

***Clostridium difficile* Public Inquiry**
Independent Report of the Expert Medical Advisory Group
(2nd October 2010)

1. *Clostridium difficile* Public Inquiry Panel

The Public Inquiry is being conducted under the terms of the Inquiries Act 2005. It was announced by Minister McGimpsey on the 31st March 2008. (www.cdinquiry.org). The Terms of Reference are:

Terms of Reference 1

- *To establish how many deaths occurred in the Northern Health and Social Care Trust Hospitals during the outbreak, for which Clostridium Difficile was the underlying cause of death, or was a condition contributing to death;*

and

Terms of Reference 2

- To examine and report on the experiences of patients and others who were affected directly by the outbreak, and to make recommendations accordingly.

2. Medical Advisory Group

2.1 The three of us were appointed by the *C. difficile* Public Inquiry Panel to assist them with their work. The instructions that we were given are outlined in Section 4.

2.2 What follows is a brief résumé of our own medical backgrounds

2.3 **Prof. George E. Griffin, BSc, PhD, FRCP, F.Med Sci**
Professor of Infectious Diseases and Medicine
St. George's, University of London

I am Professor of Infectious Diseases and Medicine at St. George's, University of London. In that capacity I am Vice Principal for Research and Head of the Division of Cellular and Molecular Medicine. I trained at King's College London, gaining a Delegacy Prize and an intercalated BSc in Pharmacology and Molecular Biology and a PhD in skeletal muscle biochemistry before completing my clinical training at St. George's. Following a Harkness Fellowship at Harvard Medical School my postgraduate medical education was at the Royal Postgraduate Medical School and St. George's as Lecturer in Medicine where I developed an interest in Infectious Diseases. This culminated in a Wellcome Senior Clinical Fellowship, during which I started to develop the Academic Unit at St. George's, alongside the Clinical Infection Unit.

My principal research interests centre on the host response to infection and vaccines at the cell, molecular and whole body level. I have built up an Academic Unit of international reputation with Principal Investigator lead groups focussing on HIV, TB, malaria, cryptococcal disease, lymphocyte turnover and vaccines. I have published some 200 peer reviewed articles and 60 scientific and clinical reviews. I have been a member of many Wellcome, MRC and Gates research committees, was elected a Founder Member of the Academy of Medical Sciences and am currently Chairman of the UK Government Advisory

Committee on Dangerous Pathogens. I chaired the investigation into the *E. coli* 0157 outbreak in Surrey 2009 and published key recommendations for implementation to help avoid a similar occurrence.

2.4 Lynne Phair, JP, MA, BSc (Hons) Nursing, RGN, RMN, DPNS, PGCCC Independent Nurse Expert Witness.

I am a Registered Mental Nurse (RMN) and a Registered General Nurse (RGN). I have a Masters Degree in Health Studies, Bachelor of Science Honours Degree in Nursing, a Diploma in Professional Nursing Studies, a Post Graduate Certificate in Community Care and an Advanced Certificate in Health and Safety. My nursing career started in 1977 and I have worked in hospitals, the community, and long term care settings, always specialising in the care of older people in both physically frail and mental health settings. I have worked for a voluntary organisation which has a number of Care Homes for Older people, as the Project Director and Nursing and Care Management Advisor.

I am currently a Clinical Advisor to the Department of Health and Consultant Nurse for Safeguarding Vulnerable Adults in a Primary Care Trust in the NHS, and a Fellow of the University of Brighton. I have written in nursing journals on a variety of subjects and have also written books and chapters since 1992. My specialist area of interest is in the care of older people who are experiencing mental health problems including dementia, physical frailty and those in long term care.

2.5 Prof. Cillian Twomey, MB, FRCPI Consultant Physician in Geriatric Medicine, Cork University Hospital and St. Finbarr's Hospital, Cork Lecturer in Medicine in University College Cork

I have worked as a geriatrician in Cork for the past 31 years. During this time I have also been involved in both undergraduate and postgraduate education. I am a fellow and examiner of the Royal College of Physicians of Ireland (FRCPI). I am the immediate past President of the Irish Gerontological Society and a member of the British Geriatrics Society.

I am a Board member of the Health Information & Quality Authority (HIQA) an independent statutory body responsible for overseeing standards of care provision in acute hospitals and residential care facilities in Ireland. I am the current Chairman of the National Steering Committee of the Hospital *friendly* Hospitals (HfH) Programme which promotes high quality End-of-Life Care in over 40 acute and community hospitals in Ireland.

3. Background to our Report

***Clostridium Difficile* Infection outbreak in the Northern Health and Social Care Trust (NHSCT)**

The *C. Difficile* outbreak occurred between 16 June 2007 and 31 August 2008 and the hospitals affected were, Antrim Area Hospital, Braid Valley Hospital, Ballymena, Mid-Ulster Hospital, Magherafelt, Moyle Hospital, Larne and Whiteabbey Hospital. These were the hospitals managed by the former United Hospitals Trust and they form a network centred on the Antrim Area Hospital, with inter-hospital transfers in both directions.

During the outbreak there were 323 cases of *Clostridium Difficile* Associated Diarrhoea (CDAD) confirmed by a positive toxin test carried out in the Antrim Area Hospital laboratory. The Northern HSC Trust conducted a study on all deaths of patients with *Clostridium Difficile* Infection (CDI) in the five hospitals during 2007-08. The results were reported in the Review Group Report to the Outbreak Control Team on 15 December 2008ⁱ. Eighty-four deaths were identified for which 80 sets of notes were available. Of the 84, 72 (86%) were aged 75 years and over. The reviewers agreed that in 9 CDI was the disease leading to death and in 6 CDI contributed to death. The figures from the death certificates were 12 and 19 respectively; of those death certificates where CDI was not recorded, one person was found where CDI was thought to be part of the primary cause of death and two additional people where it was a contributory factor. There were many more in which CDI was considered to be over-reported on the death certificates. The reviewer reported on the deficiencies in the methodology he used and, in particular, on the heavy burden of disease which contributed to a general high degree of debility and vulnerability to infection.

Our review differed in a number of respects from that carried out by the Trust. It used improved methodology, and it was carried out by experts from outside Northern Ireland. It involved an in depth review of the casenotes of 124 deceased patients who had been diagnosed with *Clostridium difficile* within the outbreak period.

Notwithstanding the earlier report on the *C. Difficile* outbreak the Northern Ireland Minister for Health decided to establish a public inquiry into the outbreak (www.cdiffinquiry.org). A *Clostridium Difficile* Inquiry Panel was appointed under the chairmanship of Dame Deirdre Hine. In turn, the *Clostridium Difficile* Public Inquiry Panel appointed the Medical Advisory Group to carry out an independent assessment of the records of patients identified by the Public Inquiry panel.

4. Instructions

- 4.1 The instructions given to us by the *Clostridium difficile* Public Inquiry Panel was to undertake a detailed independent review of the medical casenotes of those patients who died to establish the extent to which ***Clostridium Difficile*** was the underlying **cause of death** or was a condition contributing to death.
- 4.2 We were also requested to give a professional opinion on the **quality of care** provided to each of those patients as evidenced in their medical casenotes. We were not required to interview relatives or staff.

5. Disclosures of Interest

- 5.1 To the best of our knowledge we did not know any of the parties involved in this inquiry.

6. Information Sources / facts on which this opinion is based

6.1 *Clostridium Difficile*: Antibiotic Associated Diarrhoea

Clostridium Difficile is the causative organism of antibiotic-associated colitis. Colonization of the intestinal tract occurs via the faecal-oral route and is facilitated by disruption of

normal intestinal flora due to antimicrobial therapy. The organism is capable of elaborating exotoxins that bind to receptors on intestinal epithelial cells, leading to inflammation and diarrhoea. Antibiotic-associated diarrhoea and colitis were well established soon after widespread use of antibiotics. In 1978, *C. Difficile* was first identified as the causative pathogen in the majority of cases – hence the term *Clostridium Difficile Associated Diarrhoea (CDAD)*.

Since then the understanding of *C. Difficile* microbiology and epidemiology is changing rapidly. From 2003 to 2006, *CDAD* infections has been observed to be more frequent, more severe, more refractory to standard therapy and more likely to relapse than previously described. These observations have occurred throughout North America and Europe and have been attributed to a new *C. Difficile* strain namely Ribotype 027. This strain appears to be more virulent than other strains, which may be attributable to increased toxin production compared to conventional strains. *CDAD* infections due to Ribotype 27 are often, but not always, associated with a very virulent *CDAD*.

Clostridium Difficile Infection (CDI) most often occurs in older people and is usually precipitated by the use of certain broad spectrum antibiotics. Many patients with CDI have co-existing acute and/or chronic disease, sometimes severe. The contribution of CDI to death in infected patients is variable, and it may be difficult to assign its role against a background of multiple pathology.

6.2 General

Diarrhoea has been a well-known feature of treatment with antibiotics and is described as antibiotic-associated diarrhoea (AAD). As the use and types of antibiotic agents dramatically increased from the 1960's AAD was progressively observed as a greater problem and case reports were published in the late 1970's documenting a very severe and occasionally fatal form of the disease, *Pseudomembranous colitis* (PMC). It was then appreciated that AAD ranged from a simple self-limiting condition, which disappeared on cessation of antibiotic treatment, to fulminant PMC.

Initially the definitive cause of the diarrhoea was unknown and treatment was purely symptomatic, sometimes in severe case culminating in removal of the colon (colectomy) known to be the affected organ. Definition of the aetiology of the condition was slow and early findings suggested a bacterial origin (*Staphylococcus aureus*) but this was refuted. Since at this time no bacterial cause was apparent, research centred on a viral cause of the colitis and classical virological methods were employed to detect virus in stool. This involved taking fluid from stool, filtering to remove bacteria and putting this onto tissue culture cells in an attempt to grow virus. It became immediately apparent that such tissue culture cells changed shape very quickly becoming rounded up (actinomorph change).

Thus research focused on identification of the toxic substance in stool responsible for such effects. After some serendipitous experiments using the stool filtrate-tissue culture system, it was discovered that the toxin causing the cells to round up was completely neutralised by antiserum against a mixture of *Clostridial* toxins (see later). Further analysis eventually revealed that the specific toxin was from *Clostridium difficile* and that this microorganism was present in virtually all diarrhoeal stool from AAD affected patients.

Since this seminal early finding there has been much research focused on the clinical disease, diagnostic methods, microbiology of *C. difficile* and its toxins, epidemiology of

carriage in stool, clinical incidence, management and control. Whilst much has been learned about the organism, the disease it causes and its management, there are still many unanswered questions and considerable research is in progress. However, using existing knowledge, considerable steps have been made to reduce incidence and control the disease. (See General Reviewⁱⁱ)

6.3 Clinical Disease and Microbiological Diagnosis: Antibiotic-Associated Diarrhoea (AAD)

The clinical manifestations of AAD range very considerably from simple loose stool to fulminant watery/bloody diarrhoea with abdominal pain, which can be associated with dilation and perforation of the colon requiring major abdominal surgery. The latter fulminant form of the disease is fortunately rare. Diarrhoea may be present within a few days of starting an antibiotic course but may be delayed until after the course of antibiotics is complete. Virtually all antibiotics have been implicated as being associated with AAD but in terms of prevalence the commonly used B lactams (e.g. amoxicillin), quinolones (e.g. ciprofloxacin) and cephalosporins (e.g. cefotaxime) account for most cases. Repeated courses of different antibiotics also predispose to developing the disease.

AAD may affect any age group, except neonates up to the first few months of life (see later). However, the disease is of particular significance in any immobilised bed bound patient, posing a great challenge to nursing care and obvious implications for cross infection, requiring isolation. Severely ill post-operative patients (e.g. multiple trauma) and bed bound patients with dementia pose the biggest challenges for care and treatment.

The self-limiting form of AAD usually requires no specific treatment in the ambulant patient and will resolve within around a week after cessation of antibiotic treatment. More severely affected patients require careful management of fluid and electrolyte balance and specific antimicrobial medication directed against *C. difficile* (see later). In patients with severe disease, *Pseudomembranous colitis*, very close abdominal observation is essential to detect colonic dilation (clinically and using abdominal radiology) and measurement of markers of progressive inflammation (e.g. C-reactive protein) in plasma gives an indication of progression. After successful treatment and resolution of AAD relapse of clinical disease is common and may affect up to 30% of patients. Relapse is treated in the same symptomatic supportive way and change of antibiotic against *C. difficile* is indicated.

Reasons for relapse are not fully understood but are likely to involve several factors such as presence of anatomical defects, for example diverticulae and immune response to toxins. A small portion of cases have a very slow response to treatment and the vulnerable, frail and older population, particularly with co-morbidities, are at high clinical risk. Nutritional support is crucial for such patients and poses specific problems in that diarrhoea may be exacerbated.

6.4 *Clostridium difficile*: The Organism, Diagnostic Tests

6.4.1 General

Clostridium difficile is a spore forming anaerobic bacterium. This means that it belongs to a group of organisms (*Clostridia*) well known to cause human diseases by production of

toxins, which cause severe tissue damage. The anaerobic classification of the organism relates to the fact that the organism does not require oxygen to survive, unlike some other bacteria and human cells which demand oxygen for survival. Indeed oxygen is toxic to many anaerobic organisms and inhibits their growth.

C. difficile particularly under adverse conditions makes spores which are inert particles containing intact complete *C. difficile* DNA. Such spores can survive for long periods in the environment and are highly resistant to desiccation and chemicals in the resting state. The organism is widely found in the environment, particularly where symptomatic patients have been present (Society for General Microbiology, www.sgm.ac.uk). In addition, the organism is carried in the stool of some animals but the significance of such carriage to human disease is currently unknown. As soon as spores reach an appropriate environment (aqueous, anaerobic and containing suitable chemicals for nutritional support) they will germinate to produce new intact bacteria, which replicate and under the appropriate conditions produce and secrete toxins. At least two toxins, A and B, have been implicated in the aetiology of AAD. Toxin A is the toxin which was initially described to cause the cell rounding up in the tissue culture assay system.

Spores or intact organism principally gain access to the body by oral ingestion (faeco-oral route) and there is now some evidence that aerosol spread may be implicated in spread from symptomatic patientsⁱⁱⁱ, raising important considerations for nursing and isolation. After passing through the stomach and small intestine, the local environment in the human colon is ideal for *C. difficile* to grow and secrete toxins. The toxins act locally on the cells lining the colon (colonocytes) and destroy their integrity and that of the colonic lining. An intense inflammation of the colon (colitis) is thus initiated resulting in diarrhoea. In the most profoundly affected cases, severe inflammation results in significant protein loss from the circulation into the colonic lumen. This protein, classically fibrinogen, forms plaques on the inflamed colonic surface, the pseudomembranes seen in PMC. These pseudomembranes can be seen on examination of the rectum and lower colon by sigmoidoscopy and are pathognomic of PMC.

The question then arises, what is the process that permits the overgrowth of *C. difficile* in patients receiving antibiotic therapy? The human colon, the last part of the intestine, contains faecal material and within this organ there are around 10^{12} (one million million) bacteria per gram of stool. These organisms are mostly anaerobic and in normal individuals pose no clinical threat whatsoever. Bacteria within the colon are in a dynamic equilibrium with each other and this leads to a stable 'micro-flora' which encompasses many different types of microorganisms in a given individual. These organisms are alive and actively dividing. When an individual is given an antibiotic for treatment of an infection (e.g. pneumonia) this antibiotic will act against all bacteria which are susceptible, including the harmless bacteria in the colon. The stable equilibrium of the colonic microflora becomes severely altered and it is this perturbation which gives a niche for *C. difficile* to overgrow, produce toxins and cause AAD and colitis. Thus it is the administration of antibiotics which exposes the individual to overgrowth of *C. difficile* in the colon and potential to cause colitis. It is therefore essential that the prescription and type of antibiotic is carefully considered prior to commencement of such treatment.

The explanation of the cause of AAD presented above is highly simplified and indeed our knowledge of mechanisms is incomplete. For example, factors that are responsible for maintaining normal microflora in the colon are poorly understood and likely relate to dietary intake, colonic structure and immunity. Furthermore, up to 5% of normal, colitis-free adult individuals have *C. difficile* producing toxins in their stool, a carrier state. It is probable that

these individuals have inhibitory substances in the colonic lumen or have generated antibodies as part of an immune response to toxins A and B. In addition there is the intriguing observation that of up to 60% normal neonates may carry *C. difficile* and produce toxin in stool, but have no clinical disease. These children could be protected by substances in breast milk or their colonocytes may lack the receptor for the toxins.

6.4.2 Diagnosis and Ribotyping of *C. difficile*

Diagnosis of AAD is based on clinical suspicion including a history of recent (classically within the previous six weeks) antibiotic medication. Since there are many infectious causes of diarrhoea it is crucial to make a definitive microbiological diagnosis as this will direct treatment. Diagnosis of *C. difficile* has been achieved in several ways in the past, including identifying the stool toxin in tissue culture and microbiological culture of the organism in stool. However these techniques are laborious and take several days.

Consequently, rapid techniques are now available and the latex agglutination technique is used as standard in routine practice. This technique involves using commercially available validated kits which contain latex particles coated within antibodies directed against *C. difficile* toxins A and B. When *C. difficile* toxins are present in stool the latex particles bind together (agglutination). Such agglutination tests can give positive tests within hours which then can be used to direct appropriate patient management. Sometimes agglutination tests may be negative and need repeating and algorithms to substantiate diagnosis have been devised. In addition some patients, particularly those convalescing from AAD, may have toxin detected in stool but no clinical diarrhoea.

Whilst bacteria such as *C. difficile* are simple life forms they are highly complex biochemically and small variations in their genetic material can alter their biochemical properties and potential to cause disease. Such variations are important in the pathogenicity of *C. difficile*. The first relates to different strains of the organism which can now be identified biochemically by polymerase chain reaction (PCR) ribotyping. In this technique DNA is extracted from the cultured microorganism and specific sections of the DNA (non-translated portions between ribosomal RNA genes) can be expanded biochemically using PCR. These amplified sections of DNA are then analysed and characterized by separating fragments produced by enzymatic digestion of this expanded DNA on a gel. Specific patterns of these DNA fragments are generated and are used to categorise the type of *C. difficile* (ribotyping).

Several typing systems have been devised for *C. difficile*^{IV} and ribotyping has been chosen for use in the UK^V, performed by the *C. difficile* Ribotyping Network for England (CDRN) coordinated by the Health Protection Agency. Northern Ireland was incorporated into CDRN in 2009. This has resulted in valuable information on cross infection, management of outbreaks and determination of epidemiology of infections. There are many different ribotypes that can be identified using the PCR-ribotyping system. In practice around twenty are tested for and in the Northern Ireland outbreak described in this report, fifteen ribotypes were identified. In the UK and epidemiological studies have clearly demonstrated changes in the prevalence of the different ribotypes over time (see later). Furthermore, genetic analysis of the organism has led to the discovery that a hypervirulent strain of *C. difficile* (027/B1/NAP1) has evolved which leads to more serious disease because this organism produces and releases more toxin.

6.4.3 Treatment of *Clostridium difficile* infection

The aim of definitive antimicrobial treatment of AAD is to remove *C. difficile* from the colon, and therefore the source of the toxin, allowing the colon to regain normal function as the inflammatory process is reduced. The consensus view is that metronidazole is the first line of antimicrobial treatment. However the use of this antibiotic is not universally successful, with up to 25% clinical failure rate. Such failure may relate to low level of this antibiotic in the colonic lumen and the discovery of varying degrees of *C. difficile* resistance to this agent. Vancomycin is an antibiotic not absorbed in the small intestine and therefore when given orally reaches the colon in high concentration and is active against *C. difficile*. However there is concern that other organisms in the colonic lumen may develop resistance to vancomycin and themselves become serious pathogens e.g. vancomycin resistant enterococci. This was a principal reason, in the USA particularly, to reserve vancomycin as treatment for relapses or serious cases.

The use of probiotics (e.g. those in yoghurt) has been advocated as a way in which the colonic microflora may be encouraged to reconstitute and assume a normal equilibrium after antibiotic treatment. However definitive proof that this probiotic approach works is lacking. Reconstitution of the normal faecal microflora in patients with AAD using faecal enemas obtained from well individuals has not proved successful. In addition the intravenous use of pooled immunoglobulin (e.g. Sandoglobulin) is controversial and very expensive but has some scientific basis in that antitoxin antibodies may be present. Both of the latter therapies are under further investigation.

In addition, immunologically based therapies are under investigation at the moment and are promising. These include vaccination of at risk individuals with vaccine consisting of inactivated *C. difficile* toxins. In addition, the use of antibodies directed against *C. difficile* toxins administered by oral, rectal or intravenous routes is currently under active investigation. It is now commercially possible to produce such antibodies in large quantities using recombinant techniques. Both of these techniques offer potentially important ways of preventing AAD (active immunity) and treating disease when it is established (passive immunity). It is interesting to note that the appearance of specific antibodies to Toxins A and B in blood of individuals suffering from severe relapsing disease correlates with cure. Such observations lead to hope that immunological treatment will be clinically useful. However using simple measures of control, deaths in England and Wales from *C. difficile* have halved between 2007 and 2009 (National Statistics Online - Clostridium Difficile)

6.5 Epidemiology and Control of Infection

The epidemiology of *C. difficile* infection is changing rapidly^{vi}. Since the serious nature of the disease and its prevalence have been recognized in the UK, there has been a 35% fall in cases in patients aged two and over (36,097 *C. difficile* infections in 2008/9 from 55,499 in 2007/8^{vii, viii}). During this period, there has been a 20% fall in infections with the predominant ribotype 027; however this is compensated by rises in prevalence of other ribotypes. The prevalence of AAD in the older population, particularly in nursing homes is of major significance. The carriage rate of the organism in such populations is thought to be high and is under investigation.

The fall in *C. difficile* infections reflects steps taken as a result of greater understanding of the aetiology of infection, rational use of antibiotics, improved cross infection practice and

case isolation^x. Most hospitals now have guidance on clinical use of antibiotics recommending careful consideration of the clinical need for antibiotic treatment and reduced use particularly of cephalosporins and quinolones. Furthermore, the use of rigorous hand washing, disposable clothing and isolation of patients with AAD have become routine but pose great logistical problems within institutions. The spores of *C. difficile* are resistant to alcohol hand washes/wipes and hand washing using soap and water is crucial. Since spores of the organism are known to be highly resistant, the recommended cleaning and disinfection procedures for contaminated surfaces is hypochlorite (bleach) and protocols have been produced giving clear advice.

6.6 The role of the Doctor and Registered Nurse

All doctors and nurses [whether Registered General Nurses (previously referred to as State Registered Nurses (SRN), all Registered Mental Nurses (RMN) or State Enrolled Nurse (SEN)] are registered with their respective regulatory body, the General Medical Council and the Nursing and Midwifery Council of the United Kingdom. All doctors and registered nurses have a duty to abide by the code of standards of conduct, performance and ethics for their profession. Although the two professional bodies have different professional codes, they both focus on the same key elements of professional practice, Key elements include:

- Patients in the doctors or nurses care must be able to trust the professional with their health and wellbeing.
- To justify that trust the professional must, make care of people their first concern,
- treat them as individuals and respecting their dignity
- work with others to protect and promote the health and wellbeing of those in their care, their families and carers and the wider community;
- Provide a high standard of practice and care at all times, be honest and act with integrity.

Healthcare professionals are required to be professionally accountable for actions and omissions in their practice and must always be able to justify decisions. They must always act lawfully, whether those laws relate to the professional practice or personal life. A failure to comply with this code may bring the person's fitness to practice into question and endanger their registration^{x,xi}.

Health care professionals (specifically doctors and registered nurses) hold a position of responsibility. They are professionally accountable to the GMC and NMC as well as having contractual accountability to their employer and as a professional are personally accountable for actions and omissions in their practice and must always be able to justify their decisions, must always act lawfully whether those laws relate to the professional practice or personal life.

6.7 Healthcare Professionals and Record keeping

Health Care professionals are required to keep records. Good record keeping is an integral part of clinical practice and is essential for the provision of safe and effective care. It is not an optional extra to be fitted in if circumstances allow. Good record keeping whether as an individual, team or organisational level has many important functions. These include a

range of clinical, administrative and educational issues, such as helping to improve continuity, accountability and decision making. Supporting a delivery of services, supporting effective clinical judgements and decisions. Supporting patient care and communications, making continuity of care easier, providing documentary evidence of services delivered, promoting better communication and sharing of information between members of the Multi-Professional Health Care Team. Helping to identify risks and enabling early detection of complications, supporting clinical audit, research allocation of resources and performance planning and helping to address complaints and legal processes.

Principles of good record keeping apply to all types of records regardless of how they are held, which include; handwritten clinical notes, emails, letters to and from health professionals etc. The principles of good record keeping are set out by the GMC and the NMC to include; handwriting should be legible, all entries to records should be signed, in the case of written records the person's name and job title should be printed alongside the first entry. In line with local policy you should put the date and time of all records. Records need to be accurate and recorded in such a way that the meaning is clear. Records should be factual and not include unnecessary jargon. The professional should use their professional judgement to decide what is relevant and what should be recorded. They should record details of any assessments and reviews undertaken and provide clear evidence of the arrangements that have been made for future on-going care.

Records should identify any risks or problems that have arisen and show the action taken to deal with them. The professional has a duty to communicate fully and effectively with your colleagues ensuring that they have all the information they need about the people in their care. The professional must not alter or destroy any records without being authorised to do so. If records have to be altered, the change must state the name, job title and sign and date the original document. Where appropriate, the person in the professionals care or their carers should be involved in record keeping. The language that is used should be easily understood by the people in their care. Records should be readable, should not include coded expressions, sarcasm or humorous abbreviations to describe the people in their care, and records should not falsified^{xi, xii}.

7. Methodology

From the information provided by the NHSCT, the Public Inquiry panel identified 164 patients, who had tested positive for *C difficile* and died during the period between 16th June 2007 and the 30th November 2008. Of these patients, 88 patients diagnosed with CDI during the outbreak died up to 30 days after diagnosis and a further 40 died 31 to 90 days after diagnosis. The remaining 36 patients died within the time remit of the Inquiry, but more than 90 days after diagnosis. In addition to the list of patients with CDI provided by the Trust as defined above, the Registrar General's Office (RGO) confirmed that 49 people had *C difficile* recorded on their death certificates^{xiii}.

In addition to the intention to review casenotes of the 128 patients who died with CDI within 90 days of diagnosis, we were asked to review a further 2 casenotes of the only patients who died after 90 days and had CDI recorded on their death certificate. Thus of the 164 patients who tested positive for CDI and died during the defined period, 130 patients were identified for review under the criteria set by the Inquiry.

The casenotes were transported from the Trust to the Inquiry Offices in Belfast. The records included notes made by all disciplines, observation charts, and special protocols

for specific conditions. The patient records were held in secure filing cabinets within a dedicated secure office with key pad access, with the code known only to the three reviewers, Inquiry staff and the premises manager. The casenotes review was conducted in a secure office and at no time were patient records removed to any other building. The casenotes relating to 6 patients were unable to be located by the Trust. Thus the casenotes of 124 of the 130 patients were the data source which formed the basis of our review.

The three Medical Reviewers were unknown to each other prior to this Inquiry. We were briefed at the outset and given individual induction files containing relevant background information and reports in relation to the Inquiry.

Three forms – **Form A**, **Form B** and **Form C** – were devised by the Inquiry Panel (see Annex 1.1). Form A & Form C relate to the cause of death. Form B relates to Quality of Care. After an initial assessment using Form A and Form B, we agreed to some minor revisions to both forms in collaboration with some C Difficile Panel members.

Form A recorded the diagnosis of CDI, the co-morbidities, a clinical summary and the cause of death as judged by each us; each of us examined the 124 medical casenotes separately and independently and then completed a separate Form A for each patient. Subsequently we met on four occasions to discuss our individual findings and agree the consensus cause of death.

Form C recorded our agreed consensus cause of death and the cause of death as recorded on the patient's death certificate; after reviewing the Death Certificate for each patient we made a comment where our consensus opinion was significantly different from the cause of death recorded on the death certificate. A separate Form C for each of the 124 patients was then signed off by the three of us.

Form B sought to collect information in respect of thirty-four key indicators identified by the Panel to be examined by us regarding issues such as record keeping, clinical care, communication and end-of-life care. The thirty-four key indicators were split into six domains. We were asked to find evidence of documentation in each of the 34 areas. We noted whether, in our opinion, the documentation was complete or partially complete, if there was evidence that a particular area of patient care had been recorded or not or if the area did not apply to that patient. As with Form A, having examined the 124 medical casenotes, each of us completed Form B independently; subsequently our comments were collated to establish an overall impression.

The standard that we decided to adopt is that which we would expect to find in healthcare records from our own professional practice and experience as well as the standards required by the Nursing and Midwifery Council^{10, 12}, the General Medical Council¹¹ and the hospital policies of Northern Health and Social Care Trust. It is important to note that during the course of the outbreak, Trust documentation changed and evolved; however it was not always possible to determine when these new documents came into use.

Patients' death certificates were not made available to the reviewers until our assessment of the records had been completed.

8. Findings in relation to Cause of Death

In deciding whether *Clostridium difficile* was either the **underlying cause** of death or **contributed** to the patient's death we were asked to consider five levels of probability from '**definitely**', to '**probably**' to '**possibly**' to '**unlikely**' to '**no**'. These categories were also used in the Healthcare Commission proforma on which Form A was based. Subsequently, we decided to remove the '**possibly**' category and amended our opinion, where applicable, to either '**probably**' or '**unlikely**' in an attempt to provide greater clarity as to *C. difficile*'s role in each patient's illness and death. For the same reason we decided, when presenting our findings, to combine the 'definitely' and 'probably' numbers as one; similarly the 'no' and 'unlikely' numbers have been combined.

The findings, based on the balance of probability and our best clinical judgement with regard to the **underlying cause** of death and with regard to '**contribution**' to the patient's death' are summarised as follows:

When we reviewed each patient's casenotes to determine whether CDI was the underlying cause of death and/or a contributory cause of death we used the agreed 4 levels of probability described above. This resulted in a range of conclusions. For example there were 4 patients for whom, in our opinion, CDI was '**definitely**' the cause of death; there were a further 11 patients for whom, in our opinion, CDI was '**probably**' the cause of death. We decided to combine these two groups.

Accordingly, it is our considered opinion that CDI was the underlying cause of death in 15 (12%) of the 124 patients. It is also our considered opinion that CDI contributed to the patient's death in a further 16 (13%) of the 124 patients.

We were asked to compare our findings with the cause(s) of death documented in each patient's death certificate. Overall there was a good correlation between our findings and those documented on patients' death certificates. This is summarised in Table 1. The data entered in the death certificates was in agreement with our considered opinion in terms of the underlying cause of death in 117 (94%) of the 124 cases and as to the contribution of CDI to the patients' death there was agreement between us in 98 (79%) of the 124 cases.

Table 1

Medical Advisors judgement in comparison with that documented in Death Certificates	Agree fully	Under reported in Death Certificates	Over reported in Death Certificates
Column A – Underlying cause	117/124	3	4
Column B – Contributory cause	98/124	4	22
Total	124		

The age profile of the cohort group is of interest. 85% were aged 70 years or more, 52% were 80 years and over and 16% were aged 90 years or more. Only 7 patients were under 60 years of age.

We were asked, as part of our assessment of the role of CDI in patients' deaths, to comment on their likely prognosis if they had not contracted CDI. In essence we were being asked to make a clinical judgement, based on a detailed review of each patient's casenotes including their medical diagnoses and all other relevant information documented therein and offer our opinion for each patient on their likely survival / life expectancy either on hospital admission or just before the CDI occurred, whichever was later. As with the Healthcare Commission proforma this opinion was to be captured under one of three headings: a) that the patient had been likely to die within 1 month, b) within 1-12 months or c) the patient had been likely to survive more than 12 months.

It is our opinion that **32 (26%)** of the 124 patients were so ill as to have been likely to die within one month of hospital admission. We consider that a further **86 (69%)** were unlikely to have survived beyond twelve months with **only 6 (5%)** expected to survive longer than this time. These projections confirm what is already well known, i.e. that older patients who require inpatient hospital care are a particularly vulnerable group with a high risk of mortality and/or prolonged hospital stay.

We were also asked to rate the patients' degree of independence / dependency on admission or just before the CDI occurred whichever was later. This is relevant in that the more dependent patients are at greater risk of multiple illness, are less able to cope with these illnesses and they have a higher mortality. The extent of co-morbidities and the overall frailty of the patients we reviewed is highlighted by the finding that we consider that **only 7 (6%)** of the 124 patients reviewed were classified as being '**fully independent**' when their CDI was diagnosed. Conversely **89 (72%)** of the 124 patients were deemed to be '**totally dependent**' at this time. It is well established that multiple pathology, morbidity and mortality increase dramatically with increasing age.

Lastly we sought to establish whether the CDI was either **community** or **hospital** acquired. If the onset of diarrhoea and/or the *C difficile* positive toxin result was confirmed within 72 hours of hospital admission the CDI was deemed **community** acquired. Conversely if the diarrhoea and/or the *C difficile* positive toxin result were confirmed beyond this 72-hour limit then the CDI was deemed **hospital** acquired. If a patient transferred from one hospital to another and developed CDI, then such infection was also deemed to be **hospital** acquired CDI. The findings in this regard are summarised in Table 2. The definition of **community** or **hospital** acquired that we have taken is that which has been conventionally used in previous studies (iv, v). However, it does not take into account patients who may have been carriers or those who are between relapses and have previously had multiple courses of antibiotics.

Table 2

Source of CDI		
Community	Hospital	Total
37 (30%)	87 (70%)	124

As is shown the source of the CDI was **hospital acquired** in 87 (70%) of the 124 cases and was **community acquired** in 37 (30%) of the 124 cases. One third of these cases with **hospital acquired** CDI contracted their infection in hospitals in the Northern Trust other than the one where their infection was diagnosed and treated - two in the local psychiatric hospital and two in a general hospital in another Trust. Of equal interest is the fact that 13 (35%) of the patients classified with **community acquired** CDI were admitted from care

homes. Thus it is noteworthy that three patients in ten diagnosed with CDI in the acute hospital setting acquired their infection in the community setting, albeit that admissions from residential Care Homes are included under the heading of 'Community' and we submit that they are likely to be different in terms of CDI risk and exposure to patients admitted to acute hospital from their own homes .

In this review 15 different Ribotypes were identified in 55 (44.4%) of the 124 patients. The most frequent ribotype was Ribotype 027 which was isolated in 22 (40%) of the 55 patients. We consider the CDI to have been hospital acquired in 14 of these cases and community acquired in the remaining 8. Incidentally 7 of these 8 patients were admitted from Care Homes and we consider that CDI was either the cause of death or contributed to death in all 7 cases.

In the remaining 23 patients on whom ribotype data was available the type isolated was Ribotype 078 in 8 (14.6%) patients, Ribotype 001 in 7 (12.7%), Ribotype 015 and Ribotype 020 were isolated in 3 (5.5%) patients each and Ribotype 002 and Ribotype 014 in 2 (3.6%) patients each. Finally Ribotypes 005, 023, 026, 059, 118, 137, 177 and 203 make up the remaining 8 patients.

9. Qualifications / Limitations of the findings in relation to Cause of Death

C difficile carriage occurs in 20 to 50 percent of adults in hospitals and long term care facilities (the carrier rate among healthy adults is about 3 percent). In general about **20%** of hospitalized adults are *C difficile* carriers whereas in long-term care facilities the carriage rate may approach 50%^{xiv,xv,xvi}. Although asymptomatic, these individuals shed pathogenic organisms and serve as a reservoir for environmental contamination. The host immune response to *C difficile* may play a role in determining an individual's carrier status and also the propensity to relapse. Data on treatment of asymptomatic carriers are limited, and routine treatment is not recommended.

The combination of older age, complex multiple co-morbidities, frequent exposure to courses of antibiotics, associated need for hospital admission are cumulatively major risk factors for hospital acquired infections, notably *C difficile* Infection. This group of patients already has a high mortality risk, a finding confirmed in our review of the 124 patients' casenotes.

However we are also of the view that *Clostridium difficile* infection was neither the underlying cause of death nor a contributory cause of death in the majority of the patients.

Ribotypes were available in a minority of the patients reviewed and so the sample may not be sufficiently robust to draw firm conclusions. Nevertheless ribotype 027 was identified in 22 (40%) of the 55 patients that had ribotype data. CDI infection with ribotype 027 has not previously been identified in Northern Ireland. It is not possible to identify with certainty the original source of infection in patients admitted from Care Homes. It is not uncommon that Care Home residents have several hospital admissions to a variety of hospitals in their catchment area.

10. Findings in relation to Quality of Care

As already stated we were required to assess and give a professional opinion on the quality of care provided to each patient as evidenced in their medical casenotes.

10.1 Summary of conclusion

The group of patients reviewed and being cared for in this report was an extremely frail group of people and nobody should underestimate the complications and the complexity of nursing acutely ill patients with profuse and sometimes explosive watery diarrhoea as well as multiple co-morbidities, including dementia. The vast majority of the patients reviewed were totally dependent and nursing people with such complex needs requires huge skills, many of which go unnoticed. Overall the standard of clinical care was satisfactory, but the Care Plans did not always reflect the wider nursing role regarding anticipatory care to reduce the risks of complications caused by CDI. The following comments and criticisms should be seen in this context.

10.2 An overview of the quality of documentation, record keeping and nursing care plans

Record keeping is integral to a health care professionals practice. However the balance between the time spent writing detailed records and treating the patients in busy acute wards often causes tension for practitioners. The system of documentation should be designed to assist the practitioner to keep good contemporaneous records. Good practice in record keeping can help to protect the welfare of patients by ensuring high standards and continuity of care in addition to improved communication between members of the healthcare team.

The method of documentation varied across the hospitals. In Antrim a system of using multidisciplinary notes was used, with all professionals writing in one set of records. The identity of the professional was clear with the use of a label denoting their profession and name. Records from other hospitals were not always clear, in respect of following the records of interventions or care plans. This caused difficulty in obtaining specific information from the notes regarding nursing care, and to understand the exact level or type of care that had been given.

There was evidence of very good practice in respect of a discharge letter summarising the final admission which was sent to the GP. Some were sent very promptly, however, a significant number were delayed, sometimes for up to three or four months after the patient had died.

A number of entries, in some patients' medical notes, were illegible. Signatures were not recognisable; there was no contact phone number, and no time of entry was recorded.

Over the period of the outbreak, the Trust introduced new assessment forms specifically in respect of the management of CDI. The **CDI Assessment and Review Form** was found in less than 25% of the patients' files; and many of those found were not fully completed. The **Infection Control Advice Proforma** was introduced to inform clinical practice and over half of the patients' files contained this form. However approximately 66% of the care plans and records (where the form was used) did not always reflect the advice given or record that the instructions had been carried out. There was evidence to indicate an

understanding of the importance of infection control and there was documented evidence that most patients were barrier nursed or isolated in accordance with the policy.

Despite introducing these new assessment and record keeping systems, there was no evidence that staff were released from completing existing records, or that the forms were assessed for their effectiveness, or ease of use. Additional risk assessments and recording systems only appeared to add burden to the staff and perhaps any new system of record keeping should have been implemented alongside a method to streamline existing paperwork.

A **Care Plan** is a document designed to inform staff of the care needs and how those needs should be met. Core care plans were the care plan system of choice. These are standardised care plans that were photocopied and personalised depending on the patient's individual needs. The reproduction of many of the nursing care plans was of poor quality. Many seemed to have been reprinted or photocopied numerous times which left them difficult to read. One design of a core care plan had copious academic references to form an evidence base; yet this made them too large and difficult to follow. The core care plan had often not been personalised and the list of options of care had not been deleted or altered to meet the individual needs. Typed care plans often had no signature or indication on the care plan that the care had been carried out or evaluated.

The standard of care planning was variable. Some patients had valid and appropriate care plans, some had numerous care plans which could have been summarised and cross referenced and others did not have care plans to identify the care required.

10.3 Domain A. Appropriate Care for *Clostridium difficile* Infection (CDI) Specific nursing care needs for CDI

Nursing assessment and nursing interventions to meet fundamental care needs

On admission, all patients, particularly those who are older or frail, should have core assessments to determine the level of nursing intervention required to meet their fundamental care needs. The nursing assessment used for pressure risk management was the **Braden Tool**. This was usually in the patient records, but was rarely fully completed or reviewed in accordance with the instructions on the form. Aspects of the pressure risk management plan were not always completed in accordance with the care plan. Notwithstanding this, and considering the frailty of this group of patients, very few (possibly less than 6 patients) developed pressure ulcers, which infers that good pressure risk prevention was indeed carried out although not documented.

Continence assessments did not appear to be included in the nursing assessments and the assessment and management of faecal incontinence was found in only one person's care plan. Routine urinary catheterisation on admission appeared to be common, yet the rationale for this intervention was not always clear. Furthermore, catheter removal did not always occur in a timely and appropriate way. Considering the known risks of acquired catheter infections and the links between antibiotic usage and the development of CDI, this institutional practice is of concern.

Fall risk assessments were completed on most patients and it was noted that very few patients had a fall during their episode of care. Approximately 33% of the patients had a moving and handling assessment completed and regularly reviewed. Many more patients

had the form in the file but it was not completed or evaluated.

Nutritional status was assessed using **MUST (Malnutrition Universal Screening Tool)**. There were only 7 completed assessments found in the files and it was not clear when these were completed.

It was possible, from almost all of the records, to follow the patient's pathway of the medical interventions they received. Most medical needs were assessed, but the standard of assessment, review and recording varied enormously. As far as it could be judged, the majority of patients had their vital signs (blood pressure, pulse and respiration) monitored appropriately.

The records indicated that there was an understanding of the importance of infection control and the need for isolation as soon as a diagnosis of CDI was made was recorded. Most patients were barrier nursed or isolated in accordance with the policy and care plans recorded the need for good infection control procedures to be followed. However, it was not always possible to identify whether isolation was implemented in a timely way. It should also be noted that the isolation facilities changed during the course of the outbreak, in that an isolation ward was established

The nursing care plans for CDI identified the clinical needs of the patient focusing on the management of infection control, the use and administration of medication, the taking of stool samples to monitor the C Diff status and monitoring clinical signs of improvement. The CDI specific care plans did not always reflect the wider nursing role regarding anticipatory care to reduce the risk of complications caused by CDI. Although some of these risk factors may have been recorded and monitored through other care plans, the care planning system on the whole did not appear to be as efficient and effective as it could have been. The factors that should have been documented and monitored on a CDI Nursing Care Plan include:

- mouth care when someone is becoming dehydrated
- monitoring the risk of developing oral infections
- excoriation prevention and continence management
- the approved type of barrier cream to use
- management of the pain such as abdominal cramps
- poor nutrition and weight loss relating to the CDI
- the impact of prolonged diarrhoea causing general debility and lethargy
- impact of CDI on mobility, activities of daily living or rehabilitation
- psychological and emotional impact including the risk of confusion due to the infection or the possible psychological consequences of isolation

Monitoring bowel activity may be useful for a number of medical conditions. In respect of the management of CDI, monitoring bowel activity and the type of stool was the key clinical indicator to measure the impact of the treatment. Approximately half of the patients' files contained record of stools, referring to the **Bristol Stool Chart** grading system as a reference point. No charts had the visual reminder (of the shape and consistency of the stool) as part of the chart. Where stool charts did exist, some were completed more than others and reference to bowel activity in the medical or nursing records did not always correlate with the stool chart.

When there was evidence of constipation and possible overflow, the response was to send samples to rule out CDI. If that sample came back negative, more samples were sent until

eventually a diagnosis of CDI was established. This could mean that the patient had diarrhoea for up to two weeks before a positive stool was returned. The concern is that the staff became focused on only one cause of diarrhoea and did not think of other possible causes and treatments.

10.4 Domain B. Attention to Hydration and Nutrition

The management of hydration and nutrition in frail older people and acutely ill patients of any age is central to the care and treatment of any condition, and includes accurate record keeping. If records are not clear in respect of fluids and nutrition, accurate assessment and diagnosis of the reasons for difficulties regarding hydration and nutrition can prove extremely difficult.

Most patients had fluid and electrolyte replacement therapy as part of their overall medical care. Fluid balance charts were found in approximately 75% of the patients' records. The standard of completion varied from being very detailed to being sparse, some suggesting the patient had not consumed any fluids for many hours. However, it was not possible to determine whether this was the situation or whether the records had not been fully completed.

Evidence could only be found that 12 patients were weighed on admission. There was no evidence in the records of the other patients that the need to weigh them had been considered or ruled out because of acute ill health or another reason e.g. risk of contamination of equipment. Additionally patients did not have their **Body Mass Index** (which cannot be calculated without body weight and height) calculated. After admission, some entries were found whereby the dietician had requested the patient be weighed. Clearly it is difficult to weigh acutely ill or bed bound patients, and in some admissions it may not have been a priority. However the records did not record the rationale for the omission. It was difficult to establish the impact poor weight monitoring had on any condition yet alone CDI and this was particularly a concern in respect of those people with dementia, general frailty and debility.

Approximately 60% of patients were seen and assessed by the dietician and nutritional supplements prescribed. There was no record that a referral was made for this suggesting the dietician is part of the multidisciplinary team and therefore saw patients automatically, which in itself is good multidisciplinary practice, but the lack of documentation (in some records) means the involvement of the dietician is not always easily noticed. Often the dietician had to estimate the body weight. It is also not clear whether the dietician was involved in the multidisciplinary meetings, and only 6 specific care plans relating to nutrition were found. The dietician and the nurses' use of patients' dietary likes and dislikes and use of enriched foods rather than going straight on to food supplements was never documented or recorded.

10.5 Domain C. Appropriateness of drug treatment for *Clostridium difficile* Infection

The appropriateness of the drug treatment for CDI was excellent, and followed the antibiotic policy. The antibiotic policy required that all *C. difficile* positive cases were to be reviewed by the microbiologist. However, identifiable reference to the doctor making contact with the Microbiologist was documented in less than half of the patients' files. This

may be because, we were told that once the microbiologist was alerted by the lab they automatically visited the ward., However records of these visits could not be found.

The prescription and administration of medicines was well recorded and the documentation appeared complete. The system of recording administration involved the Nurse recording a code which signified the specific medicine, on a page separate to the prescription. No medication recording errors were identified.

The Trust Antibiotic Policy is welcome and will help reduce the incidence of CDI, but a clear reason for prescribing antibiotics needs to be recorded in the notes. There was some evidence of prescribing (for infections other than CDI) where no specific reason could be found. For example, patients would be admitted with a set of undefined symptoms, antibiotics would be prescribed and it could only be guessed, from the records, what the clinical diagnosis was as a clear clinical rationale for the prescription was not always recorded.

10.6 Domain D. Palliative care and decisions regarding end of life

The Integrated Care Pathway (ICP) for end of life is a tool designed to be used in order to care for someone in the last days or hours of life once it is known the person is dying. The pathway is detailed and enables review of the persons care needs every 2 hours. 25 of the patients' records indicated that the ICP was not appropriate as the patient was discharged from hospital or died suddenly. Of the remaining 102 patients, 25 had a completed ICP and family involvement in the ICP was noted in 22 patient's records.

Symptom control at end of life is a key benefit of using the ICP, and it was noted that there was a significant improvement in the management of symptoms when the Macmillan Nurses became involved in the patients care. Although it was not explicit, it is assumed the Macmillan nurses were part of the hospital team.

The need for palliative care was often recognised at the latter stages of the patient's stay, and discussions were held with relatives about the gravity of the patient's condition and the poor prognosis. Sadly there was evidence that some patients were not placed on the Care of the Dying Integrated Care Pathway at this time. Furthermore in some cases, even after these discussions, further tests or investigations were carried out despite the apparent futility of the outcome, and the patient was not put on the pathway until within hours of their death. It is unclear why some people were not placed on the Care of the Dying Pathway at the same time as family members were told of the poor prognosis.

There was no documented reference to undertaking an assessment of the patient's own mental capacity to be involved in decisions regarding their care. Discussions about end of life care and prognosis, when held, were with the relatives; no documentation of involving the patient in these discussions was found. There was also little documented reference to the patient's spiritual needs on the ICP, and on only a few occasions, involvement of the patient's spiritual advisor was recorded.

We applaud the appropriate use of the Integrated Care Pathway but it generally appeared to be implemented too late in the patients' illness, even when the "do not resuscitate" and/or "poor prognosis discussions" had been held.

10.7 Domain E. Communication in respect of *Clostridium difficile* Infection

Informal conversations take place daily with patients and relatives in all healthcare organisations and these exchanges are often not documented. The content can often be wide ranging particularly if the patient has a number of conditions being treated and lack of specific documented evidence does not necessarily indicate communication did not occur. However key conversations should always be recorded.

In general there was very little documented communication specifically about CDI. There was little evidence of focused infection prevention advice or information on laundry for families, despite the need for this as stated in the **Infection Control Advice proforma**. The communication often focussed on patients' other serious medical conditions, their poor prognosis or their end of life / terminal care management. This was obviously appropriate for this particular group of patients.

With some exceptions it is not possible, from the records, to comment on the detail or quality of discussions with relatives. More significantly it is also not possible to ascertain where the patient was included and involved in any such conversations about their care and prognosis. It is acknowledged that some patients lacked the capacity or were so seriously ill that it was felt to be in their best interests not to be involved in such conversations. Nevertheless it appeared to be the norm that patients were excluded from conversations about their care and their future management.

10.8 Domain F. Comments on Quality of Care

In general, the medical and technical (i.e. medication administration, isolation precautions and stool sample testing) nursing care administered for CDI was satisfactory for the majority of patients. However the anticipatory nursing care, and broader nursing care requirements to manage the consequences of the CDI or to prevent complications occurring for highly dependent frail people was not documented or not as thorough as it could have been.

The overall communication about the general medical condition was felt to be good for most of the patients and their families. There was very little communication documented in respect of the CDI. The communication documented was usually about the patients other critical illnesses and their management and prognosis. Medical staff documented communication regarding CDI although this was infrequent and was lacking in respect of infection control advice. Nursing staff rarely documented communication to relatives or patients regarding CDI.

It is difficult to establish (from the records) the level of compassion, the delivery of information, the timeliness of interventions or the language and tone (verbal and non-verbal) that was used when communicating with families. There were examples of outstanding care and compassion. In one, a patient's close relative visited extremely frequently assisting and sharing the care of their relative and the records indicate that the nursing staff were as concerned and caring for this close relative as they were for the patient.

There were many incidences of documented evidence of very good care; however, there

were a few incidences of care which caused concern. One example is a patient who had a very specific health need which required a specific intervention. The ward did not know how to manage this intervention and asked the family to do this intervention for them. They did seek limited help from another department but when this help was not forthcoming they reverted to the family. The care was not delivered and caused the patient, as documented in the records, to have undue swelling and increased discomfort.

There was no evidence of any lack of investigation or treatment or discrimination because of people's age or complex medical needs or past medical history. There were examples of ongoing active investigation and treatment when terminal illness was clearly established and the patients' families had been made aware of the poor prognosis. We feel that such interventions were, on occasions, unnecessarily intrusive and futile.

There was little documented evidence to illustrate the extent that patients were routinely involved in decision-making about their treatment or prognosis. There were a few exceptions to this, and it must be acknowledged that the majority of the patients were very seriously ill, frail and some had advanced dementia.

The technical nursing care appears to be delivered well but there appeared to be little recognition of how retched or sore or generally debilitated a patient might feel during an episode of CDI.

There appeared to be little consideration in the records of the complexity of the patients multiple conditions and the domino effect of having complex past medical history, complex acute medical conditions on admission with an overburden of CDI compounded by old age and general frailty. In addition there was little evidence that staff anticipated the possible complications of CDI and planned care to prevent the suffering caused by them. This concern is supported by the variable attention to assessments and care plans of wider aspects of the patients needs (including weight, nutrition, falls etc) This did not appear to be documented, although that does not mean to say that it was not considered.

It was evident in a few cases that patients were assessed as medically fit for discharge when they still had diarrhoea or they had a bout of diarrhoea less than 24 hours earlier. This did appear to occur more when people were being moved back to care homes.

Notwithstanding these comments, the overall impression was that the medical interventions and the clinical nursing care for all medical conditions including CDI in the majority of patients (around 80%) was satisfactory.

11. Qualifications / Limitations of the findings in relation to Quality of Care

The examination of records in isolation of knowledge of the patient's experience or specific concerns, means that records can only be examined against collective requirements or professional standards. This report is only able to give general subjective opinions in respect of the quality of care as documented in the records, and give a collective overall opinion. Some readers may see the information as a reflection of their experience while others may have either more negative or more positive experiences. Equally, some staff may feel negative comments made are unfair as their personal professional practice is not reflected, while others on reflection accept the criticism offered.

The 34 domains required examination of a wide variety of care issues. The impressions of whether the records were complete partially complete, not present or not relevant were in themselves subjective categories, and could not be standardised in respect of every patient record. Thus an overall standard of what could be expected to be found was agreed between the reviewers.

Our opinions have been formed solely by the evidence we gleaned from reviewing the casenotes. We did not meet with or speak to any relatives of deceased patients or hospital staff member(s) or have any knowledge of any specific concerns relating to the care of individual patients.

The necessarily qualitative nature of these findings is a limitation, something we readily acknowledge. In the main it is not possible for us to comment specifically about the quality of care provided to individual patients. The qualitative nature of the data, the lack of consistency in recording, the variation of documentation used both within and between hospitals and the complexity of the quality of care indicators make it difficult for us to make other than general comments in this report.

12. Conclusions & Key points

Cause of Death / Term of Reference 1

- In reviewing the 124 patients who died each of whom was *C difficile* toxin positive we conclude that CDI was the cause of death in 15 (12%) and contributed to death in 16 (13%) of the 124 patients.
- Not only were the vast majority of the patients elderly but many were also seriously ill with other medical pathology. We estimate, having scrutinised the patients' case notes in some detail, that the expected survival, if they had not contracted CDI, was less than a month in 32 (26%) of the 124 patients reviewed. Indeed only 6 (5%) of the overall group were considered likely to survive beyond twelve months.
- The patients reviewed were very frail and dependent as reflected by the fact that as many as 89 (72%) of the 124 patients were deemed to be 'totally dependent' at the time of their CDI diagnosis and only 7 (6%) were considered to be 'fully independent' when their CDI was first diagnosed.
- The CDI was considered to be hospital acquired in 87 (70%) of the 124 cases and to be community acquired in 37 (30%) of cases. Thus three patients in ten diagnosed with CDI were considered to have acquired the infection in the community.
- When defining 'Community Acquired' it is likely that older patients admitted from Care Homes represent a different cohort to those admitted from their own homes

Quality of Care / Term of Reference 2

- Overall quality and appropriateness of the medical and technical nursing care for CDI was satisfactory
- The antibiotic therapy policy was adhered to
- Pressure ulcer prevention management was good
- Multidisciplinary records in Antrim Hospital were good
- Most records were fully legible, but essential assessments, systematic documentation, record keeping and legible writing need to be improved
- Communication was variable
- Records of infection prevention information being given to families was poor
- The Integrated Care Pathway for the dying was not always identified or commenced when it should have been
- Nursing assessment, management and care plans could be streamlined to identify the wider nursing needs in the care of CDI-and reflect the essential and

- Given the associated risks, the decision to prescribe antibiotics in a frail older population requires sound clinical reasoning and consideration. The rationale for initiating antibiotic therapy in this patient group should be clearly documented
- Investigations, treatment and medical interventions should be clinically indicated and the benefits and risks discussed with the patients in the first instance when possible and with their families

13. ■ Witness Statement to the Public Inquiry into the Outbreak of Clostridium Difficile in the Northern Trust Hospitals

Witness Names: Prof. George Griffin
Mrs Lynne Phair
Prof. Cillian Twomey

We hereby attach a report dated _____ which forms our written statement of evidence to this Inquiry.

We declare that this statement is true and accurate to the best of our knowledge and belief.

Signed: - Prof. George Griffin

Mrs Lynne Phair

Prof. Cillian Twomey

Date: - 5th October 2010

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Annex 1.1 Forms A, B and C

Public Inquiry into the CDiff Outbreak in the Northern Health and Social Care Trust

Case Note Review – Form A

Name of Reviewer	Date of Review	
Hospital Case Reference Number	Date of Birth/...../.....	Date of Death/...../.....
Date of last Admission		
Admitted from	Home/ Care Home/ Other Hospital	
Died in	Antrim Area Hospital/ Mid Ulster Hospital/ Moyle Hospital/ Braid Valley Hospital/ Whiteabbey Hospital/other location	
Date CDAD symptoms commenced/...../.....	
Date confirmed from laboratory testing/...../..... Ribo Type.....	
CDAD source	Community/Hospital	
Other Diagnoses at time of diagnosis of CDAD.		

Clinical Summary	
How would you rate the patient's condition on admission or just before the CDAD occurred; which ever is later?	<ul style="list-style-type: none"> • The patient had an acute or chronic condition expected to be fatal within 1month. <input type="checkbox"/> • The patient had an acute or chronic condition expected to be fatal within 1 - 12 months. <input type="checkbox"/> • The patient had an acute or chronic condition expected to be fatal in over 12 months. <input type="checkbox"/> • Insufficient data to categorise as above. <input type="checkbox"/>
How would you rate the patient's degree of Independence/Dependency on admission or just before the CDAD occurred; which ever is the later	<ul style="list-style-type: none"> • Independant/Selfcare <input type="checkbox"/> • Needs assistance with mobility <input type="checkbox"/> • Needs assistance with personal care <input type="checkbox"/> • Needs assistance with feeding <input type="checkbox"/> • Totally dependant <input type="checkbox"/>
On reviewing the patients notes would the evidence suggest that CDiff: -	<p>1. Was the underlying cause of death? Definitely / Probably/ Possibly/ Unlikely / No</p> <p>2. Contributed to this patient's death? Definitely/ Probably/ Possibly/ Unlikely/ No</p>

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Case Note Review – Form B

Name of Reviewer	Date of Review				
Hospital Case Reference Number	Date of Birth/...../.....	Date of Death/...../.....			
Appropriate Care for CDAD	<p>Clinical staff identify and document deteriorating condition</p> <p>Patient's nursing care needs are assessed regularly</p> <p>Nursing interventions match level of dependency i.e. frequency of observations/ vital signs.</p> <p>Patient is barrier nursed / transferred to side room or cohorted with other infected patients</p> <p>Staff recognise the importance of controlling infection</p> <p>CDiff assessment and review form is regularly reviewed</p> <p>Infection Control advice proforma informs clinical practice</p> <p>Braden completed</p> <p>Falls risk assessment</p> <p>Moving handling assessment</p>				

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Case Note Review – Form C

PATIENT DETAILS			
Hospital Case Reference Number	Date of Birth/...../.....	Date of Death/...../.....	
1.	<p>Consensus Cause of Death</p> <p>On reviewing the patients notes would the evidence suggest that CDiff: -</p> <p>1. Was the underlying cause of death? <div style="text-align: center;">Definitely / Probably/ Possibly/ Unlikely / No</div> </p> <p>2. Contributed to this patient's death? <div style="text-align: center;">Definitely/ Probably/ Possibly/ Unlikely/ No</div> </p> <p>If consensus not reached on one or any of the above, provide details on nature of disagreement: -</p>		
2.	<p>Cause of Death recorded on Death Certificate (<i>to be completed after consensus reached at point 1</i>)</p> <p>1. (a) _____</p> <p style="padding-left: 20px;">(b) _____</p> <p style="padding-left: 20px;">(c) _____</p> <p>2. _____</p>		
3.	<p>Is the consensus cause of death at item 1 significantly different from the cause of death recorded on the death certificate noted at item 2? Yes/No</p> <p>If yes, please comment.</p>		
4.	Reviewer	Signature	Date
	Prof George Griffin		
	Prof Cillian Twomey		
	Ms Lynne Phair		