Scottish Hospitals Inquiry

Supplementary Witness Statement of

Dr Anna Maria Ewins

Witness Details

1. My name is Anna Maria Ewins. I am an Associate Specialist in Paediatric Oncology at the Royal Hospital for Children (RHC) in Glasgow. I provided a statement to the Scottish Hospitals Inquiry on 31 March 2023. I have been asked to provide a supplementary statement to expand upon and clarify certain matters within that statement.

Vulnerability of patients to infection

2. I have been asked to expand upon my evidence relating to the vulnerability of patients to infection. I am a bone marrow transplant specialist. I treat patients with leukaemia and non-malignant blood conditions. Both categories of patient have the potential to be very susceptible to infection.

3. The first phase of treatment for patients with leukaemia is usually chemotherapy. The objective of this phase of treatment is to place the patient into remission, meaning that the disease is cleared from their system. If remission is not achieved, we might think about further chemotherapy combined with other targeted agents. If that fails, a bone marrow transplant may be considered.

4. Not all patients treated in Ward 2A will require a transplant. For those with Leukaemia (ALL or AML) there are two main routes which might lead to consideration of a transplant. Genetic analysis and molecular techniques can help predict the risk of relapse and indicate resistance to chemotherapy. We can, in turn, predict the likelihood that a patient will need a transplant in the future. In these circumstances, consideration might be given to performing an

early transplant in order to reduce the need for multiple rounds of chemotherapy and other treatments, all of which have associated damage and risk.

5. The other route to transplant is when is a patient has had treatment but subsequently relapses. If a relapse occurs soon after treatment, there is a high chance that a patient will require a transplant. Some later relapses will also lead to transplant if the patient does not respond well to chemotherapy.

6. Patients with cancer will experience different levels of vulnerability to infection over the course of their disease and treatment. As clinicians, we need to think about the levels of vulnerability associated with each stage of treatment. At the most vulnerable end of the scale are transplant patients with refractory disease. Refractory disease means that the disease is resistant to treatment. It is difficult to achieve and maintain remission.

7. Patients must be in remission in order to receive a transplant. For patients with refractory disease, this means that they may have endured multiple rounds of immune-suppressing treatment to get them to the stage of remission. They can be extremely immuno-suppressed at the time of their transplants. With these patients, we cannot be sure how long the remission will hold and so we have to move as quickly as possible to transplant.

8. Immuno-suppression means that a patient has a very low white cell count. Depending on the level of immuno-suppression, a patient can have a very weak immune system or an immune system that does not function at all. Levels of immuno-suppression vary over the course of treatment. Treatment is phased with the result that immune systems can go through multiple phases of being suppressed, recovering, and suppressed again. Neutropenia, for example, is a stage of immuno-suppression. Neutrophils can be thought of as the foot soldiers of the immune system: they are the first to appear at the site of the infection and do battle with the invading organism. This is extremely important for fighting bacterial infection. Patients who are post-transplant will move from being profoundly immuno-suppressed during the early neutropenic phase, to having some neutrophils but low numbers of other white bloods cells called lymphocytes. Lymphocytes provide good protection from viruses and fungal

infection. After transplant we suppress lymphocytes to protect against rejection and graft versus host disease.

9. Patients who face a transplant following relapse are in a very vulnerable position. They have often already been through years of treatment. Their immune systems will have reduced and recovered multiple times over that period. They may be on prophylactic medication. They will have a history of infections. Their organs may be damaged by previous treatments. In preparation for transplant, a patient's immune systems will be reduced dramatically. They are screened for bacterial and viral infection. A patient will only be taken to transplant once we are satisfied that there is no evidence of infection.

10. Patients with non-malignant blood disorders can be just as vulnerable. For example, patients with severe combined immunodeficiency (SCID) are considered to have lymphocyte- based immune system.

11. All patients who are being prepared for transplant are exquisitely vulnerable to infection. This vulnerability continues post-transplant. The first month post-transplant is a particularly dangerous time due to the suppression of the immune system. Patients are vulnerable in particular to bacterial and fungal infections. After the first month, viral infections are a particular problem.

Protective Environment

12. The risk of infection to these very vulnerable patients can be mitigated by housing them in a protective environment. It is necessary for clinicians to anticipate when those periods of immuno-suppression are likely to occur. This allows decisions to be made about the best environment for the patient. At less vulnerable stages of treatment, patients might be housed in standard cubicles or even permitted to return home for periods of time. However, in more vulnerable stages a protective environment is required.

13. When the Schiehallion Unit was housed at Yorkhill, the whole unit was positively pressured. The ward had an airlock door system to minimise the transfer of air from the rest of the hospital to the ward. It also had a handful of dedicated BMT rooms with specialist ventilation. We were assured that Ward 2A would be like for like. On moving in, we discovered that Ward 2A was not like for like.

14. In 2015, Ward 2A had eight dedicated BMT rooms which was more than we had available at Yorkhill. That should have been a step up from Yorkhill. The flip side was that in Ward 2A, the rest of the unit was not positively pressured or filtered. The corridor was not positively pressured to the rest of the hospital and there was no airlock door system to seal the unit.

15. I had concerns about the results from air sampling in the corridor not long after we moved to the new hospital. I raised these concerns with Professor Craig Williams. He explained that because the corridor was not pressured and the unit not sealed, it was to be expected that there would be some background noise in the air sampling taken from the corridor. It meant there was more ambient air exposure in the ward areas.

16. I was reassured by the fact that although the base line specification of the ward was not as good as Yorkhill, there were what I believed to be eight high specification BMT rooms which in themselves appeared to be a step up from Yorkhill. I understood the rooms to be PPVL rooms. They were to have positive pressure and HEPA filtration. Shortly prior to the move, it was discovered that the HEPA filters were missing. They were installed before patients moved over.

17. Prior to the move to the new hospital, we planned the timing of transplants so that there would be no transplants within the first month or so. We anticipated that there would be the usual snagging issues that you would find in any new build and worked on the basis that they would be resolved shortly after moving in. We wanted a few weeks to make sure the HEPA filtration worked and to be satisfied that the rooms were suitable for transplant.

18. We soon discovered that there were issues with the air quality in the BMT rooms themselves. The rooms were being tested for suitability for transplant. I had a patient scheduled for transplant who was extremely vulnerable and who needed a transplant on an urgent basis. [redacted]. Clinically, there was enormous pressure to proceed with the transplant.

19. I was not satisfied that the transplant could proceed safely in the Ward 2A environment. I was concerned that the BMT rooms were not suitable for transplant. Air sampling in the rooms showed raised counts. Smoke tests showed that the rooms were not properly sealed. The view from microbiology was that the rooms had to be sealed in order to improve the air quality. Remedial work was carried out to seal the rooms. We reached a stage where we were satisfied that two of the eight rooms had tolerable counts and that the transplant could go ahead, which it did.

20. I was placed in a position where, as a clinician, I had to weigh up the risks of missing a short window of opportunity to carry out a transplant on a very sick child against carrying out that transplant in a potentially unsafe environment. Fortunately, we got to a stage where I and my colleagues were satisfied that the environment was safe enough but that is not the sort of risk balancing exercise that we, as clinicians, should have to perform. We should be able to assume that the environment provided to us is as safe as it can be. We should have been in a position to make a decision about that transplant without having to factor in concerns about the environment.

Ventilation Requirements

21. I have been shown a document titled "SBAR: 2A Patient Accommodation and Risk of Invasive Fungal Disease" dated 30 October 2017 [Ref: Bundle 4; page 113]. I understand that the SBAR was prepared by two microbiologists carrying out a lookback review of issues involving the ventilation system in Ward 2A. Under the heading "Patients at risk of Invasive Fungal Disease", the authors list four categories of patients who are profoundly immune-compromised and at

risk from fungal spores and a further three categories who are high risk but to a lesser degree. I agree broadly with these categories. However, there are stages during the treatment of these patients where they will be at less risk. Degree of vulnerability depends on the stage of treatment. For example, some ALL, neutropenic and solid organ transplant patients will attend local hospitals for aspects of their treatment. These local hospitals do not have HEPA filtration or positive pressure. Patients who are at home but who spike fevers due to neutropenia will attend their local hospitals. They do well there and do not require the highly specified protective environment. I would also note that there are some patients who have prolonged neutropenia for greater than 14 days following chemotherapy who are at home for spells during these episodes and do not necessarily require a specialised environment. However, the highly specified environment is required for transplant and SCIDS patients.

22. I have been directed to the section following the heading “Building requirements for Neutropenic/BMT patients”. The requirements listed accord with my understanding of what [was required for Neutropenic/BMT patients]: 10ACH, positive pressure at 10pa to the corridor, all air entering the room should be HEPA filtered and there should be continuous monitoring with alarms for failure.

23. The description of the ward under the heading ”Current Provision” also accords with my understanding of the ventilation arrangements in Ward 2A at that time.

24. The fact that the ward itself was not HEPA filtered and positive pressured meant that we had to think carefully about the use of the eight BMT rooms which benefitted from specialist ventilation. We had to think about the stage that each of our patients was at in their treatment and think about which patients should have priority for those rooms. This was less of a concern at Yorkhill because the whole ward benefitted from some degree of protective environment. It was sealed via airlock doors and was positively pressured to the rest of the hospital.

25. I have been shown an IMT minute dated 7 March 2013 [Ref: bundle 1; page 35]. At section 4.2 there is a sentence which reads: “*Although there are 8 BMT rooms available in ward 2A with a higher specification of ventilation, these are*

fully occupied by BMT patients which does not allow ALL patients to be nursed in these rooms". Although we did not require access to specialised ventilation for all of our ALL patients, there are some who would have benefitted from a positive pressured and HEPA filtered environment depending on the stage of their treatment.

26. When we moved to Ward 2A in 2015, I do not think we were prepared for the difference between it and the ward at Yorkhill. We had been told often that we were getting a like for like ward. This was not accurate. Not only was it not like for like in terms of provision but there were fundamental problems with the BMT rooms. I am used to having to make decisions about when is the best time to go for transplant but not having to balance that against the risk posed by the hospital environment. It was extremely stressful to have to balance the risks and make a judgment. I expected that as clinicians we would be provided with a safe environment in which to treat our patients.

Clarifications to statement

27. At paragraph 172 of my statement, I make reference to a patient who experienced infections after bathing. I would like to clarify that that paragraph is not intended to convey a concern that the water the child was bathed in caused infections. My concern at the time was that the infections were probably endogenous, by that I mean that the bath water may have contained this child's own gut flora, which in turn could gain access to the blood stream through immersion of the central line. When we stopped using the bath, we continued to wash the patient in hospital water.

28. At paragraph 174 of my statement, I refer to a request by the Schiehallion consultants for an external investigation into the possible links between a cluster of infections and the water supply. I say in my statement that it proved impossible to achieve. We wanted someone independent to tell us if there was a link between infections and the water supply. As a group, we thought there was a problem but were being advised that there was no problem. Against that, we were seeing infection control measures and escalation measures. If felt like

a problem to us but no one was identifying if it was a real problem or not. I think that management did want to provide us with someone but my understanding from senior management was that they were unable to persuade anyone to help.

29. A further difficulty was the lack of information about the experience of units in other hospitals. We did not have information about gram negative or air borne infections in other units. We did not know if we were genuinely experiencing something unusual or if other units had the same experience and were not publicising concerns. We were unable to establish if what we were observing represented an outbreak or not.

30. At paragraph 276 of my statement, I say that the incidence of infection was lower after the move to Ward 6A. For clarification, the incidence of infection was lower on ward 6A only to begin with. An issue with infections presented itself again during 2019.

31. At paragraph 203, I explain that we had continued uncertainty about the safety of the environment. We were uncertain about what was causing the unusual pattern of infections. We have had no answer to that question, even now. I do not know what the outcome of the various investigations was. We have not been told that there was a problem, what the cause was or reassured that the situation is resolved. Equally, no one has said we do not think there was a problem at all. I am not aware of any communication from the Health Board to confirm the position one way or the other. We received a statement from the Health Board explaining how good the environment is in the new Ward 2A. But I still do not know if we had contaminated water, if we had a problem with the drains or if chilled beams were an issue. We have not been told if any of these things contributed to infections or if our patients were placed at increased risk by being in that building.

32. I know that some work was done with whole genome sequencing and understand that it did not appear to show a link between environmental bugs and patient infections. I recall that we received presentations about that. At

some point we were told that there was no issue and that the change in infection pattern was a result of a change in the taxonomy of infections. I am not convinced that is correct.

33. It is possible that there are other communications out there but as far as I am aware, we, as clinicians, have been given no clear explanations for what happened.

34. At paragraph 242 of my statement, I say that we have to proceed on the basis that everything is fixed because a lot of time and money has been spent improving the facilities. We have been told that the ventilation in the new Ward 2A is superb. I have no reason to doubt that based on my experience in the ward so far. I suspect the ward is now better than any other unit in the UK. I have seen no evidence of unusual patterns of infection since we moved back to Ward 2A. We do still see fungal and bacterial infections but that is not unexpected for this patient cohort. There is no escaping the fact that infections can be the biggest killer of children who are prescribed cytotoxic drugs. We are very sensitive to the risk of infections. They are closely monitored and discussed regularly. I have seen nothing concerning since we moved back.

35. In closing, I think there is value in trying to find out what happened. The situation in 2015 was incredibly stressful. We were put in a position we should not have been in. A useful outcome would be a recommendation that when a change to a healthcare environment is planned, those in charge should sit down with the people involved in treating patients in that area to explore all of the potential problems. There should be checks before patients move in to make sure that what you expect to be in place is in place. Problems with the building should not be discovered as you go along, while patients are present.

36. I believe that the facts stated in this witness statement are true. This statement may form part of the evidence before the Inquiry and be published on the Inquiry's website.