SCOTTISH HOSPITALS INQUIRY

# Hearings Commencing
# 19 August 2024

Day 38
Wednesday, 30 October 2024

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**THE CHAIR:** Good morning everyone. Now, Mr Mackintosh.

**MR MACKINTOSH:** Our first witness today is Professor Mike Stevens from the University of Bristol.

**THE CHAIR:** Yes. Now, you say, "The first witness." I think he's probably the only witness.

**MR MACKINTOSH:** He is the only witness, but it's always good to keep ourselves on our toes.

**THE WITNESS:** Good morning, my Lord.

**THE CHAIR:** Good morning. (After a pause) Good morning again, Professor Stevens. As you understand, you're about to be asked questions by Mr Mackintosh, sitting opposite to you but, first, I understand you're prepared to take the oath.

**A** I am.

**Professor Mike Stevens**

**Sworn**

**THE CHAIR:** Thank you very much----

**A** Thank you.

**THE CHAIR:** -- Professor Stevens. We have your evidence scheduled for the morning and the afternoon. I don't know if we'll take all that time or not. We will take a coffee break at about half past 11. If you want a break at any other time, just give me an indication, and we'll take a break.

**A** Thank you very much.

**THE CHAIR:** Right. Now, Mr Mackintosh.

**Questioned by Mr Mackintosh KC**

**Q** Thank you, my Lord. Professor Stevens, I wonder if I can take your full name and your current occupation.

**A** Yeah. Michael Charles Gaston Stevens, and I don't have an occupation. I'm retired.

**Q** Do you still hold an emeritus chair?

**A** I do hold an emeritus position at the University of Bristol.

**Q** What's that one?

**A** Emeritus professor of paediatric oncology.

**Q** We've asked you to produce two documents: a statement and a short supplementary statement.

**A** Yes.

**Q** Are you willing to adopt those as part of your evidence?

**A** I am.

**Q** Yes, and you were the chair of the case notes review into 85 children with infections at the Royal Hospital for Children.

**A** I was.

**Q** How did your involvement in the case notes review come about?

**A** Well, I'm assuming that there were certain wheels turning in the background but, essentially, when I was first aware of the forthcoming Case Note Review, it was when I received a telephone call from the then Chief Medical Officer, Catherine Calderwood, who telephoned me, essentially, out of the blue to discuss whether I would be interested in taking the role, and giving me a brief background to the concerns that were to be investigated.

**Q** What was, in broad terms, the intended structure or methodology of this review as it was pitched to you in that initial phone call?

**A** I don't think that initial phone call covered any structure or methodology. It was a statement of my preparedness and I think it hinted at the terms of reference, but there was no granularity about that conversation.

**Q** When did any idea of that granularity come, certainly, to your attention?

**A** Well, I mean, following that conversation I think the next thing that happened was a telephone conference that involved Fiona McQueen, who was then the Chief Nursing Officer. I think that's the correct title. Then, in January of 2020, I paid at least a couple of visits – one here to Edinburgh and one to Glasgow – to start to shape my engagement thoughts and start to meet some of the people involved.

**Q** How many of those physical visits happened before the other two members of the expert panel were recruited?

**A** Well, there was certainly those two visits. I didn't meet Mark Wilcox and Gaynor Evans until what is really identified now as the first meeting of the panel, which I think was 24 February 2019.

**Q** Was that an in-person meeting?

**A** That was an in -person meeting, yes.

**Q** Could that well have been the only in-person meeting that the three of you had, given what happened three weeks later?

**A** I think it was, actually. I think it was the only in-person meeting. We felt like we knew each other very well by the end of the process, but we hadn't been in the room together except that once.

**Q** Where was that meeting?

**A** It was just along the road here.

**Q** Right.

**A** I can't quite remember where it was. It was in a hotel, actually. In a boardroom at the hotel.

**Q** Now, before you they became involved----

**A** Yes.

**Q** So, they must have asked you, "What are we doing?" How did you explain to them what you understood the nature of the piece of work to be?

**A** Well, actually, I had no contact with them at all prior to the meeting in February 2020. The names were essentially given to me of these two other people who had agreed to on the same panel which I had been asked to coordinate, and we met in a kind of round table format. So we didn't have that opportunity for private conversations, although after that when we started meeting independently, we started to explore together exactly how we were going to approach our task.

**Q** If I'd asked you at the beginning of that meeting, "What's this project? What are you going to do?" how would you have described what you thought were going to do at 20 February?

**A** Well, I think the task for the meeting in February was to agree the data set.

**Q** Yes.

**A** The data set had essentially been presented to us, but we were being asked to endorse it, and to talk a little bit about how the data gathering would be affected, although even that wasn't desperately clear at that time, and became less clear, of course, with COVID.

**Q** Of course. Who else was, as it were, in the room at that meeting?

**A** I did have a piece of paper with that written down on, but I haven't got it with me, I'm afraid. There were representatives: of HPS; of Scottish Government; there were-- Pat O'Connor, who led what we describe in our report as the PTT team, was there; the three of us; I think I'm correct in saying that Lesley Shepherd was there, who is an Infection Advisor to Scottish Government----

**Q** Were you aware of----

**A** Chief Nursing Officer----

**Q** Sorry, say that again.

**A** Phil Raines, who worked in the Chief Nursing Officer's department was there. There were possibly 12-- about 12 of us, I would have thought----

**Q** Were you aware of whether Professor Marion Bain was there?

**A** Yes. Marion Bain I believe was there, yeah.

**Q** Now, I appreciate you're coming up from Bristol, and the nature and the structures of Scottish Health may well have been a closed book to you at the time, but what job do you think Marion Bain had at that point?

**A** My understanding was that she was part of the Oversight Board, and that she had been asked to take an interim role in overseeing Infection Prevention and Control at GGC. That

was my understanding.

**Q** Now, one of the things that I'll come back to my questions later is the GGC response to your work.

**A** Yes.

**Q** I want to just at this point, as a sort of precursor, try and understand from your point of view at that point whether there was anybody who was, in a sense, a 100 per cent Greater Glasgow Health Board, either a clinician or manager or clinical manager, present in those early meetings that you're aware of.

**A** They weren't present at that specific meeting, no. I was aware that that was a concern, and I did go back and check the membership of that first meeting, and I don't think-- there was no one from GGC management. In the January, I had been to GGC. I had been to----

**Q** Who did you meet in January?

**A** I met Kevin Hill and Jamie Redfern, who were managers for the Women's and Children's-- or the Children's Hospital, and I think Kevin Hill was Women's and Children's Divisional Director. I met Jennifer Rogers, who was previously the Senior Nurse for Haematology and Oncology. I met Professor Leonard. I met Pamela Joannidis, who was an Infection Prevention Control Nurse.

Essentially, these were briefing meetings. I viewed them as briefing meetings.

**Q** They were briefing you at that time?

**A** Yes. I mean, I had no knowledge of really anything that had gone on or how the organisation was arranged. I had a tour of the building. I saw Ward 2A and 2B, which was, at that stage, a building site because they'd already removed the patients from there. I'm just trying to remember if I-- I met Marion Bain. I'm trying to remember if there was anyone else. I certainly didn't meet anyone at the Board level at GGC at that point.

**Q** Did you meet any of the haematology oncology consultants?

**A** I did have a meeting with them, and I think that was on the same day as my, sort of, sighting visit to Glasgow. I had a meeting with them. They were inevitably quite suspicious of what we were doing----

**Q** Yes, because a bloke comes from Bristol who's someone they've never heard of.

**A** They weren't happy, I think, and I recognised that they'd been having a very difficult time, actually.

**Q** So, one of the pieces of evidence that we've had is that, in September of 2019, a number of the paediatric oncology consultants had

written to senior managers and suggested an external review.

**A** I wasn't aware of that.

**Q** Right. So, it's not like they said, "Hey, great, the external review has arrived. The man we wanted." That wasn't the things you were being told at the time?

**A** No, I didn't-- I mean, it didn't feel like that, that I was riding in on the white horse for them, no, not at all.

**Q** One thing I think will come up again is the extent to which those meetings in the hospital when you visited would have covered the nature of the methodology or the remit or the terms of reference.

**A** No, I don't think it did at all. I felt I was there to ask them questions and to understand what the challenges were from their perspective, you know, the issues around Ward 2A, and why the patients have been moved out, and what they were doing, and a little bit about their infection-- their IPC process.

**Q** Did you meet any of the Infection Prevention and Control team, other than Marion Bain?

**A** I met Professor Leonard and Pamela Joannidis.

**Q** Right.

**A** I can't quite remember where Pamela Joannidis was in the hierarchy but----



**Q** At that time, I think she was a nurse consultant in the Infection Prevention and Control----

**A** Right, thank you.

**Q** Well, that's really helpful. What I wanted to do was to look a little bit at the choice of the cohort that arose----

**A** Yes, of course.

**Q** -- because it seems to have come up. Now, you've discussed it in your statement. I want just basically to make sure I'm talking about the right document. I wonder if we can just put Bundle 7, document 5, page 214 on the screen. So, this is the draft – we have it simply because it doesn't have the redactions in it – of October 2019 HPS review of GGC paediatric haemato-oncology data. Now, this document is something you've seen before?

**A** Yes, although I have to say this document did cause me confusion from the outset because it was initially referred to as a-- to me-- it was referred to me as a report in November 2019, and it was only very recently that I discovered there are actually two versions of this document, one which we----

**Q** Yes, if we go to page 250, we can see the next document.

**A** Yes. Okay, but they're both dated October 2019.

**Q** They are, yes.

**A** Although I understand that the

redacted version was the one that was published in November 2019.

**Q** Yes, that seems to be the order of events. What's your understanding of how this document is connected to your-- Is “cohort” the right way to describe your patients and your infections?

**A** Yes, you could call it a cohort, yes.

**Q** And how is this document connected to your cohort, from your point of view?

**A** Well, I think there are two connections. I think the principal connection is that the work that HPS did for this document more or less defined the cohort that we were going to investigate. It wasn't entirely the cohort, but they had done some work looking at several different databases, bringing them together and trying to identify the completeness of data collection under different headings, as it were.

**Q** So, if we go to page 223 in that bundle, we see a comparison of a different set of datasets. Is that effectively the exercise you're talking about?

**A** Yes. Yes.

**Q** There was evidence from one of the production team behind this document that the effective conclusion they draw from this piece of work is that all these data sets are discussing roughly the same sort of thing that's behaving in roughly the same sort of way at roughly the same sort of time.

**A** Yes, although I think there was also a kind of sub-message that maybe the CLABSI dataset was the less comprehensive, but the CLABSI dataset I'd always considered to be being used in GGC for a slightly different purpose.

**Q** So what was the issue that you saw with the CLABSI dataset?

Well, the CLABSI dataset-- I mean, I think all children's cancer units look at central line-associated bacterial infections, and I hope it came across in our report that we acknowledge the work that was done at GGC to drive down the incidents of CLABSI infections, but that's largely focusing on an entirely different group of bacteria. It's focusing on gram-positive bacteria, because the commonest cause of central line-associated bloodstream infections relates to Staphylococcal infections, and these are commensals on the skin and very readily get into central line-- the semi-permanent intravenous access that these children have.

**Q** And it's possible in a unit which has that problem to take steps to reduce those by improving practice, in essence.

**A** Yeah, just improving-- I mean, there's some basic IPC stuff like

handwashing, but there's some more technical things, like the dressings you use to put over the site of the central line and so on, and I think GGC did a great piece of work in looking at those issues. They had a working group. But, although they claim that this reduced the incidence of infection, the infections that they reduced were not the ones that we were interested in.

**Q** Yes. I mean, well, one of the questions that does arise is why this cohort – and, of course, this cohort includes people, so one has to be careful about treating it as an object – was the right cohort to look at, because we know that, obviously, the minister made an announcement, "There shall be a case notes review." You were appointed to lead it. In what sense do you feel sufficient thought was given to the question of whether this cohort was the right cohort to look at?

**A** Well, my understanding and my belief now is that this was the right cohort because essentially there was clear concern at the time we were appointed about the water system in GGC, and I think there's greater clarity about that now, but that's certainly outwith my expertise; and so we felt that that in order to explore the potential for environmental transmission of infection, you needed to be looking at a group of bacteria that essentially liked wet environments.

**Q** Yes. These are the ones you described----

**A** These are the wet ones.

**Q** --as the gram-negative environmental bacteria.

**A** Yes. Yes. But it includes, of course, also some bacteria which are described as enteric. That's why the label is sometimes gram-negative environmental enteric, which are bacteria that also are routinely found in the gut, for example, like Klebsiella.

**Q** Yes, I'm going to come back to Klebsiella. Well, I can probably do it now, usefully. One of the issues that seems to have arisen in this Inquiry is how does one tell whether an infection or a number of infections happening in roughly the same timeframe are enteric, that have somehow broken through from the gut, or have come from another place, for example, water. The patient is----

**A** Okay.

**Q** And I'd be interested to see what, in a sense, you would be looking for if it was one-- if it was enteric. If you had an enteric case, how would you spot that compared to environmental as a clinician treating the patient?

**A** Well, I think it's important to preface the comment with, "There's no perfect measure." There's no test you

can do to say, "This is an endogenously/ within the patient acquired infection versus an external infection," but the things that you would look for are some of the common complications of patients receiving chemotherapy, which are evidence of damage to the mucosa of the gastrointestinal tract, starting at the mouth and going to the anus, essentially; children with severe mucositis – that's ulcers and soreness of the mouth and throat – patients who develop abdominal pain; sometimes, in severe infections, abdominal distension; sometimes it's radiological change that suggests that there is serious inflammation of the gut mucosa, diarrhoea.

And so there's a constellation of clinical signs and symptoms that you would look for, and which we did routinely try to ascertain from the case notes in relation to making that judgment, you know, "Is this Pseudomonas infection likely to have arisen because of severe damage to the gut, or actually could it have come from the environment?"

**Q** Well, we'll pick that up in detail as we go. What I wanted to do was look at the epidemiological protocol which was produced, which I understand you might have seen at the time.

**A** I have.

**Q** So this should be now in bundle 27, volume 6, document 24. That's the one. So this-- What is the-- When did you see this?

**A** I probably saw it on the cusp of January, early February. It's dated February – I don't know whih day in February – but there was a certain amount of email transmission, because prior to the meeting at the end of February, the big round table meeting when we all got together for the first time, I was involved in a dialogue with HPS-- representatives from HPS facilitated by Phil Raines, who was the operating officer for this process, about the data that we would be needing to collect to inform our work, and when I saw this document, I wasn't entirely sure that this was what I had in mind, I suppose. There's a rather large appendix to this document----

**Q** Yes, there is.

**A** -- which I didn't feel was informative, as far as I was concerned, in terms of what I was looking for.

**Q** But couldn't, in some ways, it be described as a sort of shopping list of what data you wanted and a plan of how to deal with it?

**A** Yes. I had already actually started to write my own list, and so I produced a list and they produced a list, and I think we moved forward – perhaps not smoothly, but in steps – to identify what it is that we wanted, and then the

next step, of course, was how we were going to get it.

**Q** Well, indeed, because without going through the document line by line, most of the data is GGC data. Patient data, Health Board data.

**A** Essentially, it's all GGC data as far as I'm concerned.

**Q** So, from your point of view, this is an epidemiological protocol that you've been involved in producing with people from HPS?

**A** Well, I didn't produce this protocol. No, this was them----

**Q** But you read it, have you?

**A** I read it. I read it, and I'd got my own list, and I think I'd already sent in a list saying, "Well, this is what I want," and there were things they were suggesting and I was a bit surprised about, perhaps, and also I didn't understand at the time that HPS was going to have a role in extracting some of the information that they identified, like antibiotic doses, but in fact they were able to do that. So we eventually teased out who was going to provide what, and in the end it didn't matter as long as I got it.

**Q** Well, I appreciate that, but one of the things that's slightly thrown us is that it's our understanding – and you can comment on this – that this actual document might well never have been shown to Greater Glasgow and Clyde Health Board.

**A** I've no idea.

**Q** I suppose this is the moment to pick up and explore the privacy data of what you had and how it was ultimately distributed. So, you collected in a lot of data almost entirely from Greater Glasgow.

**A** Yes.

**Q** You conducted a process which we will discuss in a moment, and your outputs are, what, the overview report and 85 individual patient reports?

**A** Yes. Well, I think there's three outputs. There's the overview report. There's what we call our data synthesis, and there are some templates----

**Q** That's at the end of the overview report.

**A** At the end of the overview report, which is how we collated, managed and interrogated the data, and then there was the direct correspondence with the parents, and that was when we wrote to every family with our interpretation. We didn't just send them our data synthesis. We sent them certain extracts and we put some narrative around it and also offered them support and the opportunity to meet us. Then finally, for a selected group of patients who requested meetings with us, there was further correspondence.

**Q** And in that correspondence with the families, who was to see that correspondence other than the families?

**A** No one.

**Q** What was the reason for that, as far as you understood it?

**A** Well, I think it was made very clear to us-- and, to be fair, I can't be absolutely sure whether it was an edict or a sense that I acquired, but it was made very clear to us that the parents of the children concerned had had a pretty difficult time in terms of understanding what had happened to their children and what indeed had happened to the service on which their children relied, and it was clear to me/to us, as the three of us, that we were undertaking this task for those families. In large part not only for those families, because other people were going to see our report, but we were encouraged-- and I believe rightly we were encouraged to assure families that the details of their child's individual journey through these infections was not going to become public knowledge unless they wished it to be. Now, that did create some difficulty with the clinicians who said, "Well, you know, how can"----

**Q** This is clinicians in-- haemato-oncology clinicians.

**A** Yes, and, I mean, I can understand their sense. They were saying, "Well, how can we possibly respond to this unless we know?" and we agreed that we would encourage families to allow us-- to give their permission for us to share the information with their treating consultants.

**Q** And in, sort of, very broad terms, was that an offer that was taken up or not?

**A** It was about a quarter of the families, and in fact when I was preparing, I realised that there's possibly a document that the Inquiry doesn't have, which was a final, final report, because I've not seen it in any of the bundles, and I should perhaps have brought it to your attention, but there's a final report I wrote to the cabinet secretary----

**Q** Well, no, we'd be very interested in that.

**A** -- in July-- at the end of June, where we essentially say, "We've now finished our relationships-- our communications with the families. We've met families, and this is the upshot," and we summarised what the feedback from the families was, and we also attached to it a redacted sample of a letter to a family to give some idea of what the families received, and I do apologise, it was only this week when I realised that-- possibly that-- I don't quite know how that has----

**Q** Well, we also check that we haven't inadvertently missed----

**A** Okay.

**Q** -- it as well, but the question I wanted to ask that arises from that is, obviously, you produced your report after this Inquiry was set up----

**A** Yes.

**Q** -- and, from the Inquiry's point of view, your conclusions are certainly of interest, that's why you're here giving evidence----

**A** Yes.

**Q** -- but also, we've noticed – we'll come to them later – the comments that were provided by Greater Glasgow and Clyde to the draft that you sent them a month or so before publication. To some extent, is it a fair observation that to truly understand the reasons for your ultimate conclusions as to the likelihood of links over the whole 85 people, you'd actually have to read all 85 individual-- at least data summaries, if not the letters to the families, to truly understand the granularity, as you put it, of what's going on inside. Is that a fair comment, or am I----

**A** No, no, that's absolutely-- That's absolutely true. I think the letters to the parents would add a dimension, but essentially what you would need to do is look at our data synthesis outputs and try and follow the reasoning with-- by which we allocated different levels of potential.

**Q** Well, I'll come back to the reasoning and I'll come back to Greater Glasgow's response to your draft because I think both of those are related.

**A** Yes.

**Q** So, what I want to do is to look at the report itself, which is on Bundle 6 at page 999, and your term of reference, just to sort of wrap this bit up.

**A** Yes.

**Q** So, you set out the term of reference in this section. Now, what you don't actually do, which is a slightly strange thing, if you don't mind me saying so, is just write out-- cut-and-paste in a term of reference. You almost read as if you're summarising it. Is that a sort of fair critique of this part of the report? Is there an external document that we haven't seen that sets out the term of reference? "Dear Professor Stevens, please do X"?

**A** Yes, no, there is a-- There is a document. There is a document that sets out the terms of reference, which is reproduced here, and I think it says at the top of----

**Q** Page 100(sic)?

**A** Yeah, page-- A the top of this page that's on the screen, it says:

> "This chapter presents the terms of reference as written for and agreed by the Core Project Team and the Oversight Board in March, but we've added notes [it says] to indicate where we've made important adjustments."

So essentially these are the terms of reference. We didn't tamper with the terms of reference. We had an opportunity to comment on them before they were finalised, but these are the approved terms of reference.

**Q** So, how would you describe the task you were asked to do? You've gone through all the process. You've had the meetings in January. You've had the roundtable meeting in March. We went into the pandemic. This has been agreed. Not that you'd have met anybody at that point, but if you met somebody at that point and they said, "What are you up to?" in simple terms, what were you being asked to do?

**A** Well, if someone had said, "I've got one patient, I'd like you to look at it," I would say I'd do a root cause analysis.

**Q** Right.

**A** If you've got 85 patients, you have to do essentially 85 root cause analyses, and then you have to write a report that synthesises 85 root cause analyses, and I think that's what we tried to do.

**Q** When you say a root cause analysis, clearly you've discussed how you had access to-- you looked at the medical records in the report----

**A** Yes.

**Q** -- and we've looked at all the other pieces of data listed at section 11 of your overview report, and Ms Evans has described yesterday in some detail looking at water testing results, looking at maintenance records; the report describes looking at cleaning records, IPC audits.

**A** Yes.

**Q** There's discussion, which we can come back to, about the role or absence of a role for whole-genome sequencing in this exercise, but one thing that seems to be missing is a comparison between this unit and what was going on in Ward 2A and the Schiehallion unit from '15 to '19 with a comparable unit elsewhere in the country, and I wondered-- We can talk about the merits of that later, but why is that not within something that was set out as part of the term of reference?

**A** The short answer is I'm not clear, because the terms of reference were -- I think essentially the terms of reference were the Scottish government's terms of reference.

**Q** Right.

**A** My second answer is that the HPS 2019 report did make an attempt at comparison within Scotland, looking at the other units, and my third answer is that I did not know then and I do not know now how you would acquire that information, although Mr Mukherjee

clearly did by a freedom of information request.

**Q** I'll come back to that after lunch, I think.

**A** Yes.

**Q** What I wanted to do then is to think about your pathology because you've discussed it from page 121 of your statement, paragraph 157 of your statement, but probably the best place to look, sorry, is actually page 1015 of Bundle 5-- My Lord, 6. Sorry, that was entirely misspoken on my part. 1015. Now, what I'd like to do is to not spend too much time on this seemingly quite complicated flowchart but to use it to go and look at the templates at the end of the document and perhaps see if we can understand how you carried out these individual 85 root cause analyses.

**A** Yes.

**Q** We've had some evidence from Professor Wilcox and from Ms Evans already.

**A** Yes.

**Q** So, within this flowchart, figure 3.2, can you explain the process? Because it does feel like one of those flowcharts where every box is connected to every other box. So, what's happening inside the blue box?

**A** Well, I think the blue box essentially was work that we had direct control of, I suppose. You know, there were people within our wider team collecting these data. What's inside the red box is broadly the information-- well, in fact, entirely the information that we requested from GGC or other sources.

**Q** It's effectively the information listed in the epidemiological protocol, or your original list?

**A** Well, it certainly includes-- I mean, without going back and looking at that protocol, it certainly includes what's in that protocol, but I think there's more in here than----

**Q** Right. So, basically, the red box is principal data sources and the blue is the process?

**A** Well, the blue is both the process and the collection of some pretty basic information about the nature of the child's illness, the dates of admission, the dates of the infection, the dates at which the child moved around the hospital, and you may want to get into the detail about how we knew all that.

**Q** Well, I think it'd be helpful, but what I'd like to do is start, if that's the right place to start, with what you're taking from the child's medical records themselves----

**A** Okay.

**Q** -- and that seems to involve the PTT Team.

**A** Well, it did. I mean, it only involved the PTT Team because of

COVID because, you know, I had envisaged that, as the clinical member of the case note review, I would probably have to spend some time reviewing case notes myself and----

**Q** Literally in Glasgow, probably?

**A** Literally, and, you know, that was my expectation, that I would be coming to Glasgow and getting access to case notes and extracting the clinical information that I perceive to be relevant to the episode of infection for each child.

**Q** So, obviously you weren't able to do that----

**A** I wasn't.

**Q** -- but if you're doing that exercise 85 times, how do you ensure that you're consistently looking for the same sort of events and information in a set of medical notes 85 times?

**A** Well, by having a pro forma, which I think is what you see as one of our appendices.

**Q** Well, let's look at the appendices, so we'll go to----

**A** Appendix D, Part 1, the data set.

**Q** Yes. So, that is on page 1109. So, what would be helpful is if you could-- Well, maybe not every line, but give us a feeling for the sections, why each section is there, what purpose it's serving in the collection of this data set? Obviously, "other" is easy to understand, but----

**A** Yes. I mean, some of the labels in this pro forma relate to the way that these items were organised in previous versions. I mean, I think the labeling "other" is a slightly odd-- It's an identifier, I suppose. You know, gender, date of birth, and so on. We wanted to know something about the child's cancer diagnosis, because that would then give us insights into the intensity of treatment, the type of treatment, the duration of treatment, and the risks of that treatment.

**Q** So, hopefully, treatment protocol is going to be quite information-heavy?

**A** Yes, and most-- The way children's cancer care is organised in most developed countries and certainly in the United Kingdom is that, wherever possible, children with the same diagnosis are treated on the same protocol throughout the country so that, in Bristol, I would be treating a child with acute lymphoblastic leukemia in exactly the same way as a child with acute lymphoblastic leukemia is treated in Glasgow.

**Q** So, if you knew what the protocol-- If they just described the protocol there, you would know what it was.

**A** Yes.

**Q** You wouldn't have any translation errors?

**A** Yes, and now that-- You know, protocols are not simple documents and there's many different avenues you could go down, but in terms of a sense of overview, I knew I would know instinctively the burden of therapy, the complexity of the therapy, and some of the nuances of decisions that might have to be made to change therapy.

**Q** If there was a protocol being applied to a patient that you hadn't recently dealt with in Bristol, you would be able to look at the protocol and pull out that information from it?

**A** Yes. I mean, so, a child with a kidney cancer, Wilms tumour, I would know-- I mean, you know, I would know what the approach to treatment was, both in Bristol, London, Leeds, Glasgow, Edinburgh. You know, it's a-- There's a national organisation that coordinates between children's cancer centers.

**Q** Okay, and then, in terms of the delivery of the treatment in the past 30 days, what sort of data would we find in there, because that possibly is quite a detailed box?

**A** Well, that was actually quite hard, I have to say. The detail of that-- What we were probably looking for most was whether chemotherapy in particular, or perhaps radiation but less frequently, or surgery had been initiated/utilised in a period of time prior to the infection. 30 days was an empiric margin. We've considered that that was a sufficient period before the infection for any treatment variation or any treatment implementation to have had an influence.

**Q** So, effectively, you're looking for a treatment that might have had an effect that you need to take account of in this thought process?

**A** Yeah, I mean, if a child had had a major operation two weeks before the infection – particularly, say, for example, if it involved the gut – you know, that would automatically raise for me a question, "Well, you know, could that intervention have had an impact on the cause of the infection?"

**Q** Right, and then in terms of microbiology?

**A** Well, in the microbiology-- Essentially, the microbiology was delivered to us by HPS, actually.

**Q** Right, so that comes out of HPS.

**A** We didn't extract that from the case-- They extracted that and they presented it to us: the nature of the infection, genus and species. There's a small point there under item 12 about category for inclusion because there were actually-- I mean, it's a sort of slightly subtle point, but there were three groups within the cohort. There was-- Do you want me to expand?

**Q** Please do.

**A** Well, there was the largest group, which are the children with the gram-negative enteric-- environmental enteric infections. They were the lion's share. The second group were the three children with Mycobacterium chelonae, and the third group was it had been left open that a family could ask for their child to be included in the case note review if they wished, and there was one family that asked to be included because that child would have been excluded because they didn't have evidence of a bloodstream infection. It was a child who had a Pseudomonas infection. In fact, a very severe Pseudomonas infection, but never had a positive blood culture----

**Q** I see.

**A** -- but had multiple cultures of Pseudomonas from sites, and so that child was included even though he patient didn't fit the criteria for the selection to the cohort. So there was that one. So, we still reviewed that case.

**Q** Yes.

**A** We provided that-- We made a judgment, and we provided the information to the family.

**Q** And so apart from category item 12----

**A** Yes?

**Q** All these other rows in Microbiology are (a) provided by HPS and are (b) just presumably is pulled from the records of the hospital, and they all refer to that particular patient. They're not telling us the context in terms of other infections nearby that comes elsewhere?

**A** Yes, that comes elsewhere, which I can talk about now or later.

**Q** Well, we'll get on to it. Let's look at the infection episode.

**A** Yes.

**Q** Again, a lot of data here. How is this being pulled into your process?

**A** Well, some of this came from the HPS team. For example, admission dates they were able to provide. They were able to provide ward and bed locations to us, but most of the other stuff within this section was from data extraction-- sort of crude data extraction from the clinical record.

**Q** And this will involve the paediatric trigger tool? To some extent?

**A** No, it doesn't involve the paediatric trigger tool. I think it's probably quite important that we could have a short conversation----

**Q** We're going to come to that. We can have a-- Let's get to the end of this section, then we'll pick up that delicate topic of confusion.

**A** Okay, thank you.

**Q** So, most of this is coming from the medical records, and this effectively is what you would have been doing sitting in

a room in Glasgow if there hadn't been a pandemic, probably?

**A** Yes, or I would, you know, once I realised the scale of the task I probably would have got someone to help me too, and in fact I did have someone who helped me. I had a I had a paediatric trainee who worked with me to extract some of this data.

**Q** Right. Let's have a topic conversation about the paediatric trigger tool, because there has been some confusion. As I understand it, some people thought that the paediatric trigger tool was deciding whether the case was going to be in the cohort. That's not right?

**A** No, not at all. I think I've made clear, but I'll say it for clarity now. I didn't understand why we were obliged to have the paediatric trigger tool as part of the case note review----

**Q** Right.

**A** -- but it had been decided that we should----

**Q** Somewhere presumably within HPS or----

**A** No, no, no, not within HPS. It was within the chief nurses director at the Scottish Government. In fact, I think specifically it came from Diane Murray who was the assistant chief nurse. It was felt that this was an opportunity to use a well-defined and accredited tool to look at measures of potential alerts within the care of patients to identify whether there could be lessons drawn by the organisation for future improvement of healthcare, and that's a motive that's very noble, very valuable, but I didn't see personally how it lay alongside what we were trying to do.

**Q** So, in a sense, it's slightly contradictory in that your exercise we're looking at here is about pulling data.

**A** Yes.

**Q** You're spotting when things have happened, when they happened, what happened.

**A** Yes, but that's the data I'm interested in. The trigger tool is looking across a whole range of markers and, you know, you can see in the Appendix there's a template for the trigger tool.

**Q** And so am I right in thinking therefore from your explanation that the purpose might have been that use of the trigger tool would enable lessons to be learned about when in the future people should be alert to----

**A** Yes, but the trouble is I did have difficulty with some of the domains within the trigger tool because the trigger tool has been defined for it within general paediatric populations across a range of patients, and so for example----

**Q** Well, we can just briefly look at it. It's 1107.

**A** Yes, so, I mean, perhaps I can, you know----

**Q** There's a couple of ones that sort of stand out – if we go to 1107?

**A** So----

**Q** Maybe we zoom into half a page because it is awfully small?

**A** Yes, well, if you look at PL15----

**Q** So, if we go to the second half of the page, please? Over on the next page, actually.

**A** It may be on the next page.

**Q** In fact, it's on 1109 – yes.

**A** PL15, go down, yes. PL15, Thrombocytopenia, this is when the level of platelets are low in the blood and this trigger tool would be flagged as positive if the platelet level was less than 100.

**Q** Yes.

**A** Now, that's such a routine occurrence when you're giving chemotherapy, quite frankly it's of no merit. It just is unimportant. PL2, giving a blood transfusion, we give blood transfusions all the time to children having chemotherapy. So the specific relevance of some of the triggers-- I'm not saying it negates the whole exercise, all I'm saying is that some of these things didn't strike me as being triggers at all, because they're innate to the whole pathway of care.

**Q** Yes. So, I am putting words in your mouth. I'll put it to you. Is it effectively a distraction in some sense?

**A** Well, I felt-- I mean, to be absolutely honest, I felt it was a distraction but – and this is the silver lining – I think there were two points. First is, without having formed the team that were going to do this work with Pat O'Connor and Peter Davey-- and there were others, but they dropped out because of COVID, but there were others who were going to be involved. Without having that team, we didn't have anyone who was equipped to interrogate the case notes for us.

**Q** Right.

**A** So, essentially, I said, “Please carry on. Do your trigger tool work because it does have some intrinsic value of its own.” It just didn't inform our terms of reference.

**Q** So, effectively, it becomes a checklist?

**A** Well, it was a checklist----

**Q** So, you're noting, if something's on the trigger tool list, “When did it happen? That's a fact we want to know.” It boils down to that?

**A** Well, I didn't want to know. A lot of what's on this list, I didn't want to know.

**Q** I see.

**A** You know, so, essentially, Pat O'Connor and Peter Davey were

collecting data, which actually turned out, I believe, to be quite valuable because what they were able to demonstrate was the good news for GGC was that the rate of adverse events identified by the trigger tool was no worse for GGC than it was for other children's hospitals. So that's a marker of sort of it's a benchmark for----

**Q** Of general care and general----

**A** Yes, absolutely, but the other thing it did identify, which was I felt more germane to our work, was that GGC weren't using their own internal data system for reporting adverse events as effectively as they might have done.

**Q** Right.

**A** And that was something that we did look at. You know, we looked at adverse events and we made a comment on that. I wouldn't say that was a major finding of our report, but it was there. So, yes, to be blunt, the PTT was a distraction. The silver lining was, by having the team who were going to do this work, we were able to actually ask them to extract the separate template of data that we need for the case----

**Q** Which is the one we just looked at in the Appendix there?

**A** And the third thing, of course, is that it produced a worthwhile output, and they produced a separate report to the Oversight Board which then somewhat disappointingly didn't seem to



get progressed----

**Q** Well, indeed, that's one of the questions that that's been suggested I should ask you, which is why, as far as you understand it, was the PTT report which we've put in a bundle----

**A** Yes.

**Q** -- not issued to-- published?

**A** I don't know.

**Q** Were you ever given a reason?

**A** No, and it was a task for the Oversight Board, and as we were completing our review, not only was there a Scottish Government election but there was a change of personnel within the Oversight Board, and so it kind of falls for me into the same basket. We made 40-odd recommendations, and I don't know what happened to those recommendations.

**Q** Right, I'll come back to the recommendations.

**A** So publishing the PTT report and you know it's useful information for GGC it wasn't innately particularly critical of them it demonstrated some very useful points I thought and I thought they should have been given it.

**Q** And the version that we've been allowed comes from you. We didn't get it from anyone else.

**A** I had understood that finally the PTT report had been published and

made available through NSS Scotland but I don't know.

**Q** I'm sure someone will correct me.

**A** It should have been made available. It could have been usefully made available to all children's units in Scotland.

**Q** Because the PTT data is being collected across all units, so you can do a comparison of PTT trigger?

**A** Yes, and, in fact, the literature behind the PTT is that this is a template that can be used in the care of children in lots of different settings.

**Q** Right.

**A** But it's-- I mean, I hope that I've clarified that the PTT issue itself is not directly relevant to the findings of the case note review. It's a bit of a bolt-on.

**Q** Right. Well, let's go back to page 1109.

**THE CHAIR:** Can I just clarify for my own purposes? Going back to the beginning of what you were saying in relation to the PTT, I think I understand the point that the PTT is designed for many illnesses. I mean, it's not specific to paediatric cancer care.

**A** No, it's not, absolutely.

**THE CHAIR:** And a result of that is that it will note as an event of significance, something which is routine in cancer care.

**A** Yes, absolutely.

**THE CHAIR:** But it is a way or a tool, a method for interrogating the medical records of a child.

**A** It is and some hospitals use it, so perhaps on monthly basis they might select 10 case notes at random and apply the paediatric trigger tool to the admission just to see whether it identifies issues that perhaps weren't adequately addressed or might have contributed to better management of the patient. So it can be used as an audit tool.

**THE CHAIR:** It can be used as an audit tool. Correct me if I've got this wrong. When you, from your particular perspective as an oncologist, are looking at the record of a particular child, I'm supposing that the exercise that you're carrying out is a similar sort of exercise as the application of the trigger tool is designed for – in other words, looking at medical records for events which you consider are significant in the history of that particular child – or have I got that wrong?

**A** No, I think that's absolutely right. Essentially, I knew-- I hoped I knew what I was looking for in the patients who had infection. The trigger tool provides, as it were, a pre-prepared template that you can apply to a hospital admission for a child with any condition, and that's its value in the sense it can be used as an

audit tool across a range of paediatric hospitalisations and it can be readily used in different settings for comparison.

**THE CHAIR:** And did I hear in your answers to Mr Mackintosh that when you were interrogating the-- or rather the way you set about interrogating the records of the children, your team was-- or maybe you were looking at records, having regard to a different list of significant events, or did I misunderstand your answer?

**A** No, I think you're correct, my Lord. We created our own list of data that we wish to collect, and there wasn't really overlap with the paediatric trigger tool. Some of the things that are within the trigger tool we would have expected to be happening in the patients, anyway, and therefore didn't-- were of no great concern to us because they're predictable----

**THE CHAIR:** All right. So there was, as it were, a separate list.

**A** Yes.

**THE CHAIR:** Which was informed by events which you considered from your expert perspective to to be of significance?

**A** Yes, and that's what's on the screen essentially, the data set.

**MR MACKINTOSH:** Can we put 1109 on the screen, please?

**THE CHAIR:** Yes, right, thank you.



I'm just want to make sure I'm keeping up.

**MR MACKINTOSH:** So, this section that we just looked at above the middle of the page rather----

**A** Yes.

**Q** That infection episode list, ignoring the title for-- as you said. That list of events, in a sense, is that where we find the things that you thought were important?

**A** Yes, absolutely. I mean, this is the framework around which we were looking to see, you know-- was this a child that had been admitted for perhaps a routine course of chemotherapy, was well on admission but three days into the admission developed a fever and was found to have a bloodstream infection, or was this a child that had presented to the day unit with a fever, was unwell, and was found to have an infection?

**Q** No, they'll be two very different possible sources.

**A** No, they could be two very different possible sources but no doubt we'll come back to that.

**Q** Yes, and then things-- for example, if we look at that infection episode section----

**A** Yes.

**Q** -- I'm assuming "place admitted from" would include home or other hospitals.

**A** Yes, absolutely.

**Q** Right, and reason for omission, again, might be planned, might be----

**A** Might be planned, or it might be mum says he's not been so well, had a temperature at breakfast time. I mean, it might be something very mundane, but it gives you some idea of the trajectory of the illness.

**Q** Then the following-- The date of onset is would matter because of that traditional observation, that sometimes infections that occur with only 48 hours of admission might not be hospital acquired but----

**A** Yeah. I mean, date of onset-- I mean-- So, date of onset-- So, a child who was admitted on Monday who had a temperature on Wednesday, the date of onset symptoms was the arrival of the fever on Wednesday, even if the child was admitted on Monday for chemotherapy, for example, or it could be a child who comes from home and the mother said, "Well, actually, he's been off colour and complaining of tummy ache for the last 36 hours."

**Q** Right.

**A** I mean, the date of onset is pretty imprecise, actually, but you estimate how long the child may have been unwell.

**Q** But if you're trying to distinguish-- So, one of the things that we had yesterday-- and maybe I should pause this bit and look at the definitions of the conclusions you reached and then bring it back to this. So, yesterday, we had evidence from Ms Evans about the definition of "possible" and "probable", and we had evidence from Professor Wilcox about the number of different categories and whether perhaps there were too many categories originally chosen. What I wanted to do was to-- just as an *aide memoire* to this conversation, I'm not so much asking about the outcome but the categories----

**A** Yes.

**Q** To go back to-- I think it's figure 4.2, which is on page 1043.

**A** Yeah.

**Q** So, we'll come back to what the categories were-- what the outcome was later, but we were pressing both Ms Evans and Professor Wilcox on what these all meant, and they seem to have given us quite a solid explanation of what "unrelated" means, but what do you think "unrelated" means?

**A** Unrelated is a small number of episodes of infection where we were convinced that there was another story at play.

**Q** What sort of stories would there be?

**A** Well, there's one very clear

example of a child who actually didn't have cancer, had another kind of serious blood disease, nevertheless required repeated intravenous treatments, who presented three times with a very unusual infection in the bloodstream. I'm embarrassed to say I can't remember the name of the bug, but it will be in one of these lists. It's a very unusual organism to be found in a hospital setting. It's a bacteria that is known sometimes to be associated with soil and external environments, and the occurrence of this infection three times, in a child who was having a lot of intravenous treatments given at home----

**Q** Right.

**A** -- meant that we didn't have a great deal of difficulty in saying we didn't think this was to do with the hospital environment. In fact, the treating team of that child had already drawn the same conclusion, it turned out, and had suggested that there should be water sampling from the home environment.

**Q** Right.

**A** In fact, it may be that it features in the report, actually. I'm not sure.

**Q** If we move into-- passing delicately over "weak possible" for a moment, if we look at "possible", what does "possible" mean?

**A** Well, "possible" I think means



that this was an infection with a bacteria that is found in the environment, because that's how we selected this, where there was no evidence that we could see that this was an intrinsically and endogenously acquired infection. So there was no apparent gut or mouth symptoms----

**Q** The symptoms you discussed a few minutes ago?

**A** Yes, no gut or mouth symptoms. There wasn't, for example, signs of inflammation around the central line exit site, you know. There was no other sign of infection----

**Q** So that would have put it in a CLABSI gram-positives possible----

**A** Well, I mean a gram-positives is the most likely, but just occasionally you take a swab of an exit site of a central line and you find something different.

**Q** Right.

**A** But most typically it's a Staphylococcus. So, there were none of those things. So, we were left with a child who'd got an environmental infection in the bloodstream with no other apparent cause. That became possible for us as a link to the environment----

**Q** Then----

**A** -- but it wasn't supported by the finding of any environmental cultures or bacterial typing.

**Q** Would it have been associated with a-- other similar infections in the same time and place, or was that put in----

**A** No, I think-- and that's an important point, and I should have said that, that in terms of our ability to look for clusters-- and you might want to bring me back to it----

**Q** Yes, I will do.

**A** -- to tell you how we did that, but there were no apparently or potentially correlated infections in terms of----

**Q** So a "possible" is we've-- not excluded, but we think we've excluded obvious enteric gut-related----

**A** Yes.

**Q** -- infections, and we think we've-- We've not seen signs of a gram-negative in the central line----

**A** Or any other kind of infection----

**Q** -- or any----

**A** No urine or ear or-- you know.

**Q** So, those all aren't there, but at the same time we've not found a cluster, and we've not found an environmental sample, and we've not found anything else.

**A** Yeah, or we found a similar organism that occurred nine months previously, and the relationship is so weak that we wouldn't----



**Q** Same ward, but different year?

**A** Yeah but----

**Q** Right. So, before we go back to 1109, I want to just look at "weak positive" and "weak possible." So, how does something drift down from "possible" to "weak possible"? I get that Professor Wilcox's slight despair at the possibility of having too many categories.

**A** Well, I think-- I mean, when I revisited this in my preparation for today, I wondered whether we tried a bit hard to get-- because, essentially, you know-- and I think we do make this statement in our report. This is not a binary decision. It's not, "This is related to the environment." It's not. I mean, you know, that kind-- I mean, would that it could be so simple you could just say yes or no. You can't do that. You're working on a gradient of probability, and we could have had a linear analog score. We could have said, "It goes from 0 to 10, and we think this patient's about a 6," but I don't think that would have been very helpful, because we would then have to define what a 6 was.

**Q** Yes.

**A** So, I think this was our attempt to show the gradation of confidence in terms of "unrelated" to "definitely related." You see, we never got to "definitely related."

**Q** With a "weak possible," what

sort of things would cause something to slip from a "possible" to a "weak possible"?

**A** I think a "weak possible" would be a patient who perhaps had very infrequent contact with the hospital, you know, perhaps had not been coming to daycare very frequently. I mean, some patients come 20 days in a month to daycare, and they have their central line accessed all the time. Some patients, you know, might not have been seen for six weeks. So the pattern of contact with the hospital, I think, would have been a----

**Q** So there's a sort of value judgment in there----

**A** Yeah, I think there's a-- and, you know, that brings us into the territory of how do you-- what's the best denominator for infection rates.

**Q** We're going to do that this afternoon.

**A** And I think the frequency with which you re-present to the hospital presents a measure of risk. So, a patient that's only come once in six weeks compared to a patient that's, say, come six times in six weeks, there's a difference there in terms of the likely relationship to the environment.

**Q** In terms of the drift up, it's a very small number from "possible" to "strong possible." What's the sort of thing that's a-- What sort of things are pushing people into the "strong possible" category?

**A** I think it's almost certainly related to clustering, actually. I mean, without going back and looking at those four patients, I wouldn't be able to answer that.

**Q** I'm going to leave clustering and come back to this table, but I want to go back to 1109, ask you a question----

**A** Yes.

**Q** -- about appendix D.

**A** Yes. I mean, in retrospect, I think putting "strong possible" in was probably not very helpful. It was very----

**Q** The middle of the page in. Just the middle of the page. What I wanted to understand is that-- we just discussed information you would use to put something into the "unrelated" category, and we discussed information that you would look for and not find for it to be in the "possible" category, so enteric and lines and infections. Where do we see in this template structure the sort of information that will enable you to exclude things from "possible"?

**A** Well, it really comes under 22, I think, and-- well, 21 and 22: reason for admission; date of onset of symptoms. It wasn't just that we wanted a date of onset of symptoms. We wanted something about the evolution of the symptoms. So,

we wanted to know what the trajectory of that illness was. Was this a child that turned up at the day unit who was ostensibly for some routine aspect of therapy that wasn't unwell but had a slight fever and a temperature, and a culture was taken, or was this a child who actually presented catastrophically sick and ended up going to the Intensive Care Unit? So, that additional information was built around those two data lines.

**Q** So, if we were to look at one of the patient's entries for these, those two data lines would be quite full of information. It wouldn't just be a date. It would be quite a lot of narrative at this point.

**A** Yes, and I mean-- If I might ask if you move to the next slide of the----

**Q** Yes, of course.

**A** -- template.

**Q** If we can just jump out and move to the next slide, please? Next page.

**A** This summary----

**Q** Yes.

**A** -- and you know-- I mean, I did worry both then and now how we could have better illustrated the depth to which we went into the clinical circumstances of the infection, but many patients-- If you look at the white bar where it says-- There's a blue bar at the top which has got the unique patient number, the date of the episode, the dates of the panel review.

**Q** Yes.

**A** If you look under that, it's got "clinical timeline," and then there are some unshaded white lines and-- So, in there, we've got dates and events. Well, many patients would have had a complete page of narrative of dates that extended over a period of maybe two to three weeks, and sometimes much longer than that, indicating something about the date of onset of symptoms, the date of the admission, the date at which the culture was done, the date at which the culture was reported, the date at which other culture was done, the date of an evolution of symptoms, the date at which the child went to intensive care, the date which chemotherapy was subsequently re-established.

So there's a whole narrative, and I realise now that this page is a rather poor representation of-- and that's why we did submit to the Inquiry two worked examples of a relatively simple case and a more complex case, but it's difficult to make these things public documents----

**Q** Yes.

**A** -- because every child's clinical course is a footprint, essentially----

**Q** Of course, and that's why they're not in the bundle, so----

**A** No, absolutely, but perhaps

you've had an opportunity to look at them and and to understand the approach that we took.

**Q** I thought it might be helpful – because obviously this is a public inquiry, and my colleagues here and the public have to understand what we've done – to see what this exercise-- if we go back to page 1109 so I don't forget. This exercise compares to other things. Now, obviously you're now retired, but you were a treating clinician in the Bristol unit.

**A** Yes.

**Q** If there had been a single case or a small cluster of gram-negative environmental infections in your hospital, there would have been an IMT, I'm assuming.

**A** Well, the system isn't labelled quite the same way.

**Q** A similar thing would happen. There would be a----

**A** There would be an assessment, yes. I mean, the first assessment is, "Does it require further interrogation?"

**Q** Yes.

**A** Not everything gets to an IMT. It's only the minority that do.

**Q** How does the level of detail and rigour that you've applied in each of these 85 cases, in this case as a review exercise, compare to the level of data extraction and rigour and analysis that you would do in a group of cases that had got to that next level in your domestic system?

**A** Well, I think if you're dealing with an infection in real time, an awful lot of your concern and decision-making is the result of engagement with the Microbiology and the Infection Control teams, so you have a discussion. So the Microbiology team would come to the ward regularly. If there was a particularly unusual infection, the Microbiology team would come very promptly and say, "Can we discuss this patient?"

**Q** And you'd have some sort of multidisciplinary team meeting, effectively.

**A** Yes, but we didn't necessarily all go and sit down in a PAG or an IMT, but we would discuss it and the microbiologists would give advice, not only about the antibiotic treatment of the child but the isolation of the child and whether other precautions or other investigations were required to understand better how this infection came about, and so----

**Q** And so when you----

**A** I'm so sorry. Just to finish your question, when you see a list of all this information put on a piece of paper, it's a much more rigorous process because it's trying to go back and mimic the formality of that interaction in a retrospective

manner where you have to be much more prescriptive about, "This is what I want to know."

**Q** What level of comparison does it bear to-- I mean, have you given evidence in litigations in your career over the years?

**A** I've given evidence both in a criminal setting and in a medicolegal setting.

**Q** But in a medicolegal setting, how does the level of detail and rigour required for a medicolegal report produced by you on a particular child compare to the level of detail and rigour that you say you carried out in this exercise for each of the 85 children and their infections?

**A** Perhaps I need to understand the point you're reaching, I suppose.

**Q** I can advance it a little bit, which is that in a sense if you're giving evidence in a court setting as an expert witness, not only do you need to demonstrate that you are independent, that you are an expert, that there is an external body of expertise you can rely on, but you also need to show your workings in a sense.

**A** Yes, yes.

**Q** This exercise that you have carried out with your colleagues, you aren't showing your workings completely.

**A** Yes.



**Q** So, in order for us to understand to some degree, to the extent that we can, how far can we go-- We're quite interested to see if you were producing a report on-- I doubt you've ever done this, but a report on whether Child A has caught their infection in the hospital in a medicolegal negligence sense.

**A** Yes, okay.

**Q** If that report was being produced and you were required to input that as a haemato-oncologist, how does the level of analysis you say you carried out here compare to that level of analysis that would be (inaudible)?

**A** I think it would have to be the same. I think if you're looking at something as serious as, "Did this child get an infection from the environment in which they were being cared?" then I think you have to be very rigorous in terms of the acquisition of data. If you're looking after a child with an infection on a day-to-day basis, because infection is a day-to-day occurrence in children's cancer care, then you're constantly adjusting and making judgments about whether this is unusual or not.

And, you know, maybe I can illustrate that. Maybe it feels slightly off-beam, but one of the things I did fairly soon after I started doing this work is I went to meet the Infection Control team in

my own hospital and just said, "Can I just discuss with you what this feels like?" and I talked about Stenotrophomonas, and I said there seemed to be an awful lot of Stenotrophomonas infections in this cohort. I could only remember possibly one or two patients with infections with stenotrophomonas that I had treated, and I was really surprised to encounter the number of infections, and the response I got from them is, "We almost never see Stenotrophomonas in bloodstream infections in this population of patients."

So, why do I use that example? It's because I think you always have to be alert to whether what you're dealing with is consistent with everyday practice, because we know children get gram-negative environmental infections during the course of chemotherapy, or whether it's something that's completely outwith what is your experience in your own center.

**Q** Because if there was a child who got a line infection while you're trying to push the numbers down all the time, that isn't in itself unusual.

**A** No. No. I mean, if you consider how long children have little bits of plastic tube going into a big vein and coming out through the skin, it's not at all surprising that there is a degree of infection. All you can hope to do is to drive it to the minimum level possible,



and by reflecting on practice and taking advantage of technical changes to dressings and so on, you can do that, and that's what GCC did in relation to gram-positives.

**Q** What I'd like to do now is to talk about clusters and sort of get back to "probable" and we'll come to that, maybe not before the coffee break. But again, looking at this appendix D, this data collection exercise, where do we begin to see the context that's independent of the individual patient? The idea that there is another case a week before, a week after. Where does that information get collected?

**A** If you were to go back to the diagram, our process map-- Well, actually, in fact, part 2, if you stay on that screen, I can explain it here. Just a third of the way down, you see a shaded box saying "Tableau timeline", so perhaps I need to explain that.

**Q** Ms Evans said something, but I'm interested to hear what you say.

**A** Okay. So, what HPS built for us was a really very effective tool which essentially was an interactive spreadsheet. Every one of the 118 infections was listed, as it were, horizontally on the spreadsheet and by child. So some children had more than one infection. So, for each infection, what we had was a horizontal axis that

went from May 2015 to December 2019, and across that axis, for every child, we had every encounter with the hospital, every----

**Q** So there'd be a sort of coloured block --

**A** Yes. Well, or a single line, because if it was an outpatient clinic or a day case appointment or an inpatient stay, it was represented on that horizontal line. So every single contact with the hospital was represented horizontally, and you could hover your cursor over that line and it would say, "6A," for example, and you could see that the child had been admitted to 6A on 12 September 2019 and stayed in 6A until 14 September 2019 and then went to the paediatric intensive care unit, for example, and then you could see how long they stayed in the Paediatric Intensive Care Unit, and overlying that, we also had the date of every infection.

**Q** In terms of a coloured indicator or something?

**A** Well, it was usually a cross, and then you could hover over the cross and it would say "Stenotrophomonas" or whatever, and there was a selection capability, so I could go to this tableau spreadsheet and I could say, "Give me all the Stenotrophomonases," or "Give me all the Pseudomonases" or "Give me all the Elizabethkingias."



**Q** And they would all be compressed down and just show them?

**A** And then it would just show me the patients who had had or the episodes that had involved Elizabethkingia. That was a very short list. Stenotrophomonas is a longer list, obviously, and then what I could do by looking vertically down the list is I could say, "Oh, well, there was an infection there which was December 2017 and there was another one there in May 2018 in another patient." or I could say, "Give me all the patients with Enterococcus," and I could see that there were six of them within a seven-week period or whatever it was.

**Q** So, this is a visual----

**A** It's a visual thing. I mean, it was a magical tool, quite frankly, in terms of our ability to relate dates of infection to dates of contact with the hospital and the duration of that contact with the hospital, and you could also map where patients had moved internally within the same admission.

Right. So obviously the origin data behind that is GGC data, but the work was done, as you understand, by HPS?

**A** Yes.

**Q** And how is that presented? I mean, we've just got a white box, as you just admitted. Would that be narrative text or a little picture of the spreadsheet? What would you find there in each case?

**A** Well, it would be narrative text, and the reason I'm just reaching for my notes is that I've got one of my worked examples here. So, the first thing was that it enabled us to check whether the dates of admission and ward placement that we had identified from the case note review, pulling the data out of the clinical record, aligned, and sometimes they did and sometimes they didn't, and I would sometimes go back to the team and say, "The date of admission seems to be incorrect," or "It says that this patient went to 2B, but in fact they were on 2A," and, you know, there were some miscodings. We found some patients who were still being coded to 2B even after the ward had closed, so it threw up these things. It obviously allowed us to identify and record the potential for clustering, and so when you look at the summary lower down in this chart that's on this----

**Q** Next page?

**A** No, no, on this screen here. So, in the tableau timeline, let me-- I mean, I don't think there's any breach of confidence. I can read out from my example case here.

**Q** Well, maybe fudge the dates a bit, but yes.

**A** Well, it says there were eight enterobacterial infections in seven patients in four months from 28/4/18 to 20/8/18, and we listed all the patients so that we were able to go back to those records. The patient's names weren't known to us. They all had a number, so I was dealing with a patient, say, number 75, but I could see that patient 13 had also had a similar infection on a date, and therefore I could go to patient 13 if I wanted, but I could also look at the tableau and see how close----

**Q** So you could look at both your summary page on patient 13 and the tableau and bring it together.

**A** Yes. Yes, and then we could make comments about that, but lower down, under ICNet, Telepath, IMT and PAG notes, we'd make similar comments. So, under Telepath, for example, I wrote for this patient:

> "Much discussion of antibiotic choices limited by inability to use certain drugs. Notes indicate the samples were sent for both episodes for typing, but only results from the second episode are given [and so on]."

**Q** And then the relevant parts of the IMT minute can be pulled into the next section, which we've heard from Ms Evans. Is there anything else on this page that helps on the clustering issue?

**A** No, I think the clustering issue was all under tableau, essentially, because that's where we saw the clustering. I mean, that was a very useful

visual tool. We could just see where they were. Otherwise, it would've been almost impossible for us to link these infections except by rather tedious, manual comparisons, but we could do it very visually.

**Q** Well, I appreciate it can be quite a tedious process to link all the dates. What I wanted to understand is how do you deal with the criticism that-- Well, let's stop now and have a coffee break, and I'll come back to, "What does probable mean," after we've had a short break, my Lord. That's probably the best approach to it.

**THE CHAIR:** Okay. Professor Stevens, as I said, we take a coffee break about this time. Can I ask you to be back for 10 to 12?

**A** Of course. Thank you very much.

**(Short break)**

**THE CHAIR:** Mr Mackintosh?

**MR MACKINTOSH:** Thank you, my Lord. I think probably what we should do before we discuss clusters in great detail, is go back the probability-- the table of answers, as it were, on page 1043 of bundle 6. Yes, and so what we discussed, Professor, before the coffee break, “unrelated”, "weak possible", "possible" and "strong possible." What I wanted to understand is how does a infection get into the "probable" category?

**A** Well, I think what underpins a probable category is that we've crossed the threshold that on the balance of probabilities there's enough evidence to suggest that this infection is linked to the environment. So, what takes you there? Well, what would take you there is if we had convincing environmental data that linked to the infection----

**Q** That might be a sample from the environment?

**A** A sample from a drain or a tap or that-- in the proximity of the patient, but, as we made clear in our report, we really had access to rather scant information about water samples, certainly, and we didn't have any useful information. I mean, to shortcut it, I'd say we had very little useful information about maintenance on the wards because it just wasn't-- it wasn't coded adequately.

**Q** So would this mean you couldn't identify which sink was being cleaned or----?

**A** Yes, I mean, I think I did at one point look at Ward 2A over a period of a month or something and noted that the plumbers came maybe 15 times. I mean, you know, really, but you had no idea where they went – they were coming to fix a sink or a leaking shower – and, I mean, these things happen in hospitals.

We recognise that. One of the difficulties is then tracking where that work was done.

So, what put patients into the probable group more often than anything else was, apart from the absence of other hypotheses like gut translocation, was it came down to a lot of emphasis being put on clusters.

**Q** So you've got whatever you can derive from maintenance records and from environmental records and tests nearby. You've got the clusters, and we discussed the tableaux.

**A** Yes.

**Q** Is there a threshold in your mind about how much clustering you have to have, or how many environmental samples of the same species have to happen before it becomes a "probable"?

**A** No, I think it would be disingenuous for me to suggest that we had a defined threshold. We looked at the pattern of the clustering. We discussed that pattern in relation to the nature of the bacteria, the likelihood that it could be found in the environment, where it was likely to be found, perhaps. Enterobacters and drains is something that-- It's not an uncommon correlation that you find Enterobacters in drains. You find all sorts of things in drains, of course.

But there were some quite striking-- and it's evidenced in our report. There were some quite striking clusterings of patients over relatively short periods of time having the same infection.

**Q** Yes.

**A** And then, of course, the hope that typing might illuminate whether they were related, and again, as we made clear in the report, we don't believe-- we did not believe that the typing information that was provided to us was actually that useful in terms of defining or refuting our connection.

**Q** So, I'm going to come back to the whole genome sequencing later, but if we look back at the table, we have a category of "strong probable," which is sort of three of them have, as it were, leaked out of probable into strong probable. What is it that's causing them to step up to the plate and be more significant?

**A** I think it's probably the-- I think-- Again, I think it's almost certainly the emphasis placed on the clustering. It's "Does this clustering look stronger/more likely, perhaps, than in the other 30 cases?" for example.

**Q** And if we go on to the next page, page 1044, and Table 5.4----

**A** Yes.

**Q** -- you've grouped together "strong possible", "probable" and "strong

probable" into "most likely."

**A** Yes.

**Q** A moment ago you just described "probable" and "strong probable" as "more likely than not." So, there's clearly a difference between this table and "more likely than not", but is there anything particular about the infections-- the organisms that appear at the top of this table, with larger numbers, that seems to speak about clustering or grouping of events, to you?

**A** Well, I've already made a comment about the number of Stenotrophomonas in the whole series----

**Q** Yes.

**A** -- which is completely outwith my personal experience----

**Q** In a haemato-oncology ward?

**A** Yeah.

**Q** What about Klebsiella?

**A** Well, Klebsiella is certainly more common. It certainly occurs more commonly but, nevertheless, there were still a lot of Klebsiella septicemias, and although gut translocation with Klebsiella-- these are enteric organisms, but the number struck me, on an individual level, as being relatively high.

**Q** I mean, when you say that Klebsiella is not as unusual as Stenotrophomonas, is that because Klebsiella as a translocation infection is relatively-- is not unknown as a thing one comes across, or is it Klebsiella as an environmental infection is not unusual?

**A** Well, I think I'm straying out of my area of expertise a little here, and my understanding is that Klebsiella is possibly not very frequently identified in water sampling.

**Q** Well, if I can bring you back inside your area of expertise and ask the question a different way. From the perspective of a hemato-oncologist, when you see Klebsellia in your patients over your career, are you seeing it in the form of gut translocation type cases with the symptoms you described or are you seeing it in a different context?

**A** No, I think you see it both contexts, but I suppose if I were to reflect on my own personal experience, it has probably more commonly been identified with gut translocation, but not always.

**Q** How do you react to someone who-- I mean, we see it actually in the GGC commentary that they sent to you on a draft. Someone who reads this and thinks, "Well, look, they've identified 10 episodes of Klebsiella as 'most likely'," they're missing the fact that those quite often will be gut translocation. What is it you've done to ensure that those 10 cases aren't gut translocation cases?

**A** Well, there are 18 cases of Klebsiella in all the other episodes.

**Q** So those are the ones that

probably are gut translocation?

**A** Presumably. I'd have to go back and look at them all.

**Q** They might well be.

**A** I mean, I would have thought that that was the most likely basis we sorted them out.

**Q** Right. So there's been an exercise in discriminating between the two?

**A** Yeah, and I think, actually, looking at those two columns is quite helpful. There are 14 Stenotrophomonas in our "most likely" group and only seven in the other, and so the relative proportions of these organisms is possibly helpful. Pseudomonas, you see, there are only four in our "most likely" group. There are 13 in the other episodes, because Pseudomonas and Klebsiella are probably the most typical infections you would see.

**Q** And when they're typical, how would they be coming about with a patient?

**A** Well, I mean, sometimes you can have a patient who is apparently well, spikes a fever. You take a culture, and you find that they're growing a Pseudomonas, and they can rapidly become unwell if you're growing a Pseudomonas, or they could-- I said-- in the first session, I described a patient who had Pseudomonas septicemia-- not septicemia, Pseudomonas infections with raging gut toxicity. So, you can spot it that way, perhaps.

**Q** So, you're saying that the differentiation between these two columns illustrates that you've carried out a process to divide the two?

**A** I think it does tell that story. I think the other thing about this table is there are some slightly unusual infections here altogether. Now, they're not all in the most likely group, but Elizabethkingia is not an infection that comes up in my day-to-- it didn't come up in my day-to-day practice. Curtobacterium, and so on, these are not-- Serratia I would have encountered, but there's something about the pattern, and I think it's interesting that it's reflected in the unredacted HPS 2019 document because there's a very interesting graph----

**Q** I think we can probably go to that.

**A** It's a bar-- It's a sort of bar graph showing----

**Q** Yes. It's on page 233 of Bundle 7. Now, I'm keen to avoid wandering out of your area of expertise.

**A** No, but this is just a visual-- I mean, if you look at this table, these are a distribution of the different organisms found in Yorkhill, in 2A, 2B, and 6A and 4B. One of the things to remember, of

course, is that these periods are all very different. So, this is a bar graph expressed as percentage, but if you look at the size of the component-- so if you look at Stenotrophomonas in the first bar, you've got four cases at Yorkhill but don't look at the number four. Look at the size of the bar graph as it goes up of the Stenotrophomonas in 2A, 2B, and look at it in 6A, 4B. You can see that the contribution of Stenotrophomonas to the distribution of infections has increased. The same for Enterobacter, quite substantially----

**Q** So, you're saying that the proportion of what is a changing number of overall infections that's coming from Stenotrophomonas has gone up?

**A** Yes.

**Q** Even more for Enterobacter?

**A** And this was-- I don't know why this was redacted in the version of the report that we were given when we were doing our piece of work, and I only saw this when I was finally able to get the unredacted version, but I think it contributes to the story.

**Q** What was the point it's making?

**A** The point it's making is that it's not just the overall incidence of infections; it's the changing nature of the infections. You're seeing a range of very unusual infections, but you're also seeing infections that we know more about, but they're occurring more frequently.

**Q** So, it's not just that there's the unusual stuff, which is, of course, the rainbow colour at the top of the middle column----

**A** Yes.

**Q** It's the fact that the contribution to the volume from Enterobacter and Stenotrophomonas is strikingly larger.

**A** Yes, and I think it supports what we said in our report that simple observation of patterns of infection is as important as any other measure like incidence rates and SPC charts.

**Q** I wonder if I can just go back to page 1043 of Bundle 6 because I forgot to ask you a question-- put something to you. This was about "possible."

**A** Yes.

**Q** So, we have some evidence from Dr Crighton, who's now the Director of Public Health in Greater Glasgow, and she observed that a public health meaning of "possible" would mean that the features are compatible with there being this connection but other diagnosis are are possible as well. More things are possible than just one. Why is it that your approach doesn't seem to consider the possibility of other causes. It's just "this is possible" as an environmental link here. Why do you define "possible" this way?

**A** I think our definition of "possible" was by excluding other reasons for the infection, really.

**Q** In your statement on page 131, paragraph 92, you discuss-- we've obviously asked you about weighting, and you've observed:

> "I would not say that there was differential weighting to factors because the exercise involved considering all available factors in any situation. Our conclusions were not driven by the number of factors. Clustering is quite important, but we did not give any formal weighting to one factor or another. We truly attempted to integrate our knowledge of the patient, our knowledge of the behaviour of the individual bacteria and the environment. Some of those elements were incomplete but we used what we had."

How would you react to the suggestion that what this is describing is, in effect, in some ways a subjective assessment that is maybe an amalgam of your three expertises. It's just-- In a sense, it's your opinion.

**A** Would you mind if I just answered the question about waiting?

**Q** Of course.

**A** Because, just to clarify that, it's entirely possible when you undertake a process as we did to say, "Well, we're going to preemptively apply a weighting. So, we're going to take evidence of clustering as worth twice evidence of gut translocation " or something like that, but we didn't apply any rules. So, that's the purpose of paragraph 92, to say we had no pre-established rules. We just took the information. We tried to synthesise it and make a judgment. I think we've been very clear in our report to say that this is our judgement, and a judgement is inevitably partly subjective. It's based on what you're presented with objectively but in the end, you have to take and integrate and form a view on what you've got.

**Q** Which brings me to the questions of the limitations of what you've done, which you've covered in paragraph 137 at page 145. Now, obviously, we can read what you said there as we'll read the whole statement, but if the Inquiry's got to understand what weight to give to your conclusions in its thought processes, what would you consider to be the primary limitations of the work you're able to do?

**A** I think the primary limitation, actually, was our inability to obtain data which would have usefully illuminated aspects of environmental exposure, either because it wasn't available or because when it was presented to us.

We couldn't track the implications. So, I think we've given evidence where a water report was said to be positive for Stenotrophomonas or another bug, but we actually couldn't find that in the data presented to us.

**Q** Right. Because the data wasn't complete?

**A** I mean, it was quite clear to us that there were challenges in relation to coding. The locations of patient care were often expressed differently, and I think I've seen that identified in someone else's statement. There were problems with dates. There were one or two occasions when the IMT said that information was available, and we couldn't find it in the data set that was provided to us. So there was a limitation, inevitably, that we could only work with the data that we were given but what I hope that we would be able to convince you is that we used what we've got as effectively as we could.

**Q** I want to just pick up a couple of small things before we move on to the Health Board's response to your draft.

**A** Yes.

**Q** So, the the first thing I wanted to pick up is we had some evidence from Professor Leonard on 9 October. During the course of his evidence, he discussed the use-- how the use of an antibiotic, Meropenem, might have been the cause of the later spikes of infections as a consequence of antibiotic resistance. Now, I've not shown you the data he used for that. I'm proposing to, but I just wondered, in the treatment of haemato-oncology paediatric patients, is-- are the increase in number of infections in patients-- Is that something that can happen as a consequence of antibiotic resistance? Have you seen it?

**A** No, I-- Well, I haven't seen it. I mean, all antibiotics convey risks as well as benefits, and the risk is principally the risk of inducing multi-drug resistance, multi-antibiotic resistance, within organisms that respond to exposure to antibiotics by becoming resistant to them. I'm aware of a hypothesis that suggests that Meropenem might drive the appearance of Stenotrophomonas, in particular. I have to say, I haven't done a robust literature review, but I have looked at the literature. I found very little that addressed that specific point.

The most recent thing that I read was an abstract of an investigation looking at Stenotrophomonas pneumonia, which isn't necessarily the same thing as bloodstream infections, where patients who grew Stenotrophomonas in their sputum, they had had a previous exposure to meropenem, more than patients who didn't grow Stenotrophomonas in their sputum. The

trouble is that this was an abstract presented, I think, at a scientific meeting. There's no detail. These were adult patients. They may have had many other morbidities. I have no ability to say how relevant that observation is. I did see another paper, which is somewhat older, in the literature that said that there was no evidence that meropenem drove it., and then just to add my own personal experiences, a meropenem regime formed part of our approach to empirical antibiotic therapy in my own unit in the past, and I've already said to you that we almost never saw Stenotrophomonas. I mean, that doesn't mean----

**Q** No, I suppose I can take-- To the last point from it, your experience is that whatever's been going on in Glasgow in your unit, using meropenem as part of a treatment plan for a number of patients hasn't generated peaks----

**A** I suppose the other reflection I would make is that if you were using meropenem, say, as your primary antibiotic schedule for, say, two or three years-- because all units change their antibiotic schedules in time in response to the local flora, but if you'd been using it for two or three years and it was driving Stenotrophomonas appearance, then I think you'd expect to see Stenotrophomonas appearing fairly regularly, not in surges, which is what we saw.

**Q** I think you've already answered that question, so I don't need you to answer it. Right. I suppose this is a question you've answered, but I think I should give it to you cold so you can give a complete answer to it. We had some evidence from the medical director of NHS Greater Glasgow, Dr Armstrong. So, for my colleagues, it's column 212 of her transcript where she noted that-- I think this is just-- She's speaking, so this may be slightly misphrased, this next sentence, but 70 per cent of the cases were possibly or probably related to the environment – and, of course, it's "possibly" that's driving the 70 per cent – and it's not clear, she said, how you reached your conclusion. Am I getting the impression that at some level you'd accept that because you haven't provided the 85 individual reports, or would you not?

**A** I think presenting the data in that manner is unhelpful because the key message from our review was not the 70 per cent, but it was about the figure of around 30 per cent of the most likely, and in fact, interestingly, when the review was first published, that was the figure that was seized upon, and I'm rather surprised to hear the medical director reflecting it as a 70 per cent figure, because I don't think that would be the interpretation we

would seek to give.

**Q** But what I was pushing is how do you respond to her observation that it's not actually clear how you reach either conclusion because the narrative of how you reach the conclusion isn't fully available to the Health Board?

**A** Well, I suppose I'm sympathetic to that. I mean, we started early on with you asking me about who had access to this information, and I suppose there is a scenario in which all 80-odd-- well, it would be 118, actually, data syntheses are provided and could be poured over and interrogated and challenged, and I can absolutely believe that if you gave 118, essentially, RCAs – which was what they are; we agreed on that, perhaps – and gave them to another group, there wouldn't be unanimity in terms of the outcomes. But that brings me back to my point that we were very clear that, in the end, we had to use our judgment in relation to data that was presented to us, and that's what we did, and I can understand the frustration of GGC not having seen, as it were, the raw data.

My challenge, however, is that they could have done this themselves. Why, in 2020, were we asked to do this when they had been struggling for the best part of five years with a background of unusual and increasing infection? And this is a question that we raised. I mean, we recommended root cause analysis in our report. One of the responses is that, "Well, we're doing root cause analysis," but, in fact, there were only two root cause analyses done in 2019 in the era of our review.

**Q** There wasn't a retrospective exercise carried out by the Health Board?

**A** Not to my knowledge. The only thing I'd seen is two root cause-- I think we saw two root cause analyses that were done in 2019, and I think there was an onward application of RCA methodology thereafter.

**Q** I mean, we've had some evidence about that. Right. Okay, so what I want to do is to deal with the process of how you dealt with your draft and GGC responded to your draft, and ultimately pick up the letters and the meeting with the chief executive.

**A** Yes.

**Q** And then we'll come back to whole genome sequencing and some issues of that comparative epidemiology. I might just seek to actually get some information from you about different hospitals in the UK. We'll probably end up with that after lunch. Now, what I want to do is to go initially back to your statement, to page 143. Now, you describe at this point having a meeting with the chief exec following your draft

report. Now, what I want to do is just laboriously, slightly, connect the dots. So, your draft report is in bundle 25, document 2, page 45, and if we slip onto the second page, or even the third page, fourth page, we see that you've numbered the lines.

**A** Yes.

**Q** So, who received this draft report, and when was it sent?

**A** All stakeholders we defined as stakeholders received this draft report. Fundamentally, it went to GGC; it went to the oversight board; it went to HPS. I'm not sure it went anywhere else.

**Q** Right. It didn't, for example, go-- To whom did it go in GGC?

**A** Almost certainly it was sent via Elaine Van Hagen, who was the conduit for our communications with them, certainly latterly, and who indeed was very helpful, but it must have ended up on the desk of the chief executive.

**Q** Right, and then they provided a response line by line?

**A** They provided a very extensive response line by line with a lot of additional papers.

**Q** And then you produced a document that has those responses and your comments on them. Is that some sort of large teams meeting between the three of you doing those?

**A** Yeah, it was a sequence of meetings.

**Q** Right. If we can look at that document, that is also within bundle 25; it's document 5 at page 157. Now, I'm not going to go through all 70 pages because we'll be here forever, but I wanted to first understand-- is what did you understand the purpose of giving Greater Glasgow and Clyde Health Board and the other stakeholders the draft was?

**A** We were very clear in our covering letter that we were inviting comments on points of factual accuracy. We anticipated that there would be a wish to push back on some of our conclusions, and so we were clear that we really only wanted their view on things that they thought were wrong or that they had reason to believe were wrong.

**Q** What about – and there are a few in here, and we might go to them – points of disagreement about your methodology? Were you expecting to receive those at this stage?

**A** Yes, I think I probably was expecting to receive quite a lot, and it's a bit of a moot point as to whether that's a factual inaccuracy or not. I mean, it was quite a challenge to us because we were working to a very tight deadline at this stage, and for us to process this very substantial document with-- I think there were 28 embedded documents within it, it was a pretty substantial piece of work on

their part too.

**Q** And how would you respond to the suggestion that they really never got an opportunity – that is the Health Board as an organisation – to input into your methodology?

**A** Well, I mean, I can understand that that was their perception, but the reality is that we were an independent external group appointed by the Scottish government to do this piece of work, so there is no particular justification in my mind to ask the organisation that we were looking into, from this perspective, to comment on our approach.

**Q** Had they wanted to do that, when should that have been done? When should they have commented if they wanted to comment, either to you or anyone else? I mean, your methodology is something that you've described this morning as a root cause analysis multiplied by 85 or 118 times.

**A** Yes. In broad terms, yes.

**Q** And you've described going to a series of meetings in January to collect information, a single meeting around the table before the pandemic puts you all virtual, an epidemiology document that, cutting short, you didn't draft – it's come from somewhere else – and what was a shopping list of your data sources. We will come to, in a moment, suggestions that you should have done comparative exercises, that you should have included certain principles and not included other principles. When were those decisions made to do it that way, and how could GGC have influenced that process?

**A** I don't think they had an opportunity to influence the process. Whether they had an opportunity to influence the cohort, I don't know, because, you know, essentially the cohort was presented to us, but fundamentally the cohort was based on the the HPS 2019 report.

**Q** And they've used the HPS 2019 work to support their position, so----

**A** They have, so I'd be surprised if they were critical of the choice of the cohort. They didn't have an opportunity to comment on our methodology because, of course, had I written down our methodology in March 2020, it would have been a rather slim account compared to what's in the final case note review because essentially we evolved in terms of the approach we were taking, the amount of information we wanted, the necessity to look in detail at IPC policies and processes and audits and so on. So these things evolved as our understanding of the issues took place, and then we needed a bit of time to just get a few of these reviews under our belt so that we actually had an understanding of the shape of the data we were getting.

**Q** Okay. I'm going to probably pick that up at the end, but let's just walk through some of these ones. What I want to do is first go to the next page. So, do you see how at line 127 they've referenced their public health commentary?

**A** Yes.

**Q** Now, I want to talk about the public health commentary, so I felt it was probably important to jump to that, and that is elsewhere in bundle 27, volume 6, page 310. Now, this was prepared by Dr Crighton, and she's given evidence about her being asked to do it at short notice. I think it's probably fair to say that it contains a number of suggestions about methodology, and I'm conscious that you're a haemato-oncologist, not an epidemiologist, but I think probably the thing to do is to firstly pick out the second comment, which I appreciate is not your response. It's Mark's response, but I didn't have time to ask him this. Was there any discussion in your work as a group about doing a comparison with other units?

**A** Only in acknowledging that that work had, in a sense, already been presented to us in the HPS 2019 report.

**Q** Right.

**A** But I think there's more to the 2019 report than that.

**Q** Yes, because, I mean, Greater Glasgow and Clyde seem particularly interested in drawing our attention to the section that deals with the comparison with Aberdeen and Lothian but, other than that discussion, did you discuss, amongst the three of you, "Why don't we compare the rates with, say, Bristol or Leeds?"

**A** No, I don't think-- I don't think we ever had a material conversation about undertaking that because I don't think that was truly reflected in our terms of reference. The rate of infection is important clearly, in terms of the overall risk of the population, but we were being asked to identify whether individual children who had already acquired an infection were likely to have acquired that infection from the environment. So, we weren't really being asked to comment on the rate of infection, although, had we had information, as I've subsequently seen in expert reports from Mr Mukherjee, which showed the of magnitude of the rate of infection being so much greater in Glasgow-- and I know there are aspects of this that are disputed, but the order of magnitude of the rate of infection being so much greater in Glasgow than in other units, you know, I think it could have added weight to our concern about the environment.

**Q** We'll come back to Mr

Mukherjee after lunch, but there's three points made in here. The second one is the important-- The second one is they mention in the paragraph under-- if we look at-- Count them down, four paragraphs down, we have the comment about comparators, and you've mentioned the comparator units, and I discussed that yesterday with Ms Evans, and then we have the Aberdeen-Edinburgh comparison which is mentioned. Then, there's the discussion of causality and the Bradford Hill criteria.

Now, I'm conscious that you're not an epidemiologist, but to what extent did you think you were applying some form of epidemiological test in the carrying out of this root cause analysis?

**A** Well, I think, from the outset, I think we were clear that, you know, the basic premise was the "time, person, place" algorithm, as it were. I was a little surprised when I saw this reference suggesting that we should have discussed the Bradford Hill criteria. The Bradford Hill criteria are embedded in epidemiological practice, and I suppose I didn't feel there was a need to particularly comment on them. I thought it was implicit – I think that would be my response to that – and in fact the reference they gave us wasn't particularly illuminating, but-- and I'm not an epidemiologist, as you say, and I know



that, you know, what Bradford Hill described are some important principles, but it's not a checklist----

**Q** Right.

**A** -- you know? It's it's an approach to considering a set of circumstances.

**Q** Then, again, you're not an epidemiologist, but there's a discussion about use of statistical methods and the clustering illusion. The way you've described this exercise is a series of individual exercises repeated as the new data came in. Is there not a risk that you are creating a self-fulfilling prophecy: that you keep discussing the cases; because you see there's a cluster, that gives you a reassurance that there is a cluster; that means you're more likely to categorise it as probable and, effectively, you're creating something artificial out of a chance event just because the nature of the way human minds work, and therefore some form of statistical checking might have been a good idea?

**A** Well, I suppose my first response to that is the cluster was a reality to us. It wasn't a construct. I mean, you know, we could see where there were periods of-- If you drew a heat map, you could see where there were periods of intensity in terms of infection. We could see that on our tableau timeline. So the clustering was a

reality and so it was inevitable that we were going to reinterpret the sequential patients in that context, but not all patients had infections that were brought up in the context of a cluster by any means. So, it wasn't something that was applicable to every single infectious episode. I mean, it was still selective.

The statistical thing is a little bit more difficult, I think, because the statistics-- I mean, the suggestion of indirect standardisation, it relates to a statistical technique for comparing two populations. An indirect standardisation is where you don't have a complete data set for both populations so you can use a reference population by which you can look at the rate of something happening in the second population and say, "Well, compared to this reference population, it's more than you'd expect or less than you'd expect," but that takes us back to this whole issue about calculating incidence rates, which we felt that HPS 2019 had made an attempt to do, and I didn't know there was another data set available for us to do that nor did I think that it was actually our primary responsibility to do it.

**Q** Because you were driven by the actual individual cases and instances of it?

**A** Well, I think we were driven by our terms of reference, which is, you know, "What is the likelihood that these



84 children and their 118 episodes of infection derive from the environment or not?" and, you know, knowing that there was an overall increase in infection rate in the Glasgow cohort would, I suppose, have shone a stronger light on it, but I don't think of itself it would have changed our observations. It wouldn't have told us whether it was a possible or a probable or a definite.

**Q** If we go back to the discussions that were going on in the IMT in the second half of 2019, we've heard evidence that there is a suggestion-- well, a recommendation from Professor Leanord and Professor Jones in September that the ward is microbiologically safe. At that point, there is some pushback from the nurse consultants who are attending, then a series of further meetings and work, and eventually there's a video presentation in November and an acceptance by HPS that the ward is microbiologically safe and it's open to new patients, and during that period, there's a lot of data produced, including data produced by Kennedy and within GGC and a presentation is produced, and HPS isn't the only source of data. One of the observations that seems to be made is that there isn't a distinction in the rate of infections then in 2019 between what they are in 6A in 2019 and what they were back in the old

York Hill, and that's one of the factors that's used to make the decision to reopen the ward. So, there were other sources of data, but you didn't have access to those?

**A** No, and to be fair, I don't think I was aware of all that narrative. There were two things I was aware of. One is there was an SBAR produced at the end of August, I think, in that year, which I think was very clear that it didn't think the environment was safe.

**Q** Well, that was produced by the former lead ICD and one of the microbiologists.

**A** I understand, but that's one document I saw. The second document brings us back to the HPS 2019 document where I think there is a very important distinction between the redacted and the unredacted version.

**Q** That's this graph that we just looked at?

**A** No, it's the sentence in the report which was removed in the redacted version.

**Q** Well, it would be helpful just to look at that. So, we go to Bundle 7 and, I mean, I don't know whether you can find it for me because it's a distinction I haven't spotted.

**A** If you look at "Summary and Recommendations of"----

**Q** That's page 235, please.



**A** And are we looking at the redacted or the unredacted?

**Q** This is the unredacted version.

**A** So, the unredacted version, which is ostensibly the version that was first produced in October, says, if you go to the very end of "Summary and Recommendations"----

**Q** So, the next page.

**A** There's a series of dashes here.

**Q** Yes, on page 236. There's someone doing transcripts here, so I have to read out pages and things.

**A** I think this is not the redacted----

**Q** This is the unredacted version.

**A** This is the unredacted-- Okay. Well, if you look at the unredacted version, the fourth bullet point from the bottom reads:

> "NHS GGC should consider the data provided in the context of the findings from the action plan."

**Q** Right, and if we go----

**A** And then under that, it says:

> "NHS GGC should consider current control measures around restriction on services for newly diagnosed patients."

Now, that's the key statement. If you go to the-- If you go to the redacted version----

**Q** I'll just get you a page

reference. Well, the reference we've got is page 272, doesn't have any-- it's not different.

**A** It is, actually, with respect. It says-- The fourth bullet point from the bottom says:

> "NHS GGC should consider current control measures around restriction on services for newly diagnosed patients as there is no evidence from the HPS review of the data that supports continued restriction of services."

So, from the time this report was produced in October 2019 to the time it was published in apparently November, although it's still dated October, there has been the addition of this sentence.

**Q** So, the timings for that would mean that would be around the time of the discussion about whether the ward was to be re-opened, so what do you draw from the distinction here that you've now become aware of?

**A** Well, I suspect that there was a challenge to the message of the 2019 report from HPS which, you know-- I think I've written in my statement I don't believe that HPS 2019 report actually offered universal comfort to GGC about the safety of the environment.

**Q** That's related to the issue around the comparators or the general results, as it were?



**A** Well, we've already looked at that diagram where I was pointing out the change in proportion of Stenotrophomonas infections which was redacted----

**Q** Would this also be referenced to-- If we go to the unredacted version, to page 229, it would be this figure 4, perhaps, or----?

**A** No, no. These figures haven't changed although I think, for some reason, some of the y-axis measures were redacted – I don't understand why – but I think the SPC charts are fundamentally the same.

**Q** What is the thing that you that you see in the data and the analysis as opposed to the conclusions that is not entirely positive about this report?

**A** Well, I think-- I mean, my critique of this document, and I don't know if you wanted to take me to SPC charts at some point, but----

**Q** Well, there is a general critique of their use, I understand that, I don't think we need to revisit that----

**A** Okay.

**Q** -- but in terms of-- if we can take what's in your statement as read, what would you list the things that are helpful in this report?

**A** Well, I think it's the appropriateness of the SPC charts----

**Q** Right.

**A** -- in this setting is one. The second is that it's clear to me, in retrospect – and, you know, I didn't realise when I first saw this report, you know, three or so years ago – that the comparison with Aberdeen and Edinburgh I think is inappropriate because----

**Q** So that's on page 231?

**A** Yeah, it appears that this was a whole hospital comparison of data. If you look in fact, it says:

"Comparison of other Health Boards, when comparing the overall hospital rate of positive blood cultures."

So, it seems to me this was not a comparison of the haematology-oncology patients in these three hospitals. It was a comparison of whole hospitals.

**Q** That's the whole children's hospital?

**A** Well, that's what it did. Now, I did want to discuss with HPS, I did want to try and clarify this, but I think probably it was inappropriate for me to ask them to clarify it, but----

**Q** Well, I think the evidence that we had, if I recollect, and we can check the transcript, was that one of the difficulties around carrying out this work was it was done at very short notice in a 10-day window, and it's quite hard to get data?

**A** Yes, absolutely. It is very difficult to get this kind of data. But you see, I just think that, and then the second thing is that they pooled the two hospitals. The profile of the three children's hospitals in Scotland are very different in terms of their size and complexity of case mix. Aberdeen has a very small, very small, paediatric oncology unit. Edinburgh has, by UK standards, a small paediatric oncology unit. Glasgow has a substantial paediatric oncology unit with a bone marrow transplant unit. It's not the same case mix.

**Q** So it's not comparable?

**A** Well, I mean, in the end in life, you compare things with what you've got, not with what you hope you might have, but you have to bear these things in mind. So I think there was a rather – perhaps it's a bit unkind to say – casual assumption that these comparisons were comforting, and I'm not sure they're necessarily valid enough to be comforting.

The other point, of course, is it says that the rate of positive blood cultures was higher in Glasgow for environmental, including the enteric group, over the two years 2017 to 2019, and the overall rate was higher throughout the period, I think, if you look at the paragraph above.

**Q** Yes, so it reads:

"The incidence of positive blood

cultures [it's in the middle of page 231] using the case definitions 2 to 5 was higher in the RHC for environmental, including enteric group, but lower for the gram-positive group, and there was no difference in the rates for the gram-negative group and the environmental group, and then compared over two years, the rate of positive blood cultures was higher in the RHC for environmental, including enteric, and the gram-negative group, but lower for the gram-positive group, and no difference in the environmental group."

What's the point that you would draw out from that?

**A** Well, there were actually differences.

**Q** Yes.

**A** There were actually differences, but the conclusion seems-- and you know it's stated I think in Jane Grant's letter that there were no differences, and I think it's just not the case. I think there were some differences. You can debate the degree and meaning of the difference, but it seems to me that this report was interpreted less precisely than perhaps it should have been.

**Q** Right. Well, I'd like to go back to the reaction to the draft. So, that's bundle 25, page 159. Unless his Lord----

**THE CHAIR:** Mr Mackintosh, if we're----

**MR MACKINTOSH:** Back to bundle 7.

**THE CHAIR:** -- moving from the distinction in the conclusions between the redacted and unredacted drafts, I think I'd like to ask a question of Professor Stevens.

**MR MACKINTOSH:** Of course. My Lord, I'm in your hands.

**THE CHAIR:** You've pointed to a difference in the wording between the unredacted draft and the redacted draft, and if I've got them the right way around, the redacted draft is the one that comes after the un----

**A** Well, I understand so. The redacted draft is the one I only ever had access to, and I could never understand why.

**THE CHAIR:** I have to admit, I don't think I've necessarily been aware of the distinction between these two texts, and I may have been looking at them thinking I've been looking at the same document. However, if I've got this right, in the redacted draft there is additional text. Have I got that the right way round?

**A** Yes.

**THE CHAIR:** Now, what significance do you draw from the addition of that text?

**A** Well, the additional text reads, "There is no evidence from the HPS

review”----

**MR MACKINTOSH:** So it's page 236.

**A** -- of data that supports the continued restriction of services,” and I would just challenge that statement. I think that the unredacted version, without that statement, is a more honest understanding of what this paper was all about.

**THE CHAIR:** There may not be much distance we can take this. I have to admit that when I read the unredacted version, although it doesn't say it explicitly, I took the meaning from that was that you should look at your restrictions again because they need to be looked at again. The implication being that the authors of the report were unconvinced of the necessity of them.

Now, that's simply my reading of text, and it may be wrong, but you see a distinction that the addition of-- I mean, I do see the addition of text makes the position explicit. I just would invite your comment on whether that meaning was not already implicit in the unredacted draft. It may be an (inaudible) observation, but that's a different point.

**A** Yes, I think I say in my witness statement that I didn't think that GGC should have taken as much comfort from the HPS 2019 as they appeared to take, and then when I discovered-- and this is a long time after I did my witness statement-- that there was this changing in wording, it seemed to me it was just pushing that observation to a slightly more stronger position.

**THE CHAIR:** Thank you.

**MR MACKINTOSH:** I suppose what I should probably put to you is that the evidence that we've had from those involved in the events of September, October and November is that there is a change of position in HPS. They move from being unconvinced about the ward being suitable for reopening to accepting that, and that is a decision that's then made in November, and so you haven't seen the other information they were looking at. You're just looking at----

**A** No, I'm in no position to speculate why there was a change.

**Q** You're just noting it.

**A** All I'm doing is I'm pointing out there was a change.

**Q** Right. What I want to do is before lunch is to look briefly at the subject of Mycobacterium chelonae, and I wonder if we can go back to bundle 25 to page 159, the top entry?

So, we probably don't need to go to the paragraph, line 292, but in your draft and indeed your final report, you state there were three Mycobacterium chelonae cases, and you get this comment:

"We consider this statement to be accurate, as we believe there should be state two patients, not three per case reported in the IMT minutes."

Now, I want to be able to see-- This is a bit of a memory test for you, so maybe you may want to go away and think about this, but which year can you remember are the three cases of Mycobacterium chelonae?

**A** I think you could probably find it. I can't answer it, but I think you can probably find it from our overview report.

**Q** Right, well, let's go look at----

**A** Because there's a table which gives you the distribution of infections by year.

**Q** So, that's bundle 6.

**A** I've just got to find the page.

**Q** No, I'll find it. Page 1028.

**A** Two in 2018 and one in 2019 is the answer.

**Q** So, the reason I'm pushing this, this is Table 4.2, and it appears on page 1029. This is at genus level. You've got one in 2016, two in '18, one in '19, and then at species level.

**A** Oh, so, I've got four there, but one patient had two positive cultures.

**Q** Well, indeed, and that's the thing. I want to look at page 1030, if possible, because we've-- I think our experts might have worked this out independently, and I wanted to just see if you could recollect something.

So, do you see you have page 1030, two-thirds down the page, Mycobacterium chelonae one case in that column which is '16, two infections in '18 and one in '19?

**A** Yes.

**Q** Now, the patient who has the two infections in '18 is known to the Inquiry, and it's a core participant. The patient in '19 is not a core participant directly but we know of. The patient in '16 is quite interesting. How did you find it?

**A** It was in the data set presented to----

**Q** It wasn't added in because they were the Mycobacterium chelonae?

**A** No, I mean, no.

**Q** It was in the bloodstream infection data set?

**A** Yes, I think one case of Mycobacterium chelonae was not a bloodstream positive case. It was, I think, a pus-derived culture, I think.

**Q** Because the reason is that Dr Mumford has in her report identified the 2016 case from the bloodstream infection samples that we supplied to her. It appears in a footnote in her narrative. I don't know whether you noticed that?

**A** No, I didn't, actually.

**Q** But the reason that-- we just-- I wondered if you'd be able to work out

why the Health Board thought there were only two patients affected?

**A** I don't know. I could try to go back to original records and----

**Q** Well, you don't have access to them at the moment.

**A** I don't have access, but I do have access to a certain amount of data. I don't have access----

**Q** I don't think there's any dispute about the fact there was a 2016 case. That's not the point. It's that I wondered if you were able to tell us more from your engagement with the Health Board about why it was that they thought there were only two patients affected?

**A** I have no idea. I've no idea. I mean I just assumed that they'd made a mistake. I mean, we just said "We disagree, there are three," because you know we dealt with three we knew that.

**Q** Because that's the records that were you were seeing?

**A** Yes.

**Q** Right. I wonder if we can go to back to bundle 25 – go to page 162. This comment about the paediatric trigger tool. Was this the first time you'd realised there was some anxiety in the Health Board about its use, or had it come up as a problem before? Because it eventually results in letters and things.

**A** No, I mean, when I first met the haematology-oncology clinical team,



it was front and centre of their concerns.

**Q** Right.

**A** They said, you know, "Why are you doing this?" You know, why are you using this technique? I was slightly disarmed because, you know, as I've already explained to you, I didn't particularly want to do it.

**Q** Right.

**A** But I didn't know there was a Board-level anxiety about it. I think they wanted to know about the-- I mean, I can understand why they wanted to challenge the validation of any methodology we were using because they challenged-- They've challenged all the methodology we've used, and they just wanted to know, and, I mean, that's our descriptive answer. This didn't strike me as a particularly significant encounter.

**Q** Right. Can we go just briefly to 167, which is row line 1206 to 1220? This is discussion about the comments from the Health Board is in the third column in terms "normally in clusters are undefined." They're commenting-- They're drawing out the conclusions, they say, of the HPS 2019 report:

> "The data presented in this report does not apply then to a single point of exposure, and there is a need to continually monitor the risk to the patient population."

Now, you provided your response to

yourselves in there. I just wonder what your reaction to the idea is that you're looking for a single point of exposure. Is that the question you were looking-- asking yourselves or?

**A** I mean, I suppose it's an inter-- I suppose I'm slightly confused. It depends what you mean by a "single point of exposure." You know, was it a single tap in the whole institution that was the cause of a problem, or was it was there a more generalised point? I mean, I've-- we always took the view that it was very unlikely to be a single point of exposure, you know, that there was a more general, there was a more general risk from the environment.

**Q** Because one of the things that we've noticed in the evidence from those involved in the IMT is, of course, you didn't speak to the actual clinicians about the substance. It comes from the notes in your case. All your knowledge comes from the IMT minutes, rather than taking witness statements or anything?

**A** No, we didn't take witness statements, no.

**Q** Yes. So, we've had some evidence that there's a view that's not held by everybody that in 2018 the source is the water system systemically, or widespread, and it involves biofilm and it's happening across the whole hospital, and that results in point-of-use filters and controls but in 2019 there's a discussion of other things. The drains had been an issue the previous year, the chilled beam systems-- condensation on them, and also leaks from the chilling circuit. Now, all of that begins to bubble up in '19, and one of the things I've noticed about your report – I just want to put this up before the lunch break – is that you don't really discuss what the environmental causes are other than just the environment in your report. Is that a deliberate step?

**A** Yes. I think it was because we were aware that this was a recently evolving understanding. We felt that our task was to look as widely as we could at the environment in terms of seeking information. So, we were looking at IPC practices, we were looking at building interventions, we were looking at water sampling, we were looking at what we called hard surface sampling, which included drains and chilled beams. We were trying to go to every place without kind of having any apriori understanding of what was likely to be the source.

**Q** Does that mean that your conclusion, if it tells us anything, is that there's a-- 30 per cent or so of the infections have a probable or more than likely than not, whatever it is we've discussed, connection to the environment. You can't tell us precisely what the causes were? You can't

differentiate between chilled beams and the water supply and the----

**A** No, I don't think we can, but I think what's emerged since we did this work, in my understanding, is, anyway, that the water system was contaminated, and so my assumption is that supply had something to do with this, but----

**Q** That wasn't the conclusion that you reached directly?

**A** No, and I don't think you'll find that we put anything to that extent in our report. I don't think we did.

**Q** Because one of the things I realised I should have asked Ms Evans yesterday – and I can't ask her now, so I'll ask you before the lunch break – is that-- I put it to her that, in a sense, your exercise was a bit like an IMT.

**A** Yes, I think essentially it was. I mean, my understanding of an IMT is it takes something that's been flagged within a PAG as significant or serious, or whatever you like to call it, and it seeks to look in the round at what's going on, whether it's one particularly serious infection or whether it's a run of other infections. The purpose of the IMT, surely, is to try and illuminate what's going on, because if there's a remedial cause, then you need to do something about it.

**Q** But the distinction between your exercise and an IMT type system is that you're not actually drilling down to, “Sort out that sink/It's the water/It's the chilled beams.” You're leaving it at a more broad, “It's the environment.”

**A** Well, I think we were trying to do that. So, I think when we asked for records of water samples and hard surface samples and so on, at the start of this, we rather assumed that we would get a stream of information that might inform that. It was only when we looked at the data and began to say, “Well, we we can't see anything here."

**Q** But you didn't in your final overview report say, "X percentage of the probables are connected to the water system. Y connected to the chilled beams?"

**A** I don't think we were in a position to do that. There just wasn't any data to be able to direct us in that way.

**Q** Okay. Well, that's very helpful. My Lord, I suggest this is probably the right time to pause for lunch.

**THE CHAIR:** Yes. We'll take our lunch break, and could I ask you to be back for two'clock, Professor?

**A** Certainly. Thank you very much.

**(Short break)**

**THE CHAIR:** Good afternoon, Professor. Mr Mackintosh.

**MR MACKINTOSH:** Thank you, my

Lord. I wonder if we could just go back to Bundle 25, document 5, the rebuttal-- response rebuttal document----

**A** Yes.

**Q** **--** and just pick out three points which actually we're going to deal with anyway, and we'll use it as sort of an index. Go to page 180, please. So, this is the line in the middle of this page, 1621 to 1626, about the implication that more-- they seem to think there was an implication that you could have possibly made better links with more and better data. I wonder if there's anything the Inquiry needs to understand from this. Am I right in thinking that the position is effectively had you had more data, you might have been able to created more sophisticated conclusions about individual infections, but it simply wasn't there on the ground? There wasn't information about----

**A** Yeah. I mean, I think we said that anyway in our report that more data would have been helpful. I mean, I just wonder whether what-- I'm just struggling-- trying to understand exactly what it was they asked and what we say. Maybe it hinges around this bit that says:

> "We say that the lack of positive samples to provide environmental links does not exclude that one exists."



Whereas I think GGC's position we were interpreting is saying that a lack of positive samples establishes that there's no link and, you know, we're essentially saying, you know, "You can't say there's no link because the sampling was inadequate."

**Q** In respect to the sampling being inadequate, do you have any thoughts about whether, in the future, Whole-genome sequencing should be – I hesitate to use the word mandated but – encouraged to be used when there are repeated clusters of infections in a particular unit or concerns begin to grow at this sort of scale, or is this event so unusual there's no point of having a predetermined----

**A** No. I mean, I think, you know-- I'm not sure I'm quite the right person to answer the question, but I'll give a view, and the view is that if you think you're dealing with something difficult/unusual, then you should use all the tools you have in your toolbox to try and sort it out, and this would be one of the tools, but I can't envisage it would become part of routine practice on the day-to-day basis.

**Q** Is it something that you're aware of being used in in the Bristol unit when----

**A** I'm sure it is used from time to time, but I don't think it's used unless there's a particular requirement to use it.

**Q** I wanted to jump on to page 213, really as a hook, to ring out the issue of whole-genome sequencing, which you've also covered in your statement from page-- I'll go to the statement bundle, page 138. I'm conscious that Professor Wilcox-- this is his area----

**A** Yes, very much so.

**Q** -- and I discussed it with him in considerable detail yesterday.

**A** Okay.

**Q** I really wanted just to understand your perspective on it as, in a sense, a customer of his----

**A** Okay.

**Q** -- work. To put this point of challenge to you, as the customer, I get the impression from Professor Willcox yesterday that he had various reasons to deal with the data of the individual analysis of Stenotrophomonas particularly, and the closeness of the-- or absence----

**A** Yes.

**Q** But more it was about where the samples were coming from. So, he was able to point to us-- there weren't enough samples that were closely related to the wards or closely related to the year. To what extent is the point about whole-genome sequencing the same as the point about the maintenance? It's that there just aren't enough records to produce a comprehensive picture.



**A** Yes. I mean, my recollection of the data that we saw for whole-genome sequencing was that-- and I think GGC made the point or tried to make the point to us. They said, "Well, we've done this work. We sequenced this many samples," but when you look within the basket of samples, we found only a proportion of the cases of a particular bacteria – Enterococcus , say – that were included in our study. Others were patients from elsewhere in the hospital, and then there were what I would describe as random environmental samples, so there was no systematic approach. I think the problem is not with the technology of WGS, although that has to be interpreted appropriately. It lies, I think, with the systematic nature of the investigation.

**Q** Is there anything that arises from the fact that what is attempted to be demonstrated is the absence of a link, rather than the existence of the link? Does that just, at a higher level, affect how one thinks about a technology?

**A** I would have thought that-- and I think I need to be cautious that I don't stray beyond----

**Q** I want you to stay as the customer at this point.

**A** Okay. I'm the customer. I mean, my interpretation would be that if you want to prove an absence of a link,

you probably have to process quite a large number of samples. If you want to prove a link, and you get lucky and you demonstrate the link, you might do that in 5 cases or 500 cases, you know? So I think trying to prove an absence of a link is a much bigger task.

**Q** Is there any principle in the way that other forms of research are designed that can be, sort of, read across? I mean, if you're trying to prove a link between a particular medication and a particular clinical outcome, or alternatively you're trying to disprove a link between a particular medication. Does that cause a different way of designing a study?

**A** I mean, one of the key elements of a useful study is that you do it prospectively. I mean, I suppose that would be an observation I'd take-----

**Q** Yes.

**A** You set out with a structure that's predefined that you have designed in the hope that it'll answer the question you're seeking to ask. So prospective data collection is always more helpful----

**Q** Why is that?

**A** Well, because if you manage your study well, you get the data you want, and the disadvantage, of course, is it takes time. I mean, the advantage of a retrospective review of anything is that you can do it much quicker. It's the same with the challenge we have in children's cancer treatments, that if you really want to prove one treatment's better than another, you have to spend a number of years comparing the two types of treatment and looking at not only their efficacy but their side effects. So, prospective studies are better for quality of data but retrospective studies have their place because they take advantage of data that's already been collected, albeit sometimes with imperfections, and I think that describes quite nicely what we were trying to do.

**Q** Can you do a retrospective study to prove the absence of a link?

**A** I think if your sample size is big enough, yes. You probably can.

**Q** I appreciate you're not the person to ask about whether the sample size is big enough, so probably----

**A** Yeah. I mean, I don't know what the sample size would need to be, but I suspect there are ways of working out the sample size you need to deliver that.

**Q** What I want to do now is to move on to the topic-- We're going back to Bundle 25, please, and go to page 215, which deals deals with a particular-- Well, actually, I'll park that for a moment. We'll do some comparison Epidemiology, so we'll take that off the screen. What I want to do is look at the issue that we

touched on before of looking at comparators.

**A** Comparative populations?

**Q** Yes, because we've just touched on it before, and you've discussed, I think, your concerns about the HPS 2019 work in respect to Aberdeen and London-- and Lothian. So we've dealt with that, but it's really if you, as a paediatric oncology consultant, wanted to develop/understand a comparator hospital for Glasgow – now that you know quite a lot about its patients, the sort of cancers they have, because you've looked at all these records – do you feel able to suggest what are the best or ideal comparators in the UK for the Royal Hospital Children's Paediatric Oncology?

**A** Yes, and you-- I mean, you asked me that in the supplementary questions.

**Q** Yes.

**A** I'm happy to rehearse my answer. I mean, I think when you're looking to identify a comparative population for this purpose, what you need to do is to identify, ideally, more than one or two other hospitals that are broadly similar in terms of the size of the population they treat, the casemakes – that's the type of populations they treat and the treatments they deliver – and the in which that treatment is delivered. So, the shorthand for determining the size of a children's cancer center is by the number of new patients registered per year. I mean, that's the sort of the currency that we tend to use when we talk about the size of children's cancer services. Because children's cancer is relatively uncommon, no one has a unit with thousands of patients a year. It's a matter of a few hundreds, even in the largest unit, and some are well below 100 or even below 50. If you take Aberdeen, the number of new patients a year is really very small.

Glasgow is a larger than average centre in the United Kingdom, but it's not the biggest by that metric, but it is, however, a centre that delivers bone marrow transplantation. It's the national centre for bone marrow transplantation, and that will be an important metric because patients who require bone marrow transplantation are the most vulnerable of the patients we look after, and if you have a service that delivers bone marrow transplantation, you tend to attract more complicated cases of leukaemia, in particular.

And then there's a final component, which I think probably hasn't been discussed before, or perhaps it was somewhere in our report, and that's this concept of shared care. One of the challenges of delivering care to children

with cancer is that it's aggressive, persistent and quite demanding, and many, many units, particularly in England – and I would say particularly my own unit in Bristol with some others – have evolved a pattern of delivery of care by which a lot of the routine aspects of treatment are devolved to district hospitals. Now, it does happen to some extent in Scotland. So, that would have an impact on your engagement with the environment in the centre of interest.

**Q** What sort of routine aspects do you have in mind?

**A** So, for example, let's take a child with the commonest kind of leukaemia, acute lymphoblastic leukaemia. They have, say, three months of very intensive treatment early on in their phase of treatment, perhaps for some children a little longer than that, and then their chemotherapy settles down to a much more manageable, outpatient-based pattern for a period of up to two years. Now, that manageable, outpatient-based delivery of treatment can be readily devolved to another hospital. So, take the part of the world where I worked. The very far southwest of England was four hours' travel from Bristol, so sending patients back to Truro and Plymouth, for example, for more routine aspects of their treatment was something that we routinely did, and with



appropriate supervision and support, it works well, and no disadvantage from that approach has been demonstrated. What it does mean is that those patients then don't come back to Bristol very often, and if Bristol was where you were worried about the environmental infection risk, it would dilute out the exposure those patients had.

**Q** Because they wouldn't have the outpatient----

**A** Because they wouldn't-- Yes, and to some extent, it did happen here, because when things got difficult at GGC, they were, I believe, starting to send out more patients to Dumfries, say, or-- You know, I don't know exactly which units they relied on, but they were doing a certain amount of shared care. Possibly, I suspect, more than they were doing before, but I don't think it was ever quantified and, in fact, one of our kind of subsidiary criticisms is that the managed service network that glues together the three children's cancer centres in Scotland didn't seem to get involved in this game at all. I mean, they're just completely absent from the whole discussion about what was going on at GGC, and my assumption was that the network should have had some part to play.

**Q** You mean that the network could have taken some of this shared

care----

**A** Well, I think they could have taken a more proactive position in terms of-- You know, patients had to be decanted from Glasgow at one stage, and some of them were sent to English units like Newcastle, I believe. There's always a certain amount of movement around, because some patients have very specific needs and have to go to certain centers.

But to come back to your original question, I would match on the size of the unit in terms of the number of new patients a year, whether or not they do bone marrow transplantation, whether or not they do a significant amount of shared care, and what their age distribution is, because most children's cancer units now include an element of what we call a teenage and young adult service which pushes the upper age range of patients beyond what might be seen as the normal paediatric age. It takes patients up to 19, and sometimes even to 24. So you'd have to be clear about defining what the age profile of your patients was. Great Ormond Street, for example, which you might think would be a good place to go for a match, actually has a policy of taking very few patients over 12, and they also take high-risk babies. So there are variations of case (inaudible) which you'd only know



about if you were kind of, as it were, in the business.

But, from that, you can derive, you can look-- and I did give a few suggestions that-- You could find units, and if you did it prospectively, of course, you could collect all the information so these things could be taken into consideration in the analysis.

**Q** Well, the thing that I-- Well, obviously we're not doing it prospectively. We're doing it retrospectively, and we asked Mr Mukherjee to do some work. I know you looked at his report, and so I'm going to just take advantage of the fact you're here and you, sort of, can't run away by showing you a list and asking you to talk about it.

**A** Yes, okay.

**Q** So, this is his report. It's in bundle 21, and the key section starts on page 21, because what the Inquiry did was we sent freedom of information requests to a large number of units – page 21, please – and the freedom of information request made certain requests, which are listed here at 7.2.4: the year of construction; any major upgrades; the number of admissions by year in 2015-2022; the number of individual patients admitted to the unit by year, which I'm assuming is the number you were just discussing.

**A** Yes. Well, no, that would be

the number of individual-- That's the number of admissions. I was talking about the number of new patients a year defines the sort of overall business of the centre.

**Q** I see. So, we didn't ask that.

**A** No.

**Q** Total number of blood cultures taken from patients by year; positive blood cultures, and we did define that in the FOI; and a list of the number of all organisms by species isolated from blood cultures from patients on the paediatric haemato-oncology unit, whether deemed significant or not, by site, by year in the years total and de-duplicated, and we contacted – next page, 7.2.5 – this list of hospitals, and of course we don't get to choose who replies. The first question, I suppose, may be not what we want to hear, but did we miss anyone out?

**A** Do I see Liverpool there? Yes, yes. No, I think that's pretty comprehensive, yes. I don't think St Mary's Hospital should be included because they don't treat children with cancer, but they do do stem cell transplantation for other conditions.

**Q** Fortunately they didn't reply. Only four replied----

**A** Bristol.

**Q** -- in 7.2.6. Great Ormond Street, Cardiff and Vale, Leeds and Oxford. Now, it would be particularly helpful if you would be able to give a brief view as a paediatric oncologist of the extent to which each of those do or do not compare to your understanding of what is being done in the Schiehallion unit in the Royal Hospital for Children in Glasgow.

**A** Okay. I mean, just very quickly and at quite high level, I'd say that Great Ormond Street is a much busier unit, a much bigger unit than Glasgow, but it has a restricted age range, so it will be skewed to the youngest patients, particularly to under-two-year-olds. They take really all the babies from London and the southeast. Cardiff and Oxford are both relatively small units, neither of which do bone marrow transplantation, and Leeds is an above average size unit which does do bone marrow transplantation, so Leeds would be quite a good fit, I would have thought.

**Q** And Cardiff and Vale?

**A** Cardiff and Vale is Cardiff. It's the Welsh centre, and they're like Oxford. They're relatively small.

**Q** And when you say relatively small, are you able to give us a view of how they compare to, say, Lothian in Scotland, or is that not something you can comment on?

**A** No, I think they're bigger than Edinburgh.

**Q** Right. That's helpful. What I

wanted to do, then, was to ask you a particularly difficult question. So Mr Mukherjee's done three reports, and I'm not proposing to take you through all of them – we've got to do that with him on Tuesday – but he reached a conclusion in his first report which, I think it is fair to say, is not fully accepted by all core participants and which has to be drilled down into quite a lot, and I want to effectively look at the question of magnitude of difference and whether these differences with the comparators matter.

I wonder if you could just go to page 37, please, in the bundle. So, this is the first report, and I think it's fair to say, my Lord, this report-- has a flaw in it, in that the admissions data supplied by Greater Glasgow and Clyde in this table only includes overnight admissions, whereas the parameters appear to have included all admissions. Parking that aside, I think Mr Mukherjee, if he was here, would point out that there is a large difference in the rate of infections in this piece of work between the Schiehallion units and the comparative units in these years, six or eight times.

**A** This is pooled data from the comparator units?

**Q** Yes. All four are pooled together.

**A** Okay.



**Q** He repeats the exercise in this supplementary report, and we can see that in the same bundle, in a different way of presenting it, on page 86, and, again, it's fair to say that some core participants have some issues with this particular piece of work, and we will explore that on Tuesday. But, again, the purple line is the overall comparator of bloodstream infection units per 1,000 admissions where the purple line at the top is the Schiehallion unit and all the different lines at the bottom are the four comparators together and the dotted line is the aggregate of the comparators.

Now, the point I want to put to you is this: if it's the case – and it's a matter of debate – that this large differential between the comparators and the Schiehallion unit is a real thing – you can take that off the screen – and not an artefact of the way the data has been analysed, if it's a real thing, does the fact of the scale of the difference help in any way, given the problems you describe with the comparator units?

**A** Perhaps I can offer two observations.

**Q** Yes.

**A** One is that the magnitude of the difference is such that I would be surprised that the differences that I've tried to explain in relation to the lack of complete comparison with the other units

would change the message. I think that the scale of the excess seen at GGC is so substantial that the differences that could be attributed to what I've been talking about it would moderate it, but I don't think it would take it away. That's just my judgment. I mean, someone would have to do the maths, as it were.

**Q** Yes. I mean, that's something we'll deal with.

**A** The second point, if I may, is just to is to make the observation about what the denominator should be.

**Q** Well, I was going to come to that because those tables use admissions as the denominator. The second one used both day and overnight admissions in Glasgow to compare with both day and overnight admissions in the others, and we've had evidence in the Inquiry that in Scotland there's a view, I think quite widely held, that occupied bed days is the better denominator, and I wondered if you had any view on the merits of either of these positions.

**A** I think both have their disadvantages, really, and the reason is that the amount of time you spend in hospital, so occupied bed days, clearly matters because it's the amount of time you're exposed to an environment that might be imposing a risk. But what also matters, I think, is the frequency with which you bounce back into that



environment. So if we look at the way children with cancer are treated, we tend to maximise the amount of treatment that can be delivered as a day case, and we do that for what we believe is the good of the family unit but also because we recognise that hospitals aren't and never have been the healthiest place for anyone.

So, if you spend 20 days in hospital continuously, are you more or less at risk than if you come to the day care unit 20 times in, say, a four-week period? It's a moot point, and on virtually all occasions that children come to a day care unit for treatment, they would be having their central line accessed, so someone would be manipulating their central line, so that will be 20 manipulations of a central line. Now, if a child was in the hospital for 20 days, it depends what's going on, but their central line might not be manipulated every day, although it could be manipulated every day, and sometimes manipulated several times in a day, because if you're giving antibiotics several times in a day, for example, you're constantly opening and closing the line.

So it's not easy to say, "Well, clearly occupied bed days is better." I think you have to include the day cases, but then there's something about the sort of cadence/the frequency of day case

attendance. I think I'm taking you into territory that you couldn't control for, in all honesty.

**Q** No, I suspect that's the case, but it's certainly helpful to understand it. I think what I'm just doing now is checking we've covered everything before I move on. Just give me a moment. Yes, I wanted to ask you about-- Actually, we had it on the screen before when we looked at page 25. I don't need to go back to it. The idea that you cover in your statement on page 119, the use of control measures, and from paragraph 55 you discuss them in some detail, and we can clearly read that over the next two paragraphs, discussing in paragraph 55 the chlorination of the water, the enhanced cleaning measures, and I see that you observe in 56 that:

> "When considering a timeline, if you see a control measure that's been introduced and the infection numbers drop, it could potentially help you to conclude the infections were more likely to be linked to the environment."

Then you give an example. How do you react to the suggestion, I think from NHS Greater Glasgow, that the fact that major changes were made – point-of-use filters, the decant, chlorine dioxide, increased water testing – these are simply examples of the precautionary principle being implied by the



management, and they can't be used to confirm finding a link to the environment? How do you find----

**A** I agree it doesn't provide an absolute direct link, but it's very strong evidence, I believe, that the management of GGC acknowledged that there was an issue in the environment. I mean, it wasn't just chlorination of the water supply, it was a complete rebuild of the environment in which children with cancer were going to be treated. I mepagean, there's very substantial investments. I mean, those kind of decisions surely must be driven by not just a precautionary principle, although, you know, honourable though that is, but it must be driven also by a recognition that's, you know, "Well, what if we're wrong? What if there really is a problem here?"

**Q** What I want to do now is to move on to the point when you have shared the draft and you have a meeting, and you discuss receiving Ms Grant's letter of 1 March, which is Bundle 25, document 3, page 151, and you cover this in your statement from paragraph 132, but we'll stay with the letter. So, this is the cover letter for effectively the comments, isn't it? Was it later than that?

**A** No, it was later than that. I think-- I can't quite remember when the comments were sent back to us. This

was when we were-- 1 March was when we were-- I think we had seen their comments by then.

**Q** Yes.

**A** I think we'd seen-- but I don't have the date in mind, I'm afraid.

**Q** What I just wanted to understand is, between this and a letter of 5 March, you had a meeting----

**A** We did.

**Q** -- and you----

**A** 4 March, I think it was.

**Q** -- discussed the meeting at paragraph 133 of your statement on page 143. What I'm quite keen to do is to understand what the approach being taken with you by the Board was. So, firstly, who was in the meeting?

**A** I do think I have, somewhere in this file, a list of the people who were in the meeting. There were a very substantial number of people in that meeting, if you could give me a moment to identify that. Did you want me to provide a list?

**Q** Well, I was quite interested to see who was there from Greater Glasgow and Clyde, if possible.

**A** It is inevitable that when you want a piece of paper, you can't find it. I did write it out. (After a pause) Oh, here it is. On 4 March, the representatives of Greater Glasgow and Clyde who met with us were Jane Grant, the Chief Executive, Jennifer Armstrong, the Medical Director, Linda De Caestecker, the Director of Public Health. Scott Davidson, who I think is an Assistant Medical Director----

**Q** Yes.

**A** -- Alan Mathers, who I think is the Divisional Director for Women's and Children, William Edwards, who is the Director of e-Health and essentially responsible for patient records, and Elaine Vanhagen, who-- I described her previously as our conduit into the organisation in terms of the access to and receipt of information.

**Q** So, what was the broad point they wanted to make in that meeting?

**A** Well, it was----

**Q** Or what had you heard about that?

**A** It was prefaced by a request for a discussion about how the meeting should be managed. So, I had a telephone conversation with Jane Grant the day before the meeting. So, she sent the letter on the 1st-- In fact, I've just spotted there's a date error. It says 2023 but clearly it was----

**Q** If we go back to the letter, it's Bundle 25, page 151.

**A** No, not on the letter. It's in the reference in my statement.

**Q** All right.

**A** In paragraph 132, it says the letter was written on the 1st----

**Q** I think we've added that, to be fair, so that's our mistake.

**A** Yes, yes, but I just saw it shining at me. So, she wanted a conversation to ask how the meeting should be conducted and, to my memory, we had a perfectly cordial conversation on the phone. I acknowledged that it was sensible for us to talk about how the meeting was managed. I said that this was their opportunity to say to us what they wanted to say in relation to our report, but I did make it clear that, whilst we would listen, we would not guarantee to change anything in the report, you know? It was an opportunity for them to have our ear, essentially. I think that's the message I got across to them.

**Q** Did they go through, line by line, that document that we----

**A** No, they didn't, but they kind of-- Again, my memory was it was a slightly tense meeting.

**Q** Right.

**A** I think Jane Grant introduced it. I think I prepared-- I had prepared a little statement about what we had been tasked to do because I felt it was important for me to set out that we-- you know, we did have terms of reference, what we had been tasked to do, the approach that we had taken. I mean, it was a couple of minutes. It wasn't a long speech, and then several members of this team then-- in fact, most of the team apart from Elaine Vanhagen, I think, were given the opportunity to say something and they came at it from slightly different perspectives.

William Edwards was very concerned about the difficulty we'd had with the clinical records and wanted to explain that he felt that they had responded adequately and, I mean, you know, I did have some sympathy because I know that the development of electronic records in Health is a challenge for most of all-- in fact, I'd say all organisations.

Jennifer Armstrong was, I think, pretty forceful with us about essentially reaching the wrong conclusion. I mean, that's shorthand for saying that she was quite challenging to what we had produced. Scott Davidson picked up a couple of specific points, I can't remember what they were. Alan Mathers', I think, contribution was actually rather more about, "Well, you know, this is a team, the haematology-oncology team, that's had a very difficult time, this has been going on, " and I think there was, to be fair, from Jane Grant, a reference to-- I think there is in her letter, although I'd have to search for it----

**Q** Shall we go back to the letter, Bundle 25?

**A** I mean-- So, you know, they

clearly reflect in this letter a lot of the stuff that they put in their rebuttal document, but I think she wanted to, you know, point out-- yes, she says here, second paragraph of this letter:

> "This has been a challenging period... Ensuring a balanced report is critical to support and assure our patients and families, but also our staff and the wider public in terms of confidence in the services we provide."

So, you know, it was put in the context of, you know, "We really want to move forward from this."

**Q** What I wondered was whether-- Obviously, we can read the letter and we can draw from it what's there, but I wonder whether this issue about the Health Board not being able to understand the reasons, which Ms Armstrong gave evidence about in her evidence here two weeks ago, came up in the meeting, because I put that evidence from her two you, that she felt that she couldn't see what the reasons were. Did that come up in the meeting?

**A** To be absolutely honest, I can't remember how it was couched. That may have been the origin from which it was directed, and I don't remember her saying, you know, "The trouble is we haven't seen your evidence," but even if she didn't say it, it may well be the point she was moving from. I'm, you know,



happy to accept that.

**Q** The reason I say that is because, as an Inquiry, we've just discussed and we discussed yesterday with your colleagues that we don't have, for reason that makes sense to us, access to the individual 118 syntheses and the 85 family reports, and it seems clear that the Health Board don't have access to it, and we're doing our job, which is a different job, but it would be helpful to understand-- I probably should have asked her actually. I don't think I did. But you don't have a recollection of whether that issue came up in the meeting?

**A** I don't remember it being articulated, actually, I really don't, actually. I mean, I felt that the pushback was much more about our overall conclusions, you know, "You can't say that," you know, the issues about whole-genome sequencing, "You haven't taken seriously the data we've provided," you know, there was a comment about the death of a patient and that they didn't feel that we had adequately assessed the situation. They gave an alternative scenario, even though their own death certificate included reference to the infection. There was quite a lot of pushback about the criticism we had given about infection control management on page 3 of this letter.

**Q** Yes, that's page 154.

**A** If you look at the paragraph in the middle.

**THE CHAIR:** I hope this is----

**MR MACKINTOSH:** 154.

**THE CHAIR:** -- not an unhelpful intervention. Just noting what you said, Dr Armstrong you said was pretty forceful about you having reached the wrong conclusion. Now, I think that was the wording you used. The meaning I'm taking from that was that Dr Armstrong, prior to the meeting on 4 March, knew what the right conclusion was as opposed to not being convinced by your reasoning, if I might make that distinction.

**A** I don't know what her position was before 4 March. I don't think I'd met her at all before that. I mean, I think she was exercised by the fact that we had identified a significant proportion of the patients in the most likely group. I think she felt that our criticism of data collection, processing and recording was unfair. I don't-- I mean, a lot of it was about the individual components of our report, not uniquely about, "Well, it's nothing to do with the environment." I don't remember that being the core message. It was, you know, "You've not been fair about whole-genome sequencing. You've not been fair about what you said about the IMT or the IPC Team," you know, "We challenge you about your conclusion about one of the children who died," and so on.

**MR MACKINTOSH:** You were taking us to page 154.

**A** Sorry, 153.

**Q** 153, sorry.

**A** I think it was----

**Q** The section that, “We are, of course, unable to see this evidence.”

**A** Yes, she says that, yes, and that was Jane Grant. “We're unable to see this evidence,” and I don't remember that being rehearsed in the meeting, but it's clearly there in this letter. But it seems to go off in the direction of dysfunction in microbiology.

**Q** Yes, because one thing I wanted to raise with you was that it comes up here in this letter, and you touched on it in your statement – I think Professor Wilcox does it in more detail – but you eventually did come to meet-- You had met just before this, effectively, almost before the end of your work-- You'd met Dr Inkster and Dr Peters.

**A** Yes.

**Q** Is there any particular reason why you met them when you did, rather than earlier in the process?

**A** Yes, I think there was a very good reason, because although, I have to say, at that stage I didn't understand how central they were to the whole process, and I didn't know it was Dr Inkster and Dr

Peters initially. I just knew there had been whistleblowers, and I had discussed it with the Oversight Board, and I remember it was a conversation with Phil Raines, who was leaving the Oversight Board at about that time, but who had nevertheless been managing the interface between us and the Oversight Board, as well as running the Oversight-- the management of the Oversight Board.

I remember having a conversation with him about, well, should we hear from the whistleblowers? And we felt that-- I certainly felt that we shouldn't hear from them until we had had the opportunity to form our own views. I didn't-- It was a bit-- Sorry, I feel like a slightly broken record with the HPS 2019 paper. I felt that was someone else's work, and that whilst we might have a view on it, it shouldn't drive our own conclusions, and it was the same for anything they might want to say to us.

**Q** Because she told the Inquiry in her statement – this references paragraph 1042 – that you had told her at that meeting that you were concerned that the meeting might introduce bias or something like that. Is that something you might have said to them?

**A** I don't know. I don't know whether I would have said that. I mean, possibly I did, but bias in that context would mean to me that we would have heard a particularly one-sided view of issues because there's clearly a contentious relationship, and because they felt they needed to whistleblow about the situation within GGC, they had a particular view, and I thought it was very important, actually, not to introduce that view to our consciousness until we had we'd essentially done our work and we're writing up our report by the time we met up.

**Q** But you'd already heard from Professor Leanord who took over from Dr Inkster as lead ICD if I understand correctly and chaired the IMT after the change at the very beginning. So couldn't-- didn't that run a risk of introducing something like----

**A** Well, it could seem that way, but when i first met Alastair Leanord on 3 February, 2020 – I've now got my list – the conversation was about the structure and the approach to the management of Infection Control within the organisation. It was a much more kind of factual-- It was a much more kind of factual meeting. There weren't, to my knowledge, any opinions expressed.

**Q** Right.

**A** And I don't remember him raising the issue there being challenges from whistleblowers and so on, and then we did meet Alastair Leanord again at least a couple of times in our relatively

frequent meetings during October and November of 2020 when we were really trying to nail down the information from GGC that we were struggling to either get or interpret.

**Q** So these meetings were about getting information rather than asking people to interpret them for you?

**A** Well, one of the meetings actually did turn into-- and possibly we asked that it should-- it turned into an exposition of whole genome sequencing. So he presented part of his data to us to try and explain the approach they were taking.

**Q** I think we heard about that from Professor Wilcox yesterday.

**A** Yes.

**Q** Right. So you had this meeting after the 1 March letter?

**A** Yes, 4th.

**Q** And then on 4 March-- then you get a second letter, which starts at page 155.

**A** Yes, the next morning.

**Q** Yes, I mean, were you expecting a letter the next morning?

**A** No, I was very surprised.

**Q** Why were you surprised?

**A** I didn't feel that we needed a letter. I-- you know-- I mean, I can't remember if I sent an email just saying, you know, thank you for taking the time to meet us, but I didn't think anything more than that was necessary.

**Q** And what did you do with the information in this letter?

**A** I didn't really do anything with it. I just felt rather cross.

**Q** Why did you feel cross?

**A** Well, I felt that there was no necessity to write this letter, and I felt there was, rightly or wrongly – and this is highly subjective – it made me feel that this was a further nudge to us to move our final written report in the direction they wished it to go.

**Q** One of the things that seems interesting about this letter and the previous letter is they both talk about information about the microbiology you couldn't have found from the IMT minutes or the individual documents. So, for this one, it contains the generic email address information, and the previous one discusses, as we've discussed, issues in Microbiology between microbiologists and Infection Control nurses. I wonder what you did with that sort of information?

**A** Well, we had already been-- Well, when we met Dr Peters and Dr Inkster, we had quite a long meeting with them, and they were really clearly very anxious to talk about the historical perspective and their concerns from the outset, and they asked us a number of questions about, "Did we know this? Did we know that?" Some of which we

clearly didn't know, and they sent me, after that meeting, a series of documents, which included copies of email exchanges relating to their wish to send information directly to the Infection Prevention and Control nurses, and a response from Sandra Devine asking them not to do that.

**Q** And that's why that got into your draft, eventually?

**A** Yes.

**Q** But to what extent did this sort of-- I hate to simply compartmentalise it as culture, but culture and operational detail impact on the individual decisions in the 85-family report?

**A** I don't think it did at all. If anything, it kind of hardened our hearts slightly, I think.

**Q** Right.

**A** I mean, I just felt that-- and I could be challenged on this, but all I can report is how it made me feel. It made me feel, “Here is someone who's trying to turn the screw on me.”

**Q** In this case, who?

**A** Jane Grant. I felt that to get a letter 24 hours after we'd had a meeting with a high cast of personae from GGC management, reiterating points, re-emphasising points about, or trying to illustrate points about the behaviour of microbiologists was, well, I didn't understand it. I didn't understand it, and I could only think of one reason for doing it.

**Q** Which was to change your mind?

**A** Well, it was just to encourage us to think differently.

**Q** Could we go to 984 in bundle 6, please? I've got two questions, and then I think we might have a short break to see if my colleagues have any further questions. So, this is bundle 6, page 984. It's about something in your executive summary. It's the second paragraph. Now, you open the paragraph:

> We recognise" that some families will be disappointed in our ability to identify a link or links between their child's infection and the hospital environment with greater certainty than has been possible."

And this is the sentence I want to ask you about:

> "This not only represents a limit of the retrospective review and shortcomings we have described in the data we're able to access, but also highlights the fundamental challenge of identifying a specific source in all such infections. However, the purpose of continuing to try to do so is to further reduce the risk to patients in the future."

Now, we've covered that on and off throughout today, but since, to some

extent, the Public Inquiry is being asked a similar question albeit from the opposite direction down the telescope – sort of top-down – is there any advice you would give us about how to work out whether the hospital environment, particularly the built environment in the water system, might have had an impact on risk or infection links?

**A** I think I stand by the statement to say that what we were seeking to do was fundamentally challenging, because we were doing it retrospectively, but also prospectively it's difficult unless you set up a really quite significant exercise in terms of monitoring the environment at the same time as you're monitoring your patients, and you will have seen that in our report we come back on more than one occasion to our surprise that there hadn't been built in to GGC's response over the years some slightly more robust monitoring of the environment.

To come back to your question is “What advice do I give you?” is I suppose I would say that you have to recognise that there is no absolute-- there's no specific test or statistical trick or piece of information that actually is going to completely nail the environment to infections in these children, but circumstantial information and judgment in relation to the patterns of what is seen is really important.



**Q** There was one final question I want to ask which-- We asked ourselves a question, which I'm going to read out to you, but I'm only going to ask you part of it. So, we ask ourselves a question, we call it key question 4, which is, "Is there a link – and if so, in what way and to what extent – between patient infections and identified unsafe features of the water and ventilation systems?"

Now, you don't know what the features of systems are, so I can't ask you that bit. What I wanted to suggest is to what extent do you think the-- your panel can say that there is any link between the environment in the hospital and the patients and the infections that they were subject to. What's your sort of final position on this?

**A** To the water system?

**Q** To the water system or the environment in general?

**A** Well, I think the conclusion of our report is that for about 30 per cent of the cases-- You can take out the “strong possibles”; we've been there earlier today. But, nevertheless, our assessment is about 30 per cent of these patients had infections that we think, on the balance of probabilities, would derive from the environment, and I stand by that conclusion. I've seen nothing that weakens that conclusion and, in fact, I

have seen emerging evidence for the problems with the ventilation and water system, which would seem to support our positions, make the risk greater.

**Q** Thank you. My Lord, that's all the questions I have, but unless, my Lord has questions, I'm proposing to have a 10-minute break at this point to see what other people have.

**THE CHAIR:** I would welcome your help on this point, Professor. In coming to a decision on "probable" and "possible" as I understood your evidence, you attach considerable weight to instances where you identified clusters of infections.

**A** Mm-hmm.

**THE CHAIR:** I would welcome if you would just maybe tease out why it is-- I think I understand what clusters are, although it might be convenient if you just confirm that to me, but if you could just tease out the thinking which gives weight to clustering where you see it.

**A** Well, I mean, clustering really is a surge in observations of a particular event over a relatively compressed period of time. You have to define the period of time that you consider and how many events do you think are significant, and I think we've always said in our report that simple observation of numbers of events, and the way we looked at them led us to believe that something was not quite right. So we saw-- and I can't quote it, but within the report, you see there are certain periods where Klebsiella and Enterococcus and Stenotrophomonas all occurred in peaks, essentially, over a relatively compressed period of time, albeit months rather than just weeks, although there were some that were more than that. So that's a cluster.

Why does clustering matter? Well, I think clustering matters because when you consider the transmission of infection, it's not a pure situation of the environment infecting a single patient. There's also the other interactions between patient to relative or relative to patient, patient to patient, patient to staff member to another patient, and so on, and if you're encountering a little surge in your exposure to a particular infection, then there's an increased chance that inadvertent transmission of that infection could happen to other patients. So I think that would be our understanding of why it matters in terms of risk.

**THE CHAIR:** Just let me explore that just a little, and forgive me if this is ignorant or naive. If one might suppose either a random incidence of an infection, if there is such a thing, or-- Well, let's say, for example, that a particular patient suffers an infection which has an endogenous explanation from their own biome, now, might that not produce a cluster if that patient has interactions with

staff, the environment in the sense of touching things, or other patients, and also create a cluster?

**A** Yes. That's absolutely correct, and I think you could see that perhaps in an alternative setting that-- for example, in outbreaks of something like rotavirus or norovirus in hospitals, these are highly infectious viral infections, and you can get whole wards affected by patients like this because of the transmission of an infection that might start in one patient. But the behaviour of these highly transmissible viruses is, I suggest, not quite the same as the behavior of the bacteria that are under consideration in this study but, yes, you could but I would be surprised if you would get-- For example, Klebsiella, we talked about Klebsiella being an endogenously occurring organism that is sometimes associated with bloodstream infections in patients with damaged guts, but I would be surprised if you saw a cluster of Klebsiella infections that derive from the point exposure of a single patient with a damaged gut. There has to be, I think, some kind of more continuous exposure into the environment, which is what would come if you had a contaminated water supply.

**THE CHAIR:** When I was first listening to your evidence on clustering, I was wondering-- and please correct me if I've got this wrong. If clustering is to be indicative of an environmental source, does that suppose that something has, over a relatively short period of time – whatever that period of time may be – happened in the environment, or am I wrong about that? I mean, for example, does it suppose that, for whatever reason, a source of infection has located in a particular tap in a particular ward, or does it not suppose that?

**A** No, I think it probably implies a rather more diffuse exposure so that if you have a contaminated water supply, then potentially the contamination can reach many aspects-- many parts of the environment in which patients are cared for. If you have infections in drains, then you can expose several children to those drains because children move in and out of-- patients move in and out of rooms in hospitals and move around. So I think it can be a single point, one dirty drain, but it can be a more diffused stimulus, which is dirty water.

**THE CHAIR:** But if, hypothetically, one has a chronic source of infection – in other words, let us suppose chronically contaminated water system – does that produce clusters, or does it not produce clusters?

**A** Well, I mean, I suppose if it was a continuous exposure, you're possibly less likely to see a cluster, and

more a higher background rate. I feel that these are more likely questions that Mark Wilcox can answer better than me, I'm afraid, but I think it does expose the interpretation of why clusters come about, certainly.

**THE CHAIR:** Thank you, Professor. As Mr Mackintosh has indicated, we need to discover whether there's any other questions in the room. So, if I can ask you to return to the witness room for 10 minutes?

**A** Yes, thank you very much.

**(Short break)**

**MR MACKINTOSH:** My Lord, I have no rule 9 proposed questions from my colleagues.

**THE CHAIR:** Thank you, Mr Mackintosh. Professor Stevens, we have no more questions, and therefore you're free to go, but before you do go, can I thank you for your attendance today? I mean, it's quite a long day, and all the work that you'll have done in preparing for your evidence, including the preparation of your two statements. So, thank you very much indeed, but as I say, you're now free to go. Thank you.

**THE WITNESS:** Thank you, my Lord.

**THE CHAIR:** Now, that's the evidence for today. I think we resume tomorrow with Mr Bennett.

**MR MACKINTOSH:** Yes, Mr Bennett for tomorrow and Friday. Mr Connal will be dealing with Mr Bennett.

**THE CHAIR:** And with Mr Connal. Well, can I wish everyone a good afternoon and, all being well, we'll see each other tomorrow at 10. Thank you.

**(Session ends)**