

# SCOTTISH HOSPITALS INQUIRY

## Bundle of documents for Oral hearings commencing from 19 August 2024 in relation to the Queen Elizabeth University Hospital and the Royal Hospital for Children, Glasgow

## Bundle 21 - Volume 3 Responses to Expert Report of Sid Mookerjee

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#### **Scottish Hospitals Inquiry**

#### Paper by Dr Teresa Inkster and Dr Christine Peters re additional epidemiological data

#### June 2024

Having undertaken a brief initial review of this Epidemiology material we have the following preliminary comments:

It is of crucial importance when undertaking comparisons of data that like for like is compared;

- We feel that the FOI is not specific enough in its request with regards to admissions. What is the definition of an admission and does this include day case attendees for all the comparator centres?
- 2) What is the definition of a "unit", and in particular does this include day care as well as an inpatient ward?
- 3) How have blood cultures where both bottles have been positive been handled and is this consistent across all sites?
- 4) Has deduplication been the same across all sites e.g. have they all consistently applied the 14day deduplication that GGC has?
- 5) Was raw data obtained from the other centres or did they undertake their own data clean up prior to submission?
- 6) Was Glasgow data gather based solely on ward location or was it based by Consultant looking after the patient? In our experience to pick up the at risk group it is a more sensitive methodology to search for cases associated with a consultant. This will pick up patients who may have developed bacteraemia on another ward but still had links to the QEUH water system including the wards 2A, 6A.

Other observations

- It is not clear why Candida infections are included as these are typically endogenous and would not be unusual in this high-risk group with frequent exposure to broad spectrum antibiotics and steroids. Some like Rhodotorula and Exophilia are more commonly attributable as environmental yeasts.
- 2) Some environmental organisms appear to have been excluded e.g. Herbaspirillum hutiense and Raoultella spp and Pandoraea spp.
- 3) Fungi such as Aspergillus, Cryptococcus, Fusarium and Mucor would be of more relevance as these are environmental in nature. Is there a reason for their exclusion, does this possibly relate to smaller numbers?
- 4) There appear to be discrepancies in the number of organisms between this report, the case note review (who despite the same methodology and a shorter time have counted more cases for some pathogens) and the data analysed by Dr Christine Peters and Kathleen Harvey Wood. We feel this may be due to some ward codes being omitted from the data extraction. It would be important to check whether the following codes were applied when data was being extracted from tpath ;

#### CH4BMT/CHCDU/CHD2B/CH2A/CH2ASC/CH2BDC/CH2BDS/CH2BSC

For example, Dr Peters can identify additional cases:

19 Stenotrophomonas (cf 14) 8 Pseudomonas (cf 5)

2 Pantoea (cf 1)

It should be noted that Sid Mookerjee should not be blamed for any error relating to ward coding; he would have been dependent on the accuracy of the data coming in from GGC.

- 5) There is a striking reduction in admissions post 2018 until 2021, is there a clinical explanation for this? Were children being treated elsewhere? If not, it would be important to check the admission data is accurate.
- 6) For a period in early 2019 children were decanted from 6A to the Clinical decision unit (CDU) so it would be important to ensure that the CDU code has been applied.

Again, if the CDU code has not been applied then this is not an error on the part of Sid Mookerjee, as he would have been dependent on GGC providing full data.

- 7) The FOI requested data on the year of construction but this does not appear to have been included in the analysis. This is important as the RHC was a new build and therefore we would expect rates to be much lower than those in older units.
- 8) It would be helpful to understand when/what actions were put in place in other units in response to infections as well as if in their practice their data has led to IMTs/PAGs and when such data exceedance was identified.

## SCOTTISH HOSPITALS INQUIRY REVIEW BY NHSGGC OF REPORT FROM SID MOOKERJEE DATED 9 MAY 2024

[1] A report from Mr Sid Mookerjee, dated 9 May 2024, has been disclosed to core participants. With reference to Scottish Hospitals Inquiry Direction 5, Appendix B at para 2.1, specific questions to be asked of the report's author, and specific comments on the substance of the report, are set out below. The questions and comments raise new matters or issues insofar as they relate to matters either not covered or not fully addressed in the report.

[2] On behalf of NHSGGC, a fundamental issue is raised regarding the underlying data used by the expert in his comparator exercise. This fundamental issue completely invalidates the findings and conclusions of the report. It is surprising that the obvious differences in admission rates between RHC and the other hospitals were not identified, checked and addressed before the report was finalised and referred to in other expert reports.

[3] In addition to this over-arching issue, further ancillary issues arise in relation to how the expert has treated the data provided by NHSGGC, the details of which are set out following consideration of the more fundamental issue.

#### Fundamental discrepancy in underlying data used for comparison exercise

[4] The denominators used in the calculation of infection rates were different for QEUH/ RHC than for the comparator hospitals. The data request made to NHSGGC for the purpose of the comparison exercise requested that the Board specify: "1. The number of occupied bed days; and 2. The number of patient admissions for paediatric haematology and oncology patients at the QEUH&RHC from 10 June 2015 to 31 December 2022"<sup>1</sup>.

<sup>&</sup>lt;sup>1</sup> It is noted that on the request of the Inquiry, NHSGGC provided "admissions" data for the period 10 June 2015 until 31 December 2022. This reduced 7 month time period for 2015 does not appear to be reflected in the report.

[5] The response from NHSGGC noted that the inpatient admissions data was calculated "*using the admission date, all inpatient or day cases,* **who stayed overnight** (*emphasis added*), *for the period*...".

[6] The Freedom of Information Requests submitted to the comparator hospitals requested, among other data: *the number of admissions to the paediatric haemato-oncology unit, by year, for 2015-2022; and the number of individual patients admitted to the paediatric haemato-oncology unit, by year, for 2015-2022.* 

[7] It would appear that the comparator hospitals have included day cases as part of their total number of admissions over the period. The NHSGGC data provided in response to the request from the Inquiry made clear that only inpatient admissions and day cases which resulted in an overnight stay were included as "admissions." It is clear in the report that the number of "admissions" used to calculate and compare infection rates is substantially different for the comparator hospitals than RHC. Whilst size of population served is similar across the 5 hospitals, the admission numbers submitted by the comparator hospitals are over 10 times higher for GOSH and Leeds and 5 times higher for Oxford and Cardiff and Vale than the admission numbers submitted by NHSGGC. Had NHSGGC included day cases in its data for the comparison exercise, as the comparator hospitals have done, the total number of admissions to QEUH/RHC would be substantially greater.

[8] In addition, the report has not included paediatric haematology and oncology admissions to other wards within the RHC such as the Clinical Decision Unit which, for many patients, is part of the patient pathway for admissions. This would add approximately a further 1,380 admissions to the total number for QEUH/ RHC used by the expert.

[9] Given the fundamental discrepancy in the data parameters applied by NHSGGC and the comparator hospitals, the expert has, essentially, not compared like with like. Therefore, his conclusions on infection rates and comparisons of infection rates are, accordingly, invalid.

[10] NHSGGC has recalculated the infection rates and Incidence Rate Ratio (IRR) using its routine data for admissions and all day cases. The results show that the IRRs were less than one for many of the years in question. Equally, calculating IRRs between the comparator

hospitals show variability with the IRR higher between some comparator hospitals than between RHC and the comparators.

It is likely that the denominator for RHC is still an underestimate as ward attenders are included in some of the comparator hospitals but this recalculation, even with the under-estimate, illustrates that the conclusions of the report are invalid.

[11] NHSGGC has provided an updated data set to the Inquiry, in order that the infection rate comparison exercise can be conducted using the same data parameters for all hospitals referenced in the exercise, including QEUH/ RHC. NHSGGC has requested that the expert be invited to re-calculate NHSGGC's infection rates and IRR using the updated data set and to re-assess NHSGGC's place in the comparator exercise.

#### Ancillary issues arising from use of data provided by NHSGGC

#### Approach in relation to water positivity

[12] In considering the organisms causing infections attributable to the water environment, the expert has amalgamated data for blood cultures from which yeasts were isolated. In the case of QEUH/ RHC, this represents approximately 10% of isolations. The proportion of fungal isolates in the four comparator hospitals is not described. As the majority of yeast infections in haemato-oncology patients arise from their commensal flora, this inclusion will overestimate positive blood cultures associated with the environment,.

[13] The expert has correlated water data with rates of positivity for certain key pathogens found in the water. Water positivity rates are almost exclusively due to isolation of cupriavidus and fungal isolates. Cupriavidus occurs almost universally in water. There were, however, only two cases of infection with Cupriavidus noted from the total of infections considered. Further, no filamentous fungal infection is known to have occurred in the paediatric population over the period. The approach taken by the expert to the correlation of water data with water positivity rates is unclear.

[14] It is not clear why the expert focused upon Legionella spp., Pseudomonas spp., Cupriavidus spp., Serratia spp., Stenotrophomonas spp., and fungi. The selection of taxa appears to be at odds with the purpose of the report (to assess whether there is a link between water testing results and blood stream infections), given that: (i) there were no Legionella spp. in the BSI data (pp. 23-24); (ii) Serratia spp. were extremely rare in the water data; (iii) several bacterial species listed in the BSI data were also present in the water data, but have been excluded (e.g. Delftia acidovorans, Sphingomonas paucimobilis); and (iv) the heterogeneous kingdom-level grouping 'fungi' is included, despite the fact that there is almost no overlap in detected fungal species between the BSI and water data.

[15] The expert calculates what he calls a 'rate of water positivity' by agglomerating a large, varied, complex data set and reducing it to a single number per year. Fundamentally, this approach does not account for differences in the types of water tests carried out over this period. By generating a single number per year and comparing its trend over time, the expert is assuming or implying that the same 'thing' is being counted throughout this period and therefore that the values are comparable which is not the case.

[16] Routine testing specifically for Gram negative bacteria (GNB) and fungi was only introduced in 2018. Fungi would not have been reported in 2015-2017 because fungal water testing was not carried out. Any GNBs detected over this earlier period were incidental non-target findings, usually from the Pseudomonas test, and the recording of non-target results was not required nor consistent among the different testing laboratories. Those earlier GNB results are therefore not comparable to the results from GNB-specific tests carried out from 2018 onwards.

[17] The summary water testing documents provided to the expert explain how water testing at the QEUH/RHC changed over the period 2015-2020, and these changes are also obvious from the raw data sheets the expert used to generate these numbers (e.g. the 2015-2017 data sheets have no columns for fungal results).

[18] The expert states in paragraph 10.5 that the computed water positivity rates for 2015 and 2016 are likely to be underestimates. However, the expert then proceeds to use these apparent underestimates as the start point for the water positivity trend analysis, stating that there was a 'rising trend' of water positivity. Trend analysis is extremely sensitive to the start and end points, and using known underestimates as the start points biases the trend upwards (i.e. the rates can only go up once the values are no longer underestimated). Furthermore, the expert has chosen to exclude the 2020 data point, which further biases the trend upward.

#### Approach in relation to statistical analysis

[19] The expert recognises that establishing causality is complex (para 5.5.2). Two points follow from this to be recognised: (i) causality cannot be inferred from a strong correlation; and (ii) correlation can only ever show association. Correlation is not a suitable approach if the question relates to the influence or effect of one variable <u>on</u> another (rather than a simple association).

[20] It is also questionable whether the agglomerated yearly BSI rates and water positivity rates that the expert computed are even suitable for a correlation analysis, given that both are values that were measured repeatedly over time and given the small number of data points involved.

[21] In seeking to explore any association between infection rates and water positivity, the expert makes reference to the Pearson correlation coefficient analysis (para 10.2). The expert's approach to conducting a Pearson correlation analysis is unclear. Using the expert's own computed values for BSI and water positivity rates, Pearson correlation analysis shows the following:

- a) There is no clear linear relationship between these variables when plotted together;
- b) They do not obviously cluster around a straight trend line superimposed on the plot;
- c) Computing the Pearson coefficient (R) without the 2020 data replicates the value reported by Mr Mookerjee (0.66, which he rounds to 0.7);
- d) When the 2020 data point is included, the R value is lower (R = 0.54);
- e) Confidence intervals give 'the range of values which we can be confident includes the true value' and these are not provided in the report. Here, the 95% confidence intervals for the R values were -0.53 to 0.98 without the 2020 data and -0.48 to 0.94 with the 2020 data. These intervals are both large and cross zero, meaning that we cannot confidently state that any correlation exists between these variables. The 'true' value could be zero or even negative (a negative correlation coefficient would indicate that as water positivity rate increased, BSI rate <u>decreased</u>, or vice versa);
- f) Furthermore, hypothesis testing clearly shows that this is not a significant correlation. Without the 2020 data, the p-value of the correlation is 0.22, which means that with five data points, as in this analysis, there is a 22% chance of obtaining an R value of 0.66 or higher if these data were completely random. With the 2020 data included, this

percentage is 26%. Neither correlation would be considered significant by any reasonable metric.

[22] While the expert appears to have correctly computed the R value, he makes no mention of computing confidence intervals or p-values to assess whether the stated correlation is at all likely to be true, i.e. statistically significant (unlikely to have occurred through random chance alone). These metrics both clearly show that there is no correlation between the expert's calculated BSI and water positivity rates, which is the opposite of what the expert has concluded.

[23] There is a concern about using "admissions" in the calculation of infection rate in any event: an admission could be for a duration of one day for a low risk patient or 100 days for a high risk neutropenic patient receiving a bone marrow transplant and so does not give an accurate picture of risk. "Admissions" is a weak denominator and it would be more appropriate to calculate infection rate by central line days.

#### Additional points

[24] The data quoted on BSI (data provided by NHSGGC) have different values than those provided by NHSGGC. It is not clear why there are discrepancies between the data provided and the data in the report. A detailed description of these differences can be provided.

[25] In relation to whole genome sequencing, the expert states that "the robustness of reliance on the absence of an exact match is very much dependent on the comprehensiveness (including the frequency) of water testing" (para 13.6). From 2018 onwards, QEUH/ RHC was subject to more water surveillance than any other hospital within any other NHS board.

> Peter Gray KC and Emma Toner, Advocate 19 June 2024

#### 1 Introduction

- 1.1 The following is a response by Multiplex Construction Europe Limited ("Multiplex") to the expert report prepared by Sid Mookerjee dated 9 May 2024 ("Expert Report").
- 1.2 Multiplex is grateful for the opportunity to assist the Inquiry in relation to the Expert Report.
- 1.3 As noted in its response to the expert report of Dr Walker, Multiplex does not consider that a period of 5 weeks to respond has provided Multiplex with sufficient time to properly consider and formulate a response to all of the matters raised in the Expert Report. In addition, information which Mr Mookerjee refers to and relies on has not been properly made available to Multiplex. In particular, Multiplex would highlight that:
  - 1.3.1 Bundle 19 does not provide the Freedom of Information data collected for the comparator hospitals as referenced in footnote 21 of the Expert Report.
  - 1.3.2Report sections 7.2.6 and 7.2.7 refer to Freedom of Information data detailed in section 4.7.1 and<br/>4.7.2. Multiplex are unable to locate sections 4.7.1 and 4.72 within the report.
  - 1.3.3 The report prepared by Dr Mumford and Ms Dempster, and to which Mr Mookerjee makes reference, was only produced to Multiplex on 10 June 2024 ten days before this response was required.
- 1.4 The above being said, in the limited time made available, and with a view to assisting the Inquiry, Multiplex has prepared the commentary below.
- 1.5 Having regard to Section 2(1) of the Inquiries Act 2005, Multiplex's position set out in this response is provided solely to assist the Inquiry's understanding and is without prejudice to and under reservation of any further submissions Multiplex may make or evidence it may lead in any forum.

#### 2 Commentary

#### Size of Comparator Hospitals

2.1 Multiplex has concerns about the comparator institutions referenced by Mr Mookerjee. The table below narrates the number of beds which Multiplex understands are available in each hospital:

<u>Hospital</u>	Bed Numbers
Great Ormond Street Hospital	389
Cardiff and Vale Childrens Hospital	179
Leeds Teaching Hospital	1,103, 286 children

Oxford	1,300, 100 children
QEUH/RHC	1631, 256 children

2.2 The QEUH/RHC is significantly larger and thus more susceptible to contamination. Multiplex therefore has reservations as to whether the hospitals referred to are appropriate comparators.

Patient Cohort Activity Data / Admissions Considered

2.3 Multiplex has further concerns with regards to the admission data used from comparator hospitals. The admission numbers used for 2021 are repeated below by way of example:

<u>Hospital</u>	2021 admissions
Great Ormond Street Hospital	6389
Cardiff and Vale	3257
Leeds Teaching Hospital	5747
Oxford	3252
QEUH/RHC	107

- 2.4 The dataset for QEUH/RHC is based on the number of bloodstream infections (gram negative and fungi) with a rate calculated per 1000 admissions. However, these admissions were filtered to only include admissions to wards 2A, 2B, 4B & 6A. the patient cohort are highly susceptible to infection due to compromised immune systems.
- 2.5 The same filtering process does not appear to have been carried out on the comparator hospitals. The patient cohort utilised in each comparator hospital is therefore less likely to be susceptible to infection than those in QEUH/RHC. Multiplex respectfully suggests that for a more accurate comparison to be drawn either:
  - 2.5.1 The QEUH/RHC infection rate ought to have been calculated against total admissions to the hospital, rather than simply admissions in respect of wards 2A, 2B, 4B & 6A; or
  - 2.5.2 A similar filtering process, where only patients with compromised immune systems were included when calculating the relevant infection rate, ought to have been utilised for comparator hospitals.
- 2.6 There is also no identification of the number of "day patients" in each of the hospitals considered.
- 2.7 The above clearly demonstrates the potential to dilute the comparator hospital admission/blood stream infection rates compared to a focussed immunosuppressed cohort in wards 2A, 2B, 4B & 6A of the QEUH/RHC.

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2.8 Multiplex notes that Mr Mookerjee does not accept that the "*level of deprivation of the Schiehallion patient cohort*" can account for the differences in infection rate. Multiplex would respectfully suggest that the demographic between the comparator hospitals (in particular London and Oxford) are significantly different from the QEUH/RHC. This is a further issue which calls into question whether such hospitals are appropriate comparators for the QEUH/RHC.

#### **Miscellaneous**

- 2.9 Multiplex notes that the Expert Report identifies only 2 positive lab results from 80 water samples in 2015 for wards 2A, 2B, 4B & 6A, and no positive results in 2016.
- 2.10 Multiplex notes environmental conditions have not been considered in the Expert Report.
- 2.11 Multiplex is happy to discuss this response with the Inquiry team if it would be of assistance.

#### **Scottish Hospitals Inquiry**

### NHS National Services Scotland response to the report by Mr Sid Mookerjee ('Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022.')

- In this response, NHS National Services Scotland ("NSS") responds to the report submitted by Mr Mookerjee on 9 May 2024. The comments and questions below do not seek to raise new issues not covered in the report. They seek to clarify some aspects of Mr Mookerjee's methodology in the hope that this may assist in properly understanding his conclusions. They also seek to provide the context to HPS's October 2019 'Review of NHSGG&C paediatric haemato-oncology data' in light of various observations made about it by Mr Mookerjee.
- 2. NSS acknowledges the value of Mr Mookerjee's report, and its comments and questions are offered in a constructive spirit.

#### Mr Mookerjee's methodology

- 3. The Glossary of terms at section 3 defines 'Temporality' as "In epidemiology, temporality refers to the overlap in time between the exposure and the outcome." This may be too narrow a definition. NSS notes that there may be a relationship between the exposure and the outcome without there necessarily being an overlap. For example, there may be a lag between the exposure and the outcome.
- 4. At para. 4.2, Mr Mookerjee states that the epidemiological framework adopted accounted for inter alia "ii) evidence of contamination of the water and ventilation systems, collectively referred to as the 'built environment' ". However, the report focuses on water as a source of infection, without exploring ventilation. For example, there is no reference to air samples data.
- 5. In relation to para. 4.4, NSS observes that it was not approached by Mr Mookerjee to provide information for his report. He has not listed NSS reports upon which he relied.

If he relied on NSS reports, these would have been historical reports provided to him by other parties.

- 6. In para. 6.2, the Schiehallion patient cohort is referred to. NSS notes that in early 2019, the Schiehallion cohort was housed in the Clinical Decisions Unit ("CDU"). It is not clear why the patients so housed have not been included in the analysis.
- 7. Para. 8.1.1 refers to the "QEUH and RHC dataset of blood stream infections supplied by NHS GGC, covering the period 2015-2022". NSS notes that this dataset appears to include negative as well as positive infection results, so it may be more accurate to use the term "dataset of blood culture samples".
- In relation to para. 8.2.3, NSS notes that the Protocol referred to at footnote 24 does not state that positive laboratory samples taken in outpatient settings are automatically designated Heathcare Associated Infections.
- 9. At para. 8.2.5, Mr Mookerjee explains why he uses admission data to calculate a rate of infection: "Admission data, unlike bed days data, accounts for patients' each and every interaction with the hospital and its environment, and therefore a much more precise estimate of risk for this patient cohort." NSS disagrees. Admission data provides information on the number of patients entering the unit, whereas bed days data focuses on the total time spent in the hospital unit. The use of admission data will not fully capture the length of exposure to the source under investigation. Usually investigation of the relationship between the patient cohort and the exposure to the risk would be done by analysis of the length of exposure to the risk and the outcome. The use of admission data will not capture this. Further, it is unclear whether the admission data used in the report includes every outpatient appointment. Some outpatient appointments are very short, and during the pandemic many became virtual or telephone appointments. Other outpatient appointments are 'day cases', where the patient spends a substantial time in hospital receiving treatment. Such day cases are relevant and should be included in the data being analysed. Clarification is sought as to the whether all outpatient appointments have been included in the admission data used in the report.
- 10. At para. 9.1, there is reference to "the four Schiehallion units". NSS notes that there is in fact only one Schiehallion unit. When initially created, this unit cared for its patients

in Wards 2A and 2B at RHC. Patients were then shared over three other wards -4B at QEUH, 6A at RHC and the CDU – over different time periods. This is demonstrated in the Table at para. 9.1, with the exception of the admissions to the CDU which are not shown there.

11. The chart at para. 9.10 includes linear trend analysis. NSS would be cautious about using such analysis on a small number of data points, particularly where there is such variation amongst the data points.

#### HPS 2019 Review

- 12. With regards to HPS's 2019 Review A43940545 in Bundle 7, discussed in appendix 3 of the report,, it may be helpful to firstly list the three objectives of that review and then put it into context:
  - "To describe the differences in the datasets currently being used to investigate cases of bacteraemia in patients cared for in paediatric haemato-oncology wards in NHSGG&C.
  - To review the environmental Gram-negative blood cultures in the paediaric haemato-oncology population.
  - To identify whether there is a change in the type of reported environmental Gram-negative blood cultures in the paediatric haemato-oncology population."
- 13. With regards to the context:
  - a. The HPS review was a management information document requested to support a live incident management team and drafted at pace, not a robust epidemiological study. On 25th September 2019 the CNO requested a report of all data sets being used. Data was received from NHSGGC on 10th October 2019. The first draft was issued to the chair of the IMT on 25th October 2019.
  - b. It was not intended for wider publication.
  - c. A number of caveats were set out at page 21.
  - d. It was reviewed by: Professor Chris Robertson of Public Health Epidemiology in the Department of Mathematics and Statistics, Strathclyde University; Scott Heald, Director of Data and Digital Innovation, Public Health Scotland, formerly Head of Profession for Statistics NSS and Head of Statistics at HPS; and the NSS Clinical Governance Group.

- 14. At para. 16.2.4 *et seq* Mr Mookerjee is critical of the (assumed) fact that adult data was included in the analysis. NSS would like to emphasise that, in fact, adult data was <u>not</u> included in the analysis. As per the Case Definition (page 256 of the HPS review A43940545 in Bundle 7) the study population "includes patients less than 18 years of age". As a point of clarity, all patients housed in adult wards during the study were coded through ISD (S)1 to the RHC, allowing only paediatric haematology oncology patients to be included.
- 15. At para.16.2.6 *et seq* Mr Mookerjee states there is no information on how outpatients and day cases were distinguished. The HPS report A43940545 in Bundle 7, Figure 3 (page 263), includes a key note providing the source of the data as NHSGGC.

#### Questions

- A. Mr Mookerjee states that he obtained comparator infection and activity data, via Freedom of Information requests (paras. 7.2.4- 7.2.7). NSS are unable to assess the data supplied by the comparator organisations and whether these data sets were comparative with the data supplied by NHSGGC. It would be of assistance if Mr Mookerjee could provide full details of the information sought in terms of the Freedom of Information requests to the comparator organisations.
- B. It would be helpful to have more precise information on the definitions used in the report. Can Mr Mookerjee please provide definitions for the activity data used, including:
  - a. The denominator used. Table 6.1 describing outcomes of interest refers to an incidence rate that uses total occupied bed days (TOBDs) as the denominator but NSS's understanding from other areas in the report is that the denominator used was patient admissions. Table 6.1 differs from the summary of evidence in Table 7.1, where the activity data is admissions data.
  - b. Activity data: definition for "admissions" (Table 7.1)
    - What is included in this measure? E.g. outpatients, inpatients, day cases.
      What were the definitions for each subcategory? Mr Mookerjee notes that patients attending outpatient appointments received invasive treatment- how does this differ from day cases and how are outpatient

appointments without interventions distinguished? What were the inclusion/exclusion criteria?

- ii. Mr Mookerjee states in Table 7.1 that activity data for paediatric haematology was sought from the comparator organisations. This would suggest that this data may not be comparable with the GGC patient cohort (haematology-oncology as detailed in para. 7.2.2). Clarification of this is sought.
- iii. Were time parameters applied to include admissions only during the time that patients were resident in the wards e.g. 2A, 2B, 6A, 4B?
- iv. Were adults admissions excluded from the denominator (noting that infections in patients less than 19 were excluded, per para. 8.1.11)? Was the same applied to the admission data?
- were admissions from all of 2015 (as per paras 5.2, 6.2 and Table 7.1) included or only from the move to QEUH/RHC in June 2015? Patients were cared for in Yorkhill Hospital prior to that date.
- vi. In addition to para. 8.2.3, can Mr Mookerjee provide further detail on the rationale for inclusion of outpatient activity in the denominator? Were the location and nature of these appointments explored? E.g. were the appointments held in the wards of interest in regards to the environment, were some appointments delivered by phone particularly during the pandemic, did they involve any clinical intervention?
- vii. In addition to paras. 8.2.4- 8.2.6, was any consideration given to the limitations of using an admission denominator that does not account for patients with extended lengths of stay given the exposure of interest is the environment and this cohort of patients may have had extended lengths of stay? The risk associated with an outpatient appointment and with an extended length of stay in the environment is not equal, as a purely admission denominator would imply. An understanding of the rationale would assist NSS in its assessment of Mr Mookerjee's conclusion that "admission data is a much more precise estimate of risk for this patient cohort" (para. 8.2.5), as this is not the position of NSS.
- viii. In relation to the table at para. 8.2.8, was the decrease in the number of patient admissions explored and does Mr Mookerjee have information on quality assurance checks carried out to rule out an artefactual

decrease? This decrease coincides with the year that patients were transferred over from Wards 2A and 2B to Wards 4B and 6A- was a coding issue that may have affected the activity data explored? It would be unusual for such a decrease in activity even during the pandemic years, as this patient cohort would continue to be treated and meet with their clinical team. Some outpatient appointments where there is no clinical intervention may have been carried out virtually during the pandemic. Further clarity on the definitions and inclusion/exclusion criteria for the admission data is required to understand whether this decrease is artefactual. This is critical to understand the changing rates of infection as included in the report.

- C. Can Mr Mookerjee please provide definitions for the infection data used including:
  - a. Infection episode case definitions (para. 8). This includes a request for the deduplication criteria used, mentioned at para. 8.1.13.
  - b. How were inpatient and outpatient specimens defined and identified?
  - c. Were infections extracted for the ward locations only during periods when the patients were cared for in that area? Or was this done by proxy by inclusion of an age parameter?
- D. In the report's summary of findings (paras. 9 and 10), there is no express reference to significance testing. Significance/hypothesis testing e.g. calculation of p-values and confidence intervals can demonstrate that the results from analyses are not the result of random variation. It is not possible confidently to interpret the key findings without acknowledgement of and controlling for the effects of chance/random variation. This is particularly relevant to incidence rate ratios (paras. 9.2- 9.7), linear trends and time series analysis (paras. 9.9- 9.11, paras. 10.6- 10.8), and correlation coefficients (paras. 10.2- 10.3). Can Mr Mookerjee please explain what significance testing was undertaken?
- E. Can Mr Mookerjee please provide further explanation of the inclusion and exclusion criteria for the infection rate and water positivity rate correlation analyses (paras. 10.2 and 10.3)? He states that the water positivity data from 2020 was excluded from the analyses due to the consequences of access to clinical areas during the pandemic (para.

10.5). Did he have any information to suggest that the 2020 data is biased and should be excluded? There were 1469 samples taken in 2020. This is in contrast to the much lower number of samples in 2015 (n=80) and 2016 (n=47) - both years were included in the analysis. NSS notes that the inclusion of the 2020 data may change the correlation coefficient and a key finding. NSS also notes that the interpretation of the Pearson's correlation coefficient in para. 10.3 states water positivity increases over the period 2015 to 2019. The purpose of a correlation analysis is to determine the association between water positivity and infection rates and it does not provide evidence for an increasing or decreasing trend over time.

- F. NSS notes the use of correlation analyses on a small number of data points at para.10.2. Can Mr Mookerjee share the basis for this approach, ie the use of such a small number of data points to draw conclusions regarding a correlation between water positivity and infection rates?
- G. At para. 11.1, Mr Mookerjee refers to use of the correlation measure to understand the association between rates of water positivity and the undertaking of mitigation and remedial actions. These data are not presented nor is the quantitative measure for remedial actions described. Please can he provide further detail on the analysis undertaken.
- H. Mr Mookerjee does not expressly refer to the principle of confounding in the report. Whilst it is appreciated that multivariate analyses were unlikely to have been possible for this review, acknowledgement of this epidemiological issue, and how it was considered, is critical to interpretation. This issue is particularly important to consider in the interpretation of the Incidence Rate Ratio comparing the NHSGGC rate with the comparator organisations (paras. 9.5-9.7). Please can he explain what additional analytical work he undertook to assess the comparability of the cohorts?
- I. The report indicates that there was a marked increase in water samples taken in 2018 (see the Table at para. 8.4.19). It would be helpful if Mr Mookerjee could explain what consideration he gave to the cause of this increase? Did he consider that this increase in testing may be in response to the IMT investigations? Were the biases this would introduce considered in the interpretation of the data? The correlation between water

positivity and infection rates may be affected by such bias - was this considered in the interpretation of the correlation analysis?

National Services Scotland 20 June 2024



SCOTTISH HOSPITALS INQUIRY Bundle of documents for Oral hearings commencing from 19 August 2024 in relation to the Queen Elizabeth University Hospital and the Royal Hospital for Children, Glasgow

> Bundle 21 - Volume 3 Responses to Expert Report of Sid Mookerjee