Investigation

Investigation into outbreaks of *Clostridium difficile* at Maidstone and Tunbridge Wells NHS Trust

October 2007

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. The organisation has a range of new functions and has taken over some responsibilities from other commissions. We:

- have replaced the Commission for Health Improvement, which ceased to exist on 31 March 2004
- have taken over responsibility for the independent healthcare sector from the National Care Standards Commission, which also ceased to exist on 31 March 2004
- carry out the elements of the Audit Commission's work relating to the efficiency, effectiveness and economy of healthcare.

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.

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 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.

Executive summary

The Healthcare Commission carried out this investigation to look into outbreaks of *Clostridium difficile* (*C. difficile*) at Maidstone and Tunbridge Wells NHS Trust and to assess the care provided to patients with this infection. It also considered whether the trust's systems and processes for the identification, prevention and control of infection were adequate.

Our particular focus was on the care of patients infected with *C. difficile*. We looked at measures taken to control the spread of the bacterium and the state of systems to control this infection. More broadly, we sought to disseminate wider lessons for the NHS on how best to prevent, control and treat infection with *C. difficile*.

This investigation was carried out between October 2006 and April 2007. Staff from the Healthcare Commission worked with a team of external expert advisers (for membership see Appendix B). We reviewed in detail the case notes of a sample of 50 patients who had contracted *C. difficile* during an admission to the trust, and had died. We interviewed nearly 200 people including patients who had been infected with *C. difficile*, and their relatives, and past and present staff at the trust and other organisations. We examined over 1,000 documents including policies, reports, audits and records of meetings. We carried out scheduled and unannounced visits to wards.

The executive summary outlines our findings. The evidence on which the findings are based is in the body of the report.

Synopsis of events

The trust had a relatively high rate of infection with *C. difficile* over several years but no one in the trust or local health community was aware of this. In the autumn of 2005 the number of patients with the infection doubled but this was not identified. In this unrecognised outbreak 150 patients were affected, and a number died where *C. difficile* was definitely or probably the main cause of death. The number of newly infected patients declined slightly at the beginning of 2006 and then rose again. This time the trust recognised it had a major outbreak and reported this to the strategic health authority and health protection unit on 12 April 2006. From April to September 2006, 258 patients were affected. Overall, from October 2005 to September 2006 more than 500 patients developed the infection, and we estimate that there were approximately 60 deaths where *C. difficile* was definitely or probably the main cause.

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

Management of patients infected with *C. difficile*

The trust's guidelines for the management of patients infected with *C. difficile* were not sufficiently clear about the importance of isolation of patients with the infection. The trust's policy for responding to outbreaks was not fit for its intended purpose. The infection control team was keen to isolate patients with *C. difficile* but the scarcity of side rooms made this difficult. Many patients with the infection were grouped together in bays on wards, but before and during the outbreak some patients infected with *C. difficile* were not isolated; they were nursed on open wards. The other patients on these wards, and those on wards with infected patients in bays, were at risk of catching the infection and some of them did. It took four months to establish an isolation ward exclusively for patients with *C. difficile*. In our view this was partly because of the pressure on beds and the trust's desire to meet targets.

The Healthcare Commission reviewed the case notes of a sample of 50 patients who had died having had *C. difficile*. We found that in 80% of the cases, at least one element of the clinical management or monitoring of *C. difficile* infection was unsatisfactory. Areas of concern included infrequent reviews of patients by doctors, the lack of systematic monitoring of whether the patients were recovering from *C. difficile*, and the failure, in many cases, to change antibiotic treatment for *C. difficile* when a patient had failed to respond to the initially prescribed therapy. There was inadequate monitoring for common complications of *C. difficile*, especially dehydration and poor nutrition, and of serious complications, especially colitis. The review found several examples of antibiotic prescribing that predisposed vulnerable patients to developing *C. difficile* infection.

During the investigation, 26 patients and their families contacted the Healthcare Commission. They were unhappy about the care received. They told us that when patients rang the call bell because they were in pain or needed to go to the toilet, it was not always answered, or not in time. A particularly distressing practice reported to us was of nurses telling patients on some occasions to "go in the bed," presumably because this was less time-consuming than helping a patient to the bathroom. Some patients were left, sometimes for hours, in wet or soiled sheets, putting them at increased risk of pressure sores. Families claimed that tablets or nutritional supplements were not given on time, if at all, or doses of medication were missed. Wards, bathrooms and commodes were not clean and patients had to share equipment such as zimmer frames which were not cleaned between use.

The number of deaths from *C. difficile*

One of the aims of the investigation was to clarify how the trust had estimated the number of deaths from *C. difficile* since April 2004.

The trust assured us that its review of case notes involved patients who had died in hospital, had tested positive for *C. difficile* and had *C. difficile* mentioned on their death certificate. Our scrutiny of their information, however, found that the review had considered less than half of these patients. This review could not, therefore, have accurately ascertained the number of deaths since April 2004. Nonetheless the trust relied on this review to obtain a figure.

The trust told us that there had been no deaths that were definitely caused by *C. difficile* between April 2004 and March 2006. In the Healthcare Commission's sample of 50 patients who died and had contracted *C. difficile* between April 2004 and September 2006, our experts found that in 26% of the cases (13) it was definitely or probably the main cause of death and in 78% (39), *C. difficile* had definitely or probably contributed to the patients' deaths.

The 50 patients whose notes we reviewed were slightly older than the total number of patients who died and had contracted *C. difficile* infection, which may suggest they were more likely to die by reason of their age. However, at the same time, we excluded those patients with life threatening illnesses. On balance, we feel that our estimate of the proportion of deaths attributable to *C. difficile* is reasonable.

Based on this proportion identified in our review, we estimate that of the total 345 patients who died in the relevant periods who had been infected with *C. difficile,* there were approximately 90 deaths where *C. difficile* was definitely or probably the main cause of death, and about 60 of these happened in the outbreaks between October 2005 and September 2006. It is not, however, correct to conclude that these patients died because of the care they recieved.

Many of the 90 people may well have died of other causes if they had not acquired *C. difficile* infection. Some would have died of *C. difficile* infection even if they had had the best care.

Table 1: Estimated number of deaths were *C. difficile* was definitely or probably the main cause			
April 2004 - September 2005	**October 2005 - March 2006**	**April 2006 - September 2006**	**TOTAL**
30	35	25	90

The Commission is unable to say exactly how many of the deaths attributable to *C. difficile* infection were 'excess' deaths, that is, people who would not have died had they not developed *C. difficile*. However there is evidence from other studies that patients infected with *C. difficile* are considerably more likely to die than comparable patients who do not have it. The trust's own data showed that from 2003/2004 to 2006/2007, between 32.4 and 46.3% of all patients over 75 died if they had *C. difficile*, compared to between 6.1 and 6.7% of patients in the same age group if they did not.

In a press statement on 30 June 2006, the trust reported that six people had definitely died from *C. difficile* since the start of the outbreak in April. The trust quite properly used an existing classification to try to identify the number of deaths from *C. difficile*, but was mistaken in not reviewing all death certificates where *C. difficile* was mentioned. It would have been better to include probable deaths with definite deaths in press releases, particularly following the publication of the Healthcare Commission's report into outbreaks of *C. difficile* at Stoke Mandeville Hospital, which used this approach.

Our analysis also suggests that relying on death certificates leads to an underestimate of the contribution of *C. difficile* infection to the death of patients, since 20% of the patients in our sample where *C. difficile* was not mentioned on the death certificate had an infection with *C. difficile* that our experts considered was probably or definitely the main cause of death.

Arrangements for the control of infection

The individual appointed by the chief executive to be the director of infection prevention and control (DIPC) had no real understanding of the role at the outset. The DIPC failed to avail himself of sufficient knowledge about procedures and processes in other trusts such as surveillance and feedback. Management of the infection control team was inadequate. There was no strategic direction and there was confusion over who actually managed the team. There were differences of opinion between the microbiologists which meant a lack of consistency of approach.

Policies for the control of infection were on the trust's intranet, but they were nearly all out of date and not all staff could gain access to the intranet. The trust did not have several key policies that we would have expected to see. Updated training in infection control was mandatory in the trust, but between September 2005 and October 2006 only 51% of clinical staff attended this.

In the 2005 national survey of staff carried out by the Healthcare Commission, 30% of staff at the trust agreed that "the trust does enough to promote the importance of hand washing to staff." The typical score for an acute trust was 77%. For promoting the importance of hand washing to patients and visitors, the trust's score was 33% compared to a typical score of 59% for an acute trust. Of the trust's staff, only 38% agreed with the statement "infection control applies to me in my role." The typical acute trust score was 79%.

Rates of *C. difficile* infections had fallen by September 2006 and were generally maintained at or below the level seen before the outbreaks, with some small clusters of

cases. The senior infection control nurse became the acting director of infection prevention and control in April 2007. The trust has informed us that a new consultant microbiologist is also being recruited, and will be appointed as the director of infection prevention and control.

Factors contributing to the outbreaks

Many of the buildings, especially at the Kent and Sussex Hospital, were old and in a poor state of repair. Many of the wards did not have sufficient storage, space in utility rooms, or hand basins, making the control of infection difficult. The beds on several wards were much too close together, making it difficult to clean between them and seriously compromising the privacy of patients. Although there had been improvements generally in cleanliness and hygiene since the outbreak was declared, there were still some serious concerns. When we visited, we observed levels of contamination that were unacceptable, such as bedpans that had been washed but were still visibly contaminated with faeces.

Information from nurses, other clinical staff, patients and families, and from reported incidents and complaints, indicated that shortages of nurses contributed to the spread of infection because they were too rushed to undertake hand hygiene, empty and clean commodes, clean mattresses and equipment properly, and wear aprons and gloves appropriately and consistently.

The trust's bed occupancy rates were consistently over 90% in the medical wards at both Maidstone Hospital and Kent and Sussex Hospital. Higher bed occupancy led to less time for thorough cleaning of beds and the areas around them, between one patient's moving and another occupying the same bed.

'Escalation' areas were often opened up - these were areas in the hospital that did not usually function as general wards but which were used as such when there were no suitable beds available elsewhere in the hospital. They were often in unsuitable areas such as a previous children's ward or the area for day surgery. The bathroom facilities were inadequate, as were the 'dirty utility' rooms, since they were not designed for ill or adult patients. When these areas were first opened, cleaning and laundry services were not in place. By definition for these areas there were no funds for dedicated staff, and at least initially they were staffed almost entirely by bank or agency nurses, bringing little continuity of care. Many of these factors increased the risk of transmission of infection.

Arrangements for governance

There had been considerable change over the relevant period in the structure and responsibilities relating to governance and the management of risk. This had led to confusion over accountability. The trust's system for handling serious untoward incidents was poor, with little evidence of adequate investigation and very few reports being produced. Other incidents that were reported by staff consistently highlighted problems relating to the levels of staff, poor care for patients, 'escalation' wards and poor processes for handover when patients moved from one ward to another. Many of these matters required consideration and resolution at a strategic level but were rarely considered by the board, whether as a whole board or at its governance and risk sub-committees. There was no systematic mechanism to follow up any actions required or to share lessons.

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 realities and problems on the general wards.

A new structure of governance was introduced in January 2007. It aimed to increase the involvement of senior clinical staff in making decisions and taking responsibility.

The trust's board and infection control

The board stated that infection control had always been a priority. Before the outbreak it only monitored the MRSA rate, as there was a national performance target in relation to MRSA, though not as regards *C. difficile*. Until recently, the board considered the annual report on control of infection solely as a retrospective document rather than a prospective plan for the coming year where the board could influence and agree priorities.

The information presented to the board was often incomplete or inaccurate, leaving non-executives at a disadvantage in being able to perform their role to scrutinise and challenge on matters relating to the care of patients or concerning infection control.

An outbreak occurred in the autumn of 2005, and in early 2006 the trust recognised that it had a second outbreak. Despite this and the gaps in controls that they revealed, the trust in May 2006 declared itself in the Healthcare Commission's annual health check as being in compliance with the standard for control of infection in the core national standards.

Informing the public

The second outbreak was declared on 12 April 2006. The trust did not issue a press statement until an enquiry was received from the local press over two months later. Information in the press release suggested that the outbreak was due to patients with the infection being admitted to the hospital from the community. The outbreak was not discussed by the trust's board in public until 25 July 2006. On several occasions the board, and relatives of patients who attended the board's meetings, were given information that was not accurate. For example, in July 2006 it was reported that the antibiotic policy had been reviewed in line with the correspondence from the Chief Medical Officer in England, in December 2005. In fact, no action had been taken until the outbreak was declared in April 2006.

The statements from the trust concerning the outbreak under-reported the number of deaths, since they included only those in which *C. difficile* was considered to have definitely contributed and not those where *C. difficile* probably contributed. Moreover, even those figures were not accurate, since not all the cases in which *C. difficile* was mentioned on the death certificate had been reviewed.

The response of managers and the trust's board

The trust has had a challenging agenda since it was established by a merger in April 2000.

The board unambiguously stated that its top priority was the safety of patients. However, the fact that the organisation did not recognise the first outbreak of *C. difficile* is not consistent with the trust doing its best to reduce the risk of infection to patients, staff and visitors. Progress had been made in many areas but there were serious problems with high bed occupancy, the movement of patients, and with some patients with diarrhoea being cared for on open wards. The board paid insufficient attention to its responsibilities to protect patients against infection.

The lack of organisational stability, with numerous structural changes over the last three to four years, and a high turnover of senior managers, meant that managers could not settle into roles and focus on the key issues. Many felt there was little delegation. The style of management was described as reactive, with frequent changes of direction.

Developments since the investigation was announced

To increase the space between beds, a number of beds have been removed from wards at Kent and Sussex and some wards have had new sinks and macerators installed.

The trust carried out a review of the number of nurses in April 2007 and approved an increase in the number of nurses on the wards to match those of comparable trusts.

The trust has also developed an integrated approach to the clinical management of *C. difficile*, known as a 'care pathway'.

Overall conclusion

The trust had no effective system for surveillance of *C. difficile.* As a consequence, it failed to identify an outbreak in 2005 that involved 150 patients. This was a serious failing. When the second outbreak was declared in April 2006, patients were cared for on a number of wards until an isolation ward was established in the August.

The clinical management of *C. difficile* infection in the majority of the patients 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 the condition for which they were admitted, were prescribed broad-spectrum antibiotics during their stay in hospital, contracted *C. difficile* and some died.

The infection control team was not managed properly and standards of cleanliness and infection control were not good. Since the outbreaks, the number of cases has fallen to below the levels previously experienced by the trust. However, as late as April 2007, we found unacceptable examples of the use of contaminated equipment.

The trust delayed announcing the outbreak and then produced figures that almost certainly underestimated the number of deaths. We estimate that approximately 90 patients definitely or probably died from *C. difficile* in two and a half years, about 60 of these during the outbreaks from October 2005 to September 2006. It is not correct to conclude that 60 patients died because of the care they recieved. Some may well have died of other illnesses and some would have died from *C. difficile*, even if they had had the best care.

The trust struggled with a number of objectives which they regarded as imperative. These occupied senior managers' time and compromised the control of infection, and hence the safety of patients.

The roles of external organisations

The creation of the Health Protection Agency has led to some confusion about the role of various bodies in respect of the control of infection in acute trusts.

Although the primary care trusts commissioned services from the trust, they were preoccupied with the numbers of patients treated and the cost, and had given little attention to the quality of care or the control of infection. They saw the latter as the responsibility of the health protection unit (HPU), which is part of the Health Protection Agency.

The HPU did not have close routine involvement with the trust, and generally worked in a reactive way, responding to concerns. The HPU staff saw their role as being to support organisations in their management of infections, rather than to supervise or monitor infection control. Once the outbreak was reported, the HPU endeavoured to support the trust. The HPU was concerned about aspects of the handling of the outbreak and raised these matters with the trust and the strategic health authority (SHA).

It was clear that, until recently, the focus of the SHA with regard to healthcare associated infection had been more on MRSA, since it was one of the top national priorities to which a target for performance was attached. The SHA, however, responded to the concerns of the HPU and was instrumental in initiating our investigation.

The national picture and lessons for other organisations

The Healthcare Commission was concerned about the standard of medical and nursing care of patients who developed *C. difficile* infection. The diagnosis of *C. difficile* infection needs to be respected as a diagnosis in its own right. The infection needs to be taken seriously as a potentially life threatening condition. Patients should be regularly reviewed and given appropriate medical and nursing care.

The investigation into the outbreaks at Maidstone and Tunbridge Wells NHS Trust has thrown up a number of similarities with the findings of our previous investigation into outbreaks of *C. difficile* at Stoke Mandeville Hospital, part of Buckinghamshire Hospitals NHS Trust. Both trusts had undergone difficult mergers, were preoccupied with finances, and had a demanding agenda for reconfiguration and private finance initiative (PFI), all of which consumed much management time and effort. They also had poor environments, with many dormitory style wards and few single rooms which could be used for isolating patients with infections. In both we observed unacceptable examples of contamination and unhygienic practice.

Additionally, the impact of financial pressures was to reduce further already low numbers of nurses and to put a cap on the use of nurses from agencies and nursing banks. There was unrelenting pressure to reduce the number of beds. Thus, both trusts had very high occupancy levels, could not manage with fewer beds, and so had to open 'escalation' beds, often at short notice and in unsuitable environments, without proper support services and equipment in place and, by definition, without permanent staff. The effect of all this was to compromise seriously the control of infection and the quality of clinical care.

In both trusts 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 administered, charts not completed, poor hygiene practices, and general disregard for privacy and dignity. Not only were these distressing, but in the case of seriously ill patients, poor care related to hygiene, medication, nutrition and hydration may have adversely affected the outcome for the patients.

While it should be noted that improvements have subsequently been made at Stoke Mandeville, it seems unlikely that these similarities are coincidental. We are concerned that where trusts are struggling with a number of problems that consume senior managers' time, and are under severe pressure to meet targets relating to finance and access, concern for infection control may be undermined.

Lessons need to be reinforced about appropriate antibiotic prescribing, the need for effective isolation, the importance of scrupulous cleanliness and hygiene, and the need to provide a high standard of care of patients infected with *C. difficile*, including having adequate staff. More attention also needs to be paid to the accuracy of death certification.

Introduction

This investigation was undertaken following outbreaks of *Clostridium difficile* (*C. difficile*) at Maidstone and Tunbridge Wells NHS Trust. It aimed to assess the care provided to patients with *C. difficile* infection, and to establish whether the trust's systems and processes for the identification, prevention and control of infection were adequate during the outbreaks, and subsequently.

The request for an investigation initially came from the (then) Kent and Medway strategic health authority (SHA), with the agreement of the trust, in July 2006. The Healthcare Commission does not formally investigate all such requests, but always considers the matters raised and frequently undertakes interventional work in order to satisfy itself that appropriate action has been taken by the trust.

Following an initial consideration of the request for an investigation, a number of concerns remained:

- there was little or no recognition by the trust of a rise in cases between October and December 2005, which we thought may have contributed to a subsequent peak in April 2006
- data supplied by the trust in respect of numbers of cases and attributable mortality rates, were inconsistent
- Maidstone Hospital had historically suffered from high background rates of *C. difficile* infection, and no progress appeared to have been made in terms of identifying the cause or reducing these rates
- concerns had frequently been raised in public regarding cleanliness, the control of infection and standards of nursing care at the trust.

These concerns were noted by the Healthcare Commission's investigations committee which agreed that an investigation was necessary.

Terms of reference

The Healthcare Commission's investigations committee agreed the terms of reference for the investigation in October 2006. The investigation was into the circumstances surrounding the rates of *C. difficile* at Maidstone and Tunbridge Wells NHS Trust since April 2004 and the outbreaks of infection since that time. This would include an examination of:

- arrangements to identify and notify cases and outbreaks of *C. difficile* infection across the trust, including an analysis of the figures reported by the trust
- the factors contributing to the rates of *C. difficile* infection and the outbreaks, and the trust's management and clinical response to these
- arrangements at ward level to keep patients safe and assure the quality of care, particularly with regard to older patients and those with healthcare associated infection
- the trust's governance arrangements and the priority given to the control of infection, particularly in relation to *C. difficile*
- the priority given, and action taken, by the strategic health authority and local primary care trusts, to help bring about reduction in *C. difficile* infection at the trust
- the role undertaken by the Health Protection Agency to work with the trust to help to bring about reduction in *C. difficile* infection

- any other matters that the Healthcare Commission considers arise out of, or are connected with, the matters above.

Key elements of the investigation

Our investigation team worked with a team of external expert advisers and sought additional advice from an expert in *C. difficile*. The membership is listed in Appendix B.

During the investigation, the investigation team:

- made a number of visits to the trust to interview staff in relation to the investigation, and to observe wards and clinical areas in the trust
- conducted over 200 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 50 sets of individual case notes of patients who had been infected with *C. difficile* and died
- analysed more than 1,000 documents provided by the trust and other organisations (see Appendix E for a summary of sources of information and evidence).

This report

This is the second investigation that the Healthcare Commission has published related to *C. difficile*, the first being into outbreaks at Stoke Mandeville Hospital, part of Buckinghamshire Hospitals NHS Trust, which was published in July 2006.

In this report we first summarise information on *C. difficile* and look at the guidance on the control of infection in general and specifically the control of *C. difficile*. We describe the context of the trust. We consider the outbreaks and how the trust monitored the situation. We review the care that patients received. We look at the factors that were associated with controlling the second outbreak, at both ward and strategic levels. Lastly we look at the role of other relevant agencies.

This report makes a number of recommendations in relation to the care and management of patients infected with *C. difficile*, and the control of infection, particularly but not exclusively *C. difficile*.

The Healthcare Commission is responsible for this report and for ensuring that Maidstone and Tunbridge Wells NHS Trust takes action in response to our investigation. The action plan will be available on the Healthcare Commission's website. The South East Coast SHA and the Healthcare Commission will be responsible for monitoring the progress against actions.

Clostridium difficile and healthcare associated infection

What is *Clostridium difficile*?

Clostridium difficile (*C. difficile*) is the major cause of serious bacterial infectious diarrhoea acquired in hospitals in the UK.

C. difficile is a bacterium that can cause an infection of the gut. Only a minority of people (2 to 3% of healthy adults) carry *C. difficile* as part of their normal gut. Increasing proportions of older people can carry the bacterium without symptoms - around 20% of people 65 years and over in hospital. Risk of infection is significantly increased by exposure to antibiotics.

Unless controlled by other bacteria, *C. difficile* colonises the intestine, and certain strains then produce toxins that together cause extensive tissue damage to the walls of the intestine. This usually causes severe diarrhoea, but in severe cases of infection, diarrhoea may not be prominent. Other symptoms include lower abdominal pain and systemic symptoms such as fever, nausea and malaise. These symptoms in many cases are very debilitating, unpleasant and worrying for patients and their families. In some cases there is a severe inflammation of the colon

(known as pseudomembranous colitis), which is usually very serious. *C. difficile* infection can cause death in some patients.

C. difficile cannot grow in the presence of air. To help it survive under certain conditions, such as exposure to oxygen in the atmosphere, *C. difficile* produces spores. These spores are resistant to drying, chemical disinfectants, alcohol and stomach acid. They can remain in the patient and the environment for lengthy periods, thereby increasing the likelihood of cross-infection. Spores transferred to other people can subsequently develop into bacteria that colonise the colon.

What is the importance of *C. difficile*?

The number of cases of *C. difficile* in patients 65 years and over in England that was reported nationally to the Health Protection Agency in 2006 was 55,634. This was an increase of 7% from the previous year. There has also been an increase in the number of reported deaths associated with *C. difficile* infection in the UK. Figures produced by the Office for National Statistics found that in England and Wales, the number of times *C. difficile* was mentioned on death certificates rose from 975 in 1999 to 3,807 in 2005. The comparable figure for MRSA in 2005 was 1,629. There have been reports of similar increases in other countries. It is not completely clear what is responsible for these increases. Suggestions include: improved detection and reporting, together with a real increase in the incidence of infection; an increasing propensity for doctors to mention *C. difficile* on death certificates where this was diagnosed before death; and an increase in the severity of some *C. difficile* infections.

Why might infections be becoming more severe?

The Anaerobe Reference Laboratory in Cardiff has now identified approximately 160 different strains of *C. difficile*. Recent years have seen a rapid increase in the prevalence of a particular *C. difficile* strain in North America and Europe. Known in Europe as type 027, this strain initially appeared to be associated with more severe infection, and it was responsible for a number of serious outbreaks of *C. difficile* in Canada, the USA, Europe and the UK. More recent evidence suggests that type 027 is not always associated with more severe disease, and that other strains of *C. difficile* have also caused severe disease and deaths. More research is needed to clarify whether particular strains of *C. difficile* consistently cause more serious disease than others, and whether this is the reason for the apparent rise in the number of deaths recently attributed to *C. difficile*.

Why does infection occur?

For a patient to become infected, they must swallow *C. difficile* spores or bacteria. A patient could come into contact with *C. difficile* before they come into hospital, or encounter it in the hospital if the environment, equipment or clinicians' hands or clothes are contaminated. However, to develop a *C. difficile* infection, recent treatment with antibiotics is, in most cases, a prerequisite. Antibiotics destroy many of the normal bacteria that live in our intestines, and their absence makes it easier for *C. difficile* to thrive.

Patients who have had recent exposure to antibiotics are at greatest risk of infection. Broad-spectrum antibiotics, which act against a wide range of bacteria, are most often associated with the disease. They include clindamycin, cephalosporins, and fluoroquinolones. However, any antibiotic can precipitate *C. difficile* infection.

Certain groups of people seem to be particularly predisposed to developing *C. difficile* infections: for example, older people, people who have recently undergone surgery and people with serious underlying diseases. The majority of cases are in patients who are 65 years and over. This may be due to lowered resistance, prolonged hospital stay, underlying disease or reduced capacity to produce antibodies to fight the toxins. There is evidence that the risk of infection is directly related to the length of stay in hospital, rising steeply in patients staying over four weeks. On

average, *C. difficile* infection causes an increase of 21 days in the length of the stay in hospital.

Diagnosis

C. difficile infection can be reliably diagnosed by testing a sample of the patient's diarrhoeal faeces for the presence of *C. difficile* toxins. Results can be obtained within a few hours, but a more accurate test gives results the next day. No test for *C. difficile* is 100% accurate, so it is appropriate to retest patients whose initial result was negative but in whom there is still a strong suspicion that they might have *C. difficile* infection.

In outbreaks the bacterium may be referred for typing. Typing is one of the methods used to identify the strain of *C. difficile* responsible for an infection or group of infections. It involves assigning each sample of the bacterium to a recognised type, for example, type 027, and takes a few days to complete. The bacterium has to be grown from the faecal sample and sent to an anaerobe reference laboratory for typing.

Prevention and control

The measures to control the spread of the bacterium are the same for all strains of *C. difficile*. These include the timely isolation of known and suspected cases, the control of antibiotics, the application of high standards of hygiene and the restriction of the movement of patients.

Hospital sites are contaminated by *C. difficile* spores to varying degrees, depending on the amount of faecal soiling and the level of cleaning. Commodes, bed frames, sluice rooms, toilet floors and ward floors are the areas most likely to be contaminated. Cleaning is the most effective method of removing spores from the environment. Deep cleaning - that is, more frequent and extensive cleaning (including radiators and the changing of curtains) - is needed to clean wards where infected patients have been. Bleach based products (containing the chemical hypochlorite) should be used where there are patients with a *C. difficile* infection, rather than non-bleach-based agents, as the former are thought to be better at removing spores.

Spores can be transported on the hands and clothing of staff and patients and on equipment. It is therefore important to adhere to strict procedures, including: washing hands with soap and water after seeing each patient; cleaning equipment between patients; wearing new gloves and aprons for each patient; disposing of clinical waste effectively; and restricting the movement of patients around the hospital. People with the infection should be isolated from people who are unaffected in order to prevent the infection from spreading. Alcohol gel is effective against the bacterium but not against spores, which is why hand washing is so important.

To reduce the likelihood of infection in individual patients, the use of broad-spectrum antibiotics (active against a wide range of different bacteria) should be limited to only where there is a good clinical reason. Carefully considered protocols for antibiotic prescribing are essential in achieving this. These should restrict broad-spectrum antibiotics, and minimise use of multiple antibiotics and prolonged courses of antibiotics whenever possible. There should be periodic checks of the prescribing of antibiotics by type and length of course.

Treatment

The first step is to stop, wherever possible, the course of antibiotics that has allowed *C. difficile* to proliferate. Antibiotics that decrease the risk of precipitating *C. difficile* should be used where feasible for patients whose condition requires continued antibiotic treatment. About 15% of patients improve spontaneously, but it is not possible to predict which patients will recover.

If the patient continues to have symptoms after *C. difficile* has been diagnosed, specific antibiotic treatment for *C. difficile* is commenced. The two antibiotics used to treat *C. difficile* are metronidazole or vancomycin.

Although metronidazole and vancomycin have in the past been considered equally effective in eliminating *C. difficile*, recent research suggests that vancomycin may be more effective. In general, where a patient has not improved when given one of these antibiotics, a switch to the alternative is usually recommended. If a patient has repeated recurrences of *C. difficile*, it may be necessary to try more complicated regimens of vancomycin and metronidazole to gain control of the infection.

As with all cases of diarrhoea, it is essential to monitor the patient to ensure they are well hydrated and well nourished. People can lose a large amount of fluid, salt and nutrients when they have diarrhoea and the inflammation of the intestines that occurs with *C. difficile* infection. These losses need to be carefully monitored and replaced as completely as possible. Attempts to strengthen the response of the immune system remain popular yet unproven, although there have been reports of successful treatments of some cases with intravenous immunoglobin. Patients with pseudomembranous colitis (severe inflammation of the colon) are usually extremely unwell and at great risk of dying. Often, the only option for saving these patients is an operation. However, this is a major undertaking and itself often results in death.

Ascertaining cause of death

As many patients who have *C. difficile* infection were already ill from other causes, it can be difficult to determine whether the *C. difficile* was the primary cause of death, was one contributory factor among several, or was incidental and did not contribute to the death. The clinical course and severity of the *C. difficile* infection and the other illnesses for which the patient was being treated need to be taken into account when making this decision.

An analysis of a major outbreak in Canada, published in the New England Journal of Medicine in 2005, estimated that the mortality rate attributable to *C. difficile* infection was 6.9% at 30 days after diagnosis.

Reporting of outbreaks

Outbreaks need to be detected and reported at the earliest opportunity, as this allows recognition of changes in the pattern of local and national disease, and alerts external organisations to the situation. The *Clostridium difficile* Standards Group, (a review team established by the Department of Health and comprising 12 national experts) recommended that outbreaks should be defined as the "occurrence of two or more related cases over a defined period taking account of the background rate." However, this definition is not always useful in detecting problems in hospitals where the normal, background rate of *C. difficile* is high or the number of cases is continuously rising.

Trusts are required to report important or significant outbreaks to their local SHA. For the reasons outlined above, it may be the case that a trust with a low background rate has fewer cases of *C. difficile* during an outbreak than a trust with a high background rate not experiencing an outbreak. *Winning Ways* (guidance from the Department of Health) advised that "serious outbreaks of infection in healthcare settings will also be reported to the Health Protection Agency, so it can provide appropriate advice and support for management and control of the incident." There is no routine published information that identifies outbreaks and associated deaths.

National guidance on the overall control of infection

Since 1999, the Department of Health has issued guidance and initiatives that emphasise the priority to be given to the control of infection. This includes *Winning Ways: working together to reduce healthcare associated infection in England* published in 2003, and *Saving Lives: a delivery programme to reduce healthcare associated infection including MRSA*, published in 2005. In May 2006 the Department of Health published further guidance entitled *Going Further Faster: Implementing the Saving Lives Delivery Programme*, as part of the MRSA/Cleaner

Hospitals Programme. The guidance was aimed at supporting the target to halve MRSA bacteraemia by 2008, but recognised that, if implemented, it would support system-wide improvement in healthcare associated infection.

The code of practice for the prevention and control of healthcare associated infections (the hygiene code)

The Health Act 2006 set out the provision for a code of practice for the prevention and control of healthcare associated infections. The code was issued on, and was effective from, 1 October 2006. Its purpose is to help NHS organisations plan for the prevention and control of healthcare associated infections. It now forms part of the Healthcare Commission's annual health check from 2007/2008. The code is divided into three parts, with a total of 11 core duties and failure to comply with these can result in the issue of an improvement notice. The code brings together existing guidance, and NHS bodies should already be compliant with its requirements.

National guidance on *Clostridium difficile*

In 1994 a joint working group of the Department of Health and Public Health Laboratory Service produced guidance on the prevention and management of *C. difficile* infection. In February 2003 the Department of Health published the report of the National *C. difficile* Standards Group. This stated that treatment of a case of infection from *C. difficile* should include modified prescribing of antibiotics and isolation of people with the infection. It reported that the spread of infection could be prevented (but not completely eradicated) by reducing contamination of the environment through environmental cleaning and hand washing, and by restricting the inappropriate use of antibiotics.

In December 2005, the Chief Medical Officer and Chief Nursing Officer issued a letter to all NHS trust chief executives on infection caused by *C. difficile*. The letter was a reminder of the recommendations for microbiological investigation of outbreaks, the need for policies and procedures to be in place to minimise the risk of infection caused by *C. difficile* and the need to implement appropriate policies when cases occur. In January 2007, the Health Protection Agency issued a good practice guide to control *C. difficile*.

Other factors which can affect the control of infection

The report of the National Audit Office in 2000, *The management and control of hospital acquired infections in NHS acute trusts in England*, was critical of the insufficient priority given to the control of infection in the NHS. The follow up report in July 2004 indicated that there had been notable progress in putting systems in place at trust level, but that the prevention of infections continued to be adversely affected by the pursuit of other NHS trustwide priorities and policies. In particular, the increased throughput to meet performance targets resulted in considerable pressure towards higher bed occupancy. Higher bed occupancy meant that there was less time for thorough cleaning between patients and a higher probability of transmission of infection between patients. The lack of suitable isolation facilities remained a concern, as did the increase in frequency of moving patients. Moving patients increases the risk of transmitting infections.

In April 2005 the House of Commons Committee of Public Accounts (usually referred to as the Public Accounts Committee) followed this up by examining progress in reducing the risks of healthcare associated infection. It noted there were conflicts with other key targets and priorities and that these had continued to stand in the way of improving prevention and control. These included bed management policies and the need to meet waiting time targets, which could compromise

infection prevention and control. The report recommended that trusts needed to adopt more effective bed management practices to avoid moving patients too frequently.

The investigation by the Healthcare Commission into outbreaks of *C. difficile* at Stoke Mandeville Hospital, published in July 2006, found that Buckinghamshire Hospitals NHS Trust failed to bring a second outbreak under control because that trust was too focused on meeting national targets and was insufficiently focused on clinical risk. The Buckinghamshire Hospitals NHS Trust's determination to meet the target for a maximum waiting time in accident and emergency (A&E) of four hours, led to some patients with diarrhoea being put on open wards rather than in isolation facilities. Clinical staff repeatedly raised concerns about moving patients to different wards because of the likely spread of infection, but no effective action was taken to stop this happening. The investigation found that shortages of nurses probably contributed to the spread of infection. This was because staff on the wards were too rushed to take basic precautions such as washing their hands, wearing aprons consistently, emptying commodes promptly and cleaning equipment properly.

Since the inception of that investigation Buckinghamshire Hospitals NHS Trust has made a number of improvements and the rates of *C. difficile* have come down. A consultant microbiologist with a clinical understanding of infection control has now been appointed as DIPC.

The Healthcare Commission's report in 2007, *Healthcare associated infections: What else can the NHS do?*, looked at responses to a questionnaire on infection prevention and control completed by NHS trusts in May 2006. Forty-five per cent of these trusts said that they had difficulties in reconciling the management of healthcare associated infections and cleanliness with the fulfilment of the four-hour A&E target. Twenty-nine per cent had difficulties in relation to reconciling the management of healthcare associated infections and cleanliness with waiting time targets and 36% with the fulfilment of financial targets.

National structures and systems involved in the control of infection - the Health Protection Agency

The Health Protection Agency (HPA) was formed in 2003. It is an NHS 'arms length body' responsible for protecting the health and wellbeing of people in England. The HPA is accountable to the Department of Health.

One of the key roles of the HPA is to support the Department of Health to reduce levels of healthcare associated infections. The monitoring and surveillance of healthcare associated infections has been extended, and the HPA operate the surveillance system and publish the results. The remit of the Centre for Infections, which is part of the HPA, includes the provision of national expertise and of nationwide surveillance. Information on mandatory surveillance of *C. difficile* infection is sent to the Centre for Infections for national analysis and publication.

The HPA has nine regional teams that mirror the areas covered by the Government offices of the regions. Regional teams have a regional director, up to two regional epidemiologists and an information and surveillance team. Most regions have three or four health protection units (HPUs). There are 29 HPUs in total, each consisting of a director, consultants, nurses and other staff with specialist health protection skills.

One of the tasks of each HPU is to work directly with the NHS primary care trusts, acute hospital trusts, strategic health authorities and local authorities in their area. Functions include surveillance of disease occurring locally, alert systems, and the investigation and management of the full range of incidents related to health protection, including outbreaks of infection. The HPU staff work closely with acute trusts, particularly their directors of infection prevention and control, and their infection control teams.

The HPA and the Healthcare Commission undertook a survey of all NHS acute trusts in England in 2005. The survey was intended to gain an understanding of the issues facing NHS hospitals in relation to the management, prevention and surveillance of infection caused by *C. difficile*. The findings included that 40% of trusts did not routinely isolate cases of infection with *C. difficile* and 38% did not have restrictions on broad-spectrum antibiotics.

As a result of the interim findings it was emphasised to trusts in December 2005 that they should ensure that their policies on the prescribing of antibiotics were informed by current guidelines on best practice, and that these policies should be properly monitored. Additionally, trusts should review their procedures for, and capacity to, isolate patients with infection from *C. difficile*. The final report, *Clostridium difficile: Findings and recommendations from a review of the epidemiology and a survey of Directors of Infection Prevention and Control in England*, was published in July 2006. It confirmed the preliminary findings, and emphasised that the testing and reporting of cases as part of the mandatory surveillance scheme were inconsistent.

National structures and systems involved in the control of infection - surveillance

Since before 1990 in the UK there has been a scheme for laboratories to report cases of *C. difficile* on a voluntary basis to the Public Health Laboratory Service and more recently to the HPA. The figures show a dramatic upward trend of reported cases of *C. difficile*, from 1,172 cases in 1990, to 51,519 cases in England in 2006. The rise is likely to be a combination of increased awareness and an actual increase in infection, which may be accounted for by the factors referred to earlier, such as antibiotic prescribing, poor hygiene, failure to isolate patients with infections, more virulent strains, high bed occupancy, more vulnerable patients and an increase in the movement of patients in hospital.

In January 2004, reporting of *C. difficile* became part of the mandatory surveillance scheme for healthcare associated infections. As part of the mandatory surveillance programme, acute trusts were required to report cases diagnosed by the trust's laboratory even if they were acquired in the community or in another trust. In the final report published by the HPA in July 2006, it was reported that 14% of trusts surveyed were not reporting these cases in the community correctly.

The scheme initially only required reporting of cases occurring in people 65 years and over and therefore did not identify cases in younger people in England. Three sets of annual data from this surveillance have been published, and these have allowed for a comparison of rates of *C. difficile* infection within different hospital trusts and regions of the NHS.

In April 2007, changes were introduced to the mandatory surveillance system for *C. difficile* infection, such that trusts now have to report all cases in individuals aged two years and over. The new system is based on the enhanced MRSA bacteraemia surveillance system. It will help to provide information to inform the setting and monitoring of new local targets for *C. difficile*. From April 2007 primary care trusts have to agree with local providers a target to reduce *C. difficile* infections.

The Department of Health has reiterated that national reporting does not replace the need for local surveillance by trusts and strategic health authorities.

Local structures and systems involved in the control of infection - the role of the director of infection prevention and control

The report of the Chief Medical Officer in December 2003, *Winning Ways: working together to reduce healthcare associated infection in England*, required each organisation providing NHS services to designate a director of infection prevention and control (DIPC).

The guidance on the competencies required for directors of infection prevention and control was produced in May 2004. This guidance 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. If the DIPC did not have expertise and experience in infection control, management of the infected patient, decontamination protocols and antibiotic usage, they would need to have access to expert professional guidance.

The role of the DIPC is to:

- oversee infection control policies and their implementation
- be responsible for the infection control team
- report directly to the chief executive and board
- challenge inappropriate clinical hygiene practice and antibiotic prescribing decisions
- assess the impact of all existing and new plans and policies on infection control and make recommendations for change
- be an integral member of the clinical governance and patient safety teams and structures
- produce an annual report on the state of healthcare associated infection in the organisation and release it publicly.

The Healthcare Commission's report in July 2007, *Healthcare associated infection: What else can the NHS do?* found that 43% of directors of infection prevention and control were microbiologists, 36% were nursing directors or chief nurses and 11% were medical directors. Approximately half of all directors of infection prevention and control had a specific qualification in infection control.

Infection control teams

It is a requirement of the code of practice for the prevention and control of healthcare associated infections that the infrastructure of infection control teams be adequate. The Royal College of Pathologists in 1999 recommended that "the minimum input of an infection control doctor should be three consultant sessions per 500 beds on infection control." With the other related duties, for example, advice on medical management, this approximated to one full time doctor with the lead for infection control per 1,000 beds. In 2000 the National Audit Office (NAO) found wide variation in the ratio of infection control doctors to beds in NHS trusts.

The NAO found in 2000 and 2004 that numbers of infection control nurses also varied significantly. There were no national guidelines in regard to nursing levels, and the NAO in their 2004 report noted that the roles and responsibilities of infection control staff were so complex and varied that guidance on the number needed per bed was neither straightforward nor necessarily helpful. Nurses undertake specific training in order to qualify and work in infection control.

The trust's history and role

Maidstone and Tunbridge Wells NHS Trust (the trust) was created on 1 April 2000 following the merger of Mid Kent Healthcare NHS trust and Sussex Weald NHS trust. It serves a combined population of approximately 500,000, covering west Kent and parts of northeast Sussex. The trust employs approximately 5,000 staff in a range of roles and specialties.

The trust's board (the board), which consists of executive and non-executive directors, is responsible for the governance of the trust. The chairman, chief executive, and director of nursing had all been in their posts since 2003. The number of clinical directorates varied from 14 in 2004 to nine in 2006. In 2005/2006 there were five non-executive directors and 10 directors holding executive functions at various times. The director of nursing and patient services was also the director of infection prevention and control.

The trust has three hospitals and a total of between 857 and 900 beds during the

outbreaks. The administrative headquarters are at Maidstone Hospital, which is a general hospital with 437 beds. A cancer centre, which is the main provider of cancer services for Kent, is based at the hospital. Kent and Sussex Hospital is a general hospital with 284 beds providing a range of acute services. Pembury Hospital has 136 beds mainly related to women's and children's services. The two main hospitals, Maidstone and Kent and Sussex, are about 18 miles apart.

A private finance initiative to replace Kent and Sussex and Pembury hospitals has been agreed and the new facility is expected to be complete in 2010. This project is also intended to improve services at Maidstone Hospital.

The trust provides hospital services primarily to West Kent primary care trust (PCT). The PCT is responsible for organising primary care and community health services for the local population, and commissioning hospital care. Other PCTs also receive some services from the trust.

The trust is in the area of the South East Coast SHA (the SHA), which was formed in 2006. The role of the SHA includes establishing and managing annual performance agreements with PCTs and NHS trusts.

In 2002 the Commission for Health Improvement (CHI) carried out a clinical governance review of the trust. This report was published in December 2002. The key areas for action included improving the control of infection, reducing mixed sex wards, improving nursing numbers and skill mix, and improving the management of risk.

In the annual health check for 2005/2006, carried out by the Healthcare Commission, the trust's overall rating was "fair" for quality of services and "poor" for use of resources. It "almost met" the core standards, laid down by the Department of Health, which are required of all trusts. The trust declared itself compliant on the set of standards that relate to infection control. Previously, in 2004/2005, the trust was awarded one star by the Healthcare Commission in the annual performance (star) ratings. It had been awarded zero stars for performance in 2002/2003 and 2003/2004, because of poor performance on achieving targets and financial balance.

The trust has started an extensive programme to reconfigure services. The key elements include centralising planned surgery at Maidstone and emergency surgery at Kent and Sussex. An independent sector treatment centre opened in November 2006 at Maidstone Hospital to provide some routine planned surgery.

The Tinston report in 2003, *Report of the External Inquiry into the Reporting of Waiting List Data in Maidstone and Tunbridge Wells NHS Trust*, was an investigation into outpatient waiting times. It found that they had been deliberately misrepresented, and this was serious and unacceptable. Tinston considered that the pressure to succeed at all costs had contributed to the complicity of managers in this misrepresentation. The report described a trust under extreme pressure, individuals under stress, the unacceptability of failure and a perceived lack of support for people. The report considered new leadership was required and over the following year the chairman, chief executive and other senior managers left the trust.

C. difficile at the trust

Surveillance of *C. difficile*

Surveillance is the continuous monitoring of the frequency and distribution of *C. difficile* infection, undertaken both at a local and national level.

Sources of evidence

- Figures from the Health Protection Agency (HPA) mandatory surveillance scheme
- Data provided by the trust
- Interviews with trust staff and the HPU

Mandatory surveillance

Information obtained from the mandatory surveillance scheme allowed for a comparison of rates of *C. difficile* infection between different trusts, and over time. Maidstone and Tunbridge Wells NHS Trust consistently had figures that were in the upper quartile, that is, the 25% of trusts in England with the highest rates since the scheme began in January 2004. The scheme produced figures for the whole trust and did not distinguish numbers at the different hospitals of the trust.

Between January and September 2006, the trust had the twelfth highest rate of *C. difficile* per 1,000 bed days for patients 65 years and over, out of 166 trusts which submitted data. In the full year January to December 2006, the trust had the twenty-first highest rate of *C. difficile* per 1,000 bed days for patients 65 years and over, out of 167 trusts that submitted data. From January to December 2005 the trust had the twenty-sixth highest rate, while from January to December 2004 the trust had the twelfth highest rate.

The trust had the 41st highest MRSA bacteraemia rate per 10,000 bed days for the period from April 2006 to March 2007.

As part of the mandatory surveillance scheme, acute trusts were required to report all positive laboratory results for patients over 65, including samples sent from GPs for patients under their care. However the laboratory staff and microbiologists told us they did not always test these samples, because of lack of resources. For those samples from GPs that were tested, any positive results were reported. In the Health Protection Agency (HPA) report in July 2006, based on the joint survey with the Healthcare Commission of directors of infection prevention and control (DIPCs), the trust reported it was reporting this correctly, as did 80% of trusts.

Local surveillance

All trusts are required to have systems in place to enable them to detect rises in the numbers of cases of infections, so that they can respond rapidly to outbreaks and take extra precautions.

The infection control team set up a database in December 2000 to record all cases of *C. difficile*. It held details of patients and their date of admission. The information was incomplete. For example, there were no details of the dates that specimens were sent or of treatment for the patient, or any advice given by the infection control team. The data came from paper based records. The trust purchased an electronic surveillance package at the end of 2005, but did not begin using it until August 2006.

The lead infection control nurse was responsible for maintaining the database but was on sick leave throughout much of the summer of 2005 before retiring in October. Her replacement did not start until February 2006. There was no additional support for the team during this time, and no alternative

arrangements for local surveillance. The microbiologists did not assume the responsibility for the database or surveillance.

C. difficile figures were reported to infection control committee meetings, held every three months, but were generally three or four months out of date. The information was part of the pack that subsequently went to the clinical governance and risk committee, the trust management board and the trust board. There was no evidence of action in response to the figures. The data also formed part of the annual infection control report.

Typing

Typing of *C. difficile* (to identify the particular strain of bacterium) may be useful in investigating whether there are links between individual cases and in monitoring the spread of infection from particular strains of *C. difficile*. Specialist laboratories in six regional centres in England now provide this service for trusts, as well as the original reference laboratory in Cardiff, which also provides the typing for the mandatory surveillance programme.

In the published findings in July 2006 of the survey conducted by the Healthcare Commission and HPA, only 47% of trusts said that they had requested typing to help the management of an outbreak of *C. difficile*. The letter from the Chief Medical Officer and Chief Nursing Officer in December 2005 advised that trusts might need to increase typing of strains during an outbreak.

Between April 2004 and September 2006, the trust had over 1,100 patients infected with *C. difficile*. The Anaerobe Reference Laboratory informed us that between September 2005 and September 2006 the trust sent 19 faecal samples for typing. One of these was at the request of a consultant physician in December 2005. Ten samples were sent to Cardiff in March 2006 as part of the mandatory reporting programme. Seven of these samples were confirmed as type 027. The laboratory in Southampton told us that of the eight samples sent in April 2006, six were type 027. There was no evidence that the trust attempted to link cases through typing during the declared outbreak.

The numbers of cases of *C. difficile* and the outbreaks

Overall period April 2004 to September 2006

The trust had a high number of cases throughout the period under consideration. From figures provided by the trust (taken from their laboratory database) there were 1,176 confirmed cases of *C. difficile* for all age groups between 1 April 2004 and 30 September 2006. These were broken down by hospital as follows:

Maidstone - 738 cases

Kent and Sussex - 353 cases

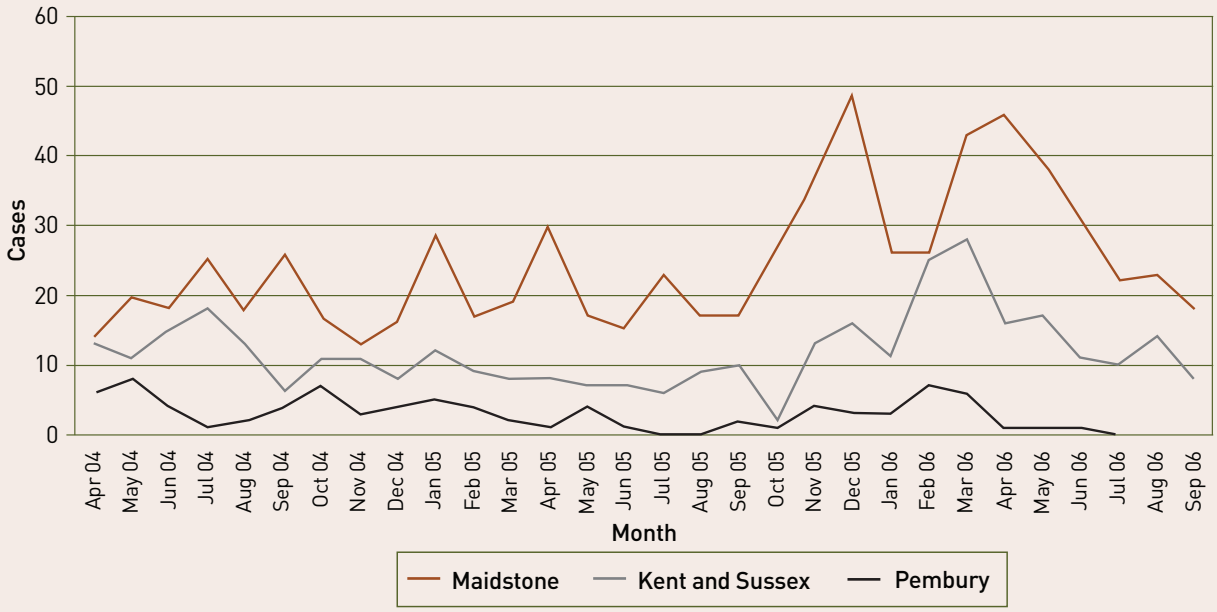
Pembury - 85 cases

Data submitted to the HPA as part of the mandatory reporting of *C. difficile* showed that 1,268 cases were reported by the trust for the same time period, April to September 2006. This figure is 92 more than were reported to the Healthcare Commission, even though data submitted to the HPA should only have included positive results in patients 65 years and over, whereas we requested data on positive cases in all patients.

One possible explanation is that tests repeated on the same patient were included in the data reported to the HPA, which also included results from private patients and those in community hospitals. We were told that cases were only counted once (even if a patient had more than one episode of the infection) in the data reported to the Healthcare Commission.

Between April 2004 and September 2006, the average number of new cases of *C. difficile* reported by the trust was 39.2 per month, 24.6 of which were at Maidstone Hospital.

Figure 1: Total number of new cases of *Clostridium difficile* at Maidstone and Tunbridge Wells NHS Trust by hospital



October 2005 to December 2005

It can be seen that the number of cases at Maidstone Hospital began to rise steeply in the autumn of 2005. From October to December 2005, Maidstone had 113 confirmed new cases of *C. difficile*, and Kent and Sussex had 31. In December the number of new cases at Maidstone Hospital was nearly 50 – more than twice the average monthly figure.

In December 2005 the infection control nurse at Maidstone Hospital notified the health protection unit (HPU) of 12 confirmed cases of *C. difficile* on two wards. The infection control nurse sent an e-mail message to the HPU on the 19 December 2005 and telephoned the unit on 5 January 2006 to confirm that the cases were under control.

Other than this, there is no evidence that the infection control team or others in the trust were aware until the second outbreak was reported in April 2006, of the increase in the numbers of patients infected with *C. difficile* that happened between September and December 2005. Despite the increase in the number of cases that autumn, the trust neither identified nor declared an outbreak in 2005.

In December 2005 a consultant physician at Maidstone Hospital was concerned about the severity of the infection in one of his patients, who subsequently died. On 16 December a specimen was sent for typing at his request and on 26 January 2006 the microorganism was discovered to be type 027, generally regarded to be more virulent. The trust board minutes for January 2006 recorded that "since this was a single incident, it was not logged as a serious untoward incident." The minutes stated that an incident review would be conducted into the case, but the trust has told us this did not happen. The microbiologists or infection control team did not take any action, although 027 was by then known to be a virulent strain.

Between December 2005 and January 2006, the number of new cases of *C. difficile* at Maidstone Hospital fell from 49 to 26, and remained at 26 in February 2006. For the same period at Kent and Sussex Hospital, new cases went from 16 to 11 and back up to 25.

April 2006 to September 2006 – the outbreak

We have labelled this period "the outbreak" because the trust reported an outbreak to the

HPU and the strategic health authority (SHA) on 12 April 2006. Although it was not formally closed as a serious untoward incident until December 2006, the number of cases returned to the background figure by September.

The number of new cases at Maidstone Hospital rose again in March 2006. From March to May, Maidstone had 128 confirmed cases of *C. difficile*, and Kent and Sussex had 61. According to the infection control committee minutes in June 2006, the position at Maidstone was that "At one stage every ward had at least one confirmed patient." The number of new cases declined but was still high during May (39) and June (31). In July at Maidstone they declined toward the level prior to the two outbreaks. There was a slight rise at both hospitals in August followed by a steady decline.

On 11 April 2006, there were 32 patients who were known to be positive for *C. difficile* infection and a further nine with symptoms. The outbreak was declared on 12 April. From the graphs in figure 1 it appears it could have been declared at the end of March, and the senior infection control nurse, who joined the trust in February 2006, acknowledged this.

The second outbreak involved large peaks in both hospitals. The minutes of the public part of the trust board in July 2006 referred to an outbreak at Maidstone, as did the press releases in June. Some staff we interviewed considered that the high background rate and outbreaks only involved Maidstone Hospital. Maidstone Hospital had a higher number of patients infected with *C. difficile* compared to Kent and Sussex Hospital throughout the period under investigation (April 2004 to September 2006). When the number of cases of *C. difficile* is presented as a proportion of total admissions, the average rate of infection during this period was 0.51% at Kent and Sussex and 0.61% at Maidstone. However, the rate of infection as a proportion of admissions was higher at Kent and Sussex Hospital during the outbreak in the spring of 2006.

After the spring 2006 outbreak, the trust changed its approach to the definition and reporting of outbreaks, erring on the side of caution. The definition of outbreaks involved careful consideration of any rise above the background figure for the particular hospital. This meant the trust was likely to be reporting outbreaks at an earlier point than other trusts.

After the investigation was announced

There was a small outbreak of patients infected with *C. difficile* at Kent and Sussex in January 2007, which was reported to the HPU. This involved eight wards and 15 cases (four of which were later identified as false positives) and was quickly brought under control.

There were large outbreaks of norovirus in February and March, first at Kent and Sussex Hospital, and then at Maidstone.

In April 2007 the trust had a small cluster of patients infected with *C. difficile* at Maidstone Hospital and later in the month there was another at Kent and Sussex Hospital. These were reported to the SHA and the HPU. The cluster at Kent and Sussex Hospital was on a ward where we had noted the bedpan washer was not working properly, and we had seen bedpans contaminated with faeces during a visit on 5 April. We reported this at the time and wrote to the trust with our concerns. The trust says that the cases were not related to the equipment not working.

An outbreak of *C. difficile* at Maidstone Hospital was declared on 20 June 2007, following a rise above background levels in May and in June. In May there were 25 new cases and six deaths of patients with *C. difficile* and in June there were 20 new cases and three deaths. Cases were concentrated in four medical wards and one oncology ward, and a cohort bay was established on Cornwallis ward on 18 May. The HPU were satisfied with the way in which the trust responded to the outbreak and it was declared over in early July.

Information on total cases and recorded deaths

When the Healthcare Commission first contacted the trust about the cases of

C. difficile, the trust identified a total of 970 patients from their laboratory database as having *C. difficile* between April 2004 and April 2006. (This figure was then updated to 1,176 for the period April 2004 to September 2006.) This list was cross-referenced by the trust with patients who had died up to May 2006, which identified 550 patients that both had *C. difficile* and died in hospital. Of these the trust was only able to retrieve 500 sets of notes. The details of these patients were compiled in a spreadsheet. The Healthcare Commission later requested data on such patients up to the end of September 2006 - the period of study.

The breakdown of patients was:

- 274 patients died in hospital and also had a *C. difficile* diagnosis between April 2004 and May 2006 (inclusive)
- 39 patients died in hospital and also had a *C. difficile* diagnosis between June 2006 and September 2006 (inclusive)
- a further 32 patients had no record of whether they died in hospital on the spreadsheet, but had a death certificate which mentioned *C. difficile,* therefore it is likely they died in hospital
- 155 patients had been discharged alive.

Based on the information provided by the trust, 345 patients (274 plus 39 plus 32) died in hospital following an admission to the trust in which they developed *C. difficile* infection between April 2004 and September 2006. We consider the contribution of *C. difficile* to those deaths in the chapter on quality of care that starts on page 31.

Findings of fact

- The trust had historically suffered from high background rates of *C. difficile* for patients 65 years and over, compared with other acute trusts, since the Health Protection Agency (HPA) mandatory surveillance began in 2004. Little progress had been made in terms of awareness, identifying the cause and reducing the rates.
- The trust was not compliant in meeting fully the requirements of the mandatory reporting scheme for *C. difficile*, in that they did not test all community (GP) patients 65 years and over. Any they did test were included in their returns.
- Between April 2004 and September 2006 the trust reported to the Healthcare Commission that it had 1,176 patients with *C. difficile* infection. There was a difference of 92 cases between the figures on *C. difficile* reported to the Healthcare Commission as part of the investigation, and those returned to the HPA as part of the mandatory surveillance.
- The 1,176 cases included a period between October 2005 and July 2006 when the trust experienced a major increase in cases, totalling over 500 cases.
- At least 345 people died in hospital between April 2004 and September 2006 following an admission to the trust in which they developed *C. difficile* infection.
- Before April 2006 figures on *C. difficile* were not reported in a way that would easily enable the trust to detect outbreaks. The information was out of date, did not include basic information and did not trigger action.
- The trust's system for local surveillance was not effective. When the senior infection control nurse was ill and then left, the trust's system for local surveillance broke down completely. The significant outbreak in the autumn of 2005 was missed and the trust has acknowledged that it should have detected the rise in cases at that time.
- In January 2006 the trust's board was informed of a confirmed case of a virulent strain of *C. difficile*. A review of this incident was announced but did not take place, and no action was taken by the infection control team.
- The outbreak in 2006 was declared on 11 April 2006. It could have been declared at the end of March.

- The rate of infection during the outbreak in April was higher as a proportion of admissions at Kent and Sussex Hospital than at Maidstone Hospital. Press releases referred only to Maidstone Hospital.
- Between April 2004 and September 2006, the trust sent 19 faecal samples for typing. Ten of these were part of the mandatory reporting programme.
- In April 2007 we observed that a bedpan washer was not working on a ward at Kent and Sussex and that bedpans were contaminated.
- There was a cluster of cases on the same ward at Kent and Sussex Hospital in April 2007.

The trust's analysis of deaths

Reviews of case notes undertaken by the trust and information provided about the outbreak

Sources of evidence

- Spreadsheets and figures provided by the trust
- Minutes of the outbreak meetings
- Interviews with the DIPC, chief executive, infection control team, other clinical staff and those involved in the reviews
- Press releases, trust statements, diaries, correspondence
- Information provided by the HPU

Following the declaration of the outbreak, and meetings with the health protection unit (HPU), the trust undertook a number of reviews of case notes. This was primarily to ascertain the number of deaths caused by *C. difficile*. In information released to the public, the trust used the 'definite' category from the analysis used at Stoke Mandeville Hospital, part of Buckinghamshire Hospitals NHS Trust. The trust obtained this classification from Stoke Mandeville shortly after the April 2006 outbreak was reported. This was on the advice of the HPU. The categories used at Stoke Mandeville were based on the contribution of the infection to the death of patients and were definite, probable, possible, unlikely and no. The basis for the classification is outlined opposite.

In the analysis of the cases from April 2004 to March 2006, the trust reported to the Healthcare Commission, from its review of patient's notes and death certificates, that there were no deaths that were definitely due to *C. difficile* during that time.

Stoke Mandeville classification

The Healthcare Commission investigation report into outbreaks of *Clostridium difficile* at Buckinghamshire Hospitals NHS Trust, published in July 2006, included an assessment of the contribution that *C. difficile* made to the patient's death, using the following classification:

Definite: Post mortem findings and/or Ia on death certificate and compatible with information in notes*

Probable: Ib or lower on the death certificate and no other reasonable cause of death found in notes

Possible: Ib or lower on the death certificate and other reasonable cause of death found in addition

Unlikely: Not mentioned on the death certificate or diarrhoea not significant prior to death

No: Response to *C. difficile* treatment - asymptomatic prior to death

This classification was produced by Buckinghamshire Hospitals NHS Trust.

*notes = case notes/patient records

It is difficult to predict accurately how many people would have been expected to die from *C. difficile* at the trust between April 2004 and March 2006. Mortality attributable to *C. difficile* infection is hard to estimate because patients with this infection often have other potentially fatal diseases. Studies have used different methods of controlling for these factors, and published estimates of mortality attributable to *C. difficile* infection vary. An analysis of a Canadian outbreak published in 2005

estimated that the mortality rate at 30 days attributable to *C. difficile* infection was 6.9%. If we apply this estimate to the 918 confirmed cases of *C. difficile* between 1 April 2004 and 31 March 2006, then 63 people would have been expected to die from *C. difficile* disease in this period. Of the 1,176 patients between April 2004 and September 2006, 81 would have been expected to die.

It is possible that the Canadian outbreak was caused by a more severe form of *C. difficile*, or that the affected patients had on average more serious other diseases, but as will be seen later the figure of 81 deaths derived by applying the mortality of 6.9% closely approximates to the Commission's estimation of the total number of deaths obtained independently from our review of patients' clinical case notes.

The medical director and the consultant microbiologist with the lead for infection control at the trust undertook an initial review of case notes. This review was of patients who had died and had *C. difficile* recorded on their death certificate. This was undertaken shortly after the outbreak was detected in April 2006. The purpose of this review was not clear. The reviewers worked separately. Neither of them was working to a specific brief or agreed methodology, and they did not consult with one another. They could not remember the exact number of cases but each said it was fewer than 15. It was not clear if they looked at the same patients. The consultant microbiologist told us that he used the Stoke Mandeville classification. The medical director had looked for consistency in death certification and did not recall using any classification. The DIPC said the Stoke Mandeville classification had not been used. There was no final report of this work.

The chief executive, in a reply to concerns expressed by the HPU, wrote on 12 June 2006 that the trust "began to review deaths as part of its proactive management of the issue. This review showed some 123 patients with a diagnosis of *C. difficile* appearing on their death certificates." The review described in the letter covered the period from October 2005 to May 2006. The letter goes on to say that in 23 cases it was cited as the main cause of death, but that some patients never had *C. difficile* despite it appearing on their death certificates. The HPU was concerned about the reliability of these statistics. The trust has not been able to explain to the Healthcare Commission where these figures came from.

A further review was undertaken by two consultant anaesthetists working in intensive care (the intensivists). The director of nursing and patient services informed us that cases were selected by identifying all patients who between April 2004 to March 2006:

- had died from any cause at the trust and
- had a positive *C. difficile* laboratory result (using the hospital pathology system) and
- had died in hospital.

Of the total number identified, the trust then selected those patients with a death certificate that mentioned *C. difficile*. We were informed that the intensivists were asked to review all patients that met the criteria above since April 2004, that is, had *C. difficile*, died in hospital and had *C. difficile* mentioned on their death certificate. The trust was unable to locate 50 sets of clinical case notes (approximately 10%) for the intensivists to review.

There was no formal written process with a specified aim and methodology for this work.

The trust provided us with a file containing copies of the intensivists' assessments of cases. They used the Stoke Mandeville classification which had been obtained directly from Stoke Mandeville Hospital. We were also given a spreadsheet listing all the patients at the trust who since April 2004 had died in hospital and had a positive laboratory test for *C. difficile*. The spreadsheet also listed whether these patients' death certificates had mentioned *C. difficile*, and if so, whether this had listed *C. difficile* as the main cause of death or a contributory factor.

The summary done by the intensivists included only 49% (38 out of 77 patients) of those who had *C. difficile* on their death

certificates after dying at the trust between April 2004 and May 2006. Therefore, contrary to the information given to us, their work and the summary did not include a comprehensive list of all people who died at the trust and had *C. difficile* on their death certificate during the specified period.

In other words, there were nearly 40 patients who had *C. difficile* diagnosed, died in hospital, and had *C. difficile* mentioned as a main or contributory cause of death on their death certificate, but who were not included in the intensivists' review. This review could therefore not have been able to ascertain accurately how many people had died where *C. difficile* was the main cause since April 2004. Any data derived from the findings of this review were similarly incomplete. We note that the results of this review were not presented to the executive team or the management board.

We received conflicting information as to when this second review of case notes was undertaken. The chief executive told us that this work produced the number of deaths mentioned in press releases dated 23 and 30 June 2006. The press releases in June 2006 referred solely to deaths since the outbreak in April 2006. They identified five and then six patients who had definitely died from *C. difficile*. However, the intensivists told us that they undertook the reviews working over the two days of 31 July and 1 August 2006, and their diaries confirmed this. The trust then said that the analysis had been syndicated, but was unable to tell the Healthcare Commission with certainty the factual basis for the numbers in the press releases. It may be that some of the work was done in batches. The system for dating documents was poor, making it hard to trace the chronology.

It would also be reasonable to expect some other deaths in which *C. difficile* did play a part, but where it was not mentioned on the death certificate. This is covered in the next chapter.

Information provided to the board and the public on the number of deaths caused by *C. difficile*

Sources of evidence

- Interviews
- Minutes of the board and papers to the board
- Press statements

The trust used the approach employed by Stoke Mandeville Hospital to categorise the contribution of *C. difficile* to the death of patients into definite, probable, possible and unlikely.

Deaths relating to the time when cases began to rise in October 2005 were not included in the statistics released by the trust. In fact, in the six months before 1 April 2006:

- 14 people had *C. difficile* as the main cause of death on their death certificate but only three of these cases were reviewed by the intensivists
- 17 patients had *C. difficile* as a contributory factor, but only one was reviewed.

The trust published information relating only to deaths following the reporting of the outbreak in April 2006, and the press release on 30 June 2006 refers to the time between April and June. The press release says that "six patients had a diagnosis of *C. difficile* that was the definite cause of their death." However, between 1 April 2006 and 30 June 2006 there were:

- 11 patients who had *C. difficile* as the main cause of death on their death certificate. The trust board was informed that all patients where *C. difficile* was written as a cause or contributory factor on their death certificates were reviewed. However, only eight of these were reviewed
- 17 patients who had *C. difficile* as a contributory factor. Of these, 16 were reviewed.

Papers that went to the board in 2006 showed the detailed breakdown into the Stoke Mandeville categories. The information in press releases from June to November 2006 gave the number of deaths from *C. difficile* using those in the 'definite' category, and grouped the others together as contributory. This was a different system to that used subsequently for the Stoke Mandeville report and subsequent publicity, where 'definites' and 'probables' were grouped together. Moreover the press releases in June described the contributory deaths as ones in which *C. difficile* was not the cause of death. This was although the deaths of some of these patients had been deemed by the trust as probably due to *C. difficile*. The report of the investigation at Stoke Mandeville was published on 24 July 2006.

As mentioned previously, the trust was unable to tell us with certainty how they had arrived at figures in the press releases. The DIPC thought that the work had been done by the intensivists, but their recollection was of doing the reviews in an intensive two day period in late July and early August.

General communication to the public about the outbreak

The outbreak was declared on 12 April 2006 and the first press release was in June. The trust issued a daily outbreak bulletin to a large number of staff, but a number of nurses, including some working on affected wards, told us that they learnt about the outbreak through the newspaper or media coverage.

At a meeting to discuss the outbreak on 13 April, the Kent health protection unit (HPU) advised the trust to issue a press release. The strategic health authority (SHA) agreed with this course of action. The director of finance was at the meeting deputising for the chief executive who was on leave. As this was just before Easter the outbreak committee agreed that it would be reasonable to delay release until after the weekend. However, a statement was not released. On her return from leave the chief executive considered it would be more appropriate to have a statement ready, should the media enquire. She explained to the Healthcare Commission that this was because of the need to include information that wasn't available, particularly regarding the number of patients who had died. The communications manager at the regional HPA was persuaded by the trust communications manager that a reactive approach should be taken, rather than her suggested proactive one, because the trust had informed her that the number of cases had dropped and that no patients had *C. difficile* on their death certificates.

On 6 June 2006, the HPU wrote to all acute trusts in Kent stating "Whilst most cases of *C. difficile* disease arise in hospital, the local acute trusts have recently seen a growing number of cases who have been admitted to hospital having been prescribed broad-spectrum antibiotics in general practice and then developed severe antibiotic associated diarrhoea".

The local HPU became concerned as it became apparent that the increase in cases at the trust had begun in October 2005 and that there had been a number of deaths. They thought the trust should be providing information to the public. On 8 June 2006 the HPU wrote to the trust with their concerns, including that they had given consistent advice at the time of the original outbreak meeting that a press statement should be issued. The chief executive responded on 12 June 2006 to a number of issues in the letter but did not give a reason for the delay in issuing a press release other than to say that the HPU proposal seemed to undermine, rather than promote, public confidence. The trust and the HPU met shortly after this exchange of correspondence and the trust agreed to undertake a review of patients who had died.

The first press release to mention the outbreak and the number of deaths was issued on 23 June 2006 in response to a query from the local media.

The press release began "Maidstone Hospital has seen cases of patients coming to hospital with diarrhoea symptoms caused by the

bacterium *Clostridium Difficile (C. diff)*. Additionally, patients in hospital with infections who are receiving antibiotic treatments can develop diarrhoea which is also *C. diff.* Both of these have occurred at Maidstone Hospital during this year. In April of this year the hospital developed an outbreak of *C. diff* caused by both of the above events." The minutes of the Maidstone External Scrutiny Committee meeting in July 2006 record the chief executive as saying "The recent outbreak had resulted from a substantial amount of patients being admitted to the hospital with *C. diff* and the hospital was unable to turn patients away." The implication was that the infection had been acquired in the community and brought into hospital.

However, for the period between October 2005 and June 2006, the proportion of cases of *C. difficile* acquired in the community, was 5.9% for Maidstone Hospital (18 out of 304 cases) and 7.9% (11 out of 140) for Kent and Sussex Hospital. Generally 90% or more of infections were acquired in hospital and patients coming from the community with the infection were consistently less than 10% of the total number. Some of these may have been readmissions of patients who initially acquired the infection in hospital.

The director of infection prevention and control (DIPC) was not able to explain why the trust chose to highlight in information to the public the patients admitted with *C. difficile* infection rather than those who acquired it in hospital.

Findings of fact on the trust's case note reviews, communication about the outbreak, and information on deaths

- The initial case note review was undertaken by the trust without a clear brief or purpose. There was no outcome from this review.
- The trust claimed that the case note review undertaken by the intensivists involved all the patients who died in hospital with *C. difficile*. However the review was incomplete and included less than half the patients where *C. difficile* was mentioned on the death certificate. There was no formal written protocol for this review.
- The number of deaths quoted by the trust in press statements only included deaths after April 2006, although there were 31 deaths in the six months before this where *C. difficile* was mentioned on the death certificate. The number of deaths quoted by the trust in press releases were only those in the 'definite' category.
- The trust is unable to explain the nature, timing and findings of the various case note reviews. Document control was poor so the different outputs from reviews could not be traced. The trust was unable to explain with certainty the source of the statistics in its June press releases.
- The trust could not find about 10% of case notes for its work in reviewing the notes of patients who died with *C. difficile* infection.
- The outbreak was reported on 12 April 2006. The HPU and strategic health authority (SHA) advised on 13 April that a press statement should be released, but this did not happen for two months.
- The HPA agreed to a reactive stance by the trust as they had been informed that the number of new cases had dropped and no patients had died with *C. difficile* on the death certificate.
- On 6 June 2006, the Kent HPU wrote to all acute trusts in Kent stating that while most cases of *C. difficile* disease arise in hospital, local acute trusts had seen a growing number of cases who have been admitted to hospital.
- The press releases in June in part attributed the outbreak to patients coming into hospital infected with *C. difficile*, despite the fact that this accounted for less than 10% of the total number of patients infected with *C. difficile* and had not increased.
- The Maidstone external scrutiny committee was informed that the outbreak resulted from patients with diarrhoea being admitted that the trust could not turn away.

The quality of care provided to patients infected with *C. difficile*

We noted that the trust's guidelines for *C. difficile* dated November 2004 contained no recommendations on the clinical care and treatment of individuals with *C. difficile* infection. These guidelines had been drawn up by the infection control team without the involvement of clinical care staff. The guidance did not recommend that a stool sample must be sent for testing in order to confirm the diagnosis. It did not mention prescribing vancomycin. We interviewed two junior doctors who had worked on wards particularly affected by the outbreaks but had left the trust and moved on to other hospitals. They commented that the care of patients infected with *C. difficile* was more organised in the hospitals where they now worked, with guidelines for the clinical management of patients with *C. difficile*. They pointed out that this may have been because of greater awareness of *C. difficile* more recently.

Healthcare Commission's review of case notes

Introduction

Between January and March 2007, the clinical experts on the Healthcare Commission's investigation team reviewed the case notes of 50 people who had died at the trust and had acquired *C. difficile*. This was to assess the quality of hospital care that patients had received for their *C. difficile* infection, and the contribution that this infection had made to each patient's death.

The 50 cases were selected by random sampling from a list of the 274 people who had a positive laboratory diagnosis of *C. difficile*, died in hospital at the trust between April 2004 and June 2006, and had information on their illnesses from the International Classification of Disease (ICD) codes provided by the trust. The sample was weighted so as to identify people who would have been expected to receive full active treatment for *C. difficile* infection, especially where the infection might have been serious enough to cause death. Patients who had a diagnosis suggesting that they suffered from an illness or illnesses that might have made it inappropriate to offer full active treatment for their medical problems (for example people with terminal cancer or advanced dementia) were excluded. Patients who had died out of hospital, or who had not had *C. difficile* during their final admission to hospital, were also excluded.

Compared to the 274 patients from whom they were selected, the average age of the sample patients was slightly older (86 vs. 83 years), but the proportions of patients of different sexes, who were cared for in the trust's three hospitals, and who had *C. difficile* as a primary and secondary International Classification of Disease coded diagnosis were all similar. They had similar average lengths of stay.

The reviewers used a standardised proforma to look at the following aspects of the management of *C. difficile* infection:

- general management of *C. difficile* infection, including involvement of specialists
- timeliness of treatment
- prescription of antibiotics
- management of fluid balance
- management of nutritional status
- assessment and management of severe *C. difficile* disease
- resuscitation status.

In addition, the reviewers assessed the contribution that *C. difficile* had made to each patient's death by evaluating the likelihood of answering yes to two different questions:

- Did *C. difficile* infection contribute to the patient's death?
- Was *C. difficile* infection the main cause of the patient's death?

For each question there were five possible assessments: definitely, probably, possibly, unlikely, and no. Reviewers were asked to make an assessment by considering evidence from the records on the severity of:

- pre-existing illnesses and clinical condition
- illnesses on admission
- illnesses that developed during the admission
- the *C. difficile* infection itself.

To reduce subjectivity, two reviewers first evaluated each record independently. They then discussed their findings and agreed on their conclusions about the care that a patient had received, and cause of death.

The limitations of this methodology are considered in Appendix D.

The quality of care of patients infected with *C. difficile*

In 10 out of 50 patients (20%), the reviewers had no concerns about the management of *C. difficile* infection. In the remaining 80%, care was thought to have been less than adequate to varying degrees. These inadequacies may not have affected the eventual outcome in many cases, for instance where fluid charts had not been completed, or where there had been no assessment of nutrition. Nevertheless, we noted all inadequacies wherever they occurred, because they could reasonably be expected to have adversely affected outcomes in some patients.

General management of patients infected with *C. difficile*

In approximately one-third of cases (34%), the medical records did not indicate that doctors had regularly reviewed patients' *C. difficile* infection after it had been diagnosed. This happened in at least seven out of 25 (28%) patients who still had diarrhoea after one week of treatment. In at least five cases, we could find no mention of *C. difficile* in the notes after it had been diagnosed. This was despite evidence of continuing symptoms from the infection, for example, diarrhoea or abdominal symptoms.

Other findings also indicated that the monitoring of *C. difficile* infection and its potential complications was not consistent or rigorous. Stool charts were used in less than 15% of cases. When they were, there was no standard description of stool such as could be found on the Bristol Stool Chart. This might have impaired accurate assessments of whether patients were responding to treatment or were showing signs of developing severe colitis.

As detailed later, there were concerns over the management of nutrition including fluid loss, reduced albumin and patients being afraid of eating. Albumin is the commonest protein in the blood and its level can give an indication of a person's nutritional status. It can also indicate the presence of a septic infection.

In total, the records suggested that a microbiologist had been involved in 17 (34%) cases, an infection control nurse in four (8%) cases, and the intensive care outreach team in six (12%) cases. In 22 cases, neither a microbiologist, infection control nurse, outreach clinician, nor gastroenterologist was involved in the care of the patient. In six of these cases, *C. difficile* infection was considered definitely or probably the main cause of death.

Timeliness

Most patients (30) had been tested for *C. difficile* within two days of developing symptoms; 17 were tested three or more days after developing symptoms; and three were started on antibiotics on the basis of clinical suspicion or a previous positive result without new testing. 35 patients were started on antibiotic treatment within two days of a positive result; five patients three or more days after the result became available; and 10 were not started on antibiotics, either because the diagnosis came too late, or for reasons not clear from the notes. In 12 cases there had been a delay of over one week between development of symptoms and starting antibiotic treatment for *C. difficile*. In 10 of these cases the reviewers were concerned about the delay before treatment was started. Three patients had had diarrhoea for over two weeks before being treated for *C. difficile*.

Where delay in treatment had occurred, this was usually because of a delay in sending a sample for laboratory testing rather than failure to act on a positive result, although the latter did occur. In most cases, diarrhoea had been recorded in the nursing notes but there was no evidence from the doctors' notes that they were aware of this fact and no sample had been sent. The reviewers were concerned that clinical staff had not considered the diagnosis or given it sufficient importance. On at least two occasions, the reviewers concluded that a delay in starting treatment had occurred because of an initially negative microbiology result that was not repeated for several weeks despite persistent diarrhoea. There was evidence of serious deterioration in a manner consistent with *C. difficile* infection during this time in one of these patients.

The management of antibiotics

The reviewers examined the prescribing of antibiotics that predisposed patients to develop *C. difficile* infection as well as antibiotics that were used to treat *C. difficile*.

In 21 (42%) of patients, the reviewers found cause for concern in the way that antibiotics that predispose patients to develop *C. difficile* infection had been used. Most commonly:

- patients received broad-spectrum antibiotics to treat conditions where a simple antibiotic (less prone to lead to *C. difficile*) would have sufficed
- excessive numbers of antibiotics were used for a simple infection, often in an additive manner rather than by substitution
- antibiotics, sometimes broad-spectrum, were used in situations where there was little evidence of a significant infection, such as a wound ooze or a mild fever without other signs of infection
- antibiotics were used for apparently excessive time periods, for example one patient received antibiotics for 23 days for a genital tract infection, and one received broad-spectrum intravenous antibiotics for 17 days for a chest infection
- in at least 10 cases, patients continued to receive broad-spectrum antibiotics despite recurrent symptoms of *C. difficile* infection.

In at least 16 (32%) patients the reviewers had concerns about the antibiotic therapy prescribed to treat the *C. difficile* infection itself. Most commonly, this was because vancomycin was not used where there was evidence that metronidazole had failed to control *C. difficile* infection.

In at least seven out of 25 patients (28%) whose diarrhoea persisted for more than seven days after metronidazole had been started, or where *C. difficile* had returned after recent treatment with metronidazole, the reviewers thought that treatment with vancomycin should have been considered since the patients were clearly deteriorating from *C. difficile* infection. In total, less than 15% of patients received vancomycin at any stage. Other concerns included several doses of antibiotic for treating *C. difficile* being missed in some patients or not given without there being a clear reason. Some patients who were unable to take an antibiotic by mouth

were not considered for intravenous medication. In two cases, no antibiotic was given for *C. difficile* after diagnosis despite evidence of ongoing diarrhoea, but it was not clear why.

Fluid management

Infection with *C. difficile* typically causes significant loss of fluid and electrolytes, and this can lead to serious complications. The reviewers felt that poor fluid management, for example where there was no evidence of regular assessments and management of fluid and electrolyte losses after diagnosis, was a cause for concern in 18 out of 50 (36%) patients. Most commonly, this was because there was no evidence of regular assessment of fluid and electrolyte status by the doctors in the clinical notes or through blood tests, or because fluid charts could not be found or were not properly completed. In many cases, these patients were recorded as being "for full active treatment" (see box opposite). Although inadequate fluid management did not always affect outcome, in at least three patients the notes suggested that this was associated with a serious deterioration in kidney function.

Nutrition management

Patients infected with *C. difficile* can become malnourished rapidly because they lose protein through their inflamed bowel. They also often stop eating. This interferes with their ability to overcome the infection and other illnesses or operations they may have had. The reviewers were concerned that in at least 17 cases (34%), patients' nutritional needs had not been appropriately assessed or managed.

In most of these cases there was very little or no mention of nutritional management despite clinical or laboratory evidence of declining nutrition status, or poor nutrition was noted but little or nothing was done about this. Ten of the 17 patients had diarrhoea that continued for over seven days, and of these, eight had not been referred to a dietician. In one case, a patient received artificial nutrition before diagnosis of *C. difficile* that was stopped because they started eating. However after diagnosis of *C. difficile* the artificial nutrition was not restarted when the patient's nutrition subsequently declined.

Assessment and management of severe disease

In general, there was little evidence that, once *C. difficile* had been diagnosed, patients were routinely and actively monitored for signs of severe *C. difficile* infection, particularly colitis. For example, clinical indications that severe disease might have been developing, including frequency of diarrhoea and development of abdominal pain, tenderness and distension were infrequently recorded or commented upon. Pseudomembranous colitis, a very severe inflammation of the colon, is the most serious complication of *C. difficile* infection. It is usually suggested by the patient's clinical course alongside examination of the patient, laboratory, radiological and sigmoidoscopy findings. In at least 15 patients (30%) the reviewers were concerned that despite suggestive histories in the records, there was no evidence that this diagnosis had been considered. In addition, in at least two patients recorded as being for "full active treatment", pseudomembranous colitis was suspected but not fully investigated or managed.

To refine this assessment we identified patients at high risk of developing colitis. These were considered to be those patients who had at least two clinical and two laboratory signs of severe disease, or at least three laboratory signs of severe disease (21 patients). The records indicated that colitis had been considered in only seven of the 21 (33%) cases. Six of the 21 patients had an abdominal X-ray, four were referred to a gastroenterologist, and only one had had an investigative examination by scope to confirm suspected pseudomembranous colitis. Two patients with histories which strongly suggested pseudomembranous colitis were not examined for this at post-mortem.

A scoring tool known as Patient at Risk (PAR score) is sometimes used in the NHS to help the early recognition of patients at risk of becoming critically ill, by providing an objective score based on vital signs. PAR scoring was in place at the trust, but was almost non-existent in the notes we reviewed.

Other concerns

The reviewers also had concerns about the speed with which new pressure sores developed, or existing ones worsened, after loose stools first appeared. Although the most common sores were at the sacrum (base of the spine), there were several heel sores, which could not be attributed to loose stools.

Resuscitation status

The medical records show that patients' resuscitation status was documented in 47 out of 50 (94%) of cases. The trust's form for recording resuscitation status classified resuscitation decisions into one of five categories (see box). It was used in 30 out of 47 (64%) of these cases. There was evidence of a discussion on resuscitation status with a patient or relative in 37 out of 50 (74%) of cases. In at least seven cases, the reviewers were concerned that patients had not been managed in accordance with their resuscitation status. This was because these patients were recorded as being for "full active treatment" (although not cardio pulmonary resuscitation) but did not receive fairly routine interventions such as nasogastric feeding or an abdominal X-ray, where it appeared that these were indicated.

Cardio pulmonary resuscitation status at Maidstone and Tunbridge Wells NHS Trust

Instructions: Resuscitation status should be documented using the numbered categories below. It should be documented on admission, confirmed by the consultant when they see the patient and reviewed not less than once per week. If the status is 4 or 5, there should be documentation in the medical notes to support this decision.

Status 1: For full active treatment and attempted cardio pulmonary resuscitation in the event of cardiac arrest

Status 2: For full active treatment but, because severity of medication condition makes likelihood of long-term success extremely remote, and that the risks: benefits: outcome ratio is adverse, Not For Attempted Cardio Pulmonary Resuscitation in the event of cardiac arrest (NFACPR)

Status 3: Known to be terminally ill and being treated palliatively, therefore Not For Attempted Cardio Pulmonary Resuscitation in the event of cardiac arrest. For full active palliative treatment (NFACPR)

Status 4: In accordance with the patient's own clearly expressed wish, Not For Attempted Cardio Pulmonary Resuscitation in the event of cardiac arrest (NFACPR)

Status 5: Because the likely quality of life after successful resuscitation would not, on the evidence available, be acceptable to the patient, Not For Attempted Cardio Pulmonary Resuscitation in the event of cardiac arrest (NFACPR)

Cause of death

Table 2: Healthcare Commission's assessment of the contribution by *C. difficile* infection to the death of patients in the sample of 50 cases between April 2004 and June 2006		
	Contributed to death (including main cause of death)	**Main cause of death only**
Definitely	21 cases (42%)	3 cases (6%)
Probably	18 (36%)	10 (20%)
Possibly	9 (18%)	
Unlikely	2 (4%)	
No	0	

Table 2 above shows that in 39 (78%) of the patients in the sample, the reviewers considered that *C. difficile* had definitely or probably contributed to their deaths. In 13 (26%) it was definitely or probably the main cause of death.

If the 50 cases reviewed were representative of the 345 people who died at the trust following an admission during which *C. difficile* had been diagnosed, based on the proportion identified in our review, we estimate that of the 345 patients *C. difficile* was probably or definitely the main cause of death in approximately 90 patients (26% of 345) between April 2004 and September 2006. We estimate that 60 of the 90 patients would have died during the outbreaks between October 2005 and September 2006. Of the 90, we estimate it was definitely the cause in 21 (6%). We note that the figure of 90 is close to the estimate of 81 deaths which would be produced by applying a mortality rate of 6.9% cited in the New England Journal of Medicine in 2005.

It can also be estimated that *C. difficile* definitely contributed to the deaths of approximately 145 out of 345 people, and probably or definitely to approximately 270 out of 345 people in the same period.

For the period between April 2004 and March 2006, for which the trust told us there were no deaths caused by *C. difficile*, we estimate that approximately 65 patients died where *C. difficile* was definitely or probably the main cause of death. We estimate a further 25 patients died between April 2006 and September 2006.

The extrapolation of cases depends on the sample cases being representative of the total population of cases from which they were selected. Clearly, it is unlikely that the sample was in every way perfectly representative of the total population of people who had died in hospital following an admission during which *C. difficile* had been diagnosed between April 2004 and September 2006. We know, for instance, that sample cases were on average three years older than the total population; therefore it is possible that they were more likely to die from a *C. difficile* infection. However, although the difference in average ages (86 compared to 83) was statistically significant, its clinical significance is less clear, and if we exclude all people in the sample over the age of 90 years from the analysis, the proportion whose death was assessed as being definitely or probably

Table 3: Estimated number of deaths were *C. difficile* was definitely or probably the main cause			
April 2004 - September 2005	**October 2005 - March 2006**	**April 2006 - September 2006**	**TOTAL**
30	35	25	90

primarily due to *C. difficile* is 22% (9/41); this equates to a total estimated number of deaths of approximately 75.

In terms of other factors such as length of stay, severity of illness and the frequency with which patients had an International Classification of Disease (ICD) code for *C. difficile*, the two groups were similar. Furthermore, since we excluded many patients with obviously terminal illnesses, who would have been more likely to succumb to *C. difficile* infection and less likely to receive full care than those who did not, the sample may have underestimated rather than overestimated mortality. Overall, therefore, the Healthcare Commission is satisfied that the sample was sufficiently similar to the total population to allow inferences to be made about the approximate number of deaths from *C. difficile* at the trust during the period of study. The deaths do not include patients who were diagnosed with *C. difficile* at the trust and died shortly after discharge.

The 50 cases reviewed represented 18% of the 275 cases from which they were selected, and 43% of the 116 cases remaining, once the 159 cases with defined severe illnesses were excluded. It is possible that the relatively small sample size might have affected our findings; we have calculated that there is a 95% chance that the correct figure for the total number of deaths definitely or probably due to *C. difficile* is between 47 and 127 people.

The Healthcare Commission acknowledges that these deaths occurred in a relatively elderly and sick population, whose risk of dying was already high compared to that in a younger and healthier group of people. In other words, many of the 90 people may well have died of other causes if they had not acquired *C. difficile* infection. Some would have died of *C. difficile* even if they had recieved the best care. The Healthcare Commission is unable to say exactly how many of the deaths attributable to *C. difficile* infection were 'excess' deaths, that is, people who would not have died had they not developed *C. difficile*. The trust's own data showed that from 2003/2004 to 2006/2007, between 32.4% and 46.3% of all patients over 75 died if they had *C. difficile*, compared to between 6.1 and 6.7% of patients in the same age group if they did not. It is possible that the patients without *C. difficile* were on average healthier and less likely to die. There is however substantial evidence from published studies that people infected with *C. difficile* are considerably more likely to die than patients of similar age and disease profile who do not have *C. difficile*. For instance, in a Canadian study 23.0% of patients with *C. difficile* died within 30 days, compared with only 7.0% of people matched in terms of age and disease severity but who did not have *C. difficile*.

Death certificates

We found death certificates in the records of 37 of the 50 patients (74%). Seventeen (45%) of these certificates mentioned *C. difficile*. Nine (53%) were recorded in category II, one (6%) in category Ia, six (35%) in category Ib and one (6%) in category Ic (see box below).

Medical certificate of cause of death

The death certificate should be completed by a registered medical practitioner who has been in attendance during the deceased's last illness.

The cause of death is broken down into the following sections:

Ia Disease or condition directly leading to death*

Ib Other disease or condition, if any, leading to Ia

Ic Other disease or condition, if any, leading to Ib

II Other significant conditions contributing to the death but not related to the disease or condition causing it.

* This does not mean the mode of dying, such as heart failure or asphyxia etc. It means the disease, injury or complication which caused death.

Every patient in the sample where *C. difficile* was mentioned on the death certificate had significant infection with *C. difficile* that probably or definitely contributed to their death, that is, there was no evidence of false positive death certification of *C. difficile*.

C. difficile was not mentioned on the death certificate of 13 (65%) patients in the sample who had a significant infection with *C. difficile* that probably or definitely contributed to their death. In four (20%) of cases where *C. difficile* was not mentioned, there was a high likelihood that *C. difficile* was the main cause of death. This means there was considerable evidence of false negative death certification of *C. difficile*. Relying on death certificates might have missed up to 65% of cases where *C. difficile* contributed to death.

During the outbreak the trust issued instructions that any doctor wishing to include *C. difficile* on the death certificate should first consult with a consultant microbiologist. The trust could not explain who issued that instruction.

Findings of fact on the Healthcare Commission's review of case notes

- In 10 out of a sample of 50 patients (20%) the reviewers had no concerns about the management of *C. difficile*. The degree of concern in the remaining 80% varied.
- The reviewers considered that *C. difficile* had definitely or probably contributed to death in 39 (78%) cases in the sample. This percentage included the 13 (26%) cases where the reviewers considered that *C. difficile* had been definitely or probably the main cause of death.
- Estimating the number of deaths from the sample of 50 needs caution, but it is likely that *C. difficile* was definitely or probably the main cause of death in approximately 90 patients, and probably or definitely contributed to the deaths of approximately 270 patients between April 2004 and September 2006. 60 of the 90 deaths occured during the outbreaks between October 2005 and September 2006.
- It is not correct to conclude that the deaths would not have occured if the patients had not developed *C. difficile* or that they had died because of the care they recieved.
- In 34% of cases reviewed, the medical records did not indicate there had been a regular review of *C. difficile* after the infection was diagnosed.
- In 21 (42%) patients in the sample there was use of antibiotics known to predispose to *C. difficile.*
- Most patients were started on antibiotic treatment within two days of a result from the laboratory which confirmed *C. difficile*. In 10 cases (20%) there was a significant delay in starting treatment.
- Less than 15% of the patients reviewed were prescribed vancomycin at any stage.
- In some cases doses of antibiotics were missed or not given without a clear clinical reason.
- In 18 out of 50 patients (36%), there was evidence of poor fluid management. Fluid balance charts were rarely complete.
- In 17 out of 50 patients (34%), the nutritional needs of patients had not been assessed or managed.
- In at least 15 patients (30%) who had signs indicating possible pseudomembranous colitis, there was no evidence that this diagnosis had been investigated.
- Stool charts were used in less than 15% of patients. When they were, there was no standard description of stool such as could be found on the Bristol Stool Chart.
- Patient at Risk (PAR) scoring was almost non-existent.
- There was no evidence of false positive death certification of *C. difficile*. However, in the sample there was evidence of false negative death certification of *C. difficile*. In four out of 20 cases (20%) where *C. difficile*

was not mentioned there was a high likelihood that *C. difficile* was the main cause of death.

Views of patients and families on the quality of care

Sources of evidence

- Interviews and written and oral testimony received from 26 patients and families
- Healthcare Commission national surveys of hospital inpatients
- Trust board minutes, leaflet on *C. difficile*

In the Healthcare Commission's surveys of patients in hospital in 2005 and 2006, the trust was not in the best 20% of trusts for any category and in 2006 was in the worst 20% for overall standards of care. It performed in the worst 20% for 22 out of 65 questions in 2005, and for 31 out of 68 questions in 2006. These included being treated with dignity and respect, and sharing a room or bay with patients of the opposite sex.

The 26 patients and families who contacted us reported some of the same concerns as the reviewers about the care of patients infected with *C. difficile*, and these are described here.

The comments we received from families and patients were mainly about nursing care and these are outlined below. However a small number also raised concerns about the difficulty they experienced in seeing a consultant and were worried that senior medical staff did not see and review their relatives often enough. Many did not feel that *C. difficile* had been adequately explained to them and thought the condition was not taken seriously enough.

The overwhelming majority of relatives and patients who contacted the Healthcare Commission were not happy with the nursing care received at the trust. Words used by a few included "despicable," "sickening," "appalling," "chaotic." Some were particularly distressed that patients had been told to "go in the bed" and were then left in their excrement for long periods.

Some of the concerns relating to nursing care included allegations that staff sometimes failed to:

- respond promptly to call bells, to assist patients to go to the toilet or use a commode, to help with patient hygiene
- respond appropriately, as when instructing patients to go in the bed
- respect the privacy and dignity of patients
- give medication promptly and appropriately, and ensure it was taken
- help with feeding and drinking
- complete charts accurately
- take proper precautions to prevent spread of infection
- pay attention to skin care, thus leading to bed sores.

Many attributed much of the poor care to the shortage of nurses and talked of seeing exhausted nurses in despair, with their heads in their hands. However others talked about poor attitude of some staff, including agency nurses. 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. One family were very concerned that after the sister on the ward had reprimanded a nurse for a further error in giving medication to their relative, they were seen "laughing and joking" together five minutes later. This gave the impression that the matter had not been taken seriously.

Some families thought that it was only after speaking to a consultant that nursing care improved, sometimes temporarily.

Although the trust board was informed that the hospital site matrons and infection control nurses were available to meet patients and

their relatives, this was not how most relatives who spoke to us recollected their experience.

Many families and patients felt that they had received very little information about *C. difficile*. They found the leaflet they were given was of poor quality and did not indicate the seriousness of the infection. A paper to the private part of the trust's board in July 2006 acknowledged that the information provided did not describe the seriousness of the condition and was not always available on all the wards. We noted that the leaflet, dated April 2006, covered many basic aspects of infection with *C. difficile*. However it:

- gave no information on the risks posed by *C. difficile*, i.e., that it can cause colitis or is potentially fatal
- did not state that staff should change gloves and wash hands between patients, or that visitors needed to wash their hands on entry to the wards
- had no information about how to clean or keep separate patients' soiled clothing, although this was often sent home with relatives
- said nothing about nutritional and fluid requirements.

Some patients and families told us they thought that the trust was unwilling to acknowledge that patients had the infection, particularly in the early months of 2006. A paper that went to the trust's board in September 2006 noted poor communication with patients and relatives.

Some families were concerned that signs and notices relating to infection and isolation were inconsistent or missing. At the meeting of the trust's board in July 2006 one family said they were not told that they should be washing their hands with soap and water, until their relative died in May 2006. Some relatives of patients who had died with *C. difficile* infection shortly after leaving hospital were upset that these deaths were not counted in the published statistics and that they were not offered support.

One family told us that when they asked for policies on infection control during the summer of 2006, there was a delay. They thought that the policies that then appeared looked unprofessional.

Findings of fact on the views of patients and families

- Patients and families who contacted the Healthcare Commission were very dissatisfied with standards of general nursing care. Much of the poor care was attributed to shortage of nurses, but some to the poor attitude of some nurses.
- Many patients and families who contacted the Healthcare Commission were dissatisfied with the information they were given about *C. difficile*. The risks of becoming seriously ill or dying were not explained in the leaflet.
- In the national survey of hospital patients in 2006, the trust was rated in the worst 20% of trusts for the overall standard of care.

Factors that contributed to the outbreaks through affecting infection control at ward/operational level

This chapter considers the factors that are considered to be important in controlling infection in general and infection with *C. difficile* in particular. These are: the establishment of an outbreak committee, the use of antibiotics, the environment, cleanliness and hygiene, the effectiveness of the infection control team, policies and procedures, training of staff, practice in infection control and isolation, numbers of staff on the wards, and bed capacity and patient moves. Finally we looked at the role of the director of infection prevention and control.

Outbreak review committee

After the outbreak was declared in April 2006 an outbreak review committee was established, which met on a weekly basis throughout April and May. It then met on a less frequent basis until December 2006 when it was agreed that the serious untoward incident relating to the outbreak was over. Key members of the trust and the Kent Health Protection Unit attended the meetings. In addition the trust established daily meetings on *C. difficile* throughout April and part of May to discuss operational matters related to the outbreak.

Finding of fact

- An outbreak committee was established when the outbreak was declared in April 2006. It had appropriate membership and met regularly.

Use of antibiotics

Broad-spectrum antibiotics are known to increase the risk of patients developing *C. difficile*, since these antibiotics remove normal micro-organisms, allowing *C. difficile* to thrive. Destruction of the normal bacteria interferes with one of the body's important defence mechanisms. There has been national guidance advising trusts to ensure they have appropriate policies for antibiotic prescribing in place. Antibiotics should only be used if clinically justified, and should be the narrowest spectrum possible for the shortest possible period.

Sources of evidence

- Antibiotic prescribing policies
- Minutes of internal committees including the infection control committee, outbreak review meetings and the drug and therapeutic committee
- Letter to all trusts from the CMO
- Copies of correspondence and interviews with HPU
- Interviews with infection control team, consultants, past and present staff, and the director of infection prevention and control (DIPC)
- Review of case notes by the Healthcare Commission

The antibiotic policy in place prior to the outbreak was a reasonably standard one and comparable to those in other similar hospitals. In common with many other trusts it did not restrict the use of broad-spectrum antibiotics.

In the response to the joint Health Protection Agency/Healthcare Commission survey on *C. difficile* in November 2005, the trust acknowledged that it did not restrict the use of broad-spectrum antibiotics. This was in common with 38% of other trusts.

There was no evidence that the trust responded in a timely way to the letter from the Chief Medical Officer and Chief Nursing Officer in December 2005, reminding trusts of existing guidance and the need to review their antibiotic policies. This letter advised that policies should minimise the use of broad-spectrum antibiotics. Nor had the trust responded to the recommendations from the Healthcare Commission and the Health Protection Agency at the same time, which included similar advice. Although these recommendations were noted at the infection control committee, action was not taken until the second outbreak, as noted below.

The case note review undertaken by the Healthcare Commission and described in the previous chapter found that 42% of patients had been prescribed antibiotics that predispose to the development of *C. difficile*. In some cases this had been followed shortly afterwards by infection with *C. difficile*.

An audit by the trust of all patients at Kent and Sussex Hospital infected with *C. difficile* from January to April 2006 showed variable compliance with the existing antibiotic policy.

The health protection unit (HPU) considered that it was crucial to change the antibiotic policy once the outbreak of *C. difficile* had been identified. There was some tension at the first outbreak review meeting on 13 April 2006 because the trust's microbiologist present was concerned that attention should be given to cleanliness and hygiene rather than focusing on antibiotics. Largely at the insistence of the HPU it was agreed at the meeting that a senior physician would review the antibiotic guidance. A letter was sent to trust staff on 17 April advising of some minor changes to the guidance, but this had little effect on the prescribing on the wards. The ward pharmacists were unaware of the proposed change and had not been involved in its development. There was also no process to monitor compliance with the guidance.

The HPU was concerned at the lack of progress and advised that a stricter antibiotic policy must be actively enforced at the trust.

The HPU wrote to the trust on 8 June expressing concerns. On 20 June the medical director and the infection control doctor wrote to medical staff at the trust and all the banned antibiotics were removed from wards. If consultants wanted to prescribe these antibiotics they were required to obtain the permission of a microbiologist.

A new antibiotic policy, for more general use, was approved in December 2006 for implementation in February 2007. Until this time the emergency antibiotic guidelines remained in place.

During our visits in late 2006 and early 2007 junior doctors were well informed about the use of appropriate antibiotics to minimise the risk of *C. difficile*. However, those who had been at the trust for some time and doctors who had worked previously at the trust confirmed this had not been the case prior to the outbreaks.

Findings of fact in respect of antibiotics

- The original antibiotic policy was similar to that in many other trusts and did not restrict the use of broad-spectrum antibiotics.
- The trust did not review its antibiotic policy following the letter from the Chief Medical Officer in December 2005. The antibiotic policy was reviewed following the start of the outbreak but the 'emergency' guidelines were not implemented effectively until 20 June 2006, and the revised policy was finally approved in December 2006.
- The health protection unit (HPU) had to insist on the review and effective implementation of the antibiotic policy.
- As found in our review of case notes, there was evidence of inappropriate prescribing in 42% of the cases we considered.

Factors that affected infection control and the outbreaks

The environment

In this section we look at those environmental factors that the trust could not change, and those that they could. We have included equipment as part of the environment. From the perspective of infection control, patients with infections should ideally be cared for in single rooms in modern, easy to clean environments.

Sources of evidence

- Audits carried out by the trust
- Observations carried out by the investigation team
- Interviews with staff past and present
- Interviews with patients and relatives, and the Patient & Public Involvement Forum
- Guidance from NHS Estates – *Infection control in the built environment – design and planning,* 2002
- 2004 - 2006 PEAT reports
- HPU reports and audits
- Patient and Public Involvement Forum reports
- CHI clinical governance review 2002
- Estate strategy, trust statements

This section relates to the hospitals before and during the time of the outbreaks and when we visited between October 2006 and April 2007.

Maidstone Hospital was opened in 1983. There was a history of underinvestment in the fabric of the buildings. In 2006 the backlog of maintenance was estimated to be nearly £3 million for Maidstone Hospital alone, and £52 million for the trust.

Kent and Sussex Hospital is made up of buildings built at different times. Much of the accommodation was built early in the twentieth century and many of the medical wards were Nightingale wards (large open plan wards offering dormitory style accommodation with most beds either side of a central area.) Pembury Hospital was partly built in the nineteenth century, originally as a workhouse.

Just over 10% of the total beds in the trust are in single rooms.

The national patient environment action team (PEAT) rates the environment in trusts on a five-point scale from unacceptable to excellent. PEAT ratings are based on self assessments and trusts are notified in advance of forthcoming visits. The national patient environment action team rated the environment as acceptable between 2004 and 2006. This is the midpoint of the scale. However a number of areas at Maidstone Hospital were described in the 2005 report as being untidy and cluttered.

At the time of our visits the décor at Maidstone Hospital was poor and the general quality of furnishings and fittings appeared worn and tired. Many wards at Kent and Sussex Hospital appeared to be towards the end of their functional life. The Nightingale wards did not have sufficient space in the 'dirty utility' rooms (sluices). A sluice is used for the disposal of potentially contaminated waste such as the contents of bedpans.

We observed 29 wards during our visits to the trust. Twenty wards at the trust were observed as having basins that were hard to reach or obstructed, either on the wards or in the utility room.

There were mixed male and female patients on 15 of the wards we visited and three had unisex toilet facilities. Even when patients of the same sex could have been grouped together in a bay, this often did not happen. It was particularly unfortunate for patients with *C. difficile* infection to be with patients of the opposite sex, since they often had diarrhoea many times a day.

The report by the Commission for Health Improvement in 2002 noted the need to

eliminate mixed sex wards as an "area for action." The chief executive reported in April 2006 that the trust would be unable to provide complete single sex facilities until at least 2010, when the new hospital was planned to open.

The buildings at Kent and Sussex Hospital in particular did not lend themselves to the efficient isolation of patients. There were few side rooms because of the age of the buildings, and the existing side rooms had not been designed for the control of infection. Only 16 had en suite facilities and nine of these were for private patients. As well as the scarcity of side rooms, there were further problems in controlling infection because of the closeness of the beds, poor storage facilities and lack of hand washing facilities.

The report by NHS Estates, *Infection control in the built environment - design and planning*, published in 2002, recommended that there should be one basin for every six beds, but one for every four beds in elderly care wards. At Maidstone Hospital there was one basin for six beds on most wards. Most wards at the Kent and Sussex Hospital had two basins for 24 beds, that is, one basin for 12 patients.

Not only were there were very few hand basins on many of the wards, but some of these were difficult to use because they were next to beds. In 2004, the existing basins were replaced on the Nightingale wards at Kent and Sussex by mistake. The intention had been to add extra ones. This therefore led to no overall improvement in the number of hand basins. All the water and drainage was at one end of the wards, which made it difficult to install extra basins.

The nature of the Nightingale wards made it difficult to nurse patients with infections together as a cohort, separate from other patients, because of the lack of areas physically separated by partitions.

The NHS Estates report in 2002 recommended that the centres of beds should be at least 3.6 metres apart, to ensure a reasonable space between beds. We found many instances where this was not being achieved. At Kent and Sussex Hospital the average space between the centres of beds was 2.3 metres, with some as narrow as 2 metres (photo 1). The trust told us that if the NHS Estates standard was achieved at Kent and Sussex Hospital, wards would have 13 instead of 23 beds. Beds in the semicircular areas at the end of the Nightingale wards (at Kent and Sussex Hospital) were particularly close together. The heads of the beds here were against the outside semicircular wall so the distance between them varied and we observed the distance to be as little as 30cm at some points.

Photo 1: Narrow spaces between beds on ward 8, Kent and Sussex Hospital (6 February 2007)

Staff, including the director of infection prevention and control, commented that the environment at Kent and Sussex Hospital made controlling *C. difficile* infection more difficult than in a modern purpose built facility.

Storage and equipment

We noted that 17 of the 29 wards we visited were cluttered and some appeared disorganised. There was inadequate storage on most wards and not enough space to keep the wards tidy. The health protection unit (HPU) and the Patient and Public Involvement Forum had consistently raised concerns about the lack of storage and consequent clutter in recent years.

During visits in 2004 and 2006, the HPU identified damaged equipment. After 2004 the Patient and Public Involvement Forum found improvements in many areas, but continued to find broken and worn equipment, furniture and fittings including dishwashers, showers, chair covers and curtains.

We observed eight bedpan macerators (machines for the destruction of disposable bedpans) to be in a poor condition on eight different wards. They were dirty, rusty and leaking. These posed a potential risk as leaks could soil the environment, with possible survival of *C. difficile* spores. The trust had a programme to replace macerators.

On an unannounced visit in April 2007 we found bedpan washers at the Kent and Sussex Hospital that were not working, resulting in bedpans that had been washed still being visibly contaminated with faeces. We raised this concern at the time and wrote to the trust. The trust explained there was a programme to replace bedpan washers with macerators. We advised the trust that until the programme was complete, wards where washers were not working properly should use disposable bedpans and dispose of them as clinical waste.

Many staff including matrons, senior medical staff, nurses and therapists told us about shortages of equipment including commodes and supplies including hand wipes, linen, giving sets and bandages. We observed that most alcohol dispensers for hand cleaning purposes contained gel. We occasionally saw bedding and equipment left lying on the floor, and a lack of waste disposal bags, bedding and pillows.

The trust undertook an audit of commodes in September 2006. This found that 48% needed replacing, including all the commodes on ward three at Kent and Sussex Hospital. The trust told us that £25,000 had been allocated to replace the commodes. When we visited in early 2007 the condemned commodes had not been replaced and were still being used.

Bins used for the disposal of sharp instruments such as needles, were observed to be overflowing on four wards. In a further three wards, the bins were on the floor (photo 2). Over the course of our observations at the trust we noted 13 fire doors on 12 wards that were partially obstructed, albeit by moveable items such as stacked chairs or lockers.

Photo 2: Overflowing bin used for the disposal of sharp instruments located on floor of Cornwallis ward, Maidstone Hospital (14 November 2006)

We had specific concerns about the environment on ward 14a at the Kent and Sussex Hospital, which we describe later in the report, and about the balcony bays on many wards at Kent and Sussex. We wrote to the trust about the latter since we considered the beds were too close together and posed a risk to patients through the potential transmission of infection.

Key findings on the environment, storage and equipment

- There was a lack of side rooms, particularly at the Kent and Sussex Hospital, and few had en suite facilities. The nature of the Kent and Sussex site made the control of infection particularly difficult.
- Many wards did not have sufficient sluice space or storage.
- The beds in several areas were closer together than recommended. Some were as little as 30cm apart at some points.
- Maidstone Hospital had sufficient hand basins for general wards (one for six beds). There was only one hand basin for 12 beds at Kent and Sussex. Some of these were hard to reach because of their position on the ward.
- Some bedpan macerators and bedpan washers were in a poor condition, posing a risk of contamination.
- Although the trust said it had allocated money to replace them, commodes that had been condemned in September 2006 were still being used four months later.
- The hospital had many mixed sex bays and wards but it did not appear significant efforts to reduce this problem had been made.

Factors that affected infection control and the outbreaks

Cleanliness and hygiene

Cleanliness and high standards of hygiene are essential to controlling infections. They are particularly important for the control of *C. difficile*, because spores persist in the environment if they are not removed by regular and thorough cleaning, using the correct cleaning agents.

Sources of evidence

- Healthcare Commission national inpatient surveys
- Healthcare Commission audit of cleanliness
- Quality monitoring reports
- Trust's audit of commodes September 2006
- Observations carried out by the investigation team, and one morning 'shadowing' a cleaner
- Interviews with staff past and present, and the infection control team
- The annual reports for infection control
- PPIF and HPU reports
- Record of BBC undercover reporter
- Clinical governance report 2002

The report on clinical governance published by the Commission for Health Improvement in December 2002 noted a lack of thoroughness in cleaning and hygiene, with inappropriate storage leading to untidiness, and also impeding access to areas used by patients.

In May 2004 an undercover reporter for the BBC, posing as a cleaner, conducted an investigation into cleaning standards at the Kent and Sussex Hospital. This uncovered poor standards of cleanliness and of dealing with contaminated linen, failings in the storage and disposal of clinical waste, deficiencies in supervision and poor cleaning techniques, such as not washing patients' water jugs. The trust took a paper to the board recommending that cleaning services be reorganised, that the responsibilities of ward sisters and site matrons be clarified, and that audits should be undertaken. Four members of staff were suspended.

In the national inpatient and outpatient surveys undertaken by the Healthcare Commission the trust's rooms and bathrooms were considered above average when rated as "clean", but below average when rated as "very clean." In 2006 the trust was rated in the

worst 20% of trusts on the cleanliness of wards, and of toilet and washing facilities.

The Patient and Public Involvement Forum carried out an inspection in 2004 and came up with a number of actions for the trust. These included expanding the number of cleaning staff and the hours worked, improved supervision of clinical and organisational aspects of cleaning, comprehensive cleaning schedules, reviewing ward storage and informing patients and visitors of infection control policy. None of these had been fully implemented by their inspection the following year.

The audit of cleanliness conducted by the Healthcare Commission in July 2005 awarded Kent and Sussex 94% (band 1) and Maidstone 87% (band 2). This audit involved a snapshot of hospital cleanliness, where band 1 indicated good performance and band 4 meant serious failings in cleanliness.

The senior infection control nurse who left in October 2005 told us that although they could use one cleaning agent (Actichlor) whenever there was an infection, they could only use the recommended cleaning agent (Actichlor+) during outbreaks, not as a routine and preventative measure. The letter from the Chief Medical Officer and Chief Nursing Officer in December 2005 advised trusts to ensure that they had cleaning protocols with increased environmental cleaning. The letter recommended the use of chlorine-based disinfectants in areas where there were patients infected with *C. difficile*. There was no evidence that the trust took action in response to this.

In January 2006, the trust's quality monitoring report noted that cleaning at Maidstone Hospital took place only between 7.30am and midday, with emergency cleaning in the afternoon. This was recognised as insufficient time to clean a whole ward. In the rest of the trust cleaning took place throughout the day. The trust told us that domestic staff at Maidstone would remove rubbish, check toilets and do 'terminal cleans' between 1pm and 3.45pm. (Terminal cleaning is a particularly thorough type of cleaning which happens after a patient vacates a bed.) There was no arrangement to have cleaners in any of the hospitals at night, so any cleaning had to be undertaken by nurses. Because of the high turnover of patients generally, and the closeness of beds on some wards, thorough cleaning of beds and the spaces around the beds was difficult.

After the start of the outbreak in April 2006 the trust arranged for cleaners to work at night at Maidstone Hospital. After 10pm a team of two staff, employed by contractors, did the cleaning. Night cleaning was extended to Kent and Sussex Hospital in September 2006. At this time staff working for the trust did most of the cleaning.

Between October 2005 and August 2006, internal monitoring of cleanliness and environmental standards at Kent and Sussex Hospital identified 13 areas that were below an acceptable standard. The reports for Maidstone Hospital were more general and lacked detail on areas of concern.

The overall impression from staff we interviewed was that cleaning had improved since the outbreak. The standard of cleaning was reasonable in many areas, particularly where there were motivated and conscientious cleaners. Nurses said that some cleaners had too much to do.

We observed that the hospitals were generally clean, but also showed some areas of poor practice, such as the failure to dust at high levels, and dirty showers and bathrooms on some wards (photo 3).

We learnt that there were sometimes not enough different heads for mops on the wards. The previous senior infection control nurse told us this was because of financial constraints. We noted that the minutes of the infection control committee in September 2006 said that there was no money forthcoming for mop heads.

Patients and relatives who contacted us described their observations in 2005 and the first eight months of 2006. They reported dirty floors, toilet areas and commodes. They gave

Photo 3: Dirty shower on ward 14a, Kent and Sussex Hospital (13 December 2006)

Photo 4: Dirty commode in Accident and Emergency, Maidstone Hospital (15 November 2006)

examples of areas not cleaned under beds, buckets full of filthy water, blood stains on trolleys and the sides of bed, bins not emptied. Equipment such as zimmer frames was shared between patients without adequate cleaning.

In 2004 audits carried out by the infection control team found 40% of areas to be partially compliant in terms of the undersides of commodes being clean. The trust's audit of commodes on 16 wards in September 2006 found that 98% were soiled. In December 2006 and February 2007 we observed dirty commodes on six wards at Kent and Sussex Hospital and on two wards at Maidstone (photo 4). Two months later we observed that there were still some dirty commodes being used.

Alcohol is not effective at killing *C. difficile* spores. However, the trust's audit of commodes found that half of the staff were using alcohol wipes to clean the commodes, as opposed to soap and water. Similarly, the majority of staff, when asked, told us that they cleaned commodes with alcohol wipes. We witnessed staff cleaning commodes with alcohol wipes.

We noted at least seven wards where the clean utility or treatment room was used as a kitchen, to prepare hot foods or drinks (photo 5). In one there was a microwave, with food and drink on the preparation surfaces. There were cups in the sink. Some refrigerators meant for clinical purposes were used to store items of food. Food, outdoor clothing and chairs were stored in another clean utility room, with an opened packet of biscuits on a preparation surface and sterile fluids stored on the floor. Another treatment room was untidy and had fluids stored on the floor; in another an overfilled bin for the disposal of sharp instruments was on the floor.

Photo 5: Cups observed in sink of clean utility room on Culpepper ward, Maidstone Hospital (3 January 2007)

The minutes of the clinical governance committee in July 2005 described the laundry as "inefficient" and that it created "high risks of cross infection." The problems identified included old and unreliable laundry machinery and a risk of infection attributed to the dirty environment and staff not wearing protective clothing. The trust took action to resolve these, providing colour coded uniforms, partitioning of areas, refurbishment of equipment and the purchase of new machinery.

Staff told us about a number of problems including linen being kept on open shelves and the slow turnaround of contaminated laundry. We observed red linen bags filled with soiled laundry being left on the floor and linen stored on open shelves. This latter practice is not uncommon in NHS trusts, but is not good practice (photo 6). Staff and patients told us some clinical waste bins were not emptied regularly enough.

Photo 6: Clean linen stored on open shelves on Mercer ward, Maidstone Hospital (15 November 2006)

Findings of fact on cleanliness and hygiene

- In January 2006 Maidstone Hospital was only cleaned between 7.30am and midday, although domestic staff removed rubbish and checked toilets after this time.
- The trust introduced cleaning at night in Maidstone Hospital in April 2006 and in Kent and Sussex Hospital in September 2006.
- General standards of cleaning were reasonable at the time of our visits, with some exceptions.
- Patients and relatives reported poor standards of cleaning before and during the outbreak.
- An audit by the trust in September 2006 found that 98% of commodes were soiled. During our visits in the spring of 2007 the cleaning of commodes was still unsatisfactory on several wards.
- Many clean utility or treatment rooms were used as kitchens, posing an infection hazard.
- The trust had taken action to resolve problems with the laundry.
- Linen was stored on open shelves on some wards.

Factors that affected infection control and the outbreaks

The functioning of the infection control team

It is important for infection control teams to have clear arrangements for accountability, effective leadership and support from the director of infection prevention and control (DIPC), and adequate resources to carry out their functions, including adequate information technology support for surveillance. The members of the team need to work together.

Sources of evidence

- Annual reports of infection control
- Minutes of meetings of internal trust committees including the infection control committee, infection control team, clinical practice committee and the trust's board

- Interviews with staff past and present, and the infection control team
- Audits
- Interviews with the HPU, patients and relatives
- Royal College of Pathologists' guidelines
- CNST report (clinical negligence scheme for trusts)
- Department of Health MRSA support team visit autumn 2006
- South East Coast SHA MRSA performance assessment August 2006
- Initial meeting with the trust at the start of the investigation

Accountability

The accountability arrangements for the infection control team were complex and not clearly understood within the trust. The professional accountability of the infection control nurses was to the director of nursing. The pathology manager held the budget for the nurses and would assist them with matters such as annual leave, but did not consider that he had responsibility for the management of infection control. The clinical director of the pathology directorate told us he had never been aware of having any responsibility for the infection control team. Because the budget for infection control was part of the pathology budget, infection control ultimately came under the responsibility of the director of operations. The former directors of operations told us that they were not aware of this responsibility. The DIPC met regularly with the nurses but did not consider he had a management responsibility for the team. The trust took steps to clarify the management accountability in September 2006.

There was an infection control committee that met every three months. After March 2004 the infection control committee reported to the clinical practice committee. The infection control doctor was not a member of the clinical practice committee. The director of infection prevention and control only attended three meetings of the clinical practice committee between 2004 and 2006. These arrangements are considered further later in the report.

Resources

There was one infection control team for the three hospitals of the trust. This consisted of the infection control nurses and microbiologists.

It was noted at the trust board in November 2003 that the infection control team was understaffed and under-resourced, although it was considered that the national requirements were being met.

The Royal College of Pathologists's recommendation is for approximately one whole time equivalent infection control doctor per 1,000 beds. The trust had 850 to 900 beds and two full time consultant medical staff in the microbiology department, one of whom was designated the infection control doctor. The consultants told us they did not have sessions specified for infection control. Their job plans, provided by the trust, designated some time each day for infection control results to be considered, alongside other tasks. The hours fell short of equating to one full time infection control doctor.

There are no national guidelines for levels of infection control nurses. The nursing team consisted of one senior infection control nurse and two other infection control nurses.

There was no infection control nurse covering the Kent and Sussex Hospital between January 2005 and May 2005. As a result the team fell behind on its audit work. In March 2005 the trust appointed a part-time surveillance nurse and additional secretarial support was provided. However to fund this, the senior infection control nurse had to reduce her hours to the equivalent of four days a week. The surveillance nurse concentrated on infections of surgical wounds and did little work on general infection control.

The senior infection control nurse went on sick leave in the summer of 2005. She returned for a week in September and retired in October. Her replacement was not in post until February 2006. No consideration was given at this time to providing locum cover during this period, although the team was over-stretched and inexperienced. During periods of annual leave between July 2005 and January 2006 there was just one infection control nurse in charge of infection control for the whole trust.

When the senior infection control nurse was not there, no one took responsibility for local surveillance. It was after she left that the cases began to rise and the first outbreak occurred, but was not detected. At this time, the team had no software to aid surveillance of infections. The system, such as it was, broke down completely. Since the microbiologists had to authorise the laboratory results confirming cases of infection, it would be reasonable to have expected them to notice the rising number of cases.

The senior infection control nurse who retired told us that she had monthly meetings with the DIPC. She did not have an appraisal from 2002 until she left in October 2005.

The infection control annual report for 2005/2006 acknowledged that reduced staffing levels meant that "much of the activity for the year for the Infection Control nursing team has been reactive in nature and, without a planned programme of work, the team have struggled to find direction."

Because of the pressures on their time, the nurses were limited in their ability to contribute to education and training, audits of practice and the environment, and the revision and development of policies.

The minutes of the infection control team meeting during the outbreak in July 2006 noted that there was no budget for the on-call work of the nurses. This meant they could not be guaranteed reimbursement for all the work they had done. It was recommended that they reduce their hours. The trust stated they did reimburse staff for this work and the senior infection control nurse confirmed this.

Audits

Audits were carried out by the trust in line with the standards of the Infection Control Nursing Association and using its audit tool. The infection control audits in 2003/2004 covered a range of topics, including commitment to infection control, waste disposal, linen handling and disposal, safe use and disposal of sharp implements, hand hygiene, decontamination, care of equipment and clinical practice. Approximately 33% of wards across Kent and Sussex and Maidstone Hospitals were targeted in these audits.

In 2004/2005 a greater proportion of wards was covered (78%), but only hand hygiene and the safe handling and disposal of sharp implements were considered. These latter audits found approximately 40% of areas to be only partially compliant or worse.

The most common areas where the wards did not comply included:

- patients being 'isolated' on the ward or in bays, indicated by a trolley at the end of their bed containing the requisite equipment
- appropriately placed clinical waste collection bins kept locked and inaccessible to unauthorised personnel
- bins for sharp instruments in appropriate locations - away from the public and small children
- clean undersides of commodes
- availability of alcohol gel and soap
- hand hygiene procedures carried out consistently, adequately and in all appropriate circumstances.

In 2005/2006 three audits were conducted using the audit tool, along with three less formal audits. The reduction in the number of audits was recognised by the trust as being due to time pressures on the infection control team as a result of being under-staffed.

We looked at audits of infection control in medical wards and found that several issues came up year after year, indicating that lessons were not learnt as a result of audits. Examples included that small bins for sharp implements were not generally available to take to the bedside, and chlorhexidine was not available at all requisite sinks. There was no overarching analysis done as a result of infection control audits.

Staff, particularly nurses, who we asked about audits indicated that any action arising from audits was generally considered to be the responsibility of the infection control team and there was a lack of ownership by wards. This was supported by the findings of the Department of Health's MRSA Improvement Programme visit in October 2006. Very few staff below the level of ward manager were aware of any feedback from audits. The South East Coast SHA's performance assessment of MRSA in August 2006 also concurred with this, finding that there was a need for clinical teams to include infection control as part of their clinical programme and to record any actions taken as the result of an audit.

Roles of the team and team work

One microbiologist was based at Kent and Sussex Hospital and the other was based at Preston Hall, where the Maidstone Hospital laboratories are located, two miles from the hospital. The microbiologist based at Kent and Sussex Hospital was officially the infection control doctor for the trust, but each microbiologist was responsible for the site where they worked.

Although the microbiologists were described as helpful by staff who had experience of working with, or contacting them, they were not seen as being natural leaders or champions for infection control. The microbiologists acknowledged and regretted that they failed to identify the outbreak in the autumn of 2005.

The microbiologists did not visit the wards regularly but were easily contactable by phone for advice. They visited the wards more often during the outbreak. Most doctors thought their advice was useful and the junior doctors said they were supportive.

On occasions the microbiologists gave conflicting or inconsistent advice. They had differences of opinion over whether to group patients with *C. difficile* infection together, and how long to leave beds empty after an infected patient had vacated the bed space. We noted that, since there is little evidence to support the practice of leaving beds empty after adequate cleaning, it is not included in national guidance. Many clinical staff and managers reported that their advice was not always consistent, and the inconsistency was noted at the executive team meeting in August 2006 and in a paper to the board in July 2006. Their differing views resulted in different practices at the two hospitals, sometimes causing problems for on-call staff covering the whole trust.

The infection control nurses visited the wards frequently and were seen as helpful. Staff told us that they responded well to concerns. It was acknowledged that they were a small team and very busy. They tended to act as the link between ward staff and microbiologists. However, it was generally acknowledged that the infection control nurses and the microbiologists had not always had close and supportive working relationships.

Directors of infection prevention and control (DIPCs) have overall responsibility for controlling infection in trusts, and report directly to the chief executive and to the board. At the trust, the director of nursing and patient services was the director of infection prevention and control. When asked, many members of staff including some senior clinicians and managers, and the non-executive directors that we asked, did not know the identity of the director of infection prevention and control. We consider the role of the director of infection prevention and control at the end of this chapter.

The infection control team met infrequently. The former senior infection control nurse said that the team met more regularly during 2004.

The trust however provided minutes for only two meetings held in 2004, three in 2005 and four in 2006. These meetings offered an opportunity for the infection control nurses and microbiologists to discuss operational matters. The director of infection prevention and control (DIPC) did not attend these meetings as he considered them to be about "team matters." We note that the second key responsibility of the director of infection prevention and control in *Winning Ways* is to be responsible for the infection control team.

The infection control committee met every three months. The membership included the director of infection prevention and control (DIPC) who usually attended. However, there was no representation from consultants at the meeting, other than microbiologists, and rarely did any senior nurses attend. At the time of the outbreaks, the committee was not working to an annual plan for infection control.

As we have noted before, after the outbreak was declared an outbreak review committee was established. It met for the first time on 13 April 2006 and continued to meet on a weekly basis throughout April and May, after which it met on a less frequent basis until December 2006 when it was agreed that the serious incident relating to the outbreak was over. Key members of the trust and the Kent HPU attended the meetings, with the intention of ensuring the trust was handling the outbreak correctly. In addition the trust established daily *C. difficile* meetings throughout April and part of May to discuss operational matters related to the outbreak.

There was an intention to have a 'link' nurse scheme for infection control at the trust. Link practitioners are found in many hospitals and are clinical staff, usually nurses, working within wards and departments who take on additional responsibilities. Responsibilities of link nurses for infection control can include training of other staff, surveillance, implementation of policies and auditing. It was anticipated that the link practitioners would share knowledge, experience and initiatives with other team members in their ward or department.

The workload of the infection control nurses made it difficult for them to support the scheme. There was also poor attendance by ward nurses at meetings about, and training on, the infection control link scheme, due to pressures on the wards. A small minority of wards did not have link nurses. Over a third of ward staff asked at interview were not aware whether they had an infection control link nurse. The annual programme for infection control in 2006/2007 included re-establishing the membership of the link nurse scheme.

Before 2006/2007 the annual report on infection control looked retrospectively at levels of infection and action taken during the previous year. In January 2006 the clinical negligence scheme for trusts (CNST) criticised the trust for not having a programme for infection control for the year ahead, and the trust acted to address this.

Findings of fact on the infection control team

- The accountability arrangements for the infection control team were not clear.
- The amount of time from microbiologists that was available for infection control was not in accordance with the recommendations of the Royal College of Pathologists.
- The microbiologists provided advice on the phone, but seldom visited the wards. Their clinical advice was generally appreciated. However, they sometimes gave conflicting advice on aspects of infection control. There was no computerised system for surveillance of infections. When the senior infection control nurse was absent, the microbiologists did not take responsibility for local surveillance of *C. difficile* and the outbreak in autumn 2005 was not identified.
- Due to ill health and then resignation, there was a period of over six months when the trust did not have a substantive senior infection control nurse. There was no extra support for the team at that time.

- The infection control nurses were seen as helpful, but very busy. The annual audit programme in 2005/2006 was not completed due to staffing shortages.
- There was little attendance of other clinical staff at the infection control committee or engagement in infection control.
- Results of audits were not fed back or acted on in an effective manner, and with the lack of ownership of infection control on the medical wards, the same concerns were raised over several years.
- The team of microbiologists and infection control nurses did not always work closely together.
- The link nurse scheme was not well established.
- In January 2006, CNST criticised the trust for lack of a forward programme for infection control.

Policies

It is important for trusts to have up-to-date policies and procedures for infection control that are easily available to staff. National guidance should inform these policies.

Sources of evidence

- Policies provided by the trust, and trust statements
- Annual reports on infection control
- CNST - the clinical negligence scheme for trusts
- Interviews with staff, patients and relatives
- Observations by the investigation team

Of the 31 policies in the trust's manual for infection control at the time the Healthcare Commission began its investigation, only one was not at least several months past its review date. The trust acknowledged that its policy for handling outbreaks at the time they declared an outbreak in April 2006 was 'not fit for purpose'. The former senior infection control nurse, who was responsible for policies, was off sick for some time before she left. The new senior infection control nurse concentrated her efforts on controlling the outbreak.

The manual included the policies for *C. difficile*, decontamination of equipment, hand hygiene and isolation nursing, all of which were due for review in November 2005. The trust did not have a policy for norovirus, for diarrhoea or for detailed arrangements for the management of beds for patients needing isolation.

In March 2005 a decision was made to remove all policies from the wards and to put them on the trust's intranet. Staff members had to attend training and were then given a password before they could gain access to the intranet. In January 2007, of the 4,768 permanent staff at the trust, approximately 3,000 (63%) had access to the intranet. Bank and agency staff did not have access.

When the Healthcare Commission inspected the trust's intranet in January 2007 there were no available policies for managing beds other than a discharge policy. There was no policy that dealt with the movement of infected patients. The policy for managing beds was only available in hard copy and it was unclear how staff would be able to obtain it. This policy did not cover the movement of patients with infections, though it stated that the bed managers should work with the infection control team. There was no standard procedure for cleaning beds after patients had left them, whether or not the patients were infected.

The intranet was easy to navigate and find policies, but it was not always up to date. Staff reported that this meant that they did not refer to policies very often. There were additional problems, such as ward 14a at the Kent and Sussex Hospital not having a computer. Otherwise, the dissemination of information about new policies relied on ward meetings, which were generally infrequent, or on the initiative of ward staff.

Cohort nursing and the trust's guidelines for the care of patients infected with *C. difficile*

A key principle of controlling the spread of harmful microorganisms is to isolate those with infections. This can be in single rooms, or in isolation wards dedicated to patients with a particular infection. Just over 10% of the beds in the trust were in single rooms. It can be difficult for trusts to establish isolation wards because of the consequent reduction in beds for general patients.

Cohort nursing is an alternative, although less desirable, way to reduce the risk of the spread of infection without having a dedicated isolation ward. The term is used to describe the nursing of a group - or 'cohort' - of patients. It applies when patients need to be physically separated from other patients within a hospital ward to prevent the spread of infection. A group of patients with the same infection is isolated in the same area. This might be a bay with four or six beds. Nursing practice is based on the principles of 'source isolation' or 'barrier nursing' and includes the wearing of personal protective equipment (gloves, aprons, etc.) and using dedicated equipment and staff where possible. Effective cohort nursing requires nurses to be dedicated to the cohorted patients. This is particularly difficult to achieve in wards with low numbers of nurses.

The trust provided us with their guidelines for the care of patients infected with *C. difficile*, dated November 2004. These were written by the infection control team and stated "If there is more than one patient and adequate side-rooms are not available, do not move affected patients unless absolutely necessary for other reasons. It is not an advantage to cohort nurse positive patients as there is a very high chance of re-infection from each other as they recover. It also increases the environmental spore load, thereby making it more of a risk for other patients."

In other words, the guidelines did not advocate cohort nursing. However, in their interviews with us, staff described cohorting patients as a large part of the way they had managed the outbreak.

The director of nursing and patient services was unaware that the *C. difficile* guidelines advised against cohort nursing. This was despite the fact that he was on the committee that approved the policy. The chief executive was equally unaware of this, and categorically stated that the policy was clear that patients should be cohorted. In May 2007 the chief executive provided us with a protocol for the management of beds where patients were identified with known or suspected infective diarrhoea. The trust told us this policy was issued on 4 July 2006 and revised on 12 July. It was not on the intranet when we checked in January 2007 and staff we interviewed were unaware of it. The agreement and introduction of the protocol was not recorded in the minutes of the relevant committees.

The guidelines for the care of patients with *C. difficile*, dated November 2004, lacked detail on the clinical management of patients infected with *C. difficile*. There was no requirement to send a stool sample for toxin testing, nothing on management of fluid balance and nutritional status, and no mention of prescribing vancomycin.

Findings of fact on policies for the control of infection

- At the start of the investigation, 30 out of 31 policies on infection control were several months past their review dates.
- The trust acknowledged that its policy for handling outbreaks was not fit for its intended purpose.
- The trust did not have policies for managing patients with diarrhoea or norovirus.
- There was no policy on the movement of patients with infections, and no policy on cleaning beds after a patient with an infection had moved on.
- Policies were not easily available to staff - not all had access to the trust's intranet where the policies were held and not all wards had computers.

- There was a contradiction between the formal guidance on cohorting patients infected with *C. difficile*, and practice on the wards. Senior staff including the director of infection prevention and control (DIPC) were unaware of this contradiction.
- The protocol dated July 2006 for the management of beds where patients have infective diarrhoea, supplied to us by the chief executive in May 2007, was not on the trust's intranet in January 2007.
- The guidelines for the care of patients infected with *C. difficile* lacked detail on the clinical management of patients.

Training for staff

Infection control staff should themselves be adequately trained and provide guidance and support to other staff across the trust. It is essential for all staff involved with patients to be well informed about the means to prevent and control infection.

Sources of evidence

- Interviews with staff past and present
- Information provided by the trust
- Healthcare Commission's national staff survey
- Interim report of the MRSA/HCAI improvement programme
- Minutes of meetings including the senior nurses

Training on infection control was mandatory for staff. It consisted of an induction for all new starters and an annual update for clinical staff.

Since 2002 the welcome day at the trust for the induction of all new staff had included a half-hour session on infection control. For clinical staff there was a second induction day with another session on infection control, this time lasting an hour. Between January and June 2006, over two-thirds of new clinical staff attended these days. Most of those who did not attend were bank staff. Less than 50% of non-clinical staff attended the welcome day in 2005/2006.

Staff could be on the wards for some time before they attended induction. In the first six months of 2006, 84% of clinical staff attended induction within three months, 16% did not attend until after working for that time.

Between September 2005 and August 2006, 51% of clinical staff attended the update on infection control. This training was mandatory for staff at the trust.

Although there had been an improvement since the 2004 survey, in the 2005 and 2006 national surveys of NHS staff, the trust was still in the worst 20% of acute trusts in terms of whether staff had received any training, learning or development in the previous 12 months. In respect of infection control, in 2005 and 2006, 44% and 45% of staff respectively reported they had had training in infection control compared to a typical score in a large acute hospital of 55% in both years.

The trust supplied information on the number of staff between September 2005 and October 2006 who chose to attend training on infection control. This information showed that 15 attended training on decontamination, 38 (nearly all from child health) attended training on techniques for hand hygiene, and seven attended ward based teaching.

The uptake of training was determined by the availability of training opportunities, the awareness of staff and their determination to access these, and the degree of support from senior staff on the ward. There was no formal arrangement for night staff to receive training on the control of infection.

It was apparent from interviews and from the minutes of the meetings of the senior nurses, that it was often difficult to release staff for training due to staffing shortages and work pressures. The trust's board in January 2007 learnt that only 40% of staff had attended mandatory training.

Appraisal

In the 2005 and 2006 surveys of staff, the trust was in the worst 20% of trusts in the country for staff reporting a well structured appraisal. The percentage of staff appraised in previous 12 months significantly decreased from 56% in 2005 to 49% in 2006.

In October 2006, roughly 50% of clinical staff were up to date with having had an appraisal and a personal development plan.

The interim report in September 2006 by the Department of Health's improvement programme for MRSA and other healthcare associated infections found that infection control was not part of appraisal at the trust.

The director of nursing and patient services said staff did not have responsibility for infection control in their job descriptions.

Findings of fact on training and appraisal

- Infection control was part of the trust's induction programme. Nearly 70% of new clinical staff and 50% of non-clinical staff attended in the first six months of 2006.
- Update training in infection control was mandatory at the trust, but between September 2005 and October 2006, only 51% of clinical staff attended the mandatory training update.
- In the national surveys of NHS staff, the proportion of staff at the trust who reported receiving training in infection control, was lower than in other acute hospitals.
- It was often difficult to release staff for training because of staffing shortages on the wards.
- Half of the clinical staff at the trust were up to date with appraisal. Infection control was not part of appraisal.

Infection control practice and isolation of infected patients

As well as having policies and trained staff in place, it is vital that actual behaviour on the wards accords with good practice. Isolation of patients with *C. difficile* is essential to control the spread of the infection, as is hand hygiene.

Sources of evidence

- Observations by the investigation team
- Policies provided by the trust
- Audits
- Interviews with patients and relatives
- Interviews with staff past and present, the infection control team and the HPU
- Minutes of *C. diff* and outbreak review meetings; outbreak bulletins
- The assurance framework 2005/2006
- Healthcare Commission staff survey 2005 and inpatient survey 2006
- Clinical governance review December 2002
- Department of Health improvement programme MRSA/HCAI

Infection control practice at the trust was universally acknowledged to have been poor, historically. The report on clinical governance published in December 2002 by the Commission for Health Improvement, noted that staff were poor at complying with procedures in infection control, including washing their hands.

In the 2005 national survey of NHS staff, 30% of staff at the trust agreed that "the trust does enough to promote the importance of hand washing to staff." The typical score for an acute trust was 77%. For promoting the importance of hand washing to patients and visitors, the trust's score was 33% compared to a typical score of 59% for an acute trust. Of the trust's staff, only 38% agreed with the statement "infection control applies to me in my role." The typical acute trust score was

79%. These questions were not included in the 2006 survey.

Despite improving in 2006 from the result in the survey the previous year, the response by staff at the trust to questions regarding the availability of hand washing materials (for staff, patients and visitors) was lower in both 2005 and 2006 than for other acute trusts. The actual percentages for these materials always or mostly being available were 90%, 79% and 79% respectively.

Since the outbreak, many staff considered that everyone was more aware of the importance of hand washing. As a result, hand washing had improved, though it was still patchy in places. The minutes of the *C. difficile* meetings and outbreak review meetings reported a clampdown on poor hand washing procedures, singling out individuals with poor compliance. Consultants were reportedly bad at following protocols on hand washing. In the national survey of inpatients in 2006, the trust was rated in the worst 20% of trusts on doctors being seen to wash their hands. The assurance framework for 2005/2006 identified poor compliance among medical staff as a medium risk. Ward staff were generally happy to challenge staff and visitors if they saw them ignoring the correct protocol for infection control.

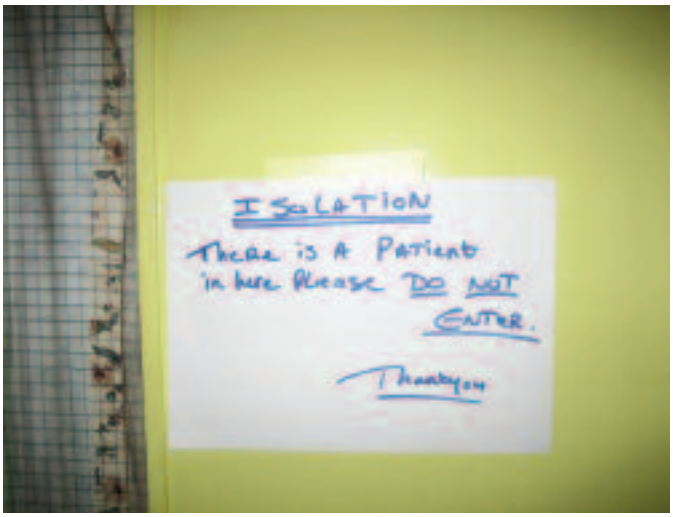
Other measures, such as restricting the number of people walking through wards and closing doors to infected patients, were increasingly enforced at the time of the outbreak, though there were reports of this not always being upheld. In April 2007, twice within an hour we observed the same doors open to a bay that was 'closed' in order to isolate patients with infections. This was particularly worrying since this was on the ward that had been dedicated to the care of patients with *C. difficile* infection the previous summer, and better practice could have been expected.

The view of the trust was that practice in the control of infection had improved with the greater provision of alcohol gels, greater emphasis on hand washing and the discarding of gloves. However, the great majority of patients and relatives who contacted us raised their concerns about the poor hygiene practice that they observed. Their comments mainly related to 2005 and the first eight months of 2006. They included a lack of isolation signs, or lack of enforcement where they were in place. Some visitors told us they were not asked to wash their hands.

A small number of families and patients informed us that commodes were often not emptied for considerable periods. They reported that some doctors and nurses had good hand hygiene and others did not. They said that some catering and cleaning staff moved trolleys between main wards and isolation areas without any precautions. They were concerned about the sharing of equipment, such as drip stands and zimmer frames, without these being cleaned. This applied in Whatman ward when this was designated the cohort ward. On the ward at this time there were some patients infected with *C. difficile* and some non-infected patients.

The minutes of the executive team in September 2006 recorded the feedback from the improvement team from the Department of Health on MRSA. The team was concerned that many policies were not being enforced. The interim report in October noted there was no evidence of recent audits of hand hygiene.

We noticed that there was little consistency between and within wards on the style of isolation signs and notices on display (photos 7 and 8). This was confusing for relatives and for staff, particularly those working on the wards on a temporary basis. We observed that it was often difficult for staff to reach hand basins, because they were obstructed in some way. We saw nurses wearing jewellery such as rings with large stones, which is not compatible with good practice in infection control.



Photos 7 and 8: Variation in style of isolation signs and notices on display at Kent and Sussex Hospital (Photo 7 ward 14A, Photo 8 Hargraves suite) (5 April 2007)

Isolation of patients with infections

We had concerns about the practice of attempting to barrier nurse in the middle of wards and bays. This involved placing a trolley with aprons and gloves at the foot of the bed and a yellow sticker to indicate that the patient had an infection (photo 9). We saw instances in which relatives did not understand the significance of the trolley. Moreover many of the beds were close together so it was difficult to barrier nurse effectively. The trust told us it shared our concerns but the scarcity of side rooms made it unavoidable.

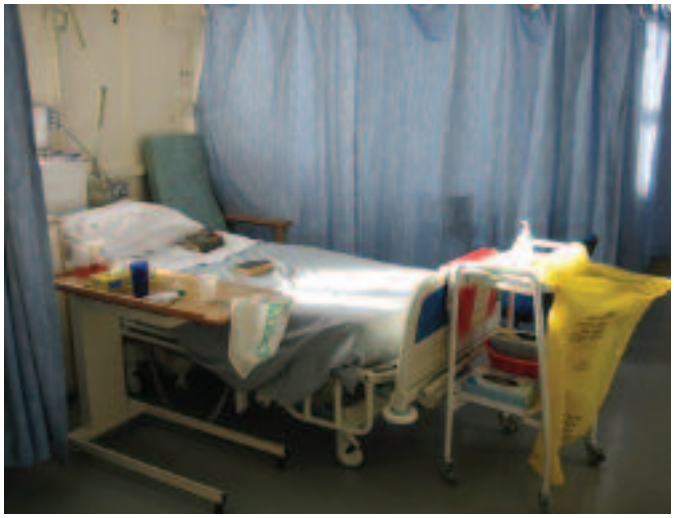


Photo 9: Trolley with aprons and gloves positioned at end of bed intended to indicate practice of barrier nursing in the middle of ward 10, Kent and Sussex Hospital (5 April 2006)

Isolation of patients with *C. difficile* infection during the outbreak in 2006

The microbiologists were normally responsible for recommending when wards should be closed to the admission of new patients. After the outbreak in 2006 was reported, many staff told us that senior managers were still reluctant to implement major infection control measures, such as closing wards or using buffer beds to separate infected patients from others on a ward. They said this was because of the shortage of beds and the need to meet targets.

Since the outbreak in 2005 was not recognised, there is no information other than from staff on whether patients were isolated. Patients were put in single rooms where these were available but, because of the scarcity of single rooms and the pressure on beds, on several occasions they were nursed on an open ward with a barrier trolley. This method increased the opportunity for cross-infection. The high bed occupancy figures exacerbated difficulties in isolating patients. We note that, in the joint HPA and Healthcare Commission survey of December 2005, 40% of trusts reported that they did not routinely isolate patients infected with *C. difficile*.

The trust, in common with many other NHS trusts, did not keep figures of the number of instances when patients with diarrhoea were on open wards, but nurses told us this had happened quite frequently, even after the outbreak had been declared. At the outbreak review meeting in July 2006 the HPU raised a concern that patients with diarrhoea had recently been admitted to an open ward. We observed patients with diarrhoea on open wards in April 2007.

Choice of cohort ward

The outbreak was recognised on 11 April 2006. On that day the first daily outbreak bulletin recorded that Jonathan Saunders ward and Whatman ward were closed to the admission of patients. A bay on Mercer ward and another on Foster Clark ward were also closed. There were concerns about the effect of these closures on the availability of beds. The outbreak was reported to the HPU and the SHA on 12 April.

Differences in advice from microbiologists delayed the decision to create a cohort ward. There was no pre-planning as to which ward to use as a cohort ward in the event of an outbreak. The policy at the time on outbreaks of communicable disease did not provide guidance to assist with the decision, and the trust acknowledged that this policy was not fit for its intended purpose.

At the time of the outbreak being declared, Jonathan Saunders ward had the most patients infected with *C. difficile*. However this ward was deemed inappropriate as a cohort ward because it was used as a thoroughfare to the unit for patients requiring planned orthopaedic operations. Whatman ward had the next highest number of infected patients on it, and on this basis it was agreed that it should become the designated cohort ward. This decision was made within 48 hours of the trust declaring a *C. difficile* outbreak. Whatman ward was not ideal to use as a cohort ward because it had a small sluice. This was not taken into account in making the original decision.

Even after this decision however, there were no criteria for admission to Whatman ward. Moreover during the first four months of the outbreak Whatman ward was not solely dedicated to the care of patients with *C. difficile*. Generally only the side rooms and two of the four six-bedded bays of Whatman ward were designated for patients infected with *C. difficile*. The other two bays continued to care for medical patients who did not have *C. difficile* infection. On one occasion three of the four-bedded bays had patients infected with *C. difficile* and the fourth did not. The senior infection control nurse was concerned about the risk that non-infected patients would contract the infection. The director of infection prevention and control did not make a case to the trust's senior managers for the creation of a ward dedicated solely to patients infected with *C. difficile*.

Further analysis suggests that Whatman ward had the highest incidence of new cases of patients infected with *C. difficile* of all the wards at the hospital in the months after it became the cohort ward - five in May, seven in June and six in July. These were additional to any patients transferred from other wards and suggest that patients became infected with *C. difficile* on the ward, that is, there was cross-infection. As the strains were not typed, it is not possible to confirm this.

During the outbreak, Cornwallis ward was used as the second cohort ward for a two-week period from the 18 April. At this time only two bays and the side rooms of Whatman ward were being used to cohort. The trust has not explained why a second ward was used to cohort rather than using the remaining two bays on Whatman ward for symptomatic patients. Subsequently Cornwallis ward often had at least one bay being used to cohort patients, and bays on other wards were used intermittently for this purpose. Staff on Cornwallis ward were not given advice when it was used as a cohort ward. It was also unclear why, given that Cornwallis was the more suitable ward for cohorting, Whatman continued to be the primary cohort ward rather than Cornwallis.

Whatman did not become an isolation ward dedicated to patients infected with *C. difficile* until 24 August 2006. Only at that time was it used for the exclusive purpose of caring for patients infected with *C. difficile*. The medical director took this decision. The director of infection prevention and control and the chief executive were on leave at this time and the medical director assumed the responsibility for covering the outbreak in the absence of the director for infection prevention and control. The decision followed a cluster of 11 new cases in the trust. Also, at least two patients on Whatman ward who did not have the infection had developed *C. difficile* after being nursed close to infected patients. This decision was also after the publication of the Healthcare Commission's investigation at Stoke Mandeville, which had criticised Buckinghamshire Hospitals NHS Trust for the delay in creating an isolation ward. The trust had begun to consider the findings and recommendations of this report.

In early 2007 we noted that patients with other infections such as MRSA were being barrier nursed on open wards. As described earlier, this was indicated solely by the presence of a trolley at the end of the bed. Often they were not grouped together on the ward. We wrote to the trust about these concerns.

Findings of fact on infection control practice and the isolation of patients with infections

- The clinical governance review conducted by the Commission for Health Improvement in 2002 found that staff failed to comply with procedures in infection control including hand washing. Compliance with hand washing procedures had improved but was variable among staff, particularly consultants.
- National surveys of NHS staff in 2004 and 2005 indicated that the trust did not give as high priority as other acute trusts to the control of infection.
- The style of notices about infection control and isolation was inconsistent and potentially confusing for staff and visitors.
- Before and during the outbreak several patients infected with *C. difficile* were not isolated or cohorted in bays, but were nursed on open wards.
- During our visits patients with other infections such as MRSA were being barrier nursed on open wards. This involved placing a trolley with aprons and gloves at the foot of the bed and a yellow sticker to denote the patient had an infection.
- There was no pre-planning of which ward to use as a cohort ward, and the outbreak policy gave no guidance on this. The ward chosen as the cohort ward had a small sluice.
- The cohort ward was not dedicated to patients infected with *C. difficile*, with other patients being cared for in other bays. Some of these acquired *C. difficile*. The director of infection prevention and control (DIPC) did not make the case to senior managers for the establishment of an isolation ward.
- The trust did not create a ward dedicated to *C. difficile* patients until late August 2006, four months after the outbreak began. This followed a cluster of new cases and

evidence of cross-infection on Whatman, and the publication of the report on outbreaks of *C. difficile* at Stoke Mandeville Hospital.

- There were no criteria for admission to Whatman ward, the cohort ward.
- Bays on other wards were also used to cohort patients, rather than accommodating these patients on Whatman ward.

Adequacy of staffing arrangements

Good practice in the control of infection should be embedded in the routine work of nurses. However, as with other aspects of nursing care, it may suffer when wards are short of staff. The Healthcare Commission found shortages of nurses to be an important contributory factor to the outbreaks of *C. difficile* at Stoke Mandeville Hospital, Buckinghamshire Hospitals NHS Trust.

Levels of nursing staff

Sources of evidence

- Acute hospitals portfolio survey 2004/2005
- Report of clinical governance review by the Commission for Health Improvement, December 2002
- Ombudsman's report November 2005
- Interviews with staff past and present
- Interviews with patients and relatives
- Complaints
- Incident reports, and data relating to incident reports
- Case note review by the Healthcare Commission
- Observations carried out by the investigation team
- Healthcare Commission staff and inpatient surveys
- Report in 2005 by the director of performance for Kent and Medway SHA for trust chief executives
- Minutes of meetings of internal trust committees, including the executive team and senior nurses
- Data on number of nurses provided by the trust

The clinical governance report by the Commission for Health Improvement in December 2002 noted low levels of staff on some wards. The report stated that shortages of staff affected care and resulted in a lack of privacy and dignity for patients.

The Healthcare Commission's acute hospitals portfolio is a collection of reviews of key services, resources or issues that are of national concern and that are important to patients, NHS trust managers and clinicians. In the acute hospitals portfolio review of ward staffing in 2004/2005, 80% of a sample of 20 medical and surgical wards at the trust had establishments (funded numbers of nurses) that were lower than the national average for the ward type and size. The average shortfall on these wards was 10%.

For actual staff on the wards, 90% of medical and surgical wards were below the national average for ward type and size. This included bank and agency staff. The average shortfall on these wards was 17%.

There was no evidence that the trust's board was told in 2005 that the trust had comparatively low levels of nurses.

We analysed the position in 2006 using data provided by the trust. We looked at 20 medical and surgical wards and found that 90% of them were below the average on funded numbers, the average shortfall on these wards was 12%. We carried out an analysis of actual staff on these wards in 2007 and found that 80% were below the national average for ward size and type, with an average shortfall of 11.6%.

The director of nursing and patient services told us that although there had been a

significant increase in funding for nursing staff, the actual numbers had not increased and they were still below establishment. He reported he had carried out an establishment review two or three years earlier but the board at that time rejected the recommendations as to increase the staff numbers to the levels recommended would have cost approximately £2.5 million.

The director of nursing and patient services advised the trust's management board in November 2006 that, despite investment in nursing staff, the trust's whole time equivalent nursing level per bed was still below national average in some areas.

More than 90 people commented in interviews that many wards had too few nurses. These ranged from patients and relatives to ward staff, consultants, junior doctors, senior nurses and senior managers. Some, including senior staff, described the number as unsafe. In the national survey of inpatients in 2006, 52% of patients responded that there were not always enough nurses on duty, compared with an average of 43% in other trusts. This meant the trust was rated in the worst 20% of trusts for having low nursing levels.

The clinical governance report published by the Commission for Health Improvement in December 2002 also noted a low proportion of qualified (registered) nurses. The analysis by the Healthcare Commission demonstrated that the proportion of qualified nurses continued to be less than elsewhere. In 2006, 80% of the medical and surgical wards we analysed were staffed below the national average for the percentage of qualified nurses. The average shortfall was 10%. In several interviews staff referred to inadequate numbers of qualified and skilled staff for the types of patients on some wards.

In September 2006 the policy unit at the Royal College of Nursing recommended a ratio of 65% qualified staff to 35% healthcare assistants. In 2007, our analysis showed that 14 out of a sample of 20 medical and surgical wards at the trust had less than 65% registered nurses.

In the Healthcare Commission's national survey of staff in 2005 and 2006, the trust came in the worst 20% in terms of staff reporting:

- having to work in addition to their contracted hours
- having to work extra hours as a result of pressure and demands of the job
- the poor quality of the balance between work and their personal life meant that their workload was more than they felt they could cope with.

Despite the findings above, the percentage of staff reporting work related stress fell significantly in 2006, as it did in many trusts nationally. For the preceding two years the trust had been in the worst 20% for staff reporting high levels of stress.

We analysed data relating to the incident forms which staff completed when they had concerns. There were 485 incidents between June 2004 and September 2006 that related to shortages of staff. We looked at those that related to the care of medical patients and found over 120 that related to shortages of nursing staff.

A report by the Health Service Ombudsman dated November 2005 (referring to an incident in June 2003) found that the trust needed to consider the risk of continuing to staff at such a low level and should also consider the skill mix on wards, and the dependency on non-nursing staff.

The report quoted the trust as stating that a further £4 million was spent on nursing budgets in 2003/2004, and £5 million in 2004/2005. In 2003/2004 the numbers of whole time equivalents increased by 79. However the additional expenditure in 2004/2005 was largely consumed by the trust's increased contribution to superannuation and other additional costs for existing staff, and had not increased the numbers of nurses. The figures on extra expenditure given to the Ombudsman by the trust do not correspond with our findings.

Some nurses and other staff told us that in their view the staffing establishments were too low. Additionally several wards had fewer staff than their establishment number. The trust told us that vacant posts were not frozen. Some posts were however being kept open to accommodate staff from wards that were destined to close. Because the closures were delayed, this in turn delayed recruitment, and wards remained understaffed.

The trust had a history of relying on bank and agency staff. The acute hospitals portfolio showed that in 2004, the proportion of nursing expenditure nationally on bank and agency staff was 11.5%. At the trust at that time the expenditure on bank and agency staff in 75% of a sample of 20 medical and surgical wards was above the national average. In 2006, 85% of a sample of 20 wards at the trust had a higher total expenditure on bank and agency than the national average. The average expenditure on bank and agency staff on these wards was 20%. The trust told us that 60% of bank staff in the trust were provided by the trust's staff, providing better familiarity with policies and the environment.

It was noted in a report in December 2005 by the director of performance at Kent and Medway SHA, that the expenditure on agency staff at the trust was the highest in Kent and Medway SHA, across all staff groups. The expenditure on agency staff at the trust was 9.22% of the total bill for nursing pay. The national average was reported to be 4.82%. The trust spent £1,664,665 on bank and agency nurses in the three months from February to April 2006.

The minutes of the meeting of the senior nurses in December 2005 recorded that all areas should restrict ('cap') the hours worked by bank and agency staff, and overtime. The minutes of the executive team meeting in the same month noted that a cap of £600,000 had been agreed for bank and agency staff. The nursing report to the board in March 2006 stated that extraordinary measures to curb bank and agency staff usage had been introduced. However the trust told us that a cap on bank and agency was not introduced until July 2006, at which point wards were only allowed to cover 50% of vacant roles. The evidence suggests some restrictions were introduced earlier.

When nurses felt they had no option but to ask for agency staff to cover a shortage, an executive director had to approve the request. This practice is not unusual in the NHS. At the trust, achieving agreement could take considerable time and the agency was then often unable to cover the shift at short notice.

In March 2006 the executive team noted that an outcome of reducing expenditure on bank and agency staff was a shift from using temporary trained staff to untrained staff.

Impact of low staffing levels on the care of patients

The acute hospitals portfolio review in 2004/2005 identified the trust as having a high overall number and rate of complaints. Out of all the 199 acute hospital organisations, the trust was in the highest group for complaints about clinical care, with a rate of 10.95 complaints per 10,000 occupied beds. The typical number was 2.14 complaints. The trust had the highest rate of complaints about clinical care in the group of 40 hospitals described as "large outside London".

In 2006, 25% of staff at the trust agreed or strongly agreed with the statement "As a patient of this trust, I would be happy with the standard of care provided" compared to 34% of staff in acute hospitals nationally. This result was worse than it had been in the previous survey in 2005 when the percentages were 32% for the trust and 38% nationally.

The vast majority of nurses and other clinical staff interviewed considered that poor care was in large part due to having inadequate staffing levels. Patients and relatives who contacted us said that they thought that low staffing levels contributed to poor care.

Most nurses reported that they had little time to spend with patients, and frequently went home upset because they had not been able to

do their job well. Examples were given of the adverse effect on patients of shortages of staff including patients having accidents because they could wait no longer to go to the toilet, then having to wait to have their sheets changed.

Other professionals confirmed the effect of a lack of nurses on their work, particularly on general wards. Consultants said that nurses were often unable to accompany them on ward rounds. This meant they could not inform the doctors about the patients, and the doctors could not discuss their plans for the patients. Dieticians said food supplements were not given and that 80% of food charts were not completed correctly. Pharmacists and therapists told us nurses often did not have time to provide them with information they needed about patients.

Many nurses told us that they had completed incident forms to report the problems that shortages of staff caused, but did not receive feedback, and some were discouraged from using forms for this purpose.

Even on wards with higher numbers of staff, in response to an acute shortage of staff in another clinical area, nurses would often be moved. This practice is not uncommon in the NHS. Several nurses told us they found it stressful to be moved from their home ward to support another understaffed ward with which they were unfamiliar. The trust's managers recognised this was not popular but said it was sometimes necessary.

Having patients placed on wards that were not the most appropriate for their illness compounded the problems of shortages of staff. Thus, for example, nurses normally working on rehabilitation wards did not always have the appropriate skills to nurse acutely ill patients with medical problems.

In our review of case notes, we found several examples of substandard care. For example, there were concerns about the speed with which new pressure sores developed and existing ones worsened. The primary care trust had complained formally to the trust about patients developing pressure sores.

Effect of the levels of nursing staff on the control of infection and care of patients with *C. difficile*

Sources of evidence

- Interviews with staff past and present, and the infection control team
- Interviews with patients and relatives
- Minutes of the board, trust executive committee, senior nurses
- CLIP reports
- Complaints
- Audit of vital signs
- The performance report for the medical directorate in June 2006
- Case note review by the Healthcare Commission

Many staff, mostly doctors and nurses, provided us with instances of shortages of nursing staff having an effect on the control of infection. Examples we were given included failure to:

- practice cohort nursing effectively
- give patients their medication
- complete fluid balance and food charts
- ensure patients took their food and nutritional supplements.
- supervise confused patients who wandered in and out of isolation areas
- practice good hand hygiene
- answer call bells and empty commodes promptly
- change soiled bedding quickly
- use new or cleaned equipment for each patient.

The performance report for the medical directorate in June 2006 reported that 38% of wards could only show some evidence that they were achieving standards in nutrition. It was noted at the meeting called CLIP

(complaints, litigation, incidents and PALS) in March 2006 that two cases where patients died of dehydration had been reported to the coroner. The trust's review of the case notes confirmed that the degree of dehydration was a material factor in the cause of death, and the coroner supported this conclusion.

The trust's own audit of patients' vital signs in November 2004 found that, of all the patients who needed additional monitoring, 49% either had no fluid chart or an incomplete one. Eleven per cent had not been fed in the last 24 hours and 38% had not had their respiratory rate monitored. Not a single 'patient at risk' score was recorded. (This score is often used in the NHS to help the early recognition of patients at risk of becoming critically ill, by providing an objective score based on vital signs.) In 2005, 72% did not have a 'patient at risk' score. In 2006, when the wards were notified in advance of the audit, 68% at Maidstone did not have a 'patient at risk' score and 32% at Kent and Sussex.

We noted in our review of case notes evidence of poor nursing care. This included inadequate fluid management in 36% and poor nutritional management in 34% of cases we looked at. The reviewers found that stool charts were used in less than 15% of cases, and 'patient at risk' scoring was almost non-existent. We did not have the information to look at staffing numbers for the cases we reviewed.

It was reported to us that moving nurses from one ward to another, to cover shortages, contributed to a lack of continuity of care and problems with completing fluid charts.

Findings of fact on levels of nursing staff and the effect on care of patients and control of infection

- For at least three years the medical and surgical wards at the trust had nursing establishments with fewer staff than other similar wards in comparable trusts. Staff were routinely moved between wards to cover shortages.
- The trust relied heavily on the use of bank and agency staff. Taking such staff into account, the number of actual nurses on medical and surgical wards was still below that of comparable wards in comparable trusts.
- Since December 2005 the trust had restricted the use of bank and agency staff. Agency staff could only be used with the permission of an executive director.
- Posts had been kept vacant to accommodate staff from wards scheduled to close - however, delay in the closures delayed recruitment and wards remained understaffed.
- The medical and surgical wards had a lower proportion of qualified nurses than comparable trusts.
- 25% of staff responded that they would be happy with the care provided at the trust, compared to an average response of 34% for acute trusts.
- The trust had been in the worst 20% of trusts for staff reporting high levels of stress for 2004 and 2005, and for staff working extra hours and having a poor work-life balance. The percentage of staff reporting work related stress fell significantly in 2006, as it did nationally. The score on the other two indicators remained in the worst 20%.
- Most staff, patients and their families considered that the inadequate numbers of nurses had a negative effect on the quality of care and good practice in the control of infection.
- Out of 40 comparable trusts, the trust had the highest rate of complaints about clinical care.

Escalation areas

The use of escalation areas was considered in this investigation because of the opinion of staff that it had contributed to problems with infection control and with the quality of care for patients.

Sources of evidence

- Minutes of meetings of internal trust committees including the patient safety review group, senior nurses and CLIP minutes and reports
- Interviews with staff past and present
- Incident reports
- Observations carried out by the investigation team
- Correspondence with the trust, statement from the trust, operational plan, escalation plan
- Bed tracker summary, spreadsheet of bed numbers

Escalation areas were areas in the hospital that did not usually function as general wards but which were used as such when there were no suitable beds available elsewhere in the hospital. We were told these had been opened more frequently as a consequence of increased admissions, fewer beds and the national target which required patients to spend no longer than four hours in A&E (accident and emergency).

The areas most commonly used for escalation included the adult day care ward and Mercer and Whitehead wards at Maidstone Hospital, and wards 11a and 14a at Kent and Sussex Hospital. Some of these beds were in clinical areas and wards that were normally only staffed for a certain number of beds, or for five days. In these areas the trust would have to open extra beds, or for the weekend, to accommodate patients.

Some clinical staff, including senior nurses, were concerned about the suitability of some of the areas in terms of their facilities. They were also worried about the commitment of the trust to find enough nurses with the appropriate skills to look after the patients. This was because of low staffing levels, and the trust's policy of restricting use of staff from agencies. Often staff were moved from other wards, leaving those other wards understaffed.

Some members of staff told us that the adult day care area at Maidstone was not suitable to function as a ward because of the lack of equipment, hand basins and bathroom, and the size of the 'dirty utility' room. Concerns had been expressed through incident reports, CLIP (complaints, litigation, incidents and PALS) reports and at meetings of the senior nurses. In March 2006 the representative of the Royal College of Nursing at the trust raised the safety of patients on adult day care as a concern with the chief executive. In September 2006 the adult day care ward at Maidstone was closed.

Ward 14a, also known as Rainbow ward, was open as an escalation ward at Kent and Sussex from January to June 2006. This ward had previously been used to care for children. At the meeting of the CLIP group in January 2006 it was noted that it had been set up as an escalation area without equipment and medicines. From January to June 2006 the bed occupancy figures on the ward were always above 90% and were between 102 and 110% for four of these months. This was because of the fast turnover of patients. It closed in June but re-opened as an escalation area in autumn 2006.

The investigating team visited this ward in December 2006 when it had been open for a few weeks. We had a number of concerns about its appropriateness. Accordingly we wrote to the trust to raise our concerns that the beds were too close together, there was poor provision for hand washing and that the toilet and showering facilities were unacceptable – there was only one toilet, the only shower was mouldy and smelt unpleasant (see photo 3 on page 48) and the shower door was damaged. We also noted that the sluice was cluttered. A patient with diarrhoea was being barrier nursed in the middle of a bay. This was indicated by a trolley at the end of the bed. There was no computer link to the wards, so there was no tracking of patients and there were delays in ordering and receipt of blood and other tests.

The only member of staff consistently present was the sister; other nurses had been taken

from other wards on a daily basis. Although patients were meant to be selected for this ward on the basis that they would be there for a very short time, some were staying for several days, and in some cases for weeks. The ward was mixed sex and there was little privacy or dignity. We heard of patients in tears because they did not obtain adequate pain relief. This was because there was no locked drugs cupboard on the ward, so the hospital's pharmacy would not dispense strong analgesics.

The ward clerk worked for approximately two days a week, leading to significant delays for some patients in arranging information for discharge, making outpatient appointments, etc. In addition, when the ward was first re-opened, the pharmacy did not dispense medication to the ward, and there was no cleaner and no linen, as the domestic supervisor had not been informed.

We were concerned that patients were being cared for under such circumstances in December 2006, particularly when the trust had closed the adult day care ward in part for similar reasons three months earlier.

The trust responded to our letter on our concerns about this ward that the primary care trust had not managed to reduce the number of admissions and indeed they had increased. However the trust had no contingency plan to deal with increased admissions, other than opening escalation beds. The trust assured us it had taken action to address the major shortcomings on ward 14a and that the ward would shut before Christmas. This happened but the ward re-opened between Christmas and New Year.

On an unannounced visit at lunchtime on 3 January 2007 the ward was found to be open although in the morning the director of nursing and patient services told us that it was closed. He later told us that he had not been informed that the ward had re-opened. Three permanent members of staff were working there, providing some continuity. However on some shifts only bank and agency staff were providing care. The shower was in the process of being refurbished, but on a visit in February it was closed with a notice declaring that it was dangerous to use. In April 2007 we were told the shower area was going to be converted into an office.

Mercer ward at Maidstone changed its function in April 2007 to become a dedicated escalation area. When we visited that month, the only permanent member of staff was the ward manager. All the other staff were bank or agency nurses. We were told that nurses from other wards were being recruited to work on this ward but in the meantime we had concerns about the continuity of care for patients.

Findings of fact on escalation

- Wards or parts of wards were opened to take patients when the trust did not have enough beds. Some of these escalation areas were inappropriate for the patients placed there. Nurses were taken from other wards to staff the escalation areas.
- Ward 14a at Kent and Sussex Hospital was used as an escalation area for weeks at a time. It had poor washing and toilet facilities, no computer link and there was little continuity of staff. Some of these problems were addressed but the ward was still without a shower four months later.
- The director of nursing and patient services told the Healthcare Commission that he did not know that ward 14a had been re-opened.

Bed occupancy and movements of patients from ward to ward

The report of the National Audit Office in 2004 found that preventing infections continued to be adversely affected by other NHS trustwide policies and priorities. The increased throughput of patients to meet performance targets resulted in considerable pressure towards higher bed occupancy, which was not always consistent with good infection control and bed management practices. Higher bed occupancy meant that there was less time for thorough cleaning of beds and bed spaces

between admissions of individual patients and a higher probability of transmission of infection between patients. Seventy-one per cent of trusts were still operating with bed occupancy levels higher than the 82% that the Department of Health reported it hoped to achieve by 2003/2004.

Sources of evidence

- PAS data
- Department of Health hospital activity statistics
- Acute Hospitals portfolio review 2003
- Minutes of meetings of internal trust committees including the outbreak review meetings, senior nurses and the trust board
- The assurance framework for 2005/2006 and 2006/2007
- Bed tracker summary and spreadsheet of bed numbers
- Interviews with patients and relatives
- Interviews with staff past and present, and the infection control team
- Complaints and incidents
- Case note review

Bed occupancy

Medical and nursing staff across the trust stated that bed occupancy levels were extremely high. They said there were rarely any empty beds. The report of the acute hospital portfolio review in July 2003 found that the number of medical and surgical beds per 1,000 population was lower than average for an acute trust. Since then the trust had further reduced the number of beds. Beds including those at Pembury Hospital had been shut and the workload transferred to Kent and Sussex. The high number of emergencies and the need to achieve both the A&E and waiting list targets led to increased admissions and higher bed occupancy levels.

The trust's figures for bed occupancy rates were comparable with the averages for England at about 85% for general and acute beds and 95% for beds for geriatrics (care of the elderly) (Department of Health hospital activity statistics 2005).

However, our analysis of the occupancy figures for the medical beds showed the rates to be consistently high in 2005/2006 and 2006/2007.

Table 4: Bed occupancy figures for medical beds at the trust from 2004 to 2007

	2004/2005*	2005/2006	2006/2007**
Maidstone	83%	95%	93%
Kent and Sussex	88%	92%	91%

**excluding February and March 2005 for Maidstone*
***up to September 2006*

For the year 2005/2006 Maidstone Hospital had a bed occupancy rate of 95% in all the medical wards, dipping to 93% in the year 2006/2007, up to September. The equivalent rate on the medical wards of Kent and Sussex Hospital was 92% bed occupancy in 2005/2006 and 91% in 2006/2007, up to September 2006.

Wards of particular concern included Boxley, the rehabilitation ward at Maidstone Hospital. Other medical wards such as Cornwallis and John Day also had high bed occupancy figures of over 100% for several months. Whatman ward consistently had a rate of between 85 and 94%. In April 2006, when functioning as a cohort ward, its bed occupancy rate increased to 110%. It dropped to 56%, a more acceptable level for a cohort ward, in September 2006 after all bays on the ward had been devoted to patients with *C. difficile*.

Movement of patients

In addition to isolating patients with *C. difficile* or undiagnosed diarrhoea, an effective supplementary measure in the control of infection is restricting the movement of patients, particularly those with infections. Conversely, excessive movement of patients increases the risk of the transmission of infections.

At the private part of the board meeting in July 2005, it was reported that patients were moved frequently between wards, increasing the risk of cross-infection. Senior nurses raised concerns at their monthly meetings about the movement of patients.

The trust's assurance framework for the years 2005/2006 and 2006/2007 stated as an objective 'having no unnecessary transfers.' The framework cited high bed occupancy as the principal risk to achieving this. The risk was changed from 'high' to 'medium' between these years, though the bed occupancy figures for the trust had not changed significantly in this time.

Clinical staff reported that patients who moved frequently from ward to ward created additional risks of contamination. Items such as beds, belongings and equipment that could cross-contaminate wards had to be moved to accompany patients.

Staff on general wards and relatives of patients told us that many patients had to move from one ward to another, some several times. We note that this is not uncommon in acute hospitals. Ward managers, junior doctors and senior nurses also told us about patients having multiple moves and said this was not uncommon. There were reports of patients, including some with *C. difficile*, being moved up to six times in one stay.

For the three months between February and April 2006, 50% of medical and care of the elderly patients at Maidstone Hospital were moved between wards at least once. The comparable figures were 41% at Kent and Sussex and 12% at Pembury.

At Maidstone 7% of patients were moved two or more times, which, though a small proportion of total patients, accounted for 161 individuals in three months. At Kent and Sussex 10% patients moved two or more times, accounting for 259 individuals. These figures do not include patients moving to different locations within the same ward.

Many of the ward moves took place at night. For the period February to April 2006, at Maidstone Hospital 21% (514) ward moves happened between 9pm and 6am. The equivalent proportion of moves at Kent and Sussex between these times was 18% (476). Site practitioners, who are senior staff in charge of the wards out of hours, made the decisions about ward moves after 4pm, so patients tended to be moved later in the day. In those three months, 223 patients across the trust were moved between 1am and 3am.

Patients and relatives of patients reported to us that moving wards a number of times caused distress to patients and their families. The number of times patients were moved was also a theme in complaints. One of the upsetting aspects was that families were often not told about the move until they tried to visit. Doctors similarly complained that on occasions patients were not seen by them for some days.

Some staff told us that when patients were moved from one ward to another, staff needed to follow a large number of processes if the move was to be successful. This can be difficult if staffing levels are low, especially at night. On occasions the patient's notes did not accompany the patient to the new ward. Families also told us that sometimes patients were moved to wards where staff did not appear to be knowledgeable about their condition.

Some nurses told us that, because they were relatively senior, they could resist pressure to take patients they felt were inappropriate, but as soon as they went off duty, managers would pressurise more junior nurses, who would be unable to resist this pressure.

Findings of fact on bed occupancy and the number of patient moves

- The number of medical and surgical beds per 1,000 population was lower than average in 2003. Since then the trust had further reduced the number of beds.
- Bed occupancy rates have consistently been high - at Maidstone Hospital, for the year 2005/2006 there was a 95% bed occupancy rate across all medical wards and the equivalent rate on the medical wards of Kent and Sussex Hospital was 92%.
- 50% of medical patients moved wards at least once; one patient with *C. difficile* was moved six times.
- Between February and April 2006, over 1,000 patients were moved from one ward to another between 9pm and 6am, and 223 of these were moved between 1am and 3am.

Role of the director of infection prevention and control

The director of infection prevention and control (DIPC) has overall responsibility for creating a culture in which effective hygiene is the norm and infection control is everyone's business. In this section we consider how this role was carried out at the trust.

Sources of evidence

- National guidance issued in May 2004 on competencies for DIPCs
- Minutes of meetings of internal trust committees including the infection control committee, infection control team meeting, risk and governance committees, trust executive committee, board and remuneration and terms of service committee
- Interviews with director of infection prevention and control (DIPC), infection control team and other clinical staff, past and present, and with the HPU
- Annual reports for infection control
- Policies related to infection control
- Case note review by the Healthcare Commission
- CNST report

The role of the director of infection prevention and control (DIPC) was introduced nationally in December 2003 in order to ensure that a senior clinician in all acute trusts was appointed to:

- oversee infection control policies and their implementation
- be responsible for the infection control team
- report directly to the chief executive and board
- challenge inappropriate clinical hygiene practice and antibiotic prescribing decisions
- assess the impact of all existing and new plans and policies on infection control and make recommendations for change
- be an integral member of the clinical governance and patient safety teams and structures
- produce an annual report on the state of healthcare associated infection in the organisation and release it publicly.

It was not possible to determine when the director of nursing and patient services also took on the role of the director of infection prevention and control. Neither he nor other senior staff could remember. The medical director at the time had not been involved in making the appointment. There was no formal appointment process and the appointment was not considered or noted by the board. Given that the director of infection prevention and control reports directly to the board and chief executive, this was surprising. The chief executive, who joined the trust in November 2003, told us that the appointment had been agreed by the remuneration and terms of service committee but the minutes provided no record of this, other than as an appendix listing the responsibilities of all the directors. The respective portfolios of all the executive directors were endorsed by the board every year.

The director of infection prevention and control acknowledged that initially he had not realised the extent of the role and the time commitment required. As director of nursing and patient services with responsibility for clinical governance and risk, he had a full portfolio.

Many people we interviewed did not know the identity of the director of infection prevention and control. Among those staff who were aware, there were mixed views as to whether he had been an effective advocate for the cause of preventing and controlling infection, although it was widely acknowledged that he worked very long hours. The support he gave to the relatives of patients with *C. difficile* who had died in hospital during the outbreak was also praised.

The director of nursing and patient services did not have specific experience or further qualifications in infection control. This was not unusual. The National Audit Office found in 2004 that 48% of directors of infection prevention and control were medical or nursing directors. The Healthcare Commission's report in July 2007 on healthcare associated infection found that 43% of directors of infection prevention and control were microbiologists, 36% were nursing directors or chief nurses and 11% were medical directors. Approximately half of all directors of infection prevention and control had a specific qualification in infection control.

The director of infection prevention and control attended the meetings of the infection control committee and the outbreak committees. He never attended the infection control team meetings. The team members said that he was always available, but until the outbreaks, had not given much time to the control of infection. His main link was with the senior infection control nurse. He did not forge strong links with the microbiologists.

When the senior infection control nurse went off sick and then left, there was no locum or extra support for the team. No one ensured there were continuing arrangements for local surveillance of *C. difficile*. The lack of effective local surveillance meant that the increase in cases in the autumn of 2005 was missed.

There had not been a timely response to the letter from the Chief Medical Officer and Chief Nursing Officer in December 2005. The Healthcare Commission was concerned that it took so long to get agreement on an appropriate antibiotic policy and to restrict the prescription of inappropriate antibiotics. Supplies had to be physically removed from the wards two months after the outbreak started. Our review of case notes found a considerable degree of inappropriate prescribing linked to the development of *C. difficile*. As has been noted earlier, the policies for infection control were months beyond their review date.

The director of infection prevention and control seemed unaware of the problems inherent in cohorting patients with *C. difficile* in bays. He did not argue the case with his executive colleagues to close wards and keep them closed during the outbreak. We noted that it took four months for a ward to be dedicated to *C. difficile*. This happened in August when the director of infection prevention and control was on annual leave.

The minutes of the trust's board in September 2006 record that the director of infection prevention and control reassured the board that all the recommendations from the Healthcare Commission's previous investigation into the management of outbreaks of *C. difficile* at Stoke Mandeville Hospital, had been implemented at the trust. We found this statement to be inaccurate, though we note that the accompanying paper did not make this claim. This is covered later in the report.

The minutes of the executive team in September 2006 recorded the feedback from an improvement team from the Department of Health on MRSA. This included their concern about a lack of focus, leadership, follow through and management. The non-executive directors to whom we put this were unaware of this criticism.

One of the designated functions of the director of infection prevention and control (DIPC) is to produce an annual report on the state of healthcare associated infection in the organisation. The annual report must be a public document. The usual practice is for annual reports to be taken to a public meeting of the board. Reports were produced for the three years from 2003 to 2006. Graphs of the numbers of *C. difficile* cases were included, but the reports did not highlight the high background rate of *C. difficile* at the trust compared to other trusts, so the board would not have been immediately aware of this. There was no detail of the wards affected or analysis of the underlying factors. The clinical negligence scheme for trusts criticised the trust because the reports did not contain a programme for infection control for the following year.

The trust did not meet all the criteria for full reporting under the mandatory surveillance scheme, as they did not always test samples from GPs. We were told this was because there was not sufficient funding to carry out the work that would be required. For those that were tested, any positive results were reported.

Although he had been responsible for organising the case note reviews, the director of infection prevention and control could not explain to us when the case note reviews had been carried out, confirm with certainty the source of the statistics on deaths in the press releases, or provide the relevant records.

Findings of fact on the role of the director of infection prevention and control (DIPC)

- The trust was not clear how the appointment of the director of infection prevention and control (DIPC) had been made. There was no formal consideration by the board of the appointment of the director of infection prevention and control.
- As director of nursing and patient services and with the lead for clinical governance, the director of infection prevention and control had a full portfolio.
- Prior to the announcement of the outbreak, the director of infection prevention and control did not have a strong working relationship with the microbiologists.
- There was no extra support for the team in the period between the resignation of one senior infection control nurse and the arrival of that nurse's replacement.
- The annual reports for infection control contained little information on *C. difficile* and no analysis of the comparative position of the trust. The board was not aware that mandatory surveillance showed that the trust had high rates of *C. difficile.*
- The response to the Chief Medical Officer's letter in December 2005 was not timely and antibiotics were not adequately policed until the 20 June 2006.
- The director of infection prevention and control had not been effective in ensuring systems were in place to identify outbreaks; nor were the infection control policies up to date. The director of infection prevention and control did not ensure the

establishment of an isolation ward; this happened in his absence.

- The director of infection prevention and control could not explain with certainty nor provide records of the case note reviews or the origin of the number of deaths in the press releases.

Factors at strategic level related to the outbreaks

This chapter looks at whether senior managers at the trust had arrangements in place to reduce risk in general, and risk from infection control in particular.

The trust's arrangements to reduce clinical risk

Although our main focus was on the control of infection, we also reviewed the trust's systems for the management of clinical risk. Systems for the management of risk should allow trusts to identify trends and potential risks, and take timely action to minimise harm. Members of the trust's board should be aware of key risks of a clinical nature and ensure that these risks are managed appropriately. One of the most important clinical risks for any hospital is that of infection.

Sources of evidence

- The clinical governance review published by the Commission for Health Improvement in December 2002
- Risk register and assurance framework, and Department of Health related guidance
- Minutes of meetings relating to risk and other minutes including the infection control committee, clinical practice committee and trust management board
- Ward assurance framework
- Interviews with trust staff

The clinical governance review published by the Commission for Health Improvement in December 2002 gave the trust the lowest rating for the management of risk. The report said there had been little or no progress at strategic, planning or operational levels. It noted poor compliance with policies and made specific reference to infection control.

In this section we consider the accountability arrangements, the risk register and assurance framework, how the trust responded to concerns from staff about risks to patients and to the risk from low staffing levels, and to complaints from patients about the quality of care.

Accountability

We found that there was a number of groups within the trust with some responsibility for managing or monitoring risk. There had been considerable change in the committee structures over the previous three to four years and there was some confusion over the hierarchy and accountability of committees. The boundaries between the committees were not clear. For example, the clinical practice committee and the operational risk committee. had a degree of overlapping membership and discussed similar subjects.

There was an infection control committee which met every three months. Originally this reported directly to the clinical governance committee, attended by the infection control doctor (a microbiologist with lead responsibility for infection control). From March 2004 there was a change and the infection control committee reported to the clinical practice committee, which did not have the infection control doctor as a member. The director of infection prevention and control only attended three meetings of the clinical practice committee between 2004 and 2006. There was no deputising arrangement during his absence. The clinical practice committee reported to the trust's governance and risk committee. In turn, the minutes of this committee went to the trust's management board and the board.

The risk register and assurance framework

A risk register is a way for trusts to record and grade risks in terms of their severity. The number of risks on the trust's register doubled from 2005 to 2006, following the team's efforts to encourage more reporting. Despite the number of entries in the register doubling in a year, the proportion that collectively related to risks regarding the physical environment, staffing, beds and infection control fell from 24% to 19% of the total entries. The proportion of these graded as high risk stayed at 8% to 9%. Many staff were not aware of the purpose of the register.

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. Although the trust's strategy for managing risk stated that the framework should be simple, we found it to be voluminous and more akin to an inventory of risks. The framework contained a section on reducing hospital-acquired infection, but there was no mention of *C. difficile* until 2006/2007. Senior managers told us there was confusion about the purpose of the register and the framework.

A report to the operational risk committee in July 2006 stated that implementation of the current risk management strategy had been fragmented and poorly understood within the trust.

Partly in response to incidents involving nursing care, the trust introduced the ward assurance scheme to monitor and improve care on the wards. This framework was implemented in December 2005 and was based on the principles of 'Essence of Care' (a toolkit developed by the Department of Health to benchmark the fundamentals of care). Ward managers assessed their ward's performance against the framework. The intention was to move to assessment by peers, that is, other ward managers. Senior nursing staff told us that the results of the ward assurance framework were reported to the trust's board and the management board, although there is little evidence they were discussed, particularly at the latter.

Findings of fact on risk arrangements

- There had been considerable change in the committee structures for the management of risk over the previous three to four years.
- The risk register and assurance framework were poorly understood within the trust.
- A ward assurance framework was introduced in December 2005 to monitor and improve care on the wards.

Systems to learn about and respond to the concerns of clinical staff about the care of patients

Clinical 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 learnt and the risk to patients in the future being reduced. Serious incidents have to be reported to the strategic health authority (SHA), and incidents affecting the safety of patients must be reported additionally to the National Patient Safety Agency.

Sources of evidence

- NPSA feedback report
- Healthcare Commission staff surveys in 2004 and 2005
- Reports of clinical and serious untoward incidents
- Trust policies regarding managing incidents
- Minutes and papers of internal committees including the patients safety review group, CLIP group, senior nurses, emergency care

directorate, risk and governance committee, trust board and trust management board

- CLIP reports
- Interviews with the board and staff

A report by the National Patient Safety Agency about incidents reported in the last three months of 2005 showed that the trust was in the middle range for the number of incidents reported per 100 admissions for the whole trust.

In the 2005 national survey by the Healthcare Commission, NHS staff were asked whether, if they had witnessed a harmful error, near miss or incident they, or a colleague, had reported it. The trust's score was in the lowest (i.e., the worst) 20% of acute trusts in England. In the 2006 survey the trust's score decreased further and it remained in the lowest 20%.

An analysis of the categories of incidents was undertaken and considered by a group called CLIP – complaints, litigation, incidents and PALS (the Patient Advice Liaison Service). This group met monthly, beginning in September 2004. The trust told us it was never intended that the minutes of the group should go to another committee, as this was a forum to share concerns and decide where they should be referred.

A report by the same name was also produced every three months, beginning with the period July to September 2004. As the name suggests, this group and the report were established to look at the themes from complaints, claims and incidents and to look at links between these. The assessor for clinical negligence scheme for trusts (CNST) in 2005 was complimentary about the CLIP reports. The first four reports went to the trust's management board but did not appear to have generated much discussion or action. Subsequently the reports went to the clinical governance and risk committee. There was evidence of increasing discussion at the clinical governance and risk committee, before its membership changed and it was superseded by the governance and risk committee in January 2007. There was no evidence that CLIP reports were shared with directorates, other than as a result of members of the management board receiving them.

Relevant themes identified by CLIP reports and meetings of the group included:

- the unsatisfactory nature of some escalation areas opened to take admissions, in particular adult day care at Maidstone
- the effect that the A&E target had on the quality of care in A&E and the poor quality of transfer and handover to the wards
- patients being cared for on wards that were not appropriate for their condition
- concerns about staffing levels, and bank staff managing wards on some shifts
- concerns about general nursing care and the quality of observations carried out by nurses
- increasing number of pressure sores
- patients becoming dehydrated and fluid balance and nutrition not being properly recorded and addressed
- responses to complaints not addressing the issues.

The Healthcare Commission was impressed by the ability of the CLIP group and the CLIP reports to identify themes and issues that posed a risk to patients or to the reputation of the trust. The Patient Advice and Liaison Service also identified many of these themes. However, it was seldom possible to see where these minutes or reports had been considered at higher levels in the trust or to identify action taken. Reports on complaints that went to the board concentrated primarily on statistical analyses and not on the nature of the complaints.

We noted that the use of escalation beds was described as a 'red' risk in the CLIP report for January to March 2006. This had been highlighted to the operational risk committee

and the trust's management board. However the use of the adult day care ward as an escalation area did not stop until September 2006. Meanwhile ward14a at Kent and Sussex was re-opened as an escalation area although it also had poor facilities.

Lessons from incidents

In a survey conducted by the Healthcare Commission in 2005, NHS staff were asked a series of questions to assess the culture of incident reporting. They were asked whether incident reporting was encouraged, whether reports were treated confidentially and to what extent the trust took action to ensure such incidents did not recur. The trust's score on this subject was not just in the lowest 20% but was the lowest, that is, the worst, of any acute trust in England. The score improved in the 2006 survey but remained in the worst 20% of acute trusts.

Many staff reported that they did not get feedback after incidents and there was little confidence that they led to change.

We noted that there had been many reports of incidents involving poor handover of patients from A&E to the wards. This matter was also noted at the meeting of the patient safety group in January 2006, and in the CLIP report for the first three months of 2006. Staff reporting these incidents usually attributed them to the pressure to meet the A&E target. There was no evidence of action taken, despite cases such as a patient covered in faeces transferred from A&E to a ward before the four-hour limit was reached, and put in a room with another patient. This was in spite of a single room having been requested on clinical grounds. There was also a serious untoward incident involving poor handover of care, poor observations of a patient, and failure to respond appropriately.

Many senior staff acknowledged that the trust was not good at learning lessons and making improvements. Some directorates held meetings at which incidents were discussed, but others, including medicine, did not.

A group was established in 2004 to review clinical risks and the safety of patients. It was originally called the clinical risk review group and then the patient safety review group. The group looked at incident reports and serious untoward incidents in detail as well as keeping abreast of claims and other aspects of the management of risk such as inspections by the clinical negligence scheme for trusts (CNST). The reporting arrangements for this group were not clear and it ceased to exist after January 2006. It was not clear where its responsibilities transferred.

Serious untoward incidents

We were interested in establishing how a serious untoward incident was identified and reported. The trust's policy for managing incidents, ratified by the board in September 2004, said that the director of nursing and patient services in conjunction with the medical director, service director for the relevant care group and appropriate executive lead would assess any potentially serious incident. If confirmed as a serious incident the director of nursing and patient services would 'instigate an information cascade'.

The minutes of the risk and governance committee in June 2006 noted a concern over the lack of clarity on reporting and managing serious untoward incidents. We were told that the likelihood of unwelcome publicity was the major factor, that there was often disagreement and that the decision could be overturned. This was sometimes a cause for concern. In the latter part of 2006, staff were consulted about a revised procedure for managing incidents.

Serious incidents should be investigated and there should be a report and an action plan. Of the 64 serious incidents declared since April 2003, the trust provided documentation for 25 (39%), in response to our request for all such information. There was a report in only 10 cases. Three of these related to power failures and three were not finalised, detailed or complete although the incidents had occurred at least six months earlier. One was written by

the clinical director of the service concerned. In the 15 other instances the trust supplied minutes, or correspondence or action plans, or sometimes a combination. Often the action plans were not finalised.

Thus, out of 64 serious untoward incidents, in only three cases was there evidence of a proper investigation and appropriate reports. Even in these instances, there was little evidence of robust root cause analysis. Most directorates took little responsibility for undertaking this work. The director of nursing and patient services and the medical director agreed that the process for investigating these incidents was not sufficiently robust. The process for investigating serious incidents was not consistent and those charged with leading the investigation were not always sufficiently impartial or objective.

We noted the case of one serious untoward incident where a patient collapsed in a toilet and staff were unable to open the door. There was a report for this incident. The report and the action plan covered in detail the work required to replace the problematic doors (although this had not been completed) but did not mention why this patient had been in the toilet in the first place, even though the patient was not meant to be mobile. We note that on that day the ward was missing a qualified member of staff.

Non-executive members of the trust board considered that they were well informed about serious incidents, though a report from the director of nursing and patient services. Several board members acknowledged however that there was no a robust process for checking that actions had been taken.

Other routes to raise clinical concerns

Clinical staff were confused about the routes for reporting concerns, other than individual incidents, and the function of the different committees.

Clinical directors could bring concerns to their monthly meeting with the deputy medical directors and the medical director. The trust was not able to provide minutes for several of the meetings. We were told that clinical directors could bring concerns to the trust's management board. There was little evidence that this happened. Some senior doctors said there was no forum at which they felt comfortable to raise their worries about the low levels of nursing staff and associated concerns about the care of patients.

Senior nurses reported they were able to raise concerns at the monthly meetings of senior nurses. However they did not feel that this often led to resolution of the issues. The minutes of these meetings were not sent to any of the meetings on risk or meetings of senior managers. The board would not have been aware of their concerns unless they had been raised by the director of nursing and patient services.

Findings of fact on systems to learn from concerns from staff about the care of patients

- National Patient Safety Agency figures showed the trust to be in the middle band of trusts in terms of numbers of incidents reported in 2005.
- CLIP (complaints, litigation, incidents and PALS) reports identified themes from complaints and incidents. These were not discussed or used effectively at the trust's management board in 2004/2005. They began to be discussed by the clinical governance and risk committee before it was superseded in January 2007 under new arrangements.
- It was not clear what criteria were used to decide when a serious incident should be reported to the SHA and how it should be managed.
- Only three out of the 64 serious untoward incidents since April 2003 had evidence of a proper investigation and a report.
- Staff had little confidence that the trust learnt from clinical incidents.
- Staff did not feel there were effective routes to raise clinical concerns.

The trust's approach to levels of nursing staff

We have seen that the number of nurses on general wards was low, and the effect that staff and patients considered this had on control of infection and care. Here we consider the trust's approach to this.

Sources of evidence

- Workforce plan
- Minutes of the trust board and nursing and clinical governance reports to the board, minutes of senior nurse meetings
- Interviews with staff past and present
- Incident reports, analysis of relevant incidents
- Ward assurance framework
- National Healthcare Commission staff surveys

Many nurses told us that they regularly reported instances of staffing shortages. An analysis of reports of incidents showed that, between June 2004 and September 2006, 485 incidents were reported that related to staffing. Two-thirds of these were at Maidstone and the most frequent wards affected were the medical wards. In the same time period, there were 1,432 incidents reported that related to medical and care of the elderly wards. Over 900 of these were categorised as patient injury. The trust had not done any analysis to see if there was a correlation between the number of reports of staffing shortages on wards and the number of reported injuries to patients.

The routine report on clinical governance to the trust's board in November 2006 showed that the trust had a higher proportion of medication incidents that were due to problems with the administration of drugs, than comparable trusts. The figures came from the National Reporting and Learning system. Administration of medicine is the process of ensuring that patients get the correct doses of the prescribed drugs at the correct time. Responsibility for the administration of medicine lies almost exclusively with nurses. Between January and March 2006, the percentage of incidents relating to administration of medicine was 78.9% at the trust compared to 58.9% in other trusts. The medical director acknowledged there was some evidence of a link between low staffing levels and medication incidents. We noted that the failure to give drugs correctly, or at all, was raised in 2006 in CLIP reports and by PALS.

There was no evidence that the trust had completed an analysis of the number of staff on the wards in relation to the dependency level of patients during the period under consideration (2004 to 2006). We were supplied with a workforce plan, but later told to ignore it. There was no formal system to match staffing levels to the dependency level of patients on individual wards.

There had been no increase in the numbers of nurses since 2003/2004. The chief executive informed us that in her first year "almost £1 million was put into nursing to bring all levels of nursing up to minimum safe levels." As shown in table 5, expenditure on the nursing workforce increased by over £3 million in 2004/2005 but this did not result in an increase in the overall number of nurses. Much of it was used in the trust's increased contribution to superannuation payments and other additional costs for existing staff. Since then the expenditure on nursing had fallen.

Table 5: Budgets, expenditure and nursing workforce from 2002 to 2007			
Year	**Budget**	**Expenditure**	**Whole time equivalents**
2002/2003	42,715,515	36,860,601	1,379
2003/2004	45,557,179	39,881,205	1,458
2004/2005	49,319,188	43,231,993	1,457
2005/2006	48,312,173	42,489,269	1,417
2006/2007	48,490,590	42,297,884	1,355

Overall the number of whole time equivalents had fallen since 2002/2003. The number of beds had also reduced and this had resulted in some fluctuations in the average number of nurses per bed. In 2006/2007 it was 1.52 nurses per bed – the same as in 2003/2004.

Traditionally most wards at Kent and Sussex Hospital were more generously staffed than their counterparts at Maidstone. We were told that it was not possible to increase the numbers at Maidstone because of the financial constraints.

Although it was known by senior managers that the wards had low staffing levels, they were not exempt from financial pressures. In the March 2006 report to the board by the director of nursing and patient services, it was stated that the continued focus on maintaining budgetary control in nursing and midwifery expenditure across the trust had resulted in nursing budgets being broadly in balance. This was despite considerable costs arising from staffing escalation beds. It was noted that the "under spends against nursing budgets were helpful in managing expenditure pressures elsewhere in clinical directorates."

Evidence from interviews and minutes of the trust board showed that some senior managers and directors at the trust did not accept that the low number of nurses on wards was a major influence on the provision of care. Some of them did not make a link between low numbers and substandard care, or were simply not aware that staffing levels were low in the trust, compared with other similar trusts. As mentioned previously, in 2005 the poor comparative position on staffing was not drawn to the attention of the board. The explanation offered for poor care was weak management of the wards, although little convincing evidence was offered in support of this assertion. The trust had implemented a programme of training for ward managers, which was considered helpful by some.

The board received regular reports on nursing. At the meeting in May 2005 the report on nursing contained a number of extracts from complaints made by patients that concerned poor standards of care for older patients. The minutes recorded that the continued pressure to make savings had affected the situation. The chief executive informed the board that ward sisters of the wards concerned had been removed for not maintaining proper standards.

We have already noted that in December 2005 the trust introduced a scheme to monitor and improve care on the wards - the ward assurance framework. Ward managers assessed their ward's performance against the framework.

The nursing report to the board in March 2006 outlined the risks of the failure to provide good standards of nursing care, as a result of cutting expenditure.

In September 2006 the director of nursing and patient services presented the report on clinical governance to the trust's board. The minutes recorded that the problems in the quality of care were not because of the low number of nurses. Later in that meeting, however, it was acknowledged that the low establishments on some wards posed a risk

when managing highly dependent patients with *C. difficile*.

At the meeting of senior nurses in September 2006 it was noted that A&E nurses present at the August meeting had felt that the chief executive and director of nursing and patient services did not understand the pressures that nurses were working under. The minutes of senior nurses' meetings did not go to the management board or the trust's board. We noted that in the 2005 and 2006 national staff surveys, the trust's score was in the highest, that is, the worst, 20% of trusts in the country on the questions that related to the extent to which staff workload was larger than they could cope with. Similarly the trust had been in the highest 20% for work related stress until 2006, when the proportion fell significantly, as it did nationally.

The minutes of the trust's management board in October 2006 noted that the solution to poor nursing standards was not related to additional resources, although no justification was given. An explanation given to us was that the management and leadership of wards needed to improve.

The report on nursing standards to the trust board in November 2006 demonstrated that the number of whole time equivalents had declined since 2002/2003. The report again stated that many of the concerns about poor care were not related to the low number of nurses. However it acknowledged that additional resources might "create the possibility of improved standards and patient outcomes" and the board was asked to support a budget setting process that ensured that nurse staffing in the trust moved towards national benchmark levels.

Findings of fact on the trust's approach to levels of nursing staff

- There had been no comprehensive review by the trust of staffing levels or determination of minimum staffing levels.
- There was little analysis of the links between different types of incidents and there was little evidence that incidents were rigorously investigated.
- The numbers of nurses on the medical and surgical wards had not increased since 2003/2004.
- In several reports to the board, the minutes noted the view that the number of nurses was not the major cause of problems with the quality of care. The ward assurance framework was introduced in December 2005.
- The board noted in September 2006 that the low establishments on some wards posed a risk when managing highly dependent patients with *C. difficile.*
- The trust had not analysed poor care in relation to staffing levels to see if there was a connection.

Systems to investigate and learn from complaints from patients and relatives

Sources of evidence

- Acute hospitals portfolio data collection 2004
- Complaints information and sample provided by the trust
- PALs reports, CLIP reports
- Interviews with patients and relatives
- Interviews with the board and staff past and present
- Information on second stage complaints

The Healthcare Commission's acute hospitals portfolio review in 2004/2005 identified the trust as having a high number and rate of complaints. Out of the 199 acute hospital organisations reviewed, the trust was in the highest group for complaints with a rate of 26.3 complaints per 10,000 beds. The typical (median) number was 3.88 per 10,000 beds. The trust had the highest rate of complaints in the group of 40 hospitals described as "large outside London." As mentioned earlier, it also

had the highest rate of clinical complaints in the same group.

Our analysis of the complaints received in the emergency care directorate between August 2004 and September 2006 showed that the most common type of complaint was about the standard of care received. This directorate included medicine. There were more complaints about care received at Maidstone than at Kent and Sussex. The number of complaints per 10,000 bed days was 4.36 at Maidstone and 3.77 at Kent and Sussex. Similarly, the Patient Advice Liaison Service had more people raise concerns about Maidstone than the other hospitals.

Many complaints covered more than one issue and relevant aspects of care that generated concern included problems with medication, lack of cleanliness and hygiene, care around the time of death, poor infection control, poor support with nutrition, poor pain relief, mixed sex wards and pressure sores.

The non-executive directors did not participate in any committee which considered complaints other than the clinical governance committee, at which general information was presented. Staff were concerned that reports that went to the board concentrated on statistical matters and it was not possible for board members to identify the content or seriousness of individual complaints.

A non-executive director who left the trust in April 2006 commented that he missed the insight into care which having a special role as complaints convenor had given him in the past.

CLIP reports identified concerns about the handling of complaints. Responses were often a description of the hospital stay, frequently technical and often with justifications from the staff concerned. They did not usually involve a robust impartial investigation of the complaint. The poor quality of documentation often made the investigation difficult.

Some directorates were reported to be better than others at investigating complaints. The process in the medical directorate was not highly regarded and consultants were not seen as committed and involved. Some wards appeared to have better systems than others. Some ward managers reported that they rarely saw the outcome of complaints or received feedback.

In July 2004 the Healthcare Commission became responsible for reviewing complaints that had not been resolved locally, and the local role of convenor was abolished. By November 2006, the Healthcare Commission had received 90 such requests relating to the trust. Analysis by the investigation team found that the trust had the second highest number of reviews of complaints when compared with other large acute trusts outside London. We analysed 13 of these complaints that appeared to be about matters relevant to the investigation. These complaints contained 47 issues, of which 30 (64%) had been sent back to the trust for further action. This suggests that there was scope to improve the handling of complaints.

Most of the staff interviewed had little confidence that that there was a system in place to draw out learning from complaints. Most medical wards did not have regular meetings. The care group or directorate of which medicine and elderly care was a part did not discuss complaints on a regular basis. The general view was that lessons were not learnt.

Documentation and record keeping at the trust

Sources of evidence

- External auditors report
- Minutes of governance and risk committees, operational risk committee
- Trust's audit of case notes
- Medical directorate performance report
- Correspondence with the trust

In the external auditor's review of data quality in 2004/2005, ward records were assessed and

found to be weak. The review found that the trust was not following good practice in record keeping.

In September 2005 it was noted at the clinical governance and risk committee that concerns about poor documentation emerged frequently in respect of litigation, and in July 2006 the operational risk committee recorded again that poor documentation was a recurring theme among legal claims.

It was reported in January 2006 at the operational risk committee that test results were not always available in medical records and in one case separate results from three different people were found in the medical notes of another patient.

An audit of clinical notes in April 2006 found that only one-third of medical notes and half of nursing notes were legible.

The report on the performance of the medical directorate in June 2006 found that half of the wards could only show some evidence of achieving the standard in documentation and 23% showed little or no evidence.

We noted that 10% of case notes could not be found by the trust for the case note reviews.

An important aspect of the investigation involved the analysis of the trust's documents, which were requested by the investigation team. However the trust was unable to provide complete sets of minutes relating to several committees and groups such as the clinical directors' board.

Findings of fact on systems to learn from complaints and on documentation

- The trust had high rates of complaints about the standard of care and a large number of complaints were referred to the Healthcare Commission for review.
- Non-executive directors were given little information on which to gain an understanding of the nature of complaints about the care of patients.
- Staff were not confident that lessons were learnt from complaints.
- The trust had poor documentation and the poor quality of clinical records was a recurrent theme in legal claims.

The system for governance

Sources of evidence

- Minutes of meetings of internal trust committees including the board and the various committees to do with risk and governance
- Clinical governance reports
- Interviews with the board, governance and risk staff, clinical directors, general managers, the infection control team, and other staff past and present.

During the time of the outbreaks, the director of nursing and patient services had the lead responsibility at executive level for governance and risk. However the overall arrangements and accountability for governance had changed several times before this, and were to change again. The director of nursing and patient services was also the director of infection prevention and control. He chaired many of the governance related committees and was seen by colleagues to be conscientious, extremely hard working and well intentioned, but overloaded. He was not generally regarded as effective at championing governance or solving problems.

Until January 2006 a report on serious untoward incidents went regularly to the patient safety group. However there was no overview of lessons learnt or identification of wider concerns. The trust's governance and risk committee received regular reports from each directorate. However there was poor attendance by clinical directors at the committee. At the trust's management group, which clinical directors attended, the minutes of the meetings and the views of staff confirmed that the committee rarely discussed the governance reports it received. Much of

the focus was on reconfiguration of services, the private finance initiative (PFI), financial matters and service agreements.

Similarly, the minutes of the trust's board indicate it was dominated by finance, targets, the PFI and reconfiguration. Although there had been repeated reports for four years or more indicating poor care on the general wards, there was little evidence that effective action had been taken. Various initiatives including the ward assurance framework had been introduced but many of the same concerns and complaints kept being raised.

Matters delegated to the directorates were not policed or monitored and there was little effective infrastructure below the governance and risk committee to deliver change. There was little learning across directorates or central collation of information relating to clinical governance. It was not possible to identify discussion at the trust's governance and risk committee or the board of the strategic matters identified by incident reports, claims or complaints.

Findings of fact on governance

- There had been considerable change in the responsibilities and structures relating to governance.
- The structure was complex and did not succeed in ensuring that serious operational problems and risks to patient safety were identified and assessed at the higher levels of the trust, and effective action taken.
- Clinical directors failed to attend the governance and risk committee, which provided little leadership to, or monitoring of, the directorates.

Involvement of the board in the control of infection

Sources of evidence

- Minutes of meetings of internal trust committees including the board, and reports to the board, minutes of Governance and Risk Committees, Strategy and Policy committee, and Infection Control Committee
- Interviews with members of the board and with past and present members of staff
- Interviews with local voluntary and statutory organisations
- Annual reports on infection control
- SUI report
- Trust statements

The chief executive of a trust carries legal responsibility for the quality of care provided by the trust and for taking the necessary steps to control infection. The board has collective corporate responsibility for the management of the trust. We wanted to discover the extent to which the board had discussed the outbreaks of *C. difficile*, the risks to patients and the actions being taken.

The board had received annual reports on infection control since November 2003, when the report for 2002/2003 was considered. At that time it was noted that the infection control team was understaffed but that "national requirements were being met". The team had asked for direct input to the board. The medical director undertook to represent the team's view.

As previously noted, there was no paper taken to the board about the role of the director of infection prevention and control (DIPC), or announcement or consideration by the board of the appointment of the director of infection prevention and control. None of the non-executive directors, including three who took up post in mid-2006, had had any training or guidance on their role in assurance of infection control, none took any special responsibility for this area and it had never been proposed as an area of special interest for non-executives. The chief executive's assertion that the non-executive directors had attended the training programme provided by the SHA was not substantiated except in one instance.

When the 2004/2005 report on infection control was presented in November 2005, the non-executive directors asked that future reports should include a league table and a range of indicators to demonstrate how well the trust was performing. There was no information to emphasise the comparatively high rates of *C. difficile*. The report for 2005/2006 still did not highlight the poor relative performance on *C. difficile* levels. The board noted with concern poor attendance by representatives of other care groups at the infection control committee.

Other than receiving the annual reports, the board heard about aspects of infection control. The director of nursing and patient services informed the board in January 2005 about an outbreak of norovirus, a highly infectious condition causing vomiting and diarrhoea. At a presentation to the private part of the board meeting in July 2005 on improving the experience of patients, it was noted that patients were moved frequently between wards, increasing the risk of cross-infection. A new model of care was proposed as the solution to this and other aspects of care for patients.

The members of the infection control team were not invited to make any presentations to the board on healthcare associated infection or *C. difficile*. One of the microbiologists gave a presentation on *C. difficile* in February 2007 to the strategy and policy committee, which is not held in public.

In January 2006, when the trust had at least 38 patients with *C. difficile*, the board was informed by the director of infection prevention and control that the trust was "on target for MRSA and that *C. difficile* was improving, although more needed to be done".

In the private part of that meeting, the board learnt about a patient who was infected with a virulent strain of *C. difficile*. It was not declared as a serious untoward incident, but the director of infection prevention and control advised that "an incident review will be conducted into the case." This did not happen. The director of infection prevention and control was unable to explain why this was the case. He was not sure whose responsibility it had been. No action was taken to establish whether the infection control team had taken any action in response to the virulent strain.

The trust's board was not informed of the visit by the Department of Health's support team in September 2006, to help trusts reduce MRSA, nor of its findings.

The mandatory Health Act 2006: Code of practice for the prevention and control of healthcare associated infections (the hygiene code) was introduced in October 2006. The executive did not take a paper on this new legislation to the next meeting of the trust's board in November, despite the fact that the trust had had two serious outbreaks of *C. difficile* in the previous 12 months and a Healthcare Commission investigation was underway. Every trust was required to analyse the extent of their compliance with the code and identify shortcomings. This 'gap analysis' was presented to the board at the end of March 2007.

The board and the 'outbreak'

The outbreak of *C. difficile* was declared to the health protection unit (HPU) and the SHA on 12 April 2006. It was discussed at the private part of the next board meeting on 30 May 2006, but not in the public part. It was noted that the outbreak should have been identified sooner. The discrepancy in the advice of the microbiologists was recorded. The board did not receive an action plan for dealing with the outbreak. The nursing report to the private session stated that the outbreak was under control and that every patient had received "the best care, in the best place in the ward." We note that this assertion is not supported by evidence that the Healthcare Commission has found about the clinical care of patients and the practice in infection control.

The press release confirming the outbreak was issued on 23 June 2006. Reference has been made earlier to the concerns of the HPU about the delay in informing the public.

The outbreak was discussed at the public meeting of the board on 25 July 2006. It was noted that a sixth patient had died. The outbreak was reported to be under control with 'fewer incidence than normal'. The nursing report to the same meeting mentioned that there had been four probable deaths. This paper also stated that the affected patients were on Whatman ward. There was no indication that bays on other wards also had patients with *C. difficile*.

There was no presentation from any member of the infection control team.

Families of some patients who had died from *C. difficile* tabled a number of questions at the July 2006 trust board meeting. The trust stated that the antibiotic policy had been reviewed in line with the correspondence from the Chief Medical Officer and the report published by the Healthcare Commission and Health Protection Agency (HPA) in December 2005. This was not a comprehensive answer as no action had been taken until the start of the outbreak and antibiotics were only removed from the wards on 20 June 2006.

In response to another question, the trust agreed that cohort nursing of patients should have happened earlier. The trust reported that the microbiologists had rewritten the procedure for when to isolate or nurse patients in cohorts. Although we requested this document several times, we did not receive it until the chief executive sent it to us in June 2007. The trust told us it was produced on 4 July 2006 and revised on 12 July. It was not on the trust's intranet in January 2007, with the other relevant policies, nor known by staff.

The explanation given to a member of the public about why the outbreak was being discussed in the private part of the meeting was that named patients were to be discussed. There was no evidence of such a discussion.

In the private part of the meeting, the minutes record that cases of *C. difficile* at Kent and Sussex "have risen to outbreak levels." This had not been added to the information in the open part of the board that the outbreak at Maidstone was "under control."

Also in the private part of the meeting the board received a paper entitled *Learning from the Clostridium difficile Outbreak*. This was mainly a reflection on the outbreak and its handling. The column headed "actions" contained broad objectives, with no deadlines for completion or named responsible person. The board was again assured that the trust had worked with, and sought guidance from, the HPU at every stage and that the HPU was happy with how the trust had managed the outbreak. There was no indication to the board that there had been aspects of the handling of the outbreak that had caused the HPU to write formally to the trust expressing concerns about the missed earlier outbreak, the failure to restrict antibiotics and the need to keep the enhanced infection control measures in place.

The board was also informed that the trust had introduced "a comprehensive on site training programme for staff working on infected wards." We could not find any evidence of this. The minutes note the action of the chief executive in requesting an external investigation with the strategic health authority.

The board was informed the outbreak could possibly have been diagnosed in October 2005. It was agreed to update the relevant policies on infection control. The policy for handling outbreaks was reviewed and endorsed by September 2006 but other policies including the management of *C. difficile* were not.

At the public meeting of the board in September 2006, the updated report on *C. difficile* acknowledged that the first outbreak began in October 2005. This was attributed primarily to the absence of the leading infection control nurse through sickness. This nurse was ill in the summer and retired in October 2005. Another factor was said to be the failure to record data contemporaneously. The paper noted that data provided to the board was "not in a format that allows it to fully consider implications."

The board received an updated report on lessons learnt and another paper comparing how the trust had managed the outbreak with

the approach at Stoke Mandeville. The minutes noted that a "detailed time limited action plan will be presented to the board."

The paper comparing the trust with Stoke Mandeville was critical of the trust (Maidstone and Tunbridge Wells) in a number of areas. For example, it acknowledged the failure to spot the outbreak in the autumn of 2005 and the tardiness in the implementation of the restricted antibiotic policy. The paper noted feedback from patients and families that indicated poor and inconsistent compliance with infection control procedures especially hand hygiene. The similarities with Stoke Mandeville, in terms of staffing levels and poor communication with patients and relatives, were acknowledged.

Although this paper to the board stated that the advice of the infection control team was "central to the management of second outbreak," we noted that the advice had not always been followed. A ward was not dedicated to isolation until four months after the start of the second outbreak, although the report stated that an isolation ward was identified and established within days of start of the outbreak.

The minutes of the meeting also record that the director of infection prevention and control (DIPC) assured the board and public that all the recommendations within the report of the Healthcare Commission's investigation of outbreaks of *C. difficile* at Stoke Mandeville Hospital, had been implemented by the trust. We note that the accompanying paper did not make this claim, and there is considerable evidence to the contrary. For example:

- there were still examples of dirty commodes, showers, etc.
- responsibility for infection control was not in the job descriptions of all relevant managers
- training in infection control was intended to be mandatory but only 50% of staff had attended
- there was poor recording of fluid balance
- there was continuing concern about the privacy and dignity of patients
- documentation was poor
- the trust had low levels of nurses by comparison with other acute trusts and had not acted to address this
- the structures for risk and governance were not clear, were not working well and consideration of clinical risk was not part of all major decisions.

In the nursing report to this meeting it was acknowledged that low numbers of nurses posed "a challenge when managing highly dependent *C. diff* (*C. difficile*) patients."

The board was advised that no other trust in England "has undertaken the same level of work as this trust to identify and address issues relating to *C. diff* and MRSA." The Healthcare Commission does not accept the trust has evidence to substantiate this assertion.

A member of the public queried whether improvements in nursing care had happened and said that wards were short of commodes. The director of infection prevention and control responded that more commodes were available on the wards. However, we observed that condemned commodes were still being used on some wards five months later.

The board was told, and it was stated in press releases, that the trust had requested the investigation. This was not the case. The original request came from the SHA. When the proposal was being put forward to the Department of Health the trust asked for it to be put forward as a joint request.

Findings of fact on the involvement of the board in the control of infection

- The board received annual reports on infection control. These did not highlight the high rates of *C. difficile.*
- The board considered other matters relating to infection control from time to

time. However, members of the infection control team were not asked to make any presentations to the board on *C. difficile.*

- There was no follow up to the incident about a patient with *C. difficile* that was reported to the board in January 2006.
- The trust's board did not receive a paper in November 2006 informing them about the hygiene code. The board received a progress report and analysis of compliance with the hygiene code in March 2007.
- The board did not receive a detailed action plan for the outbreak but received a report on lessons learnt and another comparing the trust and Stoke Mandeville.
- The board was not made aware of the concerns of the HPU about the number of deaths, infection control, antibiotic prescribing and media handling.
- The outbreak was first discussed in public at the board meeting on 25 July 2006.
- On several occasions the board was given information that was not complete or not accurate.
- Families were not given a complete picture on changes to procedures, and when action had been taken on antibiotics.

Strategic priorities

Here we look at the relative priority given to infection control compared with other objectives, and the leadership at the trust, in order to establish the context in which control of infection operated and the background to the outbreaks.

Sources of evidence

- Interviews with the board, staff past and present, and others in the health community and external organisations
- Minutes of meetings of internal trust committees including the board, executive team
- Healthcare Commission's surveys of NHS staff for 2003-2005, and inpatient survey for 2006
- Clinical governance report 2002
- Correspondence between the trust and the HPU
- Press statements
- Statements by the trust

The trust faced a challenging agenda after the merger in April 2000. Senior staff were keen to stress the importance of this and its effect on what had been achieved to date. As well as bringing together two disparate organisations, the leaders had to deliver a major reconfiguration of services and get agreement for a new hospital, funded by a private finance initiative. In the meantime, services at Kent and Sussex, and parts of Pembury, had to be delivered from poor and in part dilapidated buildings. This was against a background of demanding government targets and a health economy with significant financial problems. The trust moved from a performance of zero stars in its first year, to one star for two years. In 2005/2006 it was rated "fair" by the Healthcare Commission for quality of services when it "almost met" the core standards. It was deemed "poor" for use of resources.

Style of leadership at the trust

For an organisation to deal effectively with major outbreaks of a healthcare associated infection alongside other competing priorities, effective leadership is essential. We considered the style of leadership and managers because of its effect on the culture of the organisation, the priority given to control of infection, the identification of and response to the outbreaks, and the information given to the public.

There was a shared perception amongst staff that we spoke to, that the trust was strongly driven by the achievement of financial balance and targets. Senior staff acknowledged the scale of challenges faced and the progress that had been made.

The views of the chief executive's leadership were mixed. Many welcomed her strong, determined leadership and thought that progress would not have been achieved without her style of leadership. They commented positively on the extent of her knowledge, her high standards and how hard she worked. A few described her as supportive.

Many however, including senior managers past and present, were critical of her style which some described as "autocratic" or "dictatorial." There was widespread acknowledgement that the chief executive was difficult to challenge.

The style of management and leadership was said by many staff to be reactive. This was borne out in the trust's handling of the outbreaks and the frequent changes to roles, responsibilities, structures and committees. Some managers including senior managers described what they considered to be interference in their work and multiple changes of direction. They also reported that the chief executive controlled what went to the board. Board and management board papers were changed or withdrawn at the last minute by the chief executive. This reduced their motivation and led to staff feeling undermined. Many past and present senior managers, and other NHS organisations, felt that there was little delegation.

Three of the non-executives were new and by their own account, "did not know what they did not know". The chief executive, with her nursing background, was very much in control of the information that went to the board. Although the non-executives would challenge particularly about the PFI and finance, they were generally less able to challenge effectively on matters to do with the care of patients. In part this may have been because relevant information, such as the low staffing numbers, or the requirements of the hygiene code, was not given to the board in a timely way. This may also explain why the non-executives were poorly informed about the results of the national surveys of inpatients, including that in 2006, the trust was rated in the worst 20% on overall standard of care.

The minutes of the executive team suggested that the main focus of the executives was also on finance, the PFI, service reconfiguration, service level agreements and, latterly, foundation trust status. They rarely discussed the quality of care and only focused on infection control once it was known that there would be an investigation by the Healthcare Commission.

Management culture

The Commission for Health Improvement in December 2002 was concerned that there was a high turnover of managers at all levels. We noted that the high turnover had continued, particularly of directors. Between September 2002 and September 2006, for example, five people attended the board in five roles as director or acting director of finance. There had been at least six changes in the role of director of operations, or its equivalent. Some of this change was associated with the earlier investigation into waiting lists, but most of the turnover happened after the arrival of the current chief executive in November 2003.

Even when executive directors remained in post, their portfolios changed. Many senior staff commented on the extent and frequency of change in roles, responsibilities and structures, and argued that the degree of change meant lack of clarity about who was accountable for areas of work. Clinical staff reported having worked with four or five different managers in as many years. The consensus was that the degree of change had been damaging.

Despite meeting on a weekly basis, there was little evidence of an executive team that worked collaboratively to address problems. The executive team noted in April 2005 that they needed more confidence in being able to challenge each other more proactively. A report by Ernst and Young in May 2005 said the team was not collective or responsive. Current executive members thought the team worked well. Those who had left commented that "people kept their heads down" and the driving force was survival. They and others reported that staff generally were frightened

to speak openly and were fearful of raising concerns within the trust. They said the chief executive emphasised performance and did not tolerate failure. The chief executive stated that there was a culture of accepting personal responsibility for performance and being accountable for its success or failure.

Some senior managers reported they were managing a group of stressed managers. Managers were in fear of losing their jobs. Some staff told us that failure to achieve financial and other targets led to threats of disciplinary action. We could not establish that such action had been taken although a specific reference to potential action was recorded in the executive team minutes for November 2006. The percentage of staff experiencing harassment, bullying or abuse from colleagues or managers was above the national average in 2005, and in 2006 the trust scored in the highest (worst) 20% of acute trusts in England on this indicator.

Some senior nurses and managers described ward staff and middle managers as exhausted and downtrodden. Some nurses told us that they believed they had been blamed unfairly by the trust for the outbreaks of *C. difficile*. They said the affected wards were known to have been understaffed and staff had raised concerns about the safety of staffing levels. Morale was said to be at an all time low. The results of the Healthcare Commission surveys of NHS staff consistently found that the trust was in the worst 20% of trusts for staff's perception of the extent of positive feeling in the organisation. The score had got worse each year and in 2006 had worsened significantly. The percentage of staff in 2006 who stated that they were intending to leave the trust and look for another job showed a statistically significant increase from the 2005 survey. This figure was above the national average for acute trusts on this indicator.

Most staff we asked did not perceive the non-executives as a conduit for raising concerns even where the non-executives had a formal role. Few of the non-executives we asked about this, were aware of the policy for whistle-blowing.

Many of the consultants that we spoke to said they were not involved in decisions that were made by managers in the trust. They said there was an absence of real discussion and they didn't feel listened to. The medical director took over responsibility from his predecessor in January 2006. He told us he was shocked when he first arrived that consultants felt so disenfranchised, and was keen to change this. Until recently, clinical directors did not have dedicated time, released from clinical work, to all meet together at set times with senior managers.

Senior nurses said that the director of nursing and patient services listened to his professional colleagues and was personally supportive. However the majority we interviewed were not confident that he represented the concerns of nurses to the board, particularly about the low staffing level and the pressure on staff.

Finance and the effect of financial decisions on healthcare associated infections

The chief executive, chairman, most non-executives and some senior staff were keen to stress that finance did not dominate and that investments had been made in services other than those subject to this investigation. The perspective of most staff, including some senior staff however, was that the overwhelming priority at the trust was finance. The other main driver was seen to be national targets, particularly the A&E target. A senior manager told us "if anyone says that the top priorities aren't money and targets, they're lying."

The minutes of the executive team in November 2006 noted that "each directorate has to break even and if plans are not acted upon and implemented then the disciplinary policy will be applied." In January 2007 the minutes recorded that budgetary responsibilities were at the "top of all agendas" for directorates.

In part to save money and to meet the level of activity commissioned by the PCT, the trust had decided to reduce the number of beds. External management consultants had advised the trust that reducing the number of beds was feasible if the trust achieved changes in aspects of care such as reducing lengths of stay. The number of beds was reduced before this happened and before any reduction had occurred in the number of admissions to hospitals, which the PCT had committed to deliver.

The reduction in beds put additional pressure on the existing capacity and the result was that high bed occupancy levels persisted. At times the number of beds was not sufficient, and beds in escalation areas had to be opened up. Often these were in areas that were not appropriate as they had beds too close together and had poor washing facilities. The trust was reluctant to close the beds in the balcony bays at Kent and Sussex Hospital, because of the reduction in capacity and loss of income. The beds were close together, again a risk to the control of infection.

Another area where financial restrictions played a part in increasing the potential risk of infection was the effect on staffing levels. This has already been described. Some senior staff were keen to stress their view that the number of nurses was not the key factor related to quality of care, although we found considerable evidence of its effect. The expenditure at the trust on nursing staff had been consistently below budget since 2002, by an average of £6 million. The need to keep finances in check was seen to override the pressure on front line staff and the effect on patients.

Before the outbreak, there had been longstanding and well publicised concerns about the cleaning, some of which the trust had addressed particularly at Kent and Sussex Hospital. Once the outbreak had been declared the trust responded by increasing the hours that cleaners worked.

Many staff complained to us about the lack of supplies and equipment, and staff and relatives were concerned about shortages of equipment, leading to sharing between infected and non-infected patients. When there was a small cluster of new cases of *C. difficile* at Kent and Sussex Hospital in January 2007, it was noted in the minutes of the outbreak committee that because of financial restrictions, there was a delay in obtaining supplies, even urgent ones. The trust stated that this was not the case.

The 1999 Health Act introduced a statutory duty of quality as a counterbalance to the financial duties that already existed. This duty requires organisations to have robust arrangements in place for clinical governance in order to safeguard patients. As the senior manager responsible for the day to day running of the trust the chief executive is required to discharge this duty. The duties of finance and quality are not mutually exclusive but the evidence uncovered during this investigation suggested that there was a greater focus on finance at the trust.

Effect of targets on control of infection

Many staff told us about the consequences of targets, in particular the target that no patient should be in A&E for more than four hours. Some staff told us senior managers had given the A&E target much greater priority than the control of infection, including at the time of the outbreaks. The overwhelming view from staff was that the A&E target was a huge priority and had been largely responsible for the moves of patients from ward to ward, with patients often being sent or moved to inappropriate areas. The movement of patients increases the risk of infections being transferred from one patient to another, and we have already noted that there were incident reports of poor handovers of patients.

One senior manager said that because of the other pressures and 'over-heating' in the trust, the A&E target was delivered at the price of chaos elsewhere in the system. The trust achieved the target for patients to remain in A&E for less than four hours in three of the four quarters in 2005/2006, but failed to do so from July 2006.

Openness and transparency in handling the outbreaks

Members of the board described the board as "open" and once the outbreak was publicised, the board welcomed questions from families of those who had had *C. difficile*. The director of nursing and patient services provided support to families of patients who died at the trust from *C. difficile*. However, transparency to the public did not appear to have been a priority in the first two months after the outbreak was declared in 2006. Local organisations did not feel that the trust had been open about the outbreaks until the media became involved.

The chief executive told us that the only disagreement between the trust and the HPU was over "the press release that happened after the outbreak was declared" and that the disagreement "was around deaths." However the HPU wrote to express three other concerns. These were about the missed earlier outbreak, the failure to restrict antibiotics and the need to keep the enhanced infection control measures in place. The non-executive directors were not informed of these.

The chief executive also assured the board on several occasions that the HPU were entirely satisfied with the handling of the outbreak. The Healthcare Commission learnt that this was based on asking the HPU representative at each outbreak meeting whether there was other action the trust should be taking. At the time the representative based their judgement on information provided by the trust and was not aware of the details of the arrangements for isolation and care of patients.

In the chief executive's letter to the HPU on 12 June 2006 it was claimed that the outbreak in the trust "has now gone" and "current Clostridium difficile levels are less than the usual background levels." The first of these statements was premature and the second was inaccurate. The number of new cases in Maidstone Hospital in May was 39, and in June it was 31, still substantially higher than the background level of around 24 cases per month.

Senior staff commented that the chief executive communicated well with public and the media. Some senior clinicians and managers, and external stakeholders however, remarked upon the degree of 'positive spin' used by the trust and in particular the chief executive.

The Healthcare Commission's own experience of the trust's approach to the investigation underlined some of the concerns expressed about the extent of openness in the trust, the accuracy of statements made and of information provided.

These concerns included:

- two months elapsed before a press release was issued
- the inference that the outbreak was due to the admission of patients who had already contracted *C. difficile* outside the hospital, rather than acquired it after admission, was incorrect
- press releases in June 2006 did not mention the significant outbreak in Kent and Sussex at that time
- statements that the outbreak was "over" were premature
- the assertion that the only disagreement with the HPU was over the number of deaths
- the counting of deaths only in the definite category in press releases, particularly once the report into the outbreaks at Stoke Mandeville was published. The trust reported probable deaths as ones in which "*C. diff* was not the main cause of death"
- the disorganised approach to the review of deaths
- the information given to the Healthcare Commission that no patients had died from *C. difficile* between April 2004 and March 2006

- the statement that the trust had initiated the investigation
- some of the information given to the board about the handling of the outbreak and some responses made to relatives at meetings of the board.

As part of the response to the draft report, the trust stated that the Healthcare Commission relied on minutes of the trust's board which were not always accurate. The inaccuracies were not corrected at the following meeting. The Healthcare Commission notes that these minutes are a matter of public record.

Despite asking the trust at our first meeting with them to inform the Healthcare Commission of any outbreaks of *C. difficile* and any other serious incidents, there were two examples where we learnt about an infectious outbreak from other sources and there were two other relevant matters in the press that the trust did not tell us about. We understood it had been agreed that the trust would share any press releases regarding the investigation or outbreaks of *C. difficile* with the investigation team prior to their release, but this did not happen.

Findings of fact on strategic priorities and leadership

- The trust had many challenges, including getting agreement for a new hospital, funded by a private finance initiative, and a major reconfiguration of services.
- The leadership was seen by staff as giving top priority to the PFI, finance, access targets and the reconfiguration of services. The priority given to finance and access targets had an effect on the control of infection.
- Views of the leadership were mixed; the chief executive was seen as strong, but also by many as reactive and difficult to challenge.
- The chief executive controlled what the board saw. Some information presented to the board was incomplete or inaccurate, making it more difficult for non-executives to perform their role to scrutinise and challenge on matters relating to the care of patients or infection control.
- There was a high turnover of senior managers, accompanied by change of roles, responsibilities and structures, which staff considered had been damaging.
- The trust was in the highest (worst) 20% of trusts for staff reporting harassment, bullying or abuse from colleagues or managers.
- The trust was in the worst 20% of trusts reporting positive feeling among staff.
- Many consultants told us they felt insufficiently involved in decisions made by managers.
- Giving information to the public was not a priority during the first two months of the outbreak in 2006.
- Some information provided to the board, the public and the Healthcare Commission was incomplete or inaccurate.

Developments since the investigation was announced

This chapter looks at what has happened since the investigation was announced in September 2006.

Improvement of facilities, the environment and equipment

The Patient Environment Action Team (PEAT) 2007 results scored the physical environment across all three sites at the trust as acceptable. Although this is not an improvement on the 2006 scores, it demonstrates consistent performance by the trust.

In 2005/2006, the director of infection prevention and control (DIPC) was allocated an extra budget of £50,000 to reduce the level of healthcare associated infections within the trust. We have not been provided with complete details of how this money was spent, but understand that it was principally used to fund a new computer system for the laboratory and to replace commodes.

In February 2007, we wrote to the trust to raise the issue of the close proximity of beds at Kent and Sussex Hospital, particularly in the balcony bays. In response the trust implemented an interim solution (i.e., before the opening of the new hospital) to reduce the number of beds in these areas from six to four. Beds have been removed from three wards (7, 8 and 11) which have each had a new sink installed and wards 8 and 11 have new macerators. It is the intention of the trust that similar actions be applied to ward 10. In addition to this five wards have been subject to deep cleaning and two others are scheduled to have the same treatment.

Hygiene code

The Healthcare Commission carried out an unannounced inspection at the trust to check compliance with the Health Act 2006: Code of practice for the prevention and control of healthcare associated infections (the hygiene code). The report of this inspection is to be published shortly.

Clinical care of patients

We wrote to the trust in February 2007 with our initial observations from the case note reviews. The trust responded that a number of areas had improved and that:

- there had been improvements in the quality of case notes and that the audit department from April 2007 would increase the scope of the audit of case notes to include key areas of important clinical information
- the trust had continued its programme of infection control audits
- the trust was committed to the development of a unified nursing and medical patient record
- it was now standard practice that patients with diarrhoea would automatically have stool specimens sent by nursing staff for examination without waiting for confirmation from medical staff
- it had discussed with gastroenterologists and colorectal surgeons our concern about the lack of active investigation of some patients with symptoms of deterioration. Relevant clinical staff were working together to make improvements, and draft guidelines have been developed for the management of *C. difficile* and for pseudomembranous colitis

- surgical, medical and infection control guidelines were being brought together
- the new antibiotic prescribing policy had changed prescribing practice
- a monthly audit to check the completeness of fluid charts was being undertaken by the hospital matrons
- the Bristol Stool Chart was used across the trust
- the number of pressure sores would be monitored each month and reported to both the governance and risk committee and the trust's board.

Subsequently the trust has developed a 'care pathway' for the management of *C. difficile*.

Staffing

The trust carried out a review of the nursing establishment in April 2007 and acknowledged that there was a net shortfall in the numbers of nurses compared to national averages. The board approved an increase in the nursing establishment to match those of comparable trusts. As a result of this the budget for nursing in 2007/2008 has been protected with no requirement to contribute to the financial recovery plan. Any savings from reduction in beds have been allocated to increase the funded number of nurses and improve the skill mix.

In response to the concerns about nursing care on the wards the trust introduced a mandatory training programme for ward managers on leadership. This course began in September 2006.

The trust is implementing a system to improve accountability for nursing, focused on the performance management of standards, and the ward managers responsible for these standards. This was piloted in medicine at the start of 2007.

Changes in the arrangements for governance and clinical involvement

The medical director told us he was committed to involving consultants more in making decisions about services, and taking forward the role of clinical directors. Clinical directors were allocated a specific dedicated session to ensure they all could meet together with management at a fixed time.

Following a review of governance arrangements and the production of a governance strategy at the end of 2006, the committee structure for groups that reported to the trust's board was changed at the beginning of 2007.

The clinical governance committee that had previously reported to the trust's board was abolished, in part because clinical directors had a poor record of attendance. In recognition of the need for greater clinical ownership of clinical governance, from 2007 changes were made to the trust's management committee, which reports to the board, to enable clinical directors to discuss clinical governance. The management committee changed to meet twice a month; the first meeting to focus on clinical governance, clinical quality, risk and the experience of patients, and the second meeting to focus on corporate governance and business development. The intention was to ensure that all the clinical directors attend these meetings.

The remit of the audit committee was broadened to include clinical governance. The board noted that this was the only committee at which the non-executive directors had "an opportunity to challenge, question and gain in-depth assurance to enable them to fulfil their wider remit within the trust". From March 2007 the non-executive directors began a programme of scheduled tours and walks around the trust.

Following consultation with staff the trust's procedure for the management of incidents was revised in January 2007 and states that once briefed, the chief executive or nominated

executive director ultimately decides if an incident should be declared to the strategic health authority (SHA).

Changes at executive level and of management arrangements

The director of finance left the trust in December 2006. A director of performance and delivery and deputy chief executive was appointed in February 2007. He left in June 2007 to take up a new post. In April 2007 the director of nursing and patient services and DIPC took on a new role as the director for health planning and commissioning. The acting director of operations became the acting chief nurse, and the senior infection control nurse became the acting director of infection prevention and control. The trust has informed us that a new consultant microbiologist is also being recruited who will take on the role of DIPC and that a new clinical director for medicine has been appointed.

Role of external agencies

The Health Protection Agency

Sources of evidence

- Minutes of meetings including the outbreak review group and countywide meetings
- Interviews with staff at the HPU, trust and SHA
- Correspondence and emails, serious incident and other reports about the outbreaks
- HPA website
- Audit reports

A key role of the Health Protection Agency (HPA) is to provide advice to trusts and clinicians in managing and preventing cases and outbreaks of infectious disease, including those caused by *C. difficile*. The remit of the Centre for Infections, which is part of the HPA, includes the provision of national expertise and of nationwide surveillance.

The local and regional services division of the HPA has nine regional teams that mirror the areas covered by the Government offices of the regions. Most regions have three or four health protection unit (HPUs). Staff in HPUs work closely with acute trusts, particularly their directors of infection prevention and control, and their infection control teams. The Kent HPU, part of the South East Region of the Health Protection Agency, worked with the trust during the outbreaks.

The involvement of the Health Protection Agency in the outbreaks of *C. difficile* at the trust

The HPU relied on trusts to inform it of any problems. The staff would help a trust when requested, but did not have day-to-day contact as part of their routine work.

The HPU was represented on the trust's infection control committee but attended only three meetings between March 2003 and December 2006. The unit received the minutes of the meetings.

The meetings of the Kent infection control committee were heavily focused on infection control in the community. This committee was chaired by the HPU and attended by representatives from all NHS organisations in Kent, local authorities and prisons. Its purpose was to coordinate activities and policies for the control of infection. The trust had a good record of attendance at these meetings but not at the meetings of the Kent directors of infection prevention and control (DIPCs), which was the main forum for matters to do with infection control in acute hospitals. The meetings of the DIPCs focused on MRSA, although there was discussion in March 2005 regarding the 027 strain of *C. difficile*, and control measures, for example, antibiotic prescribing policy, cleaning of the environment and equipment.

The trust DIPC attended six out of 12 meetings between June 2004 and July 2006. There was a nine-month period between May 2005 and March 2006 when no one from the trust attended any of the meetings. The HPU was not aware of this gap in attendance. There was a special meeting on *C. difficile* held by the HPU on 22 May 2006, to which all microbiologists, infection control nurses and all DIPCs were invited. The trust's microbiologists attended this.

There was no local monitoring of *C. difficile* figures by the HPU. The laboratory reports for non-notifiable diseases including *C. difficile* were reported directly to the regional HPA office. The information from the mandatory reporting system was of total cases at the trust and bypassed the local unit. The local

HPU was not initially aware of the high background rates of *C. difficile* at the trust.

The HPU undertook an audit of infection control at Kent and Sussex in July 2004 at the trust's request, following the report from an undercover BBC reporter. The findings included a large number of areas where cleaning was unsatisfactory and others that needed upgrading and painting. There was agreement in July 2004 that the HPU would undertake a follow-up audit in six months but this did not happen. The HPU told us that they offered to repeat the audit but this was not taken up.

In December 2005 the HPU received notification that two wards at Maidstone both had six cases of *C. difficile*. The HPU accepted assurances from the trust that everything was under control. Although there was no permanent senior infection control nurse at the trust at this time, the HPU did not follow this up.

The HPU relied on trusts to report outbreaks. They did not check whether the trust had revised its antibiotic policy. The HPU saw its role as primarily about supporting rather than policing trusts.

The HPU became involved in the management of the outbreak as soon as the trust declared it on 12 April 2006. The unit jointly chaired all the outbreak meetings. There was a dispute between the consultant in communicable disease control from the HPU and the trust's microbiologist at the first outbreak meeting in the morning of the 13 April. This was over the merits of the antibiotic prescribing policy and the respective benefits of concentrating on antibiotic prescribing or hygiene and cleaning. The consultant in communicable disease control said that the microbiologist was flatly against looking at the antibiotic policy at the outbreak meeting on 13 April. However the microbiologist felt the HPU was concentrating too much on antibiotics rather than other measures such as hygiene.

The HPU advised at the meeting on 13 April that the trust should issue a press statement. This was endorsed by the SHA.

At each of the meetings of the outbreak committee the HPU's representative was asked if there was anything else the trust should be doing. Generally the representative was satisfied with measures for infection control, but they based their judgement on information provided by the trust and were unaware that the arrangements to cohort patients involved more than one ward, and that the selected ward had shortcomings. The HPU was concerned about the lack of progress on control of antibiotics and advised that a stricter antibiotic policy must be actively enforced at the trust.

The HPU became sufficiently concerned about aspects of handling of the outbreak and the information provided at the outbreak meeting on 1 June, to write to express its concerns to the trust's chief executive. The information in question was the number of deaths since October 2005. The HPU had four areas of concern. These were the:

- number of deaths associated with the infection, and the accuracy of the information
- level of infection control
- implementation of the antibiotic policy
- information to the public and handling of the media.

This led to a meeting with the trust, at which it was agreed that the intensivists would undertake their review of case notes. We have already referred to our confusion over the numbers of deaths in the press releases. The HPU was also confused by the trust's figures generally on deaths and sceptical as to their accuracy. The HPU undertook its own analysis of the number of deaths and wrote a paper which formed the basis of a report to the SHA. In turn this was modified to create the request for this investigation by the Healthcare Commission.

After the outbreak was declared the HPU undertook three infection control mini audits/inspections at the trust: two at Maidstone Hospital and one at Kent and Sussex Hospital.

Findings of fact on the HPU

- The HPU relied on trusts to inform them of any problems and did not monitor local *C. difficile* figures.
- The HPU did not take any action when cases of *C. difficile* were reported to it in December 2005. It was assured, based on information from the trust, that the situation was under control.
- The HPU became actively involved in the management of the outbreak as soon as the trust declared it to them on 12 April 2006. There was disagreement between the HPU and the trust at the start of the outbreak.
- The HPU was concerned with aspects of the trusts handling of the outbreak and raised these formally in a letter to the trust's chief executive.
- The HPU was sceptical about the trust's figures on deaths. The unit undertook an analysis of the number of deaths. It kept the SHA informed about the outbreak and its concerns.

Strategic health authority

Sources of evidence

- Minutes of committees including the SHA board, the outbreak review group
- SHA board performance reports
- Correspondence
- Interviews with SHA, trust and HPU staff

Strategic health authorities (SHAs) were originally created in 2002 to manage the local NHS on behalf of the Secretary of State. 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 geographic boundaries (other than foundation trusts). This includes putting and keeping in place arrangements for monitoring and improving the quality of health care provided to individuals in the area.

The trust was part of Kent and Medway strategic health authority until the summer of 2006. Following the reorganisation of strategic health authorities in 2006 the trust became part of South East Coast SHA (the SHA).

The perception from the trust was that the SHA concentrated on finance and targets. Clinical standards were "not on the agenda." We noted that the performance reports that went to the SHA's board focused heavily on monitoring finance and targets such as waiting times.

In terms of general performance management, the action plans relating to healthcare associated infections and *Saving Lives* formed part of a performance report that went to the SHA's board. The focus, initially, was on rates of infections with MRSA, which were first included in the report in February 2005 and became a regular feature from August 2005. In June 2006 MRSA became one of the six Key Performance Indicators.

The SHA identified healthcare associated infection as one of its five improvement areas in early 2005 and held a workshop in April to share good practice and knowledge on infection control. This involved the healthcare organisations in Kent and Medway. MRSA was the principal focus of concern, but the workshop was mainly on hygiene measures.

As far as *C. difficile* was concerned, the Department of Health had established the surveillance programme but there were no targets. The mandatory reporting of *C. difficile* was first included in the performance report to the SHA's board in August 2006. Before this the SHA was not aware of the relative performance of trusts with regard to rates of *C. difficile* infection.

The trust officially notified the HPU about the outbreak on 12 April 2006. The HPU informed the SHA. The SHA's director of public health attended the outbreak control meeting on 13 April. After this the SHA relied on the HPU for information about the outbreak and did not

attend any further meetings. The SHA told us that it contacted the trust's communications manager to discuss the benefits of a press release, and was advised that this was being considered by the trust's chief executive.

The SHA did not take any further direct action to follow up the outbreak, as the HPU, where the specialist knowledge resided, agreed to keep the SHA fully informed. There were good working relationships between the SHA and the HPU. The HPU had concerns about aspects of the outbreak, including the numbers of deaths, the level of infection control, the implementation of the antibiotic policy and the handling of the media. These concerns were shared with, and by, the SHA. The SHA was instrumental in initiating this investigation.

Key findings on the SHA

- MRSA was part of the performance report to the SHA's board from August 2005, but *C. difficile* figures from mandatory reporting were not included until August 2006.
- The SHA relied on the HPU, as the organisation with the specialist knowledge, for information on the handling of the outbreak at the trust.
- The SHA was instrumental in initiating this investigation.

Primary care trusts

Sources of evidence

- Minutes of meetings of the PCTs including the board, performance review, service level agreements, clinical governance
- Reports on performance management
- Memoranda of understanding
- Correspondence
- Interviews with PCT and trust staff past and present

A number of primary care trusts (PCTs) commissioned services from the trust. The two PCTs that related most closely to the trust, South West Kent PCT and Maidstone Weald PCT, merged in October 2006 to form West Kent PCT. Before that merger there had been considerable instability in the PCTs, particularly Maidstone Weald, with a high level of turnover of senior staff.

There was a history of poor relationships and tensions, mainly relating to finance. There were delays in completing service level agreements between the trust and the PCTs. Accompanying this were long standing disagreements about the extent to which the trust had 'over-performed', that is, had seen and treated more patients than specified in the service level agreements. This was in the context of a health economy with significant financial problems, which meant that 'over-performance' could not be afforded, that is, the PCT could not pay the trust. The PCTs and the trust had to go to arbitration in 2005 and 2006 to resolve their differences.

The trust considered that the PCTs had not been effective in treating more patients in the community and hence reducing the demand for beds in acute hospitals.

These issues meant that discussions and formal agreements between the trust and the PCTs focused almost entirely on finance and numbers of patients treated. The documents and minutes of meetings show that there was very little focus on the quality of care provided. This extended to infection control. What interest there was, was on MRSA, and not on *C. difficile*. Senior staff at the PCT confirmed this picture. They felt this represented the national emphasis at that time.

Schedule 5 of the service level agreement for 2006/2007 included two indicators for healthcare associated infection – quarterly rates of MRSA bacteraemia and monthly healthcare associated infection rates. There was no evidence of any consideration of these indicators in the minutes of meetings at which the service level agreement was monitored in 2005 and 2006.

When the HPUs were established the resources available for infection control in PCTs were re-allocated to the HPUs. The PCTs accepted responsibility for effective protection for public heath, recognising the need for infection prevention and control as an integral part of all PCT planning and development. They addressed this responsibility primarily through a memorandum of understanding with the Kent and Medway HPA. The HPU agreed to maintain surveillance systems and monitor outbreaks on behalf of the PCTs. The PCTs considered that routine monitoring of infection control and monitoring for outbreaks, was the responsibility of the HPU and not of the PCTs.

The PCTs received some information that related to healthcare associated infection, such as the trust's clinical governance minutes. Other information was tabled at meetings of the Kent infection control committee and therefore only available to those who attended. The PCT was unaware of the comparatively high background levels of *C. difficile* at the trust. The PCT was unaware that staff from the targeted support scheme on MRSA at the department of health had visited the trust in September 2006.

The PCT learnt about the outbreak in April 2006 from the HPU.

Findings of fact on the PCTs

- Communication between the trust and the PCTs focused on numbers of patients treated and associated costs. There was very little focus on the quality of care.
- The service level agreement contained two indicators related to healthcare associated infection. One of these related to MRSA. These indicators were not monitored at the SLA performance meetings; nor were they monitored by the boards of the PCTs. There was no mention of *C. difficile.*
- The PCTs in Kent and Medway had a memorandum of understanding with the HPU. This included an agreement that the HPU would monitor all outbreaks.

Conclusions

This report is set against a national background of rising rates of infection with *C. difficile*. It describes a trust trying to resolve serious financial pressures, make major changes to services, introduce an independent sector treatment centre, take forward the case for a new hospital and also manage major outbreaks of *C. difficile*.

Story of the outbreaks

An outbreak of *C. difficile* infection at the trust took place between October and December 2005. Although the monthly number of new patients with the infection more than doubled, this outbreak was not identified by the trust. In this unrecognised outbreak 150 patients were affected, and a number died where *C. difficile* was definitely or probably the main cause of death. The number of new cases dropped slightly in January 2006 and then rose again in March. An outbreak was declared on 12 April 2006. From April to September 2006, 258 patients were affected. Overall, from October 2005 to September 2006 more than 500 patients developed the infection, and we estimate that there were approximately 60 deaths where *C. difficile* was definitely or probably the main cause. The number of new cases returned to pre-outbreak levels by September 2006.

First outbreak

The serious failure to identify this outbreak was in contravention of *Winning Ways* and *Saving Lives*, and it is the view of the Healthcare Commission that the director of infection prevention and control (DIPC) failed in his duty to ensure adequate surveillance systems were in place. We also identified a failure of the consultants in microbiology to raise an alert when an increase in the number of cases occurred.

Could the second outbreak have been managed better?

The management of the outbreak in 2006 initially seemed adequate to the Healthcare Commission, but closer scrutiny showed inadequacies in the management of the outbreak, influenced by the overall pressure on beds and nurses, combined with a lack of strong leadership for the control of infection.

The trust's guidelines for the management of patients with *C. difficile* were not sufficiently clear about the importance of effective isolation of patients with the infection. The trust acknowledged that its policy for responding to outbreaks was not fit for its intended purpose. The microbiologists did not agree with each other or with the health protection unit (HPU) on the importance of controlling the types of antibiotics prescribed. The trust had not reviewed its antibiotic policy following the letter from the Chief Medical Officer and Chief Nursing Officer in December 2005. The HPU had to write to the chief executive in June 2006 with its concerns that inappropriate antibiotics were still being given to patients, and eventually these drugs were physically removed from the wards on the orders of the medical director and the infection control doctor. The Healthcare Commission considers that the time taken to control the prescribing of antibiotics was unacceptable.

We note that in response to our joint survey with the HPA in 2005, 40% of trusts reported that they did not routinely isolate patients infected with *C. difficile*. The Chief Medical Officer wrote to trusts at that time to remind them of the importance of isolating patients with infections.

The infection control team was keen to isolate patients with *C. difficile* but the scarcity of side rooms made this difficult. Many patients were cared for in 'cohorts' (that is, groups) in bays on wards, but before and during the outbreak some patients with *C. difficile* were not isolated but were nursed on 'open' wards. Although the team decided to make one ward the 'cohort' ward, until late August 2006 patients with *C. difficile* were still at times being cared for in bays on other wards. In other words, it took four months to establish an isolation ward. It is our view that this was largely because of the pressure on beds and the requirement to meet financial and waiting time targets. These same pressures led to some patients moving from ward to ward. The other patients on the main 'cohort' ward were at risk of catching the infection and some of them did. This was not acceptable.

Could the care of patients infected with *C. difficile* have been improved?

From figures provided by the trust there were 1,176 confirmed cases of *C. difficile* for all age groups between 1 April 2004 and 30 September 2006, and about 500 of these cases occurred during the two outbreaks.

We reviewed the case notes of a sample of 50 patients. Overall, the experts advising the Healthcare Commission found that at least one aspect of clinical management or monitoring of *C. difficile* infection was not satisfactory in 80% of these patients.

The review found several examples of antibiotic prescribing that unnecessarily predisposed vulnerable patients to developing *C. difficile* infection. Clinical staff did not appear sufficiently aware of the possibility of patients contracting *C. difficile* infection. On a number of occasions there was a delay in sending stool samples for testing after diarrhoea had been recorded. In addition, the failure to repeat stool testing promptly when clinical symptoms persisted, probably led to delayed diagnoses.

In general, once the diagnosis of *C. difficile* was made, treatment with metronidazole and fluids was started promptly. Thereafter, however, active management and treatment of the *C. difficile* infection was often not pursued.

We would expect to see regular reviews of the infection, systematic monitoring of whether the patient was improving and a change in antibiotic treatment if the patient failed to respond. We would expect to see monitoring for the common complications of *C. difficile* infection especially dehydration and poor nutrition. Additionally we would expect monitoring of the more serious complications especially colitis, and consideration, should such complications develop, of implementing potentially life saving treatment. These aspects of care were deficient in many of the cases we reviewed.

One explanation for the inadequate monitoring and treatment of infection with *C. difficile* may be that doctors and nurses failed to appreciate that infection with *C. difficile* can in many cases become a serious and potentially life threatening illness. Another could be a lack of belief in the value of actively treating the patient for the infection and its complications. The Healthcare Commission considers that these views need to be challenged.

Patients and their families who contacted us were unhappy about much of the care received. They told us that when patients rang the call bell because they were in pain or needed to go to the toilet, their call often wasn't answered, or not in time. Particularly distressing, nurses had told patients to "go in the bed", presumably because this was less time consuming than helping a patient to the bathroom. Some patients were left, sometimes for hours, in wet or soiled sheets, putting them at increased risk of pressure sores. Some families and patients claimed that tablets or nutritional supplements were not given on time if at all, or doses of medication were missed. Some patients and relatives also reported that the information the trust gave them about *C. difficile* was poor. The trust acknowledged, and the Healthcare

Commission agreed, that the information did not stress the potential seriousness of the infection. We were told about, and observed ourselves, instances where wards, bathrooms and commodes were not clean. Examples were given of patients having to share equipment such as zimmer frames which were not cleaned between use. All of this is unacceptable.

The trust's approach to estimating the number of deaths from *C. difficile*

One of the aims of the investigation was to clarify the work that was undertaken by the trust in its analysis of deaths from *C. difficile* since April 2004. Due to poor documentation and record keeping by the trust, a lack of agreed methods and staff being unable to recollect events, the Healthcare Commission has been unable to clarify the precise nature, timing and findings of the various case note reviews undertaken by the trust.

Despite being assured by the trust that its second case note review looked at all patients who had died in hospital, had a positive *C. difficile* result and had *C. difficile* mentioned on their death certificate, our scrutiny of the information found that the review had considered less than half of these patients. The trust relied on this review to present a figure to the Healthcare Commission on the number of deaths since April 2004, but we conclude that this figure could not have been accurately determined.

The trust has been unable to confirm the date that this work was undertaken, and the basis for the information in its press release of 30 June 2006, which reported that six people definitely died from *C. difficile* during the outbreak. It was appropriate for the trust to use the Stoke Mandeville classification to try to identify the number of deaths from *C. difficile*. However the trust was mistaken in not reviewing all death certificates where *C. difficile* was mentioned and in not including 'probable' deaths with 'definite' deaths in press releases, particularly following the publication of the Healthcare Commission's report in July 2006 into outbreaks of *C. difficile* at Stoke Mandeville Hospital, which used this approach.

The number of deaths where *C. difficile* played a part

Evidence provided by the trust showed that at least 345 people who died in hospital between April 2004 and September 2006, had developed *C. difficile* infection during their stay.

In the sample of 50 patients reviewed by the Healthcare Commission, we considered that in 26% (13) it was definitely or probably the main cause of death and in 78% (39), *C. difficile* had definitely or probably contributed to their deaths.

If this sample of 50 patients is representative of the 345 people who died between April 2004 and September 2006, based on the proportion identified in our review we estimate that *C. difficile* would have probably or definitely been the main cause of death in approximately 90 of them. This is close to the estimate of 81 deaths which would be produced by applying a mortality rate of 6.9% (cited in the New England Journal of Medicine in 2005). It can also be estimated that *C. difficile* definitely or probably contributed to the deaths of about 270 people in the same period. However, some patients may have died from other conditions if they had not contracted *C. difficile*.

Death certificates

We found death certificates in the records of 74% of the sample of patients that we reviewed. For the remainder, the certificates were not filed with their medical records. 45% of the certificates in the records mentioned *C. difficile*. There was no evidence that any patients with *C. difficile* on their death certificates had not died of it, that is, there was no evidence of false positive reporting of *C. difficile* deaths.

However 20% of patients in the sample where *C. difficile* was not mentioned on the death certificate had an infection with *C. difficile* that was probably or definitely the main cause of death, and in 65% it probably or definitely contributed.

The implication of this finding is that relying on death certificates is likely to underestimate the contribution of *C. difficile* infection to the death of patients.

Arrangements for the control of infection

The individual appointed to be the director of infection prevention and control (DIPC) had insufficient understanding of the role at the outset. The DIPC failed to gain sufficient knowledge about procedures and processes in other trusts.

The DIPC was not adequately assisted by the microbiologists or his executive colleagues, who must bear some responsibility for the failure to identify the high background levels of *C. difficile* and the first outbreak, to control antibiotic prescribing, review policies, isolate patients effectively or establish good infection control practice.

Management of the infection control team was inadequate. There was no strategic direction and there was confusion over who actually managed the team. From its early days the infection control team at the trust had struggled to manage its workload, and this had an impact on the audits carried out and the effectiveness of these. When the senior nurse left, effective arrangements were not put in place to address this gap. At the same time there were significant differences of opinion between the microbiologists which meant a lack of consistency of approach. The team of nurses and microbiologists did not always work well together and did not communicate effectively with the DIPC.

Training was still not satisfactory at the time of our visits, with only half of clinical staff attending mandatory updates on infection control. It was often difficult for staff to attend training because of shortages of staff on the wards.

Policies for the control of infection were on the intranet but they were nearly all out of date and not all staff could access the intranet. The trust did not have several key policies that we would have expected. The style of notices about infection control and isolation was inconsistent and potentially confusing for staff and visitors.

Many of the buildings especially at the Kent and Sussex Hospital were old and in a poor state of repair. Many of the wards did not have sufficient storage, space in utility rooms or hand basins, making the control of infection difficult. The beds on several wards were much too close together, making it difficult to clean and seriously compromising the privacy of patients. This was exacerbated because many of the wards were mixed sex. Although there had been improvements generally in cleanliness and hygiene since the outbreak was declared, there were still some serious concerns. From May 2007, some beds were removed from overcrowded ward areas at Kent and Sussex Hospital.

When we visited in the early months of 2007 we observed some equipment that was still in use although it had been condemned, areas of contamination that were completely unacceptable and practices that created risks of generating and spreading further infection at the trust.

Rates of C. difficile infections have now fallen and generally been maintained at below the level found before the outbreaks. The senior infection control nurse has become the acting director of infection prevention and control. The trust has been visited in connection with the Health Act 2006: Code of practice for the prevention and control of healthcare associated infections (the hygiene code). The report of this inspection is to be published shortly.

The impact of low staffing levels

The medical and surgical wards at the trust had a history over at least three years of low staffing levels and a relatively low proportion of qualified nurses. The trust relied heavily on bank and agency staff, although from December 2005 the trust restricted the use of these staff.

Staff across several professions commented that shortages of nurses contributed to the spread of infection because they were too rushed to communicate with their colleagues, wash their hands, wear aprons and gloves consistently, empty and clean commodes and clean mattresses and equipment properly. This was supported by the incidents that were reported and the observations of patients and families.

The trust considered that the quality of nursing in terms of attitudes and leadership skills was a major contributor to poor care but action to address this had not been initiated until after the investigation was announced. The trust had disputed that poor care was primarily related to the number of nurses, but decided in April 2007 that it would begin to increase the number of nurses on the wards to the levels of similar hospitals.

The impact of the number of beds, high bed occupancy and escalation areas

The trust closed a number of beds at Pembury Hospital and the workload transferred to Kent and Sussex. There was no evidence of robust planning or improved efficiencies such as reductions in lengths of stay, to help the trust cope if the plans of commissioners to manage demand failed. Higher bed occupancy led to less time for thorough cleaning of beds and the areas around them, between one patient moving and another occupying the same bed. The trust's occupancy rates were consistently over 90% in the medical wards at both Maidstone Hospital and Kent and Sussex Hospital.

There were many transfers of patients between wards, with 50% of patients at Maidstone moving at least once, and many transfers during the night. Transferring patients from one ward to another increased the risk of transmitting infection.

'Escalation' areas were often opened up. These were areas in the hospital that did not usually function as general wards but which were used as such when there were no suitable beds available elsewhere in the hospital. They were often in unsuitable areas such as a day surgical ward or a previous children's ward. The bathroom facilities were inadequate, as were the 'dirty utility' rooms, since they were not designed for ill or adult patients. When they first opened, cleaning and laundry services were not in place, and in one case the ward did not have a computer. It took time to organise a full pharmacy service and some patients did not receive adequate pain relief. By definition for these areas there were no funds for dedicated staff, and at least initially they were staffed almost entirely by bank or agency nurses, bringing little continuity of care. Staff were moved from other wards and expected to care for patients with unfamiliar illnesses and conditions. Many of these factors increased the risk of transmission of infection.

The management of clinical risk

There had been considerable change over the relevant period in the structure and responsibilities relating to governance and the management of risk, leading to confusion over accountability. The risk register and assurance framework were not well understood.

Incidents that had been reported consistently highlighted problems relating to the levels of staff, poor care for patients, escalation wards and poor handovers when patients moved from one ward to another. Many of the issues required consideration and resolution at a strategic level but were seldom considered by the board, or any of its governance and risk sub committees. There was no systematic

mechanism to follow up any actions required or to share lessons. Staff had little confidence that reporting incidents would lead to change and the evidence from this investigation suggests that their concerns were justified.

The trust's system for handling serious untoward incidents was poor. Often there was no investigation report, no consistent approach to investigation and no assurance that lessons had been learnt throughout the whole organisation.

The record of attendance by clinical directors at the various governance and risk committees was poor, and the committees did not monitor or give adequate leadership and support to the directorates. 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 realities and problems on the general wards.

The structure for governance has recently been changed, with the aim of increasing the involvement of clinical staff.

The trust's board and infection control

The board stated that infection control had always been a priority. Prior to the outbreak it only monitored the MRSA rate, as that was a priority to which a target for performance was attached. Similarly, until recently the board considered the annual report on control of infection as a retrospective document rather than a prospective planning framework for the coming year where the board could influence and agree priorities. The report did not highlight the comparatively high rates of *C. difficile* at the trust.

Although a specific case of *C. difficile* was brought to the attention of the board in January 2006 and a review was promised, there was no follow up when this did not happen.

The chief executive controlled the information that went to the board. The second outbreak was declared on 12 April 2006 but it was not discussed by the board in public until 25 July 2006. Following the declaration of the outbreak in 2006 an immediate action plan to tackle issues was not taken to the board. This meant that the trust's board could not easily demonstrate it had discharged its public accountability. The board had considered matters relating to infection control from time to time over the years but did not have a presentation from the infection control team, even during the second outbreak. On several occasions the board, and relatives of patients who attended the board's meetings, were given information that was incomplete or was inaccurate.

Since the outbreak in April 2006 the trust has been in the public eye for infection control. For an organisation claiming to focus on the safety of patients, it is worrying that the board did not receive a paper on the mandatory hygiene code in the autumn of 2006, nor the gap analysis and action plan for compliance with the code until March 2007, when the code had been introduced in October 2006. Also when three new non-executive directors took up post in mid-2006, as public attention on the trust was at its height, no basic induction on infection control and their role in its assurance, was organised. There appeared to be an expectation that the individuals would pick it up as they went along even though two had no experience of health services.

The information presented to the board on the outbreak of *C. difficile* and infection control was often incomplete or inaccurate, leaving non-executives at a disadvantage in being able to scrutinise and challenge on the handling of the outbreak and on matters concerning infection control generally.

The first outbreak occurred in the autumn of 2005, and in early 2006 the trust recognised that it had a second outbreak. Despite these outbreaks and the gaps in controls they revealed, the trust declared itself in the Healthcare Commission's annual health check as being in compliance with the standard for control of infection in the Core National Standards in May 2006.

Priorities at the trust

There is no doubt that this trust has had a challenging agenda since it was created by a merger in April 2000. Although the board members generally reported that the care of patients was a top priority, the minutes and other senior staff suggested that the main focus was on finance, the private finance initiative (PFI) and service reconfiguration. The PFI, in particular, was said to have consumed a large amount of senior executives' time, energy and focus. The 1999 Health Act introduced a statutory duty of quality as a counterbalance to the financial duties that already existed. The duties of finance and quality are not mutually exclusive but the evidence suggests that the leadership of the trust had a greater focus on finance. The chief executive's focus on the PFI, finance and reconfiguration was reflected by the board and clinical governance was not given the same level of attention.

The board unambiguously stated that its top priority was the safety of patients. The fact that the organisation missed the first outbreak of *C. difficile* does not fit with the trust doing its best to reduce the risk of infection to patients, staff and visitors. When challenged on the unacceptable crowding of beds on many wards at Kent and Sussex the response ranged from no knowledge of the real position to excusing the situation. The trust implied that the failure of commissioners to manage demand, that is, reduce the number of patients needing to be admitted, meant that in some way the suboptimal care given to some patients was inevitable. The trust paid insufficient attention to its responsibilities to protect patients against infection.

Efforts to control expenditure were implicated in a number of areas that affected the control of infection including restricted cleaning hours, the high occupancy rates of beds, beds being too close together and the failure to increase the number of nurses towards the levels found more widely on general wards in similar hospitals. These all increased the risk of transmission of infection.

Leadership

The lack of organisational stability with numerous structural changes over the last three to four years, meant managers could not settle into roles and focus on the key issues. The high turnover of executive directors and senior managers caused instability and left gaps in leadership as the trust grappled with its very busy agenda. Many staff felt the degree of change had been damaging and had contributed to the lack of clarity on accountability.

Views of the leadership were mixed. Many welcomed the strong leadership. However, the culture within the trust, and particularly the style of the chief executive, were described by others as autocratic. While understandable in a crisis, in an organisation with so many key issues to be tackled the development of managerial and leadership capability and capacity throughout the organisation should have been more of a priority. Instead we were told that there was little delegation. The style of management was described as reactive, and managers commented on frequent changes of direction.

The chief executive was widely viewed as being difficult to challenge. This may have contributed to the failure to accurately reflect the position of the trust in some cases, sometimes by exaggerating the successes and minimising the problems at the trust. Evidence shows that information given in public was inaccurate on several occasions. For example, that the trust requested the investigation, when it is clear that the SHA initiated the move to external scrutiny.

The trust did not act on the advice of the HPU and the strategic health authority (SHA) to issue a press release immediately after the outbreak was detected. The trust only issued a press release following an enquiry from the local press, and this was over two months after the outbreak was reported. Information in the press release, and that presented to the Maidstone External Scrutiny Committee, inferred that the outbreak was due to a rise in the number of patients with the infection being

admitted to the hospital from the community. This was inaccurate, as *C. difficile* infections acquired in the community were consistently below 10% of the total cases of *C. difficile* at the trust.

Also the public statements from the trust concerning the outbreak under-reported the number of deaths, since they included only the 'definites.' Even these figures were not accurate since not all the cases where *C. difficile* was mentioned on the death certificate had been reviewed.

This combination of factors heightened concerns about the extent to which the trust was transparent about the outbreak, how it was handled and how the investigation was commissioned.

Summary of conclusions

The trust had no effective system for surveillance of *C. difficile*. As a consequence it missed an outbreak in 2005 that involved 150 patients.

Some patients with conditions from which they might have been expected to have made a full recovery were prescribed broad-spectrum antibiotics, contracted *C. difficile*, and some died. The clinical management of the majority of patients with *C. difficile* that we reviewed fell short of an acceptable standard in at least one aspect of care.

When the second outbreak was declared in 2006, the cohorting arrangements were unsatisfactory and it took four months to establish an isolation ward. The infection control team was not managed properly and standards of cleanliness and infection control were not good. Subsequently the number of cases has reduced to below the levels before the outbreaks. However, as late as April 2007, we found unacceptable examples of contaminated equipment.

The trust did not make the outbreak public for two months and then produced figures which almost certainly underestimated the number of deaths. We estimate that approximately 90 patients definitely or probably died from *C. difficile* in two and a half years, 60 of these during the outbreaks from October 2005 to September 2006. It is not correct to conclude however that 60 patients died because of the care they recieved. Some would have died even if they had had the best care.

The roles of external organisations

The Kent health protection unit (the HPU) relied on local trusts to supply it with information including problems relating to infection control. The HPU was not closely involved with the trust routinely and generally worked in a reactive way, responding to concerns. The HPU staff considered their role was to be supportive to trusts in handling infections, rather than to supervise and monitor infection control.

In common with other HPUs at the time, the HPU did not monitor figures for infection with *C. difficile* in the trusts in its area, so was unaware of the comparatively high rate at Maidstone and Tunbridge Wells. The HPU was aware of previous poor standards of cleanliness and aspects of infection control at the trust since it had undertaken audits at the request of the trust.

When the outbreak was declared in April 2006, the HPU became actively involved and endeavoured to support the trust. The unit raised its concerns formally with the trust's chief executive. The HPU analysed the information that the trust provided relating to the numbers of deaths and kept the SHA informed about the management of the outbreak and concerns.

The SHA had concentrated on ensuring that trusts delivered the national priorities, so MRSA was part of the performance report to the SHA's board from 2005, but the figures on *C. difficile* were not included until August 2006.

The SHA attended the first outbreak meeting but subsequently relied on information from the HPU, with which it had a good relationship. When the HPU shared their concerns with the SHA, the latter took steps to initiate an investigation.

The primary care trusts did not have a good relationship with the trust. There were many tensions around the number of patients treated and the affordability of that care. The quality of care including the control of infection was afforded scant attention. The service level agreement contained two indicators for healthcare associated infection but these were not monitored. The PCTs had a memorandum of understanding with the HPU that included an agreement for the HPU to monitor outbreaks. The PCTs considered that this discharged their responsibility. Overall, the primary care trusts commissioned services from the trust but had not given priority to the control of infection at the trust, nor monitored it.

Lessons for the NHS

The profound risk that *C. difficile* poses to the health of the public is being increasingly recognised and it is thought to have contributed to more deaths than MRSA in England, Wales and Northern Ireland in recent years.

In this section we consider matters of concern that the investigation has found, including some that were common to our previous investigation into outbreaks of *C. difficile*, and therefore may have wider application across the NHS.

We noted that the creation of the Health Protection Agency (HPA) has led to some confusion about the respective roles of the SHA, PCT and HPA in relation to monitoring and performance managing the control of infection in acute trusts.

Despite recent dissemination of information about the potential risks from broad-spectrum antibiotics, some of the prescribing in the trust was worrying. Some patients, who might have been expected to make a full recovery from their condition at the time of admission, received broad-spectrum antibiotics, contracted *C. difficile* and some died. Antibiotics need to be seen, like all medication, as potentially dangerous drugs and only prescribed if there is a clear clinical indication. Supervision of junior doctors in this respect is particularly important. Antibiotics should be targeted; of the narrowest spectrum possible; and used for the shortest time possible. The continuing need for antibiotics should be reviewed daily.

Generally the Healthcare Commission is concerned about the standard of medical and nursing care of patients who developed *C. difficile* infection. The diagnosis of *C. difficile* needs to be respected as a diagnosis in its own right, with proper continuity of management for patients with this illness. When this diagnosis is made, the condition needs to be taken seriously, as a potentially life threatening condition. Investigations should be carried out where necessary, and the patient should be effectively monitored and receive appropriate active care. This care should involve not only management of the diarrhoea and dehydration, but should also focus on nutrition and avoiding breakdown of the skin.

The investigation into the outbreaks at Maidstone and Tunbridge Wells NHS Trust has thrown up a number of similarities with the Healthcare Commission's previous investigation at Stoke Mandeville Hospital, part of Buckinghamshire Hospitals NHS Trust. Both trusts had undergone difficult mergers, were preoccupied with finance, and had a demanding agenda for reconfiguration and PFI, all of which consumed the time and effort of senior managers. They also had poor environments, with many Nightingale wards and few single rooms which could be used for isolating patients with infections. In both we observed unacceptable examples of contamination and unhygienic practice.

Additionally, the impact of financial pressures was to reduce further already low numbers of nurses, put a cap on the use of nurses from agencies and banks, and there was unrelenting pressure to reduce the number of beds. Thus both trusts had very high occupancy levels, could not manage with fewer beds, and so had to open 'escalation'

beds, often in unsuitable environments, without proper support services and equipment in place, and by definition without permanent staff. The effect of all this was to compromise seriously the control of infection and the quality of clinical care.

In both trusts 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 and nutritional supplements not administered, charts not completed, poor hygiene practices, and general disregard for privacy and dignity. Not only were they distressing, but in the case of seriously ill patients, poor care related to hygiene, medication, nutrition and hydration may have adversely affected the outcome for the patients.

Patients in both trusts were moved for non-clinical reasons, often at night, and some were cared for on wards that were not the most appropriate for their needs. Governance arrangements were weak or overridden by other imperatives, including targets relating to finance and access.

While it should be noted that improvements have subsequently been made at Stoke Mandeville, it seems unlikely that these similarities are coincidental. We are concerned that, if organisations are struggling, they should not compromise patient safety by making decisions and taking actions that put some patients at risk. Where trusts are confronting a number of problems that consume senior managers' time, infection control may be undermined, allowing a vicious circle to develop.

It is, of course, important that waiting times are achieved and finances brought in balance, but this should not be at the price of rushed handovers from A&E, patients moving round the hospital for non-clinical reasons and being cared for in inappropriate and sometimes unhygienic areas. They may be looked after by low numbers of nurses and many temporary staff, who may fail to practice good infection control or deliver good care of patients. These are circumstances under which *C. difficile* and other infections are likely to thrive and outbreaks occur. In turn these not only can have tragic consequences for some patients but lead, in those who recover, to having to stay longer in hospital, then in turn putting pressure on beds and hence waiting times. Wards may have to be shut, adding more pressure on the system.

Lessons need to be reinforced about appropriate antibiotic prescribing, the need for effective isolation as opposed to ineffective cohorting, the importance of scrupulous cleanliness and hygiene, and the need to provide a high standard of care of patients with *C. difficile*. More attention needs to be paid to the accuracy of completing death certification in respect of this condition.

Recommendations

The Healthcare Commission expects the trust to consider all aspects of this report. Here we highlight areas where action is particularly important.

The Healthcare Commission considers the findings of this investigation to be extremely serious, and to constitute a significant failing on the part of the trust, which failed to protect the interests of patients, by missing the first outbreak, being slow to react effectively to the second, and continuing to display poor infection control and hygiene during the course of the investigation. The Healthcare Commission was concerned that during the second outbreak some important factors including the number of deaths were not accurately represented to the public.

We note that, during the course of this investigation, the trust chose to transfer responsibility for the role of director of infection prevention and control. This responsibility previously lay with the trust's director of nursing and patient services. Since April 2007 the trust's senior infection control nurse has taken on the role of acting director of infection prevention and control.

Action by the board

The trust's board must review the leadership of the trust in the light of these significant failings, to ensure it is able to discharge its responsibilities to an acceptable standard. As performance manager of the trust the SHA must take overall responsibility for ensuring that the review is conducted appropriately.

Clinical governance and the management of risk

The control of infection needs to be an integral part of clinical governance and a high priority across the trust.

The trust must improve its arrangements to manage risk. This should include appropriate reporting and proper investigation of serious untoward incidents, analysis of the risks raised by incidents and complaints, and a system that clearly demonstrates that the trust captures and disseminates the learning from incidents and complaints.

Action by the board and managers to control the risk of infection

The trust's board must give greater priority to the control of infection and the factors that may affect the ability of staff to control infection, including the environment, cleaning, the movement of patients, and levels of bed occupancy. It must ensure it has adequate information to monitor infections acquired within the trust.

The trust needs to ensure effective isolation for those patients who pose a potential or actual high risk of infection to others. The practice of 'cohort nursing' of infected patients on open wards must be reviewed in the light of the findings of this investigation, and should be stopped for patients with undiagnosed diarrhoea.

It must be demonstrated that the infection control team is functioning effectively and operating an appropriate system for surveillance.

The trust needs to make sure that standards of hygiene are acceptable and in particular ensure that cleaning and decontamination equipment on wards is functioning properly. All equipment that is dirty or contaminated must be appropriately disposed of, or cleaned appropriately, and spaces between beds must be broadly in line with recommendations published by NHS Estates in 2002.

The trust must publish criteria for the opening of escalation (overflow) areas.

Standards of care

The diagnosis of *C. difficile* needs to be regarded as a diagnosis in its own right (rather than a secondary complication) and appropriate care and treatment provided, based on clinical guidelines for the management of patients with *C. difficile*. As a minimum, doctors need to review patients regularly, and monitor and manage the infection and any complications. Similarly nurses must deliver basic aspects of care such as administering medication and take steps to prevent patients becoming dehydrated, malnourished or their skin breaking down. Adherence to these guidelines must be monitored.

The trust needs to ensure that prescribing of antibiotics follows accepted good practice and that antibiotics of the narrowest possible spectrum are prescribed for the shortest possible period.

The standard of nursing care must improve to ensure that call bells are answered, patients fed, beds are clean, privacy and dignity are respected and attention is paid to providing single sex accommodation.

Staffing levels and training

The trust must continue the work it has started to recruit additional nurses to ensure acceptable and safe care, including in escalation areas. The trust must closely monitor the situation to ensure that its actual nursing staff levels are in line with those at comparable trusts.

All staff must attend appropriate training in the control of infection.

National recommendations

The diagnosis of *C. difficile* needs to be regarded as a diagnosis in its own right, with proper continuity of management. When this diagnosis is made, the condition needs to be taken seriously, as a potentially life threatening condition. Commissioners of care should ensure that acute trusts have appropriate guidelines for the prevention and management of this infection, including the care of patients who acquire it.

Further consideration needs to be given to the education and supervision of trainee doctors, with a view to improving the recording of *C. difficile* on death certificates.

The message needs to be reinforced that antibiotics are potentially dangerous drugs. They should be prescribed only after careful consideration of the indications for their use. Antibiotics should be targeted, of the narrowest spectrum possible, and used for the shortest time possible.

The NHS and the Health Protection Agency should agree clear and consistent arrangements for the monitoring of rates of *C. difficile* infection, using all relevant local and national information. Local health protection units have an important role to play in this.

The board of every NHS trust must understand the role and responsibilities of the director for infection prevention and control, and receive regularly, information about incidence and trends in healthcare associated infections within their areas of responsibility. Duty 2 of the hygiene code addresses this issue.

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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Dr Lance Saker
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Dr Louise Teare
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Mid Essex NHS Trust

Appendix C: Interviews

The investigation team conducted a total of 202 interviews. Of these, 165 interviews involved 149 former or current trust staff (some people were interviewed more than once). Table 6 contains more details regarding the former and current staff interviewed.

The investigation team was in contact with 53 stakeholders (members of the public or members of external organisations associated with the trust). Forty stakeholders were interviewed over 37 interviews. Two people were seen or interviewed more than once. 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 investigation team. Thirteen stakeholders contacted the investigation team in writing. Tables 7a and 7b provide more details regarding the stakeholders involved in this investigation.

Table 6: Trust staff and former trust staff interviewed

Chief executive and executives including deputy medical directors and associate directors	22
Chairman and non-executive directors	9
Managers – clinical	4
Non-clinical senior and middle managers	14
Clinical directors	6
Microbiologists	3
Infection control nurses	5
Site practitioners and site matrons	8
Ward managers	8
Senior nurses and specialist nurses	6
Consultants	7
Junior and other doctors	8
Ward nurses and healthcare assistants	33
Pharmacy staff	2
Staff side and union representatives	3
Allied health professionals and chaplain	4
Communications staff	1
Coordinators/administrative staff	1
Domestic and portering staff	5
Total	**149**

Table 7a: Stakeholders interviewed	
Patients and relatives	16
South East Coast Strategic Health Authority and former Kent and Medway Strategic Health Authority	5
West Kent and former Primary Care Trusts	7
Kent Health Protection Unit	5
Voluntary organisations	2
Local government	1
Members of Parliament	2
Auditors	2
Total	**40**

Table 7b: Stakeholders who contacted the investigation team in writing	
Patients and relatives	10
Voluntary organisations	1
Members of Parliament	1
Other	1
Total	**13**

Appendix D: Critique of the case note review

There are possible limitations to this review, which are considered here. We consider that the review was sufficiently robust to evaluate quality of care and mortality fairly at the trust.

1 The review only evaluated care provided for *C. difficile* infection rather than any other illnesses for which the patient may have been treated. Any deficiencies in care for *C. difficile* do not imply similar shortcomings in the care provided for other illnesses. Of course, the reviewers did take note of the overall care a patient received, and in several cases it was illuminating to see how often patients received good care for other problems when that which they received for *C. difficile* was of a lesser standard.

2 The case notes cannot represent the full picture of care provided to any patient. There are many discussions and actions that do not appear in the notes. For this reason, wherever possible the reviewers focused on objective measures, such as treatment charts and the results of investigations. We also attempted to corroborate absence of information in the doctors and nursing notes with other information about how the patient was managed. For instance if there was no mention of an assessment for severe *C. difficile*, were the relevant tests that would have allowed an assessment of this ordered? Overall, we believe that case notes do convey a sufficiently clear picture of the care provided to allow a view to be taken.

3 The method used to evaluate the contribution of *C. difficile* to death was different to that used at Stoke Mandeville. We used a method so that its assessment would rely less heavily on whether or not *C. difficile* was mentioned on the death certificate, which we believe allowed for a more accurate assessment of how often *C. difficile* was likely to have contributed to or directly caused death in the cases reviewed.

   As far as we are aware, this method has not previously been used in the UK. Loo et al used a very similar method in an investigation into deaths from *C. difficile* in Canada (published in the New England Journal of Medicine in 2005). Their method was adapted to the Commission's case note review. For example, in the Canadian study, a case of *C. difficile*-associated diarrhoea was classified as severe if the patient required colectomy or intensive care as a result of *C. difficile*. This was not especially useful for the Commission's reviewers, since we found that few or no cases studied had been treated on the trust's intensive care units or fully assessed for their need for colectomy.

4 Since the review relied in some instances on the exercise of judgement – in particular, whether *C. difficile* had contributed to, or largely caused, death – some of the findings depend upon the quality of the assessments made. Collectively, the Commission's reviewers had considerable medical and nursing experience of looking after unwell people with multiple pathologies, including people with *C. difficile* in non-intensive care settings. Furthermore, the proforma was designed to focus largely on basic aspects of patient care, such as completion of fluid charts, monitoring for signs of disease severity and the involvement of other

professionals in serious cases in such a way that a reasonably experienced and competent medical or nursing professional should have been able to evaluate whether these criteria had been fulfilled.

Specific criteria were used to guide reviewers in making decisions on attribution of death. It should be noted that the use of professional judgements through case note reviews to assess clinical outcome in general, and mortality in particular, is well established. For example it is used to evaluate mortality reported in the Department of Health funded Confidential Enquiries into Mortality.

5 The extrapolation of cases depends on the sample cases being reasonably representative of the total population of cases from which they were selected. Clearly, it is unlikely that the sample was in every way perfectly representative. We know, for instance, that sample cases were on average three years older than the total population. Therefore it is possible that they were more likely to die from a *C. difficile* infection. Although the difference was statistically significant, it is less clear if it was clinically significant. If we exclude all people in the sample over the age of 90 years from the analysis, the proportion whose death was assessed as being "definitely" or "probably" primarily due to *C. difficile* is 22% (9/41). This equates to a total estimated number of deaths of 74, which is less than, but not extremely different from, the figure of 89 deaths.

In terms of other parameters such as length of stay, Healthcare Resource Group (HRG) severity of illness codes and frequency with which patients had an International Classification of Diseases (ICD) code for *C. difficile*, the two groups were similar. Furthermore, since we excluded many patients with obviously terminal illnesses, who would have been more likely to succumb to *C. difficile* infection and less likely to receive full care than those who did not, the sample may have underestimated rather than overestimated mortality. Overall, therefore, the Commission is satisfied that the sample was sufficiently similar to the total population to allow inferences to be made about the approximate number of deaths from *C. difficile* at the trust during the period of study.

6 Our method did not allow for an assessment of the burden of *C. difficile* mortality at the trust. We contend that our method was appropriate because the review was a descriptive study to investigate how many deaths had been caused or contributed to by *C. difficile* infection in a defined group of patients at the trust. It did not aim to investigate the overall attributable mortality of *C. difficile* infection, nor the mortality attributable to *C. difficile* compared to other diseases or to people without *C. difficile*.

7 Since the sample size (50) was relatively small, it is possible that our findings may be due to chance. To quantify the uncertainty surrounding the estimated number of deaths obtained by extrapolation contingent on sample size, we calculated the 95% confidence intervals using the formula SD = √(p X ((1-p)n)) where SD is the standard deviation, p is the proportion of cases in whom *C. difficile* was thought to be "definitely" or probably" the main cause of death (0.26) and n is the size of the sample (50). The SD around the estimated proportion of deaths therefore equals 0.06 and two standard deviations (95% confidence interval) equals 0.12. If this is used to estimate deaths in the total population at the upper (0.38) and lower (0.14) limits of confidence, we would conclude that between 47 and 127 people may have died directly from *C. difficile* during the study period.

8 Elderly patients have high mortality and are more likely to die of many types of illness, not just *C. difficile*. Nevertheless, it is important to identify the impact of treatable illnesses such as *C. difficile*, and there is much evidence that mortality in equivalent elderly patients who do not have *C. difficile* is significantly lower.

9 Our study did not involve comparison with other trusts treating patients for *C. difficile*. Therefore, we cannot comment on whether care or mortality at the trust was any better or worse than at other trusts treating *C. difficile* patients at the time. However, because we evaluated for care that could reasonably be expected to form part of the management of *C. difficile* infection anywhere, we believe that any inadequacies identified indicate deviations from what could properly have been expected of any hospital treating people with *C. difficile*, wherever this was.

Appendix E: Sources of information

- Interviews and correspondence with patients, relatives and carers
- Interviews and correspondence with past and present trust staff
- Interviews with organisations in the health community, including local PCTs, South East Coast Strategic Health Authority and the Kent Health Protection Unit
- Interviews and information provided by the Health Protection Agency, the Anaerobe Reference Laboratory and the Royal College of Nursing
- Interviews and correspondence with Members of Parliament
- Interviews with external stakeholders such as the overview and scrutiny committee
- Observations on the wards
- Selection of case notes of patients who contracted and died with *C. difficile*
- Minutes of trust meetings, including meetings of the trust board, clinical governance, audit and remuneration committees, risk management committees, the trust's management boards, the senior nurses' meetings, directorate and departmental meetings including the infection control team and committee, and outbreak meetings
- Relevant trust policies and procedures with particular reference to infection control and the management of *C. difficile*, including policies on treatment, isolation, escalation, bed management and ward transfers
- The trust's annual reports 2003/2004, 2004/2005 and 2005/2006
- Information from the South East Coast Strategic Health Authority and local primary care trusts
- Commission for Health Improvement clinical governance reviews into Maidstone and Tunbridge Wells NHS Trust December 2002
- Commission for Health Improvement Performance Ratings, 2002/2003 and 2003/2004
- Healthcare Commission annual health check scores 2004/2005, 2005/2006 and 2006/2007
- Information on relevant complaints, including reports by independent review panels
- Information on relevant incidents (including reports of serious untoward incidents)
- Clinical governance documentation, such as the risk register and assurance framework
- Self-assessments, audits and position statements by the trust
- Ward assurance framework
- Analysis by the acute hospital portfolio team at the Healthcare Commission
- Findings from Commission for Health Improvement's 2003 outpatient survey
- Findings from the Healthcare Commission's 2004, 2005 and 2006 national surveys of inpatients and staff in the NHS
- Routine and bespoke information provided by the trust
- Documentation and correspondence provided by the trust relating to staffing numbers, use of bank and agency staff, appraisal, induction, mandatory training and sickness levels
- Information for patients, for example, leaflets
- Analysis of trust data on bed moves, medical outliers and bed occupancy figures

- Reports of visits by Department of Health representatives, October 2006, and Health Protection Agency representatives, May-August 2006
- Patient environment action team 2004-2006 reports and patient environment action team 2007 information
- Auditors' reports
- Outbreak reports July 2006, January 2007 and June 2007, outbreak bulletins September 2005, December 2005, January-March 2006 and April 2006, and outbreak summaries April-October 2006
- Audits, guidance and information relating to antimicrobial prescribing
- Analysis of trust data on death certificates and mortality figures
- Infection control annual reports 2003/2004, 2004/2005, 2005/2006 and 2006/2007
- Documents and guidance relating to domestic services and training
- Documents and information relating to decontamination
- Documents and information relating to maintenance of facilities
- Environmental audits and reports 2002-2007
- Annual infection control programme 2006/2007 and 2007/2008
- Information from laboratory and administrative systems including details of *C. difficile* positive cases
- Spreadsheet provided by trust of anonymised patients with *C. difficile*
- Analysis of the Healthcare Commission's and Health Protection Agency's joint *C. difficile* survey, December 2005

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.

This information is available in other formats and languages on request. Please telephone 0845 601 3012.

ENGLISH

આ માહિતી વિનંતી કરવાથી અન્ય રૂપે અને ભાષાઓમાં મળી શકે છે. મહેરબાની કરી ટેલિફોન નંબર 0845 601 3012 પર ફોન કરો.

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