

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 received.

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 where *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 received. 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.