Thursday, 31 October 2013

(10.00 am)

(Delay in proceedings)

(10.07 am)

THE CHAIRMAN: Good morning. Mr Stewart?

MR STEWART: Good morning, sir, thank you. I call Dr Miriam McCarthy, please.

DR MIRIAM McCARTHY (called)

Questions from MR STEWART

MR STEWART: Good morning.

A. Good morning.

Q. You've been good enough to supply the inquiry with two witness statements and an addendum: the first is WS080/1, of 6 July 2005; the second, WS080/2, of 26 September of this year; and an addendum, at WS080/2, page 37, received by the inquiry this week. Are you content that they should be adopted by the inquiry as part of your formal evidence?

A. I am, yes.

Q. Thank you. You have also provided a resume of your career, a CV, which appears at WS080/2, pages 27 and 28. If we might see that page, please.

We can see that you have academic qualifications in medicine, with a commendation in obstetrics and gynaecology, and then you moved into the study of public

health, taking a master's degree at the University of Minnesota.

On page 28, just over halfway down, your career in the mid-80s, to July 1988, was as a GP, and then you have experience of moving into the DHSS as a medical officer and serving as senior medical officer in the department from October 1998 to March 2006, which is the period with which we are concerned. I see that now, or perhaps you would correct it if wrong, from June 2011 to today you are a consultant in public health?

A. That's correct.

Q. For whom do you work?

A. I work in the Public Health Agency.

Q. Yes. What areas of public health are you concerned with?

A. My area of work is primarily on the commissioning of services within the acute sector, predominantly cancer services, some specialist regional services, and specialist drugs.

Q. If we can turn to your first engagement with the issues with which we are concerned, and that was when you first learnt of the death of Raychel Ferguson. You refer to that in your first witness statement, WS080/1, page 2.

There at the top of the page you state:

"I became aware of Raychel Ferguson's death on

14 August 2001 when Dr Paul Darragh met me in my office and informed me of her death and he asked me to convene a working group."

Had you not heard of her death or a death that was hers prior to that?

A. I had not. The date 14 August was the first time that I had heard about Raychel's tragic death.

Q. Because you attended a committee meeting on 26 June, a Sick Child Liaison Group meeting, in Antrim. The minutes of that appear at WS008/1, page 15. I wonder does this jog your memory? Do you see in fact you were seen there to be -- in attendance and apologies, I beg your pardon. So the 14th is when you first learned about it. Had you had any contact from Dr Taylor before the 14th?

A. No, I hadn't.

Q. Had you any contact from Dr Carson?

A. No.

Q. How often were you in contact with the CMO at that time?

A. CMO, I would have had regular contact. CMO would have had a staff meeting most weeks on a Friday morning, and I would also have seen the CMO in the course of my work, perhaps twice, three times a week. So fairly regular contact.

Q. Did the CMO mention to you a death or hyponatraemia?

A. No, neither had been mentioned.

Q. There is the e-mail that I introduced. I know you were sitting here yesterday afternoon listening to the evidence and you probably heard me asking Dr Darragh about the content of an e-mail. This is the e-mail which appears at 021-056-135.

This was Dr Carson bringing to the CMO's attention information about hyponatraemia, information about deaths from hyponatraemia, and forwarding to him Dr Taylor's paper on dilutional hyponatraemia. In your conversations with the CMO, were these issues not mentioned?

A. I had not been aware of this and, if I may add, the reason why I can remember so clearly that it was 14 August is that when Dr Darragh came along to me on a morning in August and asked me to help with a group on the prevention of hyponatraemia, my comment to him was: I will need to know more about that because I hadn't been familiar with the issue nor had I heard anything in the past.

Q. And did he supply you with information?

A. I think at that time what he had done was advised me to contact Bob Taylor, who would provide some further background information. The information that Dr Darragh provided directly was that we were to set up a group and

prepare something that would help such a case -- help prevent such a case happening again.

Q. So if the chairman leaves you to go off and contact somebody for more information, were you surprised that the chairman had not himself gathered information?

A. It would often be my role, acting as a member of a group, to be the one to go off and gather information, and given that I had been asked to participate in a group, it was in my professional interests and it would have been a requirement that I got as much information as possible to inform myself of the issue.

Q. Did you make any enquiries as to how prevalent this condition was?

A. At that time, no. I did contact Dr Bob Taylor, who sent me the briefing paper that is also included for the first meeting and that is all I received. We didn't look at prevalence at that time.

Q. Did you communicate with Bob Taylor by e-mail?

A. By telephone as I recall.

Q. Telephone?

A. Yes. Again, somebody with whom I would have been in fairly regular contact.

Q. Did he give you any indication as to the incidence of hyponatraemic deaths in children in Northern Ireland?

A. No, he didn't. My recollection is that he had indicated

that he would send me a copy of a briefing paper that he was preparing, which he duly did.

THE CHAIRMAN: The reason for you having fairly regular contact with Dr Taylor was what?

A. I worked on a range of paediatric issues at that time and, for example, I had worked fairly closely with Dr Taylor on home ventilation and providing home ventilation for children who required long-term ventilation. So we would have been working very closely in the -- in or around the same period.

THE CHAIRMAN: If this phrasing isn't right, he was then and still is a very significant figure in the Children's Hospital?

A. Yes, I believe so. Absolutely.

MR STEWART: Were you aware of any figures relating to the incidence of hyponatraemia, whether from death or otherwise, at that time?

A. Papers that I had seen in or around that time were the Arieff paper of 1992 and, I think, a further paper in 1998, and then the BMJ paper of 2001, the Halberthal paper.

Q. Yes.

A. So that was my kind of awareness of the issue.

Q. Up until what time?

A. Those papers, I think I read probably them before the

first meeting of the working group, so between 15 August and the first meeting. I can't recall exactly when.

Q. Were you in receipt of any information from local clinicians about hyponatraemia?

A. The only other information that I'd received before the working group meeting was the paper prepared by Bob Taylor and the PowerPoint slides also prepared by Bob Taylor.

Q. I wonder can we look at the minutes of a meeting of CREST on 8 November 2001. This appears at 075-066-210 and 213. This is a CREST meeting, 8 November 2001, in Belfast, and a large meeting, and in attendance you'll see at the bottom of the first page, Dr McCarthy for item 5, and on the facing page, item 5 is "The prevention of hyponatraemia in children receiving intravenous fluids". You'll see that you're introduced by Dr Stewart, and the third line:

"Introduced Dr McCarthy who stated that the problem had come to the attention of the department through clinicians who reported an increase in the condition and felt in need of urgent guidance."

Well, were you receiving reports from clinicians?

A. I had not received any specific reports. That particular sentence I think refers to the fact that people were becoming increasingly aware of the issue as

highlighted in the graph as part of Bob Taylor's PowerPoint presentation. And that, combined with the recent literature, would have indicated that while the condition was very rare, it was recognised and certainly within the working group the risks were also recognised and therefore the role was to ensure that those risks were addressed as much as possible.

Q. But with respect, it doesn't talk about clinicians enjoying increasing awareness of the condition; it talks about clinicians reporting an increase in the condition. And it says that they felt in need of urgent guidance and, further, it says:

"... and as a result a working group had been quickly convened and comprised anaesthetists, surgeons, public health medicine ..."

Did you tell CREST that?

A. I can't remember the exact words, but I mean, I think that's an accurate reflection of what was discussed. There was certainly an increased recognition of the issue.

Q. Well, was there any increase in the condition reported to the department by clinicians?

A. The only case that the department had been aware of was the death of Raychel Ferguson. And while we would have recognised in the working group that that was a single

death, one death of a healthy -- otherwise healthy child from a preventable cause was seen to be one death too many and therefore action taken.

Q. You'll see that your explanation is and appears to be at variance with what is recorded in the minute.

A. I can see how that could be construed.

Q. I wonder, can we go to --

THE CHAIRMAN: Sorry. Can I just pause there? I agree entirely with that definition you just gave that:

"A single death of an otherwise healthy child from a preventable cause was seen to be one death too many and therefore action was taken."

A. Mm.

THE CHAIRMAN: If I regard Adam as a child who wasn't otherwise healthy because he had renal problems, which is why he was being transplanted, that wouldn't make any difference to that analysis, sure it wouldn't. A death of an otherwise unhealthy child from a preventable cause would be one death too many, which would justify action being taken; isn't that right?

A. I accept that.

THE CHAIRMAN: And the same would apply to Claire and the same would apply to Lucy.

A. Yes, I accept that.

MR STEWART: Can we see page 075-073-276, please? These are

the minutes of, this time, a subgroup of CREST and it's three months later, February 2002, and at item 3 towards the bottom of the page there:

"Prevention of hyponatraemia in children receiving intravenous fluids. Dr McCarthy, senior medical officer, reported that some months ago the department had been approached by paediatricians ..."

Were you at that meeting --

A. Yes.

Q. -- or is this a report of what you had said? In attendance, "Dr McCarthy." You are there.

A. Yes.

Q. "The department had been approached by paediatricians expressing concerns over an increase in the condition of hyponatraemia and felt in need of urgent guidance."

It's the same piece of information being given again. And consequently, as a result of those paediatricians seeking urgent guidance as a result of the increase in the condition, the small multi-professional group is convened.

A. Again, I think that's probably an accurate reflection of what was discussed. There seemed to be a growing awareness of the condition and Dr Taylor's PowerPoints would indicate that there had been a number of cases in the preceding number of years. Thankfully most of

them treated and not causing fatalities, but we knew of one fatality.

Q. But this refers to clinicians coming to the department and saying, "We need urgent guidance", and as a result of that the working group being formed. Dr Taylor's bar graph was forwarded for the meeting after the group had been formed.

A. Sorry, I didn't quite catch the last bit. I just didn't hear it.

Q. Dr Taylor forwarded his bar graph to the department, to Dr Darragh, in preparation for the first meeting --

A. That's correct.

Q. -- after the working group had been formed. These minutes refer to you saying there was an increase in the condition brought to your attention by clinicians who felt in need of urgent guidance and in consequence of that communication the working group was formed.

A. If I may just clarify: the PowerPoint presentation we received, as I recollect, before the first meeting of the working group. The working group was formed and met once, so I suppose the formation of the working group was on the same day as it would have met at the end of September and those PowerPoint slides had been seen before that.

Q. You were asked about this in one of the witness

statements, WS080/2, page 14. At the bottom, "CREST meetings":

"Please explain what you meant by clinicians having 'reported an increase in the condition'.

"My recollection is this referred to input from the clinicians who were members of the working group in which the number of cases of hyponatraemia in the Children's Hospital was discussed."

But of course we've just seen from those minutes that's not right. The minutes record you saying that it was as a result of the clinicians bringing the increase to your attention that you formed the working group.

A. I suppose in many respects it was both. Firstly, the individual case of Raychel is what stimulated the formation of the working group. When the working group met, there was a sense that, yes, we absolutely need to do this, we know that there are a number of cases of hyponatraemia that have occurred. So it tended to emphasise the requirement. That combined with the fact that there had been a sharing of the academic documents from Arieff and others that were indicating that indeed hyponatraemia was an internationally recognised, rare but recognised, issue and then the subsequent piece was everybody around the working group table absolutely recognised that there were key signs and symptoms, there

were key warnings and therefore there was a real opportunity to put out something that would help prevent, and that's really where the focus of attention was.

THE CHAIRMAN: In that context, can I ask you -- I'm not sure how much you have been able to follow the inquiry, doctor, but last week I heard from Dr Smith, and it was his colleague, Dr Lowry, who was on the working group.

A. That's right.

THE CHAIRMAN: When the working group met, did Dr Lowry say, "Actually, I agree with this. In fact I've already started work on developing some equivalent of guidelines in Craigavon"?

A. I have no recollection of that. I have gone back to my handwritten notes of that first meeting and I have no documentation to that effect.

THE CHAIRMAN: It would make sense if he did, wouldn't it?

A. Yes, it would.

THE CHAIRMAN: Because it fits into the picture you have just described as the formation of the working group as a result of Raychel's death and then the members of the working group coming together and agreeing that this was in fact an emerging issue.

A. Yes.

THE CHAIRMAN: And Dr Lowry might then be able to say,

"Well, Dr Smith and I have already been working on this in Craigavon, we've already enlisted the help of Dr Taylor, and we have already done some groundwork on this, we have a local practice there". And it makes sense for that to be raised, but it's curiously absent from any of the documentation that we've seen. I don't quite understand why because there's no doubt something was happening in Craigavon already.

A. I know that now. At the time I have no recollection of that being discussed, and indeed if it had been discussed, our normal response would have been "Let's see what you're doing and let's build on that because that's a great starting point and helps to actually move things even faster".

THE CHAIRMAN: That's right, because there's a member of the working group who's already got something in writing, so you can develop from that.

A. Absolutely.

THE CHAIRMAN: But in fact Dr Taylor would also have been able to contribute to that because the work that was done in Craigavon was done in liaison with him. So in fact there were two members of the working group who knew that something was already happening, not in the Children's Hospital, the specialist centre, but in Craigavon through the initiative of doctors Smith and

Lowry. Okay.

MR STEWART: The CMO received information from Dr Fulton that the Royal had stopped the use of Solution No. 18 because it had experienced problems. That might explain the idea of an increase of the condition.

A. I was not aware at that first meeting that the Royal had stopped using No. 18, and again that wasn't something that had come to light, either in the first meeting or subsequently. Indeed, I note that there's an e-mail from myself to the CMO in 2004.

Q. Sorry, I missed that. Can you say it again?

A. I note there's an e-mail from myself to the then CMO, Dr Campbell, in 2004 that indicates that in a conversation with Dr Crean, he had said -- he had advised that there had been no change to the policy of fluids in Children's Hospital prior to the working group producing its guidance and I do have the reference for that.

Q. The inquiry's received its own evidence in relation to the usage of Solution No. 18 at the Royal. If the CMO had shared information with you or indeed if she had shared with you the information that came to her by Dr Carson that:

"The anaesthetists in the RBHSC would have approximately one referral from within the hospital per

month, there had been a previous death six years ago in Mid-Ulster and that Bob Taylor thinks there have been five or six deaths over a ten-year period in children with seizures."

That might have explained you telling two CREST committees that there had been an increase in the condition.

A. Potentially. I had not seen that e-mail from Dr Carson.

Q. When it came to selecting the members of the working group that you were convening, how did you go about that task?

A. My recollection is that it was discussed with Dr Darragh and that we were aware that CMO had a particular interest in getting guidance out as quickly as possible. It was therefore my role and Dr Darragh's role to ensure that we achieved that outcome. So we recognised that we were establishing what we may call a task-and-finish or an ad hoc group. Our normal process for getting members on groups would be to seek formal nominations through chief executives of organisations. In this case, we did not do that because we did not want to spend any additional time going through a formality. Therefore, individuals were chosen directly because of their particular interest or their particular specialty area and we ensured that we had a representative,

a clinical representative from each trust because we recognised that we needed people from across Northern Ireland. Therefore, it was very much on who we knew maybe had a particular part to play and my recollection is that either myself, Dr Darragh or my colleague, Dr Mark, would have called each one of those individuals, advised them what we were doing and said, "Can you make a meeting? And if you can, we will be letting you know what the potential dates are".

Q. Yes. Was the CMO engaged with you in these discussions?

A. I think she was, yes.

THE CHAIRMAN: In the principle of it rather than in identifying individuals?

A. My recollection is in the principle, that we would have given the CMO a potential list of who we were proposing to get around the table and she would have indicated her agreement with that, as would be normal practice. That's what we would do in setting up any group.

MR STEWART: The CMO recalls:

"We met during August 2001 and decided upon a proposed membership for the working group."

That's the CMO, yourself and Dr Darragh. Can I ask about sounding people out? Did you ring anybody and did anyone decline the invitation?

A. Not that I recall. If anything, actually, people were

really very interested and enthusiastic. I don't recall anybody declining.

Q. Well, obviously Dr Taylor was chosen because he had had interest and experience in this matter. Dr Lowry, was his interest and experience in this matter also known to you?

A. Not any particular work that he was doing on hyponatraemia. I don't recall why Dr Lowry was mentioned specifically.

Q. But he had been engaged in developing his own protocol with Dr Smith.

A. That's correct. I wasn't aware of that at the time.

Q. Presumably you did become aware of it in the course of the discussions, did you?

A. No, no, that was not mentioned.

Q. Dr Nesbitt was chosen because of his experience with Raychel's case?

A. That's correct.

Q. And Dr Marshall, was he chosen because he came from the Erne Hospital and might also have had experience of hyponatraemia?

A. I think it was simply because we were getting a geographical spread. I don't have any recollection of him being chosen because of any particular expertise in hyponatraemia. Rather, he was the individual

representing the south-west.

Q. In terms of geographical spread, you probably heard me saying yesterday there's absolutely nothing from Mid-Ulster, nothing from Antrim or County Down. But yet here we have Dr Nesbitt who knows something about hyponatraemia because he was involved with Raychel and Dr Marshall came from the same hospital that Lucy received her treatment in before she arrived at the Royal.

A. In terms of the geographic spread we actually had two individuals from Antrim, initially Dr Jenkins and subsequently Dr Jenkins and Dr McAloon. In terms of the input from County Down, we had Liz McElkerney from the Ulster and Dr Angela Bell also had input from the Ulster.

Q. That's really Belfast, isn't it? I was thinking of Daisy Hill.

A. Daisy Hill would have been represented by the folks in Craigavon in terms of their trust. Often we specifically, in setting up a group, would firstly ensure that we had trust representation from every trust, but we may also ask for representation from the south-west because we're often aware at that time quite acutely aware of the relative geographic isolation of the south-west, so it was usually an inclusive process.

Q. How is Dr Clodagh Loughrey's interest in these matters known to you?

A. Clodagh Loughrey was a chemical pathologist and was therefore chosen in order to provide input particularly around the fluid and the fluid balance, and in fact I think the record shows that Dr Loughrey had very significant input to the content of the guidance.

Q. Yes. And Dr Crean, that's a second anaesthetist from the RBHSC; why is it necessary to have two individuals from the same hospital in the same specialty?

A. I suppose firstly because the Children's Hospital was our regional hospital and therefore any child critically ill and certainly any child needing paediatric intensive care would automatically be referred there. So they would see the more complex cases and because it is something a large facility relative to the other paediatric facilities, we would often have wanted to ensure a couple of representatives, and that would have helped also ensure that if one were busy, we would at least always have somebody from the Children's Hospital there.

Q. Because, of course, Dr Crean had some engagement with the cases of Adam, Raychel and Lucy.

A. Mm-hm.

Q. Was that known to you then?

A. No, it wasn't. The only death that we knew about was Raychel's unfortunate death.
Q. And then Dr Jenkins. Did you know, during the course of your working group deliberations, that he had knowledge of Lucy's case?
A. I did not.
Q. You say that you received from Dr Taylor certain information. Did he forward to you direct his PowerPoint presentation in draft form?
A. I can't recall whether he forwarded it directly or whether he forwarded it to Dr Darragh and it was sent on to me.
Q. That appears at 007-051-100. That's the cover page and you can see that Dr Darragh has marked it "Please copy to Miriam McCarthy".
At page 103, we find the bar graph chart of "Incidence of hyponatraemia at RBHSC". That's 007-051-103. I think in your witness statement you've indicated that the issues contained in this PowerPoint presentation were discussed by the working group and at subsequent meetings of the subgroup. Did you discuss the incidence and discuss this chart?
A. My recollection is that the key issues were discussed, but the detail around the number of cases or the timing was not discussed in detail.

Q. Clearly, it was known to you, I assume, that the 2001 death indicated was that of Raychel?
A. That's correct.
Q. And did you enquire as to what the 1997 death was?
A. I don't think that we enquired directly, and certainly my handwritten notes of the meeting do not indicate that we discussed that.
Q. Can I ask why you didn't?
A. When we met, it was clear, the facts that were known was that we had had one death in Northern Ireland. Internationally, the issue was recognised, and internationally there had been deaths, and therefore we knew that it was a rare problem, but in terms of fatality it was recognised, and the main focus of the working group -- and in fact the singular focus of the working group -- was to address the risks associated with hyponatraemia and put something out to the clinicians who were looking after children to ensure that fatalities in the future would not occur.
Q. Did you ask Dr Taylor what the two empty years signified?
A. I don't think so.
Q. Why not?
A. Well --
Q. You have to understand the prevalence of a condition

before you work out how you're going to approach the problem.
A. I think that is true, but our understanding of the prevalence was drawn more from the literature, which emphasised that while we had had a case, a death, a recent death that we knew about, such incidents were not unheard of, therefore we knew from the literature that it was indeed, firstly, a problem that there seemed to be an understanding that clinicians looking after children were not sufficiently well aware of the problem and, more importantly, were not sufficiently well aware of how to prevent it. So the focus was on looking forward and, as quickly as possible, getting draft guidance out, which we had hoped to do in a short number of months.
We were all acutely aware that we had a responsibility to get that out as swiftly as possible and not to get distracted from that course of action.
Q. Is your evidence that to look at other cases of hyponatraemia, such as may be indicated to you by this chart, was a distraction?
A. We had no remit to look at any other cases and nor indeed, from a departmental perspective, would it have been appropriate for us to be scrutinising individual cases. We were there to provide a policy and advice to

the service with the sole aim of ensuring that junior doctors, nurses and others were better informed, that they were able to take action to ensure that cases didn't happen again, and that they understood the rationale for the actions that they were to take.
THE CHAIRMAN: Mr McMillen and I had something of a debate yesterday because Professor Scally's report has caused some anxiety and is challenged by the department. Okay? And one of the areas that is going to be explored over the next week or so is the extent to which the department would expect deaths to be reported to it.
As I understand it, one of the differences between the department and Professor Scally is that the department doesn't accept Professor Scally's analysis that the trusts were accountable to the department for events, but that serious events like unexpected deaths of children should still come to the department, not through the route that Professor Scally describes, but because these are significant issues of which the department should be made aware. The department had therefore appropriately been made aware of Raychel's death in June 2001, and that would be, however that comes about, what the department would expect to happen; right?
A. Yes.

THE CHAIRMAN: If there were earlier deaths which might fit the same description, deaths of which the department should have been aware, but hadn't been made aware of at the time, then the formation of this working group then gives, at the very least, a belated opportunity for people who are aware of those events to relay some information about them to the department; isn't that right?
A. That would be correct.
THE CHAIRMAN: And Dr Darragh said yesterday, in terms, that one might regard it as disappointing that that information wasn't shared; would that also be your view?
A. Normally when we set up a group, there's a professional sharing of information. There's that informal sharing that is valuable.
THE CHAIRMAN: Yes.
A. Information on previous deaths was absolutely not shared in that group. When I now see what people knew, it is a surprise to me that that wasn't, but that is the reality.
THE CHAIRMAN: Doctor, just so that everyone understands the point again, the absence of that sharing doesn't undermine the guidelines in any way. What the inquiry has consistently recognised and what I consistently recognise is the value of these guidelines. We were

ahead of Great Britain in producing these and they were then praised, as Mr Leckey pointed out, by Dr Sumner at inquest.
The problem arising from the lack of sharing of information is the what seems to me to be the entirely avoidable additional delay which was caused to the Crawford family in Fermanagh and to Mr and Mrs Roberts. And that's something which certainly Mr and Mrs Roberts, who are here, must feel adds to their great suspicion about what on earth was going on in the Children's Hospital and then in the department.
A. Yes.
THE CHAIRMAN: You understand that's my particular interest in focusing on this questioning.
A. Absolutely, I accept that. Unfortunately, I don't have an explanation for why that information wasn't shared.
THE CHAIRMAN: Because it's the easiest thing in the world when the working group meets and you say there's a discussion, "We've had Raychel's death in Derry", and somebody says, "This is recognised in the literature", as it was recognised in the literature". The next obvious statement for somebody to make is, "It's not just Raychel we've had locally, we've had other children locally". In fact, it's almost unnatural not to mention that, isn't it?

A. Absolutely. I accept that. It was quite some time -- quite some years later that I became aware of the detail around the reports, et cetera, that had concerned Lucy at the time of her death, but that didn't come to light until quite some time later.
THE CHAIRMAN: Thank you.
MR STEWART: In relation to this graph, the witness statement request that you received, asked you:
"Please state if you recognised any significance in the two deaths being recorded on the chart."
This is at the time of your working group, whether you recognised any significance from those two deaths. Your answer, which is included in the addendum you forwarded this week, was:
"The inclusion of the two deaths in the data emphasised the need for evidence to be produced without delay."
What evidence did you call for having seen this data and these two deaths?
A. I think that should have read, "... emphasised the need for guidance to be produced without delay", and my apologies that that has been transcribed incorrectly.
Q. I'm sorry. So it is need of correction?
A. I have not seen the formal correction. I do apologise.
Q. Then let's look at WS080/2, page 37. You say that when

you said:
"The inclusion of two deaths in the data emphasised the need for evidence to be produced without delay."
You actually meant --
A. Guidance.
Q. "Emphasised the need for guidance to be produced without delay."
Of course, it would have read pretty well as evidence, wouldn't it, and does? Because that's exactly, I'd suggest to you, when deaths were being brought to the attention of the working group, what you should have said. What's the information, what is this death? How does it fit in, how can we help to prevent another death like this one?
A. Well, I suppose in terms of just addressing that point, the evidence that we had at hand at the time was the evidence of a recent death in Northern Ireland, the evidence of the papers that we had received in terms of the academic papers, and the view of all the clinicians that the knowledge base was not sufficiently robust among clinicians who were prescribing fluids. So those were the three key --
Q. Of course, the information you should have had was what the CMO might have told you about Solution No. 18 in the Children's Hospital and the problems that had been

reported, and what she might also have told you about was the deaths brought to her by that e-mail we've looked at.

A. That too would have been helpful.

Q. In your witness statement at WS080/2, page 13, at 28(a) you are asked:

"Please explain what Dr Taylor discussed at that time regarding the incidence of cases seen in RBHSC."

This comes from the minute of that meeting:

"In particular state if you discussed the deaths of Adam, Claire or Lucy."

You answer:

"I recall Dr Taylor highlighting one death, that of Raychel Ferguson. I also recall Dr Taylor advising attendees of the increased identification of cases of hyponatraemia in the RBHSC, including two cases resulting in fatality."

Which deaths did you take him to be referring to?

A. I took him to be referring to, as on the bar chart, the fact that there were an increasing number, and I can't recall the number specifically, and that the bar charts indicated two deaths, one in 2001 and the one previous one.

Q. So in September 2001 your understanding of the two deaths was that they referred to Raychel Ferguson and

the 1997 death?

A. Correct.

Q. Were near misses discussed?

A. My recollection is that there was no specific discussion on near misses, nor indeed was that defined.

Q. Was Raychel's case discussed in detail?

A. No, it wasn't.

Q. So when Dr Nesbitt says that he went on and on about it, he's entirely mistaken in that recollection, is he?

A. My recollection in that meeting was that certainly Raychel's had been mentioned and, by way of introduction to the meeting, we would have advised all members that there had been a recent death. We would not have talked about the detail.

THE CHAIRMAN: Sorry, doctor, I'm subject to correction, but I don't recall Dr Nesbitt insisting that he went on and on at this meeting.

MR STEWART: I will find the reference for you in due course, sir.

THE CHAIRMAN: I thought it was at the previous meeting that he'd raised it. In any event.

MR STEWART: I may come back to you on that point. I will check that.

MR UBEROI: My recollection of his evidence was that the "on and on" quote was referring to meetings thereafter,

effectively, where he gave his presentation, effectively, on a repeated basis. That's simply if it assists.

THE CHAIRMAN: Thank you.

MR STEWART: If you'll allow me, sir, to check that. I may be incorrect.

THE CHAIRMAN: But his presence there at the working group was because of Raychel's death?

MR STEWART: Yes.

THE CHAIRMAN: So it'd be surprising if he didn't get involved in some discussion of it.

MR STEWART: That's a matter, I'm sure, for the witness to comment on. Are you surprised now that there wasn't a discussion of Raychel's case?

A. We all knew that Raychel had died, we all knew that it was subject to an inquest, therefore my recollection is that any discussion was to alert people of the event that stimulated the formation of the working group but not to go into the details. And from a departmental perspective, we would always have been very conscious about not -- unless it was absolutely essential -- not to be discussing the details of an individual case. I'm very respectful of confidentiality. So yes, while it would have been mentioned in generalities, we didn't discuss the detail.

THE CHAIRMAN: The second point that really got to Altnagelvin, I think, is that they weren't aware of what they were led to believe was a change of policy about the use of Solution No. 18 in the Children's Hospital. But am I right in picking up that that wasn't discussed, to your recollection, at the working group?

A. That's correct. I was not aware of a change in policy during the time that I was writing the guidance. I had not been aware that Children's had a different policy in terms of No. 18 Solution.

THE CHAIRMAN: Yes. I know there's a debate about whether there was a change of policy or perhaps more of a debate about whether one formally calls it a change of policy, but we'll maybe come on to Solution No. 18 later in the questions.

MR STEWART: Solution No. 18 was something which drove Dr Fulton to bring it to the attention of Dr Carson immediately after Raychel's death. It's what drove Dr Fulton to make a phone call to the CMO, and Dr Nesbitt is down at that meeting, their chief gripe is that the Royal had discontinued the use of this fluid and hadn't told them. They felt aggrieved and you say that Dr Nesbitt simply sat on that information?

A. There's no record of that having been discussed at the meeting. I often looked at my handwritten notes, which

tend to be reliable because they're contemporaneous, and I don't have any note to that effect.

Q. Because one piece of information that came out of Dr Taylor's draft PowerPoint presentation, drawing from the Halberthal study, was that 70 per cent of those victims of hyponatraemia, 70 per cent, were actually in receipt of excessive maintenance fluids administered by clinicians. And really, very excessive, more than 50 per cent more than they should have got. So it's a clear case where a large number, the overwhelming proportion of these cases, are suffering from iatrogenic hyponatraemia. That's something which surely must have interested you?

A. Absolutely, and that was something that we were determined, as part of our guidance, to ensure we corrected and in that respect, later in the working group, there were detailed discussions as to whether we include reference to individual types of fluids or whether we keep our reference to the volume of fluids, and that was a matter for debate later.

Q. But that very point of deciding how you guide people must have meant that you had to go back to individual cases to see why this one was an excessive administration of fluids and that one wasn't, and how this fitted the normal pattern of hyponatraemia and that

didn't.

A. With all due respect, the working group's thinking of that was that there were key principles that ought to be adopted. Those key principles depended firstly on doing very careful baseline measures, weighing the child, et cetera, taking into account the child's fluid needs very carefully, both their resuscitation and their maintenance needs, monitoring very carefully and calling in expertise when needed, and reviewing through blood tests. So the group tended to focus very much on what are the key principles that need to be applied to every single child receiving fluids, either on a drip, if it's prescribed fluids, or if it's orally in each and every case.

Q. You see, all these children are different, aren't they? Because boys and girls are different.

A. Yes, but the essence of the guidance, which I think is still a valid position, is that, yes, every individual case is different, of course they are, but often in applying guidance and in applying standards there are certain key measures that ought to be applied to every child. And I think the guidance in being drawn up was being drawn up for -- and I don't mean this in any pejorative manner -- the generalist, the junior doctor who was not a specialist. Within specialist units,

cardiac and renal, there would be a much greater knowledge base and a much greater sense of expertise in dealing with fluids for individuals. But there were general principles that we wanted applied to every child who was receiving IV fluids.

Q. How are you ever to learn that your general principles were applicable to all children unless you tested it against a range of children that suffered from the condition?

A. Well, I think, in preparing standards generally, the approach tends to be "What are the principles that need to be applied?" rather than necessarily going into the detail of every case. And even today, that is still in essence the way that national groups such as NICE and others look at their guidance: what are the core principles that need to be applied? And often, in those guidance notes that come, particularly from NICE, they also emphasise that the core principles and the core standards do not negate the need for expert clinical advice, expert judgment and expert clinical decisions. But nonetheless, they are a key starting point in providing a standardised, evidence-based approach to what is needed for everybody, and they do in essence help ensure the quality of care is improved for everybody.

Q. Thank you.

I wonder, can we just go back, sir, to that issue about Dr Nesbitt. Can we have a look at the transcript from 3 September 2013, page 161? This is Dr Nesbitt talking about this working group meeting, line 6:

"There are people there who might have known about Lucy -- this is the point -- and I -- Lucy was not mentioned at that meeting. I know Raychel Ferguson was mentioned at the meeting because I kept on and on and on about it. It's not in the minutes, but it's within the bit where there was a discussion. I remember it clearly."

Do you remember it clearly?

THE CHAIRMAN: Sorry, just to add, if you look down at line 17, he says that this was actually the only meeting he attended.

MR STEWART: Yes.

THE CHAIRMAN: So I was wrong; he is only referring to one meeting and his recollection is he went on and on and on. Okay. Thank you.

MR STEWART: And looking at it as somebody who wasn't there, it would seem natural that he would go on about it.

A. I think -- my recollection is that, yes, Raychel's case was noted, people felt quite passionate about the need to do something on the back of that case, and therefore

the rest of the discussion was on the guidance. I don't have a recollection of how much Dr Nesbitt actually referred to the individual case. If I may just add that while he wasn't able to attend subsequent meetings and part of that is, based in Altnagelvin, you know, distance would be an issue, he did contribute and there are a number of e-mails back and forth, particularly in light of the fact that he subsequently raised issues of why we were not addressing the No. 18 Solution specifically, very valid issues that he articulated and that I would have discussed on e-mail with him.

Q. And he advanced that argument on the basis that they had had a death in Altnagelvin?

A. Yes.

Q. And he kept referring back to the fact that they had had a case, and it was the evidence, their clinical experience that led him to make the point to you?

A. I agree with that. It was also the experience of Raychel's case that led Bob Taylor to write to the Medicines Controls Agency to ask whether there was merit in action being taken specifically on No. 18, and their response, which obviously influenced the final drafts of our guidance, was that, yes, while there may have been an increased risk with No. 18 being a hypotonic solution, there was a risk with any fluid. And

therefore there was, in essence, I suppose, a professional debate that needed to happen around that.

Q. Basically they were saying that Solution No. 18 was safe if administered correctly; it was unsafe if administered incorrectly.

A. I think that's fair.

Q. They weren't prepared to withdraw it from the market on that basis. Tell me: how was the subgroup that went ahead with the drafting part of the guidance, how was it selected? Why was Dr Nesbitt not asked to be part of that?

A. We agreed that guidance needed to be done and we all recognised that it needed to be done very swiftly. Therefore, it was determined that the best way to advance it was for a small group, three or four people typically, to get together and start to scribe what needed to be in the guidance. My recollection is that basically people volunteered for that, that it was open to whoever wanted to participate, but we only needed a few people, that the essence of the group was to actually tease out the detail. There were some key principles discussed at the first meeting of what may be needed in guidance. The role of the working group was to actually put a bit of flesh on those key principles and make some kind of first draft of the key measures,

the messages and the detail beneath those messages for the purposes of sharing it with the rest of the group, not that they would do that in isolation, but that that would subsequently be shared with everybody.

Q. I was going to ask you about that because the e-mails passing between members of the group seem, for the most part, to be from the individual members to yourself. But they don't seem to be included in round-robin e-mails copied to everyone within the group. Why was that?

A. Well, when I look at the volume of e-mails that are available now, there may well have been more that were maybe not retained at the time.

Q. Sorry, why would e-mails not have been retained? How could they have gone missing?

A. Well, in 2001, when we were producing the guidance, I would have retained, as I would normally do, all e-mails that are relevant. If, for example, there was a round robin of people saying, "Yes, content", and nothing more, with the kind of e-mail policy we have of deleting what wasn't needed, those may have disappeared. So while this is a very substantive record of the e-mail communication, it may not be absolutely comprehensive for each e-mail. And if I may just add, while individuals may have come back to me directly when

I sent out drafts I copied to as many of the group as possible --

Q. Yes.

A. -- and that was the kind of normal practice.

Q. That would appear so. But the point I'm making is this: a group should share its experiences, share its ideas, bounce ideas off each other, work together. This group is not meeting in any real place, not face-to-face, it's what you call a virtual group.

A. Yes.

Q. Yet it's not sharing its ideas. The ideas are sent from each end of a spoke in to you at the hub. There doesn't seem to be any communication. Is that the way it was?

A. There was actually, over the couple of months, extensive communication. Some by e-mail and some by telephone call. And I accept that there are a number of e-mails where individual members of the group seem to have sent something directly to me. I would have then incorporated that and would have gone back to everybody with the revised draft, as documented. I may also have picked up the phone to a number of people, and in fact did, to say, "There's a question about whether we do A or B, should we include reference to particular fluids? What do you think?" Because my role in facilitating a really robust outcome and a tool that was going to

really make a difference -- my role was to make sure that the guidance was crystal clear, that the guidance was easily applied and that the guidance had the broad sweep of professional support from the group. So it was around my contact, which had been on a daily basis with members. But much of it would have been by telephone call.

Q. The question I'm asking you is: why don't the members appear to be communicating with each other?

A. I'm not sure that I'm really in a position to comment.

Q. Because it'd have been very easy for you to allow a debate to go on, even by e-mail, with everyone seeing everybody else's e-mails.

A. That is correct. I suppose it was my role. I was the person who was taking the lead in ensuring that all the information came to a single point and was then reflected appropriately in the subsequent drafts of the guidance.

Q. Dr Taylor has said in one of his witness statements that he wanted the working group to consult more widely prior to drafting the guidance. Do you remember that proposition being made?

A. I do not recall that proposition. My understanding was that we were to get guidance out as quickly as possible. In doing so, we drafted and then consulted within

a fairly restrictive time frame, admittedly, but we consulted with key professional groups, as in the SAC paediatrics and anaesthetics, et cetera, and there was therefore a degree of professional consultation and there was also, importantly, a very high degree of professional contentment with what was being produced.

Consultation prior to starting to draft would have delayed the entire process. I felt personally responsible and indeed responsible to the CMO to deliver an outcome as quickly as possible. It would have been exceptionally disappointing to me if I hadn't been able to get something out as swiftly as possible.

THE CHAIRMAN: On this particular point, does that mean, doctor, that when the working group met it was so clear that they agreed the guidelines were necessary and the key principles of what those guidelines would say were debated at the first meeting and there was sufficient progress then made to go straight to a subgroup?

A. That is correct. And I think the principles were articulated at the first meeting. There are several e-mails in the records that indicate that Bob Taylor was very content with drafts as they progressed, and in fact was quite complimentary to the steps that we were taking to provide concise guidance.

THE CHAIRMAN: Okay.

MR STEWART: Do you understand his chagrin of being left out of the drafting subgroup?

A. I know that that has come up in his witness statement. The group was inclusive, there was never at any point any attempt or design to exclude anybody. The subgroup only met once, after which, as you rightly say, there was a sort of virtual communication, and that was to just allow us to quickly move forward. Throughout that period, Bob Taylor's e-mails were all constructive and helpful, and I would have had conversations with him. I was not aware that he felt in any way slighted.

THE CHAIRMAN: I think your tone then is that you're surprised that he feels a bit peeved about that?

A. Yes, I'm disappointed. I'm disappointed that any member may not have felt that they were able to provide everything that they could. I'm sorry about that.

MR STEWART: Can I ask you about the guidelines? Did the committee, did the subgroup, take any steps to test them against a known set of conditions, to stress-test them against a known case to see if they met the requirements?

A. From my recollection, no, not against a known case. Now, that does not mean that clinicians, when they saw the drafts, may have done so themselves. Where we did test the guidance was in bringing them to a number of

specialty advisory committees, in which we were posing the question "Here is the guidance, do you think this set of guidance, displayed clearly as posters, will help provide the necessary information for junior medical and nursing staff to ensure a similar case doesn't happen again?" and furthermore, they would have been tested with CREST, who would of course have been our regional group normally providing guidance to test with them whether they were reasonable, whether they were sufficiently clear, whether the language was appropriate, et cetera. But not on individual cases.

Q. For example, when you took the guidelines to the Directors of Public Health at a meeting for their suggestions, they suggested that you ought to really contact the Royal College of Paediatrics and Child Health and seek their approval. Did you?

A. I actually don't think that measure was taken, and I suspect at the time that we were either close to or just about to go to the printers and there had been a fairly broad sweep of support from the Northern Ireland clinicians and we were anxious to get something out.

Q. We looked yesterday at the minute of the CREST meeting at which the guidelines were tabled. Dr Leonard at that CREST meeting suggested that perhaps steps should be

taken to ensure that the guidelines were posted in the Accident & Emergency department of every recipient hospital. Were any such steps taken and guidance given that this be done?

A. When CMO issued her letter that preceded the guidance and then subsequently issued the guidance with a short covering letter, that letter was sent to A&E consultants and indeed surgeons, and we really -- I think we ordered something like 300 posters at the time. We really wanted to ensure that every specialist who may have an interest and a need to know received the guidance. So it was widely circulated.

Q. Thank you. You mentioned earlier Dr Taylor taking a yellow card reference in relation to Raychel's case to the Medicines Control Agency. We mentioned yesterday afternoon that in fact you were copied into that correspondence.

A. That's correct.

Q. And you received a copy of his letter from the Medicines Control Agency of 23 October 2001 on 25 October 2001, and we can find it at page 012-071e-412. This is where he is asked by the Medicines Control Agency and does supply information relating to the child death that he reported, which is RF. He does that at paragraphs 1 to 10, and you can see the final two sentences where he

informs them:

"I am also conducting an audit of all infants and children admitted to the PICU with hyponatraemia. My initial results indicate at least two other deaths attributable to the use of Solution No. 18."

When you received that on 25 October 2001, what did you do?

A. In relation to this letter?

Q. Yes.

A. There was no particular action taken by the department at that time on the basis of that.

Q. What did you do?

A. I can't recall taking any particular action at that time. The contents of it would have been noted and filed, it would have been a relevant document. I note that the last sentence is:

"... indicate two other deaths attributable to No. 18 Solution."

If anything, what this would have done would have been stimulate us to move even more swiftly to get guidance out because the ...

Q. A month before you received this letter you were aware of two deaths.

A. Mm.

Q. That was Raychel's death and the 1997 death. You're now

aware, from Bob Taylor, of at least three deaths. Did you ask Dr Taylor to give you information about the additional death?

A. Not that I can recollect.

Q. Did you wonder why the additional death was not marked on his bar graph?

A. I didn't, because what he's saying in the letter is that he was currently conducting an audit and that initial results -- so I sensed from that, that that was an ongoing audit. But in any case we were not -- within the group that we were working on we absolutely did not have a remit to be pursuing individual cases or looking at individual causes of death. That can be an important matter but it wouldn't have been for our group. We were --

Q. But you are looking at your causes of death because you're trying to prevent further deaths from the same cause.

A. We were set up to provide standards and guidance that would inform the clinicians to ensure that a similar death to Raychel's would not occur again. I accept that this is material information, but it is not material information that we would have necessarily been pursuing in detail from a departmental perspective.

THE CHAIRMAN: Okay. And let's suppose that that is not

material that you pursue for the purposes of producing guidelines. Is it material that should be pursued for any other purpose? For instance, is it material to say to Dr Campbell, "I'm increasingly concerned about this, it won't affect the progress of the working group, but I wonder what on earth has gone on and should we not find out more about these two other deaths to see if they have been followed up or dealt with appropriately?"

A. I absolutely accept that that information would have alerted us to the fact that the issue around hyponatraemia and its consequences was maybe even more significant than we had first anticipated. And indeed, I recollect that, as the papers show, that we did write to the NPSA and ask if they would be interested in setting up a group to look at just this. When they set up their group -- and I was on the group, as was my colleague John Jenkins -- there was a sharing around the table and a recognition that probably hyponatraemia was more common than people had realised, and a number of individuals around the table, UK-wide, had recalled one or two cases. So that was emphasised in that also.

MR STEWART: But here, 25 October 2001, you are being told that hyponatraemia is more common than you realised.

A. Mm-hm.

Q. You didn't ask Dr Taylor about it. Did you wonder why

his bar graph was unreliable?
A. I was not sure of the detail around his audit, what time period he was looking at, whether --
Q. But you do know from the bar graph exactly what time period he's looking at there.
A. No, I didn't. It'd have gone back a decade or thereabouts.
Q. Did you tell the CMO about this?
A. I do not recall. It would have been my normal practice to copy letters to the CMO. I don't recall whether this specific one was copied to her.
Q. It should have been. It should have been copied to her; is that what you're saying?
A. I expect she would have been interested in it, yes, absolutely.
THE CHAIRMAN: Can I just check something with you? We're working on the assumption that this last sentence did actually register with you at the time. What Dr Taylor agreed to do at the working group was to report Raychel's death to the Medicines Control Agency and he fulfilled that obligation.
A. That's correct.
THE CHAIRMAN: And you were copied into what he sent to the agency. Do you recall this last sentence registering with you at all or are you speculating on why it wasn't

acted upon when it did come to your attention?
A. Well, whether it registered or not, what I don't have a recollection of is what action I took on the back of that. I recognise that at the time my focus was absolutely on getting the guidance out and that, among other pieces of work, would have been occupying me.
THE CHAIRMAN: I understand that, but I want to be fair to you in your evidence. I want to make sure I understand whether you are remembering why something was or was not done or whether you are best-guessing about why something was or was not done.
A. I don't have a clear recollection of the significance of that at the time and I don't have any record that helps me to determine that.
THE CHAIRMAN: Thank you.
MR STEWART: Would you have copied this to the chairman of the working group, Dr Darragh?
A. Um, yes. Normal practice would be that key pieces of information were copied to senior officers.
THE CHAIRMAN: I'm sorry, but is this a key piece of information? Because it's Dr Taylor, he had been asked to provide something to the Medicines Control Agency, he did that. But you've indicated to us that the detail of Raychel's death, the same as the detail of other deaths, is not particularly relevant to the working group.

A. Mm-hm.
THE CHAIRMAN: Okay. So is this a key piece of information to copy onwards?
A. In terms of the work we were doing, this information would not have altered our particular work, which was progressing well and, as mentioned previously, we were determined in any case to get something out swiftly.
MR STEWART: So in the normal course of events you would have copied this on to Dr Darragh and Dr Campbell, but you cannot recall?
THE CHAIRMAN: If it was a key piece of information.
MR STEWART: Well, it deals with RF, the death details, and Dr Taylor thought it worthwhile bringing it to your attention specifically.
THE CHAIRMAN: I'm sorry, Mr Stewart, Dr Taylor's forwarding this, in terms, because he has told the working party that he will do this, and one can interpret this letter being forwarded to Dr McCarthy to show that he has done what he was obliged to do.
MR STEWART: No, sir, with respect, this is not his yellow card alert; this is a further train of correspondence that ensues. He forwards the yellow card, they write back to say, "Thank you for that, we note it, we're going to look at it and consider it, but perhaps you'd give us some further information about this particular

death". This is what he does. And then, by e-mail, he sends you some of this correspondence. And we'll find that e-mail at 007-032-059.
This is 25 October:
"Hi M, your draft on prevention of hyponatraemia looks very good, although a little on the lengthy side. I have received a response to my letter asking for a hazard notice on Solution No. 18 from the Medicines Control Agency in which they have asked for more information. I enclose my response for your info."
So this is his additional information before they actually come back with their finding, having reviewed the proposition.
So given that the committee is considering the use of Solution No. 18, it's correspondence which fits in with those considerations.
THE CHAIRMAN: Thank you very much.
MR STEWART: If you had copied this letter in to doctors Darragh and Campbell, would you have discussed the matter further with them?
A. It's difficult for me to answer that. I think that's speculating on what may have happened.
Q. Perhaps this may assist, perhaps it may not, 075-076-287 and 292. These are the minutes of a meeting of the specialty advisory committee on paediatrics, which takes

place on 30 October 2001. That's to say, a matter of five days after you received that e-mail from Dr Taylor. One of the issues being discussed at this meeting was item 12, where you address the committee on the brief guidelines that are being drafted.

We see at that committee really almost all the players involved in the working group. We have from the department yourself, Dr Darragh and Dr Campbell. There's a Director of Public Health representative, Dr Kennedy, then Dr Angela Bell, Dr Crean, Dr McAloon, Professor Savage, Dr Taylor. Those are the people in the meeting. That would have been an ideal opportunity given that you were together and indeed you were discussing hyponatraemia --

THE CHAIRMAN: Sorry, just between Professor Savage and Dr Taylor, is that Dr Moira Stewart?

A. Probably, yes.

MR STEWART: Of course, she had engagement --

THE CHAIRMAN: I'm thinking in terms of timescale. By 30 October 2001, we'll check the dates, but by then was she involved in the first of her reports on the aftermath of Lucy's death?

MR STEWART: It's my belief that she was because Dr Jenkins was then briefed at the beginning of 2002 --

THE CHAIRMAN: Thank you.

MR STEWART: -- to give a report on Lucy's case.

THE CHAIRMAN: Yes.

MR STEWART: So there in one room is a group of individuals possessed of much knowledge about these cases, about hyponatraemia. You've just received a letter which talks about a third death being brought to your attention. Would that be something you might have discussed amongst yourselves?

A. The records would show that what was discussed was the guidance, but not any detail of either individual cases nor any increase in prevalence.

Q. That's correct, that's what --

A. And I have no recollection of anything at each of the SACs other than the content and presentation of the guidance being discussed.

Q. Moving on to the month after this, 30 November. News of a further death reaches you, that of Adam Strain. If we go to 007-025-048. This is where Dr Clodagh Loughery e-mails you, 30 November. Can we look at the paragraph halfway down the screen?

"Were you aware of the death of a four-year-old child in what sounds like very similar circumstances in Northern Ireland in 1996? I was speaking to the coroner about it today and he is to send me a copy of his report in that case. Let me know if you'd be interested in

seeing it. Perhaps you're already aware of it."

Were you aware of it?

A. No, that's the first I had heard of it.

Q. So this is death number four coming to your attention as the convenor of the subgroup. Do you discuss this death with other members of the working group?

A. My recollection -- this one was raised as a very specific issue and I did follow up. My recollection is that I called Clodagh Loughrey to get a little bit more information and she had advised that she would have a word with the coroner, who would contact me and give me more details.

Q. And did he?

A. He did, yes.

Q. And were you forwarded a copy of Dr Sumner's report?

A. Yes, I was.

Q. And did you read it?

A. Yes, I did.

Q. And did you see there in the report that Adam died of an excessive administration of fluid and that Dr Taylor was administering the fluid, making the calculations? Did you read that?

A. I saw the detail of the report, yes.

Q. And did you think then that that fitted into the 70 per cent of cases where there was an excessive

administration of fluid?

A. I do not recall associating it with that particular statistic. What struck me was that, firstly, this was a second case where we had extensive detail on the cause of death, that the circumstances were somewhat different in that it was a perioperative and a fairly significant surgical procedure, but that nonetheless there was a commonality between the issue of fluid administration and what was understood to be the case at that time with Raychel Ferguson because this was before her inquest. So yes, I was struck by the detail.

Q. Struck by the detail because it's relevant?

A. Not directly relevant to the guidance that we were producing. But, again, like other information, it stimulated us to get something out quickly because its relevance was that we needed -- we quickly needed to get professional advice out. And I was aware, as the records of the case show, that this was a case where senior medical staff had also been involved, hence the emphasis of the guidance for all medical staff who might have a role to play.

Q. But the detail must have informed the way you set about drafting the guidance.

A. By November, the way the guidance was going to be drafted was probably agreed in terms of the particular

headline information and while there still was some detail to be discussed about the content of particular sections, the actual structure of the guidance and its key message had already been agreed, so it did not, as I recollect, materially alter that.

Q. But it was a useful case for you to test the draft guidelines against, wasn't it, because it was a boy, as opposed to Raychel who was a girl, it was perioperative/intraoperative, as opposed to post-operative, and because of his condition I don't think SIADH was a live factor. Did you then use this ideal vehicle for testing within the group?

A. Within the group, no, there wasn't, as I've commented earlier, any testing of the guidance against individual cases. The testing of the guidance was a broader testing of asking professionals: are these particular standards that we are putting out in terms of our expectations for junior staff sufficient to ensure that similar cases will not and could not happen again?

Q. When this detail came to you, Dr Taylor's case of a death in 1995, as you saw from Dr Sumner's report, in which Dr Taylor might be implicated in the administration of excess fluid, did you not ask him about it?

A. I don't recall having a detailed discussion with

Dr Taylor at the time.

Q. Did you ask him about it?

A. Not that I can remember.

Q. Because you must have seen from his bar graph that he had most conspicuously left it out. Did that not strike you as odd?

THE CHAIRMAN: Mr Uberoi?

MR UBEROI: I'm sorry to interrupt my learned friend's flow. If I might just raise this point about this issue. I have said before I can, of course, understand why Dr Taylor has been asked and why questions have been asked about how it came to be that the death of Adam Strain was omitted from the bar graph. But perhaps, at the risk of repeating a point I made yesterday, in my submission, they go to different places during this stage of the inquiry's hearings because, as you yourself have said, sir, the guidelines were good, and therefore if the Adam Strain case had been mentioned, then guidelines which were already good may have been even better or improved perhaps, but they were good. And I simply rise to repeat the point that we are not in the same category which you alluded to for the other two cases, Lucy Crawford and Claire Roberts, whereby death could have been uncovered if it was mentioned, because whilst the Adam Strain case wasn't

mentioned and discussed at the meeting, it was known about. The accurate cause of death had been reached, there had in fact been a negligence action which had been settled. So it's simply that, almost the manner of the cross-examination, which I simply rise to make the point that, in my submission, there is a difference between them that is rather fundamental because of the very points you have made, sir.

THE CHAIRMAN: I think there is up to a point, but I think the point that really intrigues me about this, doctor, is that if it doesn't matter to you particularly how many other deaths there are locally -- sorry, when I say "you", I mean the group. If it doesn't particularly matter to you how many deaths there are locally, you come to your first meeting, there's one death that you're aware of, which is Raychel's, there's references in the literature, which is referred to at the meeting. When Dr Loughery contacts you and tells you about there might be another case, Adam's, why do you want or need to know anything about Adam's death? Why do you conduct any sort of scrutiny of those papers and then say it's a rather different case from Raychel's if the circumstances of other deaths and the number of other deaths aren't relevant to the working group?

A. I accept that position entirely --

THE CHAIRMAN: But does it not undermine the suggestion that the other deaths, by the fact of other local deaths and the circumstances of other local deaths, are not relevant?

A. The working group was producing guidance that needed to be by its very nature generic and applicable to all. We didn't, as mentioned earlier, see any need, nor did we, to test it against individual cases. Nonetheless, it so happened that in the course of events the coroner sent me a copy of the medical report and called me to say, "This medical report and its conclusions, rather than the details of the individual case, may have some bearing".

I received that report and I read it, and that's ... That didn't have any direct bearing on the content of the guidance, but nonetheless when I received it, I did read it.

MR STEWART: You did, and in fact you read it closely and you recognised common features between that case and Raychel's case, didn't you?

A. Mm-hm.

Q. So you were analysing it in that context. Why would you do that unless you're interested generally in what information deaths could bring to your group?

A. It would have been my role as a senior medical officer.

If I received papers, I would read them and consider them carefully. That would have been what I did.

THE CHAIRMAN: I'm sorry, but you asked for these papers. Dr Loughery advised you of the fact of Adam's death. Then you followed up the idea of getting papers so that you could give them some level of scrutiny. I don't quite understand, doctor, how that tallies with the idea that the number and the circumstances of other deaths are not relevant to the working party.

A. I accept that. Just one small point of clarification. I did not request the papers. In fact, we do not as a rule request inquest papers, would not have, as a rule, at that time certainly.

THE CHAIRMAN: I'm sorry, maybe I misunderstood how you got Dr Sumner's report.

A. I had a phone conversation with Dr Loughery and I would have been in fairly regular contact with her over the detail of the guidance, and I think she had said something along the lines of "Well, I'll be speaking to the coroner again and I'll mention that it may be worth furnishing you with a copy of the papers". The coroner then subsequently called me a few weeks later and said, "I'm happy to send a copy of this to you". So it came to me through him rather than at my request. Of course I was going to read it; it would have been of interest.

THE CHAIRMAN: It's a public document by that stage.

A. That's correct.

THE CHAIRMAN: So the privacy issues and the confidentiality issues don't really exist.

A. That's true, that's true.

THE CHAIRMAN: Okay.

MR STEWART: Can we go to WS080/2, page 25.

THE CHAIRMAN: We're going to take a break at some point, Mr Stewart. Does this suit?

MR STEWART: Let's finish this point. Well, it may take some time. It might be a convenient time.

THE CHAIRMAN: We have to take a break for the stenographer and for you, doctor, so we'll come back in about 10 or 15 minutes.

(11.36 am)

(A short break)

(12.00 pm)

MR STEWART: If we might, please, turn to page WS080/2, page 25. At question 63(b) in the middle of the page -- this is to return to this issue once more:

"Please explain if you recognised any pattern between the deaths of Raychel Ferguson and Adam Strain."

You answered:

"At the time the hyponatraemia guidance was in preparation and working group members were aware of the

deaths of Raychel Ferguson and Adam Strain ..."

Can you tell me how the rest of the working group was informed of the death of Adam Strain?

A. I can't actually recollect how the rest of the working group were informed or whether some, but not all were aware. I'm sorry, I just don't recollect how they were informed.

Q. Because they all should have been made aware, shouldn't they?

A. Inasmuch as we were drafting the guidance as a common set of standards, it would not have been necessary. On the other hand, I had certainly been made aware and Dr Loughery was aware and we knew that Dr Taylor was aware it may have been of interest. But I can't recall whether they were -- whether every member was informed. I think probably not.

Q. And it was up to you to make them aware, wasn't it?

A. It was my role as a central role in terms of facilitating and providing the leadership to the group to have ensured that those who needed to know key pieces of information did know them, yes.

Q. And the coroner thought that you should know this information, didn't he?

A. He provided me with a report because he thought it may have been of help.

Q. And did you bring this information to the CMO's attention?

A. Yes, I did.

Q. You go on in this paragraph to say:

"I recall recognising some common factors, including operative intervention, aspects of the monitoring, fluid requirement and fluid type."

So you in fact compared them, contrasted them, looked at the relevant issues in each; that was for the purposes of relevance?

A. At the time I think it was for my own information. It wasn't a rigorous analysis by any means and, from what I can recall, I had not been aware of Dr Sumner before, it wasn't a name that was necessarily familiar to me. My conversation with the coroner at the time -- I think he had indicated that, firstly, the details of the case may have been of interest, but, secondly, that Dr Sumner's particular expertise and interest around hyponatraemia may also have been of interest. And subsequently, we did follow up with Dr Sumner to seek his advice on the inclusion or otherwise of particular detail within the guidance in light of practice at Great Ormond Street.

Q. If you read the documentation and you recognised these common factors for your own information, why did you not

share that information with the working group members?
A. I don't recall sharing it and the --
Q. Why not?
A. And the essence -- well, would it have materially altered the work that we were currently bringing, as we thought at that time, to a conclusion? This was in --
Q. How do you know? How were you to know it wouldn't?
A. The guidance that we were putting out was, as mentioned earlier, intended to provide advice and guidance for every child receiving fluids. We did not intend -- it was not our remit, we did not intend and we did not do any kind of retrospective analysis of particular cases. This coincidentally came to our attention through the coroner in the course of producing the guidance, but that was more, I have to say, by coincidence. Because the coroner knew what we were preparing, the coroner had brought this to our attention and thought that the medical report may be of interest.
Q. Yes, and Clodagh Loughery of the committee thought it of interest as well.
A. Correct.
Q. And when you compared the features of the cases for your own information, it was because this case was relevant, Adam's case was relevant, relevant to Raychel's case and relevant to your understanding of hyponatraemia.

A. Yes.
Q. Can I ask, please, that we look at page 023-045-103. This is moving on to September 2004, and this is a flurry of e-mails passing between various press officers of various trusts and Mr Colm Shannon of the department. Mr Colm Shannon, was he a press officer?
A. He was. He would have been the most senior press officer at the time.
Q. He was communications director or something?
A. Yes. I'm not sure where he is now at the moment.
Q. This top e-mail, 22 September, he is e-mailing the communication manager of the Altnagelvin Hospital. He writes:
"Marie, in relation to Adam Strain, I have spoken to the Royal and to Dr McCarthy about the case of Adam Strain and there would appear to be no read-across to the Raychel Ferguson case."
That's information coming out of the department. Did you indicate to Mr Shannon that there was no read-across from Adam Strain to Raychel?
A. Not that I recall. As in my witness statement, I would have seen a read-across on some aspects, for example the administration of fluid, the volume of fluid and the monitoring, issues common, and I would have seen quite a few differences as in Adam, I know, was a child

undergoing fairly significant surgery who had previous surgery in the past and was undergoing a significant operation, whereas Raychel had been a previously healthy child, undergoing -- any operation is significant to a family, but undergoing what is generally regarded as a relatively straightforward procedure.
Q. Can you explain how it is then that the communications director of the department is indicating that you have suggested or agreed that there was no read-across one case to the other?
A. I can't explain that. If I were asked about that, I would have been indicating, reflecting what I have just reflected. There is some read-across, but there is not necessarily a direct read-across. The difficulty is I don't know to what documents this is referring in terms of --
Q. We'll just go to an e-mail --
THE CHAIRMAN: Sorry, for there to be ... no two children will ever be the same; right?
A. That is correct.
THE CHAIRMAN: And the circumstances are almost always going to have variations of greater or lesser significance.
A. Yes.
THE CHAIRMAN: So there will be some read-across but very rarely will you get a direct read-across?

A. Yes.
THE CHAIRMAN: But that means that the thrust of that sentence is wrong, isn't it? "There would appear to be no read-across to the Raychel Ferguson case" is really quite wrong.
A. I would not agree with that sentence.
MR STEWART: How could it be that the department is putting out that sort of thing and in your name?
THE CHAIRMAN: I'm sorry, to be fair to you, doctor, this is what Mr Shannon has picked up from speaking to Dr McCarthy and also from speaking to the Royal.
MR STEWART: Yes, we're just going to go to that e-mail, if we may, sir. It appears at 023-045-105. This is the information coming from the Royal, Christine Stewart at Royal Hospitals, of two days before, to Colm Shannon of the department:
"I have spoken with Bob Taylor, consultant anaesthetist at PICU, who was involved in the management of Adam Strain and gave evidence at the inquest. Following a detailed examination of the issues surrounding patient AS, there were no new learning points and therefore no need to disseminate any information."
Was that information brought to your attention by Mr Shannon?

A. Not that I can recollect.
Q. So when Mr Shannon says that he has spoken to you, can you recall any discussions with him at that time?
A. Not directly. There would have been quite a number of discussions in or around that period in relation to media enquiries. I don't recall detailed discussions. If I may just make a comment on the previous page that was up? While the e-mail was sent from Colm Shannon, the e-mail is signed "Clare Baxter", so ...
THE CHAIRMAN: She's another press officer, isn't she?
A. Yes, she is.
MR STEWART: Shall we go back to that again? It is 023-045-103. That was the e-mail from Colm Shannon to Marie Dunne of Altnagelvin with a copy to Clare Baxter. And Clare Baxter was your secretary; is that right?
A. No, Clare Baxter was another press officer. I just notice that the wording and the signature in the last line:
"I am out of the office, but if there are any issues, you can ring Claire."
Sorry, my mistake. It was from Colm. I beg your pardon.
THE CHAIRMAN: I don't know the extent to which you have followed the inquiry and I know that you're not a -- you're a public health specialist and not

a hyponatraemia specialist. But in light of what you have picked up, doctor, do you agree there were no new learning points from Adam's death and nothing to disseminate?
A. Um ... In light of what I understand, I suppose I would say that there were learning points from each of the cases and each of the deaths that all could be helpful in trying to prevent further events in the future.
THE CHAIRMAN: In fact, at the very least we know that at the inquest there was an agreed statement. That statement committed the Royal to informing anaesthetists about and keeping them trained in this, and it fell by the wayside, but Dr Murnaghan intended to hold a seminar at which a range of doctors would be present and they would discuss what the learning was from Adam's death.
A. Yes.
THE CHAIRMAN: Thank you.
MR STEWART: When you learnt of Adam's death in the RBHSC, did you have any communication with Dr Crean about it? Dr Crean of the RBHSC. Did you ask him about it?
A. Not that I recollect.
Q. Did you speak to anybody about it?
A. Um ... I don't have a recollection of discussing the detail of the case. I may have discussed it in passing with Dr Bob Taylor, but not in any detail.

Q. What would you have asked him, given what you have read?
MR UBEROI: I think we're getting into very tricky territory here, if I may so, sir. The last answer was clearly prefaced by "I don't have any recollection", so all we're really doing is fishing for speculative guesses as to a conversation 10, 12 years ago.
THE CHAIRMAN: I think that's pushing it a bit further than we need to go, Mr Stewart.
MR STEWART: Can we go, please, to the culmination of the working group deliberations and to the production of the guidelines in March 2002. They were introduced by the Chief Medical Officer by letter at 012-064c-328 and 329. Do you remember who drafted this letter?
A. I would have drafted that letter [OVERSPEAKING] CMO.
Q. Second paragraph:
"Hyponatraemia can be extremely serious and has in the past few years been responsible for two deaths among children in Northern Ireland."
We've just gone through the information relating to four deaths that you may have had. Why did you say two deaths?
THE CHAIRMAN: It might be four, it might be three.
MR STEWART: First of all, we've got Raychel Ferguson. Then we've got 1997. Then we've got at least two others, which makes it three, and I suppose, sir, if one of

those might be Adam, it's three or four.
THE CHAIRMAN: It's three or four.
MR STEWART: Thank you, sir.
Given that you know of at least three or four deaths, why do you only mention two?
A. The two deaths to which we were referring in that letter were those of Adam and Raychel. I recognise that the bar chart and other information received would have indicated that there may have been more, but the department did not have any details or any conclusive information around the nature of any other cases or the particular cause of death. So there were two that we were absolutely aware of and that was fairly definitive, and other information had not been necessarily clarified, nor was available to us at the time.
Q. But you had indications that there would be at least three, if not four, and all you had to do was pick up the phone to Bob Taylor and say, "That 1997 death, just exactly what was that and were there any others?" That's all you had to do. It looks as though you're deliberately understating the number of deaths known to the department.
A. Well, that would certainly not have been, in any respect, the intent of that. There were two that

we were aware of. We had not, in the group, been pursuing information on prevalence or incidence, and therefore we just didn't have any additional information. In light of the fact that the letter went out clearly stating that hyponatraemia can be extremely serious and the emphasis in essence was that -- and yes, it can be fatal, so it was to draw the attention of clinicians to the very serious nature and the very serious need to take due account of the guidance.

Q. But if you're trying to emphasise the seriousness and urgency of the situation, why don't you at the very least write "at least two deaths", or why don't you make the phone call and actually give the information to underline and emphasise the seriousness of what you're doing?

A. I accept that that would have been helpful and "at least two deaths" would have been more accurate. I accept that.

Q. In the paragraph at the foot of that page:

"Fluid protocols should be developed locally to complement the guidance and provide for specific direction to junior staff."

Was any thought given to giving advice to trusts in the preparation of their own localised fluid protocols?

A. In issuing any guidance, we would normally expect the trusts to take this kind of measure forward themselves, that it would depend on them within their own organisation developing the protocols. It was unusual in itself for the department to be issuing guidance. It was not normally a function of CMO's group. It was done because of Dr Campbell's intent to have something out quickly.

Nor would it have been usual for the department to have specified what an individual trust protocol would have looked like, so the expectation was that that would be something that the clinical groups within the trusts would take forward as they saw necessary in light of their patient population.

Q. Looking back now, having drafted that letter for the CMO, without putting her name to it and referring to just the two deaths, how do you feel about your fellow working group members who kept from you and the CMO the facts and the identities of the other victims of hyponatraemia?

A. The working group members that I worked with were, in terms of the work that we were asked to do, extremely helpful, constructive, enthusiastic, and their input to ensuring that the guidance was fit for purpose could not be faulted in any way. I worked with a very good group

and I have worked with very many of them since on different issues and I have huge regard for their integrity, clinically and in supporting and producing strategic documents.

Q. I have asked you how you felt now, having drafted that letter, that they kept this information from you?

THE CHAIRMAN: I understand that answer entirely and this may seem a bit unfair, doctor, and it is certainly unfortunate that we're focusing on this, but I think you know why we're focusing on this.

A. Yes.

THE CHAIRMAN: If the people who you were working with were not good, professional clinicians, the guidelines would not have emerged as quickly, effectively and successfully as they did. So I entirely accept that. But in a sense, Mr Stewart is asking you this: are you not disappointed by the fact that they had between them more information about other deaths, which was not disclosed or discussed during the lifetime of the working group?

A. Truthfully, I sort of find it inexplicable more than anything.

MR STEWART: Well, in light of that answer, do you want to reflect again upon the answer you gave a moment ago, which was to pay tribute to their helpfulness and their

integrity?

THE CHAIRMAN: We don't need to go there, Mr Stewart. I don't want to detract from what the group did because what the group did was important and it set a standard in Northern Ireland ahead of the rest of the UK, which is important to remember. My regret, which I think Dr McCarthy shares, is the inexplicable failure to draw to the attention of other people in the working group, like Dr McCarthy herself, the fact of other events.

MR STEWART: Yes, sir.

We might move on then to address the subject of the arrangements made for the audit of the guidelines that your group had produced. We might go through this in sequence. Could we please have page 007-048-094 and 095? This is, as you can see, the minute of the first meeting of your group, 26 September 2001. You'll see on the right-hand side, the last line of paragraph 3:

"Audit of guidelines is encouraged."

And at paragraph 8:

"It was decided that a small group should undertake the drafting of guidelines and audit protocol."

Can I ask you what was envisaged by the audit protocol?

A. I think what was expected in the first instance was that, when we produce guidance, we would indicate the

kind of measures that would be applied to check compliance with the guidance.

Q. Subsequent guidelines, and I think particularly of the Alert No. 22, had attached to it a compliance template.

A. That's correct.

Q. An assurance template.

A. Yes.

Q. It's that type of thing you had in mind? Perhaps less evolved, but --

A. It might not have been as clear as that, but of course nowadays when we produce any set of guidance -- and NICE certainly does the same -- they tend to be accompanied by an audit template. So it actually prompts people to measure their adherence to the guidance. That was not very well developed in 2001.

THE CHAIRMAN: At the end of Dr Darragh's evidence yesterday he said if you were doing the same thing again now, compared to 2001 and 2002, it would be done more robustly in terms of audit then was then the position, but that is just one of the advantages of the development of governance?

A. Yes.

MR STEWART: But in the interests of encouraging the guidelines, the audit and the guidelines, it was suggested that this small group undertake the drafting

of the audit protocol. We understand that that wasn't in fact done; is that correct?

A. There is a reference in one of the documents 007-035-065 --

Q. Could we have that, please?

A. We're obviously at that point, either by telephone or e-mail -- that's my writing, the manuscript -- beginning to think about what we would do as an audit tool. But I recall two factors playing a role in the development or lack of an audit tool. One is that our main focus throughout those few months was getting the guidance out. I had hoped that it would be out by early January as articulated in some of the e-mails of late December. It actually took a little bit longer because of the discussions with SACs and others. Therefore, it took maybe six months rather than the three or four months that we had originally planned. So I think we were focusing on, firstly, getting the guidance out, secondly I think we did have -- I do recall discussion around whether we could accommodate something in the guidance that would indicate an audit expectation, if not requirement. The truth was the guidance, as we were producing it as an A2 chart, simply had no space on the chart to accommodate anything else. There was an absolute scrutiny in the guidance to ensure that only

essential words were in in every circumstance and therefore the detail of an audit simply could not be included unless it was at the expense of something else.

THE CHAIRMAN: Is that for the purposes of keeping the chart as clear and comprehensible as possible?

A. Absolutely.

THE CHAIRMAN: Because the more information you add in, the more people are put off?

A. Yes, there was quite a delicate balance in that respect, that took a significant number of hours to get right. So therefore, it would have been our assumption when the guidance was issued that, yes, of course audit would be necessary, but that we would probably follow up in due course on what that audit may look like.

If I might just add, having been involved in other audits, and one that I did in a similar kind of time frame was the regional audit of thrombolysis. That took three or four months simply to plan the audit tool. The rigour required was really very significant. So we recognised that to properly plan an audit tool may take a little bit of time, but the priority was to get the guidance out first and foremost and then it was anticipated that we would follow up with an audit, as indicated in Dr Campbell's letter.

MR STEWART: Yes. Perhaps we can go to the next stage of

this sequence, which appears at WS035/2, page 347. This is you writing, it's a round-robin letter, this particular copy went to Dr Nesbitt, in relation to the final draft of the guidelines, and you say:

"If you're content, we'll go ahead to print and it will be distributed and accompanied by a CMO letter."

And:

"When the guidelines have been printed I will arrange another meeting to discuss how we may conduct an audit on use of the guidelines."

That is, I think, early 2002, before it goes to press. Did you arrange a further meeting with the group to discuss how you may best conduct the audit?

A. I don't think a further meeting was arranged. I think subsequently we allowed time for the guidance to be embedded into the system and then subsequently CMO asked for an audit to be undertaken.

Q. Yes. We're just going through this step-by-step. The next step is in fact the CMO's letter which you drafted and that's at 012-064c-328 and 329.

It's really page 329 at the top. At the top, you and the Chief Medical Officer stress:

"It will be important to audit compliance with the guidance and locally developed protocols and to learn from clinical experience."

So it looks as though the obligation to audit is passed across to the trusts. And it is stressed to be important.

A. Mm-hm.

Q. When this letter went out, did you at that stage think it was appropriate to convene a meeting to plan this audit or to give advice to the trusts?

A. My recollection is that that didn't happen at this point in time. I honestly cannot remember the detail of how it was determined, how and by whom an audit would be conducted.

Q. Moving on, six months later you come to a meeting of the specialty advisory committee. That's at 320-056-001 and 002. This is six months after the guidelines have been distributed. We see at that meeting, from the department, Dr Campbell, Dr Carson and yourself and others. On the right-hand side:

"Hyponatraemia. Members commended the guidance [which had been circulated previously] and it was suggested that an audit of the guidelines in due course would be valuable."

So that is the specialty advisory committee in paediatrics stressing again the audit is valuable. In response to that suggestion, did you take any action?

A. Well, the action on that was that members of the

committee in the trusts were to advise on whether there was a particular doctor in training who may have been suitable to work on that particular item.

Q. It seems that Dr Jarlath McAloon came forward and took hold of the situation and started his own proposition for an audit at that stage.

A. Yes.

Q. Is that correct?

A. As far as I can recall, yes.

THE CHAIRMAN: Is that independent of the CMO and the department or is that associated with the last entry you have just referred to, doctor, where Dr Campbell's asking for names of people who would be interested in taking the audit forward?

A. I think what was happening was that Dr McAloon was taking forward a particular piece of work within his trust to look at the compliance with the guidance. And really, subsequent to that, CMO thought that it would be helpful for him to take forward something on a regional basis.

MR STEWART: He's told the inquiry that, as regional adviser, he felt he had some responsibility to move the overall process along as it was an outstanding action on the agenda. That's the agenda that you were referring to a moment ago.

A. Yes.

Q. And that is in September 2002, and in fact he conducts two snapshot audits in June of 2003 and January of 2004. And you don't get the results of that until much later in 2004. But in the meantime, that's September 2002, and in February of 2003 we have the inquest of Raychel.

A. Mm-hm.

Q. And then in March 2003 you learn of the death of Lucy Crawford.

A. Mm-hm.

Q. And then, in May 2003, Conor dies.

A. Mm-hm.

Q. So at that stage if you knew perhaps of three or four deaths beforehand, you now know of five or six deaths. In November of that year, you co-author an article in the Ulster Medical Journal.

A. That's correct.

Q. It appears at 007-083-198. This is November 2003, six months or so after Conor has died. Then we look at the first sentence:

"... increasingly recognised in recent years as a potential complication of fluid therapy in children, and at least two children in Northern Ireland have died."

"At least two children." We're back to this point

again. Why is the figure being understated again?

A. I suspect that may have been lifted from the CMO's letter. What I don't recall is when that editorial was submitted to the Ulster Medical Journal. Sometimes there is a delay between submission and publication --

Q. True.

A. -- so I can't recall the timing of that.

Q. It would be a lengthy delay, though, wouldn't it? Can we go to page 007-083-200? We see that in fact you co-authored it with Dr Jenkins and Dr Taylor. It's the last sentence. You are stressing there in respect of the question of audit:

"Preventative measures to avoid this potentially fatal condition need to be instituted in all units caring for children."

"Measures need to be instituted", but at that stage you still don't know whether the department's guidelines had been instituted, implemented, monitored, working, do you?

A. It was around that time that I think Dr McAloon was in a position to provide the outcome on his audit, but yes we didn't have absolute crystal clarity, crystal-clear clarity at that point.

Q. Indeed, he hasn't even completed the second part of his audit at that stage. The next thing that happens is

Lucy's inquest happens and the coroner then writes to the CMO at 013-046a-216 and 217.

You'll see he writes consequent to the inquest of Lucy Crawford and he encloses, you'll see in the second paragraph, a full set of the inquest papers to the Chief Medical Officer. He says, as you'll see, in the third paragraph:

"Nonetheless [he suggests in light of forwarding the papers] there may be merit in the working party examining the inquest papers in relation to the death of Lucy to see if any changes to the protocol might be required."

So he's still interested in letting the department know the details of deaths. Then he goes on in the final paragraph on the right-hand side to make the point relevant to audit:

"Is there any monitoring of the standard of medical record keeping? Are nurses now briefed on a regular basis as to the implications of the protocol? I pose these questions as they relate to issues which really do concern me."

So there we are, we're in February 2004, practically two years on, you don't know whether the guidelines are in place, he's concerned to know whether they might be, the audit protocol wasn't produced, you didn't meet

again. The incentives are there for you to do something about it, the reminders are there, nothing's been done to speed things up. Why was that?

A. What was being done in 2004 was CMO had -- the working group was not a standing group, so therefore once the guidance was produced, the working group no longer existed as such. Dr Campbell had asked me to write to the members of the working group to ask whether any further update or changes to the guidance needed to be prepared. So that was one thing that they had -- that was ongoing.

On the back of that, Dr Campbell also had facilitated a meeting with Sir Cyril Chandler at which it was discussed: do we need to make changes to the guidance or is it good as it is or does it need to be supplemented by something? And then, of course, in or around the end of 2004, in the autumn of 2004, the audit was available.

The outcome of those things, which I suppose came together at some point late in 2004, was that we didn't need to change the guidance that had been issued, but what did need to happen was it needed to be complemented by a fluid pathway that would apply and Dr Campbell at that time asked Dr McAloon and others to develop a fluid pathway.

Q. If we can go back to the question of audit, what the coroner's plea did provoke was the letter from the CMO to the trusts on 4 March 2004. It seems to be a direct response to this letter from the coroner. It appears at 021-043-089.

This letter relates not only to your working group's guidelines but was also to the CREST guidelines in respect of hyponatraemia in adults:

"The purpose of this letter [as you can see in the final sentence] is to ask you [that's to say chief executives of all trusts] to assure me that both of these guidelines have been incorporated into clinical practice in your trust and that their implementation has been monitored. I welcome this assurance and ask you to respond in writing before 16 April."

So two years on, we're now asking for an indication of the implementation, monitoring, essentially an audit of compliance, by 16 April. Quite a lot of responses to this were not received by 16 April. Were any steps taken to follow that up immediately after 16 April?

A. There's no record of any steps being taken immediately after 16 April, but at Dr Campbell's request I issued reminders, but that admittedly was some months later.

Q. Quite a number of months later. You were still briefing the CMO on hyponatraemia matters on, in fact, 15 April.

A. Mm-hm.

Q. There's a letter from you to the CMO, but nothing in relation to following this up. In June of 2004, three months after this, the coroner holds his inquest into Conor Mitchell's death. And then in August 2004, Dr Jarlath McAloon comes back with his regional audit. That can be found at page 007-092-234.

That's the covering letter. You can see that he states there:

"The regional audit has been conducted in 2003/2004 to examine adherence to the guidance."

And in fact you see at the top your name is noted as having received a copy.

If we go to the next page, 235. The essential import of the report is in the summary section. The last sentence:

"This paper reports the findings of the first regional audit undertaken to examine practice following introduction of the guidance [that's your guidelines] and the evidence suggests that implementation has so far been incomplete."

If we could go to the final page of his report at page 239, his final conclusion in the concluding paragraph is:

"Given the incomplete compliance, until then it is

essential that all clinicians in Northern Ireland caring for children in receipt of fluid therapy know of the associated risks and are aware of our regional best-practice guidance and that paediatric departments initiate a process of regular monitoring of guideline adherence as part of their multidisciplinary audit and clinical governance programme."

So he's coming back to stress it's essential that they know.

At this time, you're still awaiting responses from a number of trusts as to whether they've actually implemented your guidelines, whether they're monitoring your guidelines. You haven't gone back to ask them for information. I take it you haven't actually followed up on some of the responses you have received at that time to know whether they're accurate.

A. I don't recall any follow-up with the trusts at that time.

Q. And then --

THE CHAIRMAN: You're acting on the presumption that if a trust replies to you and tells you what it has done to implement the guidelines, that you can rely on that information?

A. That would have been our assumption, although obviously we would have had the discretion to go back and either

ask them to explain or provide additional information.

THE CHAIRMAN: So you'll be aware of what was resolved last week in Conor Mitchell's case in Craigavon about the fact that the letter which was sent in response to the CMO's enquiry about audit had no basis --

A. Yes.

THE CHAIRMAN: -- which I presume you also find inexplicable as to how the CMO was provided with information like that?

A. Well, yes. When we ask trusts for assurance, we expect that to be based on what's actually happening.

THE CHAIRMAN: Yes.

MR STEWART: You have said the CMO's sent her letter asking for the Royal Belfast Hospital for Sick Children, as part of the Royal Group of Hospitals trust, to respond by 16 April. You knew the RBHSC importance in terms of the hyponatraemia deaths, the importance in terms of its pivotal position as the regional centre for excellence and a teaching hospital. And yet there's no response from them. As 2004 grinds on, UTV eventually broadcast their documentary in October 2004, and the permanent secretary, Mr Gowdy, moves to ask all relevant parties to find and secure documentation, and it's only then, on 3 November, that you write to those erring trusts who have not yet responded to you to remind them. That's at

073-041-172.

That's your letter, 3 November. That's seven months after the deadline has passed. It's three months after Dr McAloon's audit. Nine months after response. And it's written after UTV broadcast their programme:

"Unfortunately, I do not have any record of a response for your trust and I would appreciate if you could issue a response at your earliest convenience."

Were you surprised that the trusts should be so dilatory in this matter?

A. Normally trusts replied in or around the due date or sometimes requested extensions. Yes, I think it would not have been usual for so many months to have elapsed before responses were received.

Q. Would it be usual for so many months to elapse without an additional and more strongly worded reminder to go out?

A. Certainly today it would be most unusual because we tend to follow up much more rigorously. If we issue a letter and ask for a response by a particular date, we tend to follow up within a week or two of that to emphasise the need for having an early response.

Q. You did get the Royal's response finally, 16 December 2004 it's dated, and it's at 073-030-136. It's dated 16 December 2004, with date stamp as

5 January 2005. He writes not to confirm implementation, nor to confirm monitoring, let alone audit, but to confirm this information was disseminated within this trust. That's a rather sort of a brush-off, really, isn't it? It's not giving you the information you want.

A. No.

Q. Did you go back to him?

A. I agree, that's not an adequate response. By the time that was received in January 2005, I don't recall going back to him. I think my duties had probably changed to some degree such that I wasn't following up on all issues relating to children's services or hyponatraemia. But I'm not conscious that any of us went back to the Royal specifically or, sorry, to the Belfast Trust or the Royal.

Q. You see, at that time you were still engaged in hyponatraemia matters because you were a member of the NPSA external reference group, and that's the NPSA hypotonic fluids group 2005/2006, and you also served with McAloon on the fluid therapy regional working group in 2005. So you were still closely engaged with the issue?

A. Yes, I did have some engagement.

Q. Can I ask you please about Sir Cyril Chandler and his

contribution? Did he make any comments on your guidelines in writing?

A. Not that I was aware of. We did have a meeting with him and he made some general comments at that meeting about the nature of hyponatraemia and the aspects of a child's condition to be -- on which clinicians ought to be alert. But I don't recall seeing follow-up in writing.

Q. Because at one stage I think you asked for a copy of his comments, which would suggest they had been reduced to writing.

Can we have a look, please, at page 001-015-062? This is a statement prepared for the minister, Angela Smith, in the aftermath of the inquest into Lucy. You see the large paragraph towards the foot of the page and the sentence beginning:

"In response, Dr Campbell has engaged an international medical expert in the specialty of paediatrics to quality assure the guidance in light of the findings of the inquest into Lucy's death."

Was that Sir Cyril Chandler, was he the international medical expert?

A. I'm not aware of anybody else having been involved of that sort of stature, so I expect it was.

Q. So if it's being suggested that the minister should inform the public and reassure the public that the CMO

had engaged an international medical expert to quality assure the guidance, one would imagine that such a quality assurance would be reduced to writing.

A. I would have expected that.

Q. But it wasn't. Is that your --

A. I do not have a record of any report from Sir Cyril.

Q. And indeed, as I say, you asked for one. That appears at 075-008-018. There you are, it's from you, CMO, and the line there which is partially obscured by a photocopy:

"Is it possible [I think you write] to get a copy of Sir Cyril's comments on the guidance. Happy to discuss. Miriam."

So presumably, had there been a copy floating around, it would have found its way to you?

A. I would have expected it to.

Q. In 2004, in the aftermath of Lucy's case and the coroner's letter, the working group was brought back together again to look at the guidelines to see if they could be or should be amended.

A. Mm-hm.

Q. And that was the fluid therapy regional working group that I referred to a moment ago. Dr Angela Jordan was asked to form a part of that group.

A. That's correct.

Q. Do you remember now what her specialty was?

A. She was a doctor in training within public health.

Q. She thought it relevant to suggest to you by e-mail that the lessons and the points emerging from the inquest papers might be relevant to the discussions. That appears at page 320-126-123 and 124:

"I have made a list of the key learning points from the inquests into the three deaths. I am hoping to share this with the group so they can take these points into consideration when developing the care pathway."

As I understand it, it was an algorithm rather than a care pathway that was in fact decided upon?

A. That's correct.

Q. And she asks you:

"Are you happy that this be shared with the group?"

And then, on the right-hand side, she's actually listed various points which she thinks emerge from the inquests that are relevant to guidelines. Would this not strongly suggest that lessons could readily be extracted from previous cases of relevance to guidelines?

A. It could suggest that, but also, if I may suggest that the issues that Angela Jordan raised at that time were largely issues that had been included in our guidance that went out in 2002 about the awareness, the

possibility of inappropriate ADH, records of fluid calculation, recording the type, the rate, et cetera, going into a bit more detail. The handwritten notes at the bottom are mine, obviously where I was kind of thinking about what was needed in terms of knowledge, awareness and monitoring, et cetera.

So, yes, I expect that Angela was drawing both on the information originally included in the guidance and any subsequent information that had come to light.

Q. That's true, but that's an observation made with the benefit of hindsight.

A. Yes.

Q. At the time of the working group, you weren't to know what lessons might be derived from the inquests, which is why I suggest to you again it would have been an obvious thing to do.

THE CHAIRMAN: It's back to the point, really, about the working group. You can draw up the guidelines and then you might want to have a checklist of what was learnt from the inquests and what had gone wrong before, and if you read your checklist across and you'll see how complete or otherwise the guidelines are.

A. Yes.

THE CHAIRMAN: In a sense, that's what Dr Jordan was doing here, isn't it?

A. Yes, it is.
THE CHAIRMAN: She had the guidelines, she obviously had the guidelines from 2002, she had reviewed the inquests and she was cross-checking one against the other. As it turns out, as you say -- and I think rightly -- the guidelines have covered all the important points. But that's the sort of thing that would be at least a perfectly viable and reasonable route for the original working group to have taken.
A. Yes. And I suppose the other possibility may have been: put out the guidance, by all means audit, and we had committed to doing that, but also to have a system by which we knew of every case of hyponatraemia, every laboratory case among a child where the sodium was less than X, 130 or whatever, and then to say, "How did this happen? Is it because of -- that the guidance wasn't complied with or is it because the nature of the guidance didn't address the particular issue?", and that way we helped provide a safety net. But there are different ways of doing things.
THE CHAIRMAN: Yes.
A. And certainly Angela Jordan's suggestions were all relevant suggestions.
THE CHAIRMAN: Thank you.
MR STEWART: I have, sir, no further questions.

THE CHAIRMAN: Okay. Give us a last moment, doctor. Are there any questions? Mr McCrea?

Questions from MR McCREA

MR McCREA: On behalf of Claire Roberts' family, in your statement you indicated at page 14, I think it is, that --
THE CHAIRMAN: Sorry, is it the first? That must be the second statement, then. It's the longer one. It's the second statement, the longer one.
MR McCREA: The second statement, WS080/2, page 14, question 31:

"By when did you first become aware of the death of Claire Roberts?"

And your answer to that is:

"I became aware of the death of Claire Roberts when her death was included in the remit of the hyponatraemia inquiry."

What date is that according to your records? Is that 2008?
A. I actually don't recall. I certainly was not aware of Claire's death at all until there were articles in the media about the inclusion of an additional case, and that was, of course, Claire's case. So I don't know. It was certainly after 2004. I don't recall the specific date.

Q. It was certainly after 2004?
A. Yes, and it would have been through the media and issues pertaining to the inquiry rather than through any other source.
Q. It's just the family are very concerned about the proposition that you yourself, being so heavily involved in the guidelines and then the, if you like, the review of the guidelines, weren't aware of Claire's death until much later than you should have been and, secondly that it seems you find out about it in such an indirect way.
A. I can absolutely understand the position that the families are coming from. I think there's nothing more -- all of us know there's nothing more horrendous than losing your child. I can give my absolute categorical position that I did not know of Claire's death, nor indeed Adam's, when the work was first set up and I didn't know about Claire's until much later. It's unfortunate that details were not known, but that is the reality of my position.
THE CHAIRMAN: I think there's perhaps another limb to this question because the inquiry was established in 2004, that's after the UTV programme. It was the UTV programme which prompted Mr and Mrs Roberts to contact the Royal.
A. So I understand.

THE CHAIRMAN: And that led to Claire's death being referred to the coroner and the inquest was 2006; is that right?
MR McCREA: 2006.
THE CHAIRMAN: The inquest was in 2006. It's when the inquiry resumes in spring 2008, after the police and the DPP have decided not to take any action, that I announced that I was going to include Claire and, on a limited issue, Conor. So everyone will understand how there was some press coverage of the additional cases which I've included within the remit of the inquiry, but I think part of what you're being asked about is not just that you weren't aware of Claire's death when the working party was active in 2002, 2003 and 2004, but that you --
MR McCREA: And beyond, because it's recalled.
THE CHAIRMAN: -- still weren't aware of it when her inquest was then carried out in 2006.
A. I wasn't aware of any detail around that and, by then, my position in the department had moved. In fact, I was no longer in the medical branch, so I wouldn't have been as close if there had been internal discussion. But I simply wasn't aware -- after her inquest, I do recall something to the effect of "there may have been another case that looks a little bit like some of the hyponatraemia cases", but that would have been publicly

available information in the media and not anything else.

MR McCREA: The point is that Dr Carson, when he provided a statement -- and that statement is WS270/1 -- was asked when he first became aware of Claire's death. It's at page 3, question number 7. His answer was:

"I'm unable to recall, but as far as I am aware it was not before 2004/2005."

So therefore, Dr Carson is aware of Claire's death and the circumstances surrounding that because there's an e-mail trail between the coroner and Dr Carson and reports are exchanged. But you have no knowledge?

A. I was not aware. Firstly, my remit within the medical branch had moved on sometime around 2004/2005. I became much more involved in the issues around governance in the Western Trust and South West Hospital, et cetera. Any issues to do with paediatrics were taken over by my colleague, Dr Willis, at the time and then, in April 2006, I moved out of the medical professional side of the department to take up a policy position, so I would have been quite removed from any discussions and, as I said, I only learned about Claire's death through publicly available information in the media.

Q. But you still have the involvement, no doubt, and a professional interest in hyponatraemia?

A. No, no. A personal interest because I had invested much energy and time into producing the guidance, something that I felt quite proud of. But not any professional and not any policy involvement and not any role in my day-to-day work.

THE CHAIRMAN: I'm not sure we can take it any further, Mr McCrea.

I'll come to you last, Mr McMillen, since the doctor is your witness.

Are there any other questions from the floor before I get --

Mr McMillen, do you have any questions for the doctor?

Questions from Mr McMILLEN

MR McMILLEN: Yes. If I may just ask about the NPSA working group. You state in your CV attached to your statement that you're a member of the NPSA hypotonic fluids group 2005/2006. That particular group, that led to really the production of Patient Safety Alert No. 22.

A. That's correct.

Q. As well as the safety alert itself, a background paper was produced by the NPSA as well.

A. Yes.

Q. Mr Chairman, I'm not sure whether that paper could be brought up. I'm afraid I do not have the reference

number to it. It's March 2007.

THE CHAIRMAN: Give us one moment, Mr McMillen. We can find it and bring it up, I think. (Pause).

While we're waiting, because Dr McCarthy was within a few moments of finishing her evidence, there is no sitting tomorrow and we will resume on Monday. I think we're trying to resume at 9.30 on Monday. It's Professor Judith Hill and Mr Hunter. (Pause).

Is it the alert itself that you want?

MR McMILLEN: No, it's the background paper with the alert. It's a couple of fairly net points. (Pause).

THE CHAIRMAN: I will rise for a moment while this is sorted out, but we'll be able to resume in a few moments.

(1.06 pm)

(A short break)

(1.10 pm)

THE CHAIRMAN: We'll see if this works, Mr McMillen. If we could bring up, please, witness statement 035/2 at page 33. If this doesn't work, can we just do it from your reference and we can --

MR McMILLEN: Of course, I will provide the document later on to the secretariat.

THE CHAIRMAN: This is Dr Nesbitt's second statement in the context of Raychel governance.

MR McMILLEN: Yes. Well, perhaps if I --

THE CHAIRMAN: It's referring to the issue, but not to the specific document, and it's the document you want to take me to, is it?

MR McMILLEN: No, the document I'm referring to is the National Patient Safety Agency. It's described as background information and then the sub-heading is "Patient Safety Alert No. 22: reducing the risk of hyponatraemia when administering intravenous infusions to children", and the date is March 2007. I will provide that to the secretariat.

THE CHAIRMAN: Thank you.

MR McMILLEN: You were a member of the working group that produced the safety Alert No. 22.

A. That's correct.

Q. Just helpfully, at least for me, the membership of that group is listed in the document I've referred to. Professor Terence Stevenson was the chair and he was the professor of child health and consultant paediatrician at Nottingham University Hospital NHS Trust. And also on the committee was Dr Clodagh Loughery, and she was there as the representative of the Royal College of Pathologists. And Dr Jarlath McAloon was also there on the committee, and we have Dr John Jenkins from Queen's University who was on the group, and in particular Dr Stephen Playfor from Manchester Children's Hospital.

Dr Playfor had a particular expertise in this area; is that correct?
A. Yes.
Q. He certainly had written a paper.
A. He had a particular interest in it.
Q. Yes. Just returning to the documents, what the document says in the second paragraph, the last four lines is:
"Since 2000, there have been four deaths (and one near miss) following neurological injury from hospital-acquired hyponatraemia reported in the UK."
And what they do then is reference three papers: the first one is Playfor, a 2000 paper; the second is Jenkins J and Taylor B, "Prevention of hyponatraemia" in 2004; the third one is Cosgrove & Wardle. Were you familiar with those papers?
A. I was, yes.
Q. Could I ask you in particular, when that particular group was carrying out its discussions and when it was considering the nature of the problem and the design of the safety alert, or indeed the need for a safety alert, did that group carry out any analysis into the prevalence of hyponatraemia?
A. Not that I recall. That group was convened -- and I think it's worth stressing -- that group was convened, at least partly, if not entirely, at our instigation.

I had written to the NPSA, to Miss McWilliams from memory, in 2004 and then they had responded saying they would look at hyponatraemia in their work plan. Subsequently, their chief pharmacist, David Cousins, I think, from memory, wrote to me and followed up with a phone call to say that they wanted to look at the matter and they were particularly interested in drawing on the experience that we had had in Northern Ireland. Hence what is quite clearly a disproportionate membership from Northern Ireland, but they were keen to build on that.
The early meetings, they did recognise not only the number of cases where it was explicit and crystal clear that the death had been related to hyponatraemia, but there was discussion in the group with many members acknowledging that they were aware of other cases that had happened. There was no discussion in that group that I can recollect to pursue or discuss those individual cases. Rather, the discussion, almost like our own working group, focused on: what do we do now?
It might be worth mentioning that while we were recognised and applauded for what we had done, they did say, "We think, as a group, we need to go one step further and remove No. 18 from general use where that is possible". Hence the work progressed, but no further

work was done on past cases that I have any recollection of.
Q. Yes. Well, it may be implicit in what you have just said, but insofar as my learned friend Mr Stewart suggested or asked why you did not stress test your information or the Northern Ireland guidance against known cases, was that exercise carried out by the NPSA working group?
A. Not that I was aware of.
MR McMILLEN: Thank you.
THE CHAIRMAN: I just want to pick up on that, doctor, because it strikes me, by the time your group was coming to a conclusion, you were always aware of Raychel's death --
A. Yes.
THE CHAIRMAN: -- which was post-operative.
A. Mm.
THE CHAIRMAN: Adam's death was intraoperative or post-operative, depending on how I interpret the evidence. But by 2007, when the National Patient Safety Agency was working with the input of so many people from Northern Ireland, you would have been aware by then of Lucy's death.
A. That's correct.
THE CHAIRMAN: I think you say you weren't aware of Claire's

death, but let's even take Lucy. Lucy didn't have any operation at all.
A. That's correct.
THE CHAIRMAN: So her hyponatraemia and her SIADH would not be post-operative or operative.
A. Yes.
THE CHAIRMAN: So that's an indication that hyponatraemia can arise in more circumstances than operatively?
A. That's absolutely correct.
THE CHAIRMAN: Was even that general point discussed at the NPSA or do you remember?
A. I don't have a clear recollection. I mean, my memory is that, yes, we discussed the particular circumstances for surgery and the other aspects, children with vomiting and diarrhoea, children with bronchiolitis and other things, and of course our guidance also reflected that, that there were those undergoing surgery but there were those with other conditions that put them at a higher risk, so a similar position. By the time we would have been on the NPSA group, this inquiry would have been established --
THE CHAIRMAN: Yes.
A. -- and we would have known of the cases to be included in this inquiry. And I do recall at the first meeting advising the NPSA of that, therefore it may be that the

four that they quote were the four that were in Northern Ireland, but they would have just said "within the UK".

THE CHAIRMAN: Okay.

MR McMILLEN: I think in fairness, doctor, to you and for the sake of clarity, what it says is there have been four deaths reported in the United Kingdom, then cites the three papers. And it may be one would need to look at the underlying papers, but it may be that those four deaths are drawn from those papers.

A. Yes.

Q. It carries on then to make good that point about context. It carries on:

"International literature cites more than 50 cases of serious injuries ..."

And then cites a paper for that. Thank you very much.

THE CHAIRMAN: Okay, thank you.

Doctor, that brings an end to your evidence, unless there's anything else you want to add.

A. No.

THE CHAIRMAN: You don't have to, so thank you for your time. Thank you for coming.

A. Thank you.

(The witness withdrew)

THE CHAIRMAN: Ladies and gentlemen, that brings us to an end for today. We'll resume on Monday morning at 9.30. Thank you very much.

(1.20 pm)

(The hearing adjourned until Monday 4 November at 9.30 am)

I N D E X