Thursday, 7 November 2013

(10.00 am)

(Delay in proceedings)

(10.11 am)

THE CHAIRMAN: Good morning. Ms Anyadike-Danes?

MS ANYADIKE-DANES: Good morning. I would like to call Dr Henrietta Campbell, please.

DR HENRIETTA CAMPBELL (called)

Questions from MS ANYADIKE-DANES

MS ANYADIKE-DANES: Good morning, Dr Campbell.

A. Good morning.

Q. You have made three witness statements for the inquiry. They all bear the series 075. The first is dated 7 July 2005 and I think you were still Chief Medical Officer at that time.

A. I was, yes.

Q. And the second is dated 5 September of this year, the third is dated 14 October of this year; is that correct?

A. Yes.

Q. Do you have them with you?

A. I do.

Q. Subject to anything further that you may say to the chairman in the evidence today, do you adopt them and accept them as your evidence?

A. I do.

Q. Thank you very much. You've also provided us with a copy of your CV. We can pull up 338-001-001 and 002. Do you have a copy there, Dr Campbell?

A. I don't.

Q. It will come up on the screen. We can see from that that you were a doctor and you qualified in 1973; is that correct?

A. Yes.

Q. Leaving aside those earlier appointments, you first came into the Health Service as a senior medical officer in 1986.

A. Yes.

Q. And you were that from 1986 to 1990. Is that at the sort of level that Dr Miriam McCarthy was at when you were engaging with her?

A. It is.

Q. And then you became Deputy Chief Medical Officer and you were in that post for five years, 1990 to 1995. And you were then appointed Chief Medical Officer in January 1995 and you remained in post until February 2006.

A. That's correct.

Q. So you have a considerable experience of the Health Service, both before and during the time that is of interest to this inquiry?

A. That's correct.

Q. And in fact, going back as far as 1986, you have the benefit of being able to know about and therefore draw on and help us with the information that was coming out in those early times about clinical governance and matters of that sort.

A. I would hope so, yes.

Q. Thank you. When you were senior medical officer, what did you regard your role as being at that time? These things are in relation to the time of your appointment, so that would be 1986 to 1990.

A. It's quite difficult to remember because during that time, because I was still training in public health medicine, part of that time would have been spent at the Eastern Board on secondment for a year. I'm sorry, that's not noted there, but I was still a senior medical officer in the department. So I would have been helping the Chief Medical Officer at the time to undertake his full duties, so whatever he requested me to do.

Q. Yes. When we put that question to Dr McCarthy, she saw her role as focusing on working with policy colleagues to identify the strategic direction for particular service areas and the and the standards that may be appropriate to apply in Northern Ireland hospitals and, of course, whatever she might specifically be being

asked to do by you or your deputy when he came into position. Would you accept that's a fair reflection of what you might have been doing at that time?

A. It would have been part of what I would have been doing during that time. But of course, with the whole public health agenda at the time, there was a great deal of public health to do as well as Health Service issues.

Q. I understand. Then if we come now to your role as the Chief Medical Officer. When you came into that in 1995, what did you see your role as being?

A. The Chief Medical Officer role, of course, is one that's been around for several hundred years, and its primary responsibility is that of the protection and promotion of public health through advising government and government departments on what was needed in terms of policies to do that. The other part of the role was as chief doctor in the department to bring what was called resolved medical advice to the minister and to the department.

Q. I think you refer to change in your role. You talked about -- I think this is in your second statement, 075/2. We don't need to pull it up. You said:

"During [your] 11 years as CMO there were inevitably significant changes in the challenges facing public health in Health Service priorities, and perhaps more

significantly with devolution."

Then you go on to say that:

"At the time of devolution there was a restructuring of the departmental board and a move towards giving chief professionals a more inclusive role in policy decisions."

Can you help us a bit more, particularly with what the impact of, so far as you were concerned, devolution was whilst you were in post?

A. Well, devolution, of course, brought an opportunity in terms of the separation from Westminster, an opportunity to try to move things forward in a way which would more closely match the needs of the population in Northern Ireland. So I would have seen that as one of the major advantages of devolution.

THE CHAIRMAN: Just give me a tangible example of what might be moved forward better under devolution than under direct rule.

A. Yes. It's maybe not so relevant to today's discussion on hyponatraemia --

THE CHAIRMAN: I understand.

A. -- but in Northern Ireland, we had much more extensive inequalities of health than there were in the UK in general, and when you looked at expectation of life there were much greater differences in Northern Ireland

than elsewhere. So as a result of that, we were able -- one of the first things that we did in the first four or five years of devolution was to develop a policy on public health, a big public health policy, "Investing for Health", which was in effect put in place to try to meet those issues, those inequalities in health.

THE CHAIRMAN: Was this a class thing?

A. Mostly, yes. Yes.

THE CHAIRMAN: Okay, thank you very much.

MS ANYADIKE-DANES: And in terms of its impact on your work programme, you've described to the chairman how it gave you opportunities to focus your work on issues which perhaps were more distinctively Northern Ireland than they were for the rest of the UK. In the early stages of devolution, how did that process impinge on the ability for you to carry out the work at your level, or did it?

A. Well, obviously with having the Northern Ireland Assembly and with having one minister for health, whereas beforehand the direct-rule ministers would have had three or four portfolios: health, agriculture, whatever. We now had a minister for health who was able to focus directly on health issues. So it gave us much more time to work with the minister, recognising we also had to work with the executive, to try to develop those

policies which more adequately met the needs of the people of Northern Ireland.

Q. To some extent then, did it actually make your job easier?

A. Not easier, but much more rewarding, because we were able then to think about what would be appropriate for Northern Ireland.

Q. Yes. Thank you. I just want to deal with the structures within which you operated in order to carry out your role and function. We were informed by Mr Hunter and, for that matter, Mr Elliott that there was a departmental board, but the departmental board wasn't necessarily the place where these sorts of policy issues would be discussed and that there was another meeting of high-level departmental officials, which was called the "top of the group meeting", and Mr Elliott regarded that, from his point of view as the Permanent Secretary, for a period of time when you were Chief Medical Officer, as being the more important meeting.

Can you help us with that? If you were having a more structured meeting where issues to do with --

THE CHAIRMAN: Top of the office.

MS ANYADIKE-DANES: Top of the office, sorry. Thank you very much, Mr Chairman.

If you were having a more structured meeting where you would have an agenda and you'd be discussing policy initiatives and so forth, where is the place where that would happen?

A. I am trying to think back because it was -- it's quite some time since.

THE CHAIRMAN: I understand there may be more than one place from time to time, so it's not necessarily a single group.

A. Yes.

THE CHAIRMAN: But previously we thought we had an understanding about the role of the departmental board and then we were told earlier this week: look, the top-of-the-office group -- perhaps certainly for you -- might be more relevant. Does that ring a bell?

A. Chairman, I can't recall the top-of-the-office group. That might be just my memory. Certainly I know that with --

THE CHAIRMAN: Well, can I tell you what Mr Elliott said about it?

A. Yes, please.

THE CHAIRMAN: He said there was a top-of-the-office group -- he said the departmental board was primarily focused on administration, for instance, money, manpower, resources. He said the top-of-the-office

group, which included yourself and the four other chief professional officers and the Permanent Secretary, Mr Hunter, the Principal Establishment Officer, and maybe one or two more from the Management Executive. Their role was to coordinate deliveries such as working on waiting lists, working on waiting times, taking decisions about which hospital units might stay open. Does that --

A. It does. I didn't recognise the term "top-of-the-office group", but certainly senior officials -- and that would have included senior professionals -- would have been where most of the policy development decisions would have been made, yes.

MS ANYADIKE-DANES: And that was a fairly structured meeting?

A. Um ...

Q. Sorry, according to him it was. So there'd be an agenda --

THE CHAIRMAN: He said it was monthly, roughly monthly.

A. Yes, I probably remember it just as the departmental board. I don't remember there being two separate structures.

MS ANYADIKE-DANES: Okay. He also described that you would, so far as he was concerned, have an input, both in terms of assisting formulating policy --

A. Mm-hm.

Q. -- in relation to medical matters, of course, and also, how well that policy was being implemented. So if there were impediments to implementation on the medical side, that he would be expecting you to also have some role in communicating that, and indeed Mr Hunter also expected that to happen, and his role as chief executive of the Management Executive was, of course, far more to do with monitoring and implementing and so forth. Would you accept that?

A. I do, yes.

Q. He said, as the chairman has indicated, not only would we have that meeting that happened roughly monthly, with an agenda and so on and so forth, but there were other meetings that he would have with you: as the need arose, you would come to him with certain issues that you thought were relevant, he might speak to you about others, and there was a similar sort of flexibility of engagement with the chief executive; would you accept that?

A. I do.

Q. So that's you with them, and you would be accountable to the Permanent Secretary; is that right?

A. Yes.

Q. In terms of your interactions with the others in the

professional group -- and in this, I think, particularly with the Chief Nursing Officer and possibly also the Chief Pharmaceutical Officer -- how did you coordinate your meetings and interactions?

A. The Chief Nursing Officer and I were next door to each other. Our doors were always open. We had similar aspirations in terms of what we wanted to do with our role. We were, I think, open with each other and I never found any difficulties in working across that disciplinary divide.

Q. Then the chairman had asked you to give an example of something before. Maybe you can help us with an example here because sometimes they're instructive. Could you give us an example of the sort of thing which, not on a departmental board agenda, but you might think was significant enough to communicate directly with the Permanent Secretary on?

A. I'm finding, chairman, that difficult to answer.

THE CHAIRMAN: I'm sure you spoke to him regularly.

A. Yes.

THE CHAIRMAN: But we can leave it for now. If some example does come back into your mind as the day goes on, maybe you can break away from whatever it is you're talking about and come to this.

A. I shall do that.

MS ANYADIKE-DANES: If I now ask you about clinical governance, because that's an issue, as you might imagine, of considerable significance to the inquiry.

A. Yes.

Q. Could you first help us with who was responsible, so far as you're concerned, in developing clinical governance?

A. Within the department, you mean?

Q. Yes.

A. Well, I would regard it as a corporate responsibility across the department. I would have regarded my role as very important in that, for a number of reasons, because through the meetings with the Chief Medical Officers in London -- I was closely aligned with Liam Donaldson, Sir Liam -- and would have been able to bring back to Northern Ireland where the agenda was going because Sir Liam was very much seen as not just a national but an international leader on clinical governance issues. So I would have seen my role certainly as a corporate role in the department in pushing the clinical governance agenda.

I would also have seen it as an important role, chairman, in terms of the leadership role which the CMO post occupies. I would have seen an important role for me in promoting clinical governance across the medical profession.

Q. You have just used that expression: you saw yourself as having a leadership role.
A. Yes. Not by dint of any particular qualities that I have, but the CMO role, by its position, offers that opportunity to speak to, to meet with and to try to lead and promote on policy issues. I would have seen it as very much a responsibility of the role.
Q. And you would have seen, in Sir Liam Donaldson, a CMO who was indeed exercising that leadership in relationship to clinical governance.
A. Yes, indeed, very much so -- and not just, as I said, nationally, but internationally.
Q. Mr Elliott, when he was asked a number of questions in relation to your role, and when we got to the issue of clinical governance, he regarded you as having a primary role within the department to develop clinical governance; would you accept that?
A. I accept that, but inasmuch as I see clinical governance as an issue not just for doctors but for the wider Health Service, and indeed because clinical governance, and indeed the statutory duty of quality, was something which was imposed across the Health Service, was very much an issue for Health Service managers as well.
THE CHAIRMAN: Yes. In fact, one of the lessons that we're already drawing from the inquiry is that doctors have

an important role in clinical governance, but so also do senior managers and trusts and boards.
A. Yes, indeed.
MS ANYADIKE-DANES: And you were in post as Chief Medical Officer when the Charter for Patients and Clients was published. That was published in March 1992, just to help you.
A. I would have been, yes.
Q. And you'd be aware of that?
A. Yes.
Q. It has been referred to as an aspirational document and probably all charters like that are, really, but what it served to do -- as was explained to us by, I think it was Mr Elliott -- was to highlight the attention that was now going to be focused on the patient. In particular not just on the entitlements of the patient, but also in there too the quality of care, that all of that was now going to be an important focus, and that was clear in 1992. Sorry, I think you were actually Deputy Chief Medical Officer at that time.
A. Yes.
Q. But you would have been aware of a document like that coming out?
A. I would, yes.
Q. And if there was going to be a sort of slight shifting

of emphasis to make it clear that we are concerned to focus on the patient and the patient's perspective in care, you'd be aware of a shift of emphasis like that?
A. Yes, except, chairman, I wouldn't call it a shift of emphasis. I regarded it as a statement of what we were doing. It was always the intention and the aspiration of the Health Service to provide that quality of care. So I regarded it as a statement rather than a shift of emphasis.
Q. And because you've already said that you had meetings with Sir Liam Donaldson, you would be aware of the developments that were happening in the United Kingdom in relation to clinical governance?
A. Aware of what was happening in England? Yes, yes.
Q. Sorry, I should have said England. And you would have been aware then of the importance that was being attributed to clinical governance and its development particularly in terms of the improvement of the quality of care? You'd be aware of that?
A. Yes, indeed.
Q. And you would be aware that part of clinical governance was to give all those involved a better ability to identify what was happening in the hospitals so that lessons could be learnt, improvements could be instituted and all of those measured against certain

standards?
A. Yes, indeed.
Q. And you would know all of that?
A. Yes.
THE CHAIRMAN: If the 1992 charter wasn't a shift in emphasis, was it a reminder to everybody?
A. I think you could call it that because it was not just to say to the public, "This is what we're doing and providing for you", but you're right, chairman, it was also very much a reminder to the service that this is a business we're in.
THE CHAIRMAN: Thank you.
MS ANYADIKE-DANES: And if you were aware of that, presumably you would be aware of publications such as that which came out in January 1996 from the National Health Service, "The promotion of clinical effectiveness: a framework for action". You'd be aware of a document like that?
A. Yes. I can't remember the document, but I would presume I would have been aware of it.
Q. Maybe I should put it in a different way. At the time documents like that came out, you'd be aware of those?
A. At the time, documents like that would have been copied to me.
Q. Yes. And would it be part of your role to distil what

the movement was in England or the rest of the United Kingdom, see the significance, the possible application of it here in Northern Ireland and to engage with the Permanent Secretary in that way?

A. I would have regarded that as my role. Obviously, documents like that would have been copied throughout the department. And as the chairman has already noted, with the departmental board, there was very much a corporate effort to engage on these things.

Q. But insofar as it related to medical matters, you would be advising possibly both the chief executive and the Permanent Secretary about those?

A. I would, I would.

Q. And so would it also have been part of your role to assist in interpreting how that might be applied here in Northern Ireland?

A. Yes.

Q. And the extent that it should be applied in Northern Ireland?

A. Yes.

Q. That's all part of your role?

A. Yes.

Q. What steps were being taken to respond to those initiatives in England and the rest of the United Kingdom here in Northern Ireland?

A. Are you referring to the charter or --

Q. No, no, not the charter, but when, for example, the 1996 "A Framework for action in and through the NHS" came out, which was specifically dealing with the promoting of clinical effectiveness and so forth, what was happening in Northern Ireland in response to that sort of initiative?

A. I'm sorry, I'm trying to think back to 1996.

THE CHAIRMAN: I think there's a sequence. Correct me if this is wrong, but the sequence we've got is that the "Promoting clinical effectiveness" comes in 1996, there's then a White Paper in England in 1997 and then in Northern Ireland we have a consultation paper coming out from our department called "Fit for the future".

A. Yes.

THE CHAIRMAN: Does "Fit for the future" at least in part follow on as a local adaptation of what is emerging in England?

A. It did, chairman, and in fact it also tried to address some of the other issues which were felt to be very pressing in Northern Ireland, such as acute hospital reorganisation, et cetera. But, yes, it would have been a follow-on document from that.

MS ANYADIKE-DANES: Just to help you, "Fit for the future" comes out in April 1998.

A. Yes.

Q. And what role would you have had in putting together a paper like that? As the chairman's told you, it was a consultation paper about the future of the Health and Personal Social Services in Northern Ireland. So many would have regarded that as a seminal document at that time.

A. Yes.

Q. What would have been your role in the formulation of those policies?

A. I would have had a very integral role, working with colleagues across the Civil Service, the Department of Health, and certainly on medical issues and on broader clinical issues. We would have been working together to develop that document.

Q. Maybe you could help us: in terms of clinical governance, was that a development with which you were in favour and would like to see advanced in Northern Ireland?

A. Absolutely, yes.

Q. And in your work and advice to the Permanent Secretary and the chief executive, is that what you're trying to advance, to try and explain the significance of a policy like that and its possible benefits for healthcare? You'd be trying to advocate that, would you?

A. Yes, and probably with not much difficulty because I think everyone would have seen the advantage of moving in that direction.

Q. And just so that we have it from your perspective, when would you have considered that clinical governance as a policy was first instituted in Northern Ireland, irrespective of how well it was actually being implemented? When would you have regarded that?

A. Sorry, is the question when was the policy document signed off and delivered or when did the work towards that policy --

Q. I'm going to come to the work towards it. If you can help me with when you think the department now has a firm and established policy that clinical governance is what we are seeking to establish here in Northern Ireland; what would you give as the date for that?

A. I think it was probably around the seminal document "Best Practice, Best Care". There were other documents before that, for instance "Confidence in the future", which was really relating to the medical aspects of clinical governance. That came out, I think, at the end of 1999, 2000. So there were -- and with "Fit for the future", of course, beginning to signpost where we were going on that. So it was an evolution, a stepping

towards. I think "Best Practice, Best Care" is probably the document that pulled most of those things together.

Q. I think "Best Practice, Best Care" is in 2001; is that correct?

A. Yes.

Q. So from your first appreciation that clinical governance would have benefits for Northern Ireland, you've seen how it's being advanced in England, it's 2001 before the department has an established policy in that regard?

A. And it was a document about, obviously in Northern Ireland, the importance of consenting with the wider public and, indeed, across the Health Service. It was a consultation document, which then led on to implementation.

Q. And in your view, why did it take as long as that to get the policy established, that this is the way forward for Northern Ireland?

A. Prior to devolution, things may have moved slightly faster because usually there was a one-year -- about a one-year gap between policies being implemented in England and then, following consultation and whatever necessary legislation, we would have seen implementation in Northern Ireland by direct rule ministers, probably within a year.

On clinical governance, the intention was there,

everyone wanted this to move as quickly as possible. I think, looking back on the timing of where it was -- because the will was there -- I thought that we would get clinical governance really stamped well on the agenda very quickly because everyone wanted it to happen.

Q. Can I just pause you there? What was your expectation of when you would have --

THE CHAIRMAN: Let the doctor finish the question because I think she's coming to the point that you'd asked her.

I think you were going to explain, doctor, that in clinical governance it took a bit longer and I think you were going to explain why you think that happened.

A. Yes. The timing of it was difficult, chairman, and you will see that -- certainly when we were discussing it at the Central Medical Advisory Committee -- doctors wanted it to happen. Within the department we wanted it to happen. We, at that time, had direct-rule ministers who were waiting and hoping that devolution would happen very quickly. So there were not that many decisions being taken because it was felt, quite rightly, that those big decisions should be taken by our new Assembly.

So we unfortunately were entering into a time when there was a lot of political movement and I think that to my mind that certainly caused some of the impatience

that was being felt across the service that things weren't happening quickly enough, but a recognition from direct-rule ministers that they needed to wait until the Assembly would be properly in place and would take those decisions. So all of that, I think, is explainable, but certainly causing a lot of impatience across the service and thankfully a movement towards things happening, even in the absence of legislation.

THE CHAIRMAN: If I take the legislation as being the 2003 order --

A. Yes.

THE CHAIRMAN: -- and that imposes a statutory duty for quality of care on the trusts. Right?

A. Yes.

THE CHAIRMAN: It does more than that, but what I've been repeatedly told by a series of people is that whether it was a statutory duty of care or not, the duty of care was already widely understood by those in the Health Service as lying with the trusts.

A. Yes.

THE CHAIRMAN: There's an issue about what Mr McKee told the inquiry, but we'll set that aside for the moment because he seems to be something of a lone voice on that.

But that suggests to me that there was no need to wait for the Assembly to pass the 2003 legislation in

order to recognise that there was already a responsibility for the quality of care held by the trusts, held by everybody who works in the Health Service. Right?

A. Mm-hm.

THE CHAIRMAN: You're developing a theme which Mr Gowdy spoke about yesterday. I don't quite understand at the moment what the change from direct rule to home rule, if I call it that, if I'm allowed to call it that, means for the development of some initiative like progressing clinical governance. Because it seems to me that although you have put a date on it of 2001 with "Best Practice, Best Care", it was already perhaps beginning to evolve before that.

A. Yes.

THE CHAIRMAN: What you have done, at Ms Anyadike-Danes' invitation, is to put a date of 2001 on it, but 2001 doesn't come out of the blue, it follows what's beginning to happen before?

A. Yes.

THE CHAIRMAN: But what were the decisions that had to be taken by politicians?

A. The politicians obviously would have had to sign off on the legislation.

THE CHAIRMAN: Yes, but I'm curious about the significance

of the legislation in this context.

A. Okay. And the legislation, in terms of the understanding of clinical governance, and the desire to move towards it were two separate things. I think if you can look back at some of the contracts which the boards were already developing with the trusts -- and indeed I think Mr Frawley may have referred to it in his evidence -- already the service was moving towards that. They were putting in place clinical governance arrangements. I know that in our discussions with medical directors they were saying, "This is important, we see this as critical", and already steps were being taken towards ...

The big problem, I think, and relevant to the inquiry is the need, therefore, to have a sum of money, budget of money, and new money into the service, which would support things like the inspectorial service, RQIA, as it became, and, for me, the big issue about having money for contracts with NPSA and indeed the Care Improvement Authority in England.

So there was money, there was legislation -- new money and legislation. That required decisions by ministers, but on the ground a great deal was actually happening in terms of clinical governance.

And I do believe there's evidence to support that.

If you look back at some of the contract negotiations between the boards and trusts, and indeed some of the things that were already beginning to happen because of documents like "Fit for the future", "Confidence in the future" --

THE CHAIRMAN: And that's, for instance, why Mr Frawley from the Western Board thought it was entirely appropriate that Sperrin Lakeland Trust told the board about Lucy's case in 2000?

A. Yes.

THE CHAIRMAN: So that's pre-dating "Best Practice, Best Care", in 2001, and his analysis of that, I think -- if I summarise it in crude terms -- was that since the Western Board was commissioning or purchasing services from Sperrin Lakeland Trust, it needed reassurance that the trust was capable of providing a service of sufficient quality. That explains the exchanges which took place after Lucy's death between the trust and the board.

A. Yes.

THE CHAIRMAN: If I regard that as some form of embryonic clinical governance, that supports what you just said that there was a great deal already happening on the ground. I'm not sure -- I might quibble a bit about whether there's a great deal happening or whether

there's something happening. But the legislation was needed to give an extra push in some areas like the forming of RQIA, but it wasn't necessarily needed to push on in other areas; would that be fair?

A. I agree, yes.

THE CHAIRMAN: Thank you.

MS ANYADIKE-DANES: Can we go back to how Northern Ireland was characterising what clinical governance was? I'm taking this from a National Audit Office report. This report, I think, was published in September 2003, and the report is titled "Achieving improvements through clinical governance". The useful thing about it is that, in appendix 5 to it, it has a little description of what Northern Ireland is doing, what Scotland is doing and what Wales is doing. So from a comparison point of view, it's quite useful, and maybe we could pull this up, 341-002-177 and put alongside it 178.

Firstly, can I ask you whether you're likely to be aware of a report like this being published by the National Audit Office?

A. I would have been.

Q. And presumably you might have had some input into the section that deals with Northern Ireland or at least be aware of what they're going to say about Northern Ireland?

A. Yes.

Q. Then if we look at it there, firstly it says that:

"Northern Ireland has issued guidance on clinical and social care governance."

And that's governance in the Health and Personal Social Services, and that happened in January 2003, which is the outworking of the consultation "Best Practice, Best Care". So that's a benchmark there, January 2003. You probably recall that was actually the guidance that people should start putting in place structures to achieve this and then in comes the interim guidance on 7 July 2004, which is actually going to define the relevant terminology and what people should be doing about it.

It then goes on to say how Northern Ireland is defining clinical governance. Paragraph 2:

"A framework within which health and personal safety service organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care and treatment. Clinical and social care governance is about organisations taking corporate responsibility for performance and providing the highest possible standard of clinical and social care."

And that's put in quotation marks, so I presume it

comes from a document that would have been supplied to them from Northern Ireland.

So if that is how it was being perceived, it's actually a tool, is it not, for helping to deliver higher standards of -- we're concerned with the healthcare aspect of it; would you accept that?

A. A tool, a framework, a system of delivery, yes.

Q. If that's happening, then back to the point that the chairman was raising with you. There may well be aspects of that that require legislation or statutory support, but if that's the general tenor of what's trying to be achieved, it's difficult to see how some of that, the building blocks for it maybe, might not be being achieved ahead of any legislation; can you see that?

A. I agree, yes.

Q. So part of the issue would be how much was being achieved before legislation was required and whether the pace of the development of those aspects of it was as speedy as it might be?

A. Yes.

Q. You, I think, have indicated to the chairman that the devolution issues had an impact on -- well, one of the impacts they might have had was on being able to get legislation passed; yes?

A. That was one impact.

Q. That was one impact?

A. Yes.

Q. But in terms of the point that you made, and something that Mr Gowdy developed yesterday, that you might be hesitant, if you like, to tie the hands of the incoming ministers by policy that is perhaps not policy that they have developed, this is simply designed to improve healthcare. Was there any real expectation in the department that the improvement of healthcare in this manner is something that would meet resistance?

A. I would absolutely expect there to be no resistance to that.

Q. And in fact, you were already doing that, or at least some trusts were already doing that and you were already addressing special advisory committees and so forth on the benefits of clinical governance?

A. That's correct.

Q. So you didn't require anything from the Assembly to enable you to, in that way, further the development of clinical governance?

A. That's correct, yes.

Q. And in fact, if I just give you some examples just so we're clear about it, you spoke at a paediatric special advisory committee in September 1998 where you were

explaining about clinical governance coming in. In fact, there was a paper titled "Clinical quality and clinical governance", that was presented at that, and that paper was signed by Philip McClements, who's a senior officer in your department; is that right?

A. Yes, he may have been deputy at that time, certainly Principal Medical Officer.

Q. That is his paper advocating the need for clinical governance as a way of ensuring or fostering clinical quality and urging the relevant bodies to commit further to that and particularly through risk management, and that was all what you would have known was happening and, in fact, encouraging?

A. Yes, that was our paper from the CMO's office, from my office, promoting clinical governance across the medical establishment.

Q. Then you get to December 1998 where there's a CEMACH meeting, and once again "Clinical quality, clinical governance" is being discussed, as is "Fit for the future" and "The NHS: modern and dependable", and it's recorded there:

"This area must be progressed quickly and [it specifically says] decisions on the way forward could not be delayed because of the setting up of the new Assembly."

A. And that was the determined view of the medical establishment.

Q. Yes. And you would agree with that?

A. Oh, absolutely.

Q. So all that could be done to further the cause of clinical governance in the interests of the improvement of medical care, that's what should be done, and if we come across things where we need legislative input, then we'll deal with that, but we can carry on all that we can do in the absence of that. Would that not have been the mood, if I can put it that way?

A. That was the mood -- and I also recall it, chairman, as the direction of travel. And as I said, I had clear evidence from Directors of Public Health and indeed in any discussions across the service that there were determined efforts to ensure that the clinical governance frameworks were being put in place.

Q. So if that was the mood, and at that higher level amongst the sort of the Directors of Public Health directors and directors of boards and perhaps even the chief executives, if that was the general tenor of things and that's what you thought you were all working towards, then you would be particularly interested in any impediments to that, reasons why that wasn't happening as speedily as you would have liked?

A. Yes.
Q. Yes. And a place to learn about those sorts of difficulties would be your special advisory committees, meetings of the Directors of Public Health and any reports that were commissioned by the department on specific areas that nonetheless impinged on quality. All of that you would be looking at to see if you could identify any impediments to the development of clinical governance?
A. Yes, and also in my meetings with medical directors and also in the course of my work in visits to hospitals, et cetera.
Q. Exactly. In fact, Mr Gowdy said that he was very much persuaded by the concept of risk management, that was something that had started even before he came into office as Permanent Secretary, and he was looking to you, because you had more direct contact with the senior clinicians, the chief executives and the directors, to advise him if there were difficulties that perhaps could be addressed at the departmental level, and you would accept that that would be part of your role?
A. Yes.
Q. If we then look at the consultants' report that was commissioned by the department in 1998, that was a report that was carried out by Healthcare Risk

Resources International consultants. You're aware of that report?
A. I'm sorry, I'm not. I can't remember that report.
Q. If a report like that had been commissioned -- we can pull up what its terms of reference are. 338-013-001. (Pause). Unfortunately, Dr Campbell, we don't actually have the report, but we have two bits of information. It's a little unsatisfactory. We have this and we have some extracts of its findings, which found their way into an appendix to an NIAO report. So we have those two things.
When this comes up -- 338-013-001. We managed to bring it up yesterday, but there's obviously a hiccup.
THE CHAIRMAN: Just go through it slowly one more time.
MS ANYADIKE-DANES: 338-013-001.
At this stage, I think I can just read out to you what the terms are.
THE CHAIRMAN: Yes.
MS ANYADIKE-DANES: I'm just going to read out the terms of reference, and really it's for the purpose of seeing whether you are likely to have been told about a report that was commissioned of this type. Okay?
What it says is:
"In December 1998, the department commissioned Healthcare Risk Resources International to undertake

a survey of risk management in the HPSS organisations [which were the 19 trusts, the four boards and three agencies]. The terms of reference for the survey were to determine the level of application of risk management methods and the implementation of best risk management practices within these organisations."
Do you think that that is a report you're likely to have known is being commissioned?
A. I might have been, but I'm sorry, chairman, I have no recollection of the report itself.
Q. No, I understand that you've said that. In fact you said that in your witness statement, in fairness to you. What I'm trying to find out is: if the department were commissioning a report to do those sorts of things, are you likely to have been told about it?
A. I might have been. It's more likely to have been taken forward through the Performance Management Directorate.
Q. You mean the Management Executive?
A. Yes, but I cannot say that I didn't know about it or hadn't read it or heard about it. I just cannot recall that document.
Q. Can I ask you this: is that something you would want to know about insofar as it was going to discuss the uptake of appropriate risk management policies in the trusts and boards? Would you want to know about that?

A. Yes.
Q. Because that's something that you might be discussing with them in your meetings?
A. Yes.
Q. Thank you. In any event, that commission produces a report and the report is published in 1999. I'm going to pull up for you the extract of the findings we have of it. If we can go to 338-006-106. (Pause).
I'm just trying to see if I can get it from another source, Mr Chairman. Apologies.
THE CHAIRMAN: What extract is it you're looking for?
MS ANYADIKE-DANES: It's appendix 5 to the NIAO report on compensation for injuries, and that sets out the main findings of the 1999 report.
THE CHAIRMAN: I think you have it at 127-004-095 and 096.
MS ANYADIKE-DANES: Yes, but I don't think that 127 pagination is live, unfortunately. Mr Chairman, there seems to be a bit of an issue with some of this pagination. If we could perhaps --
THE CHAIRMAN: Doctor, can I ask you: were you able to follow or see the evidence that was given over the last few days by people like Mr Gowdy and Mr Elliott?
A. I was away over the last --
THE CHAIRMAN: You haven't? Okay.
A. I saw some of it late last night.

MS ANYADIKE-DANES: It might take us just five minutes, Mr Chairman. It might be faster in that way.
THE CHAIRMAN: This is unfortunate, doctor. Let's take a few minutes and see if we can get our documentation sorted out because it makes everything flow more smoothly after that.
(11.08 am)
(A short break)
(11.20 am)
THE CHAIRMAN: Let's see how we go now.
MS ANYADIKE-DANES: Just to orientate you, Dr Campbell, this is appendix 5 to an NIAO report titled "Compensation payments for clinical negligence", and that report was issued by the Assembly on 5 July 2002. Okay?
Would you see an NIAO report that was looking at medical issues, in this case for compensation for payments for clinical negligence? Is that a report that would have come to the department that you would have seen?
A. I'm terribly sorry, am I looking at the right document, "A survey of risk management"?
Q. Yes, this is appendix 5 to the NIAO report. My first question to you was: the NIAO report was about compensation payments for clinical negligence, but in the course of that report they were looking at the

ways to better manage care, improve the quality of healthcare so that you could reduce the burden on the department for paying out for medical negligence claims.
A. Yes.
Q. If a report is issued like that by the NIAO and it's a report to which the Permanent Secretary has to go to the Assembly to speak to the Public Accounts Committee, are you likely to have had that report brought to your attention?
A. I would have.
Q. Yes, you would have. In which case, although you may not have seen the original report, and we'll come to that in a minute, you would have seen this report, which had the original report as part of its appendices?
A. I would have.
Q. Yes. So then if we look at some of the concerns that are expressed in the consultants' 1999 report. You can see the first one is a concern in relation to risk management. What they say there, just looking at issue 1, Dr Campbell, is:
"It appears that greater efforts need to be made in order to ensure that the strategy [this is the risk management strategy] is endorsed fully by the board of the trust concerned and that all managers, clinicians and other professionals are fully aware of its

contents."
Presumably that's something that you would have wanted to happen?
A. Yes.
Q. And so here is a concern being flagged up that more efforts need to be made, and that would be relevant for you to know that?
A. Yes.
Q. Then if we go to the next page, you see there "incident reporting", under issue 3. They talk about the fact that there's quite a good level of reporting when it comes to slips, trips and falls, but nonetheless -- and it's the penultimate sentence:
"The major deficiency relates to the very limited and therefore probably significant under-reporting of clinical incidents and near misses. A major effort is needed in almost all trusts to improve in this area."
That would have been an important thing for you to know, wasn't it?
A. It was important to know. In fact, I did know that because in our document, "Confidence in the Future", at the end of 1999/2000, a report chaired by Ian Carson, we recognised the deficit in not having incident reporting.
Q. Yes. If I pause there, that deficit in incident reporting, is that something that was brought to the

attention of the Permanent Secretary?
A. The report "Confidence in the Future" was widely distributed across the department and indeed to the wider service.
Q. So he would have known that you'd had a report done and flagged up a concern, which you shared with Dr Carson, on under-reporting in terms of clinical incidents?
A. Yes.
THE CHAIRMAN: So in fact, he's getting it from two sources: he's getting it from the Audit Office and he's getting it internally?
A. Yes.
MS ANYADIKE-DANES: And to the extent that you wanted to address that, then that is the sort of thing that you would have discussions about, about what can be done to improve incident reporting?
A. Yes.
Q. Is that a discussion that you'd have had both with the permanent secretary and the chief executive of the Management Executive?
A. It would have been in the context of moving the quality agenda forward and certainly in "Confidence in the Future" there were quite a number of recommendations in that and this would have been part of that.
Q. Yes, if we focus just on this bit, Dr Campbell. What

I was putting to you is: would that have not only come to the Permanent Secretary's attention, your concerns about that and Dr Carson's concerns about that, but would it not also have come to the chief executive because part of that role is monitoring what's happening in the boards and trusts?

A. Yes, indeed.

Q. And if it came to their attention, would there have been some discussion about what can be done to improve incident reporting?

A. There would have been, and I believe from memory that there was, because at that time the NPSA was being established in England and we were having discussions within the department about what role we might play within NPSA and how we might take that forward.

Q. And whilst that's going on at a sort of policy level within the department, presumably you, when you meet the relevant executives and clinicians in your special advisory committee meetings and CEMACH meetings, meetings with the Directors of Public Health, that's something that you would be taking up there, would you not?

A. Yes.

Q. Then if one looks at issue 4, "Patient records":

"A low level of compliance with this amongst the

majority of trusts. There is no doubt that inadequately prepared patient records contribute to unsafe clinical care ... there is a real need for most trusts to develop an explicit policy document incorporating all the elements shown and for there to be a system in place for the routine audit of compliance with the policy."

Were you aware of that?

A. Yes.

Q. Is that something that you were taking up?

A. The quality of patient records I think has, to be honest, always been an issue in the Health Service, and efforts were made, were being made, and resources made available at trust level to try to increase the importance of patient records within institutions. But it's always been a difficult area and I would have recognised this as a problem.

Q. Is it something that you would have wanted to see audits done on the accuracy and appropriateness of the clinical records?

A. Yes.

Q. And that's something that can be measured, that's the sort of thing that the Management Executive can ask for, "Where are we in terms of the auditing of the accuracy of medical notes and records"?

A. One could, yes.

Q. If we look more specifically at "Clinical audit", it refers to there being:

"... very few examples of multidisciplinary clinical audit."

Which is what's being required, as opposed to just specific target areas for audit, and that that is being used as a robust tool for risk reduction and risk control. Were you aware of that?

A. Yes, indeed, and this was obviously a report coming in February 1999, obviously based on work before that.

Q. Yes.

A. And it's important for the chairman to know that in recognising the importance of multidisciplinary clinical audit, that quite an investment was made by the department to encourage multidisciplinary audit, and in fact to fund and resource the Regional Multi-professional Advisory Group. And I think, from probably around 1999 onwards, there was significant work done in terms of regional multi-professional audit. So I can recognise this as being a correct report of what activity levels would have been like prior to that time.

Q. Yes. Because, as you say, a report like this is essentially backward looking in terms of it's looking at a period of time and trying to give you some conclusions of that, so it's not having a snapshot of what it was in

1999 or 1998.

A. Yes.

Q. And you would have been CMO from 1995 and, prior to that, deputy CMO. So during this time that they are looking at, you would have been in post?

A. Yes.

Q. And this is part of how you're able to say, "I was aware of some of these difficulties"?

A. Yes, indeed. Clinical audit -- medical audit, as it began -- was, I think, poorly understood to begin with and not that well resourced in the first year or so in which it was initiated. But certainly in terms of the regional efforts made to encourage and promote audit, investment was made, and I actually regard that investment made in regional audit actually began to show dividends, probably after this report. But certainly, from the year 2000 onwards, I think you can still find on the website -- at least I hope you can -- some of the significant work that was done on multi-professional audit.

Q. Yes. And if you were looking back at when you do learn about the deaths of the children that are the subject of this inquiry, you could see if you're recognising the difficulties in relation to accuracy of patient records and that's looking to a time before 1998/1999. You

would have seen that that was an issue in Adam's case in certain respects?
A. Yes.
Q. And his case was in 1995. It was an issue in Claire's case in 1996.
A. Yes.
Q. So that all fits with the criticism that's being made here?
A. It does.
Q. But it was also an issue in Raychel's case in 2001, which is a period after which you were talking about initiatives having been taken to address it. That doesn't mean that there can't be one example of a deficiency.
A. Yes.
Q. But if you had been looking at it in that way, would it have concerned you that there were able to be significant criticisms of the record keeping in Raychel in 2001, several years after a report of this nature?
A. Yes. I think these quality issues are important and you cannot take your eye off the ball on them because new staff coming along, excessive pressures on the system, and yet these are important and critical quality issues.
THE CHAIRMAN: It actually might be new staff coming along who learn the lessons better and it's the old staff who

have got into slightly sloppy habits over the years who are the ones who are harder to turn around?
A. Yes, indeed.
MS ANYADIKE-DANES: So when this report is published, I asked Mr Gowdy about it, and he said that it was a report that was discussed with the professionals as to what should happen as a result of it, and that that was clearly discussed, but you don't remember that?
A. This particular report that's in the appendix or do you mean the --
Q. Yes, the report from the consultants, of which this is just some edited highlights or lowlights of it.
A. Yes. As I said, I can't remember the report, but I certainly would recognise all of these issues as being important quality components that we would have had to address and would recognise that there were deficiencies in and recognise the need for continuing attention to them and resources made to improve them.
The Health Service, because it is so complex, I think lessons need to be learnt time and time again. There isn't a time when a lesson is learnt and you move on. These are all critical issues and you can see reports time and again, which raise these. So I think in terms of health services management, these critical quality issues do have to be top of the agenda and

people need to keep returning to them.
Q. Yes. When you see that the first issue was the concerns in relation to the introduction of risk management, presumably you would be aware that the National Health Service had issued a risk management manual for the use in its Health Service, and had done that in 1994.
A. I might not have been aware of that. That kind of document to the NHS in England might not have come to me. I would have been more regularly supplied with documents that would have come from the CMO's office in London.
Q. Yes, but if, as the Permanent Secretary says, risk management was an important thing that he was seeking to emphasise, he said that he went over to London, he had discussions about it and he was persuaded of its benefits and he brought it back and that's what he wanted to do, so one of the things I presume would be happening is that you would be assisting him in that.
A. Yes.
Q. Is not the obvious thing to do to say "Let's see what they're doing in the rest of the United Kingdom about it"?
A. Yes.
Q. And that, without very much researching, would have thrown up the manual that the Health Service issued on

risk management.
A. Yes.
Q. And if that had happened and you'd be seeing that, would you not have been able to issue some guidance about risk management without too much refinement of an established manual that's already in use in the rest of the United Kingdom?
THE CHAIRMAN: When you say "you", do you mean Dr Campbell or the Management Executive?
MS ANYADIKE-DANES: I mean Dr Campbell, perhaps to recommend -- it would be in her area as a medical matter. You could recommend that to either the Management Executive or the Permanent Secretary if that was necessary.
A. Are you asking -- sorry?
Q. Whether you could have done that.
A. I could have, yes.
Q. And even if you didn't want to take it to those levels, in your interactions with the administrators and the clinicians in your own meetings, once you recognise that there is a difficulty, and you said you did with risk management, could you not have recommended that yourself?
A. Yes, I could have.
Q. There are things to help you out there, they're doing

this in the rest of the United Kingdom.
A. Yes.
Q. Did you have any thoughts about doing something like that?
A. I'm sorry, in terms?
Q. Did you think you might do something like that?
A. I do not recall having access to the document that you're talking about from the NHS at the time. Certainly on specific issues that you're raising like patient records, clinical audits, complaints, et cetera, I would have quite often discussed those issues with my colleagues across the department.
Q. Yes. This survey that I pulled up before to show you what the terms of reference were, paragraph 11 on it makes it clear that the individual results were actually sent by the department to the relevant organisations, the trusts, the boards, as the case may be. So they could see what the results in relation to their own organisation was and that would have formed a useful basis for you to engage with them, their senior representatives, when you met them in meetings, would it not, or even when you were going to the trusts, as you say you visited?
A. All of those things are true. Had I at that time had the document, I may have done, I might have those

discussions, but I really cannot recall specifically discussing this document.
Q. Yes. Then if we move on from 1998/1999, Deloittes were engaged to carry out a baseline assessment and assist in formulating an action plan for clinical and social care governance. You are aware of that?
A. Yes.
Q. And they reported in September 2003.
A. Yes.
Q. Are you aware of that too?
A. Yes.
Q. Whatever work had been done before to establish where the trusts were in relation to -- let's call it clinical governance type issues, even if you don't want to call it the clinical governance policy itself, were you hoping that this report that would come out in 2003 would be able to show what improvements had been made?
A. I would have been hoping that because I had been aware, as I said earlier, chairman, of efforts being made at trust level to implement the frameworks around clinical governance. So I would have expected to have seen improvement.
Q. Yes, because that's what you'd be discussing with their representatives in the meetings?
A. Yes.

Q. So if you're discussing those sorts of issues, which you were already aware of before the report comes out in 1999 --
THE CHAIRMAN: I've got the point.
MS ANYADIKE-DANES: Then when you see the report, the report itself was quite critical?
A. Yes.
Q. It's a very lengthy report, but one aspect that we highlighted was the comments it makes in relation to the Eastern Health and Social Services Board, and we highlight that for obvious reasons because that's the board within which the Royal Trust is located. Just so that you have it, what it says is:
"The assessment and action plan was generally poor based on most performance criteria. Significant weaknesses included no risk management policy ..."
Well, that was a thing that was being flagged up as an issue in the 1999 report and which you already knew was a concern, so that, for the Eastern Health and Social Services Board, would have been a problem of some many years' standing.
A. Yes, sorry, I haven't got the report here on the screen. Is this the --
Q. Let me see if I can pull this up for you. I'm hesitant to say that because we're having these technical

difficulties, but let me try. It's witness statement 075/1, page 87.
So you can see there the comment that's made about the Eastern Health and Social Services Board; do you have that in front of you?
A. I do.
Q. The point that I was making there was in relation to -- in fact, it goes down through a number of different points, which we have to pick up under the various headings, which I think might be quite difficult to take you through. But the first one was:
"There was no risk management policy, no complaint/customer care training, no communication policy, no workforce plan, no system for promoting best practice and no clinical governance policy."
A. Yes, indeed.
Q. So the point that I was putting to you is that the absence of a risk management policy, which is something that you had been concerned about from prior to the 1999 report, and even now, as we stand at 2003, they don't have one, was that not of some serious concern to you?
A. I think the department took this report quite seriously and recognised that there was a great deal of work that did need to be done. Yes, indeed.
Q. But you were having the direct contact with the people

who would be in charge of formulating and establishing and implementing such a policy in the board and in the trusts. So were you not saying, "What's been happening? I've been advocating the need for you to do this, we all agreed on the benefits of it, why have you not been able to institute it?"

A. Yes, I would have been having direct contact, as Chief Medical Officer, with the Directors of Public Health, and, yes, their responsibility in terms of public health and indeed clinical services would have meant that they would have had an interest and an influence in trying to push these things forward.

Q. And no system for promoting best practice, more to the point, even though your consultation document, "Best Practice, Best Care", has gone out in 2001?

A. Yes.

Q. Then Deloittes provided another report in March 2004; are you aware of that?

A. I would have been aware of that.

Q. Yes. And the results that are included in that report are also concerning; is that not the case?

A. Yes.

Q. But in all this period of time, the department doesn't have any formal system for being notified of the extreme end of the consequences of some of these deficiencies,

which is deaths in hospitals; isn't that correct?

A. That's correct. We had no formal reporting mechanism in place.

Q. So all these systems and tools, mechanisms, are designed to improve care and also designed so that you know where you are in terms of how good the care is that's being provided; isn't that right?

A. That's right.

Q. Yes, but nonetheless, even recognising the significance of all of that, the department itself had not yet required any formal notification system of deaths in hospital?

A. That's correct, there was no formal mechanism.

THE CHAIRMAN: Was there even an informal mechanism?

A. There was, chairman.

THE CHAIRMAN: I wonder, could you tell me about it because I'm afraid it's passed me by at the moment?

A. Okay. There was an informal mechanism, I think Mr Frawley referred -- he referred to it as a process, and to me I felt it was a fairly well trampled pathway in that the Directors of Public Health quite often brought issues to me of concern, not just of serious clinical incidents which had occurred, but sometimes issues about which they were concerned where they felt that things might go wrong.

They didn't, of course, bring all those issues that they were learning to me, but they did bring to me problems which they felt had a regional significance or where they felt that they could only be met by something happening at regional level. I mean, examples of that would have been, for instance, the -- I'm trying to think of some examples. A good one would have been an ambulance call to a patient with an acute stroke, and obviously what you would want would be the ambulance taking the patient to the best hospital to deal with those, whereas what was happening was that ambulances were required to take the patient to the nearest hospital. So that being brought to my attention, then we dealt with that.

Another issue I can recall -- I don't know how many examples you want.

THE CHAIRMAN: If you give me one more example and then I'll tell you what my concern is about the system.

A. All right. I would recognise those concerns. But another issue would have been maternity services in one of our hospitals, which was poorly provided for at that time by paediatric care. There was concern about things that had gone wrong or might go wrong, and that was brought to me and eventually, actually quite quickly, that hospital stopped providing maternity services.

So on big issues where it was felt that regional or departmental or indeed that ministerial decisions needed to be made, or advice gone out to the Health Service, the Directors of Public Health would have brought those issues to me.

THE CHAIRMAN: Okay. Do I understand from that that the reason why Raychel's death may have been reported to you was because it was suggested that some work might have to be done at regional level because there was a difference in practice between what the Royal was doing about Solution No. 18 and what was being done pretty broadly elsewhere?

A. Yes, indeed.

THE CHAIRMAN: Okay. So that might explain why Raychel comes to you.

A. Yes.

THE CHAIRMAN: But in terms of Adam dying through what seems to me to be an avoidable death, in terms of Claire dying entirely unexpectedly and in terms of Lucy dying, again avoidably, again unexpectedly, none of those deaths come to you?

A. Yes.

THE CHAIRMAN: Is that because your test for deaths being reported to you is if the area boards' directors of health believe that there is an issue of regional

significance or something which requires work to be done at a regional level?
A. Yes. If they had been notified or told of those deaths at local level, then if there was a regional significance -- and I think, you know, on examination on all of those, there would have been, I think, recognisable regional issues.
THE CHAIRMAN: But I think the problem is, doctor, that two of those deaths, namely Adam's and Claire's, didn't even make it from the hospital to the board, to the Eastern Board.
A. Yes.
THE CHAIRMAN: Lucy's death did make it to the Director of Public Health in the Western Board, Dr McConnell, but it didn't make it beyond Dr McConnell, despite Dr McConnell being told and despite Sperrin Lakeland knowing that there was an issue, not just about Lucy's treatment, but also about other issues which must have caused concern about the standard of paediatric care in Sperrin Lakeland.
A. Yes.
THE CHAIRMAN: So if the Directors of Public Health aren't told in the first place, they can't tell you?
A. No.
THE CHAIRMAN: Okay. So let's go back one step. Let's go

back to the trusts. In what circumstances would you, at that time, have expected, under what we're loosely calling an informal mechanism, to have been advised by a trust of an unexpected and avoidable death?
A. I think, clearly, in Adam's case where guidelines were drawn up or a statement made, I'm really disappointed that that wasn't brought to me because that, I think, quite clearly, had significant issues across the medical profession in Northern Ireland, and I would have hoped they might have felt that I could have helped in promoting that message, disseminating it.
THE CHAIRMAN: So that should have come to you either through the Director of Public Health for the Eastern Board, who should have been alerted to it by the Royal --
A. Yes.
THE CHAIRMAN: -- or, alternatively, should it also have come to you directly from the Royal?
A. I would have expected probably both.
THE CHAIRMAN: So in fact, while you might have expected two reports to you about Adam's death, you received none?
A. That's correct.
THE CHAIRMAN: Let's turn to Claire. In her case, Claire's basically a healthy child.
A. Yes.

THE CHAIRMAN: She goes in, she doesn't even have an operation, and she's dead within 48 hours.
A. Yes.
THE CHAIRMAN: First of all, do you think that Claire's death should have been reported to you?
A. I think that, immediately after Claire's death, the department should have been informed because I think ministers would have wanted to know that. I would have liked to have been informed had it been felt -- and at whatever stage it might have been concluded that there were regional, medical or clinical issues from which lessons could be learned.
THE CHAIRMAN: When you say the department should have been informed because the minister would want to know, what was it that the minister would want to know about Claire's death?
A. Well, I think ministers need to know when these things happen because of their responsibilities in terms of care.
THE CHAIRMAN: So it's not just because they might get some bad publicity or the service might get some bad publicity and the minister is the head of the service, so the publicly accountable politician? So it's not just because of that, it's because the minister needs to know?

A. I believe ministers need to know and it's not just about publicity.
THE CHAIRMAN: Okay. So the minister needs to know; is an appropriate route to the minister through you?
A. It could be through me or it could have been through the Permanent Secretary. I know that looks as if, well, who do you ring or who do you call? And certainly, for chief executives, their first port of call would have been to the Permanent Secretary, that was quite clear. And I would have heard, usually through the Directors of Public Health, because they were quite closely associated with this service, which was within their board area and there would have been a close presence there and I would have expected medical directors to let them know or indeed to let me know directly.
THE CHAIRMAN: Okay. You have given me two illustrations of Directors of Health bringing issues to you, one about the ambulance service and one about a maternity service which turned out not to be good enough, and therefore that unit had to be closed; okay?
A. Yes.
THE CHAIRMAN: I don't want you to name a name, but during your time as CMO, can you remember being told about the deaths of any children in hospitals here, apart from the ones with which this inquiry is concerned? I'm sorry,

this sounds a bit callous and I don't mean it to be. I'm not talking about children who have died of cancer, cystic fibrosis, or things where, unfortunately, nature takes a course. But can you remember any circumstances in which the death of a child was reported to you in your time as CMO?

A. In terms of an adverse clinical incident? Apart from Raychel, no.

THE CHAIRMAN: But does that not show, doctor, that whatever the mechanism was, it just didn't function at all? Because I appreciate I'm seeing the service at its worst, unfortunately, in the context of this inquiry, but it can't possibly be that there weren't adverse incidents -- serious adverse incidents as they are now called -- in terms either of death or in terms of near misses during all your years as CMO.

A. There was one which involved the ambulance service. There was one which -- and the issue was in terms of access to paediatric intensive care. There would have been -- I can't think of others at the moment, sorry, chairman.

THE CHAIRMAN: If I --

A. Having said that -- sorry, I'm interrupting you.

THE CHAIRMAN: Let me give you this opportunity: I'm not sure on the basis of the evidence I've heard this week

how I can avoid concluding in my report that there wasn't actually a mechanism.

A. I agree. There were informal mechanisms, but I absolutely agree that those were found to be totally inadequate and recognised by myself as such in 1999. Having said that, whilst you need formal reporting mechanisms, I think that certainly in the evidence that you read to date about any reporting mechanisms, they are found to have their faults. So as well as that, you need to have a very good intelligence service. I don't say that lightly. But you need to back up any reporting service with, firstly, an acknowledgment that they are formal and perhaps mandatory, but we might come back to that, but also that you need to have people on the ground who recognise when things go wrong or when things might go wrong, that there are benefits to reporting them and to where they should be reported. And I wouldn't for one moment ever begin to defend the system that we had in place.

THE CHAIRMAN: I think it must be clear to the families and everybody else that the failings in the period that I am investigating are now effectively acknowledged by the department through you and others, and I thank you for your directness about that.

The concern is, of course, I have to tell you,

doctor, that it wasn't just an accident that these deaths didn't reach you. The concern is whether these decisions were taken deliberately not to report the most serious of these deaths. And that particularly applies -- I say it particularly applies. I mean that in Adam's case there was an inquest and there was a statement, and it seemed to me when I heard the evidence in Adam's case, and you've really confirmed it now, that the fact that that didn't go beyond a small unit in the Royal is hard to understand on any innocent interpretation of events. But what happened in Claire's case in that her death is wrongly certified and the coroner isn't contacted, the Director of Public Health isn't contacted and you're not contacted, Mr and Mrs Roberts must be sitting here today thinking "That's not an accident". And, let me put it in their terms, they must think that's a cover-up.

A. Yes.

THE CHAIRMAN: Given what I've been told by people as prominent as Dr Carson about doctors not acknowledging their mistakes, why shouldn't I believe that that was a cover-up?

A. I can understand how the parents might feel about that and I can understand that that impression would be left. I certainly would never want to condone a cover-up,

Mr Chairman. It's certainly not something that we should be proud of as a service, and certainly the message that we've been trying to promote -- and it has been promoted by leadership across the medical fraternity and also across the NHS -- is that there does need to be openness, there does need to be a candour, there needs to be a commitment to learning and that efforts to do that have to continue, have to be reinforced, and the way it was in the past just was very bad and not good enough.

THE CHAIRMAN: I'm going to allow Ms Anyadike-Danes back in in a minute, but one of the other aggravating features, I have to say to you, about the inquiry is that we had an important and difficult day here a couple of weeks ago when a series of concessions was made, a series of admissions were made by counsel on behalf of the trusts.

A. Mm-hm.

THE CHAIRMAN: But it's hard for me to believe that those concessions would not have been made had there not been an Inquiry.

A. Okay.

THE CHAIRMAN: There won't typically be an inquiry. The Department of Health isn't going to set up an inquiry on a regular basis. So in the vast majority of cases, if families and patients are to get acknowledgments of

things that have gone wrong and admissions and apologies, how are they going to get that --

A. Mm-hm.

THE CHAIRMAN: -- because they can't depend on inquiries?

A. No. And I would be hopeful that the measures that have been taken are being taken and that much of what is being said now about the need for openness and candour will impact throughout the system. I think the importance of learning -- I think the incredible importance of helping families to come to terms with what has happened and to have trust that what they're being told is the whole truth. There is nothing more important than that.

THE CHAIRMAN: Okay, thank you very much.

MR QUINN: Mr Chairman, if I may just add one point here? I'm sure my learned friend will come on to this issue, but may I remind the inquiry at this stage that even when Claire's mother and father were investigating the death of their daughter in 2004 and had meetings at the Royal Victoria Hospital and Professor Young was brought on board to investigate and to report, there was still no incident report, there still was no report, because Dr Campbell was still in service in 2006?

THE CHAIRMAN: I take that point, Mr Quinn. I think that the position which was taken by Dr McBride, who was then

the medical director, was that Mr and Mrs Roberts wanted the inquiry to take on the investigation of Claire's death. Let me put it in this way: Mr and Mrs Roberts believed that they had never been told honestly and openly what had happened to Claire.

MR QUINN: Exactly.

THE CHAIRMAN: So, from 1996 to 2004, they're in the dark. In 2004, they see the documentary, they go to the hospital and they're told, in effect for the first time, "This looks like a hyponatraemia-related death". It's referred to the coroner and they make contact with the inquiry. That is due to them that that happened. One of the issues I will have to reflect on in Claire's case is Dr McBride's evidence which is, when he was asked about this, why he didn't do an investigation. His explanation was that the inquiry had been set up, nobody ever expected in 2004 or early 2005 that I'd be sitting here in November 2013. Mr and Mrs Roberts wanted the inquiry to deal with Claire's death.

MR QUINN: They did.

THE CHAIRMAN: It seems to me there's at least some basis for that explanation and I will take submissions in the near future about how complete or otherwise you think it is. If I can put it in this general way: I'm rather less concerned about the trust's response in 2004/2005

than I am about the significantly worse trust position in 1996.

MR QUINN: Mr and Mrs Roberts are concerned that the Chief Medical Officer for Northern Ireland wasn't aware of Claire's death until after she retired, according to her statements.

THE CHAIRMAN: Yes. I understand that.

MR QUINN: That's the point.

THE CHAIRMAN: I've got that, thank you.

Mr Hunter, did you want to say something?

MR HUNTER: In relations to the questions you were asking Dr Campbell about the statement made by the Royal after Adam's inquest and Dr Campbell expressed her view that she was disappointed by that and that she was going on to say that, I think, maybe if she had known that she could perhaps have helped in the dissemination of information about that. In her statement for the inquiry, she says that that one of the things that she would have done -- she would have thought that would have been a matter that could have been taken up with the special advisory committees on anaesthetics and paediatrics, and I'm wondering would there have been any other steps that she would have taken at the time, had she known? For example, would she have included it in her CMO's update or what else could she have done to

help disseminate the information at the time, had she known?

Because, of course, if the lessons and the matter had been disseminated at the time, after Adam's inquest in 1996, and if the lessons had been picked up then, perhaps none of the other children might have --

THE CHAIRMAN: Claire only came in a few months later, didn't she?

MR HUNTER: That's right, sir.

THE CHAIRMAN: Can you develop that single point? I should say that Mr Hunter represents Adam's mother. You have indicated a few minutes ago that if you'd known about the statement that was made to the coroner that you might have helped spread that rather further than the paediatric anaesthetists in the Royal.

A. Yes.

THE CHAIRMAN: And Mr Hunter is asking how might that have been done.

A. Mr Hunter is correct, there would have been a direct route through the SACs, though that would only have reached a small number, so certainly the CMO update might have been another way. Although I often worried how often things that were sent out from me or the department -- how often doctors actually had the time to read them.

The other way of doing it would have been through the local college representatives because I think that guidelines can be promulgated quite well through local college representatives.

THE CHAIRMAN: So the Royal College on Paediatrics and Child Health?

A. Yes, and the anaesthetists with the association and the college.

THE CHAIRMAN: What about nurses?

A. Yes.

THE CHAIRMAN: Maybe not so much in Adam's case, but generally.

A. Generally, now, what we would have done latterly -- and certainly I know now -- is a much more multidisciplinary approach, recognising that clinical care is about the multidisciplinary team. So you're absolutely correct, chairman.

THE CHAIRMAN: Okay. Ms Anyadike-Danes, taking account of what Dr Campbell has just said in response to my issues, can you pick up your questioning again?

MS ANYADIKE-DANES: Yes, I can, thank you very much.

A. I'm sorry, Ms Anyadike-Danes. I sometimes can't hear very well.

Q. Can you hear me better now?

A. I can, thank you.

Q. Very good.

A. It's my fault.

Q. No, no. One of the things that you mentioned to the chairman when you were answering him was a recognition of a culture, perhaps a certain defensiveness, that perhaps existed at the time, and that was something that you, not just you personally, but the department was trying to address in the sense of openness and speedier recognition of, when things go wrong, to use those as a learning point. You knew at the time that we're talking about, which is at least for these first few children, Adam and Claire, you knew that culture existed?

A. Mm-hm.

Q. Not just you, but the whole department knew that there was a culture like that?

A. Yes.

Q. And that there was a reluctance for the medical fraternity to publicise its difficulties, particularly when they end up in the death of a child; you would know that?

A. There might be reluctance --

Q. Yes.

A. -- and that is not everyone.

Q. No, no. But you knew that that was so, and that's

something that the whole department has sought to address as time has gone on?

A. Yes, indeed, and was recognised by the General Medical Council, that need to be open and to ensure that issues were --

Q. You also said in one of your answers to the chairman that you absolutely agreed that this informal or non-system of reporting was totally inadequate, in your words. For the sake of reference, it's at page 62 of the [draft] transcript, starting at line 8:

"Totally inadequate and recognised by myself as such in 1999."

A. Yes, indeed.

Q. So you knew, if you hadn't appreciated it before, that this way of you and others in the department learning that there were deaths in hospital was totally inadequate?

A. Yes. What I would do now, today, writing that, is take out the word "totally", because in some instances it worked. It was certainly inadequate, it certainly was not complete or comprehensive.

Q. Yes.

A. On some issues it did work and actions were taken.

Q. I'm actually talking about deaths in hospital at the moment.

A. Yes, and I would take out the word "totally".

Q. That's just what you said earlier, okay.

A. It is.

Q. All right. But what I want to ask you about that is: nonetheless the way you had of learning was that, first of all, the death had to come to the attention of somebody senior in the hospital. That person had to appreciate that that was the kind of death that somebody in the department, either you or the Permanent Secretary, wanted to hear about, and either report it directly to you or the Permanent Secretary or report it to the board, and then the person on the board had to recognise that that was a death that the department wanted to learn about and report it to either you or the Permanent Secretary, and all that was happening without any guidelines as to actually what were the circumstances in which you expected to receive a report, because Mr Gowdy very frankly said yesterday that there were no guidelines about that, there were discussions and so forth, but at no stage was anything explicit said, "These are the sorts of deaths that we really want to hear about and, if they happen, we want you to be telling the CMO or we want you to be telling me, the Permanent Secretary".

So it's not just that it's inadequate or even, some

might think, totally inadequate, but you recognised that the way of doing it very much depended on people recognising that this was something that should be done and taking that step, so it was like a self-referral, essentially --

A. Yes.

Q. -- and a self-referral from organisations within whom you've recognised there may not always be the most open culture about acknowledging when things have gone wrong.

A. Mm-hm.

Q. Not you personally, but in advising the department and then the department collectively, how could you have allowed something like that to carry on until July 2004 when the circumstances of the sorts of things that you want to have reported are set out and the fact that the department wants to have them reported is required? How can that have gone on for that long?

A. I think no one can excuse the fact that we -- I recognised it in 1999, in our "Confidence in the Future" document, that it was recognised in NIAO reports and that there was a UK-wide recognition of the need for reporting. So I'm not going to defend the fact that it took until 2004 to put in place or to begin to put in place a proper system. At the time, I have to say that I was hopeful that with the National Patient Safety

Agency being established in England that that would help to guide us and in fact that we might be able to use some of their learning experience to enable us to put in a proper system faster. But I can't defend the fact that it took until 2004 to put a proper system in place.

Q. Yes, in a way what I'm more asking you is why it took that long. Let me help you with something --

THE CHAIRMAN: Ms Anyadike-Danes, sorry, the witness has just accepted that she can't defend the fact that this didn't happen. So I'm taking that as a major acknowledgment of failing on behalf of the department. So I think we can take it on that and move on.

MS ANYADIKE-DANES: I understand. In a way, Mr Chairman, I was simply seeing whether, given this section is about the learning, if one identifies, with the help of those involved in it, why it happened, it might give some pointers as to what might need to change or see evidence of change to ensure that that couldn't happen again. So in a way, that's why I'm asking you if you can help to identify why, recognising the deficiencies in that, and also the likely consequences of it, which is that there may be children dying that the department doesn't know about, why or how it came to be that it took so long to have something go out as an instruction that went out for the National Health Service in England in May of

1995. Why did it take that long?

A. I'm not for a moment going to defend why it took so long or to put in place any excuses as to why that happened.

Q. Thank you.

THE CHAIRMAN: Were you overly optimistic about the willingness of doctors to face up to their mistakes?

A. I think that when the GMC came out very clearly and recognised the need for nurses and doctors to watch not just what they were doing, but how colleagues were performing, I think there was a sea change in the profession's recognition of its responsibilities. I also think, chairman, that with the medical director post being put in place and being resourced properly and given the authority that it needed within the trusts, I think that that also began a sea change in what was happening.

Now, all of these things happened slowly. I think, as you've said earlier, sometimes these lessons are learnt more easily when young people come through and is it harder to make the older generation recognise ... In some ways, I saw an impetus, a movement within the profession that was towards greater openness.

THE CHAIRMAN: Thank you.

MS ANYADIKE-DANES: Firstly, some of the answers you've given have enabled me to move on and not ask you some of

the detail because you've acknowledged certain things, but there are two particular points I would like to pick up because others have commented on them and in some way they've commented on them by reference to you, so in fairness I want to give you an opportunity to respond.

The first is this: I had taken Mr Gowdy to a report that was done of a comparative study in relation to death certification in Northern Ireland to see how accurate or, for that matter, inaccurate it was. If we pull up the first two pages, I think that's sufficient for what I put to Mr Gowdy. It's 338-012-001 and the following page, 002.

This was a comparative study that was undertaken by Alison Armour, who was in the State Pathology Department, and also Hoseni Bharucha, who is in the pathology department at the Royal Hospital. They were looking to see the incidence of inaccuracy in death certification, and if we just stick with that summary there almost about halfway down in the middle of the line it says "The commonest inaccuracies"; do you see that?

A. Yes.

Q. "The commonest inaccuracies in death certification occur in the areas of poor terminology, sequence errors and unqualified mode."

Then they go on to give, by way of a percentage, the level of inaccuracies that have been found. While they do that, they point out that:

"Four per cent of the inaccuracies were serious enough to warrant referral by the registrar of deaths to the coroner."

And as you know, there were two cases that subsequently came to the coroner that didn't start off there in the children that the inquiry is concerned about.

Then it goes to the hospital doctors, that last sentence:

"Hospital doctors being responsible for 62 per cent of inaccuracies."

That's quite a staggeringly high percentage.

A. Well, it doesn't surprise me because, actually, hospital doctors -- quite a few deaths happen in hospitals because quite often that is where terminal events occur. I can't remember quite the percentages of where deaths occur, whether in hospital or at home, but certainly hospital doctors, often junior doctors, would have been filling in death certificates. I would think general practitioners, who know their patients better, who have had patients on their list for years, would actually be able to more accurately sign death certificates.

Q. Let's see if you can help us because Mr Gowdy thought this was a significant finding. They're actually looking at just a four-week period, if you look further up at that summary. In that four week period, there were 1,138 deaths registered in Northern Ireland. 195 of those were either registered by the coroner or required further investigation.

So even if you work it out -- and in fact they've done it for you -- 195 of those deaths were found to be inaccurate at the hand of a hospital doctor completing a death certification.

A. Yes.

Q. That actually happened in relation to two of the deaths with whom the inquiry is concerned. Their death certification was inaccurate. In relation to Lucy, there seemed to be some confusion about the actual guidelines for how to accurately complete death certification. But leaving that to one side, when I asked Mr Gowdy about this he seemed to think that this was a significant factor to recognise that at that time, which would have been 1997, there was that level of inaccuracy, taken just over a short period of time, and he said he didn't know about it but it was the kind of thing that he would have expected you to bring to his attention. Did you know about it, this paper or the

study, I should say?

A. I don't recall this actual study, but I do know that we have had ... within ... well, certainly from the CMO perspective because we use death certification very regularly in terms of monitoring the state of health of the public --

Q. Yes.

A. -- and we would recognise the inaccuracies. Now, I know that considerable effort has been taken at medical school level to ensure that students are well-informed about the signing of death certificates, and I know that efforts had been made in Northern Ireland to make sure that the guidance for filling in the death certificate has been -- what would you say? -- well tested to try to ensure that it would be as helpful as possible. And I know that consistently medical directors have been trying to, as junior doctors come into hospitals -- because they're often left with the task of signing the death certificate -- that proper training is put in place.

None of that means that it is perfect, and again this will remain -- will continue to be an issue that has to be on the agenda because whatever efforts are made at times to try to increase the accuracy, you need to keep at it.

Q. Firstly, did you tell Mr Gowdy about these sorts of concerns or at least this study if it ever came to your attention?

A. I can't remember this study.

Q. And even if you can't remember the study, but you say you were aware of this and it's something that needs to remain on the agenda, everybody can see the importance and significance of it, is it the sort of thing the department has audited in terms of the accuracy of the death certification?

A. I can't remember in the recent years an audit -- anything being performed.

Q. Then what was the department doing? If it's remaining on the agenda and you think it should do, what is the department to ensure that the accuracy is improving, that these measures that it was being told were being undertaken, such as the greater teaching and training about it, that they are successful in the sense that the level of accuracy is improving? What was the department doing to make sure it knew about that?

A. I don't think that as a department we did anything specific in the way that you're talking about.

Q. But this is a regional issue.

A. It's not just regional, it is national, it is international.

Q. Then the other question that --
THE CHAIRMAN: Just before you go to that. Doctor, are you surprised that Mr Gowdy said yesterday that he would have expected you to refer that paper to him?
A. No, I'm not surprised. If I'd seen this paper and if I thought, on seeing it, that there was something that the department should be doing, then I would have spoken to Mr Gowdy.
THE CHAIRMAN: Okay, thank you.
MS ANYADIKE-DANES: Just to be clear on that, if you had seen the paper would you have thought there was something the department should be doing?
A. Well, I think that -- what could we have done? Obviously, this is an audit which is being performed by the pathologists. I think that I would have wanted, at SAC pathology, to work with the pathologists to see -- is there extra guidance we need to do, what is wrong with the guidance, which I think was extremely good guidance, that goes with the death certificate folder, and is there anything more that we should do?
I have to say that in recognising this as an issue, I do know that the pathologists -- and you can see from this report that they were interested in this issue -- were actively engaged at local level in trying to improve that, certainly within the RBHSC, but it may be

that Dr Carson or someone might be able to inform you better about that.
Q. Thank you. Then just the other issue that others have commented on, and that is in your witness statement 075/2, page 3, you're asked about quality of care in relation to your role. The question is:
"Please explain your responsibilities as CMO in regard to the quality of care provided to patients by hospitals, including any responsibilities to ensure that trusts exercised their statutory duty to provide quality of care."
You say:
"This was not part of the role of Chief Medical Officer. Prior to the introduction of the statutory duty of quality, the chain of responsibility (as I understood it) for the quality of care would have been as follows."
And you list five in that chain, but you're not there. Does that mean that you didn't see -- as Chief Medical Officer, not as a doctor -- that that position had a role in the quality of care?
A. And I need to apologise at this point because I think I actually misinterpreted this question and therefore have not replied to it in the way that I think you wanted me to. I narrowed the question down, I may have

been looking at the wrong words and focusing on those, assuming that the question that you were posing was to try to elicit where I stood in terms of a direct line of accountability of clinicians to me.
But I welcome the opportunity to absolutely say that quality was at the heart of all that I was trying to do as Chief Medical Officer. I regard it as central to the role, not just of anyone working in the Health Service, but certainly me as Chief Medical Officer. In both my roles, both in that of advising the minister on policy and what needs to be done to increase quality within the service, but also in exercising that leadership role, which we've talked about, which the CMO occupies.
I can promise you that quality is at the heart of all that I would have been trying to do.
THE CHAIRMAN: It did seem an unlikely answer and your clarification of it and correction of it is very welcome. Thank you.
MS ANYADIKE-DANES: Thank you. In the light of what you were saying, I rather thought that might be and I wanted to give you that opportunity if you wanted to take it.
A. Yes, and thank you for that opportunity, and apologies.
Q. No, no. The other thing to ask you about is, you say there you've referred to the introduction of the statutory duty of quality, and the chairman had been

asking you about that in 2003 and, in fact, putting to you that really that didn't make as much a difference as it might seem because there always was an obligation in relation to the duty of care of those involved in the administration of organisations that give medical care.
So the department, I think, has also said that there was, from their point of view, no real difference before or after 2003 in terms of responsibility for that. Why I'm asking you this is because -- and the chairman has referred to him as out on his own a bit -- Mr McKee, who was the chief executive of the Royal Group of Hospitals Trust, has expressed the view that until that statutory duty was imposed, he, as the chief executive, did not have that duty, nor did the board.
A. Mm-hm.
Q. Did you know he had that view?
A. I didn't know he had that view, no.
Q. In your involvement with the trusts and their senior executives and in relation to your concerns about improving quality of care and so forth, would you have expected to know that he did not regard the board of his trust as having a duty for quality of care? Would you have expected to know that?
A. I would have expected to know that, but I have to say that that was not the impression that I got from what

the trust were doing and certainly what the board of the trust accepted as their responsibilities. I think, actually, the Royal Belfast Hospitals Trust was one of the first to begin that movement, that evolution towards putting in place clinical governance structures.

I think they were quite early on to that issue, so I ... I can't understand that statement.

THE CHAIRMAN: Yes. Nor can I. Thank you very much.

MS ANYADIKE-DANES: Thank you. Just finally on this issue of quality, because this is also a matter that has been taken up so it's helpful to have your view on it, the inquiry's expert Professor Scally has in his report said in that early period of time -- and particularly as evidenced by the department's key document, which is the 1993 document that you probably know sought to allocate responsibility as between the Management Executive, the trusts, the boards and so forth. I won't pull it up now, but do you know the document I'm talking about?

A. Yes.

Q. His criticism is that:

"There doesn't seem to be any real evidence there of a focus on systematic monitoring of quality of care provided to patients."

Or, for that matter, an over-focus on the quality of care to patients itself as opposed to managing the

budget and all that sort of thing.

Not everybody has agreed with that, some have thought that there was quality in that, but I wonder if I can pull up an extract of Mr Simpson, who was the chief executive at the same time as you were CMO, from his witness statement, 084/2, page 4.

Mr Simpson is being put the views of Mr McKee, as I've just put them to you, and he answers in this way. He talks about the Management Executive's circular --

THE CHAIRMAN: Sorry, we're at the bottom of the page at question 9.

MS ANYADIKE-DANES: I beg your pardon. At the bottom of the page:

"'Accountability Framework for Trusts'. This set out the general 'light touch' approach determined by the ministers for the monitoring of trusts by the department. There is nothing in this circular which specifically requires trusts to account for clinical standards or safety, except for a reference at paragraph 18 ..."

And if we go over the page, that's the part that talks about:

"... the intervention by the Management Executive in the affairs of the trust, which should be exceptional, and it may be judged necessary in certain

circumstances."

Although it is recognised it doesn't say what those circumstances are.

As you were working with that document until a change was introduced, was it your view that that didn't particularly highlight quality of care to patients or the need to monitor that?

A. How can I explain this? At this time, the accountability mechanisms were based on the political ideology of the time that the market would work. The theory was that competition would drive up standards, so therefore that should all happen out there, and let it happen. I think many of us were unhappy with that approach, simply because the market isn't -- wasn't ever going to work in Northern Ireland, you know, "Daisy Hill is the only hospital I can go to", as it were, you know.

So we then began to think -- and indeed, across the UK, thought began to be put into, "How do we measure quality?" -- and if I'm going into too much detail, do stop me.

THE CHAIRMAN: Go on.

A. At this time, in terms of accountability, they were easy things that you could measure, important things about how money was being used, the public need to know that, and other measures. It was very difficult to measure

quality and to find out what indicators there might be. And there was a whole lot of work, which was resourced by the departments through King's Fund, through the Nuffield Trust, to try to find out how you might find simple indicators of quality which would help us to drive in that accountability.

It is never easy and I think we're gradually coming to realise that whatever indicators you might have, actually what you need to do is drive in a whole culture of learning and quality improvement. It's about changing the culture of the organisation rather than any top-down measurement because that's never going to be adequate.

Having said that, it is quite useful for ministers to know where money is going, where effort is going, that you are seeing returns, and I'm not now an expert in that. The department might have better thoughts now about what they're doing about measuring quality, but it was never going to be easy.

MS ANYADIKE-DANES: Of course it isn't easy, one of the things Mr Hunter thought is actually there may not have been a way of measuring quality. But if you're going to do it at all, surely the start to that is clinical audit? That's --

A. Yes.

Q. That's how you get a handle on what is actually happening. Your view is that measuring things doesn't change a culture. Of course, it doesn't. But it allows policies to develop as to what areas we need to target in perhaps helping a change in culture. Would you accept that?
A. I do, and that's why clinical audit was at the heart of many of these reforms in terms of encouraging and promoting quality improvement at local level.
Q. And you would know that the National Audit Office in England had published a paper exactly about clinical audit, and that was published in December 1995.
A. Mm-hm.
Q. That was exactly emphasising the very point that you're making as to how important it is to measure what's happening so that: (a), you understand it; (b), you can see changes in it; and (c), you can effect policies to either redress changes that are not of the sort you want or encourage the ones that you do want?
A. Mm-hm.
Q. But if the department collectively had not been able to institute a systematic clinical audit in the trusts, then you're not going to have much chance of knowing where you stand in terms of quality of care?
A. I think that there is a wrong impression here about what

was meant by "clinical audit" and what outcomes we expected from it. It was a tool which was to be used at local level in order to drive up standards of care. We did have in Northern Ireland regional audit -- at first medical, then multi-professional -- which helped to have a look at some of the issues which were felt to be important in terms of quality improvement. But none of those things, I think, fed into policy development and improvement. I think that there is something that could be done in terms of audit that would help to do that, but at that time very much the drive was towards giving clinicians the tools with which, at local level, they could focus on quality and focus on quality improvement. It wasn't seen as a regional tool to inform policy at that time.
Q. Yes. Was it thought that if the local trusts boards were instituting clinical audit so that they knew what was happening in their own organisation, that when, in the era where you had the Management Executive, where they were trying to ensure that there was proper accountability in their monitoring role, that would at least have given them a basis to see what was happening if that systematic approach was being taken. Would that be correct?
A. In terms of accountability --

Q. Yes.
A. -- and calling trusts or boards to account --
Q. Yes.
A. -- you would want to be assured that clinical audit formed a central part of the quality improvement programme.
Q. Yes, and so in your discussions with those that you were meeting in the special advisory committees and other meetings, you would be wanting to advocate clinical audit --
A. Yes.
Q. -- so that -- not just for their own purposes, but for the monitoring role the department had, who had to hold the trusts and boards to account -- they had some means of being able to see what was happening?
A. Yes, indeed.
Q. Yes. You have mentioned the regional audit. I wonder if you can help us with this: we have seen from certain extracts of committee meetings that there were bodies called the regional audit committees.
A. Mm-hm.
Q. Can you help us with what they were and how they fitted into the structure of managing the Health Service, if I can put it in those terms?
A. I don't think they fitted into a structure of managing

the Health Service, but they were a critical part of that quality improvement within the Health Service, and at medical and, later, multi-professional level. So we had the regional medical audit group initially following what I call the Thatcher reforms, which then became, in the light of the acknowledgment of a team-based multidisciplinary approach to patient care, which then became the region multi-professional audit group. They ran, over the period of each year, important audits, which were right across the region, on issues which fed out of local audits or fed out of guidelines which were developed by colleges, et cetera. And so a programme of regional audit was set by these groups.
Q. And who reported to them?
A. This was -- sorry, who reported to them?
Q. Were they collecting the results of audits that were being carried out by the trusts?
A. They were, in the light of audits that were being conducted at trusts, developing a programme of regional audits which needed to be undertaken. If an issue was discovered at local level where it was indicated that a regional audit would be an important thing to do, then that's the kind of audit that they might have undertaken.
Q. And was that then a resource for the Management

Executive?
A. Well, chairman, I'm having difficulty answering this because it was about driving up standards, it was about helping professionals themselves to take on the responsibility for quality, rather than being used as an accountability tool. I think there's a very great difference between the two. If you focus too much on accountability then you run the risk of suppressing that need to ensuring that there was professional ownership of what was going on.
Q. The reason I'm asking you about this is firstly to understand properly, if we can, how that system worked, and secondly, because in the meetings with the Directors of Public Health and the department, there are references in those minutes to that system not working properly. And when I put that to the chief executives of the Management Executive, and for that matter the Permanent Secretary, their view was that they would have wanted to know that because they did regard the successful clinical audit as important. So if that system was not working well, they would have wanted to know that and, frankly, they would have wanted to know it from you because it was you and your team who sat in on those meetings.
Let me just pull up just one of these comments which

might assist you. It's 320-067-007. It's item 5 there. You can see that there is a discussion about the regional audit committee not publishing reports and Dr Watson says it doesn't seem to be possessed of any direction and perhaps it needs to be restructured. Then Dr McClements, who is the senior person that you refer to in your department, said that:
"The committee was intended to be the driving force behind audit in Northern Ireland, but probably lacked the infrastructure to accomplish this effectively."
Actually, you're actually at that meeting. The list of those who attended is at --
THE CHAIRMAN: It's in the paragraph above.
MS ANYADIKE-DANES: Oh, thank you.
So you're at that meeting, this is being said, the chief executives of the Management Executive and the Permanent Secretary have said that kind of concern, they would have expected to hear from you or learn about from you, but they don't recall that being mentioned. It may be just a failure in their recollection, but is this the sort of thing that you would tell them about?
A. Certainly, I chaired that meeting, so I -- and Dr McClements worked directly to me, so these are concerns that we had about regional audit at the time. Representations were made for more money to support

regional audit, we then, rather than calling it regional medical audit, we reformed it totally so that it was the Regional Multi-professional Audit Group under a new chair with additional resources, with annual reporting, with annual conferences. So a great deal of work took place following this acknowledgment by Dr McClements and myself that change needed to happen.
Q. And were you able to do that without having to report that to either the Permanent Secretary or the chief executive, or would that have required you to report that?
A. That would have required me to put in a bid for additional resource from the annual expenditure of the department, and that money was given. So obviously it's quite a time now since that happened, but I have to say that the support that we got in terms of money and in terms of the changes to the audit reporting and management took place.
Q. Thank you. One final point in relation to a slightly different matter. What I'm trying to do now is tidy up a few things about what people have said about your involvement so we can move on without going through absolutely everything.
One of the references that was made to you related to how people or the department would learn about there

being a serious adverse incident involving a fatality in hospital. I think Mr Gowdy, at least -- and he may not be alone in that -- said that he would expect to be told that by you, or rather, not necessarily actually told that by you, he would have expected the report to go to you. You may bring it to his attention if you felt that there was an issue that required his attention, but if there was a report going to be made of a death in hospital, which had clinical issues involved in it, then he expected that report to be made to you. Would you agree with that or did you not think that was the route?
A. As we discussed earlier, on the informal system, that didn't work well, but a lot of those reports would have come to me. Sometimes they did come direct to Mr Gowdy and he would have informed me, but we've already touched on this as being ...
THE CHAIRMAN: We have, yes.
MS ANYADIKE-DANES: I know it is defective, but I just need to be clear -- in fact, Mr Hunter was another person who said it. So you accept they would come to you, but they could also go to the Permanent Secretary?
A. They did, yes.
Q. In fact, they did.
A. They came through both those routes.
Q. Thank you. I want really to go on to hyponatraemia, but

before that there's one area of reporting that you might help us with.

At the time that Adam had his inquest in 1996, there was no requirement for the coroner to report untoward deaths to the department. You have said that in your witness statement. He had his discretions under rule 23, but there was no formal system for disseminating any information to the department through the route of an inquest; is that right?

A. Yes.

Q. And you were aware of that?

A. Um ...

Q. At the time, I mean you were aware of that.

A. Yes.

Q. Was there any discussion about how there might be a way of inviting the coroner, not for rule 23 purposes, but just a way of alerting you to deaths in hospital, to have some sort of communication between the coronial office and the department. Was there any discussion about that?

A. Um ... If I say none until later, I actually do remember -- it was on new variant CJD where the coroner informed me of a death in Northern Ireland, and he obviously recognised the importance of that at that time. So therefore, it's not that there wasn't

communication before that. But certainly, you know, with the inquiries into how we might better use the coronial service UK-wide, then discussions did begin about how we might use it better.

I mean, traditionally, the coroners' reports and the inquest findings would have been important elements of monitoring the health of the public and I would have referred to that in various CMO annual reports in the past. But I think, certainly through hyponatraemia, we began to understand that was not the only way and not perhaps the primary way, but that by discussions with the two departments we could take things forward.

THE CHAIRMAN: When you say you referred to coroners' inquests in CMO updates, do you mean that from time to time there was an inquest of which you became aware of and you formed the view that it was worth referring to in your update?

A. Yes. I mean, sometimes --

THE CHAIRMAN: But that was, I think from what you've just said to Ms Anyadike-Danes, by picking up perhaps through the press that there had been a significant event?

A. Yes, or often the Directors of Public Health would have been at inquests. They normally did attend. Not always, but you know, if --

THE CHAIRMAN: Sorry, excuse my ignorance, but did the posts

of Directors of Public Health exist before the formation of trusts?

A. Yes.

THE CHAIRMAN: So when there were just four area boards and no trusts, the Directors of Public Health would typically attend an inquest?

A. Or their representatives, yes.

THE CHAIRMAN: So when Adam died in 1995 and his inquest took place in 1996 -- we have no information that the Eastern Board knew about this --

A. Yes.

THE CHAIRMAN: -- and what happened at the inquest was not reported to you.

A. Yes.

THE CHAIRMAN: It was reported by journalists, for instance, in the Belfast Telegraph, but it was not reported to you.

A. Yes.

THE CHAIRMAN: Had that been done otherwise then, as you have just said to myself and Mr Hunter a few minutes ago, you could have taken that forward in the CMO update or through various ways?

A. Yes.

MS ANYADIKE-DANES: Just finally on that point, because I put that also to Mr Gowdy, if we can pull up

069a-102-423. This is actually the report that I think was in the Belfast Telegraph. Why I wanted to ask you to look at it is because at least one person in the department saw this report. We routinely asked everybody that we invited to provide witness statements when they first knew about all the deaths. The answer was that we first knew about Adam's death because he had seen the reports after the inquest.

069a-102-423. In any event, in case there is a problem and it can't come up, what this report did -- obviously it had a very big heading about the death of a child. Here we are, you can see it yourself. More than halfway down in the first column, you see:

"In a statement the hospital's trust said ..."

Can you see that? There we are. Just where the pointer is. Then it is really reciting what it is the trust is going to do about taking action and that carries on over the page and you see that Dr Maurice Savage, who I'm sure that you're aware of, was Adam's consultant nephrologist. He is talking about becoming:

"... recently aware of nine other deaths in the United Kingdom which shared similarities and should be investigated."

Or he would like to have investigated. Then they

talk about the measures that they have introduced in relation to electrolyte measurement and then all of that ends up on the far right-hand side at the bottom with the coroner's statement saying that this type of death is relatively rare, but he agreed that there should be further investigation into the other cases.

Mr Gowdy said that there's obviously a press office in the department, and I am sure that they receive many reports, but is that the sort of thing that you have expected to come to your attention, maybe the senior medical officer, some medical person's attention, in the department?

A. Yes. I think later than this date the press office became actually quite well resourced and we were very regularly kept up-to-date with things like this that would have been in the press. I'm not saying that's the way we should necessarily depend on hearing about things --

Q. No.

A. -- but I didn't see this.

Q. I understand that your evidence is you didn't see it.

A. Yes.

Q. I was putting it slightly differently to Mr Gowdy, whether he would have expected something like this to have come to the attention of you or some other medical

person and ultimately to him, and would you agree with that?

A. Yes, I think in a well-resourced press office that would have happened, and certainly, as the press office became in later years, that would have been the case.

Q. Thank you very much.

THE CHAIRMAN: That would only be the third route in to you because that's the press office on top of the Director of Public Health on top of the Royal; isn't that right?

A. Yes.

MS ANYADIKE-DANES: I was going to go on to deal with the hyponatraemia guidelines.

THE CHAIRMAN: Yes, we'll take a break. It has been a long morning, Dr Campbell. We'll come back at 2 o'clock and we'll finish your evidence this afternoon.

(1.00 pm)

(The Short Adjournment)

(2.00 pm)

THE CHAIRMAN: Just before we start, in case I forget later, tomorrow morning, if at all possible, I'd like to start at 9.45 instead of 10 o'clock. We'll hear, at 9.45, from Mr Simpson. Is he available?

MR McMILLEN: Yes.

THE CHAIRMAN: Thank you very much indeed, that will help.

I think you'll have seen a note circulated over the

last day or so that instead of just the normal mid-morning break, tomorrow will be used to raise some money for the Newry Hospice, so the intention is to hear from Mr Simpson from about 9.45 until the break and hopefully that will complete his evidence. We'll then have a slightly longer break for the hospice and then I will resume with Dr Carson after that.

Could I say now that Dr Carson's coming tomorrow to give evidence about the RQIA and what is happening to date, and it's part of this sequence that we started with two doctors from Craigavon last week and will continue next week with people like the Belfast Trust and the Health & Social Care Board. So Dr Carson's evidence tomorrow will be of a different nature.

As a indication of that, just in case anybody misses the point, I won't be asking him to give sworn evidence and I won't be asking next week's panels to give sworn evidence. This is updating us on what the position is the Health Service now. Okay?

Ms Anyadike-Danes?

MS ANYADIKE-DANES: Thank you.

Good afternoon, Dr Campbell. I want to turn now to the 2002 hyponatraemia guidelines. In your witness statement, you said that on 18 June there was a meeting of medical directors chaired by Dr Carson, and

Dr Fulton, who's the medical director at Altnagelvin, described the circumstances of Raychel's death and suggested that there should be guidelines and that following that, Dr Fulton rang you, informed you of the circumstances of Raychel's death and suggested there was a need for regional guidelines in relation to the dangers of hyponatraemia when addressing IV fluids for children.

That was fairly quickly followed up by a meeting on 2 July, which you were present at, of the Directors of Public Health of the boards, and they are also agreeing guidelines should be issued to all units and Dr McConnell is highlighting the death of Raychel Ferguson.

When that information is being given to you as to the need for regional guidelines, what did you understand as the distinguishing factor that made regional guidelines the response to that as opposed to seeing whether there was some deficiency in the care that Raychel had been given at Altnagelvin that didn't necessarily involve any regional lessons?

A. I think for me, the distinguishing feature was the fact that Altnagelvin had apparently been told by the Royal that they had procedures in place, which Altnagelvin felt, had they known about, might have prevented

Raychel's death.
Q. And what were they?
A. It was around intravenous therapy. At that time, I don't know that Solution No. 18 as such was raised with me, but what I was aware of was that Altnagelvin felt that if they'd been told by the Royal about some problems that they'd had, that perhaps Raychel's death could have been prevented, and therefore was there an issue which needed to be disseminated region-wide that would ensure that any further deaths would be prevented.
Q. Can you remember whether that was something that you took the opportunity to discuss at the Directors of Public Health boards, the fact that there was a regional dimension to this in the sense that the Children's Hospital had perceived -- let's call it a difficulty or an area of risk -- in relation to IV fluids and had changed its procedures or instituted some difference in their practice which hadn't been communicated, and that was a regional element because it may be that all hospitals should do likewise. I presume that's the way you were thinking about it. So can you remember if that was discussed at the meeting of the Directors of Public Health boards?
A. I can't remember the full discussion that we had with

the Directors of Public Health, but from the minutes of that meeting, just the recognition that -- regional guidelines appeared to be something that was required.
Q. If something had happened like that that involved the Children's Hospital or any hospital which was a regional centre and an area of medical care to change its practice, would you have expected communication about that, at least to let you know they were doing it and the reasons why they were doing it?
A. The nature of regional paediatric services in Northern Ireland is that they did tend to reach out to all the hospitals in which children were being treated and I felt there should be natural lines of communication because children were constantly being referred from district hospitals to the regional centre. I would have thought there had been natural lines of communication for dissemination of such guidelines if they existed.
Q. So there would have been a way, you would have thought, naturally, whereby the Children's Hospital would have let other hospitals which treat children know that they had changed their practice and the reason why they'd done it?
A. I would have expected there to be.
Q. And would you have expected to know -- you yourself or

somebody in the department -- that the Children's Hospital had changed its practice?
A. The department didn't -- and I don't know how to explain this properly, but the department would not normally have got involved in clinical issues, you know, on all kinds of therapies otherwise we'd have been inundated with material because there's so many specialties, so many sub-specialties and so many conditions that it's not something that normally would have come to the department. The department normally would have been involved in issues which required policy direction on change of services, things like that, but not on specific clinical issues.
Q. But this is one of those, is it not? This is an extremely common fluid used by paediatricians or even non-paediatricians in relation to children, very commonly used, and the Children's Hospital, which has the specialisation in these matters, has decided that there is an area of risk in the administration of that fluid and therefore it is not going to -- at least that is what the communication seemed to be, it's not going to use that any more. That's something that affects treatment of children throughout the region.
A. Yes.
Q. So if there is an area of risk in that respect, would

you not have expected that you would come to hear of it from anybody in the Children's Hospital?
A. As I said earlier to the chairman, I would have expected people to understand that I might have been one method of communicating and disseminating that information. It would not normally be for the department to take clinical decisions on drugs to use, et cetera.
Q. Sorry, I didn't mean that, I meant to be notified of it; not necessarily to make the decision as to whether we're going to carry on using that fluid necessarily, but at least to know that there has been a change like that.
A. It wouldn't really be practical to do that because medicine treatments change daily, dependent on evidence. There are hundreds of thousands of drugs and therapies. For the department to need to be informed about changes to those, even though it was relevant to a lot of people, I don't think the department could handle or be expected to handle all of that churn of information.
Q. Would that be true now? Let's say, for example, Hartmann's, that's an IV solution that's regularly used, if the Royal Hospital had reached the conclusion that because of incidents it had seen that there were risks associated with it, the administration of that fluid, if that were to happen now, would the department expect to know that?

A. The department I would think would absolutely expect to know that because this issue is one which the department has, in a sense, owned. What we wouldn't expect to know is if there were change of therapies for cardiac failure or for osteoarthritis.

THE CHAIRMAN: Thank you.

MS ANYADIKE-DANES: Yes. So you had formed the view because of that that this really is something that would benefit from regional guidelines?

A. Absolutely.

Q. And when you were thinking about that, were you thinking regional guidelines that the department needs to issue or regional guidelines that really should be happening at a clinical level and really the Children's Hospital might be instrumental, given that it had formed the original decision, in disseminating?

A. I had felt that if there were guidelines that the Royal were using, that we might be able to help to disseminate those. Going back to my original issue, that would be a way in which we could use ...

Q. You see, I thought initially you thought that it might be the Directors of Public Health who would issue those guidelines and that wouldn't necessarily have to be something the department would be involved in.

A. Only because the Directors of Public Health -- and

particularly Dr McConnell at that time said he would take that on. So that was an offer from the Directors of Public Health.

Q. Yes. But not one that ultimately you took up?

A. Not one that we ultimately took up, no.

Q. When you heard about the problem put in that regional context, did you not wonder, even at that very early stage, well, we've got Raychel dying and this has been implicated, how many others have been involved in this kind of therapy? Did you not wonder that?

A. On hearing from Altnagelvin that they had been told that the Royal had problems, it was clear that this wasn't just a situation which was relevant only to Altnagelvin.

Q. So does that not mean you want to know, if the Royal's had problems, let me see from the Royal what the nature of those problems is and what is the extent of this concern?

A. Yes.

Q. And how did you go about finding out how many instances of either near miss or injury there might have been associated with the use of this therapy?

A. I wrote or asked Dr Carson to inform me about -- I can't remember the terms of what I asked him, but obviously if the Royal had been informing Altnagelvin that they had had problems, then obviously the Royal, through

Dr Carson, was the place to go.

Q. So you were wanting to know from him what the incidence of injury or adverse effect there might have been in relation to the use of this therapy?

A. Well, in effect, I wanted to know more about what these problems were that were being alluded to by the Royal to Altnagelvin.

Q. And in due course, did you get a document that was provided by Dr Taylor?

A. I got an e-mail from Dr Carson.

Q. Yes. Maybe we'll pull this up. 021-056-135. This is from Dr Carson to you and it is cc'd to Dr Taylor and Dr Fulton. It says that it attaches a document -- and we'll come to that in a minute -- on the subject of hyponatraemia because you also wanted some information about the condition of hyponatraemia. He is saying that:

"This reflects the current 'opinion' among experts in the management of these children, but it does not yet command full support amongst paediatricians."

Then he goes on to say that:

"The anaesthetists in the Children's Hospital would have approximately one referral from within the hospital a month."

Then it refers to:

"... a previous death six years ago in a child from Mid-Ulster and that Dr Taylor thinks there might be five to six deaths over a 10-year period of children with seizures."

Did you want to know any more about that, what were the circumstances surrounding that child who seems to have died six years ago?

A. I thought it was probably clear from the e-mail that there had been a previous death from hyponatraemia, which the Royal had recognised, and that, on the knowledge of Raychel's death, I think was ... was such important information that we needed -- I knew that we needed to move quickly.

Q. Yes, that's a slightly different question --

A. Okay.

Q. -- and to the credit that it was recognised how important this was and to move speedily on it.

But I'm asking you something else, which is: in the same way Raychel's death has come to your attention, which was associated with hyponatraemia, you know or at least you believe you know that the Children's Hospital has taken steps because of its own direct experience. Here you're hearing from a consultant paediatric anaesthetist, telling you that he thinks that there was a previous death, which obviously would not have come to

your attention six years ago, also associated with it, and on the face of it it seems that there have been five to six over a 10-year period and none of those would have come to your attention. So do you not want to know a little bit more about that?

A. Yes, of course. But the information from the e-mail seemed to indicate that there had been one previous death and that, to me -- obviously I would have expected that death to have been properly investigated and, if it were an untoward death, that it should have been a coroner's investigation. So I didn't at that time think that what I wanted to do was to spend time on investigating that, but rather in recognition that that had happened and in reading the Arieff article, to me, I recognised that that day there were children at risk and that we needed to do something.

Q. Yes.

A. So I felt that we needed to move quickly on developing guidelines, that rather than, I suspect, spending a long time investigating previous deaths, that the first and primary importance was to develop guidelines.

Q. Yes, and while that's being developed, though, could you not have raised a query with the Children's Hospital: who was the death six years ago and what are the circumstances of it? As you say, was that a death that

was recognised as involving hyponatraemia clearly at the time, was that death reported to the coroner? I mean, that doesn't have to impede the work of the working group.

A. Absolutely not.

Q. You can independently ask that of the Royal, and for that matter: who are these other five to six deaths, have they all had inquests, why were they not referred to either myself or the Permanent Secretary?

A. Just to be clear, I wasn't clear from the e-mail that those five to six deaths over a 10-year period had been in Northern Ireland because I recognised the reference to the Cochrane review, which would be UK-wide.

Q. Did you ask?

A. What I did know is that there had been one death from the Mid-Ulster, which is clearly specified in the e-mail.

Q. Right.

A. I had expected, therefore, that that information would come forward in the workings of the working group on guidelines because specifically we wanted to ensure that there were people from the Royal and specifically paediatric anaesthetists, paediatricians from the Royal, who would have been involved in the working group. So I have to say I did expect that information then to come

forward in the working group to be supplied by those members of the working group.

I have to say that I didn't specifically try to find out names and dates, but rather I felt that my energies would be on setting up the working group and in getting the guidelines underway.

Q. I understand that point entirely, but you have here -- if you leave aside the five to six deaths because you're not sure whether he was referring to Northern Ireland or not about that, but there's clearly one that he is. If I have you clearly about that, are you saying you didn't specifically ask about that death, but you expected the circumstances of that death to have come to the attention of your deputy, Paul Darragh, in the working group?

A. Yes.

Q. And did you anticipate he might ask about it?

THE CHAIRMAN: I'm sorry, if she anticipated that this would come to light in the work of the working group, I think we can take it like that and move on, Ms Anyadike-Danes.

MS ANYADIKE-DANES: I will, Mr Chairman; it's just that the way Dr Campbell had put it was the emphasis and onus on the clinicians to have mentioned it in the working group. What I was wondering is whether, because she knows about it, whether she had specifically tasked

Dr Darragh, who was going to chair that to, at the very least, find out about the circumstances of that. It was that side of it I was going to.

Did you ask him to find out about that?

A. I can't remember whether I did or not.

THE CHAIRMAN: Do I take it then, doctor, that you thought that if there was a working group looking at guidelines and looking at hyponatraemia on foot of a hyponatraemia-related death, that that working group would necessarily discuss what the incidence of hyponatraemia was and what other similar or comparable deaths or events had occurred?

A. Yes, indeed, chairman. Can I add to that?

THE CHAIRMAN: Yes.

A. Because the indications from the Arieff paper were that these were very rare incidences, I recognised the need for, firstly, a full research of the literature in order to try to see, was this just something that was only a Northern Ireland problem, just an Arieff problem, et cetera. So the first imperative was to gather the evidence from the literature to see what the incidence would be UK-wide, globally.

THE CHAIRMAN: But then you would expect local doctors who were on the working group, who were aware of local deaths, would put that into the pot --

A. Yes.
THE CHAIRMAN: -- because it would be unnatural for them not to put that into the pot?
A. I agree.
THE CHAIRMAN: If I was on the working group and I had treated a child who had died of hyponatraemia after receiving Solution No. 18 in 1999, you'd expect me to add that to the collective knowledge of the working group?
A. I would.
THE CHAIRMAN: Yes.
MS ANYADIKE-DANES: Thank you. Before we actually get to the work of the working group, the other thing it seems that you had anticipated would be taken up is the whole question that you have just been mentioning before, the change in policy of the Children's Hospital in relation to Solution No. 18. There's a discussion that you have -- you, Dr Darragh and Dr McCarthy -- about who are we going to have on this group, what sort of things are going to be addressed. And as I understand from the evidence in your witness statement, the Royal's change in its use of Solution No. 18 was one of those things that could be taken up. So not only were you expecting to learn more about the incidence of the development of hyponatraemia as a serious condition, you also were

expecting to learn more about why the Royal had changed its practice.
A. Yes.
Q. And that would all have come out of this working group?
A. Yes, but I wanted -- and it is best practice in the development of guidelines -- firstly to focus on the literature because what you can't do -- and those who are well-versed in guidelines development will tell you this -- you don't want local bias to enter into those primary discussions on guideline development. You have to go to the literature, the peer-reviewed literature, and what you're expecting to find are certainly case studies, randomised controlled trials, systematic reviews which help to show what has been proven to be best practice.
Q. Yes. And in addition to doing that, so that you'd know what the condition is, what the problem is that you're seeking to address and how that might have been addressed elsewhere, you know what the size of the problem is in your own region, you understand why certain decisions have been made by your premier children's hospital, that's all part of the context in which they're now going to actually develop some guidelines that can be of general use throughout the hospitals in Northern Ireland?

A. Yes, that's a next step.
Q. Yes. But before we get to that next step, in addition to the guidelines, once they are formulated and distributed, at a very early stage there was a discussion about the fact that the implementation of those guidelines was going to be audited.
A. Yes.
Q. And so in the way that, in a sense, CREST did it when they developed the adult guidelines, they developed guidelines and they developed an audit toolkit with those guidelines and they got issued -- or an audit template -- so it was quite clear what was required in terms of audit and you could see that that was happening in a systematic and consistent way throughout all the hospitals that were to use the guidelines.
So when you say you wanted them to be audited, did you have in mind that there would be developed with them some sort of audit template to assist. Even if they didn't necessarily go off at the same time as the guidelines, that would happen?
A. There are a number of steps in terms of audit that I expected. The first was that there would be local protocols because the guidelines actually needed to be formed in a way which matched the requirements of children in whatever specialty coming to whatever

hospital. So local protocols to be developed and those then to be audited locally. Not the central guidelines, but the local protocols needed to be audited.
Q. Yes.
A. And I think that was what I was primarily referencing when I was asking medical directors to take this forward, that there would be local audits. The next step -- and most expert guideline developers will tell you that within about one to two years of implementation, what you needed then was to audit regionally. So in terms of audit, it would have been expected to be a two-step approach.
Q. I understand, thank you. So then in that discussion, you also are discussing with Dr Darragh and Dr McCarthy who should really be part of this working group?
A. Yes.
Q. And I think you've already indicated there are certain key players you'd want: some senior people from the Children's Hospital and then, I think, Dr Darragh and Dr McCarthy had said a sort of representation from the trusts and maybe hospitals and boards in the region.
A. Yes.
Q. Did you together draw up a list of those who would be appropriate?
A. Yes, indeed. I mean, what we wanted were people who we

expected to have that research knowledge base, that could bring that ability to search the literature. But what we also wanted was to ensure that we had wide ownership of the guidelines because guidelines that are just written out from the centre are useless unless they are felt to be owned. So that was why we wanted a wider representation on the working group.

Q. Yes. In all that discussion that you're having as a prelude to the working group actually being established and commencing its work, did it occur to you to involve the Chief Nursing Officer?

A. I have thought about this because obviously it's a question that I've asked myself. Initially, the problem was around the prescribing of intravenous therapy, the decisions that doctors make. Now, that was the primary focus in those first months. I thought the issue was entirely one that was medical. I think the working group in -- and it may have been in the second steps when they began to look at some of the implications of implementing the guidelines. There was a recognition that there was a wider multidisciplinary focus to this. I'm sorry that it wasn't recognised right at the beginning because it should have been perhaps more obvious than it looked. But at the beginning, it looked as if this was solely an issue

about medical prescribing.

THE CHAIRMAN: So am I understanding that's why you involved Ms McElkerney?

A. Yes, indeed.

THE CHAIRMAN: And that's the appropriate step for them to take once they see it spreading beyond the original confines?

A. Yes, indeed.

MS ANYADIKE-DANES: Nurse McElkerney was part of the original working group.

A. Yes.

Q. So right from the very first meeting they knew they needed the involvement of a nurse?

A. They knew that they needed the involvement of a highly specialised paediatric nurse who would be in intensive care.

Q. And if that was a view that was taken right at the outset, as it was because she was contacted to attend the first meeting, which she did --

A. Yes.

Q. -- then why, when they knew they were going to involve a nurse, did you not raise that with the Chief Nursing Officer?

A. Because the issue was not seen initially as something that would impact on the wider nursing establishment,

but rather that this may be something that was about highly specialised nursing ability. Then that was why Nurse McElkerney was involved. As I've said, on reflection, to do it again, I would certainly involve the Chief Nursing Officer and more of the nursing establishment right at the beginning.

Q. Even without consulting her about how the guidelines might be formulated, as you've said at the beginning of your evidence she was just in the office next door?

A. Yes.

Q. And you've also given evidence that you personally taking on board the oversight of the provision of guidelines is not something that happened very often. So would it not be a natural thing to tell her that this is what we're doing, we've had this problem and this is how we're addressing it? Is that not a perfectly natural thing to share with her?

A. I agree.

Q. And in fact, part of what the guidelines are going to deal with -- and this happened very early on, almost the very first draft of anything talks about the importance of accurately measuring and weighing. Accurately measuring and weighing is something that the nurses are going to be involved in.

A. Yes.

Q. And they would, whenever these ultimately are released, have to be involved in training to ensure that they're now going to embrace the new requirements involved in this or at least improve the standard of what they already do if they're going to follow these guidelines?

A. Yes, which is why, when I saw the guidelines in their near-final stage and when we were thinking about ways of disseminating the guidelines, it was clear that we needed to involve the nursing officers at trust level.

Q. And when did you tell the Chief Nursing Officer about the guidelines?

A. I can't recall, but the guidelines -- when the letter that would have gone out with the guidelines would have been copied, a natural procedure is that letters that I will send out to the service should have been copied around the department. They certainly went on the departmental website as soon as they were published and, indeed, I included them in the CMO update, which is widely disseminated, not just across the service but within the department.

Q. I'm just looking at the letter that was sent out, which is dated 25 March 2002. It doesn't appear to be cc'd to her.

A. No, the CC list would not have been on that letter that went out to the service.

Q. But you think you would have sent them to her?
A. It should have been and that is normal procedure and I cannot tell you at this stage whether that happened or not.
Q. Did you think that you might tell the Chief Pharmaceutical Officer that guidelines for hyponatraemia were being developed?
A. At the beginning I thought that this was a medical issue about prescribing and, on reflection, yes, indeed, wider multidisciplinary involvement could have been a very good thing. But we didn't do it.
Q. Yes. It probably comes as no surprise to you if you have looked at the evidence that was given, or at least on reflection, that both of them have said that they would have liked to have known that you were producing those guidelines and perhaps had some input into them.
A. Mm-hm.
Q. So the working group is set up. Did you at some stage receive, perhaps from Dr Darragh who seems to have passed it on to Dr McCarthy, a PowerPoint presentation entitled "Hyponatraemia in children: a teaching aid"? I will bring it up for you, the reference is 007-051-100. This is the e-mail that Dr Taylor sends to Dr Darragh. There's a PowerPoint presentation, as you

can see right at the top, and also some recommendations. This is being sent in advance of the first meeting of the working group. If one reduces the size of that, you can see:

"Please copy to Miriam McCarthy."

If I go into it just so that you can see what it is and see if you recognise it, if you go to the next page, 101, the next page is titled:

"Hyponatraemia in children: a teaching aid. Hyponatraemia working party, Department of Health 2001".

A. Yes.
Q. Do you recall receiving that?
A. No, I didn't receive it. I can't recall seeing it. It wasn't copied to me.
Q. Would you have wanted to receive it? I mean, I'll tell you the particular bit of interest for the purposes of my questioning. There is a bar chart in it, which I'm sure you have seen subsequently.
A. Yes.
Q. There's a bar chart in it, headed up "Incidence of hyponatraemia at the Children's Hospital", and it identifies from the series of years, 1991 to 2001, those who have been admitted to the hospital with hyponatraemia and those who have died. So it shows you the incidence of admission of hyponatraemia and it shows

you -- one can move along to 103, if that comes up. There it is.

You can see that's the incidence. There appears to be two years when there was no incidence of hyponatraemia at all, and then you can see the death in 1997 and the death in 2001. And you would assume the death in 2001 to be Raychel, but you'd see that there was that death in 1997. Do you recall seeing this?

A. No, I didn't see this.
Q. At any time?
A. I have seen it recently, but not at that time.
Q. Not at the relevant time?
A. No.
Q. Thank you very much. If that kind of information was being provided prior to the working group, so while you would still be having your discussions with Dr Darragh and Dr McCarthy, would you expect to be provided with it?
A. Sorry, could you repeat the question?
Q. Would you expect to see it? You and Dr McCarthy, Dr Darragh, are discussing the work that the working group is going to do, you've already received from Dr Carson a background piece on hyponatraemia, you're in information gathering mode as to the condition and its incidence, and this piece of information is received by

Dr Darragh. Would you expect to get it yourself?
A. I delegated the work of the guideline development to Dr Darragh and Dr McCarthy. I expected them, expected Dr Darragh, to use any information which he could collect in order to further the work of the guideline development. I would not have expected to see a trail of information then coming to me. The nature of delegation is that I trusted Dr Darragh, trusted Dr McCarthy to do that work.
Q. Yes. And then if we go into the beginning of the work that was being done by the working group.

In your second witness statement for the inquiry, we don't need to pull it up, but the reference is 075/2, page 7, you're being asked:

"What steps were taken by your staff to investigate if there were any further deaths from hyponatraemia?"

And you say:

"In the course of [the answer to 11] the deliberations of the working party, I understand information was shared between members."

Does that mean that at that time you were given information to indicate that the members of the working group had discussed other deaths in Northern Ireland from hyponatraemia, or in which hyponatraemia was involved?

A. Yes. The only other death which came to my notice through that process was that of Adam, which had come from Dr Loughery, I think, and through the coroner, and then relayed to Dr McCarthy.
Q. So when you were saying:
"In the course of the deliberations of the working party, I understand information was shared between members."
What exactly did you mean by that?
A. The only information about another death that I knew of was that of Adam and I've already said that we were extremely disappointed not to have had other information shared with us.
Q. Sorry, I know that. The reason I'm pressing you a little bit about this is because some time was spent developing what actually was discussed amongst those present during the working party and the reason I have picked on this statement of yours in particular is it seems to suggest that you were informed that there was information shared between the members of the working group about further deaths from hyponatraemia. That's what that seems like. So if one takes it at its face value it would seem that when there has been a discussion about the incidence of deaths, that incidence of those have been actually shared amongst the members,

which is in fact what you thought would happen?
A. Yes and --
Q. My reason for asking you that question is that it looks like you are confirming that actually did happen?
A. And it certainly did in the case of Adam.
Q. That's the only one?
A. And that's the only one.
Q. And that happened from the member, which is Dr Loughery, direct to Dr McCarthy --
A. Yes.
Q. -- but not in the context of any discussion or general sharing amongst members in the meeting?
A. At that time, of course, there weren't meetings, there were e-mails.
Q. There was a meeting on 26 September.
A. All right. 26th of?
Q. 26 September 2001 was one meeting, and there was a meeting on 10 October 2001.
A. Yes. But I think it was only after those meetings, those formal meetings, that Dr McCarthy was informed about Adam's death.
THE CHAIRMAN: Yes, which confirms that this information was not shared in the actual work of the working party by the doctors who were involved in it --
A. That's right.

THE CHAIRMAN: -- because Dr Loughery found out about it not from any other doctor, but from the coroner.
A. From the coroner, yes.
MS ANYADIKE-DANES: Thank you.
Did you take the opportunity to discuss the work that you were doing at this stage with your colleagues in the rest of the UK at that time?
A. At that time, I'm in regular meetings with the other CMOs when we would have shared issues which were troubling us. Yes, I shared that with the other CMOs.
Q. And did you get any feedback from them about the incidences of hyponatraemia and how they were seeking to address it or how it was being addressed?
A. I was surprised that it wasn't something about which they had concerns. There did not seem to be a recognition of it as a UK-wide problem. So I recognised that it was something that we would have to continue in terms of guideline development and dissemination on our own in Northern Ireland. We did, of course, I think at some stage -- there was the yellow card that went into the British National Formulary. Again, that didn't raise the sort of response that we wanted. I think we were all hoping that this would become a UK-wide issue which could be picked up by colleges, by the Medicines Control Agency, by whatever.

But we had to, in a way, carry on on our own on this issue.
Q. Yes. I'm sorry, I have just got a note here of something I should have raised with you. I apologise for that. It's one final point on the discussion that you might have expected would happen at that first meeting.
The inquiry engaged an expert, Professor Swainson, to talk about governance matters in relation to Raychel's case. In the course of it, in his work, he had been very much involved in formulating and introducing guidelines. He was asked what he would expect in a working group like that and his view was that he would expect the doctors present to discuss any cases that they knew of or were involved in, in which hyponatraemia was involved, because that's what doctors do: they discuss their cases.
A. Yes.
Q. You're a doctor, obviously you can understand that. If you're dealing with a condition, this is the first time of formulated guidelines, if anybody's trying to think about "What are we dealing with here? What's the problem we're trying to address?", the most natural thing is to talk about the cases you have knowledge of. Would you not accept that?

A. Oh, I fully accept that.
Q. In fact, what he said is he thought it was absolutely surprising that that hadn't happened unless, of course, there was some instruction for them not to do it.
A. There was absolutely no instruction for them not to do that. I can absolutely confirm that. I would not -- if I had felt that there were issues that were being hidden or that should be hidden, that is not the way in which we would have encouraged any work to be done in the department.
Q. Yes, you can perhaps see it from the families' point of view. Their concern is that there were doctors there who did know about cases of hyponatraemia --
A. Yes.
Q. -- and that the reason they weren't discussing them is that they didn't particularly want that information to get out, and this is part of the point that the chairman was putting to you before, the deep suspicion that some of the families have in relation to potential cover-ups.
A. And whatever the reason for those deaths not being discussed in the working group, I don't know why and I'm disappointed that they weren't brought to the fore.
Q. I understand. If we go now to the audit of the guidelines. The guidelines are produced quite quickly

in the sense that the working party's first meeting is 26 September and by March 2002 you're issuing them. In fact, I think Dr McCarthy said she had rather hoped they might get out even sooner than that, such was the urgency they felt was required to get them out.
As they were being finalised, if you like, to what extent were you kept informed as to the discussions in relation to that? I know you said you delegated it and the whole point of delegating it is so that you don't have to micromanage the process. I entirely understand that. But to what extent were you kept involved as to the development of the production of these guidelines?
A. As they were being finalised and from time to time during their development, Dr McCarthy, as is her style, kept me fully informed about progress and gave me an opportunity to look at a fairly final draft of the guidelines to see what I felt. So in terms of the final product, I felt that I had been given an opportunity to look at them and to confirm whether I was happy or not.
Q. Did you know that at some stage a decision would be made as to how prescriptive they were going to be about the IV fluids?
A. Yes.
Q. And there was a point when it looked as if they were

going to say really, Solution No. 18 ought not to be used, and there was quite a bit of e-mail traffic about that very issue. Despite those in Altnagelvin and Dr Taylor in the Children's Hospital wanting Solution No. 18 to be named and shamed, ultimately a decision was made that they wouldn't do that; one would simply highlight what the areas of concern were and what people should be measuring and looking out for. Did you know that that decision, if you like that policy decision, had been made as to the content of the guidelines?
A. Yes, indeed. In fact, whether or not Solution No. 18 should continue to be used or should be banned was, in effect, initially what I felt that the guidelines would define for us. Dr McCarthy kept me well-informed on the research, on the published research on Solution No. 18. So we knew there were issues about Solution No. 18 from the Arieff article and later the Halberthal article. What we didn't have was substantial evidence about what might be safer to use. So there was a huge difficulty in determining a specific fluid. The problem being might you cause more harm in the absence of fundamental evidence of benefit.
And I think that what we heard back from the MCA about hyponatraemia being a risk with all fluids didn't

indicate to us that Solution No. 18 at that time should be banned.
Q. Ultimately, Solution No. 18 did get a very bad -- let me just pull out the point. Ultimately, that's exactly what happened in relation to Solution No. 18, wasn't it, that to a large extent, apart from very specialist areas in which it was required, like renal units, for example, it was excluded?
A. Yes, but right up until 2006/2007, still in very general use throughout the UK in paediatric departments. But at that time, we were -- what would you say? -- absolutely persuaded that we needed to stick with the evidence. So the problem was an absence of evidence in terms of what might be better.
Q. Was that a reason why you introduced the ability to have local protocols, which would allow individual trusts to take a slightly different view as to what they wanted to do for the prescribing fluids? Because, as you know, Altnagelvin excluded Solution No. 18 altogether --
A. Yes.
Q. -- and they signalled that they were going to do that and was in their local protocol.
A. Yes, but certainly for some children in paediatric intensive care, Solution No. 18 might still be the solution which is best in certain circumstances. So

you're absolutely right, it needed to be local protocols to suit local circumstances.

Q. And if that was the case it was even more important how that was working, if you like, was being audited?

A. Yes, yes.

Q. So this is the reason why, is it, that you not only included a requirement that they audit the implementation of, let's call them the department's guidelines, but they also audited the implementation of their own protocols?

A. Yes.

Q. When the guidelines were drawn up and just before issuance, you presented them to a meeting of CREST. One of your reasons for doing that is that you really wanted CREST to endorse them. I think there's a reference to giving them the Kitemark.

A. Yes.

Q. And they did, of course, do that, and you knew at that time that CREST were moving to develop adult guidelines.

A. Yes.

Q. Did it occur to you that at this point when you were going to issue them and you were going to require audit work to be done in relation to them that you might then have CREST involved in doing that as they were already formulating something of that sort in relation to the

adult guidelines?

A. That would have been the intention, that the 18-month to two-year mark, when the regional guidelines had been in place, that there would be a regional audit. I would not have wanted that conducted by CREST, but by the Regional Multi-professional Advisory Group, which was set up and established, resourced by the department, to undertake those sorts of audits.

Q. I meant something slightly different from that, although thank you for that clarification. I meant that CREST was developing, alongside the adult hyponatraemia guidelines, a sort of an audit template, which would go out with those guidelines and would be of assistance to the trusts in developing their own local audits before you get to the regional ones, if you like.

A. Yes.

Q. And this local auditing is going to provide the information that the regional audit would audit, if I can put it like that.

A. Yes.

Q. So did you think at that time that you could refer that aspect of the work that you wanted to have done to CREST and solicit CREST's assistance to provide the local audit template for the paediatric guidelines?

A. On reflection, I could have done. The issue with CREST

was that they have an extremely busy agenda and a lot of issues actually come to CREST and they have to prioritise what they're doing. So I recognise the pressure that the CREST group was on. I do know and recognise the issue about having a template for audit and that that wasn't done. We had one person, Dr McCarthy, who was doing all of this work on the guidelines together with a full-time other job. These were duties which were imposed over and above her full-time job. I think we ran out of time in terms of sending out an audit tool with the guidelines. And I suppose in recognition of the need to get the guidelines out quickly, I think the audit tool became a secondary issue.

Q. Yes, I recognise that, and that in fact was the evidence that Dr McCarthy gave. So I perhaps might approach it this way: in fact, I think I had raised it with you like that. Once you had got those guidelines out, then was there any thought that the audit tool or the template could be developed and sent out subsequently, because the benefit of that, of course, would be that the auditing that was being done at local level would be being done in a consistent way if they were all responding to a template that the department had produced?

A. That would have been a good thing to do. We didn't do that.

Q. Did you not do it because it sort of slipped your mind -- not necessarily your mind personally -- because the focus had been on getting the guidelines out or did you not do it for some other reason because you ran out of resources or for some other reason?

A. I think at that time we really ran out of resources. We had been under a lot of pressure, Dr McCarthy particularly. And I expect in the busy-ness of what is the department's work, it didn't get done.

Q. It didn't get done. When your letter goes out, it's 25 March 2005. The reference is 007-001-001, and if one can pull up 002 next to it, you can see who it's addressed to, just about everybody. It's extremely comprehensive. Then if one looks down, you can see that the work has been supported and endorsed by CREST, so they have that confirmation, and you give your explanation as to how serious it is and the risk of hyponatraemia.

And then right down at the bottom of the page you say:

"The guidance is designed to provide general advice and does not specify particular fluid choices."

And that's a decision that was made:

"Fluid protocols should be developed locally to complement the guidance and provide more specific direction to junior staff, particularly in sub-specialty areas."

Over the page you say:

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

So even if those involved in the working group had not taken that back to their respective hospitals and trusts, you have signalled to them the fact that you want audit to be undertaken. Did you wish to have confirmation immediately that that was happening?

A. I think had we been a guideline development group like NICE or indeed any of the other colleges which have guideline development units, we would have been resourced in such a way -- I mean, NICE has a budget of 70 million has 570 staff. If we'd had the staff and resources and if we had been a guideline development group -- it was just Dr McCarthy and I -- of course what we would have done would be to go out to inspect, to monitor and to ensure audit and compliance, et cetera. We quite honestly didn't have that resource and it may be naive to expect that a letter going out like this will get full compliance, but I really expected that

in the knowledge of Raychel's death this would all be taken very seriously indeed.

Q. I don't mean at this stage whether you should personally be going out, but I'm thinking of another important guidance, some many years earlier than this, which signalled a change in consent, which is a guidance that was signed off by Mr Hunter and sent out in 1995. In fact, you were probably in the department when that went out. That went out saying, similar to this, changes must occur. And the conclusion of the letter is to say:

"And we are to receive notification by [in that case it was the end of the year] that there has been compliance with this."

And that was the structure of that. When I asked Mr Gowdy whether he would have expected a letter like this, which was going to be followed by the guidelines, to have required, at the very least, confirmation that they had been received and that they were being implemented, and he said that given the importance of these guidelines he would have expected that.

A. Mm-hm.

Q. Do you accept that?

A. I accept that, yes.

Q. Thank you. Well, maybe as an alternative to that and maybe to copper fasten the significance of it, when the

adult guidelines were issued there was actually a presentation, as you probably recall, of the adult guidelines. People were invited, there was a presentation, which went through the significance of what was happening with the change. Was there any thought that there might be a presentation of these guidelines because these were the first guidelines for hyponatraemia at all, let alone for paediatric cases? Was there any thought that you might have a day like that and bring some greater publicity to the fact that this change was happening?

A. In a way, I expect that having had it endorsed by CREST that at some time in the period of their open conferences that it might be picked up. It wasn't. So we did that much later on -- I think it was in 2004. What we did, in the absence of any conference where you might get some people along, but obviously not everyone, was to try to promote the guidelines through whatever processes we could. We did that through bringing it to the specialty advisory committees where the leaderships of the various specialties were there. And I really expected and hoped that the guidelines, having been developed with an attempt to make sure that ownership was felt as widely as possible, that this would then be taken on by the profession, by the medical community,

and that ownership would be enough to take that forward. But we did what we could in whatever platforms we had to promote and to promulgate the guidelines.

Q. At the same time as these guidelines are going out to the trusts and various relevant consultant groups, did you think that you might communicate with the postgraduate dean, for example, or anybody on the training and education side to make sure, in parallel with this, given that this had arisen out of concerns about fluid management and as you had read through the literature, you recognised maybe there was a weakness there in what the clinicians, particularly in the district hospitals understood? Did you think you might tie-in the university in that way?

A. At this moment when this was going out we didn't do this. This was to reach every doctor who was currently in practice.

Q. I recognise that.

A. And we would have expected then that the guidelines be included in the -- when new doctors arrive, the processes that are in place to introduce them to the protocols and guidelines in place in each trust. And then, as you know, at a later date we did then --

Q. That's exactly why I ask you. Because in 2004 there's correspondence that goes out to Professor Savage,

there's correspondence that goes out to Dr McCluggage, and what you're seeking there -- and you're seeking as a matter of urgency -- is to know that these issues are being taught. But why I'm asking you is: instead of waiting until 2004, why didn't you include them in this initial raft so that they can be introducing whatever additions to their courses to address this while the treating clinicians are dealing with it in the hospital?

A. Yes, the letter did not go out directly to those people, but --

Q. Do you think it should have?

THE CHAIRMAN: I've got the point.

A. It should have, but also they were present at the Hospital Services Subcommittee where we would have discussed the hyponatraemia, ie I don't believe that they didn't know about them. However, we did feel that it was an important issue then in 2004 to make sure that it was again brought to their attention.

MS ANYADIKE-DANES: And what alerted you in 2004 to be doing that?

A. I think really from the audit and recognising some of the outcomes of the regional audit, that we needed to continue doing more. And at that time, it seemed quite obvious that we needed to include -- I don't know why we didn't specifically put it on the -- write out directly

to them in the initial period.

Q. You do go out to seek confirmation of that and we're just going to come to that in a letter that you send out in 2004. That post-dates Conor's death and you hear about Conor's death, is that correct --

A. Yes.

Q. -- before these go out?

A. Yes.

Q. And when you hear about Conor's death -- and in fact it's referred to you because there is some thinking that it might be something relevant to you in view of the work that has been done on the guidelines -- do you want to see to what extent Conor's death is affected by anything in the guidelines? Is there any thought that you might look at his death from that perspective?

A. I think I took it on trust from the letter from --

Q. Sorry?

A. The letter from Dr Sumner made it clear that he felt that there was still an issue around the implementation of the guidelines, and to me that was evidence enough that we still had work to do.

Q. Yes. Well, when you were asked about the possible significance of Conor Mitchell, you said -- this is your witness statement at 075/3, page 8:

"Since he was not apparently nursed in a paediatric

ward, I don't think I/the department thought Conor's death had any implications with respect to the successful implementation of the guidelines. As discussed elsewhere, however, there was a discussion shortly after this when a care pathway was proposed in response to the audit outcome and various other factors."

But if we just stick to that earlier part that neither you nor the department thought that Conor's death had any implications with respect to the successful implementation of the guidelines because he wasn't nursed in a paediatric ward. Did that not concern you that what your original letter had said is that you wanted those guidelines to go out and the poster put up anywhere where children might be treated? And given the age at which children were admitted to paediatric wards, it was quite possible that in some hospitals you would have a child treated on a non-paediatric ward?

A. Yes.

Q. That's exactly, as you know, what happened with Conor.

A. Mm-hm.

Q. So did you not think that there were implications for the implementation of the guidelines? The mere fact that a child of 15 with the body habitus of an 8 to

9-year-old was being treated on a non-paediatric ward where there may not have been any putting up of the poster, any particular training about what was in those guidelines, did you not think that was a relevant issue?

A. Yes, I absolutely agree, and, chairman, can I say that on receiving the letter from Dr Sumner, it was clear that there was more work to do on implementing the guidelines and that particularly using the postgraduate council and the dean, that might be an additional way of pushing that forward.

There is a separate issue, Ms Anyadike-Danes, which you have picked up, which is about children not being treated on children's wards.

Q. Yes.

A. And that is indeed an important issue. It shouldn't matter where a child is being treated. I know that in some hospitals, in the past, there hasn't been enough capacity in order to -- until capital development was put in place to treat children as they should be appropriately. But no matter where they're treated, those guidelines should have been in effect.

Q. Yes. I wonder if you thought that it perhaps might have made it clearer if that -- you did, in fairness to you, put in your letter that you wanted those guidelines to go out to wherever children were going to be treated,

but from the evidence or the material that the inquiry's received, it seemed very much as if that was understood in terms of paediatric wards, and that's not what you meant.

A. No.

Q. And I wonder if you thought that that perhaps could have been made a little clearer, recognising that there are hospitals where children of child size or even child age are being treated on non-specialist paediatric wards, that somehow that could have been emphasised that you really need to make sure that those people not only see these guidelines, but are trained in them? They may only periodically see children, so their experience may be even less and it might be even more important that they're taught about them.

A. I agree, yes.

Q. Thank you. Then if we go to the letter that you send out in 2004, 007-075-148. It's dated 4 March. There it is. You refer, of course, to your guidance and you refer to the trust being encouraged to develop local protocols to complement the guidance and to provide specific direction to junior staff. And you say that the guidance should be supplemented locally with detailed fluid protocols.

Then, right at the bottom, you refer to the adult

ones that have been issued by CREST. You say:

"The purpose of this letter is to ask you to assure me that both of these guidelines [I'm focusing on the paediatric ones, obviously] have been incorporated into clinical practice in your trust and that their implementation has been monitored."

And now you do give you a time when you want that assurance: you want that assurance before 16 April.

Can I just pause there and ask you: before you issued this guidance, had there been any discussion in any of those meetings that you have regularly with the senior clinicians and administrators as to how they're getting on, if I can put it that way, in implementing these guidelines? Are there any barriers that they're experiencing, any impediments, difficulties, resource issues? How is this happening? Because this was new, so you'd want to know that they were being introduced smoothly, embedded into clinical practice. Was there any interaction about that?

A. There was interaction, of course, at the specialty advisory committees and interaction with clinicians as I went around, as and when I could, visiting hospitals and particularly the paediatric units. In the absence of having the ability to inspect and monitor in a way in which RQIA might do, in the absence of that ability, but

rather in that more informal approach, I have to say that I wasn't hearing that there were difficulties in implementing the guidelines. And certainly, I can recall a visit to the Children's Hospital and obviously the history there around whether or not they had guidelines in place before these guidelines. But I wasn't hearing that there were problems in terms of implementation.

Q. Well, did you, for example, seek to know about the experiences specifically of any trust in relation to implementing this? Yes, you're discussing it with them, but are you pressing them a little and saying, "Look, these are important things, can I be confident that these guidelines are being implemented?"; is that not what you're seeking?

A. Yes.

Q. And nobody indicated to you that they weren't being implemented, presumably, otherwise you'd have done something about it?

A. That's right, but I would hasten to add I wouldn't regard that as a formal monitoring process I was undertaking.

THE CHAIRMAN: More to the point, you weren't receiving any comments that the implementation of the guidelines was in any way problematic.

A. No.

THE CHAIRMAN: Had you been told that there were, in some way, difficulties in implementing them, then that is something that you would have checked to see what the problem was?

A. Absolutely, chairman. What I was hearing was around Solution No. 18, you know, that there were -- obviously in Altnagelvin a decision had been taken, et cetera, and --

THE CHAIRMAN: Okay.

MS ANYADIKE-DANES: And you weren't hearing that we're having enormous difficulty formulating an appropriate audit tool for this or monitoring it? There was no adverse comment about the instruction that had gone out in March 2002?

A. There were no adverse comments about the guidelines.

Q. Thank you. So then you send this and you want an assurance. What do you have in mind you're going to do with the responses of these, apart from check that they're responding? If in any way you get an adverse response, what do you have in mind that you'll be doing about that when you send this out?

A. I expect that, had I heard that there were problems with the implementation or that the guidelines didn't look as if they were protecting children, then obviously what

I would have wanted would be the working group established again to check again the evidence base, et cetera. I think the purpose of this letter was as a reminder of the importance of this.

Q. Yes, but also you wanted to be assured that what you had asked to happen was in fact happening?

A. Yes.

Q. We have put together a schedule out of the responses you received. If we can pull up a two-page document, the first page, 337-006-001. The pink indicates where it doesn't seem to me -- although I may be wrong, as I'm only interpreting it -- that you've actually received the confirmation that you required.

What you're requiring is an assurance that the guidelines have been incorporated into clinical practice, one. And, two, that their implementation has been monitored. That's what you want to know. And if we look Altnagelvin at, you are told in terms of the incorporation into clinical practice:

"I can assure you the guidelines have been incorporated into clinical practice."

That's a clear response of the sort that presumably you were hoping you'd receive.

A. Mm.

Q. And then if we look under the monitoring, the

implementation, what it says there is:

"The implementation of guidance is monitored through the trust's incident reporting mechanism."

What would you have understood by that?

A. To which particular point, sorry?

Q. What would you have understood by their response to you that:

"The implementation of the guidance is monitored through the trust's incident reporting mechanism"?

A. I expect that meant that if there were untoward events and yet the guidelines had been followed properly or to the letter, that still things had gone wrong, then that would have been reported through on the incident reporting.

Q. So that incident reporting mechanism would be triggered if an event occurred in which the guidelines had not been followed?

A. Or indeed if they had been followed.

Q. If they had?

A. Yes.

Q. So guidelines would be flagged up in that system?

A. Yes.

Q. Okay. Then let's have a look at Craigavon, for example. Craigavon say the guidelines have been adopted throughout the trust, including where children are

treated by surgical teams. As you know, there was a subsequent issue about that, but at face value when you receive that, that would appear to you to give you the confirmation that you were seeking, would it?

A. On first looking at it, yes, it would.

Q. And then if we look at what happens under monitoring the implementation:

"The trust has participated in a regional audit of the guidance."

That, of course, was the one that Dr McAloon conducted. That's not what you had in mind, is it?

A. No, it's absolutely not.

Q. You wanted them to be doing that locally?

A. Yes.

Q. The results of that local monitoring or audit work are what would be the subject of the regional audit?

A. Absolutely.

Q. So when you got that, you recognised that Craigavon had not complied with what you wanted?

A. Yes.

Q. And what happened as a result of that?

A. I think it became quite clear when we saw these responses and the non-responses that simply sending out a letter asking for assurance is not an appropriate tool in terms of the monitoring and assurance of guidelines.

In the knowledge that we were, in the department, putting in place RQIA, I would have at that time acknowledged that we needed a much more systematic approach to ensuring that guidelines like these were being put in place.

Q. Yes.

A. Simply sending out a letter --

Q. I understand that.

A. -- proved itself not to be adequate at all in terms of monitoring.

Q. Yes. Although might you have anticipated that simply sending out a letter is not necessarily a way to guarantee -- not guarantee, but assure yourself that something as important as this will actually be introduced. It might be your hope and expectation, but it's not a way of satisfying yourself of that, is it?

A. It's not.

Q. When you saw this come back, and it's pretty stark, that what you wanted to happen had not happened, quite apart from saying, "Right, we need to have a body that will deal with this", is there not some response that goes back to Craigavon for their own learning? They may have misunderstood what you wanted them to do. Is there not some response that goes back and says, "That's not what I had in mind. I had had in mind, for the last two

years, that you'd be engaging in a local audit of the introduction and implementation of these guidelines"?

A. Yes. I agree that had we had the resource in the department, which could have specifically monitored, measured, even responded to these, in some cases, inadequate responses and nil responses, that we could have worked even with this information to make things better.

Q. If we just go over the page to show you the scope of it. 002. More pink.

THE CHAIRMAN: That confirms how late and inadequate many of the responses are.

A. Yes.

THE CHAIRMAN: Thank you.

MS ANYADIKE-DANES: When you saw that, were you concerned that you had been engaging with clinicians and officials from the trusts, nobody had indicated to you that they had been unable to institute the monitoring or auditing of the guidelines and local protocols that you wanted, and yet when the response comes back, it's absolutely clear that a significant number of people who should have been implementing and monitoring those guidelines were not? Either they couldn't respond to you or couldn't provide you with any evidence that they had been doing that. Did that not concern you?

A. I think what I understood was the inadequacy of these responses. They weren't telling me that the guidelines weren't being implemented. It was not enough evidence to say they were or they were not.

Q. I suppose what I'm trying to get at is this: you used these meetings that you have at the special advisory committees and so forth as a sort of barometer of where things are. This is a forum where people bring concerns, you bring concerns and you discuss them and you use them as the place to learn what's happening. Some of that, if it's relevant, you take back to, if it was appropriate at the time, the chief executive, maybe even the Permanent Secretary. So this is an important place for you to learn what's going on, quite apart from ad hoc trips you might have to hospitals and so forth. And what I'm really trying to ask you to reflect on is whether, when you see this sort of thing, does it not call into question how adequate a forum that might be for learning about the difficulties that are actually happening in the hospitals and trusts?

A. Absolutely, but we had already understood that to be the issue and under "Best Practice, Best Care" and the processes and systems that we were putting in place already at this time, being formulated and resourced and put in place, we recognised the need for, in terms of

quality assurance, that we needed a body like RQIA, as it became, that would in effect be able to undertake those sorts of processes that needed to be done. We absolutely had a recognition that this was an important issue in terms of promoting quality within and throughout the service.

Q. Yes.

THE CHAIRMAN: Okay.

MS ANYADIKE-DANES: It's a little after your time, but when you had had these responses, you've had Dr McAloon's regional audit, albeit that it was a relatively small piece, but nonetheless it was enough to highlight to you concerns, so all that had happened and you'd started to have thoughts about whether a care pathway should be developed as a response to that and tighten up the mechanisms in terms of the implementation of this sort of guidance. You then leave, yes, and the new guidance comes in in 2007, and even when that is being monitored by RQIA, who you thought is a body that would do it -- I'm sure you have seen the reports of that -- even then RQIA had deep reservations as to the extent to which there was compliance. Given the prominence that was given to these guidelines as they started in 2002, does that surprise and concern you that, even by 2008, one is not having an appropriate or at least full compliance or

anything approaching that with them?

A. It does. It confirms just how complex and difficult it is within the service to keep assuring yourself that these things are being done. Because of the churn of medical professionals, because of the need to keep reinforcing the messages, it is a complex and difficult issue to do and we have to work very hard at putting things right.

Q. I mentioned before, but in fairness to you, to give the reference, you did in 2004, as well as seeking confirmation from the trusts, you did write to Professor McCluggage on 8 July 2004. You refer there to recent coroner's inquests that have highlighted the need for:

"... better training in fluid administration and management, particularly in children."

And as part of a strategy to address the problem you say that you want him to:

"... ask the training committees to consider it a priority area."

And you refer to the guidelines that have been developed and the fact that there should be an audit programme, and you say:

"It is essential that doctors in training participate in such audits."

So you're really wanting him to address two sorts of things: one, the message to go out in terms of the importance of fluid management and how that's addressed and some of the risks; and also the message to go out -- I'm talking about training message -- about participating properly in audits. That's what you send out in 2004. You send a similar letter to Dr Savage, who was director of the undergraduate education then, also seeking to satisfy yourself that there is better training in fluid management, and you say that you regard that as an essential point. Did you get, in terms of Professor McCluggage, confirmation as quickly as you wanted that the changes in education and training were happening?

A. I'm trying to think back as to whether or not I would have got written response from Dr McCluggage on that, but I do know that at that time -- I don't know what's happening subsequently -- it was taken on board quite vigorously and particularly at local level. I have to say, chairman, that in our efforts to try to implement the guidelines and make sure that they were up-to-date and that protocols were present locally, there was -- I mean, in a way it was a small army of very committed paediatricians who were working very hard across the region to make this happen. I have to give credit where

credit is due in the work that they were undertaking.

Q. Yes.

THE CHAIRMAN: Thank you. Let's move on.

MS ANYADIKE-DANES: We were provided with information in relation to the follow-up that you were seeking. We've had it specifically in relation to the Erne Hospital and Altnagelvin Hospital and you might imagine why the inquiry would be interested in seeing what was happening there. I can pull up the response, 345-002-001 and 002.

While that's coming up, I will put to you the question that the inquiry sought:

"Please ask the Western Trust to address the following matters: were any steps taken at Altnagelvin and Erne Hospital to audit compliance with the 2002 guidance and provide copies of any protocols which were developed locally; and, if so, who was responsible for conducting this audit of compliance and who did they report to?"

I don't quite know why that letter isn't coming up, but I can maybe, in the interests of time, move on and tell you what the response was that we received from the Directorate of Legal Services. If one takes the first question, which was whether any steps were taken, in relation to the Erne Hospital what the inquiry was

told is that the trust has located an audit tool created in or around the end of 2006. That's well after Dr McAloon's audit, well after the response that you've received which created the concerns that you had. And in fact, after you'd gone, really. And they attach it together with the results of an audit of January 2007.

Then in relation to the second point, which was who was responsible, the answer is -- they actually weren't able to identify who was responsible for putting together the audit or carrying it out. They weren't able to do that until the information was coming in at around 2006/2007. So notwithstanding all the concerns that there had been at the Erne Hospital, until 2006/2007, not only couldn't they produce anything in relation to audit, but nor had it been possible to identify who might be in charge of that particular activity. By that time, is that not something that concerns you?

A. Well, it absolutely concerns me because each trust should have a designated audit manager. That was an absolute requirement. So I'm not sure who put that response together. I am not here to defend the Erne Hospital, but I'm just surprised at that response.

Q. Then I'm going to go on to ask you just a few questions about the statements that you made to the media once

these deaths and their involvement in hyponatraemia became clear. As I'm sure you're aware, the series of interviews that you gave caused the families some disquiet.

A. Mm-hm.

Q. I know you appreciate that. You've provided witness statements dealing with it. I don't propose to go through all those interviews and identify the particular aspects of them that caused such concern; they are in your witness statement. But maybe I can introduce the matter in this way: the result of it was that one family, Raychel's family, made a complaint to the GMC, and you're aware of that.

A. Mm-hm.

Q. The subject matter of their complaint is: one, that you knew or should have known that Lucy and Raychel's deaths were caused because they were given the wrong type and volume of fluid, and not because their reactions were in any way abnormal. They did not receive proper fluid management.

A. Mm-hm.

Q. Two, you knew or should have known that Lucy's inquest was delayed because information had been withheld from the coroner improperly. So Lucy didn't have an inquest when she should have done when she died in 2000 in the

Children's Hospital -- she didn't have it until much later on -- and that's because the proper information, they say, wasn't given to the coroner so that his office could require an inquest.

Then, thirdly, you knew or should have known that clinical mistakes rather than any abnormal reactions were responsible for Lucy and Raychel's deaths. And then, finally, that your comments in media interviews were a misrepresentation of the facts and not in the interests of the wider medical community in Northern Ireland. And in fact, they considered that you were seeking to cast the blame on the coroner for not knowing the extent of the problem of dilutional hyponatraemia sooner. So that is the concern, deep concern that prompted their referral to the GMC.

Just before I ask you about your response to that, one of the things that the families wanted to know is to what extent did you seek to brief yourself, or be briefed -- you'd never pretended to be a specialist in fluid management, so to what extent did you seek to be briefed before you started to give public interviews about the children's deaths?

A. Well, firstly, I think what I really want to say is that I deeply, deeply regret that anything that I said could have caused any further distress to the families.

And on reflection -- and if you want to take me through those issues I will respond to them. But on reflection I realise -- I realised much after the interviews -- that some of the things that I said could have been misunderstood in terms of what I was trying to say. They were very poorly crafted. I wasn't fully -- didn't fully brief myself on the clinical issues.

I'm a public health doctor, it was 30 years since I'd had anything to do with fluid management. So my words were not well crafted. I have to say that it is with much regret that I look back on those interviews.

I did expect only to talk about the fact that we had guidelines in place and that what we were doing was trying to prevent any deaths happening in future. I think I said at each interview that I knew that those deaths were all preventable, that they were in fact clinical accidents, they were preventable, and that is the dreadful, dreadful tragedy of that.

But from my own personal point of view, as a doctor -- and indeed as a mother, a grandmother -- when you begin to understand the grief that those families are carrying, it is with deep regret that I added to that.

Q. I understand that.

THE CHAIRMAN: Thank you very much.

MS ANYADIKE-DANES: There is one point which I think they would wish to hear from you on, if you can. You've referred to the fact that you regret the fact that what you said was interpreted in particular ways and that's not what you intended. You wanted to focus on (a) the guidelines and (b) not to deter anybody from taking their child to receive intravenous therapy if that's what was necessary in the interests of their child's proper care, as I understand you to say.

A. Mm-hm.

Q. But it was understood in a different way because of some of the terminology that was used. So do you take responsibility for the fact that what you said was capable of being understood in a way that you did not intend?

A. I absolutely take responsibility for that. As Chief Medical Officer, it was incumbent on me to have clarity and certainly not to add to any grief that the families would have felt. I have to say that I was ill-prepared, particularly for one of the interviews. Normally, when I have been interviewed in the past, it had been through our highly professional health correspondents, who are always intent on getting the message over. I wasn't prepared for the interview at Ulster Television. I could never be -- I'm not the sort of person who can

respond in that sort of stressful environment.

So therefore, I take full responsibility for saying things in a way which could have been misinterpreted. That was never my intention and it has cast a shadow over my life since.

MS ANYADIKE-DANES: I understand. Mr Chairman, I wonder if you would just give me a couple of moments to see if there is anything further?

THE CHAIRMAN: Doctor, thank you very much. That's very direct and I hope it helps you to get it said in public and I hope it helps the families to hear you say it.

We're almost finished, I will rise for a couple of minutes and Ms Anyadike-Danes will confirm whether there are any more issues to be raised from the floor. Thank you.

(3.50 pm)

(A short break)

(4.27 pm)

THE CHAIRMAN: Ms Anyadike-Danes?

MS ANYADIKE-DANES: Thank you. I'm sorry that you've had to wait longer than I intended, but there are a few queries to raise with you.

The first relates to one of your interviews. I wonder if we could pull up, first, witness statement 075/2, page 11. It's your answer to 23(a) and

in relation to Adam. As I understand it, this part of the interview where you refer to Adam was the subject of a complaint that Adam's mother made to the GMC as well, and you'll be aware of that.

You refer to Adam's case as being an entirely different clinical situation. When you were asked to expand on that, which you do at 23(a), you say that you understood Raychel had been a healthy child with no concurrent medical conditions prior to her admission to hospital:

"I considered this to be different to Adam's case since he had a chronic condition that had required significant medical interventions in the past. Adam also died during the course of a kidney transplant, which seemed like a different clinical situation to Raychel, who died following a routine appendicectomy."

The reason why that caused Adam's mother so much distress was because all the medical evidence showed that Adam was actually in possibly the best health he'd been in for some time before he went for that operation. So he didn't have ill health; what he had were defective kidneys, one of which was going to be the subject of a transplant. That was the first thing. Her concern was that this made it sound that he was ill and therefore in some way different to the other children,

say Raychel or Lucy, who hadn't been ill.

And also the reference to him dying during the course of the kidney transplant, that caused her distress because it made it sound as if, in some way, if not attributable to his condition, but perhaps attributable in some way to the operation he was having as distinct from Raychel, who was having a perfectly straightforward routine appendicectomy with no problems at all. The reason that caused her distress was because the evidence was it was absolutely nothing to do with his operation that gave rise to the development of what proved to be his fatal hyponatraemia; what it was was an egregious error in the calculation of the fluids he was to receive, both in volume and type, and that's what had given rise to the development of his hyponatraemia and cerebral oedema.

So the question that she would like you to address is: before you started to make clinical comparisons between the children and the possible significance of those, to what extent did you inform yourself as to Adam's condition and satisfy yourself as to whether, in fact, it had in any way contributed to his problems?

A. Can I say that I apologise because I did not make myself fully aware of Adam's clinical condition before his operation? I was in no way trying to infer -- and

I hope this did not come across as that -- that Adam's death was anything other than preventable. I think merely making the point that Adam's underlying medical condition meant that he had to be treated, obviously, in a regional centre, but with Raychel, here we had an appendicectomy performed many times across Northern Ireland in centres other than the regional centre, and yet here too we could see that clinical incidents could happen in such a way that we get such dreadful outcomes.

It was the fact that because of Raychel's death coming to me, the terrible implications of that -- because of the number of appendicectomies, tonsillectomies, adenoidectomies, things that are done on a daily basis in Northern Ireland, here indeed we had potentially every child at risk and therefore action needed to be taken. I'm really sorry if anything that I said inferred in any way that Adam's death was anything other than preventable.

Q. Thank you. I should just say in fairness that the two referrals of you to the GMC did not lead to any sanction on you by the GMC. Rather, they expressed some concern about the language that had been used and they asked you to reflect on that and to the impact of that. I think in fairness, lest anybody not understand what the

outcome of that was.

I'm also asked to address a few other points with you. One relates to the knowledge of the deaths of the children. I think your evidence is that you knew about Adam in 2001 and that arose out of the work that was being done by the working party. If we leave Claire to one side for the moment, you knew about Lucy in 2003 --

A. Yes.

Q. -- and you knew about Raychel in 2001 very soon after her death --

A. Mm-hm.

Q. -- as we all know. Mr Gowdy, Permanent Secretary, doesn't know about Adam until October 2004. He doesn't know about Lucy until February 2004 and he doesn't know about Raychel until February 2004. Is there any reason why, as you were learning of these deaths, you wouldn't have told Mr Gowdy about them?

A. There is no reason why.

Q. Why didn't you?

A. I don't know. It would have been, on reflection, an obvious thing to do. I suspect because I regarded these as clinical, medical issues that were about learning how to ensure that we prevent these deaths happening again I did not, I suspect, feel that -- I can't explain why. I'm sorry. It was no intention to cover up those deaths

and the implication coming out of one of the media programmes that I might in any way be involved in a cover-up was something which I found extremely distressing. It is something I could never, ever be part of.

Q. The point that I'm being asked to put to you is that by 2003, when you knew about Lucy's death, you knew about two previous deaths and you knew that you had a problem which had to be addressed by regional guidelines, and in fact you had done that. So when you get to Lucy's death, have you not got a regional issue of sufficient moment that you should be telling Mr Gowdy about?

A. I think, when I reflect on that, that is correct, yes.

Q. Thank you. On the other side, you don't know about Claire's death until after you've left the service, or at least this aspect of the service, and we know that from your witness statement at 075/3 at page 9. There, you say you found out about Claire's death after you'd retired from the department. But in fact, Mr Gowdy knows about Claire's death at the very least by January 2005 because the chairman of the inquiry writes to him because there was an issue as to whether Claire's death and the circumstances of it will be included as part of the work of the inquiry, and he's the Permanent Secretary at the time.

Given the issues that had arisen in relation to these deaths, you'd had the UTV programme, the response of the minister to that had been speedy -- or at least the one in October had been speedy in setting up an inquiry -- would you have expected Mr Gowdy to have told you that it had come to his attention that there was another child's death in which hyponatraemia may be implicated?

A. He may have done and it may be that my memory of those events is such that I had forgotten that. So I can't say whether I heard or not from Mr Gowdy, but certainly when I was replying and answering that question, I thought it was after I had left the department. I couldn't put a date on when I knew about Claire's death.

Q. Yes. And then do I take it from the way you've answered that that you'd have expected him to tell you about it?

A. Yes.

Q. Dr Carson is the Deputy Chief Medical Officer in 2005; that's correct, isn't it? So he's your deputy --

A. Yes.

Q. -- and you're in post until the following year. Does Dr Carson tell you that he knows about Claire's death? Is there a discussion?

A. No.

Q. But he knew about Claire's death in, if not August, certainly September of 2005. The reason we know that is -- and I'll pull it up, 139-089-001. This is a letter from Mr Walby, who's the associate medical director of the litigation and management office at the Royal. You see the date there. It's written to him by the coroner and it's headed up "Claire Roberts", and do you see down at the bottom it's cc'd to "Ian Carson, Deputy Chief Medical Officer". What is being discussed, of course, are the associated reports that are being prepared for Claire's inquest.

So would you have expected him to have had a discussion with you about Claire, particularly in the light of your previous involvement in the formulation of the guidelines and your interest in this area?

A. I would have expected him to have had that, but at that time I was in the neurosurgical unit of a hospital in London undergoing major surgery, and so he couldn't have told me, and in fact I was off for some months at that time.

Q. I understand. Then the final issue relates to a particular aspect of audit and the minutes of the meetings of Directors of Public Health which you attend. The one of 6 March 1995 refers to how audits of death in intensive care should take place every three years.

We can just pull it up in ease of you so you don't have to cast your mind back to something that happened in 1995. 320-063-002.

You can see that as item 4, and in fact it really comes as a suggestion from you, and you're going to write to the Directors of Public Health outlining new arrangements. So does that mean for you an audit of deaths in intensive care was something of importance?

A. Yes, these were national UK-wide audits. ICNARC was the name used for it, I can't remember what it meant. I think that's what I'm referring to here. They were conducted in the same way as the confidential inquiries in that they were voluntary. I think from memory -- I would need to check, but I think there was a pretty full implementation of that UK-wide and a national audit programme across Northern Ireland.

Q. Yes, and if that was happening in Northern Ireland, would that mean you would be able to see audits of deaths in paediatric intensive care or was that confined to adult intensive care?

A. I can't remember. I really can't. If I'd known that question would come, I would have tried to find out. I suspect it was, I think it was intensive care --

Q. Generally?

A. -- generally, but I ...

Q. I understand --
THE CHAIRMAN: Would it make sense to exclude paediatric intensive care?
A. No.
THE CHAIRMAN: So unless there was a specific reason for excluding paediatrics, we should read that as if it's all deaths in intensive care?
A. Yes, although there may have been a specific paediatric intensive care element of it. I can't tell you at this time, sorry.
THE CHAIRMAN: I wonder, could somebody follow up on that net point for us?
Mr McMillen, I'm not asking for all this to be produced, but if somebody could confirm whether Dr Campbell's instinct was right that that was all intensive care deaths and not just adults.
MR McMILLEN: Very good, Mr Chairman. We'll do that and report back.
THE CHAIRMAN: Thank you.
MS ANYADIKE-DANES: What happened to that? Did you indeed receive regular or periodic audits of deaths in intensive care?
A. I would have received the summary reports of it in the way that all confidential inquiries were summarised nationally and each of the CMOs would have received the

summary report of any outcomes of those audits. You'll be aware of the confidential inquiry mechanisms.
Q. Yes. So that's a requirement by an external body, if you like, that's to happen and Northern Ireland participates in those national inquiries. So in that way, Northern Ireland hospitals that had intensive care units, including of course the Children's Hospital, would have to have a system whereby they were accurately recording the deaths in intensive care?
A. That's almost right, except there wasn't a requirement at that time. The theory was -- and the evidence pointed to this being the case -- that voluntary participation in these confidential inquiries meant that there was a full, frank, open disclosure of all the issues and that there would be greater learning because of that. Now, there are arguments as to why it should be voluntary, there are arguments as to why or why not it should be confidential, but it was a well-trampled pathway with --
Q. But the department wanted hospitals to participate?
A. Absolutely, yes.
Q. And all the hospitals had their officers who collected the relevant information and submitted it, and with the exception of some in Altnagelvin who didn't appear to be aware of it, at least at the senior executive level,

they would be expecting compliance with these national audit systems?
A. Certainly. We were promoting the benefits of participating in these audits.
Q. Thank you. Then if we come to a sort of more discrete aspect of monitoring. That is when the hyponatraemia issue became one that came to people's attention and they wanted to know what the incidences of it were. Dr Taylor tried to gather information from paediatric intensive care to see if he could demonstrate the incidence of paediatric death through hyponatraemia. The upshot of that was that they did not record the information, although hyponatraemia is one of those standard issues for clinical coding, but nonetheless the system that they had at paediatric intensive care at that time was not sufficiently reliable that he could satisfy himself that the information he got was accurate and complete. And when he was giving his evidence, Dr Taylor that is, he said that he communicated that to Dr Darragh. So although he sent Dr Darragh the best he could do at that time, a bar chart, he did it with a caveat that he shouldn't rely on that as being necessarily complete or accurate for the figures because our system won't allow that to happen.
A. Yes.

Q. I know your evidence is, "I didn't actually see that bar chart" -- this is the one I drew your attention it and it shows a death in 1997. But would it have surprised you to know that if you had the clinical coding references and so the deaths were coded in that way, that nonetheless that couldn't be brought up in any reliable way if you were interrogating the system? Would that have surprised you if you'd known that?
A. I don't think it would have surprised me because I think there certainly has been an issue around clinical coding, which time and again the Health Service has tried to deal with. And it is about properly resourcing, training those people who are doing the codes. So it's an important piece of work that needs done when you're trying to look back for information or trying to monitor the service, but I think directly it had not been resourced in a way that would allow proper interrogation of the data.
Q. Can I pull up two things I'm sure I'm going to be asked to pull up for you, 319-019-002 and 090-055-203? That's the PICU coding for the Children's Hospital for Lucy and, on the right-hand side, is the PICU coding form at the Children's Hospital for Claire. You can see, if you work your way down, these are all standard terms for coding purposes. You can see in Lucy, the third one up

from the bottom, that's hyponatraemia, and for Claire the fourth one up from the bottom is hyponatraemia. It's pretty clear.

A. Yes.

Q. Yes. Had that found its way further forward, then it would be possible for people to have recognised that hyponatraemia sooner than they apparently did, that hyponatraemia was implicated in the deaths of those children. But it's pretty clear there on the coding form.

When you say that coding was an area that was under-resourced and so you're not surprised that you ended up with a system that was perhaps imperfect in terms of being able to call up with any degree of accuracy the incidence of deaths through any one of these coded conditions, did you know that at the time and was this an issue that you were advocating to either the chief executive or the Permanent Secretary that there's a problem here: if we don't resource coding at the very basic level, we can't see what people are dying of?

A. I think it's fair to say that coding and the inaccuracy of some coding or the difficulty in extracting the material because of poor coding historically had been an issue and efforts had been made -- and I can't recall

exactly, when I was in office, the last big effort had been made. Efforts were made to try to simplify the coding mechanisms so that they could be more properly done in a way that data could be extracted appropriately. There were efforts made, but I cannot remember when and at what date, I'm sorry.

Q. And then, perhaps as a response to the fact that he couldn't actually provide an accurate chart in terms of the incidence of hyponatraemia, when Dr Taylor is corresponding on the yellow card form, as you know from the minute of meeting he said he would, and he's reporting Raychel's death, when he's corresponding about that he identifies a fact that actually he is going to do an audit of deaths in paediatric intensive care and that so far his work in that regard has identified two other deaths. I can pull that up, 007-033-060. You can see this is him to the Medicines Control Agency. If you go down to that last paragraph of his, he says:

"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."

Was this brought to your attention at any stage, this?

A. I didn't see that letter, no.

Q. Was the information in it brought to your attention?

A. Not this information, no.

Q. When you go to Altnagelvin in the early part of 2002, you're actually given a presentation, aren't you, by Dr Nesbitt? And he gives a PowerPoint presentation in relation to hyponatraemia and in that presentation is a bar chart which refers to a death in 1997 and a death in 2001. It's largely built on Dr Taylor's bar chart that I showed you earlier. It's not exactly the same because it's got a couple of extra instances of those admitted with hyponatraemia, but in terms of deaths it's exactly the same. So if you're looking at that presentation, you'd be seeing that the information that's being told to you is that there was a death involving hyponatraemia in 1997 and one in 2001. But by that time, you know that there's a death in 1996 --

A. Mm-hm.

Q. -- because you know about Adam's death. So even if you hadn't had to ask before or found out, with your interest piqued in relation to hyponatraemia, do you not ask, "Who is that death in 1997?"

A. I'm sorry, I don't recall at that visit to Altnagelvin having picked up that difference in terms of the date of death being 1996 or 1997. I had assumed at that time that it was Adam that was the other death that was being

referred to and, I'm sorry, but I didn't pick up on the anomaly in those dates.

Q. I understand. Then the final question in relation to this audit of PICU. You say you didn't know about that. Would you have wanted an audit like that to be being done?

A. Absolutely. We expected audit to be built into all of the clinical work. In fact, when medical audit was first presented as something that should be done, it was resourced at that time in the early 1990s in a way that one half-day of each week for medical practitioners would be given over to audit. So there was a very definite expectation that audit would be being undertaken everywhere throughout the hospitals.

Q. And what Dr Taylor says in this letter -- and I appreciate you didn't see it -- is he's actually going to go further than that, and what he's doing is he's conducting an audit of all infants and children admitted to PICU with hyponatraemia. And from then on, you would be able to track their course and, if the death certification is accurate or the audit of deaths is accurate, you'll be able to see out of those coming in more accurately who died as a result of hyponatraemia.

A. Yes.

Q. If you had known that in 2001 he was conducting an audit

like that, which in fact was being started before you had actually issued your guidelines, would you have wanted to see the result of it?

A. I would indeed. I might not have expected it within one year or two years because when you look at all the case studies that had been published, they had been done over five, ten years.

Q. Yes. To get a proper series?

A. Yes.

Q. But you'd have wanted to see that and, in particular, if it was something that was being carried on, you might be able to see that in relation to the implementation of the guidelines, for example. It would take a statistician to say what the significance of it is, but you might certainly have wanted to see it.

A. Yes, and I'm quite sure that that is what the department are now doing: they are looking at long-term outcomes on audits. That would be an important part.

Q. And to your knowledge by the time you left, the department had not received the result of that audit?

A. No, and if you relate the size of Northern Ireland to the size of populations in which the published audits and case studies were being done, I would expect it to take some time before there would be an update to properly explain what was going on.

MS ANYADIKE-DANES: Thank you very much indeed, Dr Campbell.

THE CHAIRMAN: Doctor, I think that's everything so thank you very much indeed. Thank you for coming along and thank you for your directness. I suspect you've said all you want to say, but if there is anything else that's left, you're welcome to say it now.

A. No, but thank you very much, chairman, for the opportunity to speak today.

THE CHAIRMAN: Thank you, Ms Anyadike-Danes, for your final, final question in Banbridge. 9.45 tomorrow morning. Thank you very much.

(5.00 pm)

(The hearing adjourned until 9.45 am the following day)

I N D E X