SCOTTISH HOSPITALS INQUIRY

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 Department of Clinical Neuroscience; and remedial works undertaken

Purpose of the Note

This note sets out the Inquiry's understanding of issues 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 Persons and Department of Clinical Neurosciences (RHCYP/DCN) and the manner in which these issues were resolved. It also outlines the Inquiry team's understanding of actions that have been taken to remedy these issues.

It follows on from an earlier version of this note that was published on the Inquiry's website and distributed to relevant core participants. Comments were provided by NHS Lothian, NHS NSS, IHS Lothian Limited, Multiplex Construction Europe Limited and TUV SUD Limited.

The Inquiry has carefully considered the comments received, together with the supporting material submitted and other material held by it. It has reviewed and revised the note accordingly to produce this updated version.

As a result, the views expressed in this Paper are firmer than those set out in the previous one. It follows that the Chair will be invited by the Inquiry Team to make findings in fact based on the content of this note. However, while the views may be firmer, that should not be equated with "final". The Inquiry's investigations are not yet concluded and, at the time of publication, there is to be a hearing dealing with matters arising in relation to the Royal Hospital for Children and Young Persons/ Department of Clinical Neurosciences commencing on 26 February 2024. Evidence at that hearing and submissions made following it (as well as any other evidence received) may require the Inquiry to reconsider matters set out in this note. Nonetheless, in the absence of such evidence or submissions, it is likely that the contents of this note will be used as a basis for the Inquiry's report.

Readers of this note should note that section 2 of the Inquiries Act 2005 provides that an inquiry is not to rule on, and has no power to determine, any person's civil or

criminal liability. Accordingly, in the context of the Scottish Hospitals Inquiry's investigations into the matters falling within its remit in relation to the Royal Hospital for Children and Young Persons, the issue of any liability arising under the Project Agreement is not a question for the Inquiry to rule on or determine and nothing in this note should be taken as doing so.

Glossary

ac/hr	air changes per hour (air change rate for ventilation)
AE	Authorising Engineer
AHU	Air Handling Unit
BYES	Bouygues Energies & Services FM UK Limited, the facilities management contractor appointed by IHSL
DCN	Department of Clinical Neurosciences
DSSR	Engineering Consultants
ED	Emergency Department
ESG	Executive Steering Group
FM	Facilities Management
H&S	Health and Safety
HAI or HCAI	Healthcare Associated Infection
HAI-Scribe	Healthcare Associate Infection Systems for Controlling Risk in the Built Environment
HCID	High Consequence Infectious Diseases
HEPA filter	High Efficiency Particulate Air filter
HFS	Health Facilities Scotland (part of NHS National Services Scotland)
HIIAT	Hospital Infection Incident Assessment Tool
HPS	Health Protection Scotland (part of NHS National Services Scotland)
HVC	High Value Change
IHSL	Integrated Health Solutions, Lothian, the Project Company or private partner to NHSL to deliver the new hospital.
IMT	Incident Management Team
IOM	Institute for Occupational Medicine, third party validators for ventilation
IPC	Infection Prevention and Control
IPCT	Infection Prevention and Control Team
LVC	Low Value Change
OB	Oversight Board
NHSL	National Health Service Lothian

NHS NSS	National Health Service, National Services Scotland
MM	Mott MacDonald, NHSL's technical advisors
MPX	Brookfield Multiplex Construction Europe Limited, the construction contractor appointed by IHSL
MVC	Medium Value Change
NIPCM	National Infection Prevention and Control Manual
Project Agreement	the agreement between NHSL and IHSL dated 12 and 13 February 2015 for the design, build, finance and maintenance of the new RHCYP building at Little France.
RAG	**R**ed **A**mber **G**reen risk rating
RHCYP	Royal Hospital for Children and Young People (name given to the new children's hospital)
SA1	Settlement and Supplementary Agreement No.1
SA2	Project Agreement Supplementary Agreement No. 2
SBAR	Situation, Background, Analysis and Recommendation
SG	Scottish Government
SHTM	Scottish Health Technical Memorandum
SHPN	Scottish Health Planning Note
TUV SUD	TUV SUD Limited (trading as Wallace Whittle) – the building services engineer appointed as a sub-contractor by MPX
QEUH	Queen Elizabeth University Hospital

1. Introduction

1.1 Terms of Reference

1.1.1 Included in the terms of reference of the Inquiry is:

> 1. To examine the issues in relation to adequacy of ventilation, water contamination and other matters adversely impacting on patient safety and care which arose in the construction…of the RHCYP/DCN; and to identify whether and to what extent these issues were contributed to by key building systems which were defective in the sense of:
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> A. Not achieving the outcomes or being capable of the function or purpose for which they were intended;
> B. Not conforming to relevant statutory regulation and other applicable recommendations, guidance, and good practice.
>
> And,
>
> 7. To examine what actions have been taken to remedy defects and the extent to which they have been adequate and effective.

1.1.2 In July 2019, after concerns were raised about the ventilation system in Critical Care areas of the Royal Hospital for Children and Young People (RHCYP), a decision was made to delay opening the hospital until it was confirmed safe for patients. Thus, there was effectively an opportunity to remedy any potential 'defects' or issues in building systems before they could have an adverse impact on patient safety and care.

1.1.3 The focus of this note is to consider whether there were any potential issues identified with the ventilation system outside of Critical Care areas, and actions taken to remedy them, not including works under Settlement Agreement No.2 (SA2). Any references to 'defects' and 'non-compliances' in this note are taken from contemporaneous sources and are not intended by the Inquiry to be references to whether or not the contractual requirements under the Project Agreement were met.

Rather, the paper is concerned with systems that are or may have been “defective” in the sense that the term is used in Term of Reference 1 (with Term of Reference 7’s reference to “defects” being interpreted accordingly).

1.2 Identification of ventilation issues

1.2.1 In June 2019 the Institute of Occupational Medicine (IOM) undertook validation of the ventilation system. IOM reported a number of issues. An ‘IOM issues log’ was created to record all issues identified.

1.2.2 The Scottish Government commissioned NHS NSS to further investigate issues with the ventilation system, amongst other things. NHS NSS (HFS) appointed Malcolm Thomas, a consulting engineer, and John Rayner from TurnerPes, a consulting engineering company that provides Authorising Engineers and specialises in ventilation and water systems. John Rayner was NHSL’s Authorising Engineer for ventilation, appointed through the HFS framework. Following site visits they submitted separate reports on 27 July and 9 August respectively.

1.2.3 Following the discovery of issues with air handling units, the AHU manufacturer attended an all-party walkround on 7 August 2019 to discuss the issues and agree a plan to resolve them. This resulted in a checklist of 23 items to be remedied.

1.2.4 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’.

1.2.5 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 Critical Care Department). Based on an analysis of the action log and other evidence the other 80 recorded ventilation issues could be said to fall into the following categories:

a) Issues that were confirmed not 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 corresponds 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

1.2.6 The issue regarding flexible ductwork was primarily about functionality and performance, rather than any IPC risk with the potential to adversely impact on patient safety and care. Thus, it is not considered further in this paper.

1.2.7 Other 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.

1.2.8 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. 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 According to the NHS NSS review, AHUs and ductwork contained deviations from SHTM 03-01. These included “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.” Filters were also poorly fitted. 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 a multidisciplinary assessment by relevant stakeholders, 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. The design contained a natural ventilation component, but did not specify that natural ventilation would contribute to meeting a particular air change rate.

3.2 Following the decision to delay opening the hospital, NHS NSS identified two issues with this design. Firstly, while in most cases the provision of 4ac/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".

3.3 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."

3.4 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."

3.5 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 "did not reveal any further significant areas of non compliance or concern". It made a number of recommendations to mitigate risks.

3.6 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.

3.7 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."

3.8 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 & 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.

3.9 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 to make alterations to the Emergency Department took place under Medium Value Change (MVC) 157.

3.10 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 the quality of the Daikin Air Handling 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.

3.11 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]." NHSL have confirmed that this is no longer an issue.

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, In accordance with the approved design, 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. Helipad

6.1 Malcolm Thomas (consulting engineer) raised concerns about the location of air intakes below the helipad, ie that downdraughts from the helicopter landing or taking off could impact on the ventilation system. On 18th 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.