

1.1. Introduction

- 1.1.1. In October 2008, the Minister for Health, Social Services and Public Safety, Mr Michael McGimpsey, announced that he had decided to institute a Public Inquiry under the Inquiries Act 2005 into matters concerning the outbreak* (the outbreak) of *Clostridium difficile* infection (CDI) in the Northern Health and Social Care Trust (NHSCT, the Trust).
- 1.1.2. On 30 March 2009, he announced the terms of reference of the Inquiry:
- to establish how many deaths occurred in NHSCT hospitals during the outbreak, for which *Clostridium difficile* (*C difficile*) was the underlying cause of death or was a condition contributing to death
 - to examine and report on the experiences of patients and others who were directly affected by the outbreak, and to make recommendations accordingly.
- 1.1.3. The Minister also announced that he had appointed Dame Deirdre Hine to chair the Inquiry and a panel (the Panel) of three members, namely:
- Dr Jocelyn Cornwell
 - Mrs Eleanor Hayes
 - Professor Robert Stout.
- 1.1.4. The Inquiry completed its work in 23 months having been granted two extensions of time. The Panel met in private 30 times, undertook a familiarisation visit to each of the five hospitals involved, held 20 informal meetings with persons directly affected by the outbreak, and held 14 days of public oral hearings. The Inquiry received 73 completed questionnaires, 50 letters, 113 written witness statements and a total of 1,055 documents, including reports of similar outbreaks elsewhere in the UK. A full account of the work of the Inquiry is given in Chapter 2.
- 1.1.5. The Panel accepted that the outbreak occurred in the Antrim Area, Braid Valley, Mid Ulster, Moyle and Whiteabbey hospitals from 16 June 2007 to 31 August 2008 (Chapter 2).
- 1.1.6. The terms of reference of the Inquiry were quite specific. They did not require it to repeat the work done by the RQIA, which reported in August 2008 on the circumstances that lead to the outbreak and the management of it by the Trust. Nevertheless, the Panel needed to understand and take into consideration the background against which the deaths and the experiences occurred. The experiences of patients, relatives and staff were inevitably dictated to some extent by management action or inaction. To that extent only, the Inquiry took evidence and reports on issues of management.
- 1.1.7. The Trust provided detailed documentation from which the Panel was able to form a picture of the circumstances that prevailed at the Trust at the time that the outbreak began (as defined by the RQIA investigation). These are described in Chapter 3.

* The Regulation and Quality Improvement Authority (RQIA) independent review team concluded in its report dated August 2008⁽¹⁾ that there was an outbreak of gastrointestinal illness within the five hospitals in the southern part of the Northern Trust in 2007 and 2008 and that it was caused by *C difficile* ribotype 027. These hospitals were identified as Antrim Area, Braid Valley, Mid Ulster, Moyle and Whiteabbey.

- 1.1.8. Early in the first few months of its work, the Panel produced for its own guidance a detailed timeline of the outbreak that included the number of cases and deaths reported serially by the Trust, and key actions taken by the Trust and the Department of Health, Social Services and Public Safety (DHSSPS). This is included as Chapter 4.
- 1.1.9. Before reporting on the number of those who died as a result of the outbreak, the Inquiry needed to understand the way in which deaths are certified and reported to the registrar general's office. An account on the certification of death in Northern Ireland as understood by the Panel is included as Chapter 5.
- 1.1.10. It became apparent to the Panel early in the Inquiry that knowledge of *C difficile* and the illness it causes is deficient and sometimes inaccurate among the general public, patients and relatives of those who had had the infection, and even among some healthcare staff. There had also been some inaccurate information carried by the media. The Panel seeks to remedy this by producing in Chapter 6 and Appendix 5 an authoritative account of the disease, its causes, control and management.

1.2. First term of reference

- 1.2.1. In order to assist the Inquiry to meet the requirements of the first term of reference, the Chairman appointed three experts (the expert reviewers[†]) to review the clinical records of 124 patients who died within three months[‡] of testing positive for CDI during the outbreak, and to advise as to whether these deaths were due to CDI as the underlying or contributory cause.
- 1.2.2. The expert reviewers concluded that CDI was implicated in 31 of these deaths, as the underlying cause in 15 and as a contributory cause in 16. The reviewers attended the public oral hearings held by the Inquiry to give an account of their methodology and conclusions. A detailed account of how this conclusion was reached is given and discussed in Chapter 7 and Appendix 2.

1.3. Second term of reference

- 1.3.1. The Panel defined 'those directly affected by the outbreak' as the surviving patients who had been diagnosed with CDI during the outbreak, the relatives of those who had contracted the infection and died, and the staff of the Trust. All those whom the Inquiry was able to identify were invited to complete a questionnaire and, later, to attend an informal meeting with the Panel. On the basis of these meetings and the letters and questionnaires it had received, the Panel identified a number of common themes for further exploration.
- 1.3.2. A total of 281 patients, relatives and staff was then offered the opportunity to provide a written statement of evidence. The number of statements received was 106, and 54 of these witnesses were then asked to attend oral hearings to clarify and amplify their written statements.
- 1.3.3. Having taken into account all the evidence, both written and oral, given by those witnesses, the panel identified the major themes affecting patients and relatives on the one hand (paragraph 1.3.4) and staff of the Trust on the other (paragraph 1.3.5) with some experiences in common.

[†] Appointed under section 11 of the Inquiries Act 2005.

[‡] For the rationale see paragraph 2.4.4.

- 1.3.4. The experiences, both positive and negative, of patients and relatives during the outbreak are described and examined in Chapter 8, including:
- communication to both patients and relatives including information on diagnosis, prognosis and precautions
 - environmental cleanliness and hygiene
 - the impact of the disease
 - quality of care including personal care and attention, attitude of staff, number of patient transfers, medical treatment and experience of isolation
 - end of life care.
- 1.3.5. The experiences of the staff of the Trust, ranging from the chairman and senior management to the nursing and domestic staff, are described and examined in Chapter 9, including:
- the impact of caring for patients with CDI
 - workload and resources
 - responsibility and accountability
 - communication, including the impact of media reporting
 - morale and support.
- 1.3.6. The Inquiry took place over a period of two years, beginning eight months after the end of the outbreak. The findings and recommendations of the Panel are based on the evidence received of the experiences of patients, relatives and staff in the circumstances that pertained during 2007 and 2008. The Panel acknowledges that much has changed in the Trust since that time. Some examples of these changes are included as Chapter 10.

1.4. Findings, conclusions and recommendations

1.4.1. The findings, conclusions and recommendations of the Inquiry are summarised below. The recommendations are informed by the evidence received from experts, and we consider that adoption of these recommendations would improve significantly the experience of those directly affected by any future outbreak of CDI. Indeed, most of the recommendations should improve the experiences of patients, relatives and staff arising from any episode of healthcare associated infection.

1.4.2. Deaths from CDI

1.4.2.1. The Inquiry has received the report of the reviewers and accepts in their entirety the findings and conclusions expressed in that report (Appendix 2).

1.4.2.2. Finding: we find that the number of deaths that occurred in the NHSCT during the outbreak for which CDI was the underlying or a contributory cause was 31. A total of 124 clinical records was examined. Of the 31 deaths identified, CDI was the underlying cause in 15, and a contributory cause in 16.

1.4.3. Experiences of patients and relatives

Communication/information

1.4.3.1. The Panel noted the expressions of sympathy and compassion towards patients and relatives affected by CDI on the part of the chief executive and individual members of staff at all levels who testified before them. The Trust, Trust managers, doctors and nurses intended to meet high standards of patient care, including high standards of communication and information.

- 1.4.3.2. However, the weight of the evidence from the statements of patients and relatives who testified before the Panel demonstrates that many patients and relatives experienced an inability to secure relevant information about CDI and its impact on patients from the Trust and its staff. There was a failure of communication by the Trust and some of its staff to inform patients and relatives fully about the diagnosis and the nature of the disease. Timely, accurate and effective communication is vital for patients who recover from CDI to ensure that rapid and appropriate care can be instituted in the event of possible future recurrence. This could also have alleviated the anxiety of relatives about their own safety, informed them of the nature, treatment and progression of the disease, and, if necessary, have better prepared them for the often rapid deterioration and death of frail elderly patients.
- 1.4.3.3. The sample of cases examined by the Panel suggests strongly that the Trust made insufficient effort to inform itself systematically about patients' and relatives' information needs or their experience of care. There was little or no evidence of the allocation of resources required to produce good written information for patients and relatives or brief staff adequately on the key messages. The evidence before the Panel suggested that the Trust's plans to disseminate information did not result in effective distribution to the target audience. There was no evidence before the Panel to persuade it that senior management prioritised or valued sufficiently the importance of good communication with patients and relatives. Notwithstanding the existence of an infection control proforma in the notes, giving advice to the nursing staff on the precise information to give to patients and relatives, the overwhelming impression of the members of the Panel, based on the evidence from many witnesses, was that professional staff were left by management to disseminate information as they thought best.
- 1.4.3.4. Recommendation 1: we recommend that the Trust ensures that there are tangible improvements in all its communications. In particular, clinical staff must communicate effectively with patients and their relatives. The Trust board must take an active interest in complaints and seek regular feedback from patients and relatives on staff attitudes and the effectiveness of their communications (paragraph 8.21.3).**
- 1.4.3.5. Recommendation 2: we recommend that every patient who tests positive for CDI should be told the diagnosis and, if the patient agrees, appropriate close relatives should also be told. This information should be given by the medical staff responsible for the treatment of the patient, and should include the facts about CDI, the treatment proposed, the likely course of the disease, the relative importance of CDI in relation to the patient's other health problems, personal hygiene precautions, including dealing with the laundering of the patient's clothing, and the risk of infecting others. This should be reinforced by a leaflet containing the same information, provided at the meeting. Regular updates of the patient's progress should be given by doctors and nurses to the patient and relatives, and be recorded. It is the responsibility of the consultant to ensure that relatives have reasonable access to fully informed medical staff (paragraph 8.21.4).**

Patient safety, quality of care and record-keeping

- 1.4.3.6. The experiences of patients and their relatives were extremely distressing because the nature of this disease is debilitating, painful and dehumanising. This was especially so when the patient died, whether of CDI or with CDI, since they were unable to experience dignity and tranquillity in their last days.

1.4.3.7. High quality and holistic care of patients did occur in many instances and on many wards, but the sample of cases that the Panel examined raised issues over the consistency and reliability of record-keeping by the Trust and of the quality of care, including end of life care, that its staff provided. The evidence before the Panel suggests that some patients suffered poor care, which added to their suffering and that of the relatives who witnessed it. For some of those affected by the outbreak, the traumatic experience of CDI itself, compounded by the failures in communication and care, has lasted long beyond the date when the Trust formally declared the outbreak to be over.

1.4.3.8. Recommendation 3: the Trust board must review its governance arrangements and satisfy itself that it is meeting in full its responsibilities for patient safety, quality of care and record-keeping (para 8.21.13).

Isolation of patients with suspected or confirmed *Clostridium difficile* infection

1.4.3.9. The hospitals of the Trust will continue to admit patients who already have or who may develop CDI. In order to limit the transmission of the infection within the hospital it is necessary to isolate these patients. Such isolation can be distressing for patients.

1.4.3.10. At the time of the outbreak, the isolation facilities in the accident and emergency (A&E) department of Antrim Area Hospital were wholly inadequate for the purpose of treating a patient with suspected CDI. This inadequacy is self evident and accepted by the Trust witnesses who testified to the Panel. The Panel members inspected these facilities in the course of their work. It is the Panel's view that these should have been improved immediately upon the outbreak being declared in order to isolate properly and safely those patients with suspected CDI. It is difficult for the Panel to understand why the problems for patients in the isolation facilities in the A&E department were not resolved speedily. If senior managers had visited the A&E department, the problems must have been immediately apparent to them.

1.4.3.11. Recommendation 4: we recommend that patients with CDI should, where possible, be nursed in single rooms with en suite toilet facilities or cohort bays similarly equipped. Where single rooms are used, nursing staff should take care to ensure that feelings of isolation, loneliness and/or stigma are prevented as far as possible (paragraph 8.21.15).

1.4.3.12. Recommendation 5: we recommend that the DHSSPS undertakes a review of hospital A&E departments throughout Northern Ireland to ensure that they have appropriate facilities for the isolation of suspected infected patients in single rooms with en suite toilets. The redevelopment of the A&E department at Antrim Area Hospital should be expedited and must incorporate such facilities (paragraph 8.21.17).

End of life care

1.4.3.13. The efforts necessary to treat CDI and to limit its spread may have obscured the need for appropriate care of patients who are near the end of their lives.

1.4.3.14. Recommendation 6: the Trust should assure itself that end of life care is instituted at an appropriate point in the management of patients in whom a fatal outcome from any condition, including CDI, is a possibility. The need for this should be discussed with the patient and/or a close relative where appropriate. The advice of the palliative care team should be sought (paragraph 8.21.19).

Death certification

- 1.4.3.15. The responsibility of the Trust to patients and their relatives does not end at the point of death. Relatives may need help to understand what has caused the death and may need other information.
- 1.4.3.16. Recommendation 7: the Trust should satisfy itself that the responsibility of the consultant to ensure that the death certificate is completed accurately is met, and that relatives are informed of what is recorded and why, and given the opportunity to discuss the patient's illness, its treatment, and any other questions or concerns (paragraph 8.21.21).**

1.4.4. Staff experiences

The Trust and the media

- 1.4.4.1 Some efforts were made by the Trust to inform the media, for example by issuing a briefing document and inviting reporters and television crews into the hospital to see for themselves the actions being taken to control the outbreak. However, the Inquiry believes that at the start of the outbreak the flow of relevant information to the media was not well handled by the Trust. The media play an important role in communication with the public at times of untoward events such as outbreaks of infection. The Trust was at a disadvantage and its management was under pressure in not already having prepared an outbreak control plan covering all aspects of the management of an outbreak, including a crisis communication plan, when the outbreak was first recognised.
- 1.4.4.2. The Panel acknowledges that the Trust was newly formed and that the absence of a crisis management plan may be a product of timing, but the strong impression of the Panel is that the Trust misjudged the extent of its obligation to inform the public of relevant information relating to CDI and the outbreak. The Panel believes that, had this been done effectively at an early stage of the outbreak, it might have avoided the media reporting in such a manner that suggested that the principal, if not the sole, cause of the outbreak of CDI was the state of cleanliness of the hospitals. Further, proper briefing of the media may have reduced substantially the risk of its own employees being blamed by some members and sections of the public for causing the outbreak.
- 1.4.4.3. Recommendation 8: we recommend that the DHSSPS reviews the current regional guidance on infection prevention and control to ensure that trusts have comprehensive outbreak control plans that adequately cover the following elements:**
- **definitions of an outbreak, including an outbreak of an infection in hospitals**
 - **the individual(s) who have authority to declare an outbreak**
 - **the arrangements for public declaration of an outbreak**
 - **the membership, chairmanship, role, responsibilities and accountability of the outbreak control team**
 - **the resources that may be required to respond to an outbreak in terms of finance, personnel, equipment and pharmaceuticals**
 - **the arrangements for isolating and, where necessary, cohorting infected patients**
 - **the arrangements for training staff and keeping them updated**
 - **a communication strategy, specific to the outbreak, to include information to staff, patients, relatives and other hospital visitors, the public and the media**
 - **the members of staff who will act as liaison and spokespersons with the media, together with their training needs and their information sources (paragraph 9.13.5).**

- 1.4.4.4. Recommendation 9: the Trust should review its outbreak control plan at least annually to ensure that it is up to date (paragraph 9.13.6).**

Staff training

- 1.4.4.5. The Panel recognises that the experiences of the staff who were giving direct care to patients with CDI were a source of stress due to the nature of the care the patients required together with the need to observe strict hygienic precautions. This was added to by some adverse media reports.
- 1.4.4.6. The Panel was told that the Trust's nurses were confident in general infection prevention and control procedures. However, some nurses were asked, at very short notice and with little relevant experience and training, to undertake the nursing of patients who had contracted CDI. This was particularly so with those members of the nursing staff who were asked to work on the cohort ward A1 at Antrim Area Hospital from January 2008. Some of the evidence that the Panel received suggested strongly that the absence of up-to-date information and training gave rise to real difficulties in the nurses' ability to meet the demands that arose in the nursing of such patients, particularly in the days that followed the establishment of the cohort ward. There is some evidence that this served to demoralise staff in the initial period of undertaking this nursing role.
- 1.4.4.7. Recommendation 10: we recommend that the Trust gives attention to the need for staff training and support in caring for patients with CDI, particularly when they are called upon to care for patients during an outbreak and may have to change their area of practice at short notice (paragraph 9.13.8).**

Infection prevention and control team

- 1.4.4.8. The risk of an outbreak of CDI is high in any hospital admitting frail elderly patients.
- 1.4.4.9. Recommendation 11: the Trust should always take into account and act upon the advice of infection prevention and control staff. The challenges an outbreak presents to staff at all levels and the support required to maintain morale must be recognised. Where the help of outside bodies or personnel is needed, the Trust must be aware of the risk that existing staff may consider that their advice, expertise and role has been devalued or rejected. They should be fully involved in the arrangements for collaborating with new teams or additional personnel (paragraph 9.13.10).**
- 1.4.4.10. We acknowledge that the experience of staff, especially the senior managers of the Trust, during the outbreak was one of stress due to the underdevelopment of the policies, processes, responsibilities and accountabilities of the newly formed organisation, together with a deficiency of resources, both financial and of personnel.
- 1.4.4.11. Recommendation 12: organisational change should be recognised by the DHSSPS as carrying high risk for patient safety and quality of care, including the potential for a sub-optimal response to an outbreak of a healthcare associated infection. At such times of change, this risk should be addressed specifically and reported in the risk register of all trusts (paragraph 9.13.12).**
- 1.4.4.12. The recommendations of the Inquiry are addressed to the Trust and to the DHSSPS. However, the recommendations addressed to the Trust may be equally applicable to other trusts within Northern Ireland and the rest of the UK.

1.5. An observation

- 1.5.1. While we are not making a recommendation directly to the media, the evidence given to us by those affected, especially the staff of the Trust, describes the substantial impact of media reporting of the outbreak. We recognise and support the right and duty of the media to report, in the public interest, events and occurrences such as the outbreak of CDI, and to do so rigorously. However, we hope that those in positions of editorial responsibility will read this report and take note of the evidence we were given (Chapter 6 and Appendix 5). Any simplistic attribution of the causes of such an outbreak is both inaccurate and unfair in the light of the expert evidence of the true causes of CDI. Providing complete, accurate and timely figures on the number of deaths that may be due to such an outbreak is very difficult, given the problem of determining exact causes of death in older patients with multiple diseases. Journalists would be assisted in more accurate reporting if Trusts involved directed them to external and independent sources to confirm the information given.

1.6. Considerations

- 1.6.1. In reaching these conclusions and making these recommendations the Panel wishes to emphasise the following.

- This was not an Inquiry into the cause of the outbreak or to individual fault in the management of it, but an Inquiry to reach a judgement on the number of deaths, and into the experiences of those directly affected by the outbreak. However after examining evidence of the experiences of patients, relatives and staff, and in order to provide the recommendations that are required by the terms of reference, it is necessary to identify and report on weaknesses or gaps in the systems of management of the Trust.
- In the case of the number of deaths, the Inquiry has considered and accepted the conclusions formed by expert reviewers who reached these conclusions solely from examining the contemporaneous clinical records of the deceased. They had no contact with either the clinical staff that cared for the patients nor with patients' relatives.
- We could not make a decision on the factual accuracy of each experience as reported to us in evidence. Experiences are essentially subjective. However, given the number of similar accounts on various themes we have drawn general conclusions from the body of evidence as a whole. We would quote the point made by the chair of the Mid Staffordshire inquiry in 2010⁽²⁾, which applies equally to this Inquiry (with the additional inclusion of staff):

This was not an adversarial process in which the truth and reliability of witnesses was tested as would have occurred in a traditional 'trial'. Nonetheless, the quality of the evidence given by patients and their families, the dignity and care with which they did so, and the sheer number of similar accounts was highly persuasive.

Paragraph 16, page 9⁽²⁾

- We are well aware that some of the resources, systems and practices about which we have made critical comments are not unique to the NHSCT. They may have been shown to be equally inadequate or poor in other trusts within Northern Ireland and throughout the UK. This does not, however, alter the criticism or provide a sufficient reason for us not to note these inadequacies in the context of the experiences of those directly affected by this outbreak.
- 1.6.2. We are aware and have repeatedly acknowledged that the process of the Inquiry may have been distressing for those involved and may have resulted in the reopening of memories that they would have preferred to have remained dormant. We apologise for this. In these circumstances we are grateful for all the assistance they have given us and their readiness to co-operate with the Inquiry.