Scottish Hospitals Inquiry
Witness Statement
Janice MacKenzie

Witness details

1. My name is Janice Margaret MacKenzie.

2. I am now retired from my role as Project Clinical Director with Lothian Health Board (NHS Lothian or NHSL). I previously provided a written statement to the Scottish Hospitals Inquiry (the Inquiry) for the purposes of the May 2022 Hearing and the April 2023 relating to the Royal Hospital for Children and Young People (RHCYP) and Department of Clinical Neurosciences (DCN) in Edinburgh. The first statement outlines my roles with NHS Lothian, qualifications, and work history.

3. The Inquiry has asked me to provide a third written statement in advance of the Hearings to take place in February 2024, the focus of which is on the delay in the RHCYP and DCN opening as planned in July 2019. I was the Project Clinical Director at that time, and was part of the Project Team lead by Brian Currie, who was the Project Director. I then retired in October 2019, though for three months prior I was on a phased retirement gradually reducing my hours every month from full-time (5 days a week) to 2 days a week.

4. This statement has been provided in response to specific written questions provided by the Scottish Hospitals Inquiry on 22 November 2023.

Clinical Management Team

5. Part of my role as the Project Clinical Director was to engage with the Children's Clinical Management Team (CMT). Some of the core members of the CMT changed during the Project. CMT core members were:

- Fiona Mitchell (Director of Operations / General Manager for Children's services)
- Edward Doyle (Associate Medical Director Women & Children)
- Linda Cowie & Peter Campbell (Associate Director of Nursing Children Services)
- Allister Short & Mike Massaro-Mallinson (Service Manager)

6. The core members of the CMT normally met weekly and a wider CMT group including additional members met monthly. The wider group included the core members along with:

- Peter Campbell (Depute Associate Director of Nursing Children Services)
- Sharon Russell (Clinical Nurse Manager for surgery)
- Laura Reilly (Clinical Nurse Manager for Critical Care)
- Gillian McFadyen (Clinical Lead for Critical Care)
- Other clinical nurse managers within acute and community children's services
- Other clinical leads within acute and community children's services.

7. The role and function of the CMT was the day to day operational, strategic and management of the delivery of Children's Services in the community, St John's Hospital and at the Royal Hospital for Sick Children (RHSC) at Sciennes at the time. The CMT were actively involved in decisions about the planning and delivery of services to be provided in the new hospital by the Project. There was a standing item on their monthly agenda and often either I, or the Clinical Commissioning Manager, Dorothy Hanley, would provide a Project update at these meetings either in person or a written update.

8. If there were specific clinical, departmental, or operational issues arising on the Project, I, and other members of the Project Team would seek input on an ad hoc basis from either the core CMT, the broader CMT, or individual service leads. This was often done informally by way of telephone conversation or face to face discussion.

9. The CMT were asked to provide input on the risks and compromises related to ventilation pressures for multi-bedded bays because it was for the CMT to decide how it wanted to manage the delivery of services to the patients in the new hospital. The decision around the ability to cohort patients in multi-bedded rooms (which required balanced or negative pressure as opposed to positive pressure based on the advice of the Infection Prevention Control (IPC) and our technical advisors, Mott MacDonald (MM) was a hospital wide strategy that was determined by the CMT and it was not solely about critical care. It was for the CMT, including senior clinical leads for each department which had multi-bedded rooms, to advise me and the clinical commissioning managers how they wished to deliver their service, and we then fed that back to the Project Team, in particular to MM, who liaised with IHSL on our behalf in relation to all technical issues.

10. The critical care leads were consulted on the pressure regime in multi-bedded rooms. I specifically recall discussions with the critical care leads in relation to the cohorting of patients and it was considered desirable to be able to cohort patients in the critical care unit where possible (see below for more details). The Risk Assessment for multi-bedded rooms (discussed below) could not have been prepared without consultation with key members of the CMT and the particular clinical leads for each area being involved, which included critical care leads, so its existence is evidence of consultation with the relevant clinicians and IPC.

The Multi-bedded Risk Assessment

11. I am the author of the Record of General Risk Assessment dated 5 July 2017 and reviewed in January 2018 (The Multi-bedded Risk Assessment) **(A40981178 – Record of General Risk Assessment_ combinedrev300118 – Bundle 6 – Page 14)**. I co-ordinated the risk assessment in my role as Project Clinical Director and, as above, the risk assessment was discussed with the CMT and IPC whose view was that not having the ability to cohort patients would be unacceptable from a patient safety and operational perspective.

12. The reason for The Multi-Bedded Risk Assessment was that, from a clinical and operational perspective, we needed to consider how we would be able to cohort children with the same infection, for example respiratory syncythial virus (RSV). RSV is also known as bronchiolitis and is a very common childhood respiratory illness, especially in young children. It was considered important to have the ability where appropriate to cohort children with the same infection because it allows for constant clinical observation when required. When children are cohorted together in a multi-bedded bay, there would be a minimum of one nurse in that room with the patients. If these children were in single rooms, close observation can be more challenging and if their condition was unstable then they may require one to one nursing care. With children, their condition can deteriorate very rapidly, so clinicians need to closely observe their patients.

    With younger children in particular, babies and toddlers, they are not able to communicate that they don't feel well so clinicians very much rely on monitoring and observation of the child's condition to determine their clinical status. So, where clinically appropriate, e.g. if patients have the same infection, then cohorting those patients is the best utilisation of the available nursing resource and provides closer clinical observation and monitoring of the patients, which is ultimately safer for the patients.

13. The decision to have balanced pressure in the multi-bed rooms was based on advice from Health Facilities Scotland (HFS), MM as our technical advisors, and the NHS Lothian (NHSL) Hard Facilities Management Commissioning

Manager. In summary, what type of pressure is needed is the difference between requiring source isolation (this previously was known as barrier nursing) or protective isolation. Protective isolation aims to protect an immune-compromised patient at risk of acquiring micro-organisms from the environment and this is achieved in a room with positive pressure. In protective isolation you want to prevent the infection spreading from the room and that requires positive pressure. Where patients have the same airborne infection, they can be cohorted in the same room, and the understanding at the time was that multi-bedded rooms required balanced pressure for that purpose. I understand now that, in relation to critical care the ventilation requirements were different, and SHTM 03-01 required positive pressure. However, I was not aware of that at the time and nor did anyone in IHSL, Multiplex (MPX), TUV SUD, MM, or in the Project Team ever highlight or discuss that with me at the time. If this had been highlighted at the time of The Multi-bedded Risk Assessment then I believe a different course of action would have been taken in relation to critical care ventilation requirements along the lines of the action which was subsequently taken in July 2019 (as set out at paragraphs 22 – 25 below).

Multi-bed Rooms in Critical Care

14. At the time of The Multi-bedded Risk Assessment, the ability to be able to cohort patients within the critical care unit was identified, and the multi-bedded rooms were treated the same as those in the other wards. The CMT and clinical leads identified it was essential to be able to cohort in B1-063 (low acuity HDU) and B1-065 (surgical neonates), and desirable to cohort in B1-009 (critical care); and unnecessary in B1-031 (high acuity). Therefore, these three areas were identified as requiring balanced pressure.

15. The reasoning behind this is that patients in low acuity High Dependency Unit (HDU) and surgical neonates usually have lower clinical demands than patients in critical care or high acuity. They may have RSV and be on oxygen but are unlikely to be ventilated. It would be appropriate for these patients to be cohorted in a multi-bedded room to allow for close observation and make best use of the available nursing resource.

16. Patients in Critical Care and High Acuity are usually ventilated and will have a minimum of 1:1 nursing care. As I recall, however, the clinical team wanted the flexibility of being able to cohort patients if required in critical care (B1-009) for practical reasons.

TUV SUD Ventilation Proposal

17. I have been asked to review the TUV SUD ventilation proposal **(A45500123 – General Ward – Ventilation Amendment Proposal to Achieve Room Balance, Issue 7 (Final, SA1 item 13) – Bundle 10, Page 179)** which I signed off on 26 July 2018 as part of the Reviewable Design Data (RDD) process. It tended to be either me or Brian Currie (Project Director) who signed off on final documents in relation to RDD. Normally I would sign off the RDD design drawings and documents and Brian Currie would sign off the technical drawings and documents. However, there were times when either of us would sign any of the RDD documents, for example, when one of us was on annual leave. All technical drawings and documents were initially reviewed by MM on behalf of NHSL, often with comments going back and forth between MM and IHSL, before there was agreement reached for sign off. The TUV SUD ventilation proposal would have come to me to sign off on the basis it had been reviewed by MM and any issues highlighted. As far as I was aware MM didn't ever pass technical drawings and documents for either me or Brian Currie to sign off if it hadn't already been reviewed by them.

18. It appears that the purpose of the TUV SUD ventilation proposal was to record their amendment proposals to achieve balanced pressure in the multi-bed rooms. As above, we had undertaken a multi-bedded room risk assessment in which we were seeking to achieve balanced pressure and this proposal was setting out how IHSL would achieve that. I note that rows related to the multi-bedded areas in critical care and the proposed solution includes retaining the supply ventilation at 4 air changes per hour (ACH). As above, at the time, I was not aware that critical care required 10 ACH and positive pressure and I don't recall anyone in TUV SUD, IHSL, MPX or MM ever flagging that to me.

19. It is correct that the TUV SUD ventilation proposal was part of the decision-making process which led to the multi-bed rooms in critical care having 4 ACH and a balanced pressure regime, only for that to be reversed in High Value Change 107 (which required critical care to have 10 ACH and +10Pa pressure). As I've explained, NHSL had identified the need for balanced pressure in identified multi-bedded rooms (including in critical care) for clinical reasons; TUV SUD proposed a means of achieving that for these areas; and at the time NHSL agreed to that proposal. As indicated previously, I was not aware that critical care required 10 ACH and positive pressure and I don't recall anyone in TUV SUD, IHSL, MPX or MM ever flagging that to me.

20. It is important to bear in mind that NHSL's approval under the RDD process was confined to issues of operational functionality, and it was for other parties, namely IHSL, to flag any derogations from guidance to NHSL's Board (the Board), which as far as I am aware, they did not do in relation to critical care multi-bed rooms (or single rooms in critical care, as discussed below).

    As a result, I and those undertaking the risk assessment, were not aware of and did not consider that the balanced pressure arrangement we asked for in critical care rooms was itself contrary to the recommendations in SHTM 03-01. As I have stated in my previous statements, I am not an engineer and it was not my role to know what is required in terms of the technical guidance for every department. That is the role of the engineers and our technical advisors. I would have expected to have been advised either by IHSL directly or via MM where there were any proposed derogations to technical guidance and specifically what clinical areas the derogation applied to in order to assess the impact of this and be able to discuss this with the clinical leads and IPC and take an informed view. I appreciate that the NHSL risk assessments were predicated on NHSL having noted that the proposed ventilation arrangements for these rooms was contrary to SHTM 03-01 in relation to the pressure regime. That predication would likely have been on the advice of MM.

High Value Change 107 (HVC 107)

21. It is correct that the solution ultimately agreed for the multi-bedded rooms in critical care in HVC 107 (i.e., the remedial works) involved a positive pressure arrangement. This required significant clinical consideration given the change in approach from the multi-bedded risk assessment in which we had sought balanced pressure with the specific purpose of being able to cohort children with similar infections.

22. Shortly after the discovery that the ventilation in critical care did not comply with SHTM 03-01, there were meetings on 10 and 11 July 2019 to discuss the proposals for improving the critical care ventilation to ensure that it was compliant with SHTM 03-01 with 10 ACH and 10 Pa positive pressure in the single rooms and 4 bedded bays. We also reviewed the ventilation requirements in the 4 bedded bays to allow cohorting of patients with the same infections.

23. In summary, the Infection Precention and Control Team (IPCT) view as at July 2019 was that you could either cohort patients with the same air-borne infection in the 4 bedded areas that were at 10 ACH and 10Pa positive pressure or in a 4 bedded room with balanced or slightly negative pressure. It was generally agreed that neither approach increased the risk of infection spread but that it would be preferable to comply with guidance.

24. There is a full note of the meeting and I have copied the key sections into my statement as follows.

    The 10th July attendees were:

    - Julie Freeman (Consultant Critical Care)
    - Laura Reilly (Critical Care Clinical Nurse Manager)
    - Pat Smith (Critical Care Charge Nurse)
    - Janice MacKenzie (Project Clinical Director)

- Ronnie Henderson (Project Hard FM Commissioning Manager)
- Donald Inverarity (Consultant Microbiologist)
- Carol Calder (Infection Prevention and Control Nurse)

The 11th July Attendees were:

- Julie Freeman (Consultant Critical Care)
- Laura Reilly (Critical Care Clinical Nurse Manager)
- Pat Smith (Critical Care Charge Nurse)
- Janice MacKenzie (Project Clinical Director)
- Ronnie Henderson (Project Hard FM Commissioning Manager)
- Donald Inverarity (Consultant Microbiologist)
- Carol Calder (Infection Prevention and Control Nurse)
- William Evans (Infection Prevention and Control Nurse)
- Pota Kalima (Consultant Microbiologist)
- Catherine McDougall (Medical Consultant)

25. We noted the following in relation to compliance with SHTM 03- 01:

- Currently the 4 bedded rooms and single rooms have 4 air changes and this needs to increase to 10 air changes to ensure compliance with SHTM.
- It was acknowledged that the SHTM was more focused on adult critical care where the patient profile is different and the need to cohort patients was extremely rare.
- It was noted that previously a decision had been made to derogate from the SHTM with respect to pressures for the 4 bedded areas to allow patients to be cohorted with the same air-borne infection (e.g. RSV) and following consultation with the clinical team and IPCT at the time the decision was made that these areas should be at balanced or slightly negative pressure. The SHTM states that both the 4 bedded areas and single rooms should have 10 ACH and 10Pa positive pressure.

- It was confirmed that the Isolation Rooms were compliant with SHTM 03-01.
- IPCT view was that you could cohort patients with the same air-borne infection in the 4 bedded areas that were at 10 ACH and 10Pa positive pressure and that there is no reason that this would result in an increased risk of spread of infection. A design of balanced or slightly negative pressure approaches the issue of spread of infection from a cohort from a different direction but it was agreed that neither approach increases the risk of infection spread but that the SHTM 03-01 compliant design has additional benefit for neutropenic patients who could be in single rooms at 10Pa positive pressure.
- It was acknowledged that the design of the Unit also provided additional control measures to prevent spread of infection and the barriers to transmission included:-
- Bed space size
- Distance between single room doors, isolation room doors and 4 bedded bay doors as the range of droplet spread is generally considered to be between 1-3 metres
- Patients on ventilators are less of a risk of generating aerosols from coughing
- Direction of air flow in corridor space directs any air borne contaminants towards an air extract vent and away from other patient rooms. Extract ventilation may need to be improved in corridor area to take account of increased pressure
- Turnover of air dilutes any airborne organisms in patient rooms and corridors.
- It was noted that if a patient with an infection was in a 4 bedded bay or single room or a neutropenic patient in a single room the windows should not be opened and increased room cleaning would likely be required
- Confirmed that Isolation Rooms should be used for patients with infections transmitted by aerosols e.g. measles, chicken pox, TB
- Single rooms and cohort areas would be suitable for droplet infections e.g., RSV, Influenza

- Confirmed that the single cubicle in neonatal Unit will have 10Pa and 10 ACH and as it has an en-suite it will need a transfer grille on the en-suite door
- Confirmed the entire neonatal area was at 10Pa and 10 ACH with respect to the corridor.
- Because the single cubicle is within the neonatal unit it was confirmed that the single cubicle is at a balanced pressure or slightly negative with respect to the open neonatal bed bay.
- Confirmed that any 'dirty' rooms e.g., Dirty Utility, toilets have extract and any 'clean' rooms e.g., clean utility have supply and extract
- We discussed the Positive Pressure Ventilation Lobby (PPVL) isolation rooms in relation to ventilation in the Queen Elizabeth University Hospital (QEUH), specifically in relation to Multi-Drug Resistant TB, however Donald Inverarity (Consultant Microbiologist) was very cautious about making any comparisons as the context was different (paediatric critical care versus adult infectious diseases isolation ward). It was suggested that this was something that could be discussed further with HFS.
- We discussed a number of different patient groups and scenarios in relation to the use of the Isolation rooms, Single Rooms and 4 bedded bays and in light of these discussions and the points above all agreed that the SHTM 03-01 was a safe design for ventilation within the Paediatric Critical Care Unit in conjunction with the design of the unit and good practice in relation to infection control measures which all worked together as a package to achieve best outcome for patients.

We also briefly discussed:-

- Cystic Fibrosis patients and the areas that they would be treated in and whether CF patients with different infections would be treated in the same ward in RHCYP. Currently they are treated in different wards as the existing hospital, RHSC, does not have Isolation Rooms. It was confirmed that Dalhousie ward (Medical Inpatients) has 4 PPVL Isolation rooms. It was felt by IPCT that provided appropriate measures were in place about

the placement of patients within the ward then cystic fibrosis (CF) patients with different infections could be treated in the same ward. Also, Castle Mey (Acute Receiving Unit) has 1 PPVL isolation room. It was noted that currently Dalhousie Ward is classed as an Augmented Care Area, but Castle Mey is not.

This led to a discussion about other areas in the hospital where CF patients could be treated, this includes surgical wards, outpatient department (OPD), Cardio Respiratory OPD and Dirleton (Medical Day Care) and therefore whether these areas should also be classed as Augmented Care as far as water sampling is concerned. It was felt that the risk was greater in Inpatient areas. Further discussion to be had with IPCT acknowledging that the water testing regime may need a bit of tweaking when hospital occupied.

Email chain with MM on 19th June 2019

(A34822744 – Email from Colin Macrae (Mott MacDonald) to Graeme Greer attaching a tracker spreadsheet showing where bed bays do not achieve balance pressure - 19 June 2019 – Bundle 6 – Page 170)
(A34822744 – Tracker – Bundle 6 – Page 171)
(A40982525 – Email from Brian Currie (NHS Lothian) to Wallace Weir et al dealing urgent compliance concerns on AHUs – 20 June 2019 – Bundle 6 – Pages 174-198)

26. In this email exchange, Graeme Greer of MM is noting that IOM had started to do their validation testing and asks the question: *"Do the Board want to inform IOM now or wait for the report and clarify the settlement agreement amendments"*. I was aware that there were different requirements in SA1 than there were in SHTM 03-01 so this was not a surprise, but I could not immediately recall the details. I respond at 22:36 that evening to say that I was unsure *"what the SA said and the different requirements to the SHTM."* Given the hour, I assume I was working from home and did not have access to SA1 to check the exact wording.

Settlement Agreement 1 (SA1)

27. I was not involved in the commercial negotiations for SA1 but I was involved, to a limited extent, in providing clinical input where required into the technical schedule for SA1, which evolved over a period of around 12 months.

28. By way of background, on 20 and 21 February 2018, there was a RHSC + DCN Principals meeting at the Sheraton in Edinburgh. This entailed two days of negotiations between NHSL and MPX, facilitated by IHSL, in an effort to avoid court action by NHSL against IHSL in relation to the multi-bed dispute re pressure regime.

29. As I recall, negotiations continued between IHSL and NHSL beyond February 2018 which ultimately resulted in SA1 (**A32469163 - Settlement Agreement and Supplemental Agreement relating to the Project Arrangement for the provision of RHSC and DCN between Lothian HB and IHS Lothian Ltd - 22 February 2019 - Bundle 4, Page 11)**, including the technical schedule. In relation to my specific input in to the SA1 technical schedule as regards ventilation, my main focus at the time was to achieve balanced pressure in the multi-bedded rooms as per the multi-bed risk assessment to allow us to cohort patients. Individual clinicians were not directly involved in the technical schedule to SA1 because, as outlined above, the necessary discussions with the CMT about the pressure issue, which resulted in the risk assessment re multi-bedded rooms, had already taken place.

30. We had also already consulted with IPC and clinicians in relation to changes in haemato-oncology in February 2017, and these were also reflected in the SA1 technical schedule at item 4.

31. I also recall there was a separate discussion around a derogation from 6 ACH mechanical to 4 ACH mechanical and 2 ACH natural for single rooms. This was TUV SUD's mixed mode ventilation strategy. I do not recall a specific risk assessment in relation to the change to 4 ACH for single bedrooms, but I do

recall this was discussed within the Project Team and MM and also with the IPC nurse at the time, Janette Richards.

I don't recall the specific details of the discussion I had with her but do remember there was some discussion about the benefits from a patient perspective about being able to open the window in their room to assist with patient comfort. In relation to the SA1 technical schedule, any discussion around the derogation to single bedrooms from 6 ACH to 4 ACH was never in the context of single bedrooms in critical care.

32. There were many other issues beyond ventilation which I had input on in relation to the project that were then reflected in the SA1 technical schedule. For example, we discussed (i) anti-ligature measures with the Children and Adolescent Mental Health Service (CAMHS) team and (ii) how to address the presence of movement joints in clinical areas with the relevant departments. Sometimes the issues were flagged by us to clinicians and sometimes the other way round.

33. Overall, in my role as Project Clinical Director, I felt that the Project Team had a collaborative and positive working relationship with IPC. There was an IPC nurse who was allocated to support all NHSL new build projects including RHCYP & DCN and she worked closely with the Project Team often basing herself in our office. The IPC nurse would be the main conduit between the Project Team and the wider IPC team. The IPC nurse attended the majority of the design meetings and if unable to attend would submit comments. IPC were involved in technical aspects of the project, where appropriate, and these included issues pertaining to ventilation and they would also seek the advice of HFS, the NHSL Hard Facilities Commissioning Manager and MM. The input of IPC was an essential element of the Project and very much valued by myself and the wider Project Team. As indicated in my previous statements to the Inquiry, the Project Team worked very closely with the clinical teams ensuring that there was positive, productive engagement and they were actively involved in the design of the new hospital.

Declaration

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