Wednesday, 13 November 2013

(10.00 am)

(Delay in proceedings)

(10.20 am)

DR IAN CARSON

Questions from MR STEWART

THE CHAIRMAN: Good morning, thank you for waiting.

Dr Carson, thank you for coming back. I think you understand the basis on which you're here today is rather different than your previous appearances. The RQIA has been involved in the development of the hyponatraemia guidelines and follow-ups on that, which we want to explore, and we also want to explore, through Mr Stewart's questions, some other issues about the slightly wider remit of the RQIA, insofar as it is relevant to the issues that have concerned us at the inquiry. Okay? And thank you for facilitating us today after Friday's mishap.

MR STEWART: Thank you, Dr Carson. Just one formality, and that is you submitted a further witness statement, which is WS077/4, on 15 October. Are you content that that witness statement should be adopted by the inquiry as formal evidence?

A. Yes, I am.

Q. You are the chairman of the RQIA, the Regulation and



Quality Improvment Authority, and you have been since 2005?

A. Since June 2006.

Q. The RQIA has as its objective, its mission:

"To provide independent assurance [I'm reading now from an RQIA document] about the safety, quality and availability of health and social care services in Northern Ireland, and encourages continuous improvement in these services and safeguards the rights of service users."

Can I ask you about the independence of the RQIA in giving such assurance? Who sponsors the RQIA?

A. We are sponsored by the Department of Health and Social Services and Public Safety. We are funded, for the vast majority of our resource allocation by the department, through drawdown grants. We raise some funds through fees to the independent and private sector, but the vast bulk of our resources come from the department. The appointments to the board of RQIA are public appointments, but the appointment is made by a minister.

The organisation is slightly different from other members of the health and social care family in the sense that our board is a lay board. In other words, we are all non-executive directors, we don't have any executive directors on our board, so in a sense we



represent, if you like, the users of services across Northern Ireland.

In that sense, we're different from the boards of Health and Social Care Trusts and even some the other stand-alone agencies and non-departmental public bodies that exist in Northern Ireland like the Health & Social Care Board, Public Health Agency. The constitution of their boards are slightly different. And if that gives us a greater level of independence, that's one angle to it. But more importantly, I think, we derive our independence by independence of thought, the use of independent experts, increasingly frequently from outside of Northern Ireland, and that is the measure, I suppose, of the way in which we maintain our independence.

It can be -- it's an important relationship for the organisation that our independence is respected by the department. And I have to say that at times we've had to debate and reach an understanding of what that independence actually -- how it operates in practice. Our memorandum of understanding -- our management statement has evolved and developed over time to help illustrate more clearly that level of independence that we have from the department.

Q. You are described as "an arm's length body", so what you



have really been describing is the debate about the length of those arms. What is the relationship with the CMO?

A. Well, non-departmental public bodies, whether they're in health or other government departments, will have a sponsor branch within that government department. Our sponsor branch is through the CMO's office, the SQS, which is the operational agency that we would report to and keep informed of our work programme. In terms of putting in our annual business case, it would be through the sponsor branch and they would negotiate for the appropriate funding if we were wishing to develop or undertake any expansion or development of our work programme.

Q. The SQS you refer to is the Safety and Quality Standards --

A. Directorate, yes.

In terms of my personal accountability or my annual appraisal that I have as chairman of the organisation, I am responsible, as chairman of the organisation, for appraising my own non-executive board members. I, as chair, am appraised by the CMO, but the chief executive and myself have accountability reviews. In other words, the performance of the organisation is handled by the Permanent Secretary.

Q. And the department itself is said to determine your performance framework. What does that mean?
A. Well, we have to prepare an annual business case every year and that has to be approved by the department. But because of our independence, it is the board of RQIA that decides -- we make an independent decision of what our work programme is going to be. And we do that on the basis of intelligence that comes into the organisation through our inspection work, through our awareness of what is happening, not only within Northern Ireland but also at a national and an international level.

So we determine our work programme. We would have to have that cleared by our sponsor branch and through the department. That's not -- I have to say, that's not a confrontation; that is done supportively and we also allow the department the opportunity to recommend to RQIA areas that they would like us to conduct an independent investigation or a review of. So our programme of work -- we have the capacity to do about 10 or 12 reviews in our review programme a year. About three of those would emanate from the department itself as areas of work that they would like us to look at.

The remainder would be a work programme that we would generate ourselves on the basis of intelligence



and also the input of the public, input from the health and social care community itself, areas that they would like to be reviewed or looked at.
THE CHAIRMAN: Can this be triggered, doctor, by something as simple as seeing a newspaper report on something, and somebody then comes to the next board meeting and says, "I'm a bit concerned, I saw that", and you probe a bit and see if it is worth following up on?
A. Initially, chairman, the answer to that would be obviously yes. But it does need to be balanced. You need to determine the other factors that would recommend something to be looked at.
THE CHAIRMAN: But it can be --
A. It could be triggered, yes.
THE CHAIRMAN: And sometimes it might turn out there's more to it, that means you don't need to investigate or, in fact, there's more to it that you do need to investigate?
A. Absolutely. I think one of the difficulties for any regulator trying to oversee the quality and safety and the assurance, if you like, for a system that's as complicated as health and social care is the breadth is huge. So you do have to focus your attention on the basis of intelligence and other drivers that might --
THE CHAIRMAN: Yes, and we won't go there today, but you've



got a huge area of responsibility in terms of social care, mental health, children in care?
A. Well, children come under -- yes, children in care are covered by the recognised care sector, yes.
THE CHAIRMAN: And independent homes and units?
A. Yes, clinics, hospitals. Our remit has expanded -- particularly since the 2009 review of public administration, our areas of influence have increased.
THE CHAIRMAN: Right.
MR STEWART: Can you give us some idea of the size of the organisation? How many people are employed? What sort of funding do you have?
A. Our budget's about £7.5 million per year. We have roughly about -- I think it's 147 members of staff in the organisation. The majority of those -- we just have a small executive team of four people. The majority of our staff are actually involved in the inspection programme through the recognised sector, nursing homes, residential homes. So it's a small organisation in comparison to the system that we're charged with regulating. The expenditure, if you like, on regulation through RQIA is about a fifth of one per cent of the expenditure across the whole of the health and social care system, so it's not large.
Q. In terms of the focusing of resources on the statutory



sector as opposed to the regulated sector, what's your breakdown in terms of funding that that represents?
A. There is a difference between -- and there are some interesting comparisons between RQIA and CQC, as it operates in England. Our remits are almost the same, our powers are slightly different. Our powers are quite strong and forceful in the regulated sector. We can, through our inspection process, which is required by law under statute, based on standards and regulations that are defined by law, if you like -- we can, following our inspection programme, if we have any concerns, we can not only take enforcement action in regard to a facility in the regulated sector, but we can put limitations on their remit, we can close facilities, we can prosecute under our regulations.
THE CHAIRMAN: Just for people who aren't immediately familiar with the distinction, we're talking now about things like old people's homes, residential homes?
A. Residential homes, nursing homes, children's homes, and domiciliary care facilities; the whole raft of services that fall under regulation.
THE CHAIRMAN: So in that area you are, in effect, the police?
A. You could describe it that way. We are there to provide a public assurance and also to carry out enforcement

where we detect standards are inadequate or where users of services are potentially at risk.

THE CHAIRMAN: Right.

A. So we can remove -- all of these registered services must be registered, and we can remove their registration, we can stop them working.

THE CHAIRMAN: You can't open a nursing home without --

A. You've got to be registered with us. And if on the -- on the basis of our inspection findings we found cause for concern, we can put requirements for improvement notices, but we can escalate or enforce that right through to closure, removal of registration and even prosecution.

THE CHAIRMAN: Okay. That's in the regulated side. On the statutory side --

A. On the statutory side we don't have the same powers. We can, however -- the only body that is empowered to take action, ultimate enforcement action, is the Department of Health itself, and they do that by putting an organisation into special measures. You will have observed that in relation to, for example, the Belfast Trust last year or earlier this year. But we can make recommendations to the department on the basis of any of our review work or our inspection work within the hospital system that we can recommend that



the department consider taking special measures in relation to a health and social care trust.

THE CHAIRMAN: The effect of special measures is what? That in effect that the department is intervening in the activities of something like the Belfast Trust in a specific area to require improvements and changes?

A. Yes. The whole accountability framework, which currently exists between a trust and the department, would be heightened. Instead of just having their twice a year -- mid-year and end of year -- accountability meetings between the chairman and the chief executive and the Permanent Secretary, that could be escalated up to a monthly meeting and performance evidence and reports being required to be put in place. Ultimately, the department could, by choice, ultimately ask the chairman or the board or the chief executive to stand down. RQIA do not have those powers in the statutory sector.

THE CHAIRMAN: Wasn't there something -- I'm sorry, I don't remember the details of it, but wasn't there an issue about the powers of the minister at the Antrim Hospital and about who he could ask to stand down and who he couldn't? Is there a difference between the chief executive and the chairman?

A. One of the delicate balances that an arm's length body



has to manage is this relationship with the minister.

THE CHAIRMAN: Yes.

A. I think ... I stand to be corrected on this. My understanding was that the minister was expecting the chairman to remove or to take action in relation to the chief executive in the Northern Trust.

THE CHAIRMAN: Because the minister couldn't himself remove the chief executive? So he wanted the chairman to do it, the chairman wasn't doing it, so it ended up that the chairman went?

A. Well, the chairman resigned, if I remember rightly.

THE CHAIRMAN: Yes.

A. But I would have thought that the minister could exercise his influence to require a chief executive to stand down if so necessary.

THE CHAIRMAN: Yes, thank you.

MR STEWART: So really to achieve the RQIA objectives of influencing policy and improving care, that's done through recommendations, which derive from the reviews and the inspections carried out by the RQIA. Can you give us a description of how you go about planning the programme of reviews for any given period?

A. When RQIA was established in 2005, we were asked by the department to carry out two initial reviews. Our first was into the care of a patient in the Royal



Group of Hospitals. That was followed by a review of the breast screening service. Those were commissioned reviews of RQIA, but it was always the intention, I think, if you look back at the "Best Practice, Best Care" implementation programme that the department was developing in 2002 to 2003 around the time the order was published or came into fruition, the expectation was that RQIA would carry out clinical and social care governance reviews of the system.

It wasn't very specific at those times as to how that would be done or how that would be carried out, and I've hinted already that the remit is so broad, there are huge dangers -- or at least it was perceived that there would be dangers or difficulties -- in actually giving that public assurance about a system-wide, Province-wide system on the basis of review work.

In England, it's interesting, the Healthcare Commission produced what were called annual health checks. On the basis of self-assessment, NHS trusts published an annual health check. And in some ways that was innovative, but it was quite superficial, and it was prone to things slipping through the net or being not penetrating as they should be, and inevitably events or incidents emerged whenever an organisation, an NHS trust, had been given a clean bill of health through the

health check.
THE CHAIRMAN: So for instance, Mid-Staffordshire would have had a self-assessment check?
A. And a lot of the early assessments of clinical and social care governance or governance in the NHS in England were based on self-assessment exercises. That has its strengths, it has its obvious weaknesses as well.
If I can refer back to the two reports that were conducted by Deloitte in 2003 and 2004. The initial one that was commissioned by the department and reference was made to this and the inquiry have copies of that.
THE CHAIRMAN: Yes.
A. In the first one, their assessment of the status of clinical and social care governance in Northern Ireland, that painted a very poor and a very weak picture.
I would have to say, chairman, that that report carried out by Deloitte was actually a very weak report. In fact, they say -- and I have somewhere the reference to it -- in their report they said -- yes, I have the reference here. It's 075-001-079.
It was the report on clinical and social care governance published in September 2003. In paragraph 1.5, they say:
"We have not verified or validated any of the



information."
So here was a company, a consultancy, carrying out a survey of the status of clinical and social care governance, and in fact it turned out to be on the basis of self-assessment, what I would call a desktop exercise. So it was flawed. It did point out weaknesses -- and I know that a subsequent conference was held by the department with Health and Social Care Trusts and other organisations and the organisations were very upset at the findings that were portrayed through report. So fundamentally it was flawed. I'll come back to that in a moment.
Unlike their second report into risk management, which was actually a very thorough report, which engaged not just with a questionnaire, a self-assessment exercise, they actually went out and visited front-line staff who were involved in risk management processes. So that second report done by Deloitte was actually a very thorough and effective piece of work.
THE CHAIRMAN: In broad terms, that report said that things had improved, but there was inevitably some area for further improvement?
A. What I'm trying to focus on, chairman, is the way in which the review was carried out. The first piece of work was, I think, flawed and not thorough. The second



piece of work they did very was thorough, largely because they actually went out and engaged and spoke to staff who were involved. I think that was one of the -- is a feature of any review work. Purely self-assessment and desktop exercises are not adequate today.
Because, I think -- and this is speculation on my part, I have to say -- that Deloitte review of clinical and social care governance was not a particularly good piece of work, it led, when RQIA was established in 2005, to carry out a further review of clinical and social care governance. That was the basis of our early overview work about the findings as to how well clinical and social care governance had developed or otherwise in Health and Social Care Trusts.
That assessment that we made in February 2008, that was done on the basis of a self-assessment protocol, but also by visits to trusts of our review teams, independently appointed, and we used laypeople as part of that work. However, if I was to criticise that early piece of work that we did, it was -- we used people largely all from within Northern Ireland, we used people working ... For example, for the sake of argument, say the Belfast Trust would have gone and looked at practice in the Western Trust, people in the Southern Trust would have looked at practices in the Northern Trust. So we



tended to use people -- we wouldn't use people who were employed in an organisation to independently review or look at practices in another organisation.
Some of the learning within that exercise for RQIA was again that this was a very general overview of the development of clinical and social care governance. And I have to say that in terms of the way we've developed our work subsequently -- and I'm coming back to your question, Mr Stewart -- is how have we developed our review programme subsequently and how do we determine the effectiveness of clinical and social care governance within any one organisation?
I think we have now decided to focus our attention much more on specific issues and hence our review programme has moved away from what I would call general governance reviews to specific service reviews. But within those specific service reviews, we will drill down and look at the governance implications. If we're looking at maternity services or children on adult wards, we would want to penetrate and see how effective the governance systems and processes relate to that specific area of work.
The second factor in terms -- and this comes to strengthen the independence of the organisation and the credibility of the review work that you're carrying out.

We're increasingly, and now largely dependent, on bringing in independent experts from outside of Northern Ireland. Northern Ireland is quite a small community, everybody has worked with everybody else at some stage or another. So we tend to bring in independent experts from England, Scotland, Wales or elsewhere to actually quite often lead the review work. Some of our more high-profile commissioned work from the department, we've actually specifically appointed the independent expert to lead the inquiry or the investigation team.

MR STEWART: In terms of selecting issues to form the basis of the reviews, do you consult, do you take suggestions? There's reference in the papers to a serious concerns group. How do you prioritise the issues that you're going to focus on?

A. We do have a serious concerns group within RQIA. Organisations that fall under regulation are required to report to RQIA deaths in care, serious adverse incidents in care, safety issues, fire safety and other safety -- they're required to report that information into RQIA.

Q. Is there a mirror group for the statutory sector?

A. No, they're not required to report those similar types of incidents to RQIA.

THE CHAIRMAN: No, in the statutory sector the requirement



surely is to report a serious adverse incident to the Health & Social Care Board?

A. Correct.

THE CHAIRMAN: So in the regulated sector, the serious adverse incident goes to you, but not to the HSCB?

A. Well, it would also go to the organisation that has commissioned care within the sector. And the majority of service users in the regulated sector are placed there by a Health and Social Care Trust. It's the responsibility of the Health and Social Care Trust, as the commissioner working with the provider organisation, to develop a care package. That care package should be reviewed, but there is also a responsibility for the provider, if there is an incident, to let the commissioning organisation -- usually a trust -- be aware of incidents.

THE CHAIRMAN: Okay.

A. Similar lines of reporting do not exist in the statutory sector.

MR STEWART: Once the RQIA has determined its three-year programme that you use going forward, how does it decide what sort of resources and what sort of concentration it's going to focus on each review? How does it scope?

A. Before I answer that, maybe I should say that, yes, we do embark on -- before we develop a three-year review



programme, we would have had a series of consultation engagements, and we do that with the health and social care family. We would consult with trusts, we would hold public meetings, we would invite providers of services from not just the trust side, but from the voluntary and other charitable independent sector. We will have a dialogue, a debate, around issues.

And I think we had, as part of our consultation programme prior to the current three-year programme, we had over 400 suggestions or recommendations of areas that needed to be looked at. Within the organisation our executive team will develop a matrix of need or a matrix of severity, a matrix of -- an attempt to prioritise what areas to look at. And that programme of work would ultimately be approved by the board and we would share that programme in advance with the department to let them know the areas of work that we're involved in and also ask them to input suggestions as well.

Q. And the minister can himself also commission review work from you?

A. That's right, yes.

Q. What happens when you've got in place your review programme going forward for three years, what happens when an emergency occurs, something untoward that



requires RQIA involvement?

A. We do build a certain level of flexibility into our work programme. Inevitably, on the basis of experience in the last five or six years, we will find there will be one or two crises that will emerge within the system. And it would be the -- the minister can feel free to require RQIA to carry out an urgent piece of work. That may result in a slight slippage -- we try not to allow any slippage to our review programme, but inevitably if there is a major issue, for example the deaths of the babies in the neonatal units as a result of the pseudomonas outbreak, that was a very major piece of work. It was carried out very quickly and very swiftly and very thoroughly. It did have a slight knock-on effect on of what I will call our routine programme of review work. For some other pieces of work the timetable slipped by a couple of months. We try not to allow that to happen because you can't have this roll-on, knock-on effect of delays to your work programme.

It does however beg the question of whether a three-year review programme is appropriate for RQIA. We might actually shorten that period just to allow greater flexibility because as themes emerge and critical areas of review work come to our attention it

might be that we would want to do those sooner rather than wait until the next three-year review programme.

Q. Can I ask you about the methods adopted in carrying out the reviews? You discussed earlier on the desktop exercise that Deloittes had engaged in as not being entirely satisfactory. What methods are employed by the RQIA?

A. Well, they vary, Mr Stewart, on the basis of what the review work is looking at. I have to say, we still do -- well, first of all, could I make a very important point? I'm sure this will not be lost on you, chairman.

The terms of reference for any piece of work are absolutely crucial. Those have got to be clearly thought out and defined before any work is undertaken. It sets the boundaries for the piece of work. If it's not -- if an area of work is not defined within the terms of reference, then the organisations carrying out the review or investigation will not and cannot look at it.

I think some of the criticism of some pieces of work by various regulatory and inspectorial organisations has been because it wasn't clearly enough defined in the initial terms of reference. So that's absolutely fundamental. We would spend quite a lot of time before we commence a piece of work agreeing with the



department, agreeing with the sector that we're -- those terms of reference.

The next thing is in terms of the design of the review work. Again, it depends on the subject matter that you're looking at. I think it is important. We still do self-assessments within organisations and, in a sense, we believe that is still worth doing. And I think the health and social care sector have got better at doing those self-assessments as their own systems internally have improved over the years. So the information that they collect, the data that they analyse on a routine basis is better organised within -- so they're in a better position now to respond to a self-assessment.

We see the self-assessment as being a useful tool for one main reason, because it does allow the organisation at a very early stage to evaluate where their own strengths and weaknesses are. It may point out to an organisation -- without the final report that comes from RQIA or any other organisation, they can say, "This is an area of work that we need to focus on, this is an area we need to improve, this is an area we need to concentrate on". So we still use that self-assessment.

However, when we receive that self-assessment, the



most important and the most penetrating area of our work would be when we would send that expert team into the organisation to actually verify what the trust have said in their self-assessment exercise.

Q. Are there ever unannounced inspections or are they always trailed?

A. In the regulated sector, under law, we are required to carry out a minimum of two inspections a year, one of which is announced, the other of which is unannounced, and I can say something about that in a moment or two.

In the statutory sector, the review work -- we would always inform an organisation when we are sending out the review team. They will have submitted their self-assessments, they will always know when the review team is coming to carry out their penetrating analysis of facts on the ground, if you like.

The reason for that is that, at the end of our review work within our visit to an organisation, we will want to meet with the senior officers of that organisation, and quite often the chairman of the trust board will attend, the chief executive will usually attend or his senior directors responsible for that area will attend. So there's an opportunity for the review team to feed back their findings and their observations. So that's really how we conduct the report.



Sorry, I've lost my ...

Q. I was going to ask a series of question. Do you involve patient groups or focus groups in the work?

THE CHAIRMAN: Sorry, just before you go there, you were going to come back to the unannounced visits that you mentioned in passing.

A. Yes, there is one area of inspection which has developed following the clostridium difficile outbreak in the Northern Trust. Minister McGimpsey put in place a series of hygiene inspections across health and social care facilities. Those investigations, we would have conducted previously on an unannounced basis in that we would have somebody within RQIA, the chief executive or one of the executive team would have rung a chief executive on a Monday morning and said, "We're sending our hygiene team into your trust this morning". So the announcement would have been as late as that and the chief executive would just know that the RQIA hygiene team were coming on that day, they wouldn't know which wards or which facilities they were going to look at.

Following the pseudomonas outbreak -- it was interesting, our footfall in trusts was mostly in what I would call frequent fall areas where patients and service users would have been, mostly wards and

outpatients facilities. Prior to the pseudomonas outbreak we did not go into areas like intensive care areas, theatres, these were called augmented care areas. Subsequent to that report on pseudomonas, the arrangements for hygiene inspections have changed and we actually carry out both announced and unannounced inspections, and we do see benefits of an announced inspection as well as the unannounced inspection, which can occur at any time of the day, 24/7.

So our profile, our plan of those unannounced and announced inspections do change. Our review work is not usually conducted on the basis of a surprise visit, it's usually a planned visit because we want to get the right people.

If I go back to the flaws of the Deloitte thing, their initial -- we they didn't actually meet with people who were delivering services or overseeing or supervising services. That's a fundamental flaw.

THE CHAIRMAN: Thank you.

MR STEWART: I'll just discuss that a bit further. Have you ever heard the observation that culture is what happens when people don't think they're being watched? Is there anything to be gained by unannounced visits as opposed to the announced inspection?

A. I think that the main advantage of an unannounced visit



is it keeps an organisation on its toes. The advantage of the announced visit is that the right people are there with the right information. And if I can go back to the regulated sector, the care home facility, I think there is another major advantage of the announced visit, because it is a requirement for a care home, a nursing home, to publicly display the fact that RQIA are coming to do an inspection in that care facility. That is there for the benefit of family members who might have a relative in residence in a care home.

THE CHAIRMAN: Just stop a minute because the notice you are holding up, if I can read it, it also advises people that copies of the RQIA inspection report will then be available either from the home or on request from RQIA.

A. Yes.

THE CHAIRMAN: So if I have a handicapped or elderly relative who's in a home and I see that notice, then I can follow up to find out what the inspection outcome is by either one of those two routes?

A. The registered facility is obliged to make that inspection report available to family members.

THE CHAIRMAN: And if I don't happen to know that already, that notice will let me know?

A. That has got to be displayed. And that means that family members can come on the day, they know what day



RQIA inspectors are going to be in the organisation, they can meet with the inspectors, they can discuss the care of their family member with the RQIA inspection team. So that's the benefit of an announced visit. Whereas an unannounced visit, family members wouldn't know. But the unannounced visit is really there to keep the organisation on its toes. I have gone out just as a board member and I encourage my board members to actually observe the conduct of inspection visits. And that can be, as I say, 24/7.

THE CHAIRMAN: Thank you.

MR STEWART: It takes me back to what I was asking a moment ago about the involvement of patient groups or focus groups in the method of review.

THE CHAIRMAN: I think, doctor, you've helped -- when we are dealing with this and the subsequent questions, I think you've explained very clearly the scope of the RQIA's remit. I think, for our purposes, maybe if we could begin now to focus on the statutory sector with which I'm mostly concerned and the families are mostly concerned.

A. Yes.

THE CHAIRMAN: So in terms, Mr Stewart's question was about the involvement of patient groups or focus groups in the method of review.



A. Yes, chairman. I will say a little bit about our review. The review teams we put in when we're conducting a review, how do we establish that review team? I've indicated the need for independent expert leadership of the review team. That is one area. We have a group of what I'll call lay reviewers, reviewers who are laypeople, who we have trained up to involve, and many of our review subjects that we've conducted so far will have skilled people within RQIA, the independent experts from outside, from Scotland, England or Wales, but we will always have a layperson, a service user, as part of that review team.

More specifically, we have actually -- we do recognise the significant expertise that exists in a number of patient groups, advocacy groups. For example, we've done a couple of reviews -- we did a review on a child in adolescent mental health, and as part of that review we asked an organisation called VOYPIC, which is the Voice of Children and Young People in Care, to actually be part of our review process and to engage with us. And they were responsible for meeting with young people in care, they understand the language, they understand the issues that young people who are in care are undergoing. And chairman, if I can then go to the work that we've, since 2009, taken on

board in relation to the whole area of mental health following the transfer of the function of the Mental Health Commission.

We do actually use people with mental health and learning disabilities in some of our engagements with service users in mental health facilities. So we are increasingly using people who have experience of the service that we're reviewing to assist us in that process.

MR STEWART: In reviewing the quality of a service, presumably you have to apply certain standards to what you're finding. Are there audit tools that you conventionally use?

A. Again, that would vary significantly on the subject that we're looking at. I think it is important to point out, in regard to the role of RQIA what do we inspect against, what do we review against, what are the standards that we are required to operate within, and the framework that we operate -- well, as the inquiry are probably aware, and you will certainly hear from the department, the department is the standard-setting organisation for health and social care services in Northern Ireland. So they determine the standards, they write the regulations for the care sector, for example. They determine what the standards -- and they have



published those quality standards and we use those.

One of the areas that we can get into -- you're talking about the arm's length relationship with the department. We carried out a review a couple of years ago into maternity services. We knew when we embarked on that piece of work that there weren't -- the department had not actually published definitive standards for intrapartum care and we used standards that were being used in England as part of that review work. Now, there was a tense debate, I have to say, with representatives from the department on the basis of that. One of the -- and I come back to another principle of our review work. We will, in our recommendations, have recommendations for the trust that's delivering services, we will have recommendations for the Health & Social Care Board that is commissioning services. We can also make recommendations to the department where we think maybe standards need to be strengthened or new standards need to be put in place.

And if you take that review of maternity services, we were aware that there wasn't a strategy for intrapartum care, and that was one of the recommendations in the report and subsequently the department did establish a strategy group and have come up with a strategy for intrapartum care.



So in a sense, this tests the strength of the relationship between the regulator and our sponsor branch in the department.

Q. What would be the timescale for the sort of reviews that are undertaken?

A. I think this is actually quite important and obviously the inquiry will be very aware of this, given the timescale that the inquiry is involved in here. In my closing remarks, I would be advocating that things need to be speeded up very significantly in a whole range of areas. I think delay can result in suspicion and lack of trust and so on and so forth.

So we are very focused, and one of the reasons the board of RQIA like to keep a tight control of our review programme is that we do not want -- having published a programme of work, we want that to stay on schedule and we like to make sure that it is completed within the time boundary that we have set for it. And again, when the work is completed, when our review team have finished their work, we would like that work to be published as quickly as possible when the work is completed.

None of our reviews should last -- any individual review should not last longer than six months to a year. We should be able to complete it all within that time



frame.

Q. When a piece of work is completed, what's the process for having it agreed with the department and proceeding to publication?

A. In appendix 3 of our management statement, the process for completion of the work is quite clearly defined and described. But to summarise it, when we have completed our review programme, we will send a draft of that report to the department, about a month before we would hope to publish it. That allows the department to check for factual accuracy, if there are issues in relation to the department. We will share the report, also in draft form, with the service, the Health and Social Care Trusts, again for the purposes of factual accuracy. Once we have obtained factual accuracy, then I will write to the minister and inform him that the work has been completed and the work will subsequently be published.

Q. Does it also require the approval of the CMO?

A. Well, in the sense that our usual --

THE CHAIRMAN: Sorry, I just want to be careful. Mr Stewart used the term "with approval", you're not necessarily looking for approval, are you?

A. No, we're not looking for approval from the department when we publish work. We will be testing factual

accuracy only with the organisations we review and our report through the department.

THE CHAIRMAN: In a sense the approval comes whether the department and the trust, to take two examples, accept your recommendations or say, "We'll accept, 1, 2, and 3, but not 4" because of their perspective on it.

A. Absolutely.

THE CHAIRMAN: But the reports do not need approval from these bodies before publication; you're giving the people involved an opportunity to check factual accuracy but beyond that -- sorry, would that draft report also include the draft recommendations?

A. It does include the recommendations.

THE CHAIRMAN: So they know, in effect, what's coming at them?

A. Absolutely.

THE CHAIRMAN: And they don't have the power to stop them.

A. And in fairness to both the service -- I mean, in the light of some of our work, I know that people working in the service said, "We would welcome the report because we were wanting that to happen. We've been looking for avenues to reinforce the work that we're doing and we're glad that recommendation has been included". And likewise, I don't think, chairman, in any of our work that has subsequently gone to CMO and



the minister -- I think in every situation they have welcomed and accepted the recommendations within our reports.

One of the pleasing things I think that I have observed as I come towards the end of my time with RQIA is the way in which the rigour for the completion, the closure of that, the loop, if you like, of that has actually strengthened. I now see the CMO or the Permanent Secretary writing to chief executives of trusts to say, "We enclose the report from RQIA. You will note the recommendations. We would like those recommendations to be put in place", and in some situations they've actually said that "We want them to be put in place by a certain date and time". They quite often follow it up with some audit tool or other vehicle to provide assurance to the department or to the Health & Social Care Board that those recommendations have been put in place.

And if the department or the minister are unhappy about that, then they could ask RQIA to go out and do a subsequent review to assure them that the recommendations have been put in place. So the rigour of that, I think, has significantly tightened in recent years.

MR STEWART: And we can see an example of that in terms of



the RQIA work with Alert No. 22. In what format is the review published? Is it available online?

A. All of our inspection reports in the care sector, the regulated sector, and all of our review programmes are all published on our website. They're publicly available and we print them -- obviously, a small number -- for distribution to key organisations. But so far as the public are concerned, they are all publicly available.

The public are increasingly -- we ... I know we want to stay with the statutory sector, but if we use some of the experiences that we've observed in the regulated sector, we've done two things. We not only now publish the inspection report, but we also, where we've had to take enforcement action in the regulated sector, we now publish on our website any enforcement action that we've taken. So if a family member is concerned about a particular care home or residential home, nursing home, children's home, and they're aware that failings or shortcomings have been observed by RQIA, we actually put the action that we require the organisation to put in place. So that's publicly available as well.

Q. That brings us, I think, to 2008 and the RQIA involvement in its review of the implementation of



Alert No. 22 and the extent to which the guidelines, the wallchart, had been properly disseminated. Were you yourself involved in this piece of work?

A. No. It's important to recognise the role and the responsibilities of the chairman of the board. All of our board members are non-executive directors, we are not involved in the operational side of the work of RQIA. But we hold our own executive team and the -- what I would say -- the chair or the leadership of any review team, we would actually hold them to account, if you like, in terms of the delivery and the ... It's extremely important. This is another important issue because comparisons can and inevitably are made between the role of regulators, RQIA vis-a-vis CQC. It's extremely important for me personally -- and, I think, for the whole of our board -- that the work that we do is of the highest possible quality.

There is no point having a regulator who's there to oversee and assure public of the quality and safety of a service if we do not ourselves produce work that is ultimately of the highest quality and standard. So the board's role is very much to make sure that the products that come out of RQIA are not just fit for purpose but are of a high standard.

Q. In terms of the 2008 review, it was commenced by sending

out pro forma audit papers to the individual hospitals, followed up by validation visits, but not all hospitals were subsequently visited. Was that something which would not happen now? Would all hospitals be visited in such a review?

A. Um ... Sorry, could you clarify what you mean by "not all hospitals"?

Q. That is something which does appear from the papers.

A. I think every hospital where children were being admitted was inspected.

Q. Very well. It's a comment that appears from a letter from Jim Livingstone, director of safety, quality and standards, to Alice Casey, interim chief executive of RQIA, which appears at 330-045-001 and 002.

On the first page, the left-hand side, bottom paragraph, we see it's in relation to the independent review in 2008 and it is noted:

"While your review notes that HSC trusts and independent hospitals have undertaken considerable work to reduce the risk of hyponatraemia when administering intravenous fluids to children, it also makes clear that there is still some way to go before full compliance with NPSA Safety Alert No. 22 is achieved."

Then on the right-hand side there are a number of bullet points, the third of which is:



"I note that the review does not cover all hospitals. We need to be able to assure ourselves about the implementation of the NPSA Safety Alert No. 22 in all hospitals, including the Mater, Royal Victoria and Belfast City hospitals, on an individual basis. I should be grateful for the RQIA's views of current practice in these hospitals and whether it is content that representation from these hospitals at the discussion group was sufficient in this regard."

On the subsequent 2010 review, all hospitals were visited?

A. Yes. I cannot recall this, Mr Stewart, specifically. I can certainly look into it.

But my understanding was that in the initial review, those hospitals that admitted children specifically into children's facilities were reviewed in the 2008 report. But as you say, this was done at a time of significant change in the health and social care system with the review of public administration, the restructuring of trusts and so on and so forth. The 2010 report obviously was post-reorganisation and maybe covered that more fulsomely.

THE CHAIRMAN: Just for those who don't know who the writer of this letter is, Jim Livingstone, who's now retired, was a very senior official in the Department of Health



in Castle Buildings.

A. He headed up SQS, the directorate that was our sponsor branch, and he would have reported to the Chief Medical Officer.

THE CHAIRMAN: Yes.

MR STEWART: And indeed the recommendations arising from the 2008 review extended to 16 recommendations. I wonder, can I draw attention to one of them? And in fact if we can go to the next page on the letter before us to page 003. Dr Livingstone, in his final bullet point on the third page, makes reference to the fifth recommendation:

"Re NPSA recommendation 5. The review notes a general culture of under-reporting. Presumably this is intended to apply to all incidents and not just incidents related to hospital-acquired hyponatraemia. This finding is particularly worrying, especially in light of the RQIA's clinical and social care governance overview report for 2006/2007, which noted an increase in independent reporting and gradual change towards an open and learning culture. Perhaps RQIA could clarify this point."

We're interested, of course, in the culture of under-reporting. Did you find the RQIA review informative in relation to the reporting issues?



A. Sorry, did I?

Q. Did you find the report informative for you in terms of the under-reporting issues?

A. We find all of our work informative and we obviously learn from every investigation or review work that we conduct, and we use that experience to build and strengthen subsequent work. But certainly we would have been conscious -- and I think it would be an accurate reflection -- that within the health and social care system the process of reporting has improved and increased, and subsequently with the recommendations that came out in 2010 through the new reporting arrangements, I think they further enhanced -- and while we haven't looked at or reviewed that subsequent to the guidance that came out in 2010, there is every opportunity for that to be built into the subsequent work of RQIA and we'd be interested to look at that.

MR STEWART: Sir, I wonder if this is a convenient moment?

THE CHAIRMAN: Yes. We'll take a break for a few minutes and resume, Dr Carson.

(11.25 am)

(A short break)

(11.40 am)

MR STEWART: Dr Carson, the consequence of the 2008 report was that the department asked the RQIA to repeat the

review two years later, with particular attention being paid to serious adverse incident reporting and children receiving treatment on adult wards.

This was then conducted in 2010. First of all self-assessment questionnaires were sent out and then announced visits were paid to all hospitals. And indeed, considerable improvement was found in compliance in 2010, but eight further recommendations were nonetheless made.

We find the recommendations at 333-159-022. It's not coming up. The recommendations dealt with the findings. There had been a substantial decline in the use of Solution No. 18 by this time, some recommendations in relation to the continued stock that remained. Particular attention was then paid to, again, the incident reporting systems. The conclusion of the report indicated that:

"Health and Social Care Trusts and independent healthcare facilities in Northern Ireland have good operational control of the administration of intravenous fluids to children and compliance with the NPSA Safety Alert No. 22 has been substantially achieved. This is very significant and there is evidence of effective action on the part of senior managers and clinicians."

However, the conclusion went on to say:



"There is good evidence of staff awareness of incident reporting systems across all sites visited, but limited evidence of robust systems for putting the learning from incident reporting into practice."

This is the essence, isn't it, really, of clinical governance, of closing the loop, of getting the lessons learnt implemented and working? How useful has the RQIA work been in actually closing the loop?

A. I think we're getting better at it. I think certainly our initial reviews -- we were maybe presenting findings and leaving that as a, if you like, closed statement rather than trying to ensure that there was a demonstrable change in practice taking place. I think in our recommendations, as we now construct them in our reports that we've been issuing in recent years, we've been trying to make sure that the recommendations provide an opportunity for either the department or the Health & Social Care Board or trusts themselves to actually bring about a closure or a demonstrable improvement in their systems and processes.

I think when we construct our recommendations, that's, if you like, part of the psychology behind any recommendation. Rather than just come up with a finding and say "This should change", we're trying to -- one of the key roles for RQIA as a regulator is actually to



bring about improvement. Our board, as an organisation, see that as being one of our key roles as a change catalyst and a vehicle for bringing about improvement. And I think if you take, for example, the hygiene inspections in hospitals, okay, there are other factors that come into play, but we are see reduced rates of MRSA, of reduced rates of C. diff. So I think there is evidence to show that the work of RQIA is actually bringing about improvement.

Q. Is there any evidence that it's bringing about improvement to the culture of organisational safety?

A. Well, that is actually a key question, I think, and it is a key issue that will emerge from not just this inquiry but also from the Francis report, obviously, in England. People have been talking about this culture change for years. I mean, this is not something that's just emerged in the last year or two, and I can take you back to the mid-90s as well where discussions about culture were still very much in -- okay, a lot of it was about professional culture. I think what we're talking now in recent years has been about institutional culture rather than professional culture, and I think there's still a fair bit of work to do this in terms of institutional culture.

I mean, you heard obviously from the Belfast Trust



yesterday and you've heard elsewhere and you'll hear from the department. I think they will evidence and they can evidence that change is being brought about, but I still believe there are -- and I will maybe, towards the end, make reference to other comments or insights about how this can actually be achieved and the risks to not achieving it.

THE CHAIRMAN: You're the person, I have to say, doctor, who's expressed very directly and bluntly the problems with change in culture at this inquiry. You're the person who's said to me more than once that the service is good at announcing or proclaiming its triumphs, but not so good at recognising and correcting its weaknesses.

A. I'm very aware that things I've said have been used to question and challenge other people. When I made that comment, I genuinely meant that, professionally, individual doctors were very reluctant to publicise their failures. How I would caveat that now is that when a consultant stands up at a professional meeting or with his colleagues in a department in an audit meeting to talk about his successes, those have usually been built on failures or difficulties or challenges.

I worked in cardiac surgery and anaesthetised children for a congenital heart disease and we were very

conscious in the mid-1990s about the issues around the Bristol heart inquiry. I would have attended professional meetings where I heard surgeon X or surgeon Y describing how he'd had wonderful results doing surgery for transposition of great(?) vessels. But his achievement in achieving success was usually built on difficulties or problems that he'd previously encountered or that other people had encountered. So building -- I think there is ... Whilst I was maybe being a little bit dramatic in the use of that phrase, I would have to recognise that success comes out of the acknowledgment of failure. And I think that's still the case today. I think a lot of advances that have been brought about, particularly in the surgical area, have been successes that have come out of earlier failure or poor results elsewhere.

THE CHAIRMAN: Thank you.

MR STEWART: Perhaps we'll leave it to your closing comments to address that.

The 2010 review noted much improvement, but did nonetheless say that:

"There [was] a continuing potential risk associated with intravenous fluids administered to children on adult wards."

A. Yes.



Q. And indeed, we've said there was limited evidence of systems for putting learning into practice. And subsequent work was undertaken in 2012 in relation to care of children on adult wards, but in the meantime there was some work undertaken to monitor the progress of the various hospitals in terms of implementation, and we can find in a letter at 330-056-001, if that's possible, a letter from the standards and guidelines unit at the department, where it sets out some of the -- it's an update on the progress on the implementation of the recommendations of the 2010 review:

"The current position as reported by trusts [and that's in 2012] ... significant progress has been made by all trusts in implementing the recommendations. There has not yet however been full implementation."

And that's in relation to the -- and various heads are set out in relation to what may yet be done. But it is to be noted in the first bullet point, regarding the potential for the complete removal of No. 18 Solution:

"All trusts have complied and No. 18 is no longer stocked."

If we go to page 003, we find there in the final paragraph:

"Dissemination of learning from adverse incidents. Trusts have confirmed arrangements are in place to



ensure that incidents are reported and that learning from incidents is appropriately shared with trusts and across trusts as required."

How confident are you that the trusts have indeed put in place robust systems for dissemination of learning from adverse incidents?

A. Well, I think, chairman, that will be a continuing piece of work for RQIA. I note we're not copied into -- RQIA as such haven't been copied into that particular correspondence. One can never give full assurance that full compliance will ever be achieved. This is not a perfect world, unfortunately, that we live in. But I think what we are striving to do is to reduce the opportunities for non-compliance to come about. This will be continuing work, I suspect, in every area because adverse incidents -- they can emerge in every sector. It is a complex field when you consider mental health issues as well as children's services.

I think the important thing for us will be actually to continue to monitor this in every area where vulnerable patients are in receipt of care across the health and social care system. Obviously I can't give this blanket assurance though.

THE CHAIRMAN: Can I ask you this, because this raises an issue for me about the interplay between the HSCB and



the RQIA. You have pointed out that you're not copied into that. That's a letter from the Health & Social Care Board, which in a way has replaced the four area health boards; right?

A. Yes.

THE CHAIRMAN: And that's going to the standards and guidelines unit. That was Mr Livingstone's unit, I think, in Castle Buildings. We heard -- and in this context, if we could bring up a paper which your solicitors were kind enough to forward to us yesterday. It's the initial response to the Mid-Staffs inquiry report, which has been prepared by RQIA.

A. Yes.

THE CHAIRMAN: And if we bring up 338-015-002 and 004 together, please. I'm bringing up 002 because that will show everybody who hasn't seen this document so far what the document is. And then you go on, or the RQIA goes on, on the right side of the screen, to set out your initial response to the Francis report.

In the middle of the page, at 3.0, you say that one of the actions needed is:

"[To work] with DHSSPS, HSC arm's length bodies and other regulators to ensure a comprehensive system of intelligence gathering and sharing ... This would include, for example, information from complaints,

whistle-blowing, incident reporting."

Et cetera. I have heard from the Belfast Trust yesterday -- and I will hear from the HSCB tomorrow -- about the development of serious adverse incident reports. As you may know, from last month, apart from unexpected deaths and serious injury, it is now automatic that the death of a child under 18 in hospital becomes a serious adverse incident report. And on the evidence that I heard yesterday and the documents we have, it rather looks as if the serious adverse incident system has been developed to ensure that, for instance, what happened in Claire's case could not happen again.

It would automatically become an adverse incident report, even if there was no query immediately raised about medical mishap, if I put it like that. And then that in turn, that investigation takes place within whatever trust is primarily responsible for the care of the patient, but it's overseen by the HSCB. Do I understand it then that that system does not involve the RQIA? I've rather gathered that it doesn't, from what you have said.

A. I suppose it doesn't appear in a formal sense. I will maybe need to check on this.

THE CHAIRMAN: I'm not complaining or saying --



A. I understand.

THE CHAIRMAN: I'm just probing what the relationship is.

A. Well, we have a meeting -- our officers meet with SQS on a bi-monthly basis at the moment. So if there were issues coming up from the board and from trusts to the department, the SQS directorate -- there's every opportunity for them to raise those issues with us in RQIA. I think what we are getting at here in point 3, however, is slightly wider than that. I think there is a real need -- there was talk some years ago about a duty of cooperation.

THE CHAIRMAN: Between who?

A. Within the NHS. To the best of my knowledge, this concept never emerged, it was around the time of the duty of candour, the duty of quality, all these statutory duties were being talked about. But there was talk certainly in the NHS about a duty of cooperation. In a sense, if you like, the memorandum of understanding that the Health Service entered into with the Court Service, for coroners, Health and Safety Executive, that was an attempt to create a duty of cooperation. In other words, whenever an adverse event -- there would be ... the key players would not only inform each other, but they would cooperate with each other in terms of how the operation would be outworked and handled.



I think there's a wider issue around cooperation because not every statutory organisation, if that's the right word, has got all of the information on its dashboard. People talk about the dashboard that gives you early warnings of what's going on. Now, RQIA doesn't have all of those, we don't have all those dashboards illuminated, if you like, because we are not the repository of that information. Trusts will have some, the commissioning board will have others, the department ... I think there is something about a duty of cooperation and sharing of information so that nothing comes as a surprise to the department. Nothing also should come as a surprise or late to RQIA as a regulator in terms of enabling it to take action.

THE CHAIRMAN: Well, no single organisation can expect to know everything. If you were told about all the serious adverse incidents, you'd be swamped.

A. Absolutely.

THE CHAIRMAN: For instance, there is a six-monthly report which is done by the HSCB in conjunction with the Public Health Authority, which highlights some of the more important or significant serious adverse incident reports over that period and indicates what the next schedule of work will involve, so, for instance, a report published earlier this year indicated that



a phase of their work in the months ahead would be to review all incidents involving people over 65 to see if there were patterns or trends coming from that. Do you know if your organisation receives the six-monthly report?

A. Personally, I don't know.

THE CHAIRMAN: It seems to me it would be helpful if they did.

A. I would think so, I would agree. Subsequent to writing this preliminary or initial response to the Mid Staffs, we've shared this, obviously, with the department, but in relation to 3.0 on page 3, we have actually hosted a workshop or a seminar with other bodies or agencies that do have information to try and explore how we can share information in a more timely fashion. We involved the Health & Social Care Board, we involved the department -- in fact the CMO co-chaired the meeting with me, and we invited professional regulators to that workshop as well. So we are looking currently at mechanisms or means whereby this could be improved. But chairman, if that information is available, I think it would make sense, if it doesn't already, for it to go to RQIA.

THE CHAIRMAN: Well, the board will be here tomorrow, so I can raise it then. It may already happen, but in case

it doesn't ... Thank you. Mr Stewart?
MR STEWART: And indeed, the discussion picks up on something which came out of the 2012 baseline assessment of the care of children admitted to adult wards. The recommendations of that assessment appear at WS077/4, page 586.
The fourth recommendation specifically is that:
"Arrangements should be put in place to facilitate the sharing of learning and good practice between organisations in relation to the care of children in adult wards."
Is that, in a sense, a part of what you're talking about, the sharing of information?
A. Yes.
Q. Has that been taken forward in relation to this particular situation of children in adult care settings?
A. In relation to this report, I know that ... I certainly received a letter of confirmation from Michael McBride, indicating that the minister -- not only had he approved the report, but that the department would be working with the Health & Social Care Board colleagues to ensure that the recommendations in that report are taken forwards. The specific steps to achieve that, I personally am not aware of. I do know that, for example, the Public Health Agency held a conference on



the care of the acutely unwell child and young people. That was held in March this year.
Dr David Stewart, our director of reviews and our medical director, presented the findings of our report at that conference and Dr Stephen Playfor, who was our independent external expert, was also speaking at that conference on age-appropriate care. And I do know that discussions and plans are being undertaken by the Health & Social Care Board and the department to agree the age at which children should or should not be admitted to adult wards and where this boundary, age-wise, 16, is put in place. But there are other recommendations contained within that report that go beyond -- I mean, there are other problems when children are looked after in adult wards that go beyond intravenous fluids administration. There are issues around child protection and so on and so forth and the skills that are there.
So I am conscious -- and again because this is largely ... Many of these recommendations relate to commissioning and the standards that are put in place for the care of children in our hospitals. Again, that will come down to what I would call commissioning standards and standards to be set by the department.
You have heard on other occasions about the use of



what are called frameworks. And one of the sets of standards in addition to what I'll call the minimum quality standards the Department of Health are creating frameworks for care around whether -- whether it be around coronary heart disease, whether it's around stroke or whatever.
There is a framework for the care of children. I don't think that framework has yet been completed, I think it is in draft form, but one would hope that in such a significant document as a framework document for the care of children that some of these key findings that are picked up in reports by RQIA and other sources would be built into that framework. And that would then set the standard for the health and social care system.
Q. Yes.
THE CHAIRMAN: But that leads into practical issues, doesn't it, doctor? For instance the announcement last week or the week before about the redevelopment of the Children's Hospital is, as I understand it, envisaged to allow children up to the age of 16 to be treated there, which is not quite the position at the moment.
A. It's not the case at the moment and it does raise issues, not just for nursing and other support staff, but it does raise issues for clinicians, doctors, who are looking after this adolescent -- as many of these



children with complex, chronic disease processes in previous years would have not survived into adulthood, they are surviving into adulthood and there's a whole area of specialism around that that needs to be developed.
THE CHAIRMAN: You know that only a few weeks ago we were looking at some aspects of Conor Mitchell's case, and one of the concerns was where he was treated in Craigavon.
A. Yes.
MR STEWART: Indeed, it should be pointed out, sir, that in March of this year the HSC board announced that, by 2015, plans would be implemented for all paediatric services to admit children up to their 16th birthday. So essentially that's an example of the RQIA influencing policy?
A. Yes, it is.
Q. One of the tasks of the RQIA, of course, is to assess its own impact. How is that done and how do you know if the RQIA is succeeding, quite apart from that example I just raised of policy being influenced?
A. Yes, it's an important question, it's an important question for my board, it's one of the factors that a Board, a public board of a public body, is there to do. We are there to determine the strategic direction

of the organisation, develop the strategy for the organisation, and we have done a lot of work in recent years to try and refine our strategy. And certainly we have four areas: obviously the inspection, the improvement agenda, but also this final area of influencing -- influencing policy, and again this can be difficult at times for an arm's length body when they're in a relationship with the sponsoring department.

But I think what -- and all of these systems regulators -- I mean, I look with some concern in a sense at events in England. Over the period that I've been involved in RQIA, it's been a very troubled journey. And while we got off ... I recognise -- and I think everybody recognises -- we got off from a maybe a slow start in Northern Ireland in terms of putting in place a quality and safety agenda. While that may well be the case, I actually do think our system is now maturing. I do think that the evaluation and the assessment of quality in our service is improving, it's becoming more rigorous, it's becoming more genuinely evidence-based. And I believe that's the direction of travel.

But the points you're asking specifically is: how do we as a board assure ourselves? That's a difficult question. It involves a discussion, I think, with our



department. I know that public bodies like ours are subject to regular review, it's written into our management statement that the department would sit down with the arm's length body just to have this difficult conversation to make sure that, (a), we're providing value for money, (b), that we're actually helping and supporting the system and service that we work in and that we're actually fulfilling our statutory requirement.

And that's a discussion that needs to take place on a regular basis, whether it's every three years or every five years. It should take place every time an organisation writes its corporate strategy. Our corporate strategies are usually for a three-year period and if there was a weakness in it, then that needs to be discussed. It needs to be pointed out either by the body itself or by the government department that's responsible for ...

And let's be realistic. Government -- and I use that in general terms -- are usually responsible for creating these bodies in the first instance, quite often as a result of failure in the system. So there is a real need to make sure that it's still fit for purpose. We, as a board, do review our work programme. We have very serious discussions at board meetings



around -- and in our board workshops -- the direction of travel and how do we ultimately assure ourselves, and subsequently the department, that we're doing what we're required to do under the order.

THE CHAIRMAN: Okay.

MR STEWART: Looking forward now, the reviews for the next few years. Could we look, please, at page WS077/4, page 133? This is the programme for 2012 to 2015. On the left-hand column, the fifth item down:

"National Institute for Health and Clinical Excellence guidelines: topic to be confirmed."

To what extent do you work to review the implementation of NICE or, indeed as we saw, NPSA guidelines?

A. Chairman, we have actually completed our review of the implementation of NICE guidelines. That was published this year. Subsequent to that, the Chief Medical Officer has written to the service on 17 July with a letter entitled "Revised process for handling NICE guidelines". So in a sense, again I think there is evidence that RQIA, as a consequence of its work programme, have -- our report was published in July 2013. It was a baseline review of the implementation process in health and social care organisations of NICE guidelines.



The department working with the Health & Social Care Board have put in place a revised process for handling NICE guidelines. So again, that would be an example of where a piece of -- a review carried out by RQIA has helped the department see a way forward for implementation of NICE guidelines throughout the service.

Q. Does the RQIA work with other regulatory bodies in partnership or collaboration?

A. Since the organisation was established in 2005, I would say in the early days we had quite close working relationships with sister organisations in Scotland and in Wales and, to a greater or lesser extent, in regard to England. The system in Scotland and Wales, they have separated social care regulation from healthcare regulation. Scotland likewise have separated social care and healthcare regulation. Northern Ireland, because we've always had this integrated health and social care system, which I believe was one of the contributing factors in terms of developing clinical and social care governance -- it was a slightly more complex framework, it was one of the contributing factors to a delay. But setting that aside, our remit is much closer to CQC in England than it is with Scotland and Wales.

We do have meetings on -- I was going to say "on a regular basis", they have become less regular as the systems in the devolved countries have become more bespoke to suit the needs of their community. But in addition to that, we actually -- and RQIA are very closely involved working with organisations Europe-wide. There's an organisation called the European Partnership of Supervisory Organisations, which means regulators, and we've been working quite closely with colleagues in Denmark, Norway and elsewhere, and Scandinavian countries have got some really very good systems in place and we would work quite closely with them. In fact, our chief executive is currently involved in a piece of review work in Denmark, assuring the Danish government on the systems and processes that they have in place.

So through vehicles like that, we do try to learn and keep abreast of developments in other regulatory organisations. We also have close working relationships with professional regulators in the context of Northern Ireland and the Northern Ireland Social Care Council, who are responsible for the professional regulation of social workers and social care staff, the General Medical Council and the Nursing and Midwifery Council. They were invitees to the conference or



workshop that we had on information sharing. Because there's information that comes through the professional regulatory route that may not come through to a systems regulator. So there's got to be very close working relationships.

Q. Thank you. In the central column before us, "2013 to 2014", fifth item down:

"Planned review of governance arrangements in health and social care organisations (including those that support professional regulation)."

Has that been conducted?

A. That work's underway as we speak, yes. It follows on to a certain extent from some of the specific work that we did in regard to the preparedness of health and social care trusts for the revalidation of doctors. This is extending it beyond doctors, but it's building on that piece of work. I think that's an example of where -- when we see an area of work we want to not say, "That's done and dusted", and you put it on the back-burner and leave it for another five or ten. We want to try and build -- where things are in process of change or evolution, we want to, as part of our improvement agenda, to keep the momentum going, and that's an example of how a review in that particular area can do that.



Q. This particular review of the governance arrangements, would it also include "a review of reporting, investigation and learning from adverse incidents, complaints handling, whistle-blowing"?

A. Well, we're looking specifically at that in 2014/20015. If you look on the right-hand column, the very first project there is specifically looking at --

Q. We can go to pages WS077/4, page 141 and 142. On the left, you'll see, at paragraph 4.3.5, this is the review of the governance arrangements that we're talking about. And then it goes over to the next page:

"RQIA will review the governance arrangements within the HSC organisations which are designed both to assure the quality and to also assure the public that all health professionals are fit to practise. The review will include, but may not be limited to the following issues: reporting, investigation and learning from adverse incidents, complaints handling and whistle-blowing, human resources, risk management, dissemination of alerts."

So in a sense is the work going to be duplicated in two reviews?

A. I'll need to confirm that with colleagues. In the emphasis that we put on reporting, investigation and learning of adverse incidents we may deal with that at



a lower level in this particular review. Sorry, we may look at it in this review at a fairly high level in terms of the institutional governance arrangements in each organisation, but I think the work that's planned for 2014 is going to be much more specific, drilling down into looking at not only how effective the reporting arrangements are, but how well they are understood and how well they're used by staff.

There's two levels to this. There's the institutional adherence to the systems and the principles, and then the other one would be looking more at the delivery and the outworking of it. But it does illustrate in a sense the way we want to try and move the whole system forward over a work programme of three years.

Q. Let's just go back to that programme again at WS077/4, page 133. On the right-hand column we see the review discussing:

"Adverse incident management reporting and learning."

And below that:

"Advocacy services for children and adults."

That's a separate review?

A. Yes.

Q. What provoked or prompted that to be included in the

review programme?
A. I think that is a classic example of where, during our consultation on our work programme, service users have said to us that the arrangements for advocacy are either poor or not consistent or patchy, whatever language you want to use, that there's inconsistencies, variable levels of support. So I think that has been triggered by service users, by family members of not just children, but maybe adults with learning -- children or adults with learning disabilities. It tends to be stronger in Mental Health Services than it is across what I will call general hospital services. So I think that's maybe the sort of thing we would want to try and tease out.
THE CHAIRMAN: That would involve the Patient and Client Council?
A. That is an example of where we would want not only to use service users in it, but we would want input and consultation with other agencies like the -- such as the Patient and Client Council --
THE CHAIRMAN: Yes.
A. -- and their scheme. I've forgotten the name of their scheme. A cohort of about 12,000 people who --
THE CHAIRMAN: It's their membership scheme?
A. Membership scheme, that's the very word, thank you,



which we don't have and there's no need for us to replicate, it was already being in place. So we would be in discussion with the Patient and Client Council on issues like that.
THE CHAIRMAN: Yes.
MR STEWART: I find reference to a thing called the Patient and Public Involvement, PPI, Forum.
A. Yes.
Q. Does that feed into this work as well?
A. It may well. At this moment in time, I'm not actually fully up-to-date on how that's being structured or planned, but I would suspect that one of the things that we will be wanting to explore would be the depth of patient and public involvement in planning of services and the delivery of services and the advocacy for service users, particularly for those who are vulnerable and disadvantaged.
Q. Do you see the workload of the RQIA increasing in the years to come?
A. We're working at full capacity at the moment, Mr Stewart, and I think this is -- and there's a ... As with everything in the Health Service, there's a limited resource to enable this sort of work to be done. It does mean that if that resource is confined, or defined and confined, then you've got -- we are, as an



organisation, obliged to work within that. That means we've got to make some difficult and critical decisions. I would hope that -- I would hope that our improvement agenda will continue to be influential and so on. Our ability to respond to events is -- is more confined.
We can't deal with every severe and adverse outbreak that may emerge. And there have been examples in recent years where -- I'll make reference to one. There was a problem in the school of dentistry a couple of years ago at the same time as we were embarking on work on pseudomonas and there was no way we could take on another critical review at that time and the minister decided to go down a different route; he appointed a legally qualified chair to ascertain the facts.
Now, as a ... I need to be careful. To the best of my knowledge, we are being asked now to follow up on the implementation of those recommendations. I'm not sure whether that was publicly knowledgable at the moment.
THE CHAIRMAN: It is now.
MR STEWART: Can you think of ways in which the RQIA might be better enabled to fulfil its functions, apart from the obvious of more money?
A. Well, I don't want to sit here and say, "I think we're doing a great job and everything's fine". I think we are fulfilling our remit and I think also -- and



I can only reflect on the early days when I joined the organisation. I think the department had created this body, but weren't absolutely sure, you know, was the rabbit out of the hat? Could they control this if they let it loose and was it going to create all sorts of problems? And I think some of those, what I would call, early uncertainties have actually resolved and we've got a very constructive and fulfilled working relationship with the department.
Can I draw some comparisons to our equivalent organisation in England? When clinical governance emerged in England in the late 1990s, they established the Commission for Health Inspection, CHI. Now, within a matter of a few years, it had changed from CHI to CHAI, the Commission for Healthcare Audit and Inspection. It was then morphed into the Healthcare Commission and subsequently has re-emerged as CQC. So in a period of eight to ten years, the body itself has changed, there's been no stability, and I have to say it's an example, I think, of political interference. There's no other -- I mean, this is not just me saying it; this is well recognised.
So there is something extremely important that the political framework, the political environment, the Civil Service that oversee -- that there's

a constructive and a sensible way forward in terms of regulating quality and safety in health and social care. And I think, despite our slightly slow start -- which I would acknowledge, it was frustrating at the time, I have to say -- but I do think that we now have a model in place that, in the Northern Ireland context, given our scale, is actually effective and I think it's working.

It's very interesting in the light of the Francis report and again the further changes that have taken place in England with CQC now creating a Chief Inspector of Hospitals, a Chief Inspector of General Practice, a Chief Inspector of Social Work. I think there's a figure of 45 million, I think, has been the additional resource that's been put into CQC and it has just heightened and intensified the whole subject of the inspection and review of healthcare services in England.

THE CHAIRMAN: But you don't -- do I gather what you're saying is our system has now fallen into place, people know what they're doing and, for the size of our jurisdiction, while you would always like more resources, more budget and more staff, maybe the system is working on a general level pretty well?

A. I believe that it is. That's not to say that there can't -- I mean, as we're looking for improvements



in the services, I think we as an organisation will continue to want to seek improvements in the way in which we do our work. So one can't say that there's no opportunity or need for improvement; we would see that as being as important for us as it is for the service.

But I think, given the context in Northern Ireland -- and I think there is a real need, chairman, to get a balance in here, a balance that can provide the necessary public and parliamentary assurance to the Assembly that things are being scrutinised to an appropriate degree that still enables the services out there to deliver the care without being burdened by the bureaucracy that is sometimes associated with over-regulation.

THE CHAIRMAN: Yes, okay.

MR STEWART: In terms of the recommendations of the Francis report, does the RQIA foresee any role in implementing them in Northern Ireland?

A. Well, the Francis report, the chairman will be conscious, has 290 recommendations in it. 100 of those recommendations relate to regulation and that's, I think, quite a significant commentary that a third of the recommendations relate to the systems and process of regulation, whether that's professional or system regulation.



So there are obviously -- there are ... And I understand that government in London, if they haven't responded publicly today with their final -- or yesterday or today -- with their final report on their response to the Francis report, it's certainly imminent. And I suspect not only will RQIA look at it, but I'm sure the DHSS will want to scrutinise that, and in fact our contribution on that interim report was to help them form the department's thinking about a way forward from Francis.

There inevitably will be issues for us. I think some of the things that have been put in place in England by way of response at this stage, I think we will have to wait and see whether that increases the level of trust or trustworthiness. I want to touch on that maybe at the end.

As I've indicated, the tougher you make this regime of scrutiny and regulation, in a sense it almost builds distrust in the system that it's overseeing. If you have to have this so tight, so tough, the system must be really poor. So in the public eye, it can actually create a lack of trust in the system. So there's an important and a delicate balance to be achieved, and that's going to be, I think, an issue for our own department in the light of the findings,



chairman, from your report. But also taking ... They cannot ignore -- they cannot ignore significant findings such as the Francis because the type of care that we're delivering across these islands and the conditions, the vulnerability of patients, it's exactly the same. So there are bound to lessons in there that are applicable to Northern Ireland. It's just how we, in the context of our scale and in the context of the expertise that exists in Northern Ireland and the tools that are readily at our disposal to actually give that assurance --

Chairman, I came across ... In my preparation for today, I came across a final report of what's called the National Quality Board in England. I have made that available to my legal team and they were going to forward it on. The National Quality Board in England is chaired by the outgoing chief executive of the NHS, Sir David Nicholson, but within this National Quality Board all the leading players in relation to quality and safety and systems regulation are members of this national board. In addition to that, they have a number of what I would call experts who sit on this board and I'm sure there are patients and clients and service users contributing to it as well.

But that board actually provides advice to the

Department of Health in England in terms of how things are going to move forward from April of this year. I think it's actually quite a useful document and it would certainly be a document that would be worth our own department having a close look at. We don't have -- and this is the problem of scale in Northern Ireland. We don't have a National Quality Board. In England, they can draw on so many other different sources of advice and expertise that's not available in Northern Ireland.

Quality 2020 is the significant strategy document for taking forwards quality and safety in Northern Ireland. There's a steering group and there's an implementation group, and RQIA, I think, contribute to that implementation group. But there are some, I think, quite interesting signals emerging in England that we can't reproduce because we don't have necessarily all these instruments at our -- but we've got to learn from them, we've got to gather our own intelligence and build on them.

So I think I've made that available and you may find it useful for Friday.

THE CHAIRMAN: Thank you very much.

MR STEWART: You mentioned, Dr Carson, that you would like to make some comments in closing, some summary



conclusion remarks.

A. Well, I think the Francis review, and this particular inquiry's report, are going to be highly significant. I think for RQIA -- I think we would like to get into the position where we could provide assurance by monitoring the safety culture in the health and social care system.

I think it's important also for RQIA to look for breaks in what I'll call the governance chain. And also, I think one of the key recommendations out of Francis was the need to -- the greater emphasis that needs to be placed on the experience of patients and families. And I think that, I'm sure, will fit within the recommendations in your report.

An awful lot of -- this isn't the right way to express this and I'm a bit conscious of not expressing myself well, maybe, in the inquiry in the past. But there's been -- this is not the right word -- tokenism in regard to ... I will go back to ... At the times when trusts were set up, many medical directors sat on trust boards as the token doctor on the trust board, somebody wearing the white coat, somebody who, when the media were there, could address questions and that's certainly my experience to an extent in earlier days. I think there's been an awful lot talked about valuing



the contribution that patients and their families or careers can make to the development and the improvement of services.

I think that really needs to accelerate and be developed much more consistently and more robustly than it has been in the past. I've said already that I do think that there needs to be greater information sharing, and whether that information sharing should be made mandatory or not is a question that I would ask.

I think the health and social care system has gone through -- I would use the language of "unprecedented change". I noted Professor Scally's opinion that that had been greater in England. I think it's been very significant in Northern Ireland as well, not least because of what I will call the local and political dimension that's attached to hospitals and health services.

So it has been significant and we've gone through significant reorganisation. We've got now very large organisations, and whenever I say I want to make sure that there's no breaks in the governance chain, with large organisations there is always the risk that it becomes so large that that governance chain breaks down. But I think, on the counter to that, we've now got a system with five or six trusts, as it now is, that it



should be more consistent regulation across the system than was certainly the past when we had 19 trusts. And one of the major problems in England, with 360-plus organisations, is that getting consistency across the system is very difficult.

I think one of the -- a lot of -- there's been a lot of talk in the inquiry about openness and transparency. I think even more -- maybe more important than greater openness, I think there needs to be greater responsiveness in terms of timescale than there has been. I think the Health Service needs to respond much more quickly.

I've said already this morning that any delays that come into -- breed doubt and suspicion about wrongdoing and I think many of the processes that should be there to provide information to families, whether that's the complaints process, whether it is the necessity to go to litigation to find out exactly what happened or whether it's coroner's inquests or whether it's actually reviews and investigations, these things need to be done in a much more timely -- a shorter time frame because any delays do contribute to suspicion and doubt.

I think also, sadly -- I mean, the use of language is extremely important. We've seen in the context of this inquiry what some people have said has been either

misinterpreted or not fully understood and has led to heightened concern and anxiety. I think the media have got an important role to play. I don't want to downplay or criticise the media, but they do have an important role to play, and this comes back to this subject of the use of language and a sense of balance.

I think, for example -- and in the context of this inquiry, when a programme goes out with a title "When Hospitals Kill", that immediately puts the system into the defence mode. So language is extremely important and the media have an important role to play.

Obviously, we need to rebuild trust -- and chairman, just by way of final comments I would like to make reference to comments that Baroness O'Neill has made recently. Ten years ago she gave the BBC Reith lectures, and I have met and I have spoken with Baroness O'Neill and I'm hugely impressed with her intellect and her assessment of this whole area of trust.

Ten years ago she gave a Reith lecture, but recently she has wondered whether the often-asked question "How can we restore trust?" -- she's asked the question "Are we missing the point here?" She has argued that raising the bar of scrutiny, by making it more onerous, newer and deeper systems may have intensified the doubt in the



public eye that the system -- and in our case, the health and social care or the NHS system -- is trustworthy.

She goes on to say:

"Systems of accountability won't make trust easier unless people have reason to trust the systems. If they are too complex or designed for other purposes --"

And sometimes some of the accountability arrangements are in fact designed for other purposes but they've been applied to health and social care systems. Most people find them difficult to understand and to follow.

She goes on to say that:

"Transparency is another fashionable remedy, made easy by pushing information into the public domain, but as lots of people will not find the information or will find it obscure or will not know whether to trust the information itself. Transparency itself is no guarantee that people are more likely to trust."

She goes on to say that:

"Professionals who take time to listen, who use plain language, who open themselves to check and challenge, who offer others the opportunity to judge their honesty, their competence and their reliability are more likely to be trusted."



She emphasises the necessity of good communication, a factor that's been significantly missing in all of the tragic cases that the inquiry has been reviewing, and she states that good communication makes it easier to judge others' trustworthiness.

She argues that:

"What matters is not the plaintive question 'How can we restore trust?', but the practical question of 'How can we make it easier to judge trustworthiness?'"

And chairman, I still think we've got a long way to go in trying to achieve that. I think we're going in the right direction, but I still think that this is an extremely complex area, an emotive area, and it will require a lot of guidance and leadership, I think, to actually bring about organisations that, in the public eye, are trustworthy and professionals who also likewise are trustworthy and delivering high standards of care.

THE CHAIRMAN: Can I just pick up on two points there, doctor. I think one is -- I agree with you entirely about the timescale issue because if, as may be the case, the families at this inquiry think that the admissions and apologies have been extracted at great length and with resistance, whether that's right or not, that impacts on the way they receive the apologies and the admissions if they come a long, long time



afterwards. Whereas if something is acknowledged at the time or close to the time, it's bound to be -- well, I think it's almost inevitably going to be more -- create a greater impact --

A. Yes.

THE CHAIRMAN: -- and will help the families think perhaps, "Well, yes, mistakes were made. That's why our child died or that contributed to our child's death, but at least those mistakes have been recognised and faced up to without people being dragged to an inquiry years later to sort it out". So the sooner it happens, the better, and that fits in with your timescale point.

A. Absolutely.

THE CHAIRMAN: The other issue you raised was about the involvement of patients and their families in the system. I may be wrong in this, but I see the Roberts and the Fergusons here virtually every day. I suspect that they must feel entirely alienated from the system. A long meeting took place yesterday afternoon with Mr Donaghy and other people from the Belfast Trust, like Dr Stevens, and I understand that that may have helped to build some bridges, and there have been meetings with individual doctors through the course of the inquiry. But the experiences of people like the Roberts and the Fergusons might be something that the system, at some

place or at some point, could take advantage of by bringing them within the system to explain to young doctors or nurses or older doctors and nurses, "Look, when things go wrong and they go catastrophically wrong, still the best way to deal with it is to speak to those and just tell them what went wrong".

A. Chairman, I think it's essential, I really do. This is not the way this inquiry -- this ... Inquiries and investigations such as this are not the way to resolve the needs of individual families in that area. The duty of candour that we've talked about in the past was seen to be one of the means to actually address that. And I understand that in England, from April of this year, the new standard of an NHS -- the new standard NHS contract requires all NHS and non-NHS providers of services to NHS patients to comply with the duty of candour. That's in paragraph SC35 of the new standard NHS contract. So they've brought it in in England. It doesn't apply, I understand, everywhere in the NHS system, but I do think it needs to be brought in.

Chairman, I think there's another -- and this is more ... I want to move beyond maybe the families that have been most closely involved in this inquiry. But I've seen this in other situations when I was trust medical director. You would have been conscious of it



in the time of the human organ inquiry when families felt very hurt, very damaged, and carried huge burdens of pain.

Can I move on? There's something about society here as well. I don't want to imply this in relation to the families at all most closely involved with this, but I think we've got to, as a society, have some better understanding of how we redress people who have been injured -- and I use "injured" in the broad sense of the word.

Sadly, and if we look at the complaints system, the vast majority of patients who have a complaint about services in the NHS or the health and social care system, that's usually resolved at an early stage with early discussion and addressing with an explanation and often an apology. And that settles the vast majority of complaints in the system. There are always some who are dissatisfied and it almost escalates the level of their anxiety and their concern. That's what I call -- where a personal apology no longer satisfies, but then some sort of a public apology is required and the whole thing gets ratcheted.

THE CHAIRMAN: We discussed yesterday with the Belfast Trust the complaints system and they've recognised that, irrespective of this inquiry, I think, that the better



the complaints system, the more quickly problems are resolved, or it emerges that in fact there weren't problems and people need to understand that there wasn't a problem. So a better complaints system, better investigation of adverse incidents, and these were -- I think the term used yesterday was that these all come together. The difference between a complaint and an adverse incident investigation might not be as stark or as black and white as it appears sometimes on paper.

A. But I do think that families, instead of a complaint -- a complaint can be made by telephone, it can be made by a written letter. Solely to respond to that with another letter doesn't strike me as being the right way to deal with this, albeit coming from a chief executive. I think the families need to be met right at the word go.

THE CHAIRMAN: But that meeting needs to be properly planned. I agree with what you say about meetings, but the Fergusons look back on the meeting in Altnagelvin, which was supposed to achieve something which it singularly failed to do.

A. I appreciate that.

THE CHAIRMAN: Okay. Are there any issues for the doctor before he finishes? Mr McGleenan, no?

And you have finished, Mr Stewart?



MR STEWART: Thank you, sir.

THE CHAIRMAN: Doctor, thank you very much for coming today. The RQIA's role in reviewing the implementation of the hyponatraemia guidelines is important to the inquiry, but so are also your general observations and input on the role beyond that of the RQIA and your experience of the system, so I'm very grateful to you again for coming back to the inquiry.

(The witness withdrew)

Ladies and gentlemen, that finishes us until tomorrow morning at 10 o'clock when we'll have a panel from the Health & Social Care Board. Thank you.

(12.50 pm)

(The hearing adjourned until 10.00 am the following day)