Urology Services Inquiry

Oral Hearing

Day 86 – Tuesday, 20th February 2024

Being heard before:	**Ms Christine Smith KC (Chair)**
	Dr Sonia Swart (Panel Member)
	Mr Damian Hanbury (Assessor)
Held at:	**Bradford Court, Belfast**

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CHAIR: Good morning, everyone.

MS. McMAHON BL: The witness this morning is Briege Donaghy, the Chief Executive of the Regulation and Quality Improvement Authority. Ms. Donaghy is represented by Mr. Rafferty of counsel, so perhaps he can introduce himself and his instructing solicitor. 10:01

MR. RAFFERTY BL: Good morning, Panel members. My name is John Rafferty. I am instructed on behalf of Ms. Donaghy, who is your witness today from the RQIA. I'm attended today by Mr. McDermott from the DLS. 10:01 Thank you.

CHAIR: Thank you.

MS. McMAHON BL: Ms. Donaghy wants to take the oath this morning.

10:02

BRIEGE DONAGHY, HAVING BEEN SWORN, WAS EXAMINED BY MS. McMAHON BL AS FOLLOWS:

1 Q. MS. McMAHON BL: Good morning, Ms. Donaghy. Thank you for coming to give evidence to the Inquiry. You've very helpfully provided some written evidence and 10:02 I wonder if we could just formally put that in as evidence. If we go to the reply to the Section 21 notice, number 27/2023. We can find that at WIT-106000. We'll see the date of the notice sent to you was 28 November 2023. Your name is at the top of 10:02 that. If we go to WIT-106036, the signature at the bottom, and the date of 15 January 2024; do you recognise that as your signature?

A. Yes, I do.

2 Q. Do you wish to adopt that as your evidence?
A. Yes.
3 Q. We can find that at WIT-106891; we see your name at the top of that. We find your signature at WIT-10736. If we go back to WIT-106891, then if we take it to 10:03 WIT-106896. We'll see the signature at the bottom of that page and the date of 16 February 2024. Do you recognise that as your signature?
A. Yes.
4 Q. And do you wish to adopt that as your evidence? 10:04
A. Yes.
5 Q. Your final addendum statement can be found at WIT-10747. 107047, sorry, I missed a digit. 107047. We see your name at the top. If we go just down to the next page, we see a signature there and the date of 10:04 19 February 2024. Do you recognise that as your signature?
A. Yes.
6 Q. Do you wish to adopt that as your evidence?
A. Yes. 10:04
7 Q. Now we'll deal with the contents of your addendum statements, which are really just some clarification points as we go through your evidence. I'll take you to those as we need to. The main bulk of your evidence has been provided in your initial reply to the 10:04 Section 21. For the Panel's note, the entirety of the Section 21 reply, including exhibits, is WIT-106000 to WIT-106614.

Now, you have been asked to come along to give evidence as you are the Chief Executive of the RQIA, which is the Northern Ireland's independent health and social care regulator. In that capacity, the Panel obviously are interested in the function of the RQIA, what it 10:05
does, what it might do, what it would like to do and what it has the capacity to do, and the way in which it carries out its statutory agreement. So the purpose of today really is not to go through the entirety of your statement but for me to highlight some aspects of the 10:05
statement which may be of interest to the Panel, and of course then for the Panel to ask you some questions if they feel that's appropriate at the end.

Just for the note, the structure of your evidence, 10:06
I just want to break it down so you'll know the roadmap for this morning. We'll start with your background and your current role. Then we'll have a look at RQIA generally, its functions and powers, how it regulates, who it regulates and who it doesn't regulates. We'll 10:06
look at your relationship with other bodies, have a chat about the Framework Document and its relevance to your role and the way in which RQIA is funded. Then we'll look at the Right Touch Report, which is a report from 2020 from the Department, we'll have a look at 10:06
that as it suggests some grounds for reform. I'll ask your views on that and where you might be at with that. Then I'll ask about the Inquiry Terms of Reference and your knowledge of events, how RQIA came to know about

some of the issues that are before the Inquiry. Then learning; you have included some items of learning in your statement so we'll hopefully wrap it up with that and you can feel free to answer and say whatever you think is relevant for the Inquiry. 10:07

Just before we start, can I ask if you have had an opportunity to listen to the Inquiry or to read any of the transcripts or listen to any witnesses? Have you had that opportunity? 10:07

A. I haven't had a chance to listen directly to any of the live steam but I have read quite a number of the transcripts from a whole range of sources, from patients, from the Trust, from the Department of Health, SPPG, so I have had an opportunity to orientate 10:07 myself to some extent.

8 Q. So you have a good idea of the issues that are before the Inquiry and why in fact the Inquiry was called?

A. I believe so.

9 Q. I wonder if we could just start with you giving us 10:08 a brief background to your employment history and your career to date.

A. Yes. Well, as you've introduced, I'm Briege Donaghy, I'm Chief Executive of RQIA. I've worked in the health and social care service in Northern Ireland for 10:08 40 years. I am a graduate of Queen's University. In the very long time ago that I started working in the health service, my background was information technology and analytics. I'm not a clinician, I'm not

a nurse, doctor or social worker. I'm worked in
management throughout my career in the health service.
For much of that career I've worked in the Trusts, as
they are known now or have been since around 2007 -
prior to that, there was a different construct - but 10:08
I always worked out in the service delivery part of the
system. I would have worked in a whole range of roles,
nonclinical roles, so director of planning,
performance, contracting, governance, communications,
all those types of functions. For the last couple of 10:09
years before I moved to RQIA, I worked with general
practice in the reform or the move towards a greater
integration in health and social care.

But I have been working in RQIA for two and a half 10:09
years as Chief Executive. I was appointed by the
Authority with the approval of the Department. I'm an
employee of the RQIA, I am not a member of the Board,
as might be more commonly known. That's quite a unique
structure, I think, in terms of health and social care, 10:09
unlike the Trust for example. But I have the delegated
authority from the Authority to have oversight on
day-to-day running of the RQIA, including all its
staffing.

10 Q. I wonder if you could give us just a snapshot of what 10:09
the day-to-day running of RQIA involves for you as the
chief executive?

A. Well, a vast majority of it is the delivery of our
review and inspection programme. I mean, in an average

year, last year for example, we would have carried out just under 2,000 inspections, and I know we'll talk more about them later. But much of the day-to-day organising is the scheduling of inspection programmes. Although the vast majority of inspections are not announced to the provider, they are planned in advance and so we're constantly scheduling inspections across the region. We're based in Belfast but we cover a regulatory role right across the whole of Northern Ireland so there's quite a bit of logistics, staff management, those sorts of things.

The other side of it, a big part of it, is the management and assessment of intelligence that comes in to RQIA. So we get phone calls from the public, from members of staff, and quite a lot of information deliberately sent to us through what is called notification. So there's quite a lot of analysis of data and that feeding into and informing inspection and reviews. Then there's the day-to-day, you know, internal governance arrangements, managing staff, policies, procedures, keeping the Authority informed, building relationships with other organisations. All of that sort of day-to-day tasks.

11 Q. What sort of staff numbers have you at the moment?

A. RQIA is a very small organisation. In its totality if everyone was there, including all of our Authority members, there's about 140 head count. On a day-to-day basis, the operational staff numbers around 120. About

65 or so of those staff are inspectors. They are all
clinically qualified - doctors, nurses, social workers,
physios and so on. The other staff would be project
managers, admin support, IT, that sort of scale.

12 Q. In relation to funding, what's the funding structure 10:12
for RQIA?

A. Our annual income is around -- just a little over
£9 million. The majority of that comes from government
funding. So the block grant, the same in Trusts and
others, in the same way that they would be funded. 10:12
Over 8 million of it comes through an allocation from
the Department of Health. Just under a million of it
comes from fees that we can raise through registered
services. I know we'll speak more about them but some
services in Northern Ireland are required to register 10:12
with RQIA. It's an offence not to be registered, they
cannot carry on their business without being registered
and we can raise fees from those organisations. For
example, to register a new care home in Northern
Ireland is £952, and each year thereafter we can raise 10:12
a fee of £34, I think it is, for each bed or place.
Added up, that all adds up to about just under £1
million. But the vast majority comes from government
funding.

13 Q. We'll look at that structure of funding in relation to 10:13
registered services shortly.

In your first addendum statement that you provided, you
set out the staff moment in RQIA and the turnover of

staff in various posts. Could you just outline some of that for the Panel?

A. Yes. Particularly around 2020 for a couple of main different reasons, the organisation has changed, you know, enormously. In the first instance, all of our Authority members -- I know traditionally termed as a Board, strictly speaking in our legislation it's called an Authority but we do tend to use the word "Board" because it is more transferrable into other services.

In June 2020, all of the members, the chair and all the members of the Authority or Board, resigned from RQIA, and it has been subject to an inquiry, an independent Inquiry from a gentleman called Mr. Nicholl who was commissioned by the Department of Health, and the report of that whole event has been published. From my understanding of it, it came down to a lack of understanding, and possibly respect, for relationships between acknowledging the role of the Authority or Board, the senior or executive team in the RQIA, and working with the Department of Health. From my reading and understanding of the report, the Authority members felt quite disengaged and not very involved in some important decision-making about the role of RQIA, particularly at that time as it was entering well into the pandemic. That was a second factor then that caused very substantial changes in RQIA at a senior team level.

Several of the senior staff were redeployed or redirected into other parts of the health and social care system, including the Chief Executive, who was redeployed to the Public Health Agency, and that was 10:15 around March 2020. But in addition to that, another maybe eight to ten senior staff moved to take on different roles in surveillance, in vaccine programmes, a whole range of different things. As a result of that, the infrastructure today, the members of staff 10:15 who form the executive team which I chair, none of those staff were present or members of the executive team before 2020, they are all new. The Authority members, including the chair and all the Authority, are all new since 2020. So it has been quite a dramatic 10:15 change in personnel over that time.

14 Q. That's helpful context because some of the reports I'll be asking you to look at obviously predate 2020, and there seems to be, perhaps, a loss of corporate memory around those activities. Would that be a fair comment? 10:16

A. It is a very fair comment, Ms. McMahon. I mean, I've apologised to the Inquiry that I've had to modify my original statement indicating that I didn't, nor my colleagues, have knowledge of the report referred to in one of the previous witness statements, the Right Touch 10:16 Report. Despite efforts to search for a document or, as we thought at the time, a consultation, we could not trace it, nor was I able to identify from speaking with staff that they had any recollection of it. However,

on receipt of a copy of the document which the Inquiry kindly provided, I was able to see the dates of engagement with RQIA and I was able to trace the document being shared with RQIA on those dates. It was called, as far as I can recall, Regulation Review. But 10:17
I think it is a very stark example of how corporate memory can be so fragile on the basis of filing systems and search engines, as well as personnel.

15 Q. As you say, there was a slight change in name or reference to the document, so it's understandable then. 10:17
You've explained that in your second addendum statement. We'll look at the Right Touch in a moment. But for the Panel, if I can go to WIT-106893. This is your first addendum statement. If we just go to the page before, WIT-106892 and paragraph 7. This is the 10:17
part -- I just want to read this out. This is the resignation that you referred to of some of the members. You say at paragraph 7:

"On 17 and 18 June 2020, the then acting Chair of RQIA 10:18
Mary McColgan and six Authority members resigned with immediate effect. Two other members had resigned the previous week to take up other posts. These circumstances left the RQIA without an authority and without any members. 10:18

In their letters of resignation to the Minister, the ex-members of the RQIA set out their reasons for stepping down. These reasons included the following

(which are set out within the Nicholl report).
(A) Concern at the lack of effort made by the Department to consult or engage with the Authority prior to making key decisions affecting the core purpose and statutory remit of the RQIA;
(B) particular concern over the decision by the Department at the end of March 2020 to (1) redeploy the RQIA Chief Executive to the PHA and (2) appoint and extend the appointment of an RQIA interim chief executive without any communication with or involvement of the Authority; and:
(C) by excluding the Authority from involvement in any of these key decisions, the belief that the role of the Authority had been diluted and compromised".

Now, this was before you took up post, this was before your time. It would seem to indicate -- those reasons for stepping down would seem to indicate at the least very, very poor communication between RQIA and the Department, maybe at a snapshot in time. But what's the relationship like now? Is that something that is reflected in your experience or have things moved on significantly since then?
A. There has been a huge amount of learning from the events that led to those circumstances. I mean in the earlier part of that list of reasons, as well as the movement of the Chief Executive from RQIA, the role that I currently fulfil, to carry out that role in another body without engagement with the Authority

members seems to me to be... You know, I cannot appreciate or understand how that would have occurred. It certainly would not be my experience of working in any organisation, and certainly in the one I work in now.

Also, the earlier part where it referred to statutory functions of RQIA, I believe that refers to, you know, departmental, well, direction at the time to pause or suspend some of the frequency of inspections into care homes and indeed into hospital environments without, it seems obvious from the Nicholl report, the Authority members or Board being aware of that.

It's concluded in the Nicholl report, and I would concur with its findings, that it demonstrates a relationship was operating between the executive team of RQIA and the Department, but not substantially or materially involving the Authority members. Now, that is not acceptable, and it is not my experience. Since working in RQIA since July '21, I work very effectively through the chair and with all the Authority members. We have spent a considerable amount of time basically rebuilding the governance arrangements inside the organisation, the operating of the Authority itself, its public meetings, its committees and so on, the operation of the executive management team, and really building in the discipline that's essential for the organisation to operate. So that situation is

unfounded, I would say, and the fact that it led to an
independent inquiry and a public reported document,
which was issued, in my recollection, to all HSC bodies
to reflect and learn from, it certainly is not evidence
of the operating arrangements today. 10:22

We have an effective working arrangement with the
Department of Health. Myself and the chair meet with
department colleagues on a reasonably regular basis,
every other month, for example. Meetings would be 10:22
called at times when there's issues to discuss and
explore. I will ensure the executive team are all kept
appraised of any such engagement, and senior members of
the RQIA themselves engage with departmental
colleagues, policy leads, and now representatives from 10:22
the SPPG. I would say we have a very effective working
relationship, but it doesn't dilute or compromise our
independence as a regulator. We fulfil that role
without -- intrusion, I suppose, is not the right word.
Without influence or without favour, I would say. But 10:23
we do report though; the Chair reports to the Minister
through the Department, and I report to the Department
as accounting officer for the finance. I would say we
have an effective working relationship.

16 Q. Now, the reform and some of the restructuring around 10:23
RQIA's corporate governance arrangements commenced
after the resolutions, and the Nicholl report reflects
that. Even before the pandemic, relationships with the
Department, the Executive and the Authority were,

I think, dysfunctional - I think the word is used in
the Nicholl report - for some time.

The restructuring commenced under the stewardship of
the interim chief executive at the time, who was 10:23
Dr. Tony Stevens. Dr. Stevens had just recently
retired from, I think it was the Belfast Trust --

A. No, Northern Trust.

17 Q. -- where he was chief executive. He then brought about
some changes in relation to the way in which the RQIA 10:24
both engage but also operate its own internal corporate
governance.

Now, you took over from Dr. Stevens. In relation to
your following through of that or perhaps putting your 10:24
own stamp on it, what steps did you take then to
strengthen the corporate governance or to improve
things so that relationships, as you say, resulted in
being much stronger today?

A. Dr. Stevens had, with the agreement with the Authority 10:24
members of the time, developed a number of internal
arrangements, basically getting the Authority Board
established, meeting on a regular basis, ensuring that
the Authority had access to it, reports around delivery
of statutory functions, inspections, you know, serious 10:24
concerns that may be raised with us, being cited on the
financial arguments, complaints management, all of
that. He had made an excellent start on that, and also
had agreed with the Authority that the organisation

which, as I say is very small, had only at that time two directorates or divisions. It was already clear then that Mental Health Services in particular, and services for people with learning disability, needed further attention. So he had taken the step to agree the restructuring of the organisation into three directorates, now with a dedicated mental health learning disability, although it also includes children's services and prison healthcare.

When I arrived, that decision had been made but not implemented, so it was my job to begin the process of recruitment and selection and working out the finer detail of how the other functions of the organisation would support them so, for example, the function of information and information technology, HR, finance, that type of thing. The other thing was that although the Authority had been reestablished with its reporting to it, the committees of the Authority weren't yet established. The business committee, Business and Remuneration Committee, the Risk Committee, and more recently I developed, with agreement with the Authority, a third committee called the Legislative and Policy Committee, because I found, with agreement of others, that the legislation around our work is complex and it's always subject to reinterpretation, so there was a need for some dedicated scrutiny of both of the legislation and a contemporary interpretation of it. So much of my work has been about, you know,

leadership, I would say, you know encouraging staff out
of what has been, no doubt, a very dark time for
people. I mean, an organisation has been through the
change that we have seen. Plus our staff were, like
many across the HSC, heavily involved in the pandemic. 10:27
So much of my work has been about visibility, support,
ensuring that we recruit, that we fill vacancies. At
that time, for example, over 20 posts in the
organisation were vacant, not filled, not backfilled
because of all the difficulties you can imagine. But 10:27
we have addressed all of those and we have full
staffing level and have had for two and a half years;
it's a constant battle. I would say much of what
I have done has brought some internal confidence to
staff, reassurance to them that they are doing a good 10:27
job but that internal governance is every bit as
important as the governance we look for when we're out
doing inspections and reviews.

18 Q. Who is your sponsorship branch? Who do you sit under?

A. Yes. We currently report to Mr. Jim Wilkinson within 10:28
the Department, civil service construct. The division
is the Directorate of Healthcare Policy. That's
a relatively recent change. Up until several months
ago, the Department have been undergoing change
internally; we would have reported to Professor Sir 10:28
Michael McBride as the Chief Medical Officer, but
I know that the Department are focusing medical
personnel on the arrangements for medical staffing
across Northern Ireland. So a few months back,

we reported to Mr. Wilkinson.
19 Q. Do you have any view as to whether that change in sponsorship has any impact on the communication with the Department or your ability to liaise with the Chief Medical Officer; is that still something an open door for you? 10:29
A. It's early days but the Chief Medical Officer, I have to say, is very interested in the work that we do. Because he would have been present in the sponsorship role and commissioned some pieces of work we are 10:29 currently undertaking, we would still keep him informed, usually by correspondence and occasionally in a direct conversation. So, for example, the Chair and I would have met with the Chief Medical Officer and Mr. Wilkinson just before Christmas in a sort of 10:29 a briefing and a hand-over arrangement.

I can't say -- it's early days to say whether it improves things but there's no doubt we need to continue to improve things. Since Mr. Wilkinson has 10:29 took over, I've met with him, even in those short months, I would say three, four, five times. So all the indications are that there's a willingness on both parties to make this relationship effective for patient safety. 10:30
20 Q. I just want to move on and look at the powers and the function of RQIA. You mentioned that you operate under a legislative framework, you're a creature of statute. For the Panel's note, the RQIA was established under

the Health and Personal Social Services Quality Improvement and Regulation (NI) Order 2003, and you came into existence in April 2005.

Now, your functions and powers are different depending on whether a service is registered or not. As I understand it, the legislation dictates registered services and statutory services. I wonder if you could just give us a brief outline of the difference and what sort of services fall under each.

A. Yes. As you say, Ms. McMahon, the 2003 Order is complex but it is largely made up of these two parts. We refer to registered services as falling under Part 3 of the 2003 Order. Registered services are services that are required to register with RQIA. It's an offence for them to operate without that registration. The services that fall into that category and listed in the legislation include all care homes in Northern Ireland; children's homes. I should say care homes, there's about 470 in Northern Ireland. They are all required to register with us, both residential and nursing. Children's homes, of which there are probably around 40, maybe a little more. Dental practices, for which there are about roughly 400 or thereabouts. Domiciliary care services, so people in services, agencies, who provide personal care to people in their own homes or possibly in supported living environments, they are required to register with us. Day care facilities, and nursing organisations who provide

agency nurses. I may have missed one in terms of
boarding school arrangements, Ms. McMahon, but in the
main those are the list of services that are required
to register with us.
21 Q. Some of those exceptions to the normal rule of 10:32
registration, some of them sit under the Trust
slightly.
A. Yes.
22 Q. Just to clarify that for the Panel. So registered
services and then registered exceptions, effectively. 10:32
A. We consider them all to be registered but, yes, you are
quite right. You know, it doesn't matter who provides
those services, if they're provided by an independent
private sector, charity, or by the statutory service
itself, by the Trust; if it falls into that list, it is 10:32
required to register with us. So you are quite right,
if the Trust, any of the Trusts run care homes, which
they do, a very small amount of the 470, there's
probably roughly 25 care homes in Northern Ireland run
by Health and Social Care Trusts. All of the 10:33
children's homes are run -- I'm thinking off the top of
my head, I hope I'm right there, nearly without
exception would be run by or set up by the Health and
Social Care Trust. So even whilst they fall under the
jurisdiction and the management of the Trust, because 10:33
they fall under Part 3 they are required to register
with us and the Trust, like others, will have to pay
their fee and annual fees thereafter.

Not all services under that legislation, strangely
enough, do pay fees. There are some exceptions;
I don't know why. Those services that are registered
then are subject to a regular inspection programme and
the frequency of that inspection is set out in the 10:33
legislation; it follows later in 2005 Fees and
Frequency Legislation. For example, care homes are to
be visited, inspected twice a year. I just realised,
Ms. McMahon, I forgot to say in the list of registered,
independent and private hospitals would also be listed 10:34
there, required to register, as would independent
clinics - perhaps we'll come to that later - that are
not otherwise part of the health system.

There's a regime set around that in terms of frequency 10:34
of the inspection. A private hospital is expected to
be inspected annually. Dentists are expected to be
inspected once every other year, that's relatively new,
it used to be annually. And so on.

23 Q. Just on that point as an example of the way in which 10:34
there's some flexibility around inspection, you said
that dentists used to be annually, it is now
biannually. Was that on the basis that inspections
were proving that they didn't need to be inspected as
frequently or what was the thinking behind the change 10:35
of regime?

A. Well, I believe so but, of course, that change was the
Minister, I understand - before the government stood
down in Northern Ireland - was minded on the basis of

a pre-consultation exercise that had looked at fees and frequencies and, I believe, had engaged with the dental professional body, agreed with the Minister that the frequency would be changed from annually to biannually. We would be advised, instructed on that behalf, and from that point we adopt that. That is the only change I can think of or am aware of in the legislation itself. Others have remain the same.
24 Q. Does that have an impact on revenue then? Do you get paid for each inspection?
A. No, we don't get paid for each inspection. We have a small inspection team for dental services. I can't remember the numbers; it could be three or four staff, that sort of order. But we are talking here of close on or around 400 dental practices. What we have found, although it is relatively recent moving from annual to biannual, the intensity, complexity of the inspection on an biannual basis takes just that little bit longer and, thankfully, we didn't lose any revenue as a result from government. As I say, the fees would be very marginal. The fees we secure from dentists would not cover the cost of registration and regulation. It is supplemented significantly from the government funding we receive.
25 Q. Now, if you could just speak to statutory services, the hospitals, the hospital Trust effectively. Except for the services you've mentioned, if we look at those.
A. Yes. I'll refer to those perhaps as Part 4 services. They are services provided by the Health and Social

Care Trusts; it includes hospital services, acute hospitals, mental health hospitals and others as well, although there is supplementary legislation around mental health services. But as you've said, leaving aside those services the Trusts provide that are registered, the Part 4 part of the legislation covers the Trust services.

The primary part in that is that, as you've indicated in the introduction, the 2003 Order established, created, RQIA, and it began functioning in 2005. But the other very significant step that it introduced was a statutory duty of quality on health and social care trusts. In Part 4 of the legislation, it describes Trusts and, at that time, the regional boards that existed, although they later condensed into a single health and social care board. I know from your testament you're aware that that board closed in April '22 and has been replaced by the SPPG as a direct part of the Department. But in the original legislation the statutory duty of quality would have applied to the Trusts -- well, as they became Trusts later, and also to the Board. That no longer applies to the Board because it is now a part of the Department itself.

But I presume because the statutory duty of quality, i.e. the responsibility for the safe delivery of services, lies with the Trust Boards and they report directly to the Department of Health, they are a construct that the SPPG and the PHA, the Public Health Agency, have a role looking at performance, commissioning arrangements and so on. Ultimately, the Trust Board reports to the Department and they will have to provide a range of assurance mid year, assurance statements end of year and so on.

Within the Part 4, RQIA has functions that it can carry out. Its enabled to review, investigate, or inspect HSC Part 4 services. Now, those have been developed over time. They are in the main largely planned programmes of work. So, we would go out and carry out what we call a review of governance in a particular Trust, maybe a review of governance across a particular service - so maternity services. We would go out and engage with people from across the Trusts and with service users and with families and so on. Those are all planned programmes of work. They are announced, they're announced in advance, usually possibly probably even a year ahead. But certainly before we would go out to carry out a review, we would contact the chief executive of the local Trust, we would ask for a point of contact and so on, and a programme of work would be established.

Inspection is, in some ways, similar but also it has quite a different role. We can carry out inspections, however they are directly linked to what's called the HSC quality standards. They were introduced in 2006,

I presume after the statutory duty of quality became known and available in 2003, the Department then developed standards.
26 Q. Against which they assess the statutory duty?
A. That's correct. 10:40
27 Q. And that's the way in which you approach your assessment?
A. Well, that's the way we approach our inspections.
28 Q. Inspections, sorry, inspections.
A. Whereas the reviews, Ms. McMahon, would be maybe much 10:40 broader than that. If you were looking at maternity services, most often you would draw in expertise from other parts of UK or Northern Ireland, and you would not be restricted only to the HSC standard. You might look broadly at learning from other places, whether it 10:41 is Ockenden reports or maternity reviews and so on, and you would draw out a particular methodology for looking at the governance of that particular service and, on the basis of that, you would produce a report and it would make recommendations. Unlike an inspection 10:41 which, as you say, reverts to, looks at, the quality standards as the framework for assessment. It is looking for compliance; is this service complying with the standards? Is there evidence that it's complying with the quality standards? 10:41

Now, although they are dated 2006, I would say that because they're set on the basis of, you know, good governance, you're not looking back to standards from

2006. They always refer to, you know, look at contemporary setting, look at best practice now. Although they are quite old in terms of the date on the cover, they do allow us to look at five aspects of good governance, from leadership and accountability to safe 10:42
and effective care. The important thing is that where you identify, where RQIA identify failings, failing to achieve standards, then that is where we have authority to take further action. Whereas with the review, we'll have published the review, made it available, made 10:42
recommendations, but with inspection you can issue, for example, if you felt it was warranted, an improvement notice, for example. So there are further, if you like, enforcement powers available to us under the inspection work. 10:42

29 Q. The Quality Improvement plan, which part does that fall under?

A. Equality?

30 Q. A quality.

A. Sorry. It falls under inspections. 10:43

31 Q. I think you did one in relation to the Royal Hospital ED Department, Emergency Department?

A. We did.

32 Q. Could you just set that out, a brief background as an example of the way in which you can either apply 10:43
a stick rather than a carrot in some regards?

A. Yes. As I say - and I know we'll maybe touch on it - the inspection programme for - I know we say hospitals but actually it can go into any part of the service

provided by the Trust, but we say hospitals - has
historically been a planned one. You'll see back in my
statement that when we started doing inspections as
opposed to reviews, they were based on direction from
the Department because of concerns around C.difficle, 10:44
pseudomonas, Frances Report, you know, learning from
other jurisdictions and concerns, particularly about
infection and prevention control, and as a result a
programme of inspections were drawn up. In those
earlier days, at least my judgment of looking back at 10:44
that, there doesn't appear to be many inspections that
I can see that were based on intelligence being
received, if you understand me. But in more recent
times, certainly since 1920 and maybe a little before
that which we've been reflecting on from other 10:44
enquiries, there's been at least a greater element of
taking on board intelligence that you receive from the
public, maybe from Royal Colleges, from staff. In the
case of the Royal Victoria Emergency Department, we had
been contacted by staff, senior staff and staff working 10:45
on the coal face in ED; we had been contacted by The
Royal College of Nursing; we had been contacted and we
were mindful of social media from patients and others
and families - as a result of that, we have the ability
and the function to carry out inspections - we carried 10:45
out an unannounced inspection at the Royal Victoria
Emergency Department last winter, so that would have
been winter '22 into '23.

The inspection would have lasted for many weeks. You know, colleagues from RQIA would have been present on the site probably from mid November right through to January and February. Not all the time. They would have went out at key times, weekends, nighttime, hand-over periods, you know, where staff rotas are changing, that sort of thing. They would have spoken to many staff who clearly identified their real concerns about what was happening, and to families and so on. As a result of that then, we published a report, several months later, I would have to say, and I know there was some criticism around the period of time it takes to get the report produced. I would say to you I do regret that, of course we would prefer to have them published sooner. But the actions start from the day we go in to do the inspection. I mean the publication of the report is the public evidence of it, and it's important to have it, but the work starts from the time we start the inspection, and we'll maybe talk about some of those arrangements where we come across something while we're there that needs to be addressed and can't wait for a QUIP, as you've referred to earlier, a Quality Improvement plan or a report to be produced. So we published that.

As a result of that, we found very severe -- I mean, we found people coming to harm. Patients are coming to harm. That persists. That is still the case, sadly.

33 Q. What can you do about that?

A. I say -- sometimes people will say to us why report again when everybody knows this? We will persist on reporting the evidence. Everything we do is based on evidence, and that's why it's independent, that's why we bring in others with expertise. We will continue to 10:47
highlight and showcase the impact that the pressures or arrangements in place in services are having on staff, absolutely, but ultimately it is having detrimental impact on patients, and we will continue to persist in doing that. That is our role. I should have said at 10:47
the very start our primary function as a regulator is to keep the Department informed about the quality and provision of services, and to encourage improvement. So we would be neglectful of our role if we didn't persist reporting it. 10:48
34 Q. You have given a lot of information there. I just want to carve some of it up to provide examples to the Panel of ways in which RQIA can interject or seek improvement.
10:48
When I asked you initially about the Royal Victoria Hospital Emergency Department, and as I understand it failed all five standards that we were discussing earlier, they were issued with a qualitative improvement plan and they showed some actions were 10:48
taken. But on this occasion, RQIA did not place them in special measures as you took the view that most of the issues requiring attention were not within the power of the Belfast Trust but actually lay with the

Department. Based on that, the assumption must be that
special measures applies when you can fix the problem
from within or you have the capacity to reach out for
help and get it sorted, but in this particular issue
a lot of the issues that resulted in the failure of the 10:49
emergency department lay within the power of the
Department, so a special measures wasn't appropriate.
Is that a fair summary?
A. It is close to being very fair, Ms. McMahon, but
I would add, not in defence of the Department, but I'm 10:49
not sure all of it lies with the Department if there
isn't political, you know, arrangements and support
available. I'm not knowledgeable enough to be able to
expand on it. But it would be fair to say, absolutely,
that a lot of what we found wasn't within the gift of 10:49
the Trust on its own resolving.

Having said that, we would not want to diminish the
fact that several of the findings were within the gift
of the Trust, and there were things and are things, 10:49
steps they could take and were set out in the Quality
Improvement plans. These are practical steps. They
will not solve the crowding in ED, sadly, but they
would keep people safer.
35 Q. And how do you follow those up? If you make 10:50
suggestions in an improvement plan, if you undertake
a review and give it to the Department - both in review
and inspections this question is aimed at - how do
you follow up the suggestions, recommendations made by

RQIA are implemented or ignored or partially implemented? Do you have ongoing conversations with either the Trust or the Department around those?

A. If I may take those in reverse order, Ms. McMahon. I'll keep on the inspections for the moment. In the 10:50 case of the Royal Victoria, we served the Quality Improvement plan through the report and, on this occasion, we have went back to The Trust, with their agreement, and we have been back over this winter, looking again at the steps that were taken by the Trust 10:50 to address the issues that we set out for them. So, there is an opportunity in inspection to go back. But I would caution by saying, as I said earlier, the programme for hospital inspections Part 4 services is not routine, unlike care homes. When we carry out an 10:51 inspection of a care home and also issue a QIP (Quality Improvement Plan), for example, invariably we will be back inspecting that home within the year because there is a regime that requires it.

36 Q. There's a statutory duty around that? 10:51

A. Yes, we have. Of course we would very often ask a Trust, or any provider for that matter, to send information to us. You know, so if we've carried out an inspection, we've made findings and actions are required, we may very well say send us your action 10:52 plan, send us evidence of you having taken your action plan, so everything isn't inspection. Just to make the point, in registered services there would be a regular inspection and, invariably, you get the opportunity to go back and look at the last inspection, look at the actions that were required and validate whether they have been taken sustainably, and so on.

In the hospital is sector, the Part 4, the hospital inspection programme is not routine in that way. You would, therefore, not necessarily have the opportunity to go back and physically check the steps were taken. We have done so in the Royal Victoria, as I say, and as has been said the legislative umbrella does not prevent us going back; it would be capacity that would prevent us.

37 Q. Could you write to them and ask them to update you?
A. We do, Ms. McMahon. We do.
38 Q. And they give you information then?
A. They would, they would.
39 Q. If, for example, the information comes back that for whatever reason, and wherever the gift of the answer lies, they haven't been able to make any improvements, is there anything else that can be done apart from correspondence?
A. Absolutely. If a statutory body has been tasked with taking actions as a result of an inspection, we have determined that those actions are within their remit and within their gift, so to speak. So, we would ask for evidence of actions being taken and so on. If we were not satisfied that the actions were being taken or taken in a time scale that was relevant and so on, we would and could call the organisation to what we would

call a Serious Concerns Meeting. Now, that may not sound as forceful as it is. I do know that working in the health system, any Trust called to a Serious Concerns Meeting, that would be a correspondence from the Chief Executive of RQIA to the Chief Executive of 10:54 the Trust called them to a meeting within a very short period of time, a few days, asking them to bring the evidence with them, explaining we're not satisfied with the submission you've made; we don't see the progress being made and so on. They would be invited to attend 10:54 a Serious Concerns Meeting and asked to present further evidence, discuss with them. Ultimately our aim is to keep people safer. We're trying to support them and guide them and assist them.

10:54

Out of that, I mean you would like to think there would be strengthened actions taken by the Trust. If not, you could move to the most severe thing that's in our portfolio, which is the improvement notice. But, as you said earlier, we did consider special measures but 10:54 special measures are to be used, as I understand it, where the organisation is not addressing issues within their ability, or failing to have the competence to do so. In the Belfast Trust and in a follow-up inspection that we carried out this winter in Craigavon Hospital 10:55 as a result of the Belfast inspection last year, we found similarly the issues we found in Craigavon. This time we focused on people delayed in hospital waiting to be discharged, but these are all parts of

the same problem. What we found there, again, it was a series of things that the Trust and other local providers could do to work better together, but it would not resolve the primary issue which was a lack of social care provision, particularly home care, 10:55
domiciliary care, in some cases rehabilitation and in some other cases care homes.

It's not a case of commissioning more of it, it's not a case of contracting for more of it. The 10:56
infrastructure in social care is not attracting sufficient staff into that sector so it does require policy change. It is not something we could leave at the door of the Trust and say you need to develop or create more domiciliary care services. You do, but 10:56
it's an understanding that in order to do so, there's policy change needed in terms of pay, conditions, a whole range of things.

40 Q. And that's outside the remit of RQIA.

A. It's outside the remit of RQIA. 10:56

41 Q. It's a wider conversation?

A. Absolutely. It is outside the remit of the Trust although we are all players in it. I mean, I do believe we all have a part to play.

42 Q. Just if we could go back to some of the earlier points 10:56
that you made. The reports on inspections, the reviews on inspections that are carried out, you send those documents to the Trust?

A. Yes.

43 Q. To the Trust Board as well or to the chief executive and the Department? Who are the recipients of your output?
A. Well, I would send them to the Chief Executive but our chair would copy and send, and most often does a separate letter to the chair of the Trust. In terms of those reviews that we're doing, you know, maternity or choking or anything of that order, and indeed even in the case of an inspection like the Royal, where we know it is a huge organisation, it's a public interest so it will command attention, the chair would most often also send a copy to the chair of the Trust. We then also send it to our sponsor branch, the commissioner of the review, for example. Or if we have initiate the review ourselves, we will send it to our sponsor lead. Most often we would have sent it to Professor McBride, copied in Mr. May and other senior members of SPPG, Mrs. Gallagher and others would be copied in as well as our sponsor branch, and we would often meet and so on to discuss it. 10:57 10:57 10:57 10:58
44 Q. So you would be confident as the regulator that any services that are - and this is my term - at risk, if there were patient safety, quality issues that you identified, that they get a broad audience, that the right people know about this at the right time, from your perspective? 10:58
A. Yes, because we would also alert other stakeholders - you know, Older People's Commissioner, Children's Commissioner, Human Rights Commission - appropriate to

the nature of the review or inspection we've carried
out --
45 Q. But in relation to -- just I understand the wider
context of other organisations, but just in relation to
who can act on risk identified and perhaps patient 10:58
safety concerns --
A. Yes, because that is a clear --
46 Q. You're content that you have an open door to provide
that information that you have gleaned to the right
people? 10:59
A. Yes, I do. I didn't answer your question, I realise,
on the reviews. I had mentioned about inspections and
the potential for revisiting and seeking information
and so on, and that is all the case reviews are
different in that they make recommendations. They are 10:59
not findings like in the main - I can't think of any -
that are findings against the HSC quality standards.
So reviews we produce most often would have engaged
experts to assist us with knowledge of a particular
issue; maternity maybe comes to mind or something like 10:59
that. That report again would be made available to all
of the organisations who were party to the review,
largely the Trusts, and to the Department. In that
case there isn't a follow-up mechanism, so we wouldn't,
to my knowledge, generally -- there is nothing to 11:00
prevent us from doing it, we could write to an
organisation and say would you tell me how you are
progressing with the implementation of the review
arrangements -- sorry, the review recommendations for

the maternity review, but largely that doesn't fall to RQIA. The review report is provided to the Department, and the Department, with the support of SPPG, and often the PHA, they follow up on the completion and the implementation of those recommendations. It wouldn't be visible to RQIA in the main.

47 Q. We'll have a look at a couple of those reports just now - sorry, reviews - that were carried out. The first one can be found at WIT-106239. This is a Review of Clinical and Social Care Governance Arrangements in Health and Social Care Trusts in Northern Ireland. I know this is before your time. It is an overview report 2008. I think this is the first time RQIA had undertaken such a process?

A. Yes. At least that, I would agree with you, my reading of it in preparing for attending the Inquiry, I have read the report several times and I'm orienting it to its time and place. It is published in 2008 and, as I mentioned earlier, the statutory duty of quality had just come in in 2003 but the standards had just been introduced in 2006. Although this report is published in 2008, from reading the background to it I see that the fieldwork was carried out over 2006 and '07. I'm imagining that this was a direct response to the publication, the implementation, of the HSC quality standard. I think I'd amended later - I trust that I did - I found actually that there were two reports at that time. One of them, and it seems to be this one, look at the three themes there. You can see theme 3, 4 and 5. There are five themes under the HSC quality standard.

48 Q. Let me just read that in so that for the transcript we will understand what those are. The methodology for this particular review is set out, for the transcript, at page WIT-106241. This involved the six Trusts between March and April.

"This overview report provides a summary of clinical and social care governance reviews carried out by the RQIA of the six HSC Trusts between March and April 2008".

Under "Methodology", it says:

"The reviews assessed the achievement of HSC Trusts against three themes of the quality standards. Theme 3, accessible, flexible and responsive services. Theme 4, promoting, protecting and improving health and social well-being. Theme 5 effective communication and information".

You were just about to explain about the themes before I interrupted you.

A. Yes. No, I should have not interrupted you, Ms. McMahon. I see that report, as I'd indicated a moment ago, that the fieldwork had been undertaken in 2007 or 2008, and it did look at the Trusts, and that is my reading of it as well, and those are three of the five standards set out in the HSC quality standards. But I had identified that the other two themes, themes 1 and 2, leadership and accountability and I think safe and effective care, had also been reviewed and there is a second report published in 2008 which presents the findings on it. So the two together clearly made efforts to look at all five themes. It's the only time that -- certainly when I've looked through other reviews since then, it is the only time I can see where all five themes were looked at as a kind of a baseline or a benchmark. From my recollection there weren't any recommendations made but I could be corrected on that. But I think the two reports demonstrated that HSC quality standards have been implemented. The Trusts were actually reforming at that time. In this report it refers to the Trusts, whereas in the earlier one it refers to the 25 organisations. Clearly, in the middle the review of public administration must have occurred and they were different. 11:03 11:04 11:04

It seems to give a baseline around 2008 for the Trusts beginning to establish the arrangements for affecting the governance to put in place the five standards. It's the only time I can see all five reflected, because later they are more selective. 11:04 11:05

49 Q. Now, the approach taken was for the Trust to complete their own self-assessment; then the RQIA carried out site visits. I'm summarising this because you weren't there at the time and just for convenience for the

Panel. Then a report was produced on the achievements against the quality standards.

Now, I just want to go to WIT-106246. We can see there -- sorry, 106241. There's mention of clinical and social care governance on that point but it doesn't carry its way through the report under that particular title, it's been subsumed into different processes in assessing the Trust. One of them is reflected in recommendation 14 and I just want to look at that. Recommendation 14: 11:05 11:06

"The RQIA recommends that HSC Trusts develop systems and strategies to promote effective communication and information sharing". 11:06

Now, the context of that obviously was the Trusts' own internal processes.

When one reads this review - again with the caveat you weren't there - it's clear that the lens through which RQIA assess effectiveness or the standards is about process? 11:06

A. Yes.

50 Q. You look at whether the standards that are applicable are being applied rather than the outcome of those processes. Would that be a fair comment? 11:06

A. I think it is a fair comment, Ms. McMahon. I mean, we look at compliance with process with, I suppose you

could argue, the intent that the compliance with
effective processes improves safety quality and
outcomes. But you're quite right, we don't measure the
outcome, rather the process.
51 Q. Do you consider that the measurement of the outcome 11:07
against regulation, Patient Safety risk, Quality
Improvement, lies with the Trust Board or with the
Trust Executive Committee? Is that an internal matter
for the Trust as long as, from your point of view, they
are applying the procedures properly? 11:07
A. Well, yes and no, but I do think all parts of the
health and social care system, including ourselves,
can't, you know, wash our hands of outcomes. Yes, our
contribution to the process is reflecting back to
organisations independently, shining a mirror, shining 11:07
a light on areas that need strengthened. That
contributes to improved outcomes, I do believe. It is
part -- it's why we exist, it is to improve quality and
safety. That should be reflected then in outcomes.
Now, the availability of outcomes would be population 11:08
health outcomes, not just in terms of the Trust. The
Trust will have outcome measures for their population
but they'll have process measures. Like waiting lists,
for example, are potentially a measure of inefficient
systems not capable of coping with the demands on them. 11:08
But I think ultimately all of us are contributing to
population health measures. They are seen through the
Public Health Agency, they are promoted through that
arrangement. The Department of Health will also do so.

I would see us aligned to that; part of what we are doing is contributing to that. But I don't have -- I can't publish population health outcome measures, I don't have access to them.

52 Q. I suppose my question perhaps wasn't framed properly or 11:08
focused properly. It was aimed essentially at the RQIA, the dichotomy between RQIA's role as a regulator around improvement, about quality, health outcomes, the way in which the system works, and the application of
those systems to a fact base. For example, one of the 11:09
reports that we look at touches upon MHPS, Maintaining High Professional Standards, and the way that is applied. RQIA's role, as I understand it - and this is just an example so if there is a fracture line, that
that may become apparent for the Panel, or if there's 11:09
any learning in the example - MHPS could be looked at by RQIA to see whether it's applied properly. They take the structure of MHPS and apply it within their systems of management and governance. That would be
a review that you would undertake without looking at 11:10
the substance of someone going through that process --

A. Yes. Yes.

53 Q. -- the effectiveness of the process to that individual, the outcome, any recommendations, any reduction in
potential risk for Patient Safety. There is a line 11:10
beyond which RQIA do not go; is that fair?

A. That is fair. That is fair. We would assess, audit, review, whatever word might best describe adherence to a policy, process or best practice or a combination of

them. We would identify through evidence, and that evidence would come from different sources, from observation, review of documents, listening and engaging with people, and as a result we would produce a report that indicates compliance with that particular 11:10
MHPS, for example if that was the one that was being looked at, we will say we have identified the need for strengthening arrangements but we don't have the outcome measures from that.
54 Q. That was the question from earlier -- 11:11
A. Yes, we don't have the outcome measures.
55 Q. -- is that the line at which you expect the internal machinations of the Trust and the Trust Board to take over quality control and regulation?
A. The Trust Board but also through their reporting 11:11
through the Department of Health, because the Department of Health have to be satisfied that in the application of those recommendations, the improvements intended have been achieved. Because it is not the achievement of the action, I would suggest, but the 11:11
achievement of the intent of the action. I mean, if we recommend to do something in terms of a process, it is to ultimately improve the safety of that process.

I would like to think that the Department, through its 11:11
assurance arrangements and challenge, and what have you, are not only asking for the actions to be taken but also looking at the outcomes from that organisation and whether the intent has been achieved. Because if

it isn't, then we need to go back and look at other
actions because if those have not had the effect that
was intended, strengthening, safety, or oversight or
whatever it might be, then we need to revisit that.
56 Q. You have provided us with a lot of reviews, reports and 11:12
examples of RQIA inspections and containing
recommendations across a wide variety of services and
service providers. Given what you now know, given the
information from the Inquiry as well that you will have
learned from your reading, do you think you have enough 11:12
powers to properly regulate and quality improve health
and social care in Northern Ireland?
A. Such a big question, Ms. McMahon.
57 Q. We'll break it down. Do you feel that there are limits
to what you can do and would you would like to do more? 11:13
A. It's not about feeling that there are limits, there are
limits. We've expressed what those limits are. But
they are limits within the construct of how health and
social care is delivered in Northern Ireland. Trusts
are required to provide a statutory duty of quality; 11:13
they are not required to register. RQIA have a function
to review, inspect, investigate and report.
58 Q. Let's take that example. Just break that down, the
duty of quality that is a statutory duty on the Trusts.
11:13
Now, under the old structure, HSCB fell within that
duty; they had to adhere to that statutory duty of
quality. Just what that actually says, the statutory
duty of quality, it's imposed by the Health and

Personal Social Services Quality Improvement and
Regulation (NI) Order 2003, and...

"Requires HSC bodies to have effective systems of
governance in place with regard to the services they 11:14
provide and the services they commission".

It is a fairly high bar as regards governance. There's
an expectation, a statutory expectation, which is not
that unusual for lawyers but perhaps in the health 11:14
setting to have a statutory duty of that nature is
a very particular focused legislative intent. Now,
HSCB was subject to that and on that basis were subject
to scrutiny by RQIA; you could look at HSCB. Now this
SPPG, they fall outside that? 11:14
A. That's correct.
59 Q. So that statutory duty of quality no longer applies --
A. That's correct.
60 Q. -- in the statutory form. Of course they may say,
well, it applies anyway because of who we are but 11:14
purely from a legislative point of view, they fall away
from you in that regard.

Now, that's an example of an expectation of your powers
being applied to a body that, because of restructuring, 11:15
has fallen away?
A. Yes.
61 Q. Do you have any view on whether that's appropriate and
whether there should be oversight of SPPG beyond the

Department?

A. Well, in the Health and Social Care Board closing or moving, functions moving into the Department, as you say, that function of commissioning, planning, oversight, and some services that are directly commissioned through SPPG, or now the Department, now no longer fall to be under the regulatory - if you could call it that - remit of RQIA. I mean the types of things we're talking about are the functions of SPPG, as you say, but also services such as general practice. I mean, you'll have noticed and I mentioned services that are required to register with RQIA include dentists but it doesn't include general practice. General practice, for example, is commissioned and contracted for directly through, I think, the Family Practitioner Unit, now part of the Department or possibly PHA have a role in it, so they don't fall to be registered by us.

But in your question about does RQIA have enough powers and so on, I would say, you know, that's secondary. I would suggest that that is a question that is secondary to the construct of the HSC in Northern Ireland. It is considered to be a public service funded by public money, subject to statutory duty of quality, and therefore RQIA's role is -- I don't want to say on the margins of that but it's on the periphery of it, providing independent insight on the effectiveness of that system. That's the system

Northern Ireland have adopted - public service, public money, direct funding, organisations that are accountable for the quality and safety of the service; that is the construct. Our job is to check and test the effectiveness of that construct. 11:17

I would therefore say that, you know, yes, you could have some extended powers on that. I would say more visibility for RQIA in the HSC sector. Of course, all organisations would argue for more capacity but I think 11:17 that there is a further role, even within the current construct that, you know, independent regulation on a more regular basis. We're just touching the surface here and there. You look through our review programme and you'll see the very many things we touch on but 11:17 we're not routinely reverting or going back to service. I think there's possibly an expectation by the public - my judgment - that we do. People possibly think our role as maybe akin to the care homes or dental or children's homes but it is quite different. 11:18

62 Q. And should hospitals --

[Technical pause]

CHAIR: Maybe it is an appropriate time to take a break in any case, Ms. McMahon, so let's take 20 minutes and come back at 11.40. 11:42

<u>THE INQUIRY BRIEFLY ADJOURNED AND RESUMED AS FOLLOWS:</u>

CHAIR: Thank you, everyone.

63 Q. MS. McMAHON BL: Ms. Donaghy, just before the break I

think we were just discussing again some of the differences in the approach of the RQIA to different services. I suppose if I can call it my mop-up question to that section of evidence is really a very general question but perhaps one that can be answered just directly by you: Do you think that the HSC Trust should fall under the RQIA's regulatory umbrella the way that the registered services do so that there's a greater potential for involvement and proactive assessment around regulation and quality improvement? 11:43 11:43
A. Certainly we know that that's a model that is used in other jurisdictions. We know in England, for example, that's how it operates. But I would feel ill-equipped to conclude that it offers greater protections because we've seen in other jurisdictions that, with regulation, there can still be issues and challenges; the Frances Report and other things. I feel it is outside something I can comment on. I think different models can work in different places, but I think I should have said more succinctly earlier do I think that there's a greater role RQIA could play in the health and social care Part 4 sector? Yes, I do. 11:43 11:44
64 Q. And what would that role look like?
A. I think even within the current legislation there's - maybe the wrong way to say it, but an imbalance. There's a very particular sway in terms of our work to registered services. I mean, enormously so. The vast majority of the work we do is in registered services. There likely needs to be a greater balance of using the 11:44

resource we have more effectively across health and social care, and I think there is a need to move more towards an intelligence-based approach so that information from the public, staff, whistle-blowers, other sources, allows regulation to respond.

65 Q. What happens if you get intelligence from those sources? If someone phones up and says this happened, that happened, do you signpost them or what's the procedure?

A. Well, it would depend. If the matter that they're drawing to our attention falls inside our remit, and it is difficult for the public and others to be clear about that, because we don't, for example, deal with complaints about health and social care services, we deal with what we call concerns and they are basically concerns about quality and safety. But yes, we take on board the phone calls we get, the information we may follow up, checking something out, say maybe triangulating it with other sources. Ultimately depending on the nature, we might very well plan a review or inspection on the basis of a collective amount of information.

So yes, we use intelligence. We're also sometimes have whistle-blowers contacting us. Again, based on that and evidence from other sources, we would take proportionate action to maybe follow up, possibly -- certainly investigate and possibly follow up with inspection or another type of approach.

66 Q. But do you have a freestanding power to undertake an inspection or review into HSC Trust if concerns come to you by whatever route of intelligence?
A. Yes.
67 Q. So if you were to find out, for example, there were Patient Safety concerns around a particular Trust and that that was substantiated by some form of evidence, whichever way the intelligence came before you, you could instigate your own review or inspection? 11:46
A. We can. We can be directed by the Department as well, as you say, but yes, we can. The Royal Victoria, the point you made earlier, was on our own initiative based on intelligence. 11:46
68 Q. So that's an example of being able to do that?
A. Yes. 11:47
69 Q. What would be the trigger for you acting in that way? What would be, if I use, the tipping point for RQIA to undertake their own review or inspection?
A. In terms of reviews and inspections, as I say, they're most usually a planned basis. Yes, we do respond when there's a heightened scale of intelligence coming, in like the RVH, which just happens to be the most recent example, I suppose. In the main we go out and engage with service users, policy leads, providers. We try to ensure that because the health and social care system is enormous - I mean it covers everything, children's services, care of the elderly, learning disability - so we try in the review programme to make sure that we have a good coverage, so that we don't negate reviews 11:47 11:47

or inspections of that, so be it, for services just because they may be marginal or small scale. We're all aware of some of the very big scale issues across health and social care but there are quite often small groups of communities and individuals affected in part. 11:48

So, through engagement we develop a programme that tries to ensure we have a broad coverage from children, older people, adults, you know, all of that. It's not always driven by, you know, intelligence volume is what 11:48 I'm trying to say. It is not always by the volume but by seeking out what is important to people and making sure we cover it.

70 Q. Perhaps also what may be identified as being of the most risk -- 11:48

A. Yes.

71 Q. -- and Patient Safety concern, would that be something that would motivate RQIA to unilaterally engage in some sort of investigation?

A. Absolutely and I have an example of it. I'm using the 11:48 example in care homes. I know it is registered but it gives the same indication. Again we are notified, a large amount of information we receive on care homes. Although I mentioned to you that in the legislation we're required to visit care homes twice each year, 11:49 there would be several homes we visit multiple times, much more than twice, and that's based on level of risk we deem from the information we receive.

72 Q. The Panel have heard a lot of evidence around waiting

times, waiting lists and potential impact on Patient
Safety, as well as outcomes and the risk associated
with that; some evidence around red flags being the
only request responded to, or routine appointments just
sitting waiting for long periods of time. Given that 11:49
that's widely known on and the figures are in the
public domain as well as specific information before
the Inquiry and the risk that is inherent in that, is
that something that RQIA could look at to see what the
processes are in each Trust and whether they're 11:50
effective and efficient and work according to the
quality standards expected?

A. Yes, we can. In that sort of area, you would look at
whatever policies and procedures are meant to have been
adopted by the organisations and you would be checking 11:50
for compliance and consistency and, yes, that would be
an area of policy RQIA could look at or examine.

73 Q. Why have they not?

A. Well, it's back to the point I mentioned earlier.
There are multiple aspects of health and social care, 11:50
it's enormous; you know, £9 billion worth of service
provision. In terms of RQIA's capacity to look at it,
as I say, we're a small organisation, we have around
3.5 inspectors looking at health and social care Part
4; we have a small team of reviewers, four or five. So 11:50
it is a case of trying to make sure that we cover the
things that are important to people. I'm not saying
for a moment that management of waiting lists might not
be, it's an area certainly we could consider.

74 Q. Just to break your answer down slightly, there's a requirement under the legislation that you provide inspections to the regulated services, that you have to go into nursing homes, for example. The frequency is dictated by the legislation as well. So there is, 11:51
I suppose, a rolling requirement of regulation around what you're covered to look at?
A. Yes.
75 Q. There's an expectation around those services. But when it comes to the Trusts and the hospitals, they fall, as 11:51
we've understood, just slightly outside that, with some exceptions. It seems to be, from at least one argument, that there isn't as an intense regulatory focus on the hospitals as under the registered services; would that be fair? 11:51
A. I think it is fair. If intensity is equated to the volume of individual inspections, that's true. As I say, last year, full year, we've probably carried out 1,800, 2,000 inspections of registered services, probably 12 or 13 reviews or inspections of HSC but 11:52
they are much more significant.

Perhaps back to the waiting list, I briefly say we did carry out a review of the governance arrangements of outpatient services for neurology and other high-volume 11:52
specialities in Belfast Trust, and we published that in 2020. It does examine some of the provision of information to patients, staff training, rotas, appraisal; a whole range of things.

76 Q. Was that not on the back of the public inquiry? The timing was similar, was it?
A. Yes, and the Department had asked us to carry out three pieces of work relating to urology, that being one. The other was a review of governance of independent hospitals and hospices. The third was a review of deceased patient records of Dr. Watt. So yes, in fact on the outpatient review, we are currently in a programme of repeating that across all of the Trusts. But I would agree with you, we don't have the same repeat presence in HSC services as we would in registered services. 11:53 11:53
77 Q. Those engagements that you have just mentioned were on foot of the public inquiry and the issues around that, so they were fed to RQIA from the Department from a knowledge base that came from a different source? 11:53
A. That is true.
78 Q. Yes, it didn't unilaterally come from RQIA?
A. No.
79 Q. In this Inquiry, I know RQIA have undertaken a review of SAIs and that has been provided to the Department. I'll ask you about an update at the end, if you know where we are on that issue. 11:53

Also, RQIA were engaged in the Lookback Review to undertake an assessment of the appropriateness and adequacy of that. You made some recommendations. The process was tweaked and, as I understand it, RQIA were then content with the way in which the Lookback Review 11:54

was being undertaken. Is that still the position with RQIA? You're content with that?
A. I should clarify, Ms. McMahon, that the piece of work we did in the first instance was looking at the methodology adopted by The Trust in examining the structured case record review. 11:54
80 Q. The SCRR.
A. Yes, and we were satisfied, yes. There were some recommendations made about strengthening the reporting arrangements, the purpose, you know, all of the governance around it, which were, to my knowledge, accepted. Then we had a second piece of work looking at the recall methodology. Again, we were satisfied. 11:54
81 Q. Are they pieces of work undertaken out of your existing budget or is there a facility for the Department to engage RQIA specifically for that and for that to be funded separately? 11:55
A. We do and we did apply for some additional funding to pay for the expert panel members. We're talking modest amounts of money, maybe £15,000, something like that. In most cases, and particularly in those too, we would have engaged an expert from another -- I think from the University of Manchester, maybe others. So yes, the Department, often when they would ask us, direct us to do a piece of work, we would approach them for some additional funding for the expert input. Otherwise, our own staff are part of the infrastructure and it would otherwise mean displacing a planned review, maybe, for a period or waiting a little while to take 11:55 11:55

something more urgently.

82 Q. Now you mentioned in your statement - we don't need to go to it but at paragraph 15, for the Panel's note, WIT-106003 - that RQIA carries out its duties on a risk-assessed basis. Just going back to what I was 11:56 asking you just a few moments ago, given the inherent risk in waiting times and waiting lists and the fact that RQIA have not directly engaged with that as a theme - whether you go into detail or not is a matter for you - but on a thematic basis across all of the 11:56 Trusts or indeed in any Trust, is it right to say that you carry out your duties on a risk-assessed basis, given the risk inherent in those and the existence of those figures?

A. I would say on reflection, Ms. McMahon, that if 11:56 I stated that as sort of composite across everything, it would be possibly too all-inclusive. We do deploy risk assessment in care homes, in mental health units, and a whole range of areas, so I would say -- and it's difficult to say that although we all have an 11:57 appreciation, I think, of the impact of long waiting times for people, our professional teams judge risk not just on quantum, on scale, but risk for children transitioning from children's care to adult care, people living detained in hospital, lost their liberty, 11:57 people delayed in hospital coming to harm. So they're all relative and I couldn't say personally waiting lists dominates all of that. Our decision-making around where we put our effort lies in a multi-disciplinary team discussion, and we aim to ensure that we are consistent in applying that rigour, whether it's children's, prison health care, mental health, adults, we have a responsibility across all of those programmes. 11:58

83 Q. Do the Trusts fall into that, the HSC Trusts?

A. Oh the Trusts do fall into that.

84 Q. How does that process work if you're looking at -- say you want to triage your own risk assessments, or triage the subjects that are before that multi-disciplinary 11:58 panel, how do you go about deciding which issue or theme or subject comes out top and attracts then the inspection or review?

A. There are a number of ways; I'll try to be succinct. In some of the registered services, we get a very large 11:58 scale of information provided to us on registered services. They are required to send us a lot of information. So when we look at those, we judge each piece of information, so to speak, individually and then collectively. So we look for variation. For 11:59 example, if we were looking at safeguarding notifications from some of the sectors, we would look at an increase in the number of safeguarding variations, or a reduced reporting and so on, things to draw attention to changes in what's happening in those 11:59 services.

In others, for the HSC, as you know, there is no requirement for the HSC Part 4 services to advise us of anything. So we're not --

85 Q. Should there be?

A. Well, we have the authority to ask for anything we wish, to be fair. Under Article 41, we can ask. But it is important, of course, when you ask for information that you know what you're going to do with it and that you've got the capacity to act on it.

86 Q. Or you know what to ask for?

A. Or you know what to ask for, that's right.

87 Q. If the emphasis was on then providing that information for you to properly regulate and improve care, quality of care, would that ease that burden?

A. I should say I'm not sure if I'm understanding. We would use that power already regularly with HSC to seek information to inform reviews and inspections. We also have used it on a recurrent basis to seek information on safeguarding for adults living in mental health units. We could ask for more regular information but under the current arrangements with health and social care with the Trust being the statutory duty of quality, there's a sense that those pieces of information, SAIs, for example, early alerts, internal reviews or these GIRFTs, Get It Right First Time reports, and so on, that those are already available to the HSC sector, the Department of Health and the Trusts. The information that we get or solicit is from the public. So for the HSC sector, virtually all the information we get -- don't get me wrong, we do at times get other information but in the main it is from the public, from former staff, current staff. But as I said to you, it is one of the areas I think could be improved within our current role is traditionally we have planned inspections on a rolling basis, largely focused around infection prevention control, and more 12:01 recently began to look at the Royal ED or Craigavon or so on. We would like to move to that type of model more fulsomely, that we would use intelligence more routinely in the HSC sector. We do for registered because there's a huge volume of information received 12:01 from those services. But then, Ms. McMahon, with our structure, 90% of our resource is allocated to those services. We have, you know, mental health learning disability team, children's team, small but involvement in prison healthcare and so on. 12:02

I don't wish to make the idea that we work in silos, we don't, we work across that and we try to ensure that we are using consistent methodology for inspections and all of that. But I don't think we can say that, for 12:02 example, waiting lists trumps everything else. You know, children's services are very much under pressure. You know, children's homes, not sufficient places. We've heard about the numbers of young people transitioning from learning disability aged 18 or 19 12:02 and the service isn't there to equip. You know, I'm saying there is a risk approach but it is focused on each of those programmes. We are required to carry out inspections of mental health units under the Mental

Health Order; we are required to visit children's homes under the 2003 Order; we have a small resource available for health and social care. We largely get our information about it from the public and from royal colleges and staff. On the basis of that, we do our two, three, four reviews or inspections based on that intelligence. I suppose it is not an ideal answer.

I should say as well, you know, there's more to be done in RQIA around technology and the use of analytics. It is very much, yes, we have some computerisation, of course we have a little bit but there's a lot of manual effort. I have no doubt that in the future there will be a much more enabled process through, you know, analysis of the information that would drive and inform where you should put your effort.

88 Q. I suppose if I give you a specific example in trying to understand the jigsaw of where governance fits together in the arm's length bodies. You were invited by the Department to look at the SAI process; you undertook the review of that?

A. Yes.

89 Q. SAIs fell under HSCB prior to that. When they sat under HSCB, RQIA could have unilaterally looked at the SAI process; do you agree with that?

A. Yes, although we could also look at it through the angle of the coming at it from the Trusts. So we had palpation of it.

90 Q. But because of the structure and the way in which it

sat under HSCB at a time, your legislation could kick in?
A. Yes, and --
91 Q. And you could serve, for example, an Article 41 production of information notice -- 12:04
A. Yes.
92 Q. -- if you needed to. You could serve an improvement notice if you needed to?
A. Yes.
93 Q. Now that sits under SPPG, SAIs, and you no longer have 12:04 those legislative powers to look at the SAI process. Now that's just an example, SAIs have obviously been discussed at length in this Inquiry and I know there's departmental work being undertaken around what might be improved and what the future could look like around 12:05 SAIs. Just as an example of where the pieces sit together in governance, there is some movement -- a slight movement in an arm's length body can result in governance being removed from RQIA where it previously existed? 12:05
A. Yes.
94 Q. Thank you.

Just briefly on the Care Quality Commission. I know they're your sort of counterparts but much bigger in 12:05 England and Wales. They have a much larger budget, much bigger staff and in fact have greater legislative powers, as I understand it?
A. Yes.

95 Q. Do you look with envy to them around some of the things
they can do in Trusts or do you think we're covered by
what they do?
A. I do look with envy to CQC in particular because of
their funding model; they are a full-cost recovery 12:06
model. In other words, all services in England, as you
have referred to earlier, are registered with CQC,
including the Trust services. The Panel members will
no doubt be aware. CQC recover the full cost of
registration, inspection and reporting from that 12:06
mechanism. They don't receive in the main any
government funding bar a particular piece of work they
might be commissioned for. I do envy that because
I think from a public money point of view for a start,
we are using government, public money, to fund 12:06
regulation of independent services. I think that's not
in keeping with Treasury guidance and good use of
public money, so I do envy that.

But always be careful what you wish for because I know 12:06
they have the authority to take away the -- close
a hospital or home, a ward, you know. Although from
speaking with them, I don't think they exercise that
very often and you would obviously be very cautious
about doing so. But I do envy the mechanism they have. 12:07
They're not subject then to -- at least I'm sure they
have pressures but they're not subject to efficiency
savings and so on that RQIA would be, given that we're
funded from public money.

96 Q. Some of the fees you received were set out in 2005?
A. All of them.
97 Q. So almost 20 years old.
A. Yes.
98 Q. That particular piece of legislation. 12:07

Is there any appetite or conversations around looking at the model of funding to allow you to have perhaps greater capacity or certainty around your funding revenue, but also to allow you to expand what you can 12:07 do and to meet your statutory duty?
A. Yes. We are looking at the potential to adopt a full-cost recovery model. Now, clearly it would require legislative change but I have seen the Department have an appetite, I think, to at least 12:08 explore it with us. That's encouraging.
99 Q. Given you've mentioned in your statement - just for the Panel's note at paragraph 65, 66, WIT-106016 - that you have severe limits and severe limitations on capacity, does RQIA meet its statutory duty around what is 12:08 required from it given those limitations?
A. No, we're not meeting it at present, Ms. McMahon. Although I've mentioned to you that care homes should be visited, for example, twice a year by way of example, this last two or three years, certainly since 12:08 pandemic, we have not been meeting that. Care homes are inspected once per year and the remaining numbers are inspected twice or more. 50% get a second inspection, others get up to seven or eight

inspections. Overall we're delivering around 800 inspections but they are being delivered on the basis of that risk-based intelligence. So we are breaching that legislative statutory requirement which, you know, we put in the public domain. 12:09
100 Q. Which is itself a risk?
A. It is a risk, it is a risk. Despite the fact we believe it would be reasonable for us to use our resource on a risk basis, you know, using the ideas of things we spoke about earlier, nonetheless the 12:09 legislation doesn't say that. The legislation is a frequency-based model and it doesn't say 'and respond when there's heightened risks'. It doesn't say that.
101 Q. So there's no flexibility for you?
A. No, but it doesn't prevent you going out. You can go 12:09 out as often as you wish but the minimum is you should go out twice and we are not meeting that.
102 Q. Have you corresponded with the Department or the Chief Medical Officer about your breach of your statutory duty? 12:10
A. Yes.
103 Q. They know that. Is that correspondence that has been frequently sent or recently sent? What's the position with their knowledge?
A. I would say they are fully informed of it, and at every 12:10 opportunity where we're engaging with them through quarterly meetings, for example, midyear accountability, end of year and so on, it is raised with them. I also have correspondence on record to

raise it. I mean, the Department know that that is the case. Mind you, it requires legislative change or a huge increase in financing to RQIA to enable us to fulfil that role if we use extant legislation. I see an appetite, and I think it is referenced in the Right 12:10
Touch that there is it an appetite to change the legislation, but I think it is acknowledged it will take a considerable amount of time.
104 Q. We'll look at the Right Touch just now. In those correspondences are there letters back reassuring RQIA 12:11
that efforts are being made, that there's a plan of action, that there's any way of interpreting the legislation that might ease the burden and allow you to still sit within your statutory duties?
A. Not fulsomely. 12:11
105 Q. We'll look at the Right Touch Report. Sorry, I wasn't sure whether that was a shorter answer or you were pausing.
A. I do get a sense the Department have empathy but, ultimately, the breach of the legislation falls to 12:11
RQIA; it is we who are breaching that. That legislation applies to us. We're a corporate body, as you mentioned earlier, so the risk is carried by us. The Department are aware of it. The financial position we all know is very challenging. To date we have not 12:12
found a resolve to it.
106 Q. Does it feel like that risk has just been accepted as existing?
A. Possibly. I suppose when you say it like that, it

makes me think about, should I say, we're all accepting
risks across the health and social care system at
present. Risk of people come to harm; factual that
people are coming to harm. So risk of breaching
statutory regulatory is another part of that pressure. 12:12
107 Q. Do you feel that anybody has ownership of the issues
that we've chatted about at a transformational level?
A. In service transformation?
108 Q. In the identification, for example, of the statutory
breach, do you think someone has ownership of that and 12:12
who that might be?
A. Yes, the RQIA have ownership of it, the Authority have
ownership of it. We understand it is our risk, it is
our breach.
109 Q. Is this not an example where it is not within your gift 12:13
--
A. It is.
110 Q. -- like it was for the emergency department in the
Royal. It wasn't, in your words, in their gift to deal
with some of the issues so special measures were held 12:13
off?
A. Yes.
111 Q. But is this not an example where it is not in RQIA's
gift to fix their statutory breach?
A. I would argue that that is correct but I suspect it 12:13
would take a court to decide where the liability falls.
112 Q. Hopefully we won't have to do that. But from an
ownership of these issues, and either the individual or
the Authority or the sponsorship branch, whoever it

might be who might transform this, who do you think holds that ownership?

A. Well, ultimately it's the Department. I mean, we are funded through government funding and fundamentally we believe that is wrong. We believe we already should be recovering the cost of registering and regulating independent services particularly, that we should already be recovering the cost of that from those services, and that the government funding - at least in part - would be directed towards inspection, reviews, and other methods for the HSC services. At the moment public services is compensating - I can't think of another way to say it - for the lack of change to the legislation. So the responsibility for the legislation lies with the Department and government, and we lobby for change, but for the moment we carry the risk of the consequences of it not changing. 12:14 12:14 12:14

113 Q. In relation to private practice and independent clinics, what's the position of RQIA, what's their level of engagement or nonengagement? 12:15

A. With the Department?

114 Q. No, with private practice. Individual doctors' practice, perhaps not in a clinic but operating from their own homes, falls totally outside RQIA. You have no authority around that whatsoever? 12:15

A. That would not be correct, Ms. McMahon. To date, RQIA -- you are quite right in saying that RQIA have not sought to register or asked private doctors, for want of a better description, private clinics,

independent medical agencies - clinics, sorry - to register with us. The legal interpretation of the 2003 Order until recently had indicated to us that doctors working in private practice who also had a role - employment - in the health and social care system, 12:16
inside the Trusts largely or in GP practice, were not required to register with RQIA, interpretation of the legislation being that they were pursuant to the 1972 Order, in theory connected in some way to the health and social care system and therefore -- 12:16
115 Q. So they were covered by employment in the hospital?
A. That they were covered by that. I suppose in part you could understand maybe the rationale for that because doctors who work in the HSC, the Part 4 services, are subject to appraisal, full practice appraisal. When 12:16
they are appraised, as I understand it, they are required to reveal information about both their NHS work and their private work as part of their fitness to practise process.
12:16
In more recent times, I'd say within the last 12 to 18 months, as I mentioned earlier we continue to examine the legislation all the time and get a contemporary interpretation of it, and in more recent times we've been advised that there is no protection 12:17
for private doctors working as part of the HSC, that private doctors should be required to register separately with us.
116 Q. Just to be clear, up until this point they haven't

been?
A. They haven't, and that is still the case.
117 Q. That is still the case. A doctor operating out of his
home, for example, still has fallen outside to date the
RQIA framework? 12:17
A. If he or she is working as part of the local, say,
NHS Trust, yes.
118 Q. So if they work in an independent clinic and they are
employed by HSC Trust, they'll fall within the
regulation of the clinic, I presume? 12:17
A. Yes, and several clinics -- we do have a small number
of clinics registered with RQIA but these are clinics
where doctors working within them are working wholly
privately. Many of the clinics that we might refer to
actually fall to be registered as independent 12:18
hospitals. Quite a lot of the well-known private
hospitals in Northern Ireland would engage, not
necessarily employ because some of the doctors might
work there on a locum basis or some kind of other
contractual basis, but they would work inside that 12:18
setting. The private hospitals are registered with
RQIA even if many of the doctors working with them work
in the NHS.

But it's where there's a private practice where the 12:18
doctor or doctors involved don't have any connection
with HSC that register. We have about 10 or 12 of
those, to my recollection. But doctors working in
their own premises or something else, we don't have

and, to be honest, I'm not even certain of the scale of it.
119 Q. Given your issues around capacity, if it were to be the case that they would - subject to the correctness of your legal advice, I'm not doubting it for a second - 12:19
but would that be something that you could embrace, given that you are already stretched?
A. We absolutely couldn't. We would need to either adopt a full-cost recovery model for it, which I take would require legislative change, or we would ask the 12:19
Department to fund us in the interim to take on that work. We couldn't take it on at present.
120 Q. Does anyone provide oversight for a medic undertaking private work in the confines of his own home or own office? Is there any oversight? 12:19
A. Yes. As I say, doctors working privately at home but also working in the NHS are subject to a full practice appraisal system.
121 Q. So under the HSC?
A. Under the HSC. Their responsible officers, their 12:19
medical officer whom they report to, so to speak, professionally in the Trust, for example, is required to ensure that the appraisal of the doctor, that he or she reveals their private practice. I'm not familiar with the actual detail but I know there's four or five 12:20
different elements to it, you know, feedback from patients, peers, incidents and so on, and that is certainly meant to encompass both private practice and NHS. Under individual appraisal, it should be visible

to the appraiser and ultimately to the responsible
officer. What is missed in RQIA not taking on the role
we've mentioned is we would be out inspecting the
service provided from those private premises, one or
more doctors, we'd be looking at the governance 12:20
arrangements, patient experience, medicines management;
we don't appraise or regulate individual professionals.
122 Q. So the doctor then reveals his private practice under
the appraisal process and that's the way in which he is
regulated -- 12:20
A. That's my understanding.
123 Q. -- at the minute?
A. That's my understanding.
124 Q. Now, you've mentioned about the possible embracing of
independent hospitals or private clinics and the fee 12:21
recovery model that might be needed to mirror that so
public money is not subsumed by that. Is it also an
issue around the regulation and quality improvement
that it is appropriate that that scenario doesn't
exist, that there is some oversight independent from 12:21
the appraisal process to quality improve or to
regulate?
A. Are you saying to me, Ms. McMahon, that this is private
practice we're talking about?
125 Q. Yes. 12:21
A. I would agree that in light of the recent advice and
also the fact that we know that private practice,
private healthcare, is an expanding service in Northern
Ireland and elsewhere, and I think the public and

patients who are able to access it or at times can
access it would benefit from knowing that such services
are subject to regular independent scrutiny. So I do
think there is an absolute need for it.
126 Q. For the Panel's note, there's correspondence to the 12:22
Chief Medical Officer from RQIA regarding the
regulation of the independent healthcare sector,
independent clinics at WIT-106610 to WIT-106614.

We mentioned the Right Touch Report a few times this 12:22
morning. As you set out in your second addendum
statement, it was a report that initially RQIA thought
that they perhaps hadn't had sight of, but we provided
it and it became clear that previous incumbents in RQIA
were engaged in some aspects of it. I just want to 12:22
take you to that to ask your views on some of the
detail of it. It is found at WIT-43429.

The Right Touch, a New Approach to Regulating Health
and Social Care in Northern Ireland. It is 12:23
dated June 2020. If we just move down to
paragraph 1.9. Just by way of background for the
transcript, 1.9 states:

"In 2001 the Department produced a consultation paper 12:23
entitled Best Practice Best Care in which it set out
three key proposals to support the provision of a fast,
effective and high-quality health standards. These
were Setting standards, improving services and

practices; delivering services, ensuring local accountability and improving monitoring and regulation of the services".

At 1.10:

"This resulted in the establishment of arrangements for the independent monitoring of health and social care services, a wide range of minimum care standards, and a patient-focused service frameworks programme, all of which contributed to improvements in quality and standardisation of services across the HSC".

There is then mention at 1.1 of the 2003 Order which we've looked at in some detail this morning. There's mention there of the duty of quality, which we've also spoken about.

Paragraph 1.13:

"A further development to reinforce and strengthen the quality and safety agenda was the launch of the Department's quality strategy in 2011 called Quality 2020. It defined quality for health and social care in terms of three components, safe, effective, and person-centred. That is now embedded in the clinical and social care governance arrangements throughout the HSC and underpins all work undertaken to monitor and improve the quality of health and social care services across the HSC".

The policy objective of this particular document is at 1.16 and it says:
12:25
"The regulation of services that may impact on the health and well-being of the population needs to be effective and appropriate in assuring the public that they are safe and of a high standard, and that providers continue to improve the quality of that 12:25
service".

1.17:

"To measure the effectiveness of this policy a set of 12:25
indicators will need to be developed. Reviews on what these indicators should be will form part of the consultation process for this policy".

They then set out the two phases. Phase 1 is to 12:26
approve the policy proposal, and then Phase 2 is to look at each provider type and determine what type of regulation will be appropriate. So, in general terms this was a root and branch consideration of regulation to see if it was fit for purpose and what may be done 12:26
to move things forward. It is a document you are now familiar with, I take it? For the purposes of the transcript?

A. Yes.

127 Q. Yes, thank you.

2.1, please, they set out the principles of good regulation.

12:26

At 2.2:

"Why would we want to regulate in health and social care? Regulation is designed to reduce the risk of harm to the public, raise public confidence, apportion 12:26
responsibility, and support continuous Quality Improvement".

2.3:

12:27

"However, where regulation is poorly designed or overly complicated, it can impose excessive costs and inhibit innovation and the provision of quality services. Therefore it is essential to have proportionate regulation". 12:27

I don't think you would disagree with that particular statement at 2.3?

A. No, I would agree.

128 Q. They then mention about the current regulation for 12:27
health, and they set out what you have told us this morning in your evidence about the various services that fall under the registered services provision of the 2003 Order.

Then if we just move down, please, 4.1. You then set out your inspection process, the way you undertake that. If we go to paragraph 4.1, they look at what they need to regulate. Under 4.2, when they discuss statutory health and social care, they say: 12:27

"Any policy aiming to provide assurances to the public of the safety and quality of health and social care should include the work of the statutory agencies, for example, the HSC Trusts, the Northern Ireland Blood Transfusion Service, HSC Board/Public Health Agency, etcetera. These bodies are not currently regulated by RQIA". 12:28

12:28

Now this was 2020, this document. If you stop there for a moment. We're four years on almost from that. Given what I've read out so far, is this still the existing document? Are there conversations that have taken place to reflect current movement in the organisations and the way they sit and the framework document that perhaps needs updated? Are there current conversations around that to update? 12:28

A. The first time I saw this document was when the Inquiry shared it with me, which was a few days ago. Although it says on the front cover of it 2020, I note at the end of it that it began being authored, I think, 2015. 12:29

129 Q. That's right.

A. I think it shows its age. Despite much of what you

have read out, I would concur with there's clearly some
areas that would need to be addressed, even that point
about "not regulated". It's true they're not regulated
in the same way as registered but RQIA have a
regulatory role, and that was established most clearly 12:29
in the last 18 months or so when there was a judicial
review held to challenge RQIA's regulatory role of
community mental health services. The JR was conceded
because RQIA accepted that we do have a regulatory. So
I would say even some of the language needs adjusted. 12:30

Overall these types of conversations are going on, but
I must admit no one from the Department had mentioned
this particular document to me.

130 Q. Just given the context of it, and I know you've had 12:30
a look at it, just in general terms before we look at
two more aspects of it, do you think it is on the right
track around what needs to be done? It does seem to
suggest an overhaul of regulations.

A. Yes, I was very encouraged when I read it. 12:30

131 Q. Because, as you say, there is a suggestion of
legislative reform that's required that would be needed
to underpin any new regulatory processes. Does that
provide a possible avenue to address some of the
concerns you've raised this morning? 12:30

A. Most definitely.

132 Q. Then they discuss about providers currently regulated.
Then the mention of new and emerging treatments and
procedures, so there is an attempt to keep up to date.

There's mention of dermal fillers or Botox, private paramedics and independent ambulances. The landscape is evolving beyond the current boundaries of what RQIA was set up to do; would that be fair?

A. Yes. I mean, we've reflected on some of the shortcomings, for want of a better word, on the existing legislation in terms of its application to registered and HSC, but actually this points to there's large swathes of services provided nowadays that aren't provided in any sort of regulation. Online providers; air ambulance I think is mentioned there; high street services, sports clinics. There's a whole range of things that the legislation currently doesn't cover and they are unregulated. 12:31 12:31

133 Q. Then in 4.5 they mention that as well, counselling, psychotherapy services, charitable organisations offering help and support to vulnerable people, which may include medical interventions. They mention at 4.6: 12:31

12:32

"In addition, there has been an increase in the numbers of medically trained staff setting themselves up as locums/agencies which do not fall within the current legislation".

12:32

4.7:

"These developments all represent services and treatments which are currently not regulated by RQIA yet they do have the potential of causing harm if not undertaken by competent and appropriately trained staff."

If we move down to 5.8, please. You talk about the types of regulation rather than a one size fits all; this is 5.9. "Right Touch regulation allows for a more flexible response by the regulator"; that's something you spoke to this morning.

Then at 5.10:

"For those providing a service or treatment which involves vulnerable people or high-risk procedures, the system of inspections will continue to be appropriate. However, for other providers a less intensive and more proportionate system could and should be introduced".

I think you'd mentioned about the burden on the public purse of the expanding of private practice, for example Botox, those sort of services that are provided, and if there was an expectation of regulation. Does this mean that your argument around a full-cost recovery gains more traction which you look at the potential broadening of the services?

A. I would say so, Ms. McMahon. I don't recall reading in the document but I have only read it a couple of times and I may have missed it, but I don't think it mentions

the-cost recovery model, but I'm sure that could be incorporated.
134 Q. It doesn't specifically address it in 2005 but I think there is an expectation if they were to unpick the 2003 perhaps and look at legislative changes to that, there could be something that encompasses that. I don't want to put the words in your mouth but just reading between the lines here, there seems to be -- 12:34
A. No, just what I read of it I think it is very encouraging and we certainly -- I mean, independent of knowing about this document, the encouraging thing, I think, is that RQIA, a current senior team and authority had arrived at the same conclusions independent of seeing this. We would concur with a lot of what is said there but I think it needs updated to the current timeframe. 12:34 12:34
135 Q. We'll move on after this to the learning in your statement which may also inform. The reason I am drawing this to the Panel's attention obviously is because they may consider recommendations around any aspect of evidence they've heard. It is just to give them a flavour of what this particular report touches upon. 12:34

Move down to 5.16, please. Another issue they look at is something we spoke about just a while back, assessing the risks. At 5.16, they say: 12:34

"For Right Touch regulation to be successful, we need

a system of risk assessment to ensure that the right level of regulation is put in place for each provider type. As the PSA puts it: Describing regulation as risk-based in the absence of a proper evaluation of risk is, in our view, misleading and can undermine 12:35
wider confidence and trust in regulation".

Does that reflect the tenure of your evidence as well?
A. I would agree with that.
136 Q. Then they say at 5.17: 12:35

"Just to be clear when we talk about risk, we mean the risk of harm to the public that the regulator is there to reduce. It is important to take time to reflect that the regulator's role is not to eliminate all 12:35
risks, that is not feasible, nor is it to provide safe care. The one with the primary responsibility to deliver a safe and effective service is the individual providing the service and, in turn, their employer who should be supporting the practitioner through the 12:36
provision of appropriate facilities, tools/equipment and training".

Then they go on at 5.25 to look at Quality Improvement. They say at 5.25: 12:36

"It is important that it is clear what is meant by the term Quality Improvement. There is no single definition but it is generally understood to be a systemic approach based on specific methodologies for improving care. Quality Improvement is not a one-off fix but a continual process requiring a long-term commitment. It is driven from within the organisation's workforce rather than something imposed from above".

To unpick two issues, obviously regulation and quality improvement, effectively the name of your organisation, to give a definition or some sort of scope of what that may involve. I know that you hadn't seen this until we provided it but do you anticipate you would be part of any professional moving this forward?

A. Oh, absolutely. I mean, I do -- despite not having seen the document and possibly even that those I have engaged with in the Department themselves may not be fully aware of it, I will certainly now be able to bring it to their attention. I see every opportunity in that for us to be fully involved in it. I'd see no reason from the relationship that we have with the Department and other bodies that that wouldn't be the case.

137 Q. You'll be in post three years in July this year. Is it normal for the wheels of potential improvement to move so slowly around the role of a regulator?

A. Well, I'm not too experienced in the role of a regulator, but change sometimes happens very slowly and sometimes it can happen very rapidly as a result of service chaos and catastrophe. The important point

about the RQIA, I think, is there should be a control
mechanism for Quality Improvement and give people the
skills and ability to improve in every part of the
service as opposed to imposing a programme on them.
But yes, the wheels can move slowly. 12:38
138 Q. I suppose in totality, this document would seem to
suggest that the Department is well versed and well
sighted of the shortfalls in regulation that at least
existed at the time of this publication but perhaps are
each more broadly known or more widespread than this 12:38
document reflects?
A. I would agree with you. As I say, I haven't had the
opportunity yet to discuss it with colleagues and the
Authority, but I find it very encouraging. I think it
makes me feel that there's a potential for us to move 12:38
more rapidly on the points we're making through our
conversations. This seems to reveal a real appetite
for doing that.
139 Q. I know you say it is very encouraging, is it also very
worrying in some respects that this knowledge is there? 12:38
There are clear lacunas and gaps in service provision
or regulation provision, that there hasn't been
a greater movement forward to sort the issue around
regulation out, given how fundamental it is to risk and
patient safety? 12:39
A. I would agree wholeheartedly with you. I think there
needs to be a more accelerated process. It is not
reasonable for us to be sitting on legislation that is
20 years old for a modern service.

140 Q. If we just go down to paragraph 5.28. This is specific to RQIA's powers. It says at 5.28:

"For a regulator to be effective, it needs to have powers to sanctions providers who fall short of the 12:39
standards expected. Currently RQIA's powers in this regard are limited".

5.29:
12:39
"In the same way that Right Touch broadens the range and scope of the types of approach to regulation open to RQIA, it also provides for a more flexible regulatory response to providers whose care falls below expected standards". 12:40

5.30:

"It is proposed that any new legislation to bring into effect the policy of Right Touch regulation will also 12:40
extend RQIA's range of powers to impose sanctions. These may include fines for poor standards of care without the need to secure a criminal conviction; Financial penalties for organisations requiring reinspection over and above minimum statutory 12:40
requirement; debt recovery when registered establishments and agencies fail to pay fees".

Given your evidence, there might be some other sanctions that you feel may be appropriate in relation to trying to bring about the change that a review or inspection might identify as being needed?

A. I'm sure there are. I suppose even looking at those, we'd have to be careful that if such financial penalties were imposed potentially on the HSC services which is funded from the public purse, in many ways it is the public money circulating in the system. So, we'd just have to be careful of it. But one of the other examples of penalties, so to speak, that we're able to effect in registered services is the setting of conditions or providers. For example, we can, in registered services limit the service so that it can't receive new admissions until we're satisfied that they're compliant with the quality standards. That's not the case in the health and social care sector; we've no ability to set conditions. So there may be other aspects than just the service model that adds leverage to, you know, taking the actions that are necessary.

141 Q. So there could be a menu of potential sanctions that were discretionary based on the context?

A. I suspect so.

142 Q. 5.31 then, the final paragraph for our purposes:

"The detail of the sanctions to be provided will be developed in cooperation with RQIA, service providers and users included in any draft legislation, and will be subject to full public consultation before the draft legislation is submitted to the Northern Ireland Assembly".

You are specifically mentioned there as being involved in cooperating to look at the sanctions and for them to be developed with you. Also, we now have an Assembly so the last sort of words at the bottom are now in place. Is it something that you, as chief executive, would be minded to follow up on and ask the Department for an update on where they are?

A. Certainly. Any engagement we have with the political parties, now that they are reengaged, and we do, it is certainly something also that will be drawn to their attention that needs to come sooner rather than later into the legislative inbox.

143 Q. The Panel will have the benefit of hearing again from the Permanent Secretary after Easter, Peter May, so we can ask him about any movement forward in that regard.

Just on the issue of learning, for the Panel's note you deal with this at paragraphs 129 to 136, which can be found at WIT-106034 to WIT-106036. I just want to have just a brief look through to see if there's any of the issues around learning. RQIA's involvement in finding about the timeline for the purposes of this Inquiry was the early alert?

A. Yes.

144 Q. That was in July '2020.

A. Yes.
145 Q. So you had been in post just prior, just one year?
A. No, I'm in post '21.
146 Q. So this is before your time?
A. Yes. 12:44
147 Q. When you look at some of the issues that have arisen before the Inquiry to look at, are they issues that you think RQIA could have known about, should have known about, might have known about through all the different sources of intelligence available to them? 12:44
A. It's difficult to speculate but there's no doubt -- it's not required of the organisation to notify us of that situation. It's not required of us. Even when we are notified, it would be treated as part of intelligence as opposed to the necessity to have 12:44 a direct response, particularly when we know that the Trust has established a lookback exercise, the Department are involved and so on. Certainly, you know, reflecting on what we've learned so far in this Inquiry and from others, neurology and so on, I do 12:44 think RQIA have had to look in the mirror to see what more could we be doing. It is not sufficient to say the legislation needs to change. It does, but are there things we could be doing now that would make us more able to identify this? 12:45

One of the aspects is there's lots of regulation in many ways going on, or scrutiny. You know, GMC, responsible officers, Trust Boards, midyear assurance and RQIA, and yet it is very clear there are gaps between us. Some refer like the Swiss cheese. One of the things we're committed to doing is trying to work better as a collaborator with other professional regulators. We're a service regulator, others are professional regulators, you know, social care, General practice, nursing and so on. So one of the things we will take from this and from other reviews is to take a more leading role in collaborating with shared intelligence with other regulators. A colleague of mine calls it the emerging concerns protocol. It's about deliberately coming together in different parts but as regulators in a joint forum to look at issues, whether they are coming through registrants, through appraisals, through service reviews; are there areas that we could try to reduce the gaps between us?

Equally, I would have thought in terms of things like the reviews we carry out, despite legislation is unlikely to change soon, could there be more visibility of the closure of those? I, in preparation coming to the Inquiry, just took some of the recent reviews and searched on the Internet to see if I could find if Trusts had acted on those. For example, I think it was choking I looked at, one of the recommendations had been that all staff working with vulnerable people should have dysphasia training as mandatory. Now I searched around and I did come across one of the Trusts had some wonderful material published about

seeming to have acted on it and so on, but it was
difficult for me to find that. I wonder even now could
there be better visibility of actions being taken
because of the point we discussed earlier; the action
taken is only an instrument of improving safety. 12:47
But I do think it is difficult for the public, and it
said in the document earlier that part of the
regulatory role is to give assurance to the public. So
seeing closure on that, or at least completion of it,
could be something else we could possibly do, 12:47
notwithstanding the legislation needing to be
modernised. I think we could -- you know, if we say
that's the only thing, we are to wait for the
legislation to be modernised, no, we have to improve
safety long before that. We have a role as well in 12:47
terms of encouraging staff to speak up. We hear in
many of the inquiries that we've heard that sadly
families have spoken up, staff have spoken up, and
often they have not found the mechanism to be heard or
acted on. I think we regionally could have a great 12:48
role in encouraging and adding leverage to the need for
being open and transparent in these things.

We also have a role in terms of whistle-blowing. We're
an organisation that staff can contact us about 12:48
concerns about patient safety and harm. We could
promote that role, I think.
148 Q. You have mentioned inquiry's that have preceded this
Inquiry, the hyponatraemia and neurology made

recommendations around governance as well, obviously impacting on regulation and oversight for quality. Are they issues that have found their way into your operational practice and the Trusts', or is it capacity prevents you from making good the findings from those enquiries?

A. Capacity will always be a challenge. But no, we are progressing. We committed to the public and to families that if the neurology inquiry -- for example, there's seven or eight actions we're taking to share the learning from that inquiry around, you know, doctor and peer reviews and multi-disciplinary working and so on. We're developing materials out of the learning families shared with us that we will share with educators and medical personnel.

Another element of it is we're developing a Patient Safety assessment tool. We'll be looking to other jurisdictions who already are using some versions of that, and it's not saying that it is the answer to everything but it's about trying to find tools in our regulatory role that when we're out reviewing and inspecting, we are encouraging openness and requiring openness because that's a big factor. Families and staff are most often, we hear, the early alert to patient safety issues. We cannot wait for the graphs and the tables and the outcomes and the harm before we look to early indicators. We think we could play a greater role in that.

149 Q. You also suggest at paragraph 133 of your witness statement - for the Panel's note that's at WIT-106035 - and you suggest that a requirement for private medical, including surgical practices, to register with RQIA might have identified issues with the practice of this doctor. Is it just a potential of that you argue, but again that requires legislative change? 12:50
A. That doesn't because we already could register private doctors if we had the capacity to do so. I can't say that everything would be revealed but certainly a further layer of scrutiny on the practice as opposed to currently where, you know, there's individual medical assessment. I'm not expert on that by any means, but we would definitely recommended that out of this and other reviews, that we should find a way to create capacity for private practice to register with us. 12:50 12:51
150 Q. Because of your interpretation of the legislation?
A. Because of interpretation of the legislation and because I think the obvious growth in the sector and the need for the -- for us all, and the public and the patients using the services, to be assured they are inspected and are meeting minimum standards. 12:51
151 Q. You've mentioned the emerging concerns protocol with service regulators so that everyone's joined up approach for communication. You mentioned around staff feeling safe to speak up? 12:51
A. Yes.
152 Q. Is that something that you can have any impact on as

the regulator when one considers the reasons and the many reasons people don't speak up and sometimes when they do, then it doesn't always end fruitfully? Do you have a role in that changing culture?

A. Yes. A few months ago, November, we held a conference regionally, invited senior people from across the Department and Trusts, and service users and others. The conclusion of it -- it was all about speaking up and being open and creating a safe space for that. The conclusion of it is, you know, all of us have to play a part in it. We as a regulator have to play a part. We know reputationally, often people are fearful of it. So if that's the case for regulation and it is also potentially the case in employment, you know, we have to work together to create the safe space. We'll be holding another event now this May and, look, events can only punctuate the discussion, if you like, but yes is the answer, we must play a part. 12:52 12:52 12:52

When we're out on our travels, as I say, when we're out on inspections and in reviews, we have a lot of contact with staff and with patients and actually the opportunity to build up a modest relationship and trusting relationship. So, we have to use that role to create the avenues or another vehicle where people feel safe to speak up. 12:53 12:53

153 Q. Just finally at paragraph 136 you say:

"RQIA will develop a safety culture assessment tool to identify, encourage and support openness in learning. This will enable a robust report back of findings in this area to HSC organisations to assist them in taking action to improve".

12:53

Has that been developed, and how is it progressing?

A. Yes. We're in the early stages of it. A colleague of mine in the organisation, a medical colleague, is leading on it. As I said earlier, we don't see it is a panacea for everything but when we go out and do 12:53 inspections in EDs or maternity wards or anywhere else, this tool would allow our inspectors to look for what's the evidence of an organisation that is open, what's the evidence you would look for for staff feel safe to speak up, what is the evidence that this is a learning 12:54 organisation. So this tool, and there are many in place in other parts of the UK and we'll look to those as well rather than reinventing, but the idea is to add another tool in our portfolio of tools that might help us encourage and support organisations to be open, safe 12:54 environments for learning, for listening, learning.

154 Q. I've covered everything I'd like to cover for the purposes of the Panel teasing out some of the areas of potential interest. Is there anything you would like to say at this stage or anything you'd like to add that 12:54 we haven't covered?

A. Only to say that we want to be helpful to the Inquiry. If there is anything other that we can provide to Panel, Chair and members, very happy to do so. We do understand this is a whole system that is working or trying to work together and our role and primary role is patient safety. When any event occurs that clearly disrupts that or concerns us all about it, we have to look to ourselves as well. We just want to play a full part in finding, not necessarily solutions all the time but resolution to these. 12:55

The patient safety journey in the short time I have been with RQIA, I see it as never-ending. There's never a time when we can say a service is safe and walk away. It is a constant journey because the risk in the environment changes every moment. So, we're a part of this whole process and want to play a full part in any resolutions. 12:55 12:55

155 Q. I have no further questions but the Panel may have. Thank you.

CHAIR: Thank you, Ms. McMahon, thank you, Ms Donaghy. Mr. Hanbury, I think you have some questions.

12:56

THE WITNESS WAS QUESTIONED BY THE PANEL AS FOLLOWS:

156 Q. MR. HANBURY: Thank you very much for your evidence. I have one or two things for you.

12:56

The Inquiry heard quite a bit about cancer medicine surgery, and compliance in standards and guidance in multi-disciplinary team working is a big part of that. There was a peer review at the Southern Trust in about

2015, before your time in post, which they didn't do terribly well at, there was about a 65% mark. That was redone as an external peer review two years later in 2018, and that figure dropped to 35%, which obviously is not going the right direction at all. Did things 12:56
like that filter to your organisation?
A. I can't confirm absolutely and colleagues would be able to, and I'm very happy to report further. Certainly, I have seen independent peer review reports coming in from other Trusts. I'm not familiar with those ones 12:57
with this particular Trust but I have seen information shared with us from other Trusts where they engaged maybe the Royal College or someone to undertake. I can't confirm about those particular reports.
157 Q. If your organisation, if RQIA had been told about that, 12:57
would that have been a red flag to you to step in or give advice or...
A. Not necessarily because in the HSC sector there is an understanding that the Health and Social Care Trusts hold the statutory duty of quality, they have Trust 12:57
boards, they have committees, they have oversight, they have direct access to the Department of Health and so on. Generally we would wait to see is there an added value we can offer? Is there something in us stepping in that would be helpful? It is not to repeat the 12:58
investigation; it's not to, you know, compete with some other organisation but is there an added value we can bring to it?

The example of the lookback was where we, even in the effect of inquiry, internal reviews and lookbacks, we did step in to give an opinion on the robustness of the methodology but we didn't repeat the investigation. I can't say for certain but it wouldn't be usual for us 12:58 to repeat or revisit. But we would certainly use reports like that to inform intelligence. It may be that in the next series of reviews, an area such as surgery or cancer services might well feature then in something that we would review across organisations. 12:58 Where lessons have been learned in one Trust, we would seek to examine them more broadly.

158 Q. I suppose on the same theme, you mentioned GIRFT, Getting It Right First Time, and that has been a force to improving. Especially in the benign side of 12:59 neurology, things for example like stone disease where people get a stone blocking their kidney, the time from presentation to treatment, things like when a gentleman can't pass urine, go into retention, the time from that having their prostate surgery and, in more general 12:59 terms, having access to day surgery and how that is taken up.

Are you surprised that GIRFT wasn't brought into Northern Ireland slightly earlier, because they visited 12:59 and looked at urology in 2023, but that's...

A. I can only say it has a good reputation. I mean the Get It Right First Time, I know Northern Ireland now -- and I should say RQIA are not directly cited on the Get

It Right First Time work. In recent times we did
request to see the GIRFT Report in the unscheduled care
in ED because of the work that we were doing in the
Royal Victoria. But outside of that, it wouldn't be
routine for us to be engaged or involved or even 13:00
necessarily in receipt of those sort of...

Again, it falls into this category of it's a different
construct. The Department of Health and the Trust
themselves, the Department of Health engaged in GIRFT, 13:00
the Trust themselves often invited reviews; they can
invite royal colleges, they can invite outside of the
regulatory role. So I'd have to say to you there's
much going on inside the HSC system around reviews and
quality improvements that RQIA would not be closely 13:00
cited on.

159 Q. Thank you. Just one more. On the subject of national
audits and we're aware Southern Trust, some departments
like cardiology and stroke and fracture neck and femur
learned a lot through national audits. The Urology 13:01
Department either didn't or weren't enabled in some way
that I don't quite understand yet to partake in
national audits run by BAUC, which is our organisation.
Of course, then we don't have comparative surgical
outcome data so that they could compare themselves with 13:01
their peers. That again has been something that
I guess RQIA would be looking at.

A. Again, we are not particularly cited but I do know from
working in the Trusts about the national audits, and

from my recollection of it Trusts were invited and quite often regionally would be agreeing to contribute to a national audit on stroke or maternity or community services. I do agree with you, benchmarks that are published as a result of that can be very persuasive in 13:02 terms of relooking at your service model if the outcome has been achieved by others in the same field. So again, I'm not able to comment very fulsomely on it but I am aware of the value of the national audit programme. 13:02

MR. HANBURY: Thank you very much. No more questions.

160 Q. DR. SWART: I think Ms. McMahon asked you about whether you were envious of the CQC and your response indicated that you were envious of the funding model. Is there anything else you are envious of, what that has 13:02 achieved in England or perhaps what it hasn't achieved? Perhaps can you give me some observations?

A. Just a personal observation, when I see some of the products they have produced, if you like. They have very much published, for example, as Ms. McMahon was 13:02 speaking about, you know the risk framework. You can look very readily at their website and you can see how they assess risks inside organisations. They also use a rating model, for example, so services are rated. Now look, I'm certain that comes with risks because 13:03 a rating is appropriate to the day or the time you carried out the inspection or review and if you haven't been back for several years, can you stand over it?

They also have a huge involvement of service by experience experts. I mean, we recently reintroduced the idea of what we call inspection support volunteers. We have five or six volunteers starting with us on inspection. I know the CQC, I think, have over 13:03
a thousand. These are patients, public, lay people, who bring exceptional knowledge and experience to the inspection and review programme. I would be envious; we need to grow much more of that collaborative effort. Our challenges are that a small organisation which I've 13:04
described, you need to be able to provide the support to volunteers and others. Peer reviewers is another example. You need to be able to provide the support to them. Taking on big numbers of people, whether volunteers or peer reviewers, still need that kind of 13:04
investment. These are the things we struggle with in terms of growing as an organisation.

We have a really good relationship with CQC, and in fact all the UK regulators and the South of Ireland 13:04
meet regularly. I suppose "envious" isn't the right word but I do look to them as setting some models that we could replicate around intelligence, risk assessment, full cost recovery and, you know, lay people being involved in the inspection process. 13:04

161 Q. On the matter of intelligence, which you also refer to in your witness statement, it strikes me that most of your intelligence is not provided in the form of an automatic suite of indicators and information that you

can look at, which it is in England. For example, the CQC would be able to say part of the risk assessment would probably relate to that. It would say we have noticed a deviation, it might be a metric from the national audit, it might be from a number of sources, but it is not just harm or incidents or complaints, it's much more related to the quality of the service. Now, that's not just a matter for RQIA, it is a matter for the whole of Northern Ireland, I would suggest. Can you see that that's perhaps a gap in terms of how things have been looked at?

A. Most definitely. I mean you've described it very well, and I know from engaging with CQC they have made a big investment - a few years ago now - in technology and so on, but also in supporting their inspectors, I'd say, through prompting and showing trends and analysis. We are very far behind. Much of the efforts I've been describing to you about intelligence assessment are laborious, lots of Excel spreadsheets and pouring over data. So there's no doubt, small inklings of positives. We've recently signed a memo of understanding with Queen's University and Care Opinion, who you may know is a platform in Northern Ireland for patient feedback, to explore an artificial intelligence approach to examining stories and so on. Now, in some ways that's a quantum leap for us given that the data we are working on is quite old-fashioned. But if we don't have those conversations now, you know, we'd like to think that in several years now they might come to some fruition.

We know there's a huge investment in Northern Ireland to encompass this whole computerised system for the NHS Trust. RQIA are not involved in that but we are 13:07
involved in the training aspects of it, and it may be that some analytics, intelligence, whatever we might want - dashboards, whatever - might be harvested from it.

162 Q. In that context, I find it surprising just personally 13:07
that that Right Touch Report wasn't a matter of ongoing discussion. Why do you think that is? Why has that not been brought to the fore because it is quite an important document, looking at it as an outsider.

A. Yes, and looking at it as an insider, I would agree 13:07
with you. I'm putting it down at the moment to this loss of corporate memory, but I don't think that's a good enough reason.

163 Q. It isn't just RQIA who is looking at it itself. So what does it tell us? What does it tell us about the 13:08
current gaps in regulation, the fact that it is not so active in itself?

A. I mean even in searching -- as I say, it is only a few days I've had in looking where it was located in our system. I don't think from the modest review I've had 13:08
to far that it was understood in RQIA how radical it was because --

164 Q. Who had the job, though, of leading those discussions because it is not just RQIA, is it? Where do you think

that has sat for the last three years or four years?
A. I honestly don't know because I have taken --
165 Q. This is a genuine question because I don't know.
A. One I am trying to genuinely answer. I am uncertain because I know that with the colleagues I'm dealing 13:08
with in the Department, we are having these conversations and actually both of us blind to the fact that this work had went on. As I say, the report is encouraging but the fact it has obviously done so much work to get to that point seems to be stalled. I could 13:09
be speaking wrongly, when I go back and speak to departmental colleagues, they might educate me differently, but I can only say it's only through the Inquiry I learned of that. I think there's a lesson for us in that. 13:09

I have done immediately inquiry into seeing where it was placed in the organisation and so on but I'm not stopping there. I'm going to do a full-scale search to see where, to track it. To be honest with you, I have 13:09
a concern that it may not have been placed on the agenda of the Authority and that it may have been subject to executive team relationship. We've already rehearsed earlier that was dysfunctional. I'm possibly thinking - my Inquiry may fall on -- may not be 13:09
correct - but that's my fear. I believe if it had been placed at an Authority level, it would have come through in the papers and so on. It would be more difficult to fall off the end of the discussion.

166 Q. Thank you. One of the phrases you've used in terms of the things you have been able to look at with respect to the Health and Social Care Trust is you are touching the surface of the issues. As a regulator, that wouldn't be ideal, I think you would agree. What would it take to move this whole area of regulation, which may be RQIA and others, including the Trust, from where it is now to what could be described as a comprehensive regulatory framework? Not to say that regulation is everything because I think the intelligence side is just as important, but what would it take to move to that, do you think, in terms of the discussions that need to happen with Department of Health and SPPG, the Chief Medical Officer, the Trust and so on? Where do you see that conversation going and developing? 13:10 13:10 13:11

A. At present I think it has changed a little bit in recent times but, historically, regulation as provided by RQIA for the HSC sector has been seen very much as a programme of work. It's not a responsive service, it's not a service that responds to intelligence. It's a programme of work set out the year ahead and that's its place. 13:11

It has morphed, changed, since the pandemic and perhaps before it. I was reflecting with colleagues in another Inquiry - Muckamore, for example - we were looking at the changing inspection methodology that evolved, you know, over 2018, '19 and '20. I certainly see since the pandemic and since public inquiries there's 13:11

a desire by RQIA, and I think an expectation by the public, that we are a responsive service; that when things go wrong - and you'd certainly like to think that you're there long before things go wrong and that you are possibly preventing things going wrong - but when things go wrong, that you do have a role. The role of RQIA when things do go wrong, as the Panel have indicated, I think is not clear. There needs to be greater clarity on what should be expected of RQIA, even within -- 13:12 13:12

167 Q. What is going to make it happen is really what I want to know, in your view?

A. It is going to be the Department working with us. I think there is an appetite for it but it is putting some rigour into that. It needs to happen soon because we do get calls from the public and others who are concerned about things. My colleagues and ourselves at RQIA, wish to respond, we want to respond but we also have a statutory role in terms of frequency of inspection of registered services, and it is a constant balancing. So some clarity and more flexibility, even within the confines of the existing legislation, would go a long way, I think, to understanding expectations of regulation, what can be expected of it. 13:12 13:13

13:13

Actually, I would add into that the Trusts as well because I think the Trusts are probably unclear; Am I not meant to tell RQIA when something has went wrong? Am I meant to ask them to do something or will the

Department do that? I think there is a time for us to be much clearer on the added value we can bring to it all.

DR. SWART: That's all from me. Thank you.

168 Q. CHAIR: If I can just pick up on the impression that the public would have. The very name, Regulation Quality Investigation Authority, that says to the public that you can do something about the services that they get. Clearly you can only do so much under the current legislation. 13:13 13:14

A. Yes.

169 Q. I suppose, really, is it going to take more legislation or do you have a responsibility to educate the public about what you can and can't do?

A. I think we do. My fear, though, is as we do go out and engage with the public and we do make effort to -- well, we're launching annual reports or explaining something about a judicial review, it's difficult to explain and it not sound like somehow walking away. So we're struggling at the minute and figuring out how do we make best use of the capacity that we have available for the HSC service. We really cannot take from the registered sector, despite the fact that we're not meeting. I don't think it's reasonable to say, well, you're not meeting two visits a year so therefore you should take a bit more of that resource. That's not reasonable. We must try our best to meet the statutory requirements. It gives us a very limited resource for HSC but we must make every effort. This 13:14 13:14 13:15

is why I'm thinking about things like that leverage
that we could use in our role to encourage
organisations to being open, I mean. So we have to
think a bit smarter in it. We have to work better with
other regulators and others; we have to collaborate 13:15
better. We're independent but that doesn't prevent us
from being partners and collaborators in patient
safety.

We have to use the limited resources we have and build 13:15
capacity through connections with others, through the
use of tools. You know, we're using conferences and
reports and so on; they're very modest. I think
we will continue to challenge ourselves to make the
best use of it, but there is clearly a need for 13:16
legislative change.

CHAIR: Thank you very much. That's been very helpful.

Is that it, Ms. McMahon, nothing further? No. See you
again at 10 o'clock, ladies and gentlemen, tomorrow. 13:16

THE INQUIRY ADJOURNED TO 10:00 A.M. ON WEDNESDAY 21 FEBRUARY 2024