The Vale of Leven Hospital Inquiry Report

The Rt Hon Lord MacLean
Chairman

Executive Summary

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under section 26 of the Inquiries Act 2005.

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Contents

Chairman's letter to the Cabinet Secretary

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Cabinet Secretary for Health and Wellbeing
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November 2014

Dear Cabinet Secretary

On 21 August 2009, I was appointed by the then Cabinet Secretary for Health and Wellbeing to hold a public inquiry into the occurrence of *Clostridium difficile* infection at the Vale of Leven Hospital from 1 January 2007 onwards, in particular between 1 December 2007 and 1 June 2008, and to investigate the deaths associated with that infection.

The Terms of Reference were very wide-ranging and I have addressed these, I hope, comprehensively, as can be seen from the Report which I now present to you.

Yours sincerely,

RNM MacLean

Rt Hon Lord MacLean
Chairman

Foreword

The evidence adduced by the Inquiry was concluded on 28 June 2012. In July 2012 I entered hospital for what was then regarded as a fairly routine operation. The operation itself was concluded successfully but shortly thereafter my condition began to deteriorate as a result of an infection of unknown aetiology which necessitated a prolonged period of intensive care and hospitalisation for a total of five months. I may say that the irony of this was not lost on me during the time I remained in hospital. The experience did, however, enable me better to understand the plight of those who suffered from *C. difficile* infection and in some cases died from it, in the Vale of Leven Hospital.

I narrate all this, not in anyway to evoke sympathy for myself but in order to pay tribute to the Inquiry team who responded so superbly to the crisis they then had to face, namely carrying on the work of the Inquiry effectively without its Chairman. A central core of the staff, made up of the Secretary, leading Counsel to the Inquiry, and its Principal Solicitor, visited me regularly in hospital, consulted me there, and received instructions from me. After my discharge from hospital the same work was carried on during my convalescence at home. In order to ensure that Mr Neil, the Cabinet Secretary who succeeded Ms Sturgeon, was aware of the predicament I was in, I wrote a personal letter to him on 17 January 2013. He replied to this letter on 21 March 2013 and from the terms of that letter I believe he ultimately came to understand the problems I had had.

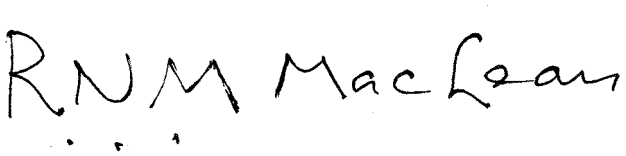
On 29 July 2009 I met the then Cabinet Secretary for Health and Wellbeing, Ms Nicola Sturgeon, in Glasgow. She thanked me for taking over from Lord Coulsfield. We discussed the terms of the remit. She was very keen on a time limit because, as she said, she wanted a short and sharp inquiry. She expected a report and recommendations on her desk by October 2010. In light of my previous experience as Chairman of two other Inquiries and membership of another (none of which had any time restriction) I demurred to such a time limit and explained that I did not consider it possible to fulfil the terms of such a wide remit within that time scale. I preferred a time limit of “as soon as possible”. The Cabinet Secretary, however, insisted, with the qualification that the Inquiry could always apply for an extension. I am clear that this was a mistake, for the reasons that are given more fully in the Report itself and summarised in the Introduction.

The result was that, as each so-called deadline approached and was not fulfilled, there was a familiar chorus of criticism from certain quarters. Significantly, none of it came from any representatives of Core Participants. Nevertheless, the Inquiry team had to face this criticism and respond to it as best they could, when, in my opinion, they were absolutely blameless.

If anything, the whole experience shows the futility of imposing time constraints on an Inquiry like this, simply because one cannot at the outset know what lies ahead of an Inquiry's investigation. My illness was just one aspect of this. Indeed, I doubt whether, unless in wholly exceptional circumstances, an Inquiry set up under the Inquiries Act should be limited in point of time.

I should add that, in my not inconsiderable experience, it is very rare to have such a cohesive and united unit as the entire Inquiry team. That is probably due to the quite exceptional skills of leadership demonstrated by the Secretary, Julie-Anne Jamieson who kept the show on the road, as it were, and maintained in the face of considerable difficulties, the high level of morale which has persisted to the end. She was exceptional.

I take this opportunity to express my gratitude to my single-minded and devoted Inquiry team. I am grateful to all those in the team who so faithfully assisted me.



Lord MacLean
November 2014

Introduction

Summary

Serious failures

Between 1 January 2007 and 1 June 2008, 131 patients who were or had been patients in the Vale of Leven Hospital (VOLH) tested positive for *Clostridium difficile* Infection (CDI). Of that number, 63 patients tested positive in the period from 1 December 2007 to 1 June 2008. During that particular period 28 of those 63 patients died with CDI as a causal factor in their deaths, either as the underlying cause of death or as a contributory cause of death. Another three patients who died in the course of June 2008 also had CDI as a causal factor in their deaths. In the period 1 January 2007 to 31 December 2008 the total number of deaths identified by the Inquiry in which CDI was a causal factor was 34. These figures are particularly damning when considered in the context of the VOLH, a hospital with around 136 beds in 2008.

CDI can be a devastating illness, particularly in the frail and elderly. It can lead to malnutrition and dehydration unless carefully managed. The frequency of diarrhoea, the impact upon patient dignity, and the challenges presented to staff are some of the factors that highlight the absolute necessity of treating CDI as a serious illness. Sadly, for reasons I set out in detail in this Report, there were deficiencies in medical and nursing care at the VOLH that seriously compromised the care of this group of patients. Furthermore, the infection prevention and control practices and systems were seriously deficient.

Governance and management failures resulted in an environment where patient care was compromised and where infection prevention and control was inadequate. The important principle of Board to ward and ward to Board means that there must be an effective line of reporting, accountability, and assurance. This was lacking for the VOLH. There were failures by individuals but the overall responsibility has to rest ultimately with NHS Greater Glasgow and Clyde (NHSGGC).

It is highly likely that there were a number of undeclared outbreaks of CDI transmission in the VOLH between 1 January 2007 and 1 June 2008. Many patients were exposed unnecessarily to CDI and had to suffer the humiliation and distress often associated with the infection.

Scottish Ministers have a duty to promote the improvement of the physical and mental health of the people of Scotland. The Scottish Government is the executive branch of government in Scotland. The duty to promote the health of the people of Scotland is discharged through Health Boards, particularly within the context of healthcare acquired infections such as CDI. There was a failure to have in place an inspection regime that could provide the necessary assurance that infection prevention and control was being properly managed and important policies and guidance implemented.

Inadequate attention was given by the Scottish Government and NHSGGC to the reports about other outbreaks in the United Kingdom. These identified failures similar to many of the failures at the VOLH discovered in the course of the Inquiry. Repeated warnings over a number of years about the importance of prudent antibiotic prescribing had no apparent impact. The Scottish Government failed to monitor the implementation of the prudent prescribing message and to remedy the failure by NHSGGC to implement that message.

Prolonged uncertainty over the future of the VOLH had damaging effects on recruitment, staff morale, and the physical environment of the VOLH. The hospital environment was not conducive to good patient care. It is hardly credible that in 2007 and 2008 a care environment existed in which gaps in floor joints were covered in adhesive tape. There was a lack of wash-hand basins in wards and toilets, and commodes were not fit for purpose.

A lack of strong management as well as personal and system failures contributed to the development of a culture in the VOLH that had lost sight of what is of the very essence of a hospital – a caring and compassionate environment dedicated to the provision of the highest possible level of care.

Background to the Inquiry

Creation of the Inquiry

On 22 April 2009 the then Cabinet Secretary for Health and Wellbeing, Nicola Sturgeon, announced to the Scottish Parliament that a Public Inquiry would be held into the "outbreak" of *Clostridium difficile* at the VOLH. She explained that this would commence at the conclusion of ongoing investigations by the police and the Health and Safety Executive, and of any prosecutions resulting from those investigations. At the same time the Cabinet Secretary announced that the Rt Hon Lord Coulsfield had agreed to chair the Inquiry.

The C.diff Justice Group, which represents a number of surviving and deceased patients, was influential in the establishment of the Inquiry. In January 2009 the Group lodged a petition with the Scottish Parliament Public Petitions Committee calling for a public inquiry to ensure that lessons were learned across the NHS and that further deaths from *C. difficile* were minimised. The petition was considered by the Petitions Committee on 27 January 2009 and formally closed on 1 November 2011.

The Group's determination to have a public inquiry has been fully vindicated by the Inquiry's findings of significant failures from which important lessons must be learned.

In June 2009 the Lord Advocate intimated that there would be no criminal proceedings and steps were then taken to establish an Inquiry Team and define its Terms of Reference. The statements obtained by the police were passed on to the Inquiry Team.

Lord Coulsfield subsequently withdrew from the Inquiry for health reasons, and my appointment was announced in his place on 21 August 2009.

The Inquiry was formally set up on 1 October 2009. The procedure of the Inquiry was subject to the Inquiries Act 2005 (the 2005 Act) and the Inquiries (Scotland) Rules 2007 (the 2007 Rules).

No other person was appointed to sit with me. The important task of fulfilling the Terms of Reference has therefore been my sole responsibility. In carrying out that responsibility I have been greatly assisted by my Assessors and the members of the Inquiry Team.

Appointment of Assessors

To assist me in my task I appointed two Assessors, under a power granted to me under section 11 of the 2005 Act. A summary of their qualifications and experience is set out in Appendix 2. The purpose behind their appointment was that of providing me with advice on matters within their own areas of professional expertise, which included nursing and medical expertise and also expertise in infection prevention and control.

The Assessors were appointed on 14 October 2009. They participated in the preparations for the oral hearings and attended the oral hearings, and I was able to rely on their advice in the course of the drafting of the Report. Their joint contribution to the Inquiry process proved invaluable, as nursing and medical matters and issues of infection prevention and control became central to the work of the Inquiry. I am extremely grateful to them for that contribution and for the commitment they continued to make to an Inquiry process that took longer than anticipated.

Meeting with NHS Greater Glasgow and Clyde Board members

Lord Coulsfield and the Secretary to the Inquiry met with NHSGGC Board members on 11 June 2009. That was an informal meeting and was not part of the evidence gathering process. It was agreed at that meeting that there could be a single point of contact within the Board for the Inquiry. I, however, did not consider it necessary to have a further meeting with Board members.

Meeting with patients/relatives

Lord Coulsfield met patients and relatives on 12 June 2009, and following my own appointment as Chairman I decided that it would also be appropriate for me to have a similar meeting. That meeting took place on 25 September 2009, and was attended by one former patient and 17 relatives of

patients. I found the meeting to be highly productive, and I gained the clear impression that the patient and relative group as a whole was anxious to be as helpful as possible to the Inquiry. Quite understandably they wanted to find out why CDI became such a problem in the VOLH.

The scope of the Inquiry

Terms of Reference

The Terms of Reference agreed with the Cabinet Secretary were in the following terms:

a) To investigate the circumstances contributing to the occurrence and rates of *C. difficile* infection at the Vale of Leven Hospital from 1 January 2007 onwards, and any increases in such rates during that period and in particular between 1 December 2007 and 1 June 2008, with particular reference to the circumstances which gave rise to deaths associated with that infection.

b) To investigate the management and clinical response at the Vale of Leven Hospital to the *C. difficile* infection rates during that period and to any such increases, and the steps taken to prevent or reduce the risk of spread or recurrence of the infection.

c) To investigate the systems in place at the Vale of Leven Hospital to identify and notify cases, increased rates of infection outbreaks and deaths associated with *C. difficile* infection, including the action taken to inform patients, their relatives and the public and the steps taken at the Vale of Leven and in NHSScotland generally for recording such incidents including for the purposes of death certification.

d) To investigate the actions of NHS Greater Glasgow and Clyde in response to the occurrence of *C. difficile* infection at the Vale of Leven Hospital, including informing patients and their relatives of the risks of such infection and the measures that should be taken to assist prevention and control.

e) To investigate the governance arrangements of NHS Greater Glasgow and Clyde in relation to, and the priority given to, the prevention and control of the infection.

f) With reference to experience within and beyond Scotland of *C. difficile*, to establish what lessons should be learnt and to make recommendations.

g) To report by 30 September 2010 unless otherwise provided by the Cabinet Secretary for Health and Wellbeing.

The Cabinet Secretary granted several extensions to the reporting date in accordance with paragraph (g) of the remit.

The breadth of the Terms of Reference

What is significant about the Terms of Reference is their breadth. I have already made the point in the Foreword that I did not consider it possible to report by a specified date, initially 30 September 2010. The Cabinet Secretary's response was the addition of the provision in paragraph (g) for extending the time limit. That did not allay my concerns. While it is readily understandable that the responsible Minister should wish an inquiry to report at the earliest reasonable opportunity, until the work of an inquiry is well under way any prediction about a time limit cannot be accurate and may be totally unrealistic. The Inquiry Team must conduct an initial investigation. Only once that initial stage is substantially complete will it become apparent what further investigation is necessary. A further factor that could not have been foreseen at the outset was that of the problems encountered in the recovery of documents, discussed later in the Report. These problems became a running sore that bedevilled the work of the Inquiry even into 2012.

For reasons set out in this Report, including the nature and extent of the Terms of Reference and the size of the task that emerged, the successive deadlines were impossible to meet. When that was apparent to me, I notified the Cabinet Secretary at the

earliest opportunity. As it turned out, because of the amount of work involved in the initial investigation, the first phase of oral hearings did not take place until June 2010, just four months before the original latest reporting date of September 2010.

The first application for an extension of time was in fact made on 10 December 2009, and following that the reporting date was extended to 31 May 2011. Subsequent extensions were necessary to allow the Inquiry to carry out as thorough an investigation as possible into the terms of the remit. The final phase of oral hearings was not completed until June 2012.

The lesson to be learned from this experience is that, except in circumstances where the issue is clear and the remit is a relatively narrow one, specific deadlines should not be imposed on public inquiries of this kind. A formula "as soon as possible" or even "as soon as practicable" should be seen as a much better option. No inquiry Chairman would fail to respond to that form of remit in a timeous manner. Unrealistic deadlines of the kind contained in the Terms of Reference create unrealistic expectations in the minds of those waiting for the Report to be published. They also create undue and unfair pressure on the Inquiry Team.

The broad nature of the remit as set out in paragraphs (a) to (g) of the Terms of Reference reflects the Cabinet Secretary's intention, when the setting up of the Inquiry was announced in the Scottish Parliament on 22 April 2009, that relevant lessons "must be learned by everyone in the NHS".

Interpretation of the Terms of Reference by NHS Greater Glasgow and Clyde

On 11 May 2011 the NHS Central Legal Office (CLO), acting on behalf of NHSGGC, delivered a Note to the Inquiry intimating an objection to evidence being led on aspects of the quality of nursing care provided to patients covered by the remit. That Note was revised on 12 May 2011. The principal thrust of the objection was in the following terms:

> "On the ground of fairness specified in s.17 of the Inquiries Act 2005 ("the 2005 Act"), and also in reference to the need (s.17(3) of the 2005 Act) to avoid any unnecessary cost (whether to public funds or to witnesses or others), GGHB respectfully submits that no evidence should be allowed or taken into account concerning various aspects of the quality of nursing care ("the aspects objected to") at the Vale of Leven Hospital in the period to date, namely hydration of patients; preparation of fluid balance charts and completion of these; nutrition of patients; completion of nutrition assessments and food charts, and the need to involve a dietician; weighing of patients; guarding against and dealing with skin and pressure damage, and taking tissue viability precautions; carrying out manual handling risk assessments; carrying out falls risk assessments; avoiding patients being injured through falling; providing proper pain relief; completion of care plans (except for care plans relevant to the contraction of Clostridium *difficile* illness or the mortality rate there from); assessing the mental state of patients and meeting their mental health needs; the quality of the personal care given to patients; Do Not Attempt Resuscitation ("DNAR") decisions; and providing end of life care pathways".[1]

Ruling on NHS Greater Glasgow and Clyde's objection

With little hesitation I repelled the objection taken on behalf of NHSGGC. The solicitor to NHSGGC was advised of my ruling and my reasons by letter dated 12 May 2011.[2] I concluded that the issues of concern raised in the nursing expert reports were in areas of nursing care which might be directly relevant to the circumstances contributing to the occurrence and rates of CDI at the VOLH. It has to be emphasised that good nursing care lies at the very heart of the appropriate management of patients who contract CDI. That care does not just begin when the diagnosis of CDI has been confirmed. Patient care has to be seen as a dynamic

1 INQ05480002-03
2 INQ05610001

process that involves regular assessment and reassessment. A patient who develops CDI may require to be managed not just for the direct effects of the infection itself, for example by the administration of antibiotics, but also for other aspects of care on which CDI might have an impact, such as hydration, nutrition, pressure management, and the risk of falls and impaired mobility due to the debilitating nature of the condition. While Do Not Attempt Resuscitation (DNAR) decisions may be only indirectly linked, these decisions can be relevant to the care of patients suffering from CDI.

Renewal of the objection

At the oral hearing on 23 August 2011 Counsel for NHSGGC renewed the objection to the leading of evidence on certain aspects of care.[3] By this time almost all the evidence of the nursing experts had been led. At this point the challenge was more restricted in nature, with the focus now only on some aspects of care. For example, it was not now being suggested that the nursing management of hydration and nutrition was not relevant to the issues that I required to examine.[4]

Having heard the argument on this renewed objection I again refused to sustain it. It was in principle the objection that had been taken earlier and repelled, and no good reason was advanced for its renewal after almost all the nursing evidence had been led. It had been clear in advance from the nursing expert reports what evidence was going to be led. As I have already explained, there are aspects of nursing care that cannot be divorced from consideration of how a patient suffering from CDI is being managed. Hydration and nutrition are clear examples, and no doubt that is why NHSGGC did not renew its objection to those aspects of care at the oral hearing. Counsel for NHSGGC argued that the Inquiry should focus only on the care planning relevant to the contraction or persistence of CDI,[5] but the fallacy underlying that argument is the assumption that the care planning for a patient who is suffering from CDI can be properly managed without regard to all that patient's problems.

3 TRA00290073-109
4 TRA00290100
5 TRA00290081

Furthermore, I was satisfied that the issue of whether any aspects of patient management were outwith the Terms of Reference was a matter that could be determined at the end of the evidence without causing any material delay to the progress of the Inquiry. In addition, most of the nursing expert evidence having been led, I was of the view that, in fairness to nurses whose standard of care had been criticised, they should be given the opportunity to respond to that criticism.

The focus and early period division

The Terms of Reference stipulate in paragraph (a) that the starting date for my investigation of the circumstances contributing to the occurrence and rates of CDI is 1 January 2007. There is no specified end date, but that same paragraph does provide that particular attention is to be directed to the period from 1 December 2007 to 1 June 2008. This period had been looked at by other Inquiries. In this Report I have labelled the period from 1 January 2007 to 30 November 2007 the "early period", and the period from 1 December 2007 to 1 June 2008 the "focus period".

Clostridium difficile infection

Clostridium difficile

Clostridium difficile (C. difficile) is a bacterium that can cause infection in the colon. Up to 4% of healthy adults carry *C. difficile* in the colon.[6] That percentage may increase to 50% in hospital, particularly in the elderly and newborn infants. These patients may not have the infection, but clearly the risk of the infection developing increases significantly in a hospital environment. There are numerous different strains of *C. difficile*, and some strains are said to be more virulent than others. These strains are normally referred to as "hypervirulent" strains because they produce high levels of toxins. It has to be stressed, however, that any strain of *C. difficile* has the potential to cause severe infection.

To acquire the organism, spores must enter the mouth and be swallowed. Many people are exposed to spores, but *C. difficile* generally does not colonise in healthy people and

6 TRA00090019

cause infection. This is because the normal healthy bacteria in the colon protect against the development of the infection. It is when these protective mechanisms are disrupted that *C. difficile* can colonise in the colon and result in infection. This disruption is usually caused by the administration of antibiotics in the treatment of another infection, for example, a urinary tract infection. This is particularly so when patients are treated with broad spectrum antibiotics, because these antibiotics eradicate many normal bacteria in the colon, making the colon more susceptible to the development of CDI. This is why prudent antibiotic prescribing is so important in patient management. An infected patient will normally develop diarrhoea, and in a hospital there is the risk of the environment being contaminated, with other patients being put at risk. Good hand hygiene is important as a preventative measure.

From an infection prevention and control perspective, the isolation of a symptomatic patient from other patients is important. Unfortunately, as set out in the Report, the general practice in the VOLH was not to isolate patients until the infection was actually diagnosed by means of a positive laboratory result. This practice meant that other patients continued to be placed at risk of cross infection.

CDI symptoms

There are a variety of symptoms associated with CDI. I have already mentioned diarrhoea, which when caused by CDI is often described as "explosive". Symptoms can also include abdominal pain, fever and nausea. In some cases the colon can become severely inflamed, a condition known as pseudomembranous colitis. This can become acute, resulting in toxic megacolon - acute distension of the colon. CDI must therefore be regarded as a serious illness that can be life-threatening, and I have already set out the number of patients covered by my remit who died with CDI involved in the death. The elderly are particularly vulnerable. Professor George Griffin, Professor of Infectious Diseases Medicine at St George's University, London, whose evidence is considered later, provided the following graphic description of the impact of CDI:

> "*C. difficile* is very unpleasant for patients. It is exceedingly unpleasant and distressing for relatives to see an old, loved patient in a bed in a pool of faeces. It is very difficult for nursing staff to have to clean a patient nine, ten times a day who is demented, immobile, (and) can't help the nurse with moving".[7]

For a patient to contract CDI in a hospital setting, a setting where the patient expects to be protected and safe, is especially tragic. CDI can deny an elderly patient a peaceful and uncomplicated death, and that is one particular reason, among others, why what was allowed to happen in the VOLH should never be allowed to happen again.

The Vale of Leven Hospital

Changes in hospital management

The Vale of Leven District General Hospital (this is its full title) is one of the smaller hospitals in the National Health Service in Scotland. It is located in the town of Alexandria, West Dunbartonshire. In 2002 the VOLH delivered a broad range of acute hospital services, and the bed complement was in the region of 234, but by 2008 this had been reduced to around 136.

Prior to 1 April 2006 the VOLH was managed by NHS Argyll and Clyde. By 2005 NHS Argyll and Clyde had incurred a cumulative budget deficit of £82 million, and on 19 May 2005 the then Minister for Health and Community Care announced in a statement to the Scottish Parliament that NHS Argyll and Clyde was to be dissolved. The administrative boundaries of Greater Glasgow Health Board (GGHB), also then known as NHS Greater Glasgow, and of NHS Highland were to be changed to allow them to take over responsibility for managing the delivery of the health services in Argyll and Clyde.

Following upon an integration process NHS Argyll and Clyde was dissolved on 1 April 2006. From that date a number of hospitals, including the VOLH, became the full responsibility of GGHB, which became known as NHS Greater Glasgow and Clyde (NHSGGC).

7 TRA00730030-31

Full integration of services did not, however, take place immediately, and a Clyde Acute Directorate was created to manage services in the former Argyll and Clyde hospitals now managed by NHSGGC, including the VOLH. Mrs Deborah den Herder was appointed as the Director of the Clyde Acute Directorate, although she did not take up her post formally until 1 October 2006.

Reduction in services

In the years up to 2007 and 2008 a significant reduction in the services provided at the VOLH had taken place. These are set out in Chapter 8. By then the future of the hospital had been uncertain over a prolonged period of time. This uncertainty had a damaging impact on recruitment and morale as well as on the hospital's physical environment. It also compromised patient care.

CDI at the VOLH

Discovery and extent of the problem

The problem with CDI in the VOLH was not apparent until May 2008. Those who worked in the VOLH did not appear to identify CDI as a particular problem over the period from 1 January 2007 to May 2008, even although a significant number of patients suffered from the illness during that period. As set out in the Report, the discovery of the extent of the problem was partly due to a press enquiry by a local newspaper requesting information on the number of cases of CDI at the VOLH in the six months prior to June 2008. Dr Brian Cowan, Medical Director and Acute Services Division Medical Director of Greater Glasgow and Clyde described his understanding of the position in the following way:

> "Here was an outbreak which raged, or a series of outbreaks that raged, for a long period of time with a significant, highly significant, number of deaths".[8]

In the period from 1 January 2007 to June 2008 there were 199 positive test results for *C. difficile* toxin from 131 patients in the VOLH, and in different wards at different times throughout that period there were patients suffering from CDI who were linked in time and place. Outbreak Policies in force during that period[9] made it clear that an outbreak consisted of two or more linked cases of the same illness, yet no outbreak was declared. The reasons for the failure to identify a problem include the dysfunctional nature of the Infection Control Team, the inadequacy of reporting systems and the failure of committee structures. Nevertheless, it is surprising that such a problem could effectively remain undiscovered for so long even in the face of such failures.

Levels of infection and fatality rates

As I set out at the beginning of this summary, in the period from 1 January 2007 to 1 June 2008 131 patients who were or had been in the VOLH tested positive for CDI. Although the focus of the Inquiry has been on the period up to 1 June 2008, patients continued to suffer from CDI until the end of 2008, but the rate was lower. The total number of patients covered by the Inquiry's remit who contracted CDI between 1 January 2007 and 31 December 2008 was 143.

I did not engage in a comparative exercise of CDI rates in Scottish hospitals, for such an exercise was outwith my remit. It is perfectly clear, however, that for a hospital the size of the VOLH the number of patients infected reveals that CDI had become a serious problem in the VOLH, even although that problem was not identified. The problem was compounded by the number of patients who died with CDI as the underlying cause or a contributory factor. In the six-month period from 1 December 2007 to 1 June 2008, CDI played a role in the deaths of 28 patients.

Death certification

Accuracy

Accuracy in death certification is important because it provides an understanding of the health needs of the population. There is also a personal need for family members to know why a relative has died. Of the 28 patients who died between 1 December 2007 and 1 June 2008 with CDI as the underlying cause or contributory factor, CDI was not mentioned in the death certificates of seven of these patients.

8 TRA01230015

9 GGC00780145; GGC27390001

Death certification involves the exercise of professional judgement. Yet although in 2007 and 2008 the available guidance provided that it was "best if a consultant, general practitioner or other experienced clinician certifies the death",[10] it seems that in practice in Scotland consultants were rarely involved in death certification at that time.[11] Certainly in the cases examined from the VOLH the majority of the death certificates were signed by junior doctors without any recorded consultation with more senior medical staff.

New guidance

New guidance was issued on death certification after the emergence of the CDI problem at the VOLH. The most up-to-date guidance provides that death certificates for patients who have died in hospital should only be completed after discussion with a consultant. Ideally this should be the patient's named consultant.[12] Boards also have to ensure that there are systems in place to identify *C. difficile* associated deaths.[13]

Scotland should not have developed the practice of consultants generally not being involved in the death certification of their patients. Consultants are best placed to accurately assess why a patient has died. I certainly endorse the mandatory duty now imposed to involve consultants. Furthermore, if a patient dies with CDI either as a cause of death or as a contributing condition, relatives should be provided with a clear explanation about the role played by CDI in the patient's death.

Patient records

Examination of patient records by experts

In the interpretation of my remit I took the decision that the patient records of the patients who suffered CDI in the focus period should be subjected to careful scrutiny. This scrutiny had not been carried out during other investigations into the VOLH CDI problem. From that exercise it became apparent to me, with the assistance of members of the Inquiry Team and my Assessors, that certain recurrent themes emerged. In order to explore those issues more fully, experts were commissioned in a number of disciplines so that the Terms of Reference could be properly complied with. The timescales involved in that process are set out in Chapter 2. I have already set out my reasoning for the division of cases into the early period and the focus period. Accordingly, expert reports were instructed on 1. medical care; 2. nursing care; 3. the prescription of antibiotics; 4. infection prevention and control; and 5. death certification for all patients who fell within the focus period. Patients for whom expert reports were obtained are listed in Appendix 1. Those patients and relatives who were core participants had an opportunity through their legal representatives to see these detailed reports.

A more restricted approach was taken in the early cases, but I still considered it necessary that, insofar as patient records were available, a nursing expert should examine these records to see whether trends apparent in the course of the focus period also existed in that early period.

Detailed examination of patient records, expert reports and all other evidence relevant to each patient's care was undertaken during the Inquiry's work in preparation of this Report. This approach reflected the approach taken during the oral hearings which involved detailed examination of patient care.

The results of that whole exercise are discussed in the Report. Suffice to say at this point that the unacceptable levels of care discovered were not the levels of care which I would have expected to find in any hospital in Scotland. That is why I have made firm recommendations in the Report which should be seen as fundamental to patient care. Ultimate responsibility for patient care in Scotland rests with the Scottish Ministers. To discharge that duty the necessary inspection and implementation systems must be capable of providing real assurance that patient care in Scotland is not at any risk of being compromised.

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11 TRA01070009-10
12 INQ02980003
13 INQ02980005

NHS Greater Glasgow and Clyde's position on the examination of patient records

In the course of submissions made on behalf of NHSGGC at the oral hearing on 13 June 2011 in connection with the legal representation of nurses, an issue addressed in Chapter 2, Counsel for NHSGGC made the following statement in connection with the reports of the nursing experts:

> "The content of the reports came as somewhat of a surprise to Greater Glasgow Health Board".[14]

As discussed in Chapter 17, the remit of the Internal Investigation set up by NHSGGC in June 2008 did not cover an examination of patient care with particular reference to the medical records. Nor did the Independent Review chaired by Professor Cairns Smith, Professor of Public Health at the University of Aberdeen. That was not part of the remit of either investigation.

Limited reviews of patient records were undertaken during the Internal Investigation. A case note review of 45 patient records was also carried out by senior nurses as part of the Outbreak Control Team's investigations that commenced in June 2008 to obtain certain data in relation to matters such as age, date of admission and to which wards patients were admitted.[15] So far as the Outbreak Control Team report discloses, the purpose of that review was to make a comparison between the status of the patients who died and the status of patients who survived. The report's conclusion was that patients who died were, on average, older than those who survived.[16] In addition, on 16 June 2008[17] two senior Consultant Physicians from outwith the Clyde division undertook a case review of 15 patient records where *C. difficile* had appeared on the death certificates to consider whether the death certification was appropriate.[18] The Outbreak Control report describes this as a "brief review".[19]

I was surprised that NHSGGC had not taken steps to examine the patient records to evaluate the nature of care afforded to CDI patients, particularly the records of patients who died with CDI as a cause, or contributory cause, of death, in order to satisfy itself that there were no apparent deficiencies in care. I would regard such an examination as one that should be at the forefront of the thinking of any Health Board in the circumstances that had emerged in the VOLH by June 2008. Mr Robert Calderwood, Chief Executive of NHSGGC, did explain in his evidence that once the Independent Review was set up on 18 June 2008 NHSGGC was invited to assist with that Review and discontinue its own investigation,[20] but as already mentioned the Independent Review did not examine patient care in any detail.

Management

The importance of questioning

It was surprising how managers at different levels within an organisation like NHSGGC failed in one of the most fundamental aspects of management, namely to ask questions.

The culture

Quite apart from a number of individual failures to investigate and be aware of what was actually happening in the VOLH, it became apparent that there was a systemic failure. Ultimately this can only be described as a management culture that relied upon being told of problems rather than actively seeking assurance about what was in fact happening. To take an example from the evidence, a manager who has a responsibility to ensure the delivery of high quality care cannot fulfil that duty simply by relying on being told when a specific problem emerges and then reacting to the problem. Some managers with responsibilities for the VOLH also had responsibilities for other hospitals operated by NHSGGC, but the Inquiry's focus, of course, was only on the VOLH, and in consequence I cannot comment on their broader performance. Nor do I know how prevalent this style of management would be generally within NHSScotland. Nevertheless, the clear lesson to be learned is that an

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15 TRA01140044-46; GGC01480004
16 GGC00600047
17 GGC07260001
18 GGC07280001; GGC0060058-59
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important aspect of management is to be proactive and obtain assurance that systems and personnel are functioning effectively.

Patients and families

Full co-operation

A Chapter in the Report has been devoted to the views of patients and families and their experiences at the VOLH. The oral evidence at the hearings from this group of witnesses was given in a measured and unexaggerated way. Those who provided written statements but were not called to give oral evidence co-operated fully with the Inquiry. These witnesses recognised the importance of having a local hospital and as a group wanted to support its continued existence.

The Inquiry's oral hearings began with the evidence of this group of witnesses. I was anxious that they should have an opportunity as early as possible to have their views expressed publicly. Much of the Inquiry's work was still to be done at that time, and that meant that when they gave their evidence they were not aware of the extent and range of criticisms that were to be made subsequently by the experts.

A common theme

A common theme from this group's evidence was the desire to have answers to what went wrong at the VOLH. A significant number of this group of witnesses had been actively engaged in a campaign for a public inquiry, and it became clear during the evidence that fundamental to their thinking was the desire that others should not be made to suffer in the same way that patients suffered in the VOLH as a result of contracting CDI. Although this group of witnesses was reluctant to be critical of the care provided to patients, many of the descriptions provided did show that there were failures in basic nursing care. Some witnesses attributed poor care to the nursing staff being too busy to render the necessary quality of care. Being busy is not an excuse. If the right kind of care requires more staff, then arrangements should be in place to have an adequate number of staff available.

Poor communication

Relatives were critical of poor levels of communication. This was particularly the case in relation to the presence and nature of CDI. One witness only became aware that his mother had been diagnosed with CDI when he saw *C. difficile* mentioned on her death certificate. Some relatives were told that it was a "wee bug". That is not an apt description of what can be a life-threatening infection. Mixed messages were provided to relatives who took patients' soiled laundry home to wash. Good communication and candour are important aspects of care.

Nursing and medical care

Nursing failures

In the Report it has been necessary to mention nursing failures. There were individual failures caused by a number of factors, including pressures of work, lack of training, and inadequate support. Poor leadership also contributed to an inadequate standard of nursing care. The individual nurses concerned may have been doing their best. What I have sought to identify is how, in a care environment that does not promote good quality care, nursing standards can deteriorate and become unacceptable. The message to be conveyed on this issue is one of the absolute importance of good quality nursing care.

There were a significant number of cases in which there were delays of over 24 hours between the taking of a specimen for laboratory analysis and the commencement of treatment. What was totally unacceptable were the delays in the commencement of treatment **after** the ward was aware of the positive result. Delay in the commencement of treatment in such circumstances represents an inexcusable level of patient care. Such failures would inevitably compromise patient care.

Medical care

The deficiencies that existed in relation to medical staffing are set out in Chapter 14. In effect, there was a layer of middle grade medical staffing missing, with the result that the brunt of the day to day care had to be borne by inexperienced junior doctors and that consultants were overstretched. The

medical review of patients suffering from CDI was inadequate, and for many patients there was no evidence that a proper clinical assessment of the patient's condition had been made. Scrutiny of antibiotic prescribing disclosed that many aspects of practice were poor. There were instances of antibiotics being prescribed when no antibiotic was necessary, and of the continued prescribing of antibiotics in cases where a laboratory test demonstrated that the organism was resistant to that choice of antibiotic.

Overall it is likely that patient care was compromised by the inadequate standard of medical care.

Infection prevention and control

Significant failures

Clearly infection prevention and control practices and systems had to be fully investigated by the Inquiry. Again experts were commissioned to assist the Inquiry in this task. The Chapter in the Report on infection prevention and control is one of the major Chapters, and there can be little doubt that the significant deficiencies in infection prevention and control practices and systems discovered by the Inquiry had a profound impact on the care provided to patients in the VOLH.

Local failures

There were personal failures by the senior nurse responsible for infection prevention and control in the VOLH. The failure not to consider as a real possibility that the number of cases with CDI was a result of cross infection was inexplicable. Over the period from 1 January 2007 to 1 June 2008 there were a number of opportunities presented when cross infection should have been actively considered.

The Infection Control Doctor

Dr Elizabeth Biggs was the Infection Control Doctor for the VOLH at least from 1 January 2007 up to early February 2008. Dr Biggs was based at the Inverclyde Royal Hospital (IRH) but was responsible as Infection Control Doctor for that hospital, the Royal Alexandria Hospital (RAH) and the VOLH. The main thrust of the evidence was that she did not attend the VOLH during that period.

Dr Biggs was under a duty to take a lead role in the effective functioning of the Infection Control Team. It is clear that Dr Biggs was unhappy with her general position and lacked professional line management support, but that does not excuse her attitude. Dr Biggs' attitude to her role as Infection Control Doctor for the VOLH was wholly inappropriate and professionally unacceptable.

Failure to address Dr Biggs' behaviour

Dr Biggs had raised issues in a number of emails and failure to address these, and to ensure an effective leader of the Infection Control Team was in place, was a serious management failure. One witness described Dr Biggs' behaviour as "accepted behaviour".[21] Such an attitude is to be deplored. Accepted behaviour that puts patients at risk has no place in any Health Board's philosophy.

System failures

The failure to meet of committees within the infection control structure meant that the structure became unfit for purpose. This was compounded by the fact that the reporting systems within the infection control system itself and under the clinical governance arrangements in place at the time were inadequate. Adequate reporting systems must ensure that there is ward to Board and Board to ward accountability. Appropriate systems would have identified the local failures at the VOLH and the failure of Dr Biggs to carry out her duties. That in turn would have identified the problem with CDI in the VOLH much sooner and saved many patients from suffering from the infection and its consequences.

National structures and systems

Structures

In order to orientate the reader of the Report, some information is provided in Chapter 6 on how the National Health Service in Scotland has been structured. In summary, ultimate responsibility for the promotion and improvement of the physical and mental

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health of the people of Scotland rests with the Scottish Ministers. The Scottish Ministers discharge that duty through Health Boards. The Scottish Government is the executive branch of government in Scotland. There are a number of organisations that provide support including NHS National Services Scotland (NSS) of which Health Protection Scotland (HPS) forms part. The Scottish Government Health Directorate (SGHD) provides the central management of the NHS in Scotland. The Cabinet Secretary for Health and Wellbeing is the Minister responsible for the SGHD.

Systems

The impact of healthcare acquired infections (HAIs) on patients has been well recognised since at least the 1990s. The HAI Task Force was created in January 2003 in recognition of the ongoing challenges presented by HAI. Its primary responsibility is to advise on the development and delivery of Scottish Government policy in order to minimise HAIs. There is no doubt that the HAI Task Force has carried out some excellent work, including the implementation of the system of mandatory reporting of all positive tests for *C. difficile* toxins to HPS on a weekly basis since September 2006. This is in effect a national surveillance system in Scotland that provides information on the extent of CDI at a national level and allows a comparison to be made of trends and data over time and between Health Boards. It is to be emphasised that the system is not designed to identify the prevalence of CDI in a particular hospital.

The Scottish Government also set performance targets that Health Boards are expected to meet. These are known as Health Improvement, Efficiency, Access and Treatment (HEAT) Targets. In November 2006 the Scottish Government announced a HEAT Target for *Staphylococcus aureus* bacteraemia (including MRSA and MSSA). The target was an overall reduction of 30% in such cases by 2010, and that target was achieved by September 2009.

The importance of the HEAT Target system lies in the fact that it places an onus on Health Boards to meet the targets by having, for example, effective infection prevention and control methods in place. CDI was only made a HEAT Target in 2009 in response to the discovery of the CDI problem at the VOLH. Had CDI been a HEAT Target earlier, that might have raised awareness of the infection, but it is to be stressed that the HEAT Target system was not designed to be a surveillance system of the kind that Boards had to have in place. Although there was no evidence that in the period prior to 1 June 2008 any consideration was being given to making CDI a HEAT Target, that is not a criticism because it was necessary to have adequate data available for comparative purposes, and as I have already indicated the system for mandatory surveillance did not come into operation until September 2006. The introduction of CDI as a HEAT Target in 2009 was an appropriate response by the Scottish Government to the emergence of the CDI problem at the VOLH.

Healthcare Environment Inspectorate

Prior to June 2008 there was no system of independent inspection dedicated to the infection prevention and control of HAI. Following upon the discovery of the CDI problem in VOLH the Cabinet Secretary had a number of meetings with family members of patients who had contracted CDI who made clear to her the view that there should be an independent inspectorate in place to review the actions taken in hospitals in relation to HAIs. This led to the establishment of the Healthcare Environment Inspectorate (HEI) in April 2009. The HEI carries out announced and unannounced inspections and publishes inspection results on its website. The inspection team measures hospitals against standards that are designed to minimise the risk of infection to patients, visitors and staff, based on evidence, best practice and expert opinion. The Health Board concerned must respond to any issues raised by the inspection process.

Inspections of the VOLH in 2011 and 2012

It is worthy of note that an announced inspection of the VOLH took place on 10 and 11 August 2011, and that an unannounced inspection took place there on 7 June 2012. The unannounced inspection in June 2012 concluded that the hospital was clean and

well maintained and that education in infection prevention and control was being well promoted. There is no doubt that had there been an inspection regime of that kind in 2007 and 2008, and had an inspection of the VOLH been carried out over that period, the conclusions would have been very different to the conclusions arrived at in 2012.

The absence of an inspection system – a failure

Since devolution the SGHD and other agencies have produced a significant amount of material for Health Boards on HAIs. For example, the Scottish Infection Manual published in July 1998 sent out a clear message on the importance of good infection prevention and control. Furthermore, the importance of prudent antibiotic prescribing had been well known at least since the 1990s. There was no doubt that the message on the importance of having sound systems in place to combat HAIs was a message that had been repeated many times over the years because of the importance attached to it. In such circumstances it is surprising and indeed regrettable that an effective inspectorate system had not been put in place prior to 1 June 2008. This is dealt with in detail in the Report, and represents a failure on the part of the Scottish Government.

Antibiotic prescribing

Prudent prescribing

The importance of prudent antibiotic prescribing had been recognised in Scotland for many years prior to 2007 to 2008. In a letter dated 21 May 1999[22] addressed to a number of people, including Health Board General Managers and Chief Executives, the Scottish Office Department of Health included prudent antibiotic prescribing as an important goal in the reduction of ill health from hospital acquired infection. That message was subsequently repeated over a number of years. An Action Plan[23] published in 2002 by the then Scottish Executive again emphasised the importance of prudent antimicrobial use. A guide on the prudent use of antibiotics published in 2005[24] highlighted as a challenge the inadequate supervision of prescribing and the inappropriate choice of antibiotics by junior doctors. Even as late as March 2008, shortly prior to the emergence of the problem with CDI at the VOLH, another Action Plan was launched by the then Cabinet Secretary for Health and Wellbeing.[25] This echoed the theme that had emerged in Scotland at least by 1999, and had been repeated over the years, that antibiotic prescribing was not being carried out in a prudent way.

Inadequate response to the prudent prescribing message

Reference has already been made to the failures in the prescribing of antibiotics in the VOLH, failures that persisted until the emergence of the CDI problem in May 2008. The repeated messages on prudent prescribing had not had an effective impact in the VOLH by June 2008. Dr Andrew Seaton, a Consultant Physician in Infectious Diseases and General Medicine in NHSGGC, said in evidence that what was happening in the VOLH in relation to antibiotic prescribing "was applicable to all our hospitals in Greater Glasgow and Clyde and, indeed, almost certainly all our hospitals in Scotland".[26] It is not within my remit to consider the position of other hospitals in Scotland, but what was perfectly apparent to me was that there had been what I describe in the Report as a mismatch between expectation and implementation. There are two targets for criticism here – NHSGGC for failing to respond to the messages being sent on the importance of prudent prescribing, and the Scottish Government for failing to identify and remedy the failure to comply with the prudent prescribing messages.

Outbreaks elsewhere

Paragraph (f) of the Terms of Reference did permit the Inquiry to see what lessons could be learned from experience of CDI in and beyond Scotland. I was, however, of the view that that paragraph did not provide

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an open ended platform from which to look at the detail of how outbreaks of CDI were handled in other hospitals. That would have been an enormous task. In light of the Terms of Reference as a whole I was of the clear view that it would be outwith their scope to embark upon a critical analysis of the infection control policies of other organisations, the governance arrangements of such organisations and the handling of any outbreaks. What I did find useful was to have regard in particular to the available reports on CDI outbreaks in England, and compare the conclusions arrived at with the conclusions I have arrived at in connection with the VOLH. What was striking was the similarity of the problems identified in these reports and the problems identified by this Inquiry. Lessons had not been learned from these reports. This is considered in Chapter 18.

Scrutiny of other hospitals

There was regular traffic of patients to the VOLH from other hospitals. In particular, patients covered by the remit were transferred from the RAH, or transferred from the VOLH to the RAH. For that reason it became necessary for the Inquiry to examine some aspects of the treatment of those patients at the RAH. As discussed later in the Report, I concluded that the prescription and administration of antibiotics to patients prior to admission to the VOLH were relevant to my remit whether that occurred at another hospital or in the community under the authorisation of general practitioners. That did not mean, however, that I considered it to be within my remit to conduct an examination of practices, policies and patient care at any other hospital, or in the community.

The proceedings

Inquisitorial proceedings

In Scotland, legal proceedings are generally conducted by way of adversarial process. For example, in a civil litigation the parties to the litigation identify the issues that are of concern to them and decide what evidence to lead in support of their respective positions. Generally a witness led by one party can then be cross-examined by the other party and, if necessary, re-examined. The judge presiding over the case has no direct part to play in that process. The judge's role is to ensure that parties conduct the case in accordance with the rules and the judge only intervenes in the evidence to seek clarification or further explanation. At the end of a case parties make submissions on the facts and the law to advance their respective positions and, ultimately, the judge decides the case by making findings in fact and law.

The purpose of an inquiry of this kind is quite different. The process is an inquisitorial one. Section 17 of the 2005 Act provides as follows:

> "(1) Subject to any provision of this Act or rules under Section 41, the procedure and conduct of an inquiry are to be such as the Chairman of the inquiry may direct.
>
> "(3) In making any decision as to the procedure or conduct of an inquiry the Chairman must act with fairness and with regard also to the need to avoid any unnecessary cost (whether to public funds or to witnesses or to others)".

In an inquiry of the kind that I have conducted it was for me to decide who would give evidence to the Inquiry and what areas should be subject to investigation, all within the parameters of the Terms of Reference. It was not in any way part of my function to resolve issues as a judge might resolve issues between parties in a litigation. The role of Core Participants is quite different to the role played by parties to litigation. Indeed their role should be seen as being one where they are under a duty to assist the Inquiry in responding to its Terms of Reference. As I said at the preliminary hearing on 1 February 2010, the focus of the Inquiry was on investigating, and the Inquiry's questions were to be about finding out what happened, why it happened and, importantly, how to make a difference for the future.

Furthermore, the extent to which Core Participants may question witnesses is significantly constrained by the 2007 Rules. Rule 9 provides:

"(1) Subject to paragraphs (2) to (5), where a witness is giving oral evidence at an inquiry hearing, only –

(a) the inquiry panel;

(b) counsel to the inquiry;

(c) if counsel has not been appointed, the solicitor to the inquiry; or

(d) persons entitled to do so under paragraphs (2) to (4),may examine that witness.

(2) Where a witness, including a Core Participant, is being examined at an inquiry hearing, the Chairman may direct that the recognised legal representative of that witness may examine the witness".

There are other provisions in the 2007 Rules regulating the examination of witnesses, but the clear message is that it is for the Chairman to decide whether a witness should be examined by a Core Participant or any other party representing a person.

Standard of proof

The 2005 Act and the 2007 Rules are silent on the standard of proof an inquiry under the 2005 Act should apply when making its findings. I have already mentioned Section 17, which provides that the procedures and conduct of the Inquiry are to be such as I may direct. Furthermore, as I have explained, I must act with fairness. It is worth pointing out that Section 2 of the 2005 Act provides that "an inquiry panel is not to rule on and has no power to determine, any person's civil or criminal liability". It is not the function of an inquiry under the 2005 Act to determine the rights and obligations of any parties. In the light of these provisions I considered it to be appropriate to apply the civil standard of proof, a standard of proof on the balance of probabilities.

Expert assistance

The contribution made by all the experts commissioned by the Inquiry cannot be overstated. An inquiry of this kind, with Terms of Reference that required investigation of a range of different factors leading to the development of the problem with CDI, could not perform its function without expert input from a number of different disciplines. I am extremely grateful to all the experts who assisted the Inquiry. Details of the experts are provided in Appendix 4.

Conclusion

Conclusion

This was a lengthy and complicated Inquiry. It was necessary to examine a wide range of topics in order to comply with the terms of the remit. I was determined to carry out as comprehensive an investigation as possible so that a full account could be provided of why the CDI problem at the VOLH was so persistent and devastating. Patients and families had to relive painful experiences in providing statements and giving oral evidence and then had to wait for some considerable time for the publication of the Report. I consider that wait to be highly regrettable but I do firmly believe that the timescales identified throughout the Inquiry process were unrealistic. The extent of the work required to undertake a thorough examination of the many relevant issues cannot be overemphasised. In the event the Inquiry has unearthed serious personal and systemic failures. Patients who suffered from CDI at the VOLH were badly let down by people at different levels of NHSGGC who were supposed to care for them. The Scottish Ministers bear ultimate responsibility for NHSScotland and even at the level of the Scottish Government the systems were simply not adequate to tackle effectively an HAI like CDI. The major single lesson to be learned is that what happened at the VOLH to cause such personal suffering should never be allowed to happen again.

The Report and the recommendations are informed by all the relevant documentation gathered by the Inquiry, the evidence contained in written statements, and the evidence at the oral hearings, including the evidence of the experts who were commissioned to assist the Inquiry. The lessons to be learned are contained within the narrative of the Report and reflected in the recommendations.

Some of the recommendations are directed to aspects of basic nursing care, for example fluid monitoring, care planning, and the prevention and management of pressure damage. I note from the important inspection work being carried out by Healthcare Improvement Scotland that these aspects of care still feature as sources of criticism, and I make no apology for including recommendations on these issues to reinforce how critical they are to good quality care. Such basic care is integral to compassionate care. The recommendations are not directed against individuals although they will have an impact on individual behaviour. Nevertheless, it is important for individuals such as nurses and doctors to realise that they have a professional responsibility to comply with what is laid down as proper practice by their professional bodies.

There may be some recommendations that have been overtaken by events. For example, as set out in Chapter 15, NHSGGC did introduce more effective reporting systems for CDI after June 2008, but again the message should be reinforced that systems must ensure that important information is relayed from ward to Board.

I am convinced that the adoption of the recommendations proposed will result in a significantly improved focus on patient care, and in particular on the care of patients who contract a hospital infection such as CDI. CDI has been the focus of the Inquiry, but I am in no doubt that, although it was the failures in how CDI was managed at the VOLH that governed the work of the Inquiry, the recommendations should have a more far-reaching impact. Indeed the express intention of the Cabinet Secretary when announcing the setting up of the Inquiry was that lessons should be learned across Scotland. The recommendations are designed to encapsulate a concept of patient care that includes skilled and considerate medical and nursing care, transparency, candour, effective systems of infection prevention and control, and strong and dedicated leadership.

Key findings

Key findings

The key findings are short summaries of issues identified in the main body of the Report. For a proper understanding of these issues the reader should read the main text.

The numbering of the introductory and subsequent headings identifies the Chapter and Section numbers upon which the findings are based.

3. Healthcare Associated Infection and *C. difficile*

3.1 Healthcare Associated Infection

Healthcare Associated Infection (HAI) is an infection acquired as a result of a healthcare intervention either in hospital or in the community. HAIs are a major public health problem. Good infection prevention and control practices can prevent HAIs.

3.2 Antibiotics and the bowel flora

The undoubted potential therapeutic benefit of antibiotics in certain circumstances has to be balanced against the risks associated with antibiotic use. Antibiotics can affect the bacteria that make up the normal bowel flora of humans. Because it is unusual for a specific antibiotic to be active only against one particular bacterial species or group of species, treatment of a specific infection with an antibiotic will be likely to have an effect on other bacteria in the bowel.

3.3 *C. difficile* – what is it?

C. difficile is an organism carried in the bowel of up to 4% of healthy adults. Under normal circumstances it does not cause symptoms because it is in relatively small numbers and constrained by other bacterial flora that make up the normal bowel flora of the healthy adult. Multiplication of the organism can be triggered by the use of broad spectrum antibiotics administered for some other suspected bacterial infection. *C. difficile* produces toxins that set in motion a process that causes *C. difficile* associated diarrhoea (CDAD). In severe cases the infection can be life-threatening.

3.4 How *C. difficile* is spread

C. difficile is able to remain in the environment in the form of resistant spores, a vast number of which can be shed by a symptomatic patient. Ingestion of spores by a patient who is receiving antibiotics can result in infection. Although any antibiotic may result in CDAD the particular antibiotics associated with CDAD are the cephalosporins, co-amoxiclav (and other broad spectrum penicillins) clindamycin and ciprofloxacin (and other fluoroquinolone antibiotics).

There are hypervirulent strains of *C. difficile* that produce high levels of toxins. The 027 strain has been described as a hypervirulent strain but any strain of *C. difficile* can produce severe CDAD.

3.5 Laboratory diagnosis of *C. difficile* infection

There are a number of tests presently available for laboratory testing for CDAD. It is important to appreciate, however, that there is no test that is both 100% sensitive and also 100% specific. The laboratory must be aware of the risk of false positive and false negative results.

3.6 Precautions against occurrence and spread of *C. difficile* infection

Because *C. difficile* can be transmitted to individuals by a number of routes, including direct hand to mouth spread, good and appropriate hand hygiene is essential. So too is good maintenance of the healthcare environment. The main way to prevent cross-contamination is to isolate the potentially infectious patient in a single room. Cohorting of infected patients under strict infection control conditions must be seen as a last resort where single rooms are not available.

An unexplained incident of loose stools should be assumed to be infectious until an alternative cause is confirmed. In the VOLH in 2007 to 2008 a potential outbreak could include two cases of potentially infectious diarrhoea linked in time and place.

3.7 Treatment of *C. difficile* infection

Treatment includes the administration of the antibiotics metronidazole or vancomycin, depending upon the duration or severity of the infection. Any existing antibiotic treatment must be reviewed urgently. Good hydration is essential. The importance of ensuring that the patient's comfort and dignity are preserved cannot be overemphasised.

3.8 Conclusion

CDAD is a significant cause of morbidity and mortality in the elderly, the immunosuppressed and severely ill patients on broad spectrum antibiotic chemotherapy. Diarrhoea in these groups of patients must be taken seriously and urgent steps taken to establish whether or not infection is involved. Patients with diarrhoea must be isolated as soon as possible. As soon as the diagnosis is confirmed appropriate antibiotic treatment must be started. Other antibiotics must be reviewed and stopped unless there are overriding clinical reasons to continue with them.

4. The number of patients with *C. difficile* and those who died

4.1 Discovery of the problem

The ongoing problem with CDI in the VOLH began to emerge in mid-May 2008. Following upon a press enquiry in early June 2008, a look-back exercise covering the six-month period from 1 December 2007 to 31 May 2008 disclosed that there had been a persistent CDI problem and associated deaths during that period. That exercise identified 55 patients who had suffered from CDI and 18 CDI associated deaths. Those figures were an underestimate of the true position. The CDI problem was identified as a result of a combination of external factors including a coincidental research project and the press enquiry.

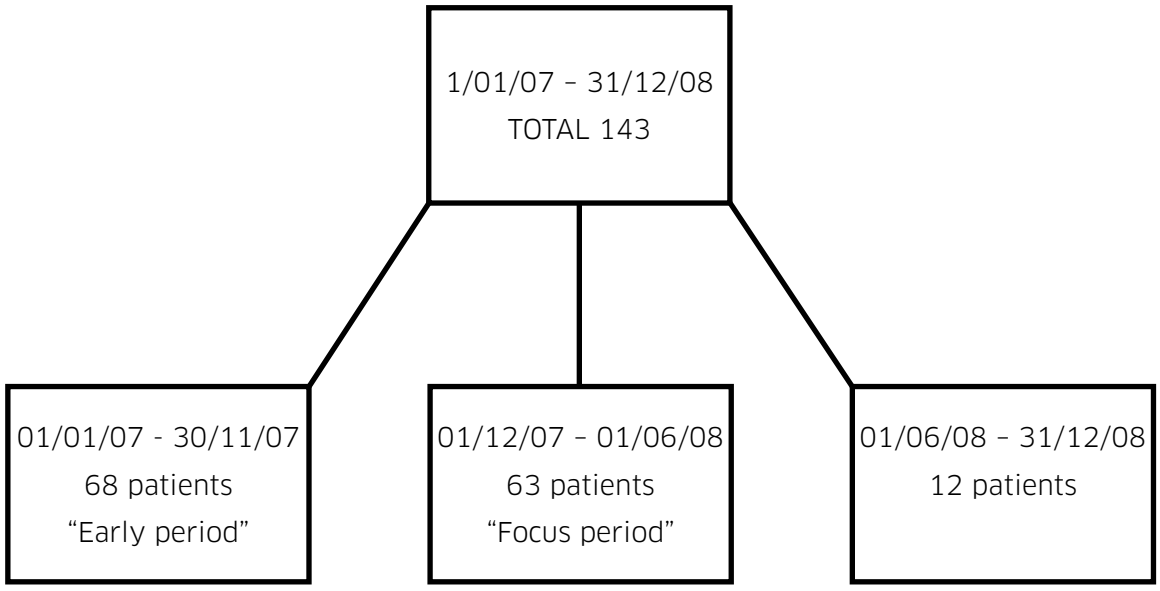
4.2 Number of CDI cases

In the period from 1 January 2007 to 31 December 2008, **143** patients who were or had been patients in the VOLH tested positive for CDI.

In the period from 1 January 2007 to 30 November 2007 (the early period) **68** patients tested positive for CDI. In the period from 1 December 2007 to 1 June 2008 (the focus period) there were **63** patients who tested positive for CDI.

In the period from 1 June 2008 to 31 December 2008 a further **12** patients at the VOLH tested positive for CDI. Furthermore, in addition, a number of patients who had tested positive prior to 1 June 2008 tested positive again after 1 June 2008.

Figure 4.1 Patients with CDI



4.3 Number of *C. difficile* deaths

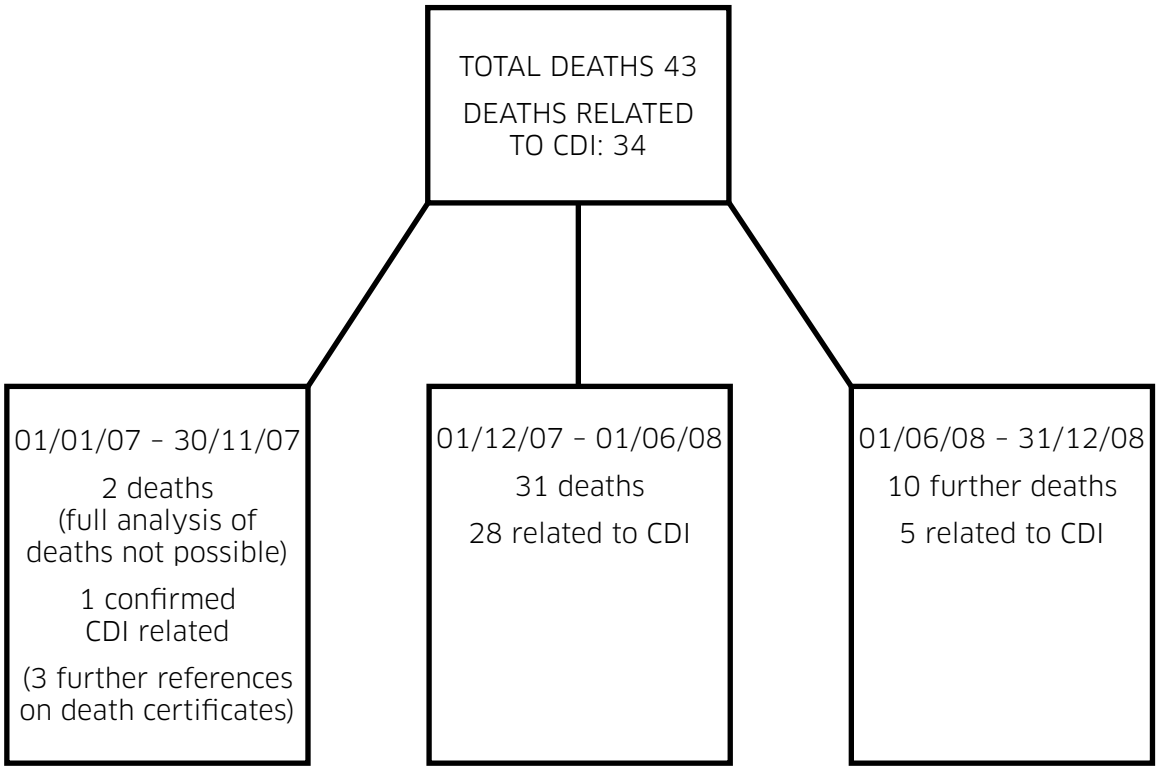
Many of the patient records of the 68 patients who contracted CDI in the early period (1 January 2007 to 30 November 2007) were not available. It was possible to conclude that CDI played a part in the deaths of at least six patients during that period.

In the focus period (1 December 2007 to 1 June 2008) 28 patients died with CDI as a causal factor in their deaths either as the underlying cause of death or as a contributory cause of death.

Ten patients died after 1 June 2008. CDI was a causal factor in five of those deaths. Three of those five patients died in June 2008.

Of the patients considered by the Inquiry, CDI was a causal factor in the deaths of **34** of those patients. In addition an examination of the death certificates of patients who died prior to 30 November 2007 revealed that CDI was mentioned in the death certificates of three of those patients. The figure for the number of deaths is an underestimate, since many patient records for the early period (1 January 2007 to 30 November 2007) were unavailable. Most of the patients who died were elderly and suffered from other conditions. These were patients who were clinically very vulnerable and in whom an infection such as CDI could have profound effects. What CDI caused was unnecessary suffering and lack of dignity to patients and enormous distress to relatives.

Figure 4.2 Deaths related to CDI



4.4 Conclusion

The fact that many of the patients were vulnerable and frail made the suffering inflicted by CDI particularly devastating. The lack of dignity suffered by patients in the final period of their lives and the enormous distress caused to relatives underline the importance of recognising CDI as a serious infection.

5. *C. difficile* infection rates and undeclared outbreaks

5.1 Definition of an outbreak

An outbreak of CDI includes two or more linked cases of CDI, by which is meant that the patients are suffering from the same strain of *C. difficile* toxin due to cross contamination. Different *C. difficile* strains can be identified by ribotyping, and if the strain of *C. difficile* is the same in two linked patients then that would indicate that a single ribotype was being transmitted between patients. The Infection Control Nurses in the VOLH were well aware of what constituted an outbreak.

When an outbreak is suspected, a number of people including the Medical Director have to be notified and, if an outbreak is confirmed, an Outbreak Control Team requires to be set up. An NHSGGC requirement is that the Chief Executive and/or the Chairman need to be informed.

5.2 The number of CDI results

In the period from 1 January 2007 to 1 June 2008 there were 199 positive results for *C. difficile* toxin at the VOLH. Ninety of these positive results were in the focus period. For a hospital the size of the VOLH (136 beds in 2008) this represents a significant level of activity.

5.3 Wards with CDI patients – the early period

In the early period (1 January 2007 to 30 November 2007) there were several occasions when the number of patients suffering from CDI in different wards in the VOLH should have been fully investigated. As early as February 2007 there were two patients in ward 6 who tested positive for *C. difficile* toxin within a day of each other. In April 2007 there were several patients who tested positive in ward 14 over a period of three to four days. In March 2007 two patients were positive in ward F on the same day, and around two days later another patient tested positive. These are examples of early opportunities in 2007 for full investigation of the real possibility of cross-contamination. Although no ribotyping of specimens took place during that period because the nature of the problem was not properly identified, it is inconceivable that there were not a number of outbreaks. The *C. difficile* problem was not confined to one ward. A number of the wards in the VOLH were affected.

5.4 Wards with CDI patients – the focus period

There were several occasions during the focus period (1 December 2007 to 1 June 2008) when at least two patients were suffering from CDI in the same ward in the VOLH. In ward 6 there were patients closely associated in time and place who tested positive in December 2007 and February 2008. In ward F the ward was aware of five patients testing positive between 9 and 25 January 2008. Several patients remained positive in ward F in February 2008.

5.5 Conclusion

If the outbreaks that occurred in 2007 had been identified at the time, and the proper procedures followed, the persisting CDI problem that continued up to June 2008 would have been significantly reduced and many patients would have been spared the devastating impact of the infection. CDI would not have been a causal factor in so many deaths. The omissions to identify potential outbreaks represented serious failures.

6. National structures and systems

6.1 Relevant parties and agencies

Scottish Ministers have ultimate responsibility to promote the improvement of the physical and mental health of the people of Scotland. It is through Regional and Special Health Boards that Scottish

Ministers discharge many of their duties. The Scottish Government is the executive branch of government in Scotland. Healthcare Improvement Scotland (HIS) has a general duty of furthering improvement in the quality of healthcare in Scotland. There are other agencies such as NHS National Services Scotland (NSS) and Health Protection Scotland (HPS), a division of NSS, that provide strategic support and expert input. HPS has a particular responsibility for HAIs.

NHSScotland is a generic description that encompasses the Health Boards and HIS.

The central management of the NHS in Scotland is undertaken by the Scottish Government Health Directorate (SGHD). The Cabinet Secretary for Health and Wellbeing is the Minister responsible for the SGHD.

6.2 Systems

The recognition of the growing challenges around HAI led to the creation of the HAI Task Force in January 2003. This is a multi-agency body responsible for advising on the development and delivery of Scottish Government policy to minimise HAIs. The Task Force membership is drawn from a wide range of expertise including medical directors, nurse directors and consultant microbiologists. Much of the HPS work on HAIs is carried out in conjunction with the Task Force.

The Task Force and HPS were instrumental in the development of a mandatory reporting system of *C. difficile* toxin specimens. Since 1 September 2006 specimens of diarrhoea from patients aged 65 years or over have to be tested for *C. difficile* toxin and the results of all positive results have to be sent to HPS on a weekly basis. From 1 April 2009 surveillance for CDI has included the collection of data for those aged 15 and over. This regime provides a national surveillance system for CDI in Scotland. The system is not designed to monitor the prevalence of CDI in a particular hospital. As part of the work of the Task Force, since November 2007, the Scottish Salmonella, Shigella and *C. difficile* Reference Laboratory at Stobhill Hospital, Glasgow, has been able to ribotype isolates to identify outbreaks and the emergence of new strains of *C. difficile*.

6.3 Accountability and monitoring

The system of direct accountability of Health Boards to the Scottish Government included monthly meetings, two-monthly meetings, and an Annual Review. The Annual Review is of particular importance, and is attended by the Cabinet Secretary, senior officials and Board members. There is a public session, and members of the public have the opportunity of questioning the Cabinet Secretary and the Chair of the Health Board. In the course of the Annual Reviews in August 2006 and October 2007 the Cabinet Secretary did receive assurances from the NHSGGC regarding compliance with infection prevention and control standards.

As part of the Scottish Government's annual auditing process of Health Boards, Chief Executives are required to sign a Statement of Internal Control to confirm that effective processes are in place for clinical governance, including appropriate mechanisms in place for HAI.

6.4 Health Improvement Efficiency, Access and Treatment (HEAT) Targets and CDI guidance

The Scottish Government sets performance targets, Health Improvement, Efficiency, Access, and Treatment (HEAT) Targets that Health Boards are expected to meet. CDI was not a HEAT Target in 2007 and 2008. In November 2006 MRSA was made a HEAT Target with a 30% reduction target by 2010, one that was in fact achieved by September 2009. CDI was made a HEAT Target in 2009 in the aftermath of the discovery of the problem with CDI at the VOLH. It was only then that the reporting regime set up in September 2006 had produced adequate data that could be used for comparative purposes.

6.5 The review system

The Clinical Standards Board for Scotland (CSBS) (later subsumed under NHS QIS, and since 1 April 2011 under HIS), was established as a Special Health Board in April 1999 to develop and run a national system of quality assurance of clinical services. In December 2001 CSBS published standards designed to ensure that the risk of infection was controlled. A revision of these standards was published in March 2008.

Following the publication of the standards CSBS undertook a process of review of all Trusts and Boards. The Argyll and Clyde Acute Hospitals NHS Trust was reviewed in July 2002. The Trust met only 24 out of 69 criteria. An update review on 12 May 2004 disclosed that 27 out of 69 criteria were met. No further reviews or assessments took place prior to June 2008.

The review process conducted by CSBS did include an investigatory process but it was not an inspection system. Nonetheless, in 2002 and 2004 significant failures in infection prevention and control were identified in the former Argyll and Clyde Trust.

6.6 Healthcare Environment Inspectorate

In 2007 and 2008 there was no inspection system to provide independent scrutiny of the state of the healthcare environment in hospitals, including infection control, cleanliness and hygiene. An inspection regime was introduced by the establishment of the HEI in April 2009 in response to the emergence of the VOLH CDI problem. It was a highly appropriate response. The focus of the HEI is on reducing the HAI risk to patients through a rigorous inspection framework that includes unannounced inspections of hospitals across NHSScotland. In the years since its establishment the HEI has identified a number of hospitals where there were deficiencies in infection prevention and control.

6.7 Conclusion

The introduction of CDI as a HEAT Target in 2009 was an appropriate and timely response by the Scottish Government to the disclosure in June 2008 of the CDI problem at the VOLH.

A rigorous inspection system of infection prevention and control should have been in place prior to 1 June 2008. This represents a failure on the part of the Scottish Government. Had such a system existed in the period from 1 January 2007 to 1 June 2008, its existence would at the very least have raised awareness of HAI throughout Scotland. If the VOLH had been inspected during that period the CDI problem would have been identified.

7. National policies and guidance

7.1 National guidance on the prevention and control of *C. difficile* before 2008

There was a considerable range of policies and guidance on HAI available to Boards in Scotland from the 1990s onwards. The Scottish Government and national organisations regarded infection prevention and control as an important priority. UK national guidance on the prevention and management of *C. difficile* was published in 1994. Launched in September 2003 the Cleanliness Champions Programme was designed to provide education in the basic principles of infection prevention and control with hand hygiene at the heart of the programme.

7.2 The role of Health Protection Scotland in developing guidance on *C. difficile*

Health Protection Scotland (HPS) was charged with delivering many aspects of plans devised to address HAI. This included the issuing of guidance on HAI. The publication by HPS of the *Clostridum difficile* associated disease (CDAD) bundle in March 2008 was guidance directed at CDI.

7.3 Developments from June 2008 onwards

A number of *C. difficile* related guidance documents were being developed in early 2008 but were not available prior to 1 June 2008. This included Scottish guidance on CDI and a checklist for preventing and controlling *C. difficile* associated disease.

7.4 Was the guidance on HAI adequate?

On 27 June 2008, after the VOLH CDI problem emerged, the Director General and Chief Executive of NHSScotland wrote to Health Board Chief Executives reminding them of their responsibilities for HAI. The six-page Appendix to that letter lists guidance relevant to HAI, a clear indication of the extent of the information available. There was adequate guidance available and the message on the importance of managing HAI had been repeated over several years.

Guidance in the form of a checklist was issued by HPS in August 2008. The first version of national guidance on CDI

was not published until October 2008. Notwithstanding the absence of specific *C. difficile* guidance there were policies in place which informed Health Boards of how to respond to cases and outbreaks of CDI. The guidance issued in October 2008 strengthened aspects of the guidance that already existed.

7.5 The provision of *C. difficile* guidance

Specific Scottish guidance on *C. difficile* was not available until October 2008. The publication of that guidance was originally planned for 2009 as part of a two year programme. Publication was brought forward as a result of emerging 027 outbreaks.

7.6 The monitoring of the implementation of guidance

Although there was a range of guidance available at national level, the persisting CDI problem at the VOLH showed that not enough attention was paid to the implementation of guidance.

After the discovery of the CDI problem at the VOLH in June 2008 a more prescriptive approach was adopted by SGHD with a specific action plan produced for NHSGGC and a more general action plan for all Health Boards.

7.7 Conclusion

The considerable range of policies available on HAI and *C. difficile* from the 1990s showed that the Scottish Government and national organisations took the threat of HAIs seriously. The weakness in the system was inadequate external scrutiny.

8. Changes in services at the Vale of Leven Hospital from 2002

8.1 Prolonged uncertainty

For some years there was real uncertainty over the range of services to be provided at the VOLH and indeed over the future of the hospital itself. Attempts had been made to develop a sustainable strategy for the VOLH, and between 2002 and 2004 a significant service reconfiguration took place in Argyll and Clyde resulting in services, including A&E services, being transferred from the VOLH to the RAH. This reduction in services meant that the anaesthetic service was not sustainable beyond the short term, because the volume of work available was not sufficient to allow anaesthetists to maintain their skills or provide a basis to sustain training accreditation. This state of affairs cast doubt on the sustainability of unscheduled admissions at the VOLH. This prolonged uncertainty had a damaging effect on staff morale, equipment and on the physical environment of the hospital.

8.2 Shaping the Future

In 2004 NHS Argyll and Clyde produced a public consultation paper, "Shaping the Future", setting out proposals for the reconfiguration of services substantially to be carried out by the end of April 2007. Significant changes were proposed across the whole Argyll and Clyde area. The proposals proved to be highly controversial, and there was no final strategy before the announcement in May 2005 that NHS Argyll and Clyde was to be dissolved.

8.3 The Lomond Integrated Care Model

The Lomond Integrated Care Model was developed as a specific measure to address the fragility of the anaesthetics service and to manage emergency admissions at the VOLH without the support of anaesthetists. This model envisaged that 85 to 88% of medical admissions would continue.

On the dissolution of NHS Argyll and Clyde on 1 April 2006 this model had not been fully implemented. On-site anaesthetic cover was still available at the VOLH. The Board of NHSGGC intended to fully implement the model, but medical consultants in the Clyde sector concluded that providing unscheduled care at the VOLH without anaesthetic cover would not be a safe system of work. This meant that the model could not proceed as originally conceived. The Health Minister was made aware of this at a meeting in September 2006. At a subsequent meeting in October 2006 attended by Health Department representatives and the Chief Executive of NHSGGC, the Chief Executive was told to carry out a full option appraisal of the proposed change.

8.4 A new strategy

In June 2007 NHSGGC produced a paper: "Clyde Health and Service Strategies: Outcome of Reviews and Proposals for Consultation". The extensive programme for change set out in that paper included the withdrawal of the Lomond Integrated Care Model at the VOLH and the transfer of unscheduled medical care to the RAH. At its meeting on 26 June 2007 the NHSGGC Board approved the proposals set out in the paper as the basis for formal public consultation and external review. The need for public consultation and external review arose because of the policy of independent scrutiny and public consultation introduced by the new Scottish Government elected in May 2007.

The external review was carried out by an Independent Scrutiny Panel. In its report published on 30 November 2007 the Independent Scrutiny Panel put forward a number of options for public consultation including the retention of the status quo. Subsequently, having initially rejected the need for public consultation at a Board meeting on 18 December 2007, NHSGGC reversed its previous decision under instruction from the Cabinet Secretary and, at a meeting on 22 January 2008, agreed to initiate a period of public consultation as soon as possible.

That consultation process was still ongoing in June 2008 when the CDI problem at the VOLH emerged. In June 2008 the Cabinet Secretary for Health and Wellbeing commissioned an Independent Review into the sustainability of anaesthetic services at the VOLH. That review concluded, as had been the conclusion in 2006, that anaesthetic services were not sustainable at the VOLH, but that selected unscheduled admissions could be retained at the VOLH with unscheduled medical admissions diverted to a suitably equipped hospital such as the RAH.

8.5 The Vision for the Vale

In September 2008 NHSGGC approved and published its consultation document "Vision for the Vale of Leven Hospital", with the consultation period running from 31 October 2008 to 30 January 2009. The recommendations of the Independent Review were adopted as the model for unscheduled medical admissions. At a meeting on 24 February 2009 the NHSGGC Board approved a plan that retained unscheduled medical admissions at the VOLH at a level of about 70% of the current level without the need for anaesthetic cover. The uncertainty surrounding the level of unscheduled medical care and the level of services necessary was therefore resolved after many years.

8.6 Conclusion

Prolonged uncertainty over the range of services to be provided at the VOLH, including anaesthetic cover, and over the future of the VOLH itself, had a damaging effect on recruitment, on staff morale and on the physical environment of the hospital. This state of affairs should not have been permitted to continue for as long as it did.

9. The creation, leadership and management of the Clyde Directorate

9.1 The dissolution of NHS Argyll and Clyde

Financial mismanagement in NHS Argyll and Clyde resulted in the then Minister for Health and Community Care announcing on 19 May 2005 in a statement to the Scottish Parliament that NHS Argyll and Clyde was to be dissolved. The administrative boundaries of NHS Greater Glasgow and NHS Highland were to be changed to allow these Boards to take over responsibility for managing the delivery of health services in the relevant areas of Argyll and Clyde.

NHS Argyll and Clyde was dissolved on 1 April 2006. From that date NHS Greater Glasgow took over responsibility for a significant part of the Argyll and Clyde area, including the VOLH, the IRH and the RAH. Since then the Board has used the descriptive name of NHS Greater Glasgow and Clyde (NHSGGC).

9.2 Integration

The options open to NHS Greater Glasgow were either full integration when NHS Argyll and Clyde was dissolved or phased integration. NHS Greater Glasgow was itself already in the process of restructuring, and the decision was made that full integration

should not be completed for a further three years. Acute Services within the Argyll and Clyde area that were to be the responsibility of NHSGGC were therefore initially incorporated as a single directorate of the Acute Division of Greater Glasgow.

The integration process after April 2006 was managed by the Clyde Transition Steering Group, chaired by the Chief Executive. The final meeting of this Group took place in November 2006.

The creation of the Clyde Acute Directorate was a sound decision. A significant amount of planning and expertise was involved in ensuring that the transition of the Argyll and Clyde Board's responsibilities to NHSGGC was as smooth as possible. Nevertheless, integration took place against a background of mismanagement of NHS Argyll and Clyde and of glaring deficiencies in infection prevention and control previously identified in Argyll and Clyde. Extensive transitional arrangements had been put in place for what was a major organisational change. Given this history, and notwithstanding the care taken in the planning of the integration process and the appropriateness of the establishment of the separate Clyde Acute Directorate as part of that process, it would have been desirable for a post-implementation audit or review by an independent party to have been carried out.

9.3 Impact of integration on the Vale of Leven Hospital (VOLH)

Although no criticism is made of the decision to establish the Clyde Acute Directorate, the decision did mean that infection prevention and control management within that Directorate initially remained separate from the rest of Greater Glasgow. Full integration at an earlier stage would have resulted in earlier recognition that the Clyde infection prevention and control system was defective.

As part of the continuing process of integration, in September 2007 the rehabilitation and assessment areas of the Clyde Acute Directorate were integrated into NHSGGC Rehabilitation and Assessment Directorate (RAD) but line management for infection prevention and control for the rehabilitation and assessment areas in the VOLH did not change.

9.4 Leadership of the Clyde Directorate

The new Clyde Acute Directorate required highly experienced leadership and strong management in order to achieve successful integration. Yet the recruitment process for the appointment of the Director was delayed. Mrs den Herder was not interviewed for the post until 19 June 2006 and only took up the post formally on 1 October 2006. From 1 April 2006 to 31 July 2006 an interim Director was appointed. After 31 July 2006, responsibilities for the Clyde Directorate were passed to individual Directorate General Managers until Mrs den Herder was in post.

9.5 The leadership of Mrs den Herder

The Clyde Acute Directorate was not directly comparable with other directorates within NHSGGC, as it was geographically defined rather than service-based. The range of services for which Mrs den Herder was responsible proved to be a considerable burden for her, and it is not surprising that Mrs den Herder did not initially give priority to infection prevention and control at the VOLH. Nevertheless in the course of 2007 she should have been in a position to acquaint herself with the outstanding deficiencies in the management of infection prevention and control.

Mrs den Herder failed to give sufficient priority to infection prevention and control. There is no doubt that in this, as well as in other aspects of her work, Mrs den Herder was let down by other members of her management team, but given her responsibility for infection prevention and control she should have exercised greater scrutiny of the structures that were in place. She should have been in a position to identify that there were system failures. She resigned her post in July 2008, at least in part because of "stress and burnout".[27] There can be little doubt that her stress levels would have impacted upon her performance as Director of the Clyde Acute Directorate.

9.6 Other managers in the Clyde Directorate

Other managers in the Clyde Directorate were insufficiently proactive, with the result that system failures, and in particular the failure

27 INQ04240005-06

of the Infection Control Doctor to fulfil her duties, were not identified.

The management approach to infection prevention and control in the Clyde Directorate was a manifestation of a culture that viewed infection prevention and control as being of low priority. NHSGGC has to bear ultimate responsibility for the existence of this culture notwithstanding the difficulties it encountered in inheriting the problems of NHS Argyll and Clyde and in the integration process.

9.7 Conclusion

The decision to establish a separate Clyde Acute Directorate was, in principle, a sound one. A post-implementation audit or review would have been desirable. There was a lack of continuity of leadership in the initial stages, although it is by no means certain that the clinical governance and infection prevention and control issues would have been recognised at an early stage given Mrs den Herder's failure to identify them in the months after she took up post. Generally, infection prevention and control was viewed as low priority by other managers.

10. Clinical governance

10.1 National policy

Clinical governance is the system through which NHS organisations across the UK are accountable for continuously monitoring and improving the quality of their services and safeguarding high standards of patient-focused care and services. Monitoring is a key element of effective clinical governance.

10.2 Clinical governance in NHS Greater Glasgow and Clyde

In December 2006 NHSGGC produced its own Clinical Governance Framework in recognition of the importance of having effective arrangements in place to improve public and staff confidence in the safety and quality of the healthcare provided. That Framework document also recognised the importance of monitoring arrangements to improve the quality of healthcare provided. Clinical governance responsibilities were a specific part of the role of senior staff, directors and other general managers, with the Chief Executive having overall responsibility. NHSGGC also produced more detailed guidance on clinical governance in December 2006 in recognition of its importance.

10.3 Clinical governance structures at divisional level

In NHSGGC an appropriate clinical governance committee structure was in place at divisional level. A Clinical Governance Committee (CG Committee) had responsibility to oversee the Clinical Governance Framework and assure NHSGGC that it was working effectively. There was a reporting line from the infection prevention and control committee structure through the Board Infection Control Committee (BICC) to the CG Committee.

The infection prevention and control reporting line to the BICC did not, however, identify the system and personal failures that resulted in the infection prevention and control system for the VOLH becoming dysfunctional. The CG Committee did not become aware of the CDI problem in the VOLH prior to June 2008.

10.4 Clinical governance in the Clyde Acute Directorate

At the level of the Clyde Acute Directorate (after 1 October 2006) Mrs den Herder, as Director, bore responsibility for leading the clinical governance agenda. That responsibility included ensuring the achievement of the highest possible quality of care. That responsibility for high quality care included HAI. As Director, Mrs den Herder chaired the senior committee in the Directorate with responsibility for clinical governance.

Mrs den Herder failed to ensure that the clinical governance arrangements for infection prevention and control were operating effectively. The clinical governance arrangements for which she has to bear ultimate responsibility were not geared to ensuring the highest possible quality of patient care in relation to HAI, and in particular CDI. She was not provided with routine infection prevention and control

information. Infection prevention and control was largely ignored as an element of importance to clinical governance.

Had clinical governance within the Clyde Acute Directorate been effective, the infection prevention and control failings set out in this Report would have been identified. Although the precise impact of earlier detection cannot be measured, the identification of these failings would have prevented many cases of CDI.

10.5 Clinical governance in the Rehabilitation and Assessment Directorate

The rehabilitation and assessment areas of Clyde were fully integrated with NHSGGC in September 2007. Ms Anne Harkness, the Director of the Greater Glasgow Rehabilitation and Assessment Directorate (RAD), became the Director of the extended RAD, with wards 14, 15 and F at the VOLH being included in her responsibilities. Ms Harkness was responsible for leading the clinical governance agenda in the RAD, as was Mrs den Herder for the Clyde Acute Directorate.

Prior to June 2008 Ms Harkness was not aware of the CDI problem at the VOLH. There were patients suffering from CDI in wards for which she was responsible, particularly in ward F in January/February 2008. The clinical governance arrangements were not sufficiently effective to alert her to the problem.

10.6 Reporting from the Clyde Sector

The NHSGGC CG Committee was unaware of the persistent CDI problem in the VOLH notwithstanding appropriate links being in place in the Clyde Sector. This was due to a lack of focus in the Clyde Sector on infection prevention and control as an integral part of clinical governance.

10.7 The Clinical Governance Committee and NHS Greater Glasgow and Clyde

Above the level of the Clyde Sector, clinical governance committee structures were in place, with a reporting line on infection prevention and control from the Board Infection Control Committee (BICC) to the CG Committee. Input on infection prevention and control issues was provided to the CG Committee from other sources, but because of the size of NHSGGC the information made available to the CG Committee was limited to issues deemed to be of importance. The CG Committee should have been alerted to the CDI problem in the VOLH, but the clinical governance arrangements within the Clyde Sector were not sufficiently effective to provide the necessary assurances that the infection prevention and control arrangements at the VOLH were operating properly.

10.8 Changes in clinical governance since 2008

Important changes in reporting practices have been put in place by NHSGGC since June 2008. Infection prevention and control is now a standing item on the CG Committee's agenda. The Board Infection Control Committee reports to each meeting of the CG Committee instead of annually.

10.9 No non-executive director for Clyde

The membership list for the CG Committee discloses an intention to appoint a designated non-executive director for Clyde to the committee. That did not happen. It would have been highly desirable to have a non-executive director on that committee with a specific responsibility for Clyde during a period of extensive organisational change.

10.10 Conclusion

NHSGGC's clinical governance system was not operating effectively. An effective clinical governance system would have identified the infection prevention and control failures that occurred in connection with the VOLH.

11. The experiences of patients and relatives

11.1 Sources of evidence

A total of 71 patients and relatives provided written statements to the Inquiry, eight of whom were patients.

The patients and relatives who gave oral evidence to the Inquiry were asked to recall events that for many had been highly

distressing. They gave their evidence with candour and with great dignity. In the oral evidence and in the evidence provided in statements to the Inquiry many witnesses did not directly criticise the care given by nursing staff. They described care that was deficient but that they believed could be explained by the nursing staff being overworked and understaffed. The evidence of these witnesses was provided prior to the evidence of the nursing and medical experts and the criticisms made by these experts.

11.2 The patients' and relatives' expectations

A common theme in the evidence of the patient and relative group was a desire for answers to two questions: firstly, why there were so many deaths in which CDI was implicated, and secondly, why the problem with CDI was not identified prior to June 2008. The other main theme that emerged from their evidence was the desire that others should not be made to suffer in the way that patients suffered in the VOLH.

11.3 Patient care

While many of the patients and relatives did not criticise the nursing staff directly, incidents described by them did represent examples of failures in basic nursing care. Patients in different wards were described by relatives as having dirty fingernails. Faeces were found under fingernails. One patient, whose catheter bag was seen to be full at visiting times, had puddles at the side of the bed on the floor in the vicinity of the catheter bag. The catheter bag was strapped to the patient's leg, and the patient developed sores on her leg where the bag was located. There were unacceptable failures in basic nursing care.

11.4 The patients' and relatives' view on staffing

The clear impression gained by these witnesses was that there was a shortage of staff on the wards and that the nurses were overworked. It was that belief that convinced them that members of the nursing staff were doing the best they could in difficult circumstances. Staff morale was perceived as low.

11.5 Communication

Relatives expressed a real concern about a general lack of communication by nursing and medical staff. Difficulties were encountered in speaking to nursing staff and in obtaining information from medical staff. The fact that the nursing shift change coincided with evening visiting caused a particular problem. One area where there was a lack of proper discussion was that of decisions not to resuscitate patients in the event of cardiac arrest.

There was also a lack of communication over CDI. A number of witnesses were not aware of relatives having contracted CDI until the relative had died. One witness only became aware that a patient had been diagnosed with CDI when he saw "*C. difficile*" on the death certificate.

Good communication should be seen as an important element of patient care so that patients, and where appropriate relatives, can be involved in decisions about care.

11.6 Ward fabric and cleanliness

It was obvious to patients and relatives that the VOLH was run down. There was some evidence that the hospital environment was not particularly clean. Storage was an obvious problem, with items stored within patient bays. Faeces were seen on items of patient clothing. Urine on the floor of one ward had not been properly cleaned and produced a stench that was described as "disgusting".[28] Commodes were seen to be dirty.

11.7 Infection prevention and control issues

In a number of wards inadequate information was given on hand washing, and many visitors were not advised of the importance of using soap and water when a patient was diagnosed with CDI. Heavily soiled laundry was taken home by some relatives of patients suffering CDI with inadequate and conflicting information on how the laundry should be managed. Most witnesses said that nursing staff did wear aprons and gloves when dealing with patients, but a number of witnesses did not recall seeing a notice

28 TRA00040030-31

outside an isolation room when a patient was suffering from CDI. Isolation practices were seen to be carelessly managed, with doors of isolation rooms left open.

11.8 Conclusion

The patient and relative group pressed for a public inquiry because they wanted a full examination of why the CDI problem had persisted for as long as it did and why there were so many deaths in which CDI was implicated. The descriptions of care provided did identify serious failures in patient care.

12. Nursing care

12.1 The Nursing and Midwifery Council Code of Conduct

The Nursing and Midwifery Council (NMC) sets standards for nurses and midwives for the provision of safe and appropriate care.

The NMC, through its Code of Conduct and other advice, emphasises that record keeping is an integral part of nursing care. If widespread failures in record keeping are identified there can be little doubt that care has been compromised.

12.2 Use of nursing experts

Seven independent nursing experts were commissioned by the Inquiry to provide professional opinions on the quality of nursing care given to patients who suffered from CDI during the focus period (1 December 2007 to 1 June 2008). They were instructed to review the patient records and Infection Control Cards and asked to use the professional standards of the NMC as a benchmark for the standard of care expected from nursing staff. Cases from different wards were allocated to each expert. An infection control nursing expert was asked to review some aspects of nursing care in that period. The available patient records for the early period (1 January 2007 to 30 November 2007) were also reviewed by one of the nursing experts.

12.3 Overall view of nursing experts

There was a catalogue of failures in fundamental aspects of nursing care. Deficiencies in nursing care were not restricted to one particular ward or limited to a particular period of time. It was apparent that standards of nursing care had been permitted to lapse over a period of time.

12.4 Record keeping

The record of a patient's stay in hospital is an essential clinical tool. Nursing is not a memory game. The standard of record keeping by the nursing staff in the VOLH was poor. It was clear that a culture had developed in which record keeping was not considered to be a priority. Nurses maintained in evidence that with small wards they were fully aware of the needs of the individual patients without having detailed and complete records. This was a seriously flawed approach and must have contributed to failures in patient care.

The NMC Guidance emphasises that auditing plays a vital part in ensuring that good quality care is being provided to patients. Deficiencies identified through auditing can be responded to by staff training and development. No auditing of records was carried out from 1 January 2007 to April or May 2008. Peer audits of patient records had taken place in the past, but none had been carried out in the VOLH since 2003.

12.5 Nursing aspects of infection prevention and control

Nurses are at the frontline of the delivery of care. To deliver care to an acceptable standard to patients with CDI nurses must have the relevant knowledge and skills.

Prior to June 2008 the majority of nursing staff in the VOLH had no formal training on CDI. Some nurses in the VOLH had completed the Cleanliness Champions Programme prior to 1 June 2008 but the uptake was poor. Infection Control Nurses at the VOLH did visit wards to provide advice, but there was little evidence in the nursing records on the advice given because generally no record was made.

Evidence of the nurses' knowledge of the seriousness of CDI as an infection was somewhat mixed. There was evidence that it was seen as a serious infection, but there was also evidence of a lack of awareness of the significance of the infection. A review

of nursing records disclosed that there was little to suggest that nurses were aware of the seriousness of CDI as an illness. The importance of fundamental aspects of care, including fluid balance management and nutrition, was not recognised. Delays in the administration of antibiotics for patients who tested positive for CDI represented a wholly unacceptable level of care for patients who in the main were elderly and vulnerable and exposed to serious risk by contracting CDI.

Although the Loose Stools Policy quite rightly provided that a patient who could contaminate the environment with faeces should be isolated unless the patient was clinically unsuitable for isolation, the practice in the VOLH was not to isolate patients until a positive laboratory result of the diagnosis was obtained. This practice was to an extent influenced by a shortage of isolation rooms but because it was usually possible to isolate once the diagnosis was confirmed it was clear that isolation could have occurred earlier. The practice was an unsafe one and put asymptomatic patients at risk.

12.6 Isolation issues specific to ward F

The admission of a patient to ward F in February 2008 was badly managed. The patient was not symptomatic for CDI, but was admitted into a bay where there was at least one symptomatic patient. This patient later contracted CDI. The investigation into a complaint by this patient's family was poorly carried out with the result that the Chief Operating Officer was misled and provided inaccurate information in response to the complaint.

12.7 Nursing assessments and care planning in the focus period

Effective patient assessment on admission to hospital is integral to the safety, continuity and quality of patient care. The assessment provides baseline information on which to plan care.

In the admission assessment documentation available in the VOLH many basic details were often not recorded. Some sections were not completed at all. Important information such as the patient's weight, assessment of the risk of pressure damage, and the baseline observations of temperature, pulse, respiration and blood pressure, was regularly omitted from the assessments.

Pro forma nutritional assessment documentation was available but had not been distributed to all wards. Where available there were deficiencies in the assessments including a failure to regularly reassess the position and delays in patients being referred to a dietician. Other assessments like moving and handling and falls risks assessments were often either not completed at all or incorrectly completed with no evidence of reassessment.

Care planning is a term used to describe the process of assessing a patient's needs. It is a prescription for care. The ability to prepare an appropriate care plan is a core skill, and the absence of an appropriate care plan makes it difficult for nurses and other members of the healthcare team to deliver consistent and coordinated care. Care planning should be seen as a mandatory professional responsibility.

Care plans were poorly completed and did not reflect all of the patient's problems. In one ward the well recognised nursing model for care planning had been abandoned in favour of a medical model that simply consisted of listing the medical instructions on the care plan documentation. This was a wholly inappropriate model of care planning. For many of the patients who contracted CDI no care plans had been prepared.

12.8 Nursing notes and charts in the focus period

The nursing evaluation records are an important part of the patient records and are the direct responsibility of the nurses caring for the patients.

There were serious failures in the recording of patient information in the nursing evaluation records. There were unacceptable gaps in some records. The handover practices adopted at the VOLH included information obtained by the nurse during the shift being noted on a handover sheet for use during handovers. On many occasions this information had not been entered into the

patient records. The handover sheets were not retained.

There were serious failures in the recording of observations in patients who were ill with CDI and in the nursing management of pain. In general there was no proper recording of stools in patients with unexplained diarrhoea and also when there had been a diagnosis of CDI. The recording of fluid balance, of obvious importance to patients suffering from CDI and at real risk of dehydration, was poor.

12.9 Pressure damage in the focus period

Immobile, sick and weak patients are unable to move effectively and are dependent upon their carers to assist them. They are at particular risk of sustaining pressure damage. Patients who are suffering from CDI with profuse diarrhoea are particularly vulnerable to skin damage. That is one reason why moving and handling techniques are important in the management of these patients.

Effective nursing care should prevent pressure damage where possible. Early assessment of the risk to the patient is imperative so that appropriate measures can be put in place to prevent pressure damage or at least reduce the risk.

In the VOLH the intention was that the risk of pressure damage should be assessed on admission by using the established criteria contained in the Waterlow Scoring system. The appropriate documentation for the implementation of this system was available to nurses in the VOLH. The Waterlow Scoring system documentation was not, however, being used in ward 6.

There were serious deficiencies in pressure management. There were failures to assess patients and failures in documentation of the risk which included incorrect scoring. In cases where initial assessments were made, there were failures to review assessments appropriately and to prepare appropriate care plans. On the whole pressure and tissue management at the VOLH was poor. Inevitably this would have had an impact on care. So far as the Inquiry can ascertain at least 37 patients in the focus group of 63 patients suffered pressure damage, although it is not possible to say how many patients might have suffered some pressure damage prior to admission.

Between January 2007 and June 2008 the VOLH did not have a dedicated Tissue Viability Nurse (TVN). That task was being carried out by one of the Senior Charge Nurses (SCNs), which placed her in a very difficult position because of her responsibility for a busy medical ward. Given the importance of tissue viability a nurse who was an SCN on a busy ward should not have been selected as the TVN for the VOLH.

12.10 Nursing care in the early period

The nursing expert who examined the patient records for the early period (1 January 2007 to 30 November 2007) had access to 33 sets of patient records out of a total of 68 patients who tested positive for CDI. The trends evident on basic aspects of nursing care in the focus period were also present in the early period.

12.11 Staffing issues and care

Adequate staffing of nurses on wards is dependent not only on having the correct number of nurses, but also on having the correct skill mix to carry out the care appropriate to the level of patient dependency. Adequate nursing staffing levels are important for ensuring patient safety and quality of care. The staffing ratios for all the wards in the VOLH were acceptable for the number and nature of patients for these wards. Similarly the ratio of registered/trained to untrained staff on the medical wards was appropriate. The use of bank and agency staff was at an expected level.

What the staffing ratios do not do, however, is take account of a number of patients becoming unwell with profuse diarrhoea and requiring additional nursing input. Nor do the ratios for the Rehabilitation and Assessment wards take account of the fact that some patients in those wards may be medically unwell and may require nursing rather than rehabilitation care. The nurses' evidence was that they were extremely busy on the wards, and that was regularly advanced as a reason why nursing records were incomplete. It is highly likely that, with patients in a

rehabilitation ward being acutely unwell and patients in different wards suffering from CDI, staffing levels were inadequate at times between January 2007 and June 2008. Activity levels on wards may very well at least partially explain why the nursing records were not kept as they should have been, but that does not in any way excuse the significant deficiencies found. Having regard to the serious failures identified, it is simply not tenable to maintain, as nurses did in evidence, that the care was in fact given.

12.12 Overall conclusions on nursing care

There were failures in fundamental aspects of nursing care of patients who suffered CDI. The SCNs must be primarily to blame for the deficiencies in their own wards.

Nursing Management was unaware of the extent of the problem with fundamental aspects of care. A functioning system of audit would have identified failures of the kind identified here and would have allowed remedial action to be taken. Effective Nursing Management would have identified the deficiencies in nursing care.

Ultimately NHSGGC must accept responsibility for the failures in nursing care identified in Chapter 12 of the Report.

13. Antibiotic prescribing

13.1 Antimicrobial policy and prudent prescribing

By letter dated 21 May 1999 addressed to Health Board General Managers and Chief Executives of NHS Trusts, among others, the Scottish Office Department of Health set out a wide range of actions aimed at reducing the emergence and spread of antimicrobial resistance and its impact on the treatment of infection. One of the key elements identified was prudent antimicrobial use.

In the years that followed this message was repeated. In 2002 the then Scottish Executive produced the "Antimicrobial Resistance Strategy and Scottish Action Plan" (the 2002 Action Plan). This was a three-year plan with aims that included the reduction of unnecessary and inappropriate use of antibiotics. Subsequently in 2005 a guide on the use of antibiotics for NHSScotland: "Antimicrobial Prescribing Policy and Practice in Scotland" (the 2005 guide) highlighted the challenges faced in antimicrobial prescribing, including concern about inadequate supervision of prescribing and inappropriate choice, duration of treatment and records of administration by junior doctors. One of the key recommendations of the 2005 guide was that a multi-disciplinary Antimicrobial Management Team (AMT) should be formed by each Health Board to be responsible for implementing antimicrobial policy and practice.

13.2 The 2008 Action Plan

In March 2008 the then Cabinet Secretary for Health and Wellbeing launched the "Scottish Management of Antimicrobial Resistance Action Plan" (the 2008 Action Plan) which was to replace the 2002 Action Plan. The 2008 Action Plan echoed the theme that had emerged in Scotland at least by 1999, and had persisted over the years, that it was known that antibiotic prescribing was not being carried out in a prudent manner.

13.3 Significant failures in implementation and monitoring

Prior to June 2008 the message on the importance of prudent antibiotic prescribing had certainly not reached the VOLH, where prescribing was far from prudent. The discovery of the CDI problem in the VOLH in May and June 2008 was a catalyst for change, but change in antimicrobial practices should have happened long before that time. Furthermore, reports into CDI outbreaks at the Stoke Mandeville and Maidstone and Tunbridge Wells hospitals published in 2006 and 2007 should have prompted an examination of antibiotic prescribing practice. A culture had developed in which clinicians, were using broad spectrum antibiotics in situations where they were no more effective against those infections that were sensitive to narrow spectrum antibiotics.

The recognition at national level of the need for prudent antibiotic prescribing and implementation of that policy produced an ineffective response by NHSGGC over a period of several years. The failure to

implement the prudent prescribing message should have been identified and remedied at an earlier stage by the Scottish Executive and later the Scottish Government. There was an obvious mismatch between expectation and implementation.

13.4 The Antimicrobial Management Team

The recommendation that Antimicrobial Management Teams (AMTs) should be set up was contained in the 2005 guide available to Health Boards from 5 September 2005. The NHSGGC AMT was not established until June 2007, but in circumstances that involved planning and financial support there was no undue delay by NHSGGC in setting up the AMT. A number of other Boards had not set up AMTs prior to June 2008, and were instructed by the Scottish Government to do so immediately after the problem with CDI at the VOLH came to light.

The NHSGGC AMT reacted swiftly and effectively to the emergence of the CDI problem at the VOLH. Steps taken to improve prudent prescribing had a dramatic impact on the number of CDI cases in the NHSGGC area even in the relatively short term.

13.5 Conclusion

The importance of prudent antibiotic prescribing had been recognised in Scotland for many years prior to June 2008. Important guidance was available but there was a mismatch between expectation and implementation that should have been addressed prior to June 2008.

14. Medical care

14.1 Inquiry medical experts

Medical experts commissioned by the Inquiry were given the patient records and Infection Control Cards of the patients allocated to them. Patient records from different wards were considered by each medical expert. The professional standards issued by the General Medical Council (GMC) were used by the medical experts as a benchmark for the standard of care expected from medical staff.

14.2 Record keeping

The GMC's "Guidance for Doctors" effective from 13 November 2006 provided that doctors should keep clear, accurate and legible records, reporting the relevant clinical findings, the decisions made, information given to patients, and any drugs prescribed or other investigation or treatment. The message for doctors who want to show that care of the necessary quality has been given is to make an accurate and complete record of that care. As with nurses, good record keeping by doctors is an integral aspect of good care.

Records made by the consultants at the VOLH were generally adequate, but the recording of a patient's condition and assessment made by junior doctors was poor. There was a real problem in identifying from some of the records why a particular antibiotic was being prescribed.

14.3 Medical staffing

Years of uncertainty over the future of the VOLH had a significant impact upon the recruitment of medical staff.

The departure of different specialist services from the VOLH over the years meant that the VOLH was regarded less and less as a potential source of senior education. Between January 2007 and June 2008 there were no middle grade doctors such as registrars in the VOLH. As a result a significant burden of managing patients was borne by junior doctors and added to the pressures on the senior medical staff. There was a lack of continuity of care. The pressure imposed upon one senior doctor because of his on-call duties had a significant impact upon his ability to conduct ward rounds.

The rehabilitation wards should have been mainly geared towards rehabilitation and not to looking after acutely ill patients. Between January 2007 and June 2008, however, acutely ill patients were in these wards, which increased the pressure on the doctors with responsibilities for these wards and impacted on care. This was recognised to an extent by management, and by at least February 2008 steps were being taken to monitor the provision of care at the VOLH while a decision on the future of the VOLH was awaited. Morale was low because of the uncertainty over the future of the hospital.

On inheriting the VOLH, NHSGGC took over a hospital that for a number of years had suffered losses of services and serious mismanagement. Uncertainty over the future of the VOLH and recruitment problems placed NHSGGC in a difficult position.

14.4 Medical management of CDI

A patient who tests positive for CDI should be reviewed that same day. That review should include a clinical assessment of the patient's condition to assess the severity of the condition. The patient records disclosed, however, that there were delays in medical intervention with patients who had tested positive for CDI, suggesting that the severity of CDI as an illness was not properly recognised. Subsequent review should also be regular, which could mean on a daily basis. Even if it is accepted that there might have been more regular reviews than have been recorded in the patient records, it is clear that there were a significant number of instances where there was no review. Because junior doctors were at the forefront of care, their inexperience resulted in failures to notify senior medical staff when senior medical involvement was necessary.

The inadequacy of medical reviews and assessment compromised patient care. The lack of proper supervision of junior doctors was simply the result of the uncertain future of the VOLH as a hospital. Senior medical staff were exposed to pressures that limited their ability to provide the necessary supervision. It may not be easy for a Board to scrutinise the levels of medical care provided but assurance can be obtained that the quality and safety of care meet the requisite standard through appropriate systems. Ultimate responsibility for standards of care not being adequate rests with NHSGGC.

14.5 Do Not Attempt Resuscitation orders

A Do Not Attempt Resuscitation (DNAR) order is a written record of a decision that if the patient suffers a cardiac arrest he or she will not be resuscitated. A significant number of DNAR orders had been incorrectly completed, for example by failure to record a date for review. There was no evidence that the auditing envisaged by the DNAR Policy ever took place.

14.6 Antibiotic prescribing

In the period from 1 January 2007 to 1 June 2008 a variety of guidelines on antibiotic prescribing was being used at the VOLH. In the main there was consistency among the junior medical staff in the use of antibiotic prescribing guidelines. There was, however, a lack of uniformity in the use of guidelines among the senior medical staff, and there were some differences between the guidelines. This situation should not have developed. In a hospital like the VOLH clinicians should have been following one common agreed policy.

The patient records disclose that 60 of the 63 patients in the focus group did receive antibiotics while in the VOLH. At least 24 of those patients received antibiotics in the community which may have predisposed them to CDI, and at least three further patients had been prescribed predisposing antibiotics at the RAH before admission to the VOLH and before receiving antibiotic treatment in the VOLH. Nevertheless, more than half of the patients in the focus group were first prescribed antibiotics which predisposed them to CDI while they were in the VOLH. The antibiotics involved in the VOLH included third generation cephalosporins, quinolones and broad spectrum penicillins such as amoxicillin and co-amoxiclav (Augmentin). The prescribing of antibiotics in the VOLH therefore played a significant role in many of the patients in the focus group contracting CDI.

Poor documentation of the reasons for the choice of certain antibiotics made it difficult to ascertain whether or not the choice was appropriate. There were many examples of appropriate prescribing for conditions other than CDI. Nevertheless, it was evident that there were instances where the choice of antibiotic was inappropriate or where antibiotics were prescribed when unnecessary. There were also instances of the continued prescription of antibiotics in cases where a laboratory test demonstrated the organism was resistant to that antibiotic. After stricter controls were introduced in June 2008 there was a significant reduction in the use of co-amoxiclav in hospitals in NHSGGC, including the VOLH.

In most cases of CDI, once the treatment was started, appropriate antibiotic treatment by the prescription of metronidazole or vancomycin was given, although there were instances where ongoing monitoring should have led to a reassessment of treatment with greater input from a microbiologist.

14.7 The process for testing for *C. difficile* toxin

Delay in the prescription and administration of appropriate antibiotic therapy for CDI can have a significant impact on the management of the condition, and tends to make the outcome worse, particularly if the patient continues to receive broad spectrum antibiotics. The general practice adopted in the VOLH (with few exceptions) was that treatment for CDI was not started until a positive result was communicated by the Laboratory. This was in accordance with normal practice, but it does mean that there must be no undue delay between the taking of the specimen and the commencement of treatment.

There were a significant number of cases where there were either delays in the processing of specimens or delays in the commencement of treatment after the ward was aware of the result. There were also cases where there was a combination of processing and treatment delays, and these combined delays resulted in treatment being delayed for periods ranging from two to seven days. The delays identified in the commencement of treatment after positive results were known by the ward were inexcusable. The patients concerned continued to be unnecessarily exposed to any existing antibiotic treatment that they were receiving and to an untreated serious and potentially life-threatening infection.

No doubt there were failures by individuals in relation to antibiotic prescribing and for the delays in the treatment of CDI patients, but the ultimate responsibility for standards having become unacceptable must rest with NHSGGC.

14.8 Conclusion

The medical care of patients suffering from CDI was inadequate. Poor record keeping, failures in carrying out proper medical assessments and review, inappropriate prescribing and unacceptable delays in the commencement of appropriate antibiotic treatment after positive results were available, compromised patient care.

15 Infection prevention and control

15.1 The constitution of an Infection Control Team

Clear guidance has been in place on the constitution of an Infection Control Team (ICT) since 2001. The ICT should include an Infection Control Doctor (ICD) and properly trained Infection Control Nurses (ICNs). The ICD should be the leader of the ICT. NHSGGC had ICTs in place for the sectors that made up the NHSGGC area. The VOLH was in the Clyde Sector as was the RAH and the IRH.

15.2 The Infection Control Team for the VOLH

During most of the period from 1 January 2007 to 1 June 2008 there were two Infection Control Nurses based at the VOLH. The senior Infection Control Nurse, Mrs Jean Murray, became interim Lead Nurse for infection control for the Clyde Directorate in July 2007, which involved taking on additional responsibility for infection prevention and control outwith the VOLH. She began a period of phased retirement in January 2008 and stopped work on 17 March 2008. The other Infection Control Nurse, Mrs Helen O'Neill, did not have a qualification in infection prevention and control. Particularly during Mrs Murray's phased retirement Mrs O'Neill bore the brunt of the infection prevention and control duties at the VOLH.

The ICD for the Clyde Sector for the period from 1 January 2007 to early February 2008 was Dr Elizabeth Biggs. She was based at the IRH. Dr Biggs was under a duty to take a lead role in the effective functioning of the Infection Control Team. Dr Linda Bagrade took over as ICD in February 2008.

No formal appraisals of the Infection Control Team members were carried out in the period 1 January 2007 to 1 June 2008. At that time there was no functioning formal system of

appraisals in place at the VOLH, a situation that had existed for several years.

15.3 The infection prevention and control management structure

Ms Marie Martin had been the General Manager of Diagnostic Services for the Clyde Sector since April 2006, with a remit that also included responsibilities for infection prevention and control. Within the infection control structure for the Clyde Sector Ms Martin was the designated line manager for Dr Biggs and for Dr Biggs' successor, Dr Bagrade. Ms Martin had a duty to ensure that there was adequate staff in place and that the staff had the resources and assistance in place to allow them to do their job. Ms Martin reported to Mrs den Herder. Within the Clyde Directorate Mrs den Herder had overall line management responsibility for infection prevention and control, with a reporting line to the Chief Operating Officer of the Acute Services Division.

Ms Martin failed to address the obvious and significant gap created by Mrs Murray's phased retirement, particularly when Mrs O'Neill was an unqualified ICN and required supervision. This was at a time when a significant problem with CDI had developed in the VOLH.

15.4 Implementation of policies and training

The Infection Control Manual available in the VOLH contained appropriate policies relevant to infection prevention and control. Medical staff had not received training in infection prevention and control (other than as part of their undergraduate training) and had little awareness of the policies contained in the Infection Control Manual. Nursing staff did have an awareness of the Infection Control Manual. The relatively small number of nurses who had undertaken the Cleanliness Champions Programme would have gained some insight into aspects of infection prevention and control. Evidence from the nurses, however, suggested that prior to June 2008, they had received no formal training in CDI.

Important policies contained in the Infection Control Manual included the Outbreak Policy, the Loose Stools Policy and the *C. difficile* Policy. The Outbreak Policy defined the action to be taken if an outbreak was suspected or confirmed. The Loose Stools Policy identified the importance of patients suffering from loose stools being placed in a single room. In the main this was not the practice in the VOLH prior to 1 June 2008, with the result that the risks of cross-contamination were greatly increased. In a significant number of cases delays in isolation after the result was known increased the risks of cross-contamination even more. The *C. difficile* Policy highlighted the importance of hand hygiene and the fact that soap and water had to be used in conjunction with alcohol hand rub before and after direct patient contact.

The message contained in guidance issued by the Scottish Executive and subsequently by the Scottish Government that infection control was everyone's business had not reached the medical staff at the VOLH, and was not practised by the nursing staff in a number of respects, including the failure to isolate potentially infectious patients, and failures in stool charting and care planning.

15.5 The Infection Control Manager

Mr Thomas Walsh, the Infection Control Manager for NHSGGC from 25 June 2007, did not have any operational or line management responsibilities for infection prevention and control. The reference to management in his job description related to "management of the processes rather that than the management of human resources involved …". The Infection Control Manager's role was based on the then Scottish Executive Health Department guidance, but after June 2008, and following upon the events at VOLH, in January 2009 the role of the Infection Control Manager was changed so as to incorporate operational and line management responsibilities. That was a highly desirable change as the role created by NHSGGC for the Infection Control Manager, as understood by Mr Walsh, was not one that produced a system providing effective leadership of infection prevention and control.

15.6 The Nurse Consultant

The Nurse Consultant for Infection Control in the period from1 January 2007 to 1 June 2008, Ms Sandra McNamee, had a

job description that required her to provide "strong strategic and clinical leadership across NHSGGC". Like the Infection Control Manager, the Nurse Consultant did not have line management or operational responsibility for the Infection Control Teams. Ms McNamee did take over managerial and operational responsibility for the Infection Control Nurses of NHSGGC from 2009 as Assistant Director of Nursing for Infection Prevention and Control, and again this was an important change of remit that could only serve to strengthen the infection prevention and control system. If the Nurse Consultant had had more operational responsibility for the infection prevention and control structures, she would have been in a better position to identify deficiencies in those structures.

15.7 The infection control committee structure

NHSGGC had in place a committee structure designed to report infection control issues from the VOLH to the Board.

Within the VOLH itself, there was a link nurse system in place. There was no reporting line from the meetings of this Group, its apparent purpose being to increase awareness of infection prevention and control issues at ward level. The meetings of this Group were poorly attended, and there was no evidence before the Inquiry that it made any effective contribution to infection prevention and control in the VOLH in the period from 1 January 2007 to 1 June 2008.

The VOLH Infection Control Working Group (the Working Group) was also a local Group based at the VOLH, and was chaired by Mrs Murray. Meetings of the Working Group were also poorly attended, and the meeting planned for December 2007 did not take place because so many apologies for non-attendance were received. The next meeting should have been in March 2008, but again no meeting took place.

The Working Group had a reporting line to the Clyde Acute Infection Control Support Group (the Support Group). The Support Group was supposed to be the main Group within the Clyde Sector for identifying, responding to and reporting infection prevention and control issues. It was chaired by Dr Biggs. At the meeting of the Support Group of 10 July 2007 Dr Biggs indicated that she felt that the ICD should not be the person to chair the Support Group. The next planned meeting on 9 October 2007 therefore did not take place, and indeed the Support Group did not meet again. The combined failures of the Support Group and the Working Group resulted in a significant gap in the reporting chain that was designed to report from ward to Board.

The reporting line for the Support Group was to the Acute Control of Infection Committee (ACIC). In the period from 1 January 2007 to 1 June 2008 the ACIC was chaired by Dr Robin Reid, Associate Medical Director Diagnostics. In addition to the Clyde Sector, all other NHSGGC areas reported to the ACIC. The ACIC reported to the NHSGGC Board Infection Control Committee (BICC) chaired by Dr Syed Ahmed, Consultant in Public Health Medicine. The BICC reported to the Chief Executive and also to the Board CG Committee. Dr Biggs was a member of the BICC but did not attend any meeting from January 2007 to 1 June 2008.

15.8 Reporting within the infection control committee structure

From 1 January 2007 to June 2008 the reporting of issues about infection prevention and control was carried out within an established system of "exception reporting" designed to control the flow of information through the hierarchy of committees. This meant that at the levels of the ACIC and the BICC an issue would only be reported if, for example, there was a concern that it was outwith normal parameters. An outbreak of CDI would qualify for exception reporting, although in practice any outbreak ought to be identified and responded to before any meeting took place.

The system of exception reporting provided an important filter of information within an organisation as large as NHSGGC. It was important that senior management was not inundated with matters that could be managed adequately at levels further down the chain. Such a system, however, does depend upon individuals recognising and reporting exceptional events. Because

there were significant individual failures within the Infection Control Team for the VOLH, important information on the nature and extent of the CDI problem in the VOLH was not being transmitted to the ACIC. Consequently there was no discussion at the ACIC level about the prevalence of CDI in the period from January 2007 to June 2008. Similarly, the BICC was not made aware of the persisting problem with CDI at the VOLH.

The exception reporting system therefore failed to identify the CDI problem that existed in the VOLH throughout most of 2007 and up until its discovery in May 2008. It is undoubtedly the case that, if the infection control structure had worked in the way it was intended to work, the problem with CDI at the VOLH would have been discovered and responded to.

Infection prevention and control is a core part of patient safety, and senior management ought to have been made aware of the rates and trends of a hospital associated infection such as CDI. The principle of Board to ward and ward to Board means that there must be an unbroken line of reporting, accountability and assurance. The failure to have a system in place whereby rates and trends of CDI in hospitals such as the VOLH were being made available at least to meetings of the ACIC and subsequently reported to the Board, was a system failure and one that contributed to the CDI problem persisting up to June 2008. This is a failure for which NHSGGC has to bear ultimate responsibility.

15.9 The failure of the committee structure

As the chair of the Working Group, Mrs Murray was directly responsible for its failure to meet after 28 September 2007. Dr Biggs was directly responsible for the failure of the Support Group to meet after 10 July 2007. Ms Martin knew the Support Group had ceased to meet and had direct responsibility to tackle the problem created by Dr Biggs' failure to convene the Support Group. Ms Annette Rankin, Infection Prevention and Control Head Nurse, was aware that the Support Group had ceased to meet and failed to raise this issue at meetings of the ACIC that she attended. Mrs Murray, as a member of the Support Group, was also aware that it had ceased to meet. She too had opportunities to raise the issue, particularly at meetings of the ACIC at which she was in attendance. Although Mrs den Herder has maintained in correspondence that she did not know the Support Group had ceased to meet, she did receive the minutes of the Support Group and it should have become apparent to her that that Group had stopped functioning.

The respective chairs of the BICC and the ACIC, Dr Ahmed and Dr Reid, were not made aware of the failure of the Support Group. Nor was the Infection Control Manager, Mr Walsh.

15.10 Surveillance systems

Effective surveillance is a necessary prerequisite of a properly functioning infection prevention and control system.

In the VOLH the Infection Control Nurses operated a T-card monitoring system. This system involved identifying a patient who had been diagnosed with CDI by entering information onto a yellow T-card which was then placed in a rack by reference to the ward in which the patient was accommodated. If there were two or three CDI cases in a particular ward at the same time there would be two or three yellow cards in a line to display that information. In that way the system could provide contemporary information on the number of positive cases and alert the Infection Control Nurses to a potential problem with CDI. As disclosed by an examination of the T-cards, the Infection Control Nurses' record keeping was totally inadequate.

The VOLH also had an Access database system. The Infection Control Nurses entered information into the system on patients who tested positive for CDI. It was then possible to access data in different forms from the database and extract those data to create reports and identify trends.

The Infection Control Nurses at the VOLH should have been able through regular visits to wards to identify the extent of the CDI problem that persisted in the VOLH during the period from 1 January 2007 to 1 June

2008. In any event the systems available were themselves perfectly adequate to enable the Infection Control Nurses to discover the existence of potential outbreaks of CDI.

15.11 Failure to identify outbreaks

The failures at local level to appreciate the nature of the persisting CDI problem at the VOLH were serious and had a profound effect on patient care. At different points in time during the period from 1 January 2007 to 1 June 2008 it was apparent in different wards that there were patients suffering from CDI who were linked in time and place. The medical staff seemed oblivious to the persisting CDI problem. Any focus given to CDI patients by nursing staff was influenced by Mrs Murray's perspective that the problem could be explained by factors other than cross-contamination.

At the meeting of the Support Group on 9 May 2007 a report was presented by Dr Biggs containing important information on the status of CDI patients in the VOLH. The report disclosed that in April 2007 there were 22 positive results for CDI in the VOLH. Another source of evidence in that report disclosed that four patients tested positive for CDI in ward 14 in the week beginning 13 April 2007. This was a relatively early opportunity to identify the extent of the problem with CDI in the VOLH, but it was an opportunity that was completely missed. An appropriate response to the information contained in the report would almost certainly have identified the CDI problem and saved a significant amount of further suffering. Dr Biggs' response, as Infection Control Doctor, was totally inadequate and professionally unacceptable.

In the period from 1 January 2007 to 1 June 2008 there were a number of opportunities to carry out a proper investigation into why there were patients suffering from CDI in different wards in the VOLH. Because no proper investigations were carried out no ribotyping of the positive *C. difficile* toxin samples was conducted which would have established whether the same strain of infection was involved. However, it is inconceivable that there were no outbreaks during that period.

Mrs Murray, as the Senior Infection Control Nurse at the VOLH, repeatedly failed to recognise that the most likely explanation for the presence of two or more patients suffering CDI in the same ward and closely linked in time was cross infection. She excluded cross infection because in her view there were other risk factors that could lead to patients developing *C. difficile* diarrhoea. Her position was completely illogical, particularly when the great majority of the cases of CDI were described in the Access database system as "hospital related". Her failures were serious failures and contributed in a significant way to the persisting CDI problem at the VOLH. The failures meant that the outbreak procedures contained in the Infection Control Manual were never invoked. If they had been, other levels of management within the infection control structure would have been alerted to the CDI problem.

15.12 Role of the Microbiologists

By 2005 there was real concern about the number of vacant microbiology posts in Argyll and Clyde, with two out of the five positions being vacant. The resident microbiologist in the VOLH had resigned in 2002 and another microbiologist had left her post at the RAH in 2005, with neither post being filled. Arrangements were made to provide some microbiology cover for the VOLH which were intended as a stopgap pending the appointment of additional microbiologists. Dr François de Villiers, Consultant Microbiologist at the IRH, and Dr Barbara Weinhardt, Consultant Microbiologist at the RAH, were involved in these arrangements, under which limited on-site clinical microbiology cover was provided at the VOLH by Dr de Villiers. Difficulties in recruitment meant that the vacant posts were not filled until early 2008, with the result that the staffing arrangements for consultant microbiologists in the Clyde Sector were unsatisfactory throughout the period from January 2007 to January 2008. The unsatisfactory nature of the arrangements was compounded by Dr Biggs' failures in her duty as ICD.

C. difficile toxin positive results required to be authorised by a consultant microbiologist. Although on occasion that did not happen, the

number of positive reports being authorised in December 2007 and into early 2008 did make consultant microbiologists in Clyde aware of an increased incidence of CDI. One of these consultant microbiologists raised the issue with Dr Biggs, suggesting that she should investigate the position in hospitals for which she was the Infection Control Doctor. There is no evidence that Dr Biggs carried out any investigation into the prevalence of CDI at the VOLH. In December 2007 and January 2008 there were patients suffering from CDI in a number of wards in the VOLH, and an investigation at that time would have disclosed the likelihood of an outbreak.

Prior to the appointment of the two additional microbiologists in early 2008, the system in place meant that a co-ordinated, integrated microbiology service was not being provided to the VOLH.

15.13 The Infection Control Doctor

Dr Biggs was the designated ICD for the Clyde Sector, which included the VOLH. This was a responsibility that certainly spanned the period from1 January 2007 to early February 2008, when Dr Bagrade took over as ICD. Dr Biggs was unable on health grounds to provide a written statement or give oral evidence to the Inquiry.

Professional line management has an important role to play in providing advice and support, but there seems to be some confusion over who was Dr Biggs' professional line manager after April 2006. Dr Elizabeth Jordan, the Associate Medical Director, should have been Dr Biggs' professional line manager until she left her post in August 2007, and there was a suggestion in the police statement Dr Biggs provided in September 2009 that Dr Jordan was her line manager at least up to May 2007. In any event there is no evidence that any real professional line management support was provided to Dr Biggs in 2007, and this is a factor that must be taken into account when considering Dr Biggs' attitude to her role as ICD. She was unhappy with her role and with changes implemented by NHSGGC, and a higher level of support should have been available to her.

Although Dr Biggs did not receive a job description providing details of her role until 19 September 2007, she could have been under no misapprehension as to what her duties were as Infection Control Doctor. She did not question the terms of the job description once she received it.

Ms Martin had line management (non-professional) responsibilities for infection prevention and control and was the line manager for Dr Biggs and Dr de Villiers. The suggestion by her that Dr de Villiers was to cover Dr Biggs' ICD responsibilities at the VOLH when he went there is not accepted by the Inquiry. This simply highlights the dysfunctional nature of the arrangements for infection prevention and control at the VOLH. In a series of emails in 2007, mainly to Ms Martin, Dr Biggs raised a number of issues in relation to her position as ICD. Dr Biggs made it clear that she had no intention of carrying out her responsibilities as ICD, an attitude that demanded a prompt and effective response.

Dr Biggs' attitude to her role as ICD so far as the VOLH was concerned was inappropriate and professionally unacceptable. She was the leader of the Infection Control Team. She was not performing her duties as ICD at the VOLH. She had minimal contact with the Infection Control Nurses there and provided little support or leadership. Her attitude to Ms Annette Rankin, Head Infection Control Nurse for NHSGGC, was unprofessional.

Dr Biggs' self-imposed restriction on her role as ICD for the VOLH was without justification, whatever reservations she may have had over changes to the infection control structure. Her failure to carry out her duties as ICD for the VOLH was a serious failure on her part and would have contributed significantly to the ongoing CDI problem there and to unnecessary suffering to patients.

15.14 Knowledge of Dr Biggs' failure as Infection Control Doctor

Clearly Mrs Murray and Mrs O'Neill knew that Dr Biggs was not attending to her ICD responsibilities at the VOLH. Mrs Murray had discussions with Ms Rankin about Dr

Biggs' failure to carry out her ICD duties, and Ms Rankin did pass on her concerns about Dr Biggs to Mr Walsh. Mr Walsh may not have been aware of the extent of the problem, but he could not avoid being aware that there was a problem, and he should have conducted some enquiries to see if the problem had been resolved.

Ms Martin knew that Dr Biggs did not attend the VOLH. She had no proper basis in fact to believe that Dr de Villiers was covering as ICD for Dr Biggs. As Dr Biggs' line manager (non-professional) Ms Martin failed to deal with the problems created by Dr Biggs in her attitude to her role as ICD. Mrs den Herder did not know that Dr Biggs was not fulfilling her role as ICD, but she ought to have been made aware of the problem. Ms Martin in particular ought to have made her aware of the problems with Dr Biggs. Ms Martin's failure to address the problems created by Dr Biggs was a serious failure.

The reality is that in the latter part of 2007 no-one was prepared to tackle the issues associated with Dr Biggs. By then there was a plan to replace Dr Biggs after the appointment of the two new consultant microbiologists but that does not excuse the failure to deal at the time with an ICD who was not carrying out her infection prevention and control responsibilities for the VOLH.

15.15 The secondment issue

Ms Martin claimed that she was on full-time secondment to the Picture Archiving Communication Systems (PACS) project from August 2007 to April 2008 and that when on secondment her responsibilities for infection prevention and control ceased.

Both these claims are incorrect. In September 2007 there had been some discussion about the possibility of early integration through which managerial responsibility for infection prevention and control for the Clyde Sector would be integrated within Greater Glasgow and Clyde but that was not pursued. The position in fact is that Ms Martin did remain responsible for infection prevention and control. Mrs den Herder recognised that Ms Martin would require support to provide her with sufficient time to undertake the PACS work. That support was not adequate and Ms Martin complained to Mrs den Herder about the pressure she was under due to the extent of her responsibilities. Mrs den Herder should have responded positively to these complaints but she failed to do so. Ms Martin's complaints of overwork should have alerted Mrs den Herder to the real possibility that the management of infection prevention and control was being neglected.

15.16 The reporting of *C. difficile* data to Health Protection Scotland and the Public Health Protection Unit

Mandatory reporting of *C. difficile* toxin positive cases was required as part of the national surveillance system from 1 September 2006. Reports providing details of *C. difficile* toxin cases are sent to Health Protection Scotland (HPS). This reporting system was never designed to be a surveillance tool; it is simply a method of identifying how many patients had been diagnosed with CDI as part of the national surveillance programme. The system of national surveillance was not intended to replace effective systems of local surveillance and reporting.

Copies of the reports sent to HPS were also sent to the NHSGGC Public Health Protection Unit (PHPU) on a weekly basis. This system of reporting did allow the PHPU to perform a surveillance function in connection with certain diseases in the community, but this did not constitute a surveillance system of CDI that was hospital acquired. The PHPU could not have been expected to identify the CDI problems at the VOLH.

15.17 Statistical Process Control Charts

The Statistical Process Control (SPC) Chart is a surveillance tool that can provide retrospective information on a monthly basis on the number of *C. difficile* toxin positive patients and trends. Although available in 2007 in some NHSGGC areas, SPC Charts were not introduced to the VOLH until April or May 2008.

Had the SPC Charts been in place in 2007, an increased level of awareness would have been generated in relation to rates of CDI at the VOLH and the CDI problem would have been discovered sooner. That having been said, the

dissolution of NHS Argyll and Clyde and the commencement of the process of integration with GGHB only took place in April 2006, and the preparation for the introduction of the SPC chart system to the VOLH was going to take some time. It was therefore not unreasonable that the introduction of the SPC chart system to the Clyde Sector, and the VOLH in particular, suffered some delay in comparison to other areas of NHSGGC. In any event, SPC Charts are not a substitute for acute observation in real time. The surveillance systems in place at the VOLH should have alerted the Infection Control Team to the extent of the problem with CDI.

15.18 The VOLH Laboratory accreditation

Following an inspection by the accrediting body in January 2003 the VOLH laboratory was granted conditional approval. That remained the position until another inspection on 18 and 19 September 2007. The September 2007 inspection produced a list of 43 non-compliances, although the inspectors' overview report described the laboratory as well managed and well led. The numerous document control issues disclosed by the inspection were explained by the fact that the laboratory was in a transitional phase of migrating to an electronic system. The inspectors concluded that despite the number of non-compliances the quality of the service being provided was not being compromised.

Despite the conclusion of the overview report the extent of non-compliances shows that the general management of the microbiology service did need to be improved.

15.19 Risk registers

Risk registers are an important strategy for the management of risk in the delivery of healthcare. The creation and maintenance of a risk register ensures that risks relevant to a particular area of healthcare have been identified. Where possible risks are removed, but otherwise the risk register ensures that appropriate controls and precautions are in place to prevent those risks materialising.

The key to the creation of a risk register is risk assessment. Within an organisation such as NHSGGC, risk registers should be maintained at different levels including hospital level. NHSGGC implemented a risk register policy on 1 April 2006, acknowledging that the continuing development of a comprehensive risk register was a core part of risk-management activity.

A risk register specifically for infection prevention and control for the Acute Services Division was first discussed at a meeting of the ACIC on 26 November 2006. Subsequently there was some further discussion at meetings of the ACIC, but the risk register for infection prevention and control was not approved until the ACIC meeting held on 3 December 2008. Reference to CDI did not feature in earlier drafts of the risk register and it was only at the meeting of 3 December that the decision was taken to include CDI. Having regard to a timescale that first began in November 2006 the approval of the risk register in December 2008, just over two years later, represents undue delay. Account does, however, have to be taken of the fact that when that process began it was one of the many issues facing NHSGGC at a time of significant change. Furthermore, the emergence of the VOLH CDI problem did increase the level of attention paid to infection prevention and control.

15.20 Hygiene, environment and audits

National *C. difficile* guidance published in 1994 emphasised the importance of personal and environmental cleanliness in the prevention and control of CDI. Hand hygiene in particular is of extreme importance in the prevention of an infection like CDI but so too are environmental factors. Damaged surfaces make cleaning more difficult because it is harder to remove micro-organisms from damaged or irregular surfaces than from smooth surfaces.

The Cleanliness Champions Programme (CCP) was launched as part of the first HAI Task Force Plan in September 2003, and was viewed as an important aspect of infection prevention and control. The programme's two main themes were safe practice and safe environment.

In a letter dated 18 March 2005 addressed to Chief Executives, NHS Boards and Nursing Directors, the Chief Nursing Officer reinforced

the importance of the CCP by requiring all G grade sisters/SCNs to undertake the CCP "forthwith" while adding that account should be taken of workload and available access to the required IT resources.

By 15 May 2007 NHSGGC was underperforming generally on completion of the CCP, an issue raised at the ACIC meeting of that date. In the VOLH the completion rate for the CCP in the period prior to June 2008 was extremely slow. The CCP did not receive the priority it should have received, and a more determined attitude to infection prevention and control would have provided more impetus to the implementation of the programme.

In the period leading up to June 2008 the fabric of the VOLH was in a poor state. Areas of flooring were damaged and covered in adhesive tape. Inspections carried out in May 2008, when the problem with CDI was emerging, identified an unsatisfactory hospital environment that included a lack of wash-hand basins, commodes that were not fit for purpose and required urgent replacement, and storage problems. At the dissolution of NHS Argyll and Clyde in April 2006 NHSGGC inherited a hospital in which underinvestment in maintenance and infrastructure had existed for a number of years. The environmental deficiencies had existed in the years prior to dissolution and persisted afterwards without resolution. There was an acceptance that because of the lack of investment, improvements were not going to happen until a decision on the VOLH's future could be made.

The infection control audit process did identify key areas of persistent non-compliance, but there was no effective process of ensuring managerial awareness at a level where appropriate action could be taken. Environmental issues that had a clear impact on infection prevention and control were not addressed. Patients were put at risk. Staff morale was affected. Uncertainty led to the acceptance of the unacceptable from the perspective of patient safety.

15.21 Changes after June 2008

The NHSGGC Board responded promptly to the discovery of the failures that had occurred in the VOLH prior to June 2008. A single management structure, with the Board Medical Director as the accountable executive officer reporting to the Chief Executive has been put in place. The Board Medical Director is required to bring infection control and HAI reports to every Board meeting. New posts have been created to strengthen the management structure so that the principle of ward to Board and Board to ward accountability is as effective as possible.

The infection prevention and control committee structure has been changed, with the VOLH now under the jurisdiction of the North West Sector of NHSGGC. Governance, accountability and reporting arrangements have been significantly changed with the aim of producing an effective monitoring and reporting system of HAIs such as CDI.

Infection prevention and control education and training programmes have been implemented for all staff. NHSGGC pursues a policy that treats patient experience and involvement as an important element in the infection prevention and control programme. NHSGGC has also established an inspection regime in which multi-disciplinary teams inspect hospitals following methodology adopted by the Healthcare Environment Inspectorate.

Between June 2008 and June 2012 a sum in excess of £4.5m was invested in improving healthcare and the general environment at the VOLH. This improvement programme included the provision of additional wash-hand basins and the creation of more single rooms. After years of neglect there has been significant investment in the VOLH by NHSGGC.

15.22 Conclusion

The personal and system failures in infection prevention and control identified in Chapter 15 had a profound effect upon the care provided to patients at the VOLH. NHSGGC must bear ultimate responsibility for these failures. NHSGGC did learn lessons from the failures by introducing significant changes after 1 June 2008.

16. Death certification

16.1 Form of death certificate

The section of the death certificate which is devoted to the cause of death is divided into two parts. Part one deals with the direct cause of death and any conditions giving rise to that direct cause. Part two deals with other conditions which have contributed to death but are not part of the main sequence of events leading to death.

Death certification is a matter of professional judgement. The doctor needs to make a judgement as to what is the direct or immediate cause of death for entry into Part 1 of the death certificate and also a judgement as to which of the illnesses suffered by the patient are relevant for entry in Part 2 of the death certificate.

16.2 The 1999 guidance on death certification and VOLH practice

Guidance on the completion of death certificates was issued by the Registrar General for Scotland in January 1999. That guidance provided that it was "best if a consultant, general practitioner or other experienced clinician" certified the death. The guidance went on to provide that for a death in hospital an inexperienced doctor should only certify the death if closely supervised and if the experienced clinician was content that the causes of death were accurately recorded.

Notwithstanding the guidance, in practice consultants in Scotland were rarely involved in death certification in 2007 and 2008. That practice was reflected in the VOLH where, of the 33 extracts from the register of deaths examined, none of the death certificates had been signed by a permanent consultant and in the majority of cases the death certificate was signed by junior doctors. There was some evidence in the patient records that in some instances junior doctors did contact a consultant, but in the majority of cases the death certificate was signed by a junior doctor without any recorded consultation with senior medical staff.

Before issuing a death certificate the doctor concerned is obliged to consider whether or not the death should be reported to the Procurator Fiscal. Guidance issued by the Crown Office and Procurator Fiscal Service (COPFS) in November 1998 set out certain categories of death that were to be reported to the Procurator Fiscal but did not make any explicit reference to HAI or *C. difficile* infection. That guidance was updated in October 2008 to include HAI.

16.3 Accuracy in death certification in the VOLH

Accuracy in death certification is crucial in order to allow collation of data to enable the identification of trends and the establishment of public health measures to prevent diseases. At a more personal level it is very important for family members to know the cause or causes of death of a family member. A number of patients who died in the VOLH did not have CDI mentioned on their death certificates when in fact CDI should have been mentioned.

16.4 Updated guidance

Guidance issued in September 2009 and in October 2011 by the Chief Medical Officer (CMO) of the Scottish Government emphasised the important role to be played by consultants in death certification.

16.5 Collation, analysis of data and future changes

In the guidance issued in September 2009 the CMO envisaged that the reporting of HAI related deaths to the Procurator Fiscal would allow the local Area Procurator Fiscal to identify any clusters of HAI related deaths. The COPFS does not in fact collate information on HAI related deaths. The function of the COPFS is to investigate, and it does not have a surveillance function of the kind envisaged by the CMO. The Scottish Government should identify a national agency to monitor HAI mortality rates, and CDI deaths in particular.

16.6 Conclusion

The guidance on death certification in place in 2007 to 2008 had been issued in January 1999 and was inadequate and outdated. Death certification was viewed as a low priority despite the important role it plays.

The Inquiry's examination of the manner in which the deaths were certified in the VOLH disclosed that there was a lack of understanding of the way in which death certification should be carried out. Doctors need to be trained in the completion of death certificates.

17. Investigations from May 2008

17.1 The Independent Review

In June 2008 the Cabinet Secretary for Health and Wellbeing announced an Independent Review of the cases of *C. difficile* infection at the VOLH. That was led by Professor William Cairns Smith, OBE, Professor of Public Health at the University of Aberdeen. The report was published in August 2008, and an audit in December 2008 of the implementation of its recommendations concluded that rapid and very significant progress had been made in the VOLH.

17.2 Vale of Leven Internal Investigation report

An Internal Investigation was commissioned by Mr Calderwood, then the Chief Operating Officer, in June 2008 when he became aware of CDI cases and associated deaths.

The remit of the Internal Investigation was a narrow one and concerned with who knew about the *C. difficile* cases, what action was taken, and to whom matters were reported. The Internal Investigation team did not in fact limit its investigation to the terms of its remit: the Internal Investigation report proposed, for example, that each Directorate's Clinical Governance Committee should have a standing item on "Control of Infection". In response to its specific remit the Internal Investigation did not identify any knowledge of the VOLH CDI problem within management.

The setting up of the Internal Investigation was an important and appropriate step, and identified some learning opportunities at an early stage. It did not identify errors or failures which must have been present to allow outbreaks to occur and to go unnoticed, but its remit was limited and its work was overtaken by the Independent Review.

17.3 Outbreak Control Team Investigation

The second investigation conducted by NHSGGC was in the form of an Outbreak Control Team (OCT) Investigation that began in June 2008 and reported in October 2008. It had a broader remit that involved investigating all aspects of the "outbreak" and ensuring that all control measures were in place.

The OCT's report identified the outbreak period as 1 December 2007 to 31 May 2008. The number of cases of CDI in that period was identified as 55, with CDI identified as having caused or contributed to the death of 18 of 28 patients who died. These were underestimates of the numbers of patients and deaths.

The OCT concluded that the number of cases of CDI at the VOLH in the period examined was more than expected, and that the fatality rate appeared to be higher than reported from elsewhere.

The OCT report identified the T-card system as the surveillance system in place at the time, but failed to mention the Access database that was capable of providing regular surveillance reports.

As was the case with the Internal Investigation, the OCT's investigation was somewhat truncated by the appointment of the Independent Review. Nevertheless the OCT report did make a number of valuable recommendations, including the review of roles and responsibilities and the communication chain for HAI, the commencement of a programme of work to improve the structural environment of the VOLH, the auditing of antimicrobial policy, and education on infection control and HAI issues.

17.4 Conclusion

The Internal Investigation and the OCT investigation did not examine the nursing and medical care given to patients who contracted CDI for the simple reason that their respective remits did not cover this issue. The setting up of the Internal Investigation was an appropriate step in the circumstances that emerged in May/June 2008.

18. Experiences of *C. difficile* infection within and beyond Scotland

18.1 The 027 strain

At the time of the Stoke Mandeville and Maidstone and Tunbridge Wells outbreaks, and in the aftermath of those outbreaks, the 027 strain was seen as a "hypervirulent" strain because it caused more severe disease and more deaths. The hypervirulent nature of the 027 strain was recognised by Health Protection Scotland in 2006, before the discovery of the CDI problem at the VOLH, as a strain capable of causing very severe disease and death.

18.2 The Stoke Mandeville and Maidstone and Tunbridge Wells reports

In July 2006 the Healthcare Commission in England published a report into two outbreaks of CDI at the Stoke Mandeville Hospital, the first between October 2003 and June 2004 and the second between October 2004 and June 2005. Many of the cases of CDI were due to the 027 strain. The report identified many failures in the management and care of patients suffering from CDI which were similar to the failures identified by the Inquiry at the VOLH. It highlighted the poor state of repair of the buildings, failures to isolate patients with diarrhoea, lack of facilities for hand washing and low priority afforded to infection control. There were nursing failures where fluid balance was given little attention and poor care planning and nursing assessments. At the time of its investigations the Healthcare Commission did, however, discover that the hospital policy on the use of broad spectrum antibiotics had already been changed in response to the cases of CDI.

In October 2007 the Healthcare Commission produced a report into outbreaks of *C. difficile* at Maidstone and Tunbridge Wells NHS Trust. That report identified a significant number of issues similar to the issues identified by the Inquiry at the VOLH, including the unnecessary administration of broad spectrum antibiotics, inadequate fluid management and an inadequate level of training on infection control. System failures were also identified. The report's recommendations, as with the recommendations of the Stoke Mandeville report, were of UK-wide relevance.

18.3 The NHS Greater Glasgow and Clyde response to Stoke Mandeville and Maidstone and Tunbridge Wells

Within NHSGGC a number of people were aware of the Stoke Mandeville report, in particular those with some responsibility for infection prevention and control. The Infection Control Manager, Mr Walsh, discussed the Maidstone and Tunbridge Wells report with the Nurse Consultant, and that report was influential in CDI being considered for the SPC Chart system.

In the VOLH itself there was also a response to the Stoke Mandeville report. On 16 February 2007 a meeting took place to discuss facilities services. Several concerns, including storage issues, poor housekeeping and poor maintenance of fabric and equipment were identified. A further review in February 2008 concluded that a number of those problems had not been resolved. There were also presentations early in 2007 and in May 2007 on infection prevention and control by Dr Weinhardt and Mrs Murray. These presentations covered what were poor infection prevention and control practices and the importance of prudent antibiotic prescribing.

18.4 NHS Quality Improvement Scotland response

No guidance appears to have been issued, or review conducted, by NHS QIS specifically in light of the Stoke Mandeville or Maidstone and Tunbridge Wells reports.

18.5 The response to the Stoke Mandeville and Maidstone and Tunbridge Wells reports by Health Protection Scotland

The work of Health Protection Scotland (HPS) in connection with HAIs is overseen by the HAI Task Force. In the Project Initiation Document produced in July 2007 for the development of a programme for reduction of healthcare associated CDI in Scotland, the HAI Taskforce did refer to the Healthcare Commission's recommendations contained in

the Stoke Mandeville report. In October 2007, shortly after the publication of the Maidstone and Tunbridge Wells report, the HAI Taskforce considered that report. Thereafter the Chief Nursing Officer wrote on 8 November 2007 to Board Chief Executives asking each Board to undertake an immediate and thorough review of its local infection control policies. His expectation was that each Board would make sure that the systems and processes were in place for effective infection prevention and control, although that expectation was not spelled out in his letter.

National guidance on the prevention and control of CDI was published by HPS in October 2008. The production of national guidance of that kind can take time. HPS also developed a checklist as a support tool to check control measures were in place, prompted by the Stoke Mandeville and Maidstone and Tunbridge Wells reports. Although production of the checklist was accelerated following discovery of the CDI problem at the VOLH it was not in fact produced until June 2008. If the publication of the Stoke Mandeville report is taken as a starting point, it took some two years for the checklist to be produced.

The checklist highlighted 32 issues seen as important in the prevention and control of CDI, including data collection at ward level, data review, and adherence to antibiotic policy. The advice contained in it was designed to lead to an overhaul of practices and to alert Boards to the dangers of the 027 strain. Earlier circulation of that advice would have been highly desirable. It could only have led to a more timely and comprehensive review of practice. It would have alerted Health Boards to the dangers of the 027 strain and the broader issues of patient safety and infection prevention and control.

18.6 The Scottish Government response

The Scottish Government did not take any action to draw the Stoke Mandeville case to the attention of Health Boards. Prior to June 2008 Scottish Government had not received any advice from any source that any action was required.

18.7 The Northern Health and Social Care Trust, Northern Ireland

The Regulation and Quality Improvement Authority for Northern Ireland (RQIA) published a review in August 2008 of the circumstances contributing to the rates of CDI in the Northern Health and Social Care Trust in 2007 and early 2008. The report of a Public Inquiry into the outbreak of CDI in Trust hospitals was published on 21 March 2011. The RQIA review identified failures similar to failures identified in this Report including structural reorganisation putting the monitoring of health infection prevention at risk, shortage of isolation beds, inappropriate use of antibiotics, poor quality of nursing notes and general lack of care plans and needs assessments.

The RQIA review and the Public Inquiry report suggest that there was also a lack of preparedness for an outbreak of CDI. This simply reinforces the need for lessons to be learned from other inquiries.

18.8 Ninewells Hospital, Dundee

In October 2009 an outbreak of CDI was declared at Ninewells Hospital, Dundee in one ward following upon two patients testing positive for CDI where the 027 strain was identified. Measures were taken in response to the outbreak including a visit by HPS. In total, between 31 July 2009 and 6 November 2009 seven patients who had been in the ward concerned were found to be infected with the 027 strain. CDI caused or contributed to the deaths of five of those patients.

The Ninewells outbreak occurred after discovery of the CDI problems at the VOLH in an environment where there was an increased awareness of the importance of infection prevention and control. The identification of the outbreak and subsequent management appeared to be in accordance with good infection prevention and control practice.

18.9 Comparison between the VOLH and Stoke Mandeville and Maidstone and Tunbridge Wells

At least 20 issues identified in the Stoke Mandeville and Maidstone and Tunbridge Wells reports were also identified by the Inquiry as relevant to the VOLH. This included the failure to isolate patients, the inappropriate prescribing of antibiotics, and failures in basic nursing care.

The findings in the Stoke Mandeville and Maidstone and Tunbridge Wells reports contained important lessons on how the management of CDI could go wrong and how it should be effectively managed. The recommendations in both reports provided valuable guidance which was available in the one case from July 2006 and in the other from October 2007.

18.10 Conclusion

There was a failure at national and NHSGGC level to utilise the Stoke Mandeville and Maidstone and Tunbridge Wells reports as a basis for timely guidance and for audit and review. There was undue delay on the part of HPS in producing the kind of advice set out in the checklist.

The findings and recommendations of the Stoke Mandeville report should have been considered by NHSGGC in a more thorough and systematic way prior to 2007, and practices and implementation of policies should have been reviewed in the light of these findings and recommendations. Had that happened, many of the factors contributing to the outbreaks at the VOLH would have been eliminated or at least reduced by June 2008.

It is important that effective systems are in place to enable lessons learned elsewhere to be applied in Scotland in a timely manner.

Recommendations

Chapter 6 National structures and systems

Recommendation 1: Scottish Government should ensure that the Healthcare Environment Inspectorate (HEI) has the power to close a ward to new admissions if the HEI concludes that there is a real risk to the safety of patients. In the event of such closure, an urgent action plan should be devised with the Infection Prevention and Control Team and management.

Chapter 7 National policies and guidance

Recommendation 2: Scottish Government should ensure that policies and guidance on healthcare associated infection are accompanied by an implementation strategy and that implementation is monitored.

Recommendation 3: Health Boards should ensure that infection prevention and control policies are reviewed promptly in response to any new policies or guidance issued by or on behalf of the Scottish Government, and in any event at specific review dates no more than two years apart.

Recommendation 4: Scottish Government should develop local Healthcare Associated Infection (HAI) Task Forces within each Health Board area.

Chapter 8 Changes in services at the Vale of Leven Hospital from 2002

Recommendation 5: Scottish Government should ensure that where any uncertainty over the future of any hospital or service exists, resolution of the uncertainty is not delayed any longer than is essential for planning and consultation to take place.

Recommendation 6: Scottish Government should ensure that where major changes in patient services are planned there should be clear and effective plans in place for continuity of safe patient care during the period of planning and change.

Chapter 9 The creation, leadership and management of the Clyde Directorate

Recommendation 7: In any major structural reorganisation in the NHS in Scotland a due diligence process including risk assessment should be undertaken by the Board or Boards responsible for all patient services before the reorganisation takes place. Subsequent to that reorganisation regular reviews of the process should be conducted to assess its impact upon patient services, up to the point at which the new structure is fully operational. The review process should include an independent audit.

Recommendation 8: In any major structural reorganisation in the NHS in Scotland the Board or Boards responsible should ensure that an effective and stable management structure is in place for the success of the project and the maintenance of patient safety throughout the process.

Chapter 10 Clinical governance

Recommendation 9: Health Boards should ensure that infection prevention and control is explicitly considered at all clinical governance committee meetings from local level to Board level.

Chapter 11 The experiences of patients and relatives

Recommendation 10: Health Boards should ensure that patients diagnosed with CDI are given information by medical and nursing staff about their condition and prognosis. Patients should be told when there is a suspicion they have CDI, and when there is a definitive diagnosis. Where appropriate, relatives should also be involved.

Recommendation 11: Health Boards should ensure that patients, and relatives where appropriate, are made aware that CDI is a condition that can be life-threatening, particularly in the elderly. The consultant in charge of a patient's care should ensure that the patient and, where appropriate, relatives have reasonable access to fully informed medical staff.

Recommendation 12: Health Boards should ensure that when a patient has CDI patients and relatives are given clear and proper advice on the necessary infection control precautions, particularly hand washing and laundry. Should it be necessary to request relatives to take soiled laundry home, the laundry should be bagged appropriately and clear instructions about washing should be

given. Leaflets containing guidance should be provided, and these should be supplemented by discussion with patients and relatives.

Chapter 12 Nursing care

Recommendation 13: Health Boards should ensure that there is a clear and effective line of professional responsibility between the ward and the Board.

Recommendation 14: Health Boards should ensure that the nurse in charge of each ward audits compliance with the duty to keep clear and contemporaneous patient records. Health Boards should ensure that there is an effective system of audit of patient records, and that there is effective scrutiny of audits by the Board.

Recommendation 15: Health Boards should ensure that nursing staff caring for a patient with CDI keep accurate records of patient observations including temperature, pulse, respiration, oxygen saturation and blood pressure.

Recommendation 16: Health Boards should ensure that the nurse in charge of each ward reports suspected outbreaks of CDI (as defined in local guidance) to the Infection Control Team.

Recommendation 17: Health Boards should ensure that where there is risk of cross infection, the nurse in charge of a ward has ultimate responsibility for admission of patients to the ward or bay. Any such decision should be based on a full report of the patient's status and full discussion with site management, the bed manager, and a member of the Infection Control Team. The decision and the advice upon which the decision is based should be fully recorded contemporaneously.

Recommendation 18: Health Boards should ensure that there is an agreed system of care planning in use in every ward with the appropriate documentation available to nursing staff. Where appropriate they should introduce pro forma care plans to assist nurses with care planning. Health Boards should ensure that there is a system of audit of care planning in place.

Recommendation 19: Health Boards should ensure that where Infection Control Nurses provide instructions on the management of patients those instructions are recorded in the patient notes and are included in care planning for the patient.

Recommendation 20: Health Boards should ensure that where a patient has, or is suspected of having, *C. difficile* diarrhoea a proper record of the patient's stools is kept. Health Boards should ensure that there is an appropriate form of charting of stools available to enable nursing staff to provide the date, time, size and nature of the stool. Stool charts should be continued after a patient has become asymptomatic of diarrhoea in order to reduce the risk of cross infection. Health Boards should ensure that all nursing staff are properly trained in the completion of these charts, and that the nurse in charge of the ward audits compliance.

Recommendation 21: Health Boards should ensure that a member of nursing staff is available to deal with questions from relatives during visiting periods.

Recommendation 22: Health Boards should ensure that any discussion between a member of nursing staff and a relative about a patient which is relevant to the patient's continuing care is recorded in the patient's notes to ensure that those caring for the patient are aware of the information given.

Recommendation 23: Health Boards should ensure that a nurse appointed as Tissue Viability Nurse (TVN) is appropriately trained and possesses, or is working towards, a recognised specialist post-registration qualification. Health Boards should ensure that a trainee TVN is supervised by a qualified TVN.

Recommendation 24: Health Boards should ensure that where a TVN is involved in caring for a patient there is a clear record in the patient notes and care plan of the instructions given for management of the patient.

Recommendation 25: Health Boards should ensure that every patient is assessed for risk of pressure damage on admission to hospital using a recognised tool such as the Waterlow Score in accordance with best practice guidance. Where patients are identified as at risk they must be reassessed at the frequency identified by the risk scoring system employed. Compliance should be monitored by a system of audit.

Recommendation 26: Health Boards should ensure that where a patient has a wound or pressure damage there is clear documentation of the nature of the wound or damage in accordance with best practice guidance, including the cause, grade, size and colour of the wound or damage. The pressure damage or wound should be reassessed regularly according to the patient's condition. Compliance should be monitored by a system of audit.

Recommendation 27: Health Boards should ensure that where a patient requires positional changes nursing staff clearly record this on a turning chart or equivalent. Compliance should be monitored by a system of audit.

Recommendation 28: Health Boards should ensure that all patients have their nutritional status screened on admission to a ward using a recognised nutritional screening tool. Where nutritional problems are identified further assessment should be undertaken to determine an individual care plan. Appropriate and timely referrals should be made to dieticians for patients identified as being in need of specialist nutritional support.

Recommendation 29: Health Boards should ensure that there is appropriate equipment in each ward to weigh all patients. Patients should be weighed on admission and at least weekly thereafter and weights recorded. Faulty equipment should be repaired or replaced timeously and a contingency plan should be in place in the event of delays.

Recommendation 30: Health Boards should ensure that where patients require fluid monitoring as part of their clinical care, nursing staff complete fluid balance charts as accurately as possible and sign them off at the end of each 24-hour period.

Recommendation 31: Health Boards should ensure that the staffing and skills mix is appropriate for each ward, and that it is reviewed in response to increases in the level of activity/patient acuity and dependency in the ward. Where the clinical profile of a group or ward of patients changes, (due to acuity and/or dependency) an agreed review framework and process should be in place to ensure that the appropriate skills base and resource requirements are easily provided.

Recommendation 32: Health Boards should ensure that there is a straightforward and timely escalation process for nurses to report concerns about the staffing numbers/skill mix.

Recommendation 33: Health Boards should ensure that where a complaint is made about nursing practice on a ward this complaint is investigated by an independent senior member of Nursing Management.

Chapter 13 Antibiotic prescribing

Recommendation 34: Health Boards should ensure that changes in policy and/or guidance on antimicrobial practice issued by or on behalf of Scottish Government are implemented without delay.

Recommendation 35: Scottish Government should monitor the implementation of policies and/or guidance on antibiotic prescribing issued in connection with healthcare associated infection and seek assurance within specified time limits that implementation has taken place.

Chapter 14 Medical care

Recommendation 36: Health Boards should ensure that the level of medical staffing planned and provided is sufficient to provide safe high quality care.

Recommendation 37: Health Boards should ensure that any patient with suspected CDI receives full clinical assessment by senior medical staff, that specific antibiotic therapy

for CDI is commenced timeously and that the response to antibiotics is monitored on at least a daily basis.

Recommendation 38: Health Boards should ensure that clear, accurate and legible patient records are kept by doctors, that records are seen as integral to good patient care, and that they are routinely audited by senior medical staff.

Recommendation 39: Health Boards should ensure that medical and nursing staff are aware that a DNAR decision is an important aspect of care. The decision should involve the patient where possible, nursing staff, the consultant in charge and, where appropriate, relatives. The decision should be fully documented, regularly reviewed and there should be regular auditing of compliance with the DNAR policy.

Recommendation 40: Health Boards should ensure that the key principles of prudent antibiotic prescribing are adhered to and that implementation of policy is rigorously monitored by management.

Recommendation 41: Health Boards should ensure that there is no unnecessary delay in processing laboratory specimens, in reporting positive results and in commencing specific antibiotic treatment. Infection control staff should carry out regular audits to ensure that there are no unnecessary delays in the management of infected patients once the diagnosis is confirmed.

Chapter 15 Infection prevention and control

Recommendation 42: Health Boards should ensure that all those working in a healthcare setting have mandatory infection prevention and control training that includes CDI on appointment and regularly thereafter. Staff records should be audited to ensure that such training has taken place.

Recommendation 43: Health Boards should ensure that Infection Control Nurses and Infection Control Doctors have regular training in infection prevention and control, of which a record should be kept.

Recommendation 44: Health Boards should ensure that performance appraisals of infection prevention and control staff take place at least annually. The appraisals of Infection Control Doctors who have other responsibilities should include specific reference to their Infection Control Doctor roles.

Recommendation 45: Health Boards should ensure that where a manager has responsibility for oversight of infection prevention and control, this is specified in the job description.

Recommendation 46: Health Boards should ensure that the Infection Control Manager has direct responsibility for the infection prevention and control service and its staff.

Recommendation 47: Health Boards should ensure that the Infection Control Manager reports direct to the Chief Executive, or at least to an executive board member.

Recommendation 48: Health Boards should ensure that the Infection Control Manager is responsible for reporting to the Board on the state of healthcare associated infection in the organisation.

Recommendation 49: Scottish Government should re-issue national guidance on the role of the Infection Control Manager, stipulating that the Infection Control Manager must be responsible for the management of the infection prevention and control service.

Recommendation 50: Health Boards should ensure that there is 24-hour cover for infection prevention and control seven days a week, and that contingency plans for leave and sickness absence are in place.

Recommendation 51: Health Boards should ensure that any Infection Control Team functions as a team, with clear lines of communication and regular meetings.

Recommendation 52: Health Boards should ensure that adherence to infection prevention and control policies, for example the *C. difficile* and Loose Stool Policies, is audited at least annually, and that serious non-adherence is reported to the Board.

Recommendation 53: Health Boards should ensure that surveillance systems are fit for purpose, are simple to use and monitor, and provide information on potential outbreaks in real time.

Recommendation 54: Health Boards should ensure that the users of surveillance systems are properly trained in their use and fully aware of how to use and respond to the data available.

Recommendation 55: Health Boards should ensure that numbers and rates of CDI are reported through each level of the organisation up to the level of the Chief Executive and the Board. Reporting should include positive reporting in addition to any exception reporting. The Chief Executive should sign off the figures to confirm that there is oversight of infection prevention and control at that level.

Recommendation 56: Health Boards should ensure that infection prevention and control groups meet at regular intervals and that there is appropriate reporting upwards through the management structure.

Recommendation 57: Health Boards should ensure that the minutes of all meetings and reports from each infection prevention and control committee are reported to the level above in the hierarchy and include the numbers and rates of CDI, audit reports, and training reports.

Recommendation 58: Health Boards should ensure that there is lay representation at Board infection prevention and control committee level in keeping with local policy on public involvement.

Recommendation 59: Health Boards should ensure that attendance by members of committees in the infection prevention and control structure is treated as a priority. Non-attendance should only be justified by illness or leave or if there is a risk of compromise to other clinical duties in which event deputies should attend where practicable.

Recommendation 60: Health Boards should ensure that programmes designed to improve staff knowledge of good infection prevention and control practice, such as the Cleanliness Champions Programme, are implemented without undue delay. Staff should be given protected time by managers to complete such programmes.

Recommendation 61: Health Boards should ensure that unannounced inspections of clinical areas are conducted by senior infection prevention and control staff accompanied by lay representation to examine infection prevention and control arrangements, including policy implementation and cleanliness.

Recommendation 62: Health Boards should ensure that senior managers accompanied by infection prevention and control staff visit clinical areas at least weekly to verify that proper attention is being paid to infection prevention and control.

Recommendation 63: Health Boards should ensure that there is effective isolation of any patient who is suspected of suffering from CDI, and that failure to isolate is reported to senior management.

Recommendation 64: Health Boards should ensure that cohorting is not used as a substitute for single room isolation and is only resorted to in exceptional circumstances and under strict conditions of dedicated nursing, with infected patients nursed in cohort bays with en-suite facilities.

Recommendation 65: Health Boards should ensure that appropriate steps are taken to isolate patients with potentially infectious diarrhoea.

Recommendation 66: Health Boards should ensure that the healthcare environment does not compromise effective infection prevention and control, and that poor maintenance practices, such as the acceptance of non-intact surfaces that could compromise effective infection prevention and control practice, are not tolerated.

Recommendation 67: Health Boards should ensure that, where a local Link Nurse system is in place as part of the infection prevention and control system, the Link Nurses have specific training for that role. The role should be written into job descriptions and job plans. They should have clear objectives set annually and have protected time for Link Nurse duties.

Chapter 16 Death certification

Recommendation 68: Health Boards should ensure that where a death occurs in hospital the consultant in charge of the patient's care is involved in the completion of the death certificate wherever practicable, and that such involvement is clearly recorded in the patient records. Regular auditing of this process should take place.

Recommendation 69: Health Boards should ensure that if a patient dies with CDI either as a cause of death or as a condition contributing to the death, relatives are provided with a clear explanation of the role played by CDI in the patient's death.

Recommendation 70: Crown Office and the Procurator Fiscal Service (COPFS) should review its guidance on the reporting of deaths regularly and at least every two years.

Recommendation 71: Scottish Government should identify a national agency to undertake routine national monitoring of deaths related to CDI.

Chapter 17 Investigations from May 2008

Recommendation 72: Health Boards should ensure that a non-executive Board member or a representative from internal audit takes part in an Internal Investigation of the kind instigated by NHSGGC.

Recommendation 73: Health Boards should ensure that OCT reports provide sufficient details of the key factors in the spread of infection to allow a proper audit to be carried out, as recommended in the Watt Group Report.

Chapter 18 Experiences of *C. difficile* infection within and beyond Scotland

Recommendation 74: Scottish Government (whether through HPS, HIS, the HAI Task Force or otherwise) should as a matter of standard practice ensure that reports published in the United Kingdom and in other relevant jurisdictions on infection prevention and control and patient safety are reviewed as soon as possible, and that, as a minimum, any necessary interim guidance is issued within three months.

Recommendation 75: Health Boards should review such reports to determine what lessons can be learned and what reviews, audits or other measures (interim or otherwise) should be put in place in the light of these lessons.

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