

## HSE investigation into outbreaks of *Clostridium difficile* at Stoke Mandeville Hospital, Buckinghamshire Hospitals NHS Trust

### Introduction

1. This investigation by the Health & Safety Executive (HSE) has been undertaken following concerns that Buckinghamshire Hospitals NHS Trust (BHT) and individuals working within it may have failed to properly manage two outbreaks of *Clostridium difficile* (*C. difficile*) occurring at Stoke Mandeville Hospital between 1<sup>st</sup> October 2003 and 30<sup>th</sup> June 2005
2. The investigation is unusual in that these concerns only came to light with publication of the Healthcare Commission (HC) report, *Investigation into outbreaks of Clostridium difficile at Stoke Mandeville Hospital, Buckinghamshire Hospitals NHS Trust*, in July 2006, which stated that 33 patients died and 334 became ill as a result of contracting *C. difficile* at the hospital.
3. The HC are empowered to investigate allegations of serious failings that have a negative impact on the safety of patients, clinical effectiveness or responsiveness to patients – matters in which HSE is not normally involved. However, in this instance, these deaths allegedly arose primarily from serious failings in the trust's management of the outbreaks, which were distinguishable from issues of clinical judgement.
4. Under the Health and Safety at Work etc Act 1974, employers such as BHT are under a legal duty to ensure, so far as is reasonably practicable, the health and safety of their staff and others who may be affected by their work – e.g. their patients. This legislation is enforced by HSE and the findings of the HC report were such that it was considered necessary for HSE to undertake an investigation
5. The HC report of its investigation provides a detailed account of the outbreaks and the factors that contributed to the spread of *C. difficile*. In looking into these matters we used the HC report as a basis for an examination of what evidence might exist to support criminal proceedings.
6. In conducting investigations with a view to bringing criminal proceedings, HSE is bound by the Criminal Proceedings and Investigations Act 1996 and the Code for Crown Prosecutors. We have to ensure evidence of a breach of legislation is:
  - admissible in a court of law;
  - of such weight and quality as to provide a realistic prospect of conviction; and
  - not undermined by other evidence which calls into question the validity of the prosecution case.

In any proceedings brought against a defendant we must be able to prove the alleged breach 'beyond all reasonable doubt'.

7. HSE regularly reviews all investigations against these criteria to ensure its efforts and resources are not wasted on trying to achieve unrealistic outcomes. This report is a product of that process.

### **Investigation of work-related deaths**

8. It appears that the 33 deaths at Stoke Mandeville Hospital arose out of, or in connection with, the work of BHT. Investigations of such incidents are conducted in accordance with the Work-related Death Protocol. The protocol facilitates co-ordination and co-operation between the Police and HSE to ensure the investigation properly justifies any subsequent allegation of breaches of serious criminal offences, whether matters for the Police and the Crown Prosecution Service (CPS) (i.e. manslaughter) or for HSE (i.e. health and safety offences).
9. HSE invited Thames Valley Police and CPS to consider the HC report. Following meetings with HC and HSE they concluded that it did not contain sufficient evidence of a causal link between the actions of any individual and the deaths of the patients involved for them to initiate a police investigation on the grounds of possible manslaughter. As a result, under the terms of the protocol, HSE has led the investigation during which we have remained alert to evidence of gross negligence by an individual that would necessitate the re-involvement of Thames Valley Police.
10. Our review of the evidence has not indicated any matters requiring the re-involvement of Thames Valley Police.

### **Clostridium difficile – what is it, who does it affect and how is it spread**

11. *C. difficile* is a bacterium that lives in the large intestine. It can be found in low numbers in a small proportion (less than 5%) of the healthy adult population. It is kept in check by the normal, 'good' bacterial population of the intestine.
12. *C. difficile* bacteria flourish when people are given broad-spectrum antibiotics that reduce the levels of 'good' bacteria. It then multiplies in the intestine, producing toxins that damage the cell lining of the intestine. The result is diarrhoea. This can range from a mild disturbance to a very severe illness. It can be fatal.
13. Most of those affected (as in the case of the Stoke Mandeville outbreaks) are elderly patients given broad-spectrum antibiotics as part of their treatment for serious underlying illnesses. Most infections occur in hospitals (including community hospitals), nursing homes etc, but it can also occur in primary care settings.

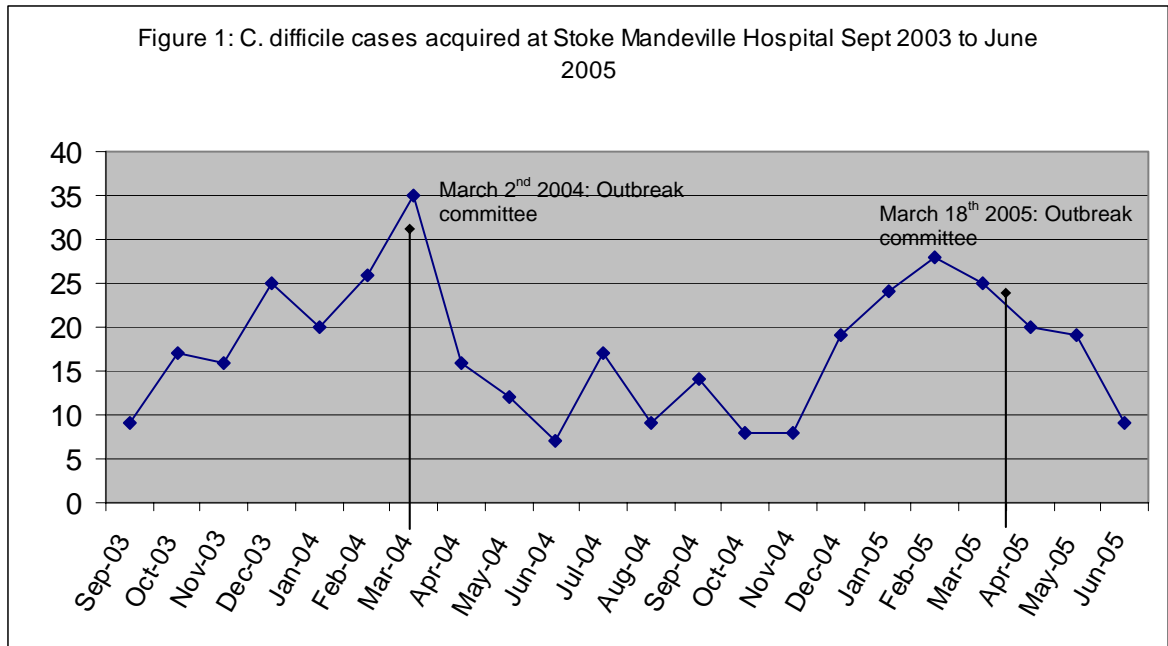
14. In most cases the disease develops after cross infection from another patient, either through direct patient-to-patient contact, via healthcare staff, or via a contaminated environment. A patient who has *C. difficile* diarrhoea excretes large numbers of the spores in their liquid faeces. These can contaminate the general environment around the patient's bed (including surfaces, keypads, equipment), the toilet areas, sluices, commodes, bedpan washers, etc. They can survive for a long time and be a source of hand-to-mouth infection for others. In combating this contamination, infected patients need to be kept separated from others, the surrounding environment kept clean and those attending to them need to follow good hygiene practices such as regular and thorough hand washing.
15. At any time, nearly all hospitals have patients infected with *C. difficile* who are symptomatically ill as a result. Small outbreaks, localised to single wards, are common and usually described as 'clusters'. The appearance and subsequent control of these clusters means that the level of *C. difficile* infection in any particular ward/hospital goes up and down from month to month. Averaged over time, these form the 'background rate' of *C. difficile* infection within a particular hospital.
16. There is also a history of major outbreaks of *C. difficile* in hospitals where the number and size of these clusters rise significantly above the normal background rate. An early example is the outbreak in three Manchester hospitals between November 1991 and May 1992 where the infection was thought to have contributed to 17 deaths.

### **Current standards of infection control at the trust**

17. Prior to undertaking this investigation, HSE carried out a management systems inspection at BHT to check current standards of infection control and progress with the recommendations on infection control arising from the HC investigation, the report of which is published in appendix 1 to this report. The audit revealed that the then current infection control procedures and supporting governance arrangements were to a good standard. At all levels, from ancillary staff through to heads of directorates, infection control was viewed as an integrated part of patient care. Levels of *C. difficile* infection at the trust are now considerably lower than prior to the outbreaks and in line with some of the best performing acute trusts in the NHS.

### **Outbreaks of *C. difficile* at Stoke Mandeville Hospital**

18. Looking at Figure 1 below it can be seen that there were two major outbreaks of *C. difficile* at Stoke Mandeville Hospital, one in the winter and spring of 2003/2004 and the other in the winter and spring of 2004/2005. In the first outbreak there were 174 new cases between October 2003 and June 2004. In the second there were 160 new cases between the same months in 2004 and 2005



Source: Investigation into outbreaks of Clostridium difficile at Stoke Mandeville Hospital, Buckinghamshire Hospitals NHS Trust, Healthcare Commission July 2006

## Legislative requirements

19. In particular this investigation examined whether BHT discharged their duties in respect of the following legal requirements.

### *Compliance by BHT as a corporate body in respect of*

- Section 3 of the Health and Safety at Work etc Act 1974 which requires employers to ensure, so far as is reasonably practicable, the health and safety of those who may be affected by their work activities – e.g. their patients.
- The Control of Substances Hazardous to Health (COSHH) Regulations 2002. C. difficile is a biological agent and thus a substance hazardous to health within the meaning of the regulations.

### *Compliance by individuals in respect of*

- Section 7 of the Health and Safety at Work etc. Act 1974 – where it is the duty of every employee at work to take reasonable care for the health and safety of himself and of other persons who may be affected by his acts or omissions at work and to co-operate with his employer in discharging any duty or requirement placed upon his employer by health and safety legislation.
- Section 37 of the Health and Safety at Work etc. Act 1974 – where if a contravention of health and safety law by the body corporate (in this case BHT) is proved to have been committed with the consent or connivance of, or to have been attributed to any neglect on the part of any person responsible for deciding corporate policy (e.g. senior

managers), they, as well as the corporate body, may be prosecuted.

### **Buckinghamshire Hospitals Trust's prevention, control and management of the outbreaks within the trust**

20. The duties imposed by the Health and Safety at Work etc Act 1974 are applicable to BHT by virtue of the fact that:

- it is an employer;
- it conducts an undertaking – i.e. the provision of healthcare services;
- the undertaking involves risks that may affect the health and safety of both staff and others (e.g. patients and visitors); and
- the way in which that undertaking is conducted (i.e. managed) should reduce those risks as far as is reasonably practicable.

21. In assessing whether BHT did all that was reasonably practicable to reduce the risks posed by *C. difficile*, we first looked at BHT's performance against the guidance on prevention and control of *C. difficile* as set out in 'Clostridium difficile Infection: Prevention and Management' published in 1994 by the Department of Health and the Public Health Laboratory Service, which was the current guidance at the time of the outbreaks. It specifies the following measures for the successful management of the risks from *C. difficile* by:

- a. Assessing the risk posed by *C. difficile* through:
  - monitoring levels of *C. difficile* infection in the hospital; and
  - identification of the particular strain involved.
- b. Taking steps to prevent and control its occurrence through:
  - controlling the use of antibiotics which can cause *C. difficile* to flourish
  - placing patients with *C. difficile* in the most appropriate facilities to minimise the spread of infection
  - restricting the movement of patients with *C. difficile* infection
  - infection control practices and procedures to prevent transmission of *C. difficile* infection in clinical areas including environmental cleanliness and good practice in personal hygiene
  - management structures and procedures to ensure these measures are reviewed, and where found to be ineffective, changed to secure improvement.

#### *Monitoring levels of C. difficile infection*

22. There was monitoring of levels of *C. difficile* infection at Stoke Mandeville Hospital. This is confirmed in the minutes of the monthly meetings of the Clinical Risk Review Panel that received reports on infection levels from the Infection Control Team (ICT). However, with small clusters of infection arising from different wards at different times, it was difficult to see the overall scale of the problem across the hospital as a whole. This

contributed to the delay in formal declaration of an outbreak. In the case of the first, this was just before the number of infections peaked, and in the second, just after the number of infections peaked.

23. Additionally, there were matters of clinical practice that delayed diagnosis and treatment of *C. difficile* infected patients. During the initial part of the first outbreak, the trust did not test diarrhoea stool samples with the frequency required to facilitate quick application of the necessary infection control measures needed in dealing with a major outbreak. There were also problems in persuading ward staff to send samples for testing as soon as possible after a patient had an episode of diarrhoea.

*Identification of the strain of C. difficile*

24. There was timely identification of the strain involved when the hospital sent samples to the National Reference Laboratory at Cardiff in March 2004. The strain was identified as 027, of which there had only been a few recorded cases in the UK – the first being detected in Preston in 1999. There were no records of any outbreaks or clusters involving this strain in the UK.

25. However, the increased risk associated with 027 only started to be understood when, in April 2005, the Cardiff Laboratory confirmed (in response to a query from the consultant microbiologists at Stoke Mandeville) that the 027 strain was the same strain responsible for recent major outbreaks of *C. difficile* in Canada and north eastern USA. Contact between the consultant microbiologists at Stoke Mandeville and Department of Health with their counterparts in Canada suggested to the BHT team that type 027:

- produces significantly more of the toxins than most;
- causes a greater proportion of severe disease;
- appears to cause more deaths in relation to the number of people infected; and
- is more easily spread between patients.

This information was later reflected in Department of Health guidance - 'A simple guide to *Clostridium difficile*' – published in July 2005.

26. The lack of information about the 027 strain at the time of the outbreaks should not have affected the Trust's application of infection control procedures and isolation policy. However, it was significant to their approach to drug treatment as detailed later (para 36).

*Restrictions on the prescription of certain antibiotics*

27. The ICT advised clinicians not to prescribe certain antibiotics associated with *C. difficile* before the first major outbreak (Aug 2003) due to concerns by the ICT of a continual re-occurrence of a cluster on Ward 11. This advice was re-issued in Dec 2003 when the ICT identified continuing rising

numbers of *C. difficile* infection. Clinicians had to balance the risks of withholding effective treatment of other conditions with these broad-spectrum antibiotics against the risk of those patients developing *C. difficile* infection. This assessment was hampered by the lack of information about the 027 strain. As the numbers of *C. difficile* patients continued to rise, the ICT rightly considered that the balance of this risk was moving strongly towards the likelihood of *C. difficile* infection and acted to physically remove stocks of the culprit antibiotics from the ward pharmacies after the first outbreak committee meeting at the beginning of March 2004.

*Appropriate facilities to minimise the spread of infection*

28. A major criticism in the HC report was the trust's failure to provide adequate isolation facilities during the outbreaks. Clearly the demand for such facilities depends upon the extent of the outbreak. Individual cases can be transferred into side rooms; small clusters can be "cohort nursed" together in one part of a ward; this can extend to the majority of a ward if larger numbers are affected. In large outbreaks it may be necessary to create dedicated *C. difficile* wards.
29. Decisions by the Trust about the creation of isolation facilities were considered against other priorities for patient care and effective delivery of health services. These included:
- a. maintaining efficient levels of bed occupancy – cohort nursing of *C. difficile* patients in one part of a ward allows the ward to remain open to admissions, whereas the creation of a dedicated ward for *C. difficile* patients can leave a large proportion of beds unoccupied when the numbers of affected patients decline;
  - b. ensuring sufficient capacity for emergency admissions – some isolation facilities have to remain reserved for emergency admissions where their infective status is still under investigation;
  - c. meeting commitments to planned surgery. Sufficient isolation facilities need to remain available on surgical wards to avoid ward closures and resultant delays in planned surgery.

In essence, consideration of these issues affected the judgement of the risk to patients from *C. difficile* infection against their need for hospital treatment.

30. HSE found that on a day-to-day basis the ICT, clinicians, bed managers and operational managers attempted to place patients in appropriate facilities with the aim of reducing the risk of infection. Balancing operational and clinical judgements led the BHT team to adopt a piecemeal approach to providing isolation facilities. The responses to the outbreaks were principally reactive, there was little evidence of the application of existing contingency plans. With hindsight, more steps to isolate patients to reduce levels of infection should have been taken and there should have been a plan in place to deal with the possibility of such outbreaks.

31. The majority of the wards at Stoke Mandeville were constructed during the Second World War without consideration of the need to isolate patients in modern-day healthcare facilities. The wards are commonly described as 'Nightingale' wards with lines of beds down each side of the ward and with the ward service facilities (toilets, sluices etc) at the entrance to the ward. These wards were used for the care of surgical patients, medical patients and the elderly (the latter two being the main groups affected by the C. difficile outbreaks) and had only two side rooms per ward.
32. Prior to the first outbreak, infected patients were nursed in side rooms where available. Wards with small clusters were closed to admissions and cohort areas created within wards. During the first outbreak, funding was made available for the erection of partitions within the wards to create cohort bays in an attempt to segregate infected and non-infected patients. All this is in accordance with DH guidance.
33. However with the service facilities being at the entrance to the wards, maintaining complete separation of infected and non-infected areas was impossible. If the designated cohort area was created at the far end of a ward, C. difficile patients (and contaminated material) had to pass through 'clean' areas to reach the toilets and sluices. Conversely, if the cohort area was in any other part of the ward, uninfected patients had to pass through areas where C. difficile patients were being cared for.
34. With the first outbreak coming under control in the summer of 2004 the trust believed that the measures they had put in place, including those to segregate patients, had been effective. The ICT still had concerns about the lack of side rooms. However the difficulties of building new side rooms within the layout of the existing hospital appeared to those concerned to be disproportionate to risk of a further outbreak as foreseen at that time, particularly in the context of recently agreed plans for extensive new facilities (including many more side rooms) on land adjacent to the existing hospital.
35. With the advent of the second outbreak, questions about the effectiveness of cohort nursing began to arise and the search for a dedicated C. difficile ward began. From the declaration of the second outbreak, minutes of the outbreak committee reveal significant difficulties faced by staff at an operational level in identifying a suitable dedicated ward for C. difficile patients. Many wards were considered, but all had deficiencies in the configuration of the beds, location of service facilities or the effect on bed occupancy levels. Consideration was also given to opening wards that had previously been closed with the reconfiguration of services as part of the Shaping Healthcare Service strategy. However, those wards that had been previously selected for closure were the most dilapidated in the estate and would have needed significant refurbishment to meet basic standards for patient care.
36. During the second outbreak, following contact between the Consultant Microbiologists at Stoke Mandeville and their counterparts in Canada, it

came to light that the 027 strain was resistant to the quinolone class of antibiotics that includes ciprofloxacin. Until then, ciprofloxacin had been considered a low risk antibiotic in respect of predisposing patients to *C. difficile* and had been used as an alternative to the more risky broad-spectrum antibiotics. This resistance of 027 to ciprofloxacin actually increased the risk of a patient developing *C. difficile*. On discovering this, the ICT immediately restricted the use of ciprofloxacin.

37. Soon after the declaration of the second outbreak, the decision as to which ward should become the *C. difficile* ward was referred to the Trust Executive Committee (TEC). However, before this consideration was actually put to the TEC a dedicated *C. difficile* ward was created by default, because of the number of *C. difficile* patients it contained, after which it was successfully managed as a dedicated isolation ward.

#### *Restriction of patient movements*

38. The trust attempted to balance the risks associated with the movement of patients during an outbreak with the other priorities described above. The HC, as part of their investigation, undertook a detailed analysis of patient movements in the hospital. We support their conclusion that these appear to have been excessive. However a number of those movements were being made in direct response to the needs of patients with *C. difficile* and so it is difficult for us to come to a firm conclusion as to the extent these movements contributed to an increased risk of exposure to *C. difficile*.

#### *Infection control procedures to prevent transmission of C. difficile infection in clinical areas*

39. During the first outbreak the trust introduced cleaning with a hypochlorite-based cleaner in areas thought to be contaminated with *C. difficile*, and made this trust-wide during the second outbreak. Witnesses have stated that there were problems with the cleaning contractor at Stoke Mandeville in that the contract was coming to an end. There were staff shortages and a reduction in the quality of management by the contractor. The trust released funds (£161,000) during the second outbreak in an effort to ameliorate these problems. We looked for documentary evidence as to the standards of cleaning in areas of possible *C. difficile* contamination, but none was available - and with the events being so long ago, witnesses were not able to give specific, reliable evidence on these matters.
40. There were continual problems throughout both outbreaks with the sluice rooms in the wards nursing *C. difficile* patients being used for the storage of hospital waste. This restricted access to the sluices and hand-washing facilities in the sluices. However, it is difficult to establish the extent to which this contributed to the spread of infection.
41. The training of staff in infection control was not mandatory within the trust prior to the HC investigation. Attendance at voluntary training sessions was patchy. The priority created by the outbreaks put pressure on the ICT's

ability to provide training. The trust identified that alcohol-based hand gels were not effective against the spread of *C. difficile* spores and instituted a policy of hand washing as the proper measure to prevent cross-infection by staff. The trust promoted the need to adhere to these measures by linking them with a national initiative to raise awareness of the importance of good hygiene in the NHS – the ‘Clean your hands’ campaign. Witnesses have stated that at ward level, standards of personal hygiene and the use of personal protective equipment was consistent with guidelines.

42. However, Appendix G of the HC report highlights a number of serious contraventions of good infection control practice as witnessed by their investigation team. In comparing this with the audits carried out by the Stoke Mandeville ICT at the time of the outbreaks, it appears that the Stoke Mandeville auditing system overly concentrated on the facilities/arrangements for infection control rather than actually observing ward level practice.
43. The HSE management systems inspection conducted immediately prior to this investigation, has provided reassurance of significant improvement in adherence to good infection control practice. Our audit team observed good standards of hygiene practice, that staff at all levels took issues surrounding infection control very seriously, and that they were committed to a programme of continued improvement in the management of these risks.

*Management structures, procedures and response to the outbreaks*

44. The formal minutes of the higher committees (e.g. the Risk Management Committee, the Governance Committee and the Trust Executive Committee (TEC)) within the governance structure for infection control show very little recorded discussion of the outbreaks whilst they were occurring. Whilst the minutes of the Clinical Risk Review Panel (CRRP), which received reports of the levels of Health Care Associated Infection (HCAI) in the trust, went to the Risk Management Committee there was virtually no discussion or comment on these minutes at this committee or at the Governance Committee to which it in turn reported.
45. In trying to determine why there was such a lack of formal discussion of the outbreaks at these committees, witnesses referred to the following as possible factors:
  - a. these committees were distracted from dealing with issues such as the *C. difficile* outbreaks as they were having to focus their energies on creating a single governance structure associated with the merger of Stoke Mandeville NHS Trust and South Buckinghamshire NHS Trust to form the new Buckinghamshire Hospitals NHS Trust, which came into being in April 2003.
  - b. the Director of Infection Prevention and Control (DIPC) - who was also the Medical Director of the trust - sat on or chaired many of the committees within the governance structure for infection control. Others

- within that structure believed that as the person with overall responsibility for infection control at the trust, the DIPC would raise the issue of the increasing numbers of patients infected with *C. difficile* at the higher committees and with the executive management team if it were deemed necessary;
- c. HCAs were regarded differently from other “Serious Untoward Incidents”. As they were reported to the Strategic Health Authority and to the Health Protection Agency they were considered as matters of public health rather than as issues to be dealt with by the internal governance arrangements.
46. The DIPC was clear that as Medical Director he was in daily contact with the Trust’s Chief Executive and other trust directors about outbreaks and measures for their control. Executive Board members were made aware of the outbreaks through weekly informal meetings of the TEC (held in between each fortnightly formal TEC meeting) that, whilst not minuted, discussed the outbreaks and actions to bring them under control. The trust concedes that formal records of these discussions should have been made. However, the lack of such records does not in itself constitute a breach of health and safety law.
47. Once an outbreak was formally declared, funds were provided for the erection of ward partitions and installation of hand basins. Further resources for the infection control team at Stoke Mandeville were approved. A method for prioritising patients needing isolation was developed (although slowly). At the end of the first outbreak, the ICT believed that standards of infection control were much improved, although the lack of isolation facilities remained.
48. The action plan, updated at the end of the first outbreak, highlighted the lack of isolation facilities - along with the continued obstruction of sluices and uncertainty as to whether the cleaning specification was being met – as unresolved issues. This plan was reviewed by the DIPC and ICT prior to the declaration of the second outbreak in February 2005. At the first Outbreak Committee meeting (18th March 2005) it was recognised resolution of the outstanding issues required board-level involvement and a revised action plan was referred to the TEC on 5th April 2005 which agreed actions to address the more intractable problems.

### **Buckinghamshire Hospitals Trust’s performance in comparison to other NHS acute trusts**

49. In October 2005, in response to the outbreaks at Stoke Mandeville, the HC and the Health Protection Agency undertook a survey of DIPCs to gain a national picture of NHS acute trusts’ performance on *C. difficile*. Interim results from the survey – ‘Management, prevention and surveillance of *C. difficile*’ – were published in December 2005, with the final report – ‘*Clostridium difficile*: Findings and recommendations from a review of the epidemiology and a survey of Directors of Infection and Prevention Control

in England' – published in July 2006.

50. These reports provide a further benchmark to assess whether BHT did enough to ensure the health and safety of their staff and patients. The following points from these reports indicate that BHT were not unusual in the levels of infection they were experiencing and difficulties they faced in attempting to control these infections.

- 67% of trusts reported an increased incidence of *C. difficile* in the past 3 years as a result of increased testing, increased reporting of cases and increased numbers of actual infections.
- Over half of trusts (56%) experienced consistently high 'background rates' of infection, in addition to any increased frequency of outbreaks.
- Half of all trusts had undertaken their own investigations of outbreaks, or what they considered to be an excess of cases during 2004/2005.
- 26% of trusts had closed wards in the past 12 months due to cases of *C. difficile* infection.
- Only 11% of trusts had a ward that could be used for cases of *C. difficile* infection.
- Over two-thirds of trusts thought that the prescribing of antibiotics and the lack of facilities for isolation represented the greatest challenges to controlling infections, whilst high numbers of both admissions and transfers of patients was cited by 28% of trusts.

51. In addition, the report indicated

- 40% of trusts did not routinely isolate cases of infection from *C. difficile*. *BHT did routinely isolate patients with C. difficile. This was not always possible due to the shortage of suitable isolation facilities and pressures on bed occupancy, but routine isolation was the trust's policy.*
- 38% of trusts had not placed restrictions on the prescription of broad-spectrum antibiotics as a way of controlling infection from *C. difficile*. *BHT did place restrictions on broad-spectrum antibiotics before and during both outbreaks.*
- Just over half of trusts (54%) did not refer cultures of *C. difficile* for typing (i.e. identification of the strain involved). *BHT did refer cultures for typing and so identified the 027 strain of C. difficile.*

### **Compliance with the Control of Substances Hazardous to Health Regulations (COSHH) 2002 by BHT as a body corporate**

52. COSHH contains a number of specific requirements aimed at preventing health related risks arising from exposure to hazardous substances.

53. Under these regulations duty holders have to assess risks to health arising from exposure to hazardous substances and take steps to prevent, or where that is not reasonably practicable, adequately control exposure. Biological agents, such as *C. difficile* are covered by the regulations.

54. Prior to the outbreaks, BHT did not have a formal written COSHH assessment of the risks associated with exposure to *C. difficile*. However, the control measures at that time were commensurate with the guidance from the Department of Health. With onset of the outbreaks the trust was under a legal duty to review their assessment, as there was good reason to suspect it was no longer valid. Whilst there is no formal record of the assessment being reviewed, the action plans generated by the outbreak committees were in essence a dynamic risk assessment and were revised as the outbreaks developed. The effect of this was to achieve compliance with the requirements of COSHH.

### **Compliance by individuals**

55. The investigation has not revealed any evidence of any negligent acts or omissions (gross or otherwise) by senior managers that resulted directly in patients being infected with *C. difficile* and their consequent death.

56. During the first outbreak and in response to the Government's 'Winning Ways' initiative to reduce levels of healthcare associated infection, the Trust appointed their Medical Director as Director of Infection Prevention and Control (DIPC) and in this role he was required to:

- be responsible for the Infection Control Team within BHT;
- report directly to the Chief Executive and the Board;
- challenge inappropriate clinical hygiene practice as well as antibiotic prescribing decisions;
- assess the impact of all existing and new policies and plans on infection and make recommendations for change;
- be an integral member of the organisation's clinical governance and patient safety teams and structures;
- publish an annual report on the state of healthcare associated infection in BHT.

57. The DIPC was a member of the Outbreak Committees; he chaired or was a member of all the committees within the governance structure for infection control; and was in regular discussion with the ICT, Directors of Operations, Clinicians, Bed Managers, Senior Nurses and Estates staff in balancing the needs of patients, in terms of their care, against the risk of their exposure to *C. difficile*.

58. The DIPC did not present the annual report on infection control to the Trust Board and publish it as a public document. However, we conclude that this omission did not amount to a failure to discharge responsibilities placed upon him by health and safety legislation.

### **Overall review of available evidence**

59. In reviewing the available evidence and considering potential breaches of the law, we focussed upon Sections 3, 7 and 37 of the Health and Safety at Work etc Act 1974 (HSW Act). These provisions cover the general

duties of an employer to persons other than their employees (i.e. the duty of the trust towards its patients) and the associated duties of individuals working within the trust. We also considered duties under Regulations 6 and 12 of the Control of Substances Hazardous to Health Regulations 2002 (COSHH). These provisions require employers to assess and control risks from biological agents such as *C. difficile* and provide necessary training for employees. In our review we looked to see if a direct link could be established between failure to manage the risks from *C. difficile* and the death of any particular patient.

60. In establishing if a prosecution should go forward we applied the Code for Crown Prosecutors. The first stage of the code tests evidential sufficiency. Only where there is sufficient evidence to give a realistic prospect of securing a conviction can a case proceed. The second stage of the test establishes if proceeding with a case for which sufficient evidence exists would be in the public interest.

61. In coming to our conclusions and deciding if there was sufficient evidence of a breach we had to balance the factors tending to support prosecution against those undermining it. We also had to weigh the potential contribution of factors about which we felt insufficient information was available to allow us to make an objective judgement about the precise situation, or level of control actually achieved by the Trust.

62. Factors indicating breaches may have been committed included:

- The failure of the governance arrangements to set adequate criteria for declaration of a major outbreak which led to both outbreaks being declared late.
- The failure to have in place, prior to any outbreak, systems and procedures to manage any outbreak.
- Failure to take sufficient steps to isolate patients (or to plan for the isolation of patients) to reduce the risk of infection particularly during the second outbreak given that this was highlighted in the report compiled at the end of the first outbreak.
- The paucity of recorded discussion and action within the governance structure suggesting a lack of appreciation by senior management as to the seriousness of the situation and the need for decisive action to bring the outbreaks under control.

63. Factors indicating that adequate standards had been achieved included:

- The *C. difficile* cases were spread throughout the hospital obscuring the extent of the outbreak, leading the trust to a piecemeal reactive approach in dealing with the spread of infection.
- Lack of information about the increased virulence of the O27 strain and its resistance to the quinolone class of antibiotics which resulted in the continued use of ciprofloxacin the treatment of *C. difficile* patients until very late in the outbreaks.

- The age and layout of the hospital facilities at Stoke Mandeville, replacement for which had been promised over many years, created significant challenges in segregating patients with *C. difficile* from others and in applying good infection control practices.
- The belief that at the end of the first outbreak the measures they had put in place had successfully controlled the first outbreak and so further measures (e.g. increased isolation facilities) whilst desirable were an unnecessary drain on resources given that new facilities (with increased isolation facilities) were finally being constructed.
- Attestations that whilst there was little formal recorded discussion of the outbreaks within the governance structure, there was considerable informal discussion between the trust board members as to actions needed to deal with the developing situation.
- The results of the National Survey of DIPCs showing that many other trusts were experiencing rises in *C. difficile* infection at this time and evidence from outbreaks in other hospitals since the ones at Stoke Mandeville illustrate the universal difficulties faced by the NHS in controlling the spread of *C. difficile* infection.

64. The passage of time and the availability of admissible evidence also affected our ability to establish a definitive picture of some of the standards being achieved by the Trust. Factors which could be relevant to our judgement, but which could not be fully established included:

- The standards of cleaning in the hospital achieved during the outbreaks.
- The extent to which patient movements contributed to the spread of infection.
- The extent to which the storage and disposal of dirty linen and clinical waste contributed to the spread of infection.
- The adherence by staff to procedures or personal hygiene and the use of personal protective equipment.

65. We conclude that, on balance, there is not a realistic prospect of securing a conviction against the trust under S3 of HSW Act and therefore no prosecution should be started. If the trust has not failed in their duty there can be no offences under S37 of the HSW Act. We also conclude that there is insufficient evidence regarding failures of any individual employee to warrant prosecution under S7 of the HSW Act.

66. We conclude that there was sufficient evidence to demonstrate breaches of Regulations 6 and 12 of COSHH. However, these breaches were largely regulatory failings or failings in record keeping. The failings could not be linked to any individual death and were not, in themselves, considered to have given rise to increased risk. We therefore conclude that a court would impose only a nominal penalty and so it would not be in the public interest to proceed with any of these cases.

## Conclusions

67. In dealing with a developing situation, the trust took steps – in line with published guidance – to control the outbreaks given the other priorities and constraints they were facing at the time, although they could have applied these measures more rigorously and with greater urgency.
68. The age and layout of the hospital facilities at Stoke Mandeville created significant challenges in segregating patients with *C. difficile* from others and in applying good infection control practices.
69. Whilst the lack of recorded discussion of the outbreaks indicates significant weakness in BHT governance structures, witnesses have attested to considerable informal discussion, at all levels of management, of potential actions aimed at controlling the outbreaks.
70. From a national perspective, the challenges facing BHT were similar to those facing many other NHS acute trusts and as confirmed by the considerable number of outbreaks reported in the media since those at Stoke Mandeville. Their performance in respect of the figures for *C. difficile* when taken as an average over all three hospitals forming the trust was comparable to many similar trusts.
71. Balancing all of the above, we conclude that there is not a realistic prospect of securing a conviction for any offences alleging a direct link between health and safety failures and patient deaths. Based on the available evidence we judge that we have explored all reasonable lines of enquiry and that further investigation would not yield evidence to change this conclusion.

## Recommendations

72. The outbreaks of *C. difficile* at Stoke Mandeville finished 18 months before this investigation. Even before the start of the investigation the trust had an action programme implementing the recommendations arising from the HC investigation – progress with which was confirmed and supplemented by the HSE management systems inspection in December 2006. We understand that the recommendations below have already been implemented by the trust, but are included here as being the key learning points ensuring a robust approach to the prevention and control of *C. difficile*.

- a. *Antimicrobial prescribing*

Key to the prevention of *C. difficile* is curbing unnecessary use of broad-spectrum antibiotics which pre-dispose patients to colonisation by *C. difficile*. The use of such antibiotics is a clinical judgement. We were concerned to find that clinical colleagues at Stoke Mandeville did not appear to appreciate the risks associated with the use of broad-spectrum antibiotics and heed the advice provided by their

microbiological colleagues.

**Action:** The trust should ensure it has in place procedures and protocols to prevent inappropriate prescription of antibiotics that unnecessarily increase the risk of a patient developing *C. difficile*.

b. *Protocols for the testing of diarrhoeal specimens*

Delays in sending diarrhoeal specimens for testing and slow turn around of that testing and results reporting in the early part of the outbreaks at Stoke Mandeville led to delays in patients with *C. difficile* having the proper clinical care protocols, such as isolation, applied in a timely manner.

**Action:** The trust should confirm that ward-level procedures for selecting stools samples for testing, and the laboratory protocols for such testing and results reporting, are sufficient to ensure the prompt identification of *C. difficile* infection.

c. *Local surveillance of C. difficile levels*

Both the first and the second outbreaks at Stoke Mandeville should have been formally declared earlier than was the case. This was due to relatively small number of cases appearing in a relatively large number of clusters across the hospital.

**Action:** The trust should set criteria (both quantitative and qualitative) for the declaration of a major outbreak and ensure governance arrangements for infection control regularly assess levels of *C. difficile* infection within trust against those criteria.

d. *Provision of isolation facilities in the event of a major outbreak*

Provision of suitable isolation facilities to cope with a major outbreak of *C. difficile* was the most significant and difficult challenge faced by BHT. Whilst the prevention of a major outbreak is of primary concern, contingency planning for the creation of suitable isolation facilities in the event of such an outbreak is of vital importance. Managers responded to the outbreak in a piecemeal fashion, there was no planned, coordinated response already developed to assist the response to the developing situation.

**Action:** The trust should have contingency plans to assist managers when responding to outbreaks. Plans should detail how and when isolation facilities will be provided, serviced and resourced in the event of an outbreak of *C. difficile* infection.

### **Acknowledgements**

73. HSE would like to acknowledge the co-operation of staff at Buckinghamshire Hospitals Trust with our investigation.

**THE MANAGEMENT OF HEALTH AND SAFETY  
AT BUCKINGHAMSHIRE NHS HOSPITALS TRUST**

**REPORT OF THE INSPECTION BY  
THE HEALTH AND SAFETY EXECUTIVE**

**DECEMBER 2006**

## 1. INTRODUCTION

- 1.1 This report presents the findings of an inspection of the management of health and safety at Buckinghamshire NHS Hospitals Trust carried out by the Health and Safety Executive in December 2006. The framework for the inspection was the guidance published by the Health and Safety Executive in '*Successful Health and Safety Management*' (HSG65).
- 1.2 The inspection was conducted by a team of HSE Inspectors to assess the response made by Buckinghamshire NHS Hospitals Trust following two major outbreaks of Clostridium difficile (C.diff) in 2003/4/5. The team members were Suzanne Denness, HSE, Basingstoke, Dennis MacWilliam, HSE, Basingstoke and Mara Ajder, HSE, Bootle.
- 1.3 The inspection methodology included the examination of key relevant documents such as policy statements, risk assessments and guidance documents. Approximately 25 staff were also seen either for formal interviews or during the inspection of the selected sample localities.
- 1.4 The inspection concentrated on infection control procedures and practises in a sample Directorate, Medicine for Older People at two sample locations, Wards 2 and 8 at Stoke Mandeville Hospital and Wards 4B and 5B at Wycombe Hospital.
- 1.5 The conclusions and recommendations made are based on the sample of localities and activities inspected; where appropriate these should be applied across the full range of localities and activities. Recommendations made are not directly linked to specific legal requirements but represent the improvements required to enable Buckinghamshire NHS Hospitals Trust to comply with its duties contained within the generality of The Health and Safety at Work etc Act 1974 and the Management of Health and Safety at Work Regulations 1999.
- 1.6 We would like to express our thanks to the management and staff at Bucks NHS Hospitals Trust for their assistance and co-operation throughout the inspection.

## 2. FINDINGS & RECOMMENDATIONS

### 2.1 Policy.

*Is there an effective health and safety policy to set a clear direction for the organisation to follow?*

- 2.1.1 There is an Infection Control Policy in place, which sets out the strategic objectives of the trust for controlling infection, which has been verified and is supported by senior managers and the Trust Board.
- 2.1.2 There is a clear policy for the prescription of antibiotics, which recognises the importance of their appropriate selection and controlled use as part of an integrated infection control strategy.
- 2.1.3 The Infection Control Policy is supported by an Infection Control Manual containing specific practical protocols and guidance for implementing the policy including most of the essential elements set out in the Code of Practice for the Prevention & Control of Hospital Acquired Infections under the Health Act 2006
- 2.1.4 The Infection Control Team oversees both the policy and the manual and the manual is currently subject to a rolling programme of review and revision by that team.
- 2.1.4 All the Trust staff spoken to during the inspection were aware of both documents, which are easily accessible either as hard copies on each ward or via the Trust's intranet.
- 2.1.5 Clinical and pharmacy staff were aware of the policy on the prescription of antibiotics, which was widely publicised on a plastic coated flash card.
- 2.1.6 The policy did not make clear the respective roles and responsibilities of staff with regard to infection control although these had been developed and documented within the Saving Lives programme.
- 2.1.7 Contract staff such as those supplied by NHS Professionals were not always aware of the policy and protocols.
- 2.1.8 Much of the guidance contained in the manual was site specific and was not setting a trust wide standard. In some cases it was significantly out of date and did not equate with the improved best practice taking place on the wards. (e.g. use of Chlorclean.)

### Recommendations

R1.The Infection Control Policy and protocols should be revised as a matter of urgency to include all the essential requirements outlined in the code of practice. The revised documents should formalise current best practice and establish them as trust wide protocols. The roles and responsibilities of all staff with regard to the control of infection should be clearly defined within the revised documentation. (See also R3 & R4)

R2.Familiarisation of the Infection Control Manual and protocols should be included in the induction of contract staff such as NHS professionals. (See also R11)

## 2.2 Organising

### *Control*

*Is there an effective management structure and arrangements in place for delivering the policies?*

- 2.2.1 Governance arrangements have recently been revised and the structure simplified.
- 2.2.2 The Infection Control Team is being restructured to reflect the current unified single trust status of the three hospitals
- 2.2.3 The roles and responsibilities of key staff involved in control of infection procedures have recently been defined and documented by the Saving Lives programme.
- 2.2.4 Staff we spoke to were clear about their roles and responsibilities with regard to infection control
- 2.2.5 Any new MRSA or C.diff infections identified by the Trust's microbiological laboratories are reported to the wards by a member of the Infection Control Team
- 2.2.6 An Infection Control Nurse visits wards where new C.diff infections have been identified during weekdays and this task is carried out by the Consultant Microbiologist out of hours.
- 2.2.7 Directorate Infection Control leads, DIPC and Infection Control Nurses are actively involved at operational level.
- 2.2.8 The cleaning contractors (Medirest and Sodexo) are operating and self monitoring to the National Cleaning Standards.
- 2.2.9 Sodexo (Cleaning contractor at Stoke Mandeville Hospital) have recently recruited to the vacant post of Domestic Manager at Stoke Mandeville Hospital to ensure adequate supervision of cleaning activities.
- 2.2.10 Activities such as patient bed moves, cleaning operations and the serving of meals to patients are co-ordinated to minimise the risk of infection spread.
- 2.2.11 Antibiotics restricted by the Antibiotic Policy can only be prescribed with the consent of the Consultant Microbiologist.
- 2.2.12 Staff have been overtly encouraged to challenge any poor hygiene practice amongst colleagues at all levels – and do so – their actions are supported by disciplinary procedures if appropriate.
- 2.2.13 Not all the good practice and procedures currently being followed are accurately reflected in the Infection Control Policy and protocols, which could give rise to confusion and potential errors by junior and less experienced staff.
- 2.2.14 There are some variations in current infection control practises and guidance given between sites.

### **Recommendations**

R3 The Infection Control Policy and Protocols require revision (See R1)

R4 the restructuring of the Infection Control Team should be completed, appointments made and roles and responsibilities clearly defined. (See R1)

## **Cooperation**

*Are there adequate and appropriate arrangements to secure the trust, participation and involvement of all employees?*

- 2.2.15 Liaison arrangements between nursing and clinical staff in the Medicine for Older People Directorate (MFOP) were generally good with regard to Infection Control.
- 2.2.16 This Directorate is acknowledged as one of the most responsive and proactive Directorates within the trust with regard to Infection Control issues.
- 2.2.17 There is close co-operation between the Directorate staff and the Infection Control Team with ward infection control link staff meeting directly with the DIPC.
- 2.2.18 A trust wide combined Drugs and Therapeutic Committee exists to ensure the rationalisation of the Antibiotics policy across all the hospitals in the trust and a review group, led by the consultant microbiologist, reports to the committee.
- 2.2.19 A single trust wide Infection Control Team is currently being established with a Lead DIPC in place and a single Lead Infection Control Nurse to be recruited.
- 2.2.20 Procedures exist to resolve potential conflicts between cleaning targets set for the Cleaning Contractors and obstacles created by nursing activities such as equipment left in the corridor
- 2.2.21 Co-operation is improving between Directorates around the negotiation of bed moves and infection control issues.
- 2.2.22 However there did not seem to be a direct formal contact between Infection Control Link staff at ward level and the clinical Infection Control Lead.

## **Recommendations**

R5 Consideration should be given to establishing formal direct contact between Directorate Clinical Leads and Infection Control Link practitioners at ward level to further reinforce co-operation over Control of Infection issues within Directorates.

R6 The best practice being established in this Directorate should be formalised into protocols and rolled out across other Directorates. (See R1 & R3)

## **Communication**

*Are there adequate arrangements to secure an information flow into, within and from the organisation?*

- 2.2.23 Managers visibly support and reinforce Infection Control measures
- 2.2.24 Infection Control Link Practitioners deliver toolbox talks on Infection Control to peers at ward level
- 2.2.25 The Infection Control Team produces an annual report for the Board.
- 2.2.26 Hand wash stations are available at all ward entrances with clear explanations and instructions
- 2.2.27 Trust wide hand cleaning procedures are set out in written, diagrammatic and cartoon form to assist comprehension by staff and contractors whose first language is not English.
- 2.2.28 Monthly briefing/monitoring review meetings take place with cleaning contractors.
- 2.2.29 Infection Control hazards are flagged up on patients notes (electronic).
- 2.2.30 An advisory leaflet on C.diff infection and guidance on laundering patient garments is available for patients and/or their relatives.
- 2.2.31 There is reliance on global e-mail communication to keep staff informed about major changes and how they will impact on the everyday work of the trust – this includes cleaning contracts, recruitment of additional permanent staff and the opening of wards to relieve winter pressures.
- 2.2.32 During the early days of the cleaning contract implementation ward staff were not kept adequately informed which led initially to difficulties and misunderstandings.
- 2.2.33 There was evidence of some confusion over terminology between ward staff and cleaning contractors such as ‘hot wash’ and ‘terminal clean’.

## **Recommendations**

R7 Ward staff should be kept better informed through face-to-face team briefings.

R8 Terminology should be clearly defined as the revised Infection Control Procedures are established and correct usage of terminology should be monitored and reinforced by senior staff.

R9 Ward staff should ensure that patients and/or relatives have a proper comprehension of the advice contained in the C.diff leaflet and that patients capable of managing their own toilet requirements are fully aware of the need for high standards of personal hygiene.

**Competence.**

*Are there systems and arrangements to secure the competence of all staff?*

- 2.2.34 Infection Control Training is now mandatory for all staff with the training records to be kept centrally by HR who monitor training attendance and frequency of refresher training.
- 2.2.35 Training records for staff in Medicine for Older People Directorate are also kept within the Department.
- 2.2.36 The Infection Control Team Microbiologists and nurses are appropriately experienced and qualified.
- 2.2.37 Link Practitioners are selected according to an agreed set of personal competencies and must have two years of post qualification experience as well as expressing a specific interest in infection control.
- 2.2.38 Attendance at Infection Control Training is taken into consideration during appraisals for clinical staff.
- 2.2.39 Qualified nursing staff on the wards demonstrated an understanding of infection control issues and in particular those issues around MRSA and C.diff.
- 2.2.40 Junior clinicians receive some information about the Trusts IC and Antibiotic Policies during their induction. It is reinforced during an Induction day on joining the Medicine for Older People Directorate and the issuing of a flash card that identifies antibiotics approved for use.
- 2.2.41 Mandatory initial and 6 monthly refresher Infection Control Training is provided to ancillary staff, such as cleaners and housekeepers, by the contract providers. It is appropriately targeted including the use of tabletop flip charts and interactive CD's.
- 2.2.42 Specific training is provided to cleaners and supervisors involved in the cleaning of isolation areas.
- 2.2.43 A Passport system is to be introduced for ancillary staff and food-handlers.
- 2.2.44 It was not clear that all Directorates other than the Medicine for Older People Directorate kept such comprehensive and consistent staff training records.
- 2.2.45 There was evidence that staff supplied by NHS Professionals were not always aware of the Infection Control Policy and protocols.
- 2.2.46 There was evidence that not all nursing staff were clear about the difference between source and protective isolation.

**Recommendations**

R10 Arrangements for the maintenance and monitoring of training records should be reviewed to ensure that all Directorates are able to access up to date information about the current competency status of all ward staff and ensure that they receive refresher training at suitable intervals.

R11 The Induction Training provided to NHS Professional staff should include familiarisation with the Infection Control Policy and Protocols. (See R2)

R12 Designation of isolation area categories (source or isolation) should be restricted to competent staff in order to ensure appropriate management of labelling and isolation rooms.

R13 Dedicated and documented training should be provided during the induction of new junior clinicians to emphasise the rationale and content of the Trust's antibiotic policy.

### **2.3 Planning and Implementing**

*Is there a planned and systematic approach to implementing the health and safety policy?*

- 2.3.1. A comprehensive Action Plan was produced in response to the HCC investigation into the C.diff outbreaks at Stoke Mandeville Hospital and progress is reviewed weekly by the executive directors and senior quality assurance staff.
- 2.3.2. Local Infection Control Care Plans are prepared for individual patients.
- 2.3.3. The Infection Control Team were involved in the design of PFI buildings to ensure optimal facilities in relation to infection control issues.
- 2.3.4. The Estates Department advise the Infection Control Team of any proposed building work to ensure that any possible infection control issues can be addressed.
- 2.3.5. Local arrangements exist for ward managers to request augmented levels of cleaning within their area of responsibility if required.

## **2.4 Measuring/Auditing**

*Is performance measured against agreed standards to reveal where and when improvement is needed?*

- 2.4.1. Supervisory staff from both cleaning contractors carry out monitoring of cleanliness standards.
- 2.4.2. Formal, documented audits of cleanliness standards are also carried out by Trust staff using the national standards template.
- 2.4.3. Informal checks on cleanliness are also made by ward staff.
- 2.4.4. IC Link practitioners carry out audits of their own areas following monthly IC meetings/lectures. The results are fed back to the Infection Control Team and the Directorate IC leads. Local managers are required to produce remedial action plans subsequently monitored by the IC Team.
- 2.4.5. The Infection Control Nurses also complete at least one Infection Control audit annually
- 2.4.5. Antibiotic usage is monitored by the pharmacy, which reports over usage of antibiotics to the Consultant Microbiologist for action.
- 2.4.6. Hospital acquired infection statistics are collated on a monthly basis and provided to the Directorates, the Board and nationally collated statistics.
- 2.4.7. We were unable to obtain any evidence of monitoring of laundry standards although we understand the subcontractors have agreed quality control standards.
- 2.4.8. There is some confusion over the standards of cleaning required for isolation rooms.
- 2.4.9. Currently no microbiological monitoring is carried out in isolation areas.

## **Recommendations**

R14 Arrangements for the monitoring of laundry standards should be reviewed and revised if necessary, and written records made of monitoring visits.

R15 The IC Manual should be revised as a matter of urgency (See R1 and R3) to ensure that it contains agreed standards and guidance for the routine and terminal cleaning of isolation areas.

R16 Consideration should be given to the development of a technical support role within the microbiological department to carry out environmental monitoring as part of the auditing of the Cleaning contract.

## **2.5 Reviewing**

*Are lessons learnt from the performance measurement and auditing processes which are effectively put into practice?*

- 2.5.1. The results of the Trust audit programme are used to prioritise capital bids.
- 2.5.2. The IC Committee develop the Trusts strategy based on the local priorities established by the auditing process as well as central DOH initiatives.
- 2.5.3. The review of monthly HAI rates ensure that a benchmark is established enabling outbreaks to be identified in a timely fashion.
- 2.5.4. Repeated failures to meet 80% of the standard specified in the national cleaning criteria automatically triggers high level discussions between senior Trust managers and the cleaning contractors to establish remedial actions.
- 2.5.5. Some instances of HAI's are investigated by the Directorate IC leads and some by Head Nurses.
- 2.5.6. Nor was it clear how information from these Directorate investigations into instances of HAI's was being used to determine improvements to guidance and procedures.
- 2.5.7. No use is being made of templates readily available on the DOH website which would enable the Trust to establish the true cost of Infection Control failures.

## **Recommendation**

R17 Procedures for the investigation of HAI's should be reviewed and formally documented to ensure uniformity of approach and a clear mechanism for feedback of the information obtained. The revised documented procedure should be included in the revised Infection Control Manual.

R18 Consideration should be given to the use of the costing templates available from DOH as a means of keeping senior managers and Directors informed of the priority of Infection control issues.

### 3. SUMMARY

- 3.1 The practises observed in the Directorate inspected were of a good standard and our recommendations are aimed at improving documentation to reflect that good practice and ensure that it continues throughout the Trust.
- 3.2 It is abundantly clear that staff at all levels take the issues surrounding Infection Control very seriously indeed and are committed to a programme of continuous improvement in the management of these risks.
- 3.3 There are high levels of infection control expertise and experience amongst staff in both the Infection Control Team and on the wards. Trust staff and the staff of contractors providing ancillary services are willing to work together to ensure the highest possible standards of cleanliness.
- 3.4 There is a risk, however, of over reliance on the expertise, experience and commitment of individuals.  
**Therefore;**
- 3.5 Steps should be taken to ensure that Infection control measures are fully embedded in the organisations management system; and
- 3.6 The reorganisation of the Infection Control Team should be completed as a matter of urgency to ensure Trust wide consistency and clear definition of roles and responsibilities.
- 3.7 Definitions of best practice which underpin those established in the Medicine for Older People Directorate should be formally documented in the Infection Control Manual that should be revised as a matter of urgency.