Supplementary Inquiry Witness Statement of Dr Musa AL-SHAMMA

PERSONAL INFORMATION

1. My full name is Musa Al-Shamma. My contact details are known to the Inquiry. I have previously given a statement to the Inquiry.

Antibiotic Prescribing

2. I have been asked what I used as a reference guide in relation to prescribing antibiotics between January 2007 and June 2008. At that particular time I would refer to the Guide of First Line Antimicrobial Prescribing January 1997 **(Production – INQ01300001),** the Guide of First Line Antimicrobial Prescribing January 2000 **(Production – INQ01310001)** and the Argyll and Clyde Adult Drug Formulary 2006
3. **(Production – GGC21790001).** Although I would have kept these three documents as references, the one I would have used as a first point of reference was the Adult Drug Formulary 2006.

4. I have been asked if, during the same period, a junior doctor could have prescribed an antibiotic without reference to a consultant. There would not have been an issue with a junior doctor prescribing antibiotics. In normal circumstances the consultants are off duty after 5 or 6 o'clock, so the junior doctors are covering the wards overnight. They can, and will, call a consultant if need be. I have taken a lot of calls after midnight where a junior doctor has been seeking advice. In any case the consultants will be back the following morning and can discuss any issue such as prescribing.

5. I would have expected a junior doctor to let me know if there had been a change in prescribing an antibiotic to a patient or if a new antibiotic had been prescribed. The important point is that the junior doctors can prescribe, depending on the circumstances of individual cases. If it was a simple case then they could go ahead and do it, but if there was any issue or complication then I would expect to be consulted.

6. The junior doctors would have been issued with the 2006 Adult Drug Formulary (**Production – GGC21790001**) on the first day of their induction at the hospital. Even if they were only attached to the Vale of Leven Hospital ("VOLH") for 3 or 4 months they would still have induction training and have been issued with the 2006 Adult Drug Formulary as well as other relevant documents during their induction training.

7. As far as I am aware there was uniformity of approach in relation to the use of the 2006 Adult Drug Formulary although I can only speak to what happened in wards 3 and 6.

8. I am not aware that there was any local policy at VOLH in relation to prescribing antibiotics.

9. I believe that the 2006 Adult Drug Formulary was kept on the wards but I had my own copy. I think it was pharmacy which supplied them and certainly did after the incidences of Clostridium *difficile* ("C.*diff*") at the VOLH.

10. During their induction the junior doctors would have had inputs from a range of people from the staff at the VOLH. This would have included consultants, pharmacists, and biochemists. On occasion I have been involved in the induction training.

11. I have been asked what I would have been using as a reference document after June 2008 for prescribing antibiotics. I have been shown the GGC Formulary 2007 **(Production - GGC18270001)** but do not recognise this document as something that I used. What we did use, and is displayed in the wards, is the Infection Management Guidelines: Empirical Antibiotic Therapy **(Production - GGC11510001).** This would have been the reference document that I would have used for prescribing antibiotics.

12. There has been a change in prescribing policy since June 2008. There are more restrictions on junior doctors and consultants in what they can do. For example, unless a positive culture result comes back, and the result suggests that there is a resistance to the antibiotic prescribed and a change of antibiotic is needed, there has to be a consultation with a microbiologist. If the figures are correct then there has been a reduction in the prevalence of C *diff* since these changes were introduced.

13. I have been asked whether patients would be isolated straight away if they had diarrhoea. As far as I am aware patients would always be isolated with such symptoms. There would be no requirement to wait for a positive lab test result. A patient would not be admitted to a general ward with such symptoms. The patient would normally stay in isolation until they had been free of symptoms for at least 48 hours.

Infection Control Manual ("ICM")

14. I have been asked what was available on the wards as guidance for infection control ("IC") between January 2007 and June 2008. As far as I am aware it was the ICM which was available on all the wards. I am sure that it was used by the staff and was the main reference document for IC. I would say that I was aware of staff following the guidance. For example, they would always use the appropriate Personal Protective Equipment ("PPE").

Surveillance of Incidences

15. I have been asked how I assessed the severity of C *diff* in a patient. I would look at a number of indicators. These would include the level of dehydration, blood results, chemical levels (such as urea, white blood cells ("WBC"), creatinine), episodes of diarrhoea, consistency of diarrhoea (which would usually be watery), co-morbidities (for example cancer) and colonic dilatation. I would also take into consideration what antibiotics were being used at the time.

16. The response in terms of treatment would always depend on the level of severity rather than there being a routine response. It really depended on the individual circumstances of each case. For example, the results of blood testing are very important in deciding what should be done. In milder cases it may be that the patient may not require IV fluids and we would just monitor the patient and keep an eye on blood pressure. This would certainly not be the case in more severe cases. Milder cases may pass in a very short time with not much more than a number of episodes of diarrhoea.

17. In any case we would normally start all such patients on metronidazole but the severity of the problem would always be assessed. The treatment response may have to be changed during the period of care. We would observe the patient and monitor IV fluids. If there was more than one relapse we would then consider vancomycin. In severe cases there would be close observation of the patient, replacement of IV fluids and daily blood tests.

18. After the initial diagnosis we would reassess the patient but, again, it would depend on individual cases as to how often this would be carried out. We would use markers to monitor progress such as C reactive protein ("CRP"), WBC, blood urea, abdominal distension, colonic dilatation and frequency of stools passed. The bloods are known as inflammatory markers. The other markers (such checking abdominal dissention) are known as physical markers. The junior doctors would

be checking these markers every day and the consultant would be seeing the patient at least 2 times per week. I would say that we were reassessing 2 times a week unless there were other concerns or issues.

19. I have been asked if I used flow charts for monitoring the progress of a patient suffering from C. *diff.* I do not remember ever using them for any case. I would have referred to the nursing notes for any information that I would have required and the nurses keep stool flow charts.

20. I am not aware of what has been described to me as a C. *diff* protocol. This is not something that I recognise, but I have mentioned elsewhere in this statement that there were changes in the management of prescribing after the incidences of C. *diff* at the VOLH and now we have a C.*diff* management protocol.

21. I have been asked what facilities were available to me to examine the colons of patients with C *diff* between January 2007 and June 2008. If I felt that it was necessary to have a colonoscopy or sigmoidoscopy then I never had a problem calling on the services of a gastroenterologist to carry out the procedure. Again, it would depend on the individual circumstances of the case. If a patient had had diarrhoea for 2 or 3 weeks then I would want the colon examined in order to rule out other conditions such as cancer. Dr Carmichael was the gastroenterologist at the VOLH at the time.

22. At the time I would routinely use the CURB-65 score system and as far as I am aware the other doctors at the VOLH used this system as well.

23. I have been asked whether I used doxycycline between January 2007 and June 2008 when treating patients with chest infections. I did use this antibiotic. It is a better choice of antibiotic when a patient has had a recent C *diff* infection.

24. I have been asked how I would have defined a patient with severe C *diff.* There would be a number of indictors such as low blood pressure, a rapid heart beat, a temperature, high blood urea, high WBC and CRP. I would also, of course, take into account the frequency of bowel moments, abdominal distension and colonic dilatation.

25. Between January 2007 and June 2008 if a patient had been on metronidazole there maybe occasions when a change of antibiotic had to be considered. This would depend on individual circumstances. If a patient had been on metronidazole for 5 days and there was no response or improvement in the patient's condition, I would consult a microbiologist. I would be considering changing from metronidazole to vancomycin, but would always consult the microbiologist before doing so.

26. In normal circumstances we would start on vancomycin if there was a 2nd relapse. If the patient had relapsed for the 3rd or 4th time then a combination of vancomycin and metronidazole might be considered. Again, this would be after consultation with the microbiologist.

27. Vancomycin and metronidazole were used in severe cases of C *diff* and this would have been routine practice.

28. I would have said that, in general, a patient could be removed from isolation if they were free from diarrhoea for a period of 48 hours. I would have considered the patient to be uninfected.

29. In the period between January 2007 and June 2008 I would have said that if 2 patients in the ward were confirmed as C *diff* positive this would have satisfied the criteria for an outbreak. This would not include patients coming into the ward with diarrhoea, which can be the case for many reasons.

30. I would have diagnosed pseudomembranous colitis by assessing the clinical picture. If cultures came back from the laboratory confirming C.*diff* toxins then I would have the patient isolated and started on antibiotic treatment.

31. I never used probiotics. In my opinion they did not make any difference to an established infection. I am not aware that my colleagues used them. I am not aware that there was guidance on the use of probiotics.

32. In the period between January 2007 and June 2008 I did not use immunoglobulin therapy in the management of patients with C *diff*.

33. I did expect nursing staff to keep an accurate record in their notes of the number of stools passed and amount. This is in order to assess how much fluid the patient might be losing. It is important to monitor fluid loss and, generally, the patient's response to the treatment given.

34. In the period between January 2007 and June 2008 I would have involved a microbiologist wherever necessary in deciding the treatment required for a patient. In relation to C.*diff* this would have tended to be in the more serious cases. It would not be necessary to involve the microbiologists in every case. Some infections are mild and can be dealt with in a short period of time. The microbiologists are not involved in the routine care of the patient but are used through consultation.

35. If I wished to consult a microbiologist I simply got in contact with whoever was on-call. Although it is easier now, it was not particularly difficult then. I was never aware of a problem in relation to getting samples analysed. Samples would normally be turned around by the lab the same day. The analysis itself only takes about 30 minutes so it was not unusual to have the response back in a few hours.

36. In the period between January 2007 and June 2008 the microbiologists did not come to the ward to discuss the patients. In any case they really did not have to. I wanted to consult the microbiologist rather than have the microbiologist present on the ward with me. There are places where there are clinical microbiologists, but we did not have them at VOLH. This was not a problem for me.

37. In relation to the involvement of pharmacists the service has improved over time. In relation *C.diff*, I would have said that there was not a problem at the time. Pharmacists had a marginal role and are not clinicians. The involvement of the microbiologist is more important than the pharmacist. The pharmacist will, of course, advise on drug interaction and possible side-effects. There might be a patient taking 20 different drugs. If we added another drug to the list the pharmacist might draw our attention to possible interactions.

38. In the period between January 2007 and June 2008 I was aware that there was a link between certain antibiotics prescribing and *C.diff*. I was aware that particular antibiotics were more likely to lead to *C.diff*. As far as I am aware the other doctors at the VOLH would have been aware of this as well.

39. I would avoid the use of certain antibiotics because they could predispose patients to *C.diff*. As far as I am aware this would have been the case for my colleagues at the VOLH. We would not have ignored this fact but it always depends on the clinical circumstances. For example, if there was a threat to the life of the patient then this could alter the prescribing options for the doctor.

40. In relation to the use of lactulose and senna, I would not have prescribed them for the conditions discussed in this statement. I would not have expected the other doctors to do this either. These are laxatives and for obvious reasons their use would not have been appropriate.

41. In the period between January 2007 and June 2008 if a patient was diagnosed with C.*diff* I would review the patient's treatment and any antibiotics they were talking. Wherever possible there would be a change to a narrow-spectrum antibiotic or possibly stopping the antibiotics altogether. We would stop the antibiotic where necessary, unless the individual's circumstances were such that we would have to find an alternative. These types of issues would be at the forefront of our thinking. I am not aware that my colleagues would have done it any differently.

42. I was not aware that proton pump inhibitors could have been a factor in C.*diff*. I am not aware of this from the text books I have used.

43. In the period between January 2007 and June 2008 I was not aware that there was a local policy for prescribing. I used the 2006 Adult Drug Formulary and this would have been the same for treating urinary tract infections ("UTIs"). I now refer to the Infection Management Guidelines: Empirical Antibiotic Therapy **(Production - GGC11510001)** for guidance on any problem.

44. I would agree with the proposition that the first line therapy for UTIs should be trimethorpim, as this has a low risk and augmentin carries a high risk, especially if administered for longer periods such as 7 days. I would describe trimethorpim as a first line treatment for simple UTIs.

45. I have been asked if, during the period between January 2007 and June 2008, tazobactum was routinely used before 2008. It was not used as it is a very broad-spectrum antibiotic and would only be used in a life threatening situation. In fact, I think the question is actually about tazocin rather than tazobactum.

46. I have been asked if there was awareness, during the period between January 2007 and June 2008 fluid management was important in the management of patients with C.*diff.* Of course we were aware of this, and I have explained the significance of fluid levels elsewhere in this statement. I would have expected the nurses to keep accurate fluid balance charts. Although there was not a protocol on this topic, I would have used my clinical experience to manage whatever was required in relation to this.

47. Where a patient required to be tube or line-fed we would, of course, seek the advice of a dietician who was on-site. I cannot remember ever having a problem with this issue.

48. I have been asked about the policy about 'not for active treatment'. I think it is not much different from "Do Not Attempt Resuscitation" ("DNAR") where most treatments are withdrawn.

Do Not Attempt Resuscitation ("DNAR") Policy

49. I have been asked about the DNAR policy in the period between January 2007 and June 2008. I cannot say what the written policy was. I have been shown the VOLH Resuscitation Policy **(Production - GGC 04470001)** but do not recognise this document. However, there was guidance on the forms themselves. In addition, I use my clinical experience in this matter.

50. That is why the DNAR forms should be signed by a consultant. They could be signed by a junior doctor in certain circumstances but would always be countersigned by a consultant. A junior doctor could take the decision to sign a DNAR form but this would only be where it was an obvious case and the consultant would still be involved at some stage. I have no idea why there would have been two different forms in use at the time.

51. I would always expect to be involved in a dialogue with a family, or the patient themselves if that was possible, before making the decision to sign a DNAR form.

52. I believe that there should be a clinical note referring to the fact that a DNAR decision had been made. I think this should be regarded as good practice. The forms are only valid for 14 days anyway.

Transfer of Patients to the Royal Alexandra Hospital

53. I have been asked about the decision to transfer patients to the Royal Alexandra Hospital ("RAH") in the period between January 2007 and June 2008. Transfers would take place on a regular basis wherever a patient required facilities that were not available at the VOLH.

54. Where a patient was being considered for transfer a clinician, who would normally be a junior doctor, would carry out an assessment (called a Pre-MT) where all aspects of the patient's condition would be assessed. A patient might be suffering from severe asthma so this would be a consideration. When the assessment was completed the consultant would be involved before the final decision was made to transfer the patient. There was a policy for completing Pre-MT scores for all patients who were ill enough to consider transferring them.

55. As regards patients coming back to the VOLH from the RAH, this was more straightforward. Quite simply patients came back to the VOLH when they were improving.

Death certification

56. In relation to junior doctors signing death certificates before 2008, it was quite in order for a junior doctor to sign where there was an obvious cause of death, such as advanced cancer where the patient had recently been admitted.

For distribution to CP's

57. My own practice was that where a patient had died while they had an active infection like C.*diff*, or were still showing symptoms or were recently recovering I would include C.*diff* as a contributory factor on the death certificate.

58. I believe that the main changes that have come about since the incidences of C.*diff* at the VOLH are that there is a clear-cut antibiotic prescribing policy, increased space between beds and in wards generally, more awareness of IC issues across all levels of staff including doctors and nurses, improved patient care, and a drop in the number of cases of C.*diff.*

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

Signed..

Dated...23/12/2010