

**PUBLIC INQUIRY INTO THE OUTBREAK OF CLOSTRIDIUM DIFFICILE IN  
NORTHERN TRUST HOSPITALS**

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**WITNESS STATEMENT OF DR MICHAEL MCBRIDE**

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**I, Michael McBride, aged over eighteen years, pursuant to a written request dated 21<sup>st</sup> July from the Public Inquiry into the Outbreak of *Clostridium Difficile*, make the following statement:-**

1. I am the Chief Medical Officer of the Department of Health, Social Services and Public Safety, (hereinafter referred to as “the Department”), Castle Buildings, Stormont, Belfast, BT4 3SQ.
2. I took up the position of Chief Medical Officer with the Department on 11 September 2006. Prior to that, I was Medical Director for the Royal Hospitals, Belfast.
3. The *Clostridium Difficile* Inquiry has asked that I address the following topics:-
  - (i) The role and importance of death certification in Public Health.
  - (ii) How deaths, epidemics and health trends are monitored in Northern Ireland.
  - (iii) The role of death certification in the management of epidemics or outbreaks of infectious disease, and in particular, of Healthcare Acquired Infections.
  - (iv) The role and importance of death certification in the outbreak of *C.difficile* infection in hospitals of the Northern HSC Trust in 2007-08. Please address the accuracy and timeliness of the information from this source.

- (v) Explain why you issued Circular HSS (MD) 3/2008 on 8 February 2008. Did it achieve its objectives?
- (vi) Comment on Circular HSS (MD) 10/2008 and on changes to the death certification process that might improve the management of outbreaks of Healthcare Acquired Infections.

**(i) The role and importance of death certification in Public Health**

4. The death certification system is of considerable age. The certification process has its origins in the first half of the nineteenth century. For the last sixty years the death certification process in England, Wales, Scotland and Northern Ireland has remained largely unchanged. Later in my statement in Section (vi) in paragraphs 57-61, I describe an interdepartmental review into the death certification process in Northern Ireland which commenced in 2008.
5. The death certification system in Northern Ireland is very similar to that in England and Wales and the layout of the medical certificate of cause of death (MCCD) is in line with World Health Organisation Guidelines. If an infection was part of the sequence of events that led directly to the death, this should be recorded in part I of the MCCD. If the infection contributed, but was not part of this direct sequence leading to death, this should be written in part II of the MCCD.
6. Death certification serves a number of functions. A MCCD enables the deceased's family to register the death. This provides a permanent legal record of the fact and cause of death and enables the family to make funeral arrangements, and to start to administer the deceased's estate.
7. Statistical information on deaths by underlying cause is important for monitoring the health of the population, designing and evaluating public

health interventions, recognising priorities for medical research and health services, planning health services, and assessing the effectiveness of those services. Information from MCCDs is used to measure the relative contributions of different diseases to mortality.

8. By law all deaths occurring in Northern Ireland must be registered with the General Register Office (“GRONI”). To register a death a MCCD issued by a doctor who has treated the deceased within twenty-eight days before the date of death must be presented to the registrar. A death should be registered no later than five days from the date of death except where the matter has been referred to the Coroner. If the deceased had not been seen by a doctor within twenty-eight days before the date of death or where the death was not caused by natural illness the case should be referred to the Coroner.
9. It is a legal responsibility on the medical profession under the Births and Deaths Registration (Northern Ireland) Order 1976 that one of the doctors responsible for the patient’s care during their last illness is required to complete a MCCD ‘to the best of his knowledge and belief’. In this as in other matters doctors are subject to regulation by the General Medical Council.
10. Under section 7 of the Coroners Act (Northern Ireland) 1959 there is a statutory duty to give information to the coroner. That duty extends, among others, to medical practitioners and organisations (in the Act described as “every person in charge of any institution or premises in which a deceased person was residing”) and requires notification to the Coroner where there is reason to believe that the deceased person died, either directly or indirectly from any cause other than natural illness or disease. This includes deaths directly or indirectly due to violence,

misadventure, negligence, misconduct, malpractice, misuse of drugs, apparently suicidal deaths or deaths from industrial disease.

11. Training on the completion of a MCCD and the referral to the Coroner is given during the undergraduate medical course. In addition it is included in the induction training of newly qualified doctors entering the Foundation Programme (F1) in Northern Ireland. This F1 training has been provided over the past 3 years by a Departmental Medical Officer or the Medical Officer to the Coroners Service for Northern Ireland and is reinforced by a mandatory electronic module.

**(ii) How deaths, epidemics and health trends are monitored in Northern Ireland**

12. As part of my Annual Report on the health of the population of Northern Ireland, I publish a set of core tables which include annual and trend data on the population, births and deaths as well as uptake of cancer screening programmes, childhood vaccination programmes and notifications of communicable diseases.

***The Northern Ireland Statistics and Research Agency***

13. The Northern Ireland Statistics and Research Agency, (“NISRA”), the parent Agency of the General Register Office for Northern Ireland (“GRONI”), is the government agency responsible for statistical analysis of the information collected at death registration. Section 51 of the Health and Personal Social Services Act (Northern Ireland) 2001 allows the Registrar General for Northern Ireland to share this information with the Department.

14. At the end of each calendar year NISRA publish the Annual Report of the Registrar General which includes finalised figures of the causes of death

in the previous year including the number of deaths which mention *Clostridium difficile* and the number which have *Clostridium difficile* as the underlying cause. Detailed statistical tables are presented as a supplement to the report and are available on the NISRA website ([www.nisra.gov.uk](http://www.nisra.gov.uk)). In March each year, NISRA produce the Annual Deaths Press Release which gives provisional data for the previous year, this release includes the number of death certificates that mention *Clostridium difficile* related deaths. NISRA also produce the Registrar General's Quarterly Reports which give birth and death information for the previous quarter and this also includes the number of *Clostridium difficile* related deaths.

15. Since 2001, in line with the rest of the UK, the Tenth Revision of the International Statistical Classification of Diseases, Injuries and Causes of Death (ICD10) is used to classify cause of death in Northern Ireland.

### ***Difficulties in the recording and coding of Clostridium difficile Deaths***

16. *Clostridium difficile* causes a range of clinical illnesses with enterocolitis being its most common manifestation. The ICD10 code used for “enterocolitis due to *clostridium difficile*” is A04.7. Pseudomembranous colitis is a complication of antibiotic therapy often caused by *Clostridium difficile* infection which causes severe inflammation in areas of the colon. Since 2006 pseudomembranous colitis has also been coded to A04.7.
17. The Tenth Revision of the International Classification of Diseases (ICD-10) does not include a specific code for *Clostridium difficile* infection itself, therefore for causes other than enterocolitis that are also known to be associated with *Clostridium difficile*, it is not possible to identify from ICD codes alone the number of deaths where *Clostridium difficile* may have contributed to the death.

18. However NISRA has been able to identify additional deaths in which *Clostridium difficile* was mentioned on the death certificate but not coded as A04.7 by examining, both electronically and manually, the cause of death written by the doctor on the MCCD. To identify deaths where *Clostridium difficile* was the underlying cause of death (or deaths where *Clostridium difficile* was mentioned) the other ICD10 codes used are A09, A41.4 and A49.8 (See Table 1). The text of these records is then searched manually for mentions of *Clostridium difficile*, *C.difficile* or pseudomembranous colitis.

19. For example if *Clostridium difficile* infection was part of the sequence leading directly to death, it should be in part I of the MCCD, which should be in the sequence of events back to the original disease being treated. If the patient had *Clostridium difficile* which was not part of the direct sequence leading to death, but which contributed at all to the death, it should be mentioned in part II of the MCCD.

**Table 1: Definition of ICD10 codes used to identify deaths where *Clostridium difficile* was the underlying cause of death. (Source: WHO International Statistical Classification of Diseases and related health problems. Tenth Revision, 1992)**

<b>ICD10 code</b>	<b>Definition of code</b>
<b>A04.7</b>	<b>Enterocolitis due to <i>Clostridium difficile</i></b> Foodborne intoxication by clostridium difficile Pseudomembranous colitis
<b>A09</b>	<b>Diarrhoea and gastroenteritis of presumed infectious origin</b> Note: In countries where any term listed in A09 without further specification can be assumed to be of noninfectious origin, the condition should be classified to K52.9.

	<p>Catarrh, enteric or intestinal</p> <p>Colitis {NOS</p> <p>Enteritis {haemorrhagic</p> <p>Gastroenteritis {septic</p> <p>Diarrhoea:</p> <ul style="list-style-type: none"> <li>· NOS</li> <li>· dysenteric</li> <li>· epidemic</li> </ul> <p>Infectious diarrhoeal disease NOS</p> <p>Excludes: due to bacterial, protozoal, viral and other specified infectious agents ( <a href="#">A00-A08</a> )</p> <p>noninfective diarrhoea ( <a href="#">K52.9</a> )</p> <ul style="list-style-type: none"> <li>· neonatal ( <a href="#">P78.3</a> )</li> </ul>
<b>A41.4</b>	<p><b>Septicaemia due to anaerobes</b></p> <p>Excludes: gas gangrene (A48.0)</p>
<b>A49.8</b>	Other bacterial infections of unspecified site

**Table 2: Number of deaths with *Clostridium difficile* mentioned and recorded as the underlying cause on the death certificate by registration year, 2001-2009<sup>P</sup>. (Source: NISRA)**

Cause of Death	Registration Year									Total (2001-2009) <sup>P</sup>
	2001	2002	2003	2004	2005	2006	2007	2008	2009 <sup>P</sup>	
<b><i>Clostridium difficile</i> mentioned on the death certificate</b>	15	26	34	44	35	63	77	191	124	<b>609</b>
<b>Of which</b>										
<b><i>Clostridium difficile</i> is the underlying cause of death</b>	8	12	17	20	18	41	34	64	39	<b>253</b>
<b>Underlying cause as a percentage of all mentions</b>	53%	46%	50%	45%	51%	65%	44%	34%	31%	<b>42%</b>

<sup>P</sup>- Provisional data

20. As demonstrated in Table 2, from 2001-2007 there was a gradual increase in the number of deaths with *Clostridium difficile* recorded on the death certificate. It is not completely clear what was responsible for these increases. Suggestions have included: improved detection and reporting, together with a real increase in the incidence of infection; an increasing propensity for doctors to mention *Clostridium difficile* on death certificates where this was diagnosed before death; and an increase in the severity of some *Clostridium difficile* infections.

21. Between 2007 and 2008, the number of deaths with *Clostridium difficile* recorded on the death certificate more than doubled from 77 to 191 deaths. In part this was due to the outbreak in the Northern HSC Trust; it may also reflect raised awareness of the importance of *Clostridium difficile* as a diagnosis in its own right compounded by the publicity and circulars during the outbreak. Since reported cases of infection (Table 3) did not show a similar increase to recorded deaths, this may support the view that doctors were more aware of the need to record *Clostridium difficile* on MCCDs.

### **Monitoring General Health Trends**

22. In terms of monitoring general health trends, Information and Analysis Directorate within the Department is responsible for the collection, validation and publication of a range of statistical data including: outpatient activity, inpatient activity, emergency care, mental health, children in need, looked after children, domiciliary care, health inequalities, the Quality and Outcomes Framework and population survey data. As with the statistical information on deaths by underlying cause, these data are used to inform policy formulation, planning of health and social care services and evaluation of those services.

## ***Monitoring of Infectious Diseases***

23. The Communicable Disease Surveillance Centre (Northern Ireland) (CDSC) was established by the Department in 1999 primarily to monitor the changes in incidence, prevalence and patterns of infectious disease. In 2001 the Department established the Healthcare Associated Infection Surveillance Centre (HISC) to assist acute hospitals in Northern Ireland to undertake healthcare associated infection surveillance. These two legacy surveillance units have now been integrated into the regional Health Protection Service in the Public Health Agency (PHA).
24. Since April 2009, when the PHA was established by the Department, its Health Protection Service has delivered and maintained a range of surveillance systems. These systems have been designed to regularly monitor the occurrence of a variety of infectious diseases across Northern Ireland and to facilitate early detection of any new outbreak or epidemic. Specialist surveillance and information staff monitor and scrutinise the surveillance systems and identify unusual disease patterns or occurrence. These are reported to Health and Social Care (HSC) colleagues and to the Department for appropriate further action.
25. Surveillance and outbreak data are published in a monthly bulletin and reports which are publically available on the PHA and legacy organisation websites. ([www.publichealth.hscni.net](http://www.publichealth.hscni.net); [www.cdscni.org.uk](http://www.cdscni.org.uk)).
26. Surveillance systems for Northern Ireland are closely aligned with and regularly report to national (United Kingdom) surveillance programmes, for example seasonal and pandemic influenza surveillance. National and international linkages are vital to ensure Northern Ireland surveillance systems are robust and intelligence attained through surveillance is delivered to HSC colleagues in a timely fashion. National and International linkages include the Health Protection Agency, London, the Health

Protection Surveillance Centre, Dublin, and the European Centre for Disease Control, Stockholm.

27. The Health Protection Service also closely monitors the uptake and coverage of childhood and influenza immunisation programmes. Ongoing review of vaccine coverage and uptake is then linked with surveillance of vaccine preventable diseases to inform targeted interventions.

### ***Monitoring of Health Care Associated Infections***

28. There are a number of mandatory Healthcare Associated Infection (HCAI) surveillance programmes in Northern Ireland. Mandatory reporting of MRSA commenced in April 2001. Mandatory surveillance for *Clostridium difficile* began on 1 January 2005 based on laboratory reports of *Clostridium difficile* toxin detected in hospitalised patients over 65 years. A similar scheme started in England in 2004. During 2005 laboratories changed their testing procedures to conform to new national guidelines. Thus 2006 was the first year with all laboratories using identical testing methods and interpretation of 2005 *Clostridium difficile* data should be undertaken with caution. (See Table 3) Surveillance of *Clostridium difficile* in Northern Ireland before 2005 relied on laboratory reports of *Clostridium difficile* toxin detected in patients of all ages. This was a voluntary reporting system so reporting may not have been complete. The target age group included in mandatory *Clostridium difficile* surveillance was extended in April 2009 to include all patients over the age of 2 years old.

**Table 3: *Clostridium difficile* and MRSA infections in Northern Ireland in the period from 2006 until present. (Source: Public Health Agency)**

	2006	2007	2008	2009	% reduction since 2006
<i>C. difficile</i> *	1073	997**	989**	559	54.1
MRSA	246	229	208	164	44.4

\* Hospital in-patients aged 65 and over.

\*\* Period includes most of the period of the outbreak in Northern Trust hospitals.

29. The initial focus of HISC was on surveillance of infection in orthopaedic in-patients and now also includes caesarian section surgical site infection surveillance. Since 2008, HISC has had an enhanced role in the surveillance of HCAs. HISC provides Trusts with baseline information on the prevalence of HCAs in acute hospitals; facilitates and assists with Device-Associated Infection Surveillance, and publishes the results for repeat HCAI prevalence surveys and device-associated infection surveillance via a secure web-based analysis tool.

30. In addition to these ongoing surveillance programmes, Northern Ireland has participated in three national prevalence surveys of the overall levels of HCAI. The most recent Prevalence Survey of Healthcare Associated Infection in Acute Hospitals in the United Kingdom and Ireland (excluding Scotland) was published in October 2006. It found that Northern Ireland with a 5.5% rate had a lower prevalence than England with 8.2% and Wales with 6.3%. The overall prevalence of 7.6% of adult patients with an infection was found to be lower in 2006 than the previous figure of 9% in 1993/4. The full survey can be found at the Hospital Infection Society website. ([www.his.org.uk](http://www.his.org.uk))

### ***Changes in the monitoring of Clostridium difficile infections***

31. Before February 2008, monitoring of *Clostridium difficile* and MRSA trends relied on internal unvalidated weekly surveillance reports and the quarterly analysis of validated data which was produced 3 months after each quarter end and also published annually. The weekly surveillance report compiled by the CDSC was used to make Trusts aware of increased reporting of MRSA or *Clostridium difficile* episodes at an early stage, whilst the quarterly surveillance report was used to monitor trends.

32. On 5 February 2008 I asked the CDSC to commence the public reporting of quarterly surveillance reports on *Clostridium difficile*. On 12 February the CDSC advised me that it would be possible to commence the earlier publication of quarterly surveillance reports at six (rather than twelve) weeks after the quarter to which they relate.
33. Since 2008 there have been a number of other significant developments in HCAI surveillance programmes to monitor trends and identify outbreaks. Developments include introduction of the regional Health Care Associated Infection web based surveillance system for more timely reporting of MRSA, Meticillin-sensitive *Staphylococcus Aureus* (MSSA) and *Clostridium difficile* infections; establishment of a *Clostridium difficile* ribotype surveillance programme; new monthly Health Care Associated Infection monitoring reports issued to Trusts (15-18 days after month end); and recently introduced enhanced surveillance of *Clostridium difficile* cases in the community.

**34. Table 4: Total *Clostridium difficile* reports in Northern Ireland, by source (Patients ≥ 65 years) (Source: PHA)**

Year	Total 'community' <sup>3</sup>	Total 'inpatient'	NI Total
<b>2005</b> <sup>1</sup>	92	1032	1,124
<b>2006</b>	115	1073	1,188
<b>2007</b>	147	997	1,144
<b>2008</b>	299	989	1,288
<b>2009</b>	222	559	781
<b>2010</b> <sup>2</sup>	75	219	294

<sup>1</sup> This surveillance programme started on 1 January 2005 and during that year laboratories changed their testing methodology to conform to new national guidelines. Therefore, 2006 was the first year with all laboratories using identical testing methods and interpretation of 2005 data should be undertaken with caution.

<sup>2</sup> Data for 2010 up to June 2010.

<sup>3</sup> (For the purpose of mandatory surveillance a community episode of *Clostridium difficile* refers to an episode recorded from a GP, nursing home and other non-acute settings.)

### **Monitoring of different strains of *Clostridium difficile***

35. More than a hundred different strains of *Clostridium difficile* have been identified. Strains can be differentiated using a molecular technique known as PCR ribotyping, and this can help establish potential linkages between cases. The Regulatory and Quality Improvement Authority (RQIA) Independent Review Team found that the Northern HSC Trust outbreak of *Clostridium difficile* could be mainly accounted for by the emergence of ribotype 027 which had not previously been identified in Northern Ireland. From September to December 2006 a snapshot *Clostridium difficile* ribotype survey was carried out and analysed by the Health Protection Agency Anaerobic Reference Laboratory Cardiff to assess circulating *Clostridium difficile* ribotypes in Northern Ireland. Sixty *Clostridium difficile* isolates were ribotyped and no *Clostridium difficile* 027 was found. A further snapshot survey was completed at the end of 2007 and analysed by the Health Protection Agency CDRN Reference Laboratory Leeds, and this identified the emergence of *Clostridium difficile* 027 in Northern Ireland.
36. Timely provision of ribotyping is necessary for the work of infection prevention and control staff, including the detection of outbreaks and the management of patients with *Clostridium difficile* infection. This has been achieved through the introduction of the Northern Ireland Ribotyping Service for all *Clostridium difficile* episodes. This was introduced in 2009 at the request of the Department. Prior to 2009 specimens for ribotyping had to be sent to reference laboratories in England or Wales, this service is now provided by laboratories in the Belfast HSC Trust which has improved turnaround time and has optimized the identification of outbreaks. We now routinely ribotype all *Clostridium difficile* episodes (in

other Administrations up to 10% of *Clostridium difficile* episodes may be typed).

### ***Community episodes of Clostridium difficile***

37. We continue to develop and enhance *Clostridium difficile* surveillance in response to improvements in technology or changes in trends or patterns of disease as they emerge. For example in response to the recognition of increasing numbers of patients who develop the onset of *Clostridium difficile* associated diarrhoea within the first 48 hours of admission to hospital and in specimens submitted from community settings (Table 4), in 2010 the PHA has established new arrangements for enhanced surveillance of community episodes. *Clostridium difficile* episodes identified in the community may have recently been discharged from hospital and/or be in receipt of other healthcare interventions. The enhanced surveillance ensures that this information is now recorded for all community *Clostridium difficile* cases.

### **(iii) The role of death certification in the management of epidemics or outbreaks of infectious diseases, and in particular, of Healthcare Acquired Infections**

38. Given its primary purposes (see paragraph 6), there are significant limitations to how useful death certification can be in helping to manage an epidemic or an outbreak of an infectious disease, especially when healthcare responses are time-critical. Although a measure of disease severity, one obvious but important limitation of MCCD data – however robust – in these contexts is that fatal cases will be a subset of the total cases. Other data sources will be much more reliable indicators of prevalence and the progress of the epidemic or outbreak.

39. A number of factors will determine how useful death certification data will be in a given epidemic or outbreak. For example, in the event of a protracted epidemic with a high death rate that is geographically dispersed, death certification data may be useful in monitoring its progress and identifying pockets of concentration or areas of lesser prevalence. In the case of a short outbreak of a disease within a single hospital, MCCD data may be of little practical value to healthcare staff in managing the outbreak. By comparison with the onset of clinical symptoms such as diarrhoea, for example, which would prompt the immediate isolation of the patient, information taken from MCCDs, even when provided weekly, will lag behind more obvious and more immediate evidence and indicators.

40. The demonstrable accuracy and the timeliness of death certification information are more important in terms of public awareness, understanding and confidence than for the immediate practical demands of containing and ending an outbreak or epidemic.

41. Given that what is recorded on the MCCD is a matter of clinical judgment, confidence in death certification will both influence and reflect confidence in clinical judgment more generally.

**(iv) The role and importance of death certification in the outbreak of *C.difficile* infection in hospitals of the Northern HSC Trust in 2007-08. Please address the accuracy and timeliness of the information from this source.**

42. My general comments in Section (iii) paragraphs 38-39 on the utility and suitability of MCCD data in managing an epidemic or an outbreak are illustrated by the experience of the Northern HSC Trust outbreak. During this outbreak the need for reliable, timely data on deaths – whether from MCCD or other records – was especially important in the context of

meeting the concerns of relatives, the wider community and elected representatives.

43. In the outbreak in Northern HSC Trust, where there were a significant number of deaths, to maintain public confidence, it was essential to communicate timely and accurate data on deaths and the scale and gravity of the problem. By the time patients who had had *Clostridium difficile* infection died, they may have had a number of diseases and complications of illness or treatment during the preceding days, weeks or months. As a result there had to be an element of clinical judgment in deciding to what extent, if any, *Clostridium difficile* had contributed to the death and what to record on the MCCD. The HSC Trusts and the Department also were not in a position to provide real time information on deaths, validated by NISRA related to *Clostridium difficile* and this led to public concern. In consequence the Department asked NISRA to carry out an immediate exercise to produce figures on the number of cases where *Clostridium difficile* was mentioned on a death certificate during 2007 throughout Northern Ireland. Furthermore in March 2008 it was agreed that NISRA would provide weekly monitoring of *Clostridium difficile* and Meticillin-resistant *Staphylococcus Aureus* (MRSA) deaths. I refer the Inquiry to my comments in this regard at paragraphs 53-55.

44. I issued circular HSS(MD)3/2008 in response to a request from the Northern HSC Trust, and also to ensure consistency in the approach to completing a MCCDs across the five HSC Trusts.

45. Given the level of public concern during this particular outbreak, it was essential that public confidence in the management of outbreaks and the safety of our health system was and continues to be maintained. That confidence must of course be based on reality, so both surveillance figures and MCCD information are crucial for this purpose.

**(v) Explain why you issued Circular HSS (MD) 3/2008 on 8 February 2008.**

**Did it achieve its objectives?**

46. On 7 February 2008, the Deputy Chief Medical Officer and the Chief Nursing officer met with the Northern HSC Trust's Outbreak Control Team. At this meeting there was discussion on the requirement to have specific regional guidance regarding the completion of the MCCD for a patient who has had *Clostridium difficile* associated diarrhoea and has died. Dr Elizabeth Mitchell, Deputy Chief Medical Officer, undertook to discuss this matter with myself with a view to having regional guidance sent out in the very near future.

47. On 8 February I issued HSS (MD) 3/2008 on *Guidance for Doctors certifying Cause of Death Involving Healthcare Associated Infection*. I issued this circular in response to the request made at the previous day's meeting. The aim of the circular was to clarify the purpose of a MCCD and to reiterate the importance of providing clear, accurate and complete information about the disease or conditions that caused or contributed to the patient's death.

48. In this circular, I also highlighted the importance of less experienced doctors in HSC Trusts discussing with a consultant the completion of the MCCD for a patient who has had *Clostridium difficile* associated diarrhoea and has died, to ensure that the MCCD is completed accurately to reflect all the contributing causes. It is a matter of clinical judgment to decide whether a condition present at or just before death contributed to the patient's death and therefore the only safeguard is the training provided to doctors and the recommendation for less experienced doctors to discuss the MCCD completion with a consultant or senior clinician.

49. This circular was issued to address a request from the Northern HSC Trust to provide further guidance and I have no reason to believe that this circular did not achieve its objectives. As shown in Table 2 and discussed in paragraph 21, the number of deaths where *Clostridium difficile* was recorded on the death certificate more than doubled between 2007 and 2008. Since reported cases of infection did not show a similar increase to recorded deaths, this may support the view that doctors were more aware of the need to record *Clostridium difficile* on MCCDs.

**(vi) Comment on Circular HSS (MD) 10/2008 and on changes to the death certification process that might improve the management of outbreaks of Healthcare Acquired Infections.**

50. On 18 March 2008, I wrote to Chief Executives of Trusts and Boards, Medical Directors of Trusts, Directors of Public Health and Consultants in Communicable Disease Control regarding enhanced monitoring arrangements for deaths in Trusts where *Clostridium difficile* or MRSA infection is mentioned on the death certificate.

51. I wrote to confirm arrangements which were agreed between the Department, NISRA, Central Services Agency (as it then was) and the Medical Director in each of the Trusts in relation to monitoring of deaths where *Clostridium difficile* or MRSA infection is mentioned as a cause of death.

52. On 1 April 2008 these new arrangements came into place which aimed to support Trusts in their ability to monitor deaths occurring in their Trust where these HCAs are mentioned on the death certificate, and to allow for more frequent regional reporting where these infections were mentioned as a cause of death.

53. In March 2008 it was agreed that NISRA would provide weekly monitoring of *Clostridium difficile* and Meticillin-resistant *Staphylococcus aureus* deaths, to allow any increases to be identified early. As previously mentioned in paragraph 18, the monitoring is completed using a text search on MCCDs, and is based on date of registration rather than date of death. The information including the person's name, date and place of death and normal address is then sent to the Business Services Organisation (originally sent to Central Services Agency prior to Review of Public Administration) which then sends the relevant data to each Trust.

54. NISRA also generate a monthly summary of case numbers but without patient identification, which is shared with Public Health Agency and the Department.

55. I have discussed the system with NISRA and they report that Trusts check the data from the weekly reports, and that the system appears to be working well. They note there will be some differences between the weekly data and final annual information following formal screening.

### **Interdepartmental Review of Death Certification in NI**

56. In 2003 the Shipman Inquiry (see 3<sup>rd</sup> Report "Death Certification and Investigation of Deaths by the Coroner") and the Luce Review of Death Certification and Investigation reported that the current death certification process in England and Wales was confusing and inadequate. The remit of the Luce Review extended to Northern Ireland, and included specific recommendations in relation to death certification processes in Northern Ireland.

57. An inter-Departmental review of the death certification process in Northern Ireland commenced in 2008 to address recommendations arising from the

Shipman Inquiry's Third Report and the Luce Review. The review involves 3 Departments – The Department of Health, Social Services and Public Safety, The Department of Finance and Personnel (responsible for registration of deaths) and The Department of the Environment (responsible for regulation of council-owned cemeteries and crematoria), and aims to increase public assurance and improve the quality of death data for statistical analysis to better inform planning for future service delivery. An informal inter-Departmental Steering Group and Working Group comprising key stakeholders was established in 2008, and the Minister for Health, Social Services and Public Safety subsequently approved this work moving to a formal basis in February 2009. I co-chaired the Steering Group meetings alongside the Registrar General.

58. The remit of the Working Group was to develop proposed options for the future strategic direction of death certification in Northern Ireland in the light of the findings of the Shipman Inquiry and the Luce Review, and to recommend options for public consultation. The recommended options were to meet the following requirements:
- a. Provide a unified system for death certification irrespective of the method of disposal of the body;
  - b. Enable adequate and independent medical scrutiny of all death certificates to identify and deter criminal activity or malpractice;
  - c. Ensure that adequate and effective clinical governance arrangements are in place to identify suspicious causes of death;
  - d. Facilitate improved analysis of all deaths to help inform policy on public health;
  - e. Involve no fundamental change to the MCCD; and
  - f. Impose no undue delays on bereaved families.

59. The Working Group produced a report in October 2009 which recommended two options for future death certification arrangements in Northern Ireland, with an initial transitional model to be followed at a later stage by the introduction of a more comprehensive model. This report was approved by the Death Certification Steering Group and the Departmental Management Board, and in July 2010 the Minister for Health, Social Services and Public Safety approved the recommendations. Simultaneous submissions have been made to the Ministers of the other Departments involved, and the Minister of Finance and Personnel and the Minister of the Environment have indicated they are also content with the recommendations.

60. In light of the cross-Departmental nature of the review, the proposals will be brought to the Northern Ireland Executive to seek its approval to proceed to public consultation. The proposals will also be copied to the Health Committee for information. Subject to receiving the necessary approvals, it is planned to launch a public consultation by November 2010.

61. The public need to have confidence in our health service and trust in the health professionals and organisations who provide those services. They need to have confidence in what we do day to day and to be assured that we can respond to any new threat or challenge as it arises. This confidence and trust must be informed, earned and maintained by what we do, how we behave and what we say. Openness and transparency and the credibility and validity of the information we present to the public is central to this.

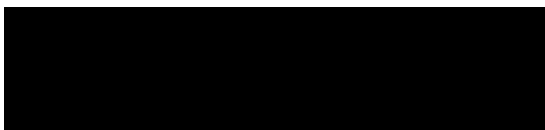
## **Conclusion**

62. The outbreak of *Clostridium difficile* in the Northern HSC Trust was a tragedy for the patients directly affected, and their relatives. It also resulted in huge demands on all staff in the organisation in very

challenging circumstances. As a healthcare system it is vital that we learn from that experience and we have sought to do so.

**I confirm that the contents of this statement are true.**

**Signed: \_\_\_\_\_**



**Dr Michael McBride, Chief Medical Officer**

**Department of Health, Social Services and Public Safety**

**3 September 2010**