Wednesday, 30 October 2013

(10.00 am)

(Delay in proceedings)

(10.12 am)

THE CHAIRMAN: Good morning, ladies and gentlemen.

Thank you for coming back for the start of the final segment of the inquiry's public hearings. What will happen this morning is Ms Anyadike-Danes will present a truncated oral version of the inquiry's own opening, which has been circulated. I think then, Mr McMillen, you're going to present your opening for the department?

MR McMILLEN: Yes, Mr Chairman, with your leave.

THE CHAIRMAN: After that, we'll have what I hope will be a short discussion about a note which I circulated earlier this week about what will happen in the final week, starting on Monday 11 November. We'll see how far that takes us in terms of time. Dr Darragh is here to give evidence, I believe; is that right? Thank you, doctor. Thank you for coming. We'll see how time goes and whether it's easiest to start your evidence before lunch or after lunch, depending on what time of day it is when the work I've already referred to has been completed. Okay?

Ms Anyadike-Danes?

Opening address by MS ANYADIKE-DANES

MS ANYADIKE-DANES: Thank you, Mr Chairman. Good morning.

As you have alluded to, Mr Chairman, there is quite a detailed written opening that all the interested parties have seen and have had an opportunity to comment on. That written opening will be published on the inquiry's website. It's quite comprehensive because what we are doing now is, having explored what happened clinically to the children in the respective hospitals, and also what happened from a governance point of view in terms of management, we're now looking over that period from the perspective of the department. And that's part of the reason why the opening is so detailed and is so lengthy, and perhaps if it might be treated more in the nature of a reference document.

Obviously, as the evidence comes through, we will see the gaps that we didn't have information on. Hopefully they would be filled in the course of the oral hearings.

So that means really that this section, when we come to view the department's position, is not just about the deaths in hospital of the children, Adam, Claire, Lucy, Raychel and Conor, nor just about the role that hyponatraemia and what we now know as Solution No. 18 played in their deaths. Of course it's all of those as

well. Mr Chairman, you've heard a great deal of evidence about that. But there's the legacy issue, which is particularly relevant now, which is, from all that material -- and I should say this with all that experience and with the benefit of hindsight -- how should lessons be learnt from the deaths of children in hospital so as to reduce the incidence of such deaths recurring. Who has the responsibility to ensure that those lessons are learned and that practice is changed accordingly?

So that's the big issue that comes out from all of this. But if we go now into the particular list of issues that we have been investigating in relation to what has become to be called the historic part of the department section. That, Mr Chairman, really arises out of a statement that you made, which is:

"I think the first issue is about who is responsible for the quality of care from the point when trusts were established in the early to mid-1990s until 2003. And to the extent there were issues before 2003, I am concerned to find out how the department actually knew what was going on in hospitals prior to that time."

And then:

"Since 2003, have the trusts exercised their statutory duty to provide quality of care, who have they

been responsible to, and how has that reporting worked?"

So that's really what sparked off the list of issues that was developed.

How the department knew what was going on in Northern Ireland hospitals generally, but more specifically in those that had the care of Adam, Claire, Lucy, Raychel and Conor, and in particular the Children's Hospital where all these children are recorded as having died.

The historic issues that came out of that and that have driven our investigation are really six fold. Who had the responsibility for quality of national health hospital care from the mid-1990s until the statutory duty of care in 2003, and how was that fulfilled? What did the department know about the deaths of Adam, Claire and Lucy, and when did they know that? What did the Chief Medical Officer and/or the Chief Nursing Officer or their senior officials, or for that matter the Chief Pharmaceutical Officer, know about the deaths of Adam, Claire or Lucy before 2001? What led to the establishment of the hyponatraemia working group? What led the Chief Medical Officer to say what she did say in 2004 about the deaths of the children? And how were the 2002 guidelines disseminated, monitored and enforced by trusts and the department, and in that particular

regard, Mr Chairman, of course you were using Conor as a way of illustrating that because, of course, his death came after the 2002 guidelines and you would have had the section just last week where certain concessions and acknowledgments were made.

So if I start really with the department because something needs to be said about the principal structures and their relationship to each other, otherwise it's quite difficult to begin to form a view as to who might have had responsibility for what. And if I can pull up 303-039-505, that is the structure of the Health Service in Northern Ireland pre-2007. You can see there, of course, it starts with the Secretary of State. Then down to the minister, a straight line down to the department, and then you've got the four boards. For our purposes, in terms of the children who were being cared for, we have really looked at three of those: the Eastern Health and Social Services Board, because that had the Royal Group of Hospitals, within which the Children's Hospital sits; and then the Southern, which had Craigavon, and that was Conor; and then the Western Health and Social Services Board with Sperrin Lakeland and Altnagelvin, and that was Lucy and Raychel.

So if we stay there with the department, the powers

of the department derive from a piece of legislation, the Health and Personal Social Services Northern Ireland order of 1972. And there has been, of course, subsequent amending legislation. Article 4 imposes on the ministry -- this is where the source of their power and responsibility derives:

"The duty to provide or secure the provision of integrated health services in Northern Ireland, designed to promote the physical and mental health of the people of Northern Ireland through the prevention, diagnosis and treatment of illness."

And that's their top-line duty. Another duty which is worth mentioning in this regard is to:

"Discharge its duty as to secure the efficient coordination of health and [of course] personal social services."

So those were the duties, along with the others that are identified in the legislation, in force at the time of the children's deaths. They were revoked in 2009 and replaced by a more detailed duty under the Health and Social Care Reform Act of 2009, which included a duty to:

"Monitor and to hold to account the regional board, regional agency, and the trusts [and others] in the discharge of their functions."

We haven't got to that stage yet. At this stage we're pre-2003.

The structure of the Health Service in Northern Ireland when the children were admitted and when they died in 1995, 1996, 2000, 2001 and 2003 are as shown really in this diagram.

Then if we go to the next stage and look at the boards. That legislation of 1972 provided, in article 16, for boards that the minister was to be able to establish Health and Social Services boards and he established four of them, which you can see there. Then article 17 said:

"The boards were to exercise, on behalf of the ministry, such functions with respect to the administration of health and personal social services as the minister may direct."

So they were acting on behalf of the ministry.

Then in 1989 the government announced a fundamental review of the Health Service and that led to the publication of a paper called "Working for Patients" and that proposed major reforms and the principal objective was to show real improvement for every patient. In Northern Ireland, what that amounted to was delegating as much power and responsibility as possible to the local level and also encouraging a small number of

hospitals to progress towards self-governing status as hospital trusts; reconstituting the Health and Social Services boards as management bodies and strengthening arrangements for the external audit of the services to ensure better value for money. There were other things as well that it did, but I'm simply identifying the ones that are of particular relevance to us.

So the delegation of responsibility for the delivery of healthcare to the local level, that was to be achieved through something that's called the internal market, where essentially the money was going to follow the patient and be directed to areas of service delivery. And that introduced something that we have been told about, and which our expert has advised us about, called the purchaser-provider split. And the boards assumed the role as service commissioners. So they commissioned the service, with the trust providing the service. They provided the healthcare.

The departmental policy document "Policy First" introduced a division between the commissioning and the provision of health and social services, and the implementation of the major community care reforms in 1993 established the boards as commissioners of services, responsible for assessing the health and social care needs and strategic planning to meet the

need. So although this all sounds rather dry, this is actually where the different bodies and organisations get the source of their duties, their roles and their responsibilities.

If we go down now to the next level, which is the trusts, article 10 of the Health and Personal Social Services order of 1991 gave the department the power to establish these Health and Social Services trusts. And they had a remit to provide local acute and community health services. And schedule 3 of that order set out the duties, powers and status of the trusts. And there was a working guide provided in 1991, and this is what it says about it:

"A key element of the changes is the introduction of the trusts. They are hospitals and other units which are run by their own boards of directors, are independent of Health and Social Services Board management, and have wide-ranging freedoms."

Then it goes on to say:

"The trusts have the power to make their own decisions, right or wrong, without being subject to bureaucratic procedures, processes or pressures from higher tiers of management."

So there was a degree of autonomy established for those trusts.

The accountability of those trusts as they exercise those powers to the department is an issue that has been addressed during earlier governance sections, which focused on Adam, Claire, Lucy and Raychel, but we're going to look at it now from the perspective of the department.

So that's the main architecture, the department, the boards, the trusts. If we look now to the individual positions, since ultimately the success or failure of those structures in terms of quality healthcare concerns the individuals that create and operate and act within those systems. If I could call up 323-027d-001.

You see the minister there. There's the Permanent Secretary. Then immediately beneath him, there are the specialist groups, and the planning and resources group is a group of interest. Strategic planning and modernisation group another group of interest and a group that we will deal with in perhaps a little more detail later on as the oral hearings get underway is the chief professionals' groups. Within that, the three that we will look at particularly are the Chief Medical Officer, the Chief Nursing Officer and the chief pharmaceutical officers. And it's right to say there were also Health and Social Services Councils and they were really established to provide the consumer

voice, and at least one of them in relation to Lucy used that voice, and Raychel for that matter.

So then if we look now at the Permanent Secretary who's sitting there beneath the minister and the departmental board. The Permanent Secretary is the most senior civil servant in the department and he's charged with running the department. At the time of Adam and Claire's admission to the Children's Hospital in November 1995 and October 1996, that person was Mr Alan Elliott. He held office from 1987 to 1997, so leaving just a year after Claire's death. He was succeeded in that position by Mr Clive Gowdy, and he was in post until 2005, so almost the entire period of time in terms of the treatment of these children, their deaths and the introduction of the hyponatraemia guidelines.

There is a list of persons. I just want to call it up briefly because you've seen a similar document in other sections. 337-001-001.

This is a more detailed list perhaps than we have previously provided. Many of these people's names will not be familiar because they haven't come up in the earlier hearings. But one of the features of it is you can see that middle section "Awareness of children's deaths". We have tried to identify as a particular

feature of this, insofar as we can from the information that's been given to us, when they were aware of the relevant children -- all five of them are across the top there -- and that will be something that will be, to the extent that it's relevant, explored during the oral hearings.

The departmental board was constituted of senior members of the different sections of the Health Service. They reported to the Permanent Secretary and they met, we understand, on a monthly basis to discuss important matters. Those who would have attended the monthly board meetings, so far as we are aware -- obviously the Permanent Secretary was there and he would be acting as chairman, the CMO, the CNO and the CPO. There were others there too, but in particular the deputy secretary of the resources and performance management group, the deputy secretary of the strategic planning and modernising group, and the principal information officer. So they would have had at least monthly liaison with each other.

If we then drill down and see who else was relevant in this structure. We can go to 323-027e-004. As you will recall from the previous diagram, there was a professionals group. Here it is in a little bit more detail. You see to the far left there's "medical and

allied services", which includes public health. At the head of that was the CMO, and that person was Dr Campbell. Then the nursing and midwifery advisory group, the head of that was Ms Hill, Chief Nursing Officer, and then if we move along to the far right, you see "Pharmaceutical advice and services", the head of that, the chief pharmaceutical officer, Dr Morrow.

We can drill down a little further, which might be relevant for some of those who are going to give evidence. 232-027f-018. (Pause). That's not coming up for some reason. That's unfortunate.

Let me help you with that. What we would be looking at is the medical and allied services group in more detail. And you would see there that the CMO, that's Dr Campbell, the deputy CMO, Dr Paul Darragh, and then below them are a level of senior medical officers, one of whom is Dr Miriam McCarthy.

That medical and allied services group deals with a considerable territory, so one of the areas of their work that is of interest to us is:

"The provision of professional medical advice and guidance on policy and operational activities to the minister, the department and the public on matters relating to public health."

And then there are some very specific areas that

they're asked to follow and develop to do with smoking, acute services, cancer and so forth. But in there particularly is child health. So that group did many other things, but that's the particular part of their work that is of relevance to us.

I'm hoping that we can drill down and look at the nursing and midwifery advisory group. That is 323-027f-020. You can see there the Chief Nursing Officer, Ms Hill. Then there's a whole row beneath her of officials to assist her. That's all been redacted because they don't form any part of this inquiry and therefore their names have been redacted, but it gives you the idea that she wasn't one person on her own.

Below are the areas that they're dealing with, and those that are of interest to us, it's very small writing, but if I help you with it:

"Education and training, research and development, clinical effectiveness, leadership, professional regulation."

Those are just some of them. Then if you go to the next block, "Administration of medicines". And we are told that medicines includes IV fluids. If we move along you see "Paediatrics, nurse prescribing" and, of course, the hyponatraemia guidelines, when they came out, were particularly directed towards nurses and

junior doctors.

Then if we move along again, we see:

"Regional acute services, strategy for nursing, information management."

And then also specific nursing services, which might include paediatric intensive care or just paediatric nursing. So that's the Chief Nursing Officer's group. Then the final one of the three that is relevant for us is the pharmaceutical advice and services group, and that can be found at 323-027f-023.

You see Dr Morrow there. That bottom line are all pharmaceutical officers and they've been redacted for the same reasons as those in the nursing and midwifery group. Just below that there are some of the functions there. Of interest is the "general pharmaceutical services", that might be one, but more particularly on the far right, "community and hospital pharmaceutical services" and "audit education and training".

So those are some of the personalities. Dr Morrow was Chief Pharmaceutical Officer from 1995 to, I think, September of this year.

If one now looks at the responsibility for care in the department. So the department provides or secures the provision of health services and it goes without saying that all five of the children we're

concerned with were admitted to hospital and they required and they received healthcare, so they obviously come within the remit of the department, and they all died. And an issue that arises in this inquiry is the role that all those people and those structures that we've just looked at played in the discharge of the department's duties to those children. And, more pertinently, whether it can properly be said that any of them bear any responsibility for any failures that might emerge in the course of this part of the investigation or, for that matter, any of the failures that have been acknowledged by the trusts in the care that those children received, and whether they bear any responsibility for any of the systems that should have avoided or detected those failures, apparently not having done so.

So this is all about responsibility. There was a change in terms of responsibility in 2003 when a duty of quality was imposed upon the trusts. But much of what we have to look at is a period of time that pre-dates that. Nonetheless, it is important to look not just at the pre-dating time, but also what happened after that duty of quality was imposed.

So if we look now at the management executive. That was one of the earliest of the structures to play a role

in responsibility. The management executive was primarily established to act as the operational arm of the department, and it was charged with ensuring that the government policies in relation to health are properly implemented. Who were those people? Well, Mr Clive Gowdy was the chief executive of the management executive from a very brief period of time, at the beginning of 1997. Prior to him was Mr John Hunter, and then after that brief period of time when Mr Gowdy was the chief executive, he was replaced by Mr Paul Simpson.

So over the period that is of principal concern to the inquiry, that chief position was held by three different people: Mr Hunter, from 1990 to 1997; Mr Gowdy, briefly, from January to March 1997; and Mr Simpson, from 1997 to 1999. These were all senior civil servants, but they were not clinical. They relied on any information relating to clinical matters to that professional group that we have just looked at. The management executive was discontinued in 2000 when the Northern Ireland Executive was created.

So if we now look at the pre-statutory duty of care. Mr Gowdy has given us his views on that and, Mr Chairman, you've also had the views of a number of witnesses from the trusts and the Western Health and Social Services Board on what they regard as the

pre-statutory duty of care. In particular, Mr William McKee, who was the former chief executive at the Royal Group of Hospitals Trusts, he has given a view. So has Mr Hugh Mills and Mrs Stella Burnside. They were both chief executives of Sperrin Lakeland Trust and Altnagelvin Area Hospitals Trust respectively. I'm not going to recite all that now, Mr Chairman, because you've heard it, but one thing that is clear is that there were differences of view between them as to what that responsibility might be and to the extent that it's necessary to explore that from the department's perspective, then that's what will happen during these oral hearings.

One can see something of what might be the department's position from Mr Gowdy's statements. He says:

"It is, of course, correct to say that there was no specific statutory duty for the quality of clinical services on trusts, their boards or chief executives prior to the 2003 [legislation]. However, it does not follow that trusts or their boards or chief executives had no responsibility for clinical care or clinical outcomes prior to the commencement of the order."

Dr Campbell, she was the Chief Medical Officer during all this period of time, she's explained that

before the introduction of the statutory duty of quality, the chain of responsibility for the quality of care was doctors and health professionals, they're personally responsible for the quality of the care they give the patients. The trusts have a duty of care to their patients for the quality of care that's provided. Any concerns about standard of care provided by a doctor or healthcare professional, that could be addressed by their regulator: if a doctor, it'd be the GMC; if it's a nurse, it'll be the NMC; or, for that matter, the commissioning body. The commissioning body is commissioning those services. Any concerns about the performance of a trust is a matter for the trust board or the commissioning body and the chair of the trust was appointed by the minister and was directly accountable to the minister. And of course, once the statutory duty of quality came in, then there was a further responsibility. So that is what she saw and she was operating as CMO throughout that time and that is how she views it.

The inquiry engaged the services of Professor Gabriel Scally. He already provided a report in Lucy's case and in that he explained that, by 2000, the trusts were accountable to the department for the management of services. In that case, he was talking

about Sperrin Lakeland in relation to the Erne Hospital. And in the exercise of that accountability arrangement, the trust could reasonably have been expected to have notified the department if they felt that a death was potentially due to inadequate treatment, and he also said:

"The role of scrutinising the action of the trust should fall squarely within the remit of the department as the body to which the trust was formerly accountable."

Well, if we now look and see what, from the government and the department's point of view, they were doing about ensuring that quality healthcare was being delivered to the population of Northern Ireland and, if it wasn't, that they were aware of it. One of the five priorities of the Northern Ireland's first programme of government in 2000 was Working Together for a Healthier People. And it acknowledged, in 2000, that Northern Ireland had fallen behind the rest of the UK in the provision of healthcare and it included a commitment to put in place a framework to raise the quality of services provided to the community and to tackle issues of poor performance.

Then that framework of how they were going to do that was set out in something called "Best Practice,

Best Care", and that was a consultation document that went out for consultation in April 2001, and what was it proposing?

"Setting standards to improve services and practice, ensuring local accountability for the delivery of healthcare and improving [importantly for us] the monitoring and regulation of healthcare."

It was recognised that:

"A more coordinated and structured approach was required and that clear, consistent evidence-based guidelines and standards would improve outcomes for patients."

They were concerned that guidelines were being produced on a reactive basis rather than on a planned agenda and that there was no systematic approach to the identification of any gaps.

Some of that had been addressed in the rest of the United Kingdom, and in England and Wales they had established NICE in 1999 to try and deal with that systematic approach to guidelines and standards, the National Institute for Healthcare [sic] and Excellence.

But if we go back to what "Best Practice, Best Care" wanted, it wanted a single, easily accessible source for producing and disseminating standards and guidelines for services, which could also handle any guidelines coming

out from NICE or any other standard-setting body such as the Royal Colleges, for example.

So that would put its objective four-square into what the inquiry has been looking at, even though it comes a little bit after some of the children that we are concerned with, namely Adam and Claire. If one looks at the "Ensuring local accountability", they wanted:

"A system of clinical and social care governance, backed by a statutory duty of quality."

It also proposed a system of clinical and social care governance that would bring together all the existing activity to the delivery of high quality services. They mentioned, in particular:

"Education and research, audit, risk management and complaints management."

How did they respond or were they proposing to respond to improving the monitoring and regulation of services, which is an area of particular concern to us? Well, "Best Practice, Best Care" noted that there must be a clear line of accountability from the front line delivery back to the executive and that, when things are going wrong in the Health Service, people need to know that failures are identified quickly, openly, and investigated and put right.

Mr Chairman, that particular proposal and expression of what they wanted to happen is something that has lain at the centre of the governance hearings throughout this inquiry. The speedy identification of failure, open investigation of that failure, recognising what the lessons are to be learnt, and then taking action to ensure that, insofar as it's possible, one reduces the chances of that event happening again.

So what happened then? In January 2003, the department issued guidelines on the implementation of clinical and social care governance, and these were the first Northern Ireland guidelines to be issued on clinical governance. So it's come sometime after the deaths of all the children that the inquiry is concerned with, save for Conor, who, of course, died in 2003.

They stress the importance of organisations taking corporate responsibility for performance and for providing the highest possible standard of clinical and social care and they placed an emphasis on adverse incident management, which is something that we will hear a little bit more about throughout the oral hearings.

What are the key points they stressed? First, audit. And what does that mean? Well, so far as we understand it, what was intended was:

"A quality improvement process that seeks to improve patient care and outcomes through a systematic review of care against explicit criteria and the implementation of change."

The key component of clinical audit is that performance is reviewed to ensure that what should be done is being done and, if not, it provides a framework to enable improvements to be made. You have to have a system for knowing what's happening.

That seems quite obvious when you put it in that way, but as one goes on and looks particularly at the hyponatraemia guidelines that were issued in 2002 with the Chief Medical Officer wanting their implementation to the audited, and think back that this is what audit means, you identify a problem or you have an issue, you set criteria and standards, you observe the practice or you collect data in relation to it, you compare that performance against the criteria and standards and then you implement change if you need to. That's the process.

The rest of the key points that emerged out of those guidelines really follow on from that. If you're doing that, you will be able to address these things:

"Identifying, promoting and sharing good practice, learning lessons from best practice as well as poor

performance, risk assessment and risk management, and adverse incident management."

All those things become possible to do if you are recording and monitoring. The other thing that those guidelines wanted was:

"An open, honest and proactive system where people can report poor performance, near misses and adverse events to allow them to be properly dealt with, lessons learned and shared within, and, where appropriate, outside the organisation."

And that's an issue we've had in these proceedings, the extent to which, for example, a lesson that might be learned in the Children's Hospital, to what extent is that lesson shared with any other hospital in the region?

As I've indicated in part, those guidelines came too late for the management and learning process that might have been taken before the deaths of all the children apart from Conor, but not too late to learn from the aftermath of the inquests of Raychel, whose inquest happened in 2003, Lucy whose inquest happened in 2004, Conor whose inquest happened in 2004 as well, and Claire whose inquest happened in 2006.

The written opening, Mr Chairman, deals with that period and what was done and I don't propose to go into

that in any more detail. It's there to be seen and, to the extent that it gives rise to issues, they will be covered in the oral hearings.

If one now looks at the post statutory duty of quality. After the introduction in February 2003 of the statutory duty of care, the accountability arrangements across the department shifted and they became like this. The department was responsible for carrying out the wishes of the ministers, its primary functions were in relation to the formulation and implementation of policy and, of course, the allocation of resources. It set the framework, priorities and targets within which the service was required to operate and maintained a high-level overview of the performance of the trusts. It also issued guidance and direction and ensured that there were effective governance systems in place. That's what the department is responsible for.

The boards acted as the planners and commissioners of health and social services for the population of those areas. The department allocated funds to the board to meet the costs of providing those services and the board in turn provided the trust with funding for the services it was commissioning. And the boards worked in close collaboration with the trusts on service, quality and finance issues. And then,

of course, down to the final tier, the trusts. They provided the services to their respective communities, and they employed the clinical and administrative staff who work in the hospitals to deliver that service. They were directly responsible for the operation of those services and for the quality. The governance within the trusts was the responsibility of the board of the trust and each trust board was made up of a chair, and non-executive directors, and appointed by the minister through the public appointments process. And of course they had executive directors.

If I move now from how the statutory framework and the structures and the individuals -- to clinical guidelines because that was the intention of the department in all those structures they put in place, both before and after the statutory duty of care. Let's see what happened in terms of clinical guidelines, which is something that we are concerned with and, in fact, what clinical guidelines means.

Mr Gowdy explains that the policy for dissemination of guidelines from the department -- because we are looking at it form, the department's perspective -- down to the boards and trusts was what he called a pragmatic one. The department judged that there was a need to issue direction and that would be set down in a circular

letter and issued to the relevant chief executives, the chairs or the chief professional officers as appropriate and they had a fairly standard format and were given a specific reference number to identify them. So that's what it did.

How did it oversee the implementation of those, or did it oversee the implementation of those? Who actually formulated the guidelines once the department has judged that that's been necessary? There was a body called the Clinical Resource Efficiency Support Team, CREST. That was established in 1988 under the department's medical advisory structure. The department funded it and it was to allow the medical profession to develop guidelines specific to Northern Ireland. Its formation was at the instigation of the medical profession because they had concerns about the increasing pressures put on scarce Health Service resources and they wanted to make sure that those were being appropriately addressed, value for money, by setting guidelines, and that's what they thought was appropriate and they were supported in that by the department.

That CREST group comprised 18 healthcare professionals from Health and Personal Social Services in Northern Ireland, all with an active interest in

promoting clinical efficiency.

So one would have thought that the issue of guidelines was well taken care of and that's an issue that we will deal with. The guidelines that we particularly are dealing with are the hyponatraemia guidelines, which incidentally for the paediatric patients were not issued by CREST, and there will be an issue that we'll explore as to why they weren't. CREST issued the adult hyponatraemia guidelines. Whether there is any significance in the fact that CREST, who nonetheless approved the paediatric ones, didn't actually issue them and they didn't actually come within its workload is a matter that we will look at.

So those are the guidelines. What about the notification of adverse incidents? So guidelines are out there to try and proactively establish good practice. If it goes wrong and ends up in an adverse incident, how does anybody know that it has gone wrong? An important issue that we have been examining during the oral hearings is the procedure and practice in Northern Ireland at the time of those children's deaths for the reporting and dissemination of information to the department and the medical community in particular of unexpected deaths in hospitals and outcomes from the coroner's inquests.

As far back as the Allitt Inquiry into the deaths and injuries on the children's ward at Grantham and Kesteven Children's Hospital, that inquiry reported in 1994, so even before Adam was admitted, there must be, is what the report said:

"... a quick route to ensure that serious matters are reported in writing to the chief executive of the hospital and, in the case of directly managed units, to the District Health Authority."

So right from then it was recognised that if things go wrong, the people with power need to know that that has happened and, in May 2000, the Health Service in England published a document on learning from adverse incidents, and it was called "An Organisation with a Memory". Even at that time, the report acknowledged that:

"There are no universally accepted criteria for identifying the occurrences or outcomes of healthcare that should constitute a basis for recording or reporting poor quality."

So it's not that there wasn't reporting, but there was no universally accepted criteria for doing so, either identifying what you should be reporting or, for that matter, how you did report.

It explained the different mechanisms that can yield

information on adverse incidents and I won't go through that because all of that is set out in the written opening. But prior to Raychel's death in 2001, there was no formal reporting requirement to the department for untoward deaths. There was no requirement that you did that at all.

The trusts had autonomy about that and in fact there were only two formal requirements in relation to the reporting of adverse incidents affecting patients to the department at that time. The first was in respect of adverse incidents and reactions and defective products relating to medical and non-medical equipment. So if you had an adverse incident that related to something like that, whether it was the food supply, the building, the equipment in the hospital, then you had to report that and you had to report that to the Northern Ireland Defect and Investigation Centre. The other one was the notification of untoward events in psychiatric and special care hospitals. In that case, you had to report a series of things, actually, if there was a patient in one of those hospitals:

"An unauthorised absence [well, you might think why you had to do that]; an accident; sudden, unexpected or unnatural death.

So it would seem that if a person in a special care

home had an accident -- not a fatal accident, just had an accident that could be classed as an untoward event -- that would have to be notified to the department. But at that time, if a child died in a hospital as a result of an adverse event, that didn't have to be, and that's just the way the reporting structures were at that time.

That death might have to be reported to the coroner if it satisfied the criteria, which you will have heard about in the previous oral hearings, but the outcome of coroner's inquests were not routinely notified to the department or circulated to other trusts for that matter, and there were no formal mechanisms for reporting, analysing or disseminating information from a coroner's inquest or untoward death.

We saw that exactly with Adam. He was a death which satisfied the criteria for an untoward death. Dr Savage, his nephrologist, was clearly of the view that he had received too much Solution No. 18 and he notified Adam's death to the coroner, and that was essentially what the coroners found. But despite all of that, Adam was not a death at that time that either the trust or the coroner was required to report to the department.

There were informal notifications systems, so just

because there wasn't a statutory requirement to notify didn't mean that there were no notifications systems at all. There was an informal system whereby chief executives and medical and nursing directors brought significant untoward incidents resulting in death to, for example, the attention of the Chief Medical Officer, and that's how Raychel's death was brought to her attention. That was part of an informal system.

Once you say it's an informal system, one recognises that that was dependent on the judgment of others, operating in the absence of clear departmental guidance. Maybe they will consider that a death was something that the department should know about, as they did in the case of Raychel, or maybe they wouldn't, as they didn't in the case of Lucy, despite the fact that senior clinicians at the Children's Hospital were concerned about the fluid management she received at the Erne and its implications for her condition. But her death was not reported to the department.

In the absence of guidance, there's no consistency as to whether you're going to get a death reported to you, no predictability. It's very difficult on that basis to build policy or to assess the success of the policy you have. And in fact one can see precisely the

problem, which is set out very clearly in the department's internal e-mail in May 2004. We can call that up. It's 010-025-180.

Just some introductions. Jonathan Bill: at that time he was deputy director of the quality and performance unit. He's sending his e-mail to Noel McCann. At that time he was director of planning and performance management. So:

"Mr McCann, for information, because this could become a big issue."

This is about Lucy and it refers to a video conference where they have had a briefing with the minister. And then he says:

"I have been doing some digging as regards the numbers of informal notification of incidents. Frankly, the picture is not a good one. Notification is patchy, the numbers small and there is no overall analysis."

Then tellingly:

"I do think minister is somewhat vulnerable to the accusation that the department is not aware what is going on as regards serious incidents."

And then in parentheses:

"The secretary has taken the line that it was usual for the CMO/department to be notified, and Lucy Crawford was an exception. We have no empirical evidence to

support this."

Well, the department, of course, did want a formal notification system, and in fact there was a recognition for some time that things had to change. A robust system for clinical governance was needed, it had to be developed, and that should include a formal notification system for adverse incidents, and some of the issues to be explored in the oral hearings is how long it took and why it took that length of time.

So let me briefly chart what happened about that because, as I say, the department wanted that. As far back as December 1998, the department commissioned Healthcare Risk Resources International to undertake a survey of risk management in all trust organisations, and the terms of reference for the survey were to:

"Determine the level of application of risk management methods within these organisations."

In other words, what were they employing to measure risk at that time? And incident reporting was one of the items that was specifically included in the survey. The consultants reported back in 1999 and they concluded that:

"Whilst there [was] a good awareness of the need to develop rigorous systems [so people knew they needed to do it for risk management], nevertheless greater efforts

need to be made in order to ensure that the strategy is endorsed fully by the board of the trust concerned and that all managers, clinicians and other professionals are aware of its contents."

Then they also went on to say:

"The major deficiency relates to the very limit and had therefore probably significant under-reporting of clinical incidents and near misses, and a major effort is needed in almost all trusts to improve in this area."

Incidentally, the reference for that, and we don't need to call it up, is 127-004-095 and 096.

The CMO sent out a circular, and that circular is dated 29 March 2000. It was specifically addressing clinical governance, clinical performance and something called revalidation, and that was to do with the standards of practice of clinicians. In that she referred to a number of developments throughout the United Kingdom, so it wasn't that they weren't aware that things were going on in the rest of the United Kingdom; they were aware about that and they wanted to do something about it, to promote high quality clinical performance and ensure its continued maintenance. These include the introduction of clinical governance. And then she acknowledged:

"No formal mechanisms have been established in

Northern Ireland."

But she referred to them being under development. In other words, in the process of being developed. Then she goes on to say:

"Whilst clinical governance will provide the framework to ensure the quality of service within the organisations, there are parallel developments addressing individual performance. The first of these addresses the need for the service to deal with poor performance in a manner that ensures public confidence. A consultation document has been published in England and guidance has been issued in Scotland and the general approach put forward is towards the prevention, early recognition and management of poor performance, and the emphasis is on the recognition of problems at an early stage before they get to be a risk to patients or there is a need to instigate formal procedures."

So one of the things that she did is that she asked Dr Ian Carson, whose name has appeared before, and he has given evidence earlier, to establish a group to produce guidance and clinical performance.

Then in October 2000, the department published "Confidence in the future for patients and for doctors", and that was another consultation document dealing with the prevention, recognition and management of poor

performance by doctors, and it recommended that methods of recording adverse events should be put in place to identify poor clinical performance.

Then, as I've mentioned before, in April 2001 comes "Best Practice, Best Care". So there is a recurring theme, there is a real recognition that they need to have arrangements in hand to monitor adverse incidents in a reliable way.

Well, we get to 2002, and the Northern Ireland Audit Office issued a report on compensation payments for clinical negligence. The reason I mention that is because it specifically looked back to that report that was published in 1999 by the Healthcare Risk Resources International consultants, the one that specifically identified greater efforts needing to be made. So this is now 2002 and the Northern Ireland Audit Office is looking at that.

For information purposes:

"The Northern Ireland Audit Office is responsible for the external audit of Central Government bodies in Northern Ireland."

And that includes Northern Ireland departments and it has a wide range of other public sector bodies that it looks at as well, including health. It undertakes these audits and reports to the Northern Ireland

Assembly. So what did it discover in its 2002 report? Well, it recognised that failures in healthcare delivery not only caused death and anguish, of course, for individuals, but it's a cost to the department, so it was looking at it, not exclusively, but mainly from the perspective of that, and it concluded:

"There remains scope for further improvements and given that DFP had issued general guidance in 1994, we would have expected further progress on this front."

So even though there had been a report to establish what was required in 1999, the audit office is, in 2002, saying that it is still not a happy picture.

Then if we move on from that report to a report of Deloitte & Touche. They produced two reports: one was in 2003 and one was in 2004. They were specifically commissioned to produce a report to evaluate clinical and social care governance. The 2003 report was published in September and it highlighted:

"A lack of understanding in the implementation of clinical and social care governance."

And that included:

"A lack of coordinated risk activities, including identification, management of risk, risk registers and risk audits."

And the report noted poor performance by, in

particular, the Western and Eastern boards in areas of risk management and adverse incident management, and Altnagelvin Hospital Trust performed lowest of the trusts evaluated, with the Royal Group of Hospitals Trust also performing poorly.

So this is 2003. Dr Campbell said in her inquiry witness statement:

"It was clear from the baseline assessment of clinical and social care governance that there was a need within the trusts for training, development and support if awareness and understanding of clinical and social care governance and the practical application of the duty of quality imposed by the legislation were to be achieved."

One would be forgiven for thinking it was a bit of a familiar theme. The Deloitte & Touche report made a number of recommendations, including a central database of lessons learnt, a publication of Northern Ireland agreed practice guidelines, an annual summation of audit results and an establishment of links with national bodies such as the National Patient Safety Agency.

Then the department commissioned a further report from Deloitte to carry out a scoping exercise on adverse incidents and near-miss reporting, and that report was

dated March 2004, and that highlighted one overwhelmingly obvious finding:

"Inconsistency of approach between the trusts or the HPSS bodies in their systems to report, record and analyse adverse incidents and near misses."

And it was noted that:

"Currently there is limited sharing of knowledge between the healthcare organisations and bodies within Northern Ireland."

And as I say, that's the position in 2004.

If we turn now to look at the guidance that was being provided in relation to reporting SAIs, serious adverse incidents. The department issued a circular on the reporting and follow-up of serious adverse incidents in July 2004. That circular defined what serious adverse incidents were. The reference for it -- we don't need to pull it up -- is witness statement 062/1, page 315.

What they are is:

"Any event or circumstance arising during the course of the business of an HSS organisation or special agency that led, did lead or could have led to serious, unintended or unexpected harm, loss or damage."

And this may be because it involves a large number of patients:

"There is a question of poor clinical and management judgment, the service of a piece of equipment has failed, a patient has died under unusual circumstances, or there is a possibility or perception that any of those things might have happened."

As I read out that -- and these are just ways in which that can happen -- one can see that a serious adverse incident of the sort that the department is saying needs to be reported is not confined to the administration of healthcare. And that's an important thing to recognise.

What did that circular require? Well, it required the bodies to report serious adverse incidents to a senior manager within their own body who has responsibility for reporting and managing adverse incidents, and if a senior manager considered an incident was likely to warrant regional action, to be of public concern or to require an independent review, then he had to provide the department with a brief report within 72 hours of that incident happening. And in response, the department would collate the information on the incidents reported to it and provide relevant analysis back to the bodies.

Since 2010, those reports are made to the Health & Social Care Board. So that was the guidance that was

issued in 2004. What happened after that? Well, in 2006, the department issued "Safety First: a Framework for Sustainable Improvement in the HPSS". Its introduction stated:

"Particular attention needed to be paid over the next few years to [I'm not going to give them all, but two specific ones]: raising awareness of risk and promoting timely reporting of adverse incidents, investigating serious incidents."

And that paper noted that in Northern Ireland there were still no common reporting or data analysis systems for adverse incidents, and therefore neither the number of adverse incidents in health and social care environments is known, nor can the number of untoward deaths be estimated. And it recommended a system approach to data analysis and intelligence gathering from a number of sources, and I'm not going to go through all of those because they are listed in the written opening.

Given the support that was being provided by the department and the direction, what happened to the pattern of reporting of SAIs? The legal team has put together a schedule of the SAIs reported. We can see that at 337-002-001. We've managed to chart it from the information we have received from 2005 to practically

present day.

There's a caveat about that because in March 1999 certain categories were removed from incident reporting. In other words, suspected suicides and admissions of under 18s to adult mental health wards. They got removed, so this is not a consistent sequence.

THE CHAIRMAN: Sorry, March 2009.

MS ANYADIKE-DANES: I beg your pardon, Mr Chairman, March 2009. There is movement, that's undoubtedly the case, but it's very difficult to tell what lies behind that movement. In particular, it's quite difficult to tell whether any of that movement relates to clinical SAIs or is in response to any of the guidance and directions that the department has been issuing. In fact, looking at that, in the information we've got, you simply can't tell where the clinical SAIs are, and you certainly can't tell where the paediatric SAIs are. So you will not be able to tell which of those SAIs relate to a death from a clinical incident or which of them relate to a death of a child in hospital.

The serious adverse incident form that we've been provided that is to be completed, whoever is completing it has to decide whether the adverse incident falls into one of five categories, one of which is:

"Serious injury to or the unexpected or unexplained

death of a service user/patient."

It is not further divided into a category such as a suspected clinical mismanagement.

The inquiry has been seeking that information from the DLS. What we want to know is how many SAIs relate to clinical deaths and, within that, how many of them relate to paediatric clinical deaths. So far as we've been told, the department doesn't know.

If one moves now to the department's knowledge of children's deaths. During the course of the oral hearings, the inquiry investigated the extent to which the risks of hyponatraemia and the matters addressed in the guidelines which were issued by the department in 2002 were or could reasonably have expected to have been known to clinicians in Northern Ireland at the time of their treatment and known to the department.

So Mr Gowdy has said that he would certainly have expected the trusts to have informed the department of all the deaths that the inquiry has been investigating. His predecessor, Mr Elliott, would have expected the department to have been informed of cases involving deaths due to possible medical mismanagement arising from complaints and inquests and legal action and so forth. But Mr Gowdy is clear: he would have expected the department to have known about all those deaths.

So the witnesses that we have sought statements from have said that the department was not aware of the deaths of Adam, Claire and Lucy prior to Raychel's death in 2001. So an important part of the investigation is whether the department could have known or should have known and why it didn't know and what might have had to be different in order for the department to have known and, then coming up to modern day, what is different to ensure that the department would know now. That is clearly a matter, Mr Chairman, to be explored during the oral hearings, so I won't go much into that now.

But there is an important issue -- I think it has been quite important for the families and probably quite important for the Chief Medical Officer -- which is to deal with the Chief Medical Officer's own response as she became aware of the deaths. She was involved in a number of interviews with the press in 2003 and 2004, and some of the comments that she made during those interviews have left her subject to criticism from, amongst other people, the families of Raychel and Adam, and they publicly called for her resignation in December 2004. In fact, she was reported to the GMC by Raychel's parents.

The solicitor acting for them said was:

"Dr Campbell, before going on television and dealing

with the media at large, should have made sure that she knew exactly what she was talking about so as not to cause any further offence and distress to our clients."

He, on behalf of his clients, Raychel's parents, described her actions as "reckless". That allegation is denied by the CMO. But the GMC did consider the notification and, in the Fitness to Practise Directorate, they decided that, in relation to the abnormal reaction, there was a comment that the CMO made -- which will be dealt with in more detail perhaps during the oral hearings -- about the extent to which the response of these children was to be considered an abnormal reaction. The GMC found that that comment was misleading in that they appeared to contradict the coroner's conclusions that Lucy had been given the wrong type of fluid and the wrong volume of fluid. They also added that her interviews were ambiguous and open to misinterpretation and that she handled them inappropriately.

However, they were not satisfied that there was any evidence that she was aware of the true circumstances of Lucy's death prior to March 2003 or that she engaged in a deliberate cover-up. The GMC was not satisfied that the criticisms that they had made of her were sufficiently serious for there to be a realistic

prospect of establishing that her fitness to practise was in any way impaired, so the outcome was to invite her to reflect on their decision and the concerns expressed by the complainants, and it closed the case in May 2010 with no further action.

But what has been the CMO's response? In a recent witness statement for the inquiry, the CMO was asked about a number of those statements that she made in 2003 and 2004, and she wanted to make it clear that she did accept that the deaths had been caused by clinical mistakes, and in addition she made this statement:

"Looking back on the interviews, I can see the potential for them to be misinterpreted and I regret that. I think this was in part due to differing agendas between the interviewers and me. Mr McKinney, for example, seemed to be under the misconception that I was somehow ultimately accountable for the provision of medical care in Northern Ireland. He seemed to want to make the case that I was responsible for the fact that guidelines had not been introduced prior to Raychel's case which could have prevented her death. I felt that was unfair. On the other hand, my main aim in attending the interviews from a public health point of view was to convey the rarity of this problem and the fact that guidelines have been introduced to address it.

I thought that if parents became worried that IV fluids were unsafe, they might not seek appropriate medical attention when their children were sick and I was concerned about the possibility of that resulting in unnecessary harm to children."

She's mentioned the guidelines, so it's right to point out that in 2001 the CMO did commission guidelines specifically to address hyponatraemia, and she did that very quickly after she became aware of some of the circumstances surrounding Raychel's death. Those guidelines were published in 2002 and the CMO asked for the trusts to develop their own local protocols tailored to their particular circumstances. She specifically asked for both the guidelines and the protocols that they would develop to be audited. Those guidelines, it's fair to say, were the first of their kind in the United Kingdom.

However, despite the fact that audit -- and if you recall back how audit was being defined -- was a specific requirement, it seems that there was no system established to identify the extent to which they were being implemented, let alone their impact -- which is something to be explored in the oral hearing - so although they were asked to audit them, there doesn't seem to have been a system established at the same time

for the CMO to be able to know whether they were being audited or not or the extent to which they were being implemented.

In fact, the department didn't know whether or not they were being implemented unless somebody happened to volunteer to tell them that. The CMO wrote out to the trusts in 2004, specifically seeking assurance, and that response that she received one might regard as being less than encouraging. We have done a schedule so that you can see that. If we can pull up 337-006-001. There are two pages to this, so we'll look at it in series.

The letter that went out on 4 March was really asking two things in relation to this area that I'm looking at now. One is to know that the guidelines have been incorporated into clinical practice. The other is that they were monitoring. She had used the expression "auditing" before, but in her letter she used the expression "monitoring their implementation".

So down the far left side there are all the trusts. Then there is the date of their response, and what is highlighted in red is what we take as less than what the CMO was looking for. So if one looks at an example, Belfast City. In relation to the incorporation into clinical practice:

"I would wish to confirm that the guidance was

disseminated within the Belfast City Hospital last year upon receipt."

It will be an issue as to the extent to which simply disseminating the guidelines is confirming to the CMO that they were incorporated into clinical practice. In fact, you can contrast that with the response just above it from Altnagelvin:

"I can assure you that these guidelines have been incorporated into clinical practice within the trust."

That's a pretty clear statement. As is their next one under "monitoring the implementation":

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

Well, that will be an issue to take up with the CMO to the extent to which that's what she had in mind. You will hear in due course that what actually happened was that there was a regional audit that was done in 2003/2004, and that disclosed some pretty disappointing results. But that's what that's referring to, not that they were doing their own hospital audit.

A number of these trusts didn't respond at all. Belfast City, for example, didn't say anything about how they were monitoring the implementation.

Then if one looks at some of the others, if we go over the page to 002, let's look at the Royal. I'm not

going to take you through them all, though you can see ahead of the Royal there are three trusts which don't respond to the monitoring question. I should point out that the Royal's response comes after there has been a chasing letter from Dr McCarthy, dated 3 November 2004. So the original letter from the CMO was March 2004 and the Royal don't actually respond until the end of the year, and after having received a chasing letter. What do they say:

"I write to confirm this information [that's the guidelines] was disseminated within the trust."

Full stop. Not incorporated into medical practice and they say absolutely nothing about monitoring.

Whether the CMO should have responded to that and wanted to know what had happened, why that by 2004 was the response to what had gone out in 2002, is an issue to be taken up in the course of the oral hearings.

It might have provided an opportunity to reflect about what one needs to put in place in terms of governance, guidelines, time limit. If one says one wants them audited, do you indicate what you mean by that, do you indicate when you want to receive that assurance or do you just wait for two years and then ask?

If I try and draw all this together, maybe

a starting point for drawing this together is the Charter for Patients and Clients that was issued as far back as March 1992. You have seen that charter before in relation to the earlier sections of the inquiry. It is worth noting what it says:

"As the minister responsible for the Health and Personal Social Services in Northern Ireland, this charter is my personal pledge to all citizens that services in Northern Ireland will continue to match the very best available in the rest of the United Kingdom."

That was the pledge that went out in 1992. What has so far been revealed is that, ahead of whatever findings you may make about the care that the children received or how that care was organised, is that in relation to each of these children the relevant trusts failed. They've acknowledged that and we can pull up 337-005-001, where we have tried to chart the acknowledgment and admission of that failure. If we start along the far left, that's the column with the children. Then you have the date of their death and the place of their death. You have the date of the inquest, you have the date of the claim, and then you have a relevant statement from the trust. In the case of Adam it was a statement made in March 1997:

"I believe that, from a liability point of view,

this contain cannot be defended."

Then you have the settlement, that happened just the following month in 1997 and that settlement was with no admission of liability and a confidentiality clause. The terms of that seemed to have caused Adam's mother some distress because she felt unable to discuss some of the things that lay at the heart of her concern about the way her child was treated.

Then we have the admission of liability, and that comes in October of this year, 17 October of this year. There was an acceptance of shortcomings in the fluid management, a full admission of liability and an apology. Of course, what was being accepted was what was known so much earlier.

Then if we look at Claire, we see her date of death, place, inquest, and Mr Chairman, you'll have heard the reason why it took so long for her inquest to occur and it may not have occurred without the instigation of her parents. Then you see the claim. No writ was issued, but a claim was made in September. There is the trust's position and in fact if one sees right down, a statement made by Mr Walby, who was the associate medical director in the litigation department, he made that statement during the course of his oral evidence in December last year. What he says was:

"I had it in my mind at the end of the inquest [which was, of course, May 2006] that we had not handled it well and, should the Roberts bring a clinical negligence claim, the trust would be settling it."

And he gave his reasons for doing that and it was all to do with the failure to carry out a further blood test. So there was a formal concession of liability, but not until 16 October of this year and then a full admission of liability and an apology the following day, 17 October.

If we look at Lucy's case, it was rather different. In Lucy's case, the writ was issued in April 2001. They knew at that stage:

"The outcome of our review has not suggested [this is what the trust was being told] that the care provided to Lucy was inadequate or of poor quality."

That's their position. But there was an admission of liability in December of 2003, just before the case was due to start, and regret and apology was included in the settlement. That was the only one of these children who had an admission of liability before these events of the oral hearings recently.

If we go over to the next page, we see Raychel's dates and her inquest, of course, was April 2003. Then the claim comes shortly after that the following year,

and the trust was trenchant -- as I think we have perhaps described it in earlier openings -- to make it clear that:

"The trust do not accept that it or its staff were negligent or, that if there was any failure to apply the appropriate standards, that failure caused or contributed to the death of Raychel."

And that's how it went on through her clinical hearings into her governance hearings, and then on 30 August 2013 there was a formal admission of liability and an unreserved apology and regret for the hurt and distress caused and, in fairness, they noted:

"Caused by the delay in admitting liability."

Then if we see Conor, see his dates there. His inquest was in June 2004, claim December 2004, and then the trust's position:

"All matters relating to Conor's death and treatment were fully and openly discussed during the inquest."

And then one comes down to October of this year and there is an admission of liability in certain respects, to deal with the matters that the inquiry was concerned with, which was a failure to comply with the CMO's guidelines and to provide them to the staff, and there was an apology for that and then there was another apology and an acknowledgment of the possibility of

seizure activity. That was a bone of contention between the trust and the family and they have acknowledged now that there was a possibility that there was seizure activity and that their communication about that with the family could have been better.

So that's what we now know and what has been revealed. So on the one hand we have the charter, on the other hand we have the deaths, whose faults have been conceded by the trusts ultimately, and the telling thing is that the department only knew about two of those contemporaneously, Raychel and Conor, and neither of them from a formal reporting system.

In the period prior to Adam's admission, over the course of that period 1995 to 2003, when the other children were being treated and died, the department issued -- there's no doubt about it -- a number of papers and bodies were established, priorities set and programmes instituted, as I have tried to show, and it's set out in much greater detail in the written opening. But what did all that amount to?

Well, we asked the inquiry's expert, Professor Scally, to address that central question of how did the department know what was going on in hospitals prior to 2003 in terms of quality of care? A fairly basic question. And we asked him to help us

with that. His answer is:

"There were two ways in which the department might know."

One was mechanisms that he referred to as being integral parts of a functioning healthcare system. So there would be information from routine clinical audit mechanisms at a local level, there would be routine collection and analysis of data, committees meeting -- in particular the CMO had her own committees, she had special advisory committees, and you have heard something about that, and of course there was the central advisory medical committee -- and there were routine meetings between the department and so on. And these are all part and parcel of the department's business and how it would have information.

Then the other way in which it might do, that was disparate ways such as elected members of councils or assemblies might give information or ask for things to be investigated, which would cause the department to obtain that information, and there's letters and communication, sometimes directly from the public. All these are rather secondary ways, he said, by which the department could have known things. And he goes on to analyse those sources of information and pointing out their deficiencies. He says although he considers it to

be perfectly clear that both the Health and Social Services boards and trusts were accountable to the department, he is of the view that there does not appear to have been a generalised understanding that the department might have an interest in the occurrence of these deaths. And he regards it as not surprising that the children's deaths from hyponatraemia did not come to the department in a systematic fashion, given the substantial deficiencies in the systems within the Health Service in Northern Ireland in relation to the quality of care. So in his view, that was almost an inescapable conclusion: if you don't have the proper systems, you're unlikely to find out.

In fact, he characterises what happened in place of organised systems as:

"A series of unstructured communications, taking place outside any recognised protocols and heavily reliant on interpersonal relationships."

In those circumstances, he regards it as unsurprising that that kind of communication didn't necessarily engender action. It doesn't mean that it wouldn't, but not necessarily. And he concludes, in answer to the question that:

"There was no effective system in place in Northern Ireland prior to 2003 and that no significant

efforts have been made at any stage to develop comprehensive and effective notification systems."

And he refers to the difference in the level of engagement of the department in Northern Ireland on issues of quality as compared to the emphasis being given them at an equivalent level in England, and he regards that difference as significant.

That is a matter with which the department takes issue. They disagree with Professor Scally's views as to the extent of the efforts made to develop appropriate notification systems and they don't accept the conclusions which he reaches about a comparison between the developments in Northern Ireland and those in the rest of the UK, and their view is that things were not entirely moving along satisfactorily in the UK either, and they refer to that report of "An Organisation with a Memory", which identified frailties in the system in England.

Well, Mr Chairman, this is something that will be the subject of the oral hearings. Professor Scally recognised, though, that there was some evidence of good practice and of local attempts to introduce principles of clinical governance, which I hope I have identified some of, but he nonetheless pointed to a very clear leadership role for the department in Northern Ireland

and concludes that there would appear to have been a failure to provide the necessary impetus to achieve progress at anything other than a very slow pace indeed.

That's also something that the department doesn't accept. It doesn't accept that there were any flaws -- well, it doesn't accept that, that they were moving at a slow pace, and if, there were flaws, then they may have been, in the system in Northern Ireland, whatever they might be, were not due to failings in leadership. That's the department's view and that's something to be addressed. Because if they are failings, then they're failings not of a body that has no animus, but of people who give direction to the body, ensure that action is being taken and that's one of the important things to explore: if there were any failings, which are the people that are involved in those failings and why did that happen? Is there any criticism to be made of them or were they really hostage to the system that they found themselves within and one which they were unable, for whatever reason, to change or change sufficiently quickly?

What happens now, of course, Mr Chairman, is the subject of the final week through panel discussions with the key players. But it's worth pointing out at this stage that as of, as I said earlier, 2013, the

department can't advise this inquiry of the incidents of deaths resulting from clinical SAIs, and more specifically the CMO, having taken the step in 2001 of commissioning the production of hyponatraemia guidelines and required their implementation to be audited, was at the time that she left -- even now maybe -- there still seems to have been an absence of any system to identify the extent to which those guidelines or their successors are being implemented.

If one thinks that this inquiry was established in 2004 and that brought attention to bear on the issue of hyponatraemia -- put a spotlight on it, one might say -- when the RQIA carried out its review of implementation in 2008 of successor guidelines, it was critical, and critical in certain perhaps troubling respects. It says:

"The necessity of ensuring that the guidance was consistently applied in adult wards where children received treatment ..."

But that was an issue in Conor, in 2003 that was an issue. The other aspect in which it was critical:

"The continued presence of Solution No. 18 in stock and on site. The provision of fluid management training for non-paediatric staff caring for older children in adult wards. The lack of evidence of a reporting

culture for incidents relating to intravenous fluids and hyponatraemia."

These were criticisms that were being made in 2008, despite the fact that the first guidelines came out in March 2002 and, by this time, there had been an inquiry up and running since -- not running all the time, but started certainly in 2004 on this very issue of hyponatraemia.

Then if we bring it up almost to present day, as we say in the written opening, the Northern Ireland Audit Office did another report in October 2012, and that report was on the safety of services provided by Health and Social Care Trusts right towards the issues that we are looking at, perhaps more particularly than the one that was previously done in 2002 in relation to medical negligence. And what did that report find?

"Levels of incident reporting are increasing, however these still fall short of what is expected, particularly in hospitals. There is no incident monitoring system that collates patient safety data across the entire HSC sector. Regional sharing of lessons learnt has not been as structured or as comprehensive as it could be."

And the controller gave evidence before the PAC in their report, and they concluded:

"Despite the introduction of a number of safety policies and initiatives, there is no reliable evidence to show that people receiving health and social care are any safer today than they were a decade ago."

And if one's going back a decade, one's going back to the time of Conor's own treatment and death. They go on to say:

"The department still lacks a reliable means of tracking the progress of the health and social care services in improving the safety of those receiving care or in holding service providers accountable for minimising preventable harm."

So that was the evidence before the public accounts committee in November 2012. The public accounts committee also noted that:

"A national reporting and learning system had been operating across England and Wales since 2003. It was described as a centralised database which aims to improve patient safety nationally. However, such a centralised system is not present in Northern Ireland, with a pilot scheme due in 2014."

Well, Mr Chairman, it will be a matter to be established, of course, during your panel discussions, the extent to which matters have moved on since that assessment in November 2012. We are going to focus on

what happened up until 2003 and follow through what has happened since the introduction of the hyponatraemia guidelines. Thank you very much.

THE CHAIRMAN: Thank you. We'll take a break, Mr McMillen, for 10 minutes and we'll take your opening at midday.

(11.50 am)

(A short break)

(12.13 pm)

THE CHAIRMAN: Mr McMillen?

Opening address by MR McMILLEN

MR McMILLEN: Thank you very much.

May I just start by very briefly outlining the identity of the team for the department in this matter. It may be particularly important because I'm perhaps a slightly latecomer. For anyone who doesn't know, my name is David McMillen, I'm a QC in practice in Belfast. I have with me my junior counsel, Dr David Sharpe, and you probably have seen quite a lot of my instructing solicitor, Catherine Rodgers.

Before I start my substantive remarks by way of the department's opening, may I just publicly deal with the question of SAIs and the reporting of SAIs? My learned friend Ms Anyadike-Danes made some comments as to the availability of information from the department's databases on SAIs.

Could I say that there has been some discussion between the department and the inquiry's legal team, particularly over the last couple of weeks, as to information that the inquiry sought. There appears to be some confusion or some perhaps breakdown of communication. Could I say that the information that we understand that the inquiry now wishes to see is available and we will enter into constructive dialogue with the inquiry to ensure the inquiry's got absolutely everything that it does require and that we can account for these various matters.

THE CHAIRMAN: That's very helpful, thank you.

MR McMILLEN: Thank you, Mr Chairman.

Mr Chairman, you have kindly allowed me to make this opening on behalf of the department. I really have three things I want to cover in general terms this afternoon.

Number 1, I want to explain the department's role in this inquiry. Number 2, I want to say a little about the historical context to the events that give rise to this inquiry. And third, I want to touch on some of the issues that will arise in this segment of the inquiry's hearing.

The first matter then is the department's role in this inquiry. This inquiry, as everyone will know, was

set up by the then minister, Angela Smith, who announced on 1 November 2004 that she had asked you, Mr Chairman, to set up this inquiry. The terms of reference were announced on 18 November 2004 and on that date Minister Smith said:

"The death of any child is tragic and it is essential that the investigation of these deaths is independent, comprehensive and rigorous. The terms of reference I have set for the inquiry and the powers available to it are wide-ranging and should ensure that the inquiry deals with all the issues of concern."

As is well-known to the people that have been taking part in this inquiry or watching it over the last months, and indeed years, the powers of the inquiry include the power to require witnesses to attend to give evidence on oath and the power to require the production of documents. These powers indeed are available to the inquiry in relation to the department itself. The inquiry has exercised these powers extensively. It has required the production of a vast amount of documents held by the department, and further it's also required that witnesses who are past or present officers of the department attend before this inquiry and give their evidence.

That the inquiry's comprehensive in its scope, we

say, can be in no doubt. Even the briefest of perusals of the inquiry's website reveals the breadth of the examination conducted. Dozens of witnesses both as to fact and as to expert matters have been called to give evidence. Thousands of documents have been examined and scores of statements and further statements called for.

That the inquiry's been rigorous, again, we respectfully say, is in no doubt. It is clearly a tribute to the inquiry's legal team that no issue has gone untested. Every witness who's either given a statement or given oral evidence has been pressed on virtually every point. No one has been allowed to get away with a general statement or to gloss over any events. No doubt some of the witnesses who have given evidence have found the giving of evidence to be a far from pleasant experience. We respectfully say that that's a small price to pay to find out the truth in this matter.

Equally, this inquiry is robustly independent. While Minister Smith set up the inquiry in 2004 and it is indeed to the present minister that the inquiry will ultimately report, the department is open to the same searching scrutiny as every other participant. Minister Smith has been succeeded most notably by the ministers of the devolved executive. Each minister has

upheld the independence of this inquiry, which clearly is, as it should be. Indeed, ministers now are directly accountable to the Assembly and thus to the people of Northern Ireland.

While it would be wrong to take away anything from Minister Smith, we say that this introduction of the direct democratic accountability via the Executive in the Assembly to the electorate brings an element that double-locks the integrity of this inquiry.

May I just then deal very briefly with some of the general issues that will arise in this segment of the inquiry? The terms of reference in the inquiry relate to the investigation of the roles of various statutory bodies, including the department that I appear for.

You, Mr Chairman, have put flesh on those bones with your remarks on 2 July 2013 in that you spoke of the dominant culture of really the medical and clinical professions of keeping quiet about mistakes and the changes that have occurred in the period since 2000, in particular.

Hopefully you'll hear evidence, Mr Chairman, that will lead you to the conclusion that change has occurred in at least two domains. The first domain is the clinical domain, how doctors and nurses deal with matters at the front line of healthcare services. We're

all aware of the old culture of "doctor knows best" and no one was ever going to second-guess him or her. We've all, certainly those of us of a certain age, been brought up with a diet, by way of books and TV series and indeed in cinema, of the tyrannical consultant. Those days, we say, have clearly gone.

There have been particular drivers behind that. Society at large is arguably less stratified and certainly people are less deferential to these traditional authority figures. Such changes may not indeed be part of the direct subject matter of this inquiry, but certainly form an important part of the historical context.

The second domain where change has occurred is the extent to which the Health Service has been developed through the concept of clinical governance. A lot has been said, and indeed will be said, on that ever-evolving concept, and I will again return to that topic later in these submissions.

As to the department's role in the Health Service, my learned friend Ms Anyadike-Danes very skilfully set out the role of the department. Indeed, her written submissions, which will be available on the website, set out in very great detail the nature of the department's role in the Health Service. Those without that level of

detailed understanding of the arrangements for the provision of healthcare may be excused for believing that it is the department that provides health services via the doctors in Northern Ireland. This, in fact, has never been the case.

When the Health Service was set up, health services were provided by regional health boards. These boards ran trusts, employed doctors, nurses and other healthcare staff. The position changed in Northern Ireland in the middle of the 1990s. As my learned friend pointed out, there is a division between what was then called purchasers -- later became known as commissioners -- of health services. These were generally the boards and GP fundholders. They were on the one side and on the other side was the providers of those healthcare services. And these providers were generally trusts, which included the hospitals.

The arrangements for the clinical governance for those at the sharp end of healthcare provision has developed over that period of time. In considering the evidence and indeed in reading my way into this particular matter, I would suggest one could not help but be struck by the fact that this concept of clinical governance, while to us now, standing here in 2013, perhaps seems a completely obvious and completely

apparent step that is useful, indeed vital, to be introduced into clinical care, it is something that's come into the Health Service at a relatively late stage. This applies not just in Northern Ireland, not just in the United Kingdom, but indeed throughout the world.

One of the leading UK commentators stated in a 2011 book covering the NHS:

"As this chapter will make clear, one of the most surprising aspects of healthcare regulation is how late it was in coming to the NHS. Indeed, until the Commission for Health Improvement, which was the regulator for trusts, began its work in assessing standards and issuing star ratings in 2002, there was no proper system of regulation in the UK for health services. The volatile history of attempts to regulate is revealing about the dogged defence of clinical autonomy extending over many years."

And indeed, I think these themes have appeared throughout the evidence of this inquiry to date and, no doubt, will appear again in the next few weeks.

Things began to change with the publication of two papers. In particular, one was published in the United States, which was "To Err is Human", and the second one was by Professor Donaldson and Professor Scally, as he now is. Their paper published

in the UK in 1998. I think it is right to say that those papers were really seminal in bringing the question of clinical governance into the minds of clinicians and those who were responsible for healthcare services.

In particular, "To Err is Human" was a very substantial piece of work produced in the United States. That paper made it clear that the majority of medical errors do not result from individual recklessness or poor performance by individuals, but are more commonly errors caused by faulty systems, faulty processes and conditions that lead people to make mistakes or at least conditions where they fail to prevent mistakes being made.

"To Err is Human" concluded that mistakes are best prevented by designing a safer healthcare system at all levels. In other words, by making it harder for people to do something wrong and easier to do it right. Further -- and this was perhaps the more controversial limb of the introduction to clinical governance -- one could not simply leave the matter with the existing orthodoxy that a skilled and well motivated and indeed caring profession could be left to its own devices, to analyse adverse events on the basis that they were caused by the faults of individuals, but rather things

needed to be considered on a system-wide basis.

The fact that clinical governance was a late arrival is not suggested by the department as an answer to the issues before this inquiry. Indeed, Mr Chairman, the department expressly disavows any suggestion that it was not responsible for the safe and effective provision of health services that the people of Northern Ireland are entitled to expect.

Indeed, Mr Chairman, the department disagrees with any suggestion that any of the bodies under consideration before this inquiry do not have any responsibility in relation to the matters that lie at the heart of this inquiry's consideration. In particular, Mr Chairman, again, as my learned friend Ms Anyadike-Danes highlighted during her submissions, there have been differences in views between a number of witnesses who have given evidence as to where responsibility lies and indeed in one instance in particular whether there's any responsibility on one body at all.

To add to that picture a little, I have referred to a paper written by the chief executive of the North Bristol NHS Trust, Ann Lloyd, who wrote in 2001, and she said:

"At the heart of these reforms is the strategy that

requires the quality of care delivered to become the driving force for the development of health services. Clinical governance has become the linchpin for that strategy. Responsibility and accountability for the overall quality of clinical care has been placed on the shoulders of the chief executive of the employing organisation, which is generally the trust. This has come as no surprise to the majority of chief executives in the country, who always assumed that accountability. Certainly in their experience of managing complaints and concerns from patients, they have always believed themselves to be held to account by the public for that responsibility.

"The really tangible change for chief executives arising from the introduction of the statutory duty in relation to quality is that they now have to demonstrate clearly that they have mechanisms in place through which they can account for this responsibility and take action on the outcome of these processes in the organisation."

THE CHAIRMAN: So in other words, Mr McMillen, the imposition of the statutory duty in Northern Ireland in 2003 and earlier in Great Britain, the significance of it isn't that it imposed for the first time a statutory duty of care on the part of the trusts, because that

always existed, but read properly, the 2003 order makes the trusts responsible for showing what they're doing?

MR McMILLEN: Yes.

THE CHAIRMAN: And for measuring what they're doing and being accountable for that?

MR McMILLEN: Yes. In many ways, one may say that even prior to the 2003 order, the trusts were responsible and also, if one's responsible in public sector, one is accountable.

THE CHAIRMAN: Yes.

MR McMILLEN: So really, what the 2003 order did is articulate the matter and brought it to the front and centre of consideration. As you'll know better than I do, Mr Chairman, in a number of spheres a pre-existing, for example, common law duty may be articulated. It may not change the four corners of the duty, but it clarifies it and brings it to the forefront of everyone's mind.

THE CHAIRMAN: Yes.

MR McMILLEN: May I say that perhaps the more difficult question is what responsibility means when applied to the circumstances of any individual organisation. Again, reading myself into this case, reading through days of transcripts, the word "responsibility" arises in a number of realms and with a number of witnesses. And

on one analysis, they weren't always ad idem on what the word "responsibility" meant in any particular officer.

Clearly, Mr Chairman, treating clinicians are responsible in the sense that they make decisions which have direct consequences for their patients. Trusts are responsible as the employers of those clinicians and as the operators of the various hospitals. The responsibility is real in both instances, but different. No one clearly expects a trust manager to stand over a clinician and either recommend a course of treatment or to supervise that treatment being provided to the patient. However, the trust itself has a clear responsibility, we say, to ensure that patients at least are treated in accordance with accepted practice. It also has a responsibility, when anything goes wrong, we submit, to investigate and take any necessary action.

Equally, the commissioners of services, I believe in this realm being the boards, had -- and we say have -- a clear responsibility for the delivery of quality. Again, one does not expect board members to sit at the desk of trust management to ensure that things are done properly. However, certainly when something goes wrong one expects that the board will be in a position to take any necessary action within the scope of its role and powers.

Equally, we entirely accept that the department has its own responsibility. At one level, clearly the department is involved in questions such as the proper expenditure of public money and not wasting the same, and the strategic direction of the Health Service in Northern Ireland. It also has responsibility in another sphere in that ministers are accountable to the Assembly, and ultimately to the electorate, and must answer for all matters of public concern arising from the Health Service. As has no doubt been highlighted before in this inquiry, the department has its own powers to make certain remedial actions when that's called for.

Underlying the responsibilities of the various statutory bodies and their ability to act presumes that they'll be provided with information that they need in a timely fashion. To take the example of the need for boards and trusts to report serious adverse incidents to the department, Professor Scally, some weeks ago, said in relation to boards:

"It's an issue around seriousness and one can define seriousness in several different ways. It could be serious in relation to the reputation of the Health Service or the individual organisations or indeed it could be serious in relation to the effect on the care

and treatment of patients. So it would be a judgment call by the senior officers of the board as to when they would inform the department."

And he went on later in the same evidence to make the same point in relation to the trusts.

So what we have in effect is a system of responsibilities, and while the same term is used in relation to trusts, boards and the department that they're responsible, the outworking of that word and what "responsibility" means in any particular sphere may be very different.

As I have already stated, the system was largely based on the assumption that professional people will act in a manner that you would expect professional people to act, and they'll do that throughout the organisation and that they will do that in a consistent manner. Perhaps if this inquiry's demonstrated one thing, it is that these assumptions were either unfounded or at least that they did not operate as an effective governance mechanism in the Health Service. Of course, Mr Chairman, you'll come to your own view on this matter. However, could I suggest that perhaps there are three interweaving factors that may have been in play?

First was the traditional notion that clinical

matters were for clinicians, and clinicians should solve them themselves, either themselves or by those close to them in professional terms, particularly being the GMC and the Royal Colleges. The second factor in play was that there was a defensive culture in that people were afraid of being blamed and people were indeed afraid of litigation, and this no doubt, Mr Chairman, had a chilling effect on effective reporting. Third, Mr Chairman, it's right to acknowledge that there are frailties in any system that is made up of well meaning and, indeed in the Health Service, well intentioned and truly caring people. People do forget things, people put things off, people are sometimes too busy or occasionally they simply make errors of judgment.

I do not think it's really for me to go into the detail of the arrangements of the Health Service. Again, Ms Anyadike-Danes has very skilfully summarised that and she's set that out with great clarity. However, it's probably fair to say that this new paradigm of clinical governance recognises that these assumptions cannot be relied upon. Procedures are now set out for reporting, for the protocols have been devised as to when reporting procedures should be invoked.

Can we say, Mr Chairman, that Ms Anyadike-Danes very

fairly set out Professor Scally's views and the fact that the department disagrees? We must part company with Professor Scally and his [inaudible word] reports, at least in relation to his analysis as to how Northern Ireland compared with the position in Great Britain. Whether, Mr Chairman, the clinical governance mechanisms in place by 2000 were adequate by the standards of that time is a matter for this inquiry. What we say is that it would be wrong for this inquiry to take from the evidence or from Professor Scally's reports that at 2000 or thereabouts the department was lagging behind the rest of the United Kingdom.

Can we say that, insofar as what follows appears to be a critique of Professor Scally's report, we don't put that forward in an adversarial manner? The department's instructed me -- and it has been the overriding imperative of the department -- to ensure that this inquiry has the best information to hand, and we respectfully say that if one read Professor Scally's third report in particular, and took it at face value, one may come away with a misleading impression.

Just if I may deal with some of Professor Scally's reports by way of outline. Professor Scally is correct in that the 2000 paper from Sir Liam Donaldson, mentioned again by Ms Anyadike-Danes, "An Organisation

with a Memory: a report of an expert group on learning from adverse events in the NHS", this did mark really a radical change in the approach of clinical governance in the NHS in Britain. It was the first clear, considered and systematic acknowledgment outside academic circles that serious adverse incidents were simply not the product of errors on the part of individuals, but rather arose from the systems themselves.

Some steps even by the time of the 2000 Donaldson paper were already underway in Great Britain and also in Northern Ireland. Local arrangements were set in train by a circular of March 2000 where the then Chief Medical Officer, Dr Henrietta Campbell, in Northern Ireland, highlighted developments in the rest of the United Kingdom. She also highlighted the absence of formal mechanisms to establish clinical and social care governance in Northern Ireland and also she highlighted the work she had commissioned on clinical standards.

She then, some seven months later, in October 2000, issued a second document "Confidence in the Future". She recommended in that document the introduction of clinical and social care governance and appraisal for all doctors in Northern Ireland. In that document the CMO made 14 specific recommendations, including the

participation in clinical audit and continued professional development, that that be compulsory for all doctors.

In particular, recommendation 12 was:

"A framework for clinical governance in the HPSS, including primary care, be established as a matter of urgency."

Furthermore, recommendation 14 suggested that:

"Methods of recording adverse incidents be put in place in every organisation and a regional register established."

And one can hear resonances with the points that my learned friend raised in the course of her opening.

Subsequently in Northern Ireland, the department issued a consultative document, "Best Practice, Best Care", in 2001, and a circular in 2002 which set out the guidelines for the implementation of clinical and social care governance arrangements.

The importance of the Donaldson paper for present purposes is that it did two things. Number one, it looked at the position in England and Wales as of 2000, and then gave some recommendations. What it did was to really, in effect, benchmark the position in Great Britain as of 2000. Professor Scally, in many ways, was asked to carry out at least a similar

exercise. He was asked:

"How did it the means of the department's knowledge or lack of knowledge compare with the rest of the UK at the relevant times [which are 1995, 1996 and 2000]?"

So we have Professor Scally on one hand, who gives his comparative analysis, but we also have the benefit of Professor Donaldson or Sir Liam Donaldson's analysis as of 2000.

Professor Scally in his latest report considered a particular circular 2 of 1993 and what he said in his report is that document does not display any interest in patient care issues. We respectfully take issue with Professor Scally on a number of bases, but what Professor Scally's report, we respectfully say, does not reflect is that document was only one of a number of documents that were in force at the material time and which reflected the arrangements in place in the Health Service in Northern Ireland as of 2000.

Also, what the professor does not appear to take into account was the role of the department at that time was, as I've outlined earlier in this opening, to, in effect, take a strategic overview of the health services within Northern Ireland and also be accountable by the minister to the Assembly, particularly in matters of public concern.

Professor Scally went on to identify various reporting mechanisms that were available in Northern Ireland in the 1990s. The analysis in 2000 by Sir Liam Donaldson in his report shows that, apart from one mechanism dealt with below, the same reporting mechanisms were in operation in Great Britain at that time. I have given a reference where one can look for the mechanisms found by Sir Liam and the mechanisms found by Professor Scally.

In any event, what Sir Liam concluded on this issue, he concluded by saying:

"There are no universally accepted criteria for identifying occurrences or outcomes of healthcare that should constitute a basis for recording or reporting poor quality."

And he's talking about England and Wales in particular:

"Neither does the NHS have a single comprehensive system of gathering data to enable service failure to be recognised. But information is available from different sources. Some are specifically set up to monitor adverse incidents while others are designed to gather more general health information."

May I just respectfully commend that quotation to you, Mr Chairman? It resounds in relation to

Professor Scally's latest report in that, in effect, he says Northern Ireland was lagging behind. And he takes the 2000 paper from Sir Liam Donaldson as suggesting that things were working well in England and they had a system in place and it was monitoring adverse events. That clearly, simply, was not the case.

As I think I've perhaps already covered, when one analyses the position in Northern Ireland and the reporting mechanisms in Northern Ireland as of 2000 that Professor Scally was directed to consider, and one looks at the ones available in Great Britain, they're either materially the same or at the very least they cover the same ground.

Arguably in Northern Ireland, Northern Ireland being Northern Ireland, the position was more favourable in one respect in that there were routine meetings, as Professor Scally himself said, between the department and organisational or professional leaders, such as directors of public health either in trusts or in boards I take it he's referring to.

What Sir Liam Donaldson's paper does not find is any such interreactions. Indeed, it is quite striking, when one reads Sir Liam Donaldson's 2000 paper as a whole, that that paper is almost totally devoid of any reference to the Department of Health in London. The

importance of that, Mr Chairman, is that Professor Scally in effect says, "Look what was going on in England. Look at the 2000 paper", and even if there were instances of adverse incident reporting, which clearly it isn't made out in itself -- what he is saying is that in England was a much better position vis-a-vis the department -- and that's an important point, the department. There's nothing in Sir Liam's Donaldson's paper that shows there was an reporting to the Department of Health other than by means of the old incident reporting matters, such as perioperative deaths and the failures of medical equipment.

So certainly the 2000 report from Sir Liam Donaldson is a very thin reed upon which to ground any criticism of the department.

The only additional factor in play in Great Britain and the only additional procedure they had in place was a local reporting system set up in 1994. By 2000, the Donaldson committee looked at that particular reporting system, it went to various trusts and in particular said, "Please give us your data on adverse reporting incidents". Most trusts weren't able even to do that. What the committee did do was it was able to collect information from the few trusts that did actually operate the system.

From those few figures, they were able to extrapolate a figure of around 2,500 adverse incidents per annum throughout England and Wales in secondary care, essentially in hospitals. The Donaldson committee carried out its own study and, on the basis of that study, they suggested that there were in the region of 850,000 hospital patients who were subject to adverse incidents per annum. So we have what is apparently, in Professor Scally's view, a well-running adverse incident reporting system which, one can extrapolate, reports 2,500 out of 850,000 adverse incidents in England and Wales per annum.

We respectfully say that it is quite clear that, both in Northern Ireland and also in Great Britain, clinical governance work was already underway by the year 2000. However, in both places it was manifestly a work in progress. The 2000 report said:

"NHS organisations are due to produce their first annual clinical governance later this year [that would be 2000] and it has been explicitly recognised that there is considerable variation in the states of readiness for the development of clinical governance and it should be seen as a medium to long-term objective."

The report carried on:

"It is also very pertinent to ask how current

mechanisms for learning from experience appear to support NHS organisations improving the quality and safety of care they provide."

And unsurprisingly, I say, the report concluded:

"There were a number of serious weaknesses."

And went on to say:

"To some extent the situation may reflect both the culture of devolved responsibility and competition under the internal market, which occurred at regional level during the same period."

So what the 2000 report found in Great Britain was things were far from good, far from satisfactory, as far as incident reporting goes. Further, it was a recognition that, in the 1990s in the NHS, this had been an area -- as again my learned friend has outlined -- market solutions had been tried in an attempt to drive down costs by creating autonomous healthcare trusts.

The way this was supposed to work is that the market would -- first it would save money insofar as trusts would compete for work. The commissioners would come to various trusts and they would ask them "What service can you provide and at what price could you provide the service at?", and that would save the commissioners of service money.

The other side of that coin is that the market forces min classic economic theory, I suppose, is intended to drive up quality insofar as service commissioners are not only interested in the price, but they're interested in getting value for that money. So if they can't get the quality and the price from a particular service provider, they will move elsewhere.

What actually happened is that clearly these mechanisms didn't work well and they did not work well particularly in Northern Ireland. Because of the small population, that availability of alternative providers simply isn't there.

What also was part of this free market idea was that -- I think the phrase used in the day was if something could be devolved, then it should be devolved. In other words, one pushed decision-making down to the lowest level. So things that were considered and decided by boards in the earlier era were devolved down to the trust level, and the idea again was that the boards would have a commissioning role and would deal with the trusts via the contracts, which would control quality, and the department had its overarching general role to keep an eye on the Health Service generally and to set the structures for reporting, particularly in terms of financial accountability.

In any event, Mr Chairman, the 2000 Donaldson report led to the National Patient Safety Agency, which started work in England and Wales in December 2001. That was followed up in the same year by a paper from the Department of Health in England "Doing Less Harm", and in 2004 by the NPSA's own publication "Seven Steps to Patient Safety", which set out the mechanisms for reporting.

It's useful to look at how well the NPSA actually worked over this period. One can find the answer to that in the National Audit Office's report in 2005, which stated:

"The role of the National Patient Safety Agency's national reporting and learning system [which we suggest is key to this matter and to adverse incident reporting] has taken two years longer than originally envisaged. By 30 September 2004, all trusts had the technology to link into the system, but many still had to map details from their local system to the national system. By the end of March 2005, some 170 acute ambulance and mental health trusts had reported 79,000 incidents."

And then it refers to further matters which aren't terribly relevant.

So I have calculated very rough figures. If one takes the three months as being the first three months

of 2005 and extrapolates the figure of 79,000-odd incidents over the three months, that makes approximately 300,000 adverse incidents would be reported per annum, which is just over one third of the Donaldson report's 2000 estimate of the adverse incidents that occurred annually.

So clearly, one cannot simply say, "Oh, by 2001, in England and Wales, they had the NPSA in place, that meant things were working well and the adverse incident reporting issue had been dealt with". It manifestly simply wasn't the case.

Indeed, in Northern Ireland we had our first guidance as to adverse incident reporting -- it came in July 2004 and it was followed up by means of a circular in 2006, and additional guidance has been given on classification by another circular, again in 2006. To some extent, if one takes simply the dates of the various reports in Northern Ireland -- we have 2001, 2004 and 2006 -- and compares that with when systems were introduced in England, one could conceivably argue and respectfully argue that at that period, after 2001, Northern Ireland was lagging perhaps a year or so behind England and Wales in the introduction of systems, but not in necessarily in the introduction of effective systems.

That to some extent was a product of the devolution of the government arrangements in Northern Ireland and indeed, as everyone in this room will know, as to the stop/start nature of the same. Perhaps, Mr Chairman, you can take some comfort from the fact that Northern Ireland has rapidly moved to close this gap. Again, it's one of the functions of the smaller population and a smaller geographical area that we can perhaps act slightly more rapidly and close the gap, and while the NPSA published its first national learning report in July 2005, ours was produced some 11 months later in June 2006.

Again, Mr Chairman, in England and Wales, and indeed in Northern Ireland, it is a work in progress and will always be so. Sir Liam Donaldson, who's the oracle in many of these areas, returned to the issue again in his report that he wrote and published in 2006. The purpose of that report was to pick up on progress that had been made since his 2000 report, again in England and Wales. Sir Liam said this:

"Important and necessary steps have been taken on the journey to improve patient safety across the NHS. There is much greater awareness among clinicians, managers and policymakers that patients are not as safe as they should be. We have seen an unprecedented growth

in the number of voluntary reports from healthcare staff about their safety concerns. Much effort and debate has gone into defining the types of interventions necessary to reduce risks and improve safety. At times within NHS organisations we have seen glimpses of potentially exciting safety products and initiatives that carry the seeds of the large-scale change that is needed to genuinely put safety first. However, the pace of change has been too slow. We are still unable to ensure NHS patients that all organisations are learning from experiences in ways that prevent harm to future patients. This, however, is the challenge for all developed countries. The NHS is not unique in this respect. Indeed, most countries recognise that they have for too long failed to give priority to patient safety compared to other areas of healthcare."

Really, on this point, Mr Chairman, we say that if one looks at the totality of the regimes in place throughout the United Kingdom and indeed the effectiveness and operation of those regimes, any suggestion by Professor Scally, or anyone else, that Northern Ireland was significantly lagging behind in the introduction of clinical governance and adverse incident reporting arrangements simply is not borne out by the evidence. Indeed, in fairness, one has to say to

Professor Scally may have had an idea that he did not have every single document or report to hand, and one could not could never, perhaps with one's own devices, find every conceivable document that may be relevant. Professor Scally, in fairness to him, put the caveat on his conclusions that they were in the absence of evidence to the contrary, which perhaps presaged the fact that he would not have been surprised if other evidence had been produced to persuade him to the contrary.

THE CHAIRMAN: Well, to the extent that there's a gap in any of the information he had, we've asked the department to fill that and I think that process has already started.

MR McMILLEN: That's correct. As I understand it, Mr Chairman, the vast amount of the documents referred to in this opening are documents that should generally be available, and they certainly are publicly available, they're all available on the Internet. Of course, one knows if one goes to the department's website or any other public body's website, there's a blizzard of documents, and of course again the department will provide the utmost assistance in the provision of any documents or any information.

THE CHAIRMAN: I think what we're looking for, Mr McMillen, is any specific documents. As you say, there is

a blizzard of documentation floating around and if there's any particular document -- but I think, if I pick up your thesis on behalf of the department, the general perspective is that he's perhaps painted the progress and rate of progress in Britain in slightly too glowing terms and then Northern Ireland compares unfavourably to that, whereas if you fill out the English picture more fully things were changing, things were improving, but it was sometimes inconsistent and sometimes a bit patchy.

MR McMILLEN: Yes, Mr Chairman, that's correct. Really it's a comparative analysis we object to and what follows on from the professor's comments on that as to the department's role. Whether the United Kingdom as a whole was moving too slowly and whether the position as a whole in the United Kingdom was unsatisfactory is a matter for you, Mr Chairman. It's simply the comparative analysis that we object to.

THE CHAIRMAN: As you'll know, without going into who has got a Salmon letter and who hasn't, the basis of a Salmon letter is that each individual is to be judged by the standards of the time --

MR McMILLEN: Indeed.

THE CHAIRMAN: -- and that's what makes this point particularly important.

MR McMILLEN: Absolutely, Mr Chairman. I'm very much obliged for that.

Mr Chairman, you really have it, but may I just say I think it's important to make my next point, which really follows on. Professor Scally has criticised the professional leadership within the department and, in particular, he has criticised the then Chief Medical Officer.

What he doesn't say -- and perhaps does not realise -- is that neither the Chief Medical Officer nor the Chief Nursing Officer had direct policy responsibility for quality or clinical governance within the department at the relevant time. Both officers, and the CMO in particular, would have a professional advisory role, ensuring that things within their purview remained central to the department's policy and strategic direction. Again, from what we've seen in my earlier comments in relation to the Northern Ireland CMO's report in 2000, "Confidence in the Future", she was actively pursuing this and she was keeping pace with the changes occurring at that time, as reflected in the 2000 Donaldson report. And she was asking that things be done as a matter of urgency. And in fairness to the CMO at that time, that has to be reflected in any balanced view and, no doubt, Professor Scally will

acknowledge that in due course, given the opportunity.

The challenge facing the NHS throughout the United Kingdom and the ongoing nature of the task, Mr Chairman, is underlined by the inquiries in England, particularly into the tragedies around Harold Shipman and Beverley Allitt and the inquiries into Bristol Royal Infirmary and indeed the Mid-Staffordshire Trust. In 21 July this year, the Secretary of State for Health, Jeremy Hunt, gave a speech where he discussed what he referred to -- and again he was talking about his area of responsibility in England and Wales -- as the silent scandal of patient safety.

He considered many of the matters already set out in this opening and he concluded by saying:

"The lesson of recent tragedies is that the NHS must never again be silent about patient safety because it matters too much. It matters to each one of the million people who have given their professional lives to the NHS and it matters to each one of the millions of patients they care for every year. A change of this magnitude will not be instant, nor will it be easy, but it is possible and our NHS should aspire to nothing less."

And we, with respect, endorse that.

Mr Chairman, I'm grateful for the time you have

allowed me. I have given you a brief tour over some of the issues that will face you over the next week-and-a-half in particular. I've referred to a number of reports and circulars and recommendations and I've quoted from a few of them, but I think it's important to say this -- and I say this on behalf of the department -- we are acutely aware that at the heart of this inquiry lie the short lives and tragic deaths of little children whose parents put their faith into the hands of the Health Service. Nothing I can say or the department can do can replace the lost years that lay ahead of each child. Nothing can be said or can be done that can make up for the immeasurable and enduring suffering of those families and all whose lives were touched by those children. While nothing can change to the slightest degree what has happened and the losses suffered, it is hoped by the very fact of the existence of this inquiry and the detailed examination and questions posed that this does provide some assurance that there is a real commitment to find out what went wrong.

Perhaps more to the point, Mr Chairman, the sincere hope of the department is that this inquiry will move us towards a situation where mistakes in healthcare -- they can never be totally excluded -- become increasingly

rare. We owe these children and their families no less.

Thank you very much, Mr Chairman.

THE CHAIRMAN: Thank you, Mr McMillen.

We had hoped to reach Dr Darragh and to start his evidence before lunch. I'm sorry, doctor, that has turned out not to be possible. We'll start Dr Darragh's evidence after lunch. But let me deal with just a couple of points.

The arrival of Professor Scally's report has caused some excitement over the last week or so and I just want to re-emphasise the extent to which this inquiry, which is into hyponatraemia-related deaths, will investigate the issues which I identified in July and then further developed.

My interest in how governance was progressing is in, so far as that progression is relevant, to the children with whom the inquiry is concerned. Adam's death in 1995 and his inquest in 1996 seem not to have been known about at departmental level. Claire's death in 1996 similarly seems to have been unknown at departmental level. Lucy's death in 2000 and the series of internal and external reviews which were conducted by Sperrin Lakeland also appear to have been unknown at departmental level.

So far as I am aware -- and there may be some

uncertainties about this -- the balance of the evidence to date is that the department's first involvement was in 2001 when it was made aware of Raychel's death at a number of levels, including direct contact with Dr Campbell, who was then the Chief Medical Officer, and Dr Carson who was then the Deputy Chief Medical Officer.

I have limited interest in the overall development of governance because that would spread the net far wider than I can or should go. Professor Scally's report, with which the department takes some issue, has to be read within the context with which I am concerned, and he has identified at paragraph 2 of his report the central question which he was asked to deal with.

He was asked that question because of my concern about the apparent lack of knowledge within the department about hyponatraemia-related deaths before Raychel's and, in essence, there are two particular issues that I focus on. One is whether there was a system in place for alerting the department to such a serious adverse incident as a child's death in hospital or, alternatively, was there no system? Because if there was a system and if it was an operating system, the department would have learned significantly earlier about Adam's death in 1995, Claire's death in 1996 and Lucy's death in 2000. So that's one point

I want to emphasise.

The other point which has already effectively been referred to by Mr McMillen on behalf of the department is that this is Professor Scally's third report and I take it, Mr McMillen, that by "his first two reports" you were referring to his original report and then his supplementary report about the aftermath of Lucy Crawford's death?

MR McMILLEN: That's correct, Mr Chairman.

THE CHAIRMAN: That report, to remind you, can be found in the inquiry papers. The initial report is at 251-002-001 and then there's a supplemental report, which is 251-004-001. But if I stick with the first report for a moment -- could you please bring up for me 251-002-015 and 016?

What I want to look at just for a moment is paragraph (l) at the bottom of page 15 and paragraph (m) at the top of page 16. The question at (l) was:

"Should the [Western Health Board] have notified [the department] of the death of Lucy Crawford and the circumstances in which she died?"

And Professor Scally says:

"Either or both of the two trusts [that's Sperrin Lakeland and the Royal] who were involved in the care of Lucy could reasonably be expected to have

notified the department if they felt the death was potentially due to inadequate treatment. There would not have been the same expectation of the Western Health Board."

And then he continues.

Then at (m) at the top of the next page, the question is:

"Should the Sperrin Lakeland trust have made a report to the department about Lucy's death?"

He says:

"As it was to the department that the trust was accountable, it would have been appropriate that the death -- and, in particular, concerns about her treatment -- should have been reported to the department. There were procedures in place requiring trusts to notify the department of certain untoward events. In particular, there were systems in place covering events affecting patients in other circumstances.

"It has to be noted, however, that there does not appear to have been a requirement for trusts so to do in relation to a potentially avoidable death or instances of serious clinical failure in other clinical areas. The replacement of the accountability of the Erne Hospital to the Western Board with accountability

of the Sperrin Lakeland Trust to the department does not appear to have been accompanied by the enunciation of a systematic protocol for the reporting of incidents. It is, however, possible to argue that there is a general duty to keep the department informed of events that have had serious consequences and which might become the subject of media attention or public controversy."

Mr McMillen, I don't need an answer immediately, but I'd like to know over the next day or so whether the trust takes issue with that analysis by Professor Scally.

MR McMILLEN: I can say now that we do. Principally, the key document one needs to look at is circular 2 of 1993, METL/2/93. Professor Scally, particularly in his first report, did not have that to hand. What that shows, we respectfully say, is that when trusts came on the scene, they took over the position whereby there was very much a hierarchical reporting from -- the boards were the employers of doctors and they managed the hospitals.

When trust status came on the scene for hospitals, in effect the management role, the direct management line management role, conducted and carried out in the past by the boards, was subsumed into the trusts. They were the autonomous self-governing bodies.

Professor Scally, particularly on page 016, where he says:

"The replacement of the accountability of the Erne Hospital to the Western Board with accountability of the Sperrin Lakeland Trust to the department does not appear to have been accompanied by enunciation of a systematic protocol [et cetera]."

If that suggests that the department took on the managerial responsibility for the then trust, we say that's incorrect. That management responsibility was subsumed into the trust itself and that theme, I think, is perhaps picked up elsewhere in Professor Scally's reports.

THE CHAIRMAN: Well, it's obviously not your fault since you weren't involved. It's a pity that this wasn't developed last spring and in May and June when we were going through this segment.

Could I ask you this then: if the trust was not accountable to the department, how did the department know what was going on in the hospital?

MR McMILLEN: Obviously there are a whole range of mechanisms for financial governance, which I won't touch upon. But what we say is that the accountability must relate to functions of the department, obviously, and we say that the department had an interest in the operation

of trusts in two principal ways. The first way or the first sphere was matters which were of interest at a regional basis. I say "interest", I mean public interest at a regional basis. Leaving aside the public health things, for example, if there was a contagious disease or something gone wrong which could have regional implications, either strategically or indeed medically, the department had a clear interest in that being brought to its attention.

The other general sphere it had an interest in was where there was a public interest, insofar as there was something, for example, which could cause the public to be concerned as to the nature of Health Service. The department had its overarching duty, obviously, to promote the Health Service and the well-being of the public and indeed the minister would be accountable and would expect to know of those matters so he could account to the Assembly or could account to the public directly. So those are the two principal spheres.

So when Mr Gowdy, for example, in his witness statement, the former Permanent Secretary, said, "We would have been expected to be notified of these deaths", that was in those particular spheres. They were matters of particular concern.

THE CHAIRMAN: That's why I understand Mr Gowdy's statements

to mean that he would have expected to have been told, for instance, about Adam's death.

MR McMILLEN: Yes, that's correct.

THE CHAIRMAN: He was still there in 2000 when Lucy died. He would have expected to have been told about Lucy's.

MR McMILLEN: That's correct.

THE CHAIRMAN: So that was his expectation. What was the system or mechanism by which he was to be told? I mean, was there a --

MR McMILLEN: There was no formal mechanism.

THE CHAIRMAN: But in terms, is he saying, "Look, this is so obvious: if a child dies who shouldn't have died or certainly shouldn't have died in those circumstances, I expect that the department will be notified because anybody involved should recognise that this is a matter of public importance"?

MR McMILLEN: Yes. There were skilled professional, caring and well-paid people in positions of authority who did readily pick up the telephone and ring him about a very wide range of matters and this is certainly something Mr Gowdy is quite clear in his statements that he would have expected to have been raised with him.

THE CHAIRMAN: So the extent to which the department disagrees with what Professor Scally has said is limited? The department agrees with Professor Scally to

the extent that the department should have been notified, but it's the exact framework within that report should have been made, which is the subject of some debate?

MR McMILLEN: Yes.

THE CHAIRMAN: The end result is not in debate --

MR McMILLEN: That's correct.

THE CHAIRMAN: -- it's the framework which is in issue?

MR McMILLEN: Professor Scally puts it in terms of management accountability. It is not management accountability; in our submission, it's strategic and public interest concerns.

THE CHAIRMAN: Okay. I'm not sure exactly how far that takes us because what I'm doing through this exercise is exploring just how great the ground is between the department's position and Professor Scally's and, on this point, I'm not sure the ground is significant to the extent they agree on the end result, but the route to that end result is ...

MR McMILLEN: That's correct, Mr Chairman, the end result. However, if clearly the department has managerial responsibility for the trust, for the operation of the trust, there would be a greater imperative to have a formal reporting mechanism. Now, if it is this general strategic oversight role that the department

has, then we would say the imperative is less to have that mechanism in place.

THE CHAIRMAN: And that has a knock-on effect, I think you say, on the chief officers.

MR McMILLEN: That's correct.

THE CHAIRMAN: That's one issue. And on the development of governance generally, I don't read Professor Scally's report as saying that the development of governance was anywhere near complete in England. The fact that he contributed to publications, I think in 1998 and 2000, means that they were identifying what the starting mechanism was rather than the end result.

MR McMILLEN: Indeed, but if one could read Professor Scally's latest report as saying things weren't going very well generally in the United Kingdom or they weren't as far advanced as one would have hoped, that's one thing. However, he then carries out the comparative analysis and then extrapolates from that criticism of professional officers in the department. We say, Mr Chairman, that if Northern Ireland was in a comparable position to Great Britain, then any such criticism falls away.

THE CHAIRMAN: He could be equally criticising Sir Liam Donaldson?

MR McMILLEN: Absolutely. If he dares, yes.

THE CHAIRMAN: Okay, yes. Thank you very much.

Let me move on briefly to the note which was circulated on Monday this week, which I said I would come back to. It's my outline of how the week of 11 November will work. What I indicated at the end of that note is that if there are any representations on the format which I'd outlined, or the schedule, they could be made today. Does anybody have any points to raise? Is there any concern about it?

MR QUINN: On behalf of all of the families that I represent and my junior counsel and solicitors, I have only one point to make. Could there be some provision put in place whereby if a solicitor cannot attend on a certain day, which apparently may be the case, that junior counsel can represent that particular solicitor at that particular time on that day?

THE CHAIRMAN: Yes.

MR QUINN: There would be no difference in the costing of that exercise, as I understand it.

THE CHAIRMAN: There is, it's cheaper.

MR QUINN: Well, I knew that!

THE CHAIRMAN: Is there any other issue? Okay. What I should say is this. I think you have a witness schedule for today and tomorrow and for next week. You will have noticed that absent from that witness

schedule is Professor Scally, and that's because he's not available to us this week and next week. He is, however, available in the following week, so the obvious date to slot him in is on Wednesday the 13th. That's slightly out of sequence because I wanted the historic issues to be complete by then. And assuming then that the ground between Professor Scally and the department still stands, he will be required to give evidence. If that ground narrows in the next week and a half, then he may or may not still need to be called. Okay?

MR QUINN: Mr Chairman, does that mean then that counsel will be required for that day and that day only?

THE CHAIRMAN: For that day only, Mr Quinn, and that's assuming -- well, you know that over the course of the last 18 months we've started off segments with expert inquiry witnesses needing to be called and then the need for them actually to give evidence has faded.

MR QUINN: Yes.

THE CHAIRMAN: Because we've made progress in the evidence of other witnesses which has made their appearance unnecessary.

MR QUINN: Mr Chairman, could I also take this opportunity, if you give me two minutes? I just want to mention two or three points arising out of the openings. It's not a very long address at all, it's only two or three

minutes.

Mr Chairman, I want to thank both my learned friends for their very comprehensive openings in this case. In particular, Mr McMillen, whose case is not easy to present in this particular format. May I first of all say from the parents' point of view, I want to make three points. If one looks at paragraph 13 of Mr McMillen's opening in relation to the publications of the United States paper and the Donaldson and Scally paper, one can see that what jumps into the mind is that the US paper from 1999 is called "To Err is Human", and the parents want to make the point that they always accept that to err is human. They concede that most performance issues arise out of a matter of negligence, a systems failure, as was suggested in that paragraph, and nobody at any time has made any case or any suggestion that there was any deliberate failure in the duty of care to a patient.

It's the failure to report that faulty system, that small error, that tiny piece of error that goes into a multitude of errors. That's what causes concern. And it's a failure to report that then leads on to something else, and that is people then brushing that failure under the carpet. So what the parents have a feel of, they feel, whether they be right or they be wrong, they

have a sense that there is a cover-up in the case and it's that particular point that causes far more distress than the human error. It is that which causes great distress and concern to the parents.

Paragraph 17 of Mr McMillen's paper also makes a very good point that the parents would want to cover. One will see there that it's accepted that things do go wrong. One doesn't expect the board managers to sit and look over the trust managers' shoulders. But once again, we accept that things do go wrong, we accept that management can't be looking over management all the time.

But that then brings me to the second point that you made, Mr Chairman, and that is that a proper system of reporting and a proper system of investigation is what we have to look at during this particular segment of the inquiry. We know, for example, that in June 2001, after Raychel died, that Mrs Burnside, who was then the acting chief executive at Altnagelvin Hospital, that she didn't follow her own guidelines. Those are the matters that we want you to look at, Mr Chairman.

Turning to paragraph 20 of Mr McMillen's paper, this brings me to the main point that I have to address on behalf of the parents. When one looks at section B of that in relation to a defensive culture, that is

something that I wanted to mention this morning, without Mr McMillen ever mentioning it, because we see the whole affair as something of a defensive culture. For example, what we had last week and the weeks before that was a series of admissions after years of waiting. Now, whether or not that is a signal and an indication that the defensive culture has changed, that may be, and we look forward to the light being, as it were, seen by those people who still adhere to that defensive culture.

But I have to remind you, Mr Chairman, that in relation to that defensive culture that in relation to anyone who was reported for investigation, that it was the Fergusons who reported the Chief Medical Officer and another doctor who I won't name at the moment because those proceedings are ongoing. It was Conor's grandmother who reported Nurse Bullas for her behaviour and her treatment of Conor just before he died.

So the theme again -- and I bring this to a close very quickly -- is that the parents still see that there is a defensive culture present within the Health Service. And I was glad that my learned friend Mr McMillen was able to refer to a speech from the health minister Jeremy Hunt, and I repeat the first few lines of that speech:

"The lesson of recent tragedies is that the National

Health Service must never again be silent about patient safety because it matters too much."

What matters here is that these children have died and the investigations have been long, drawn out and difficult because, we say, of a defensive culture that existed at that stage, and we would ask you, Mr Chairman, to investigate that defensive culture and to comment upon it specifically.

THE CHAIRMAN: I'm conscious of the fact, Mr Quinn, that -- I think today is now day 137 -- there won't always be statutory inquiries into deaths of children, and the vast majority of deaths which take place of adults or children at best lead to inquests and perhaps some lessons learned from that. But since this inquiry will not be repeated and not be repeated on a regular basis, there has to be a better way of learning lessons than this.

MR QUINN: Yes.

THE CHAIRMAN: And a far quicker way of learning lessons.

MR QUINN: Yes.

THE CHAIRMAN: Ladies and gentlemen, we'll start with Dr Darragh at 2.15.

(1.27 pm)

(The Short Adjournment)

(2.15 pm)

(Delay in proceedings)

(2.23 pm)

MR STEWART: Good afternoon. Might I call Dr Paul Darragh, please?

DR PAUL DARRAGH (called)

Questions from MR STEWART

MR STEWART: Good afternoon, Dr Darragh. You have been good enough to supply the inquiry with two witness statements, WS076/1, on 29 June 2005, and a second, WS076/2, on 26 September of this year. Are you content that the inquiry should adopt those as part of your formal evidence to it?

A. Certainly.

Q. Thank you. Your second witness statement contains a CV, and can we see, please, page WS076/2, page 2? This is your career before you became Deputy Chief Medical Officer. You had a background in community medicine and that brought you into public health issues and eventually you were seconded to the department with effect from 5 June 2000.

A. That's correct. If I might just point out, "community medicine" was the term by which public health medicine was known in those days.

Q. Thank you. You stayed at the department as Deputy Chief Medical Officer, DCMO, until the summer of 2002.

A. Yes.
Q. Do you remember what month you finished your secondment?
A. June -- 30 June, I think, 2002, starting on, I think, 5th or 6 June 2000. So it was actually a two-year secondment from my existing position.
Q. Were short-term secondments of that duration a common occurrence?
A. Yes, I think they were. They were certainly increasingly a way in which gaps could be plugged in the short-term.
Q. What gap were you brought in to assist in plugging?
A. It was the position of the Deputy Chief Medical Officer.
Q. And what was the scope of your duties?
A. Anything and everything, I suppose you could say. Basically, you work-shadowed the Chief Medical Officer. But within that, part of the work I would do is -- the department ... there was actually a much wider canvas than what we even think today from what we are hearing. There was a great deal of other activity. For example, there were 180 doctors employed in different capacities through the Chief Medical Officer's department, the Department of Health, in areas like social security benefits assessment, employment medical advisory service, Northern Ireland Prison Service, Occupational Health Service, a number of that type of area. So there

was a lot of other work done as well as the sort of work we've been talking about today.

Q. And in shadowing some of the responsibilities of the CMO, did you work closely with her at that time?

A. I did.

Q. And did you work closely with the SMOs?

A. Very much so. They were an excellent group of doctors to work with.

Q. Were you all based in the same office or the same floor?

A. The Chief Medical Officer and myself were on one floor and below us there were a number of the other senior medical officers and medical officers were there.

Q. And Dr Carson was at that time on, I think, a weekly secondment basis.

A. I'm not sure. I think I did hear that this morning and I'm not sure that there isn't a confusion about the dates at which Dr Carson was there.

Q. I think he was on a one-day-a-week secondment in 2001 to the CMO.

A. Right.

Q. Would he have been something that you'd have had regular contact with at that time?

A. Only on a friendly basis. If he was passing the door of the office, we might have exchanged some comments.

Q. And in working closely with the CMO, would you have had

daily contact with her --

A. Very much so. In and out of each other's offices, as much as was required.

Q. And discussing the topical matters of the moment?

A. Absolutely. Every day has its issues.

Q. I wonder, can we look at page 2 of this document, please? You were asked when in fact you first became aware of Raychel Ferguson's death. It's page 2 of 076/1. At the top of the page:

"I became aware of Raychel's death on 2 July 2002 when it was discussed at the meeting of the directors of public health."

Had you not heard of it before that date?

A. No. And indeed, I didn't know the case by name at that time. I realised the case was being discussed, it had occurred in the Western Board area, but apart from that I didn't really know anything more about this.

Q. Because it was brought to the attention of Dr Carson on 18 June at a meeting in Belfast.

A. Yes, I noticed that in reading the various reports, but at that time I didn't know anything until the date I have advised, 2 July.

Q. Because he relayed that information to Dr Campbell at that time. And to your recollection, it wasn't mentioned by her?

A. The first I knew was it was raised as a -- I think an any-other-business item on the Chief Medical Officer/Director of Public Health meeting.
Q. And the relay of information to Dr Campbell was followed up only a matter of four days later by a direct phone call to her by Dr Fulton of the Altnagelvin Hospital, in which he described the death of Raychel.
A. Once again, I restate: 2 July, that meeting was the first time I had any knowledge.
Q. I'm just asking you again, and perhaps again, in case it should jog your memory. Because the information relayed to the CMO at that time was that not only had there been a death in Derry, but that the Royal Belfast Hospital for Sick Children had discontinued its use of Solution No. 18. This was brought to her attention at that time.
A. As I've said, 2 July was the first I had any understanding or inkling of this issue.
Q. And then even before 2 July, Dr McCarthy, the SMO, likewise was at a meeting where hyponatraemia was discussed by Dr Taylor on 26 June. Did she mention that to you?
A. As I say, 2 July 2001 was the first occasion I had any understanding of this issue.
Q. Do you remember there being much in the way of

discussion within your department after you became aware of it on 2 July?

A. The next I heard, I became involved, was whenever the CMO approached me about chairing the working group.

Q. When was that? Can you remember?

A. Um ... The date is given. It was a number of days after that, after the meeting of the CMO.

THE CHAIRMAN: Just before we get there, doctor, can I ask you about that meeting on 2 July? Because as we understand it, there wasn't just one issue coming out of Raychel's death, but there was a second major one. The fact of Raychel's death was obviously one issue. But the second one, which was of particular concern in Altnagelvin, was that they understood that the Royal had discontinued the use of Solution No. 18 in the Children's Hospital and they were a bit put out that what might be regarded as a significant change to long-standing treatment had been altered in the regional centre for sick children without any information or notification being given to other hospitals like Altnagelvin. When it was discussed on 2 July, which of those aspects was discussed?

A. I certainly remember nothing about Solution No. 18 at that meeting.

MR STEWART: Perhaps we can go to the minute to see if it

assists. It's at 075-081-323 and we can place alongside 323 page 327. You can see from the left-hand side the note of those attending the meeting. You are attending on behalf of the department with the CMO and, indeed, Dr Mark, who subsequently served on the working group for the development of the guidelines, and also on behalf of the directors of public health is Dr McConnell, who brings the information to the meeting. We can see on the page beside it:

"Hyponatraemia. Dr McConnell highlighted a recent death in Altnagelvin Hospital of a child due to hyponatraemia caused by fluid imbalance. Current evidence shows that certain fluids are used incorrectly post-operatively. It was agreed that guidelines should be issued to all units."

Do you recall a discussion or a mention of the incorrect use of certain fluids?

A. At this distance, I do not.

Q. Because that would seem to suggest that there was a prompt there for Solution No. 18 to be mentioned.

A. I don't think that it would have been in our lexicon in those days. The first I heard of Solution No. 18 that I can recall was actually in the subcommittee.

Q. Dr Campbell had heard about it and it would have been a prompt for her to say, "Indeed, Solution No. 18

appears to have been discontinued on the basis of my informant from Altnagelvin at the RBHSC".

A. Well, I have no recollection.

Q. When the note continues there:

"It was agreed that guidelines should be issued to all units."

Was there an agreement as to who should be responsible for issuing those guidelines?

A. No, I think at that stage it was simply a recognition that this was needed and it was needed urgently, but who was to do it was undecided.

Q. I think the CMO has herself indicated that she thought at the time perhaps that the directors of public health themselves were going to take it forward and not her office. Was that your understanding as well?

A. I think it was a matter still for negotiation who would take it forward.

Q. And were there discussions then, back within the department, between yourself, CMO and the SMOs about what you were going to do?

A. I wasn't party to any discussions.

Q. Were you aware of information being passed about in relation to hyponatraemia and in relation to deaths from hyponatraemia?

A. No, sir.

Q. I wonder can we look, please, at 021-056-135. This is an e-mail passing between Dr Carson, with whom you worked, and the CMO on 30 July. I wonder if we can go to the line commencing "The problem today". Can it be highlighted, please? It is about seven lines down:

"The problem today of dilutional hyponatraemia is well recognised. See reference to BMJ editorial [that's the 'Lesson of the Week' editorial]. The anaesthetists in RBHSC would have approximately one referral from within the hospital per month. There was also a previous death approximately six years ago in a child from Mid-Ulster. Bob Taylor thinks there have been five or six deaths over a ten-year period of children with seizures, but he has not seen any Cochrane reviews. This might be a subject that would be worth CREST looking at."

There's information passing around the department going to the CMO and it's fairly startling information. Did she discuss that with you?

A. The first I saw this here was actually in the papers in the last few weeks.

Q. Would you agree with me that the piece of information about a number of deaths is a striking, alarming piece of information?

A. Of course it is.

Q. And does it surprise you, looking back now, that in your daily discussions in and out of the CMO's office that she didn't raise this with you?

A. Well, I have no idea if she actually had seen this at that time.

Q. You think that she might not have seen it? When did she first mention it to you?

A. This was never raised with me. My only job was to prepare guidelines. I wasn't given a great deal of introduction to it.

Q. All right. You see at the bottom there's a reference here to a document attaching to this. You can see it in the bottom left-hand corner:

"Dilutional hyponatraemia: e-mail document attached."

And that has been confirmed as being a document prepared by Dr Taylor entitled "Hyponatraemia in children" and it appears at 043-101-223.

Do you see this document? Had you ever seen that before you convened the first meeting of the working group to prepare the guidelines?

A. Definitely not.

Q. Okay. That would appear to be one of the few or only pieces of information prepared locally on hyponatraemia in children before your working group commenced. Can

I ask you to look, please, at the letter you wrote on 21 August? It's 007-050-099. This is the letter of invitation that you sent out to a number of local clinicians to join the working group to prepare the guidelines. You see in the second paragraph you say that you enclose a BMJ paper, which I presume is the Lesson of the Week that was referred to by Dr Carson in his e-mail:

"... and a brief resume of the problem prepared locally which should provide background reading."

What was that brief resume of a problem prepared locally which should provide background reading?

A. I have no -- I can't remember at this stage.

Q. Could it be that document we were looking at a moment ago?

A. It might have been, but its significance -- so I wouldn't have fully associated with this at that time.

Q. Presumably you were given that by Dr Carson or by the CMO?

A. If I sent it out, obviously I have to accept responsibility.

Q. If it came along with that e-mail setting out in such stark terms the number of deaths that might have been attributed to hyponatraemia, might you not also have seen that e-mail?

A. If ... No, I definitely didn't see the first e-mail with Dr Carson.
Q. When did the CMO first ask you to convene a working group?
A. I think it was ... The date is in some of the papers. I think it's 26 July. I'm not sure what it is. The date is given at some point.
Q. Yes. And what briefing was given you about hyponatraemia?
A. Well, the issue was really that we had to do something fairly quickly and I wanted to do -- to follow my brief.
Q. Were you given information by the CMO about deaths?
A. Well, we already understood that there had been at least -- there had been one death in the Western Trust --
Q. Yes.
A. -- and that's as far as I was involved. I was told there had been one death. That's the only death I knew about.
Q. Who told you that?
A. That was at the meeting of the CMO/DPHs.
Q. Yes. When you CMO asked you to convene the working group, did she tell you about deaths?
A. I don't think -- well, apart from the one that we -- that we've talked about, that was mentioned at that

meeting. I wasn't fully aware of other meetings -- deaths at that time.

Q. Were you aware at all?

A. Only of the one death.

Q. Only of the one death. Because clearly the number of deaths that you might have known about would have influenced the urgency with which you approached your task, wouldn't it?

A. Certainly.

Q. In terms of determining the remit of the committee, how was that done?

A. Well, what I wanted to have was a group of people who were regionally spread so that there was a fair representation from --

Q. Can I ask, please, about the remit as opposed to the membership? How was it decided what you would do and how you'd go about doing it?

A. Well, it was simply put to me, would I be prepared to chair a group, a working group on this, which would be something you would do on a regular basis.

Q. Because one of the things you said in your witness statement was that you were given a restricted brief, a restricted brief was handed you in respect of this task.

A. That's right. I was asked to prepare a working group --

have a working group and prepare a guideline.

Q. Because the CMO in her witness statement gives a slightly different account. She says she discussed the case with her colleagues in the department: with you, Dr Darragh, and with Dr Miriam McCarthy. She says:

"We met during August 2001 and decided on the proposed membership of a working group and its remit."

So her recollection is that the three of you discuss and decide together what's going to happen.

A. Yes, that's the way we worked very much.

Q. There's a bit of a difference between being in discussions and mutually agreeing and being in receipt of a restricted brief handed to you, isn't there?

A. Yes, but the intention was that we were -- our job was to prepare a guideline and that alone.

Q. Is your evidence to the inquiry that at that stage Dr Campbell did not tell you and kept from you the content of that e-mail sent to her by Dr Carson?

A. I don't think Dr Campbell set out in any way to keep me in the dark. The issue was -- even with one death, the issue was sufficiently important that we would crack on with it without any delay.

Q. I just pose the question again. She kept it from you, it was not shared with you?

A. I don't think that there was any intention --

Q. Yes or no. I'm not asking about the intention, I'm asking whether or not she shared that detail with you.
A. In the literal sense, it wasn't shared with me.
Q. In a literal sense?
A. Well, the actuality was it was not mentioned to me.
Q. Was the information in any way, shape or form communicated to you?
A. Not beyond the one case that we knew of.
Q. Thank you. In terms of selecting --
THE CHAIRMAN: I'm sorry, if that's right, doctor, can you explain the opening sentence in that letter? What is "... the increasing evidence that acute hyponatraemia is emerging as a significant clinical problem" if there's a single death?
A. That's just it: a single death is a single death and it's very important. Once we discover that there's an issue, that we try to address it.
THE CHAIRMAN: The reason why I have asked you that and why Mr Stewart has been asking you the last line of questions is because it seems to us, from outside the working group, that it's disappointing and perhaps curious that during the work which was done and which led to the production of the guidelines that there was at least one other death which wasn't uncovered, namely Lucy's -- and perhaps two if you add Claire -- and in

fact, on your witness statement, you think there was a possibility that Adam's was associated with hyponatraemia.

A. Yes. As we worked along, it came out that there could be other cases.

THE CHAIRMAN: Do you understand how, from the outside, it seems odd that if you've got a working group established on the basis of what you've described here as increasing evidence and if one has an e-mail which says there have been five to six deaths in the last ten years, that the working group only appears to refer to Raychel's death, which was the immediate cause of the working group, a possibility around the fringes of Adam's death, but not to any other death? And in fact those two other deaths emerge, in effect, by accident.

A. Chairman, as I've said from the beginning, I was aware of one death that was associated with this. I wasn't aware of any others at the outset of this process.

THE CHAIRMAN: And my question to you was: do you understand how it seems at least curious to me and, more importantly, to the families, that that's how it emerged? I should also put this in context, doctor, to be fair to you: the work that was carried out, which led to the production of the guidelines, stands to the credit of everyone involved, and we don't mean by this

questioning to in any way criticise the fact that guidelines were produced and were then sent out to the trusts in order for them to be followed. But in the context of this inquiry, where only two deaths emerged through what one might call the regular route, and two other deaths emerged through an irregular route, it is an issue which has concerned the families and which we're bound to pursue because it seems to me that there is a basis for the families' concern. You'll understand why I'm raising this with you.

A. Yes.

THE CHAIRMAN: Your evidence is that when you used the phrase "there is increasing evidence", that that refers only to Raychel's death?

A. Absolutely, yes.

THE CHAIRMAN: Thank you.

MR STEWART: This is a theme that we will pursue further.

A. Sure.

Q. When you came to selecting the membership of the group, you did so in discussion with the CMO and Dr McCarthy?

A. Yes.

Q. And on what basis were the members singled out and chosen?

A. Well, what I wanted to see was a range of specialists covering anaesthetics, paediatrics, and paediatric

anaesthetics, paediatrics and general surgery. I also wanted to see them representing the smaller hospitals as well as the larger hospitals, and, as far as possible, those hospitals where there was a considerable amount of paediatric work. Those were, I think, the main issues. There would be a range of people with different levels of experience and expertise, but I also needed to make sure I had some of the key people who were actually raising the issues, such as Dr Bob Taylor from the Children's Hospital.

Q. Did you think about inviting along, for example, the clinical director of the RBHSC who I think was Dr Steen at the time?

A. This particular area of work needed people with particular expertise and a number of people were going to be coming from the Children's Hospital already in terms of the paediatric intensive care unit, because Dr Taylor was going to be -- was, as far as I was concerned, was a given, and Dr Crean, and I wanted to make sure that they were represented. But equally, we didn't want people simply because they were representational; they had to be there because they had something to contribute.

Q. So why was Dr Nesbitt chosen, for example?

A. A smaller hospital and he was able to give a view from

a smaller hospital because ultimately the practicalities of some of the things that might come out would have to be considered.

Q. Might it not be because he had direct experience of Raychel's case?

A. I don't think so.

Q. Thank you. So why was Mr Marshall from the Erne Hospital chosen?

A. Mr Marshall was a surgeon in a smaller hospital and often general surgeons would find themselves having to do operations on children. So they had a particular need to know and to be aware of the issues.

Q. And of course you now know, I'm sure, from following the inquiry, that a number of people on the working group did have particular knowledge of the deaths of some of these children.

A. As I've now discovered, yes.

Q. But there's a singular absence on your working committee of a whole geographical part of Northern Ireland. There's no Mid-Ulster representation from --

A. There is no paediatric hospital in Mid-Ulster.

Q. Omagh, Magherafelt?

A. No, no.

Q. What about Antrim, Ballymena, Coleraine?

A. Antrim had Dr Jenkins and Dr McAloon.

Q. They were subsequently brought on to the committee.
A. No, Dr Jenkins was there from the outset. He didn't attend the first meeting, but he was there and very much involved, because the way we worked was a virtual working system and if you weren't there and actually present in person you would be involved in the Internet.
Q. And nobody from paediatrics down in Newry or County Down?
A. Very little paediatric -- most people from the Southern Trust area would have come up to Craigavon.
Q. Were people sounded out beforehand to see if they were willing to sit on the committee?
A. Absolutely.
Q. That's why your letter says "Thank you for agreeing to participate". Was any consideration given to involving a pharmacist or a pharmaceutical expert on the group?
A. Not in the first instance because we had people who were very adept at this. After all, doctors are also entitled to be -- they have a certain amount of training in pharmacy.
Q. Yes, but in subsequent guidelines, the guidelines that followed in the decade after your working group, the Chief Pharmaceutical Officer was involved.
A. Mm-hm.
Q. And indeed one of the very first things this working

group did was to send Dr Taylor off with his yellow card. I mean, it seems that the pharmacy and those issues were at the heart of it.

A. Yes, the Committee on Safety in Medicine is generally a medical committee, though there would be pharmacists involved as well.

Q. Did you ever consider involving a pharmacist?

A. Not in my time.

Q. Professor Savage wrote to you. That's at 007-042-087 --

A. We were not an exclusive group. We would have been open to anyone who wanted to express an interest or communicate with us. And quite a bit of the material was distributed in such a way that people were invited to comment. So if Dr Savage was there -- once I received his letter, I was quite happy to invite Dr Savage and he was invited --

Q. Yes.

A. -- to participate.

Q. Yes, a professor of paediatrics and president of the Ulster Paediatric Society:

"I am concerned that someone in my position only hears about such a group on the grapevine."

And he goes on to suggest that he would be reassured if the guidelines were scrutinised by appropriate committees, such as the Royal College of Paediatrics and

Child Health. Did that ever happen?

A. Dr Savage was invited to attend the working group. I understand he did not attend the second meeting, which he was invited to, but he also was given the opportunity, through the special advisory committee which he attended, to raise any issues or concerned.

Q. The issue he's raising there is, first of all, about the Royal College of Paediatrics and Child Health and secondly he goes on to point out that:

"Anne Burns, the paediatric pharmacist at the Royal Victoria Hospital, one of the key authors of 'Medicines for Children', the formulary on therapeutic advice ..."

And he seems to consider that's relevant for your consideration. Did you pick up on that and think that perhaps she might be --

A. I didn't pick up on that personally. But if I could just say that Dr Savage was given his opportunity -- and by the way, in terms of the Royal College of Paediatrics and Child Health, the two paediatricians who eventually were on the working group, Dr McAloon and Dr Jenkins, would both have been members of the Royal College of Paediatrics and Child Health.

Q. As a matter of interest, the matter is picked up later on by the Directors of Public Health themselves, who suggest that Dr McCarthy forward the guidelines to the

Royal College of Paediatricians for their consideration. That wasn't done.

A. That's fine. But the important thing was that we got our guidelines out. We saw there was a problem, we wanted to get our guidelines out, and it was important that those went out to alert people.

Q. Yes.

A. And anything else could come along after that, but first -- "Do no harm" was our motto, or at least my motto.

Q. I grant you, it's important to get the guidelines drafted and out, but it's also important, when you're putting together guidelines, to make sure they're right, because pitfalls must surely exist for those who don't do that. Presumably you didn't alert the Chief Pharmaceutical Officer to the working group deliberations, did you?

A. I wasn't involved in that detail.

Q. Did you alert the Chief Nursing Officer to the working group considerations?

A. We had a nurse on our working group, an experienced paediatric nurse from the Ulster Hospital.

THE CHAIRMAN: How did that come about, doctor; can you remember?

A. I can't remember the detail, but I think one of the

things we were quite keen was to actually demonstrate the multidisciplinary nature of the work that we do and also to recognise the Ulster Hospital, which is a large paediatric hospital, and Liz McElkerney was the director of the children's nursing part of the Ulster Hospital.

MR STEWART: And indeed Dr Angela Bell from the same hospital also made a contribution to the --

A. I'm not sure. It was not in my -- anything I was involved with. You know, this was not restricted in any way. We were quite happy to take on any inputs that people wanted to make and, you know -- and once it was produced it was endorsed by three appropriate special advisory committees, by the CREST system, you know, so I think we had a very good copper-fastened situation there in terms of knowledge that people had at that time.

Q. The reason I ask you is that Professor Dame Judith Hill, who was the Chief Nursing Officer, would have expected to have had the opportunity to view the guidelines, would have expected to be given the opportunity to comment on them because they were issued for nurses?

A. I understand Dame Judith Hill will have an opportunity to come to the committee and you may pursue that further. We certainly had a nurse, a paediatric nurse.

Q. Yes, but consideration wasn't given to giving her the

opportunity?

A. Well, I'm not sure just how it all came about, but I was very content that we had a very satisfactory representation.

Q. I see. Before the meeting occurred, the first meeting of the group, you received from Dr Bob Taylor some draft preliminary documents and materials for your consideration. They appear at 007-051-100. This is the covering e-mail, 18 September 2001, the week after 9/11, and you've written on it:

"Anne, please copy to Miriam McCarthy."

That's your handwriting?

A. Yes, that's right.

Q. So it goes to her:

"Here are some draft documents for your consideration in advance of the meeting on the 26 September. Bob."

Can you identify the other handwriting on this cover sheet, "Find out about attachments"?

A. No, I can't.

Q. The attachment is a draft PowerPoint presentation that Dr Taylor put together, but seemingly did not actually present at the meeting, as I understand it, and it runs to about ten pages. Included amongst it is, at page 007-051-103, Dr Taylor's draft bar graph showing

the incidence of hyponatraemia at the Children's Hospital in Belfast. You received this at the time. Presumably you looked at it and studied this document?

A. Mm-hm.

Q. And you can see that there's one death in 2001 on the extreme right-hand column. That's clearly --

A. Raychel.

Q. Raychel. And there's another death there marked in 1997. Did you ask about the 1997 death?

A. I can't recall that I did. But one of the issues about hyponatraemia is that this could have been the result of fluid, but it could have been other causes.

Q. Yes.

A. It could have been a natural feature of a progressive illness, not necessarily associated with fluids.

Q. Absolutely, which is why I suggest that it might have been natural for you to ask about that death, "What was that?"

A. I didn't pursue it at that time because, really, my main focus was to make sure that the guidelines were produced.

Q. Because there we are: we're at September 2001 and there are two hyponatraemia deaths now brought to your notice. Can we go on through the PowerPoint presentation to page

007-051-106? What Dr Taylor had been intending to do was to produce a synopsis of the Halberthal article from the BMJ. You'll see there he describes the study group that was looked at. You see the third bullet point, he reveals that, of that study group, 70 per cent received excessive maintenance fluids, that's to say more than 50 per cent over their proper amount. And he reveals elsewhere there have been five deaths in their study group. Were you taken by that figure of 70 per cent received excessive maintenance fluids?

A. Well, it's clearly a concern, but you know, our guideline was going to be addressing just this point.

Q. Because what that means, does it not, is that 70 per cent of those cases may well have had an iatrogenic component.

A. Mm-hm.

Q. That if there were five deaths in this study, 70 per cent of those five deaths may have been caused by clinical negligence. That must surely have been something that you, as chairman of that group, would have looked at.

A. Well, as I say, our guideline was designed to address this very problem.

Q. You would have looked at it because, if there was medical negligence involved in death cases like

hyponatraemia, there might be clinicians who didn't understand what they were doing, who might make the same mistake again and that posed a risk to patients.

A. And therefore they needed to be supplied with guidelines that addressed this very problem.

Q. Indeed. And there might also be cases where there might be a necessary referral to a coroner.

A. Of course.

Q. So you'd want to be interested in those cases, wouldn't you?

A. My remit was to ensure that a guideline was drafted --

Q. Yes, but you also --

A. -- and distributed.

Q. Yes. But you also would have been interested necessarily in any deaths brought about by an excessive administration of fluids, wouldn't you?

A. Of course.

Q. Thank you. You said at your witness statement, WS076/2, page 12, at the top:

"Please describe your reaction to discovering another death [I think this is Adam] in which hyponatraemia was identified as a cause of death and what action you took as a response."

You said:

"Given Dr Taylor's presentation at the working

group, there were clearly likely to be other cases emerging, but the important step of producing guidelines was the appropriate step to be taken at regional level at the time."

So you clearly understood the issues at that time and you thought it was likely that other cases would emerge.

A. Absolutely, because anything like this emerges as a sentinel event. Once you see it, you start to look for others, and the very fact that we would be producing a guideline was going to make other people consider their practice and start to notify.

Q. But also likely to emerge might be evidence of clinical negligence, excessive administration of fluids. That was, according to you, likely to emerge.

A. Yes.

THE CHAIRMAN: I just want to get it clear --

A. But there's a double lock here. There's the administration of fluid and there's also the regular testing of the blood to indicate that.

MR STEWART: There's a triple lock as well, a quadruple lock, but we're not going to go on to that.

THE CHAIRMAN: I just want to understand what that means. Does that mean that the production of the guidelines was to stop more cases emerging; isn't that right?

A. It was to stop more cases arising, but it would also alert people and, as they started to consider their practice and consider their practice in the light of a guideline, they would start to think: could this be the result of hyponatraemia?

THE CHAIRMAN: Yes, sorry, when you say, "Could this be the result of hyponatraemia?", you mean could it be that what happened to X or Y was the result of hyponatraemia? In other words --

A. Yes.

THE CHAIRMAN: -- could this be what happened in the past as a result of hyponatraemia?

A. Yes. It starts to open up.

THE CHAIRMAN: Unfortunately, of course, that didn't happen, because neither Claire's death nor Lucy's death emerged because any doctor read the guidelines and thought, "That must be what happened to Claire or Lucy".

A. Mm.

THE CHAIRMAN: And since it didn't emerge in that route, your guidelines would be, once they're implemented -- you expect that they will go a long way to preventing any more deaths from hyponatraemia. But as it turned out it didn't lead to any earlier deaths from hyponatraemia being recognised by those who had been involved in treating the children who died. Right?

A. Okay, yes.
MR STEWART: Well, let's go back to the bar graph again, please, at 007-051-103. And I stress, before Mr Uberoi does, that Dr Taylor has stressed this was based on incomplete data. You can see the incomplete data there, 1995, 1996. Did you wonder about that omission of data?
A. Given the small number of cases in the years beforehand, I thought it wouldn't have been impossible that there would have been none in the [OVERSPEAKING] particular year.
Q. Leaving aside the statistical impossibilities, did you think it odd?
A. We're talking about one or two cases.
Q. Did you think it odd?
A. Well, I suppose anything that has a missing bar would make you think. But I didn't think there was enough to be querying it in any way.
Q. Did you ask Dr Taylor about it?
A. No.
Q. So you didn't ask him about the 1997 death and you didn't ask him about the missing figures from 1995 and 1996?
A. No.
Q. Can we go in your witness statement, please, to WS076/2, page 6? There in the middle of the page at (c):

"Please explain what use was made of these materials by the working group [that's the materials we're looking at]."

Answer:

"The PowerPoint presentation helped set the issue of hyponatraemia in context. It was showing an increasing upward trend in cases, which probably indicates a greater awareness of the problem."

A. Mm-hm.

Q. So --

A. And that's what the bar chart shows.

Q. That's what the bar chart shows. We'll go back to the bar chart, that was the last page, at 007-051-103. That in your view demonstrates an increasing upward trend in cases?

A. Well, notified cases. But I think it may well be this could also be an artefact in that there's a greater awareness, so that there's simply more cases being reported because people like Dr Taylor are more aware of what they're looking for.

Q. It also may conceal unreported cases?

A. That also goes with it.

Q. So you've got a likelihood of more cases emerging, a likelihood that those cases may include cases where clinical negligence was involved and a likelihood that

more cases of death may emerge as well.
A. That follows.
Q. And yet you say that you did not take any steps to discover how prevalent the issue of hyponatraemia was?
A. As I said at the outset, my task was to prepare a guideline.
Q. Why didn't you try to find out how bad the problem was you were trying to address?
A. I thought we had plenty of evidence that there was a problem, particularly when Dr Taylor's chart is in front of us.
Q. How can you possibly hope to prevent further deaths unless you know how deaths that had occurred occurred? How can you act in a vacuum?
A. I think given that deaths and serious morbidity has arisen, that's when we should be acting.
Q. Did you discuss Raychel's case?
A. In medicine we have to act often in the absence of a total knowledge of the situation.
Q. Yes. But here you seem to be acting without any curiosity to find out any of the knowledge of what may have happened.
A. I think we had a very knowledgable group assembled. They were giving us the benefit of their experience and knowledge --

THE CHAIRMAN: No, they weren't. They weren't giving you the benefit of -- on the evidence I have received, the members of that group were not giving you the benefit of their information and knowledge. Dr Taylor and Dr Crean knew about Adam's death. Dr Taylor and Dr Crean knew about Claire's death and Dr Taylor and Dr Crean knew about Lucy's death. So you cannot say to me, I'm afraid, doctor, that the members of the working group gave you the benefit of their information and knowledge. In fact, it's almost the opposite. On the version of events I'm being given, various people in that working group knew more than was shared with the working group. So far from sharing, on one interpretation of events, they each withheld. Without any disrespect to the end product of the working group, that raises serious issues for me and for the families about what was not discussed or what was discussed and is not being admitted to at this inquiry.

You could expect that the members of the working group would share the information and knowledge they had and that expectation would be entirely reasonable. But on the evidence which I have been given by each member of that working group who has come to the inquiry so far, they just didn't do it, and I wonder why.

A. Well, in no way was I complicit with any attempt or did

I have any knowledge of what you have listed today.
THE CHAIRMAN: No, I'm saying to you that your expectation that the members of the working group would share information is entirely reasonable. In fact, that's what you would want them to do and what you would expect them to do.
A. And I had no feeling at all that I was being in any way not provided with information.
MR STEWART: Do you wonder why now they didn't mention those others cases they knew about to you in the context of the working group?
A. I would think that the problem is they may not have been secure in -- absolutely certain about things, so they might have been concerned, if they made these allegations, that they couldn't be substantiated.
Q. What happens if the allegation amounted to a confession?
MR McMILLEN: Mr Chairman, with respect, the witness has been asked to speculate on the state of mind of a third person. He can't really add anything to what doctors Crean or Taylor may have thought at a particular time.
MR STEWART: Do you remember discussing Raychel's case in the group?
A. Not in specifics, other than the fact that this was a hyponatraemia death.
Q. Because Dr Nesbitt tells the inquiry that this was

a burning issue for him and he went on and on about it. Tell me this: did the committee at that first meeting discuss the fact that Solution No. 18 had been discontinued at the Royal Belfast Hospital for Sick Children?

A. I have no recollection at this remove.

Q. It would have been relevant, would it not?

A. Of course it could have been relevant.

Q. Highly relevant. You're sitting discussing a protocol for IV fluids and there the leading children's hospital, the teaching hospital, the centre for excellence, has already decided what it's going to do. You'd have thought that the RBHSC doctors might have spoken up and discussed that and shared the benefit of their knowledge, wouldn't you?

A. That's true, yes.

Q. Are you surprised that they didn't?

A. I'm surprised by a lot of things.

Q. Are you disappointed that they didn't?

THE CHAIRMAN: Excuse me, doctor. Saying, "I'm surprised by a lot of things", is not a helpful answer to a question by Mr Stewart.

A. What answer would you like me to give?

THE CHAIRMAN: I would like to hear you answer the question.

A. Well, the answer --

THE CHAIRMAN: I have to tell you that that answer that you gave a moment ago seemed to me to be singularly inappropriate. When you were asked, "Are you surprised that they didn't?", and you answer, instead of saying, "Yes, I was surprised", or, "No, I'm not surprised", you say, "I'm surprised by a lot of things". That strikes me as somebody who's not actually here to help the inquiry and I'm sure you are here to help the inquiry. So please don't answer a question like that by saying, "I'm surprised by a lot of things".

A. Chairman, I'm sorry if I've caused problems in the way I've responded.

THE CHAIRMAN: Thank you.

MR STEWART: Well, looking back now, are you disappointed that your fellow working group members didn't share their knowledge with the rest of the group?

A. Yes.

Q. Because you would have expected it?

A. We were -- I expected everyone there to be open and honest.

Q. And if you subsequently discovered that perhaps somebody was being less than honest, would you have thought that a breach of their professional duty?

A. Yes.

Q. And would you have thought that might perhaps have been

the basis that you might have wished to report them to their own regulatory body?

A. I'm not sure that I would have gone as far as that.

Q. Why not?

A. Well, I think I would have sought to understand a lot more about the reason that they were withholding any information if they had.

Q. Well, when, for example, you subsequently learnt of the death of Adam Strain and subsequently the post-mortem report and the coroner's verdict and Dr Sumner's report were sent to you, and you read Dr Sumner's report and you saw that Adam had died in 1995 and that Dr Taylor was involved and that Dr Sumner said that it was an excess administration of fluids and Dr Sumner said Dr Taylor was implicated in that administration of fluids, and you saw that Dr Taylor had left that 1995 death out of his bar graph, would you not have been driven to the conclusion that he had misled you?

MR UBEROI: Sorry to interrupt, but I think we're getting rather off the point here. Firstly, the 1995 death wasn't included in the raw data which was alluded to earlier. Secondly, in terms of the categories which these deaths are being put into, again, in my submission, sir, it is rather unhelpful when they are all lumped together. The Adam Strain death, while

I entirely understand the question can be posed, "Would it have been helpful for it to have been raised at the meeting?", there wasn't the same level of secrecy, for want of a better word, as attended to the other deaths. There had been an inquest, there had been a finding and it's not really in the same camp as the other two deaths in my submission.

THE CHAIRMAN: That's right, Mr Uberoi, but it strikes me that makes it all the more curious that the members of the working group didn't know and were not told about Adam's death. I'm told, for instance, that Adam's death was the talk of the Royal. There's then an inquest in 1996, which leads to a public statement and the Royal writing to the editor of the Belfast Telegraph to thank him for his helpful coverage. Then we have a working group meeting in 2001, but Dr Darragh isn't aware of any of this and it might be that a hyponatraemia death in 1995/1996 didn't particularly ring bells with him given his public health specialty. I think it's entirely fair to say to him, knowing now what he knows about Adam's death and the sequence of events which followed it, including the inquest, is he disappointed that that was not raised as part of a discussion at the working group.

MR UBEROI: I recognise that, sir. I think my point would be, as you've alluded to in your observation there, it's

in a different camp, in my submission, for example because of the publicity which surrounded the inquest. In my submission, that places it in a different category. Yes, the question can be posed "Would it have been helpful to have discussed it at the meeting?", but it's not the same as saying, "And therefore subsequent steps could have been taken, such as referral to a coroner, inquest, et cetera", because those steps were taken and there was no mystery about the death of Adam Strain.

THE CHAIRMAN: Okay.

MR STEWART: All of which deflects me from the question I was asking you. When you received this information and you looked again at what Dr Taylor had indicated in this bar graph to you, did you not think that it was something you should at least take up with him?

A. Not at that time.

Q. Okay. So you didn't ask him a question and you didn't think it appropriate to think that that was perhaps something which brought his straightforwardness, helpfulness, cooperation and honesty into consideration?

MR UBEROI: Again, I'm not sure that's a fair question or proper question for this witness. There has been a wealth of evidence on this that this witness may well not be across. It's far too general a proposition to

expect a witness to answer.

THE CHAIRMAN: I've got the point. Mr Stewart?

MR STEWART: Thank you. Going back to, if I may, the issue of Solution No. 18, there are a number of people on your working group who know about the RBHSC abandonment of Solution No. 18 and the CMO knows about it. The CMO in her witness statement, WS075/2, page 7, at question 9(c):

"Did you make any enquiries with the RBHSC [this is of the CMO] about this change in policy regarding Solution No. 18 or regarding any problems with it in the past?"

Because those problems, as such, had been reported to her. She says:

"No, I left that to the working group to explore since it contained representation from RBHSC."

She will be asked in due course about this, I don't doubt, but did she ask you to explore it?

A. No.

Q. So she assumed that it had been talked about in the working group?

A. I ... I assume that, you know -- as you say, she assumed. I can't speak for her.

Q. Well, she says she left it to you because that's your job.

A. Well, I had -- I have no recollection of this at all.
Q. If it was relevant to discuss the actual fluids for administration, presumably it would be relevant to discuss the individual characteristics of children in order to determine whether or not the fluid is appropriate?
A. Can you give me your question, please?
Q. Surely if you were discussing the appropriate administration of IV fluids, you have to discuss the individual characteristics of the child patient who's going to receive those fluids because those characteristics determine the appropriateness the fluid?
A. Well, certainly the volume of the fluid and once you would understand what the biochemical -- once you had your baseline material on the biochemical composition of the individual's body fluids, then you would adjust it accordingly.
Q. Aren't you interested in the age of the child, the weight of the child, the illness --
A. Absolutely. That's absolutely understood.
Q. So in order to inform your discussion of fluids, you'd need to actually discuss cases, you'd need to discuss patients and their needs?
A. Yes.
Q. How did this committee go about discussing individual

hyponatraemic children?
A. The work that was carried out was carried out both by the working group and by the drafting committee. They would have taken into consideration those aspects in preparing the guideline.
Q. All right. What about Dr Taylor when he gave his presentation to the working group on that first meeting? Did he talk about individual cases, individual clinical experiences?
A. I have no specific recollection of any individual patients being discussed.
Q. Do you think he might have done?
A. I'm sure he did.
Q. You're sure he did?
A. But at 12 years' remove, I have no recollection.
Q. So you're sure he made reference to individual patients?
A. Because all doctors always talk about their individual experiences.
Q. Exactly my point. Do you not think, given that concession, it highly likely that that committee would have looked at hyponatraemic deaths, discussed individual cases?
A. Only insofar as it was their individual experience.
Q. And this group did have a wealth of experience, didn't it?

A. It did.
Q. Including a wealth of experience of children who died?
A. As it now turns out.
THE CHAIRMAN: Not as it now turns out --
A. Chairman, I was unaware at the time --
THE CHAIRMAN: Yes, sorry. As it now turns out, so far as you are aware --
A. Yes.
THE CHAIRMAN: -- but not as it now turns out from the awareness of some of those people who were on the working group.
A. That's correct.
MR STEWART: When the drafting subcommittee was formed, were you involved in the selection of the individual members of that subgroup?
A. No, it was really those who were willing who formed that. But it was to be understood that, as they did the work, it was to be circulated widely amongst the working group.
Q. Dr Taylor, who was certainly willing and, notwithstanding he doesn't seem to have been chosen as part of the drafting group, nonetheless he made contributions. Did you not think he was an obvious person to include and be involved?
A. As I say, it was those who were willing to spend the

time on behalf of everyone.

Q. As the subgroup commenced its work, were you copied into the e-mails passing between them?

A. Not on an ongoing basis. Dr McCarthy would talk to me and to the CMO about progress in a general way.

Q. Were you not given any e-mails or updates?

A. I can't recall. There may well have been traffic coming in and out, but I can't recall at this stage.

Q. Why were you not kept up to date in writing of what was happening?

A. Well, because I had total faith and total understanding that my two other colleagues who were involved in this, Dr Campbell and Dr McCarthy, were more than capable of continuing to act with the working group.

Q. But you remained the chairman of this group?

A. I was made the chairman of the first meeting --

Q. So you were responsible for the guidelines when they emerged at the other end?

A. I was, but ultimately this was going to be a collective because eventually anything that would come out would go out under the CMO's signature.

Q. This was a very important working group.

A. Absolutely.

Q. The CMO did not often engage in such important guideline creation.

A. No, that's quite true.
Q. You are the chairman of her group.
A. That's right.
Q. You're not asking for updated reports in writing, you're not asking to be included in and copied in on e-mails, you're not asked for regular updates. What were you doing?
A. I was keeping in touch with Dr McCarthy and Dr Campbell on an ongoing basis. If issues came up, then I would have been included in any discussion, and that was fine because we knew that the group -- we had every confidence in the group who were doing the drafting that not only would they themselves be professional and reliable, but also it was going to be sounded against the wider working group and indeed other people who were joining in.
Q. So are you saying that you were yourself unable to give the CMO any updates?
A. I wasn't asked to give the CMO updates. Dr McCarthy and myself and Dr Campbell would have been passing and meeting on a continuing basis, not necessarily about this, about many other things, and the topic may well have come up from time to time, how's the work progressing?
Q. Were you ever asked for your opinion or views, your

sanction or authority?
A. Well, I have to say, remember I'm a public health doctor, I'm not a specialist in fluid management. So we had to very much rely on those people whose business and experience was in fluid management.
THE CHAIRMAN: So in a sense, is it fair to summarise it this way: you had got the group up and going, you were then delegating the detail of the work to the subgroup?
A. Yes.
THE CHAIRMAN: You understood that it was making progress, which it was doing --
A. Yes, at a quick rate.
THE CHAIRMAN: They were bringing together the guidelines which were produced and that you were content for that to be going on unless and until you were alerted to any particular problem?
A. Yes, chairman.
THE CHAIRMAN: Thank you.
MR STEWART: And did you make any contributions to the work of the drafting subgroup?
A. Not particularly because I don't -- as I've said just now, I have no particular talent in relation to fluid management. It's a very specialist area.
Q. I just ask you again: were you asked for your authority in respect of any particular step the subgroup was

taking?
A. I'm not sure. I think perhaps in relation to inviting somebody to participate. I'm not sure if I was asked that. But I wouldn't have been asked that unless it was carefully thought out and I'm almost certain to have agreed in most instances.
Q. It was just that you seemed to be giving the impression that you stood aside from it and didn't really play a part in it and weren't updated about it. And it seems from at least one e-mail that may not have been the case.
THE CHAIRMAN: I'm not sure that he said, to be fair to Dr Darragh, that he wasn't updated, because as a result of his regular interaction with Dr Campbell and Dr McCarthy, you knew, as I understand it, that in fact the work of the group was progressing.
A. It was, and it was progressing well.
MR STEWART: I really meant, sir, in writing as opposed to being informed --
A. It was much easier to work on the hoof, as it were.
Q. There is an e-mail appearing at 007-008-014. It comes from the computer of Stafford Anne, which I take it is your computer; would that be correct?
A. It's certainly my writing.
Q. It comes from Elizabeth Garrett, who I take it is some

sort of personal assistant to Dr McCarthy, and it's sent to you, and it's in relation to the guidelines. This is in January of the following year 2002 and you were copied in to have supplied to you the original draft sent by Miriam McCarthy to the working group. And you can see:

"Latest draft attached. I have made further amendments in light of comments received. The section 'Choice of Fluid' contains a large number of changes."

It goes on in the second paragraph:

"To draw the members' attention to the bullet referring to fifth-normal saline. Not sound evidence-based to suggest that fluid carries an intrinsic risk in itself. CSM comments ..."

And going on to say:

"Whatever we produce must be supported by evidence. In light of that may I suggest that we consider deleting the bullet relating to fifth normal and rely on the preceding bullet to stress ... it is important to finalise the document and I appreciate your response as soon as possible. If you are content with the current draft (subject to deletion of bullet point on fifth normal) please confirm. Thanks for your input."

Why would that have been sent to you and why is it written at the bottom:

"Dr McCarthy to see Dr Darragh's comments"?
A. I can't comment at this time.
Q. To go back to --
A. Sorry, I mean, I just feel it was an update I was copied into. The people who are redacted are, of course, the people who were most important.
THE CHAIRMAN: What's redacted is simply the e-mail addresses of those --
A. Oh, is it? Sorry.
THE CHAIRMAN: And that's why you get "John Jenkins", then redaction, and so on, and that's to protect the privacy of their e-mail addresses.
A. Okay.
MR STEWART: The question that arises out of this -- it looks like one stray e-mail has remained with you. It looks as though you may have been copied in as a matter of course to the other e-mails. Could that have been so?
A. I think it wasn't a regular recurrence because I was able to have face-to-face contact with Dr McCarthy.
Q. Well, it happened once in January; how often do you think it might have happened?
A. Sorry?
Q. How often do you think it might have happened: just once or regularly?

A. We would have passed -- I won't necessarily say on a daily basis, but every couple of days we would have been together in some way.
Q. I'm asking you how often you'd have been copied into e-mails.
A. I have no recollection at this stage now. I have no way of knowing.
Q. Because that's the only one we could find going to you.
A. It's 12 years ago and I haven't been working in this area. I haven't had the opportunity of continual reinforcement that other people who have been working in this would have had.
Q. I see. Can we go back to the minutes of that meeting that you chaired on 26 September. It's at 007-048-094 and 095. We've seen on the left-hand side:

"Dr Taylor informed the meeting about the background and incidence of cases seen in the RBHSC and patients who are particularly at risk of hyponatraemia, a problem that had been present for many years."

And it goes on, in the facing page, paragraph 3, the final short sentence:

"Audit of guidelines is encouraged."

And then at paragraph 8:

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

And that's the small group that you left to do that work?

A. Mm.

Q. You left it to prepare not only the guidelines but also an audit protocol. What is an audit protocol?

A. Well, as we're saying there, if you're introducing a guideline, you usually subsequently try to incorporate an audit so that you can see just how effective your work has been, so you start with a baseline, you then audit --

Q. I'm not asking you what an audit is; I'm asking you what the audit protocol your subgroup was to produce was.

THE CHAIRMAN: Sorry, but you did actually ask him what an audit protocol was.

MR STEWART: I'm sorry?

THE CHAIRMAN: You did actually ask the witness what an audit protocol was.

MR STEWART: Yes, but I didn't ask him what an audit was. I'm sorry, sir.

What was the audit protocol that you expected the subgroup to produce?

A. It would be ... Some ... To draw up something that would form the basis of a future audit.

Q. Yes. Like an assurance template?

A. Yes. But not simply that it was -- what you're looking

for to see is what difference has it made, the intervention. You start off with a baseline, you then take an intervention and then you close the loop by looking and seeing did it work.

Q. Yes. And did your subgroup produce an audit protocol?

A. At this stage I don't think they did. In fact, I know they didn't. But they highlighted that this was work to come. The drawing up of the audit protocol didn't need to happen at exactly the same time because it was going to take some time before -- once the new guideline was in, it would probably take at least a year until a sufficient number of cases would have accumulated to be able to see whether there had been a cause and effect.

Q. We have sought in vain for any trace of an audit protocol. One wasn't produced?

A. Not at the time.

Q. No. What did you say to your subgroup when they failed to produce the audit protocol that you'd left them to produce?

A. I was actually very content that the guideline was being put out and got out and had all the different bodies endorsing it that we felt were appropriate.

Q. So when the minute records "Audit of guidelines is encouraged", you were happy not to encourage it?

A. No, that's not the case; that was something that could come along later.

THE CHAIRMAN: Let me put this more bluntly, doctor. In essence, did that disappear off the agenda so that while the most important work of the guidelines was completed and circulated, did the work of producing an audit protocol, in fact, get left behind?

A. I think it did, but it was picked up again in Dr Campbell's letter when the guidelines were issued, indicating that an audit would follow.

MR STEWART: Well, it was mentioned again.

A. Mentioned again. In other words, it wasn't lost, and in fact the usual thing that would happen at that time was an intervention would take place and then an audit would follow, and I think Dr Campbell was indicating very clearly, this is going to be -- we want this to be applied and we will be checking up by way of an audit subsequently.

Q. We will come, sir, tomorrow to Dr McCarthy's evidence, I hope, on that point.

Over the page then to 096 if we may. Paragraph 10. The minute records:

"Dr B Taylor undertook to inform the Committee of Safety of Medicines of a recent death in Altnagelvin Hospital associated with hyponatraemia."

Why did he undertake to do that as opposed to Dr Nesbitt, do you know?

A. I have no idea.

Q. Were you copied into the correspondence with the CSM?

A. I do believe we did receive an copy of that.

Q. Or MCA as it was, the Medicines Control Agency. Dr McCarthy received the correspondence, it was sent to her. Did she share it with you?

A. She wouldn't have necessarily shared it with me, but she would have told me that it had been received.

Q. She wouldn't necessarily have shared it with you? Did she share it with you?

A. I can't recall.

Q. Can we have a look, please, at 012-071e-412? This is part of that body of correspondence passing between Dr Taylor of the working group and the Medicines Control Agency, and this letter was sent to Dr McCarthy. She received that on the 25th. She received a copy of it on 25 October 2001. I can take you, if you want, to her witness statement where she confirms that. But do you recall seeing this letter, "Dear Dr Cheng ...", and signed Dr Bob Taylor?

A. I have no recollection, but I'm quite happy to -- if Dr McCarthy says she showed it to me --

Q. I didn't mean to suggest that. She received it, but it

doesn't say that she showed it to you. Do you think she would have showed it to you?

A. No, but we did know that Dr Taylor was intending to contact the Committee of Safety on Medicines.

Q. What he did tell them when he contacted them -- if we go to the final two sentences, he tells them:

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

Did Dr McCarthy bring that to your attention?

A. I have no recollection.

Q. Do you think she would have done?

A. I'm not sure that -- I think the difficulty in this is it's about a yellow card. We knew that this was going to happen and we knew that Dr Taylor was someone who had experience of a lot of these cases.

Q. Yes. He has results there indicating at least two other deaths. That's two other deaths apart from the death of "RF", which the body of the letter concerns itself with.

A. Have you a question?

Q. Yes. The question is: at this stage, Dr Taylor of the working group seems to be indicating that he knows of at least three deaths attributable to the use of Solution No. 18.

MR UBEROI: [Inaudible: no microphone]. Is this witness being asked whether he took steps to ask Dr Taylor what he meant by this sentence? That would be a proper question. But the proposition seems to have been left rather hanging in the air at the moment for comment.

THE CHAIRMAN: Let's approach it this way -- and I think this is what Mr Stewart's been asking in effect: you are being kept in touch by Dr McCarthy, who's on the subgroup, about the progress of the subgroup.

A. Mm.

THE CHAIRMAN: After the meeting, after the September meeting which you chaired, 26 September, Dr Taylor, in accordance with what was agreed in the minutes, contacts the Medicines Control Agency to report Raychel's death.

A. Mm-hm.

THE CHAIRMAN: He then copies this to Dr McCarthy because it's part and parcel of what's been agreed by the working group. And in the course of copying that to Dr McCarthy, it should be apparent to her that Dr Taylor isn't just talking about Raychel's death, but even on an initial results basis, there are at least two other deaths which are attributable to the use of Solution No. 18, which Dr Taylor has turned up to date on his audit of deaths in the paediatric intensive care unit in the Royal Belfast Hospital for Sick Children.

A. Mm-hm.
THE CHAIRMAN: If you are being kept abreast of things by Dr McCarthy, would you expect that information to be brought to your attention by her?
A. Well, yes, I suppose I should have expected her to have let me know. But remember, we already had Dr Taylor's bar chart --
MR STEWART: Yes.
A. -- where he indicated there's more than one death. But these --
THE CHAIRMAN: The bar chart shows a death in 1997 and then Raychel's death in 2001.
A. Mm-hm. The only one I knew of before the meeting, that first meeting, was Raychel.
MR STEWART: And there's also a distinction between deaths from hyponatraemia and deaths attributable to the use of Solution No. 18, isn't there?
A. Certainly.
Q. So if this was brought to your attention, would you be surprised if it hadn't been brought to your attention?
A. Well, I'm not -- I think the problem is that I wasn't really fully aware of all the issues to do with fluid management. While I was chairing the group, I was deferring very much to others in that group who had specialist knowledge.

Q. Yes, but we've already been through the fact that deaths are interesting to your group, they may indicate clinical negligence, they may indicate underperforming doctors, there may be interesting details emerging from those cases against which you can test the guidelines that are being developed.
A. Yes, I think you're continuing to talk about clinical negligence. Absence of knowledge may well be the issue in many of these instances.
Q. Of course, that may amount to the same thing.
A. No, it doesn't. Because if you don't already know --
THE CHAIRMAN: It may do.
A. It may do.
THE CHAIRMAN: I accept your point: it may do or it may not do.
MR STEWART: But something you should nonetheless be very interested in?
A. Very interested in, but it actually reinforces what I said at the outset: that as soon as we had the guidelines and we started talking about this, even if it was in camera to begin with, it was going to raise the whole concern of people going to start looking at their practice.
Q. Are you saying you'd have been happy enough for this working group to completely ignore evidence coming in of

deaths here, there, in Northern Ireland --
A. Absolutely not.
Q. -- ignore that because you had to get on with your work?
A. Absolutely not, absolutely not.
Q. Because it does look as though that's exactly what the working group was doing.
A. No, no.
Q. It was ignoring it.
A. No, our focus had to be on getting the guidelines out --
Q. Why then was the --
A. If more information arose, it was information that could be considered once we had the full details --
Q. But why --
A. But these were not necessarily -- at this stage, these deaths were not necessarily proven to be due to that cause.
Q. Why wasn't Dr Taylor immediately asked to give the committee chapter and verse of all these deaths that he was turning up so that the committee might consider them in the light of its required work?
A. Well, I wasn't an expert in hyponatraemia.
Q. But you're expert enough to be Deputy Chief Medical Officer and chairing this group on hyponatraemia prevention in children.
A. That's right, and hindsight's a wonderful thing.

THE CHAIRMAN: Doctor, some members of the working group might be helped in their contribution to the work and to the production of guidelines if they learn more about other deaths which result from hyponatraemia and/or the use of Solution No. 18; wouldn't that be right?

A. Certainly.

THE CHAIRMAN: So when you're drafting guidelines, you want to make sure they cover, as best they can, a range of scenarios and different circumstances which can arise.

A. That's right.

THE CHAIRMAN: And the children's deaths that we've looked at in this inquiry do cover a range of scenarios.

A. That's quite true.

THE CHAIRMAN: So if you look at Raychel's death and only Raychel's death, that's a post-operative case of hyponatraemia. Right? We've also looked at Claire's death, which is not post-operative, and we've looked at the aftermath of Lucy's death, which is not post-operative. On the other hand, we've looked at Adam's death, which occurs either during or immediately after an operation. Okay? That seems to me to be information which is relevant for the members of the subgroup, and perhaps the whole working group, to have available to them so that they can test the guidelines which they're working on against the events which have

arisen in the recent past in the local context. And that's why you're being pressed on this issue. As I understand your evidence, it certainly would have been better if that information had been shared and that information was at least, in some form, known by various people who were members of the working party.

A. I accept that.

THE CHAIRMAN: Thank you.

MR STEWART: Because other members of the working party were interested in other deaths. If we go to 007-025-048, we see an e-mail from Clodagh Loughery -- she's the chemical pathologist to the working group -- to Miriam McCarthy and Elizabeth Garrett:

"Dear Miriam [moving to the last paragraph], were you aware [she writes, 30 November] of the death of a four-year-old child in what sound like very similar circumstances in Northern Ireland in 1996?"

Actually it's 1995:

"I was speaking to Conor about it today and he's to send me a copy of his report in that case. Let me know if you'll be interested in seeing it. Perhaps you're already be aware of it. Best wishes, Clodagh."

So that's information about Adam Strain's case coming directly to the SMO. Did she bring that to your attention?

A. I don't recall it.
Q. You don't recall?
A. No.
Q. When do you remember first becoming aware of the death that you now know was Adam Strain's death?
A. Only when I received papers for this particular inquiry now.
Q. Do you think that Dr McCarthy kept it from you?
A. No.
Q. So you think it's quite likely she would have mentioned it?
A. She may well have mentioned it to me, I'm not sure --
Q. Do you get the impression that members of that working group were keeping things from you?
A. No.
Q. So you really think it's more likely to be your memory that's --
A. It's my memory.
Q. It's your memory. Do you think that this second clear case of hyponatraemia being known to the working group should have been examined by the working group, should have been looked at?
A. Well, the general issue -- as the chairman has already said, it would be helpful to know the variety of circumstances in which hyponatraemia has arisen. But

then, equally, the members of the group, as you've already pointed out, were actually quite knowledgable about the various deaths that appear to have taken place.

THE CHAIRMAN: Well, some were, some weren't. I think some of them were, I think that's the problem. The problem's about the extent to which the information and knowledge was shared.

A. I accept that.

THE CHAIRMAN: For instance, it may be that the presence of Ms McElkerney was significant, and she was -- I'm not sure if it's fair to describe her as this, but she was a nursing representative on the committee --

A. That's correct.

THE CHAIRMAN: -- or on the group. But she doesn't appear to have known. For instance, she wasn't involved in the deaths of any of these children. So the only one that she would have had any knowledge about, to the extent that it was discussed and on the basis of what I'm being told, would be Raychel's.

A. Right.

THE CHAIRMAN: I don't need to go through each member of the group, but the level of information appears to vary on the evidence I'm receiving.

A. Yes.

THE CHAIRMAN: Okay.
A. And I accept that we were very focused on providing a guideline.
THE CHAIRMAN: Again, at the risk of repetition over the next week-and-a-half, there's nobody who's critical of the production of the guidelines, but there are at least two families at this inquiry who are exceptionally frustrated at the very late raising of their child's deaths and they are bound to query whether this isn't something which not only should have been known at the time of the death of their children, but should certainly have emerged at the time of the working group's meetings and development of the guidelines. That's the problem, doctor.
A. Okay, yes, I recognise that.
MR STEWART: Adam Strain's case was quite different really from Raychel Ferguson's; it was intraoperative.
A. Mm-hm.
Q. He was a boy and there were various features that were very different. Would that fact alone have meant that his case would have been a very useful one to stress test the developing guidelines against to see if they would have helped?
A. I accept what you're saying.
Q. Would that not have been obvious?

A. Now that you put it to me in this way, I have to agree with you.

Q. And yet it wasn't done?

A. No.

Q. Can I ask about the way in which the guidelines, as they were developing, were presented to various specialty advisory committees for their comment and approval? They didn't go to pathology; is that correct?

A. No, they went to anaesthetics, surgery and paediatrics.

Q. Okay. I wonder, can we have a look at 075-084-338 and 341 together? This is the note of the special advisory committee on general surgery, which met on 11 December 2001, and you were present at that meeting with the CMO. On the left-hand side, Dr Marshall from the Erne, a member of the working group, was also present. On the second page, at item 5, hyponatraemia management is referred to and:

"The guidelines on the management of hyponatraemia were commended by the group."

I take it that is the working group that is commending them to the special advisory committee; is that right?

A. No, I would say it was the special advisory committee were commending the guideline.

Q. All right. Then Dr Leonard, presumably of the special

advisory committee, asked that the guidelines be circulated to Accident & Emergency departments. That's an important suggestion, isn't it, because he knew that children might be treated in --

A. That's correct.

Q. -- Accident & Emergency departments?

A. Yes.

Q. At that stage, did anyone take on board the possibility that children can be treated in adult settings, adult wards, and that accordingly it might be useful to specify the age limits that the guidelines applied to? Was that considered?

A. I have no idea about the age limit. This may have been discussed in the subcommittee.

Q. It seems to be a natural follow-on from what Dr Leonard is --

A. I think there's definitely an issue about children and adults and actually, as you know very well, a subsequent guideline was produced for adults.

Q. But it wasn't considered by your working group?

A. I was not involved in that technicality, but it may well have been discussed. I'm quite sure it was.

Q. What was his second suggestion that "guidance should be made more explicit in general"? I don't understand that, and, "Particularly in the use of one-fifth".

Obviously that was a major debate that was going on within the group.

A. Well, I think, as you point out, that was discussed and advice was being taken beyond Northern Ireland about what could be done and what should be done about this, and actually in the CMO's letter it also points out that there may be unfinished business in relation to the fluids that are actually available.

Q. Following on from this meeting, I wonder can we go to 007-013-027? This is Clodagh Loughery again e-mailing Dr Miriam McCarthy immediately after that. She says she's interested to hear that the subject was brought up at the specialist advice committee surgery -- that's the minute we have just looked at:

"What about [she writes] the specialist advisory committee pathology (includes clinical biochemistry) or SAC medicine?"

Do you know if those suggestions were taken up?

A. I wasn't aware of this, but I do think in retrospect it's another area we should have been looking about, particularly -- Dr Rogers is a chemical pathologist and chemical pathology was a developing specialty at that time and they often would have been brought in to help to advise in very difficult cases.

Q. Especially in derangement in hyponatraemia --

A. Fluids in general.
Q. We come to the letter that the CMO sent out with the guidelines when they were promulgated. That's at 012-064c-328 and 329. Did you play any part in drafting this letter?
A. I don't recall being directly involved with that.
Q. Okay.
A. But I'm quite sure it would have been passed -- I would have had chance to look at it.
Q. I see that the second paragraph there starts:
"Hyponatraemia can be extremely serious and has, in the past few years, been responsible for two deaths among children in Northern Ireland."
Which two deaths did you take that to be referring to?
A. I could only remember -- at that stage I was still aware of Raychel and there was discussion about another death, but I can't remember what that was, and again it had come up during the process of drafting the guideline.
Q. Was that Adam's death or was that the death --
A. I have no idea. I'm sorry, I have no idea.
Q. Because according to you, there might have been two or there might have been three, or if you'd been shown the letter Dr McCarthy had, at least three?
A. Yes. I can understand your frustration and mine too.

Q. Was nobody proofreading these things to see if they might be correct?
A. Well, all I can say is that Dr Campbell was the person who signed the letter and she must have been definitely convinced that there were two cases.
THE CHAIRMAN: Well, the information you had from the bar chart was that there were two deaths.
A. Yes, there was one case in 1995 and another one in 2001.
THE CHAIRMAN: 1997 on the bar chart and then 2001.
A. Yes.
THE CHAIRMAN: If there's a reference to two deaths, then --
A. Those would have been the two.
THE CHAIRMAN: Dr Campbell wasn't at that meeting in September 2001.
A. No.
THE CHAIRMAN: If Dr Campbell read that, she might be looking at that as Raychel's death, which has been directly reported to me, and she's also been alerted -- at least by Dr Loughery -- to what turned out to be Adam's death --
A. Mm-hm.
THE CHAIRMAN: -- from Dr Loughery's discussion with the coroner. So that's also two deaths, but with a bit of uncertainty about whether we're talking about exactly the same two deaths?

A. That's right.

THE CHAIRMAN: Then on the other hand Dr Taylor has written to Dr McCarthy, or copied her into a letter, which he sent to the Medicines Control Agency, talking about at least two deaths beyond Raychel's. That's not reflected here?

A. That's right. But whether we're double counting it -- at some point we may be double counting in here.

THE CHAIRMAN: I'm quite sure -- well, sorry, I am not quite sure about anything about these numbers, I'm afraid.

MR STEWART: The curious thing is when one refers to the Dr Taylor correspondence with the MCA, in which he refers to "at least two other deaths", which we know went to Dr McCarthy, if you go to the third paragraph of this letter to the final sentence, the Chief Medical Officer refers to:

"This has been emphasised in a recent letter received from the Medicines Control Agency, which states that while hyponatraemia is a risk with Solution No. 18, electrolyte imbalance is a risk with all intravenous solutions."

That was part of the same exchange of letters that was copied to Dr McCarthy and it looks as though it's found its way to the CMO as well.

A. That would particularly be anything to do with the

Committee on Safety in Medicine. I think it would have been drawn to Dr Campbell's attention.

Q. And in all your daily ins and outs of her office and all your discussions of matters of topicality and your work --

A. I do not recall seeing it myself, but I'm quite -- it may well have been passed to me and I wasn't aware of it. I'm not aware of it now.

Q. And at this stage did you remind Dr McCarthy of the subgroup's obligation to prepare an audit protocol?

A. No, but as you can see in Dr Campbell's letter, she refers to the necessity to have an audit.

Q. Well, she says, at the top of the second page:

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

It's correct to say, is it not, that no assistance was given to the trusts who were to receive this letter in relation to developing local protocols?

A. Audit protocols, do you mean?

Q. No, the protocols they were to draw up in relation to IV fluid therapy.

A. No, because each hospital would be dealing with a different range of cases, some more complicated than others.

Q. So --
A. They would draw up their own protocol in the light of the guidance.
Q. So they were to draw up their own protocol on the basis of their own clinical experience --
A. Mm-hm.
Q. -- unlike your working group, which didn't seem to draw on its share of clinical experience?
A. Well, our group was looking to produce generic advice, which would then go to the trusts and they would then produce their local variations, but it would be on the same theme.
THE CHAIRMAN: Doctor, can I ask you just to bring me up-to-date? Suppose equivalent guidelines were being issued in 2013 and suppose I took the view that it was important for that point to be made about auditing compliance, but it was left a bit loose, typically, would that be done a bit more firmly --
A. It would be done more robustly now.
THE CHAIRMAN: And that's part of the development of governance?
A. That's it.
THE CHAIRMAN: Thank you.
MR STEWART: Sir, thank you, I have no further questions.
THE CHAIRMAN: Okay. If you just wait one moment, doctor.

Any questions from the floor? Mr Hunter?
MR HUNTER: One matter, sir, in relation to --
THE CHAIRMAN: I should say: Mr Hunter represents the family of Adam Strain, doctor.
MR HUNTER: Thank you, sir.
One matter in relation to the composition of the working group: Dr Darragh has admitted that his knowledge of fluid management would have been quite scarce and he has also said in his evidence today, in relation to the composition of the working group, that the inclusion of doctors Taylor and Crean was a given. Can I ask: were they the first people that were approached to join the working group? And secondly, if they were, did they assist Dr Darragh in who else should be on the working group?
THE CHAIRMAN: Can you help, doctor?
A. Sorry, at this remove I can't, but they would have definitely been early on because certainly Dr Taylor was very instrumental in raising the whole issue. And Dr Crean was a similar -- from the same location.
THE CHAIRMAN: Let me explore that a bit with you. When you were putting together a group of people to work on this, at that point what do you mean when you say that Dr Taylor was very instrumental in raising the whole issue? Because that issue had in fact been raised from

Altnagelvin.

A. It had, yes.

THE CHAIRMAN: So what are you referring to when you talk about Dr Taylor being very instrumental in raising the whole issue?

A. Well, I felt that he was certainly someone who was -- once we started investigating this whole thing or, not investigating, but started to develop this, I immediately thought we need somebody from the Children's Hospital, and when we asked for someone from the Children's Hospital -- I think it was through Dr Carson -- he suggested Dr Taylor as someone who had a particular interest and it was on the basis of that.

THE CHAIRMAN: Okay.

A. I think there's correspondence actually in the papers about Dr Carson being approached for someone.

THE CHAIRMAN: As it turned out, I heard last week that Dr Smith and Dr Lowry in Craigavon had already been working on something before Raychel's death, which developed into a Craigavon forerunner of the guidelines and they had gone to Dr Taylor before, so that confirms the information you had received.

Let me just ask you one curiosity, which follows on from that: when Dr Taylor gave evidence about this, he was, to put it bluntly, a bit peeved that he had been on

the working party, but not on the subgroup. And since you have emphasised that he was one of the local leaders with an interest in this, can you remember why he wasn't on the subgroup?

A. I think there was no reason at all why he couldn't have been. He must have simply not responded or not been available at the time.

THE CHAIRMAN: Right, okay.

A. But there was no reason why he would have been excluded.

THE CHAIRMAN: In fact, on the contrary, you'd have every reason to include him?

A. Absolutely. With Dr Crean there one hoped we had the benefit of a very close colleague.

THE CHAIRMAN: Thank you. Anything else from the floor? No? Okay, thank you very much, doctor. That's all the questions we want to ask you. Unless there's anything you want to add, you're now free to go.

A. Thank you very much.

(The witness withdrew)

THE CHAIRMAN: Ladies and gentlemen, that brings us to an end for today. We'll start at 10 o'clock tomorrow morning with Dr McCarthy. I should have mentioned earlier that, if at all possible, I would like to sit a bit early on Monday, perhaps starting at 9.30. There's something, if I can get to in the afternoon,

I would like to and, if we start at 9.30, that might become possible. Thank you very much.

(4.05 pm)

(The hearing adjourned until 10.00 am the following day)

I N D E X