Friday, 17 January 2025

(9.30 am)

LADY JUSTICE THIRLWALL: Ms Brown.

MS BROWN: Yes, if we could call Mr Kark, please.

MR TOM KARK (affirmed)

Questions by MS BROWN

LADY JUSTICE THIRLWALL: Do sit down, Mr Kark.

A. Thank you.

MS BROWN: Could you please give your full name?

A. Tom Kark.

Q. You have provided a witness statement to the Inquiry dated 24 July 2024 and is that true to the best of your knowledge and belief?

A. Yes.

Q. Mr Kark, you are a barrister called to the Bar at Inner Temple in 1982, appointed as Queen's Counsel in 2010. Also in 2010 you acted as Counsel to the Inquiry in the Mid Staffordshire NHS Trust Public Inquiry chaired by Robert Francis, now Sir Robert Francis, and in 2018, you were asked by the then Minister of Health, Stephen Barclay, to examine the working and effectiveness of the Fit and Proper Person Test under Regulation 5 of the Health and Social Care Act 2008; is that correct?

A. Yes.

Q. The report you prepared with fellow barrister Jane Russell was published in February 2019 and you have set this out in your statement. But could I just ask you to explain what the reason was for the commissioning of that report in 2018 looking at the Fit and Proper Person Test as it applied to directors of hospitals and Health Trusts?

A. Yes, certainly. So the background is that Sir Robert Francis in his report recommended that there should be what he described as a new Fit and Proper Person Test with much stronger powers, including the power to effectively disqualify a director.

The Government responded to that with their document called -- and this is set out I think in my statement -- "Hard truths", where they made a, gave a number of assurances as to what they were going to do and they were going to give the CQC additional powers effectively to disqualify directors. And then I think in the middle of all of this Dr Bill Kirkup was undertaking a review of the Liverpool Trust, where things had gone badly wrong, and one of the things that he said was that there should be a review of the Fit and Proper Person Test. And I think that's what led to me being instructed to conduct that review.

Q. And why in your view was it that despite

Sir Robert Francis highlighting in 2013 the problem and despite the response of the Government in their Hard Truths document was it still identified as being a problem in January 2018 by Dr Kirkup?

A. Well, first of all the CQC wasn't given the sort of powers that the Government had said it was going to be given, and as I said in my report, they, frankly, as far as I could tell when I spoke to them, didn't want those powers and they are not set up to undertake that sort of exercise because in general terms, as you know better than I do, they, they regulate organisations.

And one of the central parts of the test was that directors should have the skills -- I can't quite remember the wording but the skills competence and the qualifications to undertake the role that they were being appointed to. But those weren't set out anywhere.

So what was happening was that if you had a very well-known very good teaching hospital you might have a queue round the block when they advertised for a director's position and they could use that test, you know, with a considerable amount of rigour.

If, on the other hand, you had a Trust that wasn't so popular, as it were, or attractive, and there was very often a dearth of applicants then what were the skills and competence to do a director's job became

something of a sliding scale. So there was no benchmark for what any of that really meant.

So parts of the test were very easy to adopt, so you can check to see if somebody is on the DBS list, you can check to see if they have been erased by the GMC or whether they are bankrupt. Those were the what I have called in my report the "barn door" tests, those are very easy but the skills and competence and qualification was much harder and so that was one of the reasons certainly that I think the test was failing.

The second obvious reason was there was no power to disqualify. So what was happening, and this has been a problem in the NHS I think for a very long time, it's been identified by people long before I identified it, was the so-called revolving door of the NHS where people have potentially misbehaved or behaved very badly, they come to a settlement agreement with the Trust to save the Trust the bother of having to go through a full disciplinary process, part of that settlement agreement is a vanilla reference.

The director moves on to the next Trust down the road and the problems get --

LADY JUSTICE THIRLWALL: Did you say a nil reference or a vanilla reference?

A. Vanilla.

LADY JUSTICE THIRLWALL: I thought that, just so we get it on the transcript.

A. One that says "X has been employed here between X date and Y date and their conduct was satisfactory" or something which is anodyne and unhelpful.

And so under the test as it was there was absolutely no way of closing that door off and also what was happening was that if, if a director had been found to have been misbehaving and they left a Trust, they would go into one of the other sections of the NHS: apparently NHS Improvement was often a welcome organisation, surprisingly.

They would spend a few years in some other bit of the NHS, then they would pop out again into another Trust and I think that was thought to be extremely unattractive.

MS BROWN: Just picking up on that, Mr Kark, so when your report was published in February 2019 that problem of poorly performing directors moving from Trust to Trust I think you refer to the revolving door that Robert Francis had highlighted. Your Inquiry or your report found that that was very much still a problem --

A. Yes.

Q. -- in 2019?

A. Certainly. And when we spoke to a number of whistleblowers and to those who were responsible for -- Speaking Up Guardians and the like, they all had stories of having been bullied effectively and found themselves out of a job, either the director who bullied them was continuing in that function or had moved to another Trust and I think Dr Bill Kirkup pointed out one of the problems was sometimes that a bullying manager would get moved to another hospital but within the same area and the person who had been bullied might find themselves actually still working for that individual.

So there was this constant sort of merry-go-round.

Q. Just thinking then a little bit about the chronology. We have got Sir Robert Francis's reporting in 2013, Dr Bill Kirkup in 2018, your report being published in 2019 and we will come to it, but the framework responding to your recommendation not being published until 2023, and it's correct, I think, that throughout this period from 2013 onwards, the problems that Sir Robert Francis had highlighted carried on being a problem?

A. They had been highlighted by Sir Ian Kennedy long, long before, and subsequently by Lord Rose and various others.

Q. And given your experience as well both as

Counsel to the Inquiry, but also then as someone writing a report, what was your understanding of why it took so long and particularly why it took so long for a response to your report that was requested from 2018 when you were commissioned to do it until 2023 when the framework came out?

A. Well, in some ways I thought the response to my report was quite quick. I don't mean to be flippant but things work very, very slowly. But also making, it is, it is easy to make a recommendation actually putting recommendations into practice I think one has to recognise takes a lot of effort and I think one does have to recognise that the work that must have gone into the framework was very extensive because of a lot of consultation et cetera. So I am simply pleased that there is now a framework and that something has happened.

Of course it could have happened quicker and it probably should have happened long before I reported.

Q. And the framework came out in August 2023. Are you aware of whether the Letby case was instrumental in promoting or prompting that framework coming out at that point?

A. I don't know.

Q. And just staying with the issue of

implementation of recommendations, are there any factors that you consider to be changed to hasten the process you have explained that it is a complex process putting recommendations into -- into practice. But are there any factors that you think could assist in that happening more quickly?

A. Do you mean in terms of when a report writer makes recommendations and then what happens?

Q. Yes, the process after a report, are there practical things that could assist in those recommendations being brought to fruition more quickly?

A. This, this has been looked at quite recently, hasn't it, by the House of Lords, the Select Committee or a Special Committee looked at the implementation of reports and it was interesting to read that the previous report that had been written by the same Committee in 2014, half of the recommendations had been adopted by the Government and then never put into effect.

So it's not just Inquiry Chairs who have this problem.

One of the difficulties that I faced, and I am currently having to face in my other role, is that as soon as you have written your report, whether you are just a report writer as I was or you are a Public Inquiry Chairman, your power dissipates as soon as you

have delivered your report and this is a common complaint, I think, by Inquiry Chairs.

Robert Francis had the clever idea of keeping his going, I think, for a while because he got the Health Select Committee on board to review his recommendations and I think -- as to which recommendations had been brought into effect, and that was I think partly successful. I think they did that for about two years and then it got lost in the ether.

And other Chairs had taken steps like issuing an interim report but holding the very, very final report back so that they could still call people back.

But I think that is one of the main problems with the Inquiries Act, that your power just dissipates once you have delivered and I personally found it very difficult keeping track of what on earth was happening about my recommendations. It's even harder, if I may say, so as a mere barrister; you have absolutely no weight at all. And it was about four years later that I discovered purely because I received an email and somebody's title was the Kark Implementation Manager and that was the first time that I knew I was being implemented that many years later, because nobody had contacted me until then.

So your report goes into the ether and very often

it's very, very difficult to keep track of what's happening.

So I think it would be -- sorry, this is a very long answer to a short question. But I think it would be very, very helpful to have somebody in the sponsoring department who is tasked with keeping you in touch with what is going on. And I know the Cabinet Office have now set up their Inquiries Section, so that may help.

Q. And if we could turn now to a specific aspect of your report and if we could call up INQ0012637, 0097, and, Mr Kark, for your reference I think you have a copy of your report in front of you, this is internal page 91.

A. Thanks.

Q. So you deal there with settlement agreements which we have touched on and you set out in your statement that in order to carry out your review you interviewed a large number of people: Trust Chairs, Chief Executives, senior nurses, whistleblowers.

And dealing with settlements, what you say there at 8.21:

"The real issue with settlement agreements, however, is not necessarily the agreement itself but the agreement as to the nature of the reference that follows the director out of one employment and into another. A

settlement agreement ought not to be able to prevent a reference from being full, open and honest."

It's here in your report you go on to talk at 8.22 about vanilla references and then at 8.23 seeking to prohibit vanilla references which may paint a misleading picture by omission.

And if I could just turning briefly to the facts of the case that we are looking at, if we could go to INQ0015683-0031, this -- just while we are waiting for it to be called up, to explain, this is what's referred to as the narrative announcement or what might be said to be the reference that accompanied the settlement agreement for Mr Chambers.

Looking down there to the third paragraph, just to pick out one of the phrases, it says there:

"Tony's stepping down as CEO at the Countess is the result of extraordinary circumstances and is not a judgement on his ability as CEO but more a reflection of his integrity as a leader."

Mr Kark, I am aware you don't know all the circumstances of this case in detail. But is that the sort of reference or announcement that led to your concern that led to a recommendation in relation to full and honest references?

A. Well, I would rather answer that in the

generality, if I may, because I know nothing -- apart from what I have read in the press, I know nothing about Mr Chambers' circumstances, so I don't, with respect, want to comment specifically on this. But what -- there is, there has been I think a real problem, probably contributed to by us lawyers, who make part of a settlement agreement an agreed reference.

And I -- I think that that is very often something which goes contrary to the wider duty of candour, the duty of candour is obviously normally focused on the patient experience. But it certainly can lead to references which are not candid and which do not set out the full circumstances of somebody's departure.

In -- in particular it's been used as a method of avoiding a full disciplinary hearing. So it's much easier for a Trust, and one can readily understand this, to come to a settlement agreement if they can, pay the individual off and agree a reference and make the problem go away.

And that is often far cheaper for the Trust to do but it has extremely unfortunate potential consequences because that then becomes a problem for the next Trust and I am not speaking about this specific case.

Q. Yes.

A. But -- but it's a very, very common, has been

a very common problem and I do remember a human resources director saying to me it would help tremendously if there was something in the statute that said: you can have a settlement agreement but it cannot dictate the terms of the reference. Because that would allow the Trust to say, well, I am very sorry but the regulator won't allow us to do this.

Q. Thank you, that could go down now, please.

In terms of the framework we will come to in a moment but while we are on the issue of references, in terms of the framework that's been put in place now, do you think that goes far enough to address that problem with references?

A. Well, I have a bit of, this is the one area where I had a bit of difficulty with the framework and what it's actually saying. I don't know if it's possible to get the framework up. It's your Inquiry reference 0036.

Q. So it's, the framework is INQ0012645?

A. And then dash 0036. And it may just be my lack of knowledge or understanding.

If you look to the second paragraph starting: "request for board member references", requests for board member references should not ask for specific information on whether there is a settlement agreement

non-disclosure agreement in place.

And then it goes a couple of paragraphs on:

"If there is a historical settlement agreement, non-disclosure agreement already in place which includes a confidentiality clause, NHS organisations should seek permission from all parties prior to including any such information in a board member reference."

Then the existence -- sorry skipping one paragraph, well no, let's just ...

"Going forward NHS organisations should consider inclusion of the term in any proposed settlement agreements to state the information about the settlement agreement can be included in the ESR."

And first of all I think those words "should consider", it seems very weak to me. Either you are telling them to do it or you are not telling them to do it. And then:

"The existence of a settlement agreement does not in of itself determine that a person is not a fit and proper person."

And then, sorry, over the page, the top of the next page:

"The reference should include information regarding discontinued, outstanding or upheld complaints."

So I was just a bit uncertain about where, where

this ended up. If you are starting off by saying that you shouldn't, when you are asked for a reference, ask for specific information about whether there has been a settlement agreement, I can't understand why not, why can't you ask the question at least?

And then I thought the words "organisations should consider inclusion of the term", I don't think with respect that is going to cut it once the lawyers get involved in a settlement agreement.

I think this probably has to be statutory to cut through -- or certainly stronger than this, to cut through lawyers' demands, you know, "X won't sign this unless you agree a settlement".

Q. Thank you.

If we can then, following on slightly from that, go through your what your recommendations were so that we can then follow them through. So if you could go back now to your report, so INQ0012637-0133, and this is internal page of your report page 127 where you set out the recommendations.

A. Yes.

Q. If I may, I am just going to go through the first five recommendations which are the most significant for the purposes of this Inquiry to seek any additional comments.

Recommendation 1, sorry, we should have --

A. I think you are on the wrong page.

Q. It's 0133, I think we have got up there 0033. It's 133, the page we are looking for.

So Recommendation 1:

"All directors, Executive, Non-Executive and Interim, should meet specific standards of competence to sit on the board of any health-providing organisation. Where necessary, training should be available."

You go on to say:

"We recommend that high level core competencies should be embodied in a schedule to the regulations and that further guidance should be issued."

Going over the page, you say:

"We recommend that the CQC should during the Well-Led Inspection review the evidence including sampling appraisals in respect of the directors to ensure that they are currently able to meet the core competencies."

Is there anything in light of what has now happened in terms of the framework that you think it would be helpful to add to that or that sums up your recommendation in terms of --

A. No, the framework obviously has -- the, what's it called? The board members' framework obviously has

to be read now in conjunction with the competency framework.

Q. Yes.

A. I think I was encouraged to see that actually the CQC does seem to have -- and I can't remember where it is and, I'm sorry, but I think the CQC in the framework is actually being asked to look at the, the actual competencies that the director has and that's something of a shift I think for the CQC because certainly when I was speaking to them they were obviously very process-driven and they would look to see if there were references in the box, they would look to see if a DBS check had been done, but they wouldn't actually look at the quality of what was in the box. And this, I think there is a bit of a shift here that on a -- and I presume it's still on a Well-Led inspection, if those still exist, I think they do, that the CQC are actually now being asked to look at the quality of the information.

I have looked at the competency framework.

Q. We can go to that now if you wish. I was going to come to that?

A. Sure, sure okay.

Q. We can look at it together maybe just so that we can work through the recommendations.

Recommendation 2:

"The central database of directors should be created holding the relevant information."

And that's something that is addressed in the framework?

A. Yes.

Q. Then on to page 136, internal page 130, Recommendation 3 I think we have dealt with this, I am just going through what the main recommendations were, the creation of a mandatory reference requirement?

A. Yes.

Q. And it's very clear what your recommendation was: full, honest and accurate mandatory employment references and we have looked a little about your reservations on the framework in relation to that.

Recommendation 4 then, page 137 internal page 131, that the Fit and Proper Person Test should be extended to all Commissioners and other arm's-length bodies?

A. Which they have done, I think. They haven't done it by statute but they have done it in the, in the framework.

Q. Yes. And then Recommendation 5, which is the one that has not yet or has not been implemented, the power to disbar directors for serious misconduct. You say there:

"We recommend the setting up of an organisation which will have the power to suspend and disbar directors covered by Regulation 5 who are found to have committed serious misconduct".

And you postulate a body that you refer to as the Health Director Standards Council. I just wonder if you could expand a little bit more, that recommendation hasn't gone into place, there is now a consultation that's going on, but what are your views now as to whether there's a need for something along those -- those lines is, that is outstanding?

A. Well, I am certainly of the same view that I was when I wrote the report. And indeed as I said, Sir Robert Francis had effectively made the same recommendation. And, sorry, some other august person also made the same recommendation even before Robert Francis but I can't remember -- I think it was Sir Ian Kennedy, actually, recommended a body overseeing all aspects of regulation to include senior healthcare managers. So that goes back to 2001, I think.

So yes, certainly, I am of the same view.

I do think it's important to define precisely what you are trying to do with this and there is a real danger of over-regulating and of making the very difficult job of senior managers in the NHS even more

difficult. And as you will have read certainly when I wrote my report, I think it was the King's Fund who said that there was 37% of Trusts were missing at least one director on their board.

So there was a real problem of recruitment to boards and I think one has to recognise that in general terms the job of being a senior Executive on the board of a Trust is a very difficult one.

So that is why Jane Russell and I came down to a very limited form of or very limited basis for disqualifying directors and that is serious misconduct.

I know you are going to come on to the consultation.

Q. Yes.

A. But I do think one's got to be very, very careful with this and I remember Harry Cayton saying to me when I spoke to him around this: you can't regulate your way to a good culture and you can't regulate core management. You have got to be very careful how you use this.

Q. Thank you. If we could just, you deal with that recommendation about what you see as misconduct and if I could just look at one particular area of misconduct that you highlight as a concern in your report, so going back to page 0020 in our numbering,

that's internal page 14 of your report.
A. Sorry 14?
Q. 14 of the report. For the bringing up on the screen it's INQ0012637-0020.
No, 0020, not 01. We are 100 pages too far on.
A. I am so glad to see you have got the same problems that we have got in our Inquiry.
Q. Yes, thank you.
This is -- you say at F there in your report:
"Apart from obvious misconduct such as dishonesty and crime [which I think you have referred to as the 'barn door', the wide, easy tests] we think there should be a focus on behaviour which suppresses the ability of people to speak up about serious issues in the health service, whether by allowing bullying or victimisation of those who speak up or blow the whistle or by any form of harassment of individuals. There should be a focus on discouraging behaviour which runs contrary to the duty of candour, so any deliberate suppression or falsification of records or relevant information should be regarded seriously. Further serious misconduct should include reckless mismanagement which endangers patients."
I just wonder if you could expand a little on why you picked out and chose to put this in your report as

a specific example of what should be regarded as serious misconduct?
A. I think bullying and harassment has been endemic issue in the NHS for probably as long as it's existed. Again, when I wrote my report, I think it was the MDA or I can't remember which organisation came up with this figure that one in five doctors said they had been bullied or harassed.
I think the King's Fund said that somebody who is bullied, 60% of their cognitive function reduces. So it is a serious problem, but not just because of the effect that it has on the individual but because of the effect that it has on the culture of the organisation as a whole because if there is that fear factor in an organisation, that is obviously going to be extremely detrimental to an open and honest discussion about what has gone wrong. And so I -- I thought it was particularly important to identify this and to flag it up, that directors who behave in this way could expect to be sanctioned.
Q. If we can turn then now to -- so that's your report, if we can turn now to deal with what occurred following your report, we have touched on it already but if we could go to paragraph 36 of your statement, where you say that together with Jane Russell, your coauthor,

you appeared before the Health and Social Care Select Committee in March 2019?
A. Yes.
Q. And then you go on to say in paragraph 38:
"... I found it difficult to ascertain with any clarity which parts of my recommendation were being positively taken forward although I did discover in 2023 that a 'Kark Implementation Group' has been set up ..."
And that is what you referred to already, that it was only by chance that you came across that.
At paragraph 41 you refer to:
".. September 23 following the convictions of Ms Letby, the Health Secretary in addressing Parliament on the setting up of your Inquiry reportedly asked the DHSC to review my fifth Recommendation."
Was it your understanding that with regard to the fifth Recommendation, so that is the disbarring of poorly performing or directors where there is an issue of misconduct, that whilst the framework may not have been --
A. Can I -- can I just -- I am so sorry to interrupt --
Q. Yes?
A. -- but it is important. It's not the disbarment of poorly performing managers, it is about

serious misconduct. Poor performance is a separate issue --
Q. Sorry --
A. -- that needs to be dealt with by performance management, sorry.
Q. Thank you for the correction, the terminology is important.
But in relation to the trigger effect of the Letby case, that was your understanding that that brought your fifth Recommendation back into focus?
A. I -- I can't remember how I discovered that but I think, I thought that was right, yes.
Q. And then at paragraph 42, you say that in December 2023 you attended a virtual meeting with Victoria Atkins MP and you recall that she was surprised there was still no central database of directors.
That of itself suggests that there isn't a proper system of follow-up between changing administrations or changing individuals.
Through all your experience and involvement with Inquiries, is that your experience that that is a problem, the loss of knowledge?
A. Yes -- well, I mean I have no doubt you spoke to Sir Robert Francis about this and his experience after, after he reported. But as I say, your report

goes out, and I am sure this won't happen to my Lady, but your report goes out into the ether and I think one's got to be very, very, very active to try to discover what is actually happening and of course there is sometimes quite a churn of civil servants. So the civil servant that you were dealing with from the sponsoring department during the course of your report may not be still there in a year's time.

I do remember this meeting with Victoria Atkins because she was absolutely astonished that there was no central database of directors and this had come about because when I was asked to do my report, the first thing I asked for was a list of all the Chief Executives of Trusts in the NHS and I was told that they didn't have one, that they could Google it for me and I found that surprising and I think Victoria Atkins found that very surprising as well.

But she did indicate then that the Government was interested in or had renewed interest in the fifth Recommendation which is I suppose as a result of that -- the new consultation has been issued or perhaps that's purely because of the new Government. I don't know.

Q. Thank you. And if we could turn then to following that the framework that did come out in August 2023, so that's INQ0012645. So this is the

framework that you say in paragraph 45 of your statement you understand the publication of the statement was in response to your report and recommendations and indeed that's what's specifically stated to be the case in the introduction and if we could go to page 4, so 0004, we see under "Purpose and benefits" first of all a reference to the recommendations from the Kark Review and that this framework is effective from 30 September 2023.

I don't propose to go through it all, but you set out in your statement that in terms of your recommendations that it covers at least broadly your first Recommendation in terms of standards of competence, the second in terms of a central database, the third the mandatory reference requirement, the fourth extending it to arm's-length bodies, but not the fifth Recommendation in relation to disbarring directors.

Just if there is anything further you want to add, Mr Kark, into your understanding of why it was that successive administrations weren't acting on that fifth Recommendation at this point certainly?

A. I think it takes a lot of political will and effort to set up a new regulator. And, and I do understand that, and there is an argument that there are

far too many regulators already. I read some of -- I can't remember it might have been Sir Robert Francis who said there was something like 90 regulators.

LADY JUSTICE THIRLWALL: I think 130, yes, something like that.

A. Yes, a huge number of regulators.

So I think one has to, to recognise the cost and effort of doing this.

But having said that, one also has to recognise the cost of not doing it, and there is both an economic cost to not doing it and a personal cost to individuals who are affected of not doing it. And I am sure you will come on to it, but I think there are real potential benefits to people knowing that there is a body to whom they can go to complain which will be effective if they believe a senior director is truly misbehaving. But one has to recognise it, it is, it is a complex thing to do.

MS BROWN: Looking at those benefits in paragraph 68 of your statement, you helpfully summarise some of the benefits: stopping the revolving door, whereby badly or incompetent directors move from one Trust to another; empowering whistleblowers; empowering members of staff who have a serious grievance; and I think the point you were just making, to reassure the general public about the competence and good behaviour

of senior directors in the NHS.

All those strong reasons are about stopping bad behaviour. Your view of a regulator, I think you call it a mini regulator, do you think they should have a role as well in promoting best practice, continuing professional development, or do you think they should be because of the problem of over-regulation, just very much constrained to stopping the bad rather than maybe promoting the good?

A. There is a genuine tension, I think, there. Because although it's very tempting to go down the full regulation route, the GMC, revalidation, accreditation, et cetera, et cetera, one of the things that was impressed upon me when I was researching for this report was the importance of ensuring that the Trust board is still responsible for its own appointments and -- and mistakes.

And there is always the danger that if you set up an all-seeing, all-dancing regulator and I think that's part of -- that is one of the suggestions in the consultation, effectively, and also taking it down to a relatively low level of management, you could find the Trust board say, "Well, thank you very much, this is now down to the regulator. They have to approve whether these people are fit and proper and we are then safe in

appointing them".

And I don't think that is safe. I think the Trust board has to be responsible for ensuring that the people who they appoint are fit and competent to do the specific job that they do because on a, on a board, you will have all sorts of skills that are needed. You will have, you will need somebody with financial skills, obviously; you will need somebody with clinical understanding; you will have somebody, need somebody with organisational understanding, and my own view is that it has to be up to the Trust board to decide the competencies and skills for each of those within a framework.

And so that was why Jane and I came down to a sort of the minimum, which is when somebody's been seriously badly behaved you can disqualify them which I think the closest regulator does that we thought was the teachers who don't really step in, they don't get involved until there is a serious complaint against somebody.

So our own view was to avoid to start -- to start small, to avoid the whole idea of validation and accreditation which also will be much, much harder to set up.

Q. At paragraph 71 you deal with a particular problem that can arise in this sector which is the issue

where doctors and nurses are already regulated by their own regulators.

A. Yes.

Q. And that is obviously something you have given thought to. I wondered if there was anything you wanted to add to that about whether that would be something that could be managed if there was a form of regulator for managers when they are already subject to their own professional regulation, whether you see that as an intractable problem?

A. Well, first of all, that to me is an encouragement to regulate directors because Medical Directors and Nursing Directors certainly said to me: this is unfair, if I make a mistake on -- a serious mistake on this board I can end up before the GMC and none of the other lot on the board can.

LADY JUSTICE THIRLWALL: Can I just ask you, Mr Kark, did you come across any examples where that had happened, that a doctor or nurse had been, had been dealt with by the GMC for management errors?

A. The only case that I can remember that there was -- there was a case called Roylance which I think is the one example I can remember, where a doctor was taken to the GMC on a management.

LADY JUSTICE THIRLWALL: Thank you, I am sure we

can find that.

A. Sorry, it's dredging my memory back to the GMC days. But I think it is called Roylance.

LADY JUSTICE THIRLWALL: No, that is okay.

A. But it's very rare.

LADY JUSTICE THIRLWALL: It is not very common.

A. No, it is very rare and I think the GMC find it quite difficult to do.

MS BROWN: If we could come on then to the leadership competency framework. This is INQ0108668. Just at the first page.

A. I am so sorry. Could I just go back to that?

Q. Yes, of course.

A. What I do think you have got to be careful of is making sure that doctors aren't double penalised. Same with nurses. So either you exclude them from the framework or you have some form of memorandum of understanding with the GMC as to who is actually going to take responsibility, but otherwise they are going to feel doubly under the cosh. Apologies, sorry.

Q. Yes. No, thank you for completing that.

So this is the competency framework which sets out the six leadership competency domains and again if we could go to page 3 we will see that specific reference is made to your review. We have looked already at one

of your concerns which was the bullying issue, the suppressing of someone who was trying to speak up.

If we go on to page 5, we have got the six leadership competency domains. And this is quite a difficult task, but looking at those competency domains, really just any thoughts you have as to whether they encapsulate, broadly speaking, the concerns you have and whether they are, whether that is adequate in effect to address your principal concerns when you did your report?

A. I -- I suppose as a -- as a lawyer I find this sort of language quite difficult to deal with because it's very aspirational and frankly a bit fuzzy.

So I can understand that these are high level or almost aspirational expectations but I would hope, and we do see this a little bit later on, that there would be much more specific competencies required of particular areas of expertise on a Trust board and if for instance we go to your page 0010.

Q. Yes.

A. You know, this sort of language: I contribute as a leader to ... the development of strategy. I assess and understand the importance ...

Well, that's great. But what about: I have got this qualification because ... or I have this experience

and I will set it out ...

And maybe that's just because one looks at this as a lawyer and you are looking for something concrete, I find these quite high level and aspirational and I suppose I expected something much more concrete, although I accept that may be much harder to formulate.

I think there was -- if we go to 4, "Robust governance and assurance", your page 13.

Q. Yes.

A. I think you are getting closer to it there:

"I understand board member responsibilities, my individual contribution in relation to financial performance, establishing and maintaining arrangements ..."

And I understand that it would be for the, I think it's under the framework it's for the Chair to ensure that each of the appointments to the board can meet these competencies. And so it will be for the Chair to assess whether the individual they are appointing meets these.

And as I say maybe it's just the use of the language which seems more aspirational than concrete.

Q. Just to be clear, because the background page we went to refers to your review. This has been built because of your review but you didn't have a role in

this, in this document?

A. I'm afraid to say it was your Inquiry that drew my attention to it, I'm afraid. I have been doing other things. But, but I only discovered this as a result of your instructions to me.

Q. Thank you. And going to then the final document I wish to turn to, that's the consultation. This is INQ0108672.

A. Yes.

Q. This is a consultation of November 2024, so a very recent consultation on proposals to regulate NHS managers and really just an open question as to what your view is on this consultation process and where we are at this stage in terms of proposals to regulate NHS managers?

A. I mean I have only had a very brief look at this in the last couple of days. It's a very wide consultation, isn't it, in terms of the options that are offered and I haven't got the whole thing in front of me.

But it -- one of the options I think is regulating managers right down to Band 8A, B, C and D. And I understand that that has to be part of a consultation.

For my part, and for what this is worth, I very much hope that that isn't where this ends up because

I think that will have a very, very -- potentially very damaging effect on recruitment and promotion within the NHS. Those levels of management should be dealt with by performance within a Trust.

And as I said, the consultation is very wide. I am very pleased to see that there is a consultation so hopefully something will come from it. But I do hope, for what it's worth, that where we end up is very much more limited than some of the options that are on the table.

MS BROWN: Thank you very much, Mr Kark. I have no further questions for you. Mr Baker doesn't have any questions now, my Lady.

I don't know whether there is ...

Questions by LADY JUSTICE THIRLWALL

LADY JUSTICE THIRLWALL: All right. Thank you very much indeed, Mr Kark, for coming.

Since I was expecting a few more questions, do you mind if I ask you a few in the additional time that I now have?

A. No, of course.

LADY JUSTICE THIRLWALL: Just looking at the framework and I think one of the other witnesses described it as "extremely wordy". I mean, there really are a lot of -- it seems to me that's a reasonably fair

description or it could be.

A. Yes.

LADY JUSTICE THIRLWALL: But one of the things that isn't mentioned anywhere is what qualifications are required, what experience is required and is there any reason other than perhaps there may be a philosophical reason why you want to talk about competency rather than qualification, although it's not easy to see why those two things should not be consistent one with the other.

A. I think they are.

LADY JUSTICE THIRLWALL: Yes.

A. Yes, I agree. I think they -- I am just wondering if competency ...

I suppose competency includes of course I suppose experience.

LADY JUSTICE THIRLWALL: Yes.

A. As well as learning and training as I suppose can qualification. But I think that either of those words could be used.

LADY JUSTICE THIRLWALL: Yes, it's a slightly curious thing because with doctors and nurses we can see what the qualifications are that are required --

A. Yes.

LADY JUSTICE THIRLWALL: -- and the experience that is required to move on within the profession and I am

sure that some of that could be characterised as competencies. But is the reason, do you think and you may not have a view about it, qualifications -- the issue of qualifications is avoided is because it's quite hard to pin down what exactly the qualifications are that you need to be a manager, a senior manager?

A. Although that is rather what I was expecting people to do.

LADY JUSTICE THIRLWALL: Yes.

A. And I -- I do think it's important that when somebody is being appointed to a Trust board, say they are the Chief Financial Officer, that they should also be expected to have some, some understanding for instance of clinical governance and I think that should be set out.

I think some of the great disasters that we have had at Mid Staffs and Liverpool were both subject to this, was that the finances overtook patient care. So you had these cost improvement plans that resulted in a huge degradation of the staff at the hospital.

And I just wonder if the -- if there was sufficient challenge or in fact we know there wasn't sufficient challenge on those boards from the Non-Exec Directors, just by way of example.

So when I suggested that there should be, should be

specific competencies or qualifications, that's what I thought we were going to see. And I think some of this language, as I have said, is either too wordy or quite woolly. It's going in the right -- I do think it is going in the right direction.

LADY JUSTICE THIRLWALL: Yes, I understand that.

A. But I think it could be more specific.

LADY JUSTICE THIRLWALL: Well, those are my questions. There was one which I had which is actually for the next witness, so thank you very much indeed for making yourself available and coming in person, it's been extremely enlightening, thank you and of course you are now free to go.

A. Thank you very much indeed.

LADY JUSTICE THIRLWALL: The next witness I think is being called by Ms Langdale.

MS BROWN: Yes, so I think the suggestion was that we would take a break now so that the next witness would start after this morning break, an early morning break.

LADY JUSTICE THIRLWALL: I think we finished a bit earlier than we were expecting. Shall we say we will start again at quarter to and then we will see how we do for a further break in the morning. So quarter to 11.

(10.34 am)

(A short break)

(10.45 am)

LADY JUSTICE THIRLWALL: Ms Langdale.

MS LANGDALE: My Lady, I call our last witness.

LADY JUSTICE THIRLWALL: Do come forward.

PROFESSOR SIR STEPHEN POWIS (sworn)

LADY JUSTICE THIRLWALL: Do sit down.

A. Thank you.

Questions by MS LANGDALE

MS LANGDALE: Can you give us your name, qualifications and a brief career history, please.

A. Professor Sir Stephen Powis and I am a registered medical practitioner.

Q. You are currently National Medical Director; is that right?

A. I am National Medical Director at NHS England.

Q. Sir Stephen, you have provided three statements to the Inquiry, two statements in March 2024 and one in April 2024.

You have obviously had support in preparing those statements, as detailed as they are. Can you confirm that the contents are true and accurate as far as you are aware?

A. I can confirm that.

Q. I understand before we go into the evidence within the statements and more generally, that you would

like to say a few words?

A. Yes. I have been a doctor in the NHS for almost 40 years and during that time, I have dedicated myself to improving patient care and ensuring patient safety. The events at the Countess of Chester were abhorrent and on behalf of the entire NHS, I apologise.

Q. We are going to come into the detail within statements and documents, but more broadly on behalf of NHS England at this point. You have obviously through Project Columbus and generally looked at the events surrounding Letby's work career and conviction.

What would you highlight, if anything, that NHS England might have done differently to avert these events or prevent some of the deaths happening when they did further down the line, if you like?

A. So we recognise that there were a number of missed opportunities where individuals within the Trust but also individuals outside the Trust including NHS in England and its legacy bodies that are now incorporated with NHS England could have intervened, could have asked questions, could have been more curious. That occurred within the Trust on a number of occasions.

NHS England was not aware of the increase in mortality until July 2016. At that point, it took the decision with the Trust to downgrade the unit to a lower

level of neonatal care, that was in agreement with the Trust, it was quite appropriate at the time and then it agreed with the Trust that an independent review carried out by Royal College of Paediatrics and Child Health would be appropriate.

It was kept informed of that review, possibly could have asked more questions about the nature of the review but as it got towards the end of 2016 colleagues at NHS England and its legacy bodies were becoming more frustrated and more concerned about the openness and the transparency of what was occurring at the Countess of Chester and you can quite clearly see that in evidence going forward into 2017.

We were not aware that there was suspicion around a particular member of staff until March of 2017 and at that point it was our view that the correct thing to do would be to involve the police.

The Countess of Chester did that through the a conversation with the CDOP process, our chair of CDOP, but if that had not been done NHS England is quite clear that it would have informed the police itself.

Q. How significant in the piece do you think a suspicion about a member of staff was? You say you weren't aware of that particular detail?

A. Sorry, I missed the first part of that

question.

Q. How significant is that piece of information that there was suspicion about a member of staff in terms of what you, NHS England, or others might have done next?

A. Well, I think it was highly relevant during the period where there was increased mortality up to the end of June 2016, at the point that Lucy Letby was removed from the unit. During that period, 16 incidents were reported through our national learning -- reporting and learning system to NHS England, but only three of them, one at the very start of that period and two right at the end, were reported through our Serious Incident process; in other words, were declared as Serious Incidents.

If more had been declared then there would have been undoubtedly more scrutiny. That scrutiny came when two were declared in July of 2016. And I think that would have led to more scrutiny, to more questioning to more curiosity during that period.

And then afterwards, if we had known that there was concerns around an individual, we would undoubtedly have required the police to be involved at an earlier point.

Q. Just addressing the concerns about an individual and a member of staff. What do you think

might have made that difficult to express that, concerns about a member of staff, whether you are a doctor or manager, what might have made that a difficult thing to articulate more widely outside the Trust and generally, do you think? Or do you not have a view on that?

A. I think there are three things relevant here. One is the culture within an organisation, that culture of curiosity and openness. Clearly from the evidence I have seen there were concerns around a particular member of staff at a very early stage right at the beginning when the first cluster of deaths occurred.

But as I have said, that curiosity to an extent was not shared and views of that were not shared with all members of the leadership team within the Countess of Chester and as I have already said, NHS England became increasingly concerned about openness and transparency and the culture of involving others.

Secondly, you have to have processes and systems in place to allow escalation. Those systems and processes were in place. Incident reporting was in place, safeguarding was in place.

An early version of Freedom to Speak Up was in place. In our view, they were not used in a way that they should have been used and that would have resulted in further escalation, further scrutiny and further

curiosity. And then finally you need to be aware of the possibility, however rare, however infrequently, that a healthcare professional could deliberately cause harm.

Clearly, that possibility did arise in the minds of the paediatricians at a very early stage and became more of a concern as 2015 progressed into 2016. But that concern was not shared or acknowledged in the same way by senior leaders within the organisation.

Q. We have seen in one of the safeguarding policies, I don't need to put it up, but there is a flowchart about information sharing, it is in a current safeguarding policy, when you can share information. Just in terms of data being shared in the NHS, do you think it's clear when information can be shared, for example about a member of staff and suspicions about them? Or do you think people may have felt a reluctance about talking about that, that it's confidential, it is an employment law issue, you have to be careful, those kinds of factors creeping in?

A. I can't pass judgment on -- on why that information was not shared but I don't think there was any barrier, nor should there be about any barrier, to share that information. If it is suspected that deliberate harm is occurring, then other agencies should be informed and of course foremost amongst those the

police.

And there were instances within the NHS where circumstances have arisen in recent years where there's been concern of deliberate harm and in those circumstances the police have been informed immediately, our Chief Nurse, who has given a witness statement to the Inquiry in his previous role as Deputy Chief Nurse, has outlined one of those instances where that occurred.

Q. So in your experience those details are shared with NHS England if there is concerns about deliberate harm or a person?

A. Yes, they are shared and they should be shared.

Q. And they should be?

A. Yes.

Q. You are clear about that?

A. Yes, absolutely.

Q. Well, would people know at the time that it should be? Is that a policy, is that a culture? What would tell people in the hospital that they should be sharing that?

A. So in my experience -- and I have worked both as a Medical Director of a provider organisation in NHS Trusts and a National Medical Director within a regulator and a Commissioner, NHS England, I have

always taken the view and I believe that others, this is frequent amongst our other leaders that regulators are clearly there to regulate and ask the difficult questions but also there to support and to provide assistance.

So in my time as Medical Director, that involved regular conversations with other local Commissioners on incidents that were occurring within the organisation, as they do in all organisations, with appropriate scrutiny.

And so that information sharing and that shared endeavour, to learn from errors, to learn from mistakes, to learn when things go wrong, indeed learn when things go right, I think is and should be at the core of everything we do in the NHS.

Q. If we can have some of your statement on the screen, please. It's INQ0017495, page 152 and it's from your first statement, paragraph 609.

You set out the consistent failings that have been identified in previous Inquiries and investigations at paragraph 609 and at 610 say:

"There are two neonatal-specific risks we have identified in the light of how we understand [Letby] murdered or attempted to murder her victims and these relate to her use of air and milk."

You also refer to:

Although insulin as a method of killing or harming babies has been used in non-neonatal settings, the particular vulnerability of neonatal babies to insulin (and air and milk) is recognised."

You gave as a second statement in relation to the work NHS England has done in respect of insulin, can you tell us about that, please? What surveys or initial insulin survey that's been conducted and what you have done in the light of this case?

A. Yes.

Q. Subsequent to this case?

A. If I may, my Lady, a little bit of context first.

So insulin is a widely used medication within healthcare to manage high levels of glucose most typically in patients who have diabetes. Its use in neonatal critical care units is infrequent. It's broadly used for two reasons, one is for that very reason to treat high levels of glucose diabetes but that is unusual in that particular setting. It is also used to reduce high levels or to aid in the reduction of dangerously high levels of potassium that can occur in certain circumstances, such as acute kidney failure.

So its use in neonatal units is much lower than in

other settings within the NHS. But nevertheless, it is a drug that from time to time must be used and therefore should be kept within neonatal units.

We obviously noted the use of insulin and as we say here that was noted in, in the Clothier Report back in 1994, too. And we were commissioned as a result of the circumstances around the Countess of Chester by the previous minister within the Department of Health to look further into the use of insulin in neonatal units.

We did that by conducting two surveys of neonatal units, to understand current practice around the use the storage the use of insulin in those units.

What we found was largely good practice around storage, around access to insulin, around the way it is used, with some variation. Variation mostly related to the presence of a pharmacist or the units to check and to aid in those processes around insulin and, and around staff training.

As a result of those two surveys we do not believe at NHS England that there are any significant changes that need to be made around the way insulin is stored, accessed and used. But we are sure that or we are noting we do note that there is a requirement to ensure that best practice is being used in all settings. So I have discussed this with the Chief Pharmacist for

England and also for the National Clinical Director for neonatal care and we do commit to ensuring that we will do what we can to ensure that all units are operating at the highest level of best practice and I should also say that there is guidance in place from other entities, NICE and the Royal Pharmaceutical Society relating to the storage of drugs.

LADY JUSTICE THIRLWALL: If I can just be clear then, so largely good practice, some variation by which you mean not good practice?

A. Not necessarily not good practice but areas where we think practice could be strengthened and therefore --

LADY JUSTICE THIRLWALL: I suppose less than good.

A. Well, there are some additional components that some units could put in place such as --

LADY JUSTICE THIRLWALL: Which would make it better.

A. -- more oversight by a hospital pharmacist.

LADY JUSTICE THIRLWALL: Is there anything else other than that oversight? I am not suggesting that is not important.

A. Those were the two things that particularly came through on the surveys, but as I said I want to keep this under review and I will commit with the Chief

Pharmacist and the National Clinical Director to ensure that we are doing what we can to promulgate best practice.

LADY JUSTICE THIRLWALL: Yes, sorry, so there are two things. I picked up oversight by a pharmacist, what was the second thing?

A. It was training around the use of drugs within neonatal units and insulin in particular.

LADY JUSTICE THIRLWALL: Training of whom?

A. Staff who -- so nursing staff in particular.

LADY JUSTICE THIRLWALL: And what's the plan in relation to the training then, is that something also the Chief Pharmacist is going to do?

A. So those are next steps and we would be very happy to provide you with further information as we develop those steps.

LADY JUSTICE THIRLWALL: If those steps were put in place you are as satisfied as you can reasonably be that that would then mean good practice everywhere.

A. Yes, yes.

LADY JUSTICE THIRLWALL: Thank you. If you would yes, please.

A. Yes.

MS LANGDALE: Can we have on the screen, please: "Summary of findings: safe and secure handling of

insulin on neonatal units."

So INQ0107008. If we go to page 2. Have a look at the method of the survey at the bottom. "Findings" at page 3.

Page 4, "Current safe and secure practice in use on neonatal units".

You see there at paragraph 17:

"A few units reported using a combination of other strategies to ensure the safe and secure handling such as keeping records of staff who have accessed insulin."

We heard from the Countess of Chester about swipe data now. Can you expand on that how that works so?

A. So there are various ways in which access to drugs are -- or access to drugs is restricted and protected. Swipe systems would be one of those, other mechanisms of locking drugs. So we support those practices, that is good practice.

Q. And then we see conclusion, paragraph 23:

"Review identified good processes and practice for the safe and secure handling of insulin units. Recommended neonatal units continue to follow national and local policies."

Given its capacity for catastrophic harm and the history of the Allitt case, Chua and Letby, a question at the outset particularly posed by the Families and

parents was why shouldn't insulin be subjected to the same security safeguards as controlled drugs?

A. So many of the practices around controlled drugs of course are replicated in access to drugs such as insulin. The designation of a controlled drug is matter for the Home Office, not for NHS England.

But I think good practice around both controlled drugs, so there are additional requirements around the use of controlled drugs including governance structures, but many of those practices are replicated in the core business of managing drugs including insulin.

Q. And how extensive was the survey? It was developed using a multi directorate group within NHSE to include experts in patient safety but in terms of the seriousness with which the task was approached, could you expand on that for us?

A. We did an initial survey which was a smaller number of units and then the second survey expanded -- I think the number is around 20, it is on one of the pages in the report. So I think it was a significant sample. So sufficient to get a clear idea of the range of practice.

Q. Thank you. That can go down now, please. The Inquiry also asked for feedback from neonatal units and more generally on the issue of CCTV and security?

A. Yes.
Q. Perhaps having cameras in incubators, in neonatal units, for many reasons not simply detecting the rare case of deliberate harm or potentially being a deterrent in relation to that but also for parents separated from babies for whatever reason?
A. Yes.
Q. Health reasons, physical space in the hospital, being able to see their baby at all times when they wanted to, given the technology we have now with mobile phones et cetera. Do you have any views about that, Sir Stephen?
A. Yes, this is another aspect of care that we have considered and again a little bit of context which you briefly alluded to. So the use of CCTV cameras in these units is usually related to control of access into the unit and therefore is not targeted or directed at individual babies within the unit.
But as you say, increasingly, and the pandemic will have driven this to an extent, there has been uses of cameras, CCTV, within individual cots, mainly to provide live streaming to parents who cannot for a variety of reasons be at the cotside. We do think that is an important advance and we do think that there are opportunities to use that technology as a form of

monitoring to ensure safety of babies as well.
There are pros and cons around doing that. There may be some privacy concerns, for example, that we need to take into account but we are of the view that that is worth exploring forward further and we do wish to understand a number of pilots with neonatal units to see how we can progress that. We do think there is value in that approach.
Q. You will be doing those pilots, is that a plan?
A. Yes. We will be doing that -- under the auspices of the Chief Nurse for England we will be undertaking that work and again we would be very happy to inform you and keep you up to date as that work progresses.
LADY JUSTICE THIRLWALL: Thank you. I don't think that's something that is in the statements and that is not a complaint, it is just sort of come out certainly we had some evidence from one of the Mothers in particular --
A. Yes.
LADY JUSTICE THIRLWALL: -- who talked about this sort of CCTV which is different from the sort of surveillance stuff --
A. Exactly.

LADY JUSTICE THIRLWALL: -- that you have at the access to wards.
A. Yes.
LADY JUSTICE THIRLWALL: But just so I can understand: what would the privacy concerns be if you had -- a parent had the phone monitoring their child?
A. It's around issues such as breastfeeding and other things that might happen, it's around close contact with babies, so I think they are overcomable but --
LADY JUSTICE THIRLWALL: But I'm not sure -- if the monitor is in the incubator then you are not going to be breastfeeding --
A. Well, exactly it depends, it depends on the visual scope of the monitor. It depends exactly how the cot is monitored. I think these are all addressable but I think whenever you are introducing a technology like this it's -- it's important to recognise potential disbenefits as well as benefits and to explore those as well. But, as I say, we do think that this is an avenue worth exploring. My apologies it hasn't been in the statements, as I hope you would expect --
LADY JUSTICE THIRLWALL: There is no need to apologise, as time moves on and the idea came from the Inquiry --

A. We have been reflecting on evidence as it's been presented to the Inquiry --
LADY JUSTICE THIRLWALL: Yes, of course?
A. -- and in discussions with the Chief Nurse we have decided that this would be an appropriate way forward.
LADY JUSTICE THIRLWALL: Yes. Good. That is very helpful and encouraging to know because certainly what is in the statements where all the problems are was, if I may put it, conventional CCTV, so the focus now is going to be on how to make a different form of it useful and you are going to pilot it. When are the pilots going to start?
A. I can't give you the exact details yet because, as you will have gathered, this is -- these are recent discussions but for all the reasons you have said around the use of this technology, we do think that there are opportunities here that we should explore.
LADY JUSTICE THIRLWALL: Yes and so when will you be able to update us on that? You or the chief nurse?
A. Can I commit to updating you in the next month or two?
LADY JUSTICE THIRLWALL: Yes, certainly, so shall we say by the beginning of March?
A. We can say by the beginning of March.

LADY JUSTICE THIRLWALL: Thank you.

MS LANGDALE: Certainly one sees in nurseries and childcare now and when people have nannies or arrangements of that kind, it's not unusual just for everyone to accept that's a way of working, people get used to it --

A. Sorry, again I missed the first bit.

Q. It is not unusual for people to get used to that way of working that there is a camera but you are not doing anything in that context you are particularly concerned about?

A. Exactly. And therefore I think with the introduction of technology that can monitor more specifically the cot rather than the general area, then this is definitely an avenue that would be worth exploring and has the double benefit of providing where -- where needed that streaming element, that remote ability to see the baby but also provide that additional safety. But there are, as I say, further considerations that we would need to take into account, for instance around storage of material rather than simply live streaming.

Q. Can we have on the screen please your statement, so INQ0017495, page 107 and it's where you deal with the Medical Examiner system if it helps you to

have it on screen at the time.

The Inquiry's been tasked to look at recommendations made by previous Inquiries, whether they have been implemented or not, and why they haven't been and you will readily appreciate that the Clothier Inquiry, some years ago now, provided or suggested, recommended, that pathology services in every case of unexpected child death where the death is clinically unaccountable should be provided and those examinations should take place.

That was in 1994. The recommendation clearly wasn't implemented around then. Would you like to expand on why it in your view it took so long for the Medical Examiner system to come into being?

A. So as you rightly said the recommendation for the Medical Examiner system has come out of previous Inquiries, including the Shipman Inquiry and, Sir Robert Francis' Inquiries into the events at Mid Staffs Hospital.

The development of the Medical Examiner system was under the auspices the Department of Health and social Care, I know you have heard from their witness two days ago, I know he has provided details as to the evolution of thinking around the Medical Examiner system.

I can't, and neither can NHS England, give you

additional detailed information about that period because we were not directly involved in the development of a potential Medical Examiner system.

What I can give you assurance about is that in 2018 -- and this is around the time that the Department of Health and Social Care published its response to the consultation it held in 2016 around the introduction of a Medical Examiner system in that period, summer, I think it was the late spring/summer of 2018, NHS England was asked, indeed I was personally asked, if NHS England would undertake to take responsibility for the implementation of the Medical Examiner system from that point, which we agreed to do. That had not necessarily been the consideration in the period that you have described prior to that. But colleagues at the Department of Health had determined that that would be the most appropriate way forward following the consultation.

We did that. And in my view --

Q. Sorry to interrupt you there, Sir Stephen, can we have the next page of the statement beginning paragraph 435 on the screen, so it's the next but one page where you are getting to now. Sorry, continue.

A. Yes. In fact we had been asked, I am sure it was around the summer of 2018, if we would take on that

examiner system. We appointed the National Medical Examiner I think in 2019, National Medical Examiner, Alan Fletcher, who again you have heard from, sits in the patient safety team within my Medical Directorate at NHS England supported by the National Patient Safety Director and Alan then set about, with support from colleagues in NHS England, but also colleagues such as the Royal College of Pathologists, who have been very instrumental in the work underlying the Medical Examiner system, to implement a Medical Examiner system.

We did that at pace, as fast as we could, and I note that there was a pandemic, as you know, in the middle of this which set us back a little bit, but not substantially, and we have now, again you will have heard, rolled that system out within hospitals and more recently within primary care, within general practices. And I should pay public tribute to Alan in all the work he has done as the National Medical Examiner in driving that forward.

And that meant that we were ready for the introduction of the system on a statutory basis in September of 2024, just a few months ago, and we are now in the phase of moving from focusing -- these are discussions I frequently have with Alan -- from the implementation of the system to try -- to beginning to

gather evidence around its benefits.

But what we are hearing that it has been well received by practitioners within the system but also by relatives and one of its main aims is to improve the transfer of information, the discussions that occur and the quality of care around bereavement with relatives who have been affected and of course other things such as improving death certificates and the accuracy of death certificates and the interaction with colleagues.

Q. Jeremy Hunt gave evidence to the Inquiry and accepted and offered an apology for the fact that in 2015 to 2016 it was under his watch and Medical Examiners were not of course in place when some of these baby deaths would have been independently examined, had they been early on.

His evidence was that there weren't enough doctors at that time, doctors who could conduct that work, who weren't required on the frontline with the patients that they were dealing with. Do you have any evidence to provide on that point, whether there were enough doctors, whether there are enough doctors now to satisfy the Medical Examiner system in full?

A. Our experience since 2018 when we were asked to implement the system is that we have had very good uptake. We have, I am, I can't give you exact numbers

but we have pretty much appointed all, or if not all, most of the examiners that we need around the country.

I don't think we have had overall difficulties in doing that. And more recently we have also done that within general practice and primary care. As I have said, I think the system has been welcomed. That doesn't mean that, as ever, when you introduce a new system there are bumps to get over and there are glitches along the way, but we were ready for statutory implementation in September.

The Royal College of Pathologists, as I have said, have been champions of the work underlying this, they have contributed hugely. I don't think there's been resistance within the medical profession or with other clinical professions to introducing this. As ever, resource needs to be deployed and funding needs to be found in order to do this.

But I am delighted that it is in place, and as I say, I can give you assurance that at NHS England we have proceeded at pace to get this up and fit for purpose.

Q. On the subject of staffing, Sir Stephen, we have seen for the RCPCH report that was done at the time of events at the Countess of Chester, mention of reduced staff numbers and we have heard evidence now how common

that was and they were consistent with others.

What's the purpose of these targets for staffing and what is supposedly safe staffing, if they are honoured in the breach, if you like?

A. So we recognise that staffing of neonatal units has been an issue, that is why it is the focus of our neonatal delivery plans at the moment to increase staffing, we have made progress in increasing staffing within neonatal units in recent years and of course in a broader context, we agreed with the Government a long-term workforce plan for the NHS to increase staff overall, that was agreed 18 months ago. We are in the process of implementing it and doing a two-year review with the new Government, so we are committed to increasing the workforce.

And of course --

LADY JUSTICE THIRLWALL: Sorry, can I just ask you a question while it is in my mind. We heard evidence from Dr Camilla Kingdon from the RCPCH, I am sure you saw that --

A. Mmm.

LADY JUSTICE THIRLWALL: -- evidence and she said, if my memory serves me correctly and it may not, that in fact there was no provision within the workforce plan for further staff for neonatal units.

A. As is the case with the first iteration of that plan at all specialty levels, so that was not unique to neonatology or paediatrics, it would be the same in any other medical discipline, that is the work of the plan following that initial publication, so the specific -- other than general practitioners, where there was a specific commitment within the plan around an increase in GPs, for no other sub specialty of medicine was there in the detail in that plan a particular plan.

But we have recognised and the Royal Colleges are aware that that is work in the next steps of the plan and that is work that we are undertaking with the current Government at the moment.

LADY JUSTICE THIRLWALL: When do you foresee that that will have fruition?

A. It is one of these things where there is never an end point because medicine evolves and the point is to ensure that we are producing or training staff that are -- the relevant numbers of staff with the relevant skills and competencies for medicine as it develops and the demand as we see it and the demand in neonatology has been changing and the nature of births, women are giving birth later, for instance, we are seeing younger children who have been born prematurely surviving, so

all of those things need to be taken into account in terms of determining the neonatal workforce. So what might be required in 2025 might be different in 2028 or 2032 and of course for many --

LADY JUSTICE THIRLWALL: I understand that. I wonder when the next iteration --

A. We agreed with the Treasury and the previous Government that this would be reiterated every two years. Clearly we are in discussions with the current Government, as you know there has been a change of Government but we are working internally towards that two years' iteration would be the summer of this year but clearly that is subject to conversations with the current Government who quite rightly would want to review the plan agreed by a previous Government and I wouldn't want to over-commit on timings.

LADY JUSTICE THIRLWALL: No, I don't think you are over-committing, if I may say so. It's just really so I can have some understanding of when the numbers get or the consideration has been given to individual units, so in particular neonatal units --

A. Yes.

LADY JUSTICE THIRLWALL: -- when will they see what the workforce plan is for their doctors and nurses.

A. So this is not just about that national plan,

it's also around local work that is being undertaken. There is local work being undertaken in Cheshire and Merseyside and this region and you have heard from the current Chief Executive of the Countess of Chester the desire to redesignate the unit. Again, the workaround staffing levels around the appropriate distribution of neonatal care within a region and an area as opposed to an individual hospital is all part of that work.

So the National Workforce Plan is part of that but it also has to take into account the local demand and local needs and local configuration of services.

LADY JUSTICE THIRLWALL: Yes, I think --

A. The final layer I put on that, and I have mentioned the National Neonatal Delivery Board, which again is there to ensure that there is a supply, not just in medical professions but in nursing professionals of course who have different career routes as well.

LADY JUSTICE THIRLWALL: I'm sorry, Ms Langdale, just to get to when they might have some idea of what's --

A. So I think on the local approach --

LADY JUSTICE THIRLWALL: Yes.

A. -- that work is being undertaken at the moment. Again I can't give you an exact timeline that is now a designated process to Integrated Care Boards

and again on the national plan which by its nature will be higher level, the agreement with the previous Government was every two years. Two years is up this summer. But we are in conversations with the new Government as to how they might want to formulate that.

LADY JUSTICE THIRLWALL: Thank you.

Then there was just one point which you reminded me of when speaking about the current Chief Executive at the Countess of Chester who had written really many months ago and has recently had a reply.

A. She has.

LADY JUSTICE THIRLWALL: Saying: we will have a meeting at some point.

A. Yes.

LADY JUSTICE THIRLWALL: But nothing arranged. It didn't feel to me as if there was any great urgency in the response from the regional office; is that a fair observation to make?

A. So that work has been ongoing within the local area around provision of neonatal care within Cheshire and Merseyside. Clearly it was not acceptable that it was such a length of time between the reply to her initial letter but I understand there have been conversations with the Countess of Chester and I am confident that that work is now progressing.

LADY JUSTICE THIRLWALL: Thank you.

MS LANGDALE: Yes, I think the response was to have a suggested meeting in January which at the time the witness had given evidence, that hadn't happened that by I think it was autumn of next year this overview of neonatal services in the region was going to be --

A. Yes.

Q. -- considered.

Which is some time to wait I suppose if they have been temporarily designated a lower tier for a number of years now?

A. Yes, and again as you are aware, these services, neonatal services, are specialised services that remain the accountability of NHS England at national level, they are on a prescribed list of specialised services. But we have in the last few years with the support of the Government been delegating responsibility down to local healthcare systems. The reason for that is that some components of maternity and neonatal care are locally commissioned and our view is that ensuring both that specialised commissioning and local commissioning is undertaken in one place is of benefit to the community and to patients.

So those decisions are now delegated down to ICBs and a joint committee of ICBs with support from the

region, which is the North West region, presently within NHS England. So these now are local decisions.

It has of course been nearly nine years since the unit was redesignated. Much has changed over that period and therefore it is quite right that any redesignation which we acknowledge is desired by the Countess of Chester is taken in the light of changes in local demand but also in local configuration of services. And that is exactly the work we would expect the Integrated Care Board to do with the support from the region and that is what they are currently doing.

LADY JUSTICE THIRLWALL: Is that the explanation, they have just been very busy?

A. Well, I think they have been looking for some time at the correct configuration of services in Cheshire and Merseyside but I will ensure that that work proceeds at pace.

LADY JUSTICE THIRLWALL: Thank you.

MS LANGDALE: You mentioned the NHS long term workforce plan. It doesn't make any commitments to investigating in children's nursing; is that the case?

A. Yes.

Q. Why not?

A. This goes back to the fact that the original plan was at a very high level so it talked about

professions as a whole, rather than individual specialties and again that was not unique to Children and Young People, it was the same in any area of medical practice with the exception of general practice where there was a specific commitment.

But it was done in the understanding, and you can actually see that in the very latter pages of the plan a commitment to do the work and this we have always said would be done with the Royal Colleges to work on requirements for individual specialties.

That is not a simple task, it requires detailed modelling and detailed understanding of where we think services are likely to be in the next decade because it takes time, particularly with doctors, to train people fully to Consultant level but that is work that we are currently undertaking.

Q. Do you agree that the majority of targets set for Hospital Trusts concern care for adults and not children?

A. Not necessarily. So many of the targets that we set, the key constitutional targets are not age-specific they apply to all ages. They may not specifically apply to children and young people but they don't specifically apply to any age group, whether that is a four-hour standard for emergency care, whether it

is our 18 week standard for elective procedures and outpatients appointments.

So those broad high level targets apply across the board. There are standards and often this conversation I think is better thinking about standards than targets. Standards much more are around the level of provision, the level of care, the quality of care that we expect that we should be providing.

Q. Do targets link to funding, though? I mean I suppose the importance of what the target is linked to is if that's where more money comes in, you might give more emphasis to those areas than, say, children's services or neonates?

A. In general, the setting of targets and standards is not related to funding. The ability to deliver those standards and targets is.

But in the initial setting of standards and targets, then my experience is that they are very much based on what we believe is the right standard of care to achieve in whatever area that standard is applicable to, but you are perfectly correct that the ability to deploy resource, in other words funding, can determine whether those standards are met or not.

Q. And if I am meeting those standards or delivering that service well, presumably I will get the

funding the next year to do the same and the same?

A. Yes, I think it's probably more complicated than that because funding comes through various streams to organisations such as hospitals. And there are a range of standards that we would expect hospitals and other providers to attain, many of those are set by clinical professionals, not just by the Government or Government policies, but many of them flow from the constitutional standards, the core constitutional standards.

Q. Can I go back to Inquiries and recommendations from Inquiries. The Clothier Inquiry around Beverley Allitt of course many years ago. How difficult is it for corporate memory to be maintained within the NHS when there's restructures of bodies, of regulators? How difficult is that? What are the barriers to making the memory of a case, for example, and its implications set down?

A. Clearly there are challenges. So again a bit of context which you have just described the NHS of course is ecosystem of many, many, many organisations, many of which have a statutory body and have their own governance structures.

So it's not the responsibility in our view of necessarily of one organisation to be conscious of

recommendations or to have a role in implementing them. To give two extreme examples, in a sense clearly Public Inquiries such as this will generate or will produce a set of recommendations that are generally for an entire system of healthcare. Individual organisations might commission reviews with recommendations that are very specific to the particular service that they want to examine.

Of course, in the latter case it would be the responsibility of that organisation to ensure that they implemented the recommendations that might come from an external report, and to ensure that was done over time in the case of a Public Inquiry, it is the responsibility of other bodies, for instance NHS England, Department of Health and Social Care, the Cabinet Office, to implement those recommendations.

So in general I think how those recommendations are implemented and the process of accepting them, depends upon the nature of the recommendation. It depends upon who the recommendation is targeted at and it's not infrequent for recommendations to be directed at to particular organisations and then of course a view of which organisation or several organisations might be best to implement that.

So if I give you a good example, if I may, from the

Infected Blood Inquiry, is one the recent Public Inquiries. So the recommendations within the final report of the Infected Blood Inquiry contained some recommendations which are in scope for the Cabinet Office relating to the Civil Service and the matter of Public Inquiries in general. There are some recommendations that are very specific to healthcare systems and therefore within the remit of NHS England.

So we have gone through a process and again we have replicated this with other recent Inquiries with the Department of Health and Social Care to be clear about which recommendations should be led by which organisation. We have a set for the Infected Blood Inquiry which are led within NHS England by Chair, a steering board, personally overseeing those recommendations, giving advice to Government as to whether they should be accepted and, if not, why not, and that is an important part of recommendations that that has been laid before Parliament and then the work of implementing them.

So I can give you assurance that for recent Inquiries -- and I include in this investigations such as Donna Ockenden's Inquiry into maternity at Shrewsbury and Telford and Dr Bill Kirkup's investigation into maternity at East Kent that we have a rigorous process

within NHS England to ensure that we understand those recommendations and we set about implementing them.

I do think there is scope though for strengthening this and you will have heard evidence from Dr Rosie Benneyworth, Interim Chief Executive HSSIB.

Q. I am going to come to that in a moment, can we go to her shortly?

A. Yes.

Q. Let's focus for a moment on remembering the Allitt case. Sir Duncan, who was Chief Executive at the time, was tasked by Baroness Bottomley to circulate information surrounding that case and one of the recommendations was to heighten awareness about the case --

A. Yes.

Q. -- about the crimes of Beverley Allitt. Didn't particularise how that might be done --

A. Yes.

Q. -- but to heighten awareness, moving forwards in time, I suppose that is safeguarding in time, isn't it, policies, thinking about deliberate harm from a member of staff --

A. Yes.

Q. -- being a possibility?

A. Yes.

Q. Can we have a look for these purposes at your statement page 195, so it is INQ0017495, page 195. It's paragraph 747, it begins. You set out helpfully the governance structure for fulfilling NHS England's statutory safeguarding responsibilities. It's quite difficult to see the governance chart there, I don't know if it gets any better if it's blown up. It does.

What assistance does NHS England provide to NHS Trusts to help them comply with safeguarding requirements?

A. Well, as I am sure the Inquiry is aware, safeguarding is an interagency approach that involves partners, not just in the health system but also in local authorities and the police and others and there are a number of key documents concerning safeguarding, the Working Together --

Q. 2015?

A. -- guidance that was previously with the Department of Education, now with the Department of Health and Social Care, is one of those documents. The intercollegiate document, produced by the Royal College of Nursing but with input from many others is another. The SUDiC guidance from the Royal College of Paediatricians and Child Health again.

We bring that together within the SAF, the

Safeguarding and Accountability Framework, produced by NHS England which sets out our expectations around how individual organisations within the NHS should approach safeguarding, the guidance they should pay attention to, the processes and structures they should put in place. That is revised on a periodic basis and it is due further revision soon.

Q. Can I ask that it's put on the screen, Sir Stephen, your paragraph 749 --

A. Yes.

Q. -- which sets out NHS England facilitating national sharing of best practice and safeguarding. Various ways that it's done and they are listed on the next page.

A. Yes.

Q. Including reference to an NHS safeguarding app?

A. Yes.

Q. Who has access to that?

A. And there is reference there, which I was going to allude to, to the NHS Standard Contract which requires organisations to put in place these processes and structures regarding safeguarding.

Q. And then at paragraph 752 you set out the NHS Safeguarding Accountability and Assurance Framework

aiming to draw together and describe safeguarding roles and responsibilities?

A. Yes.

Q. And at 755:

"The framework states robust arrangements including the following:

"Identification of a named nurse, named doctor and named midwife ... for safeguarding children."

A. Yes, those are the structures and processes I was referring to.

Q. And then over the page, a suite of safeguarding policies and procedures that support local multi-agency safeguarding procedures. The Inquiry heard from the current Chief Executive at the Countess of Chester and asked questions about the current policies and it would appear, would it, that Trusts write their own policies, they may have guidance but would there be some sense in a template provided by NHS England where they add these details, for example setting out what you said here, identification of a named nurse, doctor, so that instead of everybody writing policies -- and they will be variable, the Inquiry has seen that, having had a survey and obtained them -- having a state-of-the-art: this tells you what you need to know and what you need to do policy, would that be helpful do you think?

A. Yes, again a bit of context. It is not unusual for us to write national policies with the ability for local organisations to modify and adapt them. There is good reason for doing that because one national policy doesn't necessarily fit every single organisation. A good example of that, we may come on to this, is the Patient Safety Incident Response plans, where the Countess of Chester have adapted that plan for their local circumstances including, for instance, the fact that they are close to the Welsh border and they have to take into account patients in Wales.

But I think there is merit in us considering whether in safeguarding we can take more of a template approach, as you have suggested, and I am very happy to commit to the Inquiry that we will -- that I will discuss that with the Chief Nurse who has responsibility in this area and see whether we can take that approach in a -- in a more defined way than perhaps we have previously.

Q. Because there does seem to be confusion on the ground at least from evidence we have heard about when the SUDiC, the Sudden Unexpected Death in Infancy guidance, should be followed as opposed to Child Death Overview. Suggestions reading into a policy that you might use both. I mean this isn't a good use, is it, of

clinicians' time if it's taking six hours to fill in one of these forms following a death?

A. So I think there is a separate discussion around the time it takes to report and that is not just for safeguarding. But in general, yes, we would agree that there is scope for more clarity. There are clearly a number of documents, we have discussed the SAF, aims to bring those documents and guidance together but again I can commit within NHS England and also in the work that we do with partner organisations such as the Department of Health and Social Care and the Colleges to provide more clarity to these documents and guidance.

LADY JUSTICE THIRLWALL: I just wonder if they could be made shorter.

A. There is always a balance between providing too little detail and too much and it's one in all our guidance and documents that we are always conscious of. And if I may, my experience is you both hear from practitioners that sometimes there is too much in a document but equally from others that there is stuff that they would have liked to have been in a document and guidance that's not there.

LADY JUSTICE THIRLWALL: But it may be that there is room, isn't there, for something short and clear for when someone is having to know what to do right now

where something more discursive and perhaps a bit more academic?

A. It depends a little bit on the nature of the document --

LADY JUSTICE THIRLWALL: Of course it does, we haven't had so far anyone complaining about documents being too short.

A. No, but it does in my experience, it is not so much the shortness of documents it's -- it's could you have such and such in it or include other information.

But it is a balance. It does of course depend on the nature of the document. The more technical documents tend to be longer and we are always striving to keep that balance but I will take those views back and ensure that we scrutinise that balance appropriately and make sure that we have the right balance between providing enough information but not documents that are too long.

MS LANGDALE: Can I take you to an NHS England and NHS Improvement document that isn't too long, I suggest, and it's INQ0107001 beginning at page 1.

We asked the Countess of Chester for all of their safeguarding policies and we didn't see this. You have helpfully produced this and it's titled "Managing Safeguarding Allegations Against Staff: Policy and

Procedure".

If we go to page 3 we see what it deals with.

It's produced by the NHS Safeguarding Team, I should say. If we go to page 5, 3.3 the policy covers allegations made against staff both within and outside their NHS England and NHS Improvement duties, such as their private life, it lists what they are. The first one being:

"Commitment of a criminal offence against or related to a child young person or adult at risk."

Managing allegations, paragraph 4:

"Three separate actions must be considered when an allegation is made. Enquiries and assessment by child/adult social care into whether a child, young person or adult is at risk of harm or abuse or is in need of protection."

A police investigation of a possible criminal offence, doesn't overstate that.

Then we go over the page:

"The safety of the child, young person or adult at risk is of paramount importance and immediate action may be crucial in safeguarding an investigation. Where there is concern other individuals may be at risk of harm or abuse ... must be reported immediately. Reputational issues must be managed appropriately in

discussion with the relevant communications team. All staff must be familiar with referral procedures for the protection of children and adults at risk."

Further down, 4.8:

"It is crucial that no action taken by NHS England and NHS Improvement to manage an allegation would jeopardise an external investigation."

If we go to 5.12 at page 8:

"Police and/or social care should be consulted when they are involved in any ongoing investigation and/or when criminal investigations are pending. The staff member's line management should be asked to provide appropriate support to the individual and keep them regularly informed while the case is ongoing. Further support may also be provided by Occupational Health."

And then there is an appendix at page 14 defining those at risk, harm and relevant conduct and we see some groups are particularly vulnerable, halfway down the page, children and young people in hospital. The fourth bullet point down. And then appendix 2 is a managing allegations process flowchart.

So it doesn't look, and I am sure I will be corrected by the Countess if we are wrong, as though they had that policy certainly within their disclosure in 2014/2015. It's clearly NHS England's responsibility

to circulate policies and the like. But it's a significant document, isn't it, in the light of what we are examining?

A. (Nods)

Q. Thank you for producing it to us. But where do you think this went to in 2014/2015 and why would that not have been more widely known at the time?

A. My understanding, this is an internal NHS England document relating to our handling of safeguarding concerns, but I agree with you. It is very clear and it does provide the clarity that is required in terms of what to do, if there are concerns around a member a healthcare professional deliberately harming a patient.

And I think this is the sort of clarity that is required in documentation around safeguarding, and as I have said a few minutes ago, it is why I think we need to ensure going forward that this clarity is in all safeguarding documents and I will commit to ensuring that we do that both in the documents we are responsible for but also in our input into documents that are produced by other partners.

Q. So it appears at the time they won't have been sent anything like that and didn't have anything like that, there was a paucity of information around what to

do with allegations that a staff member is causing deliberate harm?

A. So I can't give you clear evidence of the guidance that they had at the time in terms of those local policies but I think clearly one of the key learnings is around that clarity so that staff are absolutely clear in what they should do if they have a concern.

I think there are -- as we have discussed at the start there are many things the Countess of Chester could have done to raise those concerns, safeguarding is certainly one of those things. And you have heard evidence from staff and former members of staff at the Countess of Chester that in hindsight safeguarding should have been used. But we do need to be clear about this and that clarity is required.

Q. If we can go to another document, please, INQ0012911, page 1. This is the fourth edition in 2019 of "Safeguarding Children and Young People: Roles and Competencies for Healthcare Staff".

And we see on the front page the contributing organisations. So not NHS England but a number of contributing organisations to this document. And we see if we go to page 19, this is looking at core competencies if we look at the top in the right-hand

column, it does appear, "Awareness of professional abuse and raising concerns about the conduct of colleagues", so it is in and amongst this document which isn't as short as the last one but it sets out a lot of information.

And then at page 30, depending the tier that you are being trained to, this is all about training and clinical knowledge, we see at bullet point 3:

"Understanding the effects of parental behaviour on Children and Young People and the interagency response."

And we see "have an understanding of fabricated or induced illness".

So we have got specifically how the learning is directed to understanding abuse by family members but we don't see it repeated about recognising or clinical knowledge and understanding about recognising concerns in staff members. So again another gap that if it was plugged would help with this corporate memory, wouldn't it, and realisation?

A. Yes, this is the intercollegiate document that we have referred to previously. It's produced by the Royal College of Nurses. As you saw on the cover sheet on behaviour of a large number of organisations it is not an NHS England document but I would agree ensuring that there is clarity in this document, it was one of

the documents I was referring to, ensuring there is clarity in the awareness of both -- both the awareness of deliberate harm but also what to do if there is deliberate harm I think could be improved.

Q. This is the kind of document that will be disseminated widely with this amount of collaboration, one would hope?

A. Yes.

Q. So it is an opportunity to set out the kind of knowledge NHS England has presumably looking at the previous document about incidents where those rare cases had occurred and deliberate harm has been caused and what needs to be thought about?

A. Yes, and as I said, it is not an NHS England document but we do work closely with Royal College of Nurses on a number of issues as we do with other Royal Colleges and in the commitment I made it work or input into documents that are produced by partner organisations then I, you know, commit to ensure that we make the case for the -- for clarity and within our own documents, we provide that clarity.

Q. And the final guidance document, if I can put this up, please, INQ0108740, page 1. This is the recent collaboration to produce investigating healthcare incidents where suspected criminal activity may have

contributed. Again was this memorandum put together in the knowledge that there is a need for guidance in the handling of incidents involving criminal activity in the healthcare setting?

A. Yes. Again this is a Department of Health and Social Care document. I think you have heard evidence on this. This I believe replaces a previous MOU, it is an update to a prevent MOU and it's an important update because it does give clarity as to how the NHS and the police should work together.

Q. If we go to page 4 and 5 and see the contributors, we see the National Director of Patient Safety from NHS England. Might it have been sensible to have the NHS Safeguarding Team represented here or someone with a safeguarding role, whether that is an advocate for children or something else, because in expressing the test to be applied, the requirement to keep a child safe, such as in the internal document we went to, can't be emphasised enough, can it, in this kind of memorandum and somebody with that perspective might have introduced that thinking, do you think?

A. I wasn't personally involved in a production of the MOU so I can't give you the detail as to how that was considered and whether it was considered. The National Patient Safety Director is a senior member

within the NHS England structure reporting directly in to me. It's certainly something I am happy to take back and discuss with colleagues at the Department of Health and Social Care.

LADY JUSTICE THIRLWALL: It may look as though safeguarding even now is not something that people automatically think about because one would think if it had been thought about it would have appeared here, it is difficult to see why it wouldn't or at least one would expect an explanation as to why it doesn't; in other words, there is other guidance as to what you do when it's a child --

A. So I wouldn't necessarily draw that conclusion because I think there are --

LADY JUSTICE THIRLWALL: Okay.

A. -- lots of documents relating and processes and structures related to safeguarding. Those are required, as I have said, in our standard contract and our other guidance to organisations and there is staff mandatory training, different levels of training for staff depending upon the particular interactions with Children and Young People.

LADY JUSTICE THIRLWALL: Yes, indeed, yes.

A. Sorry.

LADY JUSTICE THIRLWALL: No, I accept that

completely, it was just rather that it seems a curious absence from this document.

A. Yes, I can't comment further, but as I said I am very happy to take that up with colleagues at DHSC.

LADY JUSTICE THIRLWALL: Yes, thank you. I don't think Mr Vineall could help either about it, was my memory but I may have misremembered that. Anyway, thank you. Sorry, Ms Langdale.

MS LANGDALE: Because for example the key area where it may be relevant, for example, page 7 when the MOU applies:

"The MOU applies when more than one of the signatories needs to investigate in parallel any incident where there is a reasonable suspicion that a criminal offence has or may have been committed by an individual."

That is of course right in terms of memorandum but it's also to avoid risk to patients and particularly children who you are safeguarding, to keep them safe --

A. Yes.

Q. -- and to protect them from risk which should be a thinking in any decision that is ultimately made about sharing information and when?

A. Yes. I -- I agree this is something that we could look at further. Of course safeguarding, as you

know, involves all age groups; it is not specific to children. But I think that is a fair point and I am very happy to discuss it with Mr Vineall and colleagues at DHSC.

Q. That is something that people working in the NHS often say, all patients are vulnerable. There is a lot of vulnerable patients in particular categories, but by being in hospital, they may be vulnerable and ill.

Do you yourself see there is any distinction at all between the vulnerability of children and particularly the newborn and neonates or would you classify all patients as equally vulnerable in some sections?

A. I think probably the latter, I mean, there are clearly specific vulnerabilities for specific -- specific groups of individuals who are vulnerable and there are specific policies directed at children and young people as opposed to other vulnerable groups.

But I think the -- in my experience, the knowledge of vulnerability and safeguarding has increased over my time as a doctor. It's certainly something that in my 40 years I think has been strengthened but that is not to stay that it shouldn't be strengthened further and I think these are areas that always need to be kept under review.

Q. You mentioned Dr Benneyworth before. Shall we go to her document --

A. Yes.

Q. -- at INQ0108741, page 1. So this was the collaboration between arm's-length bodies and the DHSC producing this document, "Recommendations but no action: improving the effectiveness of quality safety recommendations in healthcare".

If we can go to page 4 of the document, I would like to invite your comment on a number of the bullet points here, the findings made.

First of all:

"Failure to implement actions following recommendations ..."

This is not just from Public Inquiries, from reviews:

"... any other safety investigations can impact public confidence in the healthcare system and compound harm to patients."

Do you have a view about that?

A. Yes, so I think this and the findings of this review are incredibly important and we would support them. This is work that was commissioned by the Department of Health and Social Care on behalf of a group of Chief Executives of our arm's-length bodies.

Latterly, we have been supporting this work within the National Quality Board, which is a cross-organisational national board looking at quality in healthcare I co-chair that with the Chief Inspector of Hospitals, so I have been close to this work that Dr Benneyworth has been undertaking and I think it makes a set of really important points, of which this clearly is one.

Q. What about the development of a searchable repository, which includes "recommendations made across the healthcare system may help to reduce the fact that some recommendations appear to duplicate or contradict others"?

A. So we would agree with that proposal. Of course it may not be one repository because as I alluded to earlier, it very much depends upon who the recommendations are directed at and who has responsibility.

So at the highest level, a Public Inquiry, clearly there are Public Inquiries that are not specifically related to healthcare, Grenfell Inquiry, Post Office Inquiry. It would be, in my view of NHS England, reasonable for the Cabinet Office, for example, to be the relevant holder of that repository.

For Inquiries, whether statutory Inquiries or non-statutory Inquiries related solely to healthcare, it

would be reasonable for the Department of Health and Social Care to hold that repository but it would also be reasonable for NHS England to hold a repository for recommendations that are made in Inquiries that it commissions, or for recommendations that it has the responsibility to carry out.

I think another important point is, as you know, structures within the healthcare system within the NHS change over time and that may be one of the contributors to recommendations not being fully implemented or tracked and for that reason Government bodies such as the Cabinet Office and DHSC, I might say, are more permanent structures I think would be appropriate over serious of a master repository. We have a repository for maternity recommendations within NHS England and we will be undertaking work to explore how we can expand that approach to recommendations across a variety of areas, not just maternity.

And the final point I would make, which I have made previously, is that recommendations come from a huge range of reviews, from Public Inquiries, through to individual pieces of work that individual organisations might commission themselves and there is a question as to if there were to be master repositories, which recommendations would be kept within that, is it all

Coroners' reports, Regulation 28 reports, for instance, HSSIB recommendations.

I think that is work to be determined. But as Dr Benneyworth points out, in the round lots of recommendations are made by lots of different bodies and by lots of different reviews and Inquiries.

Q. And the point has been made that that can be overwhelming for Medical Directors in individual Trusts trying to prioritise and know what to do with which recommendations when. Would you agree with that?

A. Not specifically -- well, I think this is not a specific issue for Medical Directors, I think it's for all leadership teams within organisations. Yes, I think -- and again Dr Benneyworth describes this, that a large number of recommendations that sometimes may not be constructed as helpfully as they might be, sometimes overlap, and without a prioritisation can be a challenge.

We have a role at NHS England, as do partners such as Department of Health and Social Care, Cabinet Office, in prioritising those recommendations and working out how they can best be implemented and again this depends on the nature of the recommendation. There are some recommendations that are best implemented by a change in national policy that can then be promulgated through to

individual organisations.

There are some recommendations that do require individual organisations to take action themselves, it very much depends upon the nature of the recommendation.

So we talked about the recommendation in Sir Cecil's report into Beverley Allitt on incident reporting. That is a good example where over time that recommendation and others has resulted in the National Incident Reporting System. So that is a national policy.

So we agree repositories are worth considering but again we need to recognise there are a lot of recommendations and prioritisation does have to occur.

Q. One of our witnesses suggested that the person fit to do that might be the National Medical Examiner, letting medical directors know how to prioritise and when and what?

A. Yes, I noted Mr Hunt made that recommendation to you.

So it doesn't necessarily have to be me or the person in my role. But we do agree that there is a need for prioritisation. To an extent that already occurs, for instance in the response to recommendations made by Public Inquiries. But all recommendations have with them resource consequences, for example, and as part of

responding to recommendations it is important to take a view as to what are the most important and most urgent to implement but also of course the nature of how they can be implemented and the resource required to implement them.

So we would agree in principle; whether it needs to be me or not I think is a second order question.

Q. If we look at bullet point 5 there is a current lack of visibility of ongoing work across arm's-length bodies that would enable collaborative working on related workstreams.

Why is there a lack of ongoing work across arm's-length bodies, do you think, because that does mean there will be duplication, wasted cost time and effort, similar to what we have been saying about Trusts drafting all their own lengthy policies?

A. I wouldn't say there is a complete lack of ongoing work and I have given you the examples of the response to the Infected Blood Inquiry and the recent maternity Inquiries as a good example of how in practice we as a set of partners, in this case the Department of Health and Social Care, the Cabinet Office, NHS England, NHS Blood and Transplant, who are the key implementers of the IBI recommendations, how we work together to ensure that there is clarity over who has responsibility

for which recommendation.

But I think what Dr Benneyworth is alluded to here is work around ensuring that individual components of the NHS, so CQC, HSSIB, for example, NHS England are not overlapping in work that results in a duplicity of recommendations in particular areas, so we would agree with her on that. And I think there was further work to be done as a consequence of the work she has done.

Q. If we look at page 7. There is reference to the National Recommendations Register for maternity and neonatal services. Do you agree that that initiative in the context of maternity and neonatal services could be replicated in other areas as well?

A. Yes, and that is why I have committed to within NHS England building on the work that's been done within the maternity and neonatal programmes, to expanding it to broader sets of recommendations that are pertinent to other areas of patient care.

Q. Is there a need to ensure recommendations are narrowly focused with specific outcomes?

A. Yes. Of course I would be hesitant to give the Inquiry a recommendation on your own recommendations but I think in general as a receiver of recommendations, the more specific they are, the clarity on who or what organisation should be responsible for that, I think is

important.

That is not always possible because the nature of recommendations but in my experience it does assist in the consideration and implementation of recommendations.

Q. Should new recommendations explicitly supersede previous related ones?

A. So I think as part of the process of setting recommendations, consideration should be made to previous recommendations. And where those new recommendations are explicitly designed to either build on or entirely supersede previous recommendations, again this is my own view, I think it would be useful if that can be made clear.

Clearly over time recommendations can be superseded because of legislative changes, that certainly happened with respect to the Clothier Inquiry, due to changes in the way healthcare is structured or indeed medical advances. So that is one reason why when you look back at previous recommendations you cannot directly see that it's been implemented at first sight because it has been superseded by others or by changes in practice, but I do think in general I would agree with you that being cognisant of previous recommendations and how a current recommendation impacts upon that would be useful.

Q. Do you think the House of Commons Select

Committee is an appropriate mechanism for monitoring recommendations and their implementation?

A. So I think as part of that process of having a repository there is -- there should be a process of monitoring recommendations and again this is not just one organisation, it's all organisations who are responsible for recommendations. But we do that within NHS England. For instance, we are still -- for the Morecambe Bay Inquiry from a few years ago we are -- until recently been monitoring the impact of those recommendations and the implementation of those recommendations.

So I can speak for NHS England saying that we are focused on ensuring that recommendations that we are responsible for are monitored and that there is a process for review.

But clearly with the volume of recommendations as you've alluded to, that can be a challenging task.

Q. Can we have on the screen, please, INQ0010447, page 1. This is an article that Dr Benneyworth I think produced for us. It's 2019 so the position may be different now, slightly different. Mapping the Regulatory Landscape, and we see results within the abstract:

"Our mapping revealed over 126 organisations who

exert some regulatory influence on NHS provider organisations in addition to 211 Clinical Commissioning Groups."

And then we see at page 2:

"The need to map the regulatory landscape."

"This short overview of regulation history in the UK demonstrates a stream of structural reforms over the last 25 plus years which have gradually increased the extent and complexity of the regulatory structures."

Do you think a review, Professor Dixon-Woods suggested it might be conducted by the DHSC or by someone, of the number of bodies in the space and what can be done about that, if anything?

A. Yes, we do agree that although with good intent the patient safety landscape in terms of regulation and oversight has become over complex. Of course, those many organisations are not just NHS or Government or arm's-length bodies, there are a number of other groups who make recommendations and look at patient safety but when it comes to national bodies of Government or arm's-length bodies, we do believe that that has become over-complex. Indeed it was one of the recommendations of the Infected Blood Inquiry that the patient safety landscape should be reviewed. And you may be aware that the Department of Health and Social

Care Secretary of State has commissioned Dr Penny Dash to undertake a review of the patient safety landscape. She is undertaking that review as we speak. We have, along with others, been inputting into that but we would agree that some rationalisation and clarity of that patient safety regulation landscape would be of benefit.

MS LANGDALE: Thank you. My Lady, I see we have been going for 90 minutes. It might be time for a break.

LADY JUSTICE THIRLWALL: Very good, thank you very much. We will take a break for the shorthand writer and for you.

A. Thank you.

LADY JUSTICE THIRLWALL: We will start again at half past 12.

(12.14 pm)

(A short break)

(12.30 pm)

LADY JUSTICE THIRLWALL: Yes.

MS LANGDALE: Sir Stephen, I am going to move now please to the topic of how Serious Incidents are reported to NHS England, how they were at the time of the events and how they are now.

A. Yes.

Q. You say at paragraph 816 of your statement if

you want to look at it, it doesn't need to come up, that:

"Concerns about the effectiveness of the previous Serious Incident Frameworks have been raised in almost every previous Inquiry, investigation or review into the NHS or a specific NHS organisation ..."

Why is that, do you think, that it's been continual, that the issue of how reports are made has been raised?

A. So I think there were a number of themes that came out of those reviews and Inquiries that have led to the development of a new Patient Safety Strategy in 2019 and also an evolution of the existing reporting system. And in general those themes were around moving from a culture that overly at times sought to or appeared to seek blame on individuals versus recognising that for the vast majority of incidents, it's not around the actions of a single individual but around a set of systems and processes that are either flawed or one component of them goes wrong.

Secondly, around a desire to move much more to a culture of improvement and therefore taking the learning often from a range of incidents, not just from an individual incident into a much more that thematic approach to learning and also then driving improvement.

Thirdly, around something that was very much heard from relatives, from patient groups, from public groups, that the engagement and the interaction with those who have been affected by incidents was not sufficient and this was happening too much over there, where we were not involving the views or the insight or involvement of patients and relatives.

So for all those and a number of other reasons around how the reporting systems were constructed and how data flows, we moved in 2019 to a new Patient Safety Strategy and a new system, PSIRF, Patient Safety Incident Report Framework --

Q. We will go to that, I will take you to that document in a moment.

A. -- which was described in the statement. But those were the key principles around the new direction of travel.

Q. If we go, please, to INQ0009236, page 1, this was the March 2015 Serious Incident Framework policy. If we go to page 13, it is page 12 of the document, page 13, INQ, in broad terms at the top:

"Serious Incidents are events in healthcare where the potential for learning is so great or the consequences to patients, families and carers, staff or organisations are so significant that they warrant using

additional resources to mount a comprehensive response."

If we go over the page:

"Serious Incidents in the NHS include acts and/or omissions occurring as part of NHS funded healthcare that result in unexpected or avoidable death." And that has a footnote 8:

"Caused or contributed to by weaknesses in care, service delivery including lapse, acts and/or omission as opposed to a death which occurs as a direct result of the natural course of the patient's illness or underlying condition where this was managed in accordance with best practice."

This appears -- or the footnote appears to suggest you need to identify the death or injury as being caused by an act or omission partly as a consequence of treatment. So you referred to the need to blame or being concerned something had happened that was incorrect or wrong, that that takes you down the route of if there's something, you know, that's wrong as opposed to just unexpected, unaccountable, don't know what's happened?

A. So we would take the view that at the time the definition did include, and you gave the high level definition of a Serious Incident on page 1 at the start of an unexplained or unexpected death, that could not be

explained by a particular omission or a particular act, should be considered by the relevant panel within an organisation, organisations had slightly different ways of dealing with this but in general incidents are reported by members of staff, reviewed by risk managers and then escalated to further review processes by senior leaders and our view is that it would have been expected and perfectly reasonable for many, if not all, of the incidents at the Countess to have been reported as Serious Incidents. The first cluster of three.

Q. Shall we go to the policy --

A. Yes.

Q. -- just to expand on what you are saying there.

If you go to page 14 of the policy, INQ number page 15, there is a section "Assessing whether an incident is a serious incident", at the bottom it says:

"Where it's not clear whether or not an incident fulfils the definition of a Serious Incident, providers and commissioners must engage in open and honest discussions to agree the appropriate and proportionate response may be unclear initially whether any weaknesses in a system or process, including acts or omissions in care, caused or contributed towards a serious outcome, the simplest and most defensible position is to discuss

openly to investigate proportionately and to let the investigation decide."

So that section appears still to refer to "acts or omissions within care" but if we go further on in the document "Reporting a Serious Incident", page INQ34, page 33 of the policy, we see there "Reporting a Serious Incident." Three bullet points including:

"Incidents which will give rise to significant media interest or the significance to other agencies such as the police or other external agencies.

"Reporting a Serious Incident must be done by recording the incident in the NHS Serious Incident Management System, STEIS or its successor system.

"The Serious Incident Report must not contain any patient or staff names and the description should be clear and concise."

Those are the extracts of the policy that are relevant to assessing and reporting. What do you say on behalf of NHS England should have been reported to you and when and with reference to which part of that policy?

A. Well, to be clear, without a level of detail of individual cases that I haven't reviewed, I will give that caveat but of the 16 incidents that were reported through the NRLS system, in other words were logged as

incidents, not all of them -- in fact, the majority of them -- were not escalated through, as far as I can see, to a Serious Incident Review Panel within the Countess of Chester for a further discussion as highlighted in this document as to whether they should be Serious Incidents or not.

There was clearly a -- that process clearly occurred for the first cluster of deaths in the summer of 2015.

Q. You are talking about the deaths of A, C and D, that cluster?

A. And of those D was reported as a Serious Incident but A and C were not.

Again, it's not entirely clear to me from the evidence I have reviewed why that decision was taken, I can't give you further clarity.

Q. There was a delay in antibiotics or concern there had been a delay, so therefore an omission or something that might have fit the category of that particular death being reported?

A. So -- so again, I think we would have expected those to have been reported and of course the fact that only one was reported meant that it did not trigger the concerns that a cluster of reports would have and a year later, as you are aware, when Baby O and P were reported

as two, you know, very short time-span, that immediately triggered concerns amongst the Commissioners to scrutinise further and to seek further information.

And so if those in that initial cluster there had been a second or a third Serious Incident reported, I am confident it would have triggered the same level of inquiry and curiosity from Commissioners that occurred a year later.

Q. And if we look for completion's sake at the 2016 policy, INQ0006466, page 3. We see again what should be reported is:

"An incident, event or circumstance which could have resulted or did result in unnecessary damage, loss or harm to patients, staff, visitors or members of the public."

So again reference to something that might have been done differently and might have been causative?

A. Yes, and again from the evidence that I have seen, even with that very first cluster of deaths, concerns around a particular member of staff were raised.

Q. Can that come down, please, and can we have a paragraph from your statement, INQ0017495, page 122. 480b, if we can highlight at the top. You are addressing here Serious Incidents and you say:

"An oversight role (consistent with its patient safety responsibilities [at] the time) to ensure there was effective serious incident reporting and subsequent management of serious incidents by the lead commissioner (that is the Clinical Commissioning Group)."

And you say:

"The experience of the North Regional team at the time was that there was a wide spectrum in the approach taken by providers when reporting Serious Incidents. Some providers over-reported (in the sense that an incident was reported that did not meet the relevant thresholds set out in the framework) whilst many other providers under-reported".

How did they know where there was under-reporting, how did they ascertain that?

A. So at the time, if I remember correctly, certainly in terms of overall incidents it was possible to see whether you were an over-reporter of incidents or an under-reporter. I cannot specifically give you information on serious incidents per se, I am very happy to look at that and see if we have got further evidence that we could provide to you in terms of what was available to individual organisations at the moment, in a sense the benchmark.

Clearly there was judgement involved in, in this.

That is clear in the policy. But clearly if there are doubts, as the policy says, that incident should be subject to further discussion and that can include Commissioners and in my experience discussing with Commissioners whether something should be classified as a serious incident or not can be a valuable approach to take as well.

Q. Did NHS England undertake any analysis of why there is the variability, ie down to a lack of clarity round the framework, or local policies and practice?

A. Again that would have been done at an area or regional level. I cannot again off the top of my head give you details. But again we can go back and look to see whether we can find evidence that that review was undertaken and whether individual organisations were cognisant of any review.

I am pretty certain that discussions around rates of Serious Incident reporting would have been discussed, the quality surveillance groups, for example, but I can't say for sure that that was the case and when it occurred.

Q. You referred a moment ago to the Patient Safety Incident Response Framework, can we have that on the screen please, INQ0009265, page 1. And if we go through it, please, page 3 first sets out the NHS's

approach to developing and maintaining effective systems and processes for responding to Patient Safety Incidents for the purpose of learning and improving patient safety:

"Patient Safety Incidents are unintended or unexpected events including omissions in healthcare that could have or did harm one or more patients."

It replaces the Serious Incident Framework. If we go to page 5.

"Compassionate engagement and involvement of those affected by a Patient Safety Incidents", page 7.

"Organisations are required to apply this framework in the development of maintenance of their Patient Safety Incident Response policy and plan."

Page 9, how to use it. We see bullet point 1 includes national templates for developing a local Patient Safety Incident Response policy and plan.

And page 11 "What next?":

"Implementation and impact of this is being evaluated by National Institute for Health Research funded studies started in May 2022."

How would you expect this to apply in the same set of circumstances? You have commented you don't know the details of the circumstances, but Sudden and Unexpected Deaths, clinically unaccountable. What would you expect

in these circumstances?

A. So as I explained before the break, perhaps after the break, this policy -- one of the aims of this policy was to drive much more towards thematic reviews, so bringing together an understanding of the incidents that were occurring frequently in an organisation rather than unconnected investigations on single incidents and in implementing this framework, Trusts have been asked to and have done that thematic analysis of their overall patient safety profile, therefore to drive where improvements need to be made.

So I think this would firstly have supported a much more thematic approach at the Countess of Chester. There were thematic reviews introduced but I think at the time or done at the time by lead, one of the lead paediatricians there. But I think this would have set out a stronger framework for doing those thematic reviews once there was concern around a series of deaths and other incidents of harm.

I think secondly this policy is, again as I have mentioned, driving much more towards involvement of patients, carers and others affected by incidents and I think that is one of the things that was missing in the Countess of Chester, the input from those who had been affected. And I think that would also drive

curiosity and a greater depth of learning and understanding of incidents.

Q. At paragraph 927 of your statement you say this has been well received by the health and care system. What do you mean the health and care system does that include clinicians, doctors, nurses on the ground?

A. Yes, as ever with the introduction of new systems there is a change but broadly the move towards the principles that I outlined that drove the evolution to the strategy have been supported. We are evaluating this approach but early signs are that it is being effective.

Q. Can we have a look, please, at INQ0009255, page 1. This is the NHS Patient Safety Strategy 2021 update. We see at page 3:

"After a year establishing the strategy initiatives and adapting them for what is becoming the new normal we expect to meet some significant progress milestones in 2021, expansion of the Patient Safety Specialist Network, publication of the Patient Safety Partners Framework and roll-out the new Patient Safety Incident management system."

And we see on page 6 patient safety infrastructure set out. I'll give people time to read that.

(Pause) we see the goal of the programme:

"To support and enable organisations to improve their safety culture through embedding a continuous cycle of understanding the issue, developing a plan, delivering the plan and evaluating the outcome."

Then if we can go to 2, "Updates and priorities". INQ0009277, page 1.

"Bulletin: Setting out patient safety strategy priorities".

Over the page, page 2:

"Medical Examiners scrutiny of details now being extended from deaths in the acute settings to deaths in non-acute settings.

"Leaders and specialists should be ensuring information intelligence from Medical Examiner offices as feeding into clinical governance, patient safety and quality to surveillance processes."

That was in 2023.

Then we see December 2023, if we can go please to INQ0009278, page 1. It sets out highlights of the impact of the NHS Patient Safety Strategy:

"Identifying and recording patient safety incidents continues to save an estimated 160 lives per year through mitigation of risk."

Over the page, page 2. Various observations

including a second one:

"We estimate 414 fewer deaths, 2,569 fewer cases of moderate harm due to long-term opioids."

And then we see medication safety improvements below as well.

So would you like to say anything about this and whether, and if so, you expect this to impact on neonatal baby safety?

A. So we have, obviously the Patient Safety Strategy and PSIRF applies across the board to all patient groups, but we do feel that it is having impact it is supporting the work of the improvement programmes within maternity and neonatal safety specifically and you have some examples there.

I think another point, if I might, my Lady, I just want to make and you saw it in some of the previous pages that this is not a policy that exists in isolation.

You will have heard from other expert witnesses the need to have layers of processes that enable that -- that I think in the words of one of your experts that you can't wriggle through the holes in the Swiss cheese and, so the National Medical Examiner system is an important adjunct to this, the safeguarding processes and principles we have discussed are an important

adjunct to this, as are Freedom to Speak Up which I am sure we will come on to.

So these should be seen together. They are not mutually exclusive.

There are multiple ways in which concerns can be raised within the NHS. This relates obviously to specifically to incidents but it should not be seen in isolation to all the other work that is ongoing.

Q. Thank you. That can go down, please. I am now going to ask you to have a look at the documents which demonstrate what NHS England did know or when they began to know about events at the Countess of Chester.

I appreciate you are not the recipient at the time, but you have seen the documents so we can go through these, please. INQ0014630, page 1. This is the Serious Incident reporting for Child O.

And we see at page 2 "unexpected", referred to as unexpected death and the same for Child P, which we don't need to put up as well. But there's nothing in these reports of themselves was there to make NHS England aware of the wider concerns around the deaths of O and P, obviously "sudden" and "unexpected" are set out there but there was nothing further at that point, at the point of the Serious Incident Report?

A. No. So two points. As I have already alluded

to, the submission of these two Serious Incidents for Baby O and P together in a very short period of time did trigger oversight and scrutiny from NHS England and its legacy bodies and Commissioners to enquire further to the Countess of Chester as to whether -- what level of concern NHS England should have.

It did as a result, and as a very rapid result, result in discussing around increased mortality and therefore the downgrading of the unit as a matter of protecting patients from a Level 2 to a Level 1 unit and a third incident Serious Incident was reported shortly afterwards --

Q. Let's go to that one, 7 July. That is the Serious Incident Reporting, the classification of the unit. So if we go to INQ0014636, page 1. If we go to page 3, the detail is set out.

A. So this formally reports and of course this was an agreed process with the Countess, the downgrading of the unit because of concerns around mortality.

What was in neither the reports on Baby O, Baby P or this Serious Incident report on or Serious Incident notification on the increased mortality as a whole was the information that a particular member of staff had been removed from the unit on 30 June 2016 and as that was an action that was specifically taken because of the

concerns in the Serious Incident Reports we would have expected to have been informed of that as part of that reporting.

Q. If we look at page 1 the email circulating this to NHS colleagues, "immediate action" is described as:

"Escalation to Executive Team, NHS England, CCG and CQC, internal analysis of data and clinical case reviews whilst awaiting an independent review with amendment to the admission criteria and implemented supported by the Neonatal Network."

So awaiting an independent review. It's clear that NHS England became aware that the RCPCH was being conducted, weren't they?

A. Yes. And -- and the decision to have an independent review of the increased mortality over the previous year was a perfectly reasonable action that would not be atypical of concerns raised around mortality when that mortality was likely, as is the case more often than not in terms of a range of different factors, so that was supported by NHS England.

Q. Let me take us to the document that demonstrates that, 31 July 2016 INQ0014760, page 1. It is the surveillance report to the Regional Quality Surveillance Group Meeting, 31 July. We see section 2:

"Information updates on areas being managed locally within the Cheshire and Merseyside QSGs."

If we go over the page, page 2 Countess of Chester Hospitals Trust:

"Trust alerted Commissioners to concerns regarding deaths within the unit. Plan in place to downgrade three neonatal intensive care cots to Level 1 whilst a comprehensive investigation is carried out. Daily monitoring continues with weekly Executive reviews of any transfers out, capacity issues, incidents of maternity and neonatal unit. A Royal College of Paediatrics and Child Health RCPCH review has been arranged for 1 to 2 September 2016."

Then we see if we go to page 6 that the level of surveillance at that time was routine. If we see at the top, Countess of Chester, so it is not on "enhanced", it is on "routine". It is appendix 1 we need, page 6. Perhaps you could take it from me it was routine at that stage at --

A. Yes, this is a completely appropriate reporting through the appropriate governance structures of the concerns that had been raised concerning the increased mortality at the Countess of Chester, the response, the external review, and also as you can see here that other than those concerns within the neonatal

unit there was not at that time broader concerns around the Countess of Chester which again reflects the regulatory, its position within our regulatory framework at the time.

Q. If we can then please go to INQ0014639, page 1.

So this is a meeting on 12 September 2016. If we can go to page 2, it is North West Neonatal Operational Delivery Network setting out the actions:

"Countess of Chester has asked the RCPCH to perform an external review of neonatal deaths scheduled for 2 to 3 September.

"The Operational Delivery Network Management Team has reviewed mortality rates and benchmarks them against other local neonatal units.

"Review of nationally collect collected data from MBRRACE in 2013 and 2014 has not identified Countess of Chester as an outlier."

Pausing there of course the relevant data wasn't available, was it, until 2017 and 2018?

A. Correct.

Q. And then the last point:

"The Operational Delivery Network data group is currently developing a monthly activity and outcomes dashboard. Neonatal mortality at ODN and locality

levels is one of the data items which ... monthly."

We see at page 3 of the document and page 4 the data that they collated. And then we see at page 7, if we go to 714687, sorry INQ0014687, page 7, this is minutes of the North Regional Quality Surveillance Meeting on 16 September 2016 and we see under:

"Cheshire and Merseyside: Countess of Chester Hospital sharing there are plans in place to downgrade three neonatal intensive care cots to Level 1. Whilst a comprehensive investigation is carried out, a Royal College of Paediatrics and Child Health review was carried out from 1 to 2 September which went well and therefore it has been agreed that the level of surveillance should be downgraded to 'routine'."

The Inquiry has received a statement from Margaret Kitching, the Chief Nurse North who says "I understood the comment the review went well" to mean there were no urgent patient safety issues being identified and also that the Trust had co-operated fully with the RCPCH for report.

Do you think retrospectively, asking for that -- the Terms of Reference for the report or the instructions for the report would have been a sensible thing to do?

A. Yes. And that occurred at a point after this,

so this is the regional -- this is the higher level quality surveillance group. The previous document was the local one. So what you are seeing here is a reporting of those concerns and the action that is taken, I have no reason to disagree with Margaret's assessment of why the text was set out as it is.

But I think in retrospect more could have been done to ask exactly what had happened in terms of the review and you will see in subsequent months NHS England became increasingly concerned as it asked for the Terms of Reference, as it asked for sight of the review, that that was not forthcoming.

Q. Let's go to the surveillance report for 16 November 2016 which is INQ0106988, page 1. If we can go to page 3, please, Countess of Chester Hospital. It is the same summary, the background summary, but what's added here is:

"The initial feedback is that no immediate risk to patient safety have been identified. However, the reviewers have recommended a forensic deep dive into a number of identified incidents to be undertaken by an independent external consultant and this is currently being arranged. There are ongoing discussions locally as to whether the neonatal unit should be placed on enhanced surveillance."

So at the point it is still on routine surveillance and I don't think ends up on enhanced surveillance until 2 December, I think?

A. Yes, this is -- this is around the point that concerns begin to increase; that NHS England is not hearing the full story.

Q. Then there is a letter received, INQ0008077, page 1 by the Assistant Regional Director of Specialised Commissioning, Andrew Bibby, it is an email from Director of Nursing Alison Kelly. And if we look at the end the first paragraph:

"You will be aware that I sent an update to Sue McGorry via email on 14 November 2016 explaining that the draft report had been received and was being checked by us for factual accuracy, this was sent back accordingly. We have only just received the final approved document from the Royal College."

Next paragraph:

"As a consequence, we currently do not have a final report of this part of the review and therefore are not comfortable in sharing the Royal College report until we have the details of the case review."

She explains:

"One of the recommendations of the report was that further independent case review was required of relevant

cases. This is being undertaken by a neonatologist from London and they require a secondary pathology review on a small number of cases before their final report is completed."

So that did demonstrate there was investigation into specific deaths, didn't it?

A. Yes. And it demonstrated that there was further investigations ongoing but it also shows there was a reluctance to share with NHS England the contents of the report and that was beginning to trigger concerns around the openness and the willingness of the organisation to share the information pertaining to those reviews.

Q. We see, if that can go down please, and we have INQ0014771, page 4, this is a note made by Michael Gregory of a meeting with Mr Harvey, 3 January 2017.

Mr Gregory's note is reviewed by RCPCH:

"Very thorough report in due course no immediate concerns. Now advised further independent review, neonatologist London. Seen draft actions, further review."

So again demonstrating further investigation at least into the deaths or some events?

A. Yes. This was a note from the Medical

Director of NHS Improvement and a conversation with Mr Harvey, the Medical Director of the Countess of Chester, and again it was a similar response in terms of the Trust as you have seen in that previous letter from December.

Q. And we then see at INQ0014644, page 1, if we can enlarge that second paragraph, please, this is Regional Specialised Commissioning Team North update 9 February 2017:

"Have published the findings of the review into unexpected baby deaths in the neonatal unit. Review carried out by the Royal College. The review concludes there is no single cause or factor identified as a means of explaining the increase in their mortality rates but gives a series of recommendations that the Trust is already implementing. Trust handling comms and media. Unfortunately a solicitor dealing with one set of parents leaked details to The Sunday Times on the weekend before publication. Follow-up article is expected in this week's Sunday Times media coverage."

So that's information provided to them?

A. Yes. Again this is the Regional Specialised Commissioning team, which is different from those quality surveillance groups that you have seen earlier, but again it is documenting the increased concerns

around the Countess of Chester.

Q. If we can go now, please, to INQ0014656, page 1, this looks, but you may be aware of other documentation, under the external review the first discussion in the detail of what's been communicated to the Families but there may have been ones that aren't recorded on paper, do you know when NHS England or regional bodies had sight of what Families were being told?

A. I don't have that again off the top of my head and again I can commit to seeing if we have further evidence that can assist the Inquiry.

Q. But if we look at "External review", it looks here at this meeting:

"IH confirmed the completed review will be shared with families and they would receive a copy.

"IH confirmed there was learning for the organisation that had been identified in the review pertaining to the care pathway.

"Action plan being developed by March end to be shared with Commissioners."

What would you understand identified in the review pertaining to the care pathway, what does "pertaining to the care pathway" suggest?

A. Well, I think that note would say to me that

the organisation was reporting that they had identified some learning and I think "pertaining to the care pathway" is a very broad terminology and very difficult from that note to be absolutely clear what that was relating to. And that would be one of the reasons that regional teams would have wanted to see the detail of the report.

Q. We then see an email 29 March from Mr Gregory to Andrew Bibby, that is INQ0014651, page 1. At the bottom, I just need the bottom email on to the next page, please:

"Hello, I spoke to Ian Harvey a few minutes ago ... told him we were aware of the meeting on Monday. To summarise our conversation, Ian had said at the start that they intend to make a significant announcement on Monday and that we would bear with them until this announcement was made."

Then if we go over the page:

"A clinician who Ian gave the impression may have another agenda on Monday night brought up a list of babies' names that he or she was concerned about."

Second paragraph:

"There is a member of staff whose presence has been seemingly disproportionate but as was discussed when we met, this was originally accounted for by rotas and

skill level. However when pushed about staff members, Ian stated this matter was best dealt with when they make the significant announcement about the decision they have taken to speak to an appropriate body on Monday. Clearly something very serious is going on and they must have their hands tied somewhere. Not sure if we can do any more until Monday unless we wish to escalate further."

We then have another email, INQ0014660, page 1, 19 April:

"I am concerned that they are avoiding the issue that we wish to see contacting the police, but I suppose we should allow this call to occur. Then if they don't call the police after speaking to CDOP, then perhaps consider we insist."

So it's crystal clear at this point that Mr Gregory wished to see contacting the police. But there is still hesitation and at some point presumably in the preceding weeks there had been discussion about that or days, however many who knows?

But what was the hesitation from NHS England's point of view if that's what you wished to see, about ensuring that that happened as soon as you -- or that view had been concluded, you know?

A. Well, to be clear, the email that you

previously showed, the 29 March conversation, was the first time the region became aware of concerns around a specific individual and certainly that went beyond any performance issues and into potential criminal activity.

Obviously that raised the level of concern that had already been apparent in terms of the unwillingness to of the Countess of Chester to share information with NHS England and I think you can see that very rapidly that moved to a position within NHS England that the police should be involved as a matter of urgency.

I don't think there was hesitancy on the part of NHS England to do this because the Countess had already, in essence, said that they would speak to CDOP and CDOP has a police component. But I think again you will see, and there is some other evidence that NHS England colleagues at the time were clear that if the police were not involved as an outcome of the conversation with I think the chair of CDOP then NHS England would inform the police themselves.

So I don't think it was a hesitancy. It was a recognition that there was going to be a conversation that would involve the police and if, for any reason, it didn't then action would be taken by the regional team.

Q. Can we have a look please at INQ0014673, page 3 and follow a series of emails through. So it's

INQ0014673, page 3.

If we look at the emails on page 3, you see at the bottom:

"Theresa and James are discussing with Robert today [this is 26 April]. I'd await this conversation. CDOP [that's Child Death Overview Panel] could take weeks. They are not sure awaiting their process will be timely enough considering the level of concern".

The email at the top:

"Spoke with Teresa at lunchtime. We both think, as does James P, we should just refer to the police now. They are happy to make the call if it helps with Trust relations".

If we go to page 2, so back in the sequence of documents, we see Margaret Kitching:

"Dear all, I have copied Richard in as important he is connected and I suspect he would want a call with Lynn Simpson before taking such a decision outside of the Trust."

If we go to the email at the top:

"Hi Margaret, I agree we do need Lynn involved and maybe we should phone Tony in the first instance, but I would be happy to do a joint call. I probably know Tony better being an FT. Remind me what does CDOP stand for?"

Then we go back to page 1, an email from Margaret Kitching to Richard:

"When I spoke with Tony [this is 26 April] he explained that the independent investigations did not identify any criminality. Two of their paediatricians are disputing/casting doubt on the findings, hence them taking further steps. We did discuss involving the police which they intend to do if full assurance is not gained. The two Ps could be the problem but we need to be sure. Tony and the team want to exhaust internal processes first as they recognise that involving the police could cause further significant distress to the families. I spoke with Vince and Michael and we agreed I would speak to the Trust at that time. Michael is worried that he believes they are being evasive, hence escalation to the national levels. Tony is not happy at this accusation as he believes they have been fully transparent. I don't think we should involve the police without appraising the Trust and giving them the opportunity to explain and contact the police if needed."

Response:

"Okay [at the top] I am sure Lynn will support your line. However, if it transpires we do need to subsequently involve the police, then the delay will not

look good and lead to further concerns for the Families."

Do you think in that email exchange there is considerable deference to the way the Trust have analysed the situation, those internally within the Trust?

A. I think there is quite appropriate discussion.

So I think, firstly, the region is clear that the police need to be involved. I think there is discussion and you can see that playing out here as to whether that should occur directly from the Trust or whether NHS England should, at that point, simply get the police involved.

I don't necessarily think it shows deference to the Trust. It recognises that there may be other considerations that are not known at the time to the region and that the further discussions on that should be undertaken with the Trust and the Chief Executive.

In the event, the conversation that the Trust, Countess of Chester, then had with CDOP did trigger police involvement and subsequently a police investigation.

Q. We see indeed 27 April, a meeting between Margaret Kitching, Stephen Cross, Ian Harvey and Vince Connolly, INQ0003193, page 1.

In this meeting, she is told:

"The Trust also sought an independent legal opinion on evidence so far and the findings were that they could not see any evidence of criminality. An independent reviewer identified out of all of the deaths that four were unexplained and therefore recommended a broader forensic review. The Trust clarified this with the reviewer and it was determined that involving CDOP would enable a further consideration which would involve the police who is a member of the Child Death Overview Panel.

"Margaret Kitching thanked Ian Harvey for his time and briefing and recognised the Trust was doing all they could to resolve this. The involvement of CDOP and the police is welcomed."

Was it considered that, really, the Trust should be the one to phone the police? I mean it's clearly internally that is the -- we have heard evidence that people thought it was for the Trust or the Execs team to contact the police. Was that also the view of NHS England; that this was really their -- they were fully sighted on it, they knew what was going on and it was for them?

A. I think the view was clear that the police needed to be involved. The Trust obviously had details

that NHS England didn't have, which would have been interest -- of interest to the police in those conversations.

So I think it was perfectly reasonable to expect the Trust to contact the police and outline the -- their concerns to the police. NHS England would not have had all of that information. As you can see, there was extreme concern around the level of information that had been provided and of course if NHS England had contacted the police themselves, they would have -- of course the police would have been required to have direct discussions with the Countess of Chester.

So I think what you are seeing in these emails over the course of those weeks in April following the information given to NHS England, much later than it should have been as I have said, that there was concerns around criminal activity, potential criminal activity of a particular member of staff that the police absolutely needed to be involved; that it would be preferable, on balance, if that was something that the Trust did but if they were not going to do that then NHS England would involve the police directly.

Q. We see at INQ0014676, page 1, on 5 May, Mr Harvey updates Margaret Kitching about a meeting with the police and DCS Wenham, who's on the CDOP. He says

he will keep them, her updated.

Indeed we see on 12 May, if we can go, please, to INQ0014678, page 1, a further update to Margaret Kitching.

Would the point of contact for NHS England usually be in the regional directors with the managers? Presumably you wouldn't be dealing directly with clinicians or nurses or anyone else, would you?

A. Yes, that's correct. So mostly in terms of conversations with Trusts provider organisations, the conversations would occur between -- at the level of senior Executives, senior leaders such as the Medical Director, the Director of Nursing or the Chief Executive. That is not exclusively the case. There can be conversations directly with clinical teams.

I understand the view of NHS England at this time was that the police absolutely needed to discuss the concerns directly with the clinicians who had raised those concerns. You can see in this email that the police are informed of specific concerns by those paediatricians and that the police recognise that they needed to speak to the paediatric lead as the sender of the email and reports.

But from conversations I have had with colleagues in NHS England, my understanding is that they would have

been very clear that the views of those paediatricians should be heard directly.

Q. That can come down, please. Then if we can have your statement INQ0017495, page 133, and it's just completing what and when NHS England would have known about those Sudden and Unexpected Deaths via Serious Incidents or increased neonatal mortality number of deaths.

It's the section that you deal with data, please, Sir Stephen, and set out what had been reviewed and what you would have ascertained from that.

I understand and the Inquiry's understanding is that the MBRRACE data was available to you 2017, 2018?

A. Yes.

Q. Was there anything, as you go through this, in the data you had at the time that alerted you to that increased number of Sudden and Unexpected Deaths?

A. So there was some conversations with the oversight -- sorry, the Operational Delivery Network and I believe the Chair of that network was involved in some discussions with Dr Brearey early in 2016 around reviews, thematic reviews of mortality.

The ODN was at a fairly early stage of its evolution there. They had only recently been set up in the couple of years before and they were not at that

point, in contrast to the work they do now, heavily involved in overseeing mortality.

So there was some knowledge within the ODN. That is clear from the evidence.

But in terms of when NHS England in terms of Local Commissioners and Specialised Commissioners and regional teams were aware of the increase in mortality, it was at the point that those two Serious Incidents were reported in July 2016 shortly after Lucy Letby had been removed from the unit on 30 June. And, again, the first time that regional teams became aware of possible deliberate harm by a member of staff was in that conversation, that email that you saw from 29 March 2017.

In relation to the increased mortality, the invitation to the Royal College of Paediatrics and Child Health to undertake an external review was, in the view of NHS England, a reasonable and proportionate response. You saw that in the governance papers that you have seen.

But as 2016 went on, there was increasing concern, as I have said, around the information that was being shared from the Countess. That really accelerated in the early months of 2017 and of course as soon as NHS England was aware that there were concerns around potential deliberate harm and criminal activity by

a member of staff it immediately took the view that the police should be involved and you have been through the discussions in those early weeks in April as to how that should be done. But it was in the event done through a discussion between the chair of the CDOP and the Countess.

LADY JUSTICE THIRLWALL: I'm sorry, Ms Langdale, just before you continue. I wonder if I can just check something because I'm not sure if it was a slip of the tongue or I misheard you.

You said that the first that NHS England knew anything about an increase in mortality was in July 2016.

A. Yes.

LADY JUSTICE THIRLWALL: And then you said that shortly after, a nurse had been removed from the unit.

A. So I was making the point that the Serious Incident reports were reported into local Commissioners after the nurse had been removed from the unit.

MS LANGDALE: Not that they identified that the nurse had been --

A. But those incident reports, as I have said, did not impart the information that somebody had been removed.

LADY JUSTICE THIRLWALL: No. That was my --

I think you may have elided two things or I maybe only heard part of what you said.

A. Sorry, yes. Yes, sorry.

LADY JUSTICE THIRLWALL: No, that's all right --

A. As I said previously to be clear --

LADY JUSTICE THIRLWALL: Yes.

A. -- our expectation is in any of those three, perhaps all of them, there should have been a report that as a result one of the actions that had been taken, as a result of the concerns around those particular incidents, was the removal of an individual from the unit and that would have triggered questions and concern from NHS England had we have known that.

LADY JUSTICE THIRLWALL: When you say that the steps taken were appropriate, considered appropriate by NHS England, for example getting the RCPCH report, that's in the context of the information that had been given to them?

A. That's in the context that there had been an increase in mortality over the preceding year.

LADY JUSTICE THIRLWALL: Yes.

MS LANGDALE: The North West Operational Delivery Network, who would be sitting on that group who feeds back to NHS England or generally because I know the clinicians. But who else is on it?

A. So typically clinicians. I am sure we could provide a list of exactly who was on the ODN.

Some of that I am sure is in the written statement, but it would be typically led by clinicians with appropriate support from operational managers and administrative staff to assist with the ODN.

MS LANGDALE: Thank you. My Lady, I see the time. That is a good point to stop for the lunch break, I think.

LADY JUSTICE THIRLWALL: Very well. So we will adjourn now for lunch and we will start again at half past 2.

(1.30 pm)

(The luncheon adjournment)

(2.30 pm)

LADY JUSTICE THIRLWALL: Ms Langdale.

MS LANGDALE: Sir Stephen, can we move please to whistleblowing and Freedom to Speak Up and you say at paragraph 766 of your statement that NHS England expects staff to speak up externally if they don't want to speak up within their organisation.

What -- how is that communicated to staff, how do they know that?

A. So I think the first thing to say is our preference of course is for whistleblowing to be managed

locally and for concerns to be raised through Freedom to Speak Up through local processes and of course resolved by local organisations near to where those concerns are.

But there are circumstances we recognise in which staff, healthcare professionals may wish for a variety of reasons to raise concerns directly with NHS England. We have set that out in our various Freedom to Speak Up policies that that is a possibility and we do receive a number each year of external -- in other words, external to NHS England -- concerns that are raised either directly --

Q. Who would they raise them to a safeguarding concern?

A. They can come through a variety of routes. We do have a Freedom to Speak Up team and there is information I think on our website as to how you contact them. But of course concerns can be raised with other, with senior members of NHS England. For instance, if a concern is raised with me, then I will seek the support and the advice of the Freedom to Speak Up team within NHS England.

Q. In 2015 to 2016, do you think there was less communication on that topic by NHS England to providers?

A. So I think the Freedom to Speak Up system in 2015/16 was certainly at a very early stage of its

evolution. And we first issued national guidance, national policy in 2016.

So the period you have just outlined would be a period where there wasn't national policy or national policy had just been produced. So I think it would be the case that at that particular period, both local Freedom to Speak Up policies and national policies were certainly less embedded and less well known and understood.

Q. And when you say in your statement you would expect people to speak externally -- apart from NHS England, where would you expect them it take any concerns, to their regulators, to other bodies?

A. So the Care Quality Commission would be another source and in fact the CQC will receive many more concerns that NHS England does, that is our experience.

I think those would be the two main national bodies.

I can't rule out that people would raise concerns with the Parliamentary Health Standards Ombudsman and raise concerns initially to other parties but certainly if they are channelled through to NHS England we have a process for responding.

Q. You also tell us you have a webpage dedicated

to speaking up. Is that effective or sufficient?

A. So I think -- difficult to know. But I would say that we have seen increases in Freedom to Speak Up across the board over the last few years. I think the last reported year was 23/24, I am talking about all Freedom to Speak Up, everything that's been raised through Freedom to Speak Up across all organisations, I think are over 25% increase.

Certainly if you compare to five, six years ago every year I think we are seeing an increased number. So that would give me confidence that the system, the processes around Freedom to Speak Up in the round are better embedded and better understood and more people are using them.

When we survey -- when people who have spoken up are asked "would you speak up again?" those that have responded, about 80% said they would feel confident to speak up again.

So, yes, in 2015/2016 it was in early stage. I think it has moved forward substantially since then but there's clearly in my view and the view of NHS England more work that needs to be done.

Q. You mentioned the CQC a moment ago. They of course did an inspection in February 2016?

A. Yes.

Q. And did not know about the increase in neonatal deaths on the unit after that inspection, or suspicions or concerns about a particular member of staff. What do you make of that? Does that lead you to question what they were asking?

A. So the CQC inspections at the time were broad whole organisation inspections and the neonatal unit would be only one part of that. Obviously I can't speak in detail. I do have experience of CQC inspections, I have chaired them myself in the past. But I have no great insight into that particular inspection and how it was carried out.

They did have access to some of the information. They have access to incident reporting. But of course they would have been looking at a whole range of data and as I outlined when we were discussing our quality surveillance groups and their oversight, there were, at that time, no regulatory concerns or other concerns around most of the other services. In the Countess of Chester the concerns that were arising were specifically highlighted on the neonatal unit.

Q. Can we have on the screen, please, INQ0017495, page 206, your statement from paragraph 784 onwards describing the Task and Finish Group.

We see there at paragraph 784 through to 787 you

say:

"The Group's primary focus is on considering the escalation routes in suspected criminal or serious patient safety cases and whether there is potential to make improvements."

Could you update us on that and while you do, do you think there is any merit in having a safeguarding unit or a unit within NHS England where people can direct that level of concern, where they are worried about the deliberate acts of harm?

A. With respect specifically to Freedom to Speak Up?

Q. No, just generally in terms of when the staff are worried and they can't speak up within their own organisation and to go to someone nationally where they are not worried about patient details and such?

A. So I think the team within NHS England that does deal with external concerns and also with internal issues and concerns that are raised through Freedom to Speak Up within NHS England are, are that team.

So I am confident that we have a mechanism for receiving concerns and for dealing with them within the various policies and also of course we -- we are able to take protected disclosures as well.

I think when it comes to strengthening, to Freedom

to Speak Up in particular, our view is that we would agree that there are a number of things that could be strengthened including the independence of guardians, potentially the powers of the Guardians Office and I think that would be what we would want to focus on in terms of future work.

Q. The Inquiry has been hearing evidence from those who were guardians for Freedom to Speak Up at the time 2015 to 2016, that occupying those roles they had a number of other roles and they weren't particularly resourced either the time or the training to give to them. Is that a fair observation, do you think, knowing what you know about the roles at that time?

A. So we don't set any particular standard in terms of the number of Freedom to Speak Up Guardians an organisations should have. We do expect them, and again this is in our contracting arrangements, that they have Freedom to Speak Up -- there is a Freedom to Speak Up Guardian and that system and process is in place.

But again as I have said previously, every organisation differs in its structure and how it's organised and therefore we do give the freedom to individual organisations to determine the correct number of Freedom to Speak Up Guardians.

For example in NHS England, and similarly in

Ambulance Trusts, for example, we are spread over a much greater geographical distribution than a hospital which is mainly based on one or two sites. So that gives a different set of considerations as to how you deploy the Freedom to Speak Up Guardians.

I do recognise that one of the things that we often hear from Freedom to Speak Up Guardians is whether they have enough time and we do encourage organisations to make sure that they have enough time.

I don't personally feel that that necessarily means somebody needs to do the Freedom to Speak Up or the guardian's job and nothing else, I think there can be advantages in having that as part of your work, that is a model we use within NHS England. But it is important that organisations resource Freedom to Speak Up processes and their guardians so that they can do the work that they need to do in a timely manner.

LADY JUSTICE THIRLWALL: Is there resource allocated to them specifically for that purpose?

A. That would be within the general resource of, of the funding of individual organisations. So it would be part of the funding -- overall funding streams. So in other words, I -- again I could confirm this for you it will not be ring-fenced funding to be used particularly for this, this aspect of work.

It will be a requirement that you do this within the overall funding of the organisation.

LADY JUSTICE THIRLWALL: Thank you.

MS LANGDALE: The Inquiry has heard evidence that where concerns are raised by individuals, grievances, countergrievances can be raised; is that something you are familiar with from an NHS England perspective, a cultural issue?

A. Yes, it is something that I am aware of. As I said I think and the evidence is that the great majority -- I think there have been over 140,000 concerns raised through Freedom to Speak Up to date in terms of the last report, I am sure the vast majority of those are dealt with well and satisfactorily.

But there are inevitably those that are not resolved for a variety of reasons. And where individuals do suffer detriment or have a perception of suffering a detriment, that is undoubtedly something that we hear at NHS England, it is of course one of the reasons why concerns would be escalated up to NHS England, we will disproportionately see those that haven't been resolved as will other organisations such as the CQC.

But yes, I recognise that is an issue.

Q. And likewise in the context of performance

management, if there's performance management issues, although the example we were given was an admin case, that there would be responses to that that might invoke other processes and procedures. Are you familiar with that?

A. In terms of the relationship between issues for individuals?

Q. Yes. So if somebody is having performance management issues addressed to raise a grievance or concern about being bullied or --

A. Yes.

Q. Immediately; in other words, not before that?

A. So I think we can see in the data from Freedom to Speak Up concerns that there is a significant proportion which are, have their base in interpersonal or relationships between members of staff or between that line management arrangement.

So by no means are they all concerning patient safety, for example. Concerns can be raised around a whole host of issues and one of the issues to consider within Freedom to Speak Up is where HR processes are the most appropriate processes to use and where Freedom to Speak Up processes are the most important to use and there is an interface there and it's important that there is a clear understanding of when it would be

appropriate to use HR processes, performance and conduct processes and where to use Freedom to Speak Up processes but there is undoubtedly an interface and undoubtedly a proportion of the concerns that are raised fall in that financial expert.

Q. Professor Dixon-Woods made the observation that HR processes are very expensive within the NHS because they take so long, the investigations take their time to happen. Again, do you have any comment on that, is that your observation that people might be suspended on full pay for a considerable period of time or investigated with no resolution --

A. Yes.

Q. -- when they are worried about it and maybe will be exonerated at the end of the investigation, it is not good for anyone, is it, the delay?

A. No, and of course our preference is -- well, first our preference is that the culture of an organisation is such and the way an organisation works, the performance management, everything that exists within an organisation is such that minimises the chance that that will occur. But nevertheless there are circumstances where disagreements, disputes occur.

As much as possible and most of our performance and conduct processes, certainly true within medical

profession, always have a stage of informal resolution to try not to get to the stage of a formal process. Inevitably unfortunately that does happen from time to time and we recognise that it can take longer than actually anybody would want and sometimes there are, you know, very rational reasons for that. It's not simply delay on the part of people, it's involvement of external legal teams or external support or gathering appropriate information but it's in everybody's interests to resolve things as early as possible and where procedures have to be undertaken in terms of conduct in terms of performance, that they are done as quickly as possible.

Q. Council of Governors. You set out in your statement, I think it's paragraph 147, some of the duties and powers of the Council of Governors at an NHS Foundation Trust, including a duty to hold the Non-Executive Directors to account and to represent the interests of the public.

Would you expect the Council of Governors of a Foundation Trust to be informed of concerns about a member of staff deliberately harming babies and when, if at all, would you expect such concerns to be raised?

A. I think not at an immediate or early stage. As you have again alluded to, Foundation Trusts have

a particular form of governance that is unique to them and that is different from NHS Trusts. It is still the response and the governors have a very specific set of responsibilities around appointments of the Chair and Non-Execs and about approval of annual accounts. So the statutory requirements of governors are quite distinct.

I would expect first and foremost those concerns to be managed within the board of the organisation. There may be circumstances in which governors should be informed but I -- and again I am giving a personal view here from experience, that that might be later in the process rather than early in the process.

Q. What effect does the public nature of the Council of Governors meetings have on their ability to be informed?

A. Again, I think if you, again, I think this would be the same question for an NHS board because of course NHS boards occur in public.

I think you have to be clear about when you put something in the public domain the rationale for putting it in the public domain, that is not a question of transparency or openness but there are certain consequences of putting things in the public domain and so at the appropriate time it is right to have things in the public domain but careful thought needs to be

undertaken as to the appropriateness of that.

Q. Does NHS England have a role in ensuring Council of Governors are provided with adequate and timely information by directors of Foundation Trusts?

A. I don't believe we do have a direct statutory role specifically around that. The Foundation Trusts, as you may be aware, were set up on the principle that they would be more autonomous and be granted more autonomy than NHS Trusts, that is their public benefit organisations, the Council of Governors, are part of that autonomy and distinction from NHS Trusts.

So particularly in the early days of Foundation Trusts the distinctions in practice are now more blurred but in the early days, and I would include 2015 and 2016 in perhaps the tail end of that period, the regulatory regime in place was unless there were significant concerns around a Foundation Trust, then they would be granted the autonomy to in effect manage their own business. That was the policy, that was the purpose of the policy and the regulatory regime that was enforced by Monitor, who were the regulator of Foundation Trusts in 2015/2016, albeit as part of NHS Improvement, that was the regulatory framework that was being followed at the time.

Q. What do you think they add in practice, the

Council of Governors to Trusts, to well-run Foundation Trusts?

A. The principle is that they add a public voice, it's not just the Council of Governors, it is the membership requirements, the Foundation Trust have to have a membership, it has that extra level of scrutiny from governors. It is providing a more direct public interest into the working of the organisation.

Clearly Non-Executive Directors function in part in that way in both Foundation Trusts and Trusts. But the principle behind Foundation Trusts was that added level of public interest, public scrutiny and public oversight would be enacted through the membership and Council of Governors of Foundation Trusts.

Q. Do you think in practice they will ever get to the nitty-gritty of where relationships are breaking down or there's serious concerns about individuals, for fear of sharing that information?

A. I don't think that is a fundamental role of the Council of Governors.

Q. Not to scrutinise that?

A. I think that is, it is their role to scrutinise the work of the board and through the statutory responsibilities that they have, but I think that is more territory of the board, the Executives and

the Non-Executives, than necessarily the Council of Governors.

Q. But to scrutinise the board you would need to know how they were managing a difficult situation, wouldn't you, so it might take you into that territory?

A. Yes, I accept that there would come a point I think certainly where the Council of Governors would need to be informed and take a view. But as I say, first and foremost I think that would be a responsibility of the Executive Team and the board as a whole, including the Chair and the Non-Execs.

Q. Your third statement, Sir Stephen, deals with Chief Executive moving on and generally related issues. If we can go, please, to INQ0100828, page 13.

Paragraph 38, 39 and 40. So 0100828, page 13.

If we can all have a read of 38, 39 and 40.

(Pause)

So this all follows on further to September 2018 and we know that Letby is arrested July 2018 and we see at paragraph 39 NHS Improvement Chief Executive had a conversation with Sir Duncan Nichol in around 2018 and recalls being assured there were no misconduct concerns with Tony Chambers.

What level of enquiry might have been made in those circumstances, do you think?

A. I can't give you exact detail. We obviously only have the evidence that we have seen in terms of those conversations but there were clearly conversations between the Chief Executive of NHS Improvement and the Chair of the Countess of Chester regarding the possibility of moving the Chief Executive to another organisation.

As you have heard, the Regional Director of NHS Improvement, at the time Ms Simpson, then was asked to facilitate a move and discussions were undertaken as to what that move might look like. In the event, Mr Chambers moved to the Northern Care Alliance, not a move that was directly facilitated by NHS Improvement, that occurred through contacts I believe he made himself, but there were discussions around moving him to other organisations within -- particularly within the North region.

Q. What would happen today? If that was a situation, someone had been arrested, that call was made, what would you expect to do? Would you find out what the issues were, would you diligently look at what had happened or would you accept what somebody said "not misconduct, nothing else"?

A. So I think the first thing to say is Ms Simpson has accepted in both oral and written

evidence that in hindsight if she had known what she knows now at the level of detail that is now apparent she would not have been comfortable facilitating that move and she would, should have been better at joining the dots around what was occurring in the neonatal unit and the request to move Mr Chambers because of perceived or actual breakdown within the organisation of relationships.

A further bit of context. There are many examples where leaders struggle in one organisation but perform extremely well in another organisation. So it is not necessarily the case because somebody has not succeeded in the way that they or we would want them to do or the board of the organisation that they cannot succeed in another environment. That could be interpersonal relationships, it might be around particular styles of leadership in particular contexts, a whole host of reasons.

So we do wish to support and develop our Chief Executives, not least because we don't want to get in a position where we haven't got a pool of senior Executives so there are circumstances where we will take a supportive role and look to move. Now, clearly if there is misconduct, and if misconduct has been proven, that would not at all be acceptable.

So today we -- it is the role of regional directors within NHS England to -- and the national team at a higher level -- support the talent pool of Executives, to ensure that there is information around who might be available for posts and that is part in a sense of everyday business. It is, however, the responsibility of individual NHS organisations to appoint Executives. We have a role in appointing the Chairs of Trusts, NHS Trusts and Integrated Care Boards, not of Foundation Trusts.

So it is important that it is the organisation and they follow due process. That due process is being strengthened, so the recent iteration of the Fit and Proper Person Test published 18 months ago strengthens the Fit and Proper Person Test. It places a requirement upon boards to produce a standard board reference for every Executive and Non-Executive member of the board and to make that available to organisations including where individuals are moving to non-board roles so that there is strength and flow of information from organisations and we expect organisations who are seeking to employ somebody to look back at least six years in terms of that record of board references.

So we acknowledge that we need to strengthen the process of appointments and the scrutiny and with that

potential movements and that has been done.

Q. Did you read or listen to the evidence of Tom Kark KC this morning?

A. I didn't have time to hear his oral evidence, clearly it was immediately before me. I have seen some of his written evidence.

Q. Was there anything -- you may not have had an opportunity to look at it properly -- that you disagreed with within that, or have you not had an opportunity to look at that?

A. Obviously Tom Kark produced a report on this a number of years ago. We are busy implementing the recommendations of that report. The strengthening of the Fit and Proper Person Test that I have just mentioned is part of the response to those recommendations and indeed those -- that response should also be seen in the context of Sir Gordon Messenger's report and I know you have taken evidence from Gordon Messenger as well.

So on both, on the recommendations from both those reports, we are strengthening our guidance and policies for leadership, including competency frameworks, codes of conducts, some have been published, some are in the process of being published and of course as they become published we are very happy to share them with the

Inquiry.

Q. Is it ever appropriate for NHS England to facilitate managed moves where an Executive faces a vote of no confidence, do you think?

A. So I think in those circumstances we would be very cautious to -- to facilitate moves without understanding more about why a vote of confidence was called.

Votes of confidence can be called for a whole variety of reasons, so it would be wrong to assume straight away that that was because of poor performance by an Executive Team, there may be something else driving that vote of confidence.

But you would certainly want to enquire as to the underlying reasons and rationale for why a vote of confidence from whatever group of staff had either occurred or was -- or there was a potential for it occurring.

Q. Do you think there is a problem in the NHS of failing Executives being moved from organisation to organisation in order to avoid the risk of employment disputes and the cost of them?

A. No, I wouldn't characterise it as that. I would repeat what I have already said: there is a desire to ensure that good leaders are supported and

if they have difficulties in one organisation to not necessarily abandon them and assume that there is not room for them to be further developed, supported and succeed in other organisations, as I said there are examples where individuals have moved from difficult positions and succeeded elsewhere.

On the other hand, it would be entirely inappropriate and wrong for us to support the movement and further employment where there is clear misconduct. Clearly there is a judgement -- levels of judgement in between, in between those two positions and that is why we want to use our leadership frameworks, our competency frameworks to strengthen FTTP, Fit and Proper Persons Test, to ensure that we have more robust procedures around potential moves and not just moves but also appointments process around senior Executives and board members.

Q. Letby was charged in November 2020. Did NHS England take any steps at that time to follow up on the Executives of the Countess of Chester at the time of Letby's crimes, would that have been appropriate to do, to see what roles they were occupying?

A. So clearly police investigation occurring at the time, the amount of information that was in the public domain and known to NHS England was limited.

I am not aware that any particular steps were taken at that particular point, but again I would be very happy to look back and see if we have any evidence that we can provide to you.

Q. Thank you. A different but related topic. We are going to turn to look at senior leadership in the NHS. Can I put some senior salaries on the screen first, please, INQ0108797, 0158. It's the annual report on senior salaries for 2024.

INQ0108797, page 158.

So we see Medium Acute Trusts, Foundation Trusts, Medical Director roles, Chief Executive roles, if we go to 159 and 160 and then I am going to suggest we go to a table that your solicitor kindly prepared. This is the source material, so page 159 and 160 as well.

Then if we go to a separate INQ number it distills it more effectively INQ0108795, it is one page.

So we see there, I will wait until it gets there.

The Trust type, whether it is Acute, Mental Health or Community or Ambulance impacts on the pay scale and then we see the lower quartile median and upper quartile in amounts. So they are the salary grades.

We can also see from the Consolidated NHS Provider Accounts 23/24, if we can go to this please, INQ0108794-0010, that when we see acute Trusts are the

best paid, if we look at 0010, the number of providers that are acute Trusts appear to be 75% of the section turnover. So 0108794-0010.

So we see there at the top if we highlight that sector turnover, 75% is acute.

That can come down. We are going to get to the question in a moment.

If we look, please, at INQ0108796, page 5. Sorry, not that reference. Can we have 108799, page 5, so 0108799, page 5.

"NHS Pay and Conditions Circular 2024 applied from 21 April 2024."

LADY JUSTICE THIRLWALL: I don't think we are looking at that at the moment.

MS LANGDALE: Sorry, that's 796, that is back in 2015. That applied from 1 April 2015, that is not the document I meant to show, but it's there now. That's fine, that is the rates for salaries for doctors in 2015 and this is annex 1, doctors and dentists in training first, page 5.

So we see there between those two pages for doctors and Executives, the Executives is public, and I am not suggesting by the way in 2015 those were the rates, they are publicly available as well, what was available or what the pay scales were for the directors at the time

of the Countess of Chester, they are there within the Countess of Chester reports. But when we look at the pay scales generally for Executives across hospitals today, by public standards they are high salaries, aren't they?

A. So we will -- it depends what your comparator is, they are not the highest salaries within the public sector or within public servants. There are sectors where you will find higher salaries.

For the size of organisations that Chief Executives are overseeing, for instance some of our NHS Trusts are around £2 billion turnovers each year, our view is that they are not inappropriate and that the general view is that they sit at a reasonable level within the spectrum of public service pay.

Clearly if you were to compare them with the private sector you would reach potentially a different conclusion. Of course people are not simply just motivated by pay.

Q. Of course.

A. There is a large vocational element in clinicians and non-clinicians, including managers, who choose to work in the NHS so I think well, our view would be that they -- they are reasonably placed within the range of Public Sector pay.

Q. But they should be sufficiently attractive that the pipeline's important, isn't it?

A. Yes.

Q. Can you take that off the screen now, thank you.

So pipeline is the question. How do you secure for these key roles to our NHS you are getting the right people for the roles?

A. So many of our senior Executives within the NHS come through NHS management structures. Of course important to say at this point that if you look at senior Executive teams, a fair proportion are clinicians by background. Clearly in Medical Director posts, in Director of Nursing posts, that would always be the case.

But individuals in other posts, such as Chief Operating Officer posts, and indeed Chief Executive posts, can and do come from a range of clinical backgrounds including from the medical profession in some circumstances. So individuals come through the NHS, for those that have not come through clinical posts many will have come through our lower grade posts within the NHS, we have a graduate training scheme within the NHS which is very well-regarded amongst graduate training schemes.

Q. How do you get people on to that graduate training scheme?

A. By appointments. Conflict of interest: both my children have been through that graduate scheme. It is through -- through application and through competition into those schemes. Typically it is post university but it doesn't have to be immediately after university.

Q. Does the NHS go round to universities, all universities in the country to encourage people?

A. Yes, I think schemes are well recognised and they have proven extremely popular and many of our senior leaders in the past gone through various graduate schemes. They are not the only route, clearly we have individuals who come into management positions in the NHS from other sectors, including from the Civil Service can come across. So there is no one route into management or through management and we do have Chief Executives and other Executives who come into the NHS direct from the private sector and from other industries.

Q. Is there a minimum qualification or specific qualifications, for example, around finance or communication?

A. There is a set of expected competencies and

that is set out in the competency frameworks, but --

Q. Is competency the same, I mean it is experience as qualification?

A. Yes.

Q. You can gather experience, which is very useful, but qualifications --

A. I would contrast management routes and I think this is probably true in many sectors, for instance clinical careers, doctors and nurses, for example, there is a very clear career structure and a requirement for particular qualifications to proceed through a regulatory process.

That is not the same in the world of management. So the requirements are not as in a sense curricular or qualification-based in the way they would be for some professions.

LADY JUSTICE THIRLWALL: Can I ask you to pause there. The graduate training scheme is competitive and you have to be a graduate?

A. Yes.

LADY JUSTICE THIRLWALL: Presumably, the clue is in the title.

So presumably then there is an expectation that the people that are going to be described as your elite, and we have had that from a few people, will have a certain

level of academic achievement. I am not saying that is the only route to being a really good manager but it is clearly thought to be important.

A. Yes, but I would not say that it exclusively required that. So firstly, for that particular scheme yes, academic achievement not necessarily in a particular subject area.

LADY JUSTICE THIRLWALL: No, of course not.

A. But there are Chief Executives that have come through to being highly regarded Chief Executives who have come through routes that will not require that sort of academic --

LADY JUSTICE THIRLWALL: No, no and I understand that completely. But what I am just trying to get at is at least with the former route you can understand how people have got into the pipeline.

A. Yes.

LADY JUSTICE THIRLWALL: With other routes you can also understand because of the various areas of achievement --

A. Yes.

LADY JUSTICE THIRLWALL: -- that they have.

But the question I have posed to a number of witnesses before you, so I might as well pose to you as well, is if those who go through the elite route, have

a particularly good experience of training, so you are academically able and then you get a very good experience of training, and opportunities in training, and one of the issues raised, and I will raise it as well, is: is there not a way in which that quality of training and preparation could be provided more widely?

A. Yes. And we have, through the NHS Leadership Academy, programmes of management training that many of our aspirant senior leaders go through and they are targeted at different levels as you go through your management career.

LADY JUSTICE THIRLWALL: When you say they are targeted do you mean the courses are targeted or are you targeting and talent-spotting the individuals?

A. So individuals on those schemes are very often talent-spotted and managed through local talent schemes and advised that: this would be an appropriate scheme if you ...

So, you know, a frequent conversation in terms of appraisal of individuals would be: in order to develop to the next stage, the next level of seniority, these are the skills, these are the -- this is the experience, this is perhaps the training and the courses that you might want to consider in order for you to get that level of skills, knowledge and experience to move up

through the various pay scales that I think you showed me for Agenda for Change, which is the management scales, it is the scales for large number of our staff.

So we do have mechanisms within the NHS of supporting and developing individuals who want to go to high levels of leadership. But there is a plurality of routes into those leadership so that is not the only route. As I say, individuals can come direct from other industries, from other sectors, bringing experience of management in other industries and they can come up through largely experiential routes.

So there is a mix in there, but we would agree with you that one of our purposes at NHS England, but also for local organisations, is to provide that developmental support and training where appropriate to give people the skills and competencies that we are describing in the leadership framework.

LADY JUSTICE THIRLWALL: But it is inevitable, isn't it, that some people are just better at the job than others. That is the same across all sorts of --

A. It is the same of every walk of life, isn't it?

LADY JUSTICE THIRLWALL: Yes, yes.

A. So it's important to support people, to where they need to improve. I have been in the NHS 40 years,

there are still things that I learn and still things that I every year reflect on in my annual appraisal that I could do better. I think that this is lifelong learning and lifelong development and I think that is what we want to promote and through the Leadership Academy, but also through lots of local initiatives as well and local schemes, that is what we are aiming to do is to develop a pipeline of future Executives recognising that we do need to ensure that there are other routes in to senior leadership positions because it is also important for the NHS that it brings in experience from other sectors and other industries and doesn't just rely on a pool of individuals who are through and through NHS. It's important to bring in learning from elsewhere too.

MS LANGDALE: How important is it that senior managers understand the work of clinicians, of doctors and nurses if they are not themselves clinicians?

A. So it is important and I think every Chief Executive, every Executive would understand that. Of course the business of delivering healthcare is not exclusively dependent on clinicians. There is a wide range of support services and, you know, from estates management through to financial management that goes into running an organisation.

And of course that is where having a unified integrated board and Executive Team with a range of skills is important because it's very rare that one person can have all the skills and all that expertise. But, yes, it is important for senior Executive positions, including Chief Executives, that they have a good knowledge of what is essentially the core business of healthcare organisations which is the provision of healthcare, although of course clinicians who by and large deliver that require a certain set of competencies and skills that are different.

Q. Doctors and nurses of course are regulated, aren't they --

A. Yes.

Q. -- for their treatment of patients and can be held responsible for their treatment of individual patients.

What about senior managers where they are not doctors and nurses, do you think they are currently held to account for the impact decisions may have on individual patients in the same way doctors are?

A. Yes, they are held to account and of course in the case of NHS Trusts and Foundation Trusts it is the role of the board to hold those individuals to account. And there are mechanisms by which through holding

organisations to account and our regulatory mechanisms within NHS England, but not just NHS England CQC and other regulators are important here, Executives can be held to account.

But on the matter of regulation, you are quite right that doctors, nurses, other clinical professions are regulated professions.

I am in a regulated profession. I am regulated by the General Medical Council. I work full time as a senior Executive within NHS England and my regulation, my annual appraisal, my revalidation through that regulatory process, is now entirely based on my performance as a senior manager because I no longer undertake clinical practice. So my scope of practice is now medical management and leadership.

In the case of Executives, managers who are not from those regulated professions and have not kept that professional regulation, we do believe that it is now the right time to look -- to go further in terms of regulation. As the Chief Executive of NHS England I have been quite clear on that in front of Select Committees that this is the right time to consider going further and that's why we support the current consultation being undertaken by the Department of Health and Social Care on regulation for managers.

I will --

Q. Why is now the right time?

A. Because I think as we are, we have strengthened as I have said our oversight, the competencies, the framework to support managers. But we do think that if we are going to go further, including in some of the recommendations that were made by Tom Kark, that would then move towards a regulatory framework.

In terms of things like registers and registers of professionals, that does require in our view a regulatory framework.

The point that I was going to make, which is a really important point for us, is one of the reasons we think it's the right time and we want to go further is because regulation is much more than just about simply striking people off and disbarring. In our view it is around that whole set of support, codes of conduct, professional support that you give to the development; that is certainly the case for regulators such as General Medical Council, the disbarring element is a small part of what they do and of course some of this is also around public confidence.

So we support the consultation on regulation. We would not wish for any regulatory system to be a simple

disbarring system. We do want it to be a wider system of development and support as per the other regulators. Why would we wish our clinicians to be regulated through one approach and our managers not to be regulated through the same approach? And there is much to learn from the way that other regulators operate as well.

So we will see what the result of the consultation is. But we are supportive of that consultation.

Q. Would you want to avoid your clinicians being regulated twice both by the GMC and then by a regulator for managers if they were managers?

A. So here I will give a personal view rather than necessarily an NHS England view.

So my preference would be to not have dual regulators for a number of reasons. The consultation sets out a number of options, they are all perfectly possible options. As I have said, clinical regulators or professional other professional regulators already act de facto as regulators for individuals who are registered with them entirely in management and leadership positions, so I think they have already got a process on which can be built.

And I think with sufficient co-operation and alignment between regulators, you could manage that through for the individual having only to be regulated

by a single prime regulator.

But I acknowledge that there are a range of options and all of them are potentially workable.

Q. Going back to the Leadership Academy. Is it mandatory for NHS Trusts and FT Executive Leaders to undertake the training?

A. So we -- I don't think it is mandatory at the moment. We are developing for instance further work on induction and further support for managers but we would strongly advise and recommend that Executives go through those, those programmes.

Q. The competency framework, you have already mentioned that, and you said the appraisal framework was to follow by September 2024. Has that followed the appraisal framework?

A. There is a number of accompanying documents being prepared so I think it's important to see these as a suite of documents and supporting guidance in response but not just in response to the Kark and Messenger Reviews. A few have been published, I mentioned the ones they are in the statement. There is a few more in development.

I am hopeful that the -- well, fairly certainly that the certain that the induction framework will be published before the end of the financial year and we

are very happy to share a version of that with you and for the others documents that are under development, again very happy to share once we have near to final drafts.

Q. The Inquiry has heard evidence that it was the Chair of the board that appraised the Chief Executive at the time?

A. Correct.

Q. Would that still be the case?

A. Yes.

Q. Singularly or would other people feed into that?

A. So typically when a chair appraises a Chief Executive he or she will seek information from other colleagues. We would recommend the use periodically of 360 appraisals, where anonymous feedback can be gathered from a range of colleagues, not just at Executive level but externally and other positions within an organisation. So we would expect that in that appraisal mechanism, as in other appraisal mechanism, the views of other individuals are taken into account to -- into that appraisal process but the appraisal itself will be between the Chair and the Chief Executive.

LADY JUSTICE THIRLWALL: Can I ask you about the 360. You say anonymous. Are they effectively

anonymous? It is my experience of 360 that everybody knows who it is?

A. So my experience of 360s is well, clearly you provide -- typically provide a list of individuals to the person organising the 360 around who you suggest information should be sought from.

LADY JUSTICE THIRLWALL: So you suggest that the person being appraised suggests --

A. Yes, but then when it comes to who has said what and often it is a combination of 360s of a set of standard question versus free text who has ticked what box in terms of the standard questions and who was given the free text.

In my experience, it's -- it's often difficult to tell, nor in my experience should you particularly want to know, what's important is the range of information that you are getting back and I think they are, they are a useful adjunct to appraisal they are not the sole input into appraisal but in my experience it is useful and within revalidation, within the General Medical Council we do expect for every revalidation cycle a 360 appraisal to be undertaken.

MS LANGDALE: Can I have please on the screen INQ0017495, page 272. This is where you reference the Perinatal Culture and Leadership Programme.

You say at 272, paragraph 1012:

"Perinatal Culture and Leadership Programme is the key means by which we are seeking to influence the culture of individual neonatal units and their relationships with maternity care by bringing maternity and neonatal managers together to work towards building positive team culture."

Can you expand on that for us, please?

A. So within our broader cultural approaches to improving and supporting culture in the NHS there are often specific programmes. This is clearly the culture and leadership programme in neonatology and perinatology so it is an example of where we seek to influence the culture of particular specialties and particular departments and units. It will -- if you require further details over and above what's in the statement, I am very happy to give them.

But typically, this sort of programme will, similarly to other programmes, focus on what good governance looks like, what data should be used within a particular service to drive improvement. How an improvement culture can be generated and sustained and how concerns can be dealt with.

Q. You also, if we go back in your statement, please, to page 178, set out the three-year delivery

plan --

A. Yes.

Q. -- from paragraph 698. I don't know if it is possible to have that page and the next page 179 on the screen together. Could you set out in practical terms what's the endeavour here, what do you hope that this will achieve?

A. Well, the endeavour here is to improve maternity and neonatal services. We have had a maternity improvement plan or transformation plan in place for some time but the purpose of the three-year delivery plan was to build on that and take the specific recommendations from Donna Ockenden's review of the events at Shrewsbury and Telford and Dr Bill Kirkup's review of maternity in East Kent into the Maternity Transformation Programme and expand it more explicitly to include neonatology. So you can see in this exhibit the themes that are at the core of that listening and working with women and families, again we have touched on that previously, so ensuring that the patient experience the experience of mothers and parents and partners is much more integrated and much more integrated -- compassionately integrated into the work we do.

The theme on workforce we have touched on

previously as well and I have alluded to the work we are doing on ensuring that the workforce is a sustainable workforce and of the right size with the right skills.

We have again, theme 3, talked about patient safety and you can see there the transition to PSIRF is one of the key aims and then finally again we have talked about data. We have talked about records. We have talked about using data and again you can see in theme 4 that is at the core of that, so it is all the components that we have touched on today set out specifically for maternity in neonatal services and taking into account some of the specific recommendations from previous investigations.

Q. Sir Gordon Messenger gave evidence and offered this constructive criticism, he described it as: 90% of the time seem to be on perfecting or polishing the product as it were and only 10% embedding in an organisation when it should be the other way round.

Do you accept that or recognise what he is describing there?

A. I would nuance it, with great respect to Gordon, who has been a great help in supporting us in this work. I don't think we always necessarily strive for perfection. But we typically want to take in a range of views and a range of expertise when we are

developing guidance. A core part of developing guidance is engaging with stakeholders, engaging with others.

So for our leadership work we have been engaging with others expert in management as to what should shape that.

So that does mean that sometimes our development of policies takes a bit longer. I actually was asked about this in the Covid Inquiry a few weeks ago and getting the balance between getting policies out in a timely way and ensuring that you have taken a range of views in to inform that policy is a balance and we need to strike the right balance.

So I think that 90% is not necessarily just about trying to perfect. I think it's ensuring that we have done the appropriate engagement and the, got the appropriate input into ensuring that we have a policy that is fit for purpose.

MS LANGDALE: Thank you, those are my questions, Sir Stephen. My Lady there are Mr Baker -- or two people asking questions. I wonder if now is a good time take a 10-minute break because then I am confident we will still conclude within the time.

LADY JUSTICE THIRLWALL: Certainly. We will take a 10-minute break and start again at quarter to.

(3.36 pm)

(A short break)

(3.45 pm)

LADY JUSTICE THIRLWALL: Mr Sharghy, just before you start, Ms Langdale, I think towards the end of the previous session we had some documents up about Chief Executives' pay and doctors' pay but I think they had become rather muddled. Certainly at one stage we were looking at a schedule of junior doctors pay so I wonder if that -- we don't need to take time on it now but perhaps the right documents can be identified and uploaded onto the website and maybe also the appropriate figures for the Countess of Chester.

Presumably it is in the annual report which we have got somewhere.

MS LANGDALE: Thank you, we will, thank you.

LADY JUSTICE THIRLWALL: Thanks, Ms Langdale, Mr Sharghy.

Questions by MR SHARGHY

MR SHARGHY: Sir Stephen, good afternoon. I represent one of the Family groups involved within this Inquiry.

I have got three topics I would like to ask you some questions on and I hope I am not going to cover a lot of what you have already given by way of your evidence.

A. Yes.
Q. The first topic is in relation to the information sharing and you gave a lot of evidence to this Inquiry about the expectations of NHS England, when it came to the Countess of Chester when they should have really precipitated the flow of information to you as an organisation?
A. Yes.
Q. Can you just help with answering this question: in the period between 2015 and 2017, so June 2015 is when --
A. Yes.
Q. -- child A dies?
A. Yes.
Q. And in relation to 2017 you said 29 March of 2017 --
A. Yes.
Q. -- was when NHS England was first informed there was an individual associated with those events?
A. Yes.
Q. What powers did NHS England have to either strongly request, or if going further, compel Trusts to provide information that they have received regarding patient safety safeguarding concerns to NHS England?
A. Limited powers. As I have said in other

evidence, Countess of Chester was a Foundation Trust and the policy for Foundation Trusts was to deliberately give them the autonomy that was felt to be beneficial at the time in terms of developing services for local populations, that was on the basis of earned autonomy.

So if they were not manifestly breaching any of our requirements, regulatory requirements, if their standards of care as assessed by the Care Quality Commission and others were assessed to be good, then it was a light touch regulatory regime undertaken by Monitor, many of the quality elements would have been de facto delegated to the CQC and others although over that period, up to that time, Monitor were, to be fair, becoming more involved directly in quality concerns.

There were no particular regulatory concerns around the Countess of Chester in that period and the concerns that arose were very specifically in relation to the neonatal unit, although as I have said that exposed other concerns around the openness and the transparency of the organisation.

So we -- when I say "we", it would have been Monitor at the time and the CQC would be the two relevant regulators. They did have a power, the power of intervening, but there would have been quite a high bar for regulatory intervention through provider

licences and standard contracts, there would have been requirements around structures and processes that were required in the Trusts such as safeguarding, such as incident reporting.

So that is different in a sense from being able to take regulatory action. That is saying: this is our expectations of you as an organisation, as a board, as to what you should provide.

But in terms of the principles of information sharing, it is good practice to share information. I don't think there is anything that would impede the information sharing in the interests of patients or public. And as I have said, we would have expected the Countess of Chester to share more information, not least because it enables the regulators to provide support and additional experience, additional set of eyes and assistance.

As I said earlier, regulators in my experience as a Medical Director, you can have challenging conversations with regulators, that is part of the role of regulation. But you can also have very supportive conversations where you can get people who have either more experience or have got different experiences to advise and because this was not reported upwards, the possibility of having additional eyes, additional

curiosity, additional questions I think was lost.
Q. The Inquiry has heard a lot of evidence from multiple external organisations or indeed sometimes individuals about how the message, the narrative, was very tightly controlled by the Countess of Chester, both in relation to the cluster of deaths and the information around the increase but in particular in relation to the association of a particular healthcare professional with those collapses, with those deaths.

And is it still the case, as you sit here today, that the powers of NHS England to encourage, to where necessary require that level of co-operation is still the same as it was back in 2015, 2017?
A. There will have been some evolution in those powers. There has clearly been a subsequent Act 2022 that brought the regulators together. But our powers of regulation are still fairly specific in terms of organisation and of course we do not have powers over individuals; that is the job of professional regulators by and large.

But I do think the situation has changed and I do think the ability to have additional scrutiny has strengthened and I would give you the Medical Examiner system as one example of a statutory system now in place that provides an extra level of scrutiny that cannot be

avoided when a death occurs that was not there in 2015 and 2016.

So as I said earlier, it is never one single approach to this that is important; it's a suite of layers all of which that are designed to provide opportunities for escalation, to identify concerns, and to respond to them.

Q. Thank you. Can I move on to the second area of questioning and this is in relation to the Patient Safety Incident Response Framework in particular that Ms Langdale took you to.

But before I take you to that document and ask you a couple of questions, can I just ask you from the position of NHS England, how important is patient safeguarding and safety?

A. Patient safety is, is the prime at the very top of NHS England's responsibilities and I would say that for every leader within the health system that is and should be the top priority. "First, do no harm" is a phrase that you will recognise, it is a phrase that clinicians, you know, live by and it is the same for organisations and senior leaders: our first duty is to "first, do no harm".

Q. And following on from that, to what extent should resources be used as a justification or an excuse

not to implement steps and recommendations, improvements when it comes to patient safety?

A. Well, obviously it is important to acknowledge that particularly in financially challenging circumstances, senior leaders have to make a decision about where they deploy their resources. But I go back to my previous answer. At the very top of everybody's list is patient safety, "First, do no harm" and I think we are very clear, we are very clear currently that the priority is not to harm and therefore I would say deploying resources to support patient safety would be at or near the top of most people's priorities.

Q. Thank you. And when Ms Langdale took you to the framework document, which we will go to in a moment, I recorded your answer as to what the aim of the policy was --

A. Yes.

Q. -- and you said this:

> **"Answer:** ... one of the aims of this policy was to drive much more towards thematic reviews, so bringing together an understanding of the incidents that were occurring frequently in an organisation rather than unconnected investigations on single incidents ..."

So in other words, looking at the global picture of events --

A. Yes.

Q. -- to finds trends, cultures. Is that a fair reflection of your answer?

A. Yes, one of the criticisms of the old policy was that it tended to see -- it tended to focus on specific individual incidents. At times, for instance you could be investigating the same incidents many times over in isolation and now of course in practice many organisations move to a much more thematic approach. A simple example would be pressure ulcers which often generate incident reports. You will learn more often by looking at those in the round as a series of incidents rather than just taking each in isolation.

So part of the aim of the new Patient Safety Strategy is to do that and I don't know whether you have had a chance to look at for instance the Countess of Chester's implementation, local implementation of that plan, but if you were to look at it, you would see they have identified the spectrum of incidents that are reported through their systems, they have themed them into various areas and then they have listed the improvement plans that they have in place around those and also the expectations around how incidents might be reported and then escalated.

And of course that approach will need to be

iterated because over time there may be a different balance of incidents and every organisation has gone through that process and I think we have provided as an exhibit the template that we provide in order to do that process locally.

Q. And can we please have the framework document on the screen so you can see it, Sir Stephen, INQ0009265 and if we can go to page 3. Ms Langdale took you to the second paragraph which was the change in relation to the definition of "safety incident"?

A. Yes.

Q. So the concept of a Serious Incident has been removed which is what the following paragraph says, so in one respect it's made it more straightforward; is that fair?

A. Yes.

Q. But that's come at a cost, hasn't it, because the following and the last sentence in that third paragraph, it says that:

"Instead the framework promotes a proportionate approach to responding to Patient Safety Incidents by open sharing resources allocated to learning are balanced with those approximate needed to deliver improvements".

So in other words, this framework on the one hand

makes definitions of what the thematic process should look at but it brings in this process and the control of proportionality and if we can go to, please, page 6, the concept of proportionality is described in a bit more detail and I just would like your assistance with it.

Paragraph 1 under heading 3:

"Considered and proportionate responses to patience safety" says this:

"Organisations have finite resources for Patient Safety Incident Response. The framework supports organisations to use the incident response resources to maximise improvement".

That's sort of management-type speak. What does that actually mean in practice?

A. What it means in practice is that we -- so one of the points of incident reporting, it is not the sole point is to drive improvement, learn where things go wrong, and as I said earlier, increasingly learn from where things go right and ensure that that drives improvement in terms of ensuring that the process is structures, learning is in place so that doesn't happen.

At the heart of that is this shift I described earlier to an improvement culture rather than a blame culture.

But I think at the heart of your question

perhaps -- and tell me if I am wrong -- is obviously we have previously discussed the need or if the incidents and the deaths at the Countess of Chester had reported as Serious Incidents they would have alerted Commissioners and therefore if the new policy does not make that distinction, would Commissioners have been alerted? And that is clearly something that needs to be addressed.

The new system ensures that all incidents are made available to a wide range of Commissioners including the ones that used to see the STEIS process and the NRLS process but we are conscious that we need to work and in much more real-time, but we are conscious that we need to work with Commissioners to help them to ensure that in their oversight they are able to pick out those incidents that need particular attention. So it does require that judgement within the organisation which is always required but it does also require that oversight from external bodies.

Q. But doesn't this new framework also lead to the likelihood that certain Trusts will use resources, whether it's financial resources, whether it's individual personnel resources, or indeed time resources, to not in fact take the necessary steps that they have identified give rise to risk and safeguarding

issues to the full potential that it should do?

A. So that is the role of Commissioners and external bodies to work with organisations and to scrutinise and to ensure including the CQC which has that responsibility too to ensure that these systems are used, being used effectively, they are being used appropriately for their purpose and that they are driving improvement, but also able to help in the detection of incidents that require further scrutiny.

But as I also said, this is not in isolation and should not be seen in isolation. In fact, the document makes that point: it should be seen in relation to other mechanisms used where things go wrong, where there are concerns that includes the Medical Examiner system, it includes the safeguarding system and indeed can include the Freedom to Speak Up system.

Q. You are absolutely correct because this document does refer to probably half a dozen other guideline --

A. Yes.

Q. -- documents but therein lies another problem, Sir Stephen, which is what other witnesses describe as the rather wordy nature --

A. Yes.

Q. -- of NHS England and Department of Health

policies, guidance procedures in that it's very rare, if at all, that a single document contains all of the key pieces of information so that an individual can use it as a reference and then seek further guidance if they need to. This document framework falls into that trap, doesn't it?

A. I wouldn't say that but I do take the point, and we have discussed that, that there is a balance between brevity of documents and ensuring that we have the detail in there that is required. But I am very happy to take that point back. I have said already that within safeguarding there is a need I think to be more clear on certain aspects of safeguarding, I accept the point that there is always a need to synthesise and to make as simple as possible, that that can occur in variety of ways, it can occur through some of our mandatory training, it can occur through documents that aim to synthesise which the SAF document in safeguarding does, but I am very happy to discuss that further with our Patient Safety Team and reflect further on that.

Q. The final point on this document is just at the bottom paragraph of page 6. There's reference to the framework setting no further rules or thresholds other than those set out in the Guide to responding proportionately to patient safety incidents to determine

what needs to be learned from to inform improvement.
Further down in that paragraph, it says:
"If an organisation and its ICB are satisfied risks are being appropriately managed and/or improvement work is ongoing to address known contributory factors in relation to the identified Patient Safety Incidents and efficacy of safety actions is being monitored it is acceptable not to undertake an individual response to an incident other than to engage with those affected and record that incident has occurred".
One of the key missed opportunities in this particular case that the Inquiry is involved with is that the initial view of the Executives and the management was that part and parcel of the increase in the deaths was because of a shortage of staff and that was, that was a process that was ongoing?
A. (Nods)
Q. So if one applies this concept by way of the background facts to this policy, it could lead, couldn't it, to a Trust believing that if a problem is already identified and something's been done about it, then no individual response to an incident -- thematic review, clusters, et cetera -- will take place?
A. So the aim of this is to ensure that you don't in essence expend time and resource investigating

repeated natures of the same incident as opposed to directing your resources towards improvements and the improvements that have been learnt. But the point you make I acknowledge. It is important. And again, judgement is required in the application of these policies, it was required in the last policy. I don't think you can take out that necessity for judgement from senior leadership and clinicians entirely, that would not be possible. But what you can do is in the work around this and culture and how processes are undertaken within the Trust, you can help to ensure that those judgements are made correctly and in an appropriate and the best possible way.
But you will always rely on judgements of clinicians and managers in complex cases but I am very happy to take the points that you have raised and discuss them further with the Patient Safety Team.
Q. Final area of questioning is in relation to the improvements in national clinical leads both in terms of neonatal clinical leads and also nursing and you deal with this in your first witness statement, I won't take you to it because it is a very short paragraph, it is paragraph, my Lady, 707, which is on page 182 of Sir Stephen's first witness statement.
And, Sir Stephen you say this that:

"Nationally NHS England has strengthened neonatal clinical leadership by appointing the first ever National Neonatal Clinical Director."
I believe that is Dr Edi-Osagi?
A. (Nods)
Q. And also a National Neonatal Nurse Lead role which, as I understand it, on the face of it is Ms Weaver-Lowe?
A. (Nods)
Q. You then exhibit the two job descriptions and a number of issues arise out of that. The first is that it is a secondment role, in other words they are both part-time roles?
A. (Nods)
Q. And by the advert that the role has attracted, in terms of Dr Edi-Osagi, she has the equivalent of 15 hours per week to dedicate to this national role which is a bottom up and a top down clinical role and Ms Weaver-Lowe has got effectively two days' worth in her week to effect the same process but from a nursing perspective.
Can I ask why these two roles, which you say in your witness statement are so crucial and critical to the improvement process, are not full time roles?
A. So they are no different from any of our other

National Clinical Directors, the model for employing our National Clinical Directors is on that secondment basis, across the full range of NCDs they will typically have usually between two or three days of time spent on the National Clinical Director role and the remainder of their role in their host clinical organisation. That is -- there is nothing unique about that for this particular role. That is the same across all National Clinical Directors and has been for some time.
The importance of this was previously it was a National Specialty Advisor role which had in a sense a lower authority but also less time, so we have increased that. When we establish these jobs we do work with the relevant teams in which they will work within NHS England to determine the amount of time that is felt to be appropriate. That can vary over time.
And in fact I am currently discussing with the Chief Nursing Officer for England, within which team this role sits, whether we need to put in additional time because of the nature of the role and the work that is required at the moment.
Q. My question was slightly more nuanced. I appreciate that that is the way that roles have been across NHS England. But the question was more specific in terms of: should these roles be full time roles,

specifically because they are so integral to patient safety and safeguarding and the prevention of all of the horrific incidences that have happened that Inquiries have led, and today with BBC News reporting Leeds Teaching Hospital, is it not time for NHS England to review the fact that these roles need to be full time?

A. I think you could make the same argument across a whole range of roles outside of maternity and neonatology. We review on a three-yearly cycle, we are focused on expanding the number of roles. As I say, we flex the amount of time, but one additional point I would make is it is a benefit that the individuals in those roles do also work clinically, in clinical environments because it means that they are direct connected in to the provision of service. And I think if you asked most of them, as I do, they would prefer to retain some clinical practice.

I don't. Members of my senior team who are National Medical Directors in various areas have a combination depending on circumstances, but clinicians will often tell you that it is a benefit to them and to their understanding of how it is working at the frontline if you want for them to do some clinical work.

So I think at the moment having that mixed model works. But I do agree it's important to make sure that

a patient or do you mean the control measures that might be applied surrounding it?

A. I think we would mean all of those and of course that paragraph needs to be read with the subsequent paragraph which points to the fact that guidance on administration of insulin is in place but it is issued by other bodies, including NICE and the Royal Pharmaceutical Society. That is not unusual. NHS England is not the sole provider of guidance and we are very careful to ensure that where others can have a role, and sometimes a better place to issue guidance, then we -- then they do that. That can be independent of us. It can be with our support and input.

Q. Yes. And it's reading it in the context of the next paragraph was why I asked the question because guidance relating to the clinical use of insulin, the following paragraphs describe how it is administered what its purpose is and things like that. So if we could go on then please to paragraph 9.

I think this is more apposite to the issues in this case:

"NHS England is one of several bodies that has a role in relation to the management of medicines."

And the "management of medicines" it goes on to say in short:

the time is reviewed and that is exactly what we are doing with the NCD for neonatology at present.

MR SHARGHY: Thank you, Sir Stephen. Thank you, my Lady.

LADY JUSTICE THIRLWALL: Thank you, Mr Sharghy. Mr Baker.

Questions by MR BAKER

MR BAKER: Thank you, my Lady.

Professor Powis, I ask questions on behalf of two of the Family groups. I have got relatively limited time so I am going to ask you specific questions about the regulation of insulin --

A. Yes.

Q. -- and the directives that are given regarding insulin and its management within a neonatal setting.

Your second witness statement deals with this exclusively, that is INQ0014552, and if I can go first of all to two specific paragraphs, the first is on page 2 and it is paragraph 5.

"NHS England has not issued guidance on the clinical use of insulin in a neonatal context."

And I just wanted to understand that statement a little bit more clearly. When you say "issued guidance on the clinical use of insulin in a neonatal context", do you mean how it is administered to

"While NHS England provides guidance on best practice around the storage and handling of medicines, including through estates guidance described below at paragraph 13. It has no overarching statutory role in relation to the regulation of controlled drugs per se".

And so this paragraph brings into it two concepts?

A. Mmm mm.

Q. One is that NHS England has a role in relation to the management of medicine, so it could issue guidance as to how to manage risk associated with medicine, but then it also brings in the concept of controlled drugs which are a different thing all together and subject to specific statutory definitions?

A. So I think from memory this was in relation to some very specific Rule 9 questions provided by the Inquiry which I think will help you maybe see how it was shaped in this particular way.

We do have some statutory duties with respect to controlled drugs, you can see those two paragraphs down in paragraph 11. But I said earlier, in terms of the designation of controlled drugs, the Home Office would be the appropriate body and as I said earlier as well, much of the practice around the use of controlled drugs does read across to the practice of non-controlled drugs as well, so there is a big overlap, clearly there are

additional regulatory and supervisory controls in place because of the nature of controlled drugs, but that does not apply to insulin.

Q. So to assist, a controlled drug is a controlled drug for what reason? Is there a specific reason why some drugs are chosen to become drugs?

A. Yes, for instance it would be opiates because of the addictive nature of opiates and --

Q. So they are drugs that have to be controlled because of a propensity of evil --

A. For a variety of reasons because of the nature of the compound, yes.

Q. Yes, because a large overdose of insulin would be just as fatal as a large overdose of diamorphine, so it is not necessarily the risk --

A. *(Redacted)*.

Q. Yes.

A. As probably would be a large overdose of many drugs because of course many drugs can cause harm if they are given in the wrong quantities.

Q. So it's not the propensity of the drug to cause harm to a patient that causes it to be controlled?

A. It is another set of reasons.

Q. It is another set of reasons often relating to abuse of that drug?

A. Yes, to a variety of factors, yes.

Q. Now, you have no powers as NHS England in defining what is and is not a controlled drug, that much is clear. But you do have powers in relation to giving guidance around protective or safety measures that might be taken in relation to specific drugs that aren't controlled drugs?

A. Yes.

Q. Yes. Has NHS England issued any guidance on measures that might be taken surrounding the storage of insulin?

A. So we have estates guidance relating to this but beyond that, as the statement says, I am not aware that we have issued specific guidance. However, as I said earlier, this is something that we have looked at in detail because of the Inquiry but also because and again related to the Inquiry a request from a former minister.

We do not think at the moment that we need to put in place additional measures but we are committed to continuing to ensure that we promote best practice and I have discussed this with the Chief Pharmaceutical Officer. If we -- I am very happy to go back and consider once again whether we need to write out specifically on this subject to ensure that best

practice is in place as we discussed earlier.

Q. Yes. I mean, because of course the Families are concerned, and whilst they appreciate that many drugs could cause harm, insulin is implicated in quite a few cases where healthcare workers have attacked patients?

A. Mmm.

Q. Victorino Chua, Beverley Allitt, this case and also Colin Norris. Those cases all involved patients being given --

A. Yes.

Q. -- improper doses of insulin.

So it is a drug that is associated with these cases.

A. (Nods)

Q. We have, I think, heard that when it came to the Countess of Chester, insulin was stored in a cupboard that wasn't locked, there was no restrictions on people accessing it in terms of people working on the ward, it wasn't kept in defined doses; in other words it could just be taken out of a bottle, so nobody would know how much was being used and whether it corresponded with prescriptions. And those would be fairly common things on a ward, wouldn't they, when it comes to insulin?

A. So in our survey I think we were assured that there were, in the majority of units, much stricter measures in place and when I alluded to previously promoting good practice, that element of storage and access was what I was referring to.

I agree insulin clearly has been implicated in other cases too. That is the reason that we wanted to scrutinise this in more detail. We have not reached a conclusion yet that other than promoting the practice that we see in the best of places, that additional controls are needed. But I am very happy, as I say, to continue discussing this with the Chief Pharmaceutical Officer for England and if we feel that it is appropriate to issue guidance around best practice, then we will do so.

Q. Yes, because control mechanisms could be relatively straightforward --

A. Yes.

Q. -- that --

A. Exactly, they are.

Q. So swipecard access to a box so you know who's taken it out would be a --

A. Yes, and in the report that we exhibited, that was exhibited earlier, I mentioned some of the areas where we saw variation and they are also areas that we

can focus on. I mentioned ensuring that staff are trained in good practice around use and access to drugs. I mention the oversight of pharmacy, so pharmacists within the hospitals having a supervisory and checking element of dispensing and prescriptions.

Also in there which I think was flashed up, you may not have time to see it, I am sure you have looked at it, was the use of electronic prescribing which provides additional scrutiny and additional assurance. So there are a range of things.

And very happy to keep this under review because of exactly the importance you have placed upon it.

Q. Can I go to a slightly different but connected issue, because of course one of the features of insulin is if you are giving an insulin dose to a patient, the harm isn't visible immediately.

So if you give a patient a large dose of diamorphine, as Harold Shipman did, they would die relatively quickly?

A. It depends on how much you give.

Q. It depends how much you give, but with insulin of course the effects evolve over --

A. And again it depends on the dose that you are administering.

Q. Yes, but it is a drug that is detectable?

A. Yes.

Q. And one of the features of the Beverley Allitt case is that in effect the thing that caused her to be caught was a laboratory discovered a blood test result with this disparity between insulin and C-peptide --

A. Correct.

Q. -- that raised an alarm bell.

Now, of course, on the face of the evidence that this Inquiry has heard, the same thing happened here but didn't result in the same outcome. Is there a space for regulation or some sort of direction to be given to laboratories by NHS England about how they should react in circumstances where a low C-peptide is found corresponding with a high insulin level?

A. Yes, and there may be possibility around flagging of results, so again very happy to take that back and discuss further with the Chief Pharmaceutical Officer and with our pathology team.

Q. Yes, and a corresponding direction to doctors to understand that where this flagging comes in, it requires a specific response?

A. Yes, so flagging of important results is common practice. So again, let me take that back and reflect on it further.

MR BAKER: I am grateful. Thank you, my Lady

I have no more questions.

LADY JUSTICE THIRLWALL: Thank you very much, Mr Kennedy, Mr Beer?

Thank you I just have one or two matters if I may.

I just have one or two matters, if I may.

Questions by LADY JUSTICE THIRLWALL

LADY JUSTICE THIRLWALL: You mentioned earlier in your evidence how you would have expected the Countess to have told NHS England more than they told them earlier than they did --

A. Yes.

LADY JUSTICE THIRLWALL: -- in a nutshell. Were there any consequences for the Countess from NHS England arising out of the fact that they hadn't done what they were expected to do?

A. As you will have seen in some of the evidence, they were put, particularly around neonatal at times, in enhanced surveillance.

LADY JUSTICE THIRLWALL: Sorry, I meant any consequences for the individuals; in other words, did anyone say, "Why didn't you tell us that before? What's going on?"

A. That would have -- from the point of NHS England at that time, as I say, we are regulators of organisations rather than necessarily individuals and we

would have expected that to have been done through board processes if there were concerns.

Our power is of --

LADY JUSTICE THIRLWALL: You mean internally within the Countess?

A. Yes, because our powers of regulation with respect to individuals are largely --

LADY JUSTICE THIRLWALL: That's the point. You don't have any --

A. -- with respect to organisations rather than individuals.

LADY JUSTICE THIRLWALL: Sorry. So technically --

A. Technically, we can't.

LADY JUSTICE THIRLWALL: -- you had no teeth, as it were, so far as the individuals were concerned and nor would you expect to have any. But, at a personal level, there was nothing said; that was just how it was and if anything was going to happen, it was going to happen or not within the board?

A. Yes, or again through referrals into regulatory bodies. Again, I can go back and look to see if we can find evidence as to whether that was done.

LADY JUSTICE THIRLWALL: Thank you.

You said on a number of occasions that you will take things back and I just wonder perhaps in a month or

so if you could let us have an update on the various things. We will let you know what you said it about. You may remember it all but in case you don't --

A. I am sure the legal team have been taking a note of it and we will have a conversation with counsel and, if you so wish, we can agree a timescale for the number of items where I have indicated we can provide further information.

LADY JUSTICE THIRLWALL: Yes, I think I may have to say what the time will be, but I am extremely happy for you to discuss that with Mr Beer and see --

A. Absolutely.

LADY JUSTICE THIRLWALL: -- because some of the things you've said you'll take back, we probably don't need you to.

A. Yes.

LADY JUSTICE THIRLWALL: So we can perhaps come to some sort of agreement about that and then I will say when it has to be done by.

A. Yes.

LADY JUSTICE THIRLWALL: Good, thank you.

Just briefly on governors in relation to Foundation Trusts. I mean, I appreciate Foundation Trusts were set up for particular purposes, including competition, which is no longer really a feature, is it --

A. Yes.

LADY JUSTICE THIRLWALL: -- of the way the NHS is run. So we have got the governing bodies for Foundation Trusts but not in relation to NHS Trusts.

A. *(Nods)*

LADY JUSTICE THIRLWALL: It's not apparent what they add in terms of patient safety. I can see what they add in terms of public accountability. But is there anything that the governing bodies add in terms of patient safety that they don't have in NHS Trusts?

A. Other than that general oversight that we have discussed earlier, not specifically, nor in the responsibilities that they have. I would say I'm not an expert on the governance of Foundation Trusts. I did work in a Foundation Trust.

So over and beyond the responsibilities they have that I have described, I don't think there is any specific responsibility. But, again, we can go and check to make sure that is a correct interpretation.

LADY JUSTICE THIRLWALL: If there is --

A. That is not to say that that, that their ability to ask questions and be curious is not important. But, as I said earlier, fundamentally this is the role of boards of Executives and Non-Executives.

LADY JUSTICE THIRLWALL: Yes. Yes, and that must

pertain in relation to NHS Trusts who don't have Foundation governance.

A. It absolutely does and it still pertains with respect to Foundation Trusts. And again, over time, as we have moved away -- and, remember, the intention in the 2012 Act was that all NHS Trusts became over time Foundation Trusts.

LADY JUSTICE THIRLWALL: Yes.

A. -- that intention were never crystallised and Government increasingly moved away from it. So, in a sense, we are now left with a situation where we have two models of governance and, in practical terms, the distinction between Foundation Trusts and NHS Trusts and how they are overseen has become less and less. And that is manifest that, rather than having one regulator for Foundation Trusts, one regulator for NHS Trusts, and a commissioner with some regulatory powers (ie, NHS England), the 2022 Act merged all of those into a single function.

LADY JUSTICE THIRLWALL: And I suppose at some point the question that will be asked is: what are governing bodies adding? Because if they are adding something, why haven't NHS Trusts got them and if they are not adding something, why have we got them?

Anyway, I am not asking you to answer that. It is

just simply an observation one could, I think, legitimately make.

A. Yes.

LADY JUSTICE THIRLWALL: And it may or may not be important.

A. Yes, that would be a reasonable observation and probably one for Government rather than NHS England.

LADY JUSTICE THIRLWALL: Yes, you or me.

Do no harm: we are all familiar with it. And I don't know if you read the evidence of Mr Jarrold, who had produced a Code of Conduct back in the early 2000s.

A. Yes.

LADY JUSTICE THIRLWALL: And his first proposition was really quite an elegant description of or exposition of "do no harm" and we know that that Code of Conduct rather fell away.

I haven't had a chance to check during the break that we had. In these competencies for board members, does that feature anywhere, that kind of -- the sort of fundamental position?

A. I would have to have another look to give you the detail but what I was, I think, trying to expose earlier was that, in my experience, for the overwhelming majority or all of Senior Executives that requirement to provide safe services is paramount and Chief Executives

above all worry about ensuring that they have safe services.

Yes, there are always competing pressures, financial pressures, pressures of where resources are deployed, but a fundamental feature of healthcare, in a sense, is its ability -- you know, in the nature of what we do, unfortunately, harm can arise.

LADY JUSTICE THIRLWALL: Of course it can.

A. And therefore it is at the front of most people's minds and not just clinicians.

LADY JUSTICE THIRLWALL: Yes, but it seemed to me that it is something that ought to be made explicit if we are looking at ultimately the regulation of managers. It's been there forever for doctors and nurses, really. So that was simply just something I wanted to -- we can explore.

A. I am very happy to go and talk to the team who are developing these and see whether that might need to be made more explicit.

LADY JUSTICE THIRLWALL: Yes and you may just want to pass on to them Mr Kark's observation that the competencies were somewhat aspirational and fuzzy, rather than, as he had expected, concrete and clear. But, again, that's something I am sure you can take away.

A. Yes, and there is a balance and my observation is that competencies also evolve over time. So when I started training in my specialty, renal medicine, 40 -- well, 30 years ago -- the list of competencies described was very minimal. Over time they have expanded, curricula have expanded, as regulation has evolved.

LADY JUSTICE THIRLWALL: Yes.

A. So these are never fixed and there is a balance between being too descriptive and prescriptive and trying to list absolutely everything, and taking that more principled approach and getting that balance right I think is one of the judgments we will need to make.

LADY JUSTICE THIRLWALL: Yes, and I have passed on the evidence.

In relation to systems, you mention -- I think you said there was an app for safeguarding?

A. Yes. I think counsel might have said that rather than me but yes.

LADY JUSTICE THIRLWALL: I think it was in somebody's statement.

A. Yes.

LADY JUSTICE THIRLWALL: I thought it was your statement.

A. Yes, yes.

LADY JUSTICE THIRLWALL: But it may have been written by somebody else, I suppose. I just wondered if we could have a link to that.

A. Yes, we can provide --

LADY JUSTICE THIRLWALL: I am sure it must be there. Thank you.

The other thing, doctor, Professor Knight made the point that within the NHS, and in her experience recently, new systems are not talking to each other or old systems are not talking to each other as a result of which BadgerNet is not being kept up to date with all relevant information.

Presumably you recognise that situation and what's being done about it?

A. That was not something that was in my mind, so I have asked our teams to look into that and to check that.

LADY JUSTICE THIRLWALL: Thank you.

No, thank you very much indeed --

A. Thank you.

LADY JUSTICE THIRLWALL: -- Sir Stephen, those are all my questions and that is the end of your evidence.

We are about to finish. I know some will have had their eye on the train but I think the train that they

may have been hoping to get will depart before they are on it, and I have a few closing observations. Please don't feel you have to wait for them. I will be about another three or four minutes, but you are free to go if you want to.

A. Thank you.

Closing remarks by LADY JUSTICE THIRLWALL

LADY JUSTICE THIRLWALL: Ms Langdale, that concludes the evidence listed for today and it marks the end of this phase of the Inquiry.

Since we began the public hearings on 10 September of last year, we have heard live evidence from 133 witnesses. The Inquiry received 396 witness statements in response to requests made under Rule 9 of the Inquiries rules. Witnesses were chosen to give evidence after consultation with all Core Participants and the evidence has been directed to all of the Terms of Reference and the questions in the annex.

Two witnesses did not attend because of illness. Transcripts of the evidence given in the hearings are on the Inquiry website.

I am grateful to witnesses who came to give evidence and I am particularly indebted to the many Parents who provided witness statements and/or gave oral evidence of the terrible events and experiences in 2015,

2016 and ever since. Their powerful evidence is an enduring reminder of the reason for this Inquiry.

Where a witness has not given evidence, the Inquiry legal team have uploaded the statement on to the website or, where appropriate, they have summarised groups of statements dealing with similar issues, read them into the record, and uploaded the summaries on to the website.

Whilst I don't rule out the possibility of any further live evidence, I am confident that any further evidence, if there is any, will not be lengthy.

I am expecting some additional written evidence where witnesses have been asked to provide it, and the last witness is a case in point, but this too will not be lengthy.

The next phase of the Inquiry is the preparation and submission by the Core Participants of their written closing submissions. They will be permitted to supplement them in oral submissions on 17 and 18 March in this building.

I have directed that the written documents be submitted to the Inquiry legal team on or before 28 February and the timetable for the hearings will be set once we know how many people wish to speak and how long they expect to take.

The arrangements will be largely the same in March as they have been since September and there will be live links in accordance with the ruling that I gave in May of last year.

In the remarks at the beginning of this public hearing, I expressed my thanks to Liverpool City Council for making the Town Hall available to us. To that, I should add my profound thanks for the warmth of the welcome everyone connected with the Inquiry has received here from all those who work for the Council. They have helped make everything run very smoothly.

I would like to extend my thanks to the team of volunteers from the Coroners' Court Support Service who, between them, have been here every day to provide support to anyone in the building who has needed it; a total of 23 volunteers who have come from across the North West and the Midlands to assist. It's been public service of a very high order to give up so much time at the busiest, and then the coldest, time of the year. Thank you. Your kindness and good humour have been of great assistance to many who have passed through this Inquiry.

Finally, I thank all of those who have been present in this room and elsewhere doing a huge amount of work. The result has been that these hearings have been

completed in accordance with the timetable. Thank you.

There is a great deal more to do, as you know. We will adjourn now and start again at 10 o'clock on 17 March 2025. Thank you, all.

(4.38 pm)

(The Inquiry adjourned until
10.00 am on Monday, 17 March 2025)

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