The Regulation and Quality Improvement Authority

Clostridium difficile - RQIA Independent Review

Review of the outbreak of *Clostridium difficile* in the Northern Health and Social Care Trust

August 2008

informing and improving health and social care
www.rqia.org.uk

Contents

Acknowledgements

The Regulation and Quality Improvement Authority would like to thank the members of the Independent Review Team for their expertise, time and commitment to this review, and all the support staff involved.

In addition the RQIA would like to thank all staff in the Department of Health and Social Services for Northern Ireland, the Northern Health and Social Services Board, the Northern Health and Social Care Trust and agencies for all their input to inform this review.

Finally, the RQIA would especially like to thank those patients who took the time to share their views and make such a valuable contribution in conveying the patient experience for this review.

The Independent Review Team

The members of the team were:

Ms Alice Casey Chartered FCIPD, MSc, MA	RQIA Interim Chief Executive and Chair of the Review Team
Dr Kieran Hand PhD Pharmacology, Msc Infection Management	Consultant Antibiotic Pharmacist, Southampton General Hospital
Mrs Elizabeth Knipe	Lay Reviewer
Mrs Janice Molloy	Lay Reviewer
Dr Bharat Patel MBBS, MSc, FRC Path	Consultant Microbiologist, Health Protection Agency
Dr Catherine Quigley MB, MSc, FFPH	Consultant Regional Epidemiologist, Health Protection Agency
Dr Ray Sheridan MRCP BSc (Hons)	Consultant in General & Geriatric Medicine, Royal Devon & Exeter Foundation Trust
Ms Alyson Smith RGN, MPH	Consultant in Health Protection, Health Protection Agency

The Regulation and Quality Improvement Authority (RQIA)

The RQIA is the independent health and social care regulator and quality improvement body for Northern Ireland established under The Health and Personal Social Services (Quality, Improvement and Regulation) Northern Ireland Order 2003. It is responsible for monitoring and inspecting the availability and quality of health and social care services and encouraging improvements in the quality of these services through its programme of inspections and reviews. Through its activities it makes an independent assessment of health and social care services to ensure these are accessible, well managed and meet the required standards. The RQIA works to ensure that there is openness, clarity and accountability in the management and delivery of all these services.

Responsibility for the registration and inspection of regulated services including nursing homes, residential care homes, children's homes and independent health care providers is an integral part of the RQIA's remit. Following the introduction of new regulations in April 2007, it began the process of regulating adult placement agencies, day care settings, domiciliary care agencies and residential family centres. It also works with health and social care organisations across Northern Ireland to support the delivery of high quality services. In its activities the RQIA promotes participation and partnership approaches with service providers and service users alike to ensure their views are taken into account.

The RQIA applies a consistent approach to regulation, inspection, review, complaints investigation and enforcement activity across the statutory and independent health and social care sectors.

Our Purpose

The Regulation and Quality Improvement Authority (RQIA) was established to monitor the availability, organisation and standards of health and social care services in Northern Ireland and to be a driving force in promoting improvements in the quality of these services.

Our Vision

Safe, effective and high quality health and social care services for everyone in

Northern Ireland.

Our Values

The RQIA is:

- independent
- accessible
- inclusive
- accountable
- honest
- fair

Our Principles

The RQIA will:

- respect every person's right to timely, high quality care
- promote choice
- listen to and work with service users and providers
- encourage learning and innovation
- challenge practice where the need for change is demonstrated
- operate with integrity

Executive Summary

Introduction

On 7th January 2008, the Northern Health and Social Care Trust (Northern Trust) declared that there was an outbreak of *Clostridium difficile (C. difficile)* infection within the Trust. The Trust had identified an increase in the number of cases, with increased mortality, during 2007 and some cases had been diagnosed with a virulent strain known as Ribotype 027. In recent years this strain has been linked to hospital outbreaks in North America and Europe. It has been associated with hospital outbreaks in the United Kingdom but had not been identified in Northern Ireland before 2007.

In February 2008, the Minister of Health, Social Services and Public Safety requested the Regulation and Quality Improvement Authority (RQIA) to undertake an independent review of the circumstances contributing to the rates of *C. difficile* infection in the Northern Trust in 2007 and early 2008. The RQIA established an Independent Review Team with professional reviewers from England and lay reviewers from Northern Ireland. The professional reviewers brought specific expertise in the fields of microbiology, infection control, antibiotic pharmacy, epidemiology and clinical management of patients with *C. difficile*.

This is the second report of the RQIA Independent Review Team. The first report focused on the organisation and management arrangements for the prevention and control of *C. difficile* in Northern Ireland. This report sets out the findings of a review of the circumstances leading to the outbreak in the Northern Trust and the response to the outbreak. The Independent Review Team plan to carry out a further phase of the Review, focusing on the implementation of the regional action plan on Healthcare Acquired Infection, called *"Changing the Culture".* A report on this phase is planned for completion by October 2008.

This Report has been developed using a process known as Root Cause Analysis (RCA). The aim of this approach was to identify and assess the factors or 'root causes' which led to the outbreak and distil the learning to reduce risk and improve practice in the

future. RCA is not designed to attribute blame to individuals as most incidents affecting organisations relate to problems in systems.

The RQIA Independent Review Team had discussions with a number of patients affected by the outbreak, and their experiences and observations have helped inform the recommendations contained in his report.

The Cause of the Outbreak

The RQIA Independent Review Team has concluded 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. The first known case of the Ribotype 027 strain in Northern Ireland was a patient who was diagnosed with *C. difficile* toxin on 16th June 2007, although the ribotype was not identified until September 2007. As at 30th June 2008, some 297 cases in total were diagnosed which met the case definition for the outbreak. The peak number of cases reported was during the month of January 2008. At the time of writing this report, the outbreak had not been declared over, although the numbers of cases had fallen significantly.

Factors contributing to spread

The Independent Review Team found that the factors likely to have contributed to the spread of the outbreak included:

- the specific characteristics of the strain of *C. difficile* known as Ribotype 027. This strain has been shown to produce a large amount of toxins in some patients. It can cause more severe symptoms and a greater number of relapses and deaths than other strains. It has been linked to causing outbreaks in a growing number of countries;

- a lack of awareness of the possible impact of the introduction of a virulent strain of *C. difficile* within Northern Ireland. There was no evidence that specific escalation plans were in place to manage an outbreak of a more virulent strain of *C. difficile* such as Ribotype 027;

- the pattern of five hospitals in the Northern Trust - Antrim, Braid Valley, Mid-Ulster, Moyle and Whiteabbey. There are frequent transfers of patients between these hospitals and all five hospitals had patients diagnosed with Ribotype 027 during the outbreak. Maintaining provision of services across the five hospitals has been recognised to be expensive and this contributed to assessed shortfalls in nursing and cleaning staff. There was a significant delay in recognising that there was an outbreak affecting the system of hospitals;

- pressure on beds in the hospitals within the system. This led to frequent transfers of patients between wards and between hospitals and will have facilitated the spread of *C. difficile* spores;

- shortage of nurses across the hospital system, and cleaning staff at Antrim Hospital in particular. The Independent Review Team found that the Northern Trust, when it was formed in April 2007, inherited significantly lower numbers of staff in these disciplines than comparable hospitals;

- the use of antibiotics in the hospitals, where audits in 2006 and after the declaration of the outbreak, showed a level of non compliance with policies. The Independent Review Team consider that there was a lack of robust systems in place to monitor the implementation of antibiotic policies and adherence to guidelines. There was also a lack of systems for routine surveillance of trends in antibiotic consumption;

- the cleaning arrangements in place during the period from June 2007 to the declaration of an outbreak on 7th January 2008 were not sufficiently robust to manage an outbreak of *C. difficile* Ribotype 027 and this may have contributed to the spread of the organism before the outbreak was declared.

Surveillance

The Independent Review Team found that there was a significant delay in recognising that there was an outbreak of *C. difficile* affecting the system of hospitals in the southern sector of the Trust. Possible contributing factors to this delay included:

- a lack of analytical support to carry out epidemiological analysis of available data on trends in *C. difficile* in the Trust and to present it in a user friendly way;

- delays in receiving ribotype information so that it was of limited use in tracking possible linked cases;

- in 2007, quarterly surveillance reports on *C. difficile* from the Communicable Disease Surveillance Centre (CDSC) (NI) were not available until three months after the quarter to which they referred;

- surveillance of *C. difficile* focused on total numbers of cases rather than outbreaks of specific ribotypes;

- pressure on the Infection Prevention and Control Lead and the Infection Control Team who had limited time to stand back and assess the overall emerging picture, as they tackled local incidents and focused on training, audits and implementing new systems.

The Independent Review Team found that the Northern Trust submitted a Serious Adverse Incident (SAI) Report to the DHSSPS in October 2007 about the emergence of *C. difficile* Ribotype 027. It was noted on the SAI Report that the Northern Health and Social Services Board (Northern Board) and Consultant Regional Epidemiologist had also been informed. The SAI Report recommended that all trusts needed to be vigilant for the emergence of Ribotype 027. Outbreaks of *C. difficile* in specific wards in Antrim and Whiteabbey hospitals were not reported to the DHSSPS using the SAI reporting system. The DHSSPS had set out the requirement for outbreaks of *C.difficile* to be reported using this system in Circular HSS(MD)9/2007 issued in April 2007. A specific

warning about the emergence of *C. difficile* Ribotype 027 in Northern Ireland was not issued until January 2008.

The Independent Review Team found that approaches being taken by the Trust to assess the number of deaths linked to the outbreak were appropriate, and it should be commended for establishing a formal review of the deaths which occurred in 2007. The Trust should continue to assess the overall impact of the outbreak on mortality until the outbreak is formally declared as 'under control'.

Governance

The Independent Review Team found that on its formation, the Northern Trust established lines of accountability for infection control in keeping with regional policy. Issues relating to infection control were reported to appropriate levels of the organisation and, when the outbreak was declared, structures were put in place for its control.

The Independent Review Team consider that decisions taken before the outbreak was declared were affected by a lack of awareness of the potential consequences of the emergence of a virulent strain of *C. difficile*.

In the period before the outbreak was declared and in the initial stages of its management, the Independent Review Team consider that the processes in place were not sufficiently robust to give the Senior Management Team (SMT) and the Board of the Northern Trust appropriate assurances that policies were being implemented at patient level.

Response to the Outbreak

After the declaration of the outbreak the Chief Executive of the Northern Trust established an Outbreak Control Team (OCT), which she chaired. The Independent Review team found that this facilitated speedier decision-making. For example, when the OCT decided to convert a purpose built isolation ward at Antrim Hospital for the use of *C. difficile* patients during the outbreak, this was done very quickly.

The Independent Review Team found that the Northern Board did provide practical and financial support to the Trust during the outbreak. The Board's Consultant in Communicable Disease Control (CCDC) played a significant role as a member of the OCT and in chairing the Epidemiological Sub-group.

The Independent Review Team does consider that it would be useful to formalise the arrangements for the involvement of public health staff in relation to hospital outbreaks in Northern Ireland. At present this appears to be dependent on an invitation to become involved, which did happen in this case.

The Independent Review Team found that the issue of Healthcare Associated Infection (HCAI) was a high priority on the DHSSPS agenda before the outbreak. DHSSPS officers became actively involved in providing advice to the health and social care system, and practical support to the Northern Trust, when the outbreak was declared.

Recommendations

The RQIA Independent Review Team made 36 recommendations in its previous report[1] to the Minister in May 2008 and consider these to remain relevant to the findings which emerged from this part of the review. These recommendations can be found on page 147 of this report. This report includes a further 17 recommendations, for additional actions to enhance the resilience of Northern Ireland in relation to virulent strains of *C. difficile.* These can be found on page 143.

[1] *Clostridium difficile - RQIA Independent Review Report May 2008*
"Protecting patients - reducing risks. The Organisation and Management Arrangements for the Prevention and Control of Clostridium difficile in Northern Ireland."

1. Introduction

On 7th January 2008, the Northern Health and Social Care Trust (Northern Trust) declared that there was an outbreak of *Clostridium difficile (C. difficile)* infection within the Trust. The Trust had identified an increase in the number of cases, with increased mortality, in the summer of 2007 and some cases had been diagnosed with the virulent Ribotype 027. This ribotype had not been identified in Northern Ireland before 2007.

In February 2008, the Minister of Health, Social Services and Public Safety requested the Regulation and Quality Improvement Authority (RQIA) to undertake an independent review of the circumstances contributing to the rates of *C. difficile* infection in the Northern Trust in 2007 and early 2008. He set the following Terms of Reference:

1. To review the circumstances contributing to the rates of *C. difficile* infection in the Northern Trust in 2007 and 2008, including the recent outbreak.
2. To review the Northern Trust's management and clinical response to its *C. difficile* rates and outbreak, including actions to inform patients, their relatives and the public.
3. To review the Northern Trust's arrangements to identify and notify cases, outbreaks and deaths associated with *C. difficile* infection.
4. To review the Trust's governance arrangements and the priority given to the prevention and control of infection.
5. To review the actions of the Northern Health and Social Services Board (Northern Board) and the DHSSPS in relation to the management of the outbreak in the Northern Trust, and actions by all Trusts, Boards and the DHSSPS to reduce *C. difficile* rates in Trusts.
6. To examine any other relevant matters that emerge during the course of the review.
7. To identify learning from the management of this incident and make recommendations for the Northern Trust and the wider Health and Social Care.

It was believed that the most immediate concern was to control and curtail the outbreak and to minimise its impact.

The independent review is being undertaken in two Phases, as set out below, to ensure that all the Terms of Reference are fully addressed

Phase 1: Part (i) Protecting Patients - outbreak containment

- Establish that all appropriate measures have been put in place to contain and manage the outbreak by the Northern Trust.

  - **end of February 2008**

Part (ii) Protecting Patients - reducing risk in Trusts

- Review the organisation and management arrangements for the prevention and control of *Clostridium difficile* in Northern Ireland (all Trusts).

  - end of May 2008

Part (iii) Review of the outbreak in the Northern HSC Trust

- Following receipt of advice that the outbreak has been controlled, the Review Team will examine the:
  a. key governance arrangements within the Northern Trust relating to control of infection;
  b. management of the outbreak including all actions taken to investigate and control it;
  c. key control measures that were put in place to control the outbreak.

- end of July 2008

Phase 2: Progressing 'Changing the Culture'

- All Trusts and Boards will be reviewed by a dedicated specialist team of inspectors to ensure that all systems and processes meet the requirements of 'Changing the Culture' and are sufficiently robust to ensure the safety of all patients.

  - end of October 2008

Phase 1: Part (i) Protecting Patients - outbreak containment - was completed at the end of February 2008.

Phase 1: Part (ii) Protecting Patients - reducing risks in Trusts - was completed at the end of May 2008. A report was then forwarded to the Minister[2].

This Report focuses on **Phase 1: Part (iii) Review of the outbreak in the Northern Trust** and is intended to inform the Minister accordingly as required in the Terms of Reference, by the end of July 2008. It was not possible to commence this part of the Independent Review until the outbreak was under substantial control because this would have diverted people and other resources away from the process of securing control. The RQIA was informed on 8th July 2008 by the Chief Medical Officer that the Northern Trust had confirmed its readiness to engage with the RQIA Independent Review Team to complete this part of the review.

[2] Regulation and Quality Improvement Authority, 2008. Protecting patients - reducing risks. The Organisation and Management Arrangements for the Prevention and Control of *Clostridium difficile* in Northern Ireland

2. The Approach To The Review

The approach to the Review involved:

a) A review of extensive documentation provided by the Department of Health Social Services and Public Safety (DHSSPS), Northern Trust and the Northern Health and Social Services Board (Northern Board). This included relevant regional, Northern Board and Northern Trust policy and organisational documents, minutes of a wide range of meetings, copies of relevant correspondence and the results of related audits;

b) A review of the actions of the DHSSPS in respect of Infection Control and *C. difficile* policy development, its promulgation, performance management and accountability arrangements. Guidance provided to the Northern Trust leading up to and during the course of the outbreak was also reviewed;

c) A review of the actions of the Northern Board in respect of its responsibilities in relation to policy development, performance management, support, advice and guidance provided to the Trust leading up to and during the course of the outbreak;

d) Attempts to elicit the concerns of patients, families and the public - this included interviews with three patients (out of 17 invited) who contracted *C. difficile,* review of complaints received by the Northern Trust, the Northern Health and Social Services Council and the Minister, as well as a review of the media coverage of the outbreak;

e) A review of all surveillance reports;

f) A Root Cause Analysis (RCA) of the outbreak. This involved an analysis of the Northern Trust's arrangements for governance, for safe infection control, prudent antibiotic prescribing and clinical care, cleanliness, and communications over the three time periods of the outbreak.
These time periods were:

1) *the period up to 16th June 2007* - the date on which a positive toxin sample was taken from a patient in Antrim Hospital for *C. difficile*. A second sample taken from the same patient on the 16th July 2007 was later sent for culture and subsequently confirmed as *C. difficile* Ribotype 027 on 14th September 2007;
2) *16th June 2007 to 7th January 2008* - the period Ribotype 027 was present prior to the outbreak being declared;
3) *7th January 2008* onwards - the period of the declared outbreak.

Root Cause Analysis (RCA) was adopted to ensure a thorough approach to the investigation of all the relevant issues. It involved all levels of staff in identifying causes and solutions, promoting a positive attitude to the control and management of incidents and to learning what actions could and should have been taken to minimise the impact of the incident and to prevent similar incidents happening in the future. The methodology consisted of two main component parts: the investigation of what happened; and, the analysis of how and why it happened. RCA facilitates the identification of human factor failures and weaknesses in organisational systems and structures.

The methodology recognises that decisions taken at strategic levels in an organisation - whilst well thought out and considered at the time - may be incorrect and may create the potential for unrecognised (latent) problems within the system. The nature of such organisational processes will have a direct bearing on how incidents happen in organisations. Latent or hidden failures will be inherent in any workplace and will influence the delivery system to the extent that weaknesses, if left unchecked, will increase the probability of breakdowns in the system. The consequences could be far reaching and may lead to serious service failures.

Latent failures are created as a result of well intentioned, but in hindsight, faulty decisions by senior management. In the Health and Social Care system different levels of management decisions impact on the actual care delivery system. These decisions may have damaging consequences which can lie dormant in the system. The consequences may only become evident once they combine and when

triggered by something different, i.e. a contributory factor. (National Patient Safety Agency, Root Cause Analysis Tool Kit)[3].

The RCA approach can help to uncover what happened when, how and why and will provide some insight into the circumstances which led to the outbreak. It cannot provide definitive evidence of the actual cause of the outbreak. The RCA approach adopted in this Independent Review involved an analysis of the state of preparedness of Northern Ireland for the introduction of a virulent strain of *C. difficile.* This analysis covered:

- the state of preparedness of the DHSSPS, the Northern Board and the Northern Trust as at Time Period 1 - up to 16th June 2007, i.e. the date on which a patient had a positive sample for *C. difficile* toxin and who subsequently had a further sample taken which was identified as Ribotype 027;
- the appropriateness of the actions taken by the Northern Trust in relation to the prevention and control of *C. difficile* during Time Period 2 - 16th June 2007 to 7th January 2008, i.e. the period Ribotype 027 was present within the Northern Trust prior to the outbreak being declared was examined;
- the appropriateness of the actions taken by the Northern Trust to minimise the impact of the declared outbreak in Time Period 3 - 7th January 2008 onwards, and to bring it under control as rapidly as possible.

[3] National Patient Safety Agency, Root Cause Analysis Tool Kit, Introduction to Human Error Theory; http://www.msnpsa.nhs.uk/rcatoolkit/course/iindex.htm

3. Organisational Roles

Department of Health, Social Services and Public Safety (DHSSPS) - is responsible for ensuring the provision of appropriate health and social care services, both in clinical settings such as hospitals and GPs' surgeries, and in the community through nursing, social work and other professional services. It also leads a major programme of cross-government action to improve the health and well-being of the population and reduce health inequalities. This includes interventions involving health promotion and education to encourage people to adopt activities, behaviours and attitudes which lead to better health and well-being. It discharges its responsibilities through:

- **Health and Social Care (HSC)**, which includes policy and legislation for hospitals, family practitioner services and community health and personal social services;
- **Public Health**, which includes policy, legislation and administrative action to promote and protect the health and well-being of the population.

Health and Social Care organisations have a statutory duty for quality. They are held to account for the implementation of policy and legislation through their Accounting Officer (the Chief Executive) Statement of Internal Control to the Permanent Secretary who is the Principal Accounting Officer for all the responsibilities of the DHSSPS.

Service Delivery Unit (SDU) - was established by the DHSSPS in 2006 to support Trusts in the delivery of key Ministerial Priorities for Action (PFA) targets. Initially the focus was on elective care, however this has since broadened to improve performance across a wide range of health and social care services, including Accident and Emergency discharge, mental health services, cancer, fractures, Allied Health Professions, learning and physical disability, healthcare associated infection, and children's services.

The SDU works with Trusts to improve performance through the implementation of a range of reform programmes and service improvement techniques. Using its network of experienced healthcare professionals, it has identified a number of evidenced good practice actions that will ensure the service to patients is improved and that services are delivered more efficiently.

The SDU is also responsible for the performance management of all non-financial targets and standards, and meets regularly with Trusts to monitor progress and address areas of concern.

Northern Health and Social Services Board (Northern Board) - is responsible for commissioning services to meet the health and social care needs of the local population in its geographical area. It will also review and monitor services provided in hospitals and in the community to ensure improvements in the care provided to the local population. It provides advice and guidance on the control of infectious diseases and monitors the statutory functions delegated to HSC Trusts. The Director of Public Health has the statutory responsibility for the control of communicable disease in the Board area. This is normally delegated to the Consultant in Communicable Disease Control (CCDC).

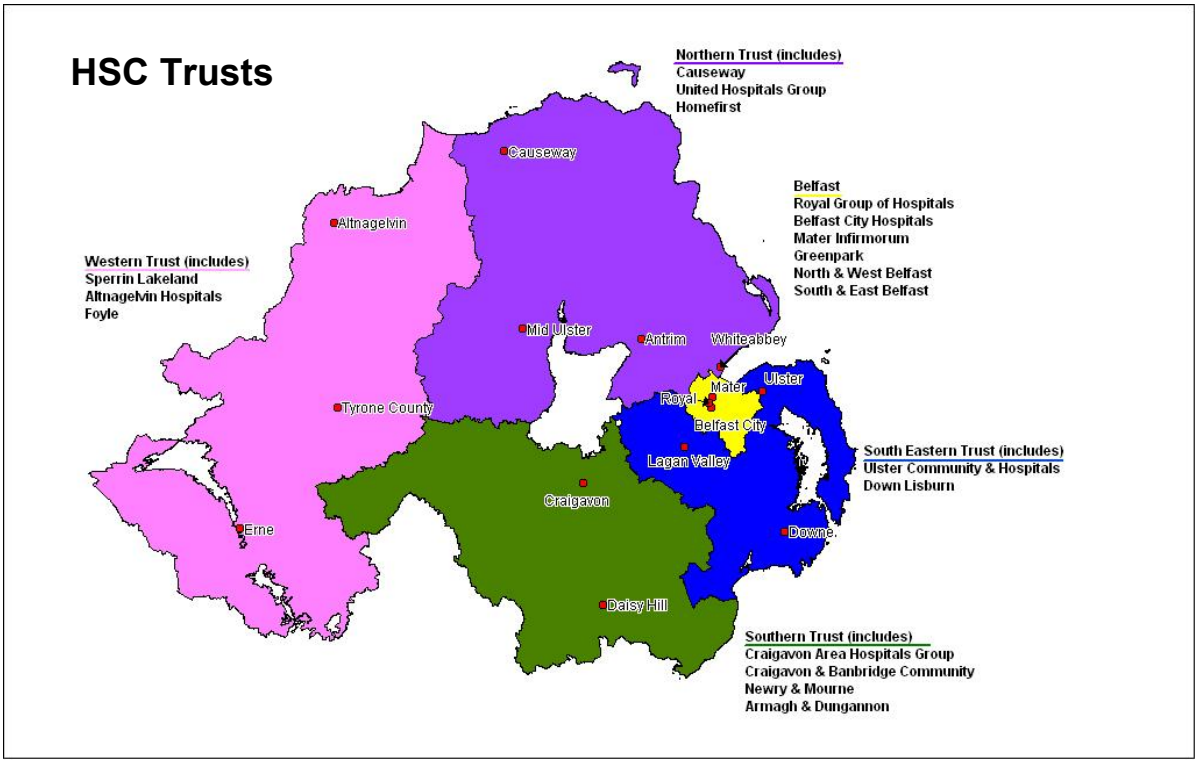
The Northern Board published its acute hospital strategy *'Towards a Better Future'* in 1998. It was reviewed in 2003/2004, in the light of the regional *'Developing Better Services'* strategy and in January 2004, the Northern Board published *'Implementing Developing Better Services - Strategic Context and Implementation Framework'* . This framework document set out the Northern Board's desired future profile of hospital services for its local population. It outlined the pathway for the modernisation of health services across the geographical area covered by the Northern Board. In particular it clarified that the current provision of care within the nine hospitals serving the population of 440,000 people was neither appropriate to provide modern health services designed to meet the changing needs of the population, nor were they sustainable in terms of the changing education and training of vital health care professionals or affordable in the developing economic climate.

It recommended that acute inpatient care should be focused on Antrim Area and Causeway Hospitals as well as continued access to other acute and regional specialist services in the Belfast, Altnagelvin and Craigavon hospitals. Whiteabbey and Mid Ulster Hospitals would become 'local' hospitals providing ambulatory care services including outpatient clinics in a wide range of specialities, therapies, a minor injuries service and day case surgery.

The Northern Board recognised that it was spending comparatively more of its funding on acute hospital services, through endeavouring to sustain vulnerable services at both Mid Ulster and Whiteabbey Hospitals. This was to the detriment of other areas of care such as community services which the Board was anxious to address. The Northern Board recognised that the problems associated with endeavouring to maintain this 'old' system of care would have latent (hidden) detrimental consequences in the longer term if not properly addressed.

There is no doubt that communities value services in their local hospital. However, failure to take appropriate strategic decisions to provide the right level of care in local hospitals is misleading to those communities.

Northern Health and Social Care Trust (Northern Trust) - is one of five Health and Social Care Trusts in Northern Ireland - see below.



The Trust became operational on 1st April 2007, following the merger of Homefirst, Causeway and United Hospitals Trusts. It covers the largest geographical area in Northern Ireland and provides services to a population of around 440,000 people living in County Antrim and parts of Counties Tyrone and Londonderry. The local government

districts of Antrim, Ballymena, Ballymoney, Carrickfergus, Coleraine, Cookstown, Larne, Magherafelt, Moyle and Newtownabbey fall within the boundary of the Northern Trust. It employs 13,000 staff and operates within an annual budget of approximately £500 million.

The Northern Trust provides a range of hospital and community services. The main acute hospitals are Antrim Area Hospital (411 beds), Causeway Hospital in Coleraine (242 beds), Mid-Ulster Hospital in Magherafelt (124 beds) and Whiteabbey Hospital (130 beds). Additional hospital services are provided at Braid Valley (36 beds), Dalriada Hospital (35 beds), Moyle Hospital (45 beds) and Robinson Hospital (25 beds). Holywell Hospital in Antrim provides a range of acute and other in-patient mental health services. The greater range of services provided by the Trust is in community-based settings, for example, services to children and older people, nursing and support services at home, outreach mental health services and work with General Practitioners in the primary care sector to support people outside a hospital setting.

The Independent Review Team was informed that the range and types of hospital provision of care within the Trust has not been rationalised to meet the changing demands of the health needs of the population, nor the education, training and development needs of the health and social care professionals providing care across these services. The Independent Review Team was also advised that the funding for acute services was stretched as services continued to be provided over multiple sites.

Communicable Diseases Surveillance Centre for Northern Ireland (CDSC (NI)) - is a local office of the Health Protection Agency (HPA) of the United Kingdom and was established in 1999. It is responsible for monitoring changes in the incidence, prevalence and patterns of communicable disease in Northern Ireland and ensuring that relevant information is communicated in a timely manner to consultants in communicable disease control (CCDC), microbiologists and others involved in the prevention, investigation and control of communicable diseases. Surveillance information is published in a monthly report, which is widely disseminated throughout Northern Ireland, to other national centres in Great Britain and Ireland and to the World Health Organisation in Geneva.

The CDSC (NI) provides advice and support to the DHSSPS and other HSC organisations including outbreak support in response to requests. It uses surveillance information, both local and national, to inform communicable disease policy and guidance. It provides 24-hour advice and support to the Chief Medical Officer and Directors of Public Health (DPH). However the CDSC (NI) does not have a statutory role in communicable disease control in Northern Ireland, neither can it direct Trusts to take action.

The CDSC (NI) undertakes surveillance, on behalf of the DHSSPS, of MRSA bacteraemia and *C. difficile* Infection (CDI) and surveillance reports are published quarterly on the CDSC (NI) website. Working closely with HPA colleagues across the UK, the CDSC (NI) provides practical support in the management of incidents / outbreaks and, in particular, contributes to the co-ordination of incidents that straddle area, regional or national boundaries.

4. *Clostridium difficile*

4.1 Introduction

C. difficile is a bacterium that is present in the gut of up to 3% of healthy adults. It is anaerobic which means that it does not grow in the presence of oxygen. *C. difficile* rarely causes problems in children or healthy adults, as it is kept in check by the normal bacterial population of the intestine. When certain antibiotics disturb the balance of bacteria in the gut, *C. difficile* can multiply rapidly and produce toxins which cause illness.

C. difficile infection ranges from mild to severe diarrhoea to, more unusually, severe inflammation of the bowel (known as pseudomembranous colitis). People who have been treated with broad spectrum antibiotics (those that affect a wide range of bacteria), those who have had multiple courses of antibiotics (affecting the protective bacteria) those with serious underlying illnesses and the elderly are at greatest risk – over 80% of *C. difficile* infections reported are in people aged over 65 years.

Prior ingestion of *C. difficile* spores or colonisation may lead to infection if the bowel flora is changed as a consequence of antimicrobial therapy. Spores can be spread on the hands of health care staff and other people who come into contact with infected patients or with contaminated environmental surfaces (e.g. floors, bedpans, toilets). Spores are produced when *C. difficile* bacteria encounter unfavourable conditions, such as being outside the body. They are very hardy and can survive on clothes and environmental surfaces for long periods.

C. difficile was first described in 1935. It was called the "difficult clostridium" as it was resistant to early attempts at isolation and grew very slowly in culture. In 1969, it was linked to gastrointestinal disease in rats. The first known human outbreak of gastrointestinal disease associated with the organism occurred in 1974, although it was not reported until 1979. This outbreak was linked to use of the antibiotic, clindamycin.

In 1981 it was demonstrated that *C. difficile* produced two toxins, Toxin A and Toxin B, which lead to illness.

In 1991 and 1992, a large outbreak affected 175 people at two North Manchester hospitals. In 1994, the Department of Health and the Public Health Laboratory Service jointly published guidance on *"The Prevention and Management of C. difficile Infection"*[4]. The recommendations included:

- "Appropriate antibiotic usage in hospitals is essential for the prevention and control of *C. difficile* infection. Adoption of an antibiotic policy is recommended."
- "Routine infection control procedures, including thorough hand-washing by all staff are essential for prevention of *C. difficile* infection."
- "Patients with diarrhoea and suspected of infection should be isolated until they have formed stools."
- "*C. difficile* spores persist in the hospital environment. Thorough cleaning is important."

These recommendations are reflected in current best practice guidance from the Health Protection Agency to minimise the risk of *C. difficile* and its effects.

There are five key measures that organisations need to put in place and rigorously maintain in order to minimise the risks posed by *C. difficile*:

1. ***Rapid Isolation of a patient with diarrhoea*** **-** to prevent the spread of infection to other patients and reduce environmental contamination;

2. ***Enhanced environmental cleanliness*** **-** to reduce the level of spore contamination of the environment and the likelihood of further transmission to other patients;

3. ***Prudent antimicrobial prescribing*** **-** to reduce the risk of destroying normal protective bowel flora and minimise the risk of *C. difficile* infection;

4. ***Scrupulous hand hygiene*** **-** to prevent person-to-person transmission of spores;

5. ***Personal protective equipment*** **-** gloves and aprons for example – for good infection practice and protection of staff.

[4] Department of Health/Public Health Laboratory Service Joint Working Group, 1994. *The Prevention and Management of Clostridium Difficile Infection.*

All of the above form the basis of a 'Care Bundle' approach to *C. difficile.* This must be implemented and maintained to a very high standard at all times to ensure a safe system of care. No single measure is sufficient to minimise *C. difficile* infections or control an outbreak. All of the above measures are required to ensure the delivery of a high quality safer service at all times. Their implementation should be achieved by appropriate education and training of all staff.

4.2 The Emergence Of Ribotype 027

More than 100 different strains of *C. difficile* have been identified and new strains continue to be recognised. Strains can be differentiated using a molecular technique known as PCR ribotyping. The strain which caused the outbreak in the North Manchester hospitals in 1991/92 is known as Ribotype 001.

In 1988 a strain, known as Ribotype 027, was first isolated in France. Until 2002, it was associated with sporadic cases of *C. difficile* associated infection (CDI). Its virulence appears to have then increased. Since 2002, it has caused major outbreaks in hospitals in Canada and the USA. The province of Quebec in Canada was the first to be affected. At least 38 states in the USA have now reported the strain. Ribotype 027 produces large amounts of toxin. It can cause a severe pattern of disease and more frequent relapses, although this does not always occur.

The current position in relation to the spread of Ribotype 027 across Europe has recently been reported[5]. Since 2005, individual countries have developed surveillance schemes to determine the extent of spread. *C. difficile* Type 027 has now been reported in 16 European countries. It has been responsible for outbreaks in Belgium, Germany, Finland, France, Ireland, Luxembourg, the Netherlands, Switzerland and the United Kingdom. Sporadic cases have been detected in Austria, Denmark, Sweden, Norway, Hungary, Poland and Spain. Within the United Kingdom, outbreaks have been reported in England, Scotland, Wales and now Northern Ireland.

[5] Kuijper, E.J., et al. 2008. Update of *Clostridium Difficile* Infection Due to PCR Ribotype 027 in Europe, 2008. *Eurosurveillance*, 13(31), article 5.

4.3 Recent Trends In *C. difficile* In Northern Ireland

Surveillance of *C. difficile* in Northern Ireland, before 2005, relied on laboratory reports of *C. difficile* toxin detected in patients of all ages. This was a voluntary reporting system and so reporting may not have been complete. Mandatory surveillance began on 1st November 2005 with hospitalised patients over 65 years as the target population for surveillance. A similar scheme commenced in England in 2004. The surveillance data is collected by the CDSC (NI) on a quarterly basis from Health and Social Care Trusts.

Figure 1 sets out the annual number of cases, for each Trust area, for the three years since the surveillance scheme was established. The overall number of cases in patients over 65 years reported in Northern Ireland fell from 1068 in 2006 to 982 in 2007. In the Northern Trust area, the number of cases rose from 183 in 2006 to 247 in 2007.

Figure 1

Number of *C. difficile* patient episodes, patients 65 years and over, by Trust, Northern Ireland 2005 - 2007

	2005*	2006	2007
Western	86	110	135
Northern	178	183	247
Belfast	318	385	265
Southern	215	138	116
South Eastern	235	252	219
Northern Ireland	1032	1068**	982

*Laboratory testing in NI came into line in 2005. therefore 2006 is the first complete calendar year with all laboratories using the same methods.

** 4 additional episodes due to the inclusion of Mullinure in the Southern Trust

Source: Healthcare Associated Infections Northern Ireland 2007, CDSC(NI)/HPA

Figure 2 sets out the rate of reported cases per 1,000 occupied bed days. This illustrates an overall rise from 2005 to 2007. Hospitals in the Northern Trust area had lower rates than the Northern Ireland average in 2005 and 2006 with the rate above the Northern Ireland average in 2007.

Figure 2

Rates of *C. difficile* patient episodes per 1,000 occupied bed days, patients 65 years and over, by Trust, Northern Ireland 2005 - 2007

	2005*	2006	2007
Western	0.668	0.831	1.098
Northern	0.797	0.859	1.219
Belfast	0.880	1.074	0.767
Southern	1.490	0.929	0.843
South Eastern	1.288	1.444	1.392
Northern Ireland	0.992	1.040	1.017

*Laboratory testing in NI came into line in 2005. therefore 2006 is the first complete calendar year with all laboratories using the same methods.

Source: Healthcare Associated Infections Northern Ireland 2007, CDSC(NI)/HPA

Figure 3 indicates that the number of cases reported, where the sample was taken from patients in community settings, in Northern Ireland have increased between 2005 and 2007.

Figure 3

Number of *C. difficile* patient episodes, patients 65 years and over, reported in community patients Northern Ireland 2005 - 2007

	2005*	2006	2007
Northern Ireland	**92**	**120**	**164**

*laboratory testing in NI harmonised during 2005; therefore, 2006 is the first complete calendar year with all laboratories using the same methods.

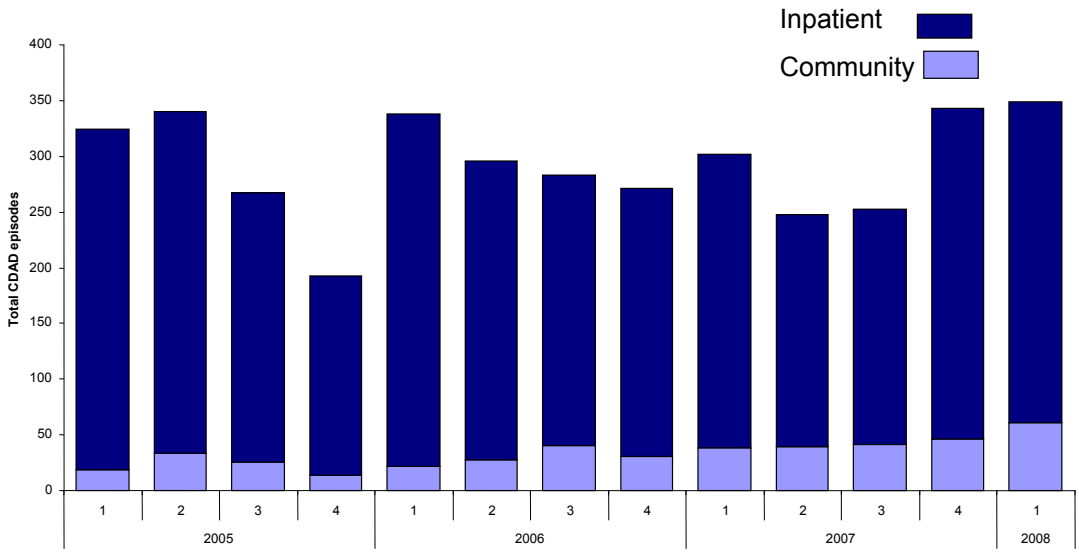
Source: Healthcare Associated Infections Northern Ireland 2007, CDSC(NI)/HPA

The Northern Ireland rates per 1000 occupied bed days have been lower than in England over the past two years. The overall rate in England was 2.45 per 1000 bed days in 2006 compared to 1.04 in Northern Ireland. In 2007, the rate in England was 2.25 compared to 1.02 in Northern Ireland. The rate in England does include community cases so the Northern Ireland rates would be expected to be slightly lower.

The CDSC (NI) has produced quarterly reports since 2005 on the *C. Difficile* surveillance information which are distributed to Trusts, Boards and the DHSSPS. Figure 4 illustrates the trends in numbers of CDI reports across Northern Ireland rates from 2005 to the first quarter of 2008. It demonstrates a rise occurring in the last two quarters reported.

Figure 4

Total CDAD reports, inpatient and community, in Northern Ireland, by quarter (patients ≥ 65 years), between 2005 and 2008.

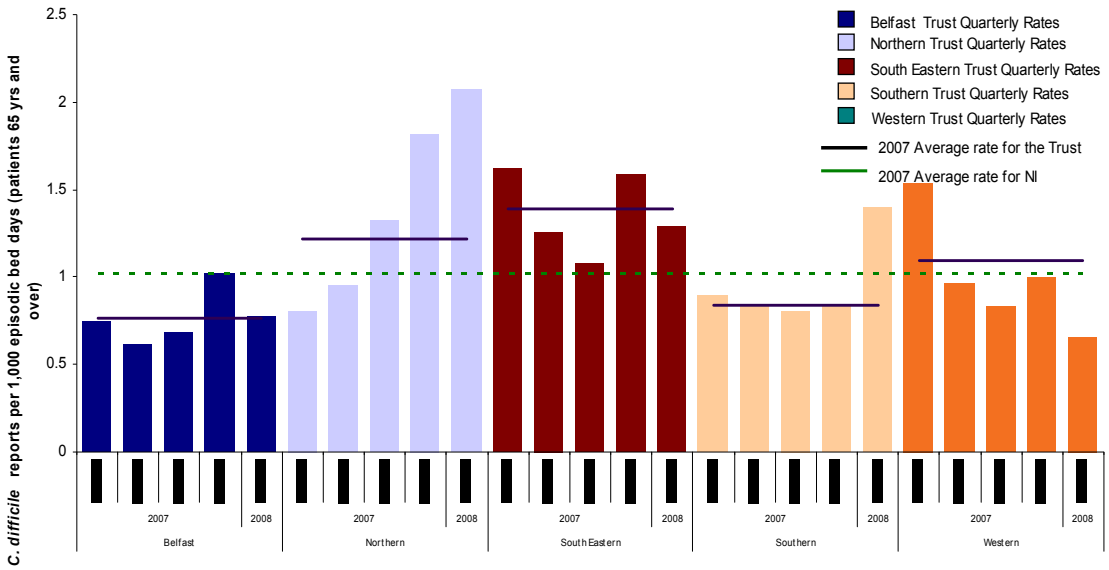


Source: CDSC Northern Ireland

Figure 5 presents quarterly rates by Trust area. It illustrates a rise in rates in the Northern Trust area from the third quarter of 2007.

Figure 5

Quarterly rates of *C. difficile* by Trust 1 January 2007 – 31 March 2008, compared with annual Northern Ireland and Trust rates for 2007; inpatients ≥ 65 years



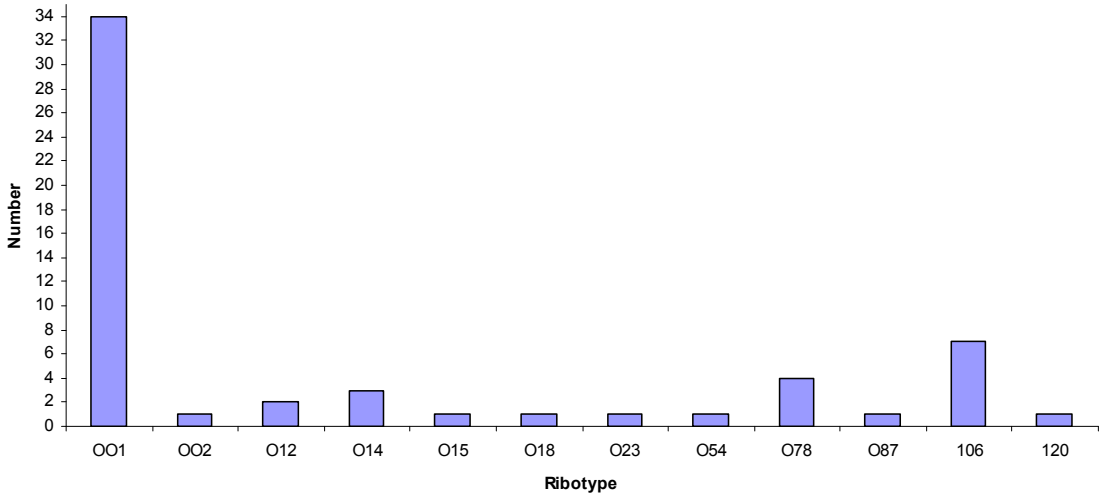
Source: CDSC Northern Ireland

4.4 Ribotyping Analysis Of *C. difficile* In Northern Ireland

Laboratory diagnosis of *C. difficile* is via detection of Toxin. However, ribotype analysis requires culture of the organism. Ribotype analysis has not been routinely carried out on all samples. From September to December 2006, a sample ribotype survey was carried out on 57 samples from laboratories across Northern Ireland. The results are shown in Figure 6. It indicates that Ribotype 001 was the most prevalent strain at that time. No cases of Ribotype 027 were identified in the snapshot survey.

Figure 6

2006 Ribotyping results, by Ribotype, from the snapshot survey, Northern Ireland (n = 57).



Source: CDSC (NI)

4.5 Trends In Deaths Registered In Northern Ireland With *C. difficile* Mentioned On The Death Certificate

The Northern Ireland Statistics and Research Agency (NISRA) recently published an analysis of deaths registered in Northern Ireland with *C. difficile* mentioned on the death certificate[6]. The report recognises that *C. difficile* is not always recorded as the underlying cause of death. Patients who die with *C. difficile* are often already very ill or frail before contracting *C. Difficile* and it is their existing illness, rather than *C. difficile,* which is recorded as the underlying cause of death. The doctor completing the death certificate should also record conditions which contributed directly to death. The NISRA report includes information on deaths where the underlying cause was *C. difficile* and also where it was not the underlying cause but a contributory factor in the death.

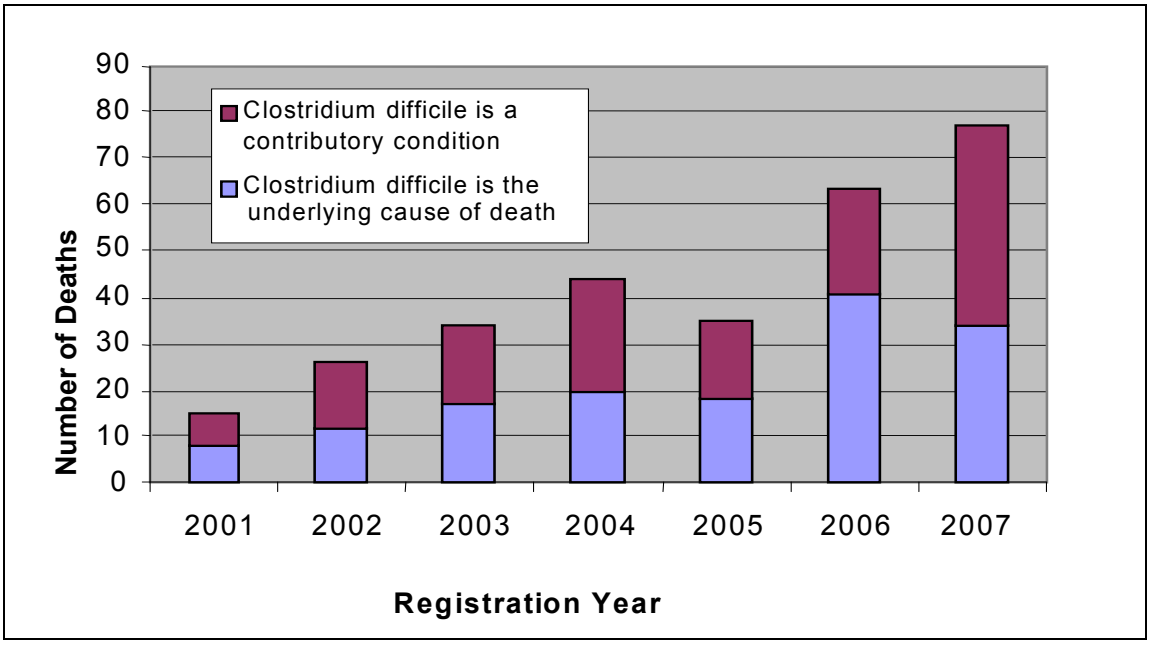
Figure 7 illustrates the trends in the number of deaths from 2001 to 2007 where *C. difficile* has been recorded on death certificates in Northern Ireland. There has been a

[6] Northern Ireland Statistics and Research Agency, 2008. Deaths Registered in Northern Ireland with Clostridium Difficile Mentioned on the Death Certificate (2001-2005).

rising trend over this period. The number of deaths where *C. difficile* was recorded as the underlying cause of death did fall from 41 in 2006 to 34 in 2007, but the number of times it was mentioned as a contributory factor rose from 22 to 43 during this period.

Figure 7

Number of deaths with *C. difficile* as a contributory factor and as an underlying cause of death in Northern Ireland 2001 - 2007



Source: Northern Ireland Statistics and Research Agency

Figure 8 sets out the number of deaths and age-specific mortality rates per 1,000,000 population for deaths, with *C. difficile* mentioned on the death certificate, by age and sex, for 2007. The data is provisional but highlights the much higher mortality rate in people over the age of 75 years and that female mortality rates were higher than for men.

Figure 8

Deaths and age-specific mortality rates* for deaths, with *C. difficile* mentioned on the death certificate, by age and sex, for 2007

Age group	Deaths with *C. difficile* mentioned 2007[p]					
	Number			Age specific Mortality Rate*		
	Male	Female	All Persons	Male	Female	All Persons
Under 45	-	-	-	-	-	-
45-74	3	7	**10**	11.4	25.1	**18.4**
75+	17	50	**67**	407.2	714.7	**599.8**
All ages	**20**	**57**	**77**	**23.2**	**63.5**	**43.7**

[p]Provisional data

*rate per million population

In 2007, 51% of all deaths registered in Northern Ireland occurred in a hospital. Where *C. difficile* was mentioned on the death certificate, 92% of these deaths occurred in a hospital.

4.6 Time Trends In *C. difficile* In The Northern Board

Figure 9 sets out the monthly trends in identifications of *C. difficile*, by Antrim Hospital Microbiology Department, at the former United Trust Hospitals, from 1998 to 2007.

During the ten year period it can be seen that there were three periods when the number of cases rose in 1999, in 2003 and in 2007.

From 2nd April 1999 to 2nd June 1999, three wards in Antrim Hospital experienced an outbreak of gastroenteritis in which 70 patients were affected. The outbreak commenced with a clinical infection compatible with viral gastroenteritis. The small round structure virus, now termed Norovirus, was confirmed in only five patients as the testing in the Regional Virus Reference Laboratory was restricted due to the number of

outbreaks occurring in Northern Ireland at that time. However, all patients were repeatedly tested for the presence of C*. difficile* toxin.

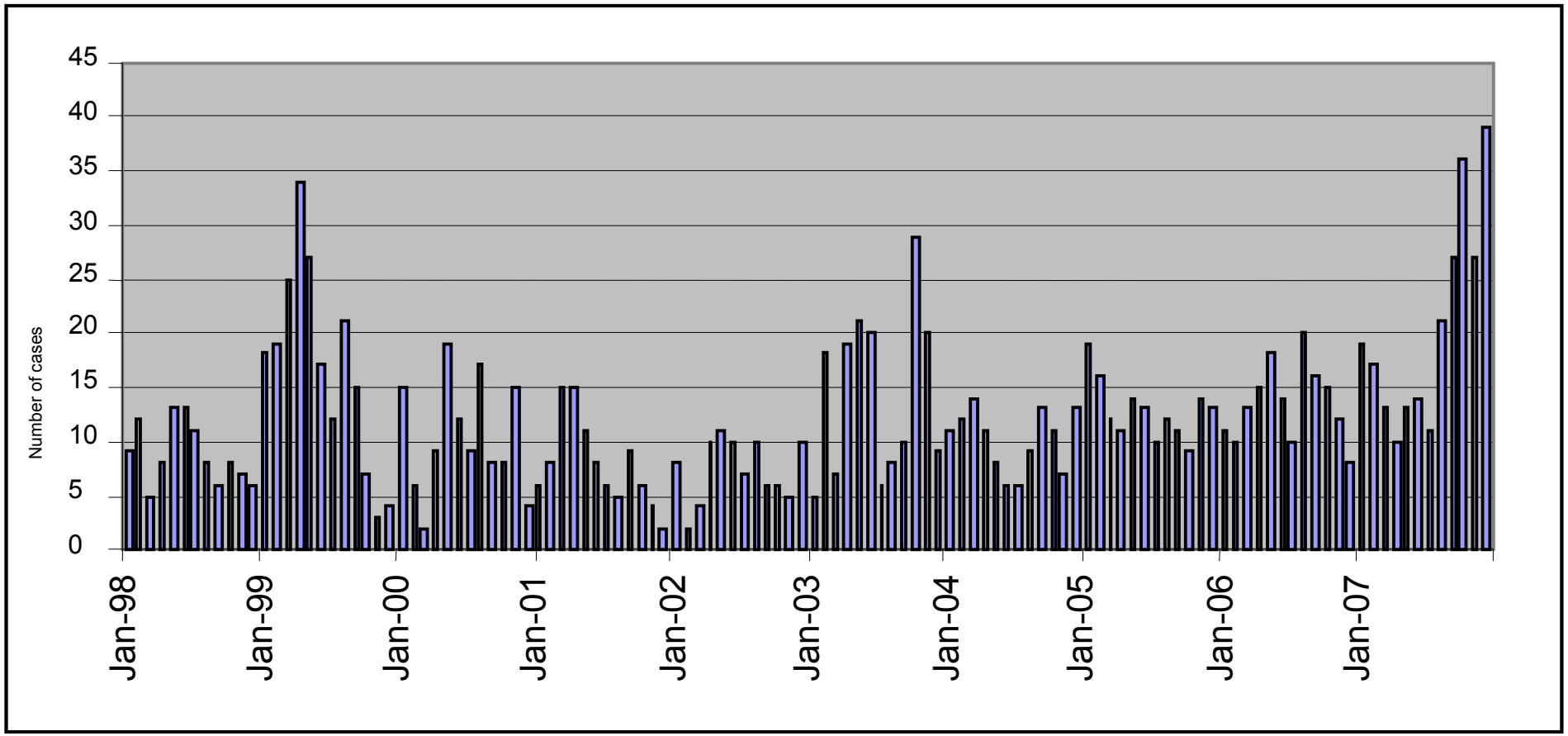
As the outbreak progressed, an increasing number of patients were diagnosed with *C. difficile*. Of the 70 symptomatic patients, 30 were confirmed as having *C. difficile* by toxin testing, and the remaining 35 had no laboratory confirmation but were presumed to be due to Norovirus gastroenteritis. The control measures implemented included contact precautions with physical isolation, enhanced environmental cleaning and withdrawal of Cephalosporin antibiotics. Ribotyping revealed that Ribotypes 001 and 078 were both involved in this outbreak.

Subsequently during the period 27th August to 24th September 1999, 12 patients in one ward at Antrim Hospital developed diarrhoea. Two patients were judged to have diarrhoea of a non infective nature with the remaining thought to be infective in origin. Three were confirmed as *C. difficile* toxin positive, two of whom were known to be previously positive, one identified in the previous outbreak. Despite repeated laboratory testing no cause was found in the remaining seven patients. Implementation of infection control measures brought the outbreak under control.

In 2003, a rise in the number of cases of *C. difficile* was investigated but did not demonstrate a significant link with the antibiotics used. Investigation at that time concluded that the introduction to the laboratory of a more sensitive toxin detection test than the one previously used resulted in the detection of additional cases.

Figure 9 illustrates a rise in the trend of cases detected from August to December 2007. In December 2007 there were 39 isolates reported, which was the peak monthly number across the ten year period.

Figure 9 Number of New Identifications of *C. difficile* in Former United Trust Hospitals 1998 - 2007



5. Time Period 1 - Up To 16th June 2007

5.1 Introduction

The first known patient with *C. difficile* Ribotype 027 in the Northern Trust had a positive toxin sample taken on 16th June 2007 whilst an inpatient in Antrim Hospital. A second sample was later sent for culture and subsequently ribotyping on 16th July 2007. The strain was confirmed with the Trust as Ribotype 027 on 14th September 2007. This is the earliest date on which the virulent 027 strain can be confirmed as having been identified in Northern Ireland.

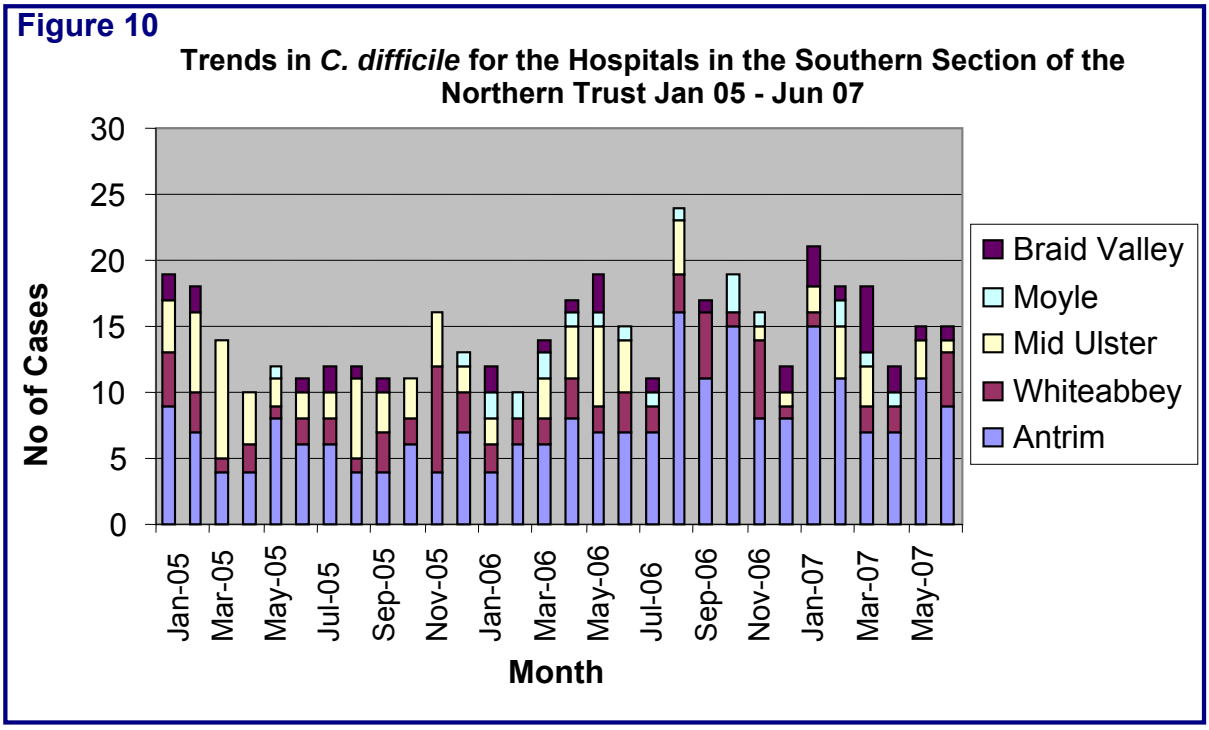
The First Time Period selected for analysis by the Independent Review Team was therefore the period up to 16th June 2007. The key question for this period is:

How prepared was Northern Ireland in general, and the Northern Trust, in particular, for the arrival of a virulent strain of C. difficile?

In considering this question, the Independent Review team reviewed a wide range of regional, Northern Board and Northern Trust documentation and analysed the position at workshops with officers from the DHSSPS, the Northern Board and the Northern Trust.

Figure 10 illustrates the trends in *C. difficile* for the hospitals in the southern part of the Northern Trust for this time period.

Figure 10



Source: Northern Trust

5.2 Chronology Of Relevant Events During Time Period 1

5.2.1 In 1998, the Chief Medical Officer for Northern Ireland reported on a major review of communicable disease control in Northern Ireland. Included among the review's recommendations was that the DHSSPS should establish a Regional Communicable Disease Epidemiology Unit, independent of, but reporting to the DHSSPS, to assist it in fulfilling its role in the control of communicable diseases. The DHSSPS subsequently entered into an agreement with the Public Health Laboratory Service-Communicable Disease Surveillance Centre (PHLS-CDSC) to provide this regional service. The Unit was established in 1999 and is now part of the Health Protection Agency (HPA) of the United Kingdom.

5.2.2 From April to June 1999, three wards in Antrim Hospital had an outbreak of gastroenteritis in which 70 patients were affected. The initial clinical presentation was compatible with viral gastroenteritis and the virus, now called Norovirus, was confirmed in five patients. All patients were tested for *C. difficile* and 30 patients out of the 70 were found to be positive. Control measures included contact precautions with physical isolation, enhanced environmental cleaning and the withdrawal of the Cephalosporin antibiotics. Ribotyping revealed that both Ribotypes 001 and 078 were involved in the outbreak.

5.2.3 In October 1999, a Hospital Infection Sub-committee of the Regional Advisory Committee on Communicable Disease Control was established. The work of this committee included:

- the development and completion of draft regional standards for environmental cleanliness which were sent to the DHSSPS who subsequently put them out to consultation;
- taking regional leadership on hand hygiene promotion;
- contributing to the development of the subsequent Controls Assurance Standard on Infection Control.

5.2.4 In April 2000, the DHSSPS issued Circular HSS(MD)9/2000 on *"The Management and Control of Hospital Infection: Action by the HPSS for the Management and Control of Infection in Hospitals in Northern Ireland."* The Circular set out a programme of action for Boards and Trusts designed to:

- strengthen the prevention and control of infections in hospital;
- secure appropriate health care services for patients with infections;
- improve surveillance of hospital infections;
- monitor and optimise antimicrobial prescribing.

5.2.5 In April 2001, the DHSSPS published a consultation document, *Best Practice - Best Care* which set out proposals focused on:

- developing and disseminating clear service standards for the HPSS;
- securing accountability at local level for the delivery of services;
- improving monitoring and regulation of the services.

5.2.6 In September 2001, the DHSSPS established the Northern Ireland Healthcare-Associated Infection Surveillance Centre (HISC) to assist acute Trusts in Northern Ireland to undertake healthcare associated infection (HCAI) surveillance. The initial focus of HISC was on surveillance of infection in orthopaedic patients.

5.2.7 In 2001 and 2002, the DHSSPS commissioned a survey of all hospital Trusts with regard to the management and control of HCAIs. The issues identified included:

- the need to improve the resources for infection control teams including appointing more infection control nurses;
- the need for computerisation of data collection systems;
- providing support for surveillance activities in Hospital Microbiology Departments in Trusts;
- increasing the priority given to infection control at Trust Board level.

5.2.8 In 2002, the DHSSPS established a Healthcare Associated Infection Surveillance Group. The group reviewed national HCAI surveillance initiatives and advised on their application to Northern Ireland. Under the auspices of that Group the surveillance of MRSA was made mandatory and Trusts were asked to undertake mandatory surveillance of *C. difficile* from 1st January 2005.

5.2.9 In February 2002, the DHSSPS published an "Antimicrobial Resistance Action Plan" (AMRAP) which established six priority areas for action, namely:

- prudent antimicrobial use in humans in the community;
- prudent antimicrobial use in humans in hospitals;
- prudent antimicrobial use in animals;

- infection control;
- education, information dissemination and research;
- surveillance.

Key recommendations for action were agreed for each area and an AMRAP Implementation Steering Group was set up.

5.2.10 In 2003, investigations took place into a rise in cases of *C. difficile* in the United Hospitals Trust. It was concluded that the introduction of a more sensitive toxin detection test than the previously used test resulted in the detection of additional cases. Consideration of possible links with the use of specific antibiotics did not detect any significant relationships.

5.2.11 The Health and Personal Social Services (HPSS) (Quality, Improvement and Regulation) (Northern Ireland) Order was introduced in 2003, following the consultation on *Best Practice – Best Care*. The Order:

- established a new, independent body, the Northern Ireland Health and Personal Social Services Regulation and Improvement Authority (the Regulation and Quality Improvement Authority) with overall responsibility for monitoring and regulating the quality of health and social care services delivered in Northern Ireland;
- introduced a statutory duty of quality to be placed on Health and Social Services (HSS) Boards, HSC Trusts and some special agencies with regard to services which they provide;
- gave the Regulation and Quality Improvement Authority (RQIA) powers to review and inspect the quality of services provided by the HPSS, including evaluating clinical and social care governance arrangements within HPSS bodies, designed to underpin the statutory duty of quality placed on HSS Boards and HSC Trusts.

5.2.12 In April 2004, the DHSSPS issued a Controls Assurance Standard on Infection Control which required all Trusts to assess their services against a defined set of 16 criteria and report on an annual basis on their performance.

Each criterion includes reference to relevant guidance and gives examples of the evidence required for verification. The overall standard is that:

"There is a managed environment, which minimises the risk of infection, to patients, staff and visitors."

The standard recognised that there was :

"A clear need to improve the general level of knowledge and understanding of infection control principles among healthcare staff working in both hospital and community settings."

5.2.13 On 30th December 2004, the DHSSPS issued Circular HSS(MD)41/2004 on *Isolation Rooms (including Mechanically Ventilated Rooms): Best Practice Standards for Capital Planning.* This document set out guidance on isolation precautions and on bed management for 'best infection control'.

5.2.14 On 1st January 2005, mandatory surveillance commenced for *C. difficile* in Northern Ireland, coordinated by CDSC(NI). The CDSC(NI) provided quarterly reports to Trusts, Boards and the DHSSPS on the surveillance information from 2005.

5.2.15 On 1st April 2005, the RQIA was established.

5.2.16 In June 2005, the DHSSPS issued for consultation *Protecting Patients and Staff – A Strategy for Prevention and Control of Healthcare Associated Infections in Northern Ireland 2005-2010.* The draft strategy set out 58 wide-ranging recommendations.

5.2.17 In September 2005, the DHSSPS Health Estates published *Cleanliness Matters – A Regional Strategy for improving the standard of environmental cleanliness in HSC Trusts 2005-2008.* The strategy set out seven Key Quality Principles to set the framework for its delivery together with detailed guidance as to how these principles were to be achieved, namely:

- accountability and Culture for Environmental Cleanliness;
- development of Trust Environmental Cleanliness Strategies;
- improving and listening to service users and staff;
- adopt appropriate regional and Trust Human Resources strategies for cleaning staff and managers;
- adoption of a risk-based approach to environmental cleanliness standards;
- consider the facility service user mix, together with its age, design and condition when selecting achievable cleaning standards;
- appropriate levels of monitoring and audit are undertaken.

5.2.18 In September 2005 Health Estates issued the *Environmental Cleanliness Controls Assurance Standard* with the requirement to achieve substantial compliance by March 2006.

In September 2005 a specific section was included on the management of *C. difficile* in the joint Infection Control Policy for the three Trusts in the Northern area, (United Hospitals, Causeway and Homefirst). The three Trusts which came together to form the Northern Trust had a common set of agreed policies and procedures for infection control.

5.2.19 On 2nd March 2006, the DHSSPS issued Circular HSS (MD) 9/2006 on *Changing the Culture: An Action Plan for the Prevention and Control of Healthcare Associated Infections (HCAIs) in Northern Ireland 2006/2009.* This action plan was developed following the consultation on the strategy document on HCAIs issued in 2005. The action plan set out 37 action points to be achieved over the three year period of the plan. The plan focused on the areas of organisation and culture of healthcare organisations, education training and practices, governance, accountability and audit, and public and patient partnership. Mandatory training for all staff and a hand hygiene campaign were recognised as key areas.

The Circular accompanying the plan stated that:

"The final accountability for infection prevention and control will lie with Trust Chief Executives and significant new governance and accountability structures are proposed for health service organisations including (i) a designated Trust Infection Prevention and Control Lead and (ii) a Trust Infection Reduction Plan."

A regional group, chaired by the DHSSPS Chief Nursing Officer, was established to oversee the implementation of the plan. The Regional Infection and Prevention and Control Action Plan Steering Group met for the first time on 27th June 2006.

5.2.20 On 14th March 2006 the Minister launched The Quality Standards for Health and Social Care in Northern Ireland. These standards were established to:

- give the HPSS and other organisations a measure against which they could assess themselves and demonstrate improvement;
- help service users and carers to understand what quality of service they are entitled to;
- help to ensure implementation of the duty the HPSS has in respect of human rights and equality of opportunity for the people of Northern Ireland;
- enable formal assessment of the quality and safety of health and social care services.

5.2.21 In April 2006, the Northern Board developed an Interim Action Plan, as required by the regional Priorities For Action, to take forward the DHSSPS strategy on HCAIs.

5.2.22 In April 2006, the then United Hospitals Trust which was responsible for the Antrim, Mid-Ulster and Whiteabbey Hospitals established an Environmental Cleanliness and Infection Control Strategy Group chaired by the Chief Executive. In May 2006, the United Hospitals Trust designated a medical microbiologist as its Infection Prevention Control Lead (IPC).

5.2.23 In June 2006, a senior manager in each of the Directorates in the United Hospital Trust was identified to assume responsibility for infection control and participate as an active member of the IPC Committee.

5.2.24 On 9th June 2006, the Northern Board established a NHSSB HCAI Committee to oversee action on *Changing the Culture* across the area. The Committee was chaired by the Board's CCDC and had representatives from each Trust in its area. The Committee subsequently established two sub-groups to consider issues specific to primary care and to nursing and residential homes.

5.2.25 In July 2006, the Healthcare Commission in England published a report of an investigation into outbreaks of *C. difficile* at Stoke Mandeville Hospital, Buckinghamshire Hospitals NHS Trust. The report identified significant failings.

5.2.26 In September 2006, in response to *Cleanliness Matters,* the then United Hospitals Trust prepared a cleanliness strategy to improve the standard of environmental cleanliness during the period 2006/2008, The strategy called *"Quality – Our Driving Force"* set the overall aim as:

"*Provide a clear sense of direction over the next three years on the key environmental cleanliness issues that need to be developed, implemented and maintained."*

A Trust Cleanliness Matters Steering Group was established to take the strategy forward. An Annual Report was prepared to highlight the progress of the group.

5.2.27 On 10th October 2006, the Health Minister launched the *Ward Sister's Charter* designed to give Ward Sisters, Charge Nurses and Ward Managers a key role in ensuring the cleanliness of their wards.

At the launch of the Charter, the Minister released the results of the first independent audit of the cleanliness of hospitals and community facilities.

The audit was carried out by KPMG. The compliance results for hospitals in the then United Hospitals Trust were:

- Antrim 77%
- Mid-Ulster 74%
- Whiteabbey 61%

With an overall score of 71%, the then United Hospitals Trust was placed in Band 3 (70-79%). Band 3 indicates that *"Trust facilities in this band are not seriously dirty, but there may be more than one-off failures in cleanliness indicating possible problems in managing their cleaning services or with underlying problems with maintaining and refurbishing facilities which the Trust needs to address."*

5.2.28 On 26th October 2006, the Regional Infection Prevention and Control Action Plan Steering Group considered the Healthcare Commission report on the outbreaks at Stoke Mandeville Hospital. It was agreed that the DHSSPS would consider how to respond to this matter.

5.2.29 On 24th November 2006, at the Regional Infection Control Symposium, which is held to bring together relevant healthcare workers and to provide a platform for Boards and Trusts to share best practice and lessons learnt from critical incidents, the Chief Nursing Officer in his opening address drew attention to the need to learn from the experience of Stoke Mandeville in controlling a protracted outbreak of *C. difficile.* This was followed by a presentation from Dr. Jean O'Driscoll, Director of Infection Prevention Control and Consultant Microbiologist at Stoke Mandeville, who explored in detail the sequence of events at Stoke Mandeville and the learning for both clinical and administrative staff. The conference was attended by over one hundred infection control staff from across Northern Ireland.

5.2.30 On 7th December 2006, the Northern Board's CCDC circulated copies of the report on the outbreaks at Stoke Mandeville to the members of the Northern Board HCAI Committee.

5.2.31 In December 2006, a snapshot survey of *C. difficile* ribotypes in Northern Ireland did not identify any cases of Ribotype 027.

5.2.32 On 22nd December 2006 the DHSSPS Health Estates issued Circular LLS/06/03 on *Healthcare Commission Investigation into outbreaks of Clostridium difficile at Stoke Mandeville Hospital.*

5.2.33 In January 2007, the then United Hospitals Trust prepared an Annual Infection Control Plan setting out actions designed to take forward each of the key areas as set out in the DHSSPS strategy *Changing the Culture.*

5.2.34 On the 1st April 2007, the Northern Trust was established, taking over the functions of the United Hospitals, Homefirst and Causeway Trusts.

5.2.35 On 12th April 2007, the Chief Medical Officer and Chief Nursing Officer jointly issued Circular HSS (MD) 9/2007 on *The Prevention of Infection caused by C. difficile.* The circular was written in the context that; *"This infection causes significant morbidity in our hospitals in Northern Ireland and has also been associated with some major adverse incidents in hospitals in the United Kingdom."* The circular was accompanied by a copy of "A Good Practice Guide to Control *Clostridium difficile"* developed by the Health Protection Agency's Regional Microbiology Network[7]. The circular stated that outbreaks of infection caused by *C. difficile* should be reported to the DHSSPS as a serious adverse incident. The circular drew attention to the recognition and investigation of outbreaks and that in all cases the management of the outbreak should be notified to, and discussed with, the local CCDC. The Circular, and the attached Good Practice Guide, did not draw specific attention to the emergence of the virulent Ribotype 027 in Great Britain and other countries.

[7] A Good Practice Guide to control *Clostridium difficile*, published by the Health Protection Agency for England and Wales in January 2007

5.2.36 On 18th May 2007, the Northern Trust's IPC Lead summarised the findings and lessons from the Healthcare Commission report into the outbreaks at Stoke Mandeville Hospital, at the Nursing and Residential Home Subgroup of the Northern Board's HCAI Committee.

5.2.37 On 16th June 2007, a positive toxin sample for *C. difficile* was taken from a patient in Antrim Hospital. Another sample taken from the same patient on 16th July 2007 was sent for culture and was subsequently confirmed as *C. difficile* Ribotype 027 on 14th September 2007.

5.3 Analysis Of Position At 16th June 2007

During a Root Cause Analysis workshop members of the RQIA Independent Review Team and Northern Trust staff considered the actions which had been taken during the time period. The following sections outline the strengths and challenges which emerged from those discussions.

5.3.1 Governance arrangements

Strengths

- lines of accountability for the prevention and control of infection in hospitals were clear. The Trust Chief Executive had accountability for prevention and control and was responsible, through the statutory Duty of Quality, to the DHSSPS for the exercise of this function. Following the publication of *Changing the Culture* in 2006, a medical microbiologist was designated as the Trust's IPC Lead. This person subsequently was designated as the IPC Lead for the new Northern Trust;
- the Governance Assurance Framework adopted for the Northern Trust was adapted from the frameworks in the legacy Trusts, although the organisational structure was not fully populated on 16th June 2007;
- the merger of the legacy Trusts was not considered to have been detrimental to infection control as there was significant continuity in staffing. The merger facilitated

a more joined up approach to the development of care pathways across hospital and community care.

Challenges

- the Northern Trust's Board and Senior Management Team had a lack of awareness of the potential seriousness of an outbreak of a virulent strain of *C. difficile* or of the emerging global trends in the spread of Ribotype 027;
- the reporting systems in place to provide assurance to the Trust Board that infection control policies were being properly implemented at ground level are now considered to have not been sufficiently robust at that time;
- the new Trust inherited a pattern of hospitals where long-term strategies to rationalise services had only been partially implemented. The pattern required a significant level of patient transfers between sites, and hospitals had very different levels of quality of estate. For example, the older hospitals had fewer side rooms to enable effective isolation of infected patients;
- bed occupancy and patient throughput levels were high. Meeting elective and emergency care targets was a high priority for the Trust along with tackling a particularly high number of delayed discharge patients and trolley waits in Accident and Emergency as well as the novovirus outbreak. These factors are recognised to have led to increased numbers of patient transfers within and between the hospitals in the southern sector of the Trust;
- the new Trust inherited recognised shortfalls in the overall staffing levels (nursing and cleaning staff) in the hospitals in the southern part of the Trust area.

5.3.2 Infection Control

Strengths

- the three legacy Trusts, which merged to form the new Northern Trust, had a common set of infection prevention and control policies. These were in place across the Trust area with hard copies available on all wards. There was a process in place to formally launch new updates in policies;

- the IPC Team had previously worked as a common resource across the legacy Trusts and was available to provide advice on a 24 hour/seven day basis;
- there were clear arrangements in place for managing localised outbreaks of infection and Infection Control Nurses visited wards on a regular basis;
- there was a reported high level of awareness among nursing staff of the need to manage cases of diarrhoea;
- Personal Protective Equipment (PPE) was widely available;
- Antrim Hospital had been designated as a receiving hospital for Severe Acute Respiratory Syndrome (SARS) patients and had a specifically designed ward which could be converted for isolation of patients.

Challenges

- policies on infection control were not implemented to the desired degree. Staff tended to contact Infection Control Nurses with queries rather than refer, in the first instance, to Trust policies and guidance;
- information systems did not facilitate the highlighting of patients with *C. difficile* or the tracking and monitoring of real time trends. Early warning systems were reliant on staff experienced in infection control recognising clusters of infections. Information was not collated or presented in a timely or user friendly format;
- bed pressures with full wards and outliers did not facilitate good infection control practice;
- Infection Control Nurses were focused on training and audit activities, with less time to devote to tackling issues in wards;
- training sessions on infection control were poorly attended. This was thought to be because of pressures on staff time due to generally low staffing levels in the Trust;
- as a result of the merger key staff had changed roles, leading to a transitional period for reporting and lines of communication;
- Personal Protective Equipment, while readily available, was not always being used appropriately;
- funding had been made available for additional infection control nurses but their appointment took longer than anticipated due to ongoing discussions between the service commissioner and provider;

- communication systems were considered weak and the linkages of Infection Control with other departments such as Information Technology (IT) and Governance were not formalised.

5.3.3 Antibiotic Prescribing and Clinical Management

Strengths

- the Trust had an antibiotic policy in place and detailed guidance had been prepared for key areas such as intravenous (IV) to oral switch. The policy was actively reviewed and updates communicated to staff. The policy was available on the Trust intranet with hard copies available on wards. Medical staff were involved in antibiotic policy development;
- the usage of antibiotics was actively monitored by pharmacists;
- integrated Medicines Management was in place with ward-based pharmacists;
- the infection control and pharmacy teams were recognised for the support they provided to clinical staff with the clinical management of patients with *C. difficile;*
- consultants did demonstrate leadership in relation to antibiotic prescribing and infection control;
- there had been little movement of medical staff as a result of the Trust mergers and consequently minimal disruption to clinical services;
- Trust pharmacy and infection control staff had a long term interest in prudent antibiotic prescribing.

Challenges

- there were recognised barriers to ensuring adherence to antibiotic guidelines and audits including, regular changes in junior medical staff, and pressures on the availability of pharmacy and clinicians' time;
- the antibiotic guidelines were detailed and there was a recognised need to develop a more concise version;
- there were difficulties in effective dissemination of guidelines, with a perceived lack of access to computers on wards;

- there was a lack of appreciation among clinical staff of the virulence of *C. difficile* Ribotype 027;
- care for patients with *C. difficile* was not provided by designated consultants;
- bed pressures, with patients outlying in different wards, impacted on the continuity of care for some patients;
- a document control system was not in place for the removal of old policies on wards.

5.3.4 Cleaning

Strengths

- a plan to implement the recommendations of *Cleanliness Matters* was in place and action was being taken forward;
- policies and procedures for Support Services had been developed and training provided. Ongoing training and induction programmes were in place for Domestic Staff;
- the 2006 KPMG Environmental Cleaning audit had identified areas for improvement. Action had been taken and the 2007 results achieved an improved score;
- processes were in place to ensure compliance with Controls Assurance Standards on Environmental Cleanliness;
- IPC Team policies and procedures were well established;
- recruitment days to speed up the recruitment of Domestic Staff were in place;
- the Ward Sister's Charter was in place and training in relation to *Cleanliness Matters* had been set up for Ward Managers;
- the Trust was participating in the *Saving Lives* campaign and this included the involvement of Support Services;
- ward A1 in Antrim Hospital had been built as a proposed designed isolation ward with eight en-suite single rooms.

Challenges

- a Review had been undertaken which had identified Antrim Hospital as having a lower number of domestic staff 'hours per bed' than other hospitals in the new Trust and in two comparable hospitals;

- in 2004/05, funding had been made available by the DHSSPS to pilot Rapid Response Cleaning Teams for six months. A business case was prepared to recurrently fund this development but was not approved for the Antrim, Mid-Ulster and Whiteabbey hospitals. It was funded for Causeway Hospital;
- the general lack of adequate storage space in the Antrim Hospital resulted in significant clutter in clinical areas. Cleaning of cluttered clinical areas was more difficult.
- additional funding for cleaning had not been allocated in line with policy decisions. This placed increased demands on cleaning services. An escalation policy was developed which enabled an additional bed to be put up in wards with no additional cleaning staff put in place. The number of 'terminal cleans' had increased from 300/ 400 over time to reach 1000, in 2007, with no additional funding;
- a programme of decanting wards to enable refurbishment had been underway and six wards were refurbished. Ward A1 had been used for decanting. This programme was halted before it was completed;
- there was a recognised shortage of laundry at times. For example, disposable sheets had to be used when the stocks of laundry ran out at weekends;
- the auto-valet system for staff uniforms did not function as well in Antrim Hospital as in Causeway Hospital. Staff working in Antrim Hospital were supplied with three uniforms compared to six for staff working in Causeway Hospital;
- the policy on open visiting caused delays for cleaning staff.

6. Time Period 2 - From 16th June 2007 To 7th January 2008

6.1 Introduction

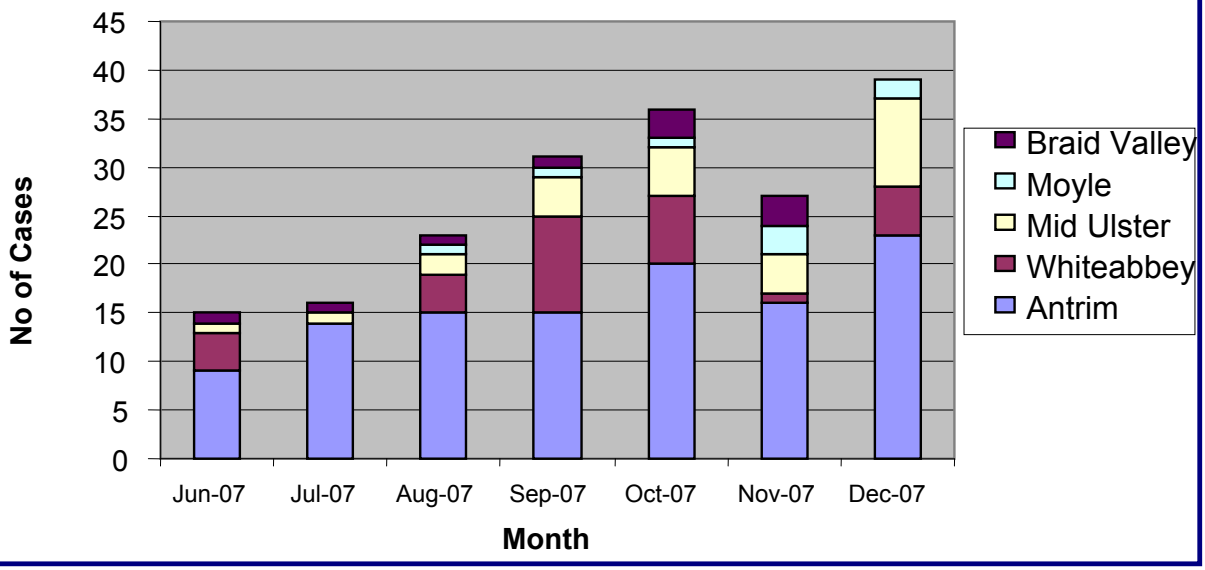
On 16th June 2007, a positive toxin sample for *C. difficile* was taken from a patient in Antrim Hospital. Another sample taken from the same patient on 16th July 2007 was sent for culture and was subsequently confirmed as *C. difficile* Ribotype 027 on 14th September 2007. On 7th January 2008, the Northern Trust formally declared that there was an outbreak of *C. difficile* within the Trust area. The time period between 16th June 2007 to the 7th January 2008 was selected by the Independent Review Team as Time Period 2.

The key question for this period is:

How appropriate were the actions taken in relation to the prevention and control of C. difficile in the Northern Trust area during the period from 16th June 2007 to 7th January 2008?

The trends in *C. difficile* during this period, for the hospitals in the southern part of the Northern Trust area are shown in Figure 11.

Figure 11



Source: Northern Trust

6.2 Chronology Of Relevant Events During Time Period 2

6.2.1 On 8th June 2007 a patient was admitted to Antrim Area Hospital with a history of acute confusion and increasing shortness of breath. At the time of admission, she had been living independently in the local community. She was diagnosed as having had a cerebral vascular accident (a stroke). During her admission, she was started on antibiotics for a urinary tract infection. She developed diarrhoea and a faecal sample, sent on 16th June 2007, tested positive for *C. difficile* toxin. The patient improved and she was transferred to the Braid Valley Hospital for rehabilitation. During July, the patient had more episodes of diarrhoea and was placed in contact isolation. Her condition deteriorated and a further sample, taken on the 16th July 2007, was confirmed to be positive for *C. difficile* toxin. She was transferred back to Antrim Hospital where she died on 18th July 2007.

In view of the severity of the patient's symptoms, the medical microbiologist decided to culture the positive sample taken on 16th July 2007 and sent it to the Reference Laboratory in Cardiff for ribotyping. At that time ribotyping was only carried out on a limited number of patients. The result was logged by the Trust on 14th September 2007 and confirmed to be Ribotype 027. This was the first time that this ribotype had been identified in Northern Ireland.

6.2.2 On 25th June 2007, the Regional Infection Prevention and Control Action Plan Steering Group met. During the meeting, progress was discussed on the appointment of the Trust's IPC Leads to the new Health and Social Care Trusts. It was noted that the Northern Trust was the only Trust in Northern Ireland to have identified a Lead (a Consultant Microbiologist) at that time

6.2.3 On 31st July 2007, the first meeting was held of the new Infection Prevention and Control and Environmental Cleanliness Committee for the Northern Trust. It was chaired by the Trust's IPC Lead and attended by representatives of directorates and the Northern Board's CCDC. The new committee was to report to the Trust Risk and Governance Group, chaired by

the Northern Trust's Medical Director. During the meeting, a Trust Infection Reduction Plan was discussed.

At the meeting the Trust's IPC Lead drew attention to a reduction target for *C. difficile* of 5-10% over the next two years. She noted that, although figures for *C. difficile* were relatively low, they were showing an upward trend. The Committee was advised that four deaths from *C. difficile* had been reported recently in the Trust and prompt action had been taken. Guidance on health care associated infections had been forwarded to the Medical Director for urgent issue to medical and nursing staff. It was emphasised that deaths from *C. difficile* should be reported as a clinical incident.

6.2.4 On 16th August 2007, a meeting was held to discuss an increased incidence of diarrhoea in Ward B2, a medical ward with 27 beds, in Antrim Hospital. It was chaired by the Trust's IPC Lead. Four patients in Bay 2, Ward B2 had developed diarrhoea since 14th August 2007 and two of these had been diagnosed with *C. difficile* infection (CDI). Advice on clinical management was provided and control measures were agreed, including:

- All symptomatic patients to be transferred to single room isolation;
- all exposed patients to be closely monitored;
- bay 2 to have a Level 3 terminal clean and then to open and function as normal;
- B2 and all single rooms to have a Level 2 clean with Antichlor Plus (sodium thiosulfate) over the following weekend.

Two of the patients affected died. No further cases were reported over subsequent days and the incident was declared over.

6.2.5 On 20th August 2007, the Trust Infection Prevention Control Accountability Structure was approved. The structure set out that:

- the Trust's IPC Lead is the Trust's expert adviser on IPC matters and will provide leadership for training, prevention and control activity and communication;
- the IPC Lead will report to the Medical Director for infection, prevention and control but she has direct access to the Chief Executive and Trust Board when required. If the IPC Lead has concerns regarding IPC performance which cannot be resolved at directorate level, these can be referred directly to the Chief Executive.
- the four service directorates in the Trust will nominate a senior officer as the Nominated Directorate Lead (NDL) who will be directly accountable to the IPC Lead for infection prevention and control in their directorate. The NDL will be responsible for submitting the annual directorate infection reduction plan and progress reports to the Trust Lead;
- the NDL is accountable to the IPC Lead for infection prevention and control and submitting directorate plans but the IPC Lead does not have managerial responsibility for the NDL. If there are concerns with IPC performance in the directorate which the IPC Lead is unable to resolve with the NDL then the IPC Lead will liaise with the Director who is responsible for performance management;
- the IPC Team will provide professional advice to managers and link IPC staff. Every ward and care facility will designate a link member of staff to work with the IPC Team. The link worker needs some protected time for IPC activity and to attend meetings and training;
- the accountability structure will be kept under review to make sure that it is 'fit for purpose'. The first formal review will be one year from implementation, i.e. August 2008.

6.2.6 In August 2007, the Consultant Regional Epidemiologist at the CDSC (NI) noted a rise in CDIs in the returns from the Northern Trust and contacted a microbiologist at the Trust to alert her to this.

6.2.7 On 4th September 2007, the Northern Board issued an approval letter to the Trust for funding for two additional infection control nurses using funding from the DHSSPS.

6.2.8 On 11th September 2007, the Minister announced new targets for reductions in HCAI's with a target reduction of 20% in *C. difficile* to be achieved by March 2009.

6.2.9 On 14th September 2007 a report logged by a Trust laboratory confirmed a patient sample with *C. difficile* Ribotype 027.

6.2.10 On 1st October 2007, a meeting was held to consider an increased incidence of diarrhoea associated with Ward 9, a rehabilitation unit with 24 beds, at Whiteabbey Hospital. It was chaired by the Senior Nurse in IPC. It was reported that from 1st August to 26th September 2007, a total of seven patients had developed CDI. This was a substantial increase over previous months as the ward had had only four cases from January to August 2007.

The majority of those affected had been in Bay C. Level 3 Cleaning had been carried out on each bed space following transfer of each new CDI case, and a deep clean of Bay C using Antichlor Plus (sodium thiosulfate) took place on 27th September 2007. Advice on clinical management was provided and control measures were agreed. Daily Level 2 cleaning with a chlorine based agent was commenced for isolation facilities in the ward.

Three of the seven patients affected died. CDI was considered a contributory cause in one of the cases. Samples from three patients were sent for ribotyping and all three were subsequently confirmed as Ribotype 027. No new cases associated with Ward 9 were reported over the next two months from 26th September 2007.

6.2.11 On 6th October 2007 a meeting was held to consider an increased incidence of diarrhoea in Ward 2, Whiteabbey Hospital. Ward 2 is an acute medical ward with 24 beds. On that day, four patients were

reported to have developed diarrhoea with one confirmed as CDI. At that time, the ward was caring for three other patients with CDI in single rooms. All patients were placed on contact precautions and daily Level 2 cleaning was initiated with chlorine based disinfectant. Samples from two patients were sent for ribotyping. One was subsequently reported as Ribotype 001 and one was confirmed as Ribotype 027. All the patients with CDI recovered and this was not considered to be an outbreak.

6.2.12 On 11th October 2007, a meeting was held to consider an increased incidence of *C. difficile* from 14th September 2007 in Ward B2 Antrim Hospital. It was reported that a total of 19 patients had been diagnosed in Antrim Hospital with *C. difficile* in the period from 14th September 2007 to date. Of these, seven were patients in Ward B2.

The first patient affected had been admitted on 15th August 2007 to ward B1 and transferred on 16th August to Ward B2 (where there was an earlier cluster of cases as indicated in paragraph 6.2.4). The patient developed diarrhoea on 13th September 2007.

Control measures were agreed. Patients were isolated in single rooms or cohort areas with contact precautions. Isolation areas were cleaned twice daily with Actichlor Plus.

Of the seven patients, three later died. The cohort area was disbanded on 25th October 2007, when single rooms were available.

6.2.13 On 11th October 2007, the Trust's IPC Lead advised a meeting of the Trust Medicine and Governance Directorate that three cases of Ribotype 027 had been reported and that this type was associated with more severe disease. It was further noted that a number of patients had died in the Trust with *C. difficile* being a major contributory factor to their death. It was agreed that the emergence of Ribotype 027 should be reported as a Serious Adverse Incident. The Medical Director advised that he had written to medical staff outlining the need for vigilance with regard to antibiotic prescribing and the need for rigorous attention to infection

control processes. It was agreed that an action plan should be formulated.

6.2.14 On 11th October 2007, the Healthcare Commission (England) published a report detailing significant failings in infection control at Maidstone and Tunbridge Wells NHS Trust in relation to *C. difficile*.

6.2.15 On 15th October 2007, the Northern Trust submitted a Serious Adverse Incident (SAI) Report to the DHSSPS. It stated that:

"*In recent months the Consultant Medical Microbiologist noted an increase in the number of referrals for advice on the management of severe C. difficile associated diarrhoea; consequently isolates from 4 patients were sent for typing. PCR ribotype 027 was identified, for the first time in the Northern Board area. This ribotype is known to have been associated with severe outbreaks in Canada and Stoke Mandeville in the past.*

The Northern Trust patients were all severely debilitated before infection and this may have been a factor."

It was noted on the SAI Report that the Northern Board and the Consultant Regional Epidemiologist were also informed. While the SAI Report did alert the DHSSPS to the presence of Ribotype 027, this was not declared as an outbreak as per Circular HSS(MD)9/2007

The SAI form recommended that all Trusts needed to be vigilant for the emergence of Ribotype 027.

6.2.16 On 23rd October 2007, the Trust's IPC Lead met with the Northern Board's CCDC to discuss issues relating to the emergence of Ribotype 027. A copy of the Trust's response to this was shared with the CCDC. The response recognised that *C. difficile* Ribotype 027 is associated with more severe disease, longer duration of symptoms and recurrences and has been responsible for a number of outbreaks, such as those in

Canada and Stoke Mandeville Hospital. It stated that a number of patients with *C. difficile,* within the Trust, had a more severe and refractory form of disease and therefore the samples had been sent for ribotyping. Three had been identified as having Ribotype 027. To contain the problem and prevent further cases the Trust had established a control plan which included:

- that Medical Microbiologists would continue to monitor referrals and request culture and ribotyping on an named patient basis;
- that a review of the antibiotic guidance for Primary Care and the Empirical Antibiotic Guidelines for Secondary Care was urgently required;
- that guidance on penicillin allergy would be issued and a baseline audit undertaken;
- that clinical medical staff will avoid inappropriate prescribing, review all antibiotic prescriptions at 48-72 hours and ensure selection of antibiotic, dose and the duration of therapy is appropriate for the specific infection;
- that all staff comply with standard infection control precautions and additional precautions when appropriate;
- that the IPC Team will establish base line information regarding the use of the antibiotics, fluoroquinolones (e.g. ciproflxacin) and restricted cephalosporins in the Antrim Hospital in the first instance;
- that the Antibiotic Implementation Committee should be re-established.

6.2.17 On 25th October 2007, the Trust's IPC Lead gave a presentation to the public Board meeting of the Northern Trust on HCAIs. In her presentation, she referred to the need to take account of the lessons of the Maidstone and Tunbridge Wells report in relation to practice in the Northern Trust.

6.2.18 On 9th November 2007, the Consultant Regional Epidemiologist at CDSC (NI) contacted the Trust's IPC Lead to advise that the numbers of *C. difficile* reports continued to be high.

6.2.19 On 16th November 2007, the Consultant Regional Epidemiologist at CDSC (NI) emailed each Northern Ireland laboratory with advice on the new standard procedure for reporting on *C. difficile* Ribotype 027.

6.2.20 Between 5th December and 22nd December 2007, there was an outbreak of gastroenteritis at Antrim Hospital affecting 80 patients and 32 staff. The patients were cohort nursed or isolated in single rooms. Norovirus was isolated from 14 samples and *C. difficile* associated diarrhoea was confirmed in seven patients. A terminal clean of all affected areas was completed.

6.2.21 On 4th December 2007, the Trust Senior Management Team (SMT) were updated on *C. difficile* by the Medical Director. A checklist for the management and prevention of patients with *C. difficile* and a Trust Action Plan were shared. The Medical Director advised that the numbers of instances/deaths had increased within the Trust and briefed members on proposed actions including a weekly meeting to monitor the situation and to make sure that appropriate action was being taken. Members approved the proposed actions and the importance of keeping a focus on trying to reduce the instances of *C. difficile.* As it was a Priorities For Action target, it was agreed that the Trust Board should be kept up-to-date through a section in the monthly performance report and the information would be used to target problematic areas.

6.2.22 On 11th December 2007, Clinical Directors were briefed that *C. difficile* numbers had risen with an increased number of deaths. A draft *C. difficile* Reduction Plan was discussed.

6.2.23 On 13th December 2007, the first meeting was held of a Trust *Clostridium difficile* Associated Diarrhoea Review Group chaired by the Medical Director. The Group was updated on the situation in relation to *C. difficile*

in the Trust and advised that arrangements were in place for weekly monitoring of cases across the Trust.

The Group reviewed the draft CDAD Reduction Plan and agreed amendments. Actions agreed included:

- Guidance on antibiotic prescribing to be finalised and sent out to staff as soon as possible;
- importance of ensuring full compliance with infection control policies to be emphasised;
- laboratory arrangements for testing samples to be reviewed to ensure patients were identified as quickly as possible;
- resources for cleaning agents for the type of cleaning regimes to be used would be raised with the Trust's SMT;
- the Medical Director agreed to raise with SMT the possibility of converting Ward A1 at Antrim Hospital to become a cohort ward for *C. difficile* patients. This was advocated strongly by the Trust's IPC Lead in order to manage patients in one area. Ward A1 had the best facilities for infection control.

6.2.24 Between 16th December and 25th December 2007 there was an outbreak of gastroenteritis at Moyle Hospital affecting eight patients. A viral cause was suspected although no organisms were detected from samples submitted.

6.2.25 On 18th December 2007, the SMT was updated on infection control issues following the meeting of the CDAD Review Group on 13th December 2007. The following actions were agreed:

- *Environmental Cleaning* - the SMT supported the proposal to use Tristel (chlorine dioxide) as a cleaning agent but 'additionality' would have to be considered in terms of the associated cost implications;

- the Medical and Nursing Directors agreed to meet to discuss issues involved with using Ward A1 at Antrim Hospital to manage all patients with *C. difficile* at that time;
- *CDAD Implementation Plan* - the Medical Director advised that the final version of the plan would be available later that week for full implementation;
- *Terminal Cleaning* - the Director of Elective and Acute Services would 'fast track' a business case for terminal cleaning teams and look at benchmarking figures for hours allocated to domestic services.

The Director of Strategic Planning and Performance Management emphasised the importance of making sure that appropriate action was being taken in the interim whilst these proposals were being implemented.

6.2.26 On 20th December 2007, the Northern Trust Board were advised at a public Board meeting, by the Medical Director, that there had been an increase in the number of deaths associated with *C. difficile.* This was being monitored very closely, although it was difficult to decipher whether a patient had contracted the infection whilst in hospital or whether they had entered the hospital with it. He briefed the Board on the measures being taken to reduce the number of instances of *C. difficile* including a review group and an action plan. He drew attention to the concern that some antibiotics may leave some patients, especially older patients, more susceptible to the *C. difficile* infection. The Medical Director agreed to forward the *C. difficile* reduction action plan to the Family Practitioner Unit, Northern Board and advise of issues associated with the use of some antibiotics. A comparison on incidence of *C. difficile* by hospital ward and month of occurrence for 2006 and 2007 was included in the performance report for November 2007.

6.2.27 On 4th January 2008, The Medical Adviser for Primary Care at the Northern Board issued an email to all General Practices in the Northern Board area titled:

"Urgent for Action - Major increase of incidence of C. difficile in NHSSB"

The email was to be brought to the attention of all medical personnel in the practice including prescribing leads. Guidance documents on the management of *C. difficile* were in the email.

On 4th January 2008, the Trust IPC Lead and the Trust Head of Governance discussed the figures for *C. difficile* infections in Antrim Hospital. In view of the number of cases reported, the Chief Executive was advised. The Chief Executive decided to convene an Outbreak Control Team.

6.2.28 On 7th January 2008, a decision was taken at the first meeting of the Northern Trust Outbreak Control Team (OCT) to formally declare that there was an outbreak of *C. difficile* at Antrim Hospital.

6.3 Analysis Of Actions Taken 16th June 2007 To 7th January 2008

During a Root Cause Analysis workshop members of the Independent Review Team and Trust staff considered the actions which had been taken during the time period. The following sections outline the strengths and challenges which emerged from those discussions.

6.3.1 Governance arrangements

Strengths

- the Trust Board, through its accountable officers of Chairman and Chief Executive, led a strong management team which was committed to do whatever was necessary within available resources to provide a safe quality service;
- there were good working relationships between the Medical Director, IPC Lead, Pharmacy and the clinical interface;
- the Infection Control specialists were alert to the emergence of the 027 ribotype of *C. difficile.*

Challenges

- there was incomplete understanding by many staff of the potential significance of the emergence of Ribotype 027 and the increase in numbers of apparently sporadic cases of *C. difficile* in the various hospitals within the Trust. This was also true at all levels throughout Northern Ireland. This led to a delay in recognising the significance of the increasing numbers of patients with *C. difficile* and consequently a delay in generating an appropriate action programme;
- there was inadequate monitoring of data: the information system was not fit for purpose; information was generally analysed manually and in retrospect. Information was not presented in a user friendly way. This meant that managerial decisions were not being made on the most up-to-date accurate information;
- the Trust was dealing with many high profile issues with conflicting agendas. For example, the need to: establish new organisational structures following the creation of the new Trust; respond to the Minister's PFA targets on patient access and the

comprehensive spending review (CSR) as well as a number of other significant governance issues. The state of flux in the system meant that the Trust Board and the SMT were not able to adequately assure themselves that all appropriate actions were being taken throughout the Trust to minimise the risk of the spread of infections;

- ownership of infection prevention and control was seen as an IPC Team problem. Rather than a Clinical Leadership issue being managed by the clinical teams with expert advice from the IPC Team.

6.3.2 Infection Control

Strengths

- the Trust had made an early appointment of an IPC Lead Consultant and had established its IPC Team structures in August / September 2007;
- the IPC Team responded rapidly to a number of localised outbreaks and applied control measures;
- the patient's consultant recognised the index case in July 2007 and discussed it with the medical microbiologist who cultured the specimen and sent it for ribotyping.

Challenges

The IPC Team was severely challenged during this period. Some members recognised the severity of the evolving problem. However, the structure and processes that were in place at the time did not allow for that knowledge to be clearly understood so that appropriate and timely decision-making could be taken at all levels. In particular:

- key messages on the significance of Ribotype 027 and its management were not communicated to the appropriate levels. Evidence from staff suggested communications and guidance were not easily accessible, nor easy to implement;
- co-ordination of existing resources and allocation of additional resources to greatest effect, e.g. early establishment of isolation ward and best use of side wards;

- poor communication both within and across clinical and support teams;
- lack of real time data to monitor overall trends in the Trust and for flagging notes in admission areas, e.g. Emergency Department, to alert clinical staff to the risk of *C. difficile* when patients are readmitted.

6.3.3 Antimicrobial prescribing and Clinical Management

Strengths

- guidelines on the prescribing of antibiotics were in place;
- guidelines on management of *C. difficile* were in place and reviewed;
- antibiotic usage overall was similar to that of other Trusts;
- the antibiotic pharmacist increased time spent on the wards and worked to improve prescribing through audit feedback and training;
- use of ciprofloxacin and clindamycin were reviewed and the need to reduce use of these was identified;
- patients with diarrhoea were rapidly isolated, although not yet in a specific isolation ward;
- re-organisation of the patient-flow processes in December 2007 led to the establishment of specialty designated wards and clinical teams. This enabled the concentration of clinical teams to specific wards / groups of patients thus reducing the need to attend to patients on a number of different wards;
- pro-active ways of working differently by Pharmacy increased ward input by senior pharmacist from 6 to 12 hours per week on direct clinical work mainly to address the antibiotic usage in light of the rise in *C. difficile* cases;
- isolation of patients took priority over meeting access targets;
- a *C. difficile* action plan was developed and rolled out in December 2007 which included actions to raise awareness amongst medical staff;
- antibiotic guidelines were updated by the consultant microbiologist and made available to staff through laminated posters on wards and desktop icons on the intranet.

Challenges

- the emerging profile of *C. difficile cases* was perceived as small clusters of patients in different wards / hospitals. It was not recognised quickly enough as a Trust-wide problem to be addressed with Trust-wide solutions;
- clinical (nursing and medical) and support staff were spread too thinly across clinical areas and across a number of hospitals;
- action to reduce use of ciprofloxacin and clindamycin did not commence until January 2008.
- the volume of inpatients generally, together with the volume of patients with *C. difficile,* led to increased lengths of stay which resulted in higher bed occupancy levels and significant pressure on clinical and support teams. Furthermore, patients had multiple transfers between hospital sites and a reduction in continuity of care was inevitable;
- redrafting complex policies / guidelines created delays in the systems and some confusion for clinical staff (both medical and nursing) in their implementation;
- making infection control everyone's business. Ensuring that clinicians take ownership of hand hygiene, prudent antibiotic prescribing and adherence to guidelines plus the audit/monitoring of these processes;

6.3.4 Cleaning

Strengths

- representatives on the Prevention and Control and Environmental Cleanliness Committee;
- representation at local meetings held regarding outbreaks in Antrim and Whiteabbey Hospital;
- new Support Services Management in place that commenced 'walkabouts' to discuss issues at a local level;
- introduction of new colour coding system for cleaning equipment;
- support Services Managers took the lead to action KPMG recommendations;
- the Support Services Team responded rapidly to requests for terminal cleaning.

Challenges

- lack of knowledge or recognition of the importance of cleaning or the skill now required by the staff;
- lack of ownership of the clutter in the clinical areas;
- lack of communication in that the right messages were not getting to the right people;
- the seriousness of the Ribotype 027 had not been communicated to the Support Services Team;
- the introduction of new cleaning products which resulted in different disinfectants being used created problems for cleaning staff as there was insufficient time for adequate training to be given;
- no increase in staff or budget as a result of the earlier outbreaks.

7. Time Period 3 - From 7th January 2008 To 30th June 2008

7.1 Introduction

The Third Time Period selected for analysis by the Independent Review Team was from 7th January 2008 onwards, after the Northern Trust had formally declared that there was an outbreak of *C. difficile* at Antrim Hospital. The key question for this period is:

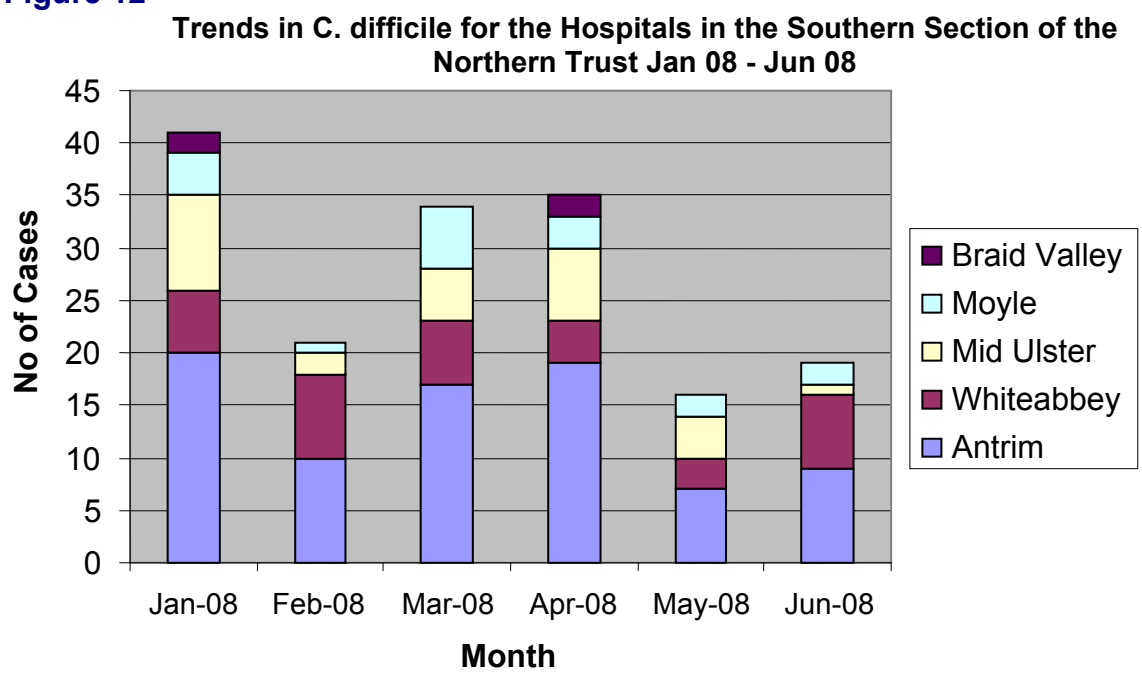
How appropriate were the actions taken to minimise the impact of the declared outbreak of C. difficile in the Northern Trust area and to bring it under control as rapidly as possible?

In considering this question the Independent Review Team:

- assessed a wide range of regional Trust and Board documentation including the minutes of the OCT meeting and guidance and advice issued during the outbreak;
- conducted an RCA workshop with DHSSPS officers;
- conducted an RCA workshop with a range of staff from the Northern Trust to review the timeline of events;
- interviewed representatives of the Northern Board's Senior Management Team;
- interviewed the Director of the Communicable Disease Surveillance Centre for Northern Ireland.

Figure 12 illustrates the trends in *C. difficile* for the hospitals in the southern part of the Northern Trust, during the period after the outbreak was declared.

Figure 12



Source: Northern Trust

7.2 Chronology Of Relevant Events During Time Period 3

7.2.1 On 7th January 2008, the Northern Trust held an OCT meeting, chaired by the Trust Chief Executive, at which it was decided to formally declare that there was an outbreak of *C. difficile* at the Antrim Hospital for the period from October 2007 to December 2007. It was agreed that this would be reported to the DHSSPS and the Northern Board using a Serious Adverse Incident (SAI) reporting form.

Actions agreed included:

- the disinfectant, Tristel, to be used at Antrim Hospital with immediate effect;
- consideration to be given to develop a terminal cleaning team at Antrim Hospital;
- the Medical Director to contact Trusts in England about the benefits and problems with setting up a cohort ward for *C. difficile* patients;
- to continue to ribotype positive *C. Difficile* stool samples to monitor the prevalence of Ribotype 027;
- dissemination of further information to primary care and hospital clinical staff.

7.2.1 On 7th January 2008, the Trust's IPC Lead contacted the Northern Board's CCDC to alert him to the outbreak.

7.2.2 On 8th January 2008, the Northern Trust completed an SAI Report stating that:

"Local data indicates significant increases in the number of C. difficile cases from October-December 2007. Trust declared outbreak status. Previous notification of PCR Ribotype 027 notified on 15th October 2007."

7.2.3 On 8th January 2008, CDSC (NI) circulated to Trusts, Boards and the DHSSPS, the July/September quarterly surveillance report for 2007 on *C.*

difficile which showed that the Northern Trust had exceeded the Upper Action Line on the chart.

7.2.4 On 11th January 2008, the SDU convened a first Performance Management meeting to discuss processes in relation to monitoring the delivery of the Ministerial targets on reducing MRSA and *C. difficile.*

7.2.5 On 14th January 2008, the second meeting of the Trust OCT was held. Actions agreed included:

- further analysis of trends of other hospitals in the Trust was required before it could be determined if there were outbreaks at hospitals other than Antrim;
- face to face meetings would be held with each clinical team at Antrim Hospital to inform them on the current situation, to provide information on *C. difficile* and to inform them about the new antibiotic policies;
- the Medical Director would write to the Chief Medical Officer in relation to informing other Trusts as it had emerged, at the SDU meeting, that other Trusts were not aware of the SAI report, sent on 15th October, concerning the identification of Ribotype 027;
- the cleaning of ward areas in Antrim Hospital was to be reviewed;
- Ward A1 at Antrim Hospital should be converted to a cohort ward for *C. difficile;*
- a Review Group should be established, to be chaired by the Deputy Medical Director, to review the outbreak and identify any of the factors which contributed to it.

7.2.6 On 15th January 2008, the Medical Director of the Trust wrote to the Chief Medical Officer, asking him to consider disseminating the information concerning the identification of Ribotype 027.

7.2.7 On 18th January 2008, Ward A1 at Antrim Hospital was converted to become a cohort ward for *C. difficile* patients.

7.2.8 On 18th January 2008, the DHSSPS asked the CCDC in the Northern Board to alert CCDC colleagues in other Boards to the outbreak. This was done on the same day.

7.2.9 On 18th January 2008, the Permanent Secretary at the DHSSPS issued Circular HSS 27/2007 to disseminate key learning arising from the Healthcare Commission reports on outbreaks in Stoke Mandeville and Maidstone and Tunbridge Wells.

7.2.10 On 21st January 2008, the Northern Trust's Medical Director invited the Consultant Regional Epidemiologist at CDSC (NI) to join the OCT.

7.2.11 On 22nd January 2008, the Northern Trust issued a press statement stating that it had declared an outbreak of *C. difficile.* The press statement confirmed that Ribotype 027 had been identified. It highlighted that an action plan had been put in place with three distinct strands:

- Containment
- Antibiotic policy
- Infection Control

Guidance was provided for patients attending hospital.

7.2.12 On 22nd January 2008, the third meeting of the Northern Trust's OCT took place. Actions agreed included:

- the Clinical Director for Acute and Emergency Medicine to write to General Practitioners of the potential use of the Acute Care at Home Team to avoid admission of patients to hospital;
- the content of a letter to be given to patients and visitors;
- the situation at Whiteabbey and Mid-Ulster Hospitals would be kept under careful review and the issue of cohort facilities should be further explored in these hospitals.

7.2.13 On 24th January 2008, the Chief Medical Officer issued Circular HSS (MD) 1/2008 with guidance to the service on *C. difficile,* and reissued the Good Practice Guide which had previously been issued in April 2007.

7.2.14 On 25th January 2008, the Minister announced £9 million investment in clean and safer care and that new hospitals should aim to provide single rooms for patients.

7.2.15 On 25th January 2008, the Consultant Regional Epidemiologist at CDSC (NI) formally reported the outbreak to the Health Protection Agency in England and asked for advice on epidemiological studies in previous UK outbreaks of *C. difficile*.

7.2.16 On 28th January 2008, the Consultant Regional Epidemiologist at CDSC (NI) sent an email to the Medical Director of Northern Trust with a checklist of questions to be considered.

7.2.17 On 29th January 2008, The Trust's OCT met. The Trust's IPC Lead informed the group that she had sought advice from a UK expert in microbiology and *C. difficile* who advised that actions being taken appeared to be robust; that they needed to review the use of the antibiotic, clarithromycin; that they needed to ensure that all patients were washed with soap and water and their bed clothes changed on a daily basis. Clarification was awaited on the use of cleaning agents. For very ill patients, the use of immunoglobulin could be helpful. It was agreed that specific guidance on this would be circulated to Clinical Directors. Other actions agreed included:

- a question and answer sheet for staff which had been developed would be circulated;
- the Medical Director would write to Clinical Directors in relation to filing death certificates in notes;
- the Chief Executive would mention the outbreak in her monthly letter to all staff;

- plans being developed to commence intensive cleaning at both Mid-Ulster and Whiteabbey Hospitals following its commencement at Antrim Hospital
- rapid response cleaning teams were to be set up at Antrim, Causeway, Mid-Ulster and Whiteabbey Hospitals;
- a meeting would be convened to discuss the practical issues about transferring patients with *C. difficile* from other hospitals to the cohort ward at Antrim.

7.2.18 On 31st January 2008, the Trust's IPC Lead contacted the Consultant Regional Epidemiologist about declaring an outbreak at Mid-Ulster hospital as there were seven active cases of *C. difficile*.

7.2.19 On 31st January 2008, the Consultant Regional Epidemiologist sent an email to the Medical Director of the Trust suggesting that the OCT set up sub-groups to help manage the workload.

7.2.20 On 4th February 2008 the system of medical care of the patients in the isolation cohort ward being provided by a small team of geriatricians was implemented. This meant that care of these patients was provided in a co-ordinated manner with close ongoing continuity of care.

7.2.21 On 5th February 2008, the Chief Medical Officer asked CDSC (NI) to commence the public reporting of quarterly surveillance reports on *C. difficile.*

7.2.22 On 7th February 2008, the Deputy Chief Medical Officer and the Chief Nursing Officer met with the Northern Trust's OCT. Actions agreed at the meeting included:

- a new outbreak control structure was discussed and agreed to become operational as soon as possible;
- the Deputy Chief Medical Officer would discuss with the Chief Medical Officer the identified need for clear regional guidance on death certification of patients who had *C. difficile*;

- the Chief Nursing Officer advised that a paper was being produced by the DHSSPS on the principles on which a visiting policy should be produced;
- patients from Mid-Ulster Hospital were generally not fit to travel to Antrim and so Ward 6 there was being used to cohort them;
- the Northern Trust's Nursing Director had sent out a reminder to all ward managers in relation to the Ward Sister's Charter;
- an IT Surveillance programme would begin in the next week;
- a Lead Clinician would be nominated on each hospital site with whom the Trust's IPC Lead would liaise;
- pharmacists were reviewing Kardexes (nursing notes) to ensure that appropriate antibiotic prescribing was taking place and exemption forms for the prescribing of antibiotics had been introduced.

7.2.23 On 8th February 2008, the Minister visited Antrim Hospital to meet with staff to discuss the outbreak. He announced that he would take every possible action to drive down the spread of infection in hospitals. He confirmed that the General Registrar's Office has been asked to carry out an immediate exercise to produce figures on the number of cases where *C. difficile* was mentioned on a death certificate during 2007.

7.2.24 On the 8th February the Chief Medical Officer and Chief Nursing Officer jointly issued Circular HSS(MD)5/2008 on *Regional Dress Code Policy and Recommendations on staff Changing Facilities for Northern Ireland.*

7.2.25 On the 8th February 2008 the Chief Medical Officer issued Circular HSS(MD)3/2008 on *Guidance for Doctors certifying Cause of Death Involving Healthcare Associated Infection.*

7.2.26 On 12th February 2008, CDSC (NI) advised the Chief Medical Officer that it would be possible to commence the earlier publication of quarterly surveillance reports at six (rather than 12) weeks after the quarter to which they relate.

7.2.27 On 12th February 2008, the Trust OCT met and agreed:

- a new sub-group should be set up known as the Epidemiology Group;
- members would review a proposed list of performance indicators to monitor achievement of agreed actions;
- a new risk-based approach would be considered for patient admission to the cohort ward.

The meeting was advised that the programme of intensive cleaning was continuing at Antrim, Mid-Ulster and Braid Valley Hospitals but had not yet commenced at Whiteabbey Hospital.

7.2.28 Between 12th and 14th February 2008, the Chief Medical Officer:

- met with the Chief Executive and the Medical Director of the Northern Trust to receive an update on the outbreak and the actions taken;
- requested that CDSC (NI) publish quarterly surveillance data as soon as possible and progress a business case for expansion of a programme for Ribotyping;
- requested that the Northern Board's CCDC act as chairman of the Epidemiology Sub-group of the Northern Trust's OCT and agreed this with the Trust's Chief Executive;
- appeared before the Health Committee together with Trust Chief Executives.

7.2.29 On 15th February 2008, the DHSSPS facilitated making available a Vaporised Hydrogen Peroxide (VHP) Cleaning Service to the Northern Trust and the availability of a Specialist Registrar in Microbiology to assist the Trust.

7.2.30 On 18th February 2008, the Chief Nursing Officer issued Circular CNO/01/08 on "*Healthcare Associated Infections - Compliance with Hand Washing Routines."*

7.2.31 On 19th February 2008, the Chief Nursing Officer issued a consultation draft of a document *"Guiding Principles for the Production of Hospital Visiting Policies."*

7.2.32 On 19th February 2008, the Trust OCT met and were informed that:

- VHP equipment was now available on loan from the Belfast HSC Trust. In the first instance, it was agreed that ward A1 and all the patient toilets should be cleaned with this equipment;
- a Clinical Progress Sheet had been developed and was being piloted in Ward A1;
- a Specialist Registrar in microbiology had been seconded from the Belfast Trust for an initial one month period and would be working on antibiotic prescribing practices in the Trust;
- theatre 'scrubs' has been introduced for doctors working in the medical wards of Antrim Hospital.

7.2.33 On 20th February 2008, the Chief Medical Officer issued HSS (MD) 6/2008 providing guidance on Microbiology Laboratory Services in relation to *C. difficile.*

7.2.34 On 20th February 2008 the DHSSPS Senior Medical Officer e-mailed to Trusts the Health Protection Agency document on *Clostridium difficile Infection: How to Deal With The Problem* and a summary list of and links to available regional and national guidance and best practice on *Clostridium difficile*.

7.2.35 On 22nd February the Chief Medical Officer forwarded a *C. difficile* containment checklist, prepared by the RQIA Independent Review Team, to the Chief Executive of the Northern Trust. He advised that the DHSSPS needed to be assured that appropriate control measures were in place to minimise the risk of further infection. He asked for a response by 29th February 2008.

7.2.36 On 25th February 2008, the Trust's OCT met and were informed that, from the beginning of February 2008, there had been a significant decrease in the amount of movement of patients between wards within Antrim Hospital. The clinical guidance had been trialled in Ward A1 and was found to be helpful. An initial audit of prescriptions had taken place which identified some issues but overall the situation was considered to be satisfactory. Two VHP machines were now on loan from the Belfast Trust and consideration was being given to use them in Mid-Ulster as well as Antrim. It was agreed that:

- the Deputy Medical Director would review an apparent discrepancy in the number of deaths reported to the Registrar General's Office and the number declared by the Trust;
- an updated Action Plan would be discussed at the next Trust Board.

7.2.37 On 28th February 2008, CDSC (NI) distributed the *C. difficile* Surveillance Report for the quarter ending December 2007 and this showed the Northern Trust had exceeded the Upper Action Limit.

7.2.38 On 3rd March 2008, the Trust OCT met and noted that the number of incident cases in the former United Trust hospitals was 19 in February compared to 41 in January. The number of deaths in February was 14 compared to seven for the month of January. The Team was advised that there had been an outbreak of *C. difficile* in a nursing home and the Northern Board were monitoring the situation carefully. It was reported that an audit of antibiotic prescribing at Antrim Hospital had showed generally good practice with a number of learning points. The Medical Director agreed to disseminate these throughout the Trust. It was agreed that:

- a proposal for an external audit of the quality of cleaning would be drawn up;
- information on the number of cases would be released to the media on a monthly basis;
- an interim report on the epidemiology of the outbreak would be prepared.

7.2.39 On 4th March, the Trust Chief Executive:

- met the Minister to discuss the status of the outbreak and what further actions could be taken to improve patient safety and care;
- wrote to all staff with an update on the outbreak.

7.2.40 On 13th March 2008, the Trust's OCT met and:

- noted that cases were occurring in a number of different wards in Antrim, Whiteabbey, Mid Ulster and Moyle Hospitals;
- was informed that there were difficulties in recruiting additional staff to the cohort ward in Antrim Hosptial;
- was informed that a programme of cleaning the undercarriage of beds had commenced;
- agreed that it would be useful to complete a Root Cause Analysis (RCA) proforma on cases. This would start with the new cases and then extend to cases from previous weeks;
- agreed that a business case should be progressed for a VHP machine;
- noted the very positive results of a KPMG audit on environmental cleanliness;
- was advised that the Review Sub Group had been linking with the Healthcare Commission regarding the methodology used for the Maidstone and Tunbridge Wells review in relation to mortality.

7.2.41 On 18th March 2008 the Chief Medical Officer issued Circular HSS(MD)10/2008 on *Enhanced Monitoring Arrangements for Deaths Where C. difficile or MRSA Infection is Mentioned on the Death Certificate.*

7.2.42 On 20th March 2008, the Trust's OCT met and:

- Amended and agreed a draft proforma to carry out a RCA on patients with *C. difficile;*

- agreed to investigate the cost of providing all patients with hand wipes to clean their hands before each meal;
- was advised that staff were being recruited for the rapid response teams;
- agreed to forward a copy of an interim epidemiology report to the Chief Medical Officer and that the Medical Director would liaise with the Chief Medical Officer in relation to meeting to discuss the contents of the report; were informed that a number of cases had arisen in Ward A3 and that steam cleaning and VHP would be carried out there as soon as possible;
- was informed that a *"Saving Lives"* programme was underway;
- was informed that in the work of the Review Group no obvious factors had been identified at that time which had contributed to the outbreak. It was agreed that a retired physician would be approached to review the case notes and charts of the people who had died.

7.2.43 On 27th March 2008, the Chief Pharmaceutical Officer at the DHSSPS wrote to Boards and Trusts advising that funding was being made available for an extra antimicrobial pharmacist for each Trust.

7.2.44 On 2nd April 2008, the Trust's OCT met and:

- agreed that there would be a 3-month trial of introducing hand wipes for each patient;
- was advised that a business case for a cleaning contract for beds was being prepared;
- was informed that a project was being set up with the University of Ulster to evaluate the effectiveness of the cleaning programme;
- was advised that a new protocol for reporting of deaths associated with both MRSA and *C. difficile* had been sent out and that staff were asked to ensure it was implemented;
- was advised that there had been 34 new cases in March and three reported deaths in the former United Trust hospitals;

- expressed concern that there were currently major pressures in the system with regard to the bed occupancy level and there was a high level of pressure on the staff of Ward A1. It was agreed that a sub-group would be convened to take stock of the situation and look at possible ways to reduce current pressures;
- agreed to suspend the shop trolley service in case this was contributing to spread of infection.

7.2.45 On 7th April 2008, a meeting was held with staff of the Cohort Ward A1 in Antrim Hospital. Issues raised which could help reduce pressure included:

- the possible diversion of activity away from the Trust;
- the possibility of having contingency plans for waiting list targets as elective activity had been restricted at the Trust;
- agreement had been reached with the Northern Board to appoint additional nursing staff to Antrim Hospital;
- a Locum Geriatrician would be retained until at least the end of May 2008;
- transfer protocols would be reviewed for patients being transferred to rehabilitation or step down care;
- patients from Moyle Hospital with *C. difficile* would be retained there rather than transferred to Antrim Hospital, with effect from Monday 14th April 2008;
- a representative from SDU present advised that the access targets were not negotiable, despite the outbreak situation.

Representatives from the SDU have explained to the Independent Review Team that access targets are tools to drive the reform and modernisation programme to improve clinical outcomes and patient experience. Non compliance with access targets e.g. to reduce crowded A&E Departments, bed occupancy levels and the numbers of inappropriate admissions to acute hospitals, would worsen the problem rather than lessen it.

7.2.46 On 7th April 2008, the Minister met with the Chief Executive of the Trust to discuss the status of the outbreak and possible further action.

7.2.47 On 9th April 2008, the Trust's OCT met and:

- received an update on the meeting held on 7th April in relation to the cohort ward and agreed on the actions proposed;
- agreed the arrangements for the use of hand wipes;
- was advised that all wards at Antrim had completed the first round of intensive cleaning and that this was ongoing at the other hospitals in the Trust;
- was advised that there were some difficulties in recruiting to the rapid response teams for night shift but the day shift staff had been appointed. It was hoped this would start in May 2008.

7.2.48 On 17th April 2008, the Trust OCT met and was advised that, as the number of cases was not diminishing, it had been decided to seek expert advice from outside the Trust through a contact in SDU. It was also suggested that some members of Trust staff should visit one of the centres in England that had dealt with an outbreak and this was agreed. The Team were informed that:

- problems had arisen in relation to laundry supply but this had been investigated and resolved;
- observational audits of cleanliness were taking place on a daily basis;
- a retired gastroenterologist had agreed to carry out an independent review of deaths that had occurred throughout 2007.

7.2.49 On 23rd April 2008, a joint letter to HSC organisations on *C. difficile* Ribotype 027 was issued by the Chief Medical Officer and Chief Nursing Officer. The letter:

- highlighted the recent surveillance data published by CDSC (NI). It noted there was a marked increase in inpatient cases and community cases in Northern Ireland in the last quarter of 2007. This had

occurred in the Belfast, South Eastern and Western Trusts as well as the Northern Trust;

- asked all Trusts to have increased vigilance in respect of Ribotype 027 and to send representative samples for ribotyping;
- emphasised the need to have systems in place for early stool sampling within 18 hours of symptoms or admission;
- emphasised that infected patients must be isolated in a side room or isolation ward;
- advised that the SDU would be working actively with Trust during 2008/09 to ensure delivery of the Ministerial targets for *C. difficile* infection;
- asked Trusts to prepare a report on the current level of single room provision across hospital facilities together with the potential to increase this provision and associated costs;
- advised that in view of the rise in community incidence of *C. difficile*, the DHSSPS would issue further guidance to ensure optimal prescribing of antibiotics by General Practitioners.

7.2.50 On 24th April 2008, the Trust's OCT met and:

- was advised that the Trust would be visited on 7th May 2008, by two representatives from the HCAI and Cleanliness Division of the Department of Health in England to look at the control arrangements in the Trust;
- agreed to develop a policy on the use of Proton Pump Inhibitors;
- noted that there had been a number of additional cases in Ward C5 Antrim Hospital and agreed to bring forward a deep clean for this ward.

7.2.51 On 29th April 2008 the Chief Medical Officer issued a letter to trust Medical Directors and Nursing Directors on *Infection Prevention and Mandatory Training*

7.2.52 On 30th April 2008, the Trust OCT met and agreed that the Trust should seek to hire or lease a VHP machine with immediate effect.

7.2.53 On 7th May 2008, the Trust was visited by two representatives of the Cleaner Hospitals Team from the Department of Health who reported back to the Trust's OCT later that day. The Cleaner Hospitals Team advised that:

- it was impressed with the facilities offered by ward A1 as an isolation and cohort ward;
- there was a need to ensure that all the information gathered was pulled together to allow better monitoring of the situation;
- there was a need to have the incidents of *C. difficile* in the Trust as low as possible and not just back to previous background levels;
- a good start had been made on antibiotics but further work was still required;
- the Trust required more information with regard to hand hygiene by ward and by time;
- further assurance was required with regard to effective cleaning of commodes, bed mattresses and the provision of linen supplies;
- whilst improvements had been made with regard to cleaning of wards, further improvements could be made;
- there was a need to ensure that there was local ownership of infection control measures and this may be helped by prompt feedback to wards;
- concerns about the cleaning of ambulances used to transport patients who had *C. difficile* should be raised with the Northern Ireland Ambulance Service;
- it may be helpful to focus on a small number of main priorities in the Action Plan each week.

The OCT advised that an audit of mattresses and commodes would be carried out as a matter of urgency.

7.2.54 On 15th May 2008, the Trust OCT met and:

- was advised that a Nurse Manager was being redeployed to act as Project Manager, overseeing the implementation of the Trust's Action Plan on *C. difficile*. She would focus on prioritisation of the Action Plan and ensure evidence was being brought to the OCT on a weekly basis. In addition, a Ward Sister would take a lead role to work with directorates and support would be provided by a Northern Board SHO in Public Health Medicine. The SDU would provide additional support through an infection control nurse specialist from England;
- was advised the audit of mattresses and commodes was almost complete and requirements for replacements were being actioned;
- agreed that a group would be set up of junior medical staff on hand hygiene;
- agreed that the Medical Director would write to consultant medical staff proposing an automatic stop date of seven days on antibiotics for urinary tract infections and chest infections.
- was advised that a contract for VHP equipment was being put in place;
- was advised that a protocol on proton pumps inhibitors had been agreed and was being circulated.

7.2.55 On 19th May 2008, the Chief Medical Officer and Deputy Chief Medical Officer met the Trust's Medical Director, Northern Board CCDC to discuss an interim report on the epidemiology of the outbreak.

7.2.56 On 22nd May the Trust's OCT met and:

- agreed the visiting policy would be launched on 29th May 2008;
- noted that hand wipes were now available;
- agreed that the Medical Director would write to Clinical Directors and Managers to ensure that appropriate staff were informed of the diagnosis of *C. difficile* and that staff commenced appropriate antibiotic treatment as soon as possible;

- noted the need to ensure locum doctors were aware of protocols and policies regarding *C. difficile* that had been brought to the attention of all consultant medical staff;
- noted that a draft Communications Strategy concerning C*. difficile* had been sent for comments and that these should be returned as quickly as possible.

7.2.57 On 27th May 2008, the Trust's OCT met and agreed that the initial focus of the Project Team which had been established would be on four main areas:

- hand hygiene
- cleaning of clinical equipment
- environmental cleaning
- use of antibiotics

7.2.58 On 30th May 2008, the RQIA Independent Review Team visited the Trust for a validation visit.

7.2.59 On 3rd June 2008, the Minister made a statement on *C. difficile* in the Assembly and released the first report of the RQIA Independent Review.

7.2.60 On 4th June 2008, the Trust's OCT met and was advised that, for the month of May 2008, there had been 16 new cases in the former United Trust hospitals. A representative of the HCAI Team from England would be visiting the Trust for two days each week to work with the Project Team on implementation of the Action Plan. The Project Team would begin work in looking at the implementation of the recommendations in the RQIA report.

7.2.61 On 12th June 2008, the Trust's OCT met and was advised by the Chief Executive that the Trust had agreed to be the first Trust in Northern Ireland to enter into a performance management arrangement with regard to action taken to manage HCAIs with the SDU. The team were advised that three cases of *C. difficile* in Antrim Hospital had originated in Ward C5. This ward had been visited by the Project Team and some issues had been identified

with regard to hand hygiene, the use of personal protective equipment (PPE) and the arrangements for isolation of patients. The Trust Action Plan was being redrafted by the Project Team with the intention of making the objectives and the accountability much clearer. It was intended to incorporate the recommendations from the RQIA Review into the Action Plan. The second round of intensive cleaning was now underway and the 24-hour Rapid Response Team for cleaning would be available at Antrim Hospital from the 1st July 2008.

7.2.62 On 18th June 2008, the Trust's OCT met and was advised that an early draft Action Plan had been developed. It was a high level Action Plan focused on four specific areas: People, Processes, Practice and Performance. It was agreed this should be taken to SMT as soon as possible and the action instituted immediately.

7.2.63 On 25th June 2008, the Minister launched the Regional "Clean your hands" campaign. The campaign was developed by the National Patient Safety Agency and adapted by the DHSSPS for use in Northern Ireland. Campaign materials include posters for wards, signs to direct visitors to hand cleaning facilities, point of care prompts for staff, a patient leaflet and staff handbook.

7.2.64 On 26th June 2008, the Trust's OCT met and:

- was advised that discussions were taking place regarding the development of a Zero Tolerance Approach to issues around infection control processes in the Trust;
- was advised that hand hygiene audits were now taking place on a weekly basis and the results would be posted on wards in a visible position to all people entering the ward.

7.2.65 On 3rd July 2008, the Trust's OCT was advised that there had been a total of 19 new cases in the previous United Hospital Trust area in June and that there had been a major reduction in the number of cases reported from the community from 20 during May to four in June 2008.

7.3 Analysis Of Actions Taken During The Period From 7th January 2008, After The Outbreak Was Declared.

During a Root Cause Analysis workshop members of the Independent Review Team and Trust staff considered the actions which had been taken during the time period. The following sections document the strengths and challenges which emerged from the discussions.

7.3.1 The Outbreak Control Team (OCT)

Strengths

- the OCT under the leadership of the Chief Executive was established on 7th January 2008, with relevant membership to make strategic decisions and to give direction and guidance. Relevant sub-groups were established and there were good working relationships, communications and appropriate collaboration;
- there was obvious commitment by all concerned to take all possible action to protect patients and their families;
- there was good engagement at a strategic level involving the DHSSPS, CDSC (NI), the Northern Board and the Trust's own Board of management. The CCDC in the Northern Board and the regional consultant epidemiologist from CDSC (NI) both joined the OCT.

Challenges

- delays in the system: for example, the delay in approving the Outbreak Action Plan resulted in a delay in making some decisions on the allocation of resources; the delays in approving some policies and guidance resulted in their slower implementation. Some important simple messages were being lost in the system;
- the IPC Team had previously managed small outbreaks very effectively. However, there was a delay in recognising that the management of a much larger outbreak would required a different control structure, including the

complete ownership of the management of patients with *C. difficile* devolved to the ward/clinical teams;

- establishing robust assurance systems to ensure that strategic decisions were being appropriately implemented at patient care level;
- the recognition at all levels throughout the Trust that *C. difficile* Ribotype 027 required different and more stringent control measures was slower than ideal and this led to delays in the implementation of the appropriate control measures;
- operational challenges included: inconsistency with the published figures, generally negative media coverage, pressure on the morale of the staff, winter pressures, lack of robust audit / feedback systems, clarity of direction at operational level and a lack of whole-systems approach.

7.3.2 Infection Control Group

Strengths

- once the decision to establish an isolation ward was taken it was implemented very quickly;
- patients with diarrhoea (or suspected of having it) were treated quickly and appropriately and those with *C. difficile* were promptly isolated;
- a programme of daily cleaning of equipment by nursing staff was initiated;
- senior managers were more visible in clinical areas and provided additional support to staff;
- inter-hospital transfers of patients were being co-ordinated through a single point of contact to improve communications.

Challenges

- the norovirus (winter diarrhoea and vomiting bug) outbreak together with the normal winter pressures were additional burdens on an already stretched staff / system;
- management and ward staff were also under pressure from the media and relatives;

- there was little information available to provide assurance that infection control and outbreak policies were being effectively implemented;
- lack of effective management information systems and real time data to monitor overall trends in the Trust and for flagging notes in admission areas, e.g. Accident and Emergency Department, to alert clinical staff to the risk of *C. difficile* when patients are readmitted.

7.3.3 Pharmacy and Clinical Management

Strengths

- there was good involvement of pharmacy staff at all outbreak control levels: advice on prudent antibiotic prescribing was sought and acted upon. Monitoring of antibiotic usage and consumption was introduced with tightened controls on prescribing;
- clear understanding by clinical staff of *C. difficile* and its potential for causing severe disease;
- the establishment of the isolation ward improved multidisciplinary team working and ownership. Leadership was provided by the Consultant geriatricians. Extra clinical staffing was provided;
- positive support was provided to staff by the Occupational Health Service;
- detailed guidelines for assessment and treatment of affected patients were further developed as the teams learnt from their exposure.

Challenges

- adequate pharmacy staff to undertake pharmacy monitoring;
- lack of focus on determining operational priorities and ensuring robust co-ordination and implementation of agreed operational strategies throughout the Trust.
- balancing the need for very detailed guidelines against benefits of abbreviated concise guidelines for day to day use by junior staff;
- longer term staffing arrangements for isolation ward whilst still developing other clinical areas under the responsibility of the geriatricians;

- maintaining clinical engagement with the *C. difficile* and infection control issues in an environment where affected patients get transferred away from general wards.

7.3.4 Cleanliness

Strengths

- formation of Best Practice Models for cleaning developed;
- the daily cleaning of ward areas in Antrim was reviewed and daily monitoring of ward areas by supervisors was introduced;
- an intensive cleaning programme was introduced for Antrim Area Hospital, Mid Ulster, Whiteabbey Hospital and Braid Valley Hospital by 12th February 2008;
- Rapid Response Teams were to be set up at Antrim and Mid Ulster Hospitals;
- the services of a VHP Cleaning Service was made available;
- results of KPMG Environmental Cleanliness Audit December 2007 showed a marked improvement in the scores achieved in 2006.

Challenges

- this was a very pressurised time for the Support Services Team;
- the Auto-Valet system for uniforms in Antrim Hospital;
- variation in the roles of Support Services Staff, for example, staff in Antrim Hospital have combined domestic and catering duties whereas in Causeway Hospital these are separated;
- variation within the Trust in the provision of a housekeeper on wards. Causeway Hospital has in place a catering hostess who carries out cleaning duties related to catering;
- staffing levels in Antrim Hospital are lower than other hospitals in the Trust. There is still only skeleton support services staffing at weekends;
- delays experienced in implementing proposals. For example, all wards were due to be deep cleaned but this was not achieved until 9th April 2008. Ward C5 was not done until the 3rd May 2008, even though there was a rise in the numbers of

patients with *C. difficile*. Also the introduction of hand wipes for patients proposed in March were not available to May 2008.

8. Communications

8.1 Introduction

In order to assess the level of public interest in the *C. difficile* outbreak in the Northern Trust the RQIA conducted an audit of media coverage, and complaints activity within the Northern Trust and the Northern Health and Social Services Council. In-depth discussion with a range of Trust staff (including communications, senior management, doctors, nurses and staff side, support services, community services, administration) also took place to establish a comprehensive view of communication during the outbreak.

8. 2 Media Audit

The Independent Review Team was informed that the first media coverage of the outbreak within the Northern Trust appeared on 22nd January 2008, reporting 16 deaths in recent months linked to the outbreak.

The majority of the coverage related to the reporting of the rates of infections and numbers of deaths, measures being taken by the Minister and the Northern Trust to address the outbreak, political comment and the Independent Review itself. There has only been limited coverage of individual cases. The media coverage indicated a general confusion between *C. difficile*, MRSA and other infections.

8.3 Complaints

During the review the Northern Trust was asked to identify the number of complaints received relating to *C. difficile* and infection control during the outbreak. The Trust identified 16 formal complaints relating to infection control and hygiene issues, four of these were from patients or relatives of patients who had contracted *C. difficile*. Ten complaints were received relating to the Antrim Hospital. In the main, most comments related to different wards / locations within the hospital and all comments related to hygiene / cleanliness issues. None specifically mentioned *C. difficile*.

The Northern Trust's IPC Team also dealt with between five and ten other queries during the outbreak. The Independent Review Team has not been informed of the nature of the queries.

The Independent Review Team also contacted the Northern Health and Social Care Council and were informed that they had not received any queries or formal complaints relating to the outbreak of *C. difficile* in the Northern Trust.

8.4 Communications Workshop

A number of staff from the Trust participated in a RCA workshop on the 30th July 2008 (including communications, senior management, doctors, nurses and staff side representatives, support services, community services and administration). The focus of the workshop was to establish the role that communication played during the outbreak and what could be learned from the experience. Below are their observations of internal and external communications during the outbreak.

Strengths

- the Northern Trust had an effective corporate communications strategy in place with clear protocols for dealing with media requests and channels for communicating information throughout the organisation;
- the Trust believed it had established good working relationships with the media prior to the outbreak;
- following the declaration of the breakout the Northern Trust established a Strategic Communication Group. This group identified clear messages regarding the outbreak and a specific *C. difficile* communications strategy was developed to ensure that appropriate staff had clear direction when responding to media requests;
- a media conference was held during the week that the outbreak was announced. At this event the Northern Trust's briefing of the media was intended to provide an open and transparent message and to maintain public confidence;
- the Trust endeavoured to provide accurate and timely statistics to the media throughout the outbreak. Initially this was daily, then on a weekly basis and moving to monthly updates as the outbreak progressed;

- the Trust was able to present spokespeople to the media who had received appropriate media training prior to the outbreak, they also ensured that both senior executives and professional staff were made available for interview.

Challenges

- while the Trust reacted quickly to establish the Strategic Communication group and develop the *C. difficile* Communication Strategy, not all staff groups were considered to be in need of information about the outbreak e.g. Community Services and Estates Services;
- the new structures within the Trust proved to be a challenge when implementing elements of the communication strategy, as many staff were still in the transitional phase of commencing in new roles following the merger and the establishment of the Northern Trust;
- the length of the outbreak and the continued negative media coverage had a significant effect on staff morale, particularly the domestic staff;
- information about the outbreak was inconsistently provided to staff at ward level;
- patient information was developed at the beginning of the outbreak but this was not always provided to patients by staff.

Suggestions for improvement made by the group

The group made a number of suggestions to strengthen future communication activity. These included:

- relevant information with regular updates should be communicated to all staff during the course of an outbreak;
- all patients with *C. difficile* should be provided with information leaflets which have been developed about the condition and the precautions to take when discharged from hospital;
- staff should ensure, as far as reasonably possible, that patients and their relatives understand the information provided and be able to respond to any further concerns they may have;

- ongoing audits of the effectiveness of internal communications should be conducted to ensure that key messages reach staff and that they are being acting upon;
- Senior Management Team should conduct 'walkabouts' focused on infection control issues;
- effective, creative, consistent and visible infection prevention and control materials such as posters should be developed and displayed throughout the Trust;
- ongoing audits of patient and public experiences should be conducted;
- Trusts should work effectively with the media to encourage improvements in the confidence of the public in their local health and social care services.

9. Patient Perspectives

The Independent Review Team asked the Northern Trust to contact a sample of 20 patients who had been contracted *C. difficile* to invite them to share their experiences with the Independent Review Team. The Trust managed to contact 17 patients. In keeping with data protection principles, the Northern Trust wrote to the patients and gave details of how to contact the Independent Review Team. Three patients made contact. Of these, two met with members of the Independent Review Team and one provided information by telephone.

The Independent Review Team recognised that this is a very small sample but felt that the patients did give a very valuable perspective on their experiences of having *C. difficile.* Of the three patients, two had been admitted to Antrim Hospital during the outbreak. One patient had been admitted to Causeway Hospital.

Strengths

The two patients who were treated in Antrim Hospital observed the following strengths in relation to their care:

- they had both been moved into isolation during their episode of care;
- most nursing staff involved in the care of the patients had washed their hands;
- visitors washed their hands;
- nursing staff worked very hard, they were caring and used good hygiene practice.

The patient who had been treated in Causeway Hospital observed that the single isolation ward in which she was treated was thoroughly cleaned, bedding was changed daily, and the frame of the bed was cleaned three times each day. Cleaners used disposable cloths to clean different areas of the room and different cloths were used to clean different areas. She commented that *"the place was spotless".* She also observed that all staff caring for her wore protective clothing

when entering the ward and washed their hands before putting on gloves and apron. These were removed before leaving the ward.

Challenges

The patients at Antrim Hospital provided examples in which they observed that care was not always satisfactory:

- they felt that doctors did not always observe good hand hygiene and that this did not set a good example for others;
- staffing levels appeared inadequate at night time. One described a situation in which a patient had been left for nearly an hour when they had diarrhoea in the bed;
- their sheets were not changed for three days in the isolation ward;
- bathrooms were not cleaned for three days;
- hand soap was not always available in ward toilets;
- there was a lack of cleaning of curtain rails and lockers;
- when a nurse was asked by a patient if she had washed her hands, the nurse did not answer the question or wash her hands. She put on a pair of latex gloves without washing her hands first;
- there was a lack of oral and written information about *C. difficile* throughout their stay.

The patient who had been in Causeway Hospital did not receive information about *C. difficile* or any information on what to do when discharged from hospital. The patient was unaware that it was possible to contract *C. difficile* again and was not told what precautions to take when discharged. One patient commented that on discharge her friends were frightened to visit her for fear of contracting *C. difficile*.

The patients felt that the following were important issues for the Trust to consider.

1. Patients and their families require relevant, timely and consistent information which is provided both orally and in writing, and that there should be monitoring of this in terms of what information is provided by whom and when.

2. Hand hygiene and environmental cleanliness should be regularly audited and the results displayed. The audits should take place at ward level and be independently verified.

3. The policy for the involvement of cleaners in food handling should be clarified and steps taken to ensure that infection control issues are fully addressed.

4. There needs to be routine checking of cleaning activity and the results of these checks to be displayed.

5. Doctors need to take more of a leadership role and set a good example in relation to infection control and hand hygiene.

6. There should be a clear hospital uniform policy. This should take account of patient views and be adhered to by all staff. If changes are made to staff uniform policy then the public need to be made aware of this. The 'bare below the elbows' approach or 'scrubs or theatre greens' if adopted, may not fulfill some patients expectations of professional dress.

7. Cleanliness standards in isolation areas do not appear to be sufficient and this needs to be addressed urgently. The views of patients should be routinely sought on this important matter.

8. Staff need further education on the appropriate use of Personal Protective Equipment.

9. Trusts should undertake specific patient satisfaction surveys among groups of patients who have experienced HCAIs.

10. Audits should be carried out on the understanding of patients at the time of their discharge in respect of their diagnosis and their care plan should the condition recur.

11. Patients should receive a personal copy of their discharge letter at the time they leave hospital as well as the copy for their GP. That letter should tell them what to do if they suffer a relapse.

10. Findings Of The RQIA Independent Review Team

10.1 Introduction

10.1.1 The Terms of Reference for the Independent Review were:

1) To review the circumstances contributing to the rates of *Clostridium difficile* infection in the Northern Trust in 2007 and 2008, including the recent outbreak.

2) To review the Trust's management and clinical response to its *Clostridium difficile* rates and outbreak, including actions to inform patients, their relatives and the public.

3) To review the Trust's arrangements to identify and notify cases, outbreaks and deaths associated with *Clostridium difficile* infection.

4) To review the Trust's governance arrangements and the priority given to the prevention and control of infection.

5) To review the actions of the Northern Health and Social Services Board and the DHSSPS in relation to the management of the outbreak in the Northern Trust, and the actions by all Trusts. Boards and the DHSSPS to reduce *Clostridium difficile* rates in Trusts.

6) To examine any other relevant matters that emerge during the course of the review.

7) To identify learning from the management of this incident and make recommendations for the Northern Trust and the wider HSC.

10.1.2 During this part of the Review, the Independent Review team have focused on the outbreak in the Northern Trust in relation to Terms of Reference 1, 2, 3 and 4. The actions of the Northern Board and the DHSSPS have been

considered in relation to the outbreak in the Northern Trust in relation to Term of Reference 5.

The Independent Review team have previously prepared a report with 36 recommendations following validation visits to all five HSC Trusts in Northern Ireland in relation to Term of Reference 5). A second phase of the Review is planned to take place to review the implementation of the *Changing the Culture* strategy in Northern Ireland which also relates to Term of Reference 5.

10.1.3 The findings of the Independent Review Team are set out in this section in relation to Terms of Reference 1 to 7. The findings are based on:

- consideration of extensive documentation, provided to the Independent Review Team, by the Northern Trust, Northern Board, the DHSSPS and CDSC (NI).
- discussions at a 2-day Root Cause Analysis Workshop which was attended by the members of the Independent Review Team and Trust managerial, clinical and support staff.
- meetings with officers from the DHSSPS, the Northern Board and the CDSC (NI)
- feedback from patients as set out in Section 9

The findings are set out in relation to each Term of Reference.

10.2 First Term Of Reference

To review the circumstances contributing to the rates of C. difficile infection in the Northern Trust in 2007 and 2008, including the recent outbreak.

10.2.1 What caused the outbreak in the Northern Trust?

Between 16th June 2007 and 30th June 2008, 297 patients who were inpatients in the hospitals of the former United Hospitals Trust when a sample was taken had a positive *C. difficile* toxin test. Figure 13 illustrates that the figures had almost doubled over this period compared with the figure for the previous two years.

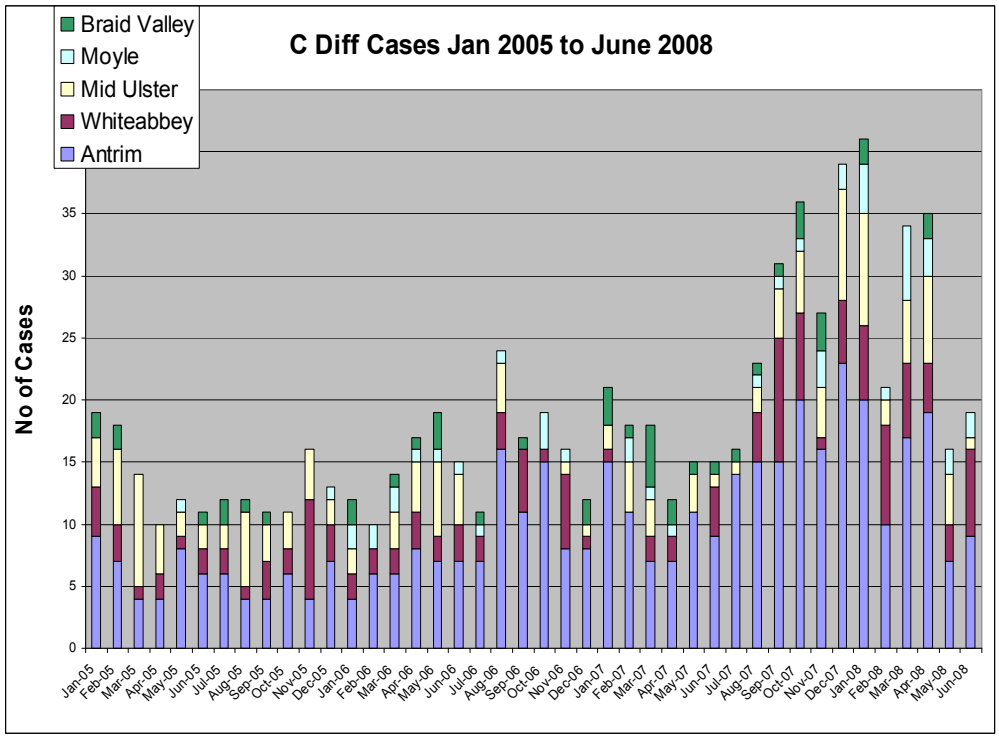
Figure 13

Positive *C. difficile* Toxin Tests from patients in the former United Hospitals

July 2005 - June 2006	150
July 2006 - June 2007	167
15th June 2007 - June 2008	297

The pattern in cases to date has been mapped by the Epidemiology Subgroup of the Northern Trust's Outbreak Control Team. Figure 14 shows the trend in cases from 1st January 2005 to 30th June 2008. It demonstrates a rise in the number of monthly cases from August 2007 to a peak in January 2008 with the numbers reducing towards previous baseline levels by May 2008.

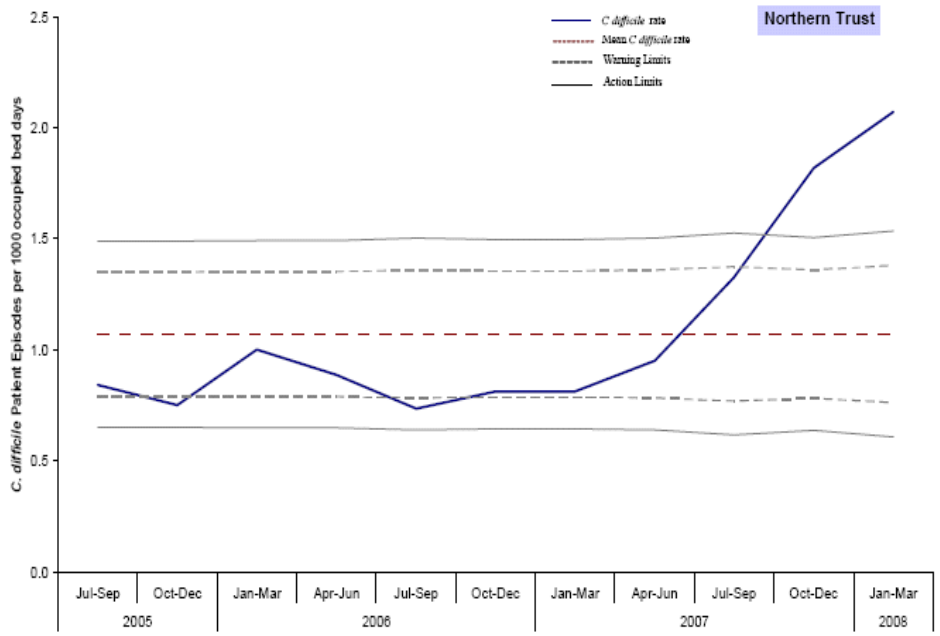
Figure 14



Source: Northern Trust

The CDSC (NI) distributes quarterly reports on surveillance of *C. difficile* in Northern Ireland. The reports contain Statistical Process Control Charts for each Trust area. Figure 15, taken from the first quarterly report for 2008, shows recent trends, by quarter, for the Northern Trust. It demonstrates that the Trust exceeded the Upper Action Limit on the graph in the last quarter of 2007 and the first quarter of 2008.

Figure 15 **Trends in inpatient *C difficile* rates for the Northern Trust by quarter 2005-2008**



Source: CDSC (NI)

SPC charts are designed to help organisations target appropriate measures to improve processes. If a result exceeds the upper limit on the chart, the focus of the organisation should be determine what was the specific factor which has led to that result. If results remain within the control limits, the organisation needs to look at measures which will improve the whole process. Results within control limits imply the system is stable but not that improvements are unnecessary.

In relation to SPC charts for *C. difficile*, therefore, a Trust, in which the results are within control limits, should be looking for measures to be applied across the whole system to bring its average levels down. Such measures could include, for example, improvements in cleaning, antibiotic prescribing and isolation arrangements.

If a Trust exceeds an upper control limit there should be an immediate investigation to identify the specific reason which has led to that result and action taken to tackle that cause.

What was the specific factor which led to the Northern Trust exceeding its upper control limit in 2007?

Ribotyping was carried out on selective patients prior to 1st December 2007 who were positive for *C. difficile* toxin. From 1st December 2007, ribotyping was introduced on all samples with positive toxin results. Ribotyping results can take several weeks to become available. There was therefore not a complete picture of ribotyping on all positive toxin samples during the outbreak.

A first positive sample for Ribotype 027 was from a patient who had an initial *C. difficile* positive toxin specimen on 16th June 2007. Of 144 samples ribotyped to 31st May 2008, 60 were found to be Ribotype 027. If these results can be taken as a sample of the overall period of the outbreak, the pattern indicates that the overall rise in *C. difficile* cases over the period, from June 2007 to June 2008, can be mainly accounted for by an introduction of Ribotype 027, which had not previously been identified in Northern Ireland.

An alternative hypothesis to explain the rise in cases over the period from June 2007 to June 2008 was that it was caused by a major breakdown in infection control arrangements over this period, compared to previous periods. The Independent Review Team consider that this is unlikely on the grounds that the level of non-027 strains of *C. difficile* did not increase significantly during the period of the outbreak.

The Independent Review Team found that an outbreak of *C. difficile* Ribotype 027 occurred in the former United Trust Hospitals of the Northern Trust during the period from 16th June 2007. The outbreak had not been formally declared over by 31st July 2008.

10.2.2 What circumstances contributed to the spread of the outbreak?

a. The nature of the organism - *C. difficile* Ribotype 027

C. difficile Ribotype 027 is considered to be a hyper virulent strain which can produce large amounts of toxins. It can cause more severe illness than other strains with high relapse rate and significant mortality, although this does not always occur. The increased amount of diarrhoea caused can facilitate the spread of the illness. It has been linked to healthcare associated outbreaks in a wide range of countries.

The Independent Review Team found that the specific nature of Ribotype 027 contributed significantly to the spread of the outbreak in the Northern Trust as it challenged the defence mechanisms in place for infection control.

b. Lack of awareness of the possible impact of the introduction of a virulent strain of *C. difficile*

The Independent Review Team found no evidence that the Health and Social Care organisations in Northern Ireland had assessed the risk of a virulent strain of *C. difficile* arriving in Northern Ireland, prior to the introduction of *C. difficile* Ribotype 027. There is clear evidence available of the development of regional policies and plans to tackle healthcare associated infections over the previous 10 years.

General guidance on *C. difficile* was issued by the DHSSPS in April 2007, and there was awareness of the findings of the Healthcare Commission Report relating to outbreaks at Stoke Mandeville Hospital by the summer of 2007.

The Northern Trust had (by October 2007) a plan to respond to the rise in cases of C. difficile infection which had been noted and the identification of three cases of Ribotype 027. The plan referred to the potential for more

serious illness and that Ribotype 027 had caused outbreaks in Canada and Stoke Mandeville Hospital.

The Independent Review Team found that a lack of awareness of the potential threat of a virulent strain of *C. difficile* meant that no escalation plan was in place to manage an outbreak if it occurred. The Independent Review Team consider that, if such a plan had been in place, control measures could have been implemented more rapidly.

c. The Pattern of Hospitals in the Northern Trust

The Northern Health and Social Care Trust inherited a pattern of hospitals part way through a long term programme of rationalisation. In the northern sector of the Trust, Causeway Hospital was opened in 2001 as a new purpose built facility. In the southern sector, Antrim Area Hospital was opened in April 1994. There have been long term plans to extend the bed provision at Antrim to enable acute services to move there from Whiteabbey and Mid-Ulster Hospitals. The hospitals have a wide variation in the quality of the estate.

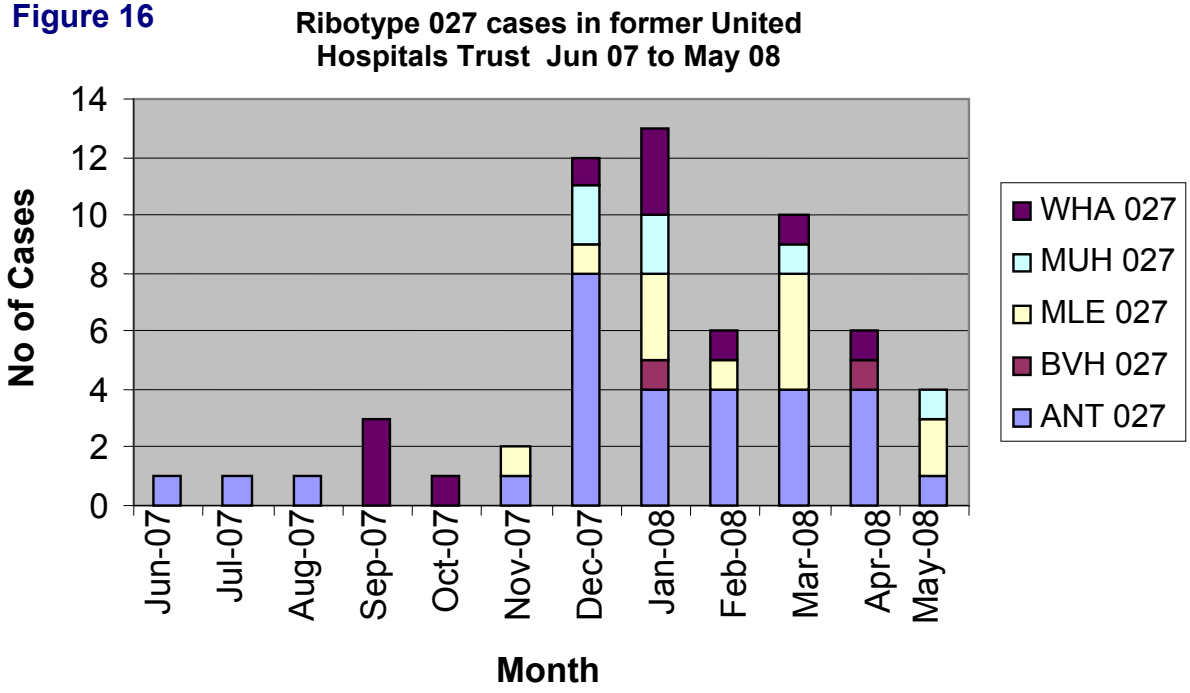
The pattern of the five hospitals in the southern sector necessitates frequent transfer of patients between sites. For example, patients are transferred to Antrim Hospital for specific investigations, and to Braid Valley and Moyle Hospitals, for step down and rehabilitation.

The Independent Review Team found that the pattern of five hospitals in the southern part of the Northern Care Trust was a contributory factor to the spread of the outbreak of *C. difficile* for three reasons:

1. **The hospital distribution led to the transfer of patients between hospitals and this facilitated the spread of *C. difficile* Ribotype 027. By May 2008, all five hospitals in the group had had patients who were first diagnosed there with Ribotype 027 (Figure 16). Patients from the same communities were being admitted to different**

hospitals for different services and this may also have facilitated spread.

Figure 16



Source: Northern Trust

2. **The pattern of hospitals has been recognised by both the Northern Board and Northern Trust to be inefficient in staffing. The Independent Review Team were advised that the level of funding available had to be spread too thinly across five sites and this resulted in lower nurse staffing and cleaning staff levels than comparable hospitals.**

3. **The distribution of services across hospitals was a likely factor underlying the delay in recognising the scale of the problem being caused by the outbreak. The epidemic curve, shown at Figure 14, clearly illustrates the rise in numbers but is based on the combined figures across the five hospital sites. The trend is less obvious if only one hospital is considered. Had all patients been in a single facility the nature of the outbreak may have been recognised at an earlier stage.**

d. Pressures on beds

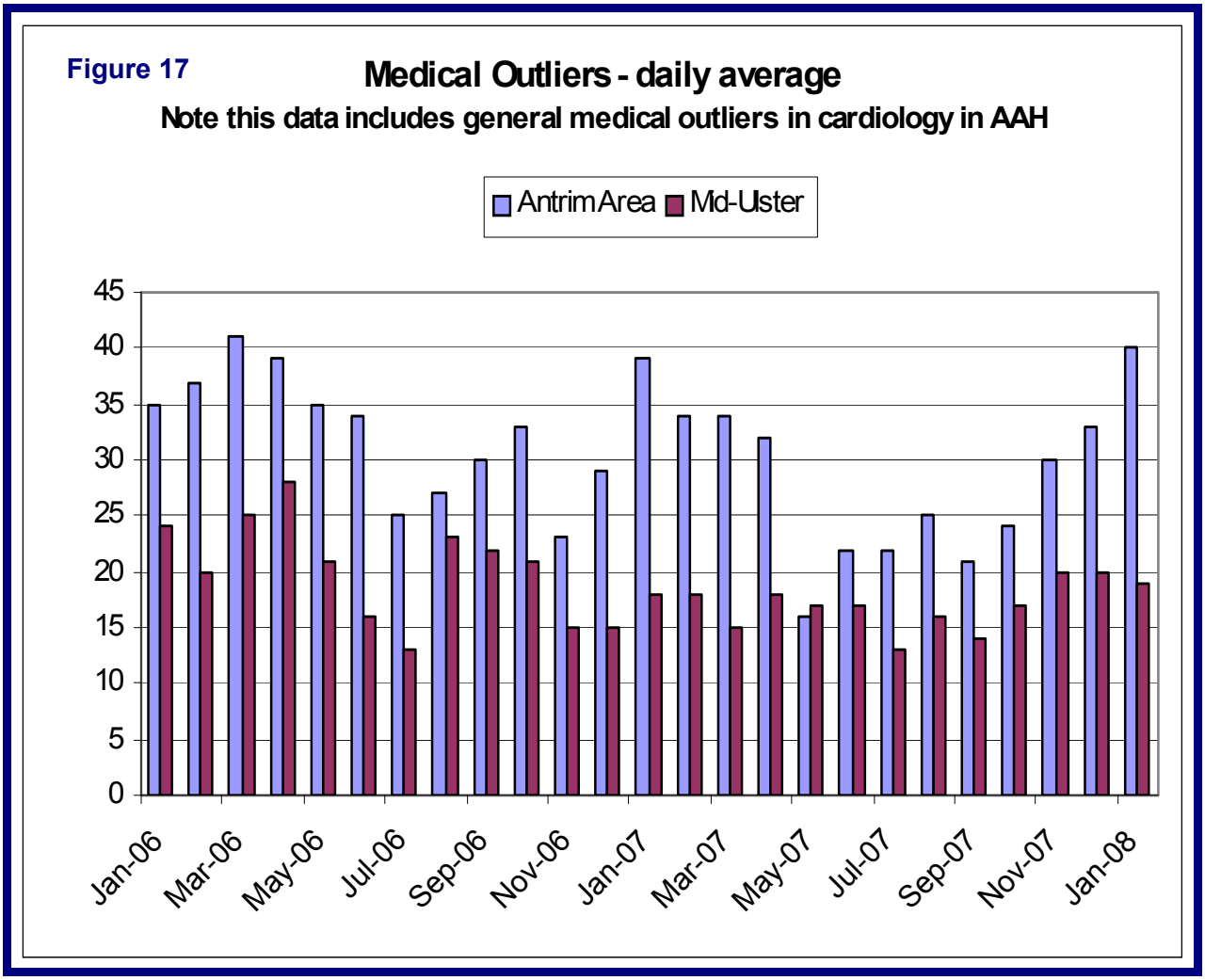
The number of beds in the former United Hospitals Trust fell from 840 in 2006 through a planned reduction to 762 at 1st March 2007. The distribution of beds by hospital was then:

Antrim Hospital	411
Braid Valley Hospital	36
Moyle Hospital	45
Mid-Ulster Hospital	124
Whiteabbey Hospital	130
Total at 1st March 2007	762

One measure of the pressure on beds in an acute hospital is the number of patients in medical specialties who cannot be accommodated in medical wards. These patients are known as outliers and are subject to greater numbers of internal hospital transfers.

Figure 17 illustrates the trends in the number of medical outliers in Antrim and Mid-Ulster Hospitals from January 2006 to January 2008. It illustrates that there was a rising trend in Antrim Hospital over the initial period of the outbreak. The number of medical outliers, as a proportion of overall beds, was very significant at Mid-Ulster Hospital over this two year period. An internal reorganisation of medical wards in spring 2008 at Antrim Hospital resulted in a reduction in the number of medical outliers.

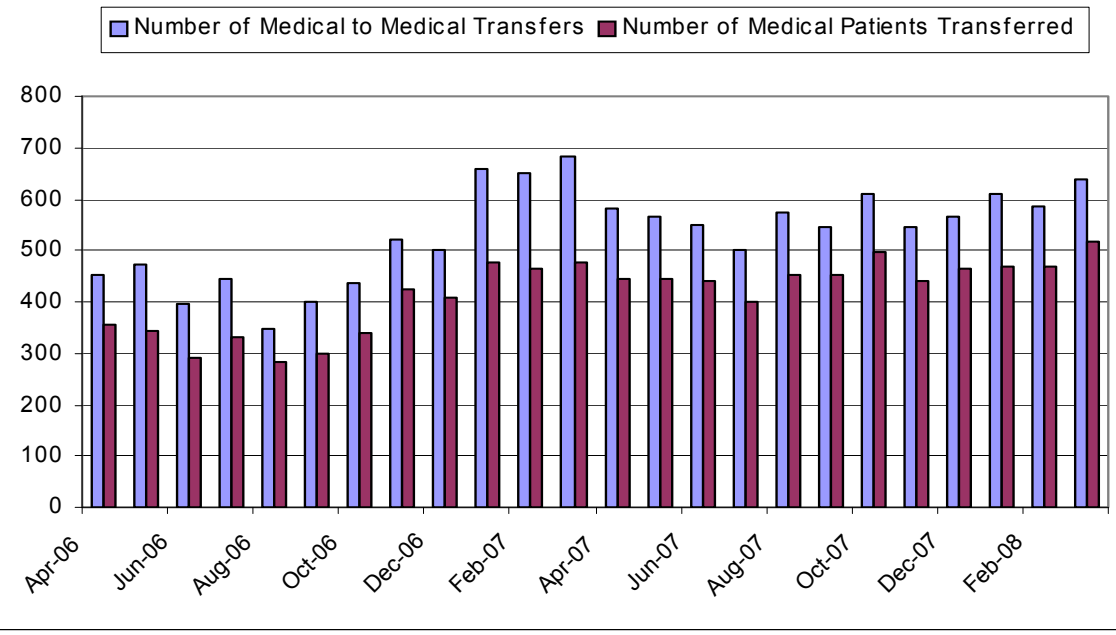
Figure 17



Source: Northern Trust

Transfers of patients between wards of different departments within a hospital can clearly be a risk factor for the transfer of *C. difficile* with the potential of contamination of a wider number of areas with spores. Figure 18 illustrates the number of medical patients transferred internally between wards from April 2006. The number was significant over this period.

Figure 18 **Medical Patients Internal Transfers Antrim Area Hospital**



Source: Northern Trust

In November 2006, the former United Hospitals Trust introduced an escalation policy that sanctioned an extra bed in each ward, when there were ten or more patients waiting in A&E for three hours. This was described as RED1 status. The circulation space in the bay, where the bed was located, was therefore reduced and it created additional pressures for nursing and cleaning staff. Between 2006 and 2007, the hospital was on RED1 status almost weekly due to pressures in the emergency care system.

A decision to close beds had a further direct effect on the potential resilience measures in place at Antrim Hospital in the event that there was a major outbreak.

In August 2005, a programme of refurbishment of wards was commenced after the IPC Lead expressed concern about hospital cleanliness. Wards were decanted into a newly built ward during the programme while each particular ward was being refurbished. The ward was a purpose built ward for isolation, which had been funded when Antrim was designated as a specific regional receiving hospital for SARS patients.

The refurbishment programme was stopped in 2007, when there was a decision to close a ward in a care of the elderly facility and move the patients into the decant ward. As a result, seven of the hospital wards were not refurbished.

A consequent effect was that a purpose build ward for isolation was not immediately available when the Trust IPC Lead asked for it to be used in December 2007, to help manage the *C. difficile* outbreak. It was allocated for that purpose in January 2008 following a decision of the OCT.

The Independent Review Team found that bed pressures were a likely contributing factor to the spread of the outbreak because they:

- **led to increased movement of patients within and between hospitals;**
- **created increased pressures for cleaning staff;**
- **led to difficulties in ensuring isolation beds were always available when required;**
- **contributed to a delay in opening a designated isolation ward for the *C. difficile* outbreak in a new purpose built facility at Antrim Hospital.**

e. Staffing levels in hospitals in the Trust

Nursing

Between June and August 2006, the Northern Board undertook a review of nurse staffing levels across the former United Hospitals Trust, focusing on Antrim, Whiteabbey, Mid-Ulster and Braid Valley Hospitals. The work was undertaken with the co-operation of Trust staff and focused on establishing a minimum safe staffing level for each ward or department. The review recommended funding of an additional 69.55 wte qualified staff and 25.24 wte unqualified staff. The total funding required was £2,275,000.

The review of nursing recognised that there was on ongoing programme of reform and that resulting closure of wards would enable funding to be released to part fund the posts required, provided it was not withdrawn as savings. The Northern Board allocated £400,000 recurrently from 1st April 2007 to address some of the issues identified in the review.

During the period of the outbreak, there continued to be a recognised need for additional nurses. The Northern Board allocated £500,000 non recurrently to assist the Northern Trust and the Northern Trust took a decision in May 2008 to approve £1.9 million recurrent funding for nurse staffing.

A benchmarking exercise was carried out in 2006 on the levels of cleaning hours per bed in different hospitals in Northern Ireland (Figure 19).

Figure 19

Number of Cleaning Staff Hours by Hospital 2006

Hospital	Beds per Ward	Daily Cleaning Hours per ward	Weekly cleaning Hours per bed
Antrim	**27**	**7.14**	**1.66**
City	**30**	**9.42**	**2.20**
Ulster	**20**	**8.21**	**2.87**
Causeway	**27**	**8.35**	**2.16**
Whiteabbey	**25**	**10.17**	**2.85**
Mid-Ulster	**24**	**8.00**	**2.33**

This revealed that domestic cleaning hours per bed in Antrim Hospital were substantially less than other hospitals, both inside the Trust, and other large acute hospitals in Northern Ireland. There had been a limited increase in cleaning staffing since Antrim Hospital opened in 1994 in spite of increased demands on the service. At the start of the outbreak, this situation was still in

place. During the outbreak additional funding was provided for cleaning services.

The Independent Review Team found that the levels of nurse staffing across the hospitals in the southern sector of the Trust and the low levels of cleaning staff at Antrim hospital in the early phases of the outbreak, are likely to have contributed to difficulties in maintaining good infection control standards at ward level and thus to the spread of the outbreak.

f. Antibiotic prescribing

The prudent management of antibiotics is a key factor in the prevention of spread of *C. difficile.* Most patients who develop CDI have received antibiotics.

The former United Hospital Trust placed a significant emphasis on the control of antibiotics over a long period. Guidance was developed in 1997 and revised and updated in 1999, 2000, 2003, 2005 and 2007. Guidance on the use of Antimicrobials in Primary Care was produced in 2003 and reviewed in 2007 and 2008.

Cephalosporins were withdrawn from the medical wards in all hospitals following an outbreak of *C. difficile* in 1999 and fluroquinolones were removed from the hospital formulary in January 2007.

In 2006, an audit of antibiotic use revealed a level of non-compliance with Trust Guidelines. In response, clinical staff were reminded about the availability of the guidelines on the Trust intranet. The Trust's Infectious Disease Pharmacist placed a hard copy on all wards and a desktop icon was placed on all ward computers to encourage access.

In discussion with Trust staff the Independent Review Team were advised that there were recognised barriers in the Trust to ensuring compliance with antibiotic guidance. These included regular changes in junior medical staff

and competing pressures for pharmacy and clinician time. The antibiotic guidelines were detailed and there was a recognised need to have a more concise version.

Audits carried out after the outbreak was declared did reveal a degree of inappropriate or unnecessary prescribing. The Independent Review Team did not find evidence of systematic processes in place for the surveillance of antibiotic prescribing at ward level before the outbreak was declared.

The Trust has been compiling a detailed database on patients affected in the outbreak including details of antibiotic use. This database will be a valuable resource to facilitate future research to potentially gain more understanding as to whether there was a relationship between particular antibiotics and the spread of Ribotype 027 in this outbreak.

The Independent Review Team found that the use of antibiotics is likely to have contributed to the spread of the outbreak given that audit results from 2006, and after the declaration of the outbreak, showed a level of non compliance with policies at patient level.

The Independent Review team consider that there was a lack of robust systems in place to monitor the implementation of the antibiotic policies and adherence to guidelines. There was also a lack of systems for routine surveillance of trends in antibiotic consumption.

10.3 Second Term Of Reference

To review the Trust's management and clinical response to its C. difficile rates and outbreak, including actions to inform patients, their relatives and the public.

10.3.1 Management and Clinical Response to *C. difficile* rates and the Trust outbreak

Evidence from successful control of outbreaks of *C. difficile* Ribotype 027 in other parts of the United Kingdom, indicates that it has been achieved through rigorous implementation of a Care Bundle of five key measures:

- Prudent antibiotic prescribing;
- Isolation of infected patients;
- Enhanced environmental cleaning;
- Hand hygiene;
- Personal Protective Equipment.

A sixth measure, Staff Education and Training, is a fundamental component of implementing the care bundle.

By implication, a rise in *C. difficile* Ribotype 027 within a hospital indicates that the control arrangements for *C. difficile* in relation to these measures, are not sufficiently robust to control this virulent strain.

The Independent Review Team has considered available evidence in relation to the implementation of the five key measures in the Northern Trust area prior to and following the declaration of the outbreak.

Prudent antibiotic prescribing

As indicated above, the Independent Review Team consider that antibiotic usage was a likely contributor to the spread of the outbreak. In October 2007, a Trust plan following the identification of Ribotype 027 focused strongly on improving antibiotic prescribing. Following the declaration of the outbreak there was a significant focus on improving antibiotic prescribing. Guidelines were amended and action was taken to disseminate user friendly versions.

A programme of audits was commenced and these did demonstrate a lack of compliance with guidelines. Subsequent audits did show improvements.

Junior doctors advised the Independent Review Team that they were aware of the guidance and found it easy to use. A policy to ensure consultant review of antibiotic prescribing was instituted during the outbreak. Regular audits of prescribing continue to take place.

The Independent Review Team found that action was taken during the outbreak to improve antibiotic prescribing but consider that this needs strong ongoing focus to ensure full compliance.

Isolation of Infected Patients

Early isolation of patients infected with *C. difficile* is essential to reduce the risk of spread of infection through contamination of the ward environment with spores.

Before the outbreak was declared, the Northern Trust did initiate an audit of isolation arrangements following the first meeting of the new Trust Infection Prevention and Control and Environmental Hygiene Committee on 31st July 2007 but there was a poor response from wards. There were no reports of failure to isolate *C. difficile* patients in the returns submitted.

During the period, before the outbreak was declared for Antrim Hospital on 7th January 2008, localised outbreaks were managed through establishing cohort bays or isolating patients in single rooms.

Antrim Hospital had previously been designated as a receiving hospital as part of a regional escalation plan for SARS. A purpose designed isolation ward was provided at Antrim but this had been used to transfer a rehabilitation ward from another hospital. The Trust IPC Lead advocated for this facility to be used as a cohort ward for patients with *C. difficile* in December 2007. When the OCT was formed, a decision was taken to establish a dedicated ward and this was promptly implemented. The ward opened as an isolation ward for *C. difficile* cases on 18th January 2008.

The Independent Review Team found that the decision to open an isolation ward at Antrim Hospital was a key measure in order to bring the outbreak under control. If this had been activated sooner, it could have contributed to the reduction in the overall spore load around the Trust and potentially facilitated more rapid outbreak containment.

Enhanced Environmental Cleaning

The Northern Trust inherited the former United Hospitals Trust's plan to implement the regional strategy *"Cleanliness Matters*" when it was formed in April 2007. As indicated above, levels of cleaning hours per bed were lower in Antrim Hospital than in other hospitals during the period leading up to the outbreak.

External audits of environmental hygiene were carried out by KPMG during December 2007 and January 2008. The results are shown in Figure 20.

Figure 20

KPMG Audit Compliance Scores on Environmental Hygiene

Hospital	2006/2007 Score	2007/2008 Score
Causeway	80%	90%
Antrim	77%	89%
Mid-Ulster	74%	86%
Whiteabbey	61%	87%

All hospitals improved their scores following the first audit, particularly at Whiteabbey Hospital.

Internal *"Cleanliness Matters"* audits for all hospitals achieved targeted 85% compliance in the period after the formation of the new Trust.

Following the declaration of the outbreak, significant enhancements were put in place to cleaning regimes including the introduction of an intensive cleaning programme and the use of VHP machines. Tristel was introduced for daily cleaning and terminal cleaning in December 2007. There were delays in putting in place Rapid Response Teams at hospitals due to difficulties in recruiting staff.

The Independent Review Team found that the cleaning arrangements in place during the period from June 2007 to the declaration of an outbreak on 7th January 2008 were not significantly robust to manage an outbreak of *C. difficile* Ribotype 027 and this may have contributed to the spread of the organism before the outbreak was declared.

Following the declaration of the outbreak there was a major focus on enhancing cleaning arrangements and new measures were put in place. Some of these required staffing enhancements which did take time to be implemented.

Hand Hygiene

The DHSSPS policy *"Changing the Culture"* requires all Trusts to use the WHO Guidance on Hand Hygiene in Health Care. This was used to inform the development of the First Annual Healthcare Associated Infection Reduction Plan for the Northern Trust for 2007-2008. Audits by the Trust IPC Team in 2006-2007 had identified areas for improvement. Hand hygiene was actively promoted by Infection Prevention and Control Staff.

Hand hygiene was a core part of the Safer Patient Initiative in the Causeway Hospital. Ward based observational audits were introduced in 2007 and continue throughout the hospital. This system was not in place in the hospitals in the southern part of the Trust before the outbreak was declared.

After the declaration of the outbreak the focus on hand hygiene increased in the southern sector hospitals. Hand wipes were subsequently introduced for patients. Arrangements are being put in place for more extensive audits of hand washing with results displayed at ward level.

The Independent Review Team were informed by patients that they had observed good hand hygiene practice by nurses and by visitors to the hospital but that doctors were not always observed to wash their hands. Patients felt that this was an important area for doctors to show leadership.

Junior doctors told the Review team that they took the issue of hand washing very seriously. At times they do wash their hands out of sight of patients and patients may not realise that this has taken place.

The Independent Review Team found that there is insufficient evidence to assess the potential contribution of deficits in hand hygiene at ward level to the spread of the outbreak.

Personal Protective Equipment (PPE)

Training in use of PPE forms part of infection control training in the Trust. No issues were raised with the Review Team about the availability of PPE in any of the hospitals in the Trust.

Patients did raise some concerns from their observations in relation to the use of PPE.

The Independent Review Team found that there was limited evidence available as to how PPE is being used in the Trust and that this should be subject to future audit.

Staff Education and Training

The DHSSPS Action Plan *"Changing the Culture*" set a regional target of 95% of all new staff to receive mandatory IPC training by 1st April 2007. By

1st April 2008, this was to be in place for all existing staff. On formation of the Northern Trust, it was recognised that the training had not been consistent between the former Trusts and that it was necessary to identify the content and coverage of existing training. Corporate Induction training was standardised across the Trust. A Regional E-learning package was developed.

A group was established in August 2007 to review the training needs of the Trust. By December 2007, it had been ascertained, through a questionnaire survey of departments, that an estimated 8,000 staff across the Trust required training. The Infection Control Department had provided training to 2,700 staff over the previous year. Further training was being put in place to cover Standard Precautions, Transmission Based Precautions and various important micro-organisms.

On 9th April 2008, the Training Needs Analysis Group were advised that, in 2007-2008, 48% of staff had been trained while 89% had been trained from 2006-2008. Face to face training had been the main method used.

The Independent Review Team has found that there was a recognised need within the Trust to enhance education and training on infection prevention and control. A training needs analysis was carried out and a training plan developed but this was still being implemented during 2008.

Clinical Management of Patients

Before the outbreak was declared at Antrim Hospital, patients with *C. difficile* were managed by clinicians in wards throughout the hospital. After the opening of the isolation ward, patients were brought together into a single location and were looked after by a team of geriatricians.

The Independent Review Team have not carried out a specific analysis of the quality of care for patients, but consider that the decision to open an isolation ward would have facilitated the development of specialist expertise in

managing patients. From that time a single team, took overall clinical supervision of affected patients which ensured a consistent approach. Vancomycin became the first line treatment for affected patients during this period.

The Northern Trust's OCT established a Review Sub-Group to consider lessons to be learned from the outbreak. This group has initiated a review of all deaths in 2007 among patients who were diagnosed with *C. difficile* in the hospitals of the former United Hospitals Trust. The aim of the review was to determine the accuracy of the certification of death in relation to *C. difficile.* This review involved the examination of 80 charts of patients by two clinicians, including a retired gastroenterologist from another Trust.

A member of the RQIA Independent Review Team has discussed the review of charts with the external reviewer. Although the purpose of that review was not to assess the quality of care, the external reviewer's observations was that the clinical management of patients, documented in the charts he had reviewed, was appropriate. The external reviewer commented that he felt that surgery would not have been appropriate for any of the patients whose chart he had reviewed.

The Independent Review Team found that the decision to open an isolation ward was beneficial from a clinical management perspective as it helped ensure a consistent management approach to patient care.

The Independent Review Team consider that it could have been helpful to the Trust to have had discussions with other units who had experience of surgical management of cases, in the event that this form of therapy had been required for particular patients. Other treatments for severe *C. difficile* have a very limited evidence base. Learning from units with experience of using additional agents might have been educational although the Independent Review Team saw no direct evidence that this would have affected outcomes for patients.

10.3.2 Actions to inform patients, their relatives and the public

When the outbreak was declared in January 2006, the OCT established a Strategic Communications Group. The OCT minutes record that significant attention was given to developing written advice in relation to *C. difficile* for patients. The Independent Review Team have been provided with copies in several languages.

The Independent Review Team were informed by the patients they spoke to that they received little information about *C. difficile* or advice when they were discharged. In particular, they had not been advised that the condition may recur. At the RCA workshop with Trust staff to consider communications it was noted that the written material available was not always provided to patients and their relatives.

The Trust did issue factual press releases and provide trained spokespeople to local media for interview. In the week the outbreak was announced the Trust convened a media briefing to provide relevant factual background information to the outbreak. The approach taken after the OCT was established was to release monthly figures. At the start of the outbreak there was a lot of media coverage and elements of confusion with other issues such as MRSA.

During the RCA workshop with Trust staff, it was noted that there were difficulties in keeping all relevant staff informed although the Independent Review Team noted that the Chief Executive included relevant information about the outbreak in her personal monthly letters to staff. As the outbreak continued it was noted that the adverse media coverage had a significant impact on the morale of staff in the hospitals affected by the outbreak.

The Independent Review Team found that the Trust did adopt a strategic approach to handling communications during the outbreak and did prepare relevant material for patients and relatives. They did strive to provide accurate information to the public through the media when the outbreak was declared at Antrim Hospital. Robust systems

were not in place to monitor the distribution of information to patients and staff.

10.4 Third Term Of Reference

To review the Trust's arrangements to identify and notify cases, outbreaks and deaths associated with C. difficile infection

10.4.1 How effective were surveillance arrangements for *C. difficile?*

Effective control of infectious diseases crucially depends on having good surveillance systems in place for early recognition of emerging problems and reporting arrangements to ensure that relevant people and organisations are informed.

The Independent Review Team found that, at regional level, there was an established mandatory system in place for the reporting of cases of *C. difficile* from the hospitals across Northern Ireland through the CDSC (NI) since 2005. The Northern Trust fully participated in that system. At the time when the outbreak was declared, quarterly surveillance reports were not available for circulation until three months after the quarter to which the data referred. A rise in cases in August and September in the Northern Trust would not therefore be reflected in the surveillance reports until January 2008.

Staff at the CDSC (NI) do review the trends in weekly reports from laboratories and on two occasions, in August 2007 and November 2007, the Consultant Regional Epidemiologist did contact the medical microbiology department at the Trust when rises in *C. difficile* had been noted.

The Review Team has been provided with data from the Trust which indicates that there has been local surveillance of cases of *C. difficile* for hospitals in the former United Hospitals Trust going back at least 10 years. A previous outbreak had been investigated in 1999 with ribotyping carried out. A rise in identified cases in 2003 was considered to have a relationship with a change to a more sensitive testing kit.

There was clinical recognition of a change in the severity of symptoms of some patients in the summer of 2007 and the medical microbiologist requested ribotyping. This led to the identification that there were cases of Ribotype 027.

The Northern Trust submitted an SAI Report to the DHSSPS in October 2007 about the emergence of *C. difficile* Ribotype 027. It was noted on the SAI Report that the Northern Board and Consultant Regional Epidemiologist had also been informed. The SAI Report recommended that all trusts needed to be vigilant for the emergence of Ribotype 027. Outbreaks of *C. difficile* in specific wards in Antrim and Whiteabbey hospitals were not reported to the DHSSPS using the SAI reporting system. The DHSSPS had set out the requirement for outbreaks of *C.difficile* to be reported using this system in circular HSS(MD)9/2007 issued in April 2007. A specific warning about the emergence of *C. difficile* Ribotype 027 in Northern Ireland was not issued until January 2008.

The Trust's IPC Lead met with the local CCDC from the Northern Board to describe the actions which were being put in place for containment. The Trust's Senior Management Team were also informed.

During the period before the outbreak was formally declared, there is evidence that local clusters of *C. difficile* cases were recognised early and control measures initiated.

With hindsight, it can be identified that the number of cases was rising from August 2007 and this trend was well established by October 2007. It was not, however, until 7th January 2008 that an outbreak was declared. The outbreak was initially declared for Antrim Hospital.

The Independent Review Team found that there was a significant delay in recognition that there was an outbreak of *C. difficile* affecting the system of hospitals in the southern sector of the Trust. Possible contributing factors to this delay included:

- **A lack of analytical support to carry out epidemiological analysis of available data on trends in *C. difficile* in the Trust and to present it in a user friendly way. For example, comprehensive data on trends in cases by ward were presented to the Trust Board in December 2007 but, without a graphical analysis. This made the data very difficult to interpret.**

- **delays in receiving ribotype information so that it was of limited use in tracking possible linked cases. The Trust approach to only ribotyping selective cases was in keeping with widespread practice and the Trust is to be commended on initiating a full ribotype analysis from December 2007.**

- **in 2007, quarterly surveillance reports on *C. difficile* from the CDSC(NI) were not available until three months after the quarter to which they referred, There is limited evidence that these reports were being used to support local surveillance.**

- **surveillance of *C. difficile* focused on total numbers of cases rather than outbreaks of specific ribotypes. This reflects the lack of ribotype analysis availability and that the control measures are the same, regardless of ribotype. This approach masks the early identification and assessment of spread of a new strain unless it is recognised, as in this case, through recognition of more severe clinical symptoms.**

- **pressure on the IPC Lead and the Infection Control Team who had limited time to stand back and assess the overall emerging picture, as they tackled local incidents and focused on training, audits and implementing new systems.**

10.4.2 How appropriate were the Trust arrangements for notifying deaths of patients associated with *C. difficile* during the outbreak?

In keeping with the Third Term of Reference, the Independent Review Team met with Trust staff to consider the approaches being taken to determine the number of deaths certified as linked to *C. difficile* during the course outbreak and the accuracy of this certification. The Terms of Reference for the Independent Review did not specifically include an analysis to determine the number of deaths which can be attributable to the outbreak. However the Independent Review Team examined the Trust's analysis of the number of deaths.

The Northern Trust OCT established two specific sub-groups who have been carrying out analyses in relation to mortality and the outbreak.

The Epidemiology Sub-group has collected and analysed information on the certified deaths among patients affected. The Review Sub-group has carried out a review of all deaths among patients who had a diagnosis of *C. difficile* in 2007, to determine the accuracy of the information recorded on the death certificates.

Many patients who develop CDI have other serious underlying illnesses at the time of admission to hospital. It can be very difficult for the clinicians involved in their care to determine the extent to which infection with *C. difficile* contributed to their death.

Epidemiology Sub-Group analysis of deaths during the outbreak

The Epidemiology Sub-group liaised with the Office of the Registrar General to collect information on the number of deaths which occurred during the outbreak.

Between 16th June 2007 and 30th June 2008, 297 patients had a positive *C. difficile* toxin test who were inpatients in the hospitals of the former United Hospitals Trust when the sample was taken.

At the time of writing this report, the Epidemiology Sub-group had ascertained the position until 30th June 2008. At that time, of the 297 patients, 96 (32%) died from all causes when in hospital during the admission, 11 (4%) were transferred to another hospital, 172 (58%) had been discharged home or to another non-hospital setting and 18 (6%) had not been discharged home and remained in hospital.

Based on information provided by the Registrar General on data held up to 31st May 2008, the Epidemiology Sub-Group were advised that *C. difficile* was mentioned on the death certificate of 41 patients out of the 297. Of these, it was included on Part 1 of nine death certificates as an underlying cause of death. It was included on Part 2 of 32 death certificates as a contributing factor to death, but not the underlying cause.

The Epidemiology Sub-Group continues to carry out further analyses in relation to the mortality of patients during the outbreak. In particular, a review is underway to determine the pattern of mortality among patients who were discharged from hospital.

Review Sub-group analysis of deaths in 2007

The Review Sub-group have carried out an analysis of the deaths in hospital among all patients who had a positive toxin test for *C. difficile* at Antrim Hospital laboratory between 1st January 2007 and 31st December 2007. The purpose of this review was to provide assurance to the OCT that death certificates were accurately completed in respect of patients with *C. difficile* and to reconcile differences in the figures reported.

Two senior clinicians, including a retired gastroenterologist from another Trust, independently reviewed case notes from patients who were known to have died by mid-February 2008. Each clinician was asked to extract information from the case notes and make an assessment on the level of contribution of *C. difficile* infection to the death of that person. This was carried out using a matrix approach developed by the Healthcare Commission. The results were

compared with the certified cause of death on the death certification certificates.

Members of the Independent Review Team have met with members of the Trust Review Sub-Group to discuss the methodology being used for this process of review and they consider it was appropriate and robust.

The review has not yet been completed but relevant information was shared with the RQIA Independent Review Team.

Antrim Hospital laboratory notified 268 positive toxin tests of *C. difficile* in 2007. Of these, 100 people were recorded as deceased on the Hospital Patient Administration System by mid-February 2008. Of these, 84 patients had died in hospitals in the former United Hospitals Trust group. Notes were retrieved for 80 of these patients. Notes on the other four patients remained missing despite extensive searching.

At the time of writing this report, the Independent Review Team was advised that the external and internal reviewers have jointly agreed on the contribution of *C. difficile* on 70 sets of notes and work is continuing on the further 10. Where joint review has not been completed, the external reviewers score was accepted. The results are shown in Figure 21.

Figure 21
Provisional results of an analysis of death certificates for the former United Hospitals Trust of patients who had a positive *C. difficile* toxin test in 2007.

	Death Certificate	Review
Disease leading to death	12	10
Other conditions contributing to death	19	5

Source: Northern Trust

The results to date indicate that the number of times in which *C. difficile* was recorded as an underlying cause of death in 2007 on the death certificate, was similar to that found during the review of notes. However, the review of notes reported that the number of times in which *C. difficile* was considered to be another condition contributing to death, but not the direct cause, was substantially less than was recorded on the death certificates.

The Independent Review Team found that the approaches being taken to analyse the number of deaths linked to the outbreak were appropriate. The Trust should be commended for establishing a formal review mechanism of the deaths which took place in 2007. The Independent Review Team recommend that the Epidemiology and Review Sub-Groups continue to carry out the analysis of deaths which is underway to enable a determination of the overall impact of the outbreak on mortality when it has been formally declared as under control.

10.5 Fourth Term Of Reference

To review the Trust's governance arrangements and the priority given to the prevention and control of infection.

The lines of accountability for control of infection for hospitals in Northern Ireland are clearly set out in Circular HSS (MD) 9/2006 which accompanied the distribution of the *"Changing the Culture"* Action Plan. The final accountability for infection prevention and control lies with Trust Chief Executives and Trusts are required to appoint a designated Trust IPC Lead and produce a Trust Infection Reduction Plan. Trust Chief Executives have a Duty of Quality under legislation and are required to report to the DHSSPS on compliance on infection control in relation to Controls Assurance Standards.

In June 2007, three months after it was established, the Northern Trust was the only HSC Trust in Northern Ireland to report at a regional meeting that it had identified a Lead for Infection Prevention and Control. The lead was a medical microbiologist who had previously been the lead for the former United Hospitals Trust.

In July 2007, the Trust established a new Infection Prevention and Control and Environmental Cleanliness Committee and a draft Trust Infection Reduction Plan had been developed. In August 2007 an Infection Prevention Control Accountability Structure was agreed for the Trust. In October 2007, The Trust IPC Lead gave a presentation to the public Board meeting on Infection Control issues.

There is therefore evidence that the Northern Trust did prioritise the establishment of governance processes for infection control in the period after it was established in April 2007. Governance arrangements were put in place in keeping with regional guidance.

The Trust did report, in October 2007, the emergence of Ribotype 027 and the declaration of an outbreak, in January 2008 to the DHSSPS using the formal SAI reporting system. From the Trust documentation provided, there is evidence that the Senior Management Team (SMT) were informed of infection control issues and the Board was informed in December 2007 about a rise in the number of deaths and subsequently was kept updated after the outbreak was declared.

In October 2007, the SMT were made aware of the identification of the Ribotype 027 strain and that there had been a rising number of patients with *C. difficile.* The Chief Executive advised the Independent Review Team that it was anticipated that the control measures being put in place at that time would resolve the problem, as had happened on previous occasions. In November 2007, the number of cases fell.

The SMT and the Trust Board were informed about a rise in the numbers of cases and deaths in December 2007. A *C. difficile* team was established and further control measures considered.

In early January 2008 the Trust Chief Executive was informed about the rise in figures at Antrim Hospital. She decided to establish an Outbreak Control Team (OCT) which she chaired.

During the early stages of the declared outbreak, the OCT were required to manage a wide range of issues. Following advice from the Consultant Regional Epidemiologist, subgroups were established for specific functions. The Independent Review Team was advised, in discussions with Trust staff, that the personal leadership of the Chief Executive of the OCT did facilitate speedier decision making.

During the period after the outbreak was declared the issue was at the top of the Trust's agenda. The Chairman and Chief Executive of the Trust has advised the Independent Review Team that the Trust has adopted a zero tolerance approach to Hospital acquired infection.

The Independent Review Team found that the Northern Trust established lines of accountability for infection control in keeping with regional policy. Issues relating to infection control were reported to appropriate levels of the organisation and, when the outbreak was declared, structures were put in place for control.

The Independent Review Team considers that decisions before the outbreak declaration were affected by a lack of awareness of the potential consequences of the emergence of a virulent strain of *C. difficile*.

The Independent Review Team consider that there were not robust processes in place to give the SMT and Trust Board assurance that policies were being implemented at patient care level in the period before the outbreak was declared and in the initial stages of outbreak management,

10.6 Fifth Term Of Reference

To review the actions of the Northern Health and Social Services Board and the DHSSPS in relation to the management of the outbreak in the

Northern Trust, and the actions by all Trusts, Boards and DHSSPS to reduce C. difficile rates in Trusts

Northern Heath and Social Services Board

The Independent Review Team received written evidence from the Northern Health and Social Services Board and met senior Board officers to discuss the role of the Board in relation to the outbreak.

The evidence submitted by the Northern Board demonstrated that the Board had responded positively to the publication of the *"Changing the Culture"* regional action plan in 2006. A Board wide HCAI Committee was established to oversee the implementation of the Action Plan. It included representatives of the three Trusts which later came together to form the Northern Trust. This group established sub-groups to consider actions in relation to primary care and residential care.

The Board's CCDC was informed of the emergence of *C. difficile* in October 2007 and met with the Trust IPC Lead to discuss the action being taken.

Just prior to the declaration of the outbreak, the Board Primary Care Adviser issued guidance to GPs on *C. difficile* following the December meeting of the Trust Board.

When the outbreak was declared in January 2008, the CCDC was invited by the Trust to join the Outbreak Control Team and subsequently went on to chair the Epidemiology Sub-group.

The Board's CCDC convened outbreak control meetings to manage two outbreaks of *C. difficile* in residential accommodation during the period after the outbreak was declared.

The Director of Public Health at the Board wrote to the Chief Executive of the Trust on 21st January 2008 to offer support. A Board SHO in Public Health

assisted in maintaining the epidemiological database which subsequently enabled the members of the OCT to have daily reports on cases.

The Northern Board provided £500,000 of additional non-recurrent funding during the outbreak to assist the Trust in managing it.

The Independent Review Team found that the Northern Board did provide practical and financial support to the Trust during the outbreak. The Board's CCDC played a significant role as a member of the OCT and in chairing the Epidemiological Sub-group.

The Independent Review Team does consider that it would be useful to formalise the arrangements for the involvement of public health staff in relation to hospital outbreaks in Northern Ireland. At present this appears to be dependent on an invitation to become involved, which did happen in this case.

DHSSPS

The Independent Review team were provided with written evidence on the role of the DHSSPS and met with Officers from the DHSSPS to discuss regional policy development in relation to HCAIs and the role of its officers in relation to the outbreak.

There has been a significant regional focus on the development of regional policies and strategies over the past decade as set out in the timeline earlier in this report. Polices were in place prior to the outbreak on prevention and control of HCAIs, cleanliness, antibiotic prescribing and isolation.

Regional groups were meeting to oversee the implementation of key policies such as *"Changing the Culture".* The implementation of this policy will be reviewed during Phase 2 of the RQIA Independent Review.

The DHSSPS did issue guidance on *C. difficile* in April 2007 to HSC organisations and, in September 2007, the Minister announced a specific 20% reduction target for *C. difficile.*

The Independent Review Team found that the Northern Trust submitted an SAI Report to the DHSSPS in October 2007 about the emergence of *C. difficile* Ribotype 027. It was noted on the SAI Report that the Northern Board and Consultant Regional Epidemiologist had also been informed. The SAI Report recommended that all trusts needed to be vigilant for the emergence of Ribotype 027. Outbreaks of *C. difficile* in specific wards in Antrim and Whiteabbey hospitals were not reported to the DHSSPS using the SAI reporting system. The DHSSPS had set out the requirement for outbreaks of *C.difficile* to be reported using this system in circular HSS(MD)9/2007 issued in April 2007. A specific warning about the emergence of *C. difficile* Ribotype 027 in Northern Ireland was not issued until January 2008.

When the outbreak was declared the DHSSPS was promptly informed. Actions taken included:

- issuing specific and general guidance to HSC organisations on issues relating to the management of *C. difficile*;
- facilitating practical support to the Northern Trust such as the secondment of a Specialist Registrar in microbiology and the loan of VHP machines for cleaning;
- responding to media requests for interviews;
- enabling the Trust, through the Service Delivery Unit, to access the specialist help of the Cleaner Hospitals Team in England;
- arranging for information on death certification of *C. difficile* to be analysed and giving advice to doctors on how to complete certificates appropriately;
- agreeing that the CDSC (NI) should make quarterly surveillance reports publicly available and that these should be published more rapidly.

The Independent Review Team have noted that the Chief Medical Officer took personal leadership of the response by the Department including responding to the media.

The Independent Review Team found that the issue of HCAIs was a high priority on the DHSSPS agenda before the outbreak. DHSSPS officers became actively involved in providing advice to the Health and Social Care System, and practical support to the Northern Trust when the outbreak was declared.

The Independent Review Team considers that the SAI reporting arrangements should be reviewed to ensure that there is clarity about the role this system in relation to serious infectious disease incidents

10.7 What measures were taken which reduced the potential impact of the Outbreak?

The spread of an outbreak is dependant on the balance between factors which facilitate spread and factors in place which inhibit spread. The Review Team has considered what factors were in place in the Northern Trust which may have contributed to reducing the spread of *C. difficile* Ribotype 027 when it was introduced:

- The Trust had a lower than Northern Ireland average level of *C. difficile* infection prior to the outbreak, reflecting the effectiveness of the containment measures then in place. The Trust now recognises that this baseline level could have been reduced through stricter adherence to guidelines.

- A medical microbiologist did identify that the change in clinical picture of a patient in July 2007 was a possible indication of a different strain and forwarded a sample for ribotype analysis. If this had not been done, confirmation that Ribotype 027 had been introduced to Northern Ireland would have been delayed.

- The IPC Team introduced control measures to contain local outbreaks in Antrim and Whiteabbey Hospitals and these were effective in preventing immediate local spread.

- The Trust had a long history of action on antibiotic policy development and guidelines were widely disseminated.

- There was minimal disruption to the IPC Team arrangements when the new Trust was established and common policies had been previously introduced across the three legacy Trusts

- When the outbreak was recognised, the Trust Chief Executive took immediate personal responsibility as Chair of the OCT. This facilitated decision making such as the rapid deployment of Ward A1 in Antrim as an isolation ward.

- The Trust did seek external expert advice on the management of the outbreak when it was declared.

11. Recommendations

11.1 In May 2008, the Independent Review Team submitted an interim report to the Minister entitled:

"Protecting patients - reducing risks. The Organisation and Management Arrangements for the Prevention and Control of Clostridium difficile in Northern Ireland."

The report was produced following validation visits to each Health and Social Care Trust in Northern Ireland including the Northern Trust.

The report contains 36 recommendation and these are set out in Appendix A on page 147.

The Independent Review Team have reassessed these recommendations in the light of the findings of this part of the review process. The Independent Review Team consider that those recommendations remain valid and address many of the issues which emerged in this review of the circumstances contributing to the outbreak in the Northern Trust and the actions taken to bring it under control.

The Independent Review Team also recommend that the following additional actions should be taken

1. A formal risk assessment system should be established in Northern Ireland to review emerging threats in relation to specific infectious diseases. The proposed new Regional Agency for Public Health and Social Well-being (RAPHSW) could be set this task. The results of the risk assessment should be shared with all relevant Health and Social Care organisations.

2. Regional arrangements for providing public health advice, and outbreak support, to Trusts, in relation to HCAIs, should be reviewed and formalised in the light of the creation of the new RAPHSW. The new body will require sufficient numbers of skilled staff to provide the levels of support required.

3. Agreed arrangements for the surveillance and benchmarking of the antibiotic consumption in hospitals and primary care across Northern Ireland should be established. There should be robust audit of the quality of prescribing and improved education on prudent prescribing for doctors and pharmacists. These recommendations could be taken forward by the DHSSPS group which is being established to review the regional AMRAP strategy

4. A robust infection surveillance system, incorporating regular monitoring of virulent strains, should be put in place at a regional and Trust level

5. The regional SAI reporting system should be reviewed and further guidance issued to ensure that there is clarity about roles and responsibilities with this system in relation to infectious disease incidents.

6. There should be a review of undergraduate education and continued professional development requirements for all professional clinical staff in relation to the effective management of infection prevention and antimicrobial prescribing.

7. The Region should consider undertaking a baseline review of all HSC Trust cleaning arrangements against current standards and methodologies

8. The arrangements for providing assurance, across the Health and Social Care System in Northern Ireland, on the implementation of key regional polices and strategies in relation to infection control should be reviewed. There is also a need to ensure that there are robust systems in place to assess and monitor compliance at patient level to give assurance to Trust Boards and Senior Management Teams and that regional policies and strategies are being properly implemented.

9. All Trusts should ensure that there are effective arrangements in place to monitor the implementation of infection control and antibiotic stewardship policies at ward level.

10. All Trusts should ensure that there are effective arrangements in place to ensure proper surveillance of HCAIs within the Trust with regular user friendly reports

available to the Trust Board and Senior Management team. Information on trends in HCAIs should be appropriately distributed throughout the Trust.

11. Trust escalation plans should be developed in relation to the specific threat of introduction of a virulent strain of *C. difficile* and these plans should include trigger points for action. Such plans should be flexible enough to deal with any virulent HCAI that has the potential for person to person and environmental transmission.

12. Every patient with *C. difficile* should have the following factors assessed every day through a care bundle approach to gauge the performance of each ward against a standard of 100% compliance. Results should be displayed at ward level.

    - Patient was in appropriate isolation throughout the past 24 hours;
    - Patient had antibiotic therapy in relation to the agreed protocol or in line with an agreed process for clinical deviation from the protocol;
    - All staff in contact with the patient used appropriate hand hygiene;
    - All staff in contact with the patient used appropriate PPE;
    - The ward area was cleaned in keeping with agreed guidelines.

    The implementation of this Care Bundle approach could be usefully facilitated by the Health and Social Care Safety Forum.

13. Every new patient with CDI should have an assessment of the risk factors which may have contributed to their condition and the results of these assessments should be collated and reviewed on a regular basis.

14. Trusts should review their ward environments to ensure that there is no impediment to safer, cleaner, tidier patient areas.

15. Trusts should ensure timely and complete information is provided to patients during their admission and stay in hospital in a manner which meets their needs and those of their carers and families. The provision of this information should be formally reviewed as part of the discharge process to ensure the patient, their

carers and family fully understand the treatment received and the patient's ongoing care plan.

16. Trusts should establish a system whereby patients views on their experiences are used to shape the delivery of services and best meet their needs. This is particularly important in relation to infection control issues.

17. The Trust should put in place a comprehensive Communication Strategy to ensure that the whole workforce are fully briefed and understand their personal responsibilities in relation to quality and safety of patient care.

Appendix A

Clostridium difficile - RQIA Independent Review Report

May 2008

"Protecting patients - reducing risks. The Organisation and Management Arrangements for the Prevention and Control of Clostridium difficile in Northern Ireland."

Summary of Recommendations

1. Consideration of Healthcare Associated Infection (HCAI) should be a standard item on each Trust Board agenda.

2. Regular (preferably weekly) visits by Chairs and Chief Executives to clinical areas should continue to focus on infection prevention and control.

3. Each Trust should identify 'clinical champions' at Consultant level to take forward action on HCAIs and implement strategies to significantly reduce the current level of *Clostridium difficile*. 'Clinical champions' should be empowered to ensure that patient care pathways for Clostridium difficile are put in place and that arrangements are established for the multidisciplinary review of patients with *Clostridium difficile.*

4. Each Trust Board should receive reports on action taken to promote sound antibiotic stewardship across the Trust and on appropriate performance indicators.

5. Each Trust should have an agreed escalation plan to manage an outbreak of *Clostridium difficile* as part of its major incident procedures and this should address operational, logistical and resource issues.

6. Each Trust should review its single room capacity (with en suite facilities) for the prompt isolation of patients with symptoms of *Clostridium difficile*.

7. Regional guidance should be developed for effective communication about *Clostridium difficile* cases between hospitals, primary care practitioners and care homes. Systems should be established to ensure that information is available and guidance provided about treatment, including antibiotic prescribing, for patients who have a subsequent episode of *Clostridium difficile* and are admitted to a different facility.

8. Consultant involvement in the prevention of HCAIs should be considered during consultant appraisal and job plan reviews. Trusts are encouraged to consider building in specific time for these activities in job planning.

9. A regional risk assessment should be carried out to identify any areas of hospital estate that have a high degree of risk in relation to the spread of infection. Agreed risk reduction plans should be developed to address these risks.

10. Organisations with responsibility for undergraduate and postgraduate medical education should review arrangements to ensure that the next generation of doctors develops competent, safe prescribing habits. The education system should be designed to provide a long-term foundation for good antibiotic stewardship. Consideration should be given to include a number of foundation year posts for junior doctors that provide exposure to infection control, medical microbiology and antimicrobial therapeutics.

11. A review of training and development needs for infection control should be carried out across Northern Ireland.

12. A regional workforce plan and career structure for infection control should be developed and kept under review. The development of nurse consultant posts in infection control should be considered across the region.

13. Regional guidance should be developed on an agreed terminology for outbreak management and case severity in relation to *Clostridium difficile*.

14. All Trusts should reinforce guidance to clinical staff of the need to be aware of the clinical symptoms and signs associated with severe cases of *Clostridium difficile*.

Identification of a patient with a severe pattern of illness may be the first indication of a more virulent strain of the disease.

15. All Trusts should have surveillance arrangements for *Clostridium difficile* in place which include systems for daily reporting of cases, trigger points for escalation, and monthly reports to Executive Teams and Trust Boards for consideration of further action. Staff with appropriate skills and dedicated time should be available for surveillance functions.

16. The project to develop a regional infection prevention and control manual should be completed as soon as possible. This will require a robust implementation programme and publicity to ensure effective communication across disciplines at all levels.

17. A regional policy for Root Cause Analysis (RCA) should be developed in respect of *Clostridium difficile*. It is recommended that RCA is carried out in all cases where Clostridium difficile is included in Part 1 (a, b or c) of death certificates and in a sample of those cases where it is included in Part 2. RCA should also be carried out whenever a 'cluster' or 'outbreak' of *Clostridium difficile* is reported. RCA must include the whole clinical and allied professional team. A regional training programme should be established on RCA for infection control staff. A system for sharing lessons learned between and across Trusts needs to be established.

18. Each Trust should establish an audit framework for infection control that ensures completion of audit cycles for:

    - achievement of isolation within agreed timescales;
    - hand hygiene;
    - antibiotic guideline / policy compliance;
    - cleanliness;
    - mortality associated with Clostridium difficile;
    - death certification in relation to Clostridium difficile.

19. Trusts should consider reviewing their arrangements to ensure that the views of service users are informing infection control processes.

20. An agreed set of information should be determined which meets the needs of both regional and Trust surveillance of *Clostridium difficile* and for performance management, to avoid duplication of reporting.

21. A regional review should be carried out of IT systems to support surveillance arrangements for infection control in Trusts.

22. Each Trust should review its arrangements for 24 hours per day, 7 days per week on-call cover for infection control and these arrangements should be shared with other Trusts and with on-call public health staff.

23. A regional workforce review should be undertaken to identify solutions within and between Trusts in the short and medium term to address current shortfalls in clinical microbiology, biomedical staffing and recruitment to vacant posts.

24. Job planning for consultant microbiologists should build in time for specific functions including:
    - adequate provision for on-call and cross cover and;
    - multi-disciplinary ward rounds for *Clostridium difficile* cases;
    - antimicrobial ward rounds;
    - teaching and training of staff within the Trust;
    - clinical audit.

Where the Consultant Microbiologist is also the Trust's Lead for Infection Control, the job plan should take account of the time and support needed for this function.

Note: The Review Team recognises that this will not be achieved across Northern Ireland until there is an enhancement of relevant staffing levels.

25. IT arrangements for laboratories need to be reviewed to ensure that laboratory and infection control staff have better access to the information required to support their functions.

26. Consideration should be given to the establishment of a regional microbiology network which includes the possibility of formal cross-cover arrangements between Trusts.

27. Arrangements for Northern Ireland based assessment of ribotype strains of Clostridium difficile should be considered with specific consideration given to epidemiological investigations of 'unusual' strains.

28. The level of specialist analytical staffing at the regional CDSC for HCAIs should be reviewed in view of the increasing demands on this service.

29. A region wide antibiotic prescribing policy for hospitals and community services should be developed to include arrangements for restrictive reporting of sensitivities on microbiology specimens. Facilities should be available to allow specialist variation when required. The prescribing policy should outline the principles of prudent prescribing and the required standards expected of prescribers.

30. Each Trust should have at least one specialist antibiotic pharmacist with protected time to undertake antimicrobial stewardship duties.

31. Each Trust should review provision of pharmacy support to wards and develop plans to ensure that an appropriate service is available across the Trust.

32. Systems for the monitoring of antibiotic prescribing trends should be available across the region with monitoring reports considered at Department, Commissioner and Trust levels in relation to regionally set targets. A programme of regular audit of adherence to the antimicrobial prescribing policy and any prescribing restrictions and guidelines should be implemented, led by clinicians in each speciality.

33. Local Trust experiences of using creative aids to support prudent antibiotic prescribing should be shared. This could be facilitated by the establishment of a forum for antibiotic management teams across Northern Ireland.

34. Trusts should nominate an individual accountable to the Trust Board with the responsibility for improving and monitoring antimicrobial prescribing.

35. Trusts should ensure that antimicrobial treatment guidelines are easily accessible in the clinical practice environment and regularly reviewed to promote prescribing of low-risk and narrow-spectrum agents, taking local epidemiology and resistance information into consideration.

36. Region wide implementation of e-learning should be used to effect the standardisation of post-graduate training in the principles of prudent and competent antibiotic prescribing for doctors and pharmacists.

Appendix B

Glossary of Abbreviations and Acronyms

Abbreviation	Term
AMRAP	Antimicrobial Resistance Action Plan
C. difficile	*Clostridium difficile*
CCDC	Consultant in Communicable Disease Control
CDAD	*Clostridium difficile* Associated Diarrhoea
CDI	*Clostridium difficile* Infection
CDSC	Communicable Diseases Surveillance Centre
CSR	Comprehensive Spending Review
DHSSPS	Department of Health & Social Services & Public Safety
DPH	Department of Public Health
HCAI	Healthcare Associated Infection
HCC	Healthcare Commission
HISC	Healthcare-Associated Infection Surveillance Centre
HPA	Health Protection Agency
HSC	Health and Social Care
IPC	Infection Prevention Control
IV	Intravenous
KPMG	KPMG in the UK is a provider of professional services including audit, tax, financial and risk advisory
MRSA	Methicillin Resistant Straphylococcus Aureus
NDL	Nominated Directorate Lead
NHS	National Health Service
NI	Northern Ireland
NISRA	Northern Ireland Statistics and Research Agency
Northern Board	Northern Health and Social Services Board
Northern Trust	Northern Health and Social Care Trust
OCT	Outbreak Control Team
PFA	Priorities for Action
PHLS-CDSC	Public Health Laboratory Service-Communicable Disease Surveillance Centre
PPE	Personal Protective Equipment
RAPHSW	Regional Agency for Public Health and Social Well-being
RCA	Root Cause Analysis
RQIA	Regulation and Quality Improvement Authority
SAI	Serious Adverse Incident
SARS	Severe Acute Respiratory Syndrome
SDU	Service Delivery Unit
SHO	Senior House Officer
SMT	Senior Management Team
VHP	Vaporised Hydrogen Peroxide

Appendix C

List of tables and graphs

Abbreviation	Term
Fig 1	Number of *C. difficile* patient episodes, patients 65 years and over, by Trust 2005-2007
Fig 2	Rates of *C. difficile* patient episodes per 1,000 occupied bed days, patients 65 years and over, by Trust, Northern Ireland 2005 - 2007
Fig 3	Number of *C. difficile* patient episodes, patients 65 years and over, reported in community patients Northern Ireland 2005 - 2007
Fig 4	Total CDAD reports, inpatient and community, in Northern Ireland, by quarter (patients ≥ 65 years), between 2005 and 2008.
Fig 5	Quarterly rates of C. difficile by Trust 1 January 2007 – 31 March 2008, compared with annual NI and Trust rates for 2007; inpatients ≥ 65 years
Fig 6	2006 Ribotyping results, by Ribotype, from the snapshot survey Northern Ireland (n=57)
Fig 7	Number of deaths with *C. difficile* as a contributory factor and as an underlying cause of death in Northern Ireland 2001 - 2007
Fig 8	Number of deaths and age-specific mortality rates for deaths, with *C. difficile* mentioned on the death certificate, by age and sex, for 2007.
Fig 9	No. of New Identifications of *C. difficile* in Former United Trust Hospitals 1998 - 2007
Fig 10	Trends in *C. difficile* for the Hospitals in the Southern Section of the Northern Trust Jan 05 - Jun 07
Fig 11	Trends in *C. difficile* for the Hosptials in the Southern Section of the Northern Trust Jun 07 - Dec 07
Fig 12	Trends in *C. difficile* for the Hospitals in the Southern Section of the Northern Trust Jan 08 - Jun 08
Fig 13	Positive *C. difficile* Toxin Tests from patients in the former United Hospitals
Fig 14	*C. difficile* cases January 2005 to June 2008
Fig 15	Trends in inpatient *C difficile* rates for the Northern Trust by quarter 2005-2008
Fig 16	Ribotype 027 cases in former United Hospitals Trust Jun 07 to May 08
Fig 17	Medical outliers daily average
Fig 18	Medical Patients Internal Transfers Antrim Area Hospital
Fig 19	Number of Cleaning Staff Hours By Hospital 2006
Fig 20	KPMG Audit Compliance Scores on Environmental Hygiene.
Fig 21	Provisional results of an analysis of death certificates for the former United Hospitals Trust of patients who had a positive *C. difficile* toxin test in 2007.

The **Regulation** and
Quality Improvement
Authority

The Regulation and Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
BELFAST
BT1 3BT

Tel: (028) 9051 7500
Fax: (028) 9051 7501
Email: info@rqia.org.uk
Web: www.rqia.org.uk