

***Clostridium difficile* Associated Disease**
at the
Vale of Leven Hospital
from
December 2007 to June 2008

Report of the Outbreak Control Team
October 2008

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1 Glossary

ADTC	Area Drugs and Therapeutics Committee
AMT	Antimicrobial Management Team
AUC	Antimicrobials Utilisation Committee
CDAD	<i>Clostridium difficile</i> Associated Disease
CHCPs	Community Health & Care Partnerships
CURB-65	Confusion, Urea nitrogen, Respiratory rate, Blood pressure, 65 years of age and older
DNAR	Do Not Attempt Resuscitation
GROS	General Register Office for Scotland
HAI	Healthcare Associated Infection
HFS	Health Facilities Scotland
HPS	Health Protection Scotland
ICD	Infection Control Doctor
ICM	Infection Control Manager
ICN	Infection Control Nurse
ICT	Infection Control Team
IMT	Incident Management Team
IRT	Independent Review Team
ISD	Information Services Division
MSc	Master of Science
OCT	Outbreak Control Team
PFPI	Public Focus Patient Involvement
PMC	Pseudomembranous colitis
PPF	Public Partnership Forum
RAGs	Red, Amber and Green
RAH	Royal Alexandra Hospital
ScotMARAP	The Scottish Management of Antimicrobial Resistance Action Plan
SGHDs	Scottish Government Health Directorates
SIGN	Scottish Intercollegiate Guideline Network
SMC	Scottish Medicines Consortium
SPCs	Statistical Process Control Charts
SSRL	Scottish <i>Salmonella</i> Reference Laboratory
VOL	Vale of Leven (Hospital)

2 Summary

2.1 *Clostridium difficile* is the leading cause of hospital-acquired diarrhoea in the UK. The epidemiology of *Clostridium difficile* infections has changed in recent years, with the occurrence of a number of large outbreaks of infections in North America, Japan and Europe, including the UK. The change has been associated with the emergence of so-called hypervirulent ribotypes, particularly 027.

2.2 Prior to October 2006, reporting of *Clostridium difficile* infections by laboratories in Scotland was voluntary. Apparent increases in the number of reports in consecutive years, coupled with concerns about the potential for the emergence of hypervirulent ribotypes in Scotland, prompted the establishment of the mandatory surveillance of *Clostridium difficile* in October 2006 for persons aged 65 years and older in the healthcare setting.

2.3 Latest surveillance data from Health Protection Scotland (HPS) showed that approximately 7,000 cases of *Clostridium difficile* Associated Disease (CDAD) were reported in Scotland every year. As of July 2008, the Scottish *Clostridium difficile* Reference Service ribotyped 442 isolates which yielded 21 different ribotypes. The top 5 ribotypes referred to the laboratory were types 106 (164 isolates : 37%), 001 (102 isolates : 23%), 027 (62 isolates : 14%), 002 (15 isolates : 3.4%) and 078 (14 isolates : 3.2%).

2.4 The incidence of CDAD in NHSGGC per 1,000 occupied bed days has been comparable to the incidence across NHS Scotland since the surveillance began in October 2006.

2.5 In late April / early May 2008, the Infection Control Team (ICT) in the Acute Clyde Division of NHSGGC became aware of a cluster of CDAD patients. Subsequent investigations identified 55 patients with CDAD diagnosis at the VOL Hospital for a six-month period from 1 December 2007 to 31 May 2008. The number of cases of CDAD was more than expected for this hospital, based on the historical data. In addition, isolates from 16 of these patients were typed and 14 had ribotype 027. This data suggests that there was an outbreak of 027 at VOL Hospital.

2.6 After a maximum of 7 months follow-up of CDAD cases diagnosed over this 6-month period (December 2007 – May 2008), a total of 28 patients had died among the cohort of 55 patients. From the review of death certificates *Clostridium difficile* was thought to have contributed towards the deaths of 18 of these cases with a crude case fatality rate of 33%.

2.7 NHSGGC set up a full Outbreak Control Team (OCT) with representatives from the NHS Board, Health Protection Scotland (HPS) and the *Clostridium difficile* Reference Service in support of the local ICT to investigate this outbreak retrospectively. The OCT met on 10 June 2008 for the first time and had 6 further meetings.

2.8 The OCT reviewed routinely available local and national data and data specifically collected by the acute services team in response to the outbreak, and initiated further collection and analysis of clinical data. The conclusions of the OCT are as follows:

2.8.1 The local ICT responded appropriately on an individual case-by-case basis and provided the clinical team with appropriate infection control advice. However the surveillance system that was in place at the time of the outbreak was inadequate in alerting the local ICT of increased numbers at a ward and / or hospital level.

2.8.2 The surveillance system at the VOL Hospital until May 2008 relied on a colour card system which flagged positive cases and a daily visual inspection of the cards to identify clustering of alert organisms including *Clostridium difficile*. The pattern of cases at the time appeared visually as sporadic to the local ICT rather than clustered (outbreak) and this was particularly due to the frequent movements of patients between wards and hospitals for clinical reasons.

2.8.3 There was an absence of Infection Control Doctor (ICD) leadership at the VOL Hospital at the onset of this outbreak. This outbreak was not recognised by the local ICT until a look-back exercise was undertaken as part of the investigations of the ribotype 027 cluster at the RAH and VOL Hospital.

2.8.4 Hand hygiene audits were routinely carried out in all acute hospitals in Scotland as part of the National Hand Hygiene Campaign. Data for the VOL Hospital do not show any evidence that the hospital was underperforming in terms of hand hygiene when compared to other acute hospitals in NHS GGC.

2.8.5 The clinical environment where some of the patients were managed did not have adequate facilities for the practice of good infection control procedure. However there is no evidence that this has in any way affected the clinical treatment of CDAD patients and / or their outcome.

2.8.6 Cleaning of the VOL Hospital environment was regularly audited as part of the national monitoring mechanism using the National Cleaning Services Specification. Monitoring data for the six months during the outbreak period did not highlight any significant issues with regards to cleanliness of the patient care environment.

2.8.7 A policy of antimicrobial prescribing was in place at the VOL Hospital at the time of the outbreak. However there were no formal arrangements in place to monitor antibiotic use or to audit compliance with antimicrobial policies. Subsequent audit by the AMT on behalf of the OCT showed that the relative use of some broad-spectrum antibiotics at the VOL Hospital was higher compared to other hospitals in Clyde. This is partly due to the case-mix of patients treated at the VOL Hospital compared to other Clyde hospitals.

2.8.8 The fatality rate among those patients affected by the outbreak appears to be higher than reported from elsewhere. Review of the casenotes of deceased patients suggests that they were a particularly vulnerable group of patients due to their age and other predisposing clinical conditions. In addition, it has been suggested that CDAD caused by ribotype 027 is more severe than that caused by other ribotypes.

2.9 The Cabinet Secretary for Health and Wellbeing set up an Independent Review Panel (IRP) in June 2008 to look into the CDAD outbreak at the VOL Hospital. The IRT Report published in early August 2008 made a number of recommendations for NHSGGC. In addition, the Scottish Government HAI Task Force produced an Action Plan in August

2008 detailing specific actions for NHSGGC and other general actions for all Health Boards in Scotland.

2.10 In addition to the IRT and HAI Task Force recommendations and Action Plans, the OCT made the following recommendations to reinforce some of the key points:

2.10.1 Based on the lessons learnt from this outbreak, the NHS Board should review and clarify roles, responsibilities and communication chain for HAI throughout the organisation.

2.10.2 The programme of work to improve the structural environment of the VOL Hospital should continue and an assessment of more significant works should be completed to facilitate optimum infection control practice.

2.10.3 The Antimicrobial Management Policy and the *Clostridium difficile* treatment protocol should be implemented in areas covering both primary and secondary care prescribing activities in NHSGGC. The Antimicrobial Management Policy should be audited at regular intervals.

2.10.4 A system should be developed to monitor the number of death of patients with CDAD and these should be regularly reviewed by the local ICT.

2.10.5 Local surveillance system should be regularly monitored to ensure that it is fit for purpose and if necessary updated based on national guidance. Local surveillance data should continue to be fed back to the senior charge nurses and lead nurses of the wards. In addition, data should be held on the number of new cases of severe alert organisms (*Clostridium difficile* and MRSA) per ward, per directorate and per site.

2.10.6 Education with regards to infection control and HAI issues should be available for all staff and the uptake of training should be monitored.

2.10.7 NHS Board should continue to work closely with Public Focus Patient Involvement (PFPI) and Patient Public Focus (PPF) leads for CH(C)Ps to review communication methods and materials used to communicate with patients and relatives and also with the wider community on HAI issues.

2.10.8 Clinicians completing a DNAR order must ensure that the decision making process is fully documented and this decision must be prominently displayed in the patients casenote.

2.11 In response to the IRT Report and the HAI Task Force Action Plan, the NHSGGC Board already implemented the following actions:

- A programme of work to improve the physical environment commenced in June 2008, this work continues to progress with up to £2M available for investment during the current financial year.
- A new Antimicrobial Prescribing Policy and a *Clostridium difficile* Treatment Protocol was developed and implemented throughout NHSGGC. An audit of these prescribing practices has been completed in the VOL Hospital in August / September 2008.
- The roll out of an electronic surveillance system based on the use of Statistical Process Control Charts (SPCs) is now complete within NHSGGC.
- An audit of key infection prevention and control policies has been completed in the VOL Hospital.

- The Local Health Board Co-ordinator for the National Hand Hygiene Campaign audited all of the wards in the VOL Hospital in September 2008.
- A document setting out a clear future vision for the VOL Hospital is currently out for consultation.
- Local and National Key Performance Indicators / Clinical Quality are being developed in order to reinforce a Board to Ward culture of accountability and responsibility.
- Senior Charge Nurse Review is being rolled out throughout NHSGGC.
- The review of the infection control structure is now complete. There will be a single spine accountability structure which supports clear reporting mechanisms from the ward to the NHS Board via the Infection Control Manager (ICM) / Medical Director.
- NHSGGC now has a system in place to transfer General Register Office for Scotland (GROS) data to local Infection Control Team (ICTs) to monitor the number of deaths among patients diagnosed with CDAD.
- NHSGGC have worked closely with Patient Public Focus Leads for Community Health and Care Partnerships (CH(C)Ps) and the Infection Control Patient Group to develop, review and update existing information on the Prevention and Control of Infection.
- 408 staff at the Vale of Leven have attended Infection Control Update Training Sessions during September and October of 2008.

3 Introduction

In April / May 2008, the ICT in the Clyde Acute Division of NHS Greater Glasgow and Clyde identified a total of 7 cases of *Clostridium difficile* 027 infections between the Royal Alexandra Hospital (RAH) and the Vale of Leven (VOL) Hospital. The initial investigations by the local ICT found an epidemiological link in time and place in 3 of these cases. Two of these 7 cases had been identified as *Clostridium difficile* in August / September 2007. These were typed in April 2008 as part of a research project and found to be ribotype 027. The ICT was made aware of this information in May 2008 to exclude any epidemiological links with the other 027 cases identified in April / May 2008.

In view of the above apparent clustering of ribotype 027 cases, the local ICT set up an Incident Management Team (IMT) to investigate these cases further and to ensure that all appropriate control measures were in place. During these investigations, the local ICT conducted a look back exercise examining the incidence of *Clostridium difficile* associated disease (CDAD) and associated mortality in the VOL Hospital in the six-month period between 1 December 2007 and 31 May 2008.

The review of the cases and deaths associated with CDAD was completed by the local ICT on 9 June 2008. This showed a higher than expected number of cases and an unusually high number of deaths attributed to CDAD. In view of this initial finding, the NHS Board set up a full Outbreak Control Team (OCT) with representatives from the NHS Board, Health Protection Scotland (HPS) and the *Clostridium difficile* Reference Service.

The OCT met on 10 June 2008 for the first time and had six further meetings. The remit of the OCT was to:

- Co-ordinate the investigations of all aspects of this outbreak.
- Ensure that all control measures were in place including treatment of cases.
- Co-ordinate communication between the Board and external agencies including the media.
- Make recommendations to the Board on its findings.

4 Background

4.1 *Clostridium difficile* 027 – Pathogenicity and Epidemiology

4.1.1 The Disease

Clostridium difficile is the leading infectious cause of hospital-acquired diarrhoea in the UK. The clinical spectrum of CDAD ranges from diarrhoea to severe life-threatening pseudomembranous colitis and toxic megacolon. Around 2-3% of healthy adults may be colonised with the organism. This figure may rise to 20% or more in hospitalised elderly patients. Resistance to developing CDAD appears to be dependent upon the presence of a functioning endogenous gut microflora. When the gut flora is disturbed, most commonly by broad-spectrum antibiotic therapy, *Clostridium difficile* organisms may establish an infection, with the production of a variety of toxins that are responsible for the clinical manifestations of CDAD. Other predisposing factors are thought to include increased age, immunosuppression and therapy with proton pump inhibitors.

Clostridium difficile is an obligate anaerobic organism. In the presence of oxygen the organism forms spores. These spores are highly resistant to desiccation, disinfection, alcohol and gastric acid. As such they may persist for long periods in the environment. They provide a reservoir for further infection via infected fomites and the hands of carers. Following ingestion the spores can germinate in the gut where they can initiate an infection in susceptible individuals. Symptomatic patients, who may have profuse diarrhoea, excrete large numbers of vegetative organisms and spores into the environment with the potential for ongoing transmission.

4.1.2 The Epidemiology

The epidemiology of *Clostridium difficile* infections has changed in recent years, with the occurrence of a number of large outbreaks of infection in North America, Japan and Europe, including the UK. This change has been associated with the emergence of so-called hypervirulent ribotypes, particularly 027. Many authors have indicated that these strains are associated with increased severity, high relapse rate and significant mortality. Although a recent UK study has questioned whether 027 is truly more pathogenic than other “epidemic” ribotypes, epidemiological studies would seem to confirm their increased communicability, and it is possible this may in part reflect an enhanced ability to persist in the environment.

Prior to October 2006, reporting of *Clostridium difficile* infections by laboratories in Scotland was voluntary. Apparent increases in the number of reports in consecutive years, coupled with concerns about the potential for the emergence of hypervirulent ribotypes in Scotland, prompted the establishment of the mandatory surveillance of *Clostridium difficile*.

Surveillance became mandatory in October 2006 for persons aged 65 years and older in the healthcare setting, including general practices, acute and non-acute hospitals. Surveillance is based upon laboratory reporting to HPS. The case definition is:

“A case of CDAD is someone in whose stool *Clostridium difficile* toxin has been identified at the same time as they have experienced diarrhoea not attributable to any other cause, or from cases from whose stool *Clostridium difficile* has been cultured at the same time as they have been diagnosed with PMC (pseudomembranous colitis).”

In order to support the objectives of the mandatory surveillance programme with respect to the emergence of ribotypes with enhanced pathogenicity and/or communicability, the Scottish *Clostridium difficile* Reference Service was established in November 2007 based within the Scottish *Salmonella* Reference Laboratory (SSRL) at Stobhill Hospital in Glasgow. As of July 2008 the laboratory has ribotyped 442 isolates which yielded 21 different types (although for half of these types, only 5 or less isolates have been received). The top five ribotypes referred to the laboratory are Types 106 (164 isolates: 37%), 001 (102 isolates: 23%), 027 (62 isolates: 14%), Type 002 (15 isolates: 3.4%) and Type 078 (14 isolates: 3.2%). Type 106 is one of the “newly-emerged” ribotypes of *Clostridium difficile*, which has been associated with a similar spectrum of disease and communicability as Type 027. Type 001 is regarded as the “classic” hospital-associated ribotype. It is of note that Type 027 has been reported by 12 laboratories located within 6 Health Board areas that are widely geographically distributed in Scotland. Although this would suggest that this strain is now circulating within Scotland, it is important to note that referral criteria for the Reference Service are currently based upon severity of disease or investigation of suspected outbreaks. This means that we do not have data on the extent to which the distribution of ribotypes observed to date reflects the distribution within the underlying population of isolates of *Clostridium difficile* at large. This would require some form of “snapshot” programme. Finally it is of note that Type 078 is within the top five ribotypes. This is another type that has been associated with enhanced communicability and pathogenicity in the literature.

4.1.3 CDAD in NHSGGC and Scotland

HPS collects data on the episodes of CDAD in all patients aged 65 years and over presenting with diarrhoea in acute and non-acute hospital and primary care.

The incidence of CDAD in NHSGGC per 1000 occupied bed days (OCBDs) is comparable to the incidence across NHS Scotland as shown in Figure 1.

Figure 1: Incidence of CDAD in persons aged 65 or over in NHSGGC and Scotland: October 2006 - March 2008 (Source: HPS)

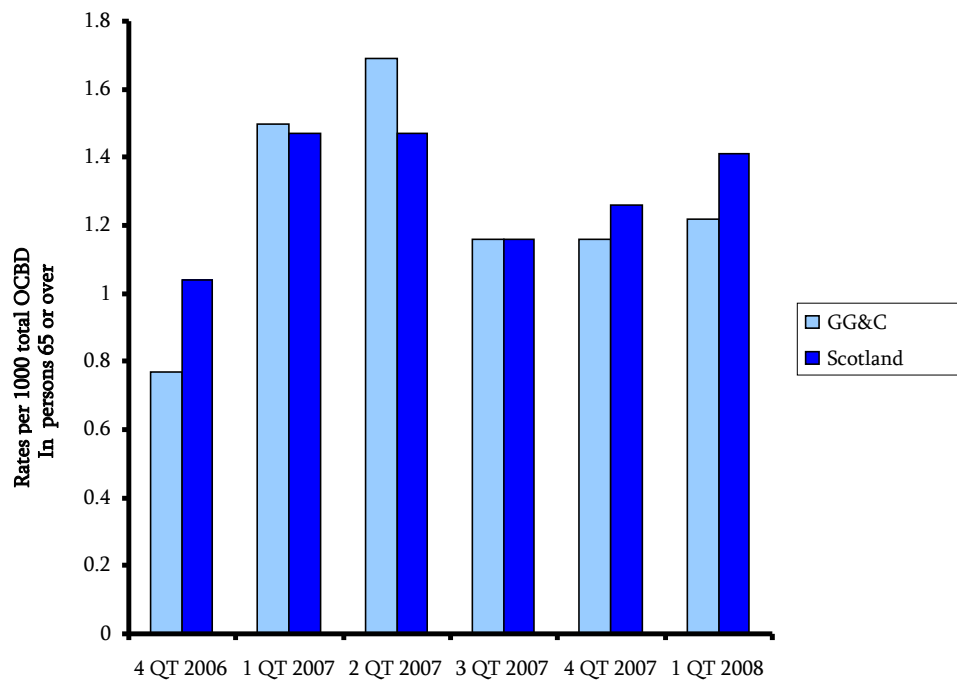


Table 1 shows the number of CDAD cases, in persons aged 65 or over, reported to HPS from VOL, RAH and NHSGGC since the mandatory reporting system began. These are the total number of cases reported and do not take account of the number of beds and case-mix within each hospital.

Table 1: Number of cases of CDAD in persons aged 65 or over reported to HPS from VOL, RAH and NHSGGC (4th Quarter 2006 - 1st Quarter 2008)

	4 th Quarter 2006	1 st Quarter 2007	2 nd Quarter 2007	3 rd Quarter 2007	4 th Quarter 2007	1 st Quarter 2008
VOL	8	14	30	13	23	27
RAH	32	48	46	47	31	42
NHSGGC	268	472	444	416	421	462

4.2 Structure and accountability arrangements for prevention and control of infection within NHSGGC

The organisational chart in Figure 2 outlines the infection control committee and accountability structures which were in place in NHSGGC between June 2006 and 1 July 2008.

NHSGGC produces a corporate Annual Infection Control Programme which is implemented and monitored on an exception reporting basis through the infection control committee structure and reported to the Board Infection Control and Clinical Governance Committees.

The detailed configuration of the Acute and Partnership Infection Control Teams, as of May 2008, is set out in Figures 3 and 4. During the period covered by the report a single Head Infection Control Nurse had managerial responsibility for all Infection Control Nurses in Greater Glasgow and Clyde. However until May 2008 overall responsibility for infection control services in Clyde lay with the Director for Clyde Acute Services, reporting directly to the Chief Operating Officer for the Acute Division of NHSGGC. Figure 5 illustrates the application of the NHS Board Risk Management Policy within the infection control service. The structure demonstrates the links established between infection control and risk management. This structure ensures the relevant risks are communicated both within the infection control structures and also to the wider clinical community for inclusion in risk registers. A link clinical risk manager was appointed to infection control from the clinical governance support unit to provide support on clinical risk issues.

Risk Registers have been developed and are reviewed by the Acute & Partnerships Infection Control Committees. Significant risks are communicated on an exception reporting basis to the Board Infection Control Committee and to the appropriate Governance Committee within Acute Services or Partnership function.

Immediate infection control related risks are managed in accordance with the NHSGGC Policy on the Management of Outbreaks supported by the organism specific policy where appropriate. This complete set of policies is available at ward and department level as part of the NHSGGC Prevention and Control of Infection Manual:

NHSGGC Infection Control Outbreak Policy

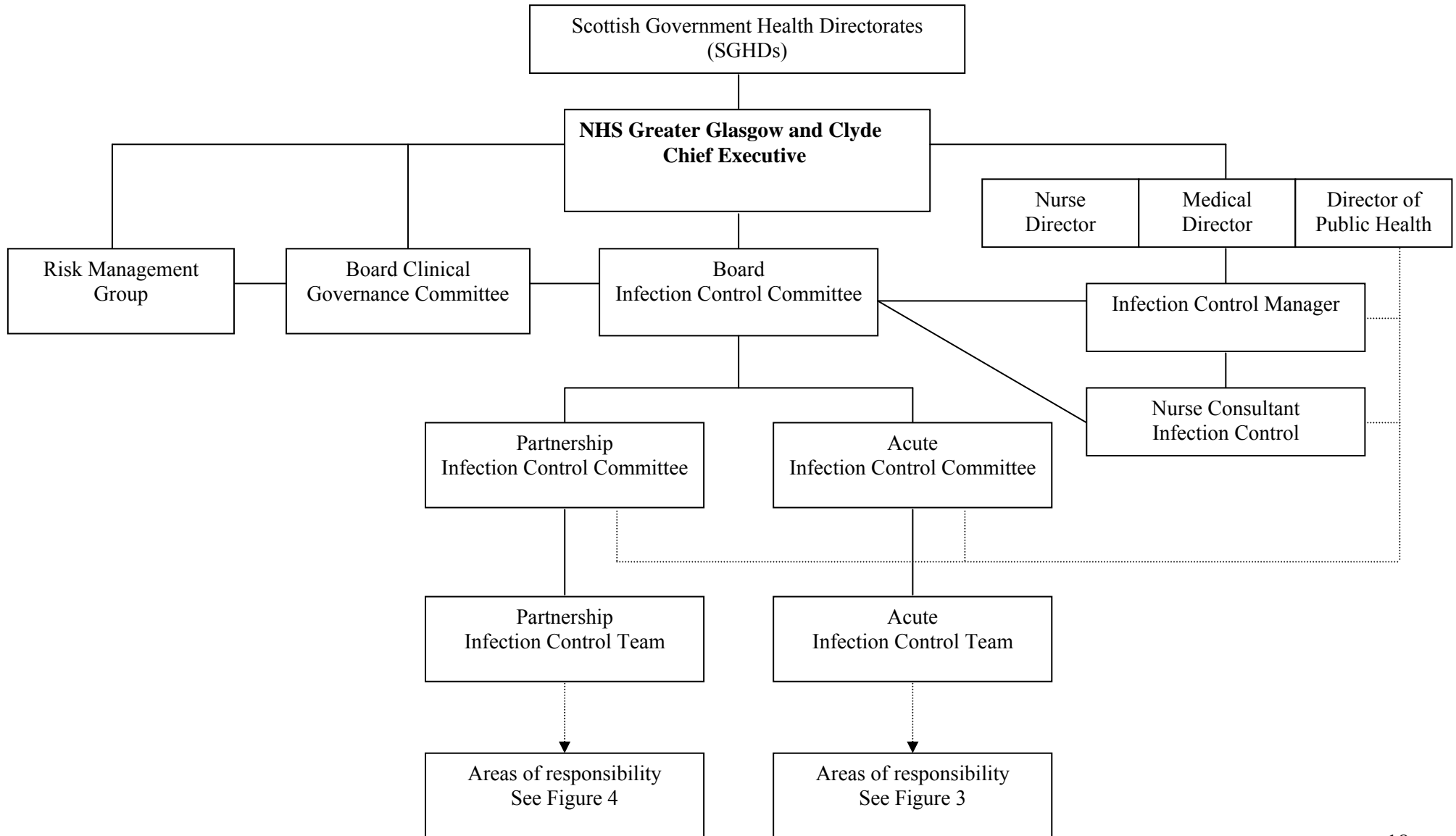
<http://library.nhsggc.org.uk/mediaAssets/Infection%20Control/Microsoft%20Word%20-%20Outbreak%202007%20final.pdf>

Infection control related incidents which do not fit the criteria / definition of an outbreak are managed in accordance with the NHSGGC Policy on the Management of Significant Clinical Incidents:

NHSGGC Policy on the Management of Significant Clinical Incidents

http://staffnet/Corporate+Services/Corp+Services/Clinical+Governance/Clinical+Risk/CG_Clinical_Incident_Reporting_CM_140207.htm

NHS Greater Glasgow and Clyde Infection Control Structure



**Acute Prevention & Control of Infection Team
(from May 2008 onwards)**

Figure 3

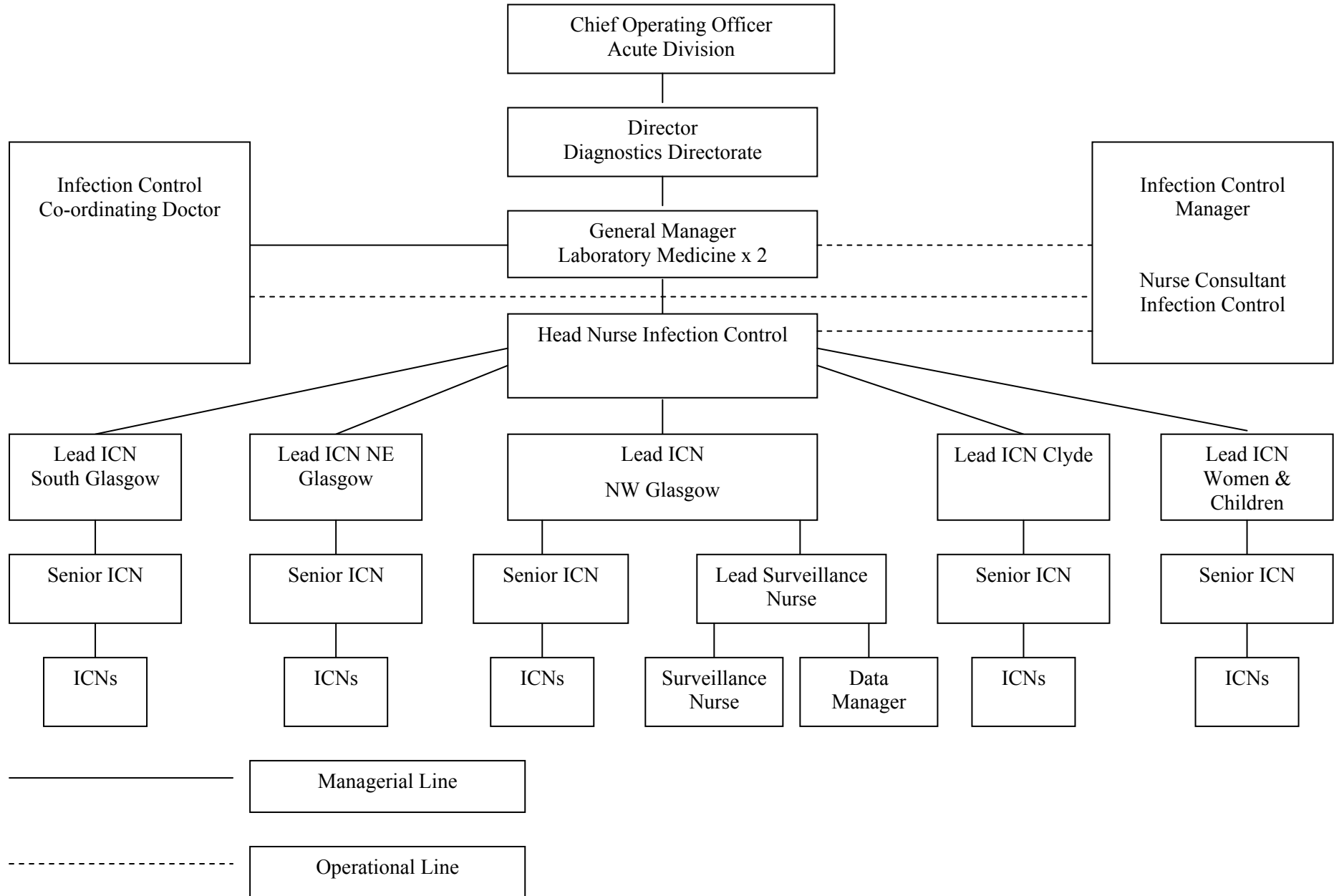
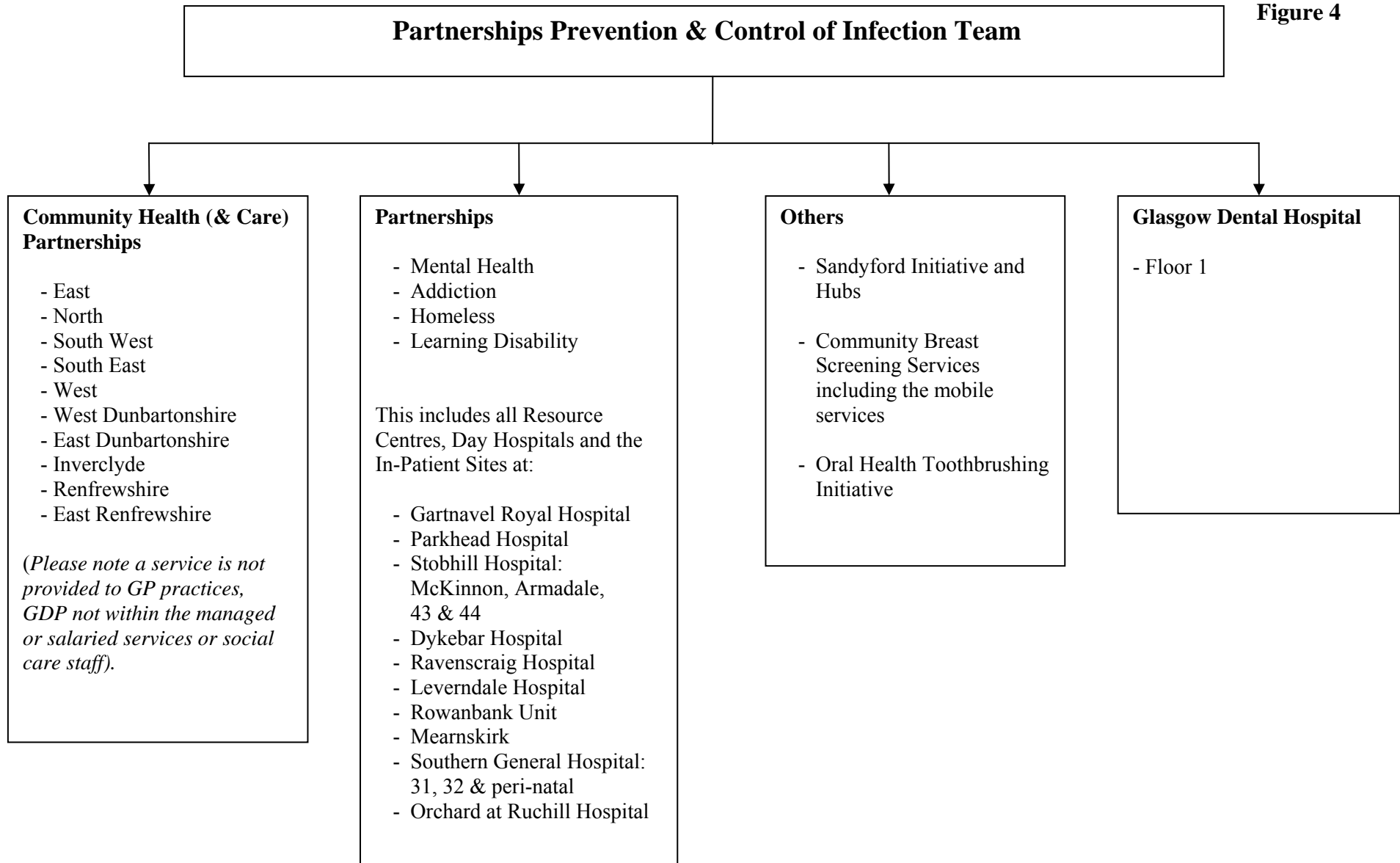
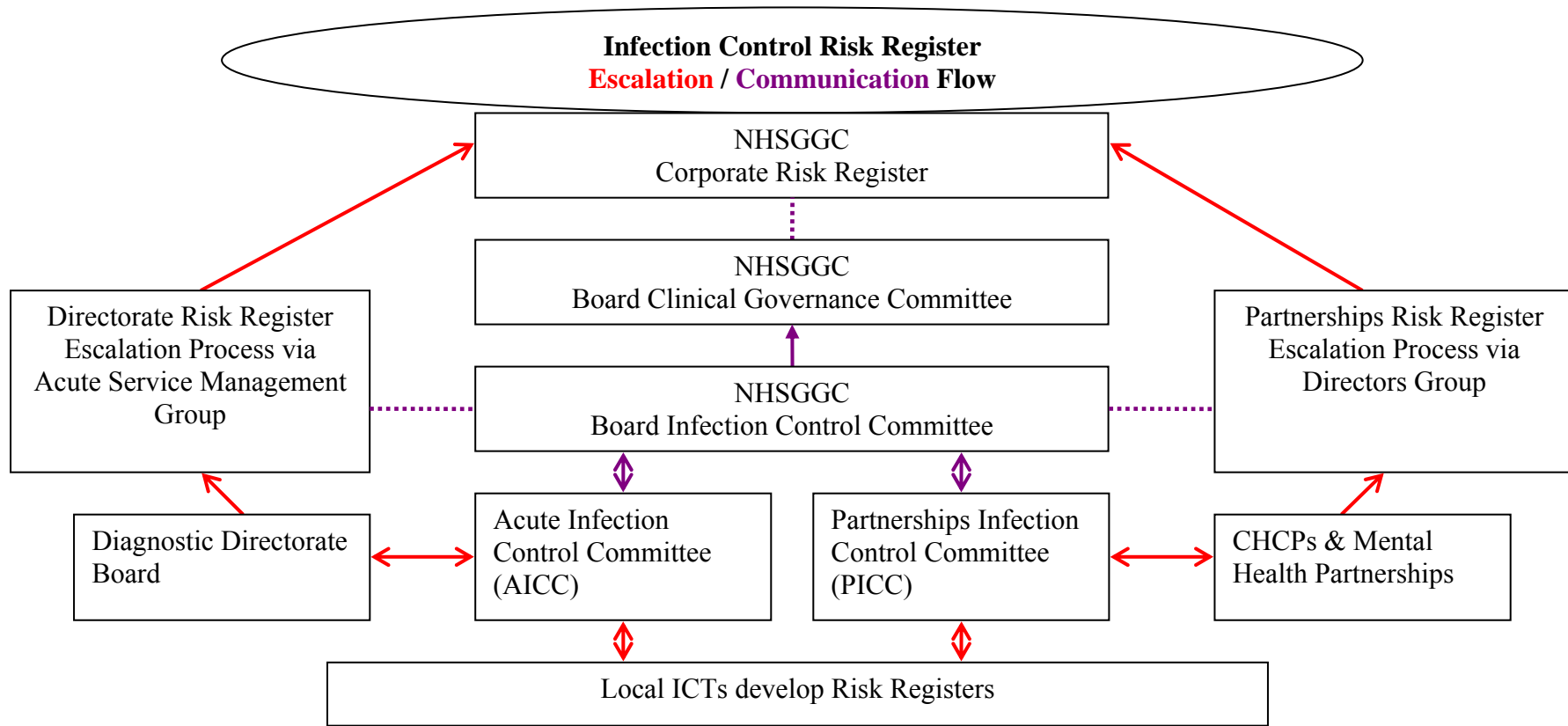


Figure 4



NHS Greater Glasgow and Clyde Risk Management Process for Infection Prevention and Control



This diagram illustrates the application of the NHS Board Risk Management Policy within the Infection Control Service

5 Investigation of cases of *Clostridium difficile* 027 at the RAH and VOL Hospital

5.1 Timeline

The following timeline summarises the sequence of events relating to the investigation of cases of *Clostridium difficile* 027 at the RAH and VOL Hospital.

28/29 April 2008: The Scottish *Clostridium difficile* Reference Service informed the Clyde Acute Division ICT that two patients had been identified as having the 027 strain of *Clostridium difficile*. ICT started an epidemiological investigation which revealed that the first of these was an inpatient at the VOL Hospital. The second had been admitted to the VOL Hospital and subsequently transferred to the RAH.

2 May 2008: Clyde ICT was informed by a biomedical scientist based at the RAH who was carrying out a research project that she had found two cases of 027 *Clostridium difficile* in the Clyde area. These cases had been inpatients at the RAH in August and September 2007 at which time stool samples had tested positive for *Clostridium difficile* toxin. The *Clostridium difficile* Reference Service did not officially become operational until 20 November 2007 however the above ribotyping was performed in April 2008 as part of an MSc Project by a member of staff from RAH working under supervision at the Scottish Salmonella Reference Laboratory, Stobhill Hospital. After epidemiological investigation by the ICT it was concluded that these two cases were unrelated to the latest cases.

2 May 2008: The ICT continued to carry out preliminary investigations including targeted environmental audits in the RAH and VOL Hospital and review of all control measures.

13 May 2008: The Scottish *Clostridium difficile* Reference Service informed the ICT of a fifth case of *Clostridium difficile* 027. This case was identified as a healthcare worker at the RAH.

14 May 2008: Local ICT discussed the situation at the Infection Control Working Group meeting and subsequently a meeting was held to specifically address the 027 *Clostridium difficile* situation at the VOL Hospital and RAH. This meeting was attended by staff from the RAH and VOL Hospital. Attendees were briefed by the ICT on the ongoing investigations and control measures already initiated by the ICT and a further action plan was agreed.

19/20 May 2008: The Scottish *Clostridium difficile* Reference Service reported a sixth case of *Clostridium difficile* 027 infection in a patient in the RAH. This patient had originally been admitted to the VOL Hospital.

21 May 2008: In view of the occurrence of new cases, the local ICT decided to set up an Incident Management Team (IMT) to investigate these cases and risk factors in more detail. The first IMT meeting was held on 21 May 2008, chaired by the NHSGGC Infection Control Manager (ICM).

27 May 2008: A seventh case of *Clostridium difficile* 027 infection was reported to the ICT by the Scottish *Clostridium difficile* Reference Service. This patient had originally been admitted to the VOL Hospital and was subsequently transferred to the RAH.

28 May 2008: After a review of all the available clinical information related to the case identified on 27 May, the ICT concluded that although it was a case of 027 it did not appear to be linked to the other cases at the RAH however, it did appear to be linked to the VOL Hospital. The local ICT therefore decided at this point to review the laboratory data to establish how many cases of *Clostridium difficile* had been identified in the VOL Hospital in the previous few months.

28 May 2008: A second IMT meeting was held, chaired by the NHSGGC ICM. At this meeting the actions from the previous meeting on 21 May were reviewed and progress against them discussed. In addition, several other actions were agreed as detailed in subsequent sections of this report.

5.2 Investigations

Of the seven cases of *Clostridium difficile* 027 identified between the RAH and VOL, six were patients and one was a member of staff. Initial epidemiological investigation found a time and place association in 3 of these cases only. Two other cases of 027 *Clostridium difficile* had been identified from specimens obtained in August and September 2007 as part of a research project within the RAH. These findings were reported to the ICT in May 2008 and were deemed unrelated. Other actions initiated by the IMT included:

- Case records, nursing notes, microbiology laboratory reports, patient management system information were reviewed for all of the patients who had 027 *Clostridium difficile* by the ICT and an epidemiological investigation was conducted and results presented to the IMT.
- Infection control environmental audits were carried out in the wards in the RAH and the VOL where patients with 027 strain of *Clostridium difficile* had been present. These audits are done routinely in all areas in NHSGGC but were repeated in response to the identification of cases of this ‘new’ subtype of *Clostridium difficile*.
- A walk round of all wards and departments at the VOL Hospital was conducted by members of the ICT, Lead Nurses and Estates to identify any areas where environmental and infection control issues needed to be addressed.
- National hand hygiene audit was undertaken in wards identified by the ICT. The national hand hygiene audit had been completed in all wards in the VOL in 2007 but this was repeated as an action point from the meeting of the IMT.
- Audit of antibiotic utilisation was proposed. The proposal also included an audit of the use of proton pump inhibitors.
- The ICT contacted the Scottish *Clostridium difficile* Reference Service who agreed to ribotype all new cases of *Clostridium difficile* identified in the RAH /

VOL Hospital to try and identify the background incidence of 027 *Clostridium difficile* in these hospitals.

- Further information was being gathered from many sources in order to expand the investigation, the types of information gathered included laboratory data, casenotes, review of the information from the infection control database, antimicrobial prescribing data and patient management system information (patient movement data).
- As the common link between most of the 027 CDAD cases diagnosed in April / May was the VOL Hospital, the ICT decided to conduct a review of CDAD cases at the VOL Hospital in the previous few months. While this process was in progress, on 5 June 2008, the NHS Board received an enquiry from a local reporter enquiring about the number of deaths at the VOL Hospital in the last six months due to *Clostridium difficile* infection. As the death data was not routinely available the ICT escalated the review of cases into a look-back exercise including collecting information on those who had died from *Clostridium difficile* infection in the six-month period between 1 December 2007 and 31 May 2008.

5.3 Findings and control measures

Based on the initial findings, the following control measures were initiated:

- Routine cleaning of ward environments in NHSGGC Hospitals is usually performed using a non-chlorine based detergent while chlorine based detergents are used as a standard practice for cleaning isolation rooms or cohort areas where patients with alert organisms, including *Clostridium difficile* are managed.

Terminal cleans of entire wards with chlorine based detergent are normally only carried out after wards have been closed due to outbreaks of infection. However, due to the possibility that this particular sub-type of *Clostridium difficile* was more transmissible, terminal cleans with a chlorine based detergent were carried out in all those wards within the RAH and the VOL Hospital where one or more patients with 027 *Clostridium difficile* had been admitted. After the meeting on 28 May it was agreed that, until further notice, a chlorine based detergent would replace all standard cleaning products in those wards in the VOL Hospital and RAH that had 027 cases.

- Education sessions on *Clostridium difficile* 027 were arranged. This included reinforcement of advice regarding the use of soap and water rather than alcohol hand gel when dealing with patients with *Clostridium difficile*.
- A memo from the ICT was prepared and issued to all staff with regards to the use of soap and water rather than alcohol hand gel when dealing with patients with loose stools. This reinforced the message delivered by the ICT during infection control induction sessions and by the NHSGGC Local Board Hand Hygiene Co-ordinator during his audits and educational sessions. This instruction is also included in the NHSGGC Control of Infection Committee Policy on the control of *Clostridium difficile*.
- Action plans in relation to the findings of both the infection control environmental audit and the review of the ward areas with regards to the general structure were prepared.

- The Scottish Ambulance Service was contacted and cleaning regime reviewed.
- Clinicians were asked to limit patient movement as far as practicable.

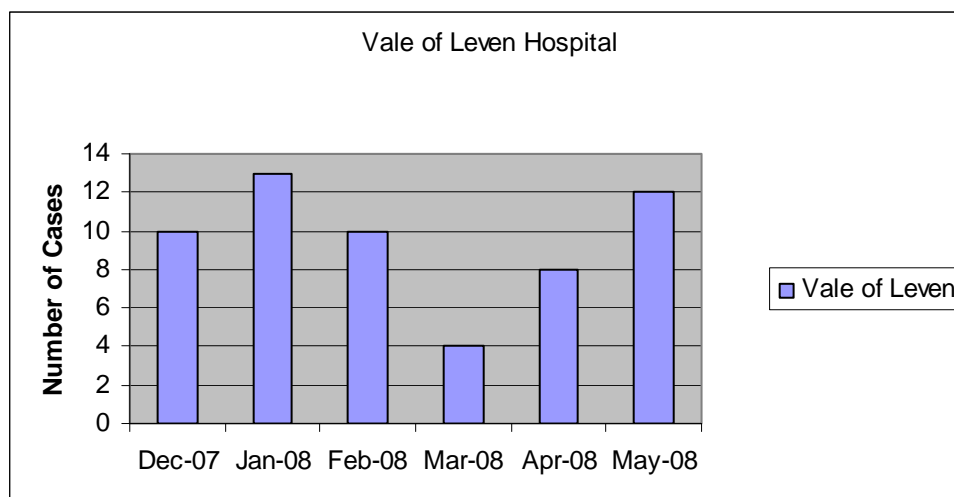
Details of findings are described in the next chapter; however, review of the cases and deaths in the previous six-month period was concluded on 9 June 2008. This showed a higher-than-expected number of cases and an unusually high number of deaths attributed to CDAD. In view of these initial findings, the NHS Board set up a full Outbreak Control Team (OCT) with representatives from the NHS Board, HPS and the *Clostridium difficile* Reference Service to investigate this retrospective outbreak. The OCT first met on 10 June 2008.

6 Investigation of cases of *Clostridium difficile* 027 in the Vale of Leven Hospital

6.1 Epidemiology

Fifty-five patients from the VOL Hospital had *Clostridium difficile* toxin isolated from faecal specimens obtained between 1 December 2007 and 31 May 2008. Figure 6 shows the number of cases on a monthly basis. Of these, 40 patients were female and 15 male. The median age of patients affected was 79 years with a range of 36 to 93 years. By the end of June 2008, and after a maximum of 7 months follow-up, a total of 28 patients had died among the cohort of 55 patients diagnosed over this 6-month period. From the review of death certificates *Clostridium difficile* was thought to have contributed towards the deaths of 18 of these cases with a crude case fatality rate of 33%.

Figure 6: Number of cases of CDAD at the VOL Hospital (December 2007 – May 2008)



In the retrospective investigation of events at the VOL Hospital not all isolates were available for ribotyping. However, of the 16 patients from whom at least a single isolate was available, 14 had ribotype 027, one had type 106 and one had type 078.

Although this would be consistent with a hypothesis of the introduction and subsequent dissemination of Type 027 within the VOL Hospital, in the absence of background ribotyping data, it is not possible to say definitively to what extent this might have reflected the normal distribution of ribotypes prior to this episode.

6.2 Surveillance System at Vale of Leven Hospital

The VOL Hospital was fully compliant with the requirements of the mandatory HPS National *Clostridium difficile* Surveillance System. However, this national system was designed to monitor trends but not pick up individual outbreaks at the ward and / or hospital level. The system used to identify outbreaks locally was, until May 2008, a coloured card system which flagged positive cases and was based on a daily visual inspection of the numbers and types of organisms / communicable diseases in each ward area. Whilst adequate for identifying and managing individual cases this system did not fully support the analysis of trends over time. The pattern of cases at the time appeared sporadic to the local ICT rather than clustered (outbreak). This was particularly due to the frequent transfers of patients between wards and hospitals for clinical reasons.

In addition, due to the lack of Infection Control Doctor (ICD) leadership at the VOL Hospital, routine infection control planning and monitoring meetings on site were held infrequently. However, a microbiologist with designated ICD remit for the hospital was appointed in February 2008.

By the time of the first OCT meeting, all of the Clyde hospitals had fully adopted the Electronic Surveillance System used in Greater Glasgow as part of the planned 2007/08

Infection Control Programme. The system is based on Statistical Process Control (SPC) charts which apply statistical theory to contextualise the incidence of infection based on the historical rate of acquisition of individual clinical areas. This system supports the local ICTs in the early identification of increased incidence or outbreaks of infection. Retrospective revision of an SPC for *Clostridium difficile* at the VOL indicates that the increase in numbers would have been detected had the system been available at the time.

6.3 Hand hygiene

One of the initial actions of the OCT was to assign the Board's hand hygiene co-ordinator to the VOL Hospital for a period of time. All wards were re-audited and a major campaign to improve compliance with the Board's strict hand hygiene protocols was initiated. This included education sessions, a poster campaign, meetings to raise awareness with clinical staff and ward visits to provide ad hoc sessions. Senior managers from NHSGGC met with clinicians and reinforced this message.

The OCT also agreed to undertake an evaluation of the results of the National Hand Hygiene Campaign. Hand hygiene audits have been routinely carried out in acute hospitals across Scotland since the campaign began in February 2007. The hand hygiene co-ordinator at NHSGGC provided the OCT with all hand hygiene data for acute division wards within NHSGGC hospitals from February 2007 until June 2008. Results were provided at ward level. These were then sorted into three directorates – Surgical, Medical, and Rehabilitation and Assessment. Results from wards within the Women and Children's directorate and Regional Services were excluded as none of the affected wards at the VOL Hospital fell into these categories. Hand hygiene audit

results for the VOL wards were then compared with other wards in the same directorate across NHSGGC to determine if there was any evidence that the VOL Hospital was performing any differently from the other acute hospitals in NHSGGC.

From these data, there was no evidence that the VOL Hospital was underperforming in terms of hand hygiene when compared with other acute hospitals in NHSGGC.

The national hand hygiene audit was repeated at the VOL Hospital in September 2008 and the scores for Medical, Rehabilitation and Assessment, and Surgical were 93%, 90%, and 93% respectively in keeping with increasing compliance rates across all acute hospitals in NHSGGC.

6.4 Physical environment

One of the immediate actions of the OCT was to review the structural environment of the clinical areas within the VOL Hospital. In fact the Chief Operating Officer of the Acute Division had already instructed members of the ICT prior to the first meeting of the OCT to prepare a list of priorities for immediate action.

Key findings of the review by the ICT, lead nurses and facilities representatives were:

- The absence of hand hygiene sinks in some patient bed bay / toilet areas and the low number of sinks to beds overall.
- Inadequate space between beds.
- Lack of dedicated hand hygiene sinks in sluice areas.
- Several areas with breaks in the flooring; this makes effective cleaning difficult to accomplish.

- Lack of adequate storage facilities.
- Some commodes were found not to be fit for use.

This review was formalised into a working group chaired by the Director of Facilities and an Action Plan was developed which detailed a 20-week programme of work to address key issues including:

- Re-instatement of Lomond Ward to improve available bed spacing throughout the hospital.
- Increased and improved access to hand washing facilities.
- General improvements to the fabric of the buildings.

The programme of work covered wards 3, 4, 5, 6, 14, 15, F, CCU, Medical Assessment Unit and the Minor Injuries Unit and work commenced on 13 June 2008.

6.5 Cleaning Services

Cleaning Services are an essential part of the multi-disciplinary approach to tackling Healthcare Associated Infection (HAI). For prevention and control of infection to work effectively, critical activities such as cleaning and hand hygiene have to be embedded into every day practice.

6.5.1 National Specification and Monitoring

As part of its work programme, the HAI Taskforce developed the ‘NHS Scotland Code of Practice for the Local Management of Hygiene and HAI’, and the ‘NHS Scotland National Cleaning Services Specification’. These documents include guidance on cleanliness and hygiene, effectively setting minimum standards for the healthcare

environment. They were issued to NHS Boards in May 2004. In addition, the HAI Taskforce commissioned Health Facilities Scotland (HFS) to develop a monitoring framework for the NHS Scotland National Cleaning Services Specification. This was developed in consultation with a range of stakeholders within NHS Scotland and was implemented in April 2006. The first quarterly report was published in August 2006.

Monitoring in this context is defined as the ongoing assessment of the outcome of cleaning processes to assess the extent to which cleaning procedures are being carried out correctly, to identify any remedial actions which are required and to provide an audit trail. An essential component of any monitoring framework is the fundamental principle of continuous improvement. Therefore the monitoring framework not only provides a reporting mechanism, but a rectification process that can be used locally to identify, prioritise and address issues of non-compliance.

Compliance is assessed within NHS Boards using a standardised monitoring template.

There are two components to the monitoring:

- Audits carried out on a routine basis by domestic services managers;
- Audits carried out by peer review teams, incorporating a public involvement element.

Cleanliness is assessed using an observational process and according to the technical requirements set out in the NHS Scotland National Cleaning Services Specification.

NHS Boards report their results to HFS on a monthly basis. From the data received the monitoring tool produces a score for all Boards and all A1 and A2 hospitals. This data is subsequently used by HFS to compile the quarterly report and fed back to Boards.

The scoring methodology is based on Red; Amber and Green (RAGs) scoring process as follows:

- $\geq 90\%$ equates to a green score
- $> 70\%$ but $< 90\%$ equates to an amber score
- $< 70\%$ equates to a red score

All cleaning rectifications are required to be made within the specified time scales.

Additionally, if an area scores amber or red, a RAGs form is completed giving details of why the area failed and how this will be rectified. A red area is re-monitored within 7 days and another score sheet completed. The amber area is re-monitored within 21 days and a further score sheet is completed. In both cases an action plan is produced to enable the rectification to be corrected.

6.5.2 Monitoring at VOL Hospital

As VOL Hospital does not fall within the A1 and A2 hospital categories due to its size and case mix, the data for VOL Hospital is not presented routinely in national reporting but incorporated into overall data for Clyde Hospitals. In the VOL Hospital, Clean Bill of Health Meetings were established as part of the former NHS Argyll & Clyde Health Board Initiative. These meetings continued following the dissolution of the former health board and are attended by the Facilities General Manager for Clyde, Facilities Site Managers for Clyde, the Infection Control Nurses for Clyde, a staff side representative and representatives from the Estates Departments. The cleaning monitoring data for the VOL Hospital is discussed at these meetings and any non-compliance issues highlighted and action plan agreed. In addition, monthly meetings are held involving the Cleaning Services Manager, Infection Control Nurse and an

Estates representative to ensure that all action plans arising from the monitoring process, are fully implemented.

In acute in-patient areas in the VOL Hospital, cleaning monitoring audits are undertaken weekly instead of the minimum monthly requirements as per the recommendations of the HFS initiative. The reporting frequency is as per the National Monitoring Framework.

From December 2007 to June 2008, 182 audits were undertaken. During this time 177 (97%) of audits scored green and only 5 (3%) scored red or amber based on the nationally recommended RAGs system. On each of these occasions actions were taken to rectify identified deficiencies within the defined national parameters of 7 days for red, and 21 days for amber in clinical areas. Managers at the VOL Hospital continue to prioritise cleaning in all clinical wards and departments, and a programme of Peer and Peer / Public Review audits was undertaken within the Hospital.

6.6 Antimicrobial prescribing

6.6.1 Background

Certain commonly prescribed antimicrobial agents predispose to CDAD. These antibiotics include cephalosporins, quinolones, broad-spectrum penicillins (eg co-amoxiclav) and clindamycin. The use of many of these agents increases in the winter months in response to increased rates of respiratory tract infections, both in hospitals and the community. In addition, the development of antimicrobial resistance has become an increasing public health problem worldwide. The Scottish Management of

Antimicrobial Resistance Action Plan¹ identifies the following threats to health posed by antimicrobial resistance:

- Some infections may become untreatable.
- Empirical antimicrobial treatment may become increasingly ineffective, and thus time may be lost in treating critically ill patients.
- Length of hospital stay, antimicrobial use, morbidity, mortality and overall costs to all involved may be increased.
- Less effective, more toxic, and/or more expensive alternative medications may be required.
- Other interventions, e.g. organ transplantation, cytotoxic therapy for cancer, hip replacements, may prove increasingly ineffective should prophylactic and empirical antimicrobial therapy fail.
- The reduced ability to control bacterial infection will impede progress in the development of innovative medical procedures.

A major factor in the development of antimicrobial resistance is exposure to antimicrobial agents. It is therefore essential that, when treating infections, doctors consider the potential risks (side effects / development of resistance) as well as the benefits when selecting which antibiotic to prescribe. Antimicrobial policies and guidelines aim to assist prescribers in this process by promoting prudent, cost effective, and evidence based prescribing of antimicrobial agents (antibacterials, antivirals and antifungals) in line with national and local guidelines.

6.6.2 The Antimicrobial Management Team

The Antimicrobial Management Team (AMT) was established in June 2007, in response to the Scottish Government Health Directorates (SGHDs) / Scottish Medicines Consortium (SMC) report on Antimicrobial Prescribing Policy and Practice (September 2005)². In accordance with these recommendations, a Lead Doctor, a Lead Pharmacist and a Lead Microbiologist were appointed as the core members of the AMT. The AMT is the executive unit of a sub-committee, the Antimicrobials Utilisation Committee (AUC) established in August 2007 that provides professional advice and a source of consultation. The AUC reports to the Board's Area Drug & Therapeutic Committee (ADTC).

At the time of the outbreak the AMT and the AUC had an agreed programme of work in place for 2008/09. This included the 'root and branch' review of antimicrobial prescribing guidelines for NHSGGC; the goal of which was to provide consistency of approach to the management of a range of hospital based infections. Part of this programme was the development of Board-wide infection management guidance and CDAD treatment guidelines.

Other priorities for the AMT include:

- Promotion of clinical and cost effective prescribing practice.
- Development of professional networks (Medical, Pharmacy, Nursing and Microbiology) in support of prudent antimicrobial prescribing.
- Development of an effective communication strategy for the dissemination of antimicrobial prescribing guidance.
- Identification of education and training needs for prescribers of antimicrobials.

- Review of prescribing trends for selected antimicrobial therapies and evaluation of the impact of the new prescribing guidelines.
- Influence on the scope and content on patient group directions supporting non medical prescribing of antimicrobial agents.
- Development of partnerships with a range of stakeholders, including ICTs at local level and SMC / ScotMARAP at national level.
- Facilitation of research and audit activity in antimicrobial therapy.

In addition to the programme of work detailed above, NHSGGC agreed to the appointment of four additional wte specialist Antimicrobial Pharmacists and a Data Analyst to support the work of the AMT across the acute hospital service, including the audit of compliance with the new infection management guidance. The recruitment process was well underway, with the data analyst and three of the pharmacists in post by 1 September 2008.

A policy for antimicrobial prescribing was in place at the VOL Hospital at the time of the outbreak. However, there were no formal arrangements in place to monitor antibiotic use or to audit compliance with antimicrobial policies. In light of this, and the role that antimicrobial prescribing can play in the development of CDAD, the OCT invited the AMT to review antimicrobial prescribing practice in relation to the outbreak at the VOL Hospital.

6.6.3 Investigations

The AMT undertook a rapid review of antibiotic utilisation in all Clyde acute hospitals: the VOL, the IRH, and the RAH. The analysis was limited to a review of the

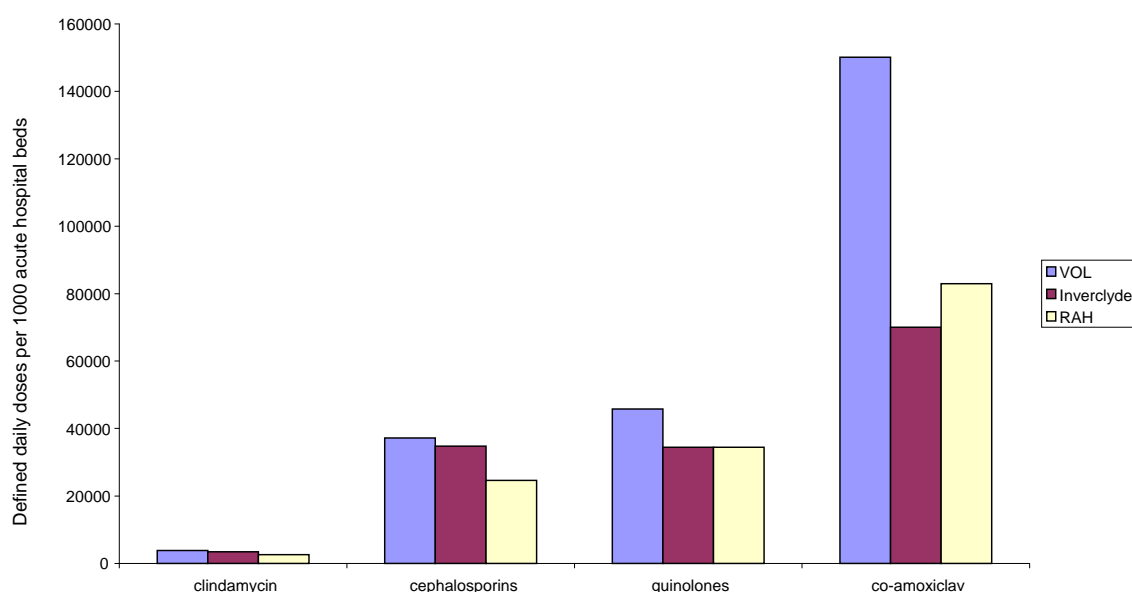
commonly used agents known to predispose to CDAD, as detailed in 4.6.1. Data on antibiotic utilisation were examined for each quarter in the period January 2007 to March 2008 and were presented, for each agent and hospital, as the number of defined daily doses per 1000 hospital beds per quarter. In addition, data on oral cephalexin use was available for the last quarter of 2007 and the first quarter of 2008 for all acute hospitals in NHSGGC.

6.6.4 Findings

The AMT found that the use of co-amoxiclav at the VOL Hospital had decreased slightly over time, but that the relative use of co-amoxiclav was higher at the VOL than other Clyde acute hospitals. Similarly, although there had been a generalised reduction in cephalosporin use at the VOL Hospital between the first quarter of 2007 and the first quarter of 2008, the use of oral cephalexin at the VOL was higher than that in other NHSGGC acute hospitals. Quinolone use at the VOL had remained stable over time, but again it was found to be disproportionately higher than in other Clyde acute hospitals. Clindamycin use at the VOL had increased significantly over time; however this represented a much smaller volume of antibiotics compared to the other agents examined.

Figure 7 shows the relative use of antibiotics known to predispose to CDAD in the three Clyde acute hospitals over the time period January 2007 to March 2008.

Figure 7: Use of antibiotics known to predispose to CDAD: Clyde hospitals Q1 2007 - Q1 2008



6.6.5 Actions and recommendations of the AMT

In response to the outbreak of *Clostridium difficile* infection at the VOL Hospital the planned work of the AMT was accelerated and the new infection management guidance and CDAD treatment guidelines were implemented across NHSGGC as follows:

Two emergency meetings with clinicians and pharmacists were convened in the VOL Hospital (12 June 2008) and the RAH (13 June 2008), where revised guidance was presented, discussed and agreed for immediate implementation.

Over the period 13 June 2008 to 17 June 2008 further revision and approval of infection management guidelines was carried out through consultation with key stakeholders and the AUC. Following a meeting with Associate Medical Directors and Clinical Directors on 19 June 2008, these were approved, with further minor revisions, for dissemination to other hospitals within NHSGGC with immediate effect. The main elements of the guidance are as follows:

1. Emphasis given to consider whether antibiotic therapy is required; **STOP and THINK before prescribing an antibiotic**
2. It is essential that the principles of prudent antimicrobial prescribing are adhered to. **Prescribers must review the need for antimicrobial therapy on a daily basis.**
3. **Surgical prophylaxis** should comply with new SIGN guidance. In particular antibiotics should not be continued longer than 24 hours and the prescription should be written in the “once only” section of the drug prescription chart or the anaesthetic chart.
4. **Empirical ceftriaxone is no longer recommended first line** except where bacterial meningitis is suspected. Other cephalosporins (oral and intravenous) should be avoided except on advice by microbiology.
5. **Empirical co-amoxiclav is restricted** to severe Community Acquired Pneumonia (CURB 65 score ≥ 3 or 2 with additional features), infected human or animal bites, peri-anal infection and spontaneous bacterial peritonitis.
6. **Empirical oral ciprofloxacin is restricted** to use in pyelonephritis
7. **Clindamycin is restricted** to use in severe Group A Streptococcal infections, necrotising fasciitis and severe soft tissue infections in parenteral drug users.
8. Amoxicillin + Gentamicin + Metronidazole is now the first line antibiotic regimen for intra-abdominal sepsis.
9. Amoxicillin + Flucloxacillin + Gentamicin is now the first line antibiotic regimen for community acquired sepsis where the source is not known.
10. **New CDAD management guidance has been developed** which stratifies patients into severe or non-severe. Oral vancomycin should be used for the former indication.

11. **Microbiology should be contacted** whenever a cephalosporin, co-amoxiclav, fluoroquinolone or clindamycin is used outwith approved indications.

6.6.6 Follow-up Audit

In September 2008, the AMT carried out a follow-up audit of antimicrobial use in the VOL hospital in which they calculated antibiotic utilisation (defined daily doses per 1000 hospital beds) for the second and third quarters of 2008. They also conducted a snapshot survey of 111 patient records to assess the frequency and appropriateness of antibiotic prescribing.

The audit showed limited and appropriate use of antimicrobial agents known to predispose to *Clostridium difficile* infection. Of the 111 patients reviewed 25 had been prescribed an antibiotic, one of which was an agent known to predispose to CDAD. The audit also showed that the use of these agents had reduced substantially between quarters 2 and 3 (Table 2).

Table 2: Changes in antimicrobial prescribing at VOL Hospital between Q2 and Q3* 2008

Antimicrobial agent	% reduction in use
Cephalosporins	48.7%
Quinolones	61.3%
Clindamycin	98.1%
Co-amoxiclav	71.3%

*data for Q3 has been extrapolated using returns for first 2 months

6.7 Infection control

Prior to July 2007, the ICT at the VOL Hospital comprised 3 members of staff; 2 ICNs and an administrator. An ICD provided services to the VOL but was based on another site within the Clyde Directorate. In July 2007 the Senior ICN at the VOL became the Lead ICN for Clyde and she continued to be based at the VOL until April 2008 when she retired. An interim lead nurse was appointed in April 2008; this individual was based in the RAH.

Whilst there is a lack of extensive guidance on the numbers of ICNs to bed ratio, a study published several years ago recommended one ICN to 250 beds (1:250). This view was supported in the Model for the Prevention and Control of Infection and Communicable Disease for Scotland 2002 (SCIEH – Kennedy Model). During the six-month period under investigation the number of ICNs to beds in the Clyde Directorate was 1:205, and at the VOL Hospital this ratio was 1:165.

In terms of Infection Control Practice on this site, the report of the Independent Review Team (IRT) of CDAD at the VOL Hospital (2008) stated “*the infection control nurse responded to these alerts (cases of Clostridium difficile infection) appropriately on an individual case by case basis with ward liaison visits*”. This would include advice on isolation of symptomatic patients, the use of personal protective clothing, hand hygiene and environmental decontamination. The NHSGGC Prevention and Control of Infection Policy manual was also present in every ward in the VOL and RAH. Standard Operating Procedures with regard to the daily and terminal clean of isolation rooms which had been ratified by the Boards Infection Control Committee in 2007 were available for clinical and facilities staff. NHSGGC *Clostridium difficile* patient

information leaflets were given to patients and relatives. The leaflets clearly state that further advice can be obtained from the local ICT. The policy of the team was to meet with any relatives who requested further information however some of the relatives who gave evidence to the IRT felt that they would have preferred pro-active face-to-face contact with professionals to discuss issues regarding this infection.

6.8 Clinical review of patients

6.8.1 Disease severity and outcome at VOL Hospital

In response to the apparent increased numbers of CDAD cases, the number of deaths associated with CDAD and the occurrence of ribotype 027, the OCT with support from HPS conducted a review to examine what factors might have contributed to the high case-fatality rate. The review collated and analysed data from:

- the local investigations led by the OCT; and
- the national retrospective review of CDAD cases in all acute hospitals in Scotland co-ordinated by HPS.

6.8.1.1 Data from investigations led by the OCT

In addition to the microbiology and hand hygiene data described earlier in this report (sections 4.1 and 4.3 respectively), the OCT analysed data collected from a casenote review conducted by three senior nurses from the acute division of NHSGGC. This review collected data from 46 of the 55 patients in the VOL cohort. All 18 patients that were identified from their death certificates as having died from CDAD (either as a primary or secondary cause of death) were included among the 46 casenotes reviewed.

The data collected included the following:

- age and sex
- date of onset of symptoms
- symptomatology
- whether the patient was classed as “Do Not Attempt Resuscitation” (DNAR)
- antibiotic therapy.

The findings on the characteristics of the 46 patients are summarised in Table 3. This shows that patients who died from any cause (CDAD and other causes) were, on average, older than those who survived. They were also more likely to have a DNAR order completed (none of the patients who survived had a DNAR completed). The descriptive statistics also suggest that there were no major differences between the three groups in relation to the treatment they received for their CDAD.

In addition to the descriptive statistics presented, the characteristics of patients identified as having died from CDAD were compared with all other CDAD patients (those identified as having died from other causes and non-fatal cases) and statistical significance testing was carried out (Fisher’s exact test). Statistical significance was only reached in relation to the presence of a DNAR order. Patients identified as having died from CDAD were significantly more likely to have a DNAR completed at any time during their stay (100% vs. 25%, $p < 0.001$). They were also significantly more likely to have had a DNAR order completed before they developed CDAD symptoms (33% vs. 7%, $p=0.042$). This suggests that those patients identified as having died from CDAD were a particularly vulnerable group of patients with other underlying pathology.

The characteristics of patients who died from CDAD were also compared with patients who died from other causes. No statistically significant differences were found. This suggests that these two groups of patients had similar levels of vulnerability to serious outcome that were independent of their CDAD status.

Table 3. Patient characteristics

Characteristic	Fatal cases: CDAD on death certificate	Fatal cases: Deaths from other causes	Non-fatal cases
Total number of cases	18	8	20
Female	12 (67%)	6 (75%)	17 (85%)
Male	6 (33%)	2 (25%)	3 (15%)
Mean age	80	81	71
Median age (range)	85 (56 – 93)	81 (73 – 89)	70 (48 – 91)
HAI (defined as symptoms starting \geq 48 after admission)	14 (78%)	5 (62.5%)	10 (50%)
DNAR (do not attempt resuscitation) order completed at any time	18 (100%)	7 (87.5%)	0 (0%)
DNAR order completed before CDAD symptoms	6 (33%)	2 (25%)	0(0%)
Any anti-Clostridial treatment given	18 (100%)	7 (87.5%)	19 (95%)
Metronidazole given	18 (100%)	7 (87.5%)	18 (90%)
Vancomycin given	8 (44%)	0 (0%)	7 (35%)
Any antibiotic given in 12 weeks before symptoms started	14 (78%)	8 (100%)	17 (85%)
Antibiotic predisposing to CDAD given in 12 weeks before symptoms started	13 (78%)	8 (100%)	14 (70%)
Any antibiotic given after treatment of CDAD started	10 (55.5%)	6 (75%)	8 (40%)
Antibiotic predisposing to CDAD given after treatment (of CDAD) started	6 (33%)	4 (50%)	5 (25%)

6.8.1.2 Data from the national retrospective review of CDAD cases

For the national retrospective review of CDAD cases co-ordinated by HPS, NHS Boards compiled data on CDAD cases in all acute hospitals in Scotland over the period 1 December 2007 to 31 May 2008. They also compiled data on CDAD deaths (using data from the General Register Office for Scotland (GROS)) and submitted these to HPS for analysis. Using data on acute occupied bed days supplied by ISD Scotland, HPS calculated CDAD incidence rates and case-fatality rates for all acute hospitals in Scotland. The results relating to NHSGGC acute hospitals are presented in Table 4. It should be noted that case-fatality rates in Table 4 are based on episodes of CDAD, e.g. VOL: $18/58 = 31.03\%$. This differs from the method adopted by the OCT which calculated case-fatality rates based on individual patients, i.e. there were 55 patients and 58 episodes of CDAD.

Table 4: National Retrospective Review of CDAD Cases: CDAD Incidence rates and case-fatality rates at NHSGGC Acute Hospitals (all ages). Dec 07 to May 08

	CDAD Incidence Rate			CDAD Case-fatality Rate (95% CI)
	CDAD Cases*	Acute occupied bed days (AOBD)	Rate per thousand AOB (95% CI)	
Vale of Leven General Hospital	58	23412	2.48 1.89 – 3.20	31.03 (19.53 – 44.64)
Inverclyde Royal Hospital	56	51673	1.08 0.82 – 1.40	16.07 (7.62 – 28.33)
Royal Alexandra Hospital	88	86367	1.02 0.82 – 1.25	6.82 (2.54 – 14.25)
Glasgow Royal Infirmary	120	121109	0.99 0.82 – 1.18	5.00 (1.86 – 10.57)
Stobhill Hospital	118	60964	1.94 1.60 – 2.32	5.93 (2.41 – 11.84)
Victoria Infirmary	122	59161	2.06 1.71 – 2.46	4.10 (1.43 – 9.30)
Southern General Hospital	115	108113	1.06 0.88 – 1.28	9.57 (4.88 – 16.48)
Western Infirmary / Gartnavel General Hospital	185	138025	1.34 1.15 – 1.55	11.89 (7.60 – 17.45)
All Scotland	3174	2090135	1.52	9.00

* CDAD cases in this table refer to episodes, e.g. VOL had 58 episodes.

6.8.2 Comments on VOL Hospital and national data

When the incidence of CDAD at the VOL defined by the retrospective national review was compared with rates in other NHSGGC hospitals, the VOL Hospital had the highest rate of CDAD in the six months 1 December 2007 to 31 May 2008. More striking however, is the case-fatality rate at the VOL, which is much greater than that experienced in all the other NHSGGC acute hospitals. It is also high when compared with case-fatality rates published elsewhere. In one Canadian study by Loo et al.

2005³, a prospective analysis of 1703 CDAD cases found that *Clostridium difficile* was either the attributable cause of death or contributed to the deaths of 14.3% of patients. This compares with a case-fatality rate at the VOL of 31.03%. It should be noted that the Canadian study only followed-up cases for 30 days, whereas cases at the VOL Hospital were followed-up for up to a maximum period of seven months. As most of these patients who died as a result of CDAD are elderly with other likely co-morbidities, the case-fatality rate among these patients is expected to increase with length of follow-up. This is reflected in a hospital outbreak in Canada where mortality rates of up to 37% had been reported at one-year follow-up⁴. In addition the NHSGGC hospital rates are crude rates, with no adjustment for age or other factors known to be associated with increased CDAD mortality, e.g. co-morbidity.

From the descriptive epidemiology, three possible explanations for this observed excess in CDAD deaths at the VOL compared with other hospitals were considered as follows:

6.8.2.1 Clinical status of cases

Data from the casenote review suggests that those who died from CDAD were, in general, older than those who survived. Detailed data on co-morbidity was not readily available from the casenote review. However, cases that died from CDAD were significantly more likely to have had a Do Not Attempt Resuscitation (DNAR) completed than those who did not and this difference was statistically significant. The higher DNAR rate amongst CDAD cases identified as having died from CDAD suggests that this group of patients may have been frailer and/ or had more serious co-morbidities than the other cases.

There is some evidence from the local casenote review that fatal cases (those who died from any cause) were more likely to have received other antibiotics (in addition to those used for CDAD treatment) than non-fatal cases. This small difference in the rate of antibiotic use may reflect a higher degree of co-morbidity in the fatal cases and the presence of other infections requiring treatment.

These findings support existing data that the VOL Hospital has a case mix of older and frailer patients than other Glasgow and Clyde hospitals and that this might be contributing to the high case-fatality rate experienced at the VOL.

6.8.2.2 The type of *Clostridium difficile* infection and associated pathology

Of the 16 isolates typed, 14 were ribotype 027. It has been suggested that CDAD caused by ribotype 027 is more severe than that caused by other ribotypes⁵. However, this theory has recently been called into question by a retrospective study of patients with CDAD which found no evidence of increased virulence associated with the 027 ribotype⁶. This is the largest cluster of ribotype 027 identified to date in Scotland. Further studies are required to establish whether ribotype 027 causes more severe disease compared to other ribotypes prevalent in Scotland.

6.8.2.3 Data Artefact

Concerns regarding the accuracy of death certificate data have been raised elsewhere⁷. As detailed in the next section of this report, a review of the VOL death certificate data conducted by two senior consultant physicians from two different hospitals in NHSGGC suggested that *Clostridium difficile* may have been more appropriately cited as a contributory cause of death in four cases where it had appeared on the death

certificate as a primary cause. However, in all of the cases the reviewing clinicians felt that *Clostridium difficile* should still appear on part II (contributory) of the death certificate. Therefore, the overall case-fatality rate would have been unaffected.

The identification of *Clostridium difficile* related deaths in the other NHSGGC hospitals was carried out using GROS data and searching for patients with cause of death coded as A04.7 or A49.8. These codes were selected because they were the two codes used by the GROS in all of the VOL cases. However, in a recent report⁸, the GROS identified two further codes that may be used to record *Clostridium difficile* infection and therefore some *Clostridium difficile* related deaths may have been missed in the figures for the other NHSGGC hospitals.

Finally, it is possible that doctors completing death certificates in the VOL Hospital may have had a more heightened awareness of *Clostridium difficile* infection than those in other hospitals, and therefore would have been more likely to include this on the death certificate.

6.8.3 Clinical management of patients

There was no evidence from the casenote review that the patients identified as having died from CDAD received less clinical treatment and care for the infection and its complications compared to the other patients. In addition, the IRT interviewed a number of relatives of deceased patients and most of them commented that they were generally satisfied with the level of care they and their relatives received whilst in the VOL Hospital.

There is some evidence that patients who died from any cause were more likely to have received antibiotics (in addition to those used for CDAD treatment) than non-fatal patients. This probably reflects a higher degree of co-morbidity in the fatal cases and the presence of other infections requiring treatment.

6.8.4 Review of Do Not Attempt Resuscitation (DNAR) orders

At the time of the outbreak, there was a resuscitation policy in place at the VOL Hospital. This included guidance on the completion of a ‘Do Not Attempt Resuscitation’ (DNAR) order. The key points from this guidance are as follows:

- A DNAR decision applies solely to cardiopulmonary resuscitation (CPR). All other treatment and care which is appropriate for the patient is not precluded and should not be influenced by the DNAR decision.
- The overall responsibility for decisions about CPR and DNAR orders rests with the consultant or GP in charge of the patient’s care. Responsibility may be devolved to other non-consultant grade but experienced members of the medical team but the decision must be fully discussed and agreed with the consultant / lead GP at the earliest opportunity.
- A DNAR order should be made only after the appropriate consultation and consideration of all relevant aspects of the patient’s condition, which should include likely clinical outcome, the patient’s known or ascertainable wishes, and the patient’s human rights.
- Unless the patient refuses, decisions should also be communicated to the patient’s family and others close to the patient.

- DNAR order, and any reviews, should be written prominently in the medical records by the doctor taking the decision.

6.8.4.1 Review of DNAR orders

Of the 18 patients who died with *Clostridium difficile* cited on their death certificate, 17 died in acute division wards and one died in a partnership (non-acute) ward. All 18 patients had a DNAR order in place at the time of death. Six of these (33%) were completed before the patient developed CDAD symptoms and twelve (67%) were completed after the patient developed CDAD symptoms.

DNAR orders for all 18 patients were reviewed. All patients who died in the VOL Hospital had a completed DNAR form (appendix 2) in their hospital casenotes. The patient who died in the RAH had a DNAR decision documented and signed in the medical casenotes. The review considered the following points for all cases:

1. Was the DNAR completed by a consultant / GP or was there clear documentation of discussion with, or review by, a consultant / GP?
2. Was there documented evidence of discussion with the patient and / or relatives?

In addition, for those 12 patients where the DNAR decision was made after the date of first CDAD symptoms, an assessment was made as to whether *Clostridium difficile* infection was a contributing factor in the completion of the DNAR order.

6.8.4.2 Findings

For 15 of the 17 patients who died in the acute division wards it was clearly documented that the DNAR decision had been discussed with, or reviewed by, a consultant. The DNAR for the patient who died in the partnership (non-acute) ward was completed by the GP with responsibility for the ward. For 13 of the patients there was documented evidence that there had been discussion with the patient and /or that the family had been informed of the DNAR decision. In a further 3 patients, although it was not clear if the DNAR order had been specifically discussed, there was evidence in the casenotes that there had been discussions with the family regarding planned care / level of intervention. It should also be noted that in those cases where discussions with a consultant or the family were not documented in the case records this does not necessarily mean that such discussions did not take place.

Of the 12 patients where the DNAR order was put in place after the onset of CDAD symptoms, 2 had no CDAD symptoms at the time that the DNAR decision was made and the documented reasons for DNAR did not include *Clostridium difficile* infection. In the other 10 patients, CDAD symptoms were present and may have been a contributing factor, along with other co-morbidities, in the decision to complete a DNAR.

6.8.5 Review of death certificates

6.8.5.1 General Register Office for Scotland (GROS) data

The GROS sends weekly listings of registered deaths to all NHS boards in Scotland. The listings include the following information for all deaths occurring in people resident within the health board area: name, date of birth, date of death, place of death,

underlying cause of death, and supplementary cause(s) of death. Working with the Public Health Information Team at NHSGGC, the OCT investigated the GROS data and explored the possibility of using this data for ongoing monitoring of deaths from *Clostridium difficile* occurring in the NHSGGC health board area.

The GROS codes cause of death using ICD-10, The International Classification of Diseases published by the World Health Organisation. When coding, the GROS selects one diagnosis from the death certificate and allocates this as the underlying cause of death. All other diagnoses on the death certificate (whether part I or part II) are coded as supplementary causes of death.

It should be noted that where certain conditions, e.g. pneumonia are listed on part I(a) of the death certificate, the GROS software will not code this as the underlying cause of death but instead selects another diagnosis from part I or II of the death certificate which it considers could have given rise to the condition in part I(a). This is to take account of Rule 3 in the ICD-10 instruction manual that states, '*if the condition selected by the general principle or by Rule 1 or Rule 2 [rules for selecting underlying cause of death] is obviously a direct consequence of another reported condition, whether in Part I or Part II, select this primary condition*'. Included in the list of such instances is pneumonia where it states, '*Pneumonia in J18.0 and J18.2-J18.9 should be considered an obvious consequence of wasting diseases (such as malignant neoplasm and malnutrition) and diseases causing paralysis (such as cerebral haemorrhage or thrombosis), as well as serious respiratory conditions, communicable diseases, and serious injuries*'.

The GROS records were examined for the eighteen patients from the VOL cohort for whom *Clostridium difficile* had appeared on the death certificate. For these patients the GROS had used the following codes in relation to their *Clostridium difficile* infection: A04.7 “enterocolitis due to *Clostridium difficile*” and A49.8 “other bacterial infection of unspecified site”. In three of the cases (due to Rule 3 as described above) CDAD had been designated the underlying cause of death despite appearing on Part II of the death certificate.

A recent report by the GROS⁸ identified two further codes that might be used when coding *Clostridium difficile* infection. These were: A41.4 “septicaemia due to anaerobes” and A09 “diarrhea and gastroenteritis of presumed infectious origin”. By using the GROS weekly listings and searching for codes A04.7, A49.8, A41.4 and A09 it would be possible to identify patients who may have died from CDAD in NHSGGC hospitals. Due to the system adopted by GROS to code the underlying cause of death, and the fact that codes A49.8, A41.4 and A09 are not specific to *Clostridium difficile*, a manual review of the death certificates would still need to be carried out to confirm that CDAD was indeed a cause of death and whether this appeared on Part I or Part II of the certificate. This could be done using the death certificate stubs held at ward level.

6.8.5.2 Death certification

Death certificate stubs held at ward level were examined for all CDAD patients from the VOL cohort who had died in the RAH or VOL Hospital. This identified 18 deaths in total where *Clostridium difficile* appeared on the death certificate either as a primary cause (on part I of the certificate) or as a contributory cause (on part II of the death certificate).

Concerns regarding the accuracy and consistency of death certificates have been raised elsewhere⁷. Because of the apparent high number of deaths attributed to CDAD at the VOL Hospital concerns were raised as to whether this could partly be due to some artefact in the way death certificates were completed. To address these concerns, in June 2008, two senior Consultant Physicians from outwith the Clyde division of NHSGGC undertook a casenote review to establish if, in the opinion of the reviewing physicians, death certification was appropriate. The physicians examined casenotes for 15 cases where *Clostridium difficile* had appeared on the death certificate.

Based on their brief review of the medical notes the reviewing physicians considered that:

- It was appropriate in all cases for *Clostridium difficile* to appear somewhere on the death certificate.
- In 4 of the cases where *Clostridium difficile* was cited as a primary cause of death, given each patient's medical history and clinical condition, it might have been more appropriately listed as a contributory factor.

Although the consultant review of death certification suggested that, in some cases, it may have been more appropriate for *Clostridium difficile* to appear on part II of the death certificate this would not have changed the overall CDAD case-fatality rate experienced at the VOL Hospital during this outbreak.

7 Communications

The OCT applied the Infection Control Outbreak / Episode Risk Matrix from the Watt Group Report in determining the communications response to the retrospective outbreak. All press releases were approved by the Chair of the OCT, or acting Chair in his absence. Communications was a standing item on the OCT agenda to allow the full membership of the OCT to consider the appropriate media/staff communications activity in response to emerging issues.

7.1 Media

A detailed press release was issued on 11 June 2008, announcing the results of the look back exercise and the further actions agreed to tackle the problem. Three further detailed updates were issued by the OCT on 16 June, 20 June and 25 June 2008.

A planned press release that was prepared on Thursday 12 June was not issued due to the fact that a further case had been identified that afternoon. NHSGGC were unable to contact the family of the individual who had died and it was decided that the press release should be withheld until the family had been contacted.

A further 48 statements were issued in response to specific questions from local and national media. These were either agreed with the Chair of the OCT or relevant executive manager, as appropriate. Media lines were also routinely shared with the Scottish Government and HPS. All four press releases were issued to all media via Newslink and also posted on NHSGGC's website.

The retrospective outbreak had a significant impact on overall media coverage on NHSGGC. Whilst final figures are not yet available, a snapshot of the impact of coverage, as reported to the Performance Review Group on 1 July, showed that the overall percentage of negative reports had increased from 7% in March – April 2008 to 29% of total media reports in May - June. Within the period 11-23 June there were 249 media reports on the retrospective outbreak alone (compared to a total of 617 reports for the entire two-month period).

7.2 Staff

Staff were kept fully informed of progress with the OCT. All four press releases were simultaneously issued to staff via a Core Brief. This is a real-time electronic briefing system which is disseminated widely to staff and posted on the Staffnet. In addition, the Chief Executive informed staff of key actions being taken in response to the retrospective outbreak via July's monthly team brief issued to all staff. A number of senior staff also met with staff at the VOL to discuss the issues.

Whilst the OCT has now concluded, communications with staff continue. The September 2008 edition of Staff Newsletter carried a major feature on infection, including *Clostridium difficile*, and how staff can help to prevent its spread. A dedicated (highly visible) clinical portal is being created on the front page of the NHSGGC StaffNet to ensure staff have easy access to the Board's new antimicrobial policy as well as a range of other clinical policies.

Since the publication of the Independent Review of CDAD at the VOL Hospital from December 2007 to June 2008 several initiatives have been in progress at the VOL Hospital to try and support staff at this time, these include:

- Infection control training sessions on multiple topics including, standard infection control precautions, *Clostridium difficile* infection including the use of the CDAD care bundle, hand hygiene and the use of statistical process control charts. As of 30 September 2008 more than 400 members of staff have attended these sessions.
- HPS CDAD care bundle is being piloted at the VOL Hospital.
- A planned programme of audit of infection control policies is in place.
- National hand hygiene audit has been repeated in September 2008 and all wards within the VOL Hospital scored over 90%.
- VOL Hospital has been identified as a flagship site for the implementation of the improvement programme 'a time to care'.
- Work is progressing regarding the upgrading of the physical environment of the VOL Hospital, with up to £2M available for investment during the current financial year.
- VOL Hospital has been identified as a flagship site for the implementation of the senior charge nurse review.

7.3 Patients and Relatives

Staff from NHSGGC responded to a number of specific enquiries from patients and their relatives concerning the care they and their relatives received while an in-patient at the VOL Hospital.

The OCT was made aware that the IRT would be meeting and taking evidence from the relatives of some of the deceased patients, therefore the OCT decided not to approach any relatives for their views on communication issues. The views of these relatives are detailed in the IRT report.

8 Conclusion and recommendations

8.1 Conclusion

8.1.1 The number of cases of *Clostridium difficile* infection at the VOL Hospital for the six-month period from 1 December 2007 to 31 May 2008 was more than expected for the hospital, based on the historical data.

8.1.2 Not all *Clostridium difficile* isolates for this six-month period were available for typing by the Reference Service but of those typed, 14 out of 16, were ribotype 027 suggesting that there was an outbreak of ribotype 027 at the VOL Hospital.

8.1.3 The local ICT responded appropriately on an individual case-by-case basis and provided the clinical team with appropriate infection control advice. However the surveillance system that was in place at the time of the outbreak was inadequate in alerting the local ICT to increased numbers at a ward and/or hospital level.

This is partly due to the absence of ICD leadership at the VOL Hospital at the onset of this outbreak. This outbreak was not recognised by the local ICT until a look-back exercise was undertaken as part of the investigations of the ribotype 027 cluster at the RAH and VOL Hospital.

The local surveillance arrangements for *Clostridium difficile* at the VOL Hospital was “in transit” during this period as NHSGGC had already initiated a programme of electronic surveillance system roll out to all its sites in the Board’s planned Infection Control Programme for 2007/08.

8.1.4 The fatality rate among those affected by the outbreak also appears to be higher than reported from elsewhere. However review of the casenotes of deceased patients suggest that they were a particularly vulnerable group of patients due to their age and other predisposing clinical conditions.

8.1.5 Cleaning of the VOL Hospital environment was regularly audited as part of the national monitoring mechanism using the National Cleaning Services Specification. Monitoring data for the six months during the outbreak period did not highlight any significant issues with regards to cleanliness of the patient care environment.

8.1.6 Hand hygiene audits were routinely carried out in all acute hospitals in Scotland as part of the National Hand Hygiene Campaign. Data for the VOL Hospital do not show any evidence that the hospital was underperforming in terms of hand hygiene when compared to other acute hospitals in NHSGGC.

8.1.7 A policy of antimicrobial prescribing was in place at the VOL Hospital at the time of the outbreak. However there were no formal arrangements in place to monitor antibiotic use or to audit compliance with antimicrobial policies. Subsequent audit by the AMT on behalf of the OCT showed that the relative use of some broad-spectrum antibiotics at the VOL Hospital was higher compared to other hospitals in Clyde. This is partly due to the case-mix of patients treated at the VOL Hospital compared to other Clyde hospitals.

8.1.8 The clinical environment where some of the patients were managed did not have adequate facilities for the practice of good infection control procedure. However there is no evidence that this has in any way affected the clinical treatment of CDAD patients and / or their outcome.

8.2 Recommendations

8.2.1 Based on the lessons learnt from this outbreak, the NHS Board should review and clarify roles, responsibilities and communication chain for HAI throughout the organisation.

8.2.2 The programme of work to improve the structural environment of the VOL Hospital should continue and an assessment of more significant works should be completed to facilitate optimum infection control practice.

8.2.3 The Antimicrobial Management Policy and the *Clostridium difficile* treatment protocol should be implemented in areas covering both primary and secondary care prescribing activities in NHSGGC. The Antimicrobial Management Policy should be audited at regular intervals.

8.2.4 A system should be developed to monitor the number of death of patients with CDAD and these should be regularly reviewed by the local ICT.

8.2.5 Local surveillance system should be regularly monitored to ensure that it is fit for purpose and if necessary updated based on national guidance. Local surveillance data should continue to be fed back to the senior charge nurses and lead nurses of the wards. In addition, data should be held on the number of new cases of

8.2.6 Education with regards to infection control and HAI issues should be available for all staff and the uptake of training should be monitored.

8.2.7 NHS Board should continue to work closely with Public Focus Patient Involvement (PFPI) and Patient Public Focus (PPF) leads for CH(C)Ps to review communication methods and materials used to communicate with patients and relatives and also with the wider community on HAI issues.

8.2.8 Clinicians completing a DNAR order must ensure that the decision making process is fully documented and this decision must be prominently displayed in the casenote.

9 References

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2. Scottish Medicines Consortium / Healthcare Associated Infection Task Force. Antimicrobial prescribing policy and practice in Scotland: Recommendations for good antimicrobial practice in acute hospitals. September 2005.
3. Loo, V.G. et al. A predominantly clonal multi-institutional outbreak of *Clostridium difficile*-associated diarrhoea with high morbidity and mortality. *N Engl J Med*, 2005. 353(23): p. 2442-9.
4. Pepin, J., Valiquette, L., Cossette, B. Mortality attributable to nosocomial *Clostridium difficile*-associated disease during an epidemic caused by a hypervirulent strain in Quebec. *CMAJ*. October 25, 2005, 173 (9)
5. Kuijper, E.J. et al. Emergence of *Clostridium difficile*-associated disease in North America and Europe. *Clin Microbiol Infect*, 2006. 12 Suppl 6: p. 2-18.
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7. Luce, T. et al. (2003). Death certification and investigation in England, Wales and Northern Ireland: the report of a fundamental review. HMSO Cm 5831.
8. GROS *Clostridium Difficile* Deaths (September 2008) <http://www.gros-scotland.gov.uk/statistics/deaths/clostridium-difficile-deaths/index.html>

Appendix 1: Membership of the Outbreak Control Team

Name	Designation	Location
Dr Syed Ahmed	Clinical Director and Chair of the OCT	NHSGGC, Dalian House, Glasgow
Tom Walsh	Infection Control Manager	NHSGGC, Dalian House, Glasgow
Sandra McNamee	Nurse Consultant Infection Control	NHSGGC, Dalian House, Glasgow
Dr Gill Hawkins	SpR Public Health	NHSGGC, Dalian House, Glasgow
Ally McLaws	Director of Communications	NHSGGC, Dalian House, Glasgow
Sandra Bustillo	Associate Director of Communications	NHSGGC, Dalian House, Glasgow
Professor John Coia	Director <i>Clostridium difficile</i> Reference Service	NHSGGC, Glasgow
Dr Linda Bagraade	Infection Control Doctor	Royal Alexandra Hospital, Paisley
Dr Anne Eastaway	Consultant Microbiologist	Health Protection Scotland
Dr Camilla Wiuff	Epidemiologist	Health Protection Scotland
Ysobel Gourlay	Lead Pharmacist	AMT, NHSGGC, Glasgow
Joan Higgins	Lead Infection Control Nurse, Clyde	NHSGGC
Annette Rankin	Head Infection Control Nurse, Acute	NHSGGC
Laura Kean	Lead Infection Control Nurse, North West	NHSGGC
Isabel Ferguson	General Manager, Laboratory Medicine and Infection Control	NHSGGC
Mary Morgan	General Manager, EC&MS, Clyde	NHSGGC
Dr Brian Cowan	Medical Director	NHSGGC
Beth Culshaw	General Manager, Rehabilitation & Assessment Directorate	NHSGGC
Anne Harkness	Director, Rehabilitation & Assessment Directorate	NHSGGC
Dr Andrew Seaton	ID Consultant / Lead Dr AMT	NHSGGC
Jim Crombie	Director of Diagnostics	NHSGGC
Dr Peter Christie	Senior Medical Officer	SGHDs (as an observer)

Appendix 2: DNAR Form

Vale of Leven District General Hospital



Patient Name: _____ Unit No: _____
 Date of Birth: _____ GP: _____
 Address: _____

**! Please ensure this form follows the patients !
 (e.g. on admission to, discharge from or transfer between hospitals)**

DO NOT ATTEMPT RESUSCITATION (DNAR)*

A decision has been taken that Mr/Mrs/Miss

Is not for cardiopulmonary resuscitation (CPR):

CPR is unlikely to be successful due to:**

- CPR is not in accord with the recorded, sustained wishes of the patient who is mentally competent.
- CPR is not in accord with a valid applicable advance directive (anticipatory refusal or living will)***
- Successful CPR is likely to be followed by a length and quality of life, which would not be in the best interests of the patient to sustain.

Discussed with the family	Spouse/patient/son/daughter/ Sibling/other	name	Date

Doctors signature	Date/Time
Print full name	

Consultant/Lead GP Signature

Reviewed	unchanged	Date	Cons/GP Signature
Reviewed	unchanged
Reviewed	unchanged
Reviewed	unchanged

* See overleaf for full guidelines
 ** Record underlying condition(s) e.g. Very poor LV function, end stage Obstructive Airway Disease, large intracerebral haemorrhage.
 *** A patient's informed and competently made refusal which relates to the circumstances which have arisen is legally binding upon doctors.

**To be fully discussed and agreed with the consultant/lead GP
 at the earliest opportunity**

GUIDELINES

Ambulance Crew Instructions

In the event of a Cardiopulmonary Arrest, please do not attempt CPR or defibrillation for this patient. All other types of supportive care should be given as appropriate as with any other patient where there is a deterioration in clinical condition. If whilst in transit the patient's condition suddenly deteriorates or death occurs, please:

- Contact (name and tel.no.) and take the patient to

This instruction is valid for transport on (dates)

Thank you for your cooperation in this matter.

Signed (Nurse or Dr): Name: Date:

For patients being discharged home only

- The appropriate GP/DN/Out of Hours (OoH) Service has been informed that a DNAR order is in place for this patient.

Yes No Reason

NB: It is essential that the GP and OoH Services are made aware of the existence of this DNAR order before the patient goes home. Send this form home with the patient or send immediately to the GP.

Decisions relating to cardiopulmonary resuscitation

A Joint Statement from the BMA, Resuscitation Council (UK) and the RCN February 2001

Where no explicit advance decision has been made about the appropriateness or otherwise of attempting resuscitation prior to a patient suffering cardiac or respiratory arrest, and the express wishes of the patient are unknown and cannot be ascertained, there should be a presumption that health professionals will make all reasonable efforts to attempt to revive the patient. Anyone attempting CPR in such circumstances should be supported by their senior medical and nursing colleagues.

An advance decision that CPR will not be attempted (a "DNAR" order) should be made only after the appropriate consultation and consideration of all relevant aspects of the patient's condition, which should include likely clinical outcome, the patient's known, or ascertainable wishes and the patient's human rights.

The overall responsibility for decisions about CPR and DNAR orders rests with the consultant or GP in charge of the patient's care. He or she should be prepared always to discuss the decision for an individual patient with other health professionals involved in the patient's care, including, in the consultant's case, the patient's GP. Unless the patient refuses, decisions should also be communicated to the patient's family and others close to the patient. The usual rules of confidentiality apply. Where possible, patients should be asked in advance whom they want, or do not want, to be involved in the decision making if they become incapacitated.

Where competent patients are at foreseeable risk of cardiopulmonary arrest, or have terminal illness, there should be sensitive exploration of their wishes regarding resuscitation. Ideally this should be carried out by the responsible doctor concerned. Such discussions, and any anticipatory decision, should be documented, signed and dated in the patient's records.

When the basis for a DNAR decision is the absence of any likely medical benefit, discussion with the patient, or others close to the patient should aim at securing an understanding and acceptance of the clinical decision that has been reached. If a DNAR decision is based on quality of life considerations, the views of the patient where these can be ascertained are particularly important. If the patient cannot express their own views then the doctors have authority to act in their patients' best interests. Unless to do so would be contrary to the patient's interests, people close to the patient should be involved in decision making in order to reflect the patient's views and preferences. It should be made clear that their role is not to take decisions on behalf of the patient. Relatives and others close to the patient should be assured that their views on what the patient would want will be taken into account in decision making but they cannot insist on treatment or non-treatment.

The DNAR decision should be reviewed by the consultant/lead GP at the earliest opportunity and should be reviewed 48 hourly for the first week and thereafter at least weekly in light of any changes in the patient's clinical condition.

Any DNAR decision should be communicated to all health professionals involved in the care of the patient including hospital staff, GPs, community nursing teams, deputising services and ambulance staff for patients in the community. All decisions regarding DNAR should be communicated when a patient is transferred or discharged.

Recording in the nursing notes should be made by the primary nurse or the most senior member of the nursing team whose responsibility it is to inform other members of the nursing team.

Discussions of the advisability or otherwise of CPR will be highly sensitive and complex and should be undertaken by senior and experienced members of the medical and nursing team. **A DNAR decision applies solely to CPR.** It should be made clear that all other treatment and care which are appropriate for the patient are not precluded and should not be influenced by a DNAR decision. To avoid any confusion, the expression "not for cardiopulmonary resuscitation" should be used and included in the patient's notes.