Tuesday, 5 November 2013

(10.00 am)

THE CHAIRMAN: Good morning. Just before we start with Mr Elliott: Mr McMillen, we referred your opening to Professor Scally and a response has come in overnight, which is being paginated and will be circulated by lunchtime. I haven't had chance to read it yet, but we'll see how far apart he still is.

MR McMILLEN: Indeed, very much obliged, Mr Chairman.

MS ANYADIKE-DANES: Good morning. Could I call, please, Mr Elliott?

MR ALAN ELLIOTT (called)

Questions from MS ANYADIKE-DANES

MS ANYADIKE-DANES: Good morning, Mr Elliott.

A. Good day.

Q. Mr Elliott, you've made one statement for the inquiry so far, and the reference for it is 348/1, and it's dated 19 September of this year. Do you have it there with you?

A. Yes, I do.

Q. Have you made any other statements in relation to the work of the inquiry?

A. No, I haven't, no.

Q. And have you had an opportunity to know something of the evidence that Mr Hunter gave yesterday?

A. He spoke to me yesterday, yes.

Q. Thank you.

A. That's, of course, from his point of view. You might say something completely different.

Q. Quite right. Thank you.

If we go to your witness statement, the second page of it, we see something of your career history. In fact, you've had vast experience in the Health Service, if you don't mind me putting it in that way, pre-dating many of the important initiatives in this clinical governance section. I think you first came in to the Health Service as an assistant principal in 1959; is that correct?

A. Yes, that's right, which I've just realised was 54 years ago.

Q. Yes. Then in 1971, you were assistant secretary?

A. Yes.

Q. And in and about 1980, you became a senior assistant secretary.

A. That's right.

Q. And then you became Permanent Secretary in 1997 and you remained in that post --

A. 1987.

Q. 1987. I beg your pardon. You remained in that post until you retired in 1997; is that correct?

A. Yes, that's right.

Q. So in terms of what was happening in the development of clinical governance over that period, you would have been a Permanent Secretary at the time when the White Paper "Working for patients" and the "Working for patients: medical audit" working paper were issued, which set out a comprehensive system of medical audit. You'd have been in post at that time?

A. Yes, I would.

Q. And also when there was the circulation of the Patient's Charter here in Northern Ireland in March 1992?

A. Yes.

Q. And by my simple calculations you would have been Permanent Secretary for about 10 years?

A. Nine years and --

Q. And a bit.

A. -- 8 months.

Q. Yes, thank you. That would take you up, so far as the work of this inquiry is concerned, that takes you up to just past the death of the second child, Claire.

A. That's right.

Q. If I can just ask you a little bit about your roles in some of those positions that you've held. As a senior assistant secretary, what was your role?

A. I was what's called the Principal Establishments and Finance Officer, PEFO for short. Really, that is the civil servant who looks after the people and the money, not being involved in particular programmes or policies, but people and money.

Q. Thank you very much. And you were involved in people and money from about 1980 to about 1987?

A. Well, yes. There were some moves round about, but that's how I ended up -- I was PEFO during the time that Maurice Hayes was the Permanent Secretary, which was a very good learning experience.

Q. I'm sure. You were Permanent Secretary just prior to the introduction of the Management Executive, because that came in at the beginning of 1990.

A. Yes, that's right.

Q. And Mr Hunter was the first chief executive in that position.

A. Yes, he was.

Q. He's explained to us -- and in doing so he was really agreeing with a characterisation of the role that Mr Gowdy gave us in his witness statement -- we don't need to pull it up, but in his witness statement it's 062/2, at page 3. He was really seeing the Management Executive as dealing with the management end of matters whereby the Permanent Secretary was focusing more on the

policy end, and there was a decision made to separate those two functions. You would have been aware of that at the time?

A. Oh yes, yes.

Q. He also agreed with the department's opening, where there was a reference to this internal market in healthcare that was created in the hope that that sort of competition would drive up quality as well as force down prices.

A. Yes.

Q. You'd have been there when that sort of discussion was going on?

A. That's right, and the purchaser/provider relationship that's talked about.

Q. Exactly.

A. All stemming, of course, from national review, triggered by the Prime Minister, Margaret Thatcher, who saw a television programme about Birmingham Children's Hospital and said, "We must do something about this", and set up an inquiry or set up a review process, which led to patients first, and the change in structure, trusts and so on.

Q. And that focus was very much to pay greater attention, or at least more direct attention, to quality of care?

A. Um ... I wouldn't have put it that way, but it

certainly had that effect, yes. I think the purpose was, as you mentioned, to bring in the internal market, to set up purchaser/provider relationship and to ensure that trusts, which would be new bodies, had as much independence as possible to do their own thing, to get on with their own affairs, subject to overall guidance.

Q. Yes. And in instituting such a system as that and, if you like, slightly distancing oneself from the direct management and control of that, you would have to be satisfied that there were systems in place so that the quality of care was not compromised in that?

A. Yes, indeed.

Q. And that was part of the monitoring and management function that was going to be the principal task of the Management Executive, to make sure that that didn't happen?

A. That's right.

THE CHAIRMAN: Do you think that we're overstating the significance which was attached to the quality of care?

A. I just jibbed at that slightly because I didn't think that the review was set up to improve the quality of care; it was set up, I think, to lead to the internal market, to the purchaser/provider split, to independence for trusts.

MS ANYADIKE-DANES: Thank you, Mr Elliott. I think I framed

that badly. Perhaps the quality of the care was more to ensure that that wasn't compromised and it continued to be improved in the new system.

A. Right, yes. Certainly.

Q. So you would have to have a way of knowing what was happening in the new dispensation and managing and monitoring it so there wasn't a compromise of quality of care and, if possible, that quality of care continued to be improved.

A. Mm-hm. Yes.

Q. Then if that was going to happen and so you were, although with overall responsibility as a Permanent Secretary, but if you were focusing more on the policy end and your contribution towards that with the expertise that you had at your disposal to assist the minister with that and the Management Executive was concentrating on how that was being implemented to ensure that the objectives of that policy were being met --

A. Mm-hm.

Q. -- what was the kind of interface between you and the chief executive at the Management Executive?

A. Well, we were just across the corridor from each other, for a start, so there was physical daily proximity, if you like. I chaired the top-of-the-office group, it was

called, which the chief executive attended, so I suppose our formal relationship collectively was through that. John would consult me, consult me a lot, about issues arising which might impinge on my responsibilities. So it was a close working relationship, bearing in mind that I didn't really have the right to tell him how to do his job.

Q. Well, I'm going to ask you a bit about that. You said it was a close working relationship; I suppose it would have to be in order for it to work successfully --

A. Yes.

Q. -- the project, if I can use that expression.

A. Yes, certainly.

Q. I asked him yesterday whether he was accountable to you, and he said he was accountable to you in overall terms because he was in the department. In terms of some of the specific functions that he had as the chief executive of the Management Executive, he was also accountable for those functions to the minister.

A. Yes.

Q. And he then said that if you had had any concerns about how he was carrying out his functions, he would have expected you to have intervened. Is that how you saw the relationship?

A. Yes, it is. I think that's quite fair.

Q. So to some extent, because you are accountable overall for what the Civil Service is doing to the minister, did that not mean that, quite apart from your working relationship, you would need to know what he was doing to some extent to be satisfied that things were moving as you would like them to?
A. Mm, yes.
Q. Would that be fair?
A. Yes, that would be fair.
Q. And if the systems that he had established for monitoring what was happening, both in terms of the discharge of the boards' responsibilities and the discharge of the trusts' responsibilities, if they were deficient, am I right in saying that ultimately you had responsibility for that?
A. Yes. Absolutely. He was not, I should say, starting from scratch to create a whole new thing. He took over that operational responsibility, really, from the Permanent Secretary.
Q. Yes, he described that. He said that in his position, before he was chief executive, that he had been doing a similar sort of thing, but this brought greater emphasis to the monitoring task than perhaps he would have had in his previous role. Would you accept that?
A. Yes, I would.

Q. Then you chaired the departmental board; is that correct?
A. Yes.
Q. And on that board would be the CMO; am I right? Perhaps you could help us. Who of the professional group would sit on that board?
A. In my time, there were two mechanisms at the top. One was called the top-of-the-office group, and that included the five chief professionals: medical, nursing, dental, pharmaceutical and social services. The departmental board was administrative, really, not involved with running Health and Personal Social Services, but dealing with the money and manpower and keeping within budgets of the DHSS.
Q. So at that board, in terms of the issues that we're dealing with, how people knew what was happening and the systems that were being brought into place in terms of clinical governance and monitoring and so forth, that board is less important for that, would you say?
A. Yes. Oh yes. It wouldn't have been involved, really.
Q. And in terms of the other board, which is the one which is actually delivering the substance of your work programme, did all the professional groups sit on that board or only some of them?
A. The what I call the top-of-the-office group, yes. We

had five chief professionals and they all sat on the top-of-the-office group, yes.
THE CHAIRMAN: Who with? So you had the CMO, the CNO and three others.
A. CDO, yes. I was chairman. John Hunter, I suppose at that stage, would be deputy secretary. The PEFO, the Principal Establishments and Finance Officer, and quite often really one or two of John Hunter's people who were concerned with the particular subject under discussion.
THE CHAIRMAN: And what was the purpose of that group?
A. It would be nice to have a single phrase, which is probably somewhere in here. It was to coordinate the policy and the delivery of the Health and Personal Social Services.
THE CHAIRMAN: So is this things like -- some of the discussion yesterday was about which units and which hospitals would stay open and which wouldn't.
A. Yes.
THE CHAIRMAN: There were issues about waiting times, there were issues about waiting lists. Is that the sort of area?
A. Yes, it would have.
THE CHAIRMAN: Would it have covered those areas?
A. Yes. It would have surfaced, yes, there.
THE CHAIRMAN: Thank you.

A. I'll maybe just add, because it maybe doesn't come out in these papers. I was -- DHSS not only ran the Health and Personal Social Services, it ran the, in my time, the social security system, which was the whole benefits/social security system, which had 7,000 staff, whereas the staff in the department concerned with Health and Personal Social Services had 700 or 800. I had 7,000 staff and a 2-billion turnover in the really completely separate social security field.
THE CHAIRMAN: Thank you.
MS ANYADIKE-DANES: How often did that top-of-the-office group meet, roughly?
A. I think once a month, roughly.
Q. Did you meet with the professional group or any part of them more often than that or was that your principal place where you met them?
A. It would be one of the places that I met them, I would say, but I would have had fairly frequent contact during the working -- during a heavy working week, most with the CMO, the Chief Medical Officer, and also the Chief Nursing Officer. Then we'd occasionally meet the dentist and the Chief Pharmaceutical Officer. Social work, social services, was really to some extent a separate world in that the Chief Social Work Adviser was not in the hospital healthcare field at all, but in

social services.
Q. Yes. The CMO has described her role as in providing or having a responsibility for advising the minister and the department on matters relating to health, and she talks about having established and chaired working groups to assist in developing policy advice for the minister and, I presume, for you also.
A. Yes.
Q. So if there were clinical issues that arose in your top-of-the-office group meetings, they would be being informed by advice from her?
A. Yes.
Q. And to some extent, if they concerned nurses, the CNO?
A. Yes, that's right, yes.
Q. She may well have had one of those roles that straddles both you, your role focusing on policy, and John Hunter's role, focusing on the management end.
A. Management, yes.
Q. Would you therefore have been in fairly frequent contact with her? On medical issues, I mean.
A. Yes, I would, yes. She was just along the corridor too, so I mean -- several times a week, certainly, I would have looked along to talk about something or she would have come in to me to exchange information.
Q. And to the extent that she had direct contact with those

who were working in the hospitals, because she had established her special advisory groups where consultants and senior management met --
A. They were there before her time. She inherited them.
Q. I beg your pardon, yes, I don't mean to say that she constructed the whole structure. But in any event she had those groups. Would I be right in characterising it this way: that you'd be relying on her through that network of contacts that she had directly with the hospitals to be bringing to you issues that the department need to address from the hospital end and the trust end?
A. Absolutely, yes. That puts it very well.
Q. Might you also have been relying on her in some part to be helping you in disseminating whatever was the policy message that was being formulated, insofar as it related to what was going to happen in hospitals, and you'd be relying on her to get that message, insofar as she could, to those who needed to implement it? Would that be a fair way --
A. The main formal way that that sort of thing was transmitted was by letter or by circular, which would go to the chief executive of boards and trusts. They then presumably circulated it within their organisation. So it wasn't solely the Chief Medical Officer's job to see

that new advice and new policy got to the doctors. The formal thing would be through the board or trust to the hospital, maybe to the doctors.
Q. But to the extent that any difficulties were being experienced in that being implemented, that might be something that either John Hunter would expect to hear in his sort of management monitoring role and/or you might expect to hear as being fed back to you through her?
A. Yes, absolutely, yes. That's right.
Q. Thank you. I want to ask you about the development of clinical governance. While you were in the department and up until you retired as being Permanent Secretary in 1997, who in the department had a role in developing clinical governance so far as you're concerned?
A. The Chief Medical Officer.
Q. Would you regard her as having the primary role as helping to develop that?
A. Yes, I would.
Q. Assisted by the Chief Nursing Officer?
A. Yes, yes. She would be alongside, that's right -- and others if they needed to be involved. But clinical governance started as -- and then spread out, but it started as medical governance --
Q. Yes.

A. -- and then, you know, spread more widely.
Q. In the papers that we've seen it seems to be a more targeted way of bringing a number of multidisciplinary processes together to try to improve the quality of care, if I put it in that simplistic way. Is that a decent running summary of it?
A. Yes, that seems fine to me.
Q. And that, to some extent, fits in well with the charter which the chairman has described as "aspirational" and, I think, Mr Hunter agreed yesterday that it was aspirational.
A. This was the charter for patients --
Q. The Patient's Charter.
A. Yes. It was very much a John Major initiative, incidentally. He focused on and picked out and promoted the interests of the patient, like the early interests of the customer, as being something that we had not paid enough attention to and which should jolly well come upfront.
Q. Given that that's published in 1992 and within your time, obviously, what systems did you seek to establish or develop so that you would be able to assist the minister as to how well that even aspiration was being achieved?
A. This is where my memory starts to get -- I get a little

vague, bearing in mind that this was 20 years ago.
Q. Yes.
A. One of the things I found in retirement is the longer you're out, the more vague and general the previous work seems to be, so I'm sorry to digress. When I drive past Dundonald House, I have a general memory of working there for 30 years, but the detail has all gone, I'm afraid. The patient and client charter was seen as an important initiative. I don't know whether we set up systems as specifically to monitor how that was being achieved.
Q. Maybe you didn't, but to the extent that you were now being told from a policy point of view that there was going to be greater focus on the patients, their needs, and also one might add to that the quality of care that they were going to receive and their experience in hospital. If that was going to be a shift in focus, which I think you've characterised it as being so, then how did the department know where they stood in trying to deliver that? Presumably you had some sorts of ways of monitoring what was going on so that you can see whether that shift was anywhere near being realised.
A. Yes. I said in my statement that the principal means of securing some kind of accountability was through accountability reviews with each board and with Health

Service bodies generally. Through that, the minister and I, but the minister generally at present, met the chairman and chief officers of the board, talking to a structured agenda, which we drew up and which the boards contributed to, saying, "We would like to talk to the minister about such-and-such". And as I say, those were formal, sometimes occasionally, all-day meetings, but certainly three-hour meetings of that kind. I would expect that the Patient's Charter would have been a topic at those meetings.
Q. Maybe I'll come back to that and ask if you can develop it a bit more, but if we look now at the gradual instruction or efforts to introduce clinical governance.
A. Yes.
Q. Mr Hunter said that he was aware of the developments in the rest of the UK in relation to clinical governance and Professor Hill said, similarly, that she was also aware. She, of course, had been working in England immediately prior to coming to Northern Ireland.
A. Yes.
Q. Can I ask you then whether you were generally aware of the developments in the rest of the UK, perhaps from meetings with your counterparts?
A. Yes. I was certainly generally aware, but I didn't ... I guess I didn't see it as one of my direct

responsibilities to introduce clinical governance.
Q. Did you think anybody had -- I think you said the CMO. That was the CMO's responsibility?
A. I think we would have thought generally that it was the -- the CMO was the lead on it, yes, on developing clinical governance systems.
Q. Well, if we go through what actually was happening in your time. In 1994, there was the Clothier report.
A. Clothier, yes.
Q. You would be aware of that? I'm pulling up now an extract of a much later report by the CMO in England. It's called "Organisation with a Memory", and it comes out in 2000, but the reason I'm pulling it up is because it actually summarises some of these events so it might be easier for you to see that rather than for me to read them out. Perhaps we can pull up pages 338-003-066 and, alongside it, 067. (Pause)
We might be having a little bit of difficulty in pulling it up, so I'll go back to telling you what was in it.
A. It's quite all right.
Q. It refers to the Clothier report and that was a report that was published in February 1994. What was said there -- and this was following on a report in relation to risk management --

THE CHAIRMAN: Sorry, Ms Anyadike-Danes, it might have been that the number was picked up wrongly. Could we try it one more time? It's 338-003-066.
MS ANYADIKE-DANES: Thank you, Mr Chairman.
A. Could you just tell me briefly what it was about, what it was there to do? I remember meeting Cecil Clothier, but I don't have a clear memory of his report.
Q. It was the report that came out of the Allitt inquiry. If I say that, that might jog your memory.
A. Yes.
Q. That was an independent inquiry that related to deaths and injuries on the children's ward at, you might remember, in Grantham & Kesteven General Hospital. One of the things that Sir Cecil Clothier referred to in his report was -- he said:
"Reports of serious untoward incidents to District and Regional Health Authorities should be made in writing and through a single channel which is known to all involved."
So that was the start of focusing on how trusts should be identifying serious untoward incidents and they should be making those reports to the District and Regional Health Authorities.
A. Mm-hm.
Q. Mr Hunter said that he was aware of that report. Were

you aware of it also?
A. No, I don't think so, no. Not in those details, not in those terms.
Q. What happened thereafter in 1994 was --
THE CHAIRMAN: Sorry, could we pause for a moment? Our arrangements were not identical to those in England.
A. No.
THE CHAIRMAN: So what would be our closest equivalent to a District Health Authority? Would that be the Eastern Board?
A. Yes, it would, the Health and Social Services was four boards.
THE CHAIRMAN: Yes, thank you.
A. And the department was, I suppose, roughly equivalent to or fulfilled the role of a Regional Health Authority.
THE CHAIRMAN: Thank you.
A. Although far -- a much smaller area than those Regional Health Authorities had, but District Health Authority would be broadly equivalent to the Eastern Board, that's right.
MS ANYADIKE-DANES: So this is now a system requiring the, in our parlance, the hospitals and trusts to report serious adverse incidents to the board, if one translates it.
THE CHAIRMAN: I'm not sure that the fact that

Sir Cecil Clothier recommends it means it becomes a system. It's a recommendation by Sir Cecil Clothier; that's --
MS ANYADIKE-DANES: I beg your pardon, Mr Chairman. This is entirely right.
That is a system which is he's recommending which I've just translated into how those bodies would be in Northern Ireland. If that system was put into operation, the trusts would be reporting serious adverse incidents to the board.
A. Yes, that's right.
Q. And he goes on, in that report, to say that:
"There must be a quick route to ensure that serious matters are reported in writing to the chief executive of the hospital and, in the case of the directly managed units, to the District Health Authority."
And:
"All District Health Authorities and NHS Trust boards should take steps immediately to ensure that such arrangements are in place."
So they have to have their own arrangements, which allow them to identify those serious --
A. Yes.
Q. -- adverse incidents and then, according to this, there should be an arrangement where they report those to the

Regional Health Authority, which is the equivalent of our board. That's what he was recommending.
A. Mm.
Q. What happened after that was a letter that the NHS Executive issued, which is comparable to the Management Executive here --
A. Yes.
Q. -- in Northern Ireland.
A. This is in London --
Q. Yes, exactly.
A. -- or Leeds, in practice?
Q. I'm sorry that we can't pull it up because it is so much easier if you can see it, but bear with me.
What that letter said was:
"Now that the regional offices are in place, it is appropriate for them to be formally notified of serious untoward incidents, whether these occur in NHS trusts or the directly managed units. I should therefore be grateful if you could discuss ..."
Here we go. Right. It's the penultimate extract starting "now that the regional offices", do you see that, down at the bottom on the left-hand side in blue?
A. Yes.
Q. Where I had got to is:
"I should be grateful if you could discuss with

trust chief executives the best means of instituting arrangements whereby you are informed in writing of any such incidents."
And you can see the reference point for that. That was a letter that went out and what that was really requiring to do is to institute, as it would appear, that system whereby they would have arrangements in place so that they could receive written reports of serious untoward incidents from the trusts.
A. Yes.
Q. Do I understand you to say that the person that you expected to keep on top of that kind of development for you and inform you of what was going on is really the CMO, your CMO?
A. No, I think it would be more the chief executive of the Management Executive.
Q. Ah, sorry.
A. Serious untoward incidents ... If it was a question of developing clinical governance, the CMO certainly would be the first port of call. To set up a system to report serious untoward incidents, I would have thought was primarily the responsibility of the chief executive at trust level or the chief executive at the Management Executive.
Q. So to the extent that this was being discussed and steps

were being taken to institute this sort of thing in the rest of the UK, you would expect, if you hadn't heard it in one of your meetings in the UK, you would expect the chief executive, Mr Hunter, to be bringing this initiative to you and discussing with you the extent to which it should be implemented in Northern Ireland, or not?

A. Not necessarily. I mean, he could have taken action on his own.

Q. If he was going to do that, would you expect him to at least discuss it with you?

A. Um ... I would expect him to keep me informed that he was going to do this more than that he would say "Should I do it?" because I was not in that position.

THE CHAIRMAN: Just in order that I get the equivalence, Mr Elliott, when it says in this extract that we've been referring to about the regional offices being in place, the regional offices of what? Is that the Regional Health Authority offices?

A. "Now that regional offices ..."

I think those would have been out stationed offices from the Department of Health.

THE CHAIRMAN: Right.

A. It's not quite clear from that, but the department itself had regional offices, which ...

THE CHAIRMAN: Are they regional offices of the NHS Executive?

A. No, I think they were regional offices of the Department of Health.

THE CHAIRMAN: Right. But that means that the formal notification of serious untoward incidents is to come into the regional offices of the Department of Health?

A. "For them to be formally notified of serious untoward incidents ... whether these come in NHS trusts or directly managed units ..."

MR McMILLEN: Just by way of information, Mr Chairman, if it helps, one sees in brackets below that, who the letter's addressed to, and also paragraph 4.16 in the bottom right.

THE CHAIRMAN: You're referring, Mr McMillen, to the italics below that quote?

MR McMILLEN: Yes.

THE CHAIRMAN: And it is a letter to the regional directors. The NHS Executive, Mr Elliott has just told me, is roughly the equivalent of the Management Executive.

MR McMILLEN: Yes.

THE CHAIRMAN: So this is a letter to our equivalent of the Management Executive from the director of corporate affairs in the Management Executive; is that right?

A. Yes. I think I may be wrong in saying that those

regional offices were, as it were, arms of the department, because in that footnote it talks about the regional offices of the NHS Executive.

THE CHAIRMAN: Yes. So to read this in context, this looks as if it's a system which is being put in place by the Management Executive for formal notification of serious untoward incidents and that fits in with what you said a few moments ago, that setting up the system would, in your eyes, be the primary responsibility of the chief executives of the Northern Ireland trusts, working together with the Management Executive, if that had been duplicated in Northern Ireland?

A. Yes.

THE CHAIRMAN: Right. Thank you.

MS ANYADIKE-DANES: Thank you very much.

I know that you have said you don't have a very clear recollection of your time when you were working as a Permanent Secretary, but have you any notion that this kind of system was ever discussed with you by Mr Hunter?

A. You mean setting up a system for the reporting of serious untoward incidents?

Q. Yes.

A. No, I really don't have any recollection of that.

Q. Do you have any recollection of the Chief Medical Officer talking about it?

A. No. I have certainly a recollection of the Chief Medical Officer, and indeed Dr Campbell's predecessor, Dr Weir, talking many times to us. It was one of his sort of priorities to get the clinicians organised in this way, and he certainly talked about it -- the top of the office would have talked about it on his initiative. But that's all to do with developing clinical governance -- medical governance leading to clinical governance.

Q. Yes.

A. I have no recollection of anyone talking to me about setting up a system to report serious adverse incidents.

THE CHAIRMAN: Okay. Just to get it clear, what you remember from Dr Weir is that he wasn't so much talking about these serious untoward incidents, but he's talking about the increasing involvement of doctors in governance?

A. That's right.

THE CHAIRMAN: And Ian Carson has told us before that there was a time when doctors were entirely outside management and governance.

A. That's quite right.

THE CHAIRMAN: So Dr Weir was a supporter of this trend to getting them involved?

A. That's right. I think that was the main driving force,

certainly, as far as he was concerned, because we had -- prior to that, there was a great gulf fixed between the administration and the clinicians, who would grumble furiously about the sins of administrators. And Bob saw this as a way of breaking that down so that doctors, or at least their representatives as chairmen of divisions and things, took part in management decisions.

THE CHAIRMAN: Thank you very much.

MS ANYADIKE-DANES: Thank you, Mr Elliott. The reason I have taken a little bit of time to ask you your recollection or knowledge of any kind of more formal system to report serious adverse incidents, as they ultimately became known, is because the department has recognised that it didn't have a formal system for doing that and, as a matter of fact, two of the children that the inquiry is concerned with died without being the subject of a report of that sort.

A. Yes.

Q. And the department didn't know about their death, even though when it heard about their deaths much later on, it recognised that those were the kinds of deaths it would have wanted to know. That's one of the reasons I'm pressing you about the extent to which there was any real discussion in these early stages of establishing a system that might, even in part, replicate the kind of

formality being built around that in the rest of the UK.

Mr Hunter did say that he was aware of these sort of developments and, to some extent, in Northern Ireland they were trying to keep pace or trying to follow on with the developments in the rest of the UK. But all that having been said, this particular aspect of it is not something that you can recall came to your attention?

A. No, that's right. With hindsight, sitting here in 2013, clearly it should have happened.

Q. Yes, actually, thank you, that's --

A. All those children dying.

Q. That is where I was going to take you to. I take it if you were aware of such a system you would have, insofar as it could be done, wanted to see more formality built around the reporting of serious adverse incidents?

A. With hindsight, yes, certainly.

THE CHAIRMAN: Can I ask you this just to clarify that? When you say the department should clearly have been informed about the deaths of the various children with whom this inquiry is concerned, I take it from that that there must inevitably have been other deaths in other circumstances of which the department was unaware.

A. Yes.

THE CHAIRMAN: What would you see as the route by which that

should have come into the department? Would you have expected the chief executive of the Royal Trust, to take an example, to ring you, or would you expect --

A. I would be thinking of introducing machinery in which, at regular intervals, serious -- or sometimes immediately -- serious adverse incidents were reported in writing, I guess, and that would be trust to the board, and then maybe from the board to the department.

THE CHAIRMAN: Right. Let's take a hypothetical example. It goes from the Belfast City Trust to the Eastern Health Board and then it goes from the Eastern Health Board to who in the department? To the CMO, to Management Executive?

A. I think to the Management Executive because my feeling is that that serious adverse incidents could be more than purely clinical.

THE CHAIRMAN: Right. Thank you.

MS ANYADIKE-DANES: Thank you very much, Mr Elliott.

I want to move on to focus a little bit more on the quality of care point that I had initially raised with you. The inquiry engaged an expert, Professor Scally, who you may have heard of, and he has --

A. I knew him, yes, at a time.

Q. He's commented on the issue of quality of care in this early period. He was really focusing on up until 2003.

What he says in his report, which is at 341-002-003, and you can see it at paragraph 3 there -- he talks about there being:

"Little evidence in the available documentation [from that he means that which he has been able to ascertain] to indicate that there was a firm expectation that either the Health and Social Services boards or the trusts would be subject to any [and this, I think, is the important point of it] systematic monitoring of the quality of care provided to patients."

I don't think he says that there wasn't any interest in finding out what was happening, but what he's talking about is a systematic monitoring of the quality of care --

A. Yes.

Q. -- or, for that matter, of adverse clinical incidents.

A. Mm-hm.

Q. Then he goes on to refer to the document which you've provided a copy for us of with your witness statement. That's the document that sets out the accountability of the Management Executive, the trusts and the boards.

A. Yes.

Q. It's called the accountability framework for the trusts. He says that, even in that document, it doesn't display any interest in patient care issues and they're not

included in the five key items which are listed in relation to monitoring the performance of trusts.

And I think if one goes to 323-001a-006 -- we're just having a little bit of trouble, but there's another route for it, maybe this will help. Witness statement 348/1, at page 13. There we are. You can see under "Monitoring", there's five matters there that the Management Executive is going to focus on in terms of the performance of trusts.

A. Yes.

Q. What Professor Scally is saying is it's not immediately apparent that there was a focus in those five targets on quality of care or there being within that any kind of systematic monitoring of quality of care. This is a section that talks about monitoring, but he doesn't see that in those five focal areas. Do you see his point?

A. Yes, I do.

Q. Would you accept that, that there doesn't seem to be highlighted there a focus that that's one of the things that should be being monitored?

A. Yes, I would accept that, on that particular point. I'm aware that my former colleagues, particularly the CMO, have, let's say, grave reservations about the conclusions which Professor Scally draws, and that may

be the subject of the paper which has just reached you.

THE CHAIRMAN: Yes.

A. But on that point, these five -- which I think it's reasonable to take as the things being seen as important -- do not refer to clinical care -- quality of care.

MS ANYADIKE-DANES: Thank you. It doesn't mean that quality of care wasn't important. I think what he is really saying is, if this is your seminal document going out on accountability, then you haven't highlighted that as something that you want the trust to pay especial attention to because you haven't indicated you're going to monitor it in any way.

A. I think that's fair.

THE CHAIRMAN: If it's not found there and assuming that the quality of care is something which the department and the Management Executive were concerned about, then where do we find it?

A. Monitoring quality of care or reference to quality of care in general.

THE CHAIRMAN: I take it as a given that the doctors and nurses in the Health Service are concerned to provide a good standard of care.

A. Absolutely.

THE CHAIRMAN: And I take it as a given that the department

is, through its various manifestations -- Management Executive, boards and trusts -- is also concerned that quality of care will be maintained and perhaps improved.

A. And improved, yes.

THE CHAIRMAN: But apart from accepting that that is the natural instinct of every doctor and nurse in the Health Service, where do we find that reflected in the programmes or in the monitoring arrangements or in what happened?

A. I really have no sort of specific reference pointing to paragraph this and paragraph that. It was certainly underlying, really, all we did, you know, to ensure that standards of care were maintained and improved. Moving on to NICE after my time, there was a lot of guidance.

THE CHAIRMAN: I don't doubt this, Mr Elliott. When you're concerned about waiting lists and waiting times, that's an aspect of quality of care.

A. It is.

THE CHAIRMAN: Because the longer somebody's sitting in A&E on a Saturday night being unattended, the lower you might say the quality of care is. If you can get in and see a doctor within an hour, that's far better for your care than seeing a doctor within five hours.

A. I have some recent experience of that situation.

THE CHAIRMAN: And when you're deciding which units stay

open in Tyrone or Fermanagh, or wherever else, one of the things that's driving you is "How good is the care which we can provide in this unit?"

A. That's right.

THE CHAIRMAN: "Is it good enough or is there not enough of a throughput of patients? Therefore we're going to have to withdraw --

A. That's quite right.

THE CHAIRMAN: -- and go somewhere else". So those are all aspects of quality of care.

A. Which had a lot of attention.

THE CHAIRMAN: Yes, they do. I think the query which we have, because unfortunately, as you'll understand, I'm rather seeing the Health Service at its weakest in this inquiry, I'm seeing where things went wrong, and what we can't quite pick up very clearly is, where there was an emphasis on monitoring, how good the quality of care was.

A. Yes. I think that's perfectly fair, chairman.

MS ANYADIKE-DANES: Mr Chairman, I wonder if now might be a good moment.

THE CHAIRMAN: Let's take a break for a few minutes.

(11.03 am)

(A short break)

(11.16 am)

MS ANYADIKE-DANES: Mr Elliott, the CMO has expressed the view that quality of care was not really part of her role as CMO. You've probably seen that in references.
A. Yes.
Q. Mr Hunter, I think, in fairness to him, didn't entirely agree with that position, nor did the CNO agree with that. I think she regarded quality of care as part of her role anyway as CNO. Do you agree, that insofar as you had involvement with her, that quality of care was not a matter that you'd have expected the CMO to be involved in?
A. I would agree with Mr Hunter and the Chief Nursing Officer that quality of care was part of her responsibilities. Maybe, in the light of all this, she may want to change her phraseology. She may have been thinking that she was not the lead in ensuring quality of care, and that would be right, but that was part of her role, I have no doubt.
Q. I think you're right, Mr Elliott: she may have been wanting to focus on the fact that the quality of care is something that the nurses and the clinicians deal with.
A. Yes.
Q. But her role as CMO, though, when she's advising and guiding you, you would have expected, as I understand you to say, quality of care to be an important part of

the advice you would be wishing to have from her?
A. Yes.
Q. Thank you. If I can move on to deal with issues surrounding accountability. Just so that we're clear, everybody was accountable to you; is that right?
A. Yes.
Q. And you were accountable to the minister?
A. I was accountable to the minister and, as accounting officer, personally to the Public Accounts Committee of Parliament, which we had to take very seriously.
Q. So if anyone had to give evidence to the Public Accounts Committee, that would be you going to give evidence in relation to the department's work?
A. When I was Permanent Secretary, yes.
Q. So I presume from that that you needed to know that there was expert experienced input going into policy formulation to assist and guide you -- I am dealing only with medical matters, Mr Elliott, now -- and you needed to know that its implementation was being properly monitored?
A. Yes.
Q. What reports did you receive from the Management Executive about the discharge of its monitoring function? Can I just pause there? I know that you have referred to having the top of the group meetings, but

what actual reports, if any, did you receive from them?
A. I really can't recall --
Q. Did you receive reports?
A. -- at this junction. Papers would have come to the top-of-the-office group from the chief executive of the Management Executive on various topics, but I have no specific references to bring you.
Q. I understand the whole point of having established the management committee is so that you didn't have to micromanage its work --
A. Absolutely.
Q. -- in terms of monitoring function, if I can put it in those terms. But nonetheless, you did have to be aware of what was happening --
A. Yes.
Q. -- and that what was happening accorded with appropriate practice?
A. Yes.
Q. You'd have to be aware of that and satisfy yourself as to that.
A. Yes.
Q. One of the things that Mr Hunter said when I was asking him about where he got his information from to satisfy himself that he was appropriately monitoring things that he needed to concentrate on, he said one of those ways

or one of the ways he could have done it is through ensuring that there were appropriate arrangements in the purchasing agreements --
A. Yes.
Q. -- because how he described it to us is: look, I can't monitor what each and every trust are doing, there's too many of them and I can't do that, but what I can do is I can keep a fairly tight rein or a tighter rein on what the boards are doing because the trusts are also accountable to the boards and, in that way, achieve some sort of oversight and monitoring ability over the conduct of the trusts.
A. Yes.
Q. So his focus was really on the boards and he had some tools at his disposal: everybody had to do business plans --
A. Yes.
Q. -- so he had that to look at, and then he had this contractual arrangement between the purchasers, the boards, and the suppliers, the trusts.
A. Yes.
Q. And that was an instrument, and what he did say is, although he couldn't remember having actually done it, but it would have been possible to have required some better scrutiny system in there between the boards and

the trusts and that's part of what he could be monitoring when he looked at the boards.

A. Yes, I see that.

Q. That's how he more or less described it to us. But how did you satisfy yourself that this system that he had of keeping tabs on what the trusts were doing was adequate?

A. I think this would have been raised in general terms at our regular meetings. Not only I, but the chief professionals might say, "Look, I think we should know more about this or that". Not a frequent thing, but I think that it could certainly have been raised. I was by and large, though, as you say, hands-off management, and therefore I would only have intervened if I thought that there was some serious gap in our monitoring systems, which needed to be filled.

Q. But in order to form a view like that, you need to have some information, you need to know, to some extent, what he's proposing to do and how that's working so that you can, if you see it, say that "I think there's a weak place there and it may be better to address it in a different way", or at least have some sort of discussion about it.

A. Yes.

Q. That's why I'm asking you what sort of information you were getting from the Management Executive to allow you

to see if you were entirely satisfied with the monitoring arrangements that it had established.

A. Mm-hm. I would have seen -- certainly for the first year or two, John would have shown me or passed to me to cast my eye over these formal contracting agreements between the boards and the trusts. I would have sort of swung through those with a general eye.

Q. So to the extent that they could have been tightened up in terms of the ways in which the trusts' accountability to the boards would be satisfied, that was at both your disposal and John Hunter's disposal?

A. Yes.

Q. One of the reasons why I'm asking you about this area is because the information that we have is that some things went awry in terms of information gathering or reliable information gathering by the trusts. So relying on the boards as a way of satisfying themselves as to what the trusts are doing might call that system into question as a particularly good one. If I give you an example of that.

Dr Carson was the medical director of the Royal in 1993 to 2002, so spanning some of the period of time in which you were Permanent Secretary and also a period of time when the trust was treating Adam and Claire.

A. Sorry, when had he taken up that role you were saying?

Q. 1993. He stayed in post until 2002. He said that what was recognised generally was that very limited resources were available to support clinical audit in the trusts. He's talking about trusts generally, not just the Royal. He says:

"In the Royal Hospitals, the audit department had at the most five or six trained audit assistants to work across all 12 clinical directorates."

We don't need to pull it up, but the reference for where he said that in his witness statement at 077/2, page 8. So what he's pointing to is a resource problem to carry out the clinical audit and it's the clinical audit and audits generally that are going to provide the basic information as to what's happening in the hospitals that presumably the Management Executive will be extracting through the boards. So information is really what we're talking about.

Why I've given you that as an example is because that presumably is an area that you and/or Mr Hunter could have ensured was being given sufficient priority by the boards.

A. Yes, yes, that's fair. You referred to Dr Carson saying there were -- was it five audit assistants?

Q. Yes.

A. This would be the audit, the audit focusing on financial

audit, I think?

Q. I think he was talking about clinical audit here. He doesn't expressly say whether those five were dealing with all forms of audit in the hospitals.

So if we move away from his point about five and stick with his first point, which was that it was being recognised generally, he says, that there were very limited resources available to support clinical audit in the trusts generally, and he puts that forward as a deficiency. And to the extent that there was one, would you accept that meant that the balance of that information gathering perhaps was not as good as it ought to be in the purchasing agreements?

A. If that's so, yes. If that's so, then that follows. But if I was exploring this -- if I was to have been exploring this, I would have wanted to know whether our clinicians or medical directors had made representations --

Q. Of course.

A. -- management that they would need twice as much -- four people rather than two, you know -- whether all that had been --

Q. Of course. But that's precisely the sort of thing that you might have wanted Mr Hunter in the Management Executive to be taking up: are they right about that or

are they misusing their resources or are they right that that isn't being given sufficient prominence by the boards and maybe we need to scrutinise better the purchasing agreements? But that's the sort of thing you'd be wanting Mr Hunter to look at?

A. Yes, certainly.

Q. And to the extent that it wasn't looked at and/or that Dr Carson is right, that would be something for which ultimately Mr Hunter and you would have to take responsibility for if it impinged in any way on care?

A. As for everything, yes.

THE CHAIRMAN: But you'd also need to know, Mr Elliott, wouldn't you, from the Royal -- if the Royal was making a submission about this, you'd also want them to spell out what is the consequence of us not having enough resources for clinical audit?

A. Mm-hm.

THE CHAIRMAN: If they had said to you, "We don't have enough resources and the result of that is that we cannot reassure you about the quality of the care which is provided in the Royal", that --

A. That would have been serious.

THE CHAIRMAN: That's a rather more serious point than saying, "We need two or three more people to help us with audit".

A. And we've tried to get these increased resources and so far the trust hasn't, you know --

THE CHAIRMAN: Because I don't think --

A. I had no idea what was going on in the trusts.

THE CHAIRMAN: With all due respect to Dr Carson, I don't think the Royal has ever made the case that it didn't do clinical audit because it didn't have enough people --

A. No.

THE CHAIRMAN: -- and therefore it followed that it was not able to monitor the quality of care that it was providing.

A. Mm.

MS ANYADIKE-DANES: Thank you very much, Mr Chairman.

If we go down or stay with the level of the trusts, if one's talking about the robustness of information or the information gathering system, some of that may depend upon what people thought their responsibilities were as to who therefore would be in charge of ensuring that there was an audit system that you or the Management Executive can rely on to tell them what's happening in the hospitals; would that be fair?

A. Yes, it would.

Q. One of the reasons I have put it in that way is because -- and you know this because we put it to you in your witness statement that Mr McKee had perhaps

a different idea as to what his responsibilities were --

A. Yes.

Q. -- prior to the legislative change in 2003 in relation to care. I'd like to pull up part of the transcript so that you can see how this develops because I think it may prove to be quite an important point. It's the transcript for 17 January 2013, and if you please pull up pages -- let's start with page 13 to give you some background into it. If you can pull up 14 next to it as well.

Right down at the bottom you can see at line 24, this is Mr McKee answering the chairman. He says:

"Until then [so until the introduction in January 2003] no duty or responsibility was placed on a chief executive in Northern Ireland or a board of directors in Northern Ireland."

So that's his first take. Now that we're on page 14, if we look at line 17. He's now being asked:

"Question: Prior to 2003 the chief executive had no responsibility for clinical --

"Answer: It's more fundamental than that: no responsibility or authority had been given to chief executives until the document dated January 2003."

And then if we go over the page, and there's quite a bit on this page of 15, this is a document that is

being read to Mr McKee by my learned junior Mr Stewart, who's asking the question. Mr McKee is not accepting the reading out of that document and then, if we go on, if you give us the whole page. About halfway down on that page, 14, Mr McKee seems to think things are going round in circles. He's been directed to this question of what is the position of the chief executive and responsibility for clinical issues prior to 2003. He goes on to say at line 20:

"There's a world of difference between encouraging your medical staff to take a system approach to undertaking their responsibilities under the GMC and then saying: so this is evidence that, in spite of what I say about the legislation, I was taking responsibility for clinical quality."

So the fact that he was encouraging his staff to do it, his argument is, does not mean he was taking responsibility for it.

If we go over the page to 16, which is where the heart of his point lies. That really follows a question put to him. We see the quote:

"The chief executive is responsible to the trust board --

The chairman asks the question:

"Can I ask you this: whatever about you personally,

did the board generally or did the board collectively have a responsibility for clinical safety?"

That is put in pretty stark turns by the chairman. And he says:

"No, chairman."

So then just to tease it out, the chairman asked him whether it's entirely a matter for the individual doctors and nurses. And you can see the way he deals with that. Ultimately, at line 18, he says:

"Okay, I'll say 'entirely'."

So there's an agreement then that this issue of the responsibility for clinical quality is entirely a matter for the doctors and the nurses prior to the legislative change in 2003.

And then Mr Stewart goes on to say:

"Question: Who was responsible for clinical safety in the Royal?

"Answer: Individual qualified doctors who came under the aegis of the GMC."

And if we go on to page 17:

"And your evidence is that neither the board nor yourself had any responsibility for the healthcare and the quality of healthcare given to patients in the hospital?"

And the answer is pretty clear:

"I have to answer that question, chairman, yes, that was the case."

Firstly, do you think that's a correct characterisation?

A. No.

Q. Did you know that that was his view?

A. No.

Q. Do you think it ought to have come to your attention that the chief executive of one of the largest trusts in Northern Ireland did not think either he or his board had any responsibility for the quality of healthcare?

A. These answers were given to this inquiry, weren't they --

Q. Yes.

A. -- not too long ago?

Q. Yes.

A. In 2013?

THE CHAIRMAN: Yes.

MS ANYADIKE-DANES: Yes.

A. That's 16 years after I was responsible.

Q. Sorry, Mr Elliott, I'm putting it in a different way. If that was his view, do you think that that was a view that you should have known about?

A. Possibly, yes, or John Hunter should have known. But I was asked whether I agreed with William McKee or with

Hugh Mills' view, which was given later.

Q. Yes.

A. And I said, I think, that I would support Mr Mills' view that the trust had ultimate responsibility, and I still think that.

THE CHAIRMAN: I think the critical thing for me is that it's a bit disturbing that such a prominent figure in the local Health Service as Mr McKee has asserted that neither he nor the board of the Royal Trust had responsibility for the quality of healthcare.

A. Yes. No disrespect to lawyers, but I think he could have been led down a road to reaching that conclusion, which, with hindsight, he would say, "No, that's not quite what I meant", you know. I'd be interested to know, but presumably you will not recall witnesses, but I'd be interested to know whether he would still stand four-square behind what was said there.

THE CHAIRMAN: I think if he does, he's on his own. Okay.

MS ANYADIKE-DANES: Yes, thank you.

If he did hold that view at the time, that might have affected what systems he required to be put in place in the trust.

A. Yes.

Q. And to the extent that it might have had that effect and none of that came to the attention of either you or

Mr Hunter, Mr Hunter says he didn't know Mr McKee had such and view and doesn't agree with it, it might therefore indicate a certain weakness in relying on the board for your information as to what's going on in the trusts and in the individual hospitals.

A. Yes, and all the more so because the Royal is, in some respects, the premier hospital in Northern Ireland.

Q. Exactly. In fact, it provides regional services, not just the services to its own catchment area.

THE CHAIRMAN: It's the primary hospital for children.

A. And for children, yes, that's right.

THE CHAIRMAN: Okay.

MS ANYADIKE-DANES: So now if I go back to a point that you were making when you were answering the chairman, which really centres around how the department held the system to account. Because that's really what had to happen. I think that you have agreed that that's part of your role as the apex of all of that.

A. Yes.

Q. When you were answering the chairman, you talked about accountability meetings.

A. Yes.

Q. Can you help us with that? How formal were those accountability meetings?

A. Now, I was directly concerned with the earlier ones.

Before the reforms, before trusts were established, the minister met the four Health and Social Services boards. It was pretty formal in the sense that there was an agenda which we drew up and to which the board could add items. One occasion I remember, there was something like ten officers of the department there on particular aspects, and the board was the chairman, chief executive, and other chief officers. It was quite a formidable gala(?) to the extent, actually, that one of our ministers afterwards said, "Too many people there, Alan. Cut it down next time".

Q. Were the trusts represented?

THE CHAIRMAN: No, this is before --

A. This is pre-trusts. This is before the trusts. When a Management Executive was established, the trusts were there. I was that much further back and did not attend these annual accountability meetings with the boards.

MS ANYADIKE-DANES: Sorry, I beg your pardon, I misheard you. Let me take you to a time when the trusts are established.

A. Right.

Q. At that stage, how do you learn about what is happening in terms of holding the system, as you described it, to account? If you don't directly attend accountability meetings, as you used to do, what's your source of

information for holding the system to account?

A. A source of information would be principally the chief executive, John Hunter. And I should have said previously maybe, but now that we're up at this one, when he was appointed and the new system came into place, he was appointed as the accounting officer for HPSS expenditure insofar as it came under the Management Executive.

Q. Yes.

A. And from then on, actually, John went to the Public Accounts Committee rather than me on health matters.

Q. Yes. Dr Paddy Woods was trying to help us with the answer to the question about how the accountability meetings worked and what the documentary evidence might be for them. He said this, which he's subsequently corrected. He said:

"Formal accountability meetings would have taken place twice a year. Individuals who would have had [in this case he was talking about Lucy's case, which was a child who died after treatment at the Erne Hospital. She died in the Children's Hospital in 2000] responsibility for the oversight of Sperrin Lakeland in 2000 and who might have received reports of issues affecting the trusts would be the Permanent Secretary, the chief executive, management secretary and others

in the Management Executive."

It seemed to suggest that at that time, which would be a time after you had left --

A. Yes.

Q. -- that there might have been accountability meetings in which the Permanent Secretary would be involved. Do you recall any instances, once the trusts were established, when you might have attended accountability meetings?

A. No. No, I don't.

THE CHAIRMAN: Because they would have gone up from four a year, one with each board --

A. To four plus 19.

MS ANYADIKE-DANES: So your source of information was really Mr Hunter?

A. Yes. That's right, and the Management Executive generally, but principally Mr Hunter.

Q. And to the extent that his own sources of information were perhaps not as robust as they might have been, then that would have had an effect on the ability for you to know what was going on?

A. Yes, I think that inevitably follows.

Q. That does take us to the issue of notification. We asked you about when you first knew about the deaths of Adam and Claire.

A. Yes.

Q. You answered that, we don't need to pull it up, but the reference for it is 348/1, page 5. You said:

"I have no recollection of being made aware of those deaths."

A. That's right.

Q. In fact, you said you only became aware of them when you read about them subsequently in the press when the inquiry was established --

A. That's right.

Q. -- which was in 2004. Coming after you, Mr Gowdy has said that he would have expected to know about those deaths as Permanent Secretary. Would you accept that?

A. This is a particular point about ... I said in my witness statement, it was question 19 -- I was asked:

"Would I have expected trusts to have done anything to inform the department in cases involving deaths due to possible medical mismanagement, were involved in complaints and inquests and ..."

I said I would have expected the department to have been informed.

Q. Yes.

A. Not necessarily, in fact probably not, a department secretary, but the department --

Q. So does that mean --

A. -- to have been informed of cases involving death. Now,

thinking about that when I was preparing for this hearing, essentially since there was no formal mechanism at that time to inform the department of such issues, I doubt whether, thinking at the time, I would have expected the department to have been regularly informed of issues like this because there was no mechanism in place at that time, as I understand it, here or in the United Kingdom generally, for informing the department about cases which are listed there, those involving formal complaints and --

Q. Sorry, Mr Elliott. If we move away from that particular question because what that question was asking you was:

"Prior to 2002, what would you have expected the trusts to have done in regard to informing the department when cases involving death, which also involved formal complaint procedures, coroner's inquests and medical negligence actions."

If we leave that aside and look at the characteristics of Adam's death, Adam was a little boy who, I think the evidence has been, shouldn't have died. So to that extent, that was a serious adverse incident that he ended up dying.

A. Yes.

Q. And he died as a result of being given too much of the wrong sort of fluid, which is something that his

consultant nephrologist appreciated almost as soon as he'd got to examine him after his operation. He had an inquest where his care was criticised by an independent expert and, as a result of all of that, or part of it, the trust changed its procedures and it issued a statement to the coroner about that. That was published in the press and there was a comment made by the coroner that he felt that those sorts of cases, albeit rare, would benefit from some further investigation.

A. Yes.

Q. So that's the sort of short narrative around Adam's death. Mr Hunter thought that that was a death that should have come to the attention of the department, for a number of reasons: one, because it was an avoidable death that had happened; it involved a child -- there aren't that many deaths like that involving children?

A. No.

Q. And it had led to a change in systems in the Royal and it had achieved the sort of publicity that might end up with the minister having to respond. And all those were the very sorts of reasons why that case should have come to the attention of the department. Would you accept that?

A. Yes, I would.

Q. So Adam's case is something that John Hunter and/or you should have known about in some way?

A. Yes, in the light of what you say, yes, that's right.

THE CHAIRMAN: But I'm sorry, you've agreed with that, Mr Elliott, as the result of a series of points. What's the most important point? Is it because the minister might be asked for a response to it? Can that really be the primary reason for reporting a death?

A. No, no.

THE CHAIRMAN: So is it the fact that it's an avoidable death as a result of which action has had to be taken to improve the system?

A. Yes.

MS ANYADIKE-DANES: Just to follow on from that, is it you, is it Mr Hunter, or is it both of you who should have known about that death?

A. Mr Hunter, I think certainly.

Q. Would you have expected him to have told you about a death like that?

A. Um ... Not in a sort of formal reporting way, but I would be surprised -- I would have been surprised if he had not mentioned it to me as something upsetting which had happened.

THE CHAIRMAN: And the mechanism, the route you described this morning was trust to board and into the department.

A. Board and into the department.

THE CHAIRMAN: Yes.

MS ANYADIKE-DANES: Yes. And then if we take the case of Claire, Claire was a slightly different case. She died within five months of Adam's inquest and her fluid management was also called into question. There were some other issues surrounding her death, but the upshot of it was that neither Mr McKee nor anybody in the department knew about that death until actually her parents made a connection when they watched the UTV documentary.

A. Which was when?

Q. 2004.

A. 2004, mm.

THE CHAIRMAN: So there's an eight-year gap between Claire's death and the recognition that it's related to hyponatraemia and that recognition is not led by the doctors or nurses involved, it's led by her parents, who happened to be watching the documentary. It's pretty hopeless, isn't it?

A. Those are circumstances of which no one in the Health Service or the department could be at all proud.

MS ANYADIKE-DANES: No. And as the chairman pointed out earlier, we happen to know about those deaths because this inquiry has been tasked to investigate them.

A. Mm-hm.
Q. There might be others who have slipped through that informal system that has been discussed of bringing deaths to the attention of the department. That's a possibility?
A. It is a possibility, although with all the publicity now round the particular deaths, I would be surprised if someone somewhere, whether a parent or a member of staff, had not drawn attention to them.
Q. Mr Hunter has agreed with you about the informal system and the CMO has said that there wasn't a formal system, so she also agrees. In fact, just about everybody agrees. It's not even clear whether you can call it a system really; there just was an absence of any kind of system to routinely notify either the Management Executive or the department of those sorts of deaths.
A. Yes, that's right.
THE CHAIRMAN: I have to say that that, in part, comes about because of the way the deaths were treated in the hospital.
A. Yes.
THE CHAIRMAN: If they aren't treated correctly in the hospital --
A. They're not going to come through, even that -- if there was a formal system, they mightn't come through it.

THE CHAIRMAN: Yes, and at that time in the 1990s, there was a culture which I'm told was more prevalent then than it is today of doctors not facing up to their mistakes and not being encouraged --
A. "Doctors know best" was a theme, deeply ingrained, so deeply ingrained that I think, even today, there's a certain hesitation about criticising doctors.
THE CHAIRMAN: But the problem about that, the reality of that, Mr Elliott, is why the need for a system which works is all the more important.
A. Yes. Yes, I agree.
MS ANYADIKE-DANES: Can I just pull up this? It's witness statement 075/1, page 3. This is the CMO. If you look at the last paragraph, Mr Elliott, you can see that she starts off by saying:
"There was no requirement for the trusts to report deaths to the department."
Well, you would accept that that's correct, there wasn't such a requirement. And then she goes on to characterise what she has called the informal system. And I wonder if --
A. Is that where she says, "Whereby medical directors of trusts ..."?
Q. Yes, perhaps we might just highlight that for you:
"So there was an informal system: the medical

directors of trusts or the directors of public health at the boards would share information arising out of unusual cases or adverse incidents."
So if we stop at that stage, that's not yet got to the department; that is the trusts and the public health directors at the boards. So that's the trust/board relationship.
Then she goes on to say:
"That information would occasionally be relayed to the department."
And that's how she says that another case, which is way past your time, of Raychel's, came to be reported to the department.
But if we just try and deconstruct that because that's all that there is that was happening. The whole thing is informal, you would accept that?
A. Yes.
Q. And there's no guidance as to what constitutes an unusual case or an adverse incident for the purposes of this discussion that's going to take place or might take place between the trusts and the boards. The department hasn't issued any guidance on that; that would be correct?
A. Up to the time of my retirement, yes.
Q. Exactly. I'm only asking you up until that time,

Mr Elliott. Up until that time, the department had issued no guidance as to what would constitute an unusual case or an adverse incident to get the trust to refer that to the board?
A. Yes.
Q. But this is the only route by which you're going to hear about it, you being the department?
A. Yes.
Q. But there's nothing put in place to ensure any kind of standardisation about that. As a result of that, the communication between the trusts and the boards is dependent upon the trusts having an adequate system so that the medical director knows a death like that has happened and could be having that discussion with the board.
A. That's right. And that may not have happened in those days.
Q. No, it may not. In fact, you're absolutely right, it hadn't happened.
A. No, it hadn't.
Q. Because Dr Carson, who was the medical director at the Royal, didn't know about Adam's death at the time that Adam died -- according to him, he doesn't recollect being told about that until Adam's inquest -- and he didn't know about Claire's death because nobody was

really acknowledging Claire died in a way that would require any reporting and he didn't know that until matters came to light in the UTV programme. So if the trusts don't have a system whereby the medical director can know, then obviously there's a break in the chain right there because they're not going to be able to have that kind of discussion with the board?

A. Let alone reaching the board or the department, yes.

Q. And it's only at that stage, when it's got to that discussion, that there's any prospect in the way that the CMO has described it of the department learning about it, and she says that it's occasionally information like that is relayed to the department. So she has not indicated there's any guidance --

A. No.

Q. -- even then when an issue like that has come to the board, any guidance as to when the board should be telling the department, whether the Management Executive, whether her or whether you.

A. Yes.

Q. It's a bit hit and miss; would that be a fair way --

A. Hardly a hit at all.

Q. And deeply unsatisfactory?

A. Unsatisfactory, certainly, yes. It is perhaps fair to say that, as I understand it, at that time, up until

maybe 2002, there was no formal system of reporting those cases anywhere in the United Kingdom.

THE CHAIRMAN: Some progress had been made in some areas in Great Britain.

A. But there was not a standard national system.

THE CHAIRMAN: Yes.

MS ANYADIKE-DANES: Leaving aside that, in a small jurisdiction like that, if the CMO could describe that as the way things were done, it doesn't take much to see that that's unsatisfactory.

A. Mm.

Q. So my question is: why was that allowed to persist for so long?

A. I really don't have a ready answer to that question, Ms Anyadike-Danes.

THE CHAIRMAN: Could I suggest, Mr Elliott, that --

A. Hindsight makes you think: of course we should have done that in 1995 or 1996 or even earlier. But if I say -- it sort of sounds flippant, but it didn't occur to anyone to say that there should be a system.

THE CHAIRMAN: Okay, I've got the point, Ms Anyadike-Danes.

MS ANYADIKE-DANES: I beg your pardon, just one final question on that. You were specifically asked about that, in fairness to you:

"Why was a formal approach not adopted for adverse

incident reporting prior to 2002?"

But in effect, from your point of view that's an unfair question, really, because the question is why was a more formal -- sorry, if you're looking for it in your witness statement, it's question 18.

A. Yes.

Q. From your point of view, why was a system not instituted before you left in 1997?

A. Yes.

Q. And your answer to the larger question was:

"There was no evidence to suggest that a formal approach was needed."

A. Mm.

Q. What did you mean by that?

A. Mm ... Looking at it now, I have some difficulty answering that question. Things simply weren't in our notice then. This applies also to coroner's inquests --

Q. Yes, I'll come to that.

A. -- and medical negligence actions, legal actions. They were simply not seen as being -- significant things, yes, but things that should be reported through a formal system to the department.

Q. But you did think that adverse incidents and reactions involving defective products that relate to medical and non-medical equipment, that was a statutory thing and

that was something that was important to be reported?

A. Yes.

Q. And if there was an untoward event involving a patient in a psychiatric or special care hospital, that also was something that was the subject of a letter, so that had a special provision?

A. That's right.

Q. And that --

THE CHAIRMAN: Sorry, was that a special statutory provision as you remember, or was it an established practice?

A. Oh, I'm not sure. It may have arisen out of a report like the Clothier report and that sort of thing.

THE CHAIRMAN: Thank you.

A. I doubt if it would have been statutory -- that was in law.

THE CHAIRMAN: Thank you.

MS ANYADIKE-DANES: In fact, the requirement for that was set out in a letter. We don't need to go to it, but it's referred to in witness statement 075/1 at page 32, and that letter was dated in May 1997. So some thought had been given to the idea that certain sorts of adverse incidents would have to be reported. And I suppose the only question is -- and maybe you've answered it by saying you don't know -- why that didn't extend to these sorts. But maybe that is your answer: you don't know

why it didn't.
A. That's right.
Q. And just because, as you've mentioned the response to Professor Scally's report, in fairness, to put this section to you which I've also put to Mr Hunter. When he was asked to characterise what happened about serious adverse incidents, he said he wasn't at all surprised that those deaths hadn't come to the attention of the department because the department didn't have a systematic way of getting that kind of information, and what you had instead was a series of unstructured communications, often by means of telephone calls, outside any recognised protocols and heavily reliant on interpersonal relationships. You would accept that, would you?
A. Yes, I would.
Q. Then finally, Professor Scally has concluded that there was no effective system in place in Northern Ireland prior to 2003, although for your purposes it would be up to 1997 because that's your tenure.
A. Yes.
Q. And:
"No significant efforts had been made at any stage to develop comprehensive and effective notification systems."

Would you accept that by the time you left?
A. I don't know how he would have known that no efforts had been made.
Q. I think he's talking about the evidence of it.
A. He had no evidence that that thought had been given? Okay, yes.
Q. And you can't recall thought being given to it?
A. No.
Q. Thank you. Then just finally on this last point with Professor Scally, he believed that there was a clear leadership role for the department in bringing in the cultural change necessary for clinical governance. I put that to Mr Hunter, but what is your view? Do you think there was a leadership role for the department in there?
A. The department had a leadership role generally in relation to the whole Health Service. When something new came along and we accepted it, we should have been -- and often were -- the lead in taking it forward and seeing that it happened, yes.
Q. And to the extent that perhaps systems weren't put in place as soon as they might have been, do you take responsibility for that as well as Mr Hunter?
A. These were the systems --
Q. Which might have allowed you to know about those sorts

of deaths.
A. -- that we're talking about: adverse incidents and coroner's cases --
Q. Yes.
A. Yes, I do. I mean, primarily, since the Management Executive and trusts and so on, it was primarily the early [sic] responsibility of the chief executive of the Management Executive, but I don't resile from the point that the Permanent Secretary was ultimately accountable for everything which happened in the department.
Q. I understand. I only have two more questions for you, Mr Elliott.
One relates to coroners because you have mentioned them, and you were asked about them. Your answer was that there was no formal process in place in 1995 for sharing information on coroner's inquests with the department.
THE CHAIRMAN: I think we've just covered this.
MS ANYADIKE-DANES: We'll leave that. The last point I wanted to address with you is a question of guidance and guidelines -- well, we've taken one example, just to use that to maybe how things might have worked, and that is the guidance in relation to patient consent. It was a letter that was issued by Mr Hunter to tell everybody involved about changes to consent. We can see

it at 305-002-003.
A. Yes.
Q. And if we can pull up 004 with it. It's only a two-page document.
A. Did this cover new consent forms?
Q. Yes, you're absolutely right about that. In fact, what trails behind this is a document that they were using that had been introduced in the UK, which is a booklet really; it deals with new consent forms and how consent is to be taken and so on. This, as you can see, issues from the Management Executive and is signed by Mr Hunter. There are two parts of it that were of interest. If one goes to the bottom of the left-hand page, you can see what the trusts are being asked to do. The trusts are asked to:
"Ensure that procedures are in place to assure that consent is obtained along the lines that are set out in the handbook."
That's what accompanies this letter.
A. Yes. I would have expressed that as "ensure", but --
Q. I understand. These things happen. And:
"To introduce revised documentation with adequate monitoring arrangements."
So they have to put in place procedures, they have to change the documentation, and they have to institute

adequate monitoring arrangements that all that is working.

If one looks at the top of the next page, the trusts have to confirm by 31 December that they've done all of that.

A. Yes.

Q. The question that I put to Mr Hunter generally, using this as an example, was: what were the systems in place when something like that went out, introducing a change -- it's quite an important one -- for making sure that not only do they receive the confirmation but those monitoring arrangements were indeed adequate and that they were working?

A. And they were not.

Q. No. In fact, as it turned out, the Royal didn't change its procedures until 2000.

A. That having come out in?

Q. In 1995.

Nor is there any evidence that they responded by confirming that they had done anything by the end of the year, which is what they had to do, nor for that matter any evidence that they were asked "Where is your confirmation?"

A. Yes.

Q. I'm not saying those things didn't exist; I'm just

saying we've asked for the evidence and we haven't received it.

A. That's right.

Q. Were you aware of what systems you expected that there would be in place when any of these guidelines or circulars went out requiring some change to occur?

A. Was I aware, sorry, of?

Q. Of any system that there was for ensuring that this was being adhered to.

A. Other than if that sort of thing was said that's in John Hunter's letter and they were to report to the department. I would have expected the department to review and to follow up and to write to or speak to trusts which had not replied and said, "Let us have your return". I would certainly have expected some follow-up system.

Q. And some system for satisfying yourself that the monitoring arrangements are indeed adequate?

A. Yes, well, I don't think that that could go so far as saying, you know, someone from the department coming down and --

Q. No, no.

A. -- examining all the systems.

THE CHAIRMAN: But it would be an issue to raise at the accountability review, wouldn't it?

A. It could be.

THE CHAIRMAN: If it's going to be an annual or biannual accountability review between the Management Executive and the trust and the Management Executive has issued fresh guidance on consent --

A. On consent.

THE CHAIRMAN: -- then that's an issue which could --

A. Yes.

THE CHAIRMAN: -- fall well to be followed up?

A. There were some instances where we used the accountability review to follow things up like that.

MS ANYADIKE-DANES: Just a final question. Are you surprised that the situation would carry on for as long as 2000?

A. Yes. Yes, I am.

MS ANYADIKE-DANES: Thank you very much.

THE CHAIRMAN: Thank you.

Any questions from the floor? No?

Mr Elliott, thank you very much for your time. That brings an end to the questioning we have for you. Unless there's anything else you want to add, you're welcome to leave.

A. No, I think that's all, chairman, except to thank you and Ms Anyadike-Danes for the courteous way in which you put your questions.

THE CHAIRMAN: Thank you very much.

A. Thank you.

(The witness withdrew)

THE CHAIRMAN: We'll take a break. It's too early to start lunch, so we'll take a break for 10 minutes and start with Dr Morrow at 12.30.

(12.20 pm)

(The Short Adjournment)

(12.30 pm)

MR REID: If I can call Dr Norman Morrow, please.

DR NORMAN MORROW (called)

Questions from MR REID

MR REID: Thank you, doctor. You have made two witness statements to the inquiry, and those are WS079/1, dated 29 July 2005, and WS079/2, dated 25 September 2013; isn't that right?

A. That's correct, yes.

Q. Would you like to adopt those witness statements as your evidence before the inquiry?

A. Yes, but if I could just make one small additional comment.

THE CHAIRMAN: Of course.

A. Just reflecting on my responses, and also in the light of the evidence that's been provided me through the inquiry, it might have been reasonable in the

circumstances to be informed of a perceived causal link to a medicine in these particular circumstances. That said, subsequent governance arrangements that we've had within the department, the pharmaceutical branch has been advised of any medicine-related incidents coming through the serious adverse events process.

THE CHAIRMAN: Right. So at the time of the events with which I am concerned, you weren't aware of any causal link between Solution No. 18 and the deaths?

A. No, I hadn't been informed of that.

THE CHAIRMAN: Right. But by the time you retired earlier this year, what had changed in terms of being notified?

A. I think -- well, particularly in relation to the serious adverse events process, as those came to the department then any of those events where medicines were implicated would have been normally passed to my branch and I or one of my colleagues would have routinely screened them to make any comments or any action that needed to be done.

THE CHAIRMAN: So that you could comment on the extent, if any, to which you agreed that there was a causal link between the use of a particular medicine and what happened to a patient?

A. Yes, or indeed any learning that we should gain from particular events. So it was part of the governance

system being developed and cemented into the system.

THE CHAIRMAN: We'll come back to that later in the evidence, but it is a helpful start.

MR REID: If I can just ask one question about that: do you mean that you would have required someone else to have come up with a causal link between the medication, the IV fluid, and the deaths, or is it that you would have wanted someone in the department in your branch to have figured out that causal link?

A. No, I would have more expected that the causal link or the perceived causal link may have come from the source. Otherwise why would you be making that particular connection?

THE CHAIRMAN: So your department would become engaged if somebody had believed there was a causal link and would then come to you for your input and you would say "Yes, you're right" or "No, you're wrong, but in any event we might be able to learn something from this"?

A. Yes, or we could have explored it further.

THE CHAIRMAN: Thank you.

MR REID: As the chairman says, we'll come back to that in greater detail later.

Have you made any other statements in relation to these events, for example, for internal use or anything like that?

A. No.

Q. Thank you. If we can bring up your career history at witness statement 079/2, at page 3, please. We see there that you were fully qualified as a pharmacist in 1975, when you were working at the Royal Victoria Hospital, and you then joined the department in 1983 as a pharmaceutical officer, then as a principal pharmaceutical officer, then a senior principal pharmaceutical officer and finally as Chief Pharmaceutical Officer; isn't that correct?

A. That's correct, yes.

Q. Then you were Chief Pharmaceutical Officer from September 1995 until April 2013.

A. That's correct.

Q. So it was 18 years as Chief Pharmaceutical Officer?

A. Yes, a long innings.

Q. And you were a member of the department for 30 years?

A. Yes, indeed.

Q. Just for avoidance of doubt, the pharmaceutical branch deals with medications, medicines and drugs and so on. For avoidance of doubt, IV fluids would be under your remit; isn't that correct?

A. Well, the pharmaceutical branch has probably got a slightly wider remit in terms of it's concerned with professional services, concerned with medicines

management and concerned with compliance with medicines regulation. But yes, intravenous fluids are medicinal products by definition.

Q. And if we actually go to page 6 of that witness statement, please. Just at the top you answer a similar question to the one I just posed:

"If [you] distinguish the product from the administration of the product, intravenous fluids are licensed medicinal products, are legally designated prescription-only medicines and would have fallen under [my] general medicines purview, as do all medicinal products."

Is that right?

A. That's right.

Q. You say:

"If I distinguish the product from the administration of the product."

Could you just explain that for us, please?

A. I was trying to answer the question as I understood it in terms of what is a medicine. A medicine is not a medicine by virtue of its administration per se, it's a medicine by virtue of its purpose, and there is a European directive -- I have got the reference with me -- that actually defines what a medicine is. So that was really the only point I was trying to make in terms

of pure definition.
Q. So in terms of the administration of the product, would, for example, recommended dosage or how a medicine is administered be under your remit?
A. Not directly inasmuch as each medicine like -- medicines are licensed products, if I make that point. Under the terms of a licence, those are all given in product specification, so there are -- by virtue of the licensing system for medicines, all of that material is laid down.
Q. So the recommended dosage and so on --
A. Is part of the specification.
Q. -- is all designated already as part of the licensing process?
A. Yes.
THE CHAIRMAN: We don't need to go into this in detail, but in general terms does the licence specify a maximum dosage but does not give a recommended dosage, or does it give a recommended dosage?
A. It tends to give a range of dose, depending on the clinical circumstances.
MR REID: And through some of the different cases in the inquiry we've heard about the British National Formulary, which is a sort of reference guidebook for the administration of medication. What involvement

would you have in your role in the production of the BNF?
A. Personally I haven't had any. One of my colleagues has been involved in helping with some of the revisions of the BNF, but it is done by way of, effectively, a national UK-wide editorial board, so there is considerable effort and input into doing that. But, no, it wouldn't normally -- it's not part of my remit.
Q. But those UK board recommendations in the BNF are incorporated almost directly into practice within Northern Ireland; is that right?
A. Well, the British National Formulary is published twice a year, so it is updated in that respect. I maybe should help distinguish because I was reading here some of your further reports. There is a British National Formulary in relation to, I suppose you could say, adult medication, but there is a British National Formulary for children --
Q. Yes.
A. -- so just to make the fact that there are two formularies.
Q. And the paediatric formulary is a newer invention; isn't that right?
A. Yes.
Q. Was it maybe the last 10, 15 years; is that correct?

A. That's correct.
Q. If we look then just at your role, if we can bring up page 4, please, of Dr Morrow's witness statement, 079/2. There you describe your role. You say:
"The pharmaceutical branch under [your direction] has direct responsibility for pharmaceutical policy, including prescribing policy."
And we've dealt somewhat with some of that. Can I ask you: would record keeping and the documentation that would go with drug administration be part of your remit?
A. Not directly, but I could allude -- we'll probably talk about it later, about the medicines governance team that we set up and they did make significant input to looking at the design of medication record charts as part of their governance role. So not directly with me, but we have done it through pharmaceutical support.
Q. And is that in any way to try and regularise medication sheets between different hospitals in Northern Ireland?
A. Yes, I think one of the -- it might be helpful for the inquiry. In relation to adverse events, whether it be with medicines or whether -- a lot of it is deemed to be systems failures as distinct from person failures, and one of the issues for us is that each trust had tended to have its own documentation. Now, that's all right at

one level, but as people move across the system, it is more helpful to have common recording systems so that you actually minimise errors through that kind of process. So something about getting consistency is actually quite an important principle in terms of trying to ensure safety.
Q. Because of the nature of the profession as well, it'd be the most junior members who would be moving around different hospitals the most; isn't that right?
A. Yes. Just recently we've set up a new pharmacy computer system, and again we've done it on a regional basis so people can adopt easily as they move.
Q. The next line says:
"The Chief Pharmaceutical Officer is responsible for the profession's contribution to the development and implementation of policy."
And later on, I think you say -- it's at the fourth bullet down:
"In co-operation with the HSC, independent sector and higher education, the branch has responsibility to act as a catalyst for change and innovation."
How, during your time as Chief Pharmaceutical Officer, did the branch act as a catalyst for change?
A. I would suggest in a variety of ways, perhaps maybe most pertinent to this inquiry was the work that we did in

setting up a medicines governance team. It may be worthwhile saying it was not set up in the light of these tragic events, but in the light of wider evidence around adverse events. And this was the first time that anyone in the United Kingdom had set up a team of this particular nature to look at medicine safety issues, and in fact we had stepped outside the tramlines, so to speak, because at that particular time there was a new executive in Northern Ireland and they had taken money back from each department and had set up executive programme funds, which allowed for the opportunity to do new things in new areas. It was through that process that I applied to that and got the funding to set up the team. Ultimately, the department continued to fund that team and, more recently, that team has been extended to primary care. So that was particularly innovative in Northern Ireland and still is very innovative.

Q. And that team was established in August 2002; is that correct?

A. That's correct.

Q. Firstly, how many people did the pharmaceutical branch employ, would you have said?

A. At what time?

Q. Did it change over time?

A. It did change over time. The job description has

changed over time. Unfortunately, I couldn't find the job description back in 1995 so I could compare it with the current one, which was just issued in July. But we did change the number of people in the team and we did change the responsibilities of the team so that, for example, some of the work that was carried out under the pharmaceutical section in the primary care branch of the department, of which prescribing policy was part, that came under my remit around 2011.

Q. And we've had the Chief Nursing Officer yesterday and we're having Dr Campbell, the Chief Medical Officer at the time, on Thursday. How would your department have compared in size to, for example, the Chief Nursing Officer's office or the Chief Medical Officer's office?

A. Over time, it probably has become bigger than the Chief Nursing Officer's group, as far as I recall, but smaller than the chief -- significantly smaller than the Chief Medical Officer's group. But again, important to say that as of now, or within the last two years, the pharmaceutical branch is part of the Chief Medical Officer's group. So we've actually brought some more coordination to all of that.

Q. I was just about to ask you that. You were a member of the departmental board; isn't that right?

A. Yes, that's correct.

Q. Were you a member of the departmental board from the time that you took up the post?

A. Yes, as I recall.

Q. And were you still a member of the departmental board whenever you retired in April?

A. Yes, I was.

Q. Okay. But your accountability --

THE CHAIRMAN: Sorry, just a moment. Did you hear Mr Elliott's evidence this morning?

A. I did.

THE CHAIRMAN: I want to avoid confusion because he was talking about different types of departmental board. He was talking about what he called the top-of-the-office group. Is that what you're talking about, a departmental board?

A. I was trying to recall.

THE CHAIRMAN: Because he put you in it.

A. Yes, he did. I was trying to recall that as far as I recall, yes, I was part of that top-of-the-office group because I know my predecessor was. But I also recall, effectively, being always on the departmental boards.

THE CHAIRMAN: Thank you.

MR REID: But you're saying the accountability structure has changed somewhat?

A. Yes.

Q. And I think we can find this actually on this page 4 that's up. At the very bottom you say:

"Accountability has changed from originally being directly accountable to the Permanent Secretary to being accountable through the deputy secretary for secondary care."

And then:

"From April 2011, [you] assumed responsibility for the wider policy matters relating to pharmacy and prescribing, which were formerly the responsibility of the primary care directorate."

A. Yes.

Q. So you were directly accountable to the Permanent Secretary; isn't that right?

A. Yes.

Q. And it changed in 2007; why did it change?

A. As I recall, different changes were taking place in the department. I think the Permanent Secretary at that time felt that he had too many direct line reporting relationships, and again the structure of the department had changed somewhat. That was, I suppose, a convenient place that we were located at that time, and then it has since moved to a different arrangement, which I think is much more rational.

Q. So there was a step introduced in accountability between you and the Permanent Secretary from 2007 on; is that correct?
A. Yes, although my view of that is that I still had professional responsibilities to the Permanent Secretary and to the minister directly. Those didn't change and they haven't changed, as I see them, in the current system. It's a more management accountability as distinct from a professional accountability.
Q. And you would have been meeting with the Permanent Secretary and the Chief Medical Officer and the Chief Nursing Officer on a regular basis at those board meetings?
A. Certainly at board meetings, yes.
Q. How closely did you work with the Chief Medical Officer and the Chief Nursing Officer?
A. I think that probably, going back, I probably worked more with their staff, depending on what the particular issues were. So we had close working relationships. In fact, I would like to think I had close working relationships right across the department because pharmaceutical issues tended to go quite widely.
Q. So there would be matters that would overlap? Professor Dame Judith Hill was talking yesterday about nurse prescribing; did you work on that with members of her

office or did you work with her directly or both?
A. No, particularly with members of her office. In fact, I did a lot of work with the nursing group in supporting them in actually achieving the delivery of nurse prescribing. Pharmacist prescribing came after and I was involved, before I left the department, with rolling-out prescribing to some of the other professional groups as that particular concept developed.
Q. If I can ask you just about quality of care. To what extent was the role of the pharmaceutical branch to set and monitor standards of care in hospitals in terms of, obviously, medication?
A. Perhaps if I can answer that in two ways. One, as far as the branch was concerned, and me personally concerned, the issue of quality and safety was quite important and led to issues like the medicines governance group, for example. We have been involved with other work with the Shipman inquiry in putting in the new legislation and arrangements to ensure that those standards ... So in terms of some of those operational type activities, then we were quite involved in assisting with that, encouraging it and helping it to develop.
So our work was much more in, I guess, a supportive

role and an encouraging, motivating role than it was about holding people to account in the service per se. They were not my directly managed staff. At the same time, it's also true to say that there were systems in place that actually gave indicators of quality adherence.
So for example, we had what was called a controls assurance standard for medicines management as there were controls assurance standards for other things, and that was a system which we used to try and encourage improvement in standards and operations within trusts, and there would have been a yearly report on that.
Q. Yes, because to some extent, I suppose, yours is a support role because the doctors' primary channel is maybe the Chief Medical Officer, the nurses' primary channel is the Chief Nursing Officer, but you get involved in the work of doctors and nurses when medications are involved?
A. Yes. Well, I take the view that medicines pervade our health system, they're the ubiquitous piece of technology that we use across the system. So in my world, then we do transcend that whole arena.
Q. So --
A. Maybe if I say, sometimes quite directly, other times more peripherally.

Q. So specifically, you would agree that in some way you did have a role in the quality of care that was being administered in hospitals?
A. Yes, I would like to think that my branch did contribute to the quality of care of patients in our Health Service.
Q. The reason I ask is that -- if we can bring up the statement of the Chief Medical Officer, Dr Campbell. It's WS075/2 at page 3, please. At question 5 there, the Chief Medical Officer in her inquiry witness statement was asked to:
"Explain [her] 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 care."
She answered:
"This was not part of the role of Chief Medical Officer."
Would you agree with that?
A. I can't speak for the Chief Medical Officer, but I can speak for myself. I feel that I did contribute and my team contributed to the quality of care of patients, and we would have taken that as a kind of intrinsic part of all that we did. In fact, if I just illustrate that. Some work that we did, quite a substantial amount of

work, on a pharmaceutical clinical effectiveness programme. It was set up on the paradigm that if we invest in quality and safety, we will get better health outcomes and efficiencies. So I would have to acknowledge that quality was an important part of the way my team operated.

Q. We've discussed already to some extent UK guidance in the form of the BNF. How did your branch work with, for example, CREST in implementing UK guidance into Northern Ireland?

A. I had some contact with CREST, although that was mediated more through the fact that there was one of the board chief pharmacists as a member of CREST, so that was the pharmaceutical representation on that group.

Q. But through that board member, were UK pharmaceutical guidelines implemented and incorporated into Northern Ireland practice?

A. Well, where there was guidelines and where there was evidence, I would have expected CREST to have picked those up or else we would have been picking up other guidelines through, I suppose you'd call them, normal pharmaceutical channels.

Q. And of course, during your time as Chief Pharmaceutical Officer, CREST became amalgamated into GAIN, the Guidelines Audit and Implementation Network. To what

extent did you work with GAIN through the pharmaceutical branch?

A. Yes, I can't remember the details, I have to confess, but yes, I did work and was part of some of those processes.

Q. If I can ask you about -- I'm sure you're aware of the Management Executive circular PEL(93)36, which is the adverse incident in relation to medical equipment and medications process from about 1993 on. Were you aware of that?

A. Could you --

Q. I'm going to bring it up now. The reference is WS062/1 at page 13. (Pause). The copy I have has page 13 at the bottom; it says "25" on screen. I'm not sure why it works that way.

THE CHAIRMAN: Did you say it's attached to Mr Gowdy's statement?

MR REID: It is, yes. (Pause).

A. Chairman, if I may help the inquiry, I might be able to explain the systems that related to defect reporting.

MR REID: Mr Chairman, I have another paper copy of it I could provide to Dr Morrow if it would assist.

THE CHAIRMAN: It is the front page of this you're looking for?

MR REID: Yes, I'll be referring to annex F in it as well.

(Handed.)

THE CHAIRMAN: If you want a cover page -- yes, if you bring up for us, please, witness statement WS062/1 at page 13. We've got page 25 on screen. If you could give us page 13 instead.

MR REID: I think that's what I was requesting.

A. I have page 25. Annex E?

MR REID: If we could look at the first page there, you have a paper copy, Dr Morrow. At page 13 of Mr Gowdy's witness statement, he's attached this Management Executive circular and it's sent to the chief executive of all of the boards, all of the trusts. This is dated 27 July 1994 and the subject line is:

"Reporting adverse incidents and reactions and defective products relating to medical and non-medical equipment and supplies, food, buildings and plant, and medicinal products."

A. Right, okay.

Q. If you turn over the page to page 14, you'll see at number 7, this is part of:

"Managers should ensure that hazard warning SAB pharmaceutical circulars and chief officer letters issued as a consequence of reports are circulated to all potential users and that prompt action is taken."

A. Mm-hm.

Q. Do you recognise this document, Dr Morrow?

A. Well, I mean, I recognise the truth of it. I can't say that I recognise it from 10 years, but I understand the point.

Q. Would you agree that this was a formal adverse incident reporting system that was in place from 1994 in relation to equipment, plant and medicinal products?

A. Perhaps I could clarify what I think may be meant by this. There has been, for a considerable period of time, a system in place in relation to defective equipment, as you're aware. There also has been a system in place in relation to defective medicinal products, and I can explain that if you wish.

Q. Yes, I was going to --

A. And those were handled through the pharmaceutical branch. So I'm tempted to think -- and I don't recall -- that that's what that was referring to, the drug defect reporting system as distinct from necessarily a wider system. But I don't recall that detail.

Q. Let me guide you through it. If we turn to page 27 of that. Do you have page 27 there? This is annex F.

A. Yes.

Q. What seems to be here -- and I will give you a moment to read it if you need it. There seems to be a dual system

in that, as you say, defective medicines, medicines that are actually defective in their manufacture or production, are notified to the pharmaceutical branch --

A. Yes.

Q. -- and the medicines that cause adverse effects to a patient are reported through the yellow card system.

A. Yes.

Q. Does that sound like a system that you are familiar with?

A. Yes.

Q. And that's contained in annex F and in the very first paragraph, it says -- we have it on screen:

"In the UK a reporting scheme for spontaneous adverse drug reactions, commonly known as the yellow card reporting scheme, is operated for the collection of suspected adverse reactions to medicinal products. The scheme receives reports from doctors, dentists, coroners and pharmaceutical companies. The reports are handled by the Medicines Control Agency on behalf of the Committee on Safety of Medicines (CSM)."

You would have been familiar in your role of the yellow card agency system --

A. Yes.

Q. -- and that that system has been around for quite a number of years; isn't that right?

A. That's correct.

Q. While the defective medicines will be something like if a particular medicine, say Solution No. 18, for example, had been produced without any sodium in it, if it had been manufactured incorrectly, that would have been a defective medicine; is that right?

A. That's correct, and there are -- defective medicines could cover a whole range of things. It could cover an error in labelling, for example, as distinct from necessarily the medicine itself. But it's about the intrinsic quality of the package or the product, including its packaging.

Q. You are asked at -- if we can --

A. May I just draw the inquiry's attention to one point here? The point that's being made here is reporting suspected adverse drug reactions.

Q. Mm-hm.

A. Now, I would make an important distinction between adverse drug reactions and adverse events, if I may explain that.

Q. Certainly.

A. Adverse drug reactions have always been traditionally thought of in terms of side effects of medicines due to their pharmacological make-up or indeed idiosyncratic reactions that patients have. So you might get

dizziness or stomach upsets as a result of taking a medicine. And there has been a long-time system in place through the MCA, now the MHRA, of pharmaco-vigilance in relation to those particular issues.

I think, as time has gone on, then there has been a realisation that, alongside adverse drug reactions, there are adverse events due to medicines which occur for other reasons. For example, somebody administers the wrong medicine or the wrong dose or administers a medicine by the wrong intravenous or intramuscular route or whatever.

So that's an important distinction to make between adverse drug reactions and adverse events due to medicines for other reasons than their intrinsic pharmacological action, if that helps to make that distinction.

Q. That is helpful, thank you, doctor. What we can see there is, at the very least, there was a formal system in place for the adverse reactions to drugs.

A. Yes.

Q. And there was also a formal system in place as far as defective medications were concerned; isn't that right?

A. That's right.

Q. And in the latter they were informed to the

pharmaceutical branch directly?

A. That's right.

Q. And in the former they were informed, through the yellow card system, to the Medicines Control Agency?

A. That's correct.

Q. In your witness statement at WS079/2, page 8, you're asked:

"Would you have expected to be notified?"

And you say that:

"if there was something defective, [you] would normally have been informed as part of the defect reporting system."

Which we have discussed.

The next question, you say that:

"The department was not routinely informed of yellow card reports made to what was the Medicines Control Agency and is now the MHRA."

Why was that, why was the department not informed of yellow card reports to the Medicines Control Agency?

A. As I understand it, the Medicines Control Agency, as was -- the MHRA now -- is set up as really the UK-wide regulatory authority in relation to medicines. And part of the work that it has been involved in for very many years is the whole issue of pharmaco-vigilance. So it acted as really the national reporting centre for

pharmaco-vigilance matters, so that's why the locus was there and you may know that in more recent years the yellow card system has been opened up to patients themselves. So they can report directly in and, again, it's all on the system to try and amass as much information as possible. So that was the system that was operated and I think that a previous witness indicated that the department didn't receive routinely yellow card reports.

THE CHAIRMAN: In short, that's because, if anything action is going to be taken, it's going to be taken by the MCA rather than by the Department of Health in Northern Ireland? Is that why the Department of Health in Northern Ireland doesn't need to have this report made to it?

A. I think there's two ways of looking at that. One is that in relation to -- when we're talking about adverse drug reactions, I make that particular distinction. The evidence suggests that, depending on the frequency or indeed the rarity of an adverse reaction, then you need critical numbers of reports to be able to actually make judgments about whether something is idiosyncratic or whether ...

So part of the thinking around a national reporting system, if we call this a national reporting system, was

to kind of get that quantum dimension. Because getting a single report may be very important, but sometimes you need the bigger numbers to do that, and there has been a lot of work done to give an indication: what will you need, what sort of numbers will you need to be able to identify a one-in-a-million reaction?

MR REID: I can certainly understand why you would have a national system in order to collate those numbers, but would it not be important or indeed simply relevant for you and your pharmaceutical branch to know of yellow card reports being raised by hospitals in Northern Ireland?

A. I think that's reasonable. Again, it's very -- the difficulty is then beginning to make the judgment about how significant -- I mean, if I ... Maybe if I be awfully trivial about it in a sense, but if somebody writes a yellow card report and says "Look, I got a headache" or there was somebody who got very severe migraine headaches because they took this particular medicine, it's very difficult on a one-off report to judge whether that is something of such seriousness -- it obviously is very serious for the patient, but in the overall scheme of things. And if you look at some of the product specifications that are issued with all products, you will see adverse reactions. Some will be

detailed as being very common and then it'll go down to indicate which are rare events. So you get some sense of the dimensions to this.

Q. That's certainly true, but if you're not informed of the yellow card results at all, you can't make any judgment; isn't that correct?

A. I understand. I take the point entirely.

Q. And do you not think that the department, at the very least maybe, should know of yellow card reports without maybe having to go the extra step of making judgments about them, which can be left to the MCA?

A. I think that's probably fair comment.

THE CHAIRMAN: But it's only telling you as a matter of interest rather than as a matter for you to do something about it, isn't it?

A. Yes, it's difficult to make a judgment.

MR REID: You weren't aware of Dr Taylor's yellow card report in September 2001 regarding Solution No. 18?

A. No.

THE CHAIRMAN: Dr Morrow, it's 1.10. I'm inclined, unless you particularly want to break for lunch, to push on and finish your evidence.

A. I'd be very happy to continue, chairman.

MR REID: I have only got the topic of the 2002 guidance.

THE CHAIRMAN: You'll be finished by 2 o'clock, if not

sooner.

A. That's fine. I am happy to do that.

MR REID: Just before I move on to that, the pharmaceutical branch would have known of the defective medicines, but were there any other ways in which the branch would have known about what was happening in hospitals in regard to medicines?

A. I suppose the simple answer to that is yes inasmuch as -- well, maybe not always so much about medicines, but certainly about services, of which medicines might be a part, inasmuch as I did meet reasonably regularly with the chief pharmaceutical officers of boards and then, after trusts were established, I did have periodic meetings with trusts. So some of those issues may have cropped up. I also chaired on behalf of Northern Ireland the regional pharmaceutical procurement group. So that was around the purchase of medicines as I was also chairing a pharmaceutical clinical effectiveness group, which was also around the choice of medications and procurement of medications. So in that sense, yes.

Q. But again, would you have been reliant on those pharmaceutical directors telling you about what was going on in the hospitals rather than you finding out by your own means what was happening? You're reliant on

them.
A. That would have been a very important conduit of information.
Q. And apart from the meetings themselves, was there any framework or guidance as to what the pharmaceutical officers should be reporting up to you?
A. No.
Q. Do you think there should have been?
A. I'm trying to think of an example. I mean, as I said, with the controls assurance standards that we had around medicines management, then there was opportunity within that to have a formal reporting. But no, there was no formal reporting as such.
Q. If I can give you an example. If I can bring up reference 022-102-317, please. This is a letter from Dr Nesbitt to Dr Fulton at Altnagelvin Hospital.
A. Yes.
Q. In the first paragraph they say:
"The Children's Hospital anaesthetists [as in the Royal Belfast Hospital for Sick Children's anaesthetists] have recently changed their practise and have moved away from No. 18 Solution to Hartmann's solution. This change occurred six months ago and followed several deaths involving No. 18 Solution."
The DLS, on behalf of the Belfast Trust, have

explained that position. I'm not sure if we can bring it up, but I'll try. It's 321-073-001. Yes, we can. They have said in the third paragraph:
"We are instructed that the change of practice most likely refers to intraoperative fluids prescribed by anaesthetists and not post-operative fluids because Hartmann's solution was not routinely prescribed post-operatively in the RBHSC."
You would agree that's a change in practice concerning those fluids?
A. Yes.
Q. First of all, were you aware of that change in practice?
A. Not that I can recall, no.
Q. Would you have expected to have been made aware of that change in practice?
A. No, I think if I can refer to my statement, if I can just --
Q. Yes, I think you want --
A. Page --
Q. WS079/2, page 6, please.
A. I've made the point on 9(b) there for the benefit of those listening:
"Prescribing practice is apt to change quite frequently, partly as a consequence of experience, new clinical guidance, emerging research, newer products

becoming available, procurement practice or indeed medicines shortages."
So there is a constant flux of change that is occurring within the system and, no, I wouldn't be routinely made aware of all those changes. It wouldn't be possible, I think, to manage.
Q. But again you're reliant on pharmaceutical officers informing you of a change such as that?
A. Yes, I would be.
THE CHAIRMAN: Does this depend in part on why the change has been made?
A. Yes. There would have to be rationale for the change.
THE CHAIRMAN: And depending on what the rationale is, that might affect your expectation as to whether you're informed or not. For instance, if one drug has become harder to obtain than a newer drug, the change towards the new drug away from the old one is explained by supply.
A. Yes.
THE CHAIRMAN: And frankly, you don't worry about supply?
A. Well, maybe not -- well, it is important.
THE CHAIRMAN: Okay. But on the other hand, if the move away from Solution No. 18 is because of concerns about the effect which it's having or might have on some patients, is that something which is more likely to be

a matter of interest to you?
A. Yes, I think so, in the sense that something occurring in one part of the service that might be safe to mention -- other parts of the service deserve to know --
THE CHAIRMAN: Yes.
A. -- and I take that letter as being part of that process of ... But I notice in the letter there was none of the pharmacy -- no pharmacist was copied in, for example. But I think that's important: trying to make sure that what happens in one place that might be significant is actually being able to communicate it to other parts of the system where it might be equally significant.
THE CHAIRMAN: Which is exactly Altnagelvin's --
A. Exactly.
THE CHAIRMAN: -- gripe, that they weren't told. That comes back to the reason, because there's a lack of clarity about the explanation for the change. But if it was to do with patient safety and if that change is being made in the regional children's centre, then apart from the fact that one might expect it to be advised to other hospitals where children are treated, it's also something that you would expect to know about?
A. Yes, I think in the sense of being able to find a way to try and make sure that there was some sense of coordination of this. I think that's maybe a reasonable

position to be in.
THE CHAIRMAN: And your coordination is not primarily your role to coordinate with doctors and nurses, but you would want to coordinate with the pharmaceutical officers who work in the different hospitals, would you?
A. Yes. I think that's fair.
THE CHAIRMAN: Thank you.
MR REID: In coordinating, you are reliant on coordinating with those pharmaceutical officers in the hospitals; isn't that right?
A. Yes, I mean, my view is that I work closely with them in relation to trying to ensure the delivery of our pharmaceutical services.
Q. You told us already this morning that you're reliant on them informing you of events of what's happening in the hospitals.
A. Mm-hm.
Q. You have said to the chairman that in certain circumstances where something needs to be coordinated around the region certain things should be informed to you.
A. Mm. I think it would be helpful.
Q. But would you accept that there was no guidance or policy or framework in place that let pharmacists or pharmaceutical officers know that they had to inform you

in those circumstances?
A. Well, let's say there was no, as I would say, no mandate as such, and I think that we would have to -- and I think in other professions as well -- we were relying on people's good intentions or them recognising this is something that we should refer on.
Q. You're reliant on their discretion and good judgment?
A. Yes, that's fair comment.
Q. And would you accept that perhaps something more formal might have assisted in those circumstances?
A. Yes, I think in the overall scheme of things. I'm not sure, from what I have seen and what I have read, the extent to which my pharmaceutical colleagues were necessarily aware of some of these events. I noticed that particular letter that you referred to has copied in the risk manager, but hasn't copied in the chief pharmacist of the trust.
THE CHAIRMAN: Yes.
A. So there are issues of internal communication as well as external communication.
MR REID: Well, that's fair.
If I can ask you just about the 2002 hyponatraemia guidelines. When is the first time that you can recall knowing about those guidelines?
A. To be honest, I cannot recall the first time. I do

recall vaguely a conversation with one of my pharmaceutical colleagues, indicating that the guidelines were being implemented, and I think it was in Altnagelvin. So I cannot precisely put a date on that.
Q. It's certainly true that neither you nor any of your staff in your branch were involved in the formulation or publication of the guidelines?
A. That's correct.
Q. Would you have wanted to be involved in the production of the guidelines at any stage?
A. I have thought about that question and that was partly my response at the beginning. If I could answer the question in this particular way: it does seem to me that the issue was deemed to be predominantly a medical matter, and I understand that. It could also have been that, in terms of pharmacy, it was perceived that pharmacy was only involved in supply, and I can understand that.
The other particular issue is as well -- and if I can draw reference to the NPSA alert, if I can just find it here. That is the perception of what intravenous fluids were. If I can refer to -- it actually is page 3 of the NPSA alert.
THE CHAIRMAN: Sorry, is this the one which you signed?
A. No, no, this is the NPSA, the patient safety alert.

THE CHAIRMAN: Sorry, it's the alert itself rather than --
A. On page 3 it makes this statement, which I think is instructive in some ways. It says:
"When fluids are prescribed they must be given the same consideration as other medicines with reference to indications, contraindications, dose, monitoring and particularly volume."
Now, I interpret that in the sense of people not necessarily viewing intravenous fluids in the same way as they may view other medicines. And that's the only observation I would make. But it is interesting that that particular statement is made in the NPSA alert, and I can only suggest that they may have had some evidence of that.
THE CHAIRMAN: Let me ask you it this way: there was a debate among the members of the working party about whether to be specific in steering doctors away from the use of Solution No. 18. And the position which was taken became one that they were deliberately not doing that, but they would leave that up to each trust to decide what to do. Then some years down the line, there was a definitive move away from Solution No. 18.
A. Mm-hm.
THE CHAIRMAN: Since we know that the working party was actively debating how far to take the guidelines and

whether to effectively prohibit the use of Solution No. 18, is that an area in which you or one of your group might have been able to make a contribution?

A. Potentially, yes, from the point of view that subsequently, as we know, it was deemed appropriate to take this particular solution out of the clinical area.

THE CHAIRMAN: Yes.

A. So that could have been -- but I have to say, you know, that is somewhat speculative in retrospect.

THE CHAIRMAN: The reason I'm asking, doctor, is this isn't a retrospect issue; this was a live issue at the time.

A. Yes.

THE CHAIRMAN: Because when Altnagelvin received the draft guidelines from the working party, they effectively protested that the guidelines didn't go far enough and that there should be this doing away with Solution No. 18, and that was not the view which was ultimately taken by the working group. So whether that decision is right or wrong, that's an issue on which you or a nominee on your behalf could have contributed.

A. Potentially.

THE CHAIRMAN: We can only guess at what the outcome of that contribution would be, but it's an area in which the department had expertise available to it which it didn't use; is that not right?

A. I think that's probably fair comment. I think it's also true to say that, as time has elapsed, there has been very substantial pharmaceutical involvement around the whole adverse effects/adverse events arena, medicines governance team, et cetera, et cetera. So in many ways, over a subsequent period of time, that has really come into play very strongly indeed.

THE CHAIRMAN: In saying that, you're referring back to your opening remarks?

A. Yes.

MR REID: As the chairman's said, there was debate as to what the appropriate fluids were and whether Solution No. 18 should be named and shamed.

A. Yes.

Q. In an e-mail, Dr Nesbitt stated it was a fudge to not include Solution No. 18 in the guidelines.

A. Mm-hm.

Q. If these clinicians are trying to decide which is the appropriate fluid used in these circumstances and there's a debate as to how much sodium should be in the fluid and how much glucose should be in the fluid, would it not be the place for a pharmacist to be involved to suggest perhaps some fluid that might meet all the requirements?

A. Potentially, yes. Some of it relates to the degree of

specialist pharmacist experience in those particular areas. But if I just make reference to the fact that a number of things that we've done more recently around what are called pharmaceutical clinical effectiveness, pharmacists are very heavily involved in distinguishing the qualities, the intrinsic qualities of medicines that would make them the most suitable medicines for choice. So there's a very substantial pharmaceutical involvement in actually that whole arena of rational choice and rational selection of drugs, based on clinical and safety parameters.

Q. There was this debate and there was also the yellow card issued by Dr Taylor to the MCA. I'm afraid, doctor, you didn't quite answer my question earlier about whether or not you would have expected to be involved at the stage of the formulation of the guidelines. Would you be able to give me an answer to that?

A. I answered it in the sense of trying to offer some rationality why we may not have been involved.

THE CHAIRMAN: Sorry, let me just make it clear, Mr Reid. I understand the doctor's evidence in response to my questions to mean that he should have been involved in the formulation of the guidelines because of the live debate about how far they went in terms of Solution No. 18.

MR REID: Thank you, Mr Chairman.

THE CHAIRMAN: Is that fair?

A. I think that's right.

MR REID: If I can bring up 007-001-001, please. The guidelines are issued alongside this letter from Dr Campbell to the medical directors of the trusts and directors of nursing of trusts. I accept that it's not sent to the pharmacists within the trusts. But in that letter at the third paragraph down, she refers to:

"There is a particular concern about the use of Solution No. 18 among children as it has been implicated in cases of hyponatraemia, and this has been emphasised in the recent letter received from the Medicines Control Agency, which stated that while hyponatraemia was a risk with Solution No. 18, electrolyte imbalance is a risk with all intravenous solutions."

Did you see a copy of this letter?

A. Not that I can recall.

Q. And was it discussed at any departmental board meetings by the Chief Medical Officer or anybody else?

A. Not that I recall. I cannot say hand on heart that I didn't see it, but I don't recall.

Q. If the Chief Medical Officer was issuing region-wide guidance --

A. Sorry, maybe -- in a lot of these types of letters there

is normally an internal copy list. I don't know.
Q. You don't know whether you might have been on it?
THE CHAIRMAN: You know from the groups of people to whom it's directed that it doesn't include pharmacists.
A. I know, but I'm not wanting to go further than I feel I can.
THE CHAIRMAN: Yes.
MR REID: Regardless, you don't think you were made aware of it until about February 2004, around the time of Lucy Crawford's inquest; is that right?
A. I couldn't put a time on it, to be honest with you.
Q. And when you did find out, did you enquire perhaps why the pharmaceutical branch hadn't been involved in the formulation of these guidelines?
A. No, I can't say I did.
THE CHAIRMAN: Doctor, again, can I ask you: without having any sort of confrontation with the Chief Medical Officer, would it not be appropriate for you to say, "Look, I think we can contribute on issues like this; we're an internal resource", so effectively it's cost-free because you're there already and, "The next time that something like this is happening, feel free to call us"?
A. I think, chairman, that actually was what was happening at that stage. By 2002, we had set up the medicines

governance team. That became a very critical resource in relation to a whole array of adverse events and they were played very heavily into the system. In fact, one of the pharmacists, in fact the team member there, was a member of the safety in health care group in the department. I can't just remember the title of it. So not only was I in that group, but she was on that group as well. So it did get played in and without any confrontation. It was a very natural process that went on.
THE CHAIRMAN: And has that raised the involvement and the use of the pharmaceutical team within the department?
A. Oh, very substantially. In fact, that particular medicines governance team -- not that we went out for this, but it won a national patient safety award across the Health Service in the whole of the United Kingdom for the work that it was doing.
THE CHAIRMAN: Very good.
MR REID: Later on, when the guidelines were being reviewed, Mr Niall Corry was involved. He was a pharmacist, is that right? Do you know Mr Corry?
A. I don't know him personally.
Q. He was involved in the paediatric fluid management working group, and then also eventually alert 22 was issued by the National Patient Safety Agency and

a letter was sent out from yourself and the Chief Medical Officer and the Chief Nursing Officer; isn't that right?
A. That's correct.
Q. Why were you involved at that stage, but hadn't been involved previously?
A. Well, things had moved on considerably. We had our safety in health and care group, of which I was a member. Normally, those alerts came through that group and we had taken the view in the department that this was a very important message and these were very important messages to the whole of the services, and therefore important that we show collective leadership at the department in terms of the three professional officers relative to this.
So at that stage it was not only important in terms of the content, but it was also important in actually who was sending this information out and the importance of working collaboratively is critically important.
Q. And following the alert, if I can call up 333-152-026 -- no? I'll just refer you to it. There was a circular sent out in October of 2007 by the department. In that, it is said:
"Trust directors of pharmacy should develop a progress report on important supply issues in respect

of all infusion fluids relevant to this regional paediatric fluid guideline [being Alert No. 22] and submit a report to the pharmacy contracting evaluation group and copy to the regional paediatric fluid therapy working group."
That was signed by you.
A. Mm-hm.
Q. Do you have any idea what happened with the progress report?
A. I can't recall in detail that, but I did chair the pharmaceutical contracting group, and normally -- and I can only assume that we did do that because that really related to the procurement of medicines, and obviously if there was a change in practice and therapy, that had an implication for what was being bought. And we were doing this on a regional basis so that we can actually make sure of this issue of consistency. So I can't actually point and say yes, I do remember a document coming, but we will have taken those in because intravenous fluids are part of a central contracting system. So I'm quite confident that it was done.
Q. Solution No. 18 was the default fluid used in paediatric care --
A. Yes.

Q. -- for quite a number of years.
A. Yes.
Q. Suddenly, there's a sea change in which it's no longer used anymore and alternative fluids have to be used. I presume that must have caused a change in the procurement of the IV fluids?
A. Yes. That's why that was necessary, to bring it to that group because of our procurement practice and because we were contracted on a regional basis. That's again quite important from the point of view of consistency of action, why we should try and do things at a regional basis.
Q. Because if Solution No. 18 is to be removed from wards and so on, then almost the first step is -- one of the steps is a lack of supply from the pharmacy to wards?
A. Yes.
Q. How quickly was that implemented, the lack of supply of Solution No. 18?
A. Yes, in the sense that those were the guidelines and we have ... In other situations where there's been a change of practice, those are the kinds of steps. So it becomes a pharmacy-controlled matter at that particular level because if you actually stop a source of supply then you begin to eliminate potential problems.
Q. Just as a final question: you retired in April this

year.
A. Yes.
Q. You've been in the pharmaceutical branch very recently at the very least. Can you offer us any insight into any current developments in the use of intravenous fluids or anything of that nature?
A. One of the things that I did plan to say to the inquiry and if I may do that at this particular time: you may have already been made aware of work in England around the South Staffordshire Hospital, but Don Berwick, who is an international expert on patient safety from the Institute of Health Improvement, he was asked by the Prime Minister to lead a piece of work in relation to how the NHS, particularly in England, could learn from its experience. And he has produced a report "A promise to learn, a commitment to act: improving the safety of patients in England" and he has outlined within that report where some of the deficits are and some of the issues and some of the recommendations in relation to how the system could be improved.

So all I was going to do in answer to your question was to commend this report to you and some of the evidence that has been deduced on a wider scale, not just to do with South Staffordshire, but also some of the issues around the way that we can do better. A lot

of that is around culture.
THE CHAIRMAN: If I've got this right, the Mid Staffs report came out and then Mr Berwick was asked to do, in effect, an analysis of how it should be taken forward.
A. That's correct.
THE CHAIRMAN: This paper which you referred to was published during the summer and it's his analysis of how the Mid Staffs report should be turned into practice.
A. Yes, it is that, but he -- I suggest that he goes further to talk about the wider system in relation to the principles of how to make sure that you have proper safety throughout the system, not just related to that experience in Mid Staffs. And I think it's instructive to this inquiry in relation to what lessons that we might have to learn in Northern Ireland.
THE CHAIRMAN: Thank you very much indeed. Are there any more questions from the floor? No?

Doctor, thank you very much for your assistance and for referring me to Mr Berwick's report. Unless there's anything more you want to say, you are free to leave.
A. No, thank you very much.

(The witness withdrew)

THE CHAIRMAN: Unless there's anything else, ladies and gentlemen, 10 o'clock tomorrow morning for Mr Gowdy. Thank you.

(1.44 pm)
(The hearing adjourned until 10.00 am the following day)

I N D E X