

Inquiry Witness Statement of

Linda BAGRADE

PERSONAL INFORMATION

1. My full name is Linda Bagrade. My contact details are known to the Inquiry.
2. I am a consultant medical microbiologist with NHS Greater Glasgow and Clyde ("NHSGGC"), and have held this position since 21st January 2008. On 1st of February 2008 I became the Infection Control Doctor ("ICD") for Royal Alexandra Hospital ("RAH"), Paisley, and the Vale of Leven Hospital ("VoLH"). I am based at the RAH site.

BACKGROUND

3. I am fully registered with General Medical Council ("GMC") and I am on the GMC Specialist Register for Medical Microbiology.
4. *Clostridium difficile* ("*C.difficile*") infection and specific issues including infection control ("IC") principles are part of the training programme in medical microbiology. All medical practitioners are required to participate in continuous postgraduate development programmes ("CPD") which includes attendance at various educational events including scientific conferences, meetings and workshops. I participate in the CPD scheme of the Royal College of Pathologists and regularly attend various national and international educational events in the field of medical microbiology and IC.

5. There are 5 consultant microbiologists based in the Clyde Sector which comprises the RAH, Inverclyde Royal Hospital ("IRH") and the VoLH. In my current role as a consultant medical microbiologist I work as part of a team of 3 consultant microbiologists based at the RAH and we provide clinical advice for the patients hospitalised at RAH and VoLH. My clinical duties include authorising laboratory test results, providing advice on appropriate antibiotic therapy and diagnostic tests for patients with infection.
6. During normal working hours I am ICD for RAH, VoLH and IRH. Out of hours infection control advice is provided by the consultant medical microbiologist on-call for the Clyde sector. All consultant medical microbiologists based in the Clyde sector participate in the on-call rota.
7. As an ICD I am a member of the NHS Greater Glasgow and Clyde ("NHSGGC") IC Service and provide clinical leadership to the local Infection Control Teams ("ICTs") within the Clyde sector and VoLH. I advise on specific IC issues on a patient-by-patient basis, review IC policies and investigate incidents or potential outbreaks.
8. Within the NHSGGC IC Service there are 5 sectors currently. Each sector is led by an ICD and a Lead ICN.

VoLH AT THE TIME (1st DECEMBER 07 – 1st JUNE 08)

Facilities

9. At my first visit as ICD at the VoLH in February 2008 I attended a walk-round of the VoLH with Helen O'Neill, ICN based at the VoLH. My impression of the building was that it was looking tired. For example, the surfaces of walls were damaged in places and the furniture looked old. The hospital did, however, look clean.

Bed-Spacing

10. I am aware of the bed-spacing guidance which applies to existing and new-build hospitals. In existing hospitals guidance indicates that this should be at least 2.7 metres. I am not aware of whether bed-spacing in the VoLH followed the guidance or not.

Transfers of patients to and from VoLH

11. I was never involved in the clinical decisions relating to the transfer of patients between hospitals. I am aware that generally patients were moved from RAH to VoLH and vice versa. The ICT would be involved in these decisions only if specific advice regarding IC is required.

12. During the winter of 2007 to 2008 both the RAH and the VoLH closed wards due to outbreaks of norovirus. This led to pressure on numbers of available beds in both hospitals. Patients were, as a result, moved between wards.

Cleaning

13. I am aware of the cleaning policies and standard operating procedures included in the Infection Control Manual ("ICM") (**Production - GGC00780001**).

14. As far as I am aware cleanliness of the wards at the VoLH was not raised as a specific issue at any IC meeting at that time.

Infection Control Manual

15. The ICM is available to staff online and as a paper copy on the wards. It is the responsibility of the ward manager to keep the ICM updated. All NHSGGC IC policies are in the ICM. The audit of compliance with infection control policies is done by ICNs and the reports will be held by ICT.

16. I am generally made aware if the results of environmental audits are unacceptable.

17. The environmental audit results carried out at the VoLH in 2007 did not give concerning scores.

18. Normally if audits highlight problems managers of the areas involved would prepare action plans to rectify the problems. The VoLH used different audit tools to the rest of NHSGGC. It was known that audit tools would be changing as soon as the Clyde sector was incorporated in the NHSGGC IC structure and the use of different audit tools was acknowledged and accepted.

Laundry

19. Hospital staff should be able to explain how to handle soiled laundry which is given to patient's family members to take home. I would expect family members to ask more questions if they are not sure if this is the correct procedure. If staff members are not sure about the advice they are giving they should contact ICT.

Location of patients

20. Criteria for patient isolation are detailed in the ICM. Isolation due to infectious disease is based on a risk assessment conducted by both clinical staff and ICTs. The record of risk assessment should be stored in the patient's notes.

21. There are single rooms for isolation available at the VoLH. The isolation room should have a toilet and wash hand basin for a patient with diarrhoea. Not all single rooms in the VoLH had this. A patient may be isolated in a single room in a different ward.

22. Cohorting of patients is the next stage if an isolation room is not available and is accepted practice.

23. Not all patients are suitable for isolation for various reasons.

Estates

24. During my walk-round in February 2008, I noticed that there was insufficient storage space throughout the VoLH.
25. There also appeared to be a lack of appropriate hand washing facilities. For example, on some wards hand wash basins were situated behind the nurses' stations. This meant it was not obvious to people on the wards where they should wash their hands.
26. I raised my concerns at the time with Jean Murray, Lead ICN for Clyde sector. She told me that this was a long standing problem. Jean Murray also told me that new wash hand basins had actually been bought for the wards, but due to budget restrictions had not been installed. I mentioned this during an informal conversation to Marie Martin, General Manager (Diagnostics), and this was highlighted at the local IC meetings and Acute IC Committee meeting.

Staffing

27. I was given a job description when I started my duties (**Production - GGC02180018**). When I took the role of consultant medical microbiologist I was told that I would be responsible for provision of microbiology services for the RAH and the VoLH. I was, however, told that IC services across NHSGGC were under review and that my role and responsibilities might be subject to change.
28. Prior to my appointment as ICD, Dr Elizabeth Biggs had been the ICD for RAH, VoLH and IRH. She was based at the IRH. Dr Barbara Weinhardt was Head of Department at RAH and VoLH microbiology lab and Marie Martin was the General Manager for Diagnostics in Clyde.
29. NHSGGC IC Services were restructured in May 2008. IC Services were split into 4 sectors and the co-ordinating ICD was Professor John Coia. Isabel Ferguson was General Manager for Lab Medicine and IC.

30. My clinical duties as medical microbiologist are scheduled according to the internal rota. For IC related issues I visit VoLH or IRH whenever I deem it necessary. I also meet local IC teams regularly.

31. I did not have managerial responsibility for the laboratories at VoLH or RAH. Dr Weinhardt was Head of Department for RAH and VoLH Microbiology Labs and Dr Biggs took over in the reorganisation in May 2008.

Staff morale

32. I was made aware when I began my duties that the VoLH had been in an uncertain position for a number of years. Staff seemed to be unsure of what was going to happen generally. On the whole I would say staff morale was affected by uncertainty.

Do Not Attempt Resuscitation (“DNAR”) policy

33. I am not involved in DNAR decisions.

C. DIFFICILE

Infection Control

34. The colour coded card system used for the local IC surveillance at the VoLH gave information on current cases at the hospital at that particular time and was useful to manage daily IC work, but it did not give information about the trends over a certain period of time.

35. I raised the issue with Marie Martin (General Manager for Diagnostics) and Annette Rankin (Head Nurse IC NHSGGC) several times between February and April 2008. I was assured that a new IC surveillance system was being introduced. The data collection process was in progress and the new unified system (Statistical Process Control

Charts ("SPCCs")) would be put in place and was about to be rolled out across the service.

36. I was told there was a delay in rolling out the SPCCs because healthcare acquired infection ("HAI") data collected in the Clyde sector were not compatible with the data collected in other sectors. In Clyde (previously part of NHS Argyll and Clyde) the definition for "HAI" was infection which occurs more than 72 hours after admission to hospital whereas definition used in NHS Greater Glasgow used a 48 hour timeframe. There was no electronic data collection system in RAH. The assessment of whether a particular case was a HAI or not, using the new HAI definition, had to be done manually, thus slowing down the process.

37. The use of colour coded cards was discontinued in late May 2008 when SPCCs were issued

Infection Control Team

38. All groups of staff involved in patient care have an opportunity to identify increased numbers of *C. difficile* infection ("CDI") cases, for example medical microbiology laboratory staff, ward medical and nursing staff, ward pharmacists. The ICT monitors the number of CDI cases using surveillance systems.

39. At the time of increased incidence of CDI cases at the VoLH, I was working with two IC management teams – the Acute IC Management Team managed by Isabel Ferguson and the Board IC Management Team managed by Tom Walsh. The role of ICD was not always clearly identified in the ICT structural flowcharts (**Production – GGC0060001**).

40. Lead ICN for Clyde sector, Jean Murray, was on phased retirement in February 2008 and retired in March 2008. Head ICN Annette Rankin, General Manager (Diagnostics) Marie Martin and I were due to conduct interviews for a replacement lead ICN but these were cancelled due to

problems with job descriptions and uncertainty over the viability of the Lead ICN position due to the integration of Clyde with the rest of NHSGGC.

41. Helen O'Neill was an ICN based at the VoLH. She was a member of Clyde ICT and was supported by other ICNs, usually from the RAH. Helen O'Neill attended Clyde ICT meetings and there was cross cover from the ICNs at the RAH in the case of annual leave and sickness. Clyde ICT members based at the VoLH were Helen O'Neill and Isobelle McIntyre who is ICT secretary.
42. For two weeks Clyde sector did not have a Lead ICN. At the beginning of April 2008 Joan Higgins was appointed as an interim Lead ICN for Clyde. As the result of changes in NHSGGC IC service, the VoLH became part of the North West IC sector in June 2008 and the Lead ICN was Laura Kean. I remained as ICD covering the VoLH. The RAH and IRH were covered by the Clyde sector ICT.
43. My job description (**Production -GGC02180001**) states that I act as a leader of the ICT but that I provide only clinical not managerial leadership.

Meetings

44. The IC Working Group was a forum for local ICT, clinicians, nurses and Estates and Facilities staff to discuss relevant IC issues.
45. The Clyde IC Support Group meetings would have representatives from all three (RAH, IRH, VoLH) Clyde IC Working groups.
46. IC concerns would be raised at either the IC Working Group or the Clyde IC Support Group meetings. Unsolved issues then reported to the Acute IC Committee which would report to the Board IC Committee.

47. Due to the ongoing review of IC services the structure of local meetings was not clear and some of the meetings were cancelled.

Education

48. The corporate induction module which includes IC is available online for all new staff members. It is the ward manager's responsibility to make staff available for training. There are also several other self-learning modules available for all groups of staff, for example Cleanliness Champions and Training Tracker. The induction programme for medical staff always includes IC.

49. IC education sessions on specific issues delivered by the ICT are available upon request.

50. Hand hygiene is included in the medical staff induction programme and there are educational modules available online. Additional hand hygiene sessions are available on request.

INCREASED INCIDENCE OF *C. difficile* AT THE VoLH FROM 1 DEC 07 TO 1 JUNE 08

Awareness

51. The first information about *C. difficile* 027 cases in the Clyde area was received in late April 2008 when the Scottish Salmonella, Shigella and *C. difficile* Reference Laboratory informed me about 2 cases in RAH. This information triggered an epidemiological investigation done by the Clyde ICT.

52. During May 2008 we were notified about further 5 cases of *C. difficile* 027 in RAH and VoLH. We extended the epidemiological investigation and at the same time we were looking at the environmental audits, hand hygiene practices and facilities, antimicrobial and proton pump

inhibitor prescribing and other risk factors for acquiring CDI. Issues regarding hand hygiene facilities were raised at the Acute IC Committee Meeting on 3rd June 2008 (**Production -GGC01870001**).

53. These findings were first reported at the Clyde IC Working Group meeting on 14th of May 2008 (**Production -GGC01280001**). At the meeting on 14th May 2008 regarding *C.difficile* cases in the Surgical Directorate we discussed these issues in detail and agreed on an action plan (**Production - GGC01310001**). Dr John Dixon, the Associate Medical Director, issued an e-mail reminding all staff about hand hygiene and the uniform code.
54. The next meeting on 21st May 2008 was called specifically to discuss the developing situation with *C.difficile* 027 cases and was chaired by Tom Walsh, the Board IC Manager (**Production -GGC01290001**).
55. The meeting on 28th May 2008 (**Production - GGC01300001**) chaired by Tom Walsh looked at actions taken so far and we agreed on an additional action plan. At that point of time we had evidence which linked a few identified *C.difficile* 027 patients to VoLH, and the ICT started a look-back exercise to identify CDI patients at the VoLH in the previous 6 months.
56. The Clyde ICT informed the IC Management team about the findings of the look-back exercise on 9th June 2008. The first Outbreak Control Team meeting was called by Dr Syed Ahmed on 10th June 2008.
57. As previous antibiotic therapy is one of the main risk factors for CDI, we needed to look at antimicrobial prescribing policy. The meeting to discuss these issues was called mid-June 2008. ICDs, Dr Andrew Seaton (infectious diseases consultant), Ysobel Gourlay (lead antimicrobial pharmacist) and Dr Brian Jones (consultant microbiologist) attended this meeting.

58. Prior to June 2008 there was no agreed protocol for assessment of CDI severity in NHSGGC. A protocol for CDI severity assessment and therapy was issued in June 2008.

Samples

59. In general, faecal samples submitted for *C.difficile* testing are kept by the microbiological laboratory for a fixed length of time. For example, faecal samples are kept for 3 months if they test positive for *C.difficile*, which allows the performance of additional tests later if required.

60. At the meeting on 28th May 2008 it was decided that all *C.difficile* isolates from VoLH patients and RAH affected wards would be sent for ribotyping to the *C.difficile* Reference Laboratory. Prior to that, only samples which met the agreed criteria were ribotyped, for example if the patient had severe CDI, if it was an outbreak situation or if death occurred within 30 days of the patient being identified as *C.difficile* positive.

CLINICAL RESPONSE

Surveillance of increased incidence of CDI cases

61. Initially we treated the situation as an increased CDI incidence with associated mortality and reported this to Professor Coia (coordinating ICD), Annette Rankin (Head Nurse IC) and Isabel Ferguson (General Manager for Lab Medicine and IC).

62. The generic definition of an "outbreak" is if there are 3 or more patients with infectious disease and they can be linked in time and/or place. Several factors have to be taken into account to apply this definition to a specific infection, for example the route of transmission and incubation period.

63. Health Protection Scotland were informed about all 7 CDI patients included in the initial cluster and were informed about the situation updates and agreed actions after every local meeting regarding the CDI cases.

Hand Hygiene

64. Hand hygiene audits, as a part of agreed action plan, were conducted by Stephan Morton, NHSGGC Hand Hygiene Coordinator. These were in addition to the routine hand hygiene audits at the VoLH.

Treatment of patients with *C.difficile*

65. There was an NHSGGC Drug Formulary available at the VoLH. There was a section within that on antimicrobial therapy.

66. To prescribe restricted or alert antibiotics outside established indications doctors would need to discuss this with the microbiologist.

67. The choice of antibiotics is based on the clinical judgement of the medical staff. The microbiologist would be contacted if the case is complicated or the first line therapy can not be given.

68. I am not aware of any audit of the antibiotic prescribing at the time of the increased incidence of CDI at the VoLH. It was audited later at the request of the OCT.

69. I have no objection to my witness statement being published as part of the evidence to the Inquiry. I believe that the facts stated in this witness statement are true.

Signed..

Dated.....10/02/2011.....