SCOTTISH HOSPITALS INQUIRY

Provisional Position Paper 7
Supplementary

Note on issues with the ventilation system outside of Critical Care areas with the potential to adversely impact on patient safety and care at the Royal Hospital for Children and Young People and the Department for Clinical Neurosciences; and remedial works undertaken

Purpose of the note

This note has been produced to assist the Chair in addressing the terms of reference. It outlines the Inquiry team's initial understanding of issues with the ventilation system outside of Critical Care areas that could have had the potential to adversely impact on patient safety and care, and which arose in the construction of the Royal Hospital for Children and Young People and the Department for Clinical Neurosciences (RHCYP/DCN).

The purpose of the note is to aid in advancing the Inquiry's understanding of the identification and nature of the ventilation issues ultimately contained in the 'ventilation issues log' (aside from the issue of air change rates in High Dependency Unit (HDU)/Critical Care); and the manner in which these issues were resolved. CP's are invited to comment on the content contained herein.

In due course, the Chair is likely to be invited by the Inquiry Team to make findings in fact based on the content of this note. It is open to any Core Participant, or indeed any other person holding relevant information, to seek to correct and/or contradict it by way of response to this note. In considering those responses, and in taking forward its investigations, it is therefore possible that the Inquiry's understanding of matters set out in the note may change, and so the position set out in this paper at this point remains provisional.

If it is the case that the Inquiry's understanding does change significantly, a revised edition of this note may be published in due course.

While it is possible that the matters covered in this note will be touched upon to a greater or lesser extent at a subsequent hearing held by the Inquiry – something that may also change the Inquiry's understanding of matters – this is not guaranteed, and if parties wish to address the issues dealt with in this note, they are invited to do so now. If they do not do so, as noted above, the Chair is likely to be invited by the Inquiry Team to make findings in fact based on the content of this note.

All responses to this note received by the Inquiry will be published on its website as soon as possible after the deadline for responses has passed.

Contents

1. Overview

1.1 NHSL commissioned the Institute of Occupational Medicine (IOM) to validate the ventilation system following concerns about the commissioning process raised by the Infection Prevention and Control Team. IOM found a number of issues, amongst them the problem of inadequate air change rates in Critical Care areas which later led to the delay to the hospital opening. An 'IOM issues log' was created to record all issues identified.

1.2 The Scottish Government commissioned NHS NSS to further investigate issues with the ventilation system, amongst other things. NHS NSS commissioned Malcolm Thomas, a consulting engineer, and John Rayner (TurnerPes), NHSL's authorising engineer for ventilation. Following site visits they submitted separate reports on 27 July and 9 August respectively.

1.3 On 7 August 2019 Q-Nis, the AHU manufacturer, visited the site to verify compliance with SHTM 03-01, during which further issues with air handling units were discovered.

1.4 NHS NSS issued their review on 9 September 2019. The issues identified in these reports were added to the 'IOM issues log' and renamed the 'ventilation action log'.

1.5 In total 81 issues with ventilation were recorded in the action log. One of these was related to air change rates in High Dependency Units (within the Critical Care Department). Based on an analysis of the action log and other evidence, the other ventilation issues could be said to fall into the following categories:

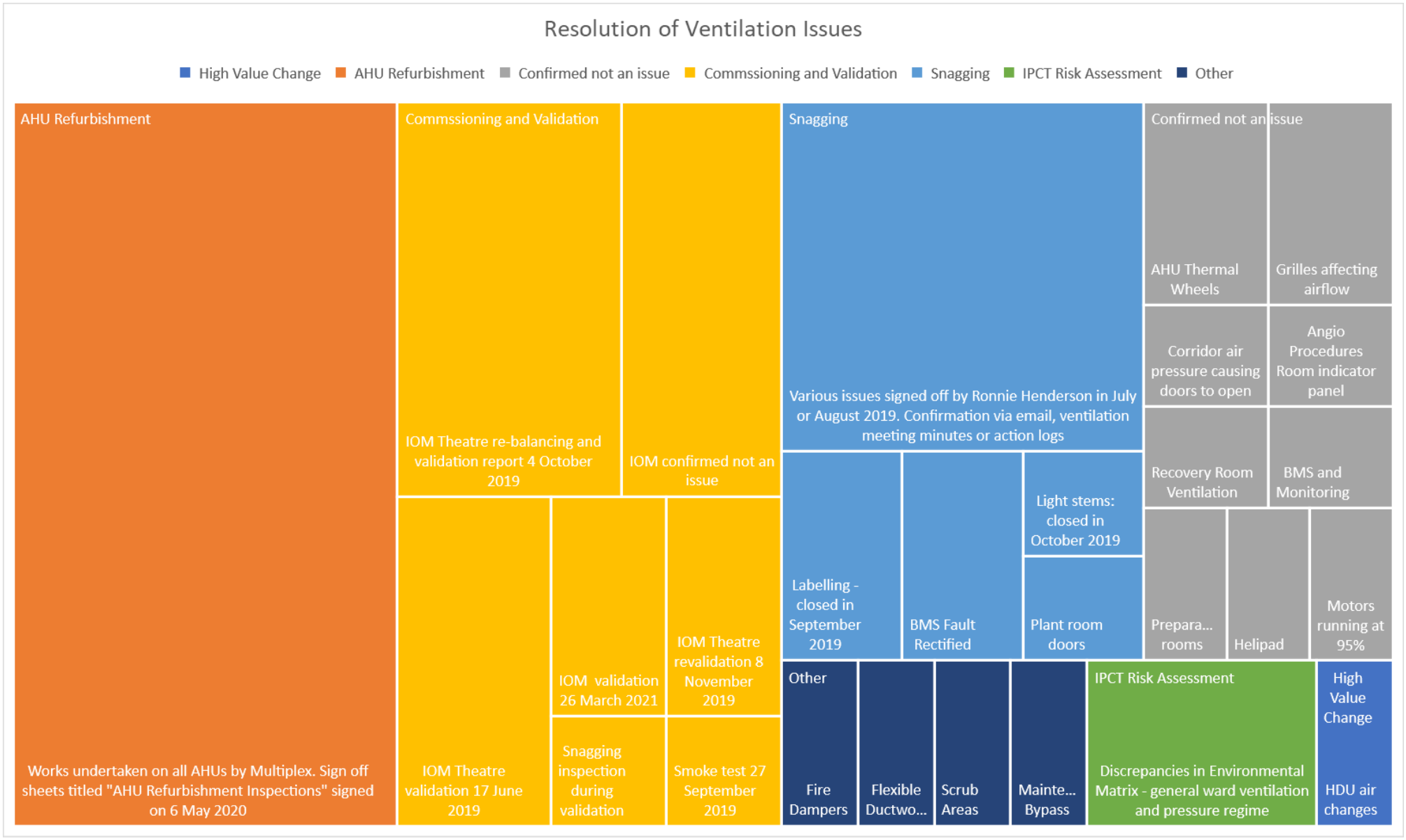
a) Issues that were confirmed <u>not</u> to be an issue following inspection or demonstration.
b) Relatively minor or 'snagging' issues that were straightforward and quick to resolve, or that could be addressed during a normal commissioning and validation process.
c) Issues that involved non-compliance with guidance and required further works, risk assessment or other demonstration to close.

This largely correlates with the issues identified as a ‘major priority’ by NHS NSS and includes:

- Air Handling Units
- Maintenance bypass
- Single and multi-bed ventilation design
- Discrepancies in the environmental matrix

As well as some issues with theatres:

- Excessive flexible ductwork
- Scrub areas


Resolution of Ventilation Issues
High Value Change
AHU Refurbishment
Confirmed not an issue
Commssioning and Validation
Snagging
IPCT Risk Assessment
Other
AHU Refurbishment
Works undertaken on all AHUs by Multiplex. Sign off sheets titled "AHU Refurbishment Inspections" signed on 6 May 2020
Commssioning and Validation
IOM Theatre re-balancing and validation report 4 October 2019
IOM Theatre validation 17 June 2019
IOM validation 26 March 2021
Snagging inspection during validation
IOM confirmed not an issue
IOM Theatre revalidation 8 November 2019
Smoke test 27 September 2019
Snagging
Various issues signed off by Ronnie Henderson in July or August 2019. Confirmation via email, ventilation meeting minutes or action logs
Labelling - closed in September 2019
BMS Fault Rectified
Light stems: closed in October 2019
Plant room doors
Confirmed not an issue
AHU Thermal Wheels
Grilles affecting airflow
Corridor air pressure causing doors to open
Angio Procedures Room indicator panel
Recovery Room Ventilation
BMS and Monitoring
Prepara... rooms
Helipad
Motors running at 95%
Other
Fire Dampers
Flexible Ductwo...
Scrub Areas
Mainte... Bypass
IPCT Risk Assessment
Discrepancies in Environmental Matrix - general ward ventilation and pressure regime
High Value Change
HDU air changes

1.6 Issues involving non-compliance with guidance had the potential to impact on patient safety either through the provision of inadequate ventilation to disperse air-borne pathogens, or because non-compliant installation created a risk of contamination.

1.7 Most ventilation issues were closed out by 1 May 2020. At the final meeting of the Oversight Board on 8 April 2021, the final action log for ventilation "showing all actions now closed following discussions and correspondence with Ian Storrar" was accepted. An issue with DCN theatre corridor ventilation was not fully resolved and continued to be considered a defect. However the issue did not impact on patient safety and so does not require further consideration by the Inquiry.

2. AHUs and ductwork:

2.1 Air handling units (AHUs) and ductwork contained deviations from SHTM 03-01, including "loose internal cabling in the airflow, cable routes allowing air to bypass filters, air leakage at penetrations and possible fan replacement difficulties which need to be corrected." Loose cabling inside the air ducts posed a fire safety and infection control risk, and was considered by the Infection Prevention and Control Team to be 'unconventional'.

2.2 Multiplex proposed a solution that involved "bespoke metalwork to fix [cabling] in place within the unit" and demonstrated their solution on a 'benchmark AHU' which would act as a blueprint for all the other AHUs (outside of Critical Care and Neutropenic patient areas). Other options to resolve the issue either had significant time and cost implications, presented an unsatisfactory risk, or required a Board Change. Following an IPCT assessment which found the proposed solution to be 'acceptable' with some caveats, the Oversight Board agreed to proceed with it subject to:

- written confirmation of acceptance from HFS, IOM and the Board's Authorising Engineer (AE)
- all IPCT recommendations being implemented

- IHSL/MPX providing outstanding confirmation and information required regarding the cleaning methodology, details of anti-bacterial sealant and other specific IPCT queries.

2.3 Thirty seven separate sign-off sheets (one for each AHU in the hospital) were created, titled “AHU Refurbishment Inspections”. Each sheet listed 23 items from the ventilation action log. On 6 May 2020 the sheets were signed by Ronnie Henderson, the NHSL Commissioning Manager for Hard FM (facilities management), John Rayner, the authorising engineer for NHSL, and P.W Jameson, the Authorising Engineer for Independent Validation – IOM. They stated:

> “The signatories below confirm that the AHU meets the definition contained in Section 8 of SHTM 03-01 as follows: ‘The system will be acceptable to the client if at the time of validation it is considered fit for purpose and will only require routine maintenance in order to remain so for its projected life.’”

3. Single and multi-bed ventilation and the Environmental Matrix

3.1 Single and multi-bed ventilation had been designed with four air changes per hour mechanical ventilation, and a natural ventilation component (involving openable windows). There were two issues with this design. Firstly, while in most cases the provision of 4 ac/hr through mechanical ventilation had been validated by IOM, the natural ventilation component had not been proven. For example, it was not clear whether natural ventilation could increase the air change rate for bedrooms to the 6 ac/hr required in SHTM 03-01. Secondly, opening windows would affect the pressure regime, which meant that the pressure differential and direction of airflow described in the Environmental Matrix “cannot be relied upon when windows are open”.

3.2 NSS’s requirements to close out the actions, logged as V7 and V8 on the action log, were to:

> “Confirm that all areas served by this arrangement are suitable for categorisation as listed in SHTM 03- 01 Part A, Appendix 1. Undertake an IPCT risk assessment ward by ward/speciality specific in relation to the guidance.” and

> "A full assessment of the services and patient population should be carried out and mechanisms for monitoring established."

3.3 NHSL were also asked to

> "demonstrate through risk assessment, that the Board is assured that the provision of 4 air changes per hour on mechanical supply, rather than 6 air changes per hour on mechanical supply does not compromise patient safety by introducing either an increased risk of transmission of infection or acquisition of healthcare associated infection."

3.4 The IPCT team completed an "SBAR Risk Assessment regarding Impact of Design Ventilation on managing HAI risk in RHCYP & DCN clinical areas (not including Paediatric Critical Care)" on 27 September 2019. The report outlined risk mitigation measures appropriate for patients based on their risk profile (for example, how vulnerable they were to infection) and the airborne infections they were likely to be exposed to in different parts of the hospital. The review, which "did not reveal any further significant areas of non compliance or concern" made a number of recommendations to mitigate risks.

3.5 A further review of all outpatient and therapy areas was undertaken to address "the potential of further discrepancies in the Environmental Matrix" which was logged as a separate issue, V2 on the ventilation action log.

3.6 As part of a broader "dialogue with HFS" across NHSL's programme of works, in November 2019 Iain Graham (Director of Capital Planning and Projects, NHSL) attended a short stay elective technical workshop organised by programme managers and HFS to go through "a range of challenges with the interpretation of their guidance in anticipation of the new regime." The issue of air change rates and provision of natural ventilation and 4 ac/hr, vs 6 ac/hr mechanical ventilation, was discussed. It was clear that there was a lack of clarity regarding interpretation of guidance. Feeding back to colleagues Mr Graham noted

> "Much discussion was had about the failure of Boards to be clear…[regarding ventilation requirements] but equally about the need for the guidance to be updated."

3.7 In addition to the issues identified above, concerns were raised about whether appropriate ventilation had been provided for neutropenic patient areas. This issue had been identified during construction and a resolution was agreed in Settlement Agreement 1. However following the delay to the hospital opening, and the receipt by NHS Greater Glasgow and Clyde (NHS GGC) of an Improvement Notice regarding inadequate provision of specialist ventilation to haematology, oncology and renal transplant patients, NHSL undertook further work to improve ventilation in neutropenic patient areas. This was included in the works undertaken under the High Value Change Notice 107, under Settlement Agreement 2.

3.8 After the Covid-19 outbreak, guidance relating to Infection Prevention and Control advice for acute care settings was updated, which impacted on the requirements for isolation of 'high consequence infectious diseases' (HCID) in the Emergency Department. Following engagement between NHSL and NHS NSS on how to meet new requirements, the Oversight Board agreed on a recommended solution on 18 June 2020. Works took place under Medium Value Change (MVC) 157.

3.9 On 2 March 2021 IOM issued its validation audit taking into consideration:

- Design Assurance Statement from John Rayner (AE) received on 4 February 2021 following a site visit on 19 – 21 January 2021. This confirmed the AHUs met the full requirements of SHTM 03-01 and was fit for purpose.
- AHU factory visit on 20 July 2020 by Paul Jameson, AE (ventilation) of the IOM, confirming that the Daikin Air Handling Units were superior to the original Sandometal units.
- Hepa filter integrity test on 23 January 2021 which confirmed that filter systems were properly installed with no bypass leakage and free from defects.
- Confirmatory readings carried out by IOM. IOM "compared data with H&V commissioning services of all the grilles in G-A1 based on the Hoare Lea design data through January and February 2021. During this time all three

parties along with NHS Lothian made changes as required in line with SHTM 03-01."

- Calibration certificates including an aerosol generator certificate of compliance and electrical safety test were included.

3.10 Thus while some single and multi-bed rooms in the hospital retained the ventilation solution which had been a source of concern, infection control measures were put in place to reduce the risks of infection for the types of patients likely to stay in those rooms. Separate, technical, ventilation solutions were found for neutropenic patient areas accommodating particularly vulnerable patients and the emergency department for receiving patients with high consequence infectious diseases.

4. Maintenance Bypass

4.1 According to the NHS NSS report,

> "SHPN4 supplement 1, recommends that each isolation room should ideally have its own air handling unit, such that if an air handling unit fails, or is offline for maintenance, only one isolation room is out of commission.
>
> The building, as built, has an air handling unit serving each area of the building, including any contained isolation rooms. This means that up to five out of 19 isolation rooms may be not performing as intended in the event of an air handling unit failure. NHS Lothian have advised that the strategy for maintenance is that a bypass duct will be used to feed an area from an adjacent air handling unit. This mode has not yet been proven and the successful operation of isolation rooms and other spaces in the event of use of this bypass has not been demonstrated."

4.2 Maintenance bypass was considered in the above-mentioned IPC "Risk Assessment regarding Impact of Design Ventilation on managing HAI risk in RHCYP & DCN clinical areas", which outlined "the actions required if one or more air handling unit fails resulting in the loss of isolation room supply ventilation." The report noted that

> "in the absence of an infectious disease of high consequence, and providing all other standard and transmission based precautions required by HPS NIPCM [National Infection Prevention and Control Manual] are in place, the risk of infection to patients, staff or visitors is likely to be low...
>
> Depending on the nature and duration of the AHU failure, and in line with NHS Lothian Prioritisation of Isolation Guidance, a clinical risk assessment would be required in conjunction with the IPCT to determine any further actions required on a case by case basis…."

4.3 According to the action log final evidence of closure of this issue was "Email providing details from BYES on frequency and duration of planned PPM downtimes, AHU maintenance information attached." At the Oversight Board meeting 23 April 2020 it was noted that maintenance bypass "has now been demonstrated on all Air Handling Units being retained and the documentation was being awaited for the 2 units being removed under HVC107 works [the remedial works for Critical Care Areas and enhancement of neutropenic patient areas]."

5. Scrub areas

5.1 NHS NSS reported an issue with airflow in scrub areas, which were "narrow and deep" and thus were "unlikely to be scavenged effectively by theatre air changes and require alternative means of achieving removal of contaminants as per SHTM 03-01." Instead of installing low level extract for removing air from the room, Multiplex had installed high level extract which was less effective and "is not in accordance with the requirements of SHTM 03-01". Multiplex/Tuv Sud moved scrub extracts to a low level. No board change was required. When IOM revalidated theatres in March 2020 they found no issues with scrub rooms.

6. Excessive Flexible Ductwork:

6.1 Flexible ductwork longer than 1 meter in length was found in Theatre 35. This was not compliant with SHTM 03-01 part A paras 5.54 and 5.55 which state that 'flexible ductwork should never exceed 1m in length' and 'never be used in lieu of a bend'. Flexible ducting was rectified in Theatre 35 specifically on

29 August 2019. However, NHSL were not satisfied with the overall response from IHSL, who would not inspect the hospital for further instances of non-compliant use of flexible ductwork because, according to Mercury (a sub-contractor of Multiplex, responsible for commissioning the ventilation system), this had been done before.

6.2 To close out the issue, Ronnie Henderson outlined the Board's position in an email sent to Wallace Weir (HCP), Craig Simpson (HCP), Graeme Salmon (HCP) David Wilson (MPX) Colin Grindlay on 20 September 2019. The final paragraph stated:

> Whilst noting IHSL's position, the Board remain concerned of the heightened risk of defects arising due to potentially other instances of flexible ductwork being in excess of 1m in length and/or with bend(s). The Board remind IHSL that it is for critical ventilation systems to be independently validated annually and that any materials or methods used in the construction of ventilation systems must not contribute to an increased risk of the spread of infection.'

6.3 It is not clear to the Inquiry whether this issue was adequately resolved and would invite further explanation.

7. Helipad

7.1 Malcolm Thomas (consulting engineer) raised concerns about the location of air intakes below the helipad, i.e. that downdraughts from the helicopter landing or taking off could impact on the ventilation system. On 18 March 2020 helicopter test flights, including take-off and landing manoeuvres, were carried out. The building management system (BMS) was monitored during these tests and the results showed no adverse effect on the ventilation system pressures. Thus the location of the helipad was found not to be an issue.

8. Questions

8.1.1 Do Core Participants agree with the above content of the note?

8.1.2 Are Core Participants aware of any further unresolved issues or defects with the ventilation system not discussed above that could have an adverse impact on patient safety?

8.1.3 How are health boards assisted in the interpretation of guidance?

8.1.4 What steps are being taken to clarify guidance?

8.1.5 What is the current situation regarding excessive flexible ductwork?

a. Is there excessive flexible ductwork in the hospital's ventilation system?
b. Are measures in place to mitigate any risks of contamination and the spread of infection due to flexible ductwork?

8.1.6 Could NHSL provide a copy of the HAI Scribe 4 IPCT sign off of the RHCYP and DCN that took place prior to the hospital opening in 2021.