted by the trust between March and July 2008, looking at the time taken for patients with a broken neck of femur to go to theatre for their operation. The percentage of patients operated on within 24 hours was 56% on average. The target in the trust was 80% for patients who were medically fit to be operated on within 24 hours and 100% for all patients within 48 hours.

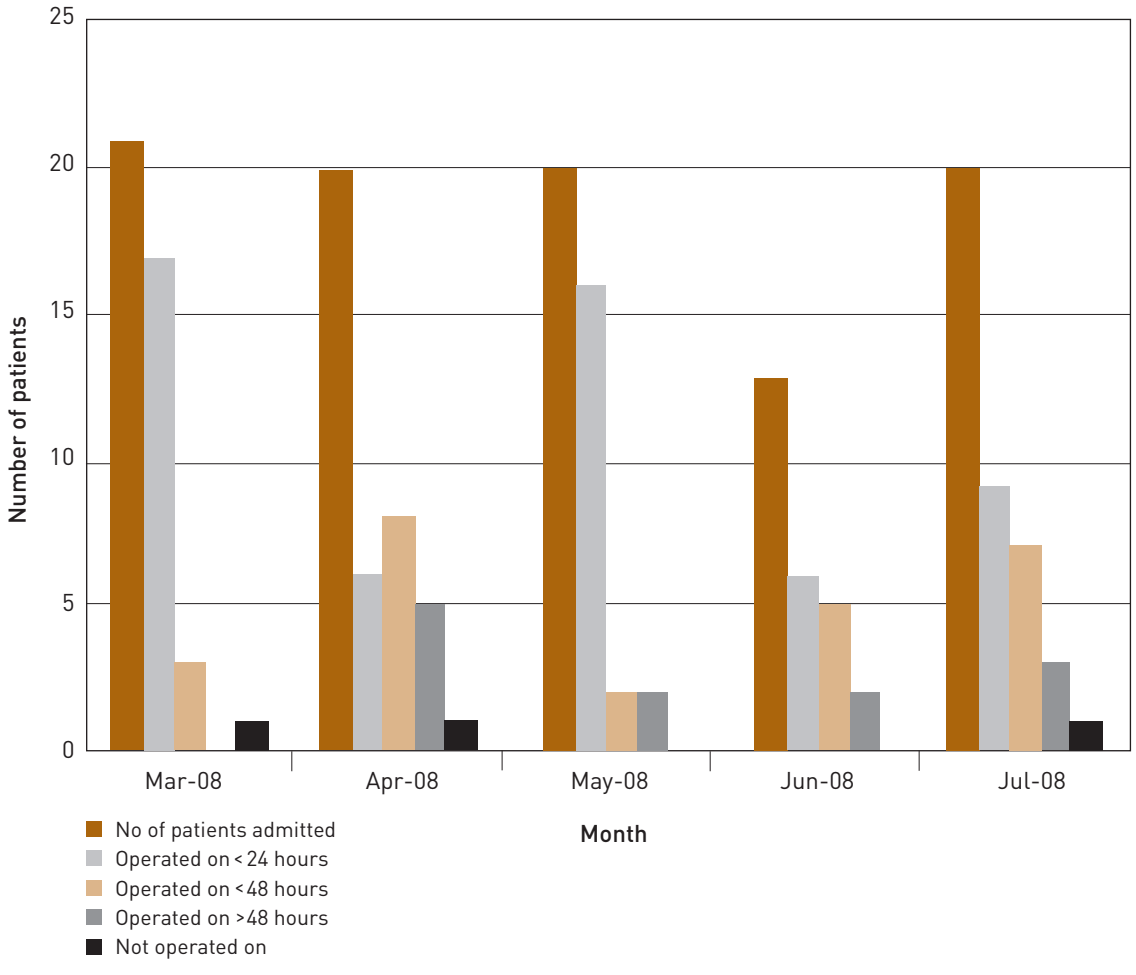
In February 2008, the trust's mortality group reviewed two cases of patients with a fractured neck of femur where the lack of emergency theatre availability was considered to be a contributing factor to their deaths. There had been a delay in surgery over the weekend. The group wrote to the theatre user group and explained that they had reviewed the deaths of two patients who were waiting for surgery. It was the view of the mortality group that this was unacceptable and that appropriate theatre provision over the weekend with appropriate staffing was needed urgently.

In our review of cases, we also identified a patient who had died after a delay of three days before they had an operation on their fractured hip.

At the meeting of the mortality group in May 2008, it was reported that surgery within 24 hours of admission for fractured hip during the week was being achieved but that there were problems at weekends. It was reported that 86% of patients requiring surgery were operated on within 24 hours.

This issue had not been resolved during our visits in the summer of 2008 and we highlighted our concerns to the trust.

Figure 3: Time to operations for patients with a fractured neck of femur (hip), March-July 2008



We were also told by many staff that, when patients had to wait for their operations, often being scheduled and then cancelled, their drugs, fluids and food were stopped for long periods. Sometimes a patient's operation might be cancelled four days in a row, and they would receive 'nil by mouth' for most of the day, four days running. We refer later in this report to a case where a patient did not have medication for a heart condition for three consecutive days.

Another concern related to trauma patients was the lack of regular input from an ortho-geriatrician. These are specialist consultants who advise on the medical management of older patients who are awaiting, or have had, orthopaedic surgery.

The undated protocol for the medical review of patients with fractured hip identified that patients had a delayed 'patient journey' due to the lack of medical management.

A senior trainee told us that this was the first hospital they had worked in without daily input from an ortho-geriatrician. The consultants reported that they had been trying to get the matter resolved. One said that they also needed more dedicated ortho-geriatric input for patients post-operatively. There had been only limited input from an ortho-geriatrician twice a week, although the trust was attempting to improve this.

Findings of fact on time to operation

- There was no system for prioritising operations for emergencies at weekends.
- Delays in operations were quite commonplace, especially for trauma patients at weekends. In some cases, the delays had contributed to poor outcomes.
- Between March and July 2008, an average of 56% of patients with broken hips were operated on within 24 hours.
- There was little input and advice from specialist ortho-geriatricians.

Theatres

We noted several references in the minutes of the trust's board to inefficiency and under-utilisation of theatres. There had been a number of reviews of theatres in recent years, including one report to the hospital management board in March 2006. The new theatre manager provided a report to the private section of the board in August 2007, which was described as "disturbing". It stated that the establishment was too low, there was a deficit in training and a high level of sickness. There was a report on theatre utilisation in March 2008 by a consultancy firm, which included a recommendation that reports from the theatre should be amended to include reasons for delays and cancellations, and what corrective action was to be taken. The problems were still apparent during our visits in the summer of 2008. We have already noted the lack of a process to prioritise emergency operations at weekends. This led to tense relationships and occasional confrontations.

Some staff told us that operations were not realistically timed, with the likely time for the procedure being underestimated or an inadequate time being allowed between operations for giving anaesthetics etc. This led to lists running late and sometimes cancellations. Others, however, said that staff in theatre were inflexible and would not start an operation after 4pm in case it did not finish by 5pm.

We were also informed that problems on the wards with patients not being ready, or lacking an escort, contributed to late starting times and inefficient use of theatre time.

We were told that the department had lacked strong leadership and that there had been a high turnover of theatre managers, some leaving after a short period. The department also had high sickness rates. In June 2007, the rate of sickness was noted to have reduced to 9%. The minutes of the theatre users group in June 2008 recorded levels of overall sickness of 9.9%, which were noted to be the lowest for two years.

The data available about the use of theatres were very poor and we could not reconcile this information with, for example, that from Hospital Episode Statistics (HES). The trust had purchased a new system for recording such data but there were technical problems for many months, during which the system reverted to recording on paper. Particular difficulties were encountered when trying to establish volumes of specified procedures for each of the surgeons carrying them out. A number of routes were used to try and obtain this information, specifically with regards to vascular procedures over the period from April 2005 to the most recent information available.

Initial analysis of HES indicated some potential errors with regard to the surgeons recorded as carrying out vascular procedures, the majority of which would be expected to be by the trust's two specialist vascular consultants. The trust then supplied their full surgical log, which contained information about which procedure was carried out and the surgeon involved. However, this log appeared to be incomplete. For example, of 13 procedures relating to the repair of abdominal aortic aneurysm that had been identified in HES, only four could be found in the surgical log. We then asked the trust's information department whether they could supply us with the information we required. Although the information was supplied, it was incomplete due to the fact that the trust's old 'korner card' surgical log system involved the manual input of information, including the patient identifier. This led to errors and an inability to link with other information systems in the trust. Because the trust's data were poor, we could not undertake analysis of the volume of surgical work and its outcomes.

Observation of patients by staff and identification of complications of surgery

Common complications of surgery include infection or bleeding or failure of an anastomosis, which is the join between two tubular structures. Surgery may also result in unintended internal injury, such as perforation of part of the bowel.

Although good surgical technique should reduce these events to a minimum, if they do occur early recognition and intervention are essential. Deterioration in the patient's condition is indicated by vital signs, which should be routinely recorded. This happens by staff recording frequent observations of certain important aspects of how the body functions, including heart rate, respiratory rate, temperature and blood pressure, and responding appropriately to changes.

From our review of case notes and from the reports of inquests, there was evidence that staff on occasions failed to identify when patients were deteriorating after an operation. We have noted previously that 33 of the 51 inquests for which the trust provided summaries appeared to involve surgical patients, and many of these involved complications of operations.

We have already identified that many wards in the trust had low staffing levels. When wards are short of staff, observations may not be completed. We noted that not all nurses carried out observations properly or with sufficient frequency on the EAU or the medical wards. Some surgical patients were cared for on these types of wards. Some staff expressed concerns that patients who had colorectal surgery and those who had vascular surgery were cared for on the same ward (ward 7). This ward was described as being very busy and nurses often could not attend ward rounds.

There had also been a shortfall generally in the training of nurses.

The review of the nursing establishment found that the shortfall of nurses in surgery was 30 whole-time equivalents. Generally, the surgical nurses were thought to be more skilled in identifying patients whose condition was deteriorating. However, some of the doctors in training were also worried about whether all the nurses on the surgical or trauma wards were good at recording and responding to observations. This included using the modified early warning score (MEWS).

The lack of review of cases where complications occurred meant there was little opportunity for such shortcomings to be identified and addressed.

Findings of fact on theatres and on observations of patients by staff

- There was a long history of concern about under-utilisation of theatres.
- There had been several theatre managers between 2005 and 2008.
- There were high levels of sickness among theatre staff.
- There were concerns about the monitoring of patients whose clinical condition was deteriorating, especially on the EAU and the medical wards.
- The data available on the use of theatres and surgical volume were very poor, and prevented us from undertaking further analysis.

Some specific issues: anticoagulation and the management of pain

These issues are not solely confined to surgical patients, but they are important aspects in the care of patients having operations, so we consider them here.

Anticoagulation

Anticoagulation (also known as thromboprophylaxis) involves the prevention of life threatening blood clots in the veins of the legs and pelvis. When these clots dislodge, they are an extremely common cause of death of patients in hospital and are largely preventable. They are said to account for between 25,000 and 32,000 deaths in the UK every year.

In 2007, the National Institute for Health and Clinical Excellence reported that deep vein thrombosis (DVT) occurs in more than 20% of surgical patients and in more than 40% of patients undergoing major orthopaedic surgery. Most of these thromboses are minor; the blood clot itself is not life threatening, and often does not cause any symptoms. But if the blood clot comes loose, it can travel in the bloodstream to the lungs and cause a life threatening obstruction; this is called a pulmonary embolism. Pulmonary embolism following lower limb DVT is the cause of death in 10% of patients who die in hospital, many of them after surgery.

At the meeting of the hospital management board in October 2005, it was noted that anticoagulation was not robust in the trust. In April 2006, the trust conducted an audit of anticoagulation in acute surgical admissions to determine whether it was prescribed and applied properly according to surgical guidelines. The results showed that 60% of patients did not have special stockings according to the guidance and 17% of patients did not get the right drug.

We were told that, in April 2008, the trust decided to follow NICE guidelines produced in 2007 on preventing venous thromboembolism. However, some consultants told us that the prescribing of two of the main drugs for preventing clots continued to be at variance with the guidance for inpatients.

An audit of all inpatients started on warfarin from January to March 2008 (following the Anticoagulation Alert 18 from the National Patient Safety Agency) was presented at the surgical governance meeting in September 2008. It showed that an unacceptable number of patients had not been treated according to the protocol – only 10% of patients at Cannock Hospital and 30% at Stafford Hospital had been treated appropriately. The audit also found that there were three different anticoagulation prescription sheets in use in the trust.

Relief of pain

Patients and relatives who came to see us were concerned that, in many instances, patients had not been given timely or adequate relief for their pain.

One said: "After the operation, on ward 6, he was in a lot of pain, but the nurse said he should not be, as he had an epidural. He was given paracetamol intravenously, although this did not provide adequate pain relief. Apparently, morphine had been prescribed but

was not given. Three days later, it was found the epidural was sited wrongly. At the inquest, it was also noted that he did not receive adequate pain relief for the first three days following the operation and that morphine was prescribed but not given."

Another said: "Her mother was not on pain relief as far as she and her husband were aware. They recall that she was sometimes screaming with pain."

We noted that, at the meeting of the clinical governance group in November 2006, there were two to four complaints a week about poor control of pain.

It was difficult to establish if there was a specialist service to advise ward staff on the management of pain. There had been previous recommendations that such a service should be developed and, at various times, a group had been set up to consider how to achieve this. One or two staff thought there was an acute nurse for pain, while a larger number said that there was no dedicated nurse or specialist team for pain. The trust informed us that one of the advanced practitioners had taken on this role, that one of the consultant anaesthetists led on the management of pain, and that the critical care outreach team also gave support.

There was also considerable confusion among staff as to whether there were protocols in the trust for the assessment of pain and provision of pain relief. Some staff said that there were no such guidelines for the relief of post-operative pain. One nurse said that they had protocols on pain relief and pain scores, but that an audit showed that the pain scores were not always filled in, although this was improving.

In January 2007, an audit was undertaken on training on the management of pain. The aim of the audit was to determine whether the suggested standards for this training were being met. The standards of the Royal College of Anaesthetists in 2006 were used as the benchmark. The results were that the standards were not met by either junior doctors or nurses and that the trust was in the same position as in the previous audit of 2003.

In June 2007, the clinical quality and effectiveness group noted that little progress had been made by the "pain group" in improving the management of pain.

Several members of staff told us that low levels of staffing were an important factor in delayed relief of pain for patients. Some staff felt that there were not enough people on the ward who were competent in the assessment and management of pain, and a lack of nurses on the wards to dispense it in a timely manner. It was also said to vary with the number and mix of doctors on duty. Nurses said it was often difficult to get junior doctors to prescribe medication for pain relief at weekends, because of the scarcity of doctors available.

Findings of fact on anticoagulation and the management of pain

- In October 2005, the hospital management board noted that anticoagulation was not robust in the trust.
- In September 2008, an audit found that only 30% of patients had been given warfarin in accordance with the trust's protocol.
- The clinical quality and effectiveness group learned in November 2006 that there were two to four complaints a week about the poor management of pain.
- An audit in 2007 found that there had been no improvement in training on the management of pain.

Governance in the surgical division

Sources of evidence

- Interviews with staff past and present
- Trust documents including audits, and minutes of meetings

- External reports, for example a review by the Royal College of Surgeons
- Case notes and reviews of case notes

We have already noted the lack of departmental protocols in general surgery. There was also no protocol on how to prioritise patients on the emergency operating list out of normal hours.

The trust was asked to provide a summary of all clinical audits in the three-year period of the investigation. Of the 25 summaries provided for the surgical division, 19 were new audits and six were re-audits.

There were 11 audits that had a proposed re-audit date before January 2008. None of the proposed re-audits had been undertaken. This included audits on subjects such as the prevention of clots in the veins of the legs (anticoagulation) and the management of pain. We have already noted that the finding of an audit on the management of pain in 2007 showed that they were in the same unsatisfactory position as the previous audit in 2003.

In 2005, an audit was undertaken on laparoscopic cholecystectomies (an operation to remove the gall bladder using a small incision and laparoscope) to compare the trust's results against recently published results. This was because there had been concerns about the outcomes of this operation. The audit suggested that the trust's results were comparable to the published data. However, because of the small number of operations, the conclusion was not robust. The audit summary stated that the trust needed to continue with the audit to make it robust. However, no further audit of these operations had been undertaken in the following three years. This was despite a review by the Royal College of Surgeons in 2007 making a recommendation on the importance of audit in this area.

We received many comments from staff on the unsatisfactory state of audit in the surgical division. There was no systematic approach to selecting audits and, for example, no audits had been carried out on correct site surgery.

The meetings that were often referred to as "audit meetings" in the surgical division were meetings usually involving only medical professionals. They were also referred to as the mortality and morbidity meetings and included reviews of selected cases. On occasions, audits were presented. The meetings were described as being "closed door" and informal. No minutes were taken and there was no systematic way for any findings or lessons to be incorporated in the divisional governance or more widely in the trust. The attendance by consultants at these meetings was described as poor. One trainee told us there had only been one of these meetings in orthopaedics within three months.

We noted one case of a patient with multiple complications following several operations that involved different surgical specialities. An inquest had occurred, but this case had not been reported as an incident nor discussed in any formal hospital setting.

One of the alerts that the trust received related to cases coded as operations involving the jejunum. This alert was received in the summer of 2007. In October 2007, four deaths were examined and the review concluded that death was inevitable in each case. The review noted that one patient, who had heart problems, had been "nil by mouth" for three days pending an operation and during that time had received none of their usual medication for their heart.

One of the two recommendations made was that the surgical division needed to review the management of medical problems in surgical patients who were nil-by mouth. This was to be considered by the surgical clinical governance group and reported back to the next clinical quality and effectiveness group.

By March 2008, the surgical clinical governance group had still not discussed the jejunal deaths and the recommendation, and no action had been taken. At that time, there was no further report to the clinical quality and effectiveness group. The deputy medical director, a senior consultant surgeon, told us

that the forum in the surgical division that could have been used to discuss the jejunal reviews would have been the mortality and morbidity meetings, but these meetings did not necessarily discuss individual cases that warranted specific attention. At the end of 2008, over a year after the problem was identified, the matter of 'nil by mouth' and medication had not been resolved satisfactorily.

Two of our advisers reviewed these cases and considered that while the deaths may have been inevitable, there were other concerns that should have been addressed. These included the lack of a timely review of these patients by a consultant. We noted earlier in this report the importance of early assessment by a senior doctor. Another involved the prevention of life threatening blood clots in the veins of the legs, which can be the cause of fatal pulmonary emboli. This matter has also been referred to earlier in this report.

The post of head of the division of surgery had been held consecutively by two consultant anaesthetists and the clinical lead for governance in the division was also an anaesthetist.

We noted relatively poor attendance by consultants at the meetings of the surgical governance committee. For example there were at least four meetings in 2008 where only two consultants attended. There were two meetings in 2007 where only one consultant was present.

The trust requested a review by the Royal College of Surgeons in 2007 because of concerns about aspects of surgical practice. The review noted that there were poor working relationships and no cohesion in the department of surgery. We were also told in interviews, including by consultant general surgeons, that relationships were generally poor among the general surgeons. The trust had taken some steps to address this; but it was too early to assess the success of these measures. Little benefit had as yet been demonstrated.

In addition to poor relationships between the consultants, there was little evidence of multidisciplinary teamwork. The meetings to consider mortality and morbidity were only attended by doctors. With regards to meetings in the division, their focus had been on mortality and morbidity rather than audit, they were not well attended or multi-disciplinary, and minutes were not taken.

We observed that, of the eight items on the risk register for surgery in April 2007, seven were still on the register a year later. The items included issues on staffing, finance, targets and capacity.

Findings of fact on governance in surgery

- There were poor relationships between the consultants in general surgery and little evidence of multidisciplinary teamwork.
- There were no common management protocols in colorectal surgery.
- Re-audits had not been carried out, even when recommended by the Royal College.
- Reviews of notes of patients who had died were not sufficiently rigorous, and failures were not identified and rectified.
- Opportunities were missed to learn from cases that had been the subject of inquests. These included the lack of a timely review by a senior doctor.
- When concerns were raised, lessons were not translated into action.
- There was no system in place to identify failure or to assure quality of care.

Provision of critical care (intensive care) beds

The critical care unit (CCU) had 12 beds: six beds for high dependency patients and six for those needing intensive care. They were run flexibly depending on the needs of patients in the unit.

Because there were usually only six staff on duty and 1:1 or 1:2 staffing was required for intensive care or high dependency patients respectively, this meant that the most number of beds used was between six and eight.

The CCU had been funded for seven nurses per shift but, due to long-term sickness and redeployment, this dropped to six per shift. This applied for most of the period of this investigation. In July 2008, extra funding was allocated to recruit 5.5 whole-time equivalents.

Some members of staff said that beds were closed or were unavailable because staffing numbers were inadequate. Winter, particularly Christmas time, was reported to be difficult.

A report from the surgical division to the clinical quality and effectiveness group in January 2008 said that a high number of critical care patients had to be transferred to other units because of a lack of beds. We were also told about disagreements between clinicians about which patients could go to the unit, and about access to advice from medical staff in critical care. On one occasion, this had resulted in a serious incident.

Many staff said that there was insufficient capacity in the CCU, mainly because of lack of staff. When there was no bed available, very sick patients, such as ventilated patients, were on occasion taken from other wards to the recovery area of theatres until a bed on the CCU could be made available. In this area, the anaesthetist stayed with the patient because the recovery staff were not trained to look after intensive care patients. This could have an effect on other operations performed out of normal hours. These patients could come from theatre, the EAU or A&E.

When this happened, the patient was usually in recovery for a few hours or overnight. If this was at the weekend or out of normal hours, then operating had to stop as the anaesthetist was looking after the patients.

There was concern from staff on the CCU that, if they accepted a patient on the high dependency unit before they transferred another patient to a ward, the nurse to patient ratio on the unit was reduced, which was unsafe. If a patient had to wait in the EAU for a bed on the CCU, this was when a decline in the condition of the patient was likely to occur.

We were also informed that there was frequently a problem finding a bed on the general wards in order to transfer a patient from the CCU. This sometimes meant the patient stayed in the high dependency unit longer than necessary, which in turn made access to the high dependency unit difficult.

We noted from interviews and case notes that record-keeping and multidisciplinary teamwork were good on the unit. Patients and relatives were also full of praise for the care received.

Some staff were also concerned about the capacity of the general wards to care for patients transferred from critical care. The trust had a team to provide outreach from critical care. The team consisted of predominantly critical care nurses, one full-time and two part-time. They provided a service from 9am to 5pm from Monday to Friday. They advised and supported ward staff who were concerned about a deteriorating patient. They also followed up patients who had been discharged from the CCU and they provided some formal and informal education and training. The surgical nurses were said to be more receptive to the outreach team, although acute medicine had a higher number of patients requiring critical care support than surgery.

The main concerns of the outreach team were that observations were not being performed on the wards and the slow progress made with the MEWS scores. Numerous incident forms were said to have been submitted about this.

Findings of fact on critical care

- At times there were too few staff to open a sufficient number of critical care beds. There was some confusion and tension about access to medical advice when beds were not available.
- The critical care outreach team operated from 9am to 5pm Monday to Friday.
- The critical care staff had noted a decline in standards of nursing care on the wards since the reconfiguration and loss of staff.
- There had been occasions when very sick patients were looked after in the recovery area by an anaesthetist until a CCU bed could be made available. This had an effect on operations out of normal hours.

Healthcare-associated infections and the control of infection

We considered the control of infection, since it is an important aspect of the quality of care, and healthcare-associated infections can be a significant cause of death of patients in hospital.

Sources of evidence

- Interviews with staff past and present
- Interviews with patients and relatives
- Data about rates of infection from the Health Protection Agency
- Trust documents, including the infection control annual report, minutes of meetings, and data about rates of infection
- Complaints

The arrangements for the management and accountability for infection control

In December 2003, the report of the Chief Medical Officer stated that every organisation providing NHS services must designate a director of infection prevention and control (DIPC). The guidance that followed said that the DIPC would have overall responsibility for creating a culture in which effective hygiene is the norm and infection control is everyone's business. The DIPC would report directly to the chief executive and the trust's board.

The role of DIPC was first held by the previous director of nursing at the trust, who left in July 2006. The newly appointed medical director took over the role in September 2006. There was no reference to this appointment in the minutes of the trust's board, despite the importance of the role. The new director of nursing acquired the role in August 2007. The new management arrangements were presented to the board, although not detailed in the minutes. The rationale for the second change was that, nationally, infection control was being driven from the office of the Chief Nursing Officer and also because the infection control nursing team were coming to the director of nursing for professional guidance.

Since the director of nursing became the DIPC in August 2007, she had reported regularly to the trust's board.

During 2006 and 2007, the infection control team consisted of two consultant microbiologists and two infection control nurses. There had been some turnover, with the two nurses leaving and being replaced in 2007 by a matron and an experienced nurse undertaking training in infection control. The team met regularly, usually weekly.

We noted that, during 2005, the previous DIPC was frequently absent from meetings of the infection control committee. She explained that this was because she could not always make the meetings. She reported that she met regularly with the lead microbiologist. The infection control committee was scheduled to meet every three months, but did not always do so.

In August 2007, the arrangements changed and the steering group for infection prevention and control was established. The chief executive chaired the new committee and it met monthly. It included a wider membership and had more members of the executive team and senior management.

One of the responsibilities of the DIPC is to produce an annual report on the state of healthcare-associated infection and release it publicly. In most trusts, the mechanism for this is to take the report to a public meeting of the trust's board. There was no evidence that an annual report on infection control had ever been taken to a public meeting of the board.

The medical director provided us with a three-page annual report for 2005, but there was no record of this being taken to the board. There was an eight-page report that covered the period January 2006 to March 2007. This was taken to the board in July 2007, but only to the private, confidential part. Thus, for over two years, there was no public record of the state of healthcare-associated infection at the trust. Towards the end of 2007, the trust began to share information with the overview and scrutiny committee and trust governors and members. In 2008, the 40-page annual report was taken to the meeting of the board in April 2008. This was not a public meeting. However, the report was placed on the trust's website.

Cleanliness and hygiene at the trust

We have already noted that patients and relatives had very critical comments about cleanliness and hygiene. These concerns occurred throughout the three years covered by the investigation, but were particularly pronounced for the last few months of 2007. Here are some examples:

"Generally, the hospital was dirty. There were balls of dust in the corners of rooms, hallways and on the stairs. They even saw blood in the lifts and a trail in the corridors. When leaving the hospital hours later it was still there. Rubbish was stacked in the corridors, both normal and surgical waste." (2006)

"And they witnessed a cleaner coming into the room with a pink J-cloth, which she used to wipe faeces off the bed frame. She then cleaned the table, the sink, their mother's drip stand and the cupboard next to the table with the same cloth." (2007)

"Their mother was moved into a side room. It smelt terrible and obviously had not been cleaned. Dirty washing was still in there on the en-suite, the bin was overflowing and the sink smelt terrible. The dirty washing was still there 24 hours later – they took it out. They didn't wash off her nighties before giving them to the family to wash. On one occasion, a cleaner just came in and poured bleach down the sink. On another occasion, syringes were just left by the sink. An empty tablet packet was on the floor. They left it to see if it would ever get cleared up; after a week it had not." (2007)

At the meeting of the infection control committee in October 2005, it was noted that the wards were struggling to meet the hygiene standards. In December, it was noted that "environmental cleanliness was not being maintained".

The minutes of the meeting of the infection control team in January 2007 noted that a complaint regarding a patient on ward 11 was going to the local press. The complaint was thought to be due to blood splashed on a wall, but the team noted it had also highlighted issues regarding standards of care on the ward.

The minutes of the infection control committee in December 2006 noted the need to replace damaged commodes and to improve isolation facilities. The report covering the period January 2006 to March 2007 stated that the audit of the kitchen, environment and equipment continued to highlight the ongoing issues related to cleaning. However, the report stated some improvements had been demonstrated during the audits that were undertaken during this period.

The Healthcare Commission found the trust to be compliant with regard to the hygiene code when it inspected the trust in January 2007. At this time, the check was mainly of documentation.

An audit of commodes in August 2007 found that approximately 35 commodes needed replacing. It was noted during the audit that up to 50% of the commodes were soiled with faeces. The audit noted that this highlighted a training issue, which the company conducting the audit would provide. The commodes were replaced in December 2007 and a subsequent audit in May 2008 found that 37 out of 46 were clean.

In March 2008, the Department of Health team for cleaner hospitals noted improvements since their visit in October 2007.

When we visited the trust in February 2008, we found that many of the wards and other areas had damaged floors and some were grubby and stained. At that time, many parts of the hospital that we visited appeared scruffy. On the medical wards on floor two, every door to every single room being used for isolation was left open.

During our subsequent visits, we found that cleanliness and hygiene had improved.

Findings of fact on infection control arrangements at the trust

- The trust had three DIPCs in just over a year. The first did not regularly attend the infection control committee.
- Patients and relatives who contacted us were very critical of standards of cleanliness and hygiene at the trust, particularly in 2006 and 2007.
- The trust was found to be compliant with the hygiene code in January 2007.
- From August 2007, the chief executive chaired the steering group for infection prevention and control. It had a larger membership and met more regularly.
- Although a requirement since 2004, there was no public record of infection control at the trust in the form of an annual report until April 2008, when one was put on the trust's website.
- The Department of Health team for cleaner hospitals noted improvements in infection control between October 2007 and March 2008.
- We observed an improvement in cleanliness and infection control between February and September 2008.

Prescribing of antibiotics

Careful consideration needs to be given when prescribing antibiotics, for two main reasons. One is to prevent the unnecessary prescribing of these drugs and reduce the development of resistance by bacteria. The other is to avoid, wherever possible, the types of antibiotics which are particularly likely to put patients at risk of developing *C. difficile* infection.

In December 2005, the Chief Medical Officer and Chief Nursing Officer wrote to all trusts asking them to review their policies for antibiotics. Many senior staff conceded that changes in the prescribing of antibiotics at the trust had been protracted. We were told that there were discussions in different forums, such as the medical division and the medicines management group, but these were slow to achieve change. Although policies had been produced, these had not been adhered to. The protocol for managing antibiotics was dated September 2007.

One of the reasons put forward for the slow progress was resistance from the medical professionals. Doctors in training and some other staff said that they were often told which antibiotics to use by the consultants. They said that, in reality, it was the consultants who made decisions on which antibiotics to use, and consultants sometimes deviated from the guidelines and used medications of personal preference.

The pharmacists that we interviewed were concerned that there were too many policies for antibiotics and that the policies were not easily accessible. They thought that you had to "hunt" for them and that generally they were not being widely used.

One of the pharmacists had, as part of their job description, the role of antibiotic pharmacist. Unlike many other trusts, there was not a pharmacist dedicated to each ward. Staff mentioned that pharmacists checked prescription sheets and had begun to deal with non-compliance, that is those not prescribing in accordance with the guidelines. A junior doctor, however, said that they had not had any feedback on their prescribing, in contrast

to their previous post. We were told that pharmacists could only help if they had extra resources so they could be involved on the wards.

We noted that, in September 2007, the surgical division governance meeting learned that doctors in colorectal surgery had not complied with the policy for antibiotics and there had been three cases of *C. difficile* in that month. In November 2007, the steering group on infection control noted that the antibiotic policy was still rated "red". In April 2008, an audit found that most intravenous antibiotics were being given according to the policy, but 15.8% were not.

The trust's own root cause analysis of cases of *C. difficile* carried out in 2008 suggested that antibiotics played a major part in predisposing patients to this infection. The steering group strengthened the protocol and compliance has improved.

We were also told that it was not unusual for there to be a delay in the administration of antibiotics and for doses to be missed.

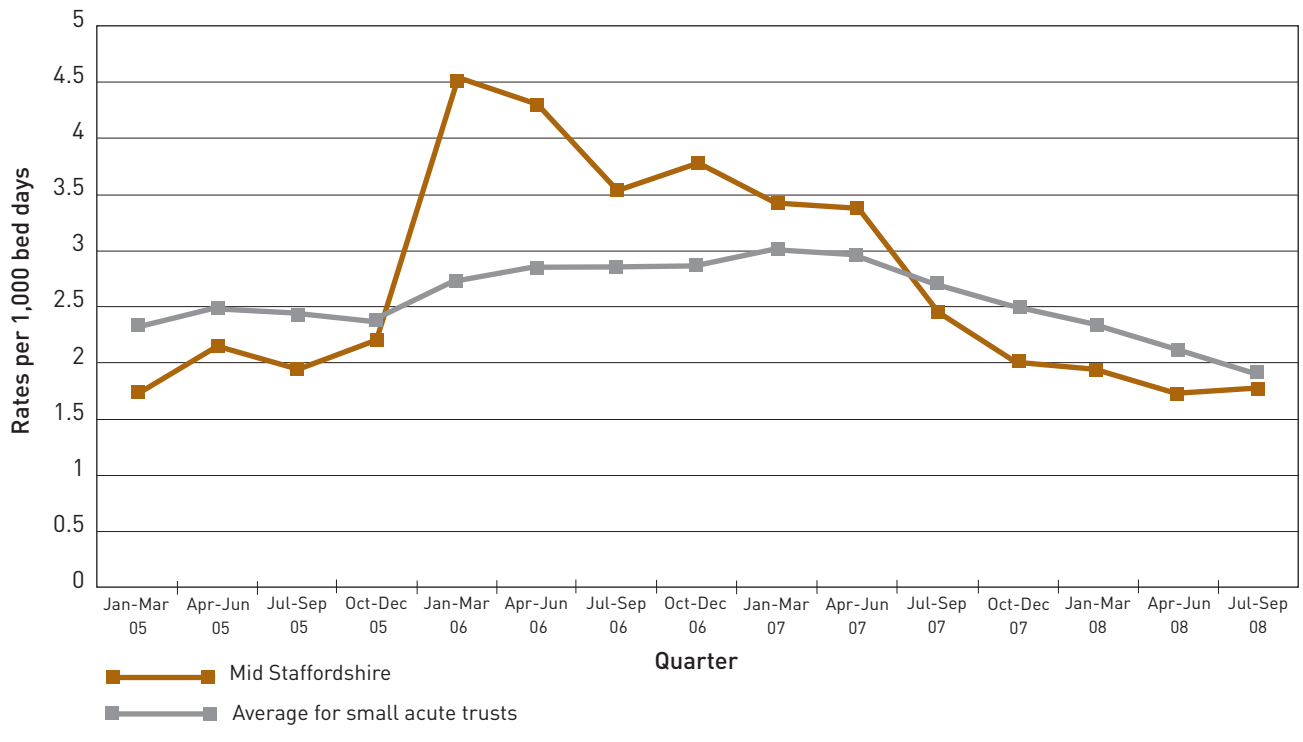
C. difficile

Clostridium difficile (C. difficile) is the major cause of serious bacterial infectious diarrhoea acquired in hospitals in the UK and is a very unpleasant illness. The death rate associated with *C. difficile* infection has been estimated to be 6.9% at 30 days after diagnosis.

The figures for 2005/06 show that, in January 2006, there were 48 new cases of *C. difficile* at the trust. The previous three months had shown a consistent number in the high teens, with an average of 18.

It is evident there was a significant increase in the rate of cases of *C. difficile* in the early months of 2006. Figure 4 identifies this clearly. Such a rise is strongly suggestive of an outbreak. At least some of these cases were cross-infection, where *C. difficile* was transmitted from one patient to another. The rate stayed high in 2006 and it also appears that there was a smaller outbreak later in that year. Figures from the Health Protection Agency show that, in 2006, the trust had the

Figure 4: *C. difficile* rates at the trust per 1,000 bed days by quarter, January 2005-September 2008



sixth highest rate out of 32 similar trusts. There had been a decline in the rates since the last three months of 2006.

The trust's board minutes did not contain any reference to *C. difficile* in any of the meetings from 1 December 2005 to 8 August 2006. During this time, there was one reference to concerns being raised about cleanliness in the hospital. When the report of the Healthcare Commission's investigation into outbreaks of *C. difficile* at Stoke Mandeville hospital, part of Buckinghamshire Hospitals NHS trust was published in July 2006, the trust's board did not discuss the report.

There was evidence that the infection control team was aware of a sharp rise in cases, but this was not described as an outbreak or reported as such. The meetings of the control of infection committee were only quarterly. In March 2006, the minutes record that there was an awareness of the rise in cases in January. The infection control team developed an action plan and took steps to isolate patients, improve cleaning and control the prescription of antibiotics.

A surveillance report was compiled in the summer of 2006, which stated that during November and December 2005 there had been 18 and 19 cases identified respectively. In January 2006, this had risen to 48 "sporadic cases" being reported. It concluded that "analysis of surveillance data did not indicate an outbreak". However, as the cases had not been typed (that is, categorised into specific types of *C. difficile*), this conclusion could not be drawn. Even if none of the cases were linked, an increase in cases of this proportion should have been reported to the Health Protection Agency, the SHA and the trust's board. At the meeting of the committee in March 2006, the representative from the Health Protection Agency asked if outbreaks and ward closures were reported to the SHA. The previous DIPC replied in the affirmative, but neither had been reported.

The usual practice would be to establish an outbreak committee, involving estates and facilities as well as management and clinical staff. This did not happen. The surveillance report found:

- Delays in sending samples for testing prior to *C. difficile* toxin being detected.
- Limited evidence of review of antibiotic therapy.
- Delay in commencing appropriate treatment for patients that showed symptoms.
- Poor documentation and communication between nursing and medical staff regarding patients that showed symptoms.
- Poor communication with infection control when patients' symptoms were not improving.
- Patients not being nursed in isolation due to lack of side rooms.
- Inadequate cleaning of commodes, bedpan holders and slipper pans between patients.

As we have noted, an action plan was developed and the microbiologists and infection control nurses acted to instigate the isolation of infected patients and address the identified problems. However, none of the deficiencies in practice were drawn to the attention of the trust's board.

The 'annual' report of infection control that covered this period spanned from January 2006 to April 2007. Therefore the 'outbreak' period was covered by an annual report over a year later. The report did not go into detail beyond mentioning the figures for *C. difficile* and noting that an action plan was implemented in March 2006. This report did not use the word 'outbreak' or highlight the problems that were found, and it was not released publicly.

A former member of the patient and public involvement forum (PPIF) commented that it was difficult to obtain information from the trust on *C. difficile*. He felt this should be in the public domain. He obtained a copy of the infection control minutes for the meeting on

21 September 2006, which recorded that there had been 341 cases in total, of which 285 were inpatients, averaging 36 per month between January and September 2006. The minutes were not marked as confidential. When this information was released by him to a newspaper, he was expelled from the forum for breaching the code of conduct of the PPIF. He told us that the chair of the trust met with the chair of the PPIF and said that confidential documents would not go to the PPIF any more. The chair of the PPIF stated that, following this incident, matters of a confidential nature were then given to him by the trust's chair for onwards transmission as deemed necessary. These events were after the publication of the Healthcare Commission's report into outbreaks of *C. difficile* at Stoke Mandeville Hospital, part of Buckinghamshire Hospitals NHS trust, which had criticised that trust for lack of openness about outbreaks.

Over the summer of 2006, the committee for the control of infection did not meet for six months, despite continuing high levels of infection.

Since the end of 2006, the rates of infection with *C. difficile* declined steadily and by mid-2008 were lower than the average for similar trusts. However, the control of prescribing of antibiotics proved difficult, as previously considered. Root cause analyses of cases of *C. difficile* in 2008 still showed some cases to be associated with the prescription of inappropriate antibiotics.

MRSA

During the timeframe of the investigation, that is from April 2005, the rates for MRSA showed large fluctuations, with two peaks. One was between July and September 2005 and the other between January and March 2007.

The trust missed its target for the agreed maximum number of MRSA bacteraemias in both 2006/07 and 2007/08. However, the rate has shown a general decline since January 2007.

Findings of fact on antibiotic prescribing, *C. difficile* and MRSA

- Prescribing of antibiotics was not compliant with good practice and there were no regular audits of practice until October 2007.
- There was an outbreak of *C. difficile* in early 2006.
- An outbreak was not declared or reported, and an outbreak committee was not established. An action plan was developed. The trust's board was not informed.
- A report by the trust at that time found problems with isolating infected patients, inadequate cleaning of commodes and bedpan holders, poor communication between wards and infection control, and delays in starting treatment.
- Since the end of 2006, rates of *C. difficile* and MRSA have declined.

Factors at a strategic level to reduce risk and protect the safety of patients

This chapter looks at whether senior managers at the trust had arrangements in place to reduce risk and protect the safety of patients, and the quality of these arrangements. This is considered both in general and with particular reference to emergency admissions.

The trust's approach to nursing and to levels of nursing staff

We include this section since there is considerable evidence linking the number of nurses to standards of care, particularly for emergency admissions.

Sources of evidence

- Interviews with staff past and present
- Interviews with patients and relatives
- The acute hospital portfolio reviews, 2004/05
- Observations carried out by members of the investigation team
- Trust documents, including the business case for the surgical floor reconfiguration and performance reports
- Nursing skill mix review
- Complaints
- National level of absence due to sickness, provided by the Information Centre for Health and Social Care

The previous director of nursing, who was appointed in 1998 and left in July 2006, told us that she had been committed to the development of nursing, and gave us examples of training and programmes to develop leadership among nurses. She reported that there had been considerable support for the reorganisation of the wards into clinical floors. However, many staff told us that nursing had not been valued as a profession under the previous director of nursing. We were told that many nurses and other clinical staff had been unhappy about the clinical floors programme, but that they were worried about expressing their views. Those who did raise concerns told us they had been ignored. It was reported that nurses had become too demoralised to protest.

Staff felt that the position of nursing had improved since the arrival of the new director of nursing in December 2006. They felt that nursing had a voice, that the number of nurses had begun to increase and that training was improving.

Staffing levels

In January 2002, a review of clinical governance at the trust was published by the Healthcare Commission's predecessor, the Commission for Health Improvement. It pointed out that staffing levels were a cause for concern, particularly in nursing, and that the number of nurses was low compared to other similar hospitals.

The report from the acute hospital portfolio review in 2004/05 showed a mixed picture on overall staffing levels in wards. There were some wards (11 in total) with fewer staff than the average and some with more (five in total). This was also the case for the percentage of qualified staff in post. There were also a further eight wards with incomplete data.

As we have seen earlier, the acute hospital portfolio report on ward staffing in July 2005 noted that the trust was the worst of five local trusts in terms of perceptions of nursing care.

It was the second worst for complaints about nursing care per 10,000 occupied bed days, out of 24 small acute trusts outside London.

We also noted that there was information available within the trust in 2006 and 2007 that suggested continuing concerns about nursing care. This has been covered elsewhere in the report.

We observed that, between April 2004 and May 2008, the number of nursing staff in post had never reached the number of posts in the funded establishment.

The trust had embarked upon a programme to reconfigure its clinical services when the previous director of nursing took up post in 1998. She described an innovative training programme for nurses to support the changes. An important step was the establishment of the emergency assessment unit in September 2004. The next stage, in 2005 and 2006, was to replace the individual medical and surgical wards with 'clinical floors'. This was a view of nursing taken from the United States and supported by the previous director of nursing. She viewed traditional wards as being expensive because of duplication of roles, and unnecessarily hierarchical.

She told us that the reconfiguration was primarily to improve the experience of patients and ensure that staff focused on the planning and delivery of patient care, rather than on duplicating structures and administration. She said that it was not related to the generation of financial savings. However, the minutes of the confidential meeting of the board in August 2005 referred to a saving of £700,000 from the reconfiguration. This related mainly to the closure of a ward at Cannock Hospital. We noted that one of the benefits listed in the presentation in January 2006 of the business case for the surgical floor was savings of nearly £600,000, and savings were noted of over £300,000 for the medical division.

Part of the reconfiguration programme involved a significant loss of beds. Although a reduction in staff was said not to be part of the original intention, it involved a change in skill mix. The programme was meant to involve recruiting more healthcare support workers, and some of the healthcare support workers received extra training, particularly between 2002 and 2004. Another element was the reduction in the number of qualified staff, especially on the medical wards, and particularly a 60% reduction in the number of senior sisters. The previous director of nursing stressed that this was not her intention or responsibility and did not happen during her tenure. She left in July 2006.

It appears that, whatever the original intention of the clinical floors programme, it became inseparable from the programme to make financial savings. The net result was a reduction in numbers of nurses, and a dilution of the skill mix because of the loss of senior posts and qualified nurses. Throughout the period of the investigation up to at least the end of March 2008, there were only three matrons for the entire trust, when more might have been expected for a trust of this size. As we note in the section on developments, there are now 12.

We noted that vacancy levels had been consistently high at the trust. In the trust's risk register report for 2002-2006, there was an entry from March 2005 about the general high level of vacancies. We noted several references to high vacancy levels in the minutes of the trust's board throughout 2006 and 2007, but saw little evidence that the possible risks of this situation were considered by the board. For example, in August 2005 there were 108 vacancies in nursing. In January 2007, there were 86 total vacancies, and in September 2007, 104.

The minutes of the trust's board also made frequent references to the high levels of staff sickness. In 2007/08, the rate varied between 5.44% and 6.04%. In 2004, the national level of absence from sickness was 4.6% across all trusts in England and 4.4% across acute trusts in England.

In 2006/07, the trust was in the position of having to make significant savings, like most

of the NHS that year. The trust has said it had to set a target of saving £10 million in order to achieve financial balance. This equated to about 8% of turnover. Since its largest expenditure was on staff, the trust decided that a significant proportion of the savings would have to come from reducing the number of people employed by the trust. The minutes of the trust's board and the hospital management board show the proposal was to lose 150 to 170 posts, two-thirds of them to be from non-clinical staff, such as those in facilities.

We noted from the figures for staff in post that the largest reduction in the number of nurses occurred between April 2006 and April 2007. The reduction of staff in post in that 12-month period was nearly 130 whole-time equivalent nurses. In four years, the figure declined from 2,359 in April 2004, to 2,318 in 2005 and 2006, 2,189 in 2007 and 2,157 in 2008. By April 2008, there had not yet been any increase in the number of staff actually in post, although recruitment had begun.

Between the years 2005 and 2008, there was a reduction in beds as well as in nurses. There were 101 fewer beds and 297 fewer nurses (healthcare support workers as well as qualified nurses). When analysed as the number of nurses per beds, this represents a drop from 2.95 nurses per bed at the end of March 2006 to 2.44 nurses per bed by the end of March 2008. This figure includes all healthcare support workers and nurses, including managers and matrons. In other words, it is not the physical number of nurses per bed but an indication of the nursing workforce compared to the beds available. This analysis does not take into account any change in the dependency of patients, although this was unlikely to have decreased.

We have previously noted that there was only one band seven nurse for the 78 beds on floor two, one for A&E, and only three matrons for the entire trust.

Although problems about the standards of care were evident through reports on complaints in early 2007, the trust did not take any action to increase the number of nurses in 2007/08. In February 2007, the minutes of the board stated that the "improvement in the numbers would continue".

At the meeting of the governance executive group in March 2007, the group received a report that showed that there had been 40 formal complaints in February, compared with 14 in January. The main categories related to basic nursing care. However, the only discussion reflected in the minutes related to response times to complaints, not about the poor standards of care raised by the complaints. This meeting commented on the result in the national patients survey that showed the trust did not perform well on cleanliness. But the minutes did not mention that the survey also showed the trust to perform poorly on the question about there being enough nurses to provide care.

Also in March 2007, the clinical quality and effectiveness group received a report from the medical division that there had only been two nurses on floor two to look after 40 patients.

A senior consultant told us that staff in critical care had observed changes in the quality of care on the wards at this time, due to the reduction in the number and levels of experience of nurses. He had made his views known through correspondence with directors and heads of departments.

In May 2007, the private part of the trust's board noted that the trust had scored badly in the national NHS staff survey. In particular, only 27% staff said they would be happy with the standard of care provided as a patient.

In response to a complaint about nursing care that it had investigated, the complaints department of the Healthcare Commission wrote to the chief executive in July 2007. The letter recommended that the trust considered reviewing the nursing establishment and skill mix to ensure the staffing levels were adequate for the workload and patient dependencies. At this time, the review of skill mix had already been commissioned by the new director of nursing.

The report on incidents that went to the clinical quality and effectiveness group in December 2007 showed that there had been 93 incidents reported about staffing levels between July and September 2007 and the figures for October and November were similar.

The need for a review of the skill mix and numbers of the workforce was included in the business plan for 2006/07, to be completed by November 2006. The trust has now told us that this was a wider review of skill mix related to the reduction of the workforce. When the new director of nursing took up her post in December 2006, she identified that it was important to ensure a thorough and independent review of the nursing establishment and skill mix. This was in the business plan for 2007/08 and was carried out between August and December 2007. It was conducted by a nurse acting as an independent adviser to the trust.

The results were taken to the meeting of the board of directors in March 2008. The review found an overall deficit of 120 whole-time equivalents. The surgical division had a staffing gap of 30.3 whole-time equivalents, while in the medical division the gap was 76.8 whole-time equivalents.

The review also noted that there was a need to reduce sickness levels and to slow down turnover to ensure staffing levels were maintained. The review proposed a £1.7 million investment in the nursing workforce. Recruitment began in January 2008.

In the interim, before the review was completed, a 'virtual ward' was set up in October 2007. It consisted of seven whole-time equivalent nurses, managed by the corporate nursing team. The nurses were not newly qualified and could be moved to wherever necessary, or slotted into vacancies on wards so that they could be used instead of agency staff. Nurses that we spoke to did not mention this as having made a significant difference to staffing problems at that time.

At the meeting of the board of directors in March 2008, a question was asked as to whether the board had been right to reduce the number of nurses at the time of the reduction of the workforce. The response was that they did not believe that the £10 million had had a big effect on what was an historic issue. The board noted that difficulties had arisen due to the combination of turnover, sickness and difficulty in recruiting, and asked that more focus be given to the speed of recruitment. The board approved an increase from three to 12 matrons and they have said they also approved a senior nurse for wards 11 and 12, to allow closer monitoring of the standards of care and improved leadership at ward level.

Findings of fact about the trust's approach to levels of nursing staff

- In 2002, the review of clinical governance by the Commission for Health Improvement pointed out that the number of nurses was low compared with other similar hospitals.
- In 2005, the trust had more wards with below the national average number of nurses than wards with above the average, by almost two to one.
- The combination of the programme to create clinical floors and the cost saving programme in 2006/07 led to a reduction in the number of nurses in post, and the proportion of senior nurses.
- Vacancy and sickness levels were high from 2005 to 2008.
- Although there was evidence early in 2007 about the effect of low staffing levels, the trust did not act to increase the number of nurses in 2007/08.
- A review of the nursing establishment and skill mix was undertaken in the autumn of 2007.
- The review found a shortfall of 120 whole-time equivalent nursing posts.
- In March 2008, the trust agreed to invest £1.7 million in the nursing workforce.

The trust's arrangements for managing risk

Although our main focus was on the care of patients admitted as emergencies, we also reviewed the trust's systems for the management of clinical risk. These should allow trusts to identify potential risks and take timely action to prevent harm. Members of the trust's board should be aware of any significant risks to the safety and wellbeing of patients and take action accordingly to manage the risks.

A risk register is a way for trusts to record and grade risks in terms of their seriousness.

At the meeting of the hospital management board in July 2006, it was noted that nothing was being recorded on the risk register. Staff also told us that the register had been inadequate, out of date and rarely used, before the summer of 2006.

We reviewed the trust's risk registers as they stood at the end of March 2006, 2007 and 2008. The earliest version covered a period from 2002 to October 2006; relatively it contained fewer entries and was of a different style, with different details from later registers.

The 2007 and 2008 registers contained some entries that correlated with the issues that are part of this investigation. For example, the 2007 register contained an entry regarding the inability to ensure that there were safe levels of staff in clinical areas during workforce reconfiguration, leading to a potential reduction in the quality of care.

The 2008 register contained more entries, including:

- "The cost improvement programme leading to a shortfall of staff on EAU which the bank cannot fill. Has led to complaints and compromising patient safety and possibility of serious untoward incidents reoccurring."
- "Inability to meet NICE guidance for patients needing non-invasive ventilation due to lack of suitably trained staff."
- "There are no portable suction machines available across the trust as the existing equipment was condemned."
- "Failure to deliver adequate and timely care to patients in A&E that need surgical or orthopaedic interventions due to reduced surgical cover."

From the different versions of the registers that were supplied to us and from what we were told by staff, it was evident that there had been a move to produce and review risk registers in the divisions in the trust. However, the head of governance told us that this was still not fully embedded within the divisions. We have previously noted the existence of certain items on divisional risk registers from one year to another. We had some concerns about whether the divisions had been expected to resolve problems that were partly trust-wide in nature, such as poor staffing levels.

A trust-wide panel to moderate risk was introduced to review and ensure consistency in the scoring of risks. Any risk with a score of more than 15 was added to the corporate risk register that was considered by the executive governance group and the board.

The trust supplied us with information about what the divisions had considered were the risks of the reduction in the workforce in 2006/07. We could not find any evidence that the trust had at a corporate level considered these risks.

Assurance framework

In March 2003, the Department of Health issued guidance on how to construct an assurance framework. Its purpose is to identify the principal risks to the achievement of the organisation's objectives and to identify the key controls to reduce these risks.

Internal audit informed the trust board in July 2006 that the framework had not been updated the previous year and that there had not been a regular flow of assurances to the board. There were weaknesses in design, and the inconsistent application of controls had put the

achievement of the organisation's objectives at risk. A new framework that was devised following advice from the internal auditors and input from executives was presented to the board. It had 10 key objectives: the first was to achieve financial balance, the second was to achieve the required quality of care and the third related to acquiring foundation trust status. The trust has subsequently said that the objectives were not ranked in order of priority.

In March 2007, the trust's board was presented with a framework for 2007/08. This had the achievement of quality of care standards as the first key objective; achieving financial balance and foundation trust status were the penultimate and last (of 10) objectives.

The framework for 2008/09 was presented to the board in March 2008. This was organised differently to previous years, being grouped under six strategic goals. The first of these related to being the provider of choice for acute services and included objectives to implement the outcome of the establishment skill mix review, achieve divisional cost improvement targets and improve data coding so to recover all income.

The head of governance told us that the aspects of the assurance process that related to the management of risks originally had not been fully integrated with the other aspects of governance for which she was responsible, but had recently been brought together under the director of nursing.

Systems to investigate and learn from complaints

Sources of evidence

- Interviews with patients and relatives
- Interviews with staff past and present
- Complaints
- The acute hospital portfolio reviews, 2004/05
- Information and analysis of second stage complaints
- Report of the internal auditors on complaints
- Trust documents, including minutes of meetings

In July 2005, the Healthcare Commission's acute hospital portfolio review on ward staffing in 2004/05 compared the trust with five other trusts in the local area. It identified the trust as being the worst for perceptions of nursing care for adult patients. It was also the worst for complaints about nursing care per 10,000 occupied bed days.

At the national level, the trust was the 17th worst in the country with a rate of 11 complaints about nursing per 10,000 beds. The most typical (median number) was 3.88. In terms of its peer group of 24 small acute trusts outside London, the trust was second worst.

Until mid-2005, the trust had a committee to review individual complaints, chaired by a non-executive director. This reviewed complaints on a quarterly basis and met with the divisions. It was described as time consuming, but it ensured that non-executives were well informed about the nature and seriousness of complaints. At that time, there were concerns about the medical wards, many about basic nursing care.

We requested copies of the trust's analysis of complaints and reports on complaints for the three years 2005 to 2008. We did not receive a complete set for 2006, as there were no reports produced for some of that period. We looked at the internal reports on complaints and found that some of these were inaccurate. For example, the attachment for January to March 2006 in the complaints section of the clinical governance report was the same document with the same information as for October to December 2005. The table in the complaints report for July to September 2007 was headed comparisons between quarter one and quarter four, but was actually a comparison of quarters one and two. The columns themselves were headed correctly. This error was repeated in the next quarter.

We noted that the graphical representation of reports sometimes did not allow important information to be easily identified. For example, the annual report on complaints for 2006/07 showed a decline of 7% in overall complaints. However, there had been a rise in complaints about inpatients (from 187 to 218), but this was masked by the substantial decline in complaints about outpatients.

Moreover, the breakdown of complaints was very limited, with 227 complaints identified simply as "all aspects of clinical care". This was the same type of analysis as was undertaken in many trusts, but was not in sufficient depth to identify specific problems. Even when there was sub-categorisation, it was not possible to determine the seriousness of complaints. Thus, the trust's board would not have had adequate information on which to assess the standards of care. We noted that, after the demise of the complaints review committee in 2005, non-executive directors had never looked at any individual complaints to get an indication of their nature. Again, this was not unusual. The minutes of the private meeting of the trust's board in April 2007 said that the executive governance group would look at the details of complaints, but this did not happen in respect of any consideration of actual complaints.

The analysis changed in later reports to include more categories. However, the categories were still very broad. The category of communication, for example, could range from minor failures of communication to serious concerns. Such broad categories restricted the usefulness of complaints as a means to learn about possible shortfalls in services.

We have noted that at the meeting of the governance executive group in March 2007, the group concentrated on the response times, not on the poor standards of care raised by the complaints. This meeting also commented on the result in the national patients survey that showed the trust did not perform well on cleanliness. But the minutes did not mention that the survey also showed the trust to perform poorly with respect to there being enough nurses to provide care.

Handling of complaints and learning lessons

As part of the plan for internal audit in 2006/07, the trust asked its internal auditors to review the way complaints were dealt with. The report was produced in January 2008. The auditors were concerned that not all staff who conducted investigations into complaints had been trained in how to investigate. Neither had all staff involved in complaints attended training on report writing. Staff told us that minor incidents and complaints were dealt with at ward level and that the quality of investigation and feedback depended upon the particular nurse concerned.

The auditors noted that complaints were not assessed in terms of their seriousness in line with the policy for the management of risk. They also noted that recommendations and action plans arising from complaints were not clearly logged and monitored.

Responsibility for responding to the issues raised through complaints had been devolved to the divisions in January 2007, but there was little evidence that this had resulted in change. Managers told us that incidents and complaints were reviewed and discussed at directorate meetings, with learning and action points being generated. Our analysis suggested, however, that in respect of complaints only numbers and response times were considered. Most frontline staff seemed unaware of both action plans and subsequent actions. They reported a lack of learning from complaints and incidents. They were unaware of any reflection on patterns or any formal system to ensure that action plans following complaints were translated into action.

Patients and relatives who came to see us provided evidence that this was indeed the case. They brought action plans that had been sent to them in response to a complaint but where it was apparent that the same problem had occurred again, well beyond the date given by the trust for the action to have been completed.

Many patients and relatives who came to see us were unhappy with the response to complaints. We were contacted by more than 100 people and 38 raised their dissatisfaction with the complaints process. No one in this group was happy with the response they received.

They considered that their concerns had frequently not been dealt with properly or that they were being "fobbed off". For example, they were sent copies of policies, but in their experience the policy had not been followed, and the trust had not recognised this. Several brought the trust's response with them and we could see that some were incomplete; others were poorly written with sentences repeated. In one, it was claimed that "with regard to the general modes of spread of the organism Clostridium Difficile, it is very uncommon for Clostridium Difficile to be passed from one patient to another". It added that "direct patient-to-patient transmission appears rare but certainly transmission can occur from infected surfaces". In our view, the first statement is potentially confusing since *C. difficile* is easily transferred between patients, albeit via contaminated commodes, shared equipment or utensils and infected surfaces.

In 2004, the Healthcare Commission became responsible for reviewing NHS complaints that had not been resolved locally. We analysed referrals for three years from April 2005 to March 2008 for the group of small acute trusts outside London and found that the average number of complaints referred to the Commission was 31.6, with a range of 12 to 64. The trust had 64 referrals and was the highest in this category. This suggests that there was greater dissatisfaction with how complaints had been handled than in other comparable trusts.

Findings of fact about complaints

- In 2005, the trust had the second highest rate of complaints about nursing care in the group of small trusts outside London.
- Not all staff undertaking investigation of complaints had been trained to do so.
- In line with much of the NHS, the analysis of complaints was limited in scope; there was no indication of the seriousness of complaints.
- Of the 103 patients and relatives who contacted the Healthcare Commission, 38 were dissatisfied with the response when they complained and no one in this group was happy with the response received.
- The trust had the highest number of referrals to the second stage complaints procedure of small acute trusts outside London.
- There had been no system to ensure that action plans translated into action, and considerable evidence that they did not.

Systems to learn from incidents

Staff are required to report incidents where something has gone wrong, or could have gone wrong, with the care of patients. The analysis of such incidents should lead to lessons being learned and the risk to patients in future being reduced.

Sources of evidence

- Interviews with staff past and present
- Healthcare Commission NHS staff surveys
- Trust documents, including reports of serious untoward incidents and minutes of meetings

In the national survey of NHS staff undertaken in 2007 by the Healthcare Commission, staff were asked about the fairness and effectiveness of procedures for reporting errors, near misses and incidents. They were

asked whether staff who reported incidents were treated fairly, whether the trust took effective action to prevent the incident happening again and whether staff received feedback. The trust came in the worst 20% in the response to these questions, and their result had deteriorated since the survey in 2006. The trust was also in the worst (that is, highest) 20% on the percentage of staff witnessing errors, near misses and incidents.

In other words, staff reported that they witnessed a high level of errors but had little confidence that anything would be done about them. There was no evidence that this had been drawn to the attention of the board or that the trust had taken any action in response to these findings.

Most staff that we asked told us that when they reported incidents they did not get feedback and there was little confidence that this led to change.

We noted there had been many incidents related to staffing. For example, the trust was asked to supply any records and details of staff concerns about nursing staff working on wards 10, 11 and 12 in relation to patient care. They provided us with 515 of these covering the period from April 2005 to August 2008. Of these, 191 (37%) related to staffing. These were wards about which there was also concern about standards of care from patients and relatives. We have noted that 93 incidents were reported about staffing shortages generally in the trust between July and August 2007. These had not been drawn to the attention of the board.

Reports on incidents were produced for the various committees concerned with governance. Since June 2007, this had been the clinical quality and effectiveness group and the executive governance group.

We noted that the reports on incidents that went to the clinical quality and effectiveness group in July 2007 contained some very specific information on types of incidents, including violations of clinical guidance, omission of treatment and surgical complications. However, the report to the executive governance group in the same month had categorised the same incidents differently, presenting a more anodyne picture of problems that were categorised as "admission, transfer and discharge". There was no reference to the specific nature of the incidents, such as complications of surgery.

Two non-executive directors attended the executive governance group. The trust subsequently explained to us that the executive group received less specific detail as it considered all incidents, not just clinical ones. There was no evidence that any of the issues had been identified and generated action. In subsequent reports to the clinical quality and effectiveness group, much of the clinical detail and significance was no longer provided there either, and less informative categories were used.

Responsibility for responding to the issues raised by incidents had been devolved to the divisions, but there was little evidence that this had resulted in change. For example, although summaries of incidents that went to the clinical quality and effectiveness group might identify problems in surgery, as in the paragraph above, usually there would be no sign of these being discussed at the governance meeting of the surgical division. This was despite the assertion that it was the responsibility of the divisions to resolve the problems.

The online reporting system had been introduced in April 2007 because of a poor paper-based system. However, many staff who we interviewed reported difficulties with the online system. These included the fact that it was online, was not user friendly, was difficult to classify incidents in the specified categories and was too time consuming. This reduced the likelihood of staff using the system.

Many senior staff acknowledged that the trust had not been good at learning lessons and making changes to avoid repetition of problems.

Serious untoward incidents

Serious incidents for non-foundation trusts have to be reported to their strategic health authority (SHA) and those affecting the safety of patients have to be reported to the National Patient Safety Agency.

The trust defined serious untoward incidents in accordance with the expectations of successive SHAs. This meant, from 2007, full reporting of instances of healthcare-associated infection and reporting of other incidents liable to result in adverse publicity. However, it did not mean that all serious clinical incidents were reported. The trust appeared to have reported relatively few, other than for healthcare-associated infection.

We asked for all the serious untoward incidents that had been reported by the trust. We noted a number of cases, for example, that had been the subject of inquests that should have been reported and investigated as serious untoward incidents. The inquests covered such issues as deaths associated with complications of surgery, missed fractures of the spine and two cases of ruptured spleen. A patient wrongly given penicillin in August 2007 was not reported. This patient died, but the hospital summary for the inquest stated that the penicillin did not cause the death.

Some investigations had been conducted by the trust's solicitor and these were generally comprehensive in nature. However, there was no evidence of a robust mechanism to ensure that the recommendations were followed.

There were also two incidents involving patients who absconded since April 2005. In September 2005, a patient on the emergency assessment unit jumped from a first floor window and was badly hurt. The patient was being treated for alcohol withdrawal and was agitated and aggressive. Prior to his incident, he was attempting to help restrain another disruptive patient. The report into the incident did not comment on the levels of nursing staff on the ward at the time but noted the lack of a security officer. The trust relied on porters for security. Staff on the unit were unaware of the protocol for alcohol withdrawal, and the policy for missing persons was out of date and inappropriate. The report also noted confusion about contacting various organisations in the event of a serious incident.

In October 2007, a patient disappeared from ward 11 and was found dead five days later about half a mile away in the grounds of St George's Hospital (part of a different trust). The investigation report found poor communication and handovers between medical and nursing staff. It also found poor history taking and documentation. Staff were not aware of the policy for missing persons, despite the previous incident. They were also unaware of how to assess and monitor vulnerable patients. This case was discussed by the clinical quality and effectiveness group in February 2008 and recommendations were made for all the relevant areas, including the need to set up a group to look further at this matter. This did not happen until August 2008.

We noted that there had been a number of serious untoward incidents involving a patient being given the wrong medication or one to which they were allergic. In October 2005, there was an instance of a patient allergic to penicillin being given the drug in error, and a subsequent repeat error in January 2007, fortunately without reaction. However, this patient was also not given other important drugs they had been prescribed for years. The report identified poor liaison and handover between A&E and the ward, a matter reported to us as commonplace by many staff over a year later. The report also noted poor recording of clinical notes, especially in A&E.

In April 2007, there was an instance of a patient not being given insulin. The internal investigation found a number of failures but these cannot be listed in this report, as this case was the subject of a police investigation. We noted in the minutes of the mortality group in May 2008 that there was another instance of a patient not given medication for their diabetes.

There was a serious untoward incident in the emergency assessment unit in September 2006, which involved the accidental infusion of lignocaine (a drug used to suppress fast

rhythms of the heart and for pain relief) during attempts to resuscitate a seriously ill patient. There were multiple missed opportunities to check the infusion, which should not have been on the trolley. The patient subsequently died. This case has been the subject of an inquest at which a 'narrative' verdict was recorded.

In the report of his investigation, the solicitor noted that "if a similar incident occurred which could be linked to the management of the resuscitation trolley and action has not been taken by the trust, the consequences could be serious". We noted during our unannounced visit in February 2008 that a resuscitation trolley on ward 10 had not been checked for some months, was missing some items and contained some medication and infusions that were out of date. The trust explained that this was not the resuscitation trolley used on the ward. However, this could have been confusing, particularly to an agency nurse. The trust took immediate action to remove the trolley. The other trolley, that was meant to be the one in use, had not been checked for 10 days. The investigation report also mentioned the lack of an ITU bed.

One of the recommendations from this incident was that "the trust needs to satisfy itself that appropriate training is being given on basic life support skills (BLS) and that appropriate staff are attending". However, we found that the training on BLS was part of induction and mandatory training, both of which had variable attendance records. For example, in November 2007 the board noted that the reduction in attendance at induction was "disappointing" and the hospital management board the same month noted that a third of staff had not attended.

In July 2008, there was another error involving an infusion. Staff noticed that a patient being resuscitated in A&E was being given an infusion with an inappropriate component. The procedure was stopped and the patient suffered no ill effects. It was noted that the trust's policy had not been followed.

In May 2007, during the refurbishment of A&E, an ambulance crew arrived at 1.30am but found that the normal doors they used were locked. They had to use an alternative route, which led to a delay. The report into this incident found that staff were confused as to the proper procedures for the closure of the doors. The report also noted problems in respect of the support for staff, their morale and information. It recommended that senior management needed to address the management structure and resources within A&E as a matter of urgency.

It was not clear to us at what point serious untoward incidents were reported to the trust's board. The trust explained that board members were notified by email when a serious untoward incident was reported electronically. The serious incident involving the infusion of lignocaine happened in September 2006 but was not reported to the board until its private meeting in January 2007. Serious untoward incidents were reported to the executive governance group, which reported quarterly to the board, but few details were provided. There was little evidence in the minutes of discussion of the issues raised by serious incidents. There was no record of the board discussing at the time the serious incident in April 2007 that became the subject of a police investigation.

Inquests

The trust acknowledged that they needed a process to learn from inquests and also all the cases that come through litigation. We noted that there was no link between inquests and the other components of governance. Many cases that went to inquest should have been reported as adverse events and properly investigated.

A discussion was held in the summer of 2008 with the legal team on how to improve the process. The legal team had not been sharing their investigation reports; they had paid for reports for litigation cases where there were investigations but the reports had not been considered as part of risk management.

The trust acknowledged that they should attend relevant inquests and, in advance of these, the trust should routinely undertake an investigation to identify any concerns.

Findings of fact on incident reporting and serious untoward incidents

- The trust was in the top (that is, worst) 20% for staff witnessing mistakes and near misses.
- Staff, including senior staff, had little confidence that the trust learned from incidents.
- Responsibility for responding to the issues raised by incidents had been devolved to the divisions, but there was little evidence that this had resulted in change.
- Some serious incidents were not reported as serious untoward incidents. These included many cases that went to inquest.
- There had been repetition of some types of serious incidents.
- There was delay in reporting the serious incident involving lignocaine to the trust's board; there was little evidence of discussion of serious incidents by the board.

The trust's system for identifying and responding to information about outcomes for patients

The trust had a history of poor performance on mortality. The data from Dr Foster show a three-year hospital standardised mortality ratio from 2003-2006 of 125. This was the fourth highest ratio in England. There was no evidence that the trust had taken any action in respect of this at that time.

The first reference to the Dr Foster hospital standardised mortality ratio (HSMR) was in the minutes of the executive governance group in February 2007, when they referred to the provisional score in 2006 of 114. In May 2007, the medical director presented the figures to the hospital management board. The HSMR had been adjusted to 127 and the trust was the fifth worst in the country for its standardised mortality when using the 55 diagnoses and procedures that comprised the HSMR. The medical director announced that a group had been set up specifically to look at mortality.

In the next meeting of the executive governance group, it was reported that the clinician with responsibility for clinical governance was looking into apparently high rates of mortality at the weekends for medical admissions. Later, it was noted that, since the appointment of the acute care physicians, this weekend peak had vanished.

By July 2007, the executive governance group had been reassured that the high HSMR was because of poor coding. It was noted that an in-house team had looked at all the case notes of deceased patients over the last quarter and found that 75 diagnoses had changed.

In the meeting of the executive governance group in April 2008, the feedback from the mortality group was that 70 deaths had been reviewed and that most were predictable with no "care issues" identified. The clinical quality and effectiveness group noted in February 2008 that four or five cases needed further investigation because of poor notes or no review by a senior clinician. The clinicians who reviewed the notes had volunteered to be involved. As noted earlier in this report, they did not use a structured proforma or have a systematic approach to the review. We have already identified concerns that these reviews failed to identify poor care and learn lessons. Even when concerns were identified, action was not taken in a timely manner.

For example, we saw earlier in the report that the review of the care of four patients who had died (following operations coded as "jejunal') identified some concerns. These involved the failure to give medication to a patient who was 'nil by mouth'. This matter had not been resolved satisfactorily one year later.

Clinical audit

Sources of evidence

- Minutes of the meetings of the trust's board and of the clinical audit committee
- Interviews with staff past and present
- Summary audit reports

Clinical audit is a process that aims to improve the care of patients and outcomes for patients by carrying out a systematic review and implementing change. Aspects of care are selected and evaluated against explicit criteria and, where necessary, changes are made at an individual, team or service level. Further monitoring can then be used to assess the improvements.

Although there was a central team to facilitate clinical audit, which was meant to maintain a comprehensive database of audit projects, they were not always aware of all audit activity in the trust. The audit facilitators attended governance meetings in the divisions. However, the clinical audit lead said there had been some disconnection between the divisions, and departments within them, and the central audit team.

Before April 2007, when the current clinical lead for audit started, there had been a gap of a year when there had not been a lead. The trust-wide group for clinical audit also did not meet for a year between May 2006 and April 2007. The current lead for clinical audit took the role on in addition to other research and development commitments and acknowledged that it represented a substantial workload.

Some staff, including senior clinicians and those in senior governance and executive roles, described audit as having been weak. Many staff described audit as being "disjointed", both with regards to the central audit function and the absence of a link between audit and the other components of governance.

The chief executive told us that it was his expectation that audit should be stronger and he was disappointed that it had not been so.

We were interested to know how data influenced clinical audit; for example, if evidence of poor outcomes triggered audit in the relevant area. Senior medical staff in the clinical divisions said that audit was not driven by data.

Participation in national audits is an effective way of comparing the performance of the trust with others. Members of the central audit team were aware of national audits and said they tried to ensure that the trust participated. Some clinicians that we spoke to said that they were aware of participation in, for example, chronic obstructive pulmonary disease, stroke, the Myocardial Infarction Audit Project (MINAP), and patients with gastrointestinal bleeds. However, they were not able to produce any results other than for stroke. The trust did not participate in specialist colorectal or vascular or other audits run by some of the specialist societies.

A number of senior clinical staff described the audit planning process as poor or patchy. Some were unsure how it was meant to work and one non-executive director described the plan presented to the board two years ago as "a mess". The board asked the internal auditors to review clinical audit. Their report considered that clinical audit did not provide the board with assurance that clinical audit functioned as well as it should.

We were also told by many staff that when audits were undertaken, changes did not usually occur and there was a lack of follow-up and closing the loop. However, an audit in pharmacy had resulted in an increased number of pharmacy staff on the emergency assessment unit.

Findings of fact on the approach to outcomes, and on clinical audit

- The trust had a history of poor performance in respect of reported mortality.
- The trust did not take action on mortality rates until the HSMR of 127 was published in April 2007.
- The trust considered that the cause of the high rate was poor coding and took action to address this.
- The trust established a mortality group.
- The reviews of deaths were not structured or robust.
- The trust-wide group for clinical audit did not meet for a year.
- There was no lead for clinical audit for a year.
- Clinical audit had not been well planned.
- Clinical audit was not linked to the other components of governance.
- Data on outcomes was not used to generate audit.
- The trust did not participate in the audits of the specialist medical and surgical societies.

The trust's overall system for clinical governance

Sources of evidence

- Interviews with staff past and present
- Trust documents, including minutes of meetings and reports on clinical governance

There had been several changes to the arrangements and accountability for governance at the trust since 2005. When the chief executive arrived in an interim capacity in August 2005, the arrangements for governance included a risk management committee and a clinical governance committee. However, there was a consensus among the staff we interviewed that the arrangements were not effective at that time.

We noted that, in March 2006, the trust's board decided that the clinical governance committee would no longer report to the public meeting of the board, but only to the private part of the meeting. The chief executive and chairman could not recollect the basis for that decision.

An integrated risk and governance committee was established in December 2005 as a sub-committee of the board, in order to improve the arrangements for governance. Following the results of a review by internal audit, this was replaced by the executive governance group, which had two non-executive directors as members. This group reported to the audit committee, which reported to the trust board.

For much of the time under consideration, there had been little in the way of a team to support the head of governance and the clinical lead for governance. More recently, a governance team had been created.

During 2007, the trust took steps to revise the reporting mechanisms for governance. The clinical governance committee was replaced by the clinical quality and effectiveness committee in June 2007. Clinical groups fed into the clinical quality and effectiveness committee. This reported to the executive governance group.

From April 2007 to October 2008, the executive governance group reported on a quarterly basis to the audit committee. All non-executive directors, apart from the chair, attended this committee.

Much of the executive responsibility for clinical governance rested with the director of nursing, but the responsibility for clinical effectiveness and clinical audit was with the medical director.

The governance structures had been subject to external scrutiny as part of the process of acquiring foundation trust status. In addition,

the NHS Litigation Authority had assessed the standards for risk management, and the Healthcare Commission had assessed standards as part of the annual heath check. For both of these, the trust provided evidence that the structures were adequate and this was accepted.

However, although we could see that reports on key elements of governance such as clinical incidents and complaints, went to the clinical quality and effectiveness committee and the executive governance group, there was little evidence from the minutes of the board that these were ever discussed or that action was taken in response. The secretary to the board and members stated that the minutes did not reflect the balance of what was discussed, since decisions and action were noted rather than any debate. We noted, however, that this did not appear to apply to finance or marketing, and that few actions were noted in respect of quality.

As demonstrated in this report, the structures did not serve to raise awareness of serious problems with clinical care in emergency services in the trust, or the potential implications of the major reduction in staffing in 2006/07.

Turnover at the board

There had been considerable change in the membership of the board since April 2005. The chief executive, who had been in post for many years, went on secondment in the spring of 2005 and then left. The current chief executive joined on an interim basis in August 2005 and took the post on a permanent basis in February 2006. The previous medical director retired in March 2006 and a replacement was not appointed until September. In the interim, the deputy medical director supported the board. The previous director of nursing left in July 2006 and her replacement took up post in December that year. A senior nurse acted in the post for six months. That meant that, for much of 2006, the trust's board did not have a permanent clinical director in post. It was during this time that the major reduction in workforce was agreed and implemented. The proposals were considered and supported at the hospital management board, which the clinical heads of division and other clinical post holders attended.

Clinical engagement

Engagement and openness with clinical staff, and getting their input and buy-in, is an important means of improving quality in the NHS. We gathered an overall impression from interviews and minutes of divisional meetings that the trust was at an early stage in respect of clinical engagement. There had been little understanding or ownership by senior doctors of the role, for example, of heads of divisions (clinical directors) or clinical leads.

Members of the board generally felt that engagement with clinicians had improved but that there was still progress to be made.

The chief executive told us that there had been a huge amount of work in relation to clinical engagement. This included appointing clinical leads across the trust for audit, training, governance and so on, and the development of divisional governance structures in which the trust wanted full participation. The post of medical director was considered to be significant in promoting engagement but this post was effectively vacant for much of 2006, in between the retirement of the previous medical director and his replacement taking up the post.

Evidence from minutes and interviews suggested that many of the clinicians were not fully engaged with governance, or even resisted it. For example, a senior consultant told us that meetings to consider mortality were for the profession only and were nothing to do with governance. In the surgical division, attendance by consultants at the divisional governance meetings was poor. For example, there were at least four meetings in 2008 where only two consultants attended and two meetings in 2007 where only one consultant was present.

Many consultants recognised that the trust had a clear direction and had made progress in controlling finances. However, a recurrent criticism of clinical engagement was a perception of a top-down approach by management at the trust. The managerial approach was described as an attempt to "dictate and impose", creating what one consultant described as an "us and them" culture. Several were critical of the decisions made by management, especially when they were not consulted on the decision prior to its implementation. It was reported that this contributed to a sense of professional disempowerment. One consultant summarised that consultants were becoming workers rather than professionals, as governance at the trust was something that staff felt happened to them rather than engaged with them.

Some clinicians considered that the trust did not respond to the problems they raised. These included the ongoing problems in A&E, the low nurse staffing levels and the failure to have adequate operating time at weekends. Many reported that there was a gap in communication, whereby managers did not consider the impact of changes on the care of patients and clinicians' views were not taken into account. Many doctors told us they believed that some decisions had been purely driven by finance, without regard for patient care. Some reported that they had identified the risks of the programme for the reconfiguration of the clinical floors and the low nurse staffing levels, but had been ignored. Others felt "steam rollered" into accepting the proposal. Many consultants that we spoke to felt that senior managers did not welcome critical comments, the management style was inflexible and they felt marginalised.

Findings of fact on the overall system for governance and clinical engagement

- Many staff said that governance was weak in the trust until 2005.
- The committees and reporting arrangements had been revised; the structure for governance did not report to the public meetings of the board.
- For six months in 2006, the trust did not have a substantive medical director or director of nursing.
- Many senior managers and board members considered that progress had been made in ensuring that clinicians were properly engaged in governance processes.
- Attendance by doctors was poor at surgical governance meetings, and many doctors felt marginalised in general and disengaged from the system of governance.
- Many consultants considered that they were not listened to, and that the trust did not welcome constructive criticism or heed concerns that proposals could have a negative effect on the care of patients.

Culture of the organisation

The clinical governance review in 2002 advised that the trust needed to develop an open and learning culture.

In the national NHS staff survey for 2006, the trust did well with a low percentage of staff experiencing harassment, bullying or abuse from either patients or other members of staff. It did poorly on appraisal, training and the extent of positive feeling within the organisation.

In the 2007 survey, again a relatively low percentage of staff said they had experienced harassment, bullying or abuse from patients, but in this survey the trust was in the worst 20% for bullying or abuse from staff.

It continued to perform poorly on appraisal, training and the extent of positive feeling. In this survey, the results showed the trust to be in the worst 20% with regard to the pressure of work felt by staff and on work-life balance. Overall, the trust featured as one of the worst 20% of trusts in 14 sections of the survey, as one of the best 20% of trusts for one section, with the remainder falling into the intermediate group of trusts.

We did not gain an impression from staff that the trust had had an open culture in which concerns could be raised, were welcomed and resolved. We have noted above that several consultants considered that the trust did not welcome criticism or concerns.

The trust's board appeared averse to criticism of services. Poor results from inpatient or staff surveys were not discussed in public. The trust had a good relationship with the chair of the patient and public involvement forum, who was very supportive of the trust. It did not welcome concerns being raised by individual members of the forum. The information on the doubling of the rate of *C. difficile* infection in the early months of 2006 was not released to the board or the public. This was when the previous director of nursing was the director of infection prevention and control. At the meeting of the hospital management board in June 2006, it was noted that the trust was the fourth worst in the SHA in terms of *C. difficile*. There was also a high proportion of deaths in patients with *C. difficile*. This information was not shared with the board or the public either. We were told by relatives and members of the public that the trust at that time was reluctant to release information relating to *C. difficile*.

Many staff told us that the chief executive was clear and decisive and that he had "turned the trust round". Many said he had a visible presence in the trust, although some disagreed. Some, particularly consultants, said that he had a heavy hand and did not want to hear about the potential problems posed by the decisions made about services.

How the board functioned

We were told that, since the arrival of the chairman and the current chief executive, the board had become much more effective, particularly in having a clear strategic direction and receiving the information on performance to help to deliver this. The previous board was said to have lacked focus and there had been concerns about internal controls. The new board had achieved financial stability and acquired NHS foundation trust status. Links with external organisations were said to have improved. Many staff wanted to give credit to the leadership for this, even if they had concerns about aspects of care for some patients.

We analysed the minutes of the trust's board meetings from April 2005 to 2008. The minutes indicated that discussion at the board was dominated by finance, targets and achieving foundation trust status. Other areas that commanded much of the board's time included the trust divesting itself of the laundry service. The minutes of the various governance committees were noted, but there was no record of any discussion and issues they raised were not highlighted.

Although we have seen that there was evidence 'in the system' about poor standards of nursing care, there was little evidence that this had been discussed by the board or that effective action had been taken. It was seldom possible to identify discussion at the board of corporate matters raised by reports of clinical incidents, claims or complaints. As we have noted before, the secretary to the board stated that the minutes did not accurately reflect discussion at the board. There was no record in the minutes of decisions or action taken on these matters.

When the responsibility for most of the system for risk management and governance was devolved to divisions in early 2007, initially there was no accompanying robust system to police or monitor this. The trust has said that internal audit reviewed these processes after six months as planned.

Although the trust's board sought to reduce the proportion of clinical jobs to be lost, the decision by the board in 2006 to reduce significantly the number of staff had an effect on the number of clinical staff, particularly nurses. The trust could not provide evidence of a formal assessment by the board of the potential risks that this reduction might have on the quality of care. The programme to reconfigure the clinical floors meant that senior sister posts were also lost. The effects of this have been considered earlier in this report.

We noted that the trust's board generally discussed matters in private. Discussions in private should normally be restricted to matters that are commercially confidential or relate to individuals. In June 2005, the minutes of the private part of the meeting recorded that the Scottish country dancing club met weekly in the gym.

In March 2006, the trust's board decided that only the audit committee would continue to report to the public part of the board meeting. Other committees, including governance and risk, and finance, would report only to the confidential part. This was an unusual arrangement, which reinforced a preference to conduct the board's business in private. Neither the chief executive nor the chairman was able to explain why this decision was taken.

We noted that many items of business of the trust's board that would normally be discussed in a public meeting were only discussed in private session. These were not matters of commercial confidentiality. For example, we have mentioned that there was a serious outbreak of *C. difficile* in the early months of 2006 and the numbers stayed high for the rest of the year. The outbreak was not reported to the board or the SHA.

Matters that could have been of interest to the public were noted only in private, such as the decision in August 2006 to take on the services of a public relations company, following the departure two months earlier of the communications manager. This was at the time that the trust was losing at least 150 posts. Another example that was not discussed at a public meeting of the board was the reported high hospital standardised mortality ratio. In July 2007, after Dr Foster agreed that the rate could be considered to be below average if a wider comparison was made, the board decided that a press release would be counterproductive. We assume this was to avoid drawing attention to the original published rate, which was high.

Other examples of matters discussed only in private included the alerts on high mortality received by the trust from Dr Foster, the results of the national staff survey, the hygiene code visit in 2007, the annual report on infection control, the report of the local supervising authority for midwives in the West Midlands in January 2007 and the review of A&E in May 2007.

The trust did not discuss in public the shared vascular on-call rota with the University Hospital of North Staffordshire in Stoke whereby, for five weekends out of seven, patients coming as emergencies with vascular problems would be treated at University Hospital. This rota was agreed in September 2007. In the private meeting of the board that month, it was reported that the surgeon would go to the patient rather than the other way round. This was not actually correct, since the ambulance service had instructions to take patients to the trust that was on call. The trust has explained this was an uncorrected error in the minutes.

In November 2006, the trust agreed to meet in public every three months instead of monthly.

In February 2007, at the private meeting of the board, it was agreed that the minutes should avoid using the names of contributors. We noted that when the trust gained foundation trust status, the directors decided to hold all their board meetings in private. This is not a requirement for foundation trusts, some of whom hold their meetings in public. The meetings of the governors were held in public, as is required.

Findings of fact on the culture of the organisation and how the board functioned

- In 2007, the trust was in the worst 20% on the extent of positive feeling among staff.
- Most staff did not feel that the trust had an open, learning culture.
- Most senior staff considered that the board now had a clear strategic direction.
- The minutes of the board show that finance and achieving foundation trust status were given high priority. There was little recorded discussion about quality of care.
- The trust's board preferred to conduct its business in private.
- Many important matters of public interest were not discussed in public, including an outbreak of *C. difficile*, the high hospital standardised mortality ratio, and the annual report on infection control for 2006/07.

The history of key issues, including the financial position of the trust and the process of becoming a foundation trust

The final deficit on income and expenditure for the year 2004/05 was £2.15 million. This included a £500,000 deficit from the previous year.

In August 2005, the interim chief executive attended his first meeting of the confidential part of the trust's board. He said that marginal closures were not enough and radical moves were needed to get the trust back on track financially. The previous director of nursing presented a paper from the executive directors on the reconfiguration of wards. This was to reduce beds, staffing costs and lengths of stay.

In October 2005, the trust predicted a deficit at the end of the year of £2 million. In the event, it achieved a surplus of £500,000, because of actions taken and an agreement with the PCT.

At the meeting of the trust's board in October, the minutes recorded the huge amount of work entailed in the programme to become a foundation trust and the need to ensure that the core business was not affected. We noted that the board had had at least two 'away days' to consider foundation trust status, one in May 2006 and another in June 2007.

The trust, under the previous chief executive, had an earlier attempt at becoming a foundation trust, but this was unsuccessful. In December 2005, the trust established a committee to achieve foundation trust status. It was noted at the board meeting the following month that the project for the surgical floors would save nearly £600,000.

In March 2006, the board received an assurance from the previous director of nursing that there were robust plans to ensure that patients were not disadvantaged during the next phase of the reconfiguration of services. She confirmed that appropriate facilities would be in place to provide patients with privacy and dignity. In April, the previous director of nursing told the board that the clinical floors project had been focused on delivering care in a different way, and improving the environment for privacy and dignity.

In March 2006, the minutes of the trust's hospital management board stated that the worst-case scenario was a £370 million deficit for the SHA. The minutes recorded that a 2% top slice reduction of the allocation for PCTs and a further 1% reduction on a differential basis had been discussed at the chief executives meeting in February. The chief executive of the trust stated this was a serious position and plans needed to be in place to address this. At the board meeting that month it was noted that the trust had started the year with an underlying deficit of £2.15 million. From April, the trust would face a shortfall of £10 million. The trust initiated action to remove beds and reconfigure wards, and to remove 150 posts at the trust.

At the meeting in April 2006 of the trust's board, it was noted that the financial aspect of foundation trust status would be "easier to

handle if the trust were on a firmer financial footing". In the confidential part of the meeting, the director of finance also referred to the difficulties facing the then strategic health authority.

The year 2006/07 was generally a difficult one for NHS trusts, as there was a national requirement to bring the service into financial balance.

The director of finance at the SHA (Shropshire and Staffordshire SHA) at that time, however, did not recollect that the trust had a particularly difficult financial position or that the trust was asked to make draconian cuts. However, the trust provided evidence that he had been given details of their planned reduction in costs. The financial handover to the new strategic health authority in July 2006 noted that the trust had done well in 2005/06 with a surplus of £500,000 and was on schedule to deliver a £1 million surplus in 2006/07.

Although the divisions had undertaken risk assessments, we could not find any evidence that there had been an assessment of the risks at corporate level of the workforce reductions in 2006/07.

In June 2006, the board noted that the surplus at the end of 2005/06 was an excellent outcome, particularly leading up to application for foundation trust status.

In July 2006, the board received an internal assessment of progress on the National Service Framework for Older People. This stated that the trust was proactive with regard to privacy and dignity. In the private session of the board, it was noted that the trust had performed poorly in a review of children's services due to the failure to provide information. It was agreed to take action. The board discussed the need to build positive relationships with the media and agreed to take on the services of a public relations company with immediate effect. This was to replace the communications manager who had left two months earlier. The hospital management board that month noted that 50 redundancies had been agreed and a head of marketing had been appointed, as part of the restructuring of management arrangements.

In August 2006, the trust's board learned that the internal auditors considered that now the trust had developed an assurance register, it had moved from the lower to the upper quartile of trusts in respect of governance.

In private session, some non-executives said it was hard to challenge at public meetings. Another said it would have been difficult to have had, in public, the debate they had had at the finance committee.

In September 2006, the trust's board was informed by the director of finance that the trust must adjust to new staffing levels. The marketing plan was presented. The next month was when A&E had no middle grade or consultant cover for four nights a week, for a fortnight. In November 2006, in private session the board learned that the trust was on track to deliver £10 million in savings in 2006/07 and recurrently from 2007/08. In December, the private meeting of the board was informed that action across the whole of the West Midlands health economy was required following identification of a £205 million cash pressure. The West Midlands SHA has told us it does not recognise this.

By January 2007, the minutes of the board and the hospital management board record that the trust was on course to deliver a £1 million surplus at the end of the year. Although there was evidence of clinical problems of which the board was aware in a number of areas, including A&E and the medical wards, no suggestion appears to have been made to reinvest in staff at this time. The trust has now told us that this £1 million was not a true surplus, but to repay brokerage to the PCT.

In May 2007, at the meeting of the trust's board it was noted they had achieved a surplus of £1.12 million for 2006/07. It was also recorded in the minutes of the private meeting that day that the trust had had its score reduced on the risk rating for finances for becoming a foundation trust. It was confirmed that Monitor looked for a score of three or above. The minutes note that "the

only way that the trust could increase the score to four would be by a major increase in surplus".

At the same meeting, the trust learned from the national survey of NHS staff that a high proportion of staff did not have confidence in care and treatment at the trust. This was described as disappointing. The marketing team presented its first report to this meeting and the minutes for this covered a page, as did the section on the laundry. The results of the 2006 national survey of inpatients took up one paragraph in the minutes. They recorded that action plans were in place to address areas where the trust was in the worst 20%. However, there was no mention of the patients' concerns about there being too few nurses and there was no action plan to increase the number of nurses. The minutes record the need for more discussion in public, but state that a high percentage of the items to be discussed were commercially sensitive.

The board secretary said that her approach was to make the minutes as short as possible and record decisions taken by the board and not the detail of debate. She reported that Monitor would be looking for evidence of the board's decision-making process and challenge, in respect of the laundry and finance, and therefore produced fuller minutes on those issues than she would otherwise have done. She reported that the balance in the minutes was not a reflection of the debate that took place.

In June 2007, the board discussed at some length in private session the Dr Foster Hospital Guide, which ranked the trust as fifth highest in the country for its mortality rates. This was explained as being partly due to "data capture". The board learned that a mortality group was being set up.

In July 2007, the board in private session agreed a draft strategy to engage with patients and the public. A detailed report on marketing was presented and it was agreed that the trust needed to be increasingly aware of competition. This was the month when the 'annual' report on infection control was received, but the minutes do not record that the outbreak of *C. difficile* in 2006 had been discussed. A programme to improve the prevention of infection was agreed.

The board also noted progress towards a cost improvement programme to achieve savings of £8 million recurrently over the next two years. If this were achieved, it would meet the national requirement to improve costs and increase the surplus. The board had learned in the same month that there were 103 vacancies. The board noted a vicious circle in some areas: the actual number of staff was below the establishment, leading to high levels of sickness, which in turn put pressure on budgets due to overtime. The need to break the circle was noted and blockages to recruitment were identified.

In August 2007, the minutes of the board in private session covered one and two sides respectively on marketing and the laundry. The only clinical matters minuted were infection control and theatres, which occupied one side.

In September 2007, it was recorded at the private meeting of the board that there were 104 vacancies but that significant numbers of new staff were due to start. The trust would have a target of £3.48 million for the cost improvement programme for 2008/09. The three alerts from Dr Foster were also noted. The last public meeting of the board in November 2007 noted good progress on finance.

On 1 February 2008, the trust achieved foundation trust status. In the March meeting of the board of directors, it was recorded that at the end of February the trust had a surplus of £1.87 million. It was agreed to invest in nursing. In April, the surplus at the end of the 2007/08 year was reported to be £853,354.

In May 2008, it was confirmed to the hospital management board that the trust had achieved a surplus of £1.2 million in 2007/08.

At the meeting of the hospital management board in August 2008, it was noted that the trust would aim to save £3 million in 2008/09.

We noted that much of the board's time was taken with the process of the application to become a foundation trust, including considering issues such as business development and marketing.

Members of the trust's board were adamant that the quality of care had always been a top priority for the trust. They were not however, able to point to evidence of any significant scrutiny of standards of care of patients that they had undertaken. Many members of staff at all levels and in different professions told us that the trust's priorities had been finance and achieving foundation trust status.

Findings of fact

- The year 2006/07 was generally difficult for NHS trusts, as there was a national requirement to bring the service into financial balance.
- The trust made savings in 2006/07 and in 2007/08 to maintain financial stability, having ended the previous years with a declared financial surplus.
- In early 2006, the trust's board was reassured by the previous director of nursing that the reconfiguration of services would not disadvantage patients.
- There was no evidence of any assessment at corporate level of the risks to patients from the reduction in the workforce.
- The board was focused on becoming an NHS foundation trust, which it achieved on 1 February 2008.
- Members of the board insisted that quality of care was a top priority, but the minutes did not support this.
- Many staff considered that the priorities had been finance and achieving foundation trust status.

Developments at the trust since the start of the investigation

Following our final visit to the trust in October 2008, we wrote to the trust to outline those areas that it needed to concentrate on before receiving the draft report. This letter is reproduced in appendix H. The trust replied outlining the progress it had made on the matters raised.

Progress in A&E

During an investigation, it is our policy to raise any issues of concern regarding the safety of patients immediately with the trust being investigated. As we have noted, the trust received formal notification from the Commission on 23 May 2008 about the A&E department. This covered three main areas of concern: staffing, the structure and operation of the department, and governance.

The trust responded that they took the concerns "extremely seriously" and set up an emergency care steering group that has met monthly since June 2008 to address the issues. This group engaged an external lead, previously a national lead for emergency care at the Department of Health. The improvement project for the department was based on a model of care and was split into eight work streams.

The trust commissioned an expert team from the Heart of England NHS Foundation Trust to conduct a review of the department.

In a press release of 25 September 2008, the Healthcare Commission acknowledged that the trust had responded positively and rapidly to the concerns raised.

The trust appointed two consultants in emergency medicine and one long-term locum consultant. However, the original consultant is on long-term sick leave. One of the new consultants has been appointed as the clinical lead for the department. The expansion of the middle grade medical rota has resulted in an improvement in the training and education available to junior doctors. The department has structured programmes for junior and middle grade medical training in conjunction with University Hospital of North Staffordshire NHS Trust. Unlike previously, these are protected sessions that are not cancelled on operational grounds. The dean for postgraduate medicine is satisfied with the changes that have been made. Junior doctors have a mentor in the department, and given the greater presence of middle grade doctors, a more supportive environment. The trust now operates a rota with permanent staff that is compliant with requirements. The acute physicians no longer participate in the rota.

The trust increased the nursing establishment to 53.2 whole-time equivalents and all posts except the lead nurse have been filled. The trust appointed a matron to cover A&E and the emergency assessment unit. A number of relatively senior nurses left the department between May and August 2008 and, therefore, the recruitment programme was partly a process of replacing experienced nurses who left the department with inexperienced ones. A nurse to take forward professional development was also recruited and she developed a training programme, which is being implemented. However, there is still only one band seven nurse acting in a clinical capacity.

From October, triage was being performed by nurses between 10am and 10pm. A trial was started in August 2008 with general practitioners working in the department assisting with triage and the minor patient stream. They were undertaking triage between 6pm and 10pm.

Both the Healthcare Commission's investigating team and the reviewing team from the Heart of England Foundation Trust were concerned about the use of the four-bed 'assess and treat' unit. The latter recommended it was closed immediately. During an observation of the department in September 2008, the directorate manager for emergency care explained that due to the problems associated with it, the 'assess and treat' area was closed. We understand it is currently used only for patients waiting to go home or for an assessment by an occupational therapist.

During interviews with staff and observations of the department in September and October 2008, the investigating team was consistently told that equipment had been ordered. In August 2008, a department business meeting told how equipment on order was due in approximately four weeks. However, in September, the team were told there was no confirmation of arrival and in October 2008 the team was again informed that the requested equipment was still on order. Most of the equipment has now arrived.

Access to radiology, particularly CT scans, remained a concern in October 2008, with one locum consultant stating they were very surprised to have joined the trust and found there was almost no relationship between the emergency department and radiology. The trust has told us that this has improved.

A new model of care, also incorporating the emergency assessment unit and clinical decision unit, was introduced in the department on 1 September 2008 with full implementation of the model planned for October 2008. The trust reported early indications that the model was working effectively and progress would be monitored by the emergency services steering group. Additionally, the medical director reported that the pathway from A&E to theatre was being looked at.

Governance arrangements had improved with the new leadership, with regular monthly meetings including reviews of mortality and clinical audit.

Emergency assessment unit, wards and theatres

Following an unannounced visit that we made to the emergency assessment unit (EAU) in February 2008, concerns were raised about an area of eight beds at the far end of the unit that were out of sight from the nurses' station. In May 2008, 12 beds were removed from the 48 beds and were used to open a clinical decision unit in the A&E department. As a result, the bed capacity of the unit was reduced and with staffing levels unchanged there was an increased ratio of nurses per patients.

In October 2008, four beds were temporarily reopened in this area of the unit, a decision made by the executive on-call. Due to "significant pressure" on the trust, it was intended that five additional beds would be based on the EAU, with bank and agency staff being used to cover while the recruitment of additional staff is undertaken. Since then, continuing pressure on beds has led to extra beds frequently being used.

A refurbishment of the unit had been scheduled for March 2009. The trust has now appointed healthcare planners to review capacity and configuration of clinical areas and a report is anticipated in March 2009.

In July 2008, there was one trained member of staff to every 10 beds on the EAU. In September 2008, it was reported that, as there were 5.2 whole-time equivalent staff on maternity leave (described as some of the more experienced and competent staff), it could be May 2009 before they would be operating on full numbers. The trust assured us that the unit received additional resources and that bank and agency staff were booked to cover vacancies.

In August 2008, it was noted that the number of junior doctors for the EAU had increased and funding was available for a third senior nurse advanced practitioner. In September 2008, we learned that the rota with three acute physicians might not be sustainable, especially if they tried to match the Royal College of Physicians recommendations of

seeing patients within a given time. In October 2008, the trust stated they believed the number of doctors in support of medical patients on the EAU was appropriate. The trust outlined intentions to increase the dedicated senior presence to four acute physicians and bid for an acute medicine specialist registrar early in 2009.

A band seven nurse for professional development in emergency care was appointed, with the post holder taking up position in October. An analysis of training needs was undertaken to identify training requirements and prioritisation.

Following concerns of the Healthcare Commission regarding the recording of modified early warning scores (MEWS), a rapid training assessment was undertaken by the trust practice development team. During August 2008, 21 members of staff from the EAU were trained, and the training programme is ongoing.

A training assessment undertaken by the trust's practice development team agreed actions specific to the cardiac monitors in the EAU. These included education aimed at all nurses and healthcare support workers; design and implementation of guidelines for the use of cardiac monitors; and competency-based training for use of the monitors and recognition of life threatening arrhythmias. The trust would evaluate and monitor the effectiveness of the guidelines and training. The trust says it has now trained all the staff on the EAU, and some on A&E with more to follow.

In September 2008, the following actions had been identified and were implemented: ward-based training was provided to all medical clinical areas (including the EAU); expectations regarding the use of MEWS were communicated to all clinical areas; MEWS training was provided on new starter days for nurses and healthcare support workers; matrons were to ensure full completion of MEWS on their quality ward round; and audit of the effectiveness of current MEWS charts with action on findings as required.

Following a medical division assessment that found there was poor compliance and accuracy with fluid balance charts, it was agreed that a single chart should be used across the trust with explicit expectations regarding the standard of documentation, and ward-based training provided.

In October 2008, one of the acute physicians was completing an audit around direct admissions and length of stay. Although some patients stayed on the assessment unit for more than a week, overall compliance with the maximum length of stay outlined in the operational policy was good, with an estimated 5% remaining on the unit over 72 hours. Patients staying in excess of this were primarily those requiring side rooms. The average length of stay in October 2008 was 1.6 days.

In October 2008, the trust acknowledged that, although there were some pathways in place for emergency admissions, this was an area that would benefit from further development. The operational policy, last revised in December 2005, was being updated in October 2008. This would review the policies in place for the emergency department and set out pathways for all types of patients on the EAU. The policy required reworking to reflect the fact that bed numbers had been reduced since the policy was last revised, a new method of working had been introduced and there was a new set-up of senior medical staff.

The clinical lead for emergency care suggested the key next steps for the EAU would involve changing the emergency patient flow through the hospital. As part of this, GP referrals would not go through the A&E department. To begin with, these would go through the clinical decision unit until the assessment unit was functioning effectively.

In November 2008, new cardiac monitors were installed on the acute coronary unit. The trust has told us that portable suction equipment is now available and is being rolled out across the trust.

The trust had made representation to its commissioner for extra resources to improve stroke services. The PCT, however, considered

that the trust should do this within existing resources and the trust has agreed plans to do this. On a specific issue, the trust has introduced a new type of thickened drink for patients with difficulties in swallowing after a stroke.

The trust is clarifying the position in respect of access to critical care beds at the trust and elsewhere, and access to advice from critical care doctors, in the event of a bed not being available.

Surgery

'Hospital at night', a national initiative to ensure that the best possible care is provided for patients given the changes in permitted working hours for doctors in training, has been in effect since August 2008. As part of this, an analysis of activity was undertaken to define the roles and responsibilities of the hospital at night team. In October 2008, the head of division of surgery and the clinical tutor wrote to all junior staff to encourage them, pending a more robust solution, to seek a senior opinion whenever they considered it necessary.

In July, we were informed of several changes and proposals to take place in the surgical division. An action plan on surgical governance arrangements was included. This covered areas such as the risk register, adverse incident reporting, complaint management, alerts issued via the Safety Alert Broadcast System, the NHS Litigation Authority standards, workforce information, staff appraisals, clinical audit, sickness absence management and Dr Foster intelligence.

We were also told of changes that were being made to the management structure for theatres, anaesthetics, the hospital sterilisation and decontamination unit and critical care, including appointing a clinical lead and a matron to work jointly across theatres and the critical care unit. An action plan has been developed for theatres. The initial problems with the electronic system for collecting data from theatres have been resolved.

The trust reviewed the surgical emergency pathway and the levels of input from surgical doctors. A four-bedded surgical assessment unit was opened in November 2008 to enable surgical patients referred by GPs and patients admitted from A&E to be assessed. Initially for patients with general surgical problems and open until 8pm, the trust reports that there are plans to extend the service. Although the unit has helped to support the resident surgical officer on duty, their workload is still considerable.

Two additional beds have been opened on the trauma ward to reduce the need for trauma patients to be on other wards. The trust is reviewing the provision of emergency operating lists at weekends to reduce delays to patients. In the interim, additional sessions have been arranged at short notice if there is a build-up of emergency patients requiring operations. By the end of January 2009, there had been four such sessions. Discussions are underway about increasing the provision of the ortho-geriatric service.

The trust has told us that a group is being established to help prevent venous thrombo-embolism.

Staffing

In September 2008, the trust told us that, since January 2008, 153 nurses started at the trust (82 qualified nurses and 71 healthcare support workers). These additional staff resulted in growth (net of turnover) during the same period of 46 qualified nurses and 51 healthcare support workers. One additional band seven had been recruited to cover wards 11 and 12. The number of matrons has increased from three to 12. Some staff said that, while they welcomed the additional number of nurses, many of the new staff were inexperienced or newly qualified, requiring extra support.

At the November 2008 meeting of the trust's board, it was noted that recruitment had been stopped at 40 posts below the agreed level because of the difficult financial position for 2008/09. The trust, though, has told us that

the board has not stopped recruitment and will, as part of the 2009/10 business plan, revisit the establishment review and take a view of recruiting to the outstanding posts.

Quality of nursing care

In June 2008, the trust's board approved an action plan to incorporate all the key issues related to quality of care. This programme was developed with the support of an external nationally regarded professional advisor, Sir Steven Moss. The areas included in the plan are quality of care, communication with patients and carers, learning and development, staffing and clinical practice. A steering group chaired by the director of nursing was established in July 2008 and is responsible for the ongoing monitoring and implementation of the actions identified. The trust told us that, since April 2008, the number of complaints about nursing has fallen, but information about seriousness was not available. However, the trust board in November 2008 noted an increase in complaints about wards 10, 11 and the EAU.

A new chart for recording observations has been on trial. Similarly, the trust says it has introduced one chart across the trust for recording fluid balance. The trust has told us that the matter of identifying patients whose condition is deteriorating is one they have elected to work on as part of the leading improvements in patient safety (LIPS) course.

In August 2008, a group was established to look at the issue of patients who may wander or abscond.

Details of developments in nursing at the trust from early 2007 to early 2009 were supplied by the trust and can be seen in appendix I. In addition to these, the trust has also said that there have been the following developments:

- A balanced score card reflecting that quality has been developed (and will develop further in time) and is presented to the board on a quarterly basis.
- Development of a robust clinical skills programme.
- Increased uptake of training programmes.
- Establishment of divisional patient and carer councils, which are now meeting.

Governance and monitoring performance, including mortality

The trust has appointed a new medical director, who will take up the post in April 2009.

The mortality group has extended its remit to look at a wider range of outcomes. It was renamed the clinical outcomes group in October 2008 and is chaired by the chief executive. The trust is using a technique involving the global trigger tool to identify issues of harm to patients. A team from the trust completed the LIPS course provided by the Institute of Innovation and Improvement. The trust reports it has developed a consistent approach to the review of case notes and has begun to consider how it can learn from deaths that are the subject of inquests.

As mentioned earlier in this report, four further mortality alerts (two generated by the Dr Foster Research Unit and two generated by the Healthcare Commission – see appendix E) occurred after the investigation was launched. We wrote to the trust about three of these in January 2009. The trust responded to us about the three alerts in a timely fashion and their responses have been considered by the multidisciplinary panel that oversees the Commission's outlier work.

For the second quarter of 2008/09 (July to September 2008), the Dr Foster HSMR for patients admitted as emergencies was 79.7, which was significantly better than expected when measured against the 2007/08 national benchmark. However, there can be seasonal effects reducing the HSMR for the summer months. The crude mortality rate, among the HSMR group of patients, for this quarter was 7.8%, which is below the rates reported for the corresponding quarter in the two previous years (which were over 9.2% and 9.7%) and similar to the 2005/06 quarter 2 rate of 7.6%.

The most recent Dr Foster HSMR information currently available is for October 2008, for which the HSMR is 82.9 and the crude mortality rate is 8.2% for emergency admissions. These are lower values than for the previous three years.

Since December 2008, the executive governance group has reported directly to the board. There is more evidence of discussion of matters of quality of care. Clinical audit is now managed under the umbrella of governance. The frequency of the meetings of the trust-wide group for clinical audit increased to monthly from December 2008. There is more support for the clinical divisions, with each being allocated a manager for risk and patient safety. The trust is reviewing the form for reporting incidents to make it easier to use. There are still concerns about the identification and investigation of serious incidents.

There is evidence that the trust is aware of problems in the manner that it deals with complaints and has plans to rectify these. The trust has provided training to officers who investigate complaints. However, the executive governance group noted in July 2008 that there were still concerns with the provision of service, noting that: "Investigating Officers are failing to make verbal contact with the complainants within 48 hours and agree a plan of action for the management of the complaint."

There is little evidence of an improvement in the general analysis of complaints. None of the board minutes show any evidence of evaluation of complaints to ascertain seriousness. The divisional governance groups do not minute discussions about issues raised by complaints. The medical divisional governance group noted in September 2008 "significant failure in A&E particularly to adequately deal with these incidents and a general failure across the division to feed back to staff involved in dealing with the complaint". A date of September 2009 was agreed for "robust arrangements [to] be in place across the division to respond to and learn from adverse events and complaints including feedback to relevant staff involved".

A panel to review complaints was established in the medical division in June 2008 but it is at an early stage. In the surgical division, a panel has not yet been established.

The trust implemented a new patient experience tracker system in May 2008. This aimed to "gather patient and carers views at the point of service and give a more accurate reflection of the services that are provided by the trust" and "ensure that any shortfalls are addressed immediately". These reports are provided to wards and included in the quarterly reports to the executive governance group. The trust board noted in November 2008 that patients rated levels of cleanliness as low.

The governors are taking an increasing role and the trust has told us that they carry out unannounced visits. However, we understand that these occur at regular times. In a recent evening visit we made to the trust, none of the staff in A&E, the emergency assessment unit or wards 10, 11 and 12 was aware of any inspection by governors.

Infection control

In October 2008, the trust was subject to an unannounced inspection by the Healthcare Commission's hygiene code team as part of the inspection programme of all NHS acute trusts during 2008/09. The programme is to check whether trusts are meeting the 11 mandatory duties outlined in the Government's hygiene code, which came into force as part of the Health Act 2006.

The hygiene code team found that the trust was demonstrating compliance with the code. No breach of the code was identified in any of the four duties considered.

Recent audits of prescribing of antibiotics have found improved compliance with the policy. A new prescription chart has been developed. The infection control team has been expanded with another training post and a member of staff on secondment, who is targeting hand washing.

The role of other agencies

South Staffordshire Primary Care Trust

Sources of evidence

- South Staffordshire PCT website
- Minutes of meetings and reports
- Letters and reports from locality commissioning consortia
- Interviews with the senior managers at the PCT

South Staffordshire Primary Care Trust (PCT) serves a population of approximately 604,000 and is located within the geographical boundaries of Staffordshire County Council. The PCT employs just over 2,000 staff and its turnover for 2007/08 was £725 million.

The geographical area of the PCT is largely rural but contains a number of urban centres including Burton upon Trent, Cannock, Lichfield, Rugeley, Stafford, Tamworth and Uttoxeter.

The PCT was established in October 2006, when the four former PCTs, Burntwood, Lichfield and Tamworth, Cannock Chase, East Staffordshire and South Western Staffordshire, were merged.

On its website, the PCT described its approach to providing healthcare as based on focusing on prevention; targeting resources where need is greatest; working with partners on other factors which impact on ill-health; and where treatment is needed, offering choice and commissioning high-quality services with no delays.

The PCT, as part of its commissioning of patient services, was the host commissioner for Mid Staffordshire NHS Foundation trust, taking the lead role in commissioning services from the trust on behalf of other PCTs whose patients also receive services from the trust.

Staff from the PCT involved in commissioning told us that they inherited a chaotic situation, with no detailed handover from the previous PCTs that had merged to form the new PCT. They were aware that the relationship with their predecessors and the trust had been difficult with regard to the contracts between them. Access to data and information about services was reported to be difficult.

The minutes of the PCT's performance and finance committee did not reveal any evidence that the PCT was aware of any problems in the quality of service being provided by the acute trust prior to the Healthcare Commission's announcement of its investigation.

Commissioning had not inquired in any depth into specific aspects of the quality of care being provided. A number of projects were underway to redesign various pathways of care, for example for patients with diabetes, and in November 2007 there was a project in A&E. The general consensus of those that we spoke to was that, prior to the investigation, there had been little information, including from GPs, that care was not sufficient.

There had been aspects of monitoring of the quality in the service level agreements. These involved the processes for handling complaints and the trust's performance in relation to targets regarding cancelled operations and appointments and waiting times in A&E.

We were told that such quality monitoring is now the subject of a national piece of work in the NHS.

With regard to A&E, the PCT were not aware of the problems of having a single A&E consultant, or the problems with the recruitment and retention of middle grade doctors and A&E nurses.

The PCT told us that it had gained assurance from the trust's performance in the annual health check of NHS trusts. The PCT also considered that the trust and its activities were the subject of scrutiny as part of its application for foundation trust status. With regard to the HSMR figure published by Dr Foster in 2007, the PCT agreed with the actions being taken by the SHA as it did not feel that it had the expertise to undertake its own study.

All of the senior staff at the PCT that we spoke to recalled that finances in the NHS generally were challenging in the year that the trust made savings. The chief executive of the PCT was not in post at the time but was subsequently informed that the trust had achieved a saving of £10 million. The PCT had not been alerted that the savings could have affected the quality of care provided.

Prior to the announcement of the Healthcare Commission's investigation, the chief executive of the PCT had personally visited GP surgeries in the PCT and had asked about the quality of care delivered by the acute trust. Nobody had raised any serious concerns apart from the problem of delays in receiving clinical letters from the trust.

Some GPs had participated in a pilot scheme to support discharge from the A&E department at the trust. In addition, from April 2008 a GP out-of-hours primary care centre service commissioned by the PCT had been on the same site and just yards from the A&E department at the trust. However, the PCT was unaware from these sources of any problems in the department.

Just prior to the Healthcare Commission's investigation, the PCT's chief executive came into contact with the 'Cure the NHS' campaign group when representatives attended one of his regular open meetings. Clinical staff from the PCT supported by the PALS team subsequently met with 15 individuals and acted as advocates for them to help resolve their complaints.

In addition, the PCT then contacted its two local commissioning groups to ascertain the views of GPs on standards of care. The responses were highly critical and further raised the concerns of the PCT. The PCT carried out an unannounced visit to the acute trust in April 2008 to check for themselves the standards of care. During the visit, the team from the PCT visited both the trust's A&E department and a number of wards. The PCT ensured that an action plan was immediately put in place to address staffing shortages and clinical leadership in the short term.

In April 2008, the board of the PCT received a report from its lead director of quality and performance regarding the Commission's concerns about the trust. The minutes recorded that the PCT's board had previously been told about the review of the nursing establishment and skill mix at the trust. The minutes highlighted the concerns the PCT had learned from the local campaign group, the commissioning consortia and the unannounced visit it had undertaken.

The PCT agreed to provide some additional funding to the trust to support a number of short-term initiatives to improve quality, including employing additional senior nursing staff in the A&E department. The amount that it agreed to fund was less than the trust had requested, as the PCT suggested that the trust used the internal reserves it had generated through its planned surplus.

Ongoing mechanisms for monitoring improvements since the beginning of the Healthcare Commission's investigation included involvement in an action plan to improve standards of nursing care, monthly commissioning meetings where complaints and serious untoward incidents were detailed and the A&E Improvement project, which was initiated after the Healthcare Commission raised its concerns about the department.

The PCT also set up and extended the pilot GP service in A&E to help divert patients waiting inappropriately for treatment.

Findings of fact

- There was a lack of information handed over from the predecessor PCT organisations regarding services provided by the trust.
- Neither the commissioning process nor other sources of information indicated concerns about the quality of care provided to patients at the trust.
- The financial situation was known to have been challenging.
- The PCT had been assured by the trust's ratings in the annual health check and its application to become a foundation trust.
- The PCT became aware of concerns at the same time that the Healthcare Commission raised concerns.
- The PCT responded to the concerns of the 'Cure the NHS' group and acted as an advocate to help resolve their concerns.
- Since becoming aware of the concerns, the PCT has provided practical and resourced support to the trust, particularly in the area of A&E.

West Midlands Strategic Health Authority

Sources of evidence

- Minutes of meetings of West Midlands and former SHAs
- West Midlands SHA timeline of events
- Email correspondence
- Interviews with senior staff from the West Midlands and former Shropshire and Staffordshire SHAs

Strategic health authorities (SHAs) were originally created in 2002 to manage the local NHS on behalf of the Secretary of State for Health. Each SHA is responsible for developing a strategic framework for the local health and social care community, and managing the performance of providers of healthcare in the NHS within its geographical boundaries. This includes putting and keeping in place arrangements for monitoring and improving the quality of healthcare provided to individuals in the area.

The trust was part of the Shropshire and Staffordshire SHA until the summer of 2006. Following the reorganisation of SHAs in July 2006, the trust became part of West Midlands SHA.

The SHA relinquished the above responsibilities in relation to the trust when it attained foundation trust status in February 2008. From that point, Monitor assumed ongoing responsibility for managing the performance of the trust.

The senior staff from West Midlands SHA that we spoke to told us that there had not been a formal or comprehensive handover of information and intelligence from the predecessor organisations and organisational memory had therefore been lost. A former director of finance who had worked at one of the predecessor SHAs told us that he had left handover information about financial issues. The current SHA was able to provide us with a copy, and the matters are detailed later in this section.

The general perception of the SHA regarding the trust was that, unlike some other trusts in its area, it did not have information to suggest that there were concerns relating to the quality of care that it provided. As with the PCT, the SHA was aware that the trust had applied to become a foundation trust and was therefore subject to scrutiny in this regard.

The minutes of the board meeting of the Shropshire and Staffordshire SHA in November 2004 noted that a £18 million deficit was forecast for the SHA for the full year. The SHA announced the development of robust recovery plans including incentive schemes for trusts that were under-spenders and increased reporting for over-spenders. The forecast deficit for 2004/05 was estimated to be £39.5 million, according to the minutes of the SHA board in July 2005.

In October 2005, it was recorded in the trust's hospital management board minutes that the financial position of the SHA was dire. In March 2006, the minutes of the trust's hospital management board stated that the worst-case scenario was a £370 million deficit for the SHA. The minutes recorded a 2% top slice of the allocation for PCTs and a further 1% on a differential basis had been discussed at the chief executives' meeting in February. The chief executive of the trust stated that this was a serious position and plans needed to be in place. The trust subsequently initiated action, as discussed previously in this report, to remove beds and reconfigure wards, and to remove 150 posts at the trust.

Staff that we spoke to from the current and former SHAs confirmed that finances were difficult in 2006/07, as they were generally in the NHS. Previously the trust had made small deficits and surpluses but none of them could recall the SHA explicitly requiring the trust to make a £10 million saving. We were told that a saving of this order would have represented a non-achievable sum in relation to the trust's turnover. The current SHA has informed the Healthcare Commission that the former SHA required the trust to make a saving of 3.5% of its turnover, which was £125 million. The 3.5% was the combination of the NHS efficiency requirement of 2.5% and 1% towards repaying their deficit. Anything in addition to this would have been an internal trust decision, to address cost pressures and its underlying deficit.

Handover information provided to the new SHA from the director of finance at the Shropshire and Staffordshire SHA detailed the previous financial performance of the trust as outlined above. With regard to the 2006/07 financial plan, it noted that the acute and primary care trusts in the former Shropshire and Staffordshire SHA anticipated revenue deficits of £4.7 million and £5.6 million respectively (£10.3 million collectively). The trust anticipated a surplus of £1 million that, together with other similar amounts for other trusts, had already been used to offset what would have been a greater deficit for all of the acute trusts. The current SHA told us that the previous SHA planned to balance the deficits by savings at the SHA.

Following publication of the Hospital Guide by Dr Foster Intelligence in April 2007, which listed six trusts within the West Midlands SHA region as "poor performing" in terms of their hospital standardised mortality ratios, the SHA commissioned academics from the University of Birmingham to undertake research and produce a report to determine whether the poor results were a consequence of poor coding. One of these six was the trust.

Before deciding to commission the research, the SHA called the chief executives of the five trusts that were not foundation trusts to a meeting to determine what actions the trusts were undertaking. During that meeting, it emerged that there was a variable approach to clinical governance, with a general lack of systematic approach to clinical audit, management of serious untoward incidents, complaints, and the use of benchmarking internally of clinical indicators on a regular basis. It was not clear how much engagement there was at board level. It was made clear to the chief executives that the SHA would be expecting early remedial action from the trusts. The SHA was assured by what the trust informed them and therefore concentrated its attention on others where they felt less confident and where the performance reported by Dr Foster Intelligence was of more concern.

One way that SHAs undertake their role in performance managing providers of healthcare services and being aware of potential patient safety concerns is by knowing about serious untoward incidents (SUIs) that occur. In the board minutes of Shropshire and Staffordshire SHA in February 2005, it was noted that further work needed to take place within local NHS organisations to improve the reporting arrangements for SUIs, and in particular the need to share learning gained from investigating them.

In November 2007, a continuing lack of consistency in reporting was noted in that some trusts were reporting SUIs to the

National Patient Safety Agency and not to the SHA and vice versa. It was noted that there had been a degree of variety of types of SUIs reported. SUIs in foundation trusts have to be reported to the relevant PCT as well as to Monitor and SHAs can access information through their performance management of PCTs. Since early 2008, all SUIs in all trusts that relate to infections have to be sent to the SHA.

In April 2008, a revised SUI policy was introduced. Staff from the SHA informed us that further work was underway regarding how best to learn from SUIs.

In March 2005, a report to the Shropshire and Staffordshire SHA board on healthcare acquired infections noted an escalation of the SHA's performance management approach to these infections and emphasised that the SHA would not take on responsibility of individual organisations. In May 2006, the director of performance and finance reported on hospital cleanliness, citing Burton Hospital as a poor performer in relation to MRSA and stated that performance at Stafford hospital was about the same. Unlike Burton, Stafford was not required to produce an action plan as they were able to articulate clearly to the SHA how they were addressing the matter.

Findings of fact

- There had been no formal or comprehensive handover of information from the predecessor organisations to the new SHA following reorganisation, and intelligence about the trust was primarily limited to financial matters.
- The SHA was not aware of any concerns regarding the quality of services provided by the trust before Dr Foster Intelligence published its Hospital Guide in April 2007.
- Although overall there were financial pressures in the SHA, the SHA did not recall insisting that the trust make savings of £10 million in 2006/07.
- The SHA commissioned the University of Birmingham to undertake research into the findings in the Dr Foster Hospital Guide 2007.
- The SHA was assured by what the trust told them it was doing in relation to the Dr Foster report and healthcare-associated infections.

Conclusions

This section of the report brings together our overall assessment of the areas covered in the terms of reference. It is based on our findings in the report. We address the questions that are key to understanding what happened to patients admitted as emergencies at the trust.

What was the experience of patients and relatives at the trust?

When we announced the investigation we had an unprecedented response, with 103 relatives and patients contacting us. Of these, 99 were critical or had had a poor experience. The main areas of concern were A&E, the emergency assessment unit and medical wards 10, 11 and 12. Concerns were also expressed about some surgical wards. A major concern was poor standards of nursing care.

Although we recognise that this was not a statistically representative sample of patients and relatives, their concerns reflected what we found through observations, case note reviews, complaints and interviews – disorganisation, delays in assessment and pain relief, poor recording of important body functions, symptoms and requests for help ignored, and poor communication with patients and families.

In the Healthcare Commission's 2007 survey of inpatients (the latest national survey available), the trust was in the worst 20% for 39 out of 62 questions, and the in the best 20% for two questions. This was a poor result. The trust was in the worst 20% for overall standards of care and whether patients felt they were treated with respect and dignity in the hospital.

Did the trust have a high mortality rate?

The trust's mortality rate for patients aged over 18 admitted as emergencies had been high since 2003. If outcomes were the same as would be expected for other similar trusts, the standardised mortality ratio would be 100. The value for the trust varied from 127 to 145 for the three years covered by the investigation. The crude mortality rate was also significantly high for the same three years.

The mortality was found to be high across a range of conditions (analysed by the standard system of healthcare resource groups), including those involving the cardiac system, vascular system, nervous system, respiratory system, haematology and infectious diseases. This strongly suggested that there were systemic problems across the trust's entire emergency care system, rather than being confined to one area or specialty.

Did the trust have adequate arrangements for collecting and analysing data and for responding to high mortality rates?

The trust had a long history of poor quality information about its services. Since the summer of 2007, the coding of clinical data had improved. However, it was still difficult, if not impossible, to match information between systems. In part, this was due to the poor system for recording activity in theatres. Data that we had from different sources, such as the theatre log and national Hospital Episode Statistics data, could not be reconciled. When challenged, neither the trust nor individual consultants could produce an accurate record of clinical activity or outcomes for patients. This meant we could not analyse the volume of surgical work and its outcomes.

The trust's response to alerts about high mortality was inadequate. The trust assumed that the raised mortality was primarily due to poor coding of information, but could not substantiate its claim. The trust established a group to investigate mortality. It did this by looking at samples of the case notes of patients who had died. However, the reviews were not systematic and were not robust. The default position appeared to be that the deaths had been inevitable and there were no problems with the care of the patients. Although our case reviews were undertaken on a small scale, they threw significant, and troubling, light on the clinical quality and governance arrangements prevailing in the trust. We found that there had been problems with care that had not been identified, and the trust had missed opportunities to learn lessons.

What did we find out about the care of patients admitted as emergencies?

The A&E department

Most patients admitted as emergencies come first to an accident and emergency (A&E) department. Such patients should expect timely and thorough assessment by trained and skilled staff, followed by an appropriate plan of care. In the trust, patients arrived at a department that was poorly led, understaffed and poorly equipped.

The position when the Healthcare Commission visited the department in May 2008 was so worrying that we asked for an urgent meeting with the chief executive to raise our concerns, and we followed this up immediately with a formal letter requiring urgent action.

The department had been refurbished in the summer of 2007. This had improved its appearance, but an opportunity had been missed to improve the function of the department. The layout meant that it was difficult for staff to see patients in the waiting room. The view from the reception desk was limited and this was especially worrying as the receptionists were relied upon to observe the patients. This was despite one of the objectives in the project plan for the refurbishment being better visibility of patients.

The department lacked many items of equipment including trolleys, cardiac monitors in the resuscitation bays, sufficient lighting and portable suction. Access to CT scanning out of normal hours was difficult and sometimes led to delays in diagnosis and treatment.

Administrative staff in reception assessed patients (other than those arriving by ambulance) because there were too few nurses to perform triage. These staff did not have any qualification or training for this task. We were given examples of patients who had been adversely affected by the lack of adequate assessment. Many patients waited for hours with no pain relief, observations, dressings or antibiotics.

There was a longstanding shortage of consultants in emergency medicine in the department. This was exacerbated by the turnover of managers. When we visited in May 2008, there was only one consultant in post when there should have been at least three. It was only possible to have consultant cover for a maximum of 12 hours per day. This was a completely unacceptable situation.

The trust mistakenly treated as interchangeable the roles of acute physicians and consultants in emergency medicine, and the acute physicians were asked to cover aspects of A&E that were outside their professional competence. This was unacceptable.

There was also a longstanding shortage of middle grade doctors. For two weeks in October 2006, there was no consultant or middle grade cover between midnight and 7am on weekdays. This was also unacceptable.

The shortage of consultants and middle grade doctors meant that junior doctors were not adequately supervised or supported, which put patients at risk. For some months in 2008, there was virtually no educational activity and teaching sessions were frequently cancelled. The lack of leadership, feedback on performance and opportunities to develop left the junior doctors demoralised, frustrated and

concerned. Junior doctors rarely received feedback on their performance.

There was also concern that, in order to achieve the target that no patient should wait more than four hours in A&E, junior doctors were frequently put under pressure to make rapid decisions to discharge or to admit. This was especially unfortunate, as the doctors in training were not adequately supported in making these decisions.

Many staff considered that the focus on the four-hour target led to a distortion of clinical priorities, as on occasions doctors were asked by managers to stop treating seriously ill patients in order to see and treat patients with minor ailments.

There was also a shortage of nurses in the department and a worrying deficit in senior nurses and senior nursing leadership. Nursing staff were concerned about their capacity to observe and monitor patients, and deliver minimum standards of care. Few nurses had undertaken any nationally recognised course in A&E nursing.

Sometimes, patients were moved from A&E to the emergency assessment unit without a proper plan of care, which resulted in delays in patients receiving fluids and antibiotics. Sometimes patients with injured limbs were moved to wards before they had been x-rayed.

On other occasions, patients were moved to the small clinical decision unit in order to 'stop the clock'. This area did not have a formal allocation of staff, as A&E nurses were meant to cover it. Since there was often a shortage of staff, particularly at night, patients in this area were not properly monitored. Some of these patients were quite unwell and we concluded that it was not a safe environment for these patients. Again, this was unacceptable.

There were few protocols or guidelines in use in the department. There was no regular clinical audit. When audits were completed by doctors as part of their training, the results were not acted upon, even if they showed an unsatisfactory clinical situation.

There were no meetings to discuss mortality or morbidity (that is, complications or adverse consequences of treatment) within the department, and hence to gain feedback on the quality of care. There was no systematic monitoring of patients who had to return because they should not have been sent home in the first place.

There was no formal discussion of serious incidents, even though some of these were examples of repeated errors, such as the administration of penicillin to patients who were allergic to it.

Therefore, we conclude that the A&E department was fraught with hazards for patients. It had too few staff, who were inadequately trained and poorly led, with a poorly designed environment and lack of equipment. The focus on the four-hour target often meant that doctors were moved from treating seriously ill patients to those with more minor ailments. There was no effective system for governance in the department.

The emergency assessment unit

The capacity of the emergency assessment unit (EAU) had not been planned with an understanding of the demand for emergency admissions. The unit in the trust was unusual in that it took surgical, trauma and gynaecology patients as well as medical patients. However, it did not have appropriate staffing or equipment for these patients.

Until May 2008, it was a large unit, with 48 beds and a dysfunctional layout. Eight beds were far from the nurses' station and could not easily be observed. It was a noisy, busy place, frequently described by patients, relatives and staff as chaotic. In 2007/08, it had performed poorly in a trust audit for compliance with good hand hygiene and infection control. Neither did it perform well in 2007 on an audit of prevention of pressure sores.

Some patients were admitted to the EAU before they had been properly assessed in the A&E department. Other patients had to remain in the EAU for longer than was desirable because of the lack of a bed in their specialty. This included

patients who should have been in the acute coronary unit.

The EAU did not have the recommended ratio of one qualified nurse for every six patients. The trust's plan to save money in 2006/07 resulted in a reduction in staff numbers. At the end of 2007, the nurse to patient ratio was close to one nurse for every 15 patients. This was clearly inadequate for the many acutely unwell patients on the unit. The situation improved in May 2008, when 12 beds were removed from the unit and by July there was one qualified nurse for every 10 patients.

The shortage of nurses compromised communication with doctors and other healthcare professionals. Doctors said they often could not find a nurse who knew about their patients. Lack of communication was a frequent theme in complaints about the unit.

Many patients and relatives told us about patients not receiving basic care, such as help to eat and drink. Buzzers were not answered. Telephones often went unanswered. Many patients did not receive the correct medication in time, or at all.

There was also concern that surgical patients and those with traumatic injuries were not well managed on the EAU, because the unit did not have nurses with the right skills.

By May 2008, the unit had its full complement of three acute physicians. However, their inclusion in the A&E rota has already been criticised in this report as inappropriate.

There was little training for nurses on the unit in 2007/08 because of operational pressures on the service. This deficiency included training in life support and in July 2008 only one member of staff had a qualification in advanced life support.

We were particularly concerned that nurses did not have the expertise to recognise when a patient's condition was deteriorating, to read cardiac monitors, or to complete and interpret fluid balance charts. All of these deficits put patients at considerable risk.

It was deeply worrying to us that nurses made simple arithmetic errors in adding up the scores for the modified early warning system (MEWS), supposedly designed to alert clinical staff to patients becoming seriously ill. Similarly, it was a very serious concern that staff responsible for patients in the bed spaces with cardiac monitors on the EAU did not understand the monitors. On occasions, for this reason, nurses turned off the monitors. This put patients at risk and was unacceptable. We noted that the trust's own audit in July 2008 found that a large number of patients on the EAU were succumbing to cardiac arrest. This suggests the important need for staff in the EAU to be competent in the use of cardiac monitors.

Many doctors were worried that nurses did not carry out observations of, for example, patients' heart rates and blood pressure, frequently or thoroughly enough. This was particularly true at night.

Many patients did not have their fluid balance adequately monitored and nurses were not using the right equipment to ensure that patients received the correct amount of intravenous fluid in the correct time period. Of 20 infusions that we observed on one visit, only two were running on time. On subsequent visits, more of the infusions that we observed were running on time.

Overall, we found the EAU to be another clinical area that was full of hazards for patients admitted there. There were too few nurses and many of those that worked there did not have the right skills, since they did not understand cardiac monitors and made errors in identifying whether the condition of a patient was deteriorating. A proper system for clinical governance might have identified these deficiencies and sought resources to improve standards of care, but this was not in place.

Medical admissions

The reconfiguration of medical wards, which were merged into 'floors', was associated with a reduction in the number of qualified nurses, particularly the more senior ward nurses. For example, until the summer of 2008, there was just one senior sister for the 78 beds on floor

two. This clinical area, comprising wards 10, 11 and 12, included many acutely unwell patients with strokes, chronic respiratory conditions and diseases of the digestive system.

There was considerable concern from doctors and nurses that the number of nurses on floor two was inadequate. The trust's own review of staffing levels in 2007 identified a shortfall of 77 nurses in medicine. The lack of nurses was compounded by high sickness levels.

Staff had reported many instances of low staffing levels involving risk to patients, and there had been many complaints from patients and relatives. These were around buzzers not being answered, privacy and dignity being ignored and patients receiving little or no help with food or drink. Staff in other professions raised concerns about the standards of basic nursing care, such as poor hydration and nutrition of patients. Staff and relatives were also worried about the failure to ensure patients received the correct medication.

Poor attention to the care of skin and pressure points meant that many patients developed pressure sores. An audit by the trust in January 2008 found that 55% of 38 patients on ward 10 had some degree of pressure damage. Only four of these patients had any pressure damage when they were admitted to hospital.

Senior staff told us that many medical patients ended up on the "wrong" ward – for example, a patient with alcoholic liver disease could be on the respiratory ward. They would then be looked after by a respiratory physician, not a gastroenterologist.

Care on the acute coronary unit was held in high regard by patients and relatives. However, we have already noted that many patients with heart attacks did not come to the coronary unit but remained on the EAU, where many nurses did not understand cardiac monitors. There had also been a longstanding problem with the cardiac monitors on the acute coronary unit. Although noted in July 2007, the problem had still not been resolved over a year later.

Stroke patients were always admitted first to the EAU, although many staff thought this was not a good environment for these patients. The trust had only four beds, located on ward 10, dedicated to the care of patients with an acute stroke. This was not enough for the number of patients admitted with a stroke. The trust did not meet the criteria for an acute stroke unit. Nor did it meet the guidance of the Royal College of Physicians that imaging of the brain should be undertaken within at least 24 hours of onset of a stroke. The mortality rate for patients with stroke at the trust was above the European average. There were also concerns about the basic care provided to some patients with stroke, including poor mouth care and inadequate help with feeding and drinking.

Unlike over 90% of trusts, the trust did not have facilities for non-invasive ventilation on the medical wards, even on the respiratory ward. This was despite the recommendation of the National Institute for Health and Clinical Excellence. Non-invasive ventilation is a means of supporting breathing, using a mask or similar device. Since there were often no beds on the critical care unit, some patients who needed it did not get this important type of care.

The trust failed to ensure that resuscitation trolleys were always appropriately stocked. In February 2008, we found a trolley on a ward that had not been checked since July 2007 and that contained some items that were out of date. The trust explained that this was not the resuscitation trolley used on the ward. However, this was of particular concern, given the incident in September 2006 when a patient was mistakenly given an infusion that should not have been on the trolley. The patient was seriously ill and the error occurred during attempts at resuscitation. The unchecked trolley could have been confusing, particularly to agency staff.

The availability of portable suction equipment had been limited in the trust. Most bed spaces had suction as part of the permanent equipment available. However, patients could require resuscitation in locations other than these beds. We also noted that the bleep

system for cardiac arrests had been unavailable on a number of occasions. This meant the cardiac arrest team would not be aware of a cardiac arrest and would not respond. A contingency plan of using mobile phones was adopted.

Emergency surgical admissions including those with traumatic injuries

Care for patients admitted as surgical emergencies was not generally provided in line with agreed protocols.

Many staff had concerns that the nurses on the emergency assessment unit did not have the skills to look after surgical patients or those with traumatic injuries. Because of a lack of surgical and trauma beds, these patients might also be sent to medical wards. Again, it meant that patients were not always cared for by nurses who understood their conditions and had the necessary skills or equipment, for example to establish lower limb traction.

There had been a period when trauma patients were located between wards 6 and 7, on floor one, in a "no man's land". At this time there was no reception area, no nurses' station, no telephone, and no access to a computer. The layout meant that some beds could not be observed. We noted that it was in this location that a serious untoward incident had occurred.

There was inadequate cover by doctors for surgical patients at night and weekends. There was just one foundation year one doctor (the most recently qualified) to cover all the surgical patients on the wards. The most senior doctor to cover admissions for surgery after 9pm was the resident surgical officer. Some of the resident surgical officers were inexperienced. The only support they had was from a consultant on call from home. Although the consultants were available to be called, some doctors in training admitted they had left patients to the morning rather than call the consultant at night.

At weekends, there was only one emergency operating list per day. There was no system to prioritise cases for the emergency theatre list. Priority was generally given to general surgical patients or obstetric cases, which meant that patients with traumatic injuries often did not get operated on at weekends. We heard many examples of where patients with broken hips had their operations cancelled several times, sometimes resulting in a delay of several days. The guidance is that such patients should be operated on within 24 hours. In the trust's own review of patients who had died, the lack of availability of emergency theatre time was considered to be a factor contributing to some deaths. Similar delays occurred for patients with other fractures of long bones.

When patients had to wait for their operations, often being scheduled and then cancelled, their drugs, fluids and food were stopped for quite long periods. Thus, a patient might have to experience three or four days in a row of being 'nil by mouth' for most of those days. We noted an instance of a patient who died, who had not had their medication for their heart problem for three days prior to their operation.

There had been concerns for at least three years about the inefficiency and under-utilisation of theatres. There had been a high turnover of theatre managers and high sickness levels among theatre staff. The poor information available about the number of operations performed and the outcomes of these operations meant we could not undertake further analysis about the volumes of specific surgical procedures.

On occasions, staff failed to identify that the condition of a patient was deteriorating after surgery. This meant that some complications of surgery were missed or only identified after a delay, with serious consequences for patients. The lack of regular review of such cases also meant that opportunities for learning were lost.

The trust had failed to implement an effective and consistent system of preventing blood clots in the veins of the legs and pelvis. When such clots dislodge, they can cause fatal obstruction to the blood flow to the lungs. This is a common and largely avoidable cause of

death in patients in hospital. We noted the frequent occurrence of deep venous thrombosis and pulmonary embolism in case notes and the reports of inquests. Although concerns about this had been expressed at the hospital management board in October 2005, it was clearly still a problem nearly three years later. An audit presented in September 2008 showed that only 30% of patients had been given an anticoagulant in accordance with the trust's protocol.

The relief of pain was also an area that generated complaints and where there had been little if any improvement.

Relatives and patients were generally complimentary about the critical care unit. However, at times there were too few staff to open a sufficient number of critical care beds, and some confusion and tension about access to medical advice from critical care.

What were the reasons for the failings at the trust?

It is the view of the Healthcare Commission that there were deficiencies at virtually every stage of the pathway of emergency care.

When patients arrived in A&E, they were usually assessed by reception staff with no clinical training, before waiting in an area out of sight of the staff in reception. There was no regular check by nursing staff of the patients in the waiting room. Some essential equipment such as cardiac monitors was missing or not working.

There were too few doctors and nurses, and poor training and supervision, and junior doctors were pressurised to make decisions quickly without the advice and support from more senior doctors. Doctors were moved from treating seriously ill patients to deal with those with more minor ailments in order to avoid breaching the four-hour target. Patients were moved to the clinical decision unit to 'stop the clock', but were then not properly monitored since this area was not staffed. Patients had to wait for medication, pain relief, wound dressings and antibiotics. There was only a relatively junior doctor available after 9pm to give advice on surgical patients. There was no specialist trauma team. In summary, the care and assessment of patients fell well below acceptable standards.

Sometimes patients were rushed to the emergency assessment unit without proper assessment or discussion and without appropriate specialist care.

The emergency assessment unit was a very large ward with a poor layout. It was busy, noisy and sometimes chaotic with too few nurses. Many of the nurses did not understand the cardiac monitors and did not always carry out observations adequately to identify if a patient's condition was deteriorating. There were many instances of patients not receiving the medication they needed.

There were too few stroke beds, not all patients with heart attacks went to the acute coronary unit, there was no non-invasive ventilation on the respiratory ward, and critical care beds and support were not always available. The medical wards on floor two were seriously understaffed and there were grave concerns about the standards of nursing care.

There were too few theatre sessions at weekends and consequent delay in getting to theatre, especially for trauma patients, and some patients did not get essential medication. Post-operative complications were not always recognised.

Surgical practice was idiosyncratic, relationships were poor and there was little multidisciplinary team work. There were concerns about the level of medical cover at night and at weekends. We identified many instances, in the areas we considered, of the lack of timely review by a senior doctor.

Across the trust there were shortcomings in resuscitation and arrangements to avoid potentially fatal blood clots were inconsistent.

It is our view that all these factors would have contributed to a poor outcome for patients.

What arrangements did the trust have for the prevention and control of healthcare-associated infections?

The patients and relatives who contacted us were very critical of standards of cleanliness and hygiene at the trust in 2006 and 2007. They provided us with graphic examples of a dirty environment and sloppy practice. In August 2007, the committee arrangements were changed and the chief executive chaired a steering group for infection prevention and control. The director of nursing also became the director of infection prevention and control (DIPC). In 2008, following these changes, the prevention and control of infection improved.

For at least three years, there was no public record of infection control in the form of an annual report until one was put on the trust's website in April 2008.

In early 2006, there was a doubling of the rate of *C. difficile* infection, strongly suggestive of an outbreak. The infection control team isolated infected patients and improved cleaning, but the outbreak was not reported to the strategic health authority nor to the trust's board, and therefore the public was unaware of it. A report by the trust some months later noted the lack of isolation of patients, inadequate cleaning of commodes and bedpan holders, delay in sending samples to test for *C. difficile*, poor communication between health professionals, and delay in commencing treatment for symptomatic patients. None of these deficiencies were drawn to the attention of the trust's board.

The trust did not publicise information about the number of cases of *C. difficile*. The trust had been slow to control the prescribing of antibiotics. This was not compliant with good practice and there were no regular audits of practice.

Since the end of 2006, the rates of *C. difficile* and MRSA had declined. The control and prevention of infection had improved in 2008 following the establishment of the steering group and the appointment of the new DIPC in the previous year. The trust was inspected in October 2008 and judged to be meeting the duties in the Government's hygiene code. The trust deserves credit for this.

What governance arrangements did the trust have to monitor and improve its services?

In March 2006, the trust's board decided that, in future, reports on governance would come only to the private meeting of the board. Neither the chairman nor chief executive could explain this decision.

We have noted the almost complete absence of governance in the A&E department, which was part of the medical division. We have commented on the longstanding awareness of problems in the department and the failure to take effective action.

In surgery, there was no effective governance structure or audit process, and in at least one specialty consultants had no agreed common protocols. There were poor relationships between the general surgeons, and little multidisciplinary team work. This had inhibited the development of common protocols and agreed ways of working. There was little information available about the volume and outcomes of specific operations. The surgeons had a poor record of attendance at divisional governance meetings.

There were no meetings in the medical division to discuss mortality and morbidity (that is, complications or adverse consequences of treatment). In surgery, there were some meetings, involving only doctors, to discuss audit results and mortality and morbidity, but these were not minuted, and there was no systematic way for findings to be shared or lessons learned.

Overall, we considered that the approach of the mortality group to reviewing patients who had died was not sufficiently systematic or robust. This meant that important failings, such as lack of early review by a senior doctor, were often missed. Even if they identified that something had gone wrong and needed to be addressed, this did not necessarily happen. Thus, although the mortality group had identified in October 2007 the concern about

failure to give essential medication to 'nil by mouth' patients, a year later no effective action had been implemented to prevent this happening again.

Clinical audit should improve the quality of care through review of achievements against standards and making changes where necessary. The trust did not have a consultant with lead responsibility for clinical audit for a year and the trust-wide group did not meet at all during this period. When audits were carried out, there was no robust mechanism to ensure that changes were implemented. There was little effective clinical audit undertaken in the medical or surgical division. When re-audits were required, they were often not undertaken, even if they had been recommended by a Royal College. The trust did not participate in many of the specialist national audits run by the specialist societies.

We were concerned that the trust made a number of errors in the returns to the Commission for its review of urgent care, and that some reports to the board and committees were inaccurate or incomplete.

Were doctors actively engaged with governance and the business of the trust?

The chief executive told us that there had been considerable efforts made to engage with clinical staff and felt that progress had been made. However, we found that many senior doctors were disillusioned, since they considered that the trust had not heeded their concerns about the impact of the clinical floors programme, the lack of staff in A&E or the £10 million cost savings in 2006/07. It was notable that the trust did not have a substantive director of nursing or medical director in place for much of 2006.

Many consultants that we spoke to considered that the trust's decisions were driven primarily by financial considerations. Although they acknowledged that the trust now had a clear direction, many felt marginalised because of the trust's inflexible ways of imposing change. Some appeared to have given up expressing their views, since managers were said to dislike critical comments and to ignore them.

Although most non-clinical staff told us that care at the trust was good, the majority of doctors would not have been happy for a relative to be treated at the trust. In the national survey of NHS staff in 2006, only 27% of staff said they would be happy with care at the trust, compared to 42% nationally.

Worryingly, many consultants considered that governance at the trust was something that was done to them, rather than being a key part of clinical activity in which they had a major part to play. A symptom of this was the insistence by one senior doctor that meetings to discuss, for example, unexpected deaths, were for professionals only and were not part of governance. Since clinical governance has been in existence for over 10 years, this was a significant concern. The poor relationships between the consultants in general surgery and the lack of teamwork were also worrying.

Did the trust have appropriate arrangements to identify and manage risk?

The trust had poor arrangements to manage risk. Items appeared on divisional risk registers from one year to the next without resolution and it appeared that the trust expected the divisions to manage some problems that were trust-wide, such as low staffing levels.

We have noted the failure in the medical and surgical divisions to resolve problems such as nil by mouth, cardiac monitors, the cardiac bleep system, portable suction, antibiotic prescribing and preventing blood clots and pulmonary embolism. Often these issues were listed on the corresponding risk register, but no effective action had been taken.

The trust had a high rate of complaints compared to other trusts and also high numbers of patients and relatives who were dissatisfied with the trust's response. Managers did not appear to be aware of these

signs of systemic problems. The investigation and handling of complaints was poor and, when action plans were produced, action often did not follow. No mechanism existed for the board to ensure such commitments were met.

The routine reports on performance that went to the board were so 'high level' that they did not identify the failings in care of patients. The information presented to the board on complaints was often incomplete or so summarised that it left non-executives at a disadvantage in being able to perform their role to scrutinise and challenge on issues relating to patient care. The trust's board never looked at any individual complaints, even when serious, which meant they missed out on this important way of learning about the experience of patients and the accompanying insight into actual practice.

Even the combination of serious complaints, staff saying they would not be satisfied with care at the trust and poor results in the national patients' survey, did not persuade managers and the board that standards of care were poor, or at least merited their attention and careful scrutiny. The trust missed other opportunities to learn from errors unearthed at inquests or during litigation.

Staff had little confidence that reporting incidents achieved change and the evidence we saw confirmed they were correct. We were concerned that many serious incidents were not reported as such or adequately investigated. Problems identified at inquests were not investigated further. Some types of serious incidents had been repeated, for example patients absconding, patients given incorrect infusions, and patients given drugs to which they were allergic. We have noted problems related to resuscitation. At board level, there was little focus on the investigation of incidents and subsequent learning.

Responsibility for dealing with complaints and incidents had largely been devolved to the divisions, but the trust did not monitor this.

What was the trust's approach to nursing and nurse staffing levels?

Many nurses told us that there had been little support for nurses and their development for some time, but that this had improved more recently with the arrival of the new director of nursing and the recruitment of more staff.

In 2002, the independent review of clinical governance at the trust by the Healthcare Commission's predecessor, the Commission for Health Improvement, reported that staffing levels were a cause for concern, particularly in nursing. In 2005, the trust had many wards with below average number of nurses.

The combination of the programme to create clinical floors and the decision to make extensive savings in 2006/07 led to a reduction of the number of nurses in post and the proportion of senior nurses. Additionally, in part because of the lack of staff, there was a serious shortfall in training.

The total number of nurses declined from 2,359 in April 2004 to 2,157 in April 2008. The number of nurses per bed also fell between 2006 and 2008. There were only three matrons for the entire trust. The loss of confidence and morale led to a further loss of skilled and experienced nurses.

The trust did not reinvest in staff in 2007/08, despite declaring a financial surplus in 2006/07, and despite information that could have been extracted from complaints, surveys and incidents that there were too few nurses and that this was having an adverse effect on the care of patients. The trust has told us that the surplus had to be used to repay brokerage to the PCT.

A review of the skill mix and numbers of nurses took place in the autumn of 2007. It found an overall deficit of 120 whole-time equivalent nurses. Recruitment began in January 2008, although the board did not approve the expenditure until the end of March 2008, after the announcement of this investigation. At least 12 months had elapsed between the formal recognition of a serious problem and the board sanctioning remedial

action. The problem was compounded because in at least two areas, A&E and floor two, the problems were widely recognised and merited action ahead of the outcome of a complex review process.

The culture of the organisation, the trust's board and its priorities

The clinical governance review in 2002 advised that the trust needed to develop an open culture, but we did not gain an impression from staff that this had happened, or that concerns were welcomed and could be discussed and resolved. In the 2007 national survey of NHS staff, the trust came in the worst 20% for staff reporting bullying by other members of staff.

The information about the outbreak of *C. difficile* in 2006 was not shared with the board or released to the public.

The leadership operated a closed culture. The trust's board clearly preferred to conduct much of its business in private, including much that would be discussed in public in other trusts. Poor results from the national staff and inpatient surveys were not discussed at public meetings of the board. Much of the routine business of the trust that would normally be discussed in public meetings was only considered when the board met in private session. This included annual reports on infection control and the hospital standardised mortality ratio.

Most staff considered that the board had a clearer direction with the chairman and the current chief executive. We noted that much of the discussion at the board was dominated by finance, targets and achieving foundation trust status. It had at least two 'away days' to discuss becoming a foundation trust. In 2007, the board allocated considerable time to discuss reports on marketing and competition with neighbouring trusts. For example, in the minutes of the board meeting in May 2007, the discussion on marketing covered a page, but the corresponding discussion on how the trust performed in the national patient survey occupied one paragraph.

Although board members assured us that the care of patients was their top priority, this was not apparent from the minutes, or from the decisions they took. The minutes and papers for the governance committee were only taken to the private meetings but, even there, there was no record of them being discussed and little generally about the quality of care. The secretary to the board stated that the minutes did not reflect the balance of what was discussed, since decisions and action were noted rather than debate. We noted, however, that this did not appear to apply to finance and that few actions were noted in respect of the quality of care.

The trust's response to the financial imperatives that faced the NHS in 2006/07 was misjudged. The trust agreed to make savings of £10 million to improve its financial position. This equated to about 8% of turnover. Of this, £1 million was to create a surplus, which the trust has said it had to use to repay brokerage to the PCT.

In making the decision to save £10 million, the trust did not conduct a rigorous assessment of the effects on services to patients of losing at least 150 posts. It did not consider in which areas the trust could not afford to lose staff. While the stated aim was to minimise the number of clinical staff that would be affected, managers did not control the redundancy programme and there was a failure to recognise the negative effect that this was having on morale and so lost more key staff than intended.

When the trust declared a surplus of £1 million at the end of 2006/07, it did not reinvest in staff, but has said it had to repay brokerage to the PCT. In July 2007, the board agreed a further £8 million cost improvement programme over the next two years, to meet national requirements and improve the surplus. These decisions were divorced from the reality of care for patients in A&E or on the wards where emergency patients were treated. The trust board was aware at this time that a high proportion of their own staff would have no confidence as a patient in the care at the trust.

What actions has the trust taken since the start of the investigation?

It is, of course, impossible to determine what actions would have been taken if there had not been an investigation. The agreement at the end of March 2008 to fund the deficit in nursing numbers was taken after the board knew there was going to be an investigation.

Since January 2008, there has been a net gain of 46 qualified nurses and 51 healthcare support workers. The trust has increased the number of matrons from three to 12. However, in November 2008, the trust's board noted that the trust was 40 nurses below the previously agreed establishment. The minutes of the meeting also record that no further funding or recruitment was planned because of the difficult financial position for 2008/09. The trust, though, has told us that the board has not stopped recruitment and will, as part of the 2009/10 business plan, revisit the establishment review and take a view of recruiting to the outstanding posts.

When we have expressed concerns to the trust, it has welcomed our comments, responded positively and begun to take action. The trust received formal notification of our concerns about the A&E department on 23 May 2008. It immediately set up a steering group for emergency care, led by an external individual who was previously the national lead for emergency care at the Department of Health.

Considerable progress has been made in A&E, but there is a need to maintain and build on the improvement. Two new consultants were appointed in November, but the original one went on long-term sick leave. The middle grade rota was fully staffed and there was a programme of training for junior and middle grade doctors. The number of nurses increased, but many of the new staff were quite inexperienced and there is still only one band seven nurse for clinical practice. A new model of care was introduced in the autumn of 2008. A triage system was put into place for 12 hours a day.

Ward-based training on the use of the modified early warning score (MEWS) was introduced in the autumn of 2008. A training package was agreed to ensure competency for the use of cardiac monitors. A four-bedded surgical assessment unit was opened. Two additional beds were opened on the trauma ward. The trust is reviewing the provision of emergency theatre lists at weekends. Additional sessions have been arranged at short notice when necessary.

The mortality group has become the clinical outcomes group and is now chaired by the chief executive. The trust reports that it is taking action to ensure that change happens following complaints. Early signs are that mortality for emergency admissions is lower than previously.

Summary of conclusions

Despite a system that looked good on paper, the trust did not have a clinical governance structure or audit process that worked. It had no effective system for monitoring outcomes for patients and so failed to identify or understand the cause of high death rates among patients admitted as emergencies. This was a serious failing. When the high mortality rates were drawn to the attention of the trust, it looked primarily to problems with data as an explanation, rather than poor care. The trust's board and senior leaders did not inform themselves sufficiently about the quality of care.

The clinical management of many patients admitted as emergencies fell short of an acceptable standard in at least one aspect of basic care. Some patients, who might have been expected to make a full recovery from their condition at the time of admission, did not have their condition adequately diagnosed or treated. Often, these shortcomings were not recognised and lessons were not learned.

The trust stabilised its finances and successfully focused on becoming a foundation trust. However, it lost sight of what should have been its main priority: to provide

high quality care to all of its patients. It took a decision to significantly reduce staff without properly assessing the consequences. Its strategic focus was on financial and business matters at a time when the quality of care of its patients admitted as emergencies was well below acceptable standards.

The trust deserves credit for responding positively to the concerns raised by the Commission and taking action.

The role of external organisations

South Staffordshire Primary Care Trust (PCT) received little information from the predecessor primary care trusts regarding services provided by the trust. Neither the commissioning process nor other sources of information indicated concerns about the quality of care at the trust. The PCT told us it was also reassured by the trust's ratings in the annual health check and its application to become a foundation trust.

The PCT became aware of concerns at the same time as the Healthcare Commission raised concerns, in early 2008. It responded to the 'Cure the NHS' group by acting as an advocate to help resolve the concerns of individuals. It also contacted its two local commissioning groups to check the views of GPs on the quality of care. The responses were highly critical of the trust. The PCT then undertook an unannounced visit to the trust in April 2008 and identified a number of concerns. It ensured that action was taken by the trust to address staffing shortages and the lack of clinical leadership.

The PCT agreed to provide some additional funding to the trust to support a number of short-term initiatives to improve quality, including employing additional senior nursing staff in A&E. The PCT also suggested that the trust used the internal reserves it had generated through its planned surplus. Additionally, it set up a GP service in A&E to help manage patients who needed primary care rather than an emergency service.

The West Midlands Strategic Health Authority (SHA) also suffered from an inadequate handover of information from its predecessor bodies regarding the performance of the trust. It was not aware of any concerns regarding the quality of services provided by the trust until the publication by Dr Foster of its Hospital Guide in April 2007. This showed the trust to have a hospital standardised mortality ratio of 127 for 2005/06. Other trusts in the West Midlands also had high rates. The SHA accepted without detailed scrutiny the trust's account of its actions in relation to mortality. Again, it told us it was reassured by the trust's ratings in the annual health check and its application to become a foundation trust.

The SHA also commissioned the University of Birmingham to undertake research into the mortality rates published in the Hospital Guide in April 2007.

We considered that information from the coroner would be useful for this investigation, and we were disappointed that he declined to provide us with any.

The national picture and lessons for other organisations

A number of the findings of this investigation in respect of acute hospital care are potentially relevant to the whole NHS. These include the need for:

- Trusts to be able to access timely and reliable information on mortality and other outcomes, and for trusts to conduct objective and robust reviews of mortality rates and individual cases, rather than assuming data errors.
- Trusts to recognise if the quality of care provided to patients admitted as emergencies falls below acceptable standards and to ensure that a focus on elective work and targets is not to the detriment of emergency admissions. Care must be provided to an acceptable standard 24 hours a day, seven days a week.

- Trusts to ensure that a preoccupation with finances and strategic objectives does not cause insufficient focus on the quality of patient care.
- Trusts to ensure that systems for governance that appear to be persuasive on paper actually work in practice, and information presented to boards on performance (including complaints and incidents) is not so summarised that it fails to convey the experience of patients or enable non-executives to scrutinise and challenge on issues relating to patient care.
- Senior clinical staff to be personally involved in the management of vulnerable patients and in the training of junior members of staff, who manage so much of the hour-by-hour care of patients.
- Trusts to identify and resolve shortcomings in the quality of nursing care relating to hygiene, provision of medication, nutrition and hydration, use of equipment, and compassion, empathy and communication.
- Good handovers when reorganisations and mergers occur in the NHS.
- PCTs to ensure that they have effective mechanisms to find out about the experience of patients and the quality of care in services they commission.

Recommendations

In this report, we have drawn together the different strands of numerous, wide-ranging and serious findings about the trust which, when brought together, we consider amount to significant failings in the provision of emergency healthcare and in the leadership and management of the trust.

We have therefore written to Monitor, the regulator of NHS foundation trusts, in accordance with the Health and Social Care (Community Health and Standards) Act 2003 (s53(6)), to highlight these significant failings. We had previously raised concerns with Monitor about the leadership of the trust, and we note that both the chairman and chief executive have left the trust in the two weeks leading up to the publication of this report.

Irrespective of the above, we expect the trust to consider all aspects of this report, including all our findings, which detail serious failings at different levels and across different parts of the trust's services. Here, we highlight where action is particularly important.

Action by the board

The trust's board must ensure that there is a systematic means of monitoring rates of mortality and other outcomes for patients. This information should inform the board's discussions about the quality of services at the trust, and also inform action taken to improve outcomes for patients.

More generally, the trust's board needs to reflect on its arrangements for overseeing the quality and safety of clinical care within the trust. In particular, how the trust:

- Develops and promotes an open, learning culture.
- Collects and reports information accurately, both internally and externally, and in sufficient detail.
- Identifies and mitigates risks to the safety of its patients.
- Identifies correctly, and then reports, investigates adequately and learns from serious incidents and unexpected deaths.
- Learns from, and ensures that necessary improvements are made following incidents, near misses and complaints.
- Engages clinicians and develops effective clinical audit.
- Considers and acts on the views and experiences of patients who use the trust's services.

A&E department

Recent improvements to the emergency department must be sustained and extended to ensure that the service is safe, that it meets the needs of patients, and that the department is adequately staffed and equipped at all times.

Staffing and capacity

The trust must continue the work it has started to recruit additional nursing and medical staff, to ensure that care provided to patients throughout the trust, including at night and at weekends, is safe and keeps to accepted standards.

The trust needs to review the training and supervision of its nursing staff and junior doctors, to ensure that they are undertaking appropriate roles, are confident and clear about the expectations placed on them, and are receiving all necessary support.

The trust must ensure adequate availability of theatre sessions to ensure that it is able to handle demand in an emergency without delay, and has an effective means of determining which cases requiring emergency surgery should receive priority.

The trust must ensure that there is adequate access for clinical staff to advice and support from medical staff in the critical care (intensive care) service, and ensure this is independent of the availability of beds in the critical care unit.

Standards of care

The trust must ensure that its medical and nursing staff deliver basic aspects of care, such as reviewing patients on a regular basis, monitoring their condition, and identifying and managing any complications that may arise. The trust must ensure that there is timely review of patients by senior doctors.

In the light of specific findings in this report, the trust needs to audit its arrangements for and, where appropriate, equipment used in relation to: medication (particularly on admission and for patients who are 'nil by mouth'); the resuscitation of patients; non-invasive ventilation; cardiac monitoring; and anticoagulation.

National recommendations

Analysis undertaken in this and other trusts* shows worrying variations across the NHS in the quality of coding of clinical outcomes, and variations in the extent to which statistical information is used to monitor the quality of local services and inform decisions at a senior level within NHS trusts.

This is of concern in a modern, information-driven health service where the interpretation and use of data is a fundamental means of improving clinical care. We recommend formally that all NHS trust boards have access to comparative data on outcomes for patients, including mortality, that is accurate, complete and as up-to-date as possible.

While recognising the challenges in ensuring that mortality rates are accurate and expressed in a way that does not cause unnecessary alarm among patients, or lead to unhelpfully risk-averse behaviour among clinicians, we believe that mortality rates can be published in a meaningful way to help patients to make informed choices about the quality of clinical care.

Boards of NHS trusts need to be focused at all times on the safety and quality of the services provided to patients. This includes having information available to boards that properly captures the experience of patients, so that non-executives can scrutinise and challenge the care received by patients.

The NHS and appropriate professional and educational bodies need to examine why the experience of patients on general wards in trusts that we have investigated continues to be of a poor standard, and take urgent action to improve the quality of nursing care in these areas.

PCTs need to develop more effective mechanisms to learn about the quality of care, the actual experience of patients and the outcomes of care in services that they commission, and give more priority to this aspect of commissioning.

The NHS needs to ensure effective handovers when reorganisations and mergers occur, so that information on services is transferred effectively to the new organisation.

* Healthcare Commission, *Following up mortality 'outliers': A review of the programme for taking action where data suggest there may be serious concerns about the safety of patients*, February 2009

Appendix A: The Healthcare Commission's criteria for an NHS investigation

The Healthcare Commission works to improve the quality of healthcare provided by the NHS and the independent (private and voluntary) sector. One of its functions is to investigate serious failures in NHS services.

What will the Healthcare Commission investigate?

The Healthcare Commission will investigate allegations of serious failings that have a negative impact on the safety of patients, clinical effectiveness or responsiveness to patients. This may include:

- A higher number than anticipated, or unexplained, deaths, serious injury or permanent harm, whether physical, psychological or emotional.
- Events that put at risk public confidence in the healthcare provided, or in the NHS more generally.
- A pattern of adverse effects or other evidence of high risk activity.
- A pattern of failures in service(s) or team(s) or concerns about these.
- Allegations of abuse, neglect or discrimination against patients.

Other failings with less serious effects on patients' safety may be subject to a review. In determining whether to investigate, the Healthcare Commission will consider the extent to which local resolution, referral to an alternative body, or other action might offer a more effective solution.

The Healthcare Commission does not investigate:

- A complaint that has not been pursued through the NHS complaints procedure or the Healthcare Commission's independent stage, unless it raises an immediate concern.
- Individual complaints about professional misconduct.
- Changes to service configurations.
- Matters being considered by legal process.
- Specific matters already determined by legal process.

This does not preclude the Healthcare Commission from investigating circumstances surrounding such matters, particularly if there are general concerns about patient safety or suggestions that organisational systems are flawed.

Appendix B: The investigation team

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Mr Graham Johnson
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Lindsey Scott
Chief Nurse and Director of Governance
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Mark Taylor
Former Chief Executive
Royal Brompton and Harefield NHS Trust
Vice Chairman of the National Institute for Health and Clinical Excellence

Dr Simon Walford
Consultant Physician
Former Medical Director
Royal Wolverhampton Hospitals NHS Trust

Appendix C: Interviews

The investigation team conducted a total of 309 interviews. Of these, 205 involved 197 former or current trust staff (some people were interviewed more than once). Table 1 contains more details regarding the former and current staff interviewed.

The investigation team were in contact with 139 stakeholders (that is, members of the public or members of external organisations associated with the trust). Of these, 125 stakeholders were interviewed in more than 100 interviews. Stakeholders were interviewed face-to-face or by telephone, either as a result of contacting the investigation team or in response to an invitation from the team. Tables 2 and 3 provide more details regarding the stakeholders involved in this investigation.

Table 1: Trust staff and former trust staff interviewed	
Chief executive and executives	10
Chairman, non-executive directors and governors	10
Senior nurses and specialist nurses	19
Ward nurses and healthcare assistants	41
Consultants (including clinical directors and heads of division)	33
Junior and middle grade doctors	28
Senior and middle managers	29
Pharmacy staff, allied health professionals and chaplain	10
Administrative and legal staff, and analysts	9
Domestic and portering staff	5
Union representatives (trust staff)	3
Total	**197**

Table 2: Stakeholders interviewed	
Patients, carers and relatives and members of the patient and public involvement forum	96
West Midlands Strategic Health Authority and the former Shropshire and Staffordshire Strategic Health Authority	7
Postgraduate medical dean for the West Midlands Deanery	1
South Staffordshire Primary Care Trust	6
University Hospital of North Staffordshire NHS Trust	3
West Midlands Ambulance Service NHS Trust	2
Coroner for the Staffordshire (south) district	1
Union representative (non-trust staff)	1
Local government	5
Members of Parliament	1
Auditors	2
Total	**125**

Table 3: Other stakeholders who contacted us	
Patients and relatives	7
Members of Parliament	4
Others	3
Total	**14**

Appendix D: Sources of information

- Interviews and correspondence with patients, relatives, carers and members of the patient and public involvement forum.
- Interviews and correspondence with past and present trust staff.
- Observations on the wards.
- Case notes and the trust's reviews of the case notes of a sample of patients who had died at the trust.
- Interviews with staff from South Staffordshire Primary Care Trust (PCT), West Midlands Strategic Health Authority (SHA) and other organisations in the local health community.
- Interviews and correspondence with Members of Parliament.
- Interviews with local councillors, including members of the overview and scrutiny committee.
- Minutes of trust meetings, including meetings of the trust's board, clinical governance, clinical audit group, audit and remuneration and terms of service committees, risk management committees, the trust's hospital management boards, the senior nurses' meetings, directorate and departmental meetings including the infection control team and committee and outbreak meetings.
- Reports to the trust's board, audit committee and other trust committees.
- Relevant trust policies and procedures including operational policies for A&E and the emergency assessment unit (EAU), and staffing shift patterns for A&E and the EAU.
- Reports on emergency care incidents and complaints.
- Nursing skill mix review 2007/08.
- The trust's training policies, and plans and details of training completed by different groups of staff.
- The trust's data on deaths following emergency admissions.
- Ombudsman reports supplied by the trust.
- Such annual reports on infection prevention and control from 2005 as were available.
- Infection control outbreak reports.
- List of outbreaks of healthcare-associated infections reported to the Health Protection Agency and the SHA since 2005, and data on numbers of new cases of hospital-acquired MRSA and *C. difficile* by month.
- Information from the trust on incidents in the medical and surgical divisions (including reports of serious untoward incidents).
- Details of relevant complaints regarding the medical and surgical divisions.
- Clinical audit summary reports.
- The trust's audit on inpatient drug prescriptions in the EAU in 2008.
- 'Snapshots' of the trust's risk registers and the trust assurance framework.
- Information on relevant complaints.
- Clinical governance documentation, such as the risk register and assurance framework.
- Self-assessments, audits and position statements by the trust.

- Ward assurance frameworks, and reports and briefing details on these.
- Analysis of trust data on death certificates and mortality figures.
- The trust's submission to the Healthcare Commission's urgent care review.
- The trust's website.
- Information from West Midlands SHA, South Staffordshire PCT and other organisations in the local healthcare community.
- Information from the Audit Commission, Postgraduate Medical Education and Training Board and other statutory stakeholders.
- Information from the National Confidential Enquiry into Patient Outcome and Death (NCEPOD).
- Analysis by the acute hospital portfolio team at the Healthcare Commission.
- Findings from the Healthcare Commission's national surveys of adult inpatients and staff in the NHS.
- Details of NHS second stage complaints received by the Healthcare Commission from 2005 to 2008.
- Reports commissioned by the trust, including the clinical review by the Royal College of Surgeons of colorectal services.
- Survey by Ipsos MORI commissioned by the trust in May 2008.
- Mortality data supplied by the Dr Foster Research Unit at Imperial College of Science, Technology and Medicine.
- Report of the Department of Health's Cleaner Hospitals Team visit in October 2007.
- Report of South Staffordshire PCT's visit to the trust in April 2008.
- Royal College of Physicians' National Sentinel Stroke Audit for 2006.
- Guidance from the National Institute for Health and Clinical Excellence, NCEPOD, the Royal College of Physicians and the Society of Acute Medicine.
- Summaries by the trust of some inquests involving the trust and their findings.
- Clinical Negligence Scheme for Trusts' report, April 2008.
- Hospital Episode Statistics.
- Mortality data provided by the Office for National Statistics.
- Department of Health statistics and trust data on surgical volume.
- National sickness absence level provided by the Information Centre for Health and Social Care.

Where appropriate, we also took account of the absence of relevant information and the trust's inability to provide us with information or evidence in particular areas.

Appendix E: Statistical appendix

Concerns about outcomes at the trust: outlier alerts

Table 4 details the mortality alerts generated in relation to the trust. It shows the source of the alert, when it was generated and the patient groups that they relate to.

Dr Foster Intelligence real-time monitoring system

The real-time monitoring system produced by Dr Foster Intelligence uses standardised methodologies (designed by Professor Sir Brian Jarman and Dr Paul Aylin) to allow trusts to compare their clinical outcomes against all other acute trusts in England, and against a local peer group. The system is also able to monitor outcomes for specific consultant teams, and by specialty. Where a significant divergence in a clinical outcome is detected, an automated alert is produced. Dr Foster states that 70% of acute trusts have purchased their real-time monitoring system.

The Healthcare Commission was provided with output from the trust's real-time monitoring system for non-elective admissions for 2007/08. Table 5 shows where the trust signalled with significantly high mortality (shown in normal text) and significantly lower than expected mortality (shown in italic text). The output below shows the number of spells (that is, stay in hospital: a period commencing with admission to hospital and ending on discharge) over the year in each patient group and the number of deaths within that group compared to the number that would be expected given the risk adjustment used in Dr Foster's model.*

Standardised in-hospital mortality

Outcomes for patients admitted as emergencies

Table 6 shows that standardised mortality ratios at the trust have been significantly high, at the 5% level ($p < 0.05$), for the 18+ age group, over the three financial years covered by this investigation. SMRs are also significantly high for the separate subgroups of patients aged 18 to 74 and 75+. SMRs for the 18+ age group are also illustrated in a funnel plot (figure 5). The horizontal axis represents the number of expected deaths at the trust in each year. This is higher in 2007/8 in comparison to the previous two years mainly because more patients are being assigned higher risk HRGs. This could reflect more complete coding.

Outcomes for patients admitted electively

Equivalent standardised mortality analysis was carried out to examine mortality outcomes for elective admissions at Mid Staffordshire. This analysis did not indicate any concerns about higher than expected mortality (See table 7).

Figure 6 shows that the trust's SMRs for elective admissions aged 18+ have been consistently within expected limits.

* Bottle A, Aylin P, "Intelligent Information: A National System for Monitoring Clinical Performance", *Health Services Research* 2008; 43:10-31

Table 4: Patient groups identified as mortality outliers for Mid Staffordshire NHS Foundation Trust

Patient group	Generated by	Date generated
Alerts generated prior to the launch of the investigation		
Operations on jejunum	Dr Foster	July 2007
Aortic, peripheral and visceral artery aneurysms	Dr Foster	August 2007
Diabetes	Healthcare Commission	August 2007
Peritonitis and intestinal abscess	Dr Foster	August 2007
Epilepsy and convulsions	Healthcare Commission	September 2007
Repair of abdominal aortic aneurysm	Healthcare Commission	October 2007
Other circulatory disease	Dr Foster	November 2007
Alerts generated after the launch of the investigation		
Chronic renal failure	Dr Foster	July 2008
Non-transient stroke	Healthcare Commission	October 2008
Other non-viral infections	Healthcare Commission	October 2008
Pulmonary heart disease	Dr Foster	November 2008

Table 5: Output from the trust's real-time monitoring system for non-elective admissions for 2007/08

Diagnosis group (discharge)	Spells	%	Deaths	%	Expected	%	Relative risk
All	8826	100%	934	10.6%	807.4	9.2%	115.7
Abdominal pain	976	11.1%	0	0%	3.8	0.4%	*0*
Cardiac dysrhythmias	404	4.5%	1	0.3%	7.7	1.9%	*13*
Acute cerebrovascular disease	353	4%	129	36.8%	95.2	27.1%	135.5
Urinary tract infections	340	3.9%	6	1.8%	18.2	5.4%	*32.9*
Noninfectious gastroenteritis	315	3.6%	2	0.6%	7.4	2.4%	*26.9*
Other lower respiratory disease	120	1.4%	17	14.2%	9.6	8%	177.6
Cancer of bronchus lung	82	0.9%	36	43.9%	23.9	29.1%	150.6
Septicemia (except in labour)	72	0.8%	46	63.9%	26.8	37.3%	171.4
Cancer of ovary	20	0.2%	8	40%	2.9	14.5%	276.6
Intestinal infection	11	0.1%	5	45.5%	1.6	14.3%	317.5
Cancer of rectum and anus	10	0.1%	6	60%	1.9	19.1%	313.8
Other infections including parasitic	3	0%	2	66.7%	0.2	6.2%	1067.2
Peri- endo- and myocarditis cardiomyopathy	2	0%	2	100%	0.2	8.5%	1172.7
Sickle cell anaemia	1	0%	1	100%	0	1.1%	9147.7

Table 6: Cross-sectional standardised in-hospital mortality outcomes for Mid Staffordshire NHS Foundation Trust (emergency admissions)

Financial year	18 to 74	75+	All aged 18+
2005/06	SMR = 148 p = <0.001	SMR = 144 p =<0.001	SMR = 145 p =<0.001
2006/07	SMR = 147 p = <0.001	SMR = 134 p =<0.001	SMR = 137 p =<0.001
2007/08	SMR = 136 p = 0.01	SMR = 124 p = 0.01	SMR = 127 p = 0.003

Source: Hospital Episode Statistics

Figure 5: Cross-sectional standardised in-hospital mortality outcomes for Mid Staffordshire NHS Foundation Trust (emergency admissions aged 18+) by year

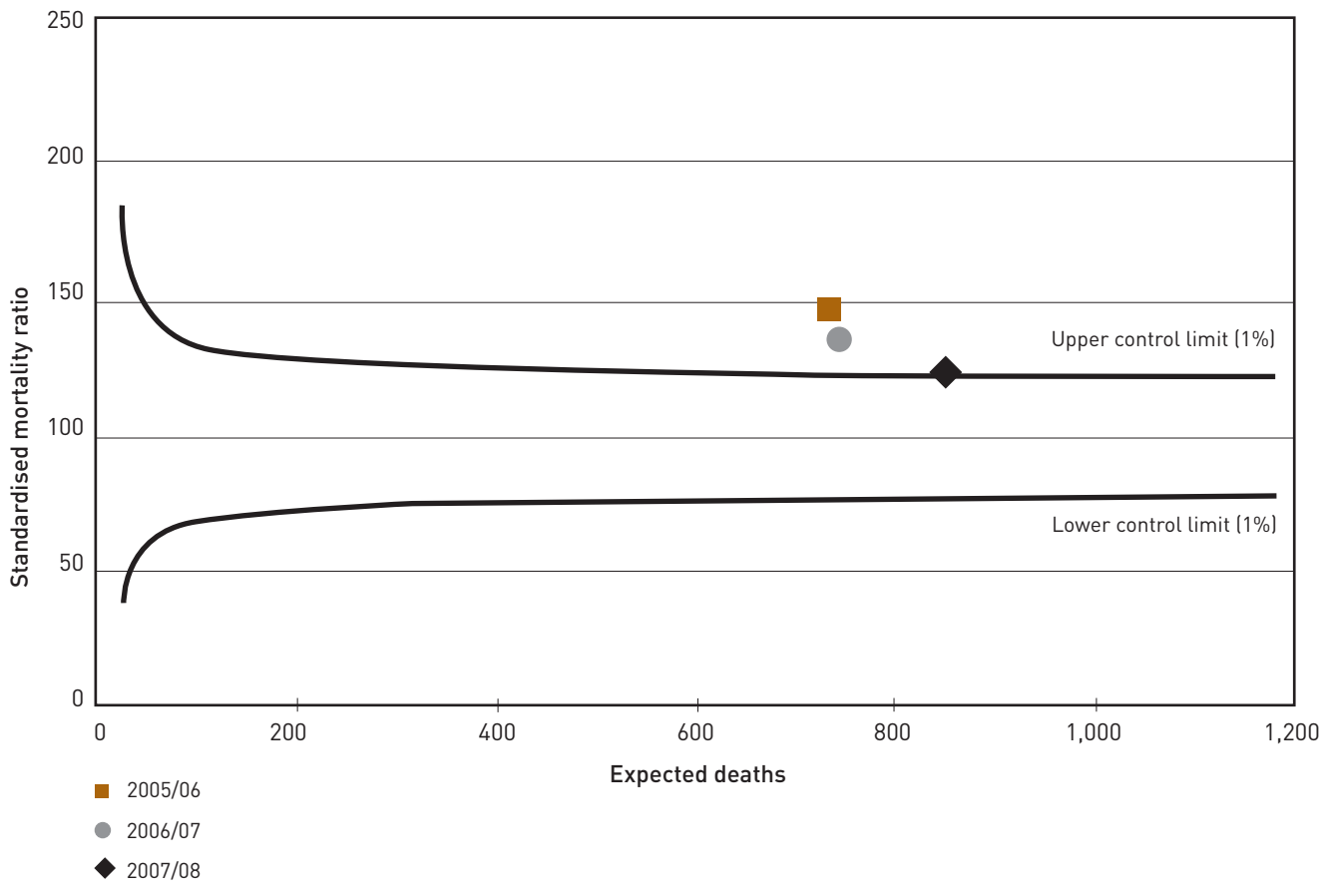
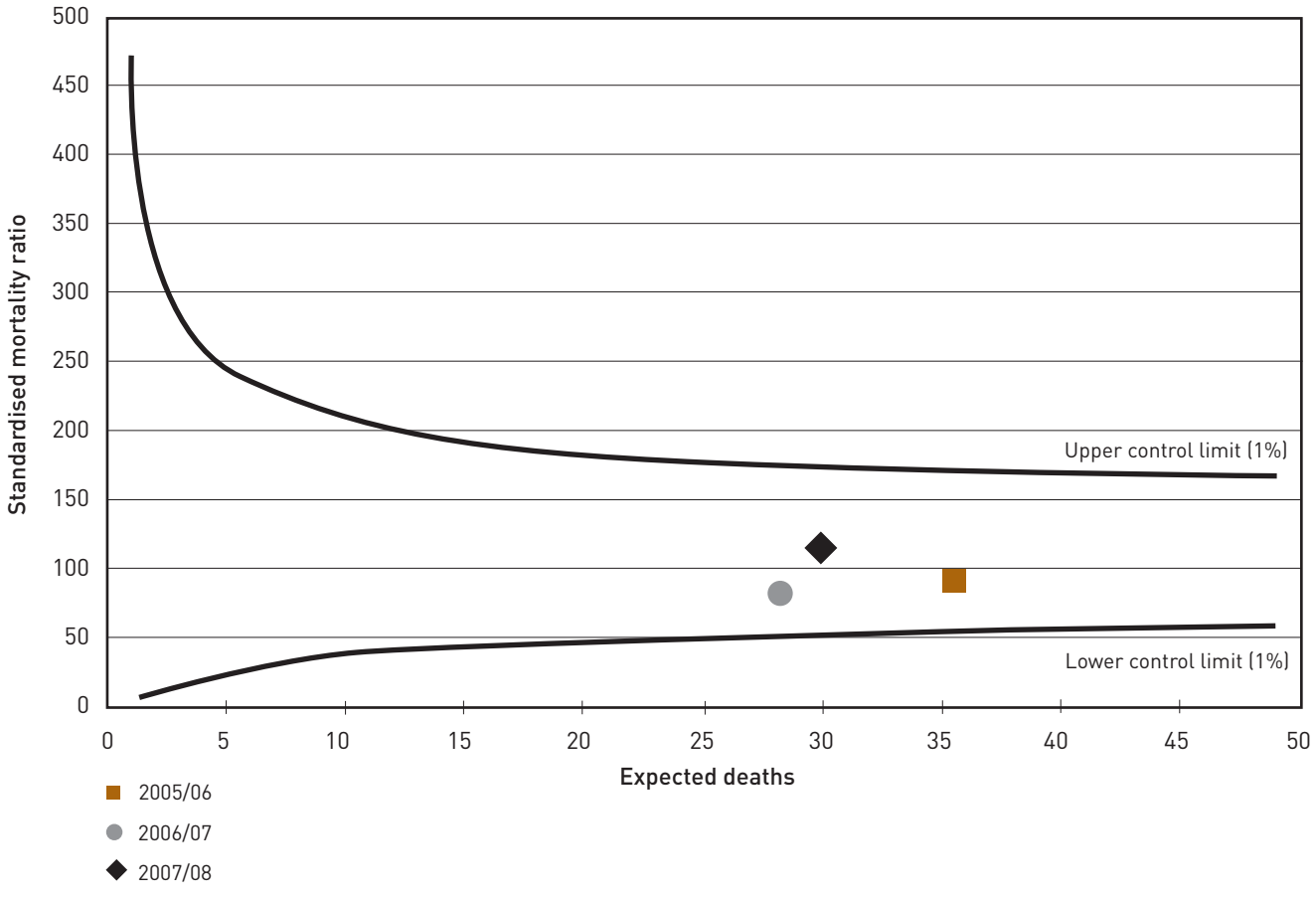


Table 7: Cross-sectional standardised in-hospital mortality outcomes for Mid Staffordshire NHS Foundation Trust (elective admissions)

Financial year	18 to 74	75+	All aged 18+
2005/06	SMR = 118 p = 0.29	SMR = 74 p = 0.83	SMR = 96 p = 0.56
2006/07	SMR = 73 p = 0.81	SMR = 97 p = 0.54	SMR = 85 p = 0.73
2007/08	SMR = 97 p = 0.53	SMR = 118 p = 0.29	SMR = 107 p = 0.39

Source: Hospital Episode Statistics

Figure 6: Cross-sectional standardised in-hospital mortality outcomes for Mid Staffordshire NHS Foundation Trust (elective admissions aged 18+) by year



Non-standardised in-hospital mortality rates for emergency admissions

Table 8 shows the crude mortality rate at the trust within each age group by financial year, and a p value indicating how significant the difference is when the trust's rate is compared to other non-specialist acute trusts.

Figures 7 and 8 show the trust's crude quarterly mortality rates for emergency admissions, compared with the mortality rates for all non-specialist acute trusts in England and for a peer group of nine other trusts (see next section) identified by Casp Healthcare Knowledge Systems (CHKS, a UK provider of comparative information and quality improvement services for healthcare professionals).

Over the three years covered by the investigation (from 2005/2006 onwards), the trust's rates have been consistently higher than both the national and peer group of trusts each quarter, both for admissions aged 18 to 74 and those aged 75 and over (with the exception of the 75 and over age range in the second quarter of 2005/06). During 2003/04 and 2004/05, a similar pattern was seen for the 18 to 74 age group, while the rates for the 75+ age group were more variable and on occasion were lower than the peer group mortality rate. See table 9 for the numbers of admissions and deaths at the trust upon which this analysis is based.

Peer group comparison

The peer group suggested to the Healthcare Commission by the trust was established by CHKS, by matching trusts of similar size, demographics of surrounding population and clinical activity. The trusts included in Mid Staffordshire's peer group are:

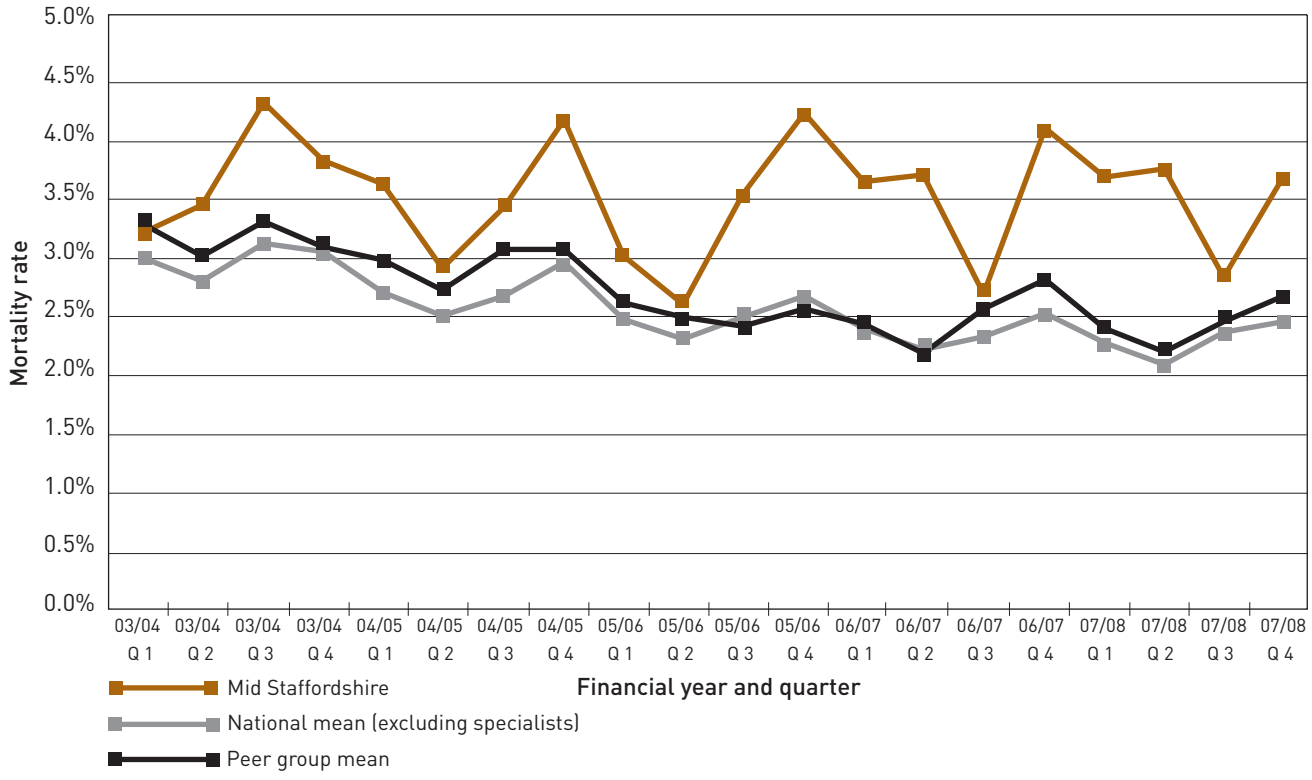
- Airedale NHS Trust
- Barnsley District General Hospital NHS Foundation Trust
- Burton Hospitals NHS Trust
- Dudley Group of Hospitals NHS Trust
- East Cheshire NHS Trust
- Southport and Ormskirk Hospitals NHS Trust
- The Countess of Chester Hospital NHS Foundation Trust
- The Rotherham NHS Foundation Trust
- Wrightington, Wigan and Leigh NHS Trust.

Table 8: Cross-sectional non-standardised in-hospital mortality outcomes for Mid Staffordshire NHS Foundation Trust (emergency admissions)

Financial year	18 to 74	75+	All aged 18+
2005/06	Rate = 3.3% p = 0.02 National rate = 2.5%	Rate =16.2% p = 0.01 National rate = 12.7%	Rate =7.8% p = 0.02 National rate = 5.7%
2006/07	Rate =3.5% p = 0.003 National rate = 2.3%	Rate =16.2% p = 0.004 National rate = 12.3%	Rate =8.0% p = 0.005 National rate = 5.5%
2007/08	Rate =3.5% p = 0.001 National rate = 2.3%	Rate =16.0% p = 0.002 National rate = 11.9%	Rate =8.1% p = 0.002 National rate = 5.3%

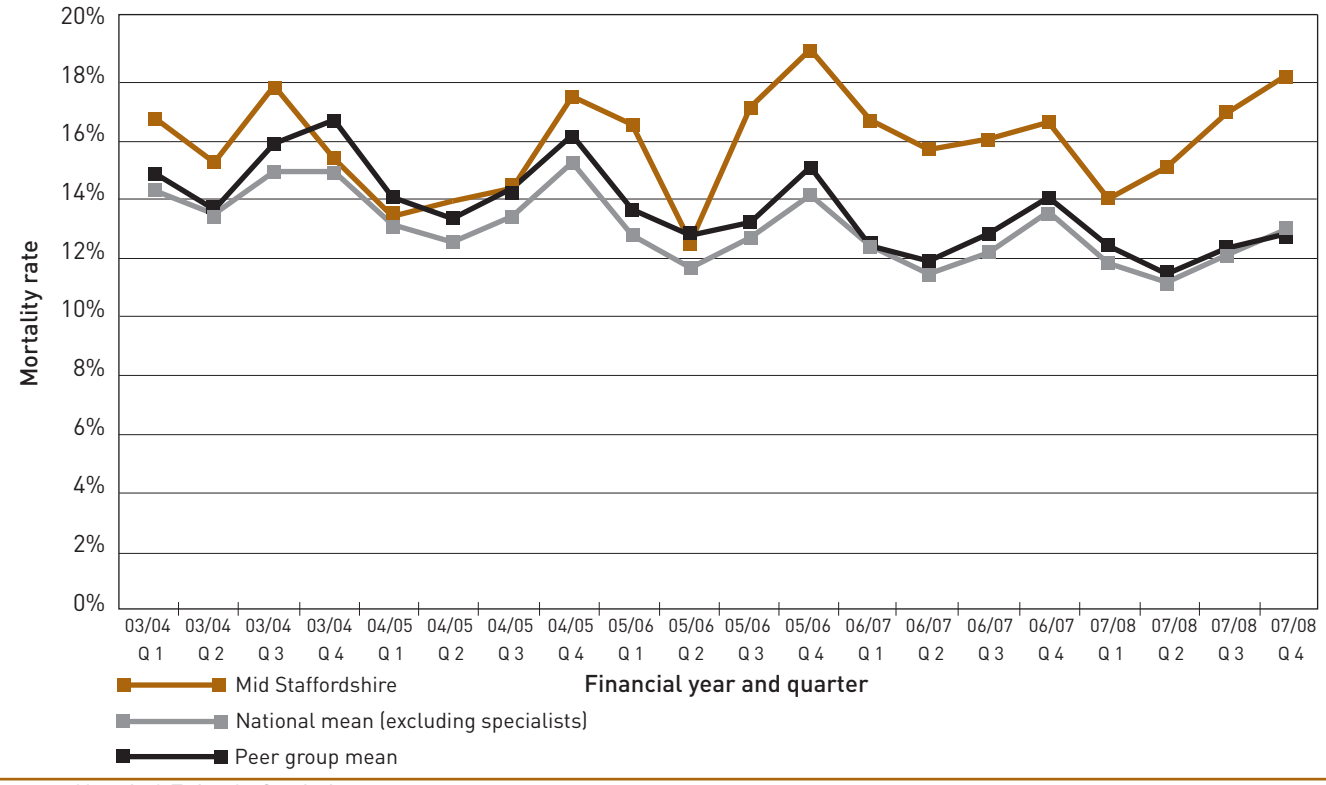
Source: Hospital Episode Statistics
National rate is for all non-specialist acute trusts in England

Figure 7: Non-standardised in-hospital mortality rates among emergency admissions aged 18 to 74 (April 2003 to March 2008)



Source: Hospital Episode Statistics
Note: The vertical line represents the start of the period covered by the investigation

Figure 8: Non-standardised in-hospital mortality rates among emergency admissions aged 75+ (April 2003 to March 2008)



Source: Hospital Episode Statistics
Note: The vertical line represents the start of the period covered by the investigation

HES-submitted emergency activity at Mid Staffordshire NHS Foundation Trust

Table 9 shows, for each quarter from 2003/04 to 2007/08 by age group, the numbers of patients that were discharged from the trust, the numbers of patients that died and the associated mortality rate.

Standardised HRG chapter level in-hospital mortality for emergency admissions

Cross-sectional standardised in-hospital mortality outcomes by HRG chapter and age group (emergency admissions)

Chapters and age groups that have significantly high mortality (at the 5% level, $p < 0.05$) are shown as shaded in table 10. HRG chapters with persistently high mortality over both 2006/07 and 2007/08 were:

- Cardiac surgery and primary cardiac conditions (ages 18-74)
- Vascular system (ages 18-74)
- Nervous system (ages 75+)
- Respiratory system (ages 75+)
- Haematology, infectious diseases, poisoning and non-specific groupings (ages 18-74 and 75+).

Additionally, chapters that became significantly high in 2007/2008 were:

- Nervous system (ages 18-74).
- Musculoskeletal system (ages 75+).

Standardised HRG chapter level ONS-linked total 30-day mortality

Outcomes are categorised into whether they are higher, lower or similar to expected compared with other acute trusts in England, when standardised by sex, age, admission method and HRG. In particular, the HRG chapters relating to 'nervous system', 'respiratory system', 'cardiac surgery and primary cardiac conditions', 'digestive system', 'spinal surgery and primary spinal conditions' and 'haematology, infectious diseases, poisoning and other non specific groupings' were all categorised as having much higher than expected outcomes. Additionally, chapters 'mouth, head, neck and ears', 'vascular system', and 'mental health' were categorised as higher than expected. The 'obstetrics and neonatal care' chapter was the only chapter categorised as having lower than expected outcomes. See table 11 for information on outcomes for all HRG chapters.

Table 9: Numbers of discharges and deaths after emergency admission at Mid Staffordshire NHS Foundation Trust (2003/4 Q1 to 2007/8 Q4)

	18 to 74			75+		
Quarter	Discharges	Deaths	Mortality rate	Discharges	Deaths	Mortality rate
2003/4 Q1	1984	63	3.18%	988	165	16.70%
2003/4 Q2	2044	70	3.42%	999	151	15.12%
2003/4 Q3	2098	90	4.29%	1073	191	17.80%
2003/4 Q4	2056	78	3.79%	1123	172	15.32%
2004/5 Q1	2309	83	3.59%	1124	149	13.26%
2004/5 Q2	2128	61	2.87%	1127	156	13.84%
2004/5 Q3	2357	80	3.39%	1194	170	14.24%
2004/5 Q4	2394	99	4.14%	1298	226	17.41%
2005/6 Q1	2243	67	2.99%	1180	194	16.44%
2005/6 Q2	2342	60	2.56%	1220	151	12.38%
2005/6 Q3	2333	82	3.51%	1186	202	17.03%
2005/6 Q4	2098	88	4.19%	1229	234	19.04%
2006/7 Q1	2185	79	3.62%	1140	189	16.58%
2006/7 Q2	2122	78	3.68%	1038	162	15.61%
2006/7 Q3	2109	56	2.66%	1227	196	15.97%
2006/7 Q4	1966	80	4.07%	1167	193	16.54%
2007/8 Q1	2108	77	3.65%	1281	178	13.90%
2007/8 Q2	2143	80	3.73%	1153	173	15.00%
2007/8 Q3	2112	59	2.79%	1300	219	16.85%
2007/8 Q4	2157	79	3.66%	1257	228	18.14%

Source: Hospital Episode Statistics
HES submitted activity from 2005/06 Q1 onwards agreed by the trust

Table 10: Cross-sectional standardised in-hospital mortality outcomes by HRG chapter and age group

HRG Chapter	Description	2006/07		2007/08	
		18 - 74	75+	18 - 74	75+
A	Nervous System	SMR = 135 P = 0.075	SMR = 143 P = 0.003	SMR =173 P = 0.002	SMR = 145 P = 0.001
B	Eyes and periorbita	SMR = 0 P = 0.728	SMR = 0 P = 0.794	SMR = 0 P = 0.687	SMR = 0 P = 0.708
C	Mouth, Head, Neck and Ears	SMR = 51 P = 0.790	SMR = 153 P = 0.221	SMR = 0 P = 0.991	SMR = 170 P = 0.176
D	Respiratory System	SMR =125 P = 0.067	SMR =121 P = 0.045	SMR = 115 P = 0.156	SMR =121 P =0.029
E	Cardiac Surgery and Primary Cardiac Conditions	SMR =159 P = 0.005	SMR =144 P =0.004	SMR =144 P = 0.029	SMR =118 P = 0.123
F	Digestive System	SMR =155 P = 0.004	SMR =126 P = 0.054	SMR =131 P = 0.088	SMR =95 P = 0.638
G	Hepato-Biliary and Pancreatic System	SMR =139 P = 0.120	SMR =111 P = 0.347	SMR =107 P = 0.412	SMR =115 P = 0.276
H	Musculoskeletal System	SMR =224 P = 0.004	SMR =112 P = 0.294	SMR =167 P = 0.078	SMR =151 P = 0.020
J	Skin, Breast and Burns	SMR =133 P = 0.221	SMR =82 P = 0.677	SMR =77 P = 0.724	SMR =72 P = 0.823
K	Endocrine and Metabolic System	SMR =250 P = 0.019	SMR =130 P = 0.207	SMR =81 P = 0.647	SMR =85 P = 0.657
L	Urinary Tract and Male Reproductive System	SMR =138 P = 0.161	SMR =156 P =0.008	SMR =129 P = 0.198	SMR =105 P = 0.400
M	Female Reproductive System	SMR = 0 P = 0.979	SMR = 346 P = 0.096	SMR =240 P = 0.109	SMR =81 P = 0.590
N	Obstetrics and Neonatal Care	SMR =0 P = 0.560	Not Applicable	SMR =0 P = 0.564	Not Applicable
Q	Vascular System	SMR =251 P = 0.004	SMR =130 P = 0.189	SMR =296 P = 0.001	SMR =113 P = 0.329
R	Spinal Surgery and Primary Spinal Conditions	SMR =146 P = 0.317	SMR =202 P = 0.093	SMR =0 P = 0.970	SMR =69 P = 0.714
S	Haematology, Infectious Diseases, Poisoning and Non-Specific Groupings	SMR =151 P = 0.034	SMR =160 P = 0.005	SMR =193 P = 0.002	SMR =165 P = 0.001
T	Mental Health	SMR =0 P = 0.843	SMR =165 P = 0.232	SMR =0 P = 0.934	SMR =156 P = 0.184

Source: Hospital Episode Statistics

Table 11: Total 30-day mortality by HRG chapter at Mid Staffordshire NHS Foundation Trust (April 2006 to December 2006)				
Much worse than expected	**Worse than expected**	**Similar to expected**	**Tending towards better than expected**	**Better than expected**
Chapter A Nervous system	Chapter C – Mouth, head, neck and ears	Chapter G – Hepato-biliary & pancreatic system	Chapter B – Eyes and periorbita	Chapter N – Obstetrics and neonatal care
Chapter D – Respiratory system	Chapter Q – Vascular system	Chapter H – Musculoskeletal system		
Chapter E – Cardiac surgery and primary cardiac conditions	Chapter T – mental health	Chapter J – Skin, breast and burns		
Chapter F – Digestive system		Chapter K – Endocrine and metabolic system		
Chapter R – Spinal surgery and primary spinal conditions		Chapter L – Urinary tract and male reproductive system		
Chapter S – Haematology, infectious diseases, poisoning and non- specific groupings		Chapter M – Female reproductive system		
		Chapter P – Diseases of childhood		
		Chapter U – Undefined groups		

Source: Hospital Episode Statistics linked ONS Mortality data
Analysis is based on all ages and all admission methods

Table 12: Discharges and deaths at Mid Staffordshire NHS Foundation trust by specialty (emergency admissions, aged 18 +)

	2006/07			2007/08		
Specialty	Discharges	Deaths	Mortality rate	Discharges	Deaths	Mortality rate
Surgical						
General Surgery	2198	106	4.8%	2428	101	4.2%
Urology	25	0	0.0%	24	0	0.0%
Trauma & Orthopaedics	1172	52	4.4%	1190	61	5.1%
ENT	73	0	0.0%	38	*	2.6%
Oral Surgery	*	0	0.0%	0	0	na
Accident & Emergency	517	37	7.2%	261	19	7.3%
Anaesthetics	*	*	33.3%	0	0	na
Overall surgical	3989	196	4.9%	3941	182	4.6%
Medical						
General Medicine	7897	774	9.8%	8482	845	10.0%
Clinical Haematology	14	*	*	27	*	*
Rehabilitation	*	0	0.0%	0	0	na
Dermatology	7	0	0.0%	*	0	0.0%
Thoracic Medicine	377	48	12.7%	383	44	11.5%
Neurology	0	0	na	*	0	0.0%
Rheumatology	73	*	*	69	*	*
Paediatrics	0	0	na	8	0	0.0%
Paediatric Neurology	*	0	0.0%	0	0	na
Geriatric Medicine	200	10	5.0%	115	10	8.7%
Obstetrics	18	0	0.0%	31	0	0.0%
Gynaecology	374	*	*	447	*	0.7%
Overall medical	8963	838	9.3%	9566	909	9.5%

Source: Hospital Episode Statistics
Numbers between 1 and 5, and their associated proportions, have been suppressed and replaced with '*'.

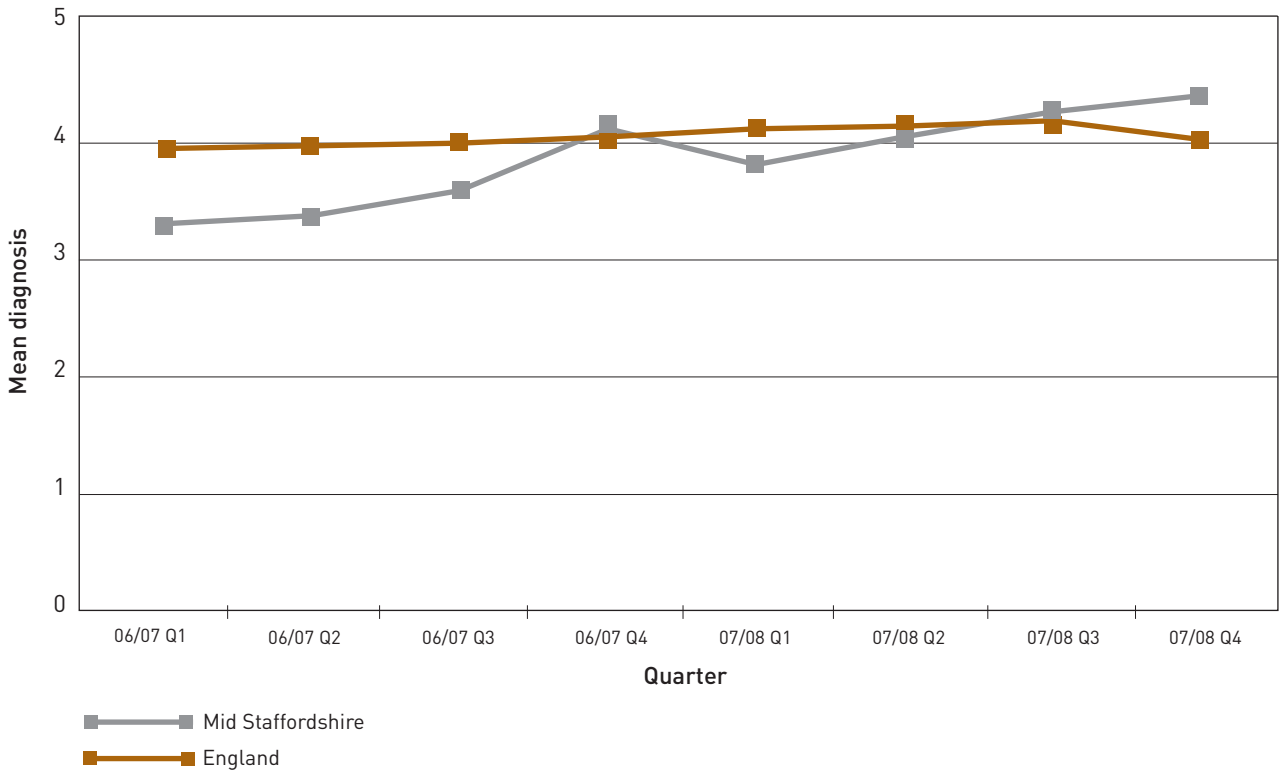
Discharges and deaths at Mid Staffordshire NHS Foundation Trust, by specialty

Table 12 outlines the specialty to which discharges and deaths were coded for their admission episode at the trust. The specialty coded is based on the contracted specialty of the consultant, rather than the specialty under which they were working at the time.

Coding depth

Figure 9 shows the mean number of diagnoses coded per episode at Mid Staffordshire compared with other acute trusts in England. Deeper coding is an indication of better quality coding, as more diagnosis codes give a more comprehensive picture of a patients condition and treatment. While in 2006/07 quarter 1 Mid Staffordshire had fewer diagnoses per episode than the national average, by 2007/08 Q4 their coding was deeper than England overall (4.4 codes per episode compared with 4.0 nationally).

Figure 9: Mean diagnosis codes per episode, 2006/7 Q1 to 2007/8 Q4 (emergency admissions, aged 18 +)



Note: England comparison excludes Mid Staffordshire NHS Foundation Trust

Methodology of measuring deviation of mortality from a national standard

Cross sectional comparisons of standardised mortality ratios

To assess the significance of observed mortality rates we indirectly standardise against national mortality rates according to the case mix of patients. A trust's outcomes are compared against an expected value which represents mortality at the national rate, allowing for differences in patient ages, gender and Healthcare Resource Group (HRG). We further standardise by time period (calendar quarter) so that comparisons are always local to each period and effects of seasonality and national trends are avoided.

If O_i represents observed mortality for patients assigned a particular HRG within trust i, and E_i the expected value, we calculate the standardised mortality ratio (SMR) as one hundred times the ratio Oi/Ei. In this way, if observed and expected values are equal the SMR has a value of 100. Values greater than 100 indicate that observed outcomes are higher than expected and, conversely, outcomes are lower than expected if the SMR is less than 100.

To assess the significance of deviations of the SMR away from the expected value of 100, we approximately normalise the values using a square root transformation and then standardise by subtracting the expected value and dividing by the standard deviation. If we also assume a Poisson distribution of outcomes, $\sqrt{(O_i/E_i}$ has expected value of 1 and a standard deviation approximately equal to $1/(2\sqrt{E_i})$. The standardised normal variate, or z-score, is then calculated as:

$$z_i = 2\sqrt{E_i}\left(\sqrt{\frac{O_i}{E_i}} - 1\right) = 2(\sqrt{O_i} - \sqrt{E_i})$$

It is possible that due to insufficient benchmarking or the presence of common-cause factors these values are over-dispersed, i.e. their true variances are greater than one. We therefore allow for such over-dispersion by assuming an additive random effects model. With this approach, a trust's true expected value is assumed to be distributed about the national rate with standard error τ. For cross-sectional comparisons this involves readjusting the z-scores by calculating

$$z_i^* = \frac{z_i s_i}{\sqrt{s_i^2 + \tau^2}}$$

where the S_i is the standard error of $\sqrt{(O_i/E_i)}$ assuming the national rate is true

$$s_i = \frac{1}{2\sqrt{E_i}}$$

Values for τ can be estimated with the formula:

$$\tau^2 = \frac{N\phi - (N-1)}{\sum_{i=1}^{N} w_i - \sum_{k=1}^{N} w_k^2 \Big/ \sum_{i=1}^{N} w_i}$$

where N denotes the number of trusts for which z-scores are calculated,

$$\phi = \sum_i z_i^2 \Big/ N$$

and

$$w_i = \frac{1}{s_i^2}$$

Before calculating τ and ϕ we Winsorise the data by shrinking the most extreme z-scores.

Control limits for the adjusted z-scores, z_i^* can then be set at appropriate multiples of

$$\sqrt{s_i^2 + \tau^2}$$

These can also be converted back into control limits for the SMRs.

Longitudinal comparisons of outcomes for specific patient groups

To compare outcomes over time for specific groups of patients we use the CUSUM, which is a statistical process control (SPC) technique that is used to detect persistent deviations from a reference value. This is a sequential hypothesis testing approach by which evidence in favour of outcomes occurring at the expected rate (the null hypothesis, H_0) is continually weighed up against evidence that a change has occurred (the alternative hypothesis, H_1). CUSUM control charts are plots of the cumulative log likelihood ratio between these two hypotheses. They are also constrained not to fall below zero. So, for example, if a CUSUM is designed to detect series of outcomes that are worse than expected, it cannot build up credit for series of good outcomes. If the CUSUM exceeds a predefined threshold, or control limit, then the hypothesis of a change (H_1) is accepted in favour of the null (H_0) and this constitutes an 'alert' or 'signal'. After each alert, the CUSUM is reset to zero so that if any changes subsequently occur there is time for them to take effect. Alternatively, if poor outcomes persist then a further signal is likely to occur at a later time. Control limits have to be set to guard against too many 'false alarms' occurring as a result of random variation, but not be set at too a high a value that it becomes very difficult to detect any differences in mortality.

Mathematically, if C_t denotes the CUSUM value and w_t the log likelihood ratio at time t then:

$$C_0 = 0$$
$$C_t = \max\{C_{t-1} + w_t, 0\}$$

The values w_t are called the CUSUM weights.

For series of outcomes we calculate the z-scores as for the cross-sectional analysis, but using SMRs appropriate for the smaller patient group. To allow for over-dispersion their distribution is modelled with a hierarchical structure: if z_{kt} represents the z-score for trust k at time t,

$$z_{kt}|\theta_k \sim N(\theta_k, \sigma^2)$$
$$\theta_k \sim N(0, \tau^2)$$

i.e. a trust's z-scores are normally distributed about a local mean for that trust, θ_k, with standard deviation, σ. These trust mean values are themselves normally distributed about zero with standard deviation, τ. The parameters θ_k, σ and τ can be calculated from the data.

To set a null hypothesis for the CUSUM we set a value for the local mean that is in the upper part of its probability distribution, i.e.

$$H_0 : \theta_k = \gamma_1 \tau$$

where γ_1 can be interpreted as a tolerance factor for the mean. We are thus allowing the expected value for a trust to be greater than zero (see figure 10). This is tested against the alternative hypothesis:

$$H_1 : \theta_k = \gamma_1 \tau + \gamma_2 \sigma$$

With these assumptions the CUSUM weights are calculated as:

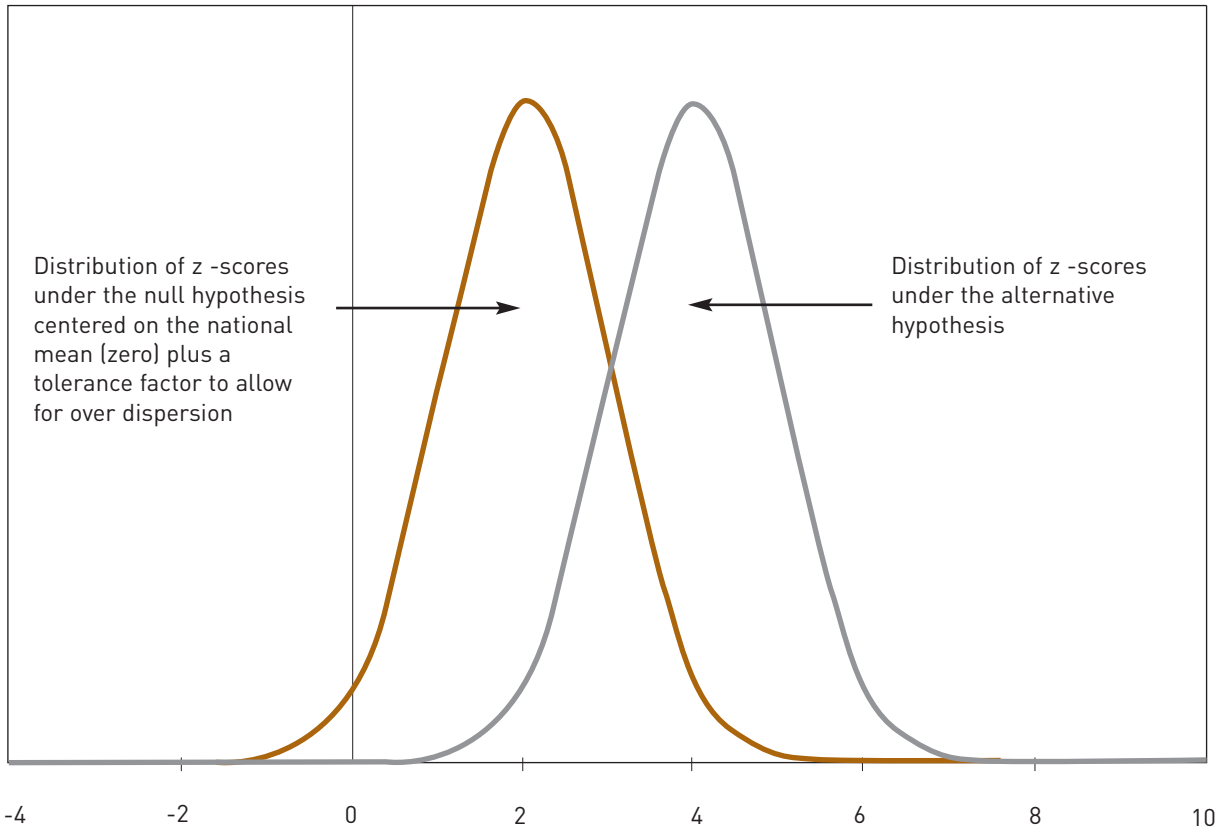
$$w_t = \gamma_2 z^*_{kt} - \frac{\gamma_2^2}{2}$$

where

$$z^*_{kt} = \frac{z_{kt} - \gamma_1 \tau}{\sigma}$$

For such a CUSUM it is possible to estimate steady-state p-values which can then be used for setting a stopping rule based on the false discovery rate (FDR). They also enable constant limits to be set that correspond to pre-specified tails of the null distribution of the CUSUM. We typically use the limit that corresponds to the upper 0.1% tail of the adjusted z-scores, z_{kt} (a CUSUM z-score approximately equal to 3).

Figure 10: Assumed distribution of z-scores for testing higher than expected mortality



Appendix F: Letter from the Healthcare Commission to the trust concerning A&E, 23 May 2008

Mr M Yeates
Chief Executive
Mid Staffordshire NHS Foundation Trust
Stafford Hospital
Weston Road
Stafford
ST16 3SA

23 May 2008

Dear Martin,

As you know the Healthcare Commission is currently undertaking an investigation of apparently high death rates and concerns about poor nursing care at your trust. We visited the Accident and Emergency department from 20 to 22 May 2008, as part of the investigation.

As we explained on 26 March 2008, when we met with you and your Chair and members of your executive and senior team, the Commission's policy is to raise any issues of concern regarding the safety of patients without delay, directly to the trust being investigated, rather than waiting for our report to be drafted. This letter follows our meeting with you on 22 May and is formal notification of the concerns of the Healthcare Commission about the emergency department.

The concerns cover three principal areas. These arise, in the main, from interviews, observations and other evidence gathered during our most recent visit (20-22 May) but are also informed by other evidence collected so far during the course of our investigation. Whilst we accept that our findings are therefore provisional, they are represented here following detailed discussion with the Commission's specialist advisors, who were present during our recent visit and who have been a major influence in us raising these concerns with you at this time. As you are aware, these advisors include specialists in emergency medicine, nursing, governance, medicine and surgery as well as senior leadership in the NHS.

1. Staffing

It is the view of the Commission and its advisors that the department is understaffed in relation to medical and nursing staff.

There is a single-handed emergency consultant in Accident and Emergency despite the fact that the College of Emergency Medicine recommends that there should be a minimum of four. This consultant appears not to be providing leadership to the department. The acute care physicians provide some support for the care of medical patients but cannot cover across the spectrum of undifferentiated illness and trauma that presents at A&E. There are periods of time when the most senior person in the department is a doctor who, although experienced, has no postgraduate qualification in emergency medicine. In the periods when the consultant is not in A&E the clinical accountability for patients is not clear.

There are insufficient middle grade doctors to provide adequate cover. The middle grade rota is not robust, the hours are not compliant with the European Working Time Directive and neither the middle grades nor junior doctors get sufficient breaks. One long-term locum doctor works only at night and sometimes works a long sequence of (more than 10) consecutive nights.

The lack of sufficient senior and middle grade cover means that junior doctors in training do not get sufficient support and advice. There is virtually no educational activity and teaching sessions are frequently cancelled, often for operational reasons. The lack of leadership, feedback on performance and opportunities to develop has left the junior doctors demoralised, frustrated and concerned.

There is also an inadequate number of nurses, with evidence that the current recruitment drive may not only not increase staffing levels as intended but not compensate for those leaving or intending to leave.

There is no nurse leader with clear accountability for nursing and leadership. There is no regular appraisal, induction or preceptorship. There is low morale demonstrated via "distressed" staff, excessive hours, no meal breaks and turnover.

2. Structure and operation of the department

The recent refurbishment appears to have been a missed opportunity. Insufficient thought was given to equipment and the department lacks trolleys that can be used in X-ray and has cardiac monitors that can no longer be repaired. The current arrangements at reception are far from satisfactory, since the fixed windows mean that neither the staff nor patients can easily hear what the other is saying. Patients in the waiting room are largely out of the sight of staff.

We note that the trust performed poorly in the latest national survey of inpatients, including in relation to waiting times, and privacy and dignity in A&E.

Effective initial assessment of patients is not in place. Although nurses have been trained in triage, the staffing situation means that they frequently cannot be released to triage patients. Receptionists are undertaking this function, placing patients who walk in to the department, in the major or minor category. Those in the minor category may then wait for hours in the waiting room. Particularly considering that patients in the waiting room are not clearly visible to either the receptionists or nursing staff, we believe that this constitutes a serious risk.

The four-bedded area originally described as the CDU (clinical decision unit) is used for a number of different types of patient. The staff that we spoke to are not clear about the existence of a protocol for placing patients in the CDU. We have noted that the combined operational policy for A&E and EAU with which we have been supplied is an undated first draft version and does not detail circumstances and arrangements for when patients are placed in either of the CDUs. Some patients stay overnight in the unit although it has minimal staffing, and during times of pressure, patients may not be adequately monitored. Staff that we spoke to do not understand the function of the 'new' (larger) CDU and are concerned that some of its nursing staff have been taken from A&E.

There is no clear system to move patients through the department, and when the four-hour limit is approaching, junior doctors can be put under undue pressure to make quick decisions. This is particularly undesirable given that there is often insufficient support from more senior doctors. On occasions, when the number of minor patients is significant and there are worries about breaches, concerns have been expressed that nurse managers may pressurise the middle grades to work in minors, rather than in majors or resuscitation where they may be needed more.

The department's accountability and reporting lines appear to be unclear. This relates to a number of areas: professional; managerial; and specialty.

3. Governance

There are few protocols or pathways in use in the department, and those that are in use are not audited. There is little use of data to monitor performance (other than the four hour target) and very little clinical audit. When audits have been done, e.g. of the adequacy of pain relief in children, they appear not to have been acted on, even though the results showed an unsatisfactory situation.

There are no multidisciplinary meetings for staff in the department to reflect on their performance and consider improvements. There are no meetings to discuss mortality or morbidity, or near misses and little opportunity to learn. Junior doctors rarely get feedback on their performance.

In summary, there appears to be an almost complete lack of effective governance.

Although we noted some positive factors, such as the presence of an occupational therapist in the department, our judgement is that the staffing shortages, operational problems, and lack of leadership and governance mean that, despite the efforts of staff, the quality of care is compromised and that this constitutes a risk to the safety of patients.

The Healthcare Commission requires you as a matter of urgency to consider these matters and take steps to address the shortcomings outlined in this letter. Given the seriousness of these issues, I should be grateful to receive a formal response from the trust no later than Tuesday 3rd June. We will write to you again as soon as we have had the opportunity to consider your response.

I am copying this letter to South Staffs PCT and the West Midlands SHA, and have also asked colleagues in the Healthcare Commission to pass a copy on to Monitor and the Department of Health to ensure that all of these bodies are informed of the concerns set out in this letter.

If you would like to discuss the content of this letter in more detail, please do not hesitate to contact me.

Yours sincerely

Dr Heather Wood
Investigation Manager
Healthcare Commission

Appendix G: Letter from the Healthcare Commission to the trust about concerns raised by patients and relatives, 7 July 2008

Mr M Yeates
Chief Executive
Mid Staffordshire NHS Foundation Trust
Stafford Hospital
Weston Road
Stafford
ST16 3SA

7 July 2008

Dear Martin,

As you know the Healthcare Commission is currently undertaking an investigation of apparently high death rates, particularly relating to patients admitted as emergencies, and concerns about poor nursing care at your trust.

As part of any investigation we invite feedback from patients, relatives and members of the public who have experience of the services at the trust that we are investigating. Thus far we have heard from over 100 individuals, and relatives and patients continue to contact us. This letter follows our analysis of the majority of the information that we have so far received. Whilst we accept that our findings are therefore provisional, they are represented here because the messages are very consistent.

The reason we are writing is to ensure that you are aware of the concerns and to ask you to address any that are not currently part of your plans to increase staffing levels and improve services. At this point this letter does not require a response, other than on the specific issue of medication.

The concerns that have been expressed to us cover a number of areas. Most stakeholders had several issues they wanted to raise and many relate to experiences at your trust within the last year.

The first area of concern relates to basic nursing care and covers such matters as the supply of, and help with food and drink; a timely response to call bells and buzzers; attention to the hygiene needs of patients; and respecting the privacy and dignity of patients. A related area is that of cleanliness, hygiene and infection control. Concerns about these matters occurred in over half of the feedback we received.

The second area relates to medication. A number of patients and relatives noted that patients were not given the correct medication or were given incorrect medication. This issue was referred to in a third of feedback. In several instances patients were not helped to take their medication. In others patients were taken off or not given their routine medication when they came into hospital and this appeared to have adverse consequences for their health. We are aware that this was also an issue that the trust had itself discovered in at least one serious untoward incident and in its review of jejunal operations. We would therefore like to know about any improvements the trust has made or is planning to make in this area. It would be helpful to have a progress report on this by the end of July.

The third area related to failure of clinical care such as nurses completing charts, weighing patients, checking intravenous infusions, dressing wounds, avoiding pressure sores etc. These concerns also featured in about a third of feedback. About a third of patients or their relatives were distressed by delays in admission from A&E or delays in diagnosis and treatment. Others were upset by transfers within the hospital, often late at night.

Another major area related to problems with communication with relatives, and with the complaints process and difficulties in getting a response. Over a third of stakeholders mentioned these issues.

We note that many of these areas of concern correlate with the findings of the 2007 inpatient survey.

If you would like to discuss the content of this letter in more detail, please do not hesitate to contact me.

Yours sincerely

Dr Heather Wood
Investigation Manager
Healthcare Commission

Appendix H: Letter from the Healthcare Commission to the trust following the conclusion of formal interviews, 15 October 2008

Mr M Yeates
Chief Executive
Mid Staffordshire NHS Foundation Trust
Stafford Hospital
Weston Road
Stafford
ST16 3SA

15 October 2008

Dear Martin,

This is to follow up the discussion at our meeting on 9 October 2008, after the formal interviews had been concluded.

As we explained then, we hope to be able to send you the draft report before Christmas for the trust to check factual accuracy. In advance of the report we wanted to tell you some key areas where we have ongoing concerns about the experience of patients and where we think you need to concentrate efforts in the interim to improve clinical services.

These matters are not as urgent as those in A&E where we felt there was a deteriorating and potentially unsafe position, but none-the-less they need attention, and we therefore wanted to inform you about them without delay. We have derived our information in the main from observations and interviews and other evidence gathered during our site visits, and we are have also been informed by other evidence collected so far during the course of our investigation. As previously, our views are represented here following discussion with the Commission's specialist advisors.

It is important however to stress that what follows is not the definitive list of concerns, or the sole areas where action needs to take place. It represents those requiring immediate focus before you receive the draft report.

We feel that the trust needs to concentrate on the emergency care pathway and within that, there are three principal clinical areas of concern, and one further issue that is related to modelling and use of specific care pathways

1. Emergency Admissions Unit (EAU)

It is the view of the Commission and its advisors that the Emergency Admissions Unit is generally understaffed in relation to medical and nursing staff, given the case mix of patients in the Unit. Currently the unit receives medical (including stroke and cardiac), surgical, gynaecology and trauma patients.

As well as concern about the actual number of registered nurses, we also have concerns about whether all the nursing staff on EAU have adequate training for this busy multispecialty ward. It is clear there has been a longstanding deficit in training in this unit.

As you know, we have previously communicated about this and we understand that work is underway to raise skills. Our original concerns covered poor recording of fluid balance and in particular the inadequate reconciliation of input and output; the failure to use pumps for intravenous infusions; the failure to conduct observations in a timely manner, and/or to complete a modified early warning score (MEWS) accurately. We also had cause to question whether staff were clear about how to act on MEWS appropriately. The recruitment drive may have marginally increased staffing levels but there are many newly qualified and inexperienced staff on the unit. We are particularly concerned that the monitored area on EAU is still being staffed by nurses some of whom have not been trained or assessed as competent in the use of cardiac monitors.

We know that patients often stay on the Unit in excess of the anticipated 72 hours and may be there for four or five days. This strongly suggests that the functions of EAU as both an assessment area and short stay facility have not been effectively matched against the expected work load. We noted that some of the eight beds on EAU that had been closed following our first visit, had been opened for at least a week due to bed pressures and we were concerned about the effect of this on the staffing of EAU, and hence on the quality of care.

There are few multidisciplinary meetings for staff in the Unit to reflect on their performance and consider improvements. There are no meetings to discuss mortality or morbidity, or near misses and little opportunity to learn. There are concerns about continuity of care and junior doctors rarely get feedback on their performance.

2. Trauma patients

We have a number of concerns about trauma patients. These worries start in A&E and are related in part to the seniority of medical staff making assessments out of hours. We have mentioned above the skill mix of nurses on EAU and this is especially relevant in the case of patients admitted with traumatic injuries, where regular and purposeful observation is extremely important and appropriate equipment for traction should be readily available. There is limited input from orthogeriatrics to EAU or other wards.

Another significant issue is the insufficient theatre time for emergency cases, particularly at weekends. Trauma patients are competing with general surgical emergencies and are often losing priority, so they may have to wait a number of days for their operation. During this time they are often on the EAU or outlying on other wards where the nurses are not skilled trauma nurses used to dealing with the particular needs of these patients. We have encountered a number of cases of significant preoperative delays and cancelled operations, with patients being nil-by-mouth for several days.

The lack of beds on the trauma wards also means that postoperative trauma patients are not always cared for on the trauma ward and onward rehabilitation and care for frailer people seems to take a long time to organise.

3. Surgical cover out of hours

The third area that we raised with you was the lack of senior surgical cover on site after 9pm.

The Resident Surgical Officers (RSOs) are called to A&E and may also be asked to attend the wards or scrub for theatre. They have to cover trauma, general surgery and gynaecology. In the case of general surgery there is no other cover other than the consultant who is not on site.

The RSOs have variable knowledge and experience. The group includes some very junior doctors whose sole surgical experience is four months at FY1 level.

It is frustrating for senior and middle grade staff in A&E to have to ask for general surgical opinions from staff who are frequently considerably less experienced than they are themselves.

We are concerned that such junior staff may well be reluctant to call the consultant general surgeon during the night, preferring to put off decisions until the morning.

We would ask you to revisit the seniority of surgical cover on site, out of hours.

4. Use of care pathways and capacity modelling for emergency admissions

There are few protocols or pathways for unscheduled care in use in the trust, and those that are in use are not audited. There is little use of data to monitor performance and little clinical audit.

It would be helpful for the trust to review its unscheduled care activity and develop models of the pattern of demand for emergency admissions in order to predict the admission of patients and to develop sensible pathways for the common important types of emergency.

The Healthcare Commission suggests that you consider these matters and begin to take steps to address them.

I am copying this letter to Monitor, the Department of Health, South Staffs PCT and the West Midlands SHA, for information only.

If you would like to discuss the content of this letter in more detail, please do not hesitate to contact me.

Yours sincerely

Dr Heather Wood
Investigation Manager
Healthcare Commission

Appendix I: Developments in nursing at the trust from early 2007 to early 2009, as supplied by the trust

- A patient and public engagement strategy has been developed and is being implemented through the patient experience group. This group is multi-professional and has patient and public involvement.
- An establishment and skill mix review of the whole nursing and midwifery workforce has been undertaken. The review concentrated on ensuring the provision of an appropriate workforce with the right level of clinical leadership at ward level.
- Recruitment to the agreed investment has been undertaken.
- A review of the nursing structures in the divisions has been undertaken and culminated in the line management responsibility for nursing moving.
- Increase in matron posts from three to 12 to ensure clinical leadership at ward level is enhanced.
- An annual recruitment plan has been developed.
- Dashboards used in the clinical areas used to chart progress against 'nursing' performance indicators have been reviewed and refined. A balanced score card that reflects quality has been developed (and will develop further in time) this has been presented to the board and will be reviewed quarterly by the board.
- 'Essence of care' is being implemented against a defined rollout programme. Progress is reported at the divisional governance groups and the clinical quality and effectiveness group.
- 'Quality rounds' are carried out by the matrons and the deputy director of nursing. In addition to ad hoc clinical visits the director of nursing has clinical days during which all clinical areas are visited.
- A nurses forum is held every six weeks at which issues relating to quality and the patient experience are discussed. The forum is open to all bands of nursing staff.
- Matrons meetings are held fortnightly.
- Guidance relating to the role of the nurse in charge has been developed.
- A process for standardising practice and competence associated with nursing clinical expanded procedures across the trust has been developed.
- A decision tree for action to be taken following nursing drug errors has been implemented. This includes re-assessing clinical competence following drug errors.
- There is zero tolerance in relation to poor prescribing practice.
- The Age Concern Volunteers pilot that was carried out in Cannock Hospital has been expanded to cover the Stafford site. Recruitment to this project is progressing well.
- There has been investment in learning and development and this has included recruitment to a clinical skills training post. This post has allowed a clinical skills programme to be developed.
- A series of 'confidence in caring' study days have been held – for all grades of nursing staff. These days have focused on quality of care, infection control and customer care. A relative has been instrumental in delivering these study days.

- The 2008 director of nursing study days are under way – these are focusing on quality of care and documentation. The documentation sessions are being delivered by Bond Solon – Documentation on Trial.
- Training sessions relating to the Mental Capacity Act and learning disabilities have been delivered.
- A series of elderly care champion study days have been held.
- A training plan for nursing and therapists has been developed and implemented
- Funding has been secured so that the Productive Ward can be implemented in two pilot areas. A bid for additional funding has also been submitted and has been successful. This will allow the programme to be rolled out across the trust.
- Funding for additional development opportunities has been secured. Funding is detailed below:

  Coaching: £37,500
  Leadership: £40,000
  Infection control training: £25,000
  Being Open training: £5,000
  SHA – Productive Ward pilot: £50,000
  Sign Off mentor training: £5,000
  Customer care training: £12,000
  Clinical Skills Training Equipment: £34,000
  Increasing mentoring capacity: £10,000

- The director of nursing writes to all relatives of deceased patients and offers them to opportunity to discuss any issues relating to care that they may have.
- A document that sets down expected behaviour of the trust's staff has been developed through the nurses forum and is being formatted for trust-wide implementation.
- Monthly quality rounds with the commissioners are in place.
- A nursing audit schedule is in place.
- Staffing escalation plan has been developed.
- Dr Foster's Real Time Patient Experience Trackers have been purchased and a cycle of real-time reviews is being implemented with results presented to the board.
- A review of the clinical nurse specialists has been carried out and the findings presented to the board.
- The advanced practitioner for pain has moved from the surgical division to the corporate nursing team to ensure a trust-wide pain service will be reviewed.
- Unannounced visits to clinical areas are in place. These visit are conducted by trust governors, matrons and external healthcare professionals.
- Divisional patient and carer councils are being set up in the divisions to promote patient and care involvement. A launch event has been held and was attended by approximately 35 interested parties. Those interested have expressed interest in specific divisions.
- A corporate professional development nurse post has been created and the post holder will commence shortly.

If you would like this information in other formats or languages, please telephone 0845 601 3012.

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