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Wednesday, 15 January 2025
 (10.00 am)
 LADY JUSTICE THIRLWALL: Ms Langdale.
 MS LANGDALE: My Lady, may I call Professor
 Sir David Spiegelhalter, please.
 PROFESSOR SIR DAVID SPIEGELHALTER (affirmed)

PROFESSOR SIR DAVID SPIEGELHALTER (affirmed)

Questions by MS LANGDALE

LADY JUSTICE THIRLWALL: Thank you very much indeed, Dr Spiegelhalter, do sit down.

10 **MS LANGDALE:** Can you give us your name and 11 qualifications, please?

A. My name's David Spiegelhalter, I am Emeritus Professor of Statistics at the University of Cambridge.

Q. And you are an author on books on statistics; is that right?

16 A. Yes, yes, I have written various academic17 textbooks and more popular books on statistics.

18 **Q.** And you say in your statement you have mainly 19 worked as a medical statistician; is that right?

20 **A.** Yes, I have worked as an academic and medical statistician trying to -- specialising in new methods, statistical methods in medical statistics.

Q. You have prepared two statements for us,
Sir David, one dated January 2024 the other dated
January 2025.

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A. Well, all sorts of roles of course. You know, working clinical trials and epidemiology and just, just the general statistics of how the health service is working, we hear them all the time.

My particular interest, and our interest here, is in terms of actually keeping track of in particular adverse events, whether I have particularly worked on surgical outcomes and so on trying to spot clusters of failures, and in other contexts where one would like to detect as quickly as possible where problems are arising.

And the reason why statistics are so important is that, you know, numerous studies and personal experience have shown that humans are not very good at judging data, they can miss long-term trends, slowly accumulating changes, they can miss that.

And on the other hand they can get, you know
perhaps pay too much attention to sporadic runs of, you
know, bad outcomes due to unknown factors and trying to
find patterns that may not actually exist. So these are
well-known human characteristics and that is why -- that
is why we need statistical analysis.

Q. You tell us that you worked in the context of
 previous Inquiries with the Shipman Inquiry, Bristol

1 Can you confirm the contents are true and accurate 2 as far as you are concerned?

A. As far as my knowledge, my knowledge, yes.

Q. Before we enter into the detail of the

5 evidence in the statements, I understand you would like6 to say something?

7 A. Yes. Yes. My evidence is going to concern8 counts of deaths, neonatal mortality rates and so on.

9 This is the language of statistics and I realise that it

10 can sound rather harsh and cold when it actually

11 addresses individual tragedies for patients, families

12 and staff; that is what statistics does. But

13 statisticians do realise that underneath all their data

14 lie these individual stories and all the humanity and

15 complexity.

But I personally feel and my whole profession feels it is only by aggregating those individual stories into summaries that one can get a feeling for the magnitude of what has happened and if possible design systems to detect problems as early as possible.

21 **Q.** So what is the role of statistics in the 22 context of our health service then?

23 **A.** Sorry, I am having -- I am finding it 24 difficult to hear.

25 **Q.** What is the role of statistics in our health

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1 Royal Infirmary Inquiry; that's right?

A. And Infected Blood Inquiry.

Q. And Infected Blood.

Can we look at the Shipman Inquiry first and can
I ask if we have on the screen please, INQ0008966,

6 page 4.

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7 This is a page from your first statement,

Sir David, and pages 4 and 5 contain graphs, charts?

A. Yes.

10 Q. I don't know if it's possible to have both

11 pages on the screen, Mrs Killingback, at the same time.

12 If not, we can have 4 and then 5.

A. Yes, I have got it now. So we produced thatgraph based on data that was collected by someone else

15 on behalf of the Harold Shipman Inquiry chaired by

16 Dame Janet Smith. And the first picture on page 4

17 illustrates the kind of plot, sometimes called VLAD

18 plots, or Observed minus Expected plots, which are --

19 which are common in this whole area and used extensively

20 in clinical monitoring.

In this case it's looking at the observed numbers of deaths in Harold Shipman's practice both for males

23 and females and subtracting from it the number that

24 would be expected.

Now, the number expected you calculate just from

1 the death rates in the community, in which

- 2 Harold Shipman was working and taking into account the
- 3 breakdown of his practice in terms of ages and sex and
- 4 you can work out how many deaths you would expect to
- 5 have happened each year. And by looking at the observed
- 6 amounts expected and accumulating that, not just looking
- 7 at each year but getting a cumulative total you can see
- 8 a steadily increasing amount of what can be called
- 9 excess deaths.

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- I avoid that phrase whenever I can. I think it can
- 11 be, I have used it in the past and I regret it because
- 12 in fact if you looked across all hospitals half of them
- 13 by this definition would have excess deaths, you know,
- 14 half of all hospitals are worse than average.
 - So it can be a very misleading term because it
- 16 suggests some, some problem.
- 17 However, when those numbers get big enough you
- 18 really do have a problem or there was a problem with,
- 19 with Harold Shipman. What's interesting is that by
- 20 1997, he had 180 excess deaths of females and about 40
- 21 of males about 220 and this corresponded almost exactly
- 22 to the number of deaths that he was, that the Inquiry
- 23 concluded that he had definitely committed as murder.
- 24 So just this statistical system identified almost
- 25 exactly how many victims he had got.
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- 2 Q. So the fact that the signal happened would not
- 3 of itself have told anybody that Dr Shipman was
- 4 a murderer, but it would have necessitated investigation
- 5 by a human to look at what was happening?
 - **A.** This is one of the most important points.
- 7 A statistical monitoring system cannot say why
- 8 something has happened. In a way it's the standard
- 9 phrase "correlation is not causation". We can say that
- 10 he does have excess mortality and he's got a higher
- 11 mortality rate, we cannot say why.
- 12 I wonder if we could -- maybe you are going to come
- 13 to it -- talk about when my colleagues investigated
- 14 a monitoring system?
 - Q. Of course.
- 16 A. Yes. When my, my colleagues in the Shipman
- 17 Inquiry later tried out a similar system on 1,000 GPs
- 18 around the country, and found that 12 triggered an
- 19 alert, one of whom was Shipman but 11 actually triggered
- 20 before Shipman did.
- 21 These GPs were investigated, completely
- 22 confidentially, and it was found that they were working
- 23 with hospices, with retirement communities. They, they
- 24 had -- they were experiencing a very high mortality rate
- 25 for the very best of reasons. And that for me, there's,

- 1 But the statistical issue is where do you, if you
 - were plotting that which nobody was, where would you,
- 3 where would you blow the whistle, where would you draw
- 4 the line and the problem is you have got 26,000 GPs in
- 5 the country and you can't start investigating all of
- 6 them all the time so you have to have fairly stringent
- 7 criteria for identifying a problem.
- 8 We adapted in that case industrial quality control
- 9 techniques that it actually been developed in the
- 10 Second World War and were used for identifying when
- 11 a production line had gone a bit out of kilter, we
- 12 adapted those to this medical context and on page, top
- 13 of page 5, one can see the results.
- 14 That means producing a slightly different statistic
- 15 not very complicated but it enables you to draw
- 16 horizontal lines on the graph that act as thresholds,
- 17 triggers for alerts or alarms.
- 18 And from that we concluded that there's this very
- 19 basic system by 1985, just looking at female deaths
- 20 alone would have triggered a very strong alarm indeed
- 21 that he's, his mortality rate was substantially or
- 22 double what would be expected.
 - And if people had actually acted on that, if that
- 24 system had been in place, and investigated him, that
- 25 would have been after only 40 murders instead of over
- in Dr Edile Murdoch mentions this and shows the graph in
- 2 her witness statement. This, you know --
- 3 Q. Shall we put that on the screen while you are
- 4 speaking?

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- A. Yes.
- Q. Let's take these two off --
- A. If we could put that up.
- 8 Q. -- INQ0106962, page 12. So this is an extract
- 9 of a second statement from Dr Murdoch who's the
- 10 Consultant neonatologist and chair of the NHS England
- 11 Maternity and Neonatal Outcomes group and in her
- 12 statement she also refers to the Shipman data. So let's
- 13 put that graph up, since you have referred to it.
- 14 **A.** Yes.
- 15 Q. Just blow the top up. We don't need
- 16 paragraph 36.
- 17 **A.** Yes, the top picture just shows 12 GPs who
- 18 signalled and Shipman was only one of those. As I said,
- 19 the others were -- were confidentially investigated,
- 20 found to be very good and generous GPs. And if we could
- 21 go back to open to the whole page again, I would just
- 22 like to support -- you have got it somewhere else, but
- 23 Dr Edile Murdoch gives a very succinct phrase about the
- fact that a signal can only indicate that someone should
 look carefully at what is going on. It cannot indicate

the reason for any signal. 1

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Thank you. That can go down. Bristol Royal Infirmary, tell us, if you can, anything about data collection there or statistical analysis that could or did assist?

6 Α. Yes. I -- I headed the team of statisticians 7 for the Bristol Royal Infirmary Inquiry. One of the 8 issues there is that there were seven different datasets 9 on mortality and in the cardiac surgery for -- for 10 congenital heart disease and none of them agreed. That really taught me about the fact that it's extremely --11 people might think that it's very easy to count the 12 13 number of serious events that happen. But different datasets disagree for all sorts of reasons, even 14 counting how much surgery there had been. 15

And so it -- it shows it's very difficult to get an absolutely precise number. However, by looking at multiple datasets we could get a very strong picture which was so strong that it didn't actually matter, you know, whether we had the numbers precisely right or not. And the point about Bristol is that it was a clear outlier, by which I mean there was clear water between it and the other 11 centres we were looking at which were reasonably tightly clustered, not completely, and Bristol stuck out very clearly indeed. It was a classic

circumstances or because of some differences in case mix and so on, so there's always variability.

Now, it's useful to try to distinguish two archetypical cases although it's not a hard and fast division. The first which I have mentioned already with regard to Bristol is an outlier, somebody who's clearly separate from the bulk of the other centres -- I have lost my page.

9 Q. We all have. It will come back in a moment, 10 it is a technical issue, I think.

> A. It's not just me, okay.

Q. But we saw it. Do continue?

A. Okay. An outlier which is where there is clear water between it and the bulk of the other, of the other centres. However, the other archetypal situation is where someone is high or in the tails or fairly extreme; in other words, they are still kind of within

the distribution but up in the tails. And traditionally, and this is just convention, in 20 the tails is considered, a tail of about 2.5% about, 1 in 40 chance of being higher than that. If you are in

the tail that contains a 40th of the distribution, that 23 would be considered as high or extreme or in the tails

and would be considered a reason for an alert.

Classically, it would be two standards deviations.

case of an outlier, again, which should have been 1 2 detected earlier. You know, we demonstrated that if -a good monitoring system in place would have blown 3 4 a whistle substantially before that actually occurred.

In the context of language used, can you 5 6 explain the difference for us, please, between an 7 outlier, when there is an alarm, when there is a signal. Do these have technical terms; what are the differences? 8

9 Yes, there is not an exact definition for 10 this. I don't know -- I have got a picture in my second report of a, you know, which shows ... 11 12

Q. Shall we have that on the screen, INQ0108786,

13 page 3.

14 So I tried to illustrate with a simple A. 15 diagram.

16 Q. Do you want to wait actually it is up, sorry

17 Sir David.

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A. Yes, let's wait until it comes up.

19 Q. Just give people a moment to see it. 20

21 Yes, the picture at the top, that sort of 22 distribution is supposed to show what is the typical 23 distribution of results say across centres or within centres over time. There's always variability that goes 24

on both because of the way of, you know, unforeseen

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However and something that was in a way much further out a real outlier, suspicions of that would be 3

an indication for an alarm, something that you were pretty convinced is not just normal variation, but

4 5 there's some special cause behind it. And obviously you

6 can be in between, this is not a -- you are not one or

7 the other, but it's fairly -- I think it is quite

a useful division to make and it is one that's made

9 within this whole area of statistical monitoring.

10 Q. And that can come down now, thank you. 11 Infected Blood, what about the role of statistics 12 there or analysis?

13 The role of statistics in Infected Blood, we 14 deliberately refused to try to answer questions on when something could have been detected earlier, something 15 that we did do for the Shipman Inquiry. 16

17 But we did agree to try to answer the question of how many people had been infected with contaminated 18 blood products or contaminated blood, and how many 19 20 people had subsequently died.

21 For that, for some areas we could do that with considerable confidence: for example, for HIV due to 22 23 multiple data sources, registries and so on, that one 24 could triangulate to some extent and be fairly confident 25 about the numbers.

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For other areas, hepatitis C, in particular, we had to model it, we can't count them. Many people will have been infected by hepatitis C and will still not know.

So we had to just estimate that from statistical modelling. Therefore we have a substantially more uncertainty about the results.

For hepatitis B we refused to answer how many people had been infected. The evidence was so poor and we would not feel confident about making any numerical iudament at all.

So again that reflects the fact that certain questions can be answered and certain other questions no matter how worthwhile sometimes the data is just not there

- 15 At the time of the Mid Staffordshire Inquiry Q. 16 there was a Dr Foster unit, wasn't there, at
- 17 Imperial College --
- 18 A. Yes.

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- 19 Q. -- running data? Do you know much about how 20 that one worked at the time?
- Yes, the --21 Α.
- 22 Q. That has ceased, hasn't it?
- 23 A. The Dr Foster system was very good and it used
- modern CUSUM methods, I knew the team, and were 24
- 25 operating sending alerts in to the -- what was then the
- 1 look at it.

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- It set off a signal, "a human should look at this data", and it may -- the apparent outlier could have been because of just a data entry problem or so on. So it was making no conclusion about why the system had, had, you know, issued an alarm an alert or an alarm.
- 7 It, it just said: a human should look at this.
- I should emphasise this was an outlier detection system, it was looking for really extreme results. If it had, if it had been triggering from just results that had been that were high, it would have been overwhelmed 12 by signals.
- 13 Q. Too many?
- 14 It would be completely impractical so because this was a central system operating nationally, it could 15 only look at the most extreme results. And it got 16 turned on just about the time of Mid Staffs and 17
- Mid Staffs went "ping ping ping ping", it identified it 18 immediately as having issues. 19
- 20 So you support that system as a safety system
- to detect outliers in the way that it can? 21 22 Yes, I -- I thought it was excellent and
- 23 I left the, I stopped working for them and I know that
- 24 it carried on being used right up to the start of Covid,
- it was being used at the time at Countess of Chester 25

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- Healthcare Commission, I think, I think before it became 1 2 CQC
- 3 CQC had its own or Healthcare Commission had its 4 own mortality monitoring system that I helped design, we 5 might come to later.
 - You can tell us about that now.
 - So 2007, around then, you were involved in helping to design the system at the CQC?
- 9 Yes. After the Bristol Inquiry I had
- 10 a secondment to the Healthcare Commission for one day
- a week in developing monitoring systems and their 11
- risk-based investigation systems and inspection systems 12
- that the Healthcare Commission developed. And in 13
- particular we built a statistical monitoring outlier
- detection system for mortality that monitored every 15
- 16 Trust in the country, and for every Trust, 150 or so
- 17
- 18 So I think we were monitoring at least 10,000
- 19 simultaneous in mortality indicators using
- 20 administrative hospital episode statistics data.
- 21 The point about that is that it's impossible for 22 a human to monitor this centrally and so if this was
- 23 done now it would be considered as artificial
- intelligence in that it was automatically screening 24
- 10,000 or so signals and identifying when a human should

- during 2015/16. It stopped being used at the time of
- 2 Covid and as far as I know, has not been reintroduced.
 - And what do you think about that?
- 4 Α. I think it's very unfortunate indeed. As far
- 5 as I know, it was operating well. I saw some of the
- 6 outputs. It was in a way issuing a controllable number
- 7 of alerts about apparently spikes in mortality right 8 across the NHS.
- I think it's very unfortunate that a system like 9
- that is not working because Dr Foster is not doing this 10
- any more. You know, when I am sitting here again at 11
- another Inquiry into something that's going on, I don't 12
- 13 want to be hearing: why wasn't there a monitoring system
- 14 in place?

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- And you say indeed in one of your statements 15 Q. that it's over the last two decades that there have been 16
- real advancements on monitoring systems in this country. 17
- Why is that? Why has it happened in the last two 18
- 19 decades?
- Well, I think it is because of the scandals 20 Α.
- I think it is because of Bristol and Shipman and that 21
- provoked a lot of interest in these methods in -- among 22
- 23 the medical community and in the statistical community.
- Even before Bristol I was working closely with Great
- Ormond Street because a surgeon there Marc de Leval, had

a cluster of failures, he had a series of deaths from doing a switch operation for transposition of the great arteries. And, you know, was really shocked by this he went and retrained, changed his methods and then had 100 -- did 100 without a death.

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But we wrote a paper, a really, you know, path breaking paper, on how these industrial quality control methods could be used within surgery to detect such problems rapidly and these have become adopted. We could talk about that later in the areas where these have become adopted and become completely standard.

12 Similarly, you know, in heart surgery there was 20 13 or so years ago, 25 years ago there was concern about, you know, differing mortality rates across the country, 14 an obsession with league tables and so on. And adult 15 16 cardiac surgery were some of the first to start 17 standardising data collection, publishing the results by Trust, even by individual surgeon, again that stopped, 18 19 I think, which is a real shame. You used to be able to 20 find out every surgeon, cardiac surgeon in the country, 21 his individual rates of -- mortality rates, risk 22 adjusted for the severity of the illness and my 23 understanding is that since all that occurred, perhaps 24 there's some people stopping operating.

The other type is where you are continuously monitoring what's going on, there's no concern about the start and the end of a particular year, you are just treating it as a series of observations.

It now makes very little difference where you are

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Now, the point is that, I think a better term for that would be "fixed period" versus continuous monitoring.

Because although in my first witness statement I call this "prospective real-time monitoring" that is only in perhaps an extreme version, I think an appropriate version, because continuous monitoring might for example only report quarterly or so on. It may not be, you know, day by day or even week by week.

So I -- I think the big distinction is between looking at aggregated results over a year perhaps in a fixed period and systems that accumulate evidence over time regardless of moving from one year to the next.

18 And both I think are really vital.

Q. Why are they both vital?

A. Yes, I think the continuous monitoring is there for early detection of problems. That's what it's built for. It's built to, you know, sound alerts, you know, which could lead to different forms of intervention.

The fixed period is much more concerned with the 19

operated on in this country. The experience in America
 and the US is that by dedicated data collection,
 comparison of the results across centres, you get a huge
 reduction in the variation across centres.

Q. Can we go to your second statement, please,
INQ0108786, page 1. I am going to ask you to define
some of the terms, please, if you would?

Sorry, I didn't hear that.

9 Q. To define some of your terms, if you would.

10 If we look at this page 1.

11 **A.** Yes.

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12 Q. "Fixed period versus continuous monitoring"?

13 **A.** Yes, yes.

14 Q. And you refer to retrospective audit and

15 prospective real-time monitoring?

A. Yes.

17 Q. In your earlier statement.

18 Can you expand, please, on this?

19 **A.** Yes, in my, in my first statement

20 I distinguished, I think appropriately, two types of

21 surveillance. What I call retrospective audit, which is

22 the type that MBRRACE have traditionally done of

23 collecting data and for usually a year, then some time

24 afterwards reporting that data for the whole year and

25 producing annual results.

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bigger picture for what's going on across the countryand allow comparisons across centres as, as for the

3 whole -- looking at the whole picture, comparing

everybody, trying to spot differences on a larger scaleacross, across the country.

Again fixed period quite often can be three years
as well, it doesn't have to be just annual. It could be

7 as well, it doesn't have to be just annual. It could be
8 a moving, a moving window.
9 Q. And the continuous monitoring, would that be

something that a Trust could view its own at its highest because it wouldn't have gone through the appropriate steps and measures to be a national picture, they can view their own continuous monitoring, is that the idea?

A. Exactly. The fixed period has traditionally been a system where people sort of submitted data to a central registry and then some time afterwards,

17 possibly a year or two years afterwards, a report comes

18 out, you know, in which the, their performance is

19 examined and relationship to other -- other centres,

20 perhaps similar, similar centres.

And there is a problem with that of people feeling a lack of ownership of the system and the feeling that it's -- you know, in a way it's always too late.

The continuous monitoring is very a very different picture. At its best there is a strong feeling of local

1 ownership.

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2 The -- I am a big admirer of what's happened in 3 congenital heart disease, again since Bristol, where the 4 system is that individual centres do their own, there is 5 central monitoring, but individual centres do their own 6 monitoring, produce graphs that are presented at the --7 at the regular meetings of all the staff -- Morbidity 8 and Mortality Meetings, in which all the staff are 9 present, all the nurses and everybody to examine the 10 trends and to see what's going on rapidly. Where little blips on the graph can be -- people know who they are, 11 they know the patient who is the -- produced that change 12 13 in the graph.

We will come to that, I am sure, but the systems that are now being developed for neonatal monitoring, you know, MOSS and the real-time MBRRACE system, both have that, you know, potential to be absolutely part of the routine practice of a unit.

Q. If we can have on the screen please
INQ00067551, so 00067551, this is a screenshot that
Professor Knight explained to us and indeed it's already
out of date, there's a more sophisticated or I think
another option now looking at data within MBRRACE.
But my question, Sir David, is directed at the
skill required for people reading the data and looking

monitoring system looking at days between deaths.

Now, the point about that is that every mark on that graph is an individual patient. We know people -- you could put a very local unit, nurses could put a name on these, on these patients. That produces a feeling of real, of ownership, responsibility and so on.

And graphs like this can look, you know, daunting when you first look at them. But that's not the way to evaluate them. You need to --

Q. You don't need to be a clinician to evaluate them, you can be a manager, you can be a Medical Director?

A. No, no, it is absolutely vital that managers and nurses of every scale should be able to understand these you know, with, with some experience. Not immediately, you don't look at them and immediately grasp what they mean, so with some experience --

Q. In terms of entering the data, does the whole system rely on people entering the data as they should?

A. It absolutely relies on the quality of the data entry. And one of the principles that, you know, I and many others propose is that you should only ever enter data once so there, you do not require specialist data entry for monitoring system.

You there should not be an additional burden on 23

1 at the data within a unit?

A. Yes.

Q. Professor Knight spoke about it would be
better to have a lead person who understood the data,
understood how to access it, what it meant.

6 **A.** I -- I agree that the monitoring systems, the
7 dashboards that are being introduced and being piloted
8 can at first -- at first -- appear rather complex and
9 daunting. Experience shows that very quickly people
10 learn how to interpret them and use them.

11 So I agree that a lead person who has been trained deliberately is important for when these systems are 12 introduced but the evidence, the practical evidence 13 suggests that when people feel an ownership, when they 14 can identify as I said a blip in the graph with someone 15 16 they know, their own experience, then that, that very 17 rapidly leads to a development of local skills for 18 interpretation.

LADY JUSTICE THIRLWALL: Just before you continue,
 we still haven't got the document.

21 **MS LANGDALE:** I know. I am going to give the 22 reference again. Just give me one moment, Sir David, it 23 is INQ0006755, page 1.

24 There.

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A. Yes, so this is the MBRRACE real-time

staff, this should be an asset to staff and nota burden.

That means that the data entry of course has to be, you know, carefully done by people who are obsessive about correctness and accuracy. Who -- and, you know, that again requires, you know, appropriate procedures for making sure that's -- making sure that's done.

But experience in other areas such as intensive care show that this is possible. Of course, you know, again, you know the multiplicity of information systems that exist now in hospitals should mean that this is, you should not have to enter data specially, the data should be just there and visible by everybody.

Q. Can we have on the screen now please -- that
can go down, the document there, your statement again,
INQ0108786, page 2?

17 **A.** Sorry, I -- while this graph is still up, 18 could I just make a quick point?

19 **Q.** Of course.

A. This was developed, this shows 2019 as
 a real-time monitoring system. Since then, MBRRACE have

22 developed, have started putting some statistical process

23 control metrics on this, in other words to use this

24 graph and others I believe as -- to -- to sound alerts

25 which is a very natural development to do and it seems

to me that it's an extremely valuable innovation because 2 otherwise you are relying again on human intuition and 3 looking at graphs and humans are not, as I have said before, very good at it.

You know, very -- humans are not very good at judging when something's beyond a coincidence or things are happening too close together and so on because, you know, events do tend to cluster and so on and this actually to determine whether something is, you know, too surprising and should be examined, is -- is a professional issue. It's a professional thing, it cannot be left up to human intuition. Sorry to repeat myself.

Q. Not at all?

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- A. But it is my bread and butter.
- 16 So can we go now to 0108786, page 2 of your 17 statement where you set out some principles for monitoring systems. You have been involved, perhaps 18 19 while we are calling that up, with the MOSS project.

20 Dr Bill Kirkup of course conducted an Inquiry into 21 maternity and neonatal services in East Kent. His 22 report was published in October 2022 and a taskforce was 23 established as recommended by Dr Kirkup to drive the implementation of a system capable of differentiating 24 signals for maternity and neonatal outcome measures.

trigger different management actions.

It is not my job to say what those actions should be. Generally, the first level would be known as an alert level and that would trigger an internal investigation. Going above the next level, it goes above an alarm level, would perhaps trigger a central investigation.

So -- but that -- what is done is not part of my role. As I say, that is management actions.

Minimise burden on staff. This is absolutely vital 10 and again the rapid feedback using attractive 12 visualisations to encourage local ownership of the 13 system. This is not some alien thing being imposed on 14 people but something that people welcome, they go to and they can identify with this shared by all staff. 15

So, and as far as I know those -- all those principles have been sort of taken into account in the MOSS project which I am very pleased with.

Can I just -- while it's up there, can I just point again to the little statement that I tried to refer to earlier in my 4.2, when Dr Murdoch said:

"The signal is simply a prompt for a rapid 23 assessment to understand what has caused the signal." In other words the signal -- again, sorry to go on

24 about it, does not indicate the cause. It just says 25

about that? 3 4 Α. Yes, I -- I -- I really welcomed Bill Kirkup's commentary on East Kent and the Government response was 5 6 to say: yes, we agree and to invest in an NHS-based 7 neonatal surveillance system and maternity surveillance system. So this was the MOSS project and I was asked to 8 9 be an advisor on that project, and I still am, with Bill

You have been involved in that as well, haven't

you, working with Dr Bill Kirkup, do you want to tell us

10 and others and right at the beginning I came up with just aspects I thought were important and it's quite 11

a useful summary I think of this sort of ideas, the 12

statistical ideas which concerned me and which I have 13 14 already mentioned a number of.

15 So just to go through those. There is the 16 possibility of multiple indicators, you don't need just 17 a single monitoring system, but you might combine common 18 outcomes as has been done or combine outcomes into 19 what's known as the basket, but just a pooled measure 20 and that's been done in MOSS.

21 The importance of using cumulative data both to identify long-term trends and sudden shifts in 23 performance, setting explicit thresholds, usually two thresholds, an alert and an alarm threshold, which would 24 identify different levels of unusualness and would

someone should look at this.

the screen at the moment.

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Sure. Can I refer you to something else in Dr Murdoch's statement, if we go to INQ0108744, page 7.

4 The Inquiry asked Dr Murdoch whether MOSS could 5 measure preterm neonatal deaths or whether there would 6 be limitations on the effectiveness of the data analysis 7 in including premature babies as a separate group with 8 any joint data analysis and her response should be on

If you can read paragraph 27 at the bottom and we 10 can scroll slowly through 27, 28, 29 and 30? 11

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13 Yes, again I should emphasise this is not, not my 14 job. You know, what the -- the design of a system in terms of what outcomes are being monitored is, is 15 determined by the aims of the system, what is it trying 16 17 to detect, what is it trying to ...

18 And MOSS and the real-time MBRRACE system are doing different things and are monitoring different outcomes. 19 MOSS only looks at term births because as you said it is 20 21 designed to support the improvement in maternity and 22 neonatal outcomes at term.

23 So the -- any -- it is not looking at neonatal care 24 of premature babies, it was not what it was designed for, whereas the MBRRACE system is looking at events for

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any babies born after 24 weeks' gestation. So they are 1 2 looking at different metrics, you might expect them to 3 signal in different circumstances, sometimes in the same circumstances and I have got to say it's still being 4 5 worked out how these two systems --

> Q. Work alongside.

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-- might be used, how they might fit together, hopefully how they might complement each other.

So I -- I -- that is it still in a state of flux at the moment, MOSS is being piloted in a range of hospitals, the MBRRACE system is being added on to their existing system that was plotting the graphs which we have seen at the moment. They also use different in a way statistical methods to -- to trigger alerts.

So these are different systems. And it remains to be seen how they might complement each other.

17 And whilst instinctively certainly I suppose 18 for people entering the data or even viewing the data 19 that's produced it might be preferable to have one 20 system. It looks, do you agree, with paragraph 29 of 21 the statement in front of you, with Dr Murdoch's analogy 22 to think about a car whether a number of targeted 23 signals that have been designed to be specific to the safety issue that they relate to, provided the user 24 knows what each signal relates to --

page 3, so INQ0108786, page 3 and it's where you deal with risk adjustment?

> A. Oh, yes.

Q. Can you explain to us the significance of 5 risk-adjusted systems and how more effective they are, 6 how they are being developed and the limitations currently?

A. Well, risk adjustment came to particular prominence within adult cardiac surgery because there is a big variation in the severity of illness and the risks involved in people being operated on and if you just count what are known as crude mortality rates, which is what MBRRACE call them, it's again a rather harsh term, but it just means how many people have died out of how many operations, then that was considered unfair to the surgeons doing the more advanced surgery.

And so the risk adjustment methods were developed in which for every patient detailed patient specific information is collected as to the severity of their illness and by, you know, a pretty basic statistical method, you use that to actually calculate an expected -- well, it's actually a probability of, of death or survival for that particular patient.

So that means that if a very high risk patient is being operated on, and they do unfortunately not 31

Α. Yes

2 Q. -- it is more effective to have a number of 3 specific signals than one generalised signal, a single 4 red light on a dashboard?

Yes, I think that is a reasonable thing.

6 I mean, there is some overlap in the cases, the 7 events that were triggered, you know, that would go into both MOSS and the MBRRACE system but they are measuring 8 different things and they -- they might agree and they 9 10 might disagree and I think that would give some 11 additional insight into what is going on because these systems -- again they are just signals saying: have 12 a look at this. They are not the answer to the problem 13 and so there's, you always need the ability to drill down further, you know, to start looking at what has 15

17 In practical terms, would it be a lot more 18 onerous to furnish data to two systems or do you think 19

triggered these, what sort of events?

20 Well, it shouldn't be because again the data 21 should be there anyway. If, if it's -- if it's onerous 22 to put the data in then the system isn't working 23 properly. It really shouldn't be an additional burden 24 to the staff. These should just be assets to them.

Can we go back to your statement please, at

survive, the surgeon is penalised less than if it was a very low risk patient. And that, sorry, I am using 2 the term of "penalised" I really shouldn't say that, 4 I should just say it contributes to a signal less than 5 if it was a low risk patient who died.

6 And so that it is generally considered advisable 7 where possible to risk adjust for pre-existing 8 conditions in order to -- so that the signal is sensitive to what might be considered unexpected deaths, 9 rather than deaths which while not expected were, were 10 11 not so unlikely.

12 And so within for example paediatric intensive care 13 and adult intensive care, where there is standardised 14 data collection upon admission, national standardised data collection, they can risk adjust and so they, every 15 patient when they come into intensive care, you know, it 16 sounds again very harsh, is given a probability of 17 survival, that they will in fact survive or die. 18

19 And that's used then to -- within the monitoring 20 system which in fact is the system we developed for Harold Shipman, they used, to in a way take more notice 21 22 of what one might consider as unexpected deaths.

23 Is it easier to risk adjust for adults with 24 a known medical history than for neonates, for example? 25

Α. Yes.

O Newborns?

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A. The point is in some areas cardiac surgery, the risk factors are known. We can collect them fairly easily, it is fairly easy to develop a formula.

Even in paediatric cardiac surgery it was, it's really quite challenging, it took a long time to develop a system because there is such an enormous variety of different conditions, it's very difficult just to summarise the condition of the child in a limited number of metrics.

And so there -- the MBRRACE system does do one of their metrics, does do some risk adjustment on basic ideas such as gestational age and so on but just essentially demographic data.

But risk adjusting for pre-existing conditions of 16 neonates, again that's a clinical issue but my understanding is that that would be challenging. So not only would you have to decide the important risk factors, you would have to standardise data collection across the entire country and that's a big ask.

21 It is very challenging. It has been done in 22 certain areas such as intensive care and adult cardiac 23 surgery and, you know, of course it is an ideal situation which I would hope people might move towards 24 25 but it's quite a big ask but until that happens it does

would you like me to put the figures that were in the MBRRACE report and the table? Which is easier for you? You have summarised it here.

4 A. I think -- I mean, this is all taken from the 5 MBRRACE report.

Q. Yes.

7 So I'm not sure, I think this probably is 8 sufficient, I refer to the figures.

> This will suffice. Q.

10 So the idea is that in my first witness A. statement I was covering completely general issues about 11 the vital importance of statistical monitoring systems, 12 right across the board, in all clinical areas and how in 13 14 a way it's I think more than unfortunate that they have not been in place in neonatal care but that is now being 15 16 remedied

But in the second report, I did have a look at what systems did say at the time in 2015 and 2016 at Countess of Chester using the evidence that's been provided to the Inquiry because this was not previously available. Some of it was, some of it wasn't.

21 22 And this is very much in the spirit of, as we did 23 perhaps with Shipman, because for Shipman none of those 24 monitoring systems were in place, this was a purely in a way imaginary world: if things had been in place, what 25

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mean that in a way everyone -- every case contributes, 1 is given the same weight in the monitoring system which may not be entirely appropriate. 3

4 And indeed a monitoring system or a data uploading system could require you said unexpected 6 deaths but sudden and unexpected could be a factor 7 uploaded in any event in a monitoring system, a human 8

9 Yes, but, you know, to calculate expected 10 deaths requires a formula, it is an algorithm, which has to be developed on a good database and then has to be 11 applicable to every new patient. So it's -- it's 12 a matter of really of data availability --13

14 Q. Okay.

15 A. -- is the limitation.

16 Q. Can we scroll up to have the whole of

17 paragraph 8, please. So 8.1 to 8.7.

18 This is your statement -- a bit further down,

19 please, scrolling. So 8.1 can we see as well.

20 This is your response to what the MBRRACE system 21 showed for 2015 to 2016 at the Countess of Chester and 22 of course we have heard from Professor Knight and we 23 have looked at the figures you refer to here.

24 Which would you prefer, Sir David, to tell us what 25 the MBRRACE data represents looking at your statement or

1 might they have said? And so this is both what systems 2 did say and perhaps what they could have said.

3 Q. What they could have said earlier because they 4 said it in 2017?

Α. Yes, could have said earlier.

And 2018? 6

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So the MBRRACE system has been going for some

8 time, it's a well-established system, it reports -- for

neonatal deaths, it reports two outcomes: a crude 9

neonatal mortality rate, which is just the number of 10

11 deaths divided by the number of admissions to the

12 neonatal -- no, it's birth, the denominator is births,

13 not admissions to neonatal unit.

14 And it also records adjusted and stabilised 15 neonatal mortality rates, which is more complex.

There's some adjustment for demographic risk factors of 16

17 the mother and child, including ethnicity and

gestational age. And the stabilisation is a little bit 18

difficult to explain. It's a way of trying to eliminate 19

some of the random variation that one gets from year to 20

year due to in a way risk factors that have not been 21

22 taken into account and that, that means that estimates

23 are sort of pulled in or shrunk towards the mean of the

24 relevant group to allow for some unexplained variation

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25 between units.

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It's designed to identify extreme units in the 1 2 tails of the distribution, not outliers, and it is 3 important; it is not an outlier detection system, it's an in the tails detection system and that should be very 4 5

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In Lisa Annaly's witness statement she said that --I should also say --

> That is the CQC statement, Lisa Annaly? Q.

8 9 Yes, I should say that MBRRACE then summarises A. 10 centres in terms of colours, we are particularly interested in red, which means they are estimating it's 11 10% higher than the average for their -- for their tier 12 13 for their group.

And so for 2015 it concluded more that it was red, 14 more than 10% higher; 2016 up to 10% higher. It's 15 16 important to note that the 2015 data was only published 17 in 2017 and the 2016 only published in 2018. So again showing one of the problems with these retrospective 18 19 fixed period audits.

Professor Knight's witness statement is slightly different, saying that in 2015/2016 Countess of Chester was red for both crude and adjusted and stabilised neonatal mortality rates in both years. In my next point I do -- you know, just being red

is not a major signal. In 2015, around 30% of units

delay, Countess of Chester as having higher rates in 2015 and 16. It was highest in its tier but I -- that would not be considered generally an outlier but it would be sufficient to generate a signal and alert warranting investigation.

Can you have a look now, please, at paragraph 1 onwards, if we scroll down. So at a national level you say it would have warranted investigation, what was seen, but what could have been known locally --

A. 11 Yes.

12 -- what about the mortality data on its own to 13 the hospital have shown, can you take us through 14 paragraph 11, please?

This -- I have done all of this since Monday, 15 I should say because it is only on Monday that 16 17 I received or became aware of or I think this document is now public, document INQ108781. 18

Shall we put that on the screen first? Q.

20 A. Can we put that up there? It is rather

important. 21

22 This was dealt with with the Countess of Q. 23 Chester corporate witness and is the evidence in 24 relation to numbers of death that the Inquiry has received, so it's INQ0108781. 25

were classified as red both for crude and adjusted and 1 2 stabilised rates.

3 So, you know, on its own that's, it says they are 4 high, it certainly doesn't indicate they are outliers.

5 But actually Countess of Chester's crude neonatal 6 mortality rate in 2015 was 2.96 per 1,000, there were about 3,000 deaths -- 3,000 births, so that means there is about, there was nine deaths they had counted in their definition in its tier and it was the highest in 10 its tier of centres with 2,000 to 4,000 deaths a year.

11 I have to say only just. Blackpool had eight deaths compared with Countess of Chester's nine. 12

13 So again it was high, it was in the tails, one 14 would not call that an outlier.

15 And similarly for 2015, it's adjusted and 16 stabilised rate was the highest in the tier, Burton 17 being second highest and a little way behind in 2016.

Again 30% of units were red for the crude neonatal 18

19 mortality rates which puts -- which is -- so it is not

20 a very discriminating metric, it is certainly not

indicating an outlier but again Countess of Chester was 21

22 the highest for adjusted and stabilised rates out of the

23 39 units in its tier and rather higher than Sherwood

24 Forest at 1.26

25 So MBRRACE identified of course after substantial

Just as some background before we get to that.

The point is that all the monitoring systems I am 2

talking about, the MBRRACE, the CQC outlier detection 3

4 system, MOSS and so on, all make use of information from

5 other centres in order to assess what's going on in

6 a unit. It's comparing with other centres, it's -- and

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However, an alternative approach is just to use the 9 data from a unit alone, to try to identify where the changes happen and there are a variety of what are 10

called SPC, Statistical Process Control, methods in 11

12 place to do that, I think some of which have been

13 implemented now by the MBRRACE real-time data monitoring

14 system.

15 You see on this document, Sir David, the first Q. is the Lead Clinicians in a summary saying what he 16 17 understood the number of deaths were.

18 The second was the ward manager with numbers of deaths and emails. And the third is something that the 19 20 Head of Risk and Patient Safety and the Director of Nursing drew together preparing a position paper on 21

22 neonatal mortality.

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And we see there under the heading "Mortality 24 Data":

"Data discrepancies between the differing systems 40

in place has led to a number of challenges in obtainingan accurate account of ... unit activity over time."

A. Yes.

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Q. "Having reviewed outputs et cetera the actual number of deaths occurring within the neonatal unit recorded from January 2010 up to including June 2016 is as follows ... "

And there are the numbers that they have ...

A. Yes, I would like to draw attention to that first sentence they give:

"Data discrepancies between the differing systems
in place has led to a number of challenges in obtaining
an accurate account of the neonatal unit activity over
time."

I think, you know, that again represents what I reinforces what I said before about Bristol, is that one would naively think that these numbers would be clear and recognised and agreed by everybody. But in fact that's not the case and so I would not want to make any comparisons on a system over time unless I felt that it had all been collected to a common standard using a common protocol.

Assuming this has been done now in this table, you do get a series of from 2010 a number of neonatal unit deaths: 1, 3, 3, 2, 3, 8. And I think it's important,

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1 those five years of data and then it goes to 8, how

2 surprising is that? And if we assume -- I'm sorry about

3 the technical language, but statistically one would

4 assume that observations are from what is called a

5 Poisson distribution which is just the rate of

6 distribution we expect for rare events. We would say

7 the average over that period was 2.4 deaths per year and

we can think of that as some sort of underlying rate.

And there is uncertainty about that because there is only five numbers that contribute to it.

Allowing for that uncertainty, and doing a little bit of technical stuff, the probability of getting eight or more deaths in 2015 I assessed to be around 0.008. Just by chance alone, assuming that nothing had actually changed, that the underlying rate had stayed the same, the probability of getting, you know, eight or more is that which is about -- which is less than 1%.

That would generally be considered sufficient to trigger an alert signal, someone should look at this locally. But not extreme enough to be considered an outlier and I think this is very useful to put this in perspective.

There are about 150 neonatal units in the UK
covered by MBRRACE and therefore we would expect one
signal of this magnitude to occur each year just by

1 you know, on the face of it yes, that is a change. But

2 it requires, what I have done is actually look, do some

3 you know pretty statistics to get an idea of how big

4 a change that is and what sort of attention that might

5 warrant.

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Q. Shall we go back to your statement?

A. Yes

Q. So we go back to INQ0108786, page 5.

9 A. As I said, I should emphasise all that has

10 been done since Monday.

11 Q. If you want to caveat or add to it afterwards,

12 please do?

A. Yes, I am.

Q. If you think there is anything that you needto correct or change or would like to add, we don't want

16 you to be under pressure of time in any way?

17 **A.** If we go on to the next page, page 6. Yes.

Yes. So the number of deaths between 2010 and

19 2014, 1, 3, 3, 2, 3, it actually shows surprising

20 consistency. I would have expected more variability;

21 a 4 and a 0 and so on.

22 Anyway, it went up to 8 in 2015. Again,

I apologise if this sounds harsh in describing tragic

24 events.

So one approach is just to say: well, we have got

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1 chance alone. Through no underlying cause, nothing2 special changing at all.

special changing at all.So I think it's important to give it that sort of

4 context that this is a surprising event within Countess5 of Chester but from a national level, this is not very

6 surprising at all; we would expect this to happen every

7 year, somewhere, somewhere.

8 You know, an alternative is to say: well, what if 9 the underlaying rate were three neonatal deaths per year 10 then the probability of getting eight or more deaths is

11 about 2%, again an alert signal. And to put this in

perspective we would expect three such signals in the UKjust by chance alone.

I do emphasise, which I didn't write here, that
I am only looking at 2015 data because that was the
complete data I had in that table. Since 2016 was also
a high year that would of course generate an additional
signal but what I am saying is that the 2015 data alone,

19 taken completely internally, would justify an alert,

20 an internal investigation, that this is unusual.

21 **Q.** And clearly the Lead Clinician and the ward 22 manager were talking about an unusual number of deaths 23 at a human level there in the unit?

A. Yes, which no doubt happened but what I amsaying is that a background statistical method analysis

1 would have done that automatically.

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Q. Is there anything else you would like to say about that topic before I take the statement off and move to a different question?

A. No, I think that's, that's it. I mean, all sorts of -- you know, I mean, that is a very short series of five observations, so I wouldn't want to do anything massively sophisticated with that. But it's exactly the situation where real-time monitoring, you know, at least continuous time monitoring is so vital you shouldn't even have to wait until the end of a year if something is going on.

Q. Thank you. That can come down.

Sir David, are you able to give examples of where the use of statistical monitoring systems have worked effectively in the healthcare sector to promote patient safety and prevent harm and conversely where such a system has failed to do that?

A. Yes, I would point to the continuing success and use of PICANET in paediatric intensive care which adopted the systems we presented in, in Shipman and they combine both types of system.

And I wonder if we could just go to my first evidence, my first witness statement.

Q. Yes, we can.

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the funnel and they say it is not going to be flagged as an outlier as it closed in 2020.

So I -- I think this sort of system is incredibly valuable and it allows them to make statements like: "there was no evidence that any paediatric intensive care unit had an excess mortality rate compared to what would be expected based on a level of sickness at the time of admission across the three-year reporting period".

10 If that's correct, it doesn't matter which intensive care unit you go to in the country, which is 11 12 an amazingly important thing. And if you plot adult 13 cardiac surgical results, they look like that now they 14 are in the funnel; it doesn't really matter who you go to. Obviously centres are all different but what that shows also is it is completely pointless to produce any 16 17 sort of league table or to say who's top and who's 18 bottom. It's all nonsense. They are indistinguishable 19 essentially.

So an enormously powerful tool to incept. But of course when somebody lies outside then it is another matter and it would trigger these outlier detection these are quite extreme limits. So those would trigger a national -- you know, a central investigation.

So I think that again shows the power of

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A. I produce a graph from PICANET.

Q. I will just get it on the screen, INQ0008966,

3 page 3.

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4 **A.** Just to say a bit more. Yes. PICANET does 5 the real-time monitoring and has got alert and alarm

6 systems, fully risk-adjusted and I think has been a huge7 success.

success.
 But they also do a retrospective analysis for -- on
 a three-year period looking across all centres that they
 are monitoring and they use this device called a funnel

plot that I and others developed, you know have -- haveproposed many years ago and it's become very popular and

13 I particularly like it because what it shows is the

14 funnel broadly shows where would you hope centres to lie

15 in.

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a lot more variability just by chance alone. They can
have good years and bad years just because they have got

It's a funnel because small centres you expect

19 such small numbers, you get a lot more variability, so

you tolerate that more. Whereas for large centres, youhave much less tolerance for variability: you expect

22 them to have a pretty constant rate and so what that

22 them to have a pretty constant rate and so what that

23 shows is amazingly the, the paediatric intensive care

24 lie within the funnel. They, they point out -- yeah,

25 what's interesting is ZE, Harley Street, is just outside

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retrospective national audits over a fixed period, but

2 of course it's too late in a way. Much too late. If

3 there is a problem there, it should have been detected

4 by a real-time monitoring system. This is an assurance

5 to people that, you know, it doesn't really make

6 a difference where you go but if there is a problem, you

7 shouldn't have to wait for it to be an outlier here.

Q. That is how it works effectively. Would you say any failures are failures of the system because of time delay, that you don't get in there early enough?

11 **A.** It is certainly a failure because systems 12 weren't in place, you know and I think neonatal care 13 shows that.

14 I -- I don't know of -- I don't know enough about
15 where there's been delays in, I can't say there's been
16 a delay in finding something a problem because of only
17 using retrospective data. Quite possibly. I can't -18 I can't quote an example. I am sure there have been.

19 **Q.** While we are on your statement, can we go to 20 the previous page, page 2 and give you an opportunity to 21 comment, if you want to, either on the National

22 Matawaity Daalahaand on the National Necestal Avid

22 Maternity Dashboard or the National Neonatal Audit

23 Programme?

A. No, I -- as I said, there have been so many
 programmes about monitoring, you know, neonatal care and

- 1 maternity care, I am not going to make a general2 statement about that.
- Q. Okay.

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- A. My interest is completely restricted to this, you know, rather technical issue of early detection of using statistical systems of problems.
 - Q. That can come down, thank you.

8 How can, should policies, procedures or guidance be 9 drafted to ensure the data is accurately collected, 10 entered and analysed to avoid missed opportunities? Do 11 you think hospitals and those analysing the data, there 12 needs to be shared policy around that? Or do you

13 think --

A. Well, I mean, this is happening anyway because
of, you know, hospital information systems are being
used. That means that one person enters the data and
then it's being used everywhere by everybody.

So quality control about data entry now should be an integral part of medical care because that data then is -- you know, can be accessed, can be used, will be used.

So again it's -- I -- it's very easy for me because
I just say that data should be only entered once and it
should be accurate and there should be -- you know,
there should be a responsible individual who takes

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- 1 underlying in a way mortality risk, what the
- 2 statistician might call the underlying rate, the
- 3 long-term rate is, is another matter that would have to
- 4 be identified or whether it's a run of, you know,
- 5 particularly just in a way circumstances, unusual
- 6 circumstances have led to that, is a matter for
- 7 investigation.
- 8 So I don't think -- I think I wouldn't use that
 9 phrase myself. I would say there is increased mortality
 10 of undetermined cause, perhaps, or something like that.
 - Q. But the numbers have gone up?
- 12 **A.** The numbers have gone up.
 - Q. The fact is that they are small numbers as
- 14 well?

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- 15 **A.** The numbers have gone up, they are small numbers, but just because numbers have gone up does not mean necessarily that, you know, that, you know, there is a special cause for it. That is something to investigate.
 - Q. As is explained, that needs investigation?
 - A. It needs to be investigated.
- 22 Q. Before Mr Skelton, I think, is going to ask
- $\,$ 23 $\,$ you questions, is there anything else that I have left
- 24 out you would like to add?
- 25 A. Just -- I would like to mention in my second,

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1 responsibility for that, ultimate responsibility for

2 that.

3 It's not, I am very fortunate it is not my role to
4 actually discuss the implementation of those, of that,
5 of that data collection. Sorry, I avoid those things.

6 **Q.** Fair enough. Can you have a look, please, finally from me at this document, INQ0004657, page 1.
When it comes up, Sir David, this is a Risk Register at the hospital and we see at the top, if we can highlight

10 the top, in July 2016 there's a record of the risk:

"Potential damage to reputation of neonatal service
and wider Trust due to apparent increased mortality
within the neonatal unit."

You have seen the numbers on Monday and they were circulated. The use of the word "apparent", is that something a statistician would say? I am just trying to

17 understand that word.

Α.

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18 A. I mean, I think I don't think that's -19 I think we would avoid that phrase because the mortality
20 rate has gone up.

21 **Q.** The deaths are absolute; they happened?

You know, there is 2, 3, 3, 3 and then it went

23 to 8. So I think the number, the mortality rate has24 gone up.

25 Whether that actually indicates a change in the

1 my recent report. I did look at what MOSS and the CQC

2 monitoring system ...

Q. Yes

A. Well, the CQC modelling system did say MOSS
 might have, would have said, had it been in place at the
 time.

7 Q. Shall we go to that INQ --

A. Yes, could we go --

9 Q. -- 0108786, so the CQC outlier system,

10 paragraph 9.

11 A. Yes. So when we come to that, the CQC --

12 **Q**. Page 4

13 A. You know, I feel a connection with the system

14 because I helped design it and as I said, it was

15 designed to monitor thousands of outcomes right across

16 the NHS using routine administrative data but it wasn't

17 definitely an outlier detection system looking for

18 really odd results, not just extreme results otherwise

19 it would have been overwhelmed.

Lisa Annaly reported that it did not flag as outliers in 2015 and '16 and that was reinforced by

22 Ann Ford's statement. In a way I am not surprised, in

23 a way. I don't know how high it would have to be to

24 trigger but it would have had to be really quite

25 remarkable.

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1 **Q.** For Dr Shipman it was 40, but different 2 system?

A. But Bristol would have been a bigger idea of would have triggered with an outlier. Shipman would have eventually triggered as an outlier but the Bristol should have would have triggered as a clear outlier.

And in the next section 10, I talk about MOSS because Dr Murdoch in her second witness statement, the MOSS team did run the Countess of Chester data through but always keeping in mind this is just on term births,

11 this is not considering pre-term births and she reports

12 that if MOSS were in place at the time, the signals

13 would have prompted a standardised critical safety

14 assessment to understand why the signal occurred. It

15 was an alert, not an alarm. It just got up to the level

16 to trigger a local investigation, standard safety

17 critical assessment at the local level, which -- so

18 again reinforces that, and that again was not even

19 looking at premature babies, that the signal at Countess

20 of Chester would not be sufficient to trigger a real

21 outlier.

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22 **Q.** No.

23 A. But would have been sufficient to trigger, as

24 it did, you know, using statistical methods, an

25 investigation, local investigation.

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1 the -- to the wider community because this is public.

Q. Thank you. Anything else before I hand over to Mr Skelton?

4 **A.** No, I think that is everything I wanted to 5 say.

MS LANGDALE: Mr Skelton.

LADY JUSTICE THIRLWALL: Mr Skelton.

Questions by MR SKELTON

9 MR SKELTON: Sir David, I ask questions on behalf10 of one of the Family groups.

11 **A.** Sorry?

12 Q. Sir David, I ask questions on behalf of one of13 the Family groups. Can you hear me okay now?

A. Fine.

15 Q. I am going to use your book, if I may,

16 I'm afraid I confess I haven't read all of it but I have

17 got through most of it and I didn't understand most of

18 it.

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A. Good.

Q. But I understood some of it.

You have talked about retrospective analysis in

22 your note this week looking at the 2015 and 2016 data.

23 What about real-time analysis, because we know for

24 example that the first murders occurred within

25 two weeks, so three murders within two weeks in

Q. And you are clear that that's what was

triggered, an alert for an investigation, not an outlier

3 but something that required investigation?

4 A. Yes, so that again, from a -- whatever did

5 happen with the benefit of hindsight and if these

6 methods had been in place, it would have been triggered.

Q. Sure.

A. And I think having a statistical system in

9 place to trigger something, not only does it happen

10 fast, but in a way it avoids a lot of argument because,

11 you know, it's gone, it's been pre-designed, these are

12 predetermined thresholds that have been set, there are

13 standard operating procedures. It is almost no longer

14 a matter of discussion: sorry, that's happened, this is

15 what now must take place. And I think that's

16 a considerable advantage.

17 Q. But as we have said, the MBRRACE data was only

18 available 2017 and 2018 --

19 **A.** Yes, yes.

Q. -- respectively?

21 A. Again now they have got a real-time monitoring

22 system. Again I don't think it is a choice between the

23 two. PICANET show the huge advantage of both having

24 a continuous monitoring system and, you know, every year

25 doing a retrospective audit almost as reassurance to

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1 June 2015. Is it possible for you to say whether your

2 real-time analysis would have picked up that cluster as

3 being a signal, or a "ping", as you put it, or would it

4 just have been like the three airline crashes over

5 a 10-year period, something more likely?

A. Yes. No I think, I can't say because

7 I haven't done the analysis, but a proper real-time

8 analysis would not just, I just looked at data for the

9 whole of 2015, but a real cluster of events, it would,

10 it should pick up without having to wait to the end of

11 the year, if that is the case.

12 And I -- but I haven't run it through any system

13 but statistical systems are designed to pick up

14 a cluster like that as quickly as possible.

15 You mention the fact that in my book I talk about

16 the fact that, you know, clusters do occur --

Q. Yes.

18 A. -- across the whole, you know, if you look in

the bigger picture, you know, over 10 years, you know,

20 looking over the whole world you will get many, you

21 know, such events occurring. And I think that's -- the

22 difference in perspective there is between a local just

23 looking at the data itself and if you look at a whole

24 national system where you do have to take into account

that you are looking at many units and lots of things

will be happening in those, in those units, that is why I said that the 2015 count you would expect something like that somewhere every year in the UK.

So that means that when you are looking at many units you have to be really cautious about making the grand claims about apparently outlying results.

If you are looking just within a unit, a single system, not looking outside, then really it's much of a self-contained system, you still must be cautious because bad things, you know, do tend to cluster but the statistical approach should be able to identify the difference between -- I mean, I hate to use this phrase, a sort of random cluster, just a run of bad outcomes and the idea is it should identify where there has been some systematic change for whatever reason.

16 So it's telling you something basic: something 17 might be going on which is out of the ordinary, you need to investigate? 18

A.

20 Q. And your last point to Ms Langdale I think was that the system must respond to that, that is the 21

22 benefit of it?

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23 A. Yes. So there is going to be standardised response 24 Q.

25 of investigation. I would like to ask, really all of my

A. Yes.

-- the fact that I think there are over a million patients treated in the NHS a day, so I am not going to try and do the arithmetic, but billions of patients treated over a 50-year period, and half a dozen people murdering them in that time, it is a tiny, tiny fraction of the number of patients. Do you think that statistic has any rational value?

A. I think the rarity of an event, it is important to take it into account when, when judging evidence. This is a standard, you know, it is known as a Bayesian argument, that if things are rare you have to be very careful about the use of detection systems the classic idea being perhaps breast screening which is, you can say, 90% accurate in terms of if you have got

cancer it will detect it 90% of the time; if you haven't, it will reassure you 90% of the time correctly. However, because the people being screened, it's quite rare, when you get a positive mammogram, the majority of those are false positives. Now, this is quite -- I do it in the book and do it in multiple books it is quite difficult, it is not intuitive, it is not intuitive. The fact that if something's rare, even a fairly accurate detection system will mainly be detecting false positives.

questions are going to be about how to respond to the 1 2 "ping", not in terms of paediatrics or neonatology but all the things you talk about in your book are about the 3 way people respond to uncertainty and it is that that 4

6 The first thing I would like to ask you about is 7 layperson's understanding of homicide and in a healthcare context in particular. 8

I would like to just test with you.

9 From your involvement in the Shipman case and your 10 knowledge of other cases, and indeed the public knowledge, it seems that homicides in a healthcare 11

context are exceptionally rare, there's been half 12

a dozen or so convictions over the last 50 years. Is 13

that a fair statement? 14

15 A. I -- of course, those are just the 16 convictions, we don't know --

17 Q. Indeed.

18 Α. -- what else might have happened but yes, it 19 is rare. ves.

20 Q. So there is a known unknown about the people 21 that may have been murdered without anyone ever 22 realising?

23 Α. Yes, yes.

24 Q. Do you think that that fact which will bear

upon a layperson's mind --

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1 But in terms of the person responding to 2 a suspicion, that is my focus. The fact that it's 3 something exceptionally rare will inevitably infect your 4 thinking?

Yes. It's actually quite a tricky thing because, I mean, it is a bit like a clinician

7 investigating a disease. They have to keep into account

8 that rare things do happen.

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Q. Absolutely.

10 But of course actually you do investigate the 11 more common things and the very, very rare things. You require a much bigger signal in order to take them 12 13 seriously.

And the consequences of what you are dealing 15 with will also bear upon that analysis as well so something might be very, very rare and inconsequential 16

17 but something might be very, very rare and highly

consequential, which is your rare disease or in this 18

19 case a homicide?

20 Α. Yes. And I think this is -- I mean, it's -it depends, if you are thinking yes if -- if there is 21

22 a severe consequence, then obviously you take it, you

23 know, for example in cancer diagnosis or something like

that, even if the signals, if it's quite a low

probability, then you do full investigation because the

1 consequences of getting it wrong are extreme.

And so you are absolutely right that the rareness of something and the severity of in a sense a mistake do dictate the, you know, what actions one might take.

I mean, the problem is as you said that in the end, what I am describing are things with a standardised operating procedures, statistical systems respond in a certain way and they need to be designed to take these aspects into account in order to prevent excessive attention to what may be false alerts at the same time as not letting through a problem for whatever reason, whether it is a crime or not.

So, I mean, in any investigation you are trading off to some extent the two types of mistake you can make.

- **Q.** Yes, there is an interesting tension though between the learning from the Allitt Inquiry, which was that if certain types of event occur, you should think the unthinkable and not exclude the rare event which would be the murder of a child or a patient and, at the same time, the practitioner on the ground thinking: Well, this isn't going to happen in my hospital --
- A. Yes.

Q. -- this happens in someone else's hospital in 25 some other year in the past and it's how the responding

you know, in any situation, control myself, you know, to have some insight into your own personal -- you know, like we all have got, our own, you know, characteristics that we use in our judgments and try to -- it is very difficult but try to have some insight into those.

- **Q.** You were speaking in the context of forecasters, but I am trying to apply the same sort of sensibility or rationalism to the person analysing retrospective events: presumably the same characteristics apply when you try to look at what happened in the past as you are when looking into the future?
- **A.** Yes, yes, but as I said it's actually quite difficult to do, but one should always try to, you know, reflect on your cognitive process, reflect on how you are thinking about stuff, that is very --
- **Q.** The third characteristics was humility and it is a theme that comes up again and again in your book, it is the limits of knowledge and the limits of your understanding or your own personal characteristics which seems to be quite an important aspect of the rational response to an uncertain situation, could you explain that?
- **A.** Yes, I think in the book I hardly mention 25 rationality but I mention a lot about humility, so again

1 person rationalises those tensions?

A. Yes. But again that's getting outside my
area, I am not a psychologist of decision-making and
I -- you know that is not my area. If you think of it
purely from, you know, I don't like this phrase,
a rational, a sort of reasonable perspective then, you
know, even rare events need to be kept in mind. But
they would tend to need, you know, stronger evidence in
order to bring them to the fore.

Q. You talk in your book about putting
 uncertainty into numbers and using multiple sources of
 information, aggregation, as you call it, metacognition.
 Could you explain what metacognition means in the
 context of responding to an unusual and uncertain event?

Yes, I talk about what makes people good forecasters and good at making judgments in the face of uncertainty and one of those is taking advantage of multiple sources of information. The metacognition is having some insight into one's own biases. So basically having some self-reflection that acknowledges what you might be bringing to the argument and actually possibly distorting the evidence.

So trying to avoid confirmation bias where you only look for things that support what you already thought.

I know I am a chronic optimist and so I have to try to,

the humility is to try to think: I may be wrong. Youknow, that not to have overconfidence about one's

judgments and to -- well, it's what humility is, to have
 a -- to have a -- how can I explain humility apart from

5 saying it is humility? Yes, not to be so confident

6 about your judgments that you blind yourself to evidence

7 that might be pointing in another direction.

8 Q. So would it be fair to try and use your three,
9 aggregation, metacognition and humility, to try and
10 understand how best to respond to an uncertain situation
11 that is occurring in a healthcare context. Is that
12 a fair starting point at least?

A. Yes, it could be. Again it's not, how people
actually deal with situations of uncertainty is not my,
you know, professional expertise whatsoever. It's -what I am more concerned with is how one could set up
systems that in a sense don't take that off their
shoulders but produce a standardised response to
particular signals.

Q. And one of the other aspects I think you talk
21 about when you are dealing with making decisions in
22 response to signals is constructing a list of actions,
23 with the consequences of actions. So you need to work
24 through logically your plan and where it might lead you
25 in response to an uncertain situation. Is that a fair

summary?

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A. Yes, the ideal approach in situations of uncertainty is that you do list what your options might be and then you think of what -- under each option what the consequences might be. You know, in a theoretical point of view you -- you -- you would actually put probabilities and values on all of those but that's, you know, rarely applicable in practice.

But just structuring the problem in terms of what are -- you know, what are the options, what are the unknown quantities and what are the possible futures is obviously a valuable thing to try to do.

- **Q.** Do you have any other guidance for someone dealing with an uncertain statistical situation and responding to it in a healthcare context where the consequences are extremely serious of the decision-making?
- A. Again I feel this is somewhat outside my
 expertise, except again to go back to the
 characteristics that you -- that you mentioned before,
 which is trying to keep an open mind of seeking multiple
 perspectives, you know, from people with different views
 and having been cautious about overconfidence in any,
 about any particular conclusion.
 - Q. I think it's also important, as I understand

Ms Langdale, there was just one thing I wanted to check. You began asking a question about Dr Foster system when you were going through the chronology and then we diverted to look at something else, was there anything about the Dr Foster process that you wanted to bring out in evidence?

Further questions by MS LANGDALE

MS LANGDALE: None other than Sir David also knew of that system that it would have raised the signal that you said in respect of the --

- A. Sorry?
- Q. You go on. You tell us about Mid Staffs --
- 13 A. Mid Staffs.
 - Q. -- and what that system would have told us?
- 15 **A.** That was, you know, a monitoring system would 16 have very quickly raised signals on that.

Questions by LADY JUSTICE THIRLWALL

18 LADY JUSTICE THIRLWALL: Thank you. I have just19 got really a couple of very small points.

The first is, are you aware of some evidence that we had the other day in relation to BadgerNet which is another data collection system, that in some places it's no longer being used, either data is not being put in, ie because a new system in a particular hospital or

25 hospitals does not speak to the other system, it's kind 67

it, one of your chapters is about communication of
 uncertainty; that the person who is dealing with
 uncertainty communicates it successfully -- properly and

4 fairly and in a trustworthy way to those that are making

decision?

6 **A.** Yes, I mean that -- that again is -- I even -7 I am quite critical of some people who are not very good
8 at that or don't want to do that and I have got to say
9 politicians are -- part of their job is to always appear
10 completely confident about everything they say and all
11 their conclusions.

But I think trustworthy communication of
uncertainty acknowledges what is unknown and
acknowledges limitations of - of what is known. But
also emphasises the fact that more will be known and
things will change. And that's part, that sort of in
a way provisionality, this is not the final word,

18 I think is part of trustworthy communication in a state
19 of uncertainty in that we will learn more and things
20 will change.

21 **MR SKELTON:** Thank you, Sir David, those are all my 22 questions.

LADY JUSTICE THIRLWALL: Thank you very much
 Mr Skelton, anyone else have any questions for
 Sir David?

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of rather dispiriting evidence because the point you
 have made repeatedly, it seems to me quite rightly, is,

3 you know, single data entry is very important.

4 **A.** The lack of intra-operability of medical 5 systems, whether it's between hospitals, whether it's 6 between hospitals and other agencies, whether it's 7 between general practice and hospitals, is an utter 8 disaster in this country. Utter disaster.

9 It's absurd that I have one system for my GP and 10 one system for my hospital and there is no communication 11 between the two. So that's just from a very personal 12 level.

So these things make a statistician or anyone
 involved in information despair because the whole point
 about, you know, the modern world is that you shouldn't

have to put in information twice. You know, we put itin one place and you should just be able to transfer it

to another one, now obviously with appropriate protocols

19 and privacy constraints and things like that.

But it doesn't surprise me but it's deeply depressing.

LADY JUSTICE THIRLWALL: Yes, thank you. And thank
 you also for the clarity of the explanations that you

24 have given us in the course of your evidence. I don't

25 have any more questions for you. Tempting as it would

1	be to invite you to develop some of the areas that you
2	say are you rightly say are outside your area of
3	expertise, but upon which I am sure we would be helped
4	in all sorts of aspects.
5	So thank you very much for coming today, I know
6	it's not been convenient and you've worked in a very
7	short timeframe in recent days, so renewed thanks for
8	that and if I may just add on a personal level thanks
9	also for all the reassurance and authoritative guidance
10	you gave us during the pandemic, when your voice was
11	very much more familiar, it was rather interesting to
12	see the voice and the person all in one place today so
13	renewed thanks for that and you are now free to go.
14	Thank you.

Thank you very much indeed.

16 LADY JUSTICE THIRLWALL: And we will rise now until

17 12 o'clock.

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(11.43 am) 18

19 (A short break)

20 (12.00 pm)

LADY JUSTICE THIRLWALL: Mr De La Poer. 21

22 MR DE LA POER: My Lady, our second witness for

today is Mr William Vineall, I wonder if he would like

to come forward, please. 24

LADY JUSTICE THIRLWALL: Would you like to come

1 Q. And which department did you join?

2 A. Department of Health.

3 Q. And have you been in the Department of Health

4 since that time?

5 Yes. I went out to a regional office for a year but that was actually at that time a part of the 6 7 Department of Health, so, yes.

8 In that time, have you been aware of a number 9 of Inquiries and investigations that have taken place into the functioning of the NHS, many of which were 10 11 critical of the circumstances that were found?

12 A. Yes, they were, yes, I have.

Q. In particular --

14 May I -- sorry, may I make -- I wanted to make a point of apology at the outset. May I do that just

15

before we get into the question? 16

17 Of course, but Mr Vineall may I apologise for

18 taking you into that before?

No, that is fine, I wanted to go into the 19 A. rubric.

20 So I just wanted to start by saying that on behalf 21

of the Department of Health and Social Care that we 23 fully endorse the apology that the previous Secretary of

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State made at the Inquiry last week on behalf of the

health system, and that the Department is indeed 25

1 forward, please, Mr Vineall.

2 MR WILLIAM VINEALL (sworn)

3 Questions by MR DE LA POER

4 LADY JUSTICE THIRLWALL: Do sit down.

MR DE LA POER: Please could you state your full 5

6 name?

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Α. William Graham Robert Vineall.

Q. Mr Vineall, is it correct that you have

9 provided to the Inquiry three witness statements, one

10 dated 5 April, the other the next 14 August, and the

third 30 August, all of last year? 11

> A. That's correct.

And is the content of those witness statements Q.

true to the best of your knowledge and belief? 14

A. 15 Yes, it is.

16 Q. Are you currently the director of NHS Quality

17 Safety and Investigations?

18 A. Yes.

19 Q. Have you held that role since 2020?

20 Α.

Q. 21 That's you as at today?

22 Α. That's right.

> Q. Let's go all the way back to the start of your

24 career, when did you join the Civil Service?

I joined the Civil Service in 1998.

1 ultimately responsible for the NHS insofar as there were

lessons not learned from Inquiries and systems not 2

3 followed through from policies that could have helped

4 potentially prevent part of this awful tragedy. 5

So I just wanted to say that at the start. On the subject of previous Inquiries, did you

7 in fact have a role in the Mid Staffordshire Public

8 Inquiry?

Yes. Not the Mid Staffordshire Public

Inquiry, I was the Secretary of the first Mid Staffs 10

11 Inquiry which was a non-statutory Inquiry. It wasn't,

like this, subject to the 2005 Act and that was 2009 to 12

13 '10 and it was into the functions of the hospital,

14 whereas the Public Inquiry was into the regulatory

structure around the hospital. 15

16 As we move forward through your career, what

position did you hold within the Department of Health 17

during the period 2015 to 2017? 18

19 2015 to '16 was the first year I was

a director and I was responsible for the CQC, I was 20

responsible for some investigations, principally 21

22 Morecambe Bay and the Jimmy Savile investigations at

23 that time and I was also responsible for professional

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25 What changed after 2016 which was when my post was 1 made substantive was I maintained the responsibility for

- 2 CQC and quality and safety, I had a sort of formal
- 3 expanded role for Inquiries and investigations across
- 4 the Department, excepting Covid, which I wasn't involved
- 5 in when it came, and I also took up responsibility for
- 6 maternity policy, which I had until 2023 and in 2021
- 7 I picked up the brief on health ethics and all those
- 8 kinds of things, and actually in 2016 I also took on the
- 9 litigation role.
- So I had -- 2015/16 I had a narrower role on
- 11 quality, safety and professional regulation. 2016
- 12 onwards I had a broader role, which was Inquiries,
- 13 litigation and patient safety that I still have,
- 14 maternity that I got then, and no longer have.
 - Q. Remaining with the theme of your knowledge and
- 16 understanding of Public Inquiries, I think you also gave
- 17 evidence to the Infected Blood Inquiry relatively
- 18 recently?

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- 19 A. I did. I gave evidence in May 2021 with the
- 20 Secretary of State at the time and I was particularly
- 21 giving evidence on the compensation -- not the
- 22 compensation, the payment arrangements that we had in
- 23 place then for people who were the victims of
- 24 Infected Blood and I was the lead official in this role
- 25 for the Infected Blood Inquiry since 2018, including up
 - 73
- 1 you can't give full closure, to the people who have been
 - the victims of the errors that are by and large under
- 3 discussion at Public Inquiries.
- 4 Q. We have talked in the generality there. We
- 5 will come back to that in due course. But just to tell
- 6 you where we are going today, there are 11 topics that
- 7 I want to ask you about, I will signpost them as we go.
- 8 The first is really a summary that we seek from you
- 9 about the DHSC's role and its relationship with NHS
- 10 England and in particular I think there have been some
- 11 developments that you speak about in your third
- 12 statement which bring us up to date.
 - So just in summary form what is the role of the
- 14 DHSC and what is its relationship with NHS England?
- 15 A. Yes. DHSC is a Government Department headed
- 16 up by the Secretary of State that makes policy and does
- 17 some other things, which I will come back to in
- 18 a minute.
- 19 NHS England is an arm's-length body of the
- 20 Department of Health and Social Care and is established
- 21 in statute with particular sets of roles and
- 22 responsibilities.
- 23 How does that break down into the practicalities?
- 24 The Secretary of State has a set of powers to provide
- 25 a comprehensive health service, to reduce inequalities

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- 1 til now.
- 2 Q. Would it be fair to say that you have a very
- 3 good understanding from all the various roles and
- 4 positions that you have held, including that as
- 5 a witness, of how Public Inquiries work and are supposed
- 6 to work?

7

- A. Yes.
- Q. Are you familiar in the sense that you have
- 9 heard it said, whether true or not is a different
- 10 matter, but are you familiar with the concern which
- 11 exists in some quarters that sometimes things don't get
- 12 done until a public servant is confronted with the idea
- 13 of having to give evidence at a Public Inquiry about
- 14 that topic?
- 15 A. Yes, I have heard that said. What do I think
- 16 of that? I don't think it's wholly untrue and I don't
- 17 think it's wholly true. What -- what is the purpose of
- 18 a Public Inquiry? It's to bring an external rigorous
- 19 focus beyond the confines of departmental structures to
- 20 issues that the Government considers are of significant
- 21 importance and particularly in a Public Inquiry to do it
- 22 in a way that is rigorous and is able to call people
- 23 substantively, whether they want to come or not and
- 24 I think in more recent years a good development, to try
- and give a sense of explanation and understanding, if
 - 74
 - to promote quality, all those sorts of things.
- 2 He takes that forward through -- through his
- 3 Department, through five main ways: us supporting him in
- 4 strategy, in direction, us being the accountable unit
- 5 back to Parliament for both expenditure through the
- 6 Permanent Secretary and in all of the accountability
- 7 functions that we help ministers discharge through their
- 8 accountability to Parliament debate speeches,
- 9 Parliamentary questions, all those sorts of things.
- 10 Then we have two other functions that are pretty
- unique to Government Departments, not just us: one is we do legislation and we do funding, so that is sort of one
- 13 point together; and then secondly obviously we deal
- 14 with, you know, unforeseen events that only a Government
- 15 Department can catch as a catch-all, say, something like
- 16 Covid or in my area when we changed the arrangements for
- 17 GP indemnity because they won't working four or five
- 18 years ago, and we did that.
- 19 NHS England by contrast -- or complementary, not by
- 20 contrast, it is by contrast but it is complementary --
- 21 has responsibility really for the day-to-day operation
- 22 of the NHS. How does it execute that? Through its
- 23 arrangements with Foundation Trusts and with NHS Trusts,
- 24 with ICBs, now that they exist since 2022, Integrated
- 25 Care Boards, and through the Integrated Care Boards the

various primary care practitioner contracts: GPs, dentists, optometrists and the like, which are contracted through the ICBs.

NHS England has some also has some pretty big practical functions that is it coheres on behalf of the NHS: one of them is all the mechanics of workforce; a second one is digital; a third one is education and training.

So if you take those two things together and the point I would like to end on is the togetherness, we are at the top end of the process with the policy and the strategy and the ministers and the big picture funding issues.

They are then taking those forward through the contracts and arrangements and the structures that they operate on our behalf and there's a meeting point in the middle which is roughly at the point of the mandate and the planning guidance where the two come together.

Obviously since 2012 we have been separate organisations, we were previously under one roof, we have been walking down a path towards greater co-ordination ever since and certainly our new set of ministers from July made it perfectly clear that we should be complementary and working in lockstep with one another so that a Policy and Strategy decision that we

1 patient safety.

And all of this will be published on the Inquiry website in due course so we don't need to go through it line by line but there are some that I would like to pick out with you.

A. Yes, sorry.

7 Q. The first is at your paragraph 121, which is
8 a -- and I am simply taking them in the order they
9 appear in your witness statement here, which is
10 a proposal as you set out there or a plan for a series
11 of statutory instruments in relation to professional
12 regulatory bodies. Do you see that?

Yes, I have got it, sorry.

Q. Now, the first thing bearing in mind that we have had a change of Government since then, is: is it still intended to roll out those statutory instruments or is that a matter which is under consideration?

A. No, it is, it is still the plan. And I was enquiring about this, or this general point before -- before I came here and the reform and changes to professional regulation have been quite a long time in the works, partly because it takes a lot of legislation to change all the different regulatory bodies, professional regulatory bodies.

But the Government does still plan, I think, to 79

1 may make at one end of the system translates to
2 an effective policy and hopefully improved health of the
3 individual receiving the care at the other end.

4 So it's one thing with a division and we work 5 together.

Q. And is there a physical co-location to --

A. No, there isn't. So NHS England are now
8 located at Wellington House at Waterloo and we are at
9 39 Victoria Street. In the previous pre-2012
10 arrangement we were, or at least headquarters of the NHS
11 was in the same building and, if you like, the
12 headquarters function the NHS is now separated. But to

be perfectly honest the thing has only been going in onedirection since 2012 which is to bring us closer

15 together so I don't think the geographic distinction is

16 significant.

Q. So that being, I am sure you would agree, very
much a thumbnail sketch of, or summary, as I invited you
to give, of the DHSC's role and its relationship with
NHS England.

I will move to my second topic, which is one that
you deal with in your first witness statement. It may
help you to turn it up, so if you could go to page 42 of
your first witness statement. This is under the heading
of improvements in patient safety or developments in

write fairly shortly setting out what its plans in thoseareas are, which are about greater consistency and some

3 modernisation of the arrangements. We have to make them

4 a bit more svelte and focused and consistent.

Q. You have said that is to:

"... modernise their workings and give them the powers and flexibility to make their systems fairer and faster and more effective in [the] public protection."

A. Yes

Q. Can you give us some examples of the sort of 11 changes that are likely to be brought in?

A. I can't give the examples in detail, but
13 I know that one of the things that has been in people's
14 minds from a long time is to have a broader consistency
15 of approach about how you handle things, you know, when
16 you are disciplining in professional regulation or when
17 you are bringing complaints to bear, because people get

wou are bringing complaints to bear, because people get different experiences through different sets of

organisations when they are ostensibly, you know, askingfor the same issue.

And we need to look at ways of making that, you know, both more consistent and more efficient.

Q. One of the matters that Dr Clamp gave evidenceabout --

A. Yes.

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Q. -- he being the Chief Exec of the PSA, was about the possibility of a shared Code of Conduct between professional regulators or at least a core that they shared with possible subsidiary codes specific to their profession.

Is that any part of these coming --

- **A.** I don't know of any specific plans about that and I think I would have thought that professional regulators, you know, are quite keen on having their own codes because it gives some distinction to their professional bodies which are very different.
- 12 **Q.** I think from Dr Clamp's perspective thinking
 13 about it at the patient end, which of course is the
 14 interest that the Department is able to represent, that
 15 knowing that the person you are dealing with is going to
 16 be subject to exactly the same standards which are all
 17 to be found in the same place --
- 18 **A.** Yes.

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- 19 **Q.** -- that everybody else that they deal with 20 are, may be helpful to the patient's experience of the 21 care they receive?
- 22 **A.** Yes, I think -- I think things to make 23 consistency of behaviours and experience for the 24 individual coming to the organisation is, is very 25 sensible. I don't think that has to absolutely

the changes?

- 2 Well, I don't know the details of that but 3 I would have thought that if there were any plans, we 4 would need to ensure, a bit like the argument with 5 manager regulation, that if you are going to make 6 changes they are appropriately supported so that people 7 can come up to the standards so there are not things 8 that they go in unsupported about and therefore can't 9 achieve because obviously the point of professional regulation, indeed any regulation, it's meant to be 10 11 a virtuous circle that both improves standards and makes 12 standards that the public can expect that much clearer.
- Q. So although you can't say sitting there that
 you know of such plans, does your evidence amount to
 this: such plans will be necessary as part of the
 rollout of this to make sure that everybody knows what
 the changes mean for them?
- A. I think you -- yes, I think you would have to
 look very carefully at the support you give to people if
 you are going to change what they are expected to do.
 - Q. Yes, and from whom should that support come?
- A. Well, it should probably come from the professional regulators themselves. I imagine the PSA would have some -- would want to have some input into that on the basis that they in a sense oversee

translate into an absolute commonality of rubric or codefor each of those organisations.

- 3 Q. I think it was not as between organisations,
 4 but as between -- I suppose it may be you are saying the
 5 same thing, but as between individual professionals so
 6 where you are treated by a team of nurses and doctors
 7 that the patient knows that there are certain things
 8 that each of those people, the language being identical,
 9 are bound to observe?
- A. I don't know of plans to draw that out
 specifically but I can entirely see the logic of what
 he's suggesting.
- Q. Well, it may be, and I know that bearing in
 mind there is a consultation what you can say on it is
 limited, but that will feed into also the idea that
 there is if there is a code for senior managers, that
 they too will be the subject --
- 18 A. There will be a consistency; I take your19 point.
- 20 Q. Exactly so.

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- So in terms of the roll-out of that statutory instrument or instruments, is there any planning in place for what training will accompany that in terms of how it will affect individual frontline staff and how members of staff will be informed about the effect of
- professional regulators and I think, you know, I imagine the Department would want to know that it was done in a sufficiently consistent and uncomplicated way and that it was useful for both the patients particularly and the professionals and that therefore --we will probably come on to it later -- you know, the likelihood of
- 8 **Q.** Whilst each of those professional regulators 9 may, and perhaps should, support their own membership in 10 terms of educating the public across the piece, does 11 ultimately responsibility lie with the Department given 12 the Department is bringing about this change?

an effective implementation was maximised at the outset.

- A. I don't think it doesn't -- I don't think it
 lies just with the Department. I mean, you said
 "ultimately". Because of course the professional
 regulators are independent organisations that are
 accountable to Parliament, they aren't directly
 accountable to us, you know, the GMC, 1861, pre-exists
 the health service by nearly 100 years.
- 20 So we always in our work with professional 21 regulators look for them to take the lead so we can 22 maximise the importance of independent, you know, 23 self-regulation.
- But at the same time, the Department would need to clearly have a role if we are going to be promulgating

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(21) Pages 81 - 84

these changes through a set of new policies.

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Continuing to your paragraph 123, which is just over the page, the duty of candour is one of those improvements in patient safety standards which you identify in a list of a number of such initiatives.

In relation to the duty of candour, is the Department aware of the concern which has emerged from some quarters in this Inquiry about the challenge of applying that to circumstances in which a person suspects deliberate harm?

Yes, we are and of course we were asked to do a consultation on our statutory duty of candour by the previous Government and we published the results of that last November under this Government in conjunction with a consultation on manager regulation and that showed that the duty of candour was working in places but was probably somewhat underwhelming in totality. And other people, you know, Lord Darzi said in his report that the NHS still struggles with the duty of candour, Judy Smith in her piece here said the duty of candour had made good progress but there was still more work to do.

And I think we would agree, and the Inquiry has probably shown, that there is still more we can do to popularise the duty of candour as it stands in addition to the potential extensions, you know, into management.

1 do so in particular circumstances.

- 2 Well, we will come back as a separate topic to Q. 3 that.
 - A. Yes.
 - Q. Remaining with your list. At paragraph 123d, you identify the fact that the first Patient Safety Commissioner was established in 2022. My question about this is, as you acknowledge that role is limited to the safety of medicines and medicinal devices, is there any consideration being given to extending that remit?
- 10 Well, it more or less has been extended 12 because the logic of the position and the need for the 13 role to expand has become fairly apparently fairly 14 quickly. It was done for medical and medical devices because we wanted to put it in legislation and the piece 15 of legislation going through was about medical devices 16 17 so there was a degree of pragmatism in 2020, it was, you know, at the height of Covid and there wasn't that much 18 legislation going through Parliament, but that was to 19 sort of straighten medicines up, having left the EU. And obviously one of the things that Henrietta Hughes
- 20
- 21
- 22 has done in her two plus years in the post has been to
- 23 look at things like redress in the case of sodium
- 24 valporate and mesh and to make the case for the fact
- that speaking up is a virtue not just because you should

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Q. The issue that I would like you to consider 1

though is not just about the visibility and application

3 but whether or not guidance is required to help people

4 in that very particular circumstance of where they

suspect deliberate harm and whether the duty of candour 5

6 does or doesn't apply and if it does, at what point.

7 Because of the peculiarly --

> A. Yes.

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9 Q. -- and distressing act of telling a family

10 member or perhaps a patient that there is such a suspicion when such a suspicion may be resolved into 11

nothing? 12

13 Well, duty of candour does apply but obviously Α.

in extreme situations is there a case where you need to 14

give it further bolstering? I mean obviously one of the 15

16 things we have done and that we have published before

17 Christmas was the memorandum of understanding in 18 relation to the Williams Review about if you feel that

19 you need to go to the police because it's not just

20 a normal duty of candour, I didn't quite explain the

21 thing properly, but it's something more significant, 22 that that memorandum of understanding, one, offers

23 a process to do that; but probably more importantly, and

the point that you are getting at, gives people 24

an authority to do that if they feel that they need to

be able to hear what patients have got to say but

because what patients have got to say can also 2

3 contribute to the quality of the health services.

4 And she is the person in a sense on behalf of the 5 Department and NHS England who's taken forward all the 6 work on Martha's Rule which is, as you know, being able

7 to go for not a second opinion but a further doctor 8 review if you see signs of deterioration.

9 So that role has already extended and I think has

10 proved popular with the people who have been able to 11 benefit from it and obviously it amplifies the patient voice and it is a consistent presence that is able to 12 13 make those points.

14 Does anything in your view need to be done to 15 regularise the situation to make clear that the role is more expansive than it was originally specified to be? 16

17 I would say no because everybody's fairly aware of the fact, is what I would say. 18

LADY JUSTICE THIRLWALL: Does she have more 19 20 resources as a result of this --

21 She doesn't have more resources; she has the Α. 22 same resources.

23 LADY JUSTICE THIRLWALL: Same resources. Are there 24 any plans to increase those?

There aren't at the moment, no.

LADY JUSTICE THIRLWALL: So does that mean she is doing more for the same -- with the same resources?

She is doing more and different I would say. LADY JUSTICE THIRLWALL: But it is the more that I am particularly interested in.

She is doing as much as she can, that is what I would say.

LADY JUSTICE THIRLWALL: Yes.

MR DE LA POER: Now, at your paragraph 124, you deal with the NHS Patient Safety Strategy which you identify as being led by the NHSE.

A. Yes.

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13 Q. Could you just briefly give us a summary of what this is as a springboard to just a couple of questions that I am going to ask you about it? 15

16 Yes, well, I mean, over and above the 17 initiatives that the Department has taken forward, you know, the science of patient safety and the challenge to 18 19 reduce avoidable harm is effectively what's encapsulated 20 in the Patient Safety Strategy and in a sense that is 21 why it is a lead of the NHS, not the Department, because 22 it is about the on-the-ground improvements in patient 23 safety and trying to quantify the harms avoided and potentially the resources saved as a result of improved 24 systems and improved awareness and heightened powers of

1 them in the handling of those events. And it came out 2 in 2019 it replaced a strategy that went back to 3 something like 2012 and going back to my kind of 4 division of labour point, it is the principal tool by 5 which NHS England pursues patient safety on the ground 6 on a day-to-day basis over and above any other 7 initiatives that might be taking place.

Does the Department have any oversight over the success or otherwise of that programme?

Yes, I mean we sit on the National Patient

Safety Committee which is a committee like we have got 11 12 for all sorts of other things which is where you bring experts together and NHS England and people from the 13 14 Department and although we haven't had any formal read-out of the progress of this, which really, you 15

know, the old systems were switched off I think last 16

17 April, so we have only had the new system fully in place

for a short period of time, but I was at a presentation 18

before Christmas where it was very, it was very clear to 19

20 me that the new systems were working and particularly

the PSEF was very popular with staff because it allowed 21

22 them to focus on the things that were most important

23 with a degree of flexibility but the same amount of

24 accountability rather than in the old system where you

often had to investigate the same incident multiple

1 investigation and a greater degree of openness in terms 2 of discussing errors.

3 And obviously the components of the Patient Safety 4 Strategy are effectively safety alerts, a syllabus, safety champions, so some of the infrastructure, and two 5

6 significant changes that have been going on and are now

virtually complete, which is the Learning from Patient Safety Events, which is the replacement for the two

systems, NICE and STEIS, that they used to have for 9

10 collecting patient safety data and that's been taken

forward in line with having a more sophisticated way of 11

being able to analyse large amounts of data because you 12 have system learning rather than just having a group of

people who are able to analyse a cut of the data which

is what you would have done in a sense 15 years ago when 15

16 this started.

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17 And then the Patient Safety Incident Response

18 Framework, I know there is a lot of acronyms here,

19 replaces the Serious Incident Framework which is how do

20 you handle the most serious incidents and gives a degree

21 of flexibility to the people on the frontline to be

22 proportionate in how they respond to those events,

23 number one, and number two puts an onus very much on

engaging with patients and involving them and 24

understanding what their concerns are and learning from

1 times with nugatory amounts of learning.

2 In terms of the Learn From Patient Safety

Events part of that strategy, and this is a level of

4 detail, albeit an important level of detail, do you know

whether or not that integrates seamlessly with the

6 National Neonatal Audit Programme?

7 I don't know the answer to that. I expect it 8 probably doesn't entirely, and I was aware I have been 9 told that my predecessor here this morning was saying 10 that we have a question to address about how different 11 databases speak to each other. I imagine -- well, LFPSE 12 is going to be oracular of all patient safety incidents

13 and the other programme that you mentioned is probably

14 more specific to a certain number of maternity

incidents, but I can't describe the precise 15

interrelationship. 16

LADY JUSTICE THIRLWALL: Sorry, Mr De La Poer.

Just so you understand, we did have some evidence 18

I think about two weeks ago about the fact that 19

20 different systems don't speak to each other. I -- I was

simply asking whether Professor Spiegelhalter was aware 21

22 of that and he described it as "very disappointing"

23 which one can understand, so just so you know the

24 context.

> A. Yes. No, I mean it was Marian Knight he was

1 talking about, wasn't he?

2 LADY JUSTICE THIRLWALL: That's right, yes.

A. And MBRRACE and MOSS and how they relate.

LADY JUSTICE THIRLWALL: Yes.

5 **MR DE LA POER:** I mean, is that a problem that the

Department recognises as being a real and pressing one?

A. Yes, I think the Department recognises that we

can always do more to integrate systems and information

9 such that the right information is available but you

10 know the burden is, is, is reduced wherever possible in

11 terms of collection. And obviously, I mean, LFPSE and

12 PSIRF have been examples of trying to have much more

13 systematic arrangements that take advantage of

14 technology rather than the old much more paper-based

15 systems.

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16 Q. Is there a plan that you are aware of to make

17 sure that all of those legacy systems that are

18 continuing to operate are going to be completely

19 integrated, so in other words --

A. I don't -- I don't have any knowledge of an

21 overarching plan to do that.

Q. Well, ought there to be such a plan?

A. I'm not sure if there ought to be a plan but

24 we could always look more carefully at those issues.

Q. Doesn't it require quite a systematic approach

1 further at this time.

2 LADY JUSTICE THIRLWALL: Leaving aside whether you

3 can commit to anything, just so that I am clear, there

4 is at the moment no plan and no intention to seek to

5 integrate systems?

6 A. There is no plan that I am aware of.

LADY JUSTICE THIRLWALL: Well, you would likely

8 know, wouldn't you, if there was one?

A. Yes.

10 LADY JUSTICE THIRLWALL: Yes. And no intention to

11 have such a plan?

12 A. I don't know about intention. I only know

13 that I am not aware of a plan at the moment. So I mean,

14 I -- I don't know.

15 LADY JUSTICE THIRLWALL: All right. Thank you.

MR DE LA POER: Martha's Rule is a development

17 which you deal with in your third witness statement,

18 again remaining with my topic 2 of developments at

19 paragraph 11, you touch upon it.

20 Part of this initiative envisages the opportunity

21 for a second opinion for patients --

22 **A.** Yes.

Q. -- put crudely.

24 Are you aware of any steps being taken by the

25 Department or NHS England to ensure that in the case of

1 where you identify every single legacy system, you make

2 an assessment of how well it integrates and then you

3 take software steps to make sure that the two speak to

4 each or --

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A. It would do and that would be something

6 predominantly for NHS England because they are

responsible for the digital arrangements in the NHS.

8 Q. But from the Department's point of view that

9 is an objective that you would regard as being

10 an important one?

A. I think it's always an important one. But

12 I don't know of current plans about it, so I can't

13 commit us to any further activity than saying I think

14 it's an important issue.

Q. And a question for NHS England, you would say?

16 **A.** I think the practicalities would be a question

17 for NHS England. They would probably say there is

18 a question of overall strategy for us as well. So it

19 might go both ways.

20 Q. Well, how is this Inquiry to resolve that if

21 each side is or potentially, and I appreciate we aren't

22 heard what NHS England say on this to ensure that what

23 needs to be done is done?

24 A. Well, as I have said, it is an important point

5 for consideration, but I can't commit to anything

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1 paediatrics there are sufficient paediatric staff to be

2 able to operate in that second capacity?

A. No, I am not aware of anything specifically in

relation to Martha's Rule that specifically focuses on

paediatric staffing numbers.

6 Q. For it to be effective, would you agree there

7 needs to be confidence that there are sufficient staff

to perform that secondary function if required?

9 A. Yes, I think that would be true for most sets

10 of services. But I think Martha's Rule is about

11 changing attitudes and having a system that enables

12 large, larger numbers of people to come forward and ask

13 for another view if necessary and I certainly know that

14 from the most recent data from the last couple of months

15 there were around about 500, 600 instances where people

16 came forward and about three-quarters of those came from

17 families or advocates or family members.

18 So I think although those numbers in the world

19 picture of the number of patients the NHS sees are

20 small, I think it demonstrates the proof of concept and

21 that there will be some good learning to come from

22 Martha's Rule.

23 Q. National Neonatal Safety Champion, are you

24 aware?

25 A. Sorry, can you just say that again?

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- Q. The National Neonatal Safety Champion?
- 2 A. Yes, yes.

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- 3 Q. Part of your preparation included an extract
 - from the RCPCH President's witness statement?
 - A. Yes
- 6 Q. Where she identifies that a National Neonatal
 - Safety Champion is something that both the RCPCH and
- 8 BAPM, a perinatal charity, or organisation rather, have
- 9 been calling for. Is the implementation of a National
- 10 Neonatal Safety Champion something that is in
- 11 contemplation or development?
 - A. My understanding is that advice is going to go
- 13 to ministers shortly.
- 14 Q. Finally on the topic of changes, although some
- 15 of these will be matters of detailed questioning in due
- 16 course. Can you identify any change which is specific
- 17 in the last decade to changing the culture? So here we
- 18 are not talking about reports that identify that culture
- 19 is a problem; we are talking about practical initiatives
- 20 which are aimed at changing culture?
- 21 A. Well, I think there's a number of initiatives
- 22 that have had culture as part of what they have tried to
- 23 achieve. Part of the reason why we introduced the duty
- 24 of candour was to encourage greater openness, we have
- 25 talked about that.

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- 1 boards operating in an open way and boards that are
- 2 curious and boards that are -- that listen to patient
- 3 experience and have both the facts that we were just
- 4 talking about, PSIRF and LFPSE, and some of the stories
- 5 at their disposal so that you get open organisations and
- 6 not closed organisations.
- Q. My third topic, likely to be my most
- 8 substantial, is memorandum between the police and NHS
- 9 bodies.
- 10 **A.** Yes
- 11 Q. And you deal with this in your second
- 12 statement --
- 13 A. Yes.
- 14 Q. -- Starting at paragraph 3.
- 15 **A.** Yes
- 16 Q. And in providing the context for the
- 17 development of the first memorandum of understanding, if
- 18 I can term it that?
- 19 **A.** Yes.
- 20 Q. You start with the date of 2000 and the expert
- 21 group chaired by the then chief Medical Officer Sir Liam
- 22 Donaldson and the report published at that time, the
- 23 title of which was "An organisation with a memory:
- 24 Report of an expert group on learning from adverse
- 25 events in the NHS."

I think it's working. I think it's fair to say it

- probably isn't working as quickly as we'd like and that
- 3 is what -- the gist of other evidence. The reason why
- 4 we introduced the Health Services Safety Investigation
- 5 Branch was to try and encourage a culture of openness
- branon was to try and encourage a culture of openiness
- 6 where people could come forward and speak up about
- 7 patient safety issues and could do it in the confidence
- 8 of a safe space and obviously, you know, throughout the
- 9 work of the CQC since 2014, you know, the question of
- 10 being safe and responsive and Well-Led has been trying
- 11 to encourage people to speak up.
 - And obviously in response to the Robert Francis
- 13 Report in 2015, we introduced the Freedom to Speak Up
- 14 Guardian and the series of National Guardians which are
- 15 advisory and facilitation roles across the NHS and in
- 16 NHS Trusts that try and encourage a culture of speaking
- 17 up if people otherwise feel nervous and give people
- 18 advice and try to ensure that the ability to speak up
- 19 per se doesn't come into conflict with any of the other
- 20 systems that are, you know, around in the NHS.
 - So we have had -- probably not all of them, but we
- 22 have had quite a lot of significant and major
- 23 initiatives and I suppose over and above that, you know,
- 24 there have been you know regular statements by, you
- 25 know, successive ministers about the importance of

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- A. Yes.
- 2 Q. So that's the origin of the first MOU; is that
- 3 correct?
- 4 A. Yes, that's right. I mean, you know the kind
- 5 of modern patient safety movement really sort of dates
- 6 from the turn of the century because we became aware of
- 7 systems in other organisations, including aviation, that
- 8 were just, I mean, to cut a long story short, were more
- 9 systemic about handling and learning from their mistakes
- 10 and part of their process of doing that was they were
- 11 more open about them when they happened and I think it's
- 12 fair to say that wasn't the culture or the system in the
- 13 NHS.
- 14 And Liam, when he was the Chief Medical Officer,
- 15 really spearheaded all of these moves and obviously was
- 16 encouraged by, you know, some of the hospitals in
- 17 America that were doing sort of cutting edge work on
- 18 that. And "An organisation with a memory" was the first
- time we tried to get to an acknowledgement of how can webetter catch both facts, fact and stories and the
- 21 information about things that had gone wrong to make
- 21 Information about things that had gone wrong to h
- 22 things go right in the future.
- 23 And therefore this memorandum of understanding,
- 24 although it didn't come out until 2006, was in a sense
 - one of the things around about that time that was being

produced. The National Patient Safety Agency that I was 1 2 talking about before dates from about that time.

So that was the contextual source.

So let's bring up that MOU, INQ0014686.

If we go to page 2., we can see what is said in the foreword:

"As a result, the police and HSE may conduct initial investigations into matters of concern reported to them and the threshold for taking these forward is usually set at a high level."

11 So it's the fourth paragraph.

> A. Yes.

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Q. "This means that such an investigation should take place only when there is clear evidence of a criminal offence having been committed or where a breach of health and safety requirements is the likely cause or significant contributory factor."

So that is the foreword. If we then move forward to page 5, please. We can see paragraph 1. Again I will just read it into the record, it's not a document the Inquiry has looked at in any detail before:

21 22 "NHS patient safety incidents involving unexpected 23 deaths or serious untoward harm and requiring investigation by the police and/or the HSE are rare. 24 25 However, there has been an increase in the number

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And I'd just simply bookmark for the time being what's said there about sharing information and timely discussions are essential ingredients according to this MOU.

If we then move forward to page 7 of the document, we can see that guidelines are referred to. Pausing there for a moment, Mr Vineall, you can confirm that accompanying this document was a set of guidelines and we are going to have a look at that in just a moment?

A.

11 O. We won't come to it just yet, but that's again just a call forward to a document we are going to look 12 13 at in a moment.

If we then move forward to page 11, please. We can see "Patient safety incidents that may involve the police or the police and HSE" is the heading.

About a quarter of the way down at 2.7:

17 18 "The types of patient safety incident that may prompt an NHS Trust to involve the police are those that 19 20 display one or more of the following characteristics: evidence or suspicion that the actions leading to harm 21 22 were intended, evidence or suspicion that adverse 23 consequences were intended, evidence or suspicion of 24 gross negligence and/or recklessness in a serious safety incident including as a result of failure to follow safe 25 103

reported in the past few years. Such incidents must be 1 2 handled correctly both for the sake of the public's safety as well as confidence in the NHS, police and HSE 3 4 and in the interests of fairness and justice."

So that is the start of the introduction.

5 6 If we look to paragraph 2, we can see that the 7 first in the list of things that is are said to be important and need to be ensured is public and patient 8 safety is assured. Again you will forgive me, 9 10 Mr Vineall, if I just identify each of these before we 11 come to a question.

12 A. Yes.

> Q. Page 6, paragraph 3, we can see that:

13 14 "To achieve these objectives it's important the 15 three organisations communicate and work with one 16 another in a consistent and well-coordinated manner. 17 This will include informed decision-making about those 18 incidents that require investigation by the police 19 and/or HSE, appropriate discussion and continued 20 attention to the matter of safety. Sharing information and timely discussion are essential ingredients for such 21 22 outcome. Both need to be conducted in a way that do not

23 impede the statutory responsibilities and duties of the

three organisations or the Coroner or jeopardise any 24

legal proceedings."

102

1 practice or procedural protocols."

2 So I have read the whole paragraph including all 3 three bullet points. But the language, would you agree, 4 in this document is talking about evidence or suspicion 5 as being a threshold for the involvement of the police?

> Α. Yes.

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7 Then if we move forward please to page 19, we 8 can see -- and we don't need to read all of this -- but there are a number of paragraphs devoted to the 9 importance of securing and preserving evidence which, as 10 11 a matter of common sense, would you agree, ties back to 12 the importance of timely contact and communication as 13 one of the consequences of such timely contact is 14 evidence can be secured and preserved?

Α.

16 Q. So that's the MOU as at 2006. Let's turn now 17 to the guidelines which I think were published some months later in November 2006. 18

19 A. Yes

20 Q. These are at INQ0107019 and we see that it's 21 expressed as being in support of the document that we 22 have just had a look at.

23 Now, this is just a Department of Health, as it was 24 then, document. So whereas the other was an agreement

between a number of organisations this is in effect 25

- 1 internal guidance to the NHS?
- 2 A. Yes, it's the handbook.
- 3 Q. For how, the how?
 - A. Yes.

- 5 Q. So look at page 4, please. We can see that
- 6 the aim is stated there; that this is:
- 7 "... to provide practical advice to NHS
- 8 organisations about what to do when faced with a patient
- 9 safety incident or incidents that may require
- 10 investigation by the police or HSE.
- 11 And again that just to note that theme of
- 12 preserving and safeguarding evidence is one in the list
- 13 which falls beneath that.
- 14 If we move forward please to page 8 of the
- 15 document. We will see at paragraph 17 at the bottom
- 16 under the heading, "Making a referral to the police
- 17 and/or HSE: "
- 18 "There will be occasions when the NHS will need to
- 19 refer matters to the police. NHS organisations may need
- 20 to consider whether a safety incident should be reported
- 21 to the police and/or HSE. In these circumstances it is
- 22 best practice to make early contact with the police
- 23 and/or HSE to discuss concerns and to take their advice
- 24 on further [if we just go over the page, thank you]
- 25 action. The NHS organisations risk management or
 - 105
- 1 warrant a police investigation. This decision should be
 - taken by an appropriately senior person preferably at
- 3 Executive level in the organisation."
- 4 So again we see that the threshold, as expressed in
- 5 this practical guidance, is seriousness and suspected
- 6 criminal intent?

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- A. Yes
- 8 Q. Now let's just see how that is expressed in
- 9 example terms. So we go to page 10, please. We have
- 10 the first of a number of case studies and we are going
- 11 to look at number 1 and number 2. Now, I will just
- 12 pause to leave this on the screen. I am not going to
- 13 read it out.
- 14 But, in summary, if we go over the page to page 11,
- 15 thank you very much indeed, we can see that there was
- 16 a concern in this example about equipment and, in
- 17 particular using the language of the example we see at
- 18 the top of the box, in the lower half of the screen, the
- 19 second sentence:
- 20 "It was unusual for suction units to be out of
- 21 order so the possibility that someone had tampered with
- 22 them was considered. The ward manager contacted the
- 23 senior manager and risk manager. After discussion with
- 24 the Clinical Director they called the police."
- 25 So in this example, there is a suspicion based on 107

- 1 equivalent person with risk management responsibility
- 2 with the agreement of the Chief Executive or
- 3 nominated representative should take responsibility for
- 4 ensuring that this advice is sought and, if necessary,
- 5 a referral made."
- 6 So again just pausing to note what people are being
- 7 told in a practical sense: that effectively, do you
- 8 agree, what this paragraph is saying is if you are not
- 9 sure speak to the police to take advice before you
- 10 formally refer anything?
- 11 **A.** Yes.
- 12 Q. Again, would you agree that that serves the
- 13 objective that we have already looked at of ensuring
- 14 that evidence is preserved and that the contact is
- 15 timely?
- 16 A. Yes. If in doubt speak to the police and if
- 17 you do so, hold on to any relevant evidence.
- 18 Q. Exactly. Finally, paragraph 18 in terms of
- 19 the text of the guidance and then we will look at two
- 20 case studies:
- 21 "It is impossible to present a comprehensive list
- 22 of examples that may prompt an NHS organisation to
- 23 consider a referral. Most incidents are investigated by
- 24 the NHS. Therefore, circumstances should be
- 25 sufficiently serious and criminal intent suspected to
 - 10
 - a possibility, effectively of an unusual event in the
- 2 context of a serious outcome that led to internal
- 3 discussion and the police were contacted.
- 4 So that's example 1. Do you agree that is a fair
- 5 summary of the substance of it?
 - A. Yes.

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- 7 Q. If we look at example 2, which is on page 15,
- 8 we can see here, thank you very much indeed, the concern
- 9 here is following a patient being found deceased and
- 10 a syringe attached to his intravenous line, that
- 11 although there was a history of taking overdoses given
- 12 that it was considered by the staff as a scene
- 13 effectively, following discussion, the Trust board lead
- for patient safety and the crash team contacted thepolice, and police then came in and the incident was
- 16 resolved. As we can see in the bottom box, "Police
- 47 desided as feed about
- 17 decided no foul play".
- But again on the incident we have here an unusual
- 19 event, albeit that there was a context that might
- 20 explain it, a concern, the police were brought in?
 - A. Yes

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- 22 **Q.** Again, fair summary?
- 23 A. Yes. But not -- not with a role for the
- 24 equipment like the first example.
 - Q. I beg your pardon?
 - 108

A. But not with a role for the equipment like the first example.

Q. No. The final case study for us to look at is on page 24. Again just to highlight this. This is a different sort of circumstance. This is a concern about a patient who wasn't responding correctly.

We can see that there was some investigation into equipment and there was discovered to be a particular problem with the equipment that, as a result of that, the Coroner was notified and in fact in the example the Coroner reported it to the police because of the similarity between that and other cases. So not a case in which the police were directly contacted but a case in which similarity identified by the Coroner resulted in the police being called?

A. (Nods)

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Q. So those are the matters that I would like to look at in this document.

If we just return to what you say about how the roll-out of this occurred and you deal with that in paragraph 10 of your second statement. Thank you very much indeed, we can take that document down.

You tell us that it was launched with a training programme which was delivered at a regional level and which was about encouraging good relationships between 109

about needing to contact the police, that as at that point in time there wasn't in fact any guidance for them to turn to?

A. I think that's right. I mean there is no -it's clear that some people were still using the
document, so it was existing in places in the NHS. But
the fact that it had been archived meant it wasn't
a live document at the time because of the decision that
had been made to archive it and therefore the Williams
recommendation to reintroduce it.

Q. And having reviewed it together there, do you agree that had it been a live document or there been an equivalent in similar terms, that would have been a useful thing for people in the position of those in the Countess of Chester?

A. I think it would have been useful. I don't think it's the only thing you needed.

People have the ability, if they think there is a significant problem, to go to the police and as you know the ex-policeman Mr Wenham said, you know, in evidence here, you know, people can pick up the phone and go to the police.

23 So whilst I agree with you that there wasn't an MOU
24 that people could immediately turn to, I don't think
25 that stopped people approaching the police in the normal
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1 police and their NHS Trusts; is that right?

A. Yes.

Q. Then as we move forward in time, what you say
in your witness statement is that there came a point
when it was archived. I mean, do you know, sitting
there, exactly why it was archived?

7 No, I don't sitting here know exactly why it was archived. I don't know that. My more than 8 9 speculation but less than absolute certainty is that 10 there were a lot of documents where the organisations that they were addressed to ceased to exist when we had 11 the 2012 changes because it was a wholesale change and 12 that some documents, as we have said here, therefore got 13 archived and the archiving, you know -- there is no 14 evidence that there was a positive decision, that's what 15 16 we say at the top of paragraph 12, to do the archiving.

So it may be that it was an oversight because people thought given that we don't have PCTs and Strategic Health Authorities and all the other things that it had been addressed to, that it was archived as a result.

Q. And does that mean that it meant that as far as the people on the frontline and their managers were concerned, that when we reach 2016 and clinicians within the Countess of Chester are raising with senior managers

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1 course of events.

2 Q. Well, whilst of course they can do that, where as may be found to be the case there is a dispute 4 between people within the hospital about whether the 5 threshold had been reached, having something in writing 6 that has come from the Department or from NHS England 7 saying in terms: This is an example of where calling 8 the police is perfectly acceptable, this is where you 9 have a suspicion or evidence, contact the police early ... Those are just the sort of documents that 10 11 will be useful in breaking such a deadlock because each 12 party can look at them and those in favour can say: 13 Look at this. We ought to do this?

14 **A.** Yes, I think they certainly contribute to 15 breaking what you describe as a deadlock. I also think 16 that they're useful because they give people authority 17 to act.

But I do want to reiterate that I don't think they
stop people from going to the police anyway and I think
our expectation of a decently operating organisation was
if they had a significant doubt about whether or not to
go to the police then they should go to the police.

MR DE LA POER: Well, we will fill in the history and then bring ourselves right up to date but perhaps, my Lady, after the lunch break.

LADY JUSTICE THIRLWALL: Very good. So we will adjourn now and start again at 2 o'clock. (1.02 pm)

(The luncheon adjournment)

5 (2.00 pm)

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LADY JUSTICE THIRLWALL: Yes.

MR DE LA POER: Mr Vineall, we have moved to the point in our chronology in relation to this MOU to 2018.

A. Yes.

When Professor Sir Norman Williams reported 10 Q. under the heading "gross Negligence Manslaughter in 11

healthcare" and I will ask for that document to come up 12

on your screen, INQ0002383. You see it's dated 13

June 2018 and if we move forward, please, to page 25, 14

our focus will be on paragraph 9.13 initially. So there 15

16 we see what Professor Williams says is the principles of

17 this MOU, referring to the document in the preceding

paragraph, which is the one that has been archived, and 18

19 the relationship that is set out between police

20 investigations and local safety investigations is as

21 relevant today it was in 2006. However, the MOU has not

22 been renewed since the demise of ACPO in 2015. The

23 panel believes that a similar MOU should be developed to

set out the respective roles of the police, CPS, HSE and 24

health service bodies such as the CQC and HSSIB, as they

there is an investigation: following the Williams review a new MOU is being developed to replace the 2006 protocol."

So that's the only mention of it in your first statement, namely that work is in train.

So turning then to some questions about this. Why, given that the recommendation was in June of 2018, was there no new protocol at the time that you were giving your statement in early 2024?

Well, the simple answer is it hadn't been finished and the more longer considered answer is that we could and should have done it sooner. We did have Covid and it did prove more complex to agree than I think anybody had expected at the outset.

But it wasn't ready at that time and it was still in train in April and it was being developed.

So just help us to understand that a bit further. Do you know when after Professor Williams' report somebody first sat down and began to work on this, was it immediately or was it not until 2024?

21 No, I couldn't tell you when but I am pretty 22 sure that some work started before Covid, not in a huge 23 amount of detail but there were some, some startings and 24 then it stopped and then it picked up in earnest 25 afterwards.

were, and healthcare professional regulators in 1

2 investigating unexpected deaths in the healthcare

setting in order to ensure that patient safety lessons 3

4 can be understood and acted upon.

5 If we then go over the page, we see the third

6 bullet point that a new memorandum is one of

Professor Williams' recommendations. 7

8 So that is June of 2018, so thank you, we can take

that down. Now, Professor Williams' work was something 9

10 that was mentioned in your first witness statement.

Paragraph 105 -- forgive me, page 105 you will need to 11

12 turn to.

13 Α. Yes.

14 Q. And we will see it appears on the preceding page under "Update on key recommendations" and what you 15

16 say in this statement which was dated in the spring of

17 last year --

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Α. Which page am I on, or paragraph?

19 Q. Page 105. The paragraph is paragraph 24d, it

20 is the final --

> A. Yes, got you.

22 Q. -- subparagraph on page 105?

23 Α. Yes.

24 Q. What you say is:

25 "Arrangements between the NHS, police and CPS when 114

And the highly publicised circumstances around Letby's trial, it would appear, were insufficient by way

3 of catalyst to finish that?

4 I wouldn't say they were insufficient catalyst to finish it, I would say that work was ongoing and it

6 was finished in an expeditious way but as I said at the

7 start, it took some time.

> Q. So in an expeditious way?

9 Α.

10 Q. Why do you say it was finished in an

11 expeditious way?

Because we did it as quickly as we could 12 recognising that we had had Covid and we had the 13 14 complexity and then we tried to get it completed and we 15 did get it completed, you know, at the end of last year.

16 So when was the -- well, help us just to

17 understand the process, given that you say it was done

as expeditiously, was it written by somebody within the 18

Department and then sent out to individual signatories 19

20 for their comments?

21 That happened on a number of different Α. 22 occasions because there was a lot of toing and froing 23 between the various parties is my understanding. It was

24 a document that the Department finally produced but

there was a committee. It took some time in the way of

these things to get responses from some people to what were complicated issues and to pull everything together.

And, and it was completed, as I say, at the end of last year and then published quickly.

- 17 December of last year?
- A. That's right.
- 7 Q. So approximately 20 days before you came to
- 8 give your evidence?

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- A. Yes, yes.
- 10 And we are going to have a look at that
- document now, as you say, it deals with some complicated 11
- issues but it isn't a very long document, is it? 12
- 13 A. No.
- 14 Q. And I would just like for us to bear in mind
- what you say about expeditious as we consider it, 15
- 16 INQ0108740. So it appears in this way because it's
- 17 a document available online, isn't it?
- 18 A. That's right.
- 19 I am sure there is a pdf version of it but
- 20 this is effectively extracted from the online version
- which is why it appears to read as a webpage. We can 21
- 22 see the date of publication. And just speaking in
- 23 general terms, it is very similar in a number of
- 24 respects to the 2006 MOI; is that right?
- 25 Yes, it is.

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- 1 So let's move forward to page 6 and we can see 2 there that at paragraph 2.3 the recommendations of 3 Professor Sir Norman Williams are set out as being 4 effectively the history of this document, so recorded 5 there.
 - Is there any reason why the fact that there was effectively no MOU for a period of time not recorded here because I just invite you to consider this and comment on it, an uninformed reader may think reading that that there was an MOU in 2006 that that subsisted, Professor Williams made the recommendation that he did and the new MOU came out and not included within that history is the fact that there was a period of time when
- 15 Well, I don't think that's a deliberate exclusion and obviously if you read the Williams Review 16 17 it's very clear that there hadn't been anything since the archiving in 2015. 18
- 19 So let's turn to the substance of what this 20 says. Can we move forward please, to page 7. We can 21 see at the bottom section 4:

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22 "When the MOU applies.

there was no MOU?

- 23 "The MOU applies when more than one of the
- 24 signatories needs to investigate in parallel any
- incident where there is reasonable suspicion that 25

- Q. Would you say that it contains any major 1 2 innovation or improvement over that 2006 MOU?
- 3 I'm not sure it contains particular
- 4 innovations. I think it's an improvement because it is
- up to date on the side of the NHS in particular with the 5
- 6 different structures. The one in 2006 had heavy
- 7 reference to the Health and Safety Executive who in
- a sense were a sort of backstop function for
- 9 investigations into matters in the NHS at the time
- 10 whereas when we get to 2024 we have got CQC and HSSIB
- and other organisations, so I think there are some 11
- pretty significant changes to the infrastructure that 12
- 13 needed to be reflected in what we said.
- 14 I think some of the language about learning and 15 speaking up is obviously with the benefit of the
- 16 knowledge of the intervening 18 years. But I mean the
- 17 original recommendation of, of the Williams Review was
- to I don't know if they use the word "replace", but was 18
- 19 effectively to replace and update what had preceded.
- 20 So I think it's fair to say that the structure and
- 21 the purpose aren't vastly different. But I think
- 22 there's a reasonable amount of the detail that means it
- 23 is a considerably more useful document in terms of the
- 24 advice and the facts and the structure that it explains
- than if we had still had the 2006 version.

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- a criminal offence has or may have been committed by an
 - 2 individual providing healthcare services in a health or
 - 3 care setting that leads to or significantly contributes
 - 4 to the death or serious life-changing harm of a patient
 - 5 or service user."
 - 6 So just to flag at this stage one particular phrase
 - 7 that we are going to come back to. If we go to the
 - 8 preceding page just to look at it, you will see that the
 - phrase "reasonable suspicion" is used as being a trigger 9
 - for when the circumstances apply or when the MOU 10
 - 11 applies. So let's just have a look and see paragraph
 - 12 4.5, which is back on the next page.
 - Here would you agree that this is addressed to the
 - 14 NHS organisation and its state of mind?
 - A.

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- 16 Q. "It may not be immediately clear following the
- 17 incidents that a criminal offence may have been
- committed. The types of incidents that may prompt an 18
- NHS organisation to involve the police are those that 19
- display one or more the following characteristics: 20
- reasonable suspicion that the actions leading to harm 21
- 22 were intended to cause harm or reasonable suspicion of
- 23 gross negligence and/or recklessness."
- 24 So do you agree we again see that threshold state 25

of mind as being reasonable suspicion?

- **A.** Yes and it's, it's a prompt for people in those circumstances to be curious.
- Q. So just focusing on the language of
 paragraph 4.5, that what it's saying is if an incident
 occurs where you have a reasonable suspicion that the
 actions leading to harm were intended to cause harm, you
 might call the police?
 - A. (Nods)

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9 Q. So let's go and have a look at the definition
10 as given by this document of what "reasonable suspicion"
11 means and that's on page 23.

"A person is taken to have a clear and reasonable
suspicion in this context if they have clear, objective,
specific facts, observations or evidence that justify
that suspicion. The grounds for suspicion are taken to
be objective if a reasonable person given the same
information would form the same suspicion."

So my question which I will then follow up dependent on your answer is: doesn't that set the bar too high for contacting the police?

- 21 A. No, I don't think it sets it too high.
- 22 Q. So let's look at it from a different
- 23 perspective. Reasonable grounds to suspect, which means
- 24 the same thing, is a statutory threshold test for
- 25 particular actions within a police investigation which

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a disagreement between some senior managers and some paediatricians about whether the threshold had been met to contact the police and you will have heard phrases like "gut feeling" no doubt permeating.

But what witnesses have agreed was in fact being said is the clinicians exercising their expert judgment were saying: these were deaths which I would not have expected and I have a good gauge on when to expect a death. We have investigated all of the ordinary explanations which may go to quality of care and excluded them, and we are left with an explanation that is supported by the fact that such a person would have been able to do it in the sense that they had access.

13 been able to do it in the sense that they had access.
14 And a number of members of staff and one in
15 particular, Sue Hodkinson, talked about that wasn't
16 evidence. Nowhere within this definition are you
17 accommodating the expert opinion of a clinician, are
18 you?

A. Well, I think we are because I think
a reasonable suspicion can be brought forward by the
expert view of a clinician.

Q. Well --

23 **A.** And if you look at the context here about 24 clear objective, specific facts, observations or 25 evidence, the doctors in particular had quite a lot of

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1 interfere with an individual's rights and that's a lot

2 of legal verbiage to say: one needs reasonable grounds

3 to suspect if one is a police officer before you can

4 arrest someone, so in other words it is a state of mind

5 within a developing investigation.

6 It is not the state of mind that necessarily7 a police investigation starts with?

A. (Nods)

Q. And the police investigations can just start
 with suspicion.

So that is the first point as to why the threshold may have been set too high, because effectively the

language is adopting an important legal threshold when

14 you are interfering with the rights of a citizen, not

15 the test for whether the police are going to open

16 an investigation which is a lesser state of mind, or can

17 be

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So that's the first thing. Do you have any comment about that and whether you agree or disagree with the analysis that I have just presented you with?

21 **A.** Well, I don't have any comment because 22 I wasn't aware of the difference.

Q. All right.

Secondly, if we look at the language here, we know from the facts of the Countess of Chester that there was

1 objective and specific facts that they utilised to make

2 their case and indeed there were also a set of

3 observations which just weren't made by the doctors but

4 by the nurses too that one person was on the ward at the

5 time of all of the deaths.

So there was quite a lot of evidence that to my mind would -- would fit with making a case for reasonable suspicion.

Q. Well, firstly you say that they had facts.

10 I think the main fact they had was the fact that

11 Letby was present, that was a fact.

12 **A.** Yes

Q. The rest was opinion which --

14 **A**. Well --

15 Q. -- or certainly in large part was opinion

16 which does not appear. If one looks at the list here

17 "clear objective specific facts, observations or

18 evidence", we don't seem to see that language included?

19 **A.** Well, I think an opinion can be an observation 20 and an opinion can be taken as evidence if it's

21 justifiable so I don't think opinions are entirely

22 excluded, particularly from observations.

Q. So you think that that adequatelyaccommodates?

25 A. I think it can do, yes.

- Q. Because obviously one of the big concerns of this Inquiry is whether or not current systems would 3 provide the adequate protection if they were applied to those past circumstances and a pretty good rule of thumb is if they wouldn't, then they are inadequate?
 - Α. Mm-hm.

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We can see here: Q.

"The grounds for suspicion are taken to be objective if a reasonable person given the same information would form the same suspicion."

Again, if we just test that by reference to the facts that we have. 12

13 If you had a non-clinical person as a director who is effectively the gatekeeper, they may consider 14 themselves a reasonable person but they aren't going to 15 16 be able to understand it in the way that the clinicians 17 will understand it from their expert point of view. 18 Doesn't this give rise to the risk that an Executive 19 Director will say: well, I am a reasonable person, 20 I don't have a suspicion, therefore, there is no 21 reasonable suspicion?

Well, I don't think an Executive Director would have a particularly greater hierarchy in the groups of people who can have -- who are reasonable people or have grounds for suspicion. And I mean in

1 a barrier rather than a pathway and I come back to what 2 I said earlier, that it is obviously the expectation 3 that people on a board, and indeed people who are 4 serving on a board, would have a sensible overview of 5 the range of events going on in their organisation and 6 would understand where, you know, a clearly unusual set 7 of events like the ones we are talking about would be 8 grounds for further examination and I think that would 9 generate reasonable suspicion in people's minds so 10 I'm afraid I don't think it is a barrier.

O. But we know on our facts that people were resistant to calling the police?

13 People were resistant to calling the police 14 but you are asking me if this MOU would make it easier for people to call the police and I am saying I think it 15 would. The fact that people didn't, they didn't for all 16 17 the reasons that you have been through over the last couple of months, and indeed as you said earlier the 18 fact that they didn't is partly as a result of the fact 19 20 -- well, not partly as a result of the fact, may have been aided and abetted by the fact at that time we 21 22 didn't have a memorandum of understanding.

23 So let's just test this against the examples 24 given in the previous guidelines. We know that we had a situation where there was a concern that there was

this case, there were quite a few different people who, 1 2 you know, looked at the rota and things like that and came to the conclusion that -- that that was a fact that 3 4 was worth investigating. 5

So inevitably you are sometimes going to have 6 discussions between different reasonable people but 7 I don't think that scenario that you have described is automatically the case. And I don't think this would 8 9 stop people going forward with their concerns.

10 I also think the fact -- I mean, as you said yourself earlier that there is, that this MOU now exists 11 again is a way of giving credibility and support to 12 people who feel that they need to go and test out their 13 14 reasonable suspicions.

15 But isn't it capable, given that we know that 16 there was resistance from the top of the hospital to 17 contacting the police, isn't it capable of having the very opposite effect that a board or a Chief Executive 18 19 who is resistant will say: I don't think your suspicion 20 is reasonable, I'm not reporting this.

21 And that by importing this term of "reasonable" 22 rather than setting it at the threshold which is capable 23 of starting any police investigation, that you are in 24 fact creating a barrier rather than a pathway? 25

No, I don't accept that this is creating 126

a possibility of harm either by way of deliberate harm

either way of tampering with a machine that didn't 2 ordinarily -- wasn't ordinarily defective or because

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a patient was dead and a syringe was inserted into the

5 line, would you regard both of those examples as passing 6 this test?

7 Yes, I would. I mean, they are slightly more, 8 I mean when you were reading them out earlier they are slightly more conventional patient safety incidents 9 whereas this is something that is more in the realm of 10 more extremely unusual, certainly in the context of the 11 12 health service.

13 Q. Well, they were resolved as patient safety 14 incidents as a result of the involvement of the police 15 and the investigation at the time?

> A. Yes

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17 Q. Those at the coalface simply know this is unusual, I think that harm is a possibility, deliberate 18 harm is a possibly, that is why I think the police 19 should be involved and I am just wondering whether you 20 think looking at that test that those which were 21 22 previously examples of good practice would in fact pass 23 the new threshold?

24 Yes, I think they would pass the new threshold. I mean, I just -- I do. 25 128

- 1 Q. Do you think there's a problem with this MOU
 2 in terms of the fact that it is trying to deal with, as
 3 we saw earlier, two very different challenges for the
 4 NHS, namely on the one hand gross negligence
 5 manslaughter, which is extremely legally complex?
 - A. Yes.

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- **Q.** And on the other hand, potential deliberate harm, which might be said to be extremely emotionally complicated because it involves an allegation against a member of staff and that is bound to provoke reactions?
- A. Well, I think it can deal with both of them.

 I don't see a reason why it can't deal with both of them

 and obviously the memorandum was agreed in conjunction

 with all the relevant organisations, including, you

 know, the police and the HSE and all the professional

 regulators and they came to a conclusion that this was

 a suitable document to meet that Inquiry recommendation.
- 19 **Q.** Do you know where the origin of the word 20 "reasonable" -- which in the previous guidance it was 21 simply "suspicion", where the word "reasonable" has come 22 from and what it is intended to add?
- 23 **A.** I don't -- I don't know that. I don't know 24 that.
 - Q. Do you think there is merit in you, bearing in 129
- having input into it because we wouldn't have written
 a document like that without ensuring it was legally
 assured.
 - **Q.** Now, one of the things that this document doesn't contain which the previous documents did, and in particular the guidelines, was the idea that if in doubt, as you characterised it, make an informal approach to the police to find out what they think. Is there any good reason why that sentiment is not included in this document?
- 11 Δ No, I just think it was focusing on the -- on the details of the issue but I think it's, it's clear 12 and I don't think it would have taken this piece of 13 14 guidance to make the point that if people are in doubt at a local level and they see something serious that they think may be the result of malevolent behaviour 16 17 that they are able to call the police. I mean, that is a I think it's fair to say a common sense expectation 18 19 that we would all have of most institutions.
- 20 **LADY JUSTICE THIRLWALL:** Do you think -- sorry,
 21 Mr De La Poer, that is very neatly encapsulated if I may
 22 say so. Is there any reason why we ought to look at
 23 whether a really clear statement of what you should do
 24 in that situation couldn't be put on one page?
- 25 **A.** Well, we can take that away and give it 131

- mind you told us a moment ago that you didn't perceive
 a difference between "reasonable suspicion" and
 "suspicion" and I have drawn to your attention the way
 that lawyers use it, that that's worth having another
 look at?
- 6 **A.** Well, I mean, we are due to -- we have only 7 just sent the guidance out and we are due to see how 8 it's going in some months time so I am sure we can take 9 cognisance of what you have suggested.
- 10 Q. What was their legal input into the language11 there of "reasonable suspicion"?
- A. Yes, there was. Because I mean, we had -I don't know the details but we had lawyers, you know,
 involved in the capturing of this thing it wasn't just
 written off its own back and obviously it had to be
 agreed pretty carefully with a range of organisations,
 much larger range of organisations than in 2006.
- 18 **Q.** And if we look at page 24, we will see that in 19 fact that appears to be a copy and paste from a legal 20 dictionary rather than an independent bespoke 21 definition?
- 22 **A.** (Nods)
- Q. But quite aside from whoever was responsiblefor that, there were lawyers having input into this --
 - A. Yes. My understanding is there were lawyers 130
- 1 consideration.

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- 2 LADY JUSTICE THIRLWALL: But is it something you 3 think that's of value?
- 4 A. Well, it may be, I think there would be quite
 5 a lot of difficulty in trying to replace something that
 6 we have only just put out and pulled together. I am not

saying that bureaucratically but just because it would

- 8 I think potentially reduce the impact but I think
- 9 something I think we are going to have a look at how10 this is going after a year, it's just been promulgated
- this is going after a year, it's just been promulgated
- 11 through various bodies and is still being discussed at
- 12 events and whether in the light of that period it
- 13 appears there is something that you are suggesting that
- 14 would improve and build on what we have got, then
- 15 obviously we stay open-minded about that.
- LADY JUSTICE THIRLWALL: May I just ask one other question, Mr De La Poer, which I should have noticed before now but if we look at 0007, chapter 4, when the MOU applies. And I must say I hadn't picked this up but it applies when:
- "... more than one of the signatories needs toinvestigate in parallel any incident."
- I just wonder what's that getting at? So itapplies when more than one of the signatories.
- 25 **A.** I think it's getting at the fact that if one

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- 1 of the organisations raises the issue and another one
- 2 responds in, in kind, then that's a way to take things
- 3 forward and that is often between, you know, the
- 4 healthcare provider and the police.
- 5 LADY JUSTICE THIRLWALL: And the police.
- A. Yes.
- 7 LADY JUSTICE THIRLWALL: Yes, so it presupposes an
- 8 earlier stage, doesn't it?
- 9 A. Yes, that you have established a set of facts
- 10 that you think are credible.
- 11 LADY JUSTICE THIRLWALL: There must be something
- 12 that's taken you to the police in the first place or to
- 13 somebody else, a regulator?
- 14 **A.** Yes, yes.
- 15 LADY JUSTICE THIRLWALL: Thank you. I hadn't
- 16 noticed that earlier but I think it's probably
- 17 important.
- 18 A. I think the presupposition that you say is
- 19 a working assumption that this MOU is here if you have
- 20 originally found to have, let's call it a problem, in
- 21 your local workplace and you feel that you have got to
- 22 take it to the next stage and therefore this MOU gives
- 23 you a guide for how to achieve that.
- 24 LADY JUSTICE THIRLWALL: Once you have taken it to
- 25 another body?
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- 1 look back at the opening statement made on behalf of the
- 2 Department, there isn't in fact any mention of
- 3 contacting the police in that. When serious concerns
- 4 develop about an individual the opening talks about the
- 5 importance of going to the NMC. I am just wondering
- 6 whether that was deliberate, an oversight or just not
- 7 thought to be a necessary point for the Department to
- 8 make?
- 9 A. I think probably the last.
- 10 Q. So I am going to turn to my topic 4, please.
- 11 So we can take that down. The timing of implementation
- 12 of the Medical Examiner system.
 - A. Yes.
- 14 Q. Here we note that that system was introduced
- 15 on a national basis on 9 September of last year; is that
- 16 right?

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- 17 **A.** That's right.
- 18 Q. That there had been an ongoing serious of
- 19 pilots since about 2019; is that right?
- 20 **A.** Yes, there had been a basically national
- 21 non-statutory scheme since 2019 and there had been pilot
- 22 schemes running since 2005/6/7 in a much smaller number
- 23 of places across the country, single figures.
- 24 Q. And that announcement was made just two days

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25 before this Inquiry opened its oral evidence hearing; is

- A. Yes.
- 2 LADY JUSTICE THIRLWALL: One of the other
- 3 signatories, then it applies.
 - A. Yes, yes.
- 5 **LADY JUSTICE THIRLWALL:** Yes, all right, thank you.
- 6 MR DE LA POER: Although, if I may, my Lady if we
- 7 look at 4.5 --
- 8 LADY JUSTICE THIRLWALL: Yes.
 - MR DE LA POER: -- that is talking about the prior
- 10 stage because that is talking about when the NHS
- 11 organisation which is operating on its own may reach out
- 12 to the police.
 - LADY JUSTICE THIRLWALL: Yes.
- 14 MR DE LA POER: So the trigger for taking it to
- 15 that joint investigation stage still, would you agree,
- 16 appears to pass through the threshold of reasonable
- 17 suspicion?
- 18 A. Yes, I don't think -- I wasn't arguing against
- 19 the point of reasonable suspicion. I was just sort of
- 20 expanding on the process point.
- 21 Q. Is it a concern for the Department that cases
- 22 which ought to be the subject of a police investigation
- 23 get there as quickly as possible?
 - A. Yes, I mean, obviously.
- 25 **Q.** Well, you say it's obvious. But if we were to
 - 13
- 1 that right?
 - A. Yes, I mean, the date of the implementation
- 3 had been announced in April.
 - Q. As the 9 September?
 - A. As 9 September. And was actually was
- 6 announced in a written ministerial statement in April
- 7 and reannounced because obviously we had to go to the
- 8 new Government to get approval for, you know, proceeding
- 9 with the policy, at the end of July.
- 10 **Q.** And bearing in mind that by April the Inquiry
- 11 was established --
- 12 **A.** Yes.
- 13 Q. -- what reassurance, if any, can you give as
- 14 to whether or not that scheme was rolled out nationally
- 15 as a result of this Inquiry?
- 16 A. No, it wasn't rolled out nationally as
- 17 a result of this Inquiry. Medical Examiners is a long
- 18 story but to answer your specific question, we got to
- 19 a position in 2018 after various twists and turns, which
- 20 I can go into if you want, where there was a decision
- 21 that Medical Examiners should operate through the NHS.
- 22 It was a consultation in 2016 in response to the
- 23 consultation in 2018 that said Medical Examiners should
- 24 be in the NHS.
- The legislation didn't allow for that at the time

because in 2012 the legislation had transferred Medical 1 2 Examiners from an NHS function to local government and 3 in the intervening period, you know, the Department and 4 the Government had come round to the fact it was better 5

6 We didn't immediately have legislation available. 7 And I was just coming into my responsibility for this at 8 that time, mid-2019. What was decided effectively by my 9 predecessor, with me inheriting it, was the way to go 10 forward was to enable both the National Medical Examiner and the Local Medical Examiner legal provisions to be 11 turned on, so they were established as posts, but for 12 them to not in any way operate the new medical 13 certificate cause of death which is the second doctor 14 sign-off that the Medical Examiner gives to the 15 16 attending doctors cause of death and is in a sense the 17 second -- the second doctor opinion that gets to the heart of what was the matter in the Shipman case. 18 19

So that is the kind of fulcrum bit. So we then ran between mid-2019 and last September what we called loosely the non-statutory scheme. So we didn't have the actual medical certificate cause of death being what needed to be signed off by the Medical Examiner before you could get a death certification.

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So we got to the middle of 2019 and that system was

focus at the end of 2019. We didn't, one of those things.

We then had Covid. We did legislate in 2022 and then we had the period before the introduction last September.

So we had had about -- we had had five years or so of full coverage through the hospitals and by the time we got to last September we were up to about two-thirds of GPs being engaged.

Obviously you couldn't force that because it was a non-statutory scheme. So that's how we got to the introduction in September that was confirmed by the Government last July after we sought their approval for the package of measures that they had inherited from the previous Government and asked them if they wanted to go forward with it.

What is your understanding of the relationship between the Medical Examiner system and HSSIB?

Well, the Medical Examiner system is a part of death certification reforms, so it sits within that context and it provides a focus on getting patterns of care, including malevolent patterns of care, which is where it comes from, from Shipman.

But also, and I think this has grown in the 20 years since Shipman, about giving people 139

established and we did actually try to legislate for the 1

2 changes to bring the system back to the NHS in 2019 and

we had a bill which was doing that and putting HSSIB 3

4 similarly on a statutory footing. And that was

introduced to the Lords in November 2019 and had

6 a second reading and then it fell because we had

7 a general election. And after the general election we

had Covid and we then reintroduced -- sorry, we

introduced the Health and Social Care Bill which took 9

10 the clauses that had been in the 2019 Bill into that

Bill which passed into law and gave us the 2022 Act that 11

had Medical Examiners back in NHS statute where they had 12

actually originally come from in 2009, if you go back 13

14 far enough.

15 And we continued to operate the non-statutory 16 scheme for the two years between 2022 and last 17 September: one, because we still wanted it to bed down; 18 secondly because we had good but not a complete 19 engagement from the GP world and we wanted more coverage

20 and awareness and ownership before we introduced the new 21 scheme; and thirdly because we needed time to introduce

22 the new thing and lots of other logistical arrangements.

23 So the short answer to your question is after 2019 24 we had a non-statutory scheme. We tried to legislate,

which would have enabled us to bring it into statutory

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an explanation of deaths for all of those that are 2 non-coronial deaths, whereas previously it was only the

3 coronial deaths that got, you know, significant

4 attention.

5 HSSIB, which is how we say it, has a slightly 6 different purpose, which is it's not part of the death 7 management system. First of all it is an arm's-length 8 body of the Department of Health and the purpose of the organisation is really a few of the things that were 9

alluded in the 2006 document in the blurb at the front 10

11 which is to give a better focus on investigations for

the purposes of learning and for the purposes of 12

promulgating that learning across the NHS. 13

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And they take a number of sort of sentinel cases 15 each year and then they distribute the learnings and they put requirements on different organisations to 16 17 respond to specific recommendations.

18 So Medical Examiners is a -- is a catch-all system is a part of the death certification system and gives 19 20 everybody one, a check and two, an explanation of why somebody has died, for all the non-Coronial cases, about 21 22 85%, 85% Medical Examiners, whereas in contrast HSSIB 23 has a sort of much tighter end learning and safety focus within the NHS for particular patient safety incidents and operates a safe space whereby the information can be

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- held centrally and examined and also has a separate 1
- 2 function, there isn't an equivalent one for Medical
- 3 Examiners, which is about encouraging improved learning
- 4 and competence in undertaking investigations locally, so
- every time something happens in a sense the one area 5
- 6 where the two areas elide is you are trying to give
- 7 everyone through the Medical examiner system a better
- 8 explanation of a death and in HSSIB you are trying to
- 9 get people to be better at investigations locally when
- 10 they need them, so in both instances lack of
- understanding or a lack of explanation from the health 11
- service at the ground floor doesn't generate the need 12
- for greater enquiries up the line so that is where there 13
- is a point of similarity or a point of similar purpose, 14
- but they are two very, very different structures. 15
- 16 Q. Is information shared between the two
- 17 directly?

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- A. 18 No, it isn't.
- 19 Q. Bearing in mind they have that overlap, do you
- 20 think there should be some direct conduit?
- 21 Well, I think I mean obviously Medical
- 22 Examiners, the system is four months old so, I mean,
- 23 more or less bedded in. I think we will need to take
- the learning from the kind of trends that the Medical 24
- 25 Examiners are finding and it may be that some interface
- 1 evidence before the election, as it turned out, although
 - we didn't know it at the time we were sending it to you,
- 3 you saw the documents that were discussing the pros and
- 4 cons of regulation and the various issues relating to
- 5 it. But there wasn't a hard and fast plan, therefore
- 6 I say not in contemplation to get that out as
- 7 a consultation document. Obviously the Government
- 8 published it, the now Government published its manifesto
- at the end of May, it included a commitment to manage 9
- the regulation and the Secretary of State made perfectly 10
- 11 clear, when he came in, that he wanted that to happen as
- 12 quickly as possible.
- 13 We did clearly -- we were obviously fairly au fait
- 14 with the arguments, so we were able to put together
- a consultation and that was published, you know, as, as 15
- quickly as possible and came out at the end of November 16
- 17 because ministers want to do that consultation and they
- want to make progress as quickly as possible. 18
- 19 So I would -- well, I wouldn't, I am saying
- 20 genuinely that the fact that the consultation went out
- in November was a function of it being a manifesto 21
- 22 commitment and a clear commitment of the Secretary of
- 23 State and obviously officials, you know, respond to the
- 24 wishes of their ministers and the timings.
- 25 You have had a chance to consider the evidence 143

- with HSSIB is going to be useful and similarly 1
- 2 vice versa, but they are both pretty new. HSSIB has
- only been going in current statutory format for 3
 - 16 months but I take your point.
 - Topic 5, the consultation in relation to the
- 6 regulation of senior managers and --
 - Α. Yes
 - -- the Code of Conduct. Q.
- 9 Was the potential regulation of senior managers
- 10 something that was in contemplation in 2023?
 - I don't think it was in contemplation. It was
- under discussion and consideration and, you know, we 12
- have shared the documents with you that showed the 13
- debates that were happening at the time. But I don't 14
- think we ever got to a contemplation of actually doing 15
- 16 a consultation that that didn't happen. Whereas
- 17 obviously that changed when the new Government came into
- 18 place in 2024 because it was one of their manifesto
- 19 commitments and now we are taking that forward.
- 20 So again perhaps answering the concern that
- 21 may exist in the minds of some, the timing of the
- 22 consultation, namely right in the middle of these
- 23 hearings, was in fact entirely unconnected?
- 24 It was entirely unconnected, to be perfectly
- 25 honest. We -- you know, when we were sending you the
- of Mr Jarrold.

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- Α. Yes.
- 3 Q. I am just going to bring up the document that
- 4 he produced, INQ0107810 and we will go to page 7. What
- 5 I am not going to go into is the precise mechanics here
- 6 of what regulation might look like bearing in mind
- 7 that's subject of a consultation by your Department.
- 8 This is more about a principle. Mr Jarrold gave
- evidence about the formulation of this and in particular 9
- 10 the:
- 11 "Make the care and safety of patients my first
- concern and act to protect them from risk." 12
- 13 I mean, is it thought within the Department that
- 14 that should be the first responsibility of NHS managers?
- 15 Well, the equivalent Code of Conduct to this
- document is something that NHS England is working on at 16
- 17 the moment with a number of bodies. So the manager
- regulation is doing -- well is doing a slightly 18
- 19 different thing.
- As I understand it, and, I mean, NHS England are in 20
- charge of the code, the code of leadership and conduct 21
- 22 for NHS managers is focusing on values and purposes and
- 23 commitments in its current iteration.
- 24 And does that statement there fit within what
- 25 you understand, what did you say values, commitments?

- A. I think, I think it would fit within those values and commitments as I understand it. But it doesn't to my understanding state that precise phrase in, in the current version.
- And do you, as the Department, have an understanding for why not given the public's concern about how senior managers might prioritise what they are doing?
- 9 A. Well, I think we as ministers made fairly 10 clear that patient safety is a significant priority and I think, you know, there are other ways in which we can 11 explain that patient safety is significant. I don't 12 think it's a deliberate omission in the code and 13 obviously the current code is being discussed with 14 various other organisations as well and I think they 15 16 consider that the six rounded values are the best way of 17 explaining what should be a Code of Conduct for NHS 18 managers.
- 19 I am sure you chose your words carefully, you 20 said "significant". Mr Jarrold's perspective, he not 21 being in Government or in the Civil Service, his 22 perspective is that that needs to be the primary 23 commitment as opposed to one of a number of potentially competing ones which will inevitably include the 24 25 management of money.

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- But it appears to be that that occurred in the context of an effort to develop a memory about events and --
- I think the MOU itself, to be precise, occurred in the context of a large organisational restructure and that that document was archived as an oversight. I think the "organisation with a memory" he's talking about as I think I said the learning from Patient Safety Events, not necessarily the handling of memorandums and codes, although I take your general point.
- And we have a number of strands of evidence that have developed about corporate memory and the difficulties that there appear to be with it.

Mr Jarrold, as you have seen, had a degree of uncertainty about what exactly happened to his code and why it appears to have fizzled out. Dr Clamp says on behalf of the PSA he doesn't even know whether that original code is still policy because he can't find an answer to it.

22 Is that problem generally, which was also spoken to 23 by Professor Smith, about the lack of version control or 24 iterations, the fact that new policies come along but old ones aren't withdrawn, is that something that the 25 147

Does the Department have a view on whether that 1 2 should be the primary?

3 A. I don't think we have a hard view on it but, 4 I mean, we can certainly feed that back in terms of how the code is being developed. I think we certainly do 5 6 agree that the range of things that I have spoken about 7 make clear that patient safety is an absolute priority for everybody providing services, including managers.

9 I am certainly not going to paraphrase what 10 Mr Jarrold has said about why he formulated it in this way, but you can satisfy everybody here that you have 11 read that and you understand what he is saying? 12 13

Α.

14 My sixth topic is that of corporate memory and Q. there are a number of aspects to this. We have already 15 16 touched upon Sir Ian Donaldson's report "An organisation 17 with a memory" back in --

18 Α. Liam Donaldson.

a particular issue.

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19 Sorry, forgive me, Liam Donaldson's report "An 20 organisation with a memory", do you agree it's somewhat 21 ironic that that report, "An organisation with 22 a memory", led to the production of an MOU which was 23 then lost to the mists of time in terms of why it was 24 then withdrawn?

Α. Well, I think as I said before it's 146

1 Department recognises as a problem for the NHS?

2 I think we think it's an issue and I wouldn't quite describe it as version control I think there is 4 a slightly wider issue that lots of people have brought 5 up and Gordon Messenger encapsulated in his report and 6 the Secretary of State in November completely concurred 7 with, which is we need to get better and more structured 8 at how we support managers and organise training and have that as a systematic approach that isn't 9 particularly dependent on a particular time or 10

12 And of course one of the reasons why regulation of 13 managers is so important, not just for the obvious 14 reasons of having a set of structures for professional improvement and public confidence, is I think that if we

15 do, when we do get to having that system, it would mean 16

17 that things like training and codes and memorandum of

understanding would always be necessary because you have 18 to -- you have an established regulated profession who 19

20 need those sorts of documents for their support.

21 So I think there is a question about how we can be 22 more systematic about those things. So I think in

23 a sense if we are going to be regulating managers what goes hand in hand with that is having a more

sophisticated set of arrangements to support those

managers, which was in a sense the point Helene Donnelly 1 2 made when she came here, which she said manager 3 regulation is fine, but please make sure people are 4 supported to do it. So they are not, I mean, a point 5 you are making to me before lunch, they are not exposed 6 when they have got a new set of responsibilities and 7 they don't feel they have got the necessary support to 8 carry them out effectively.

Q. And if it is an issue, and clearly in the minds of some people a problem, whose responsibility is it that we have reached this stage now with the uncertainty we have, who ought to have ensured that rigour and structure was imposed sooner?

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14 Well, I suppose you know previous administrations should have done. But, I mean, I think 15 16 there's been a pretty -- a pretty clear picture since 17 the Messenger Report came out, which was June 22, that 18 we need to ensure between ourselves and NHS England that 19 we have more structured long-term arrangements for these 20 things and of course it's -- as I said before, it's the 21 decision of this Government to go ahead with manager 22 regulation and that provides, you know, a significant 23 bolstering tool of that which I think, you know, is extremely welcome and obviously that is a result of the 24

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set of ministers taking a lead on this issue.

1 you know? Why, when there is a 70-page Child Death 2 Review policy that we did in 2018 and is still extant do 3 you need to do that duplication? No, you don't. Maybe 4 there is something for us about making clear, you know, 5 when we produce a policy that we think it's fit for 6 purpose and use, but we never require people to rewrite 7 or reorder a policy on its production from the centre.

So does it come to this then: the Department and NHS England's position is that such common policies are produced at the central point and it's then up to individual hospitals to decide whether they are going to adopt that or start again?

No, it's not a question of whether they are going to adopt it, there was no question of "whether" in what I said. What I was talking about was the "how".

Clearly we operate in a structure that if you produce guidance and if you direct it and if you send it to Trusts and all those other things, going back to my opening answer to your question, the expectation -- in fact the requirement -- is that people then deliver on it. And obviously the fulcrum body for doing that is 21 22 the board, that is what you have boards for: they hold 23 the organisation to account. NHS England holds the board to account on our behalf and we promulgate

a certain set of key priorities that we want NHS England

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O. Wider than the issue of those policies which 1 apply directly to senior managers, there is a school of thought that there is a significant amount of time and 3 resource at a local level writing policies which are 4 applicable to the institution which are in fact carbon 5 6 copies of policies which exist elsewhere or which are 7 very only slightly different to those other policies.

8 Does the Department have a view about whether there 9 should be a central policy centre within the NHS for 10 writing a number of these policies or the core of a number of policies to save time at the local level to 11 avoid these things being written from scratch? 12

13 I don't think we have got a hard and fast 14 position but I think the basic thing I would say is probably we would see ourselves and NHS England as 15 16 having the job of producing most of those policies 17 obviously in conjunction with other people with whom we 18 discuss them, but for producing them, and once produced, 19 we would hope having done that necessary consultation, 20 small C, that they were suitable for use.

21 And it's never our assumption when we produce a policy that it needs to be replicated or duplicated or 23 regurgitated for the purposes of its implementation. So the example Jane Tomkinson gave on Monday which was, you 24 know, they have got a SUDiC policy of 150 pages long,

1 to send down the line through the mandate and the 2 planning guide.

3 So it's not a question of whether; it's a question 4 of how. And the "how" is -- my previous answer is you 5 probably don't need to you know rewrite or regild things 6 if they have already come out. And the second "how" is 7 clearly that it is the responsibility of organisations 8 locally led by their boards to implement policies according to what the Government and NHS England have 9

set out, because we are all part of one structure. 10 11 LADY JUSTICE THIRLWALL: Sorry, Mr De La Poer. So 12 does that mean there's a straightforward

13 misunderstanding certainly at the Countess of Chester?

14 I think we were told there are 2,000 policies --

15 With the, you know --

LADY JUSTICE THIRLWALL: -- in the hospital.

17 There may well be a lot of policies. I am not denying the fact that there are different policies. 18

LADY JUSTICE THIRLWALL: No, but the reason I am 19 20 asking you about that is if the hospital is under the impression that they have to draft individual policies 21

22 for everything, then --

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I don't think they --Α.

24 LADY JUSTICE THIRLWALL: -- that is a lot of management time which we were told about which is being 25

spent on something which is entirely superfluous.

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I don't think they necessarily do, is my starting point. There will be some things inevitably where you need to explain the guidance or the practicalities of it but there is no need to rewrite or completely reboot all the pieces of guidances we send out. We send them out so they can be used by people and critically and more and more over the years, you discuss those with groups of people, I mean, including the NHS in a sense of the regional tier and the ICBs and the sort of higher ends of the Trust. You know, we at NHS England would interface with them on significant pieces of policy in order that it is something that is

The days when the Department was a sort of separate semi-academic institution writing these things, you know, by itself disappeared many years ago and good practice in any production of policy guidance is to sense-check it. is to discuss it. is to consult on it. in order that when it goes out, it is correct.

going to be useful as, as sent out.

So, I mean, when I saw that evidence I did think: yikes that isn't our expectation that you have to then, you know, regenerate that into a different product on each and every occasion. And when there are, I mean all right, let's take Medical Examiners as a live example.

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1 conditions or whatever it is?

Yes, I mean, they have to implement it.

LADY JUSTICE THIRLWALL: Yes.

A. And they have to have structures in place for the implementation and they have to have ways of assuring themselves that it's been implemented but the core of the policy, the purpose of the policy does not need to be rewritten because in the end you write policy once because you think it is applicable across the piece and because we have a single NHS and we want a consistent health service.

LADY JUSTICE THIRLWALL: I feel we are slightly moving away. I just want to be clear about what is expected of the Trust. Sorry, is it the fact that the guidance goes out or the directive goes out and the Trust has it, this is what we have to implement, and this is how we are going to implement it?

Yes, that is -- that is what we expect.

LADY JUSTICE THIRLWALL: But that, I mean I am assuming that is not something that would be very complicated or complex, the implementation?

21 22 No, it shouldn't be. I mean, look, we -- we 23 try and write guidance in such a way that it achieves 24 its aims and objectives and does so in a -- in a fairly clear and efficient manner. And if you put anything on 25 155

We put out -- I mean, that was a big change for 70 years 1 we put out a reasonable amount of guidance on gov.uk that we thought was going to be appropriate for people 3 4 to be able to operate the Medical Examiner system. We 5 did not engage in discussions about, you know, producing

6 extra pieces of guidance in order, you know, that that 7 was better understood. 8 You always -- I mean, in this instance the National

9 Medical Examiner, the Regional Medical Examiner, the 10 Medical Examiner's office, you always have people in the system who are responsible for that certain area of 11 policy who can do that bit of explanation and 12 understanding for people who may be less au fait. But 13 we don't have an expectation that on the production of a piece of guidance that then necessitates an equal and 15 16 parallel exercise on its receipt.

17 LADY JUSTICE THIRLWALL: Yes, even if it is not 18 equal and parallel the point is that it is understood 19 that something has to be done and that someone has the 20 time to do that when they might be doing something else.

> Α. Yes.

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LADY JUSTICE THIRLWALL: That latter part is my 22 23 addition. So if there is that misunderstanding it needs 24 to be removed, doesn't it, so that Trusts know and the boards know that they don't have to rewrite it for local 154

gov.uk you have to make the language into plain English 2 so that anybody can read it and understand it. So there

are quite some pressures on us, which are good

4 pressures, to improve the clarity of our policy making.

5 And it certainly isn't the expectation that on 6 receipt of a piece of policy it then needs rewriting or, 7 you know, reframing.

8 LADY JUSTICE THIRLWALL: Thank you, so that is 9 something obviously for me to consider what, if 10 anything, needs to be done about that, for reasons that 11 are obvious. Can I just ask you something else because 12 you were about to go back on to Medical Examiners, 13 I think.

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14 Yes 15 LADY JUSTICE THIRLWALL: We heard evidence from Jeremy Hunt, who as well as being Health Secretary had 16 17 been Chancellor more recently and it's really just to help about this: talking about the willingness or the 18 desire to introduce Medical Examiners, if I may say so, 19 20 what you have described as has been a sort of -- not quite an iterative process but an introduction an 21 22 openness to it, and then some piloting. 23

And the way Mr Hunt described it was that this was Medical Examiners were something that he had been supportive of but the NHS did not support it for

financial reasons and it was when he -- either it came across his desk or he instigated it, one way or the other he decided to tell the Treasury to make the money available

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Is that something which accords with your recollection of how it went?

Well, let me tell you what my recollection is because it is the sort of the other part of the story that I didn't go through with you because you didn't precisely ask me about it.

The other thing that was difficult with Medical Examiners was the funding.

13 LADY JUSTICE THIRLWALL: Yes, that is why I thought 14 I had better ask you about it.

Yes, exactly. The funding started off life, the funding was assumed to come with the NHS when it started life in 2009, when we got to 2012 it was then back in local government, there was no funding to do it.

19 LADY JUSTICE THIRLWALL: So change of Government, 20 or the Lansley Reforms?

21 No, 2012 was the Act.

LADY JUSTICE THIRLWALL: Those were the reforms.

23 So the 2012 Lansley Reforms went into local government, ergo it was going to be a local government 24 provided service so it would have come out of local 157

So we used that money, to cut a long story short, we took that money, stopped using crem Form 5 and we added that money to our central funding that paid for the non-statutory scheme, okay? So that was how we provide for the non-statutory scheme and that was how we paid for the non-statutory scheme until 2022 and the reason why it was 2022 was because we had a spending review in 2022.

The important thing that happened between 2020 and 2022 was we made some reflections obviously for the very sad circumstances of Covid, a lot of people died, there was a lot of focus on bereavement, most of the people dying were in the hands of the health service and the person who worked for me on Medical Examiners at the time directly said: William, we have got a position where the Medical Examiners are going to be in the NHS, we understand that, the purpose of the Medical Examiner policy as well as finding out suspicious patterns of deaths is very much to give, as I was just saying, an explanation and to help with people at their moment

21 of need. 22 But actually what we are also going to say is that 23 is going to be NHS service and we are going to charge you for it. Charging people at that point is obviously rather difficult and insensitive; and secondly, we don't

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2 would have been some charging involved because one, that 3 is how local government raises quite a lot of its money; two, there was already various charging regimes, the 4 crematorium forms and all the rest of it that existed in

government funds and -- and the likelihood was there

6 the death certification system.

7 We then got to a position where that wasn't 8 resolved and by 2018 we had got to a position which he answered in my previous question to you, Mr De La Poer, 9 10 which was we decided the service should operate out of the NHS and we had been public about that and we had 11 made that clear. 12

13 How did we fund the non-statutory scheme whilst it 14 was still a local government function? We had some central funding from the NHS that we "found", and we 15 16 also had we used the crem Form 5, crem Form 5 was the 17 form that families used to pay the doctors for funerals 18 and was an arrangement that came out of the 1953 Birth 19 Registration structures and in a sense although it was 20 in the time of the NHS kind of preceded the sort of 21 concept of the NHS and it was just something doctors did

22 and it just went straight to doctors, it didn't come 23 through any of us, it was effectively just an

arrangement between effectively local government, crem 24

Form 5 and the doctors.

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tend to charge people for NHS services apart from a few 2 long-established things in primary care.

3 So we went back to ministers a couple of times 4 during the Covid period and put what I have said to you 5 in sort of fuller terms and combined that with 6 a proposal that --7

LADY JUSTICE THIRLWALL: 2022, the spending review?

This was being done in 2021.

LADY JUSTICE THIRLWALL: I see.

9 10 2020 and 2021 so sort of in a sense, you know, as a result of our observations in Covid we went back to 11 ministers and said: we think a better solution given the 12 13 service subject to the passage of the Act in 2022 is 14 going to go in the NHS, that there shouldn't be a charge for Medical Examiners and it should be funded in the 15 normal way in the way that other NHS services are, which 16

17 is out of the money granted to Parliament for NHS

18 services and they said yes to that.

19 So we got to a position by 2022 where a couple of things combined, one, the Act got passed, so the Medical 20 Examiners was back in the NHS; and two ministers had 21 22 agreed to funding through the NHS and we secured the 23 funds through the spending review to do that; and three, the previous arrangements we had had using crem Form 5

and all the rest of it they stopped and that all

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happened to take place at the time that Covid was 1 2 stopping in the spring of 2022. So the Ministry of 3 Justice who had been going to take away crem Form 5 at 4 the time we introduced the Medical Examiner statutory system withdrew it at that time because it wasn't needed 5

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any more for their purposes, and we had sorted out the funding stream.

So we got to a position in 2022, finally, where Medical Examiners was back in NHS legislation. We had the agreement that the Medical Examiner scheme should be funded in the typical way through the NHS and we had secured the resources in the spending review for that.

12 13 And when I say secured the resources, what I mean is the cost of the Medical Examiners offices is 14 basically the cost of the scheme, it is about 15 16 £50 million, which is about 400K for each of the 129 17 Medical Examiner offices, which gets you three or four part-time staff and an administrator. That's what I'm 18 19 talking about and then there's a bit of central costs 20 for us on the forms and a few other things, but about

22 the rest of it. 23 So between 2022 and 2024, and indeed now, we have 24 been funding the non-statutory scheme and since September the statutory scheme through the settlement

50 million for the scheme on the ground, 7 million for

the difference that we turned on the full statutory scheme last September.

LADY JUSTICE THIRLWALL: Thank you. Sorry, 3 4 Mr De La Poer.

MR DE LA POER: Not at all my Lady.

6 Topic 7, the introduction or potential introduction 7 of an overriding objective of patient safety in 8 employment matters in the context of the NHS and here 9 the evidence the Inquiry has heard is from Professor John Bowers King's Counsel and you have had 10

11 an opportunity to consider his evidence and you will understand the context for that on the facts the Inquiry 12

13 has been investigating, namely the fact that Letby

14 raised a grievance process and in the end those who were

raising concerns about the threat that she may pose as 15

far as they were concerned ended up apologising and 16

17 potentially compelled into mediation, although that

18 never came to pass.

> Professor Bowers gave evidence about this being a wider problem in the NHS or a wider challenge the use of grievance processes and other employment processes and the risk that patient safety gets lost in it, so that is the run-up to wicket.

23 24 Does the Department have a view about whether what 25 Professor Bowers is proposing is a good idea?

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1 that we reached in the spending review.

LADY JUSTICE THIRLWALL: Very good.

3 And that's now completely normalised and it's 4 there and it is in the baseline

LADY JUSTICE THIRLWALL: That was my last question 6 so it is in the --

Α. It is in the baseline.

LADY JUSTICE THIRLWALL: Yes.

9 Because it applies to every Trust, there is

10 basically a sum which exists within every Trust

baseline, even though I said 129 officers, there's 125 11

in England and they cover about two Trusts each because 12

you don't have one Trust each, you have about two Trusts 13

14 per Medical Examiners Office.

15 So now we are back to a perfectly conventional 16 position where we have legislation that establishes it 17 in the NHS and we pay for it through the normal route 18 which is through the funds that go to the health service 19 and there is no charging at all.

20 And the charging thing was difficult for a long 21 time, as long as it was in local government it was going 22 to be charged for and then we had to make the case for 23 it to have the normal pattern of funding through the 24 NHS. That's what happened between 2019 and 2022 and that system, those structures have run since 2022 with 162

1 No, we don't have a firm policy position. But 2 I read the evidence with interest and obviously what he was saying was you shouldn't let, you know, matters of 4 grievance or HR, to use his words occlude the need to 5 follow through on patient safety incidents.

6 And I think we would say that clearly there is 7 obviously a place for HR policies, you know correctly 8 managed. But we also think that if there is a patient

safety issue people should be encouraged to speak up 9

through the various routes that I have discussed, 10

11 whistleblowing or Freedom to Speak Up Guardians.

12 Whistleblowing is, you know, in a sense when it gets

13 more extreme, often because people don't take the

14 concern seriously. And otherwise you should be able to,

you know, freely raise a patient safety incident through 15

Patient Safety Incident Response Framework and other 16

17 mechanisms.

18 I think again it comes partly back which I sort of think he was saying in part, it partly comes back to the 19 20 culture of the organisation that you should have an organisation that tolerates people being able to follow 21 22 up patient safety concerns of whatever kind and you 23 should be able to distinguish between that and genuine 24 HR issues. But there shouldn't be a need to use HR

issues to resolve patient safety matters and in a sense 25

we know that that is the -- that is the difficulty that whistleblowers sometimes feel that they are forced into.

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So that is the aspiration it shouldn't happen. He's made a practical suggestion which is above and beyond the existing structures but actually to ensure that those who are have that concern in front of them whether it be a grievance or a disciplinary process, that they are reminded as you are approaching this you must remember patient safety at all times or however it's framed, that's his suggestion. You have told us there is no policy position on that as yet.

Is it something that the Department is going to take away having considered as evidence and reflect on whether that additional nudge in terms of culture is one that should be introduced or has it been ruled out already?

17 No, it hasn't been ruled out. I think we 18 can -- we can look at it. I would say, you know, 19 "additional nudge on culture" is a nice way of putting 20 it because I think -- I think you have to be careful 21 that you don't introduce more myriad new systems that 22 might get in the way of what we hope are natural 23 responses to speak up through the existing mechanisms.

My eighth topic is seeking to refine or improve the overall system of regulation and this is

would be in a slightly unusual position.

The part of the Francis evidence that referred to the -- you know, the distinction between, you know, regulatory requirements and professional requirements, the professional requirements have long, you know, existed and as I said earlier, you know, pre-date even the NHS and have always operated in a sort of independent structure within the NHS.

I think it is important that we are always looking carefully at, you know, regulatory and other bodies outwith the areas I have sketched out and of course in recent years we have actually taken steps to simplify the system. First of all we went down from having five or six bodies that were responsible for the NHS on a day-to-day basis to one, which is NHS England, we don't have the TDA, we don't have Monitor, we don't have NHS Improvement, we don't have NHS Digital and we don't have Health Education England, so there is one simplification. And secondly we have obviously got the outstanding Penny Dash review that is looking at, you know, whether there is any better co-ordination between the number of the patient safety bodies.

22 23 So I think, you know, my mid-point between your two 24 poles that you asked is obviously we are always mindful of not complicating the system. At the same time there 25 167

a short topic but we have heard from a number of 1 2 witnesses from the outset when Sir Robert Francis gave 3 his evidence about the proliferation of organisations within the NHS with a regulatory function, sometimes 4 126, sometimes 130, some people aren't sure how many. 5

6 Is the problem for the patient is that often they 7 don't know who they should be turning to and what the role of the different organisations is for. 8

9 Is that a problem that is recognised by the 10 Department in the sense that the NHS is just too complicated at the moment or does the Department not see 11 that as a problem? 12

13 A. I don't think either of those things would 14 quite be the position. Within that large number of -that large number you quote, whatever, you know, 15 16 whatever it is constructed of, part of it is made up of 17 professional regulatory bodies with long standing, part of it is made of by Royal Colleges with long standing, 18 19 part of it is made up by arm's-length bodies that have 20 pretty long standing.

21 So if you start to deconstruct the large figure, 22 quite substantial parts of that figure are long set and 23 long established and if we were to say: we won't have the GMC we won't have the Royal College of Physicians 24 and we won't have the CQC or NHS England, I think you

is a good reason for a number of the organisations that we have. So you have to strike a balance between having 2 3 the requisite number of organisations to give the right 4 amount of oversight or indeed improvement or data

5 capture and ensuring, as you were saying to me earlier, 6 that that still enables the people on the ground to, you

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know, operate and do their day jobs fairly unencumbered. 8 Obviously one the things that's going on with CQC

at the moment is going back to a more focused approach

to how they collect data rather than slightly 10

11 complicated arrangements they have had in the last

12 couple of years.

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13 So we are always trying to look at where we can 14 improve data and data management tasks. But at the same 15 time, there is a pretty good reason for a large number

of the organisations that we presently have. 16 17

MR DE LA POER: My Lady, I have three more short topics and then there is permission for 15 minutes' 18 worth of questions. I wonder whether this would be 19 20 a convenient moment, but my expectation in terms of my 21 remaining time is about 15 minutes or so.

22 LADY JUSTICE THIRLWALL: Very good. So we will 23 take the break now and we will come back at 25 to 4. 24 (3.17 pm)

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(A short break) 168

(3.35 pm)

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LADY JUSTICE THIRLWALL: Yes.

MR DE LA POER: Mr Vineall, topic 9, senior

managers moving and being moved.

- Α. Yes
- 6 Q. Evidence has been given, including from 7 Tony Chambers and Lyn Simpson about the existence of 8 what is dubbed the "donkey sanctuary", that was 9 Mr Chambers, and Lyn Simpson in writing talked about 10 rehabilitation periods and their standard lengths.

Does the Department consider that there is a problem in this area that needs addressing?

Well, I'm not sure if the Department has a fixed position on this but speaking on behalf of the department, I think there are some issues that arise from the set of evidences you have just been referring

I don't recognise certainly the first phrase and I don't recognise the second phrase as established good practice. I would say two things, first of all, moving people per se is not wrong. It happens in all walks of life, I have been moved. It happens.

I think the issue is if you are moving people in circumstances that are complicated and, shall we say, a little bit murky then it is a different thing. If you 169

that person is like.

Now, of course as we were just rehearsing before the break, we don't have a system -- we don't have regulation of managers at the moment, we just don't have it. We have regulation of lots of other things but we don't have regulation of managers. So if you take all of that in the round I think the practices that we have seen here probably wouldn't be right by any measure and present some structural issues that I think the

11 Well, regulation of senior managers in 12 whatever form it may come to pass --

- A. Yes.
- Q. -- may address that in part?
- 15 A.
 - Q. But doesn't there need to be very clear guidance on what needs to be done if a person is to be moved, in other words as you have just listed and they are just common sense, you need to establish the full facts you need to act transparently?

21 Yes, I mean, one would hope you didn't really 22 need to say that because it would be a part of good HR 23 process anyway and of course leaving aside if there are 24 untoward reasons for moving people, part of the reason why you move people is to get a right fit between the

are moving people to rehabilitate them because they are 1 2 going to get better and it's all fine that's okay. If rehabilitation is a catch-all for helping people to 3 shuffle on because something has gone wrong that hasn't 4 been addressed and acknowledged, that is a wholly 6 different matter.

7 And I worked in a region 25 years ago and some of 8 it happened then. So it's been happening for a long time but I think increasingly people understand that and 9 10 it really goes to some wider policy issues here, that if you are going to move people on, you need to do it in 11 a reasonably open and transparent way, you need to have 12 the full facts at your disposal, which without having 13 time to go into the details one way or another wasn't the case here, people weren't being told the whole 15 16 story, said they weren't being told the whole story, it 17 is not quite clear what was happening.

18 And I think you have to have an ability to check 19 people's credentials if you are going to move them, 20 which in a sense the Fit and Proper Person Test is the start of being able to do that. And fundamentally if 21 22 you have a situation in which you move people through 23 approaches that, you know, could best be described as delphic or opaque, you probably need a regulatory 24 structure so you can have some reference point to what 170

individual and the organisation so it's not very good HR practice in terms of talent if you don't a proper

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4 The fit and proper fern test is starting to give us 5 a sense I think of places where, having done checks on 6 individual's credentials and profiling and references 7 and all the rest of it, you can start to distinguish 8 between the people who genuinely need development, and, 9 I mean, development in the proper sense of the word and the people for whom there is a fundamental problem and 10 the Fit and Proper Person Test has only been operating 11 12 in full form for a bit over a year, but my understanding 13 is that when NHS England went back to Trusts and said 14 are you operating this process, 100% of Trusts said they were and there were figures produced that showed a low 15 sort of small single figurish number of people for whom 16 17 there were significant problems of the kind you might be

fortunately for whom you need some kind of development. 20 So I think we have got, you know, some of the 21 components of the approach in place, we don't have 22 manager regulation in place clearly because we are 23 consulting on precisely what format, that is 24 something --

alluding to here and a much larger number of people

LADY JUSTICE THIRLWALL: I'm sorry Mr Vineall, 172

Government is, you know, full tilt ahead at addressing.

- I hope this is not a question of the pot calling the 1 2 kettle black, but you are speaking really quickly.
- 3 Sorry.

4 LADY JUSTICE THIRLWALL: And the shorthand writer,

5 who is very quick, I think is probably find this a bit

6 hard.

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All right, I will slow down.

8 LADY JUSTICE THIRLWALL: If you could go just a bit 9 slower.

I think I had more or less finished that 10 Α. sentence which was to say we have got the components of 11 12 the system in place.

But we need to draw it together and it may well be that emerging from that we need some clearer, you know, protocols if you like about how you approach these situations in order that we can distinguish where there's a significant and serious problem and where there is a more conventional issue of moving somebody to a different position.

MR DE LA POER: And is that something that responsibility for which would sit with the Department, 22 that you are handing that down to NHS England saying: 23 this is what we need to do or is it internal to NHS 24 England for them to produce it?

If we did that I think it would be something 173

went to four different committees, two of which were to the one that was related to Cheshire and predominantly Cheshire. And that meant that you couldn't get any sense of patterning because it was too split up which is in a sense what Hayley Frame said in her evidence piece.

The legislation in the Children Act 2004 says you must examine it by residency and you may examine it by, you know, by wider areas.

So I think we need to clear up, you know, how -how optional the second of those is, if you look at the history of the guidances over the period of time, the 2010, 2018 and 2023 guidance allow for some optionality.

The 2013 and the 2015 guidance, which is the ones that the hospital was operating against in the period of this time, didn't and said you needed to do it according to the residence.

Now of course what's changed since the 2004 Children Act is that the Department of Health received the responsibility for Child Death Reviews in 2018. Why was that? It was because of the Wood review in

20 2016 that said 45% of neonatal deaths are in the health 21 22 service so would it not be logical for us to take over 23 that responsibility?

24 The majority of those neonatal deaths are either going to be in hospital or people who are transferred 25 175

that we would need to share on, probably I would have

2 thought. Because, I mean, manager regulation is led by

us with their very significant involvement, Fit and 3

4 Proper Person they do the mechanics of but we are

heavily engaged. So I think it would sit across those 5

6 two.

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Q. Topic 10, the Child Death Review process?

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q Q. Very narrow.

10 Α. Yes.

11 Q. The Inquiry has received evidence, we don't need to go into the precise geography, that a potential 12 failing in the existing system is, particularly with 13 neonates who may never have been themselves resident 14 anywhere, that by taking the families' residence address 15 16 as determinative of the area as opposed to the place in 17 which they died can lead to deaths being spread across

a number of Child Death Overview Panels. 18 19 Is that an issue that the Department recognises as 20

requiring some adjustment or finesse? 21 Well having seen the evidence that's been presented in the Inquiry, and I wasn't -- I don't do 23 children's policy so I have learnt up about CDOPs and all the rest of it, I think there probably is an issue 24 we need to look at. So we had seven deaths here that 174

1 into hospital, so the hospital is the place of the 2 death

3 So there would be a logic, wouldn't there, in 4 ensuring that whatever arrangements we have are grouped 5 around those sets of institutions, hospitals with 6 neonatal units, that see the majority of those deaths.

7 So I think we do need to take away and look at 8 that. I'm not positing a position because we haven't 9 got one and we haven't been through it and we need the approval of our ministers, but I can see from the 10 11 evidence presented that there is something fairly 12 straightforward you could do to clear up this issue and 13 I notice somebody last week -- I can't remember who it

14 was -- who said you could do it at the ICB level. There

is only 42 ICBs, you would get bigger pattern on 15

a number of 42, et cetera. So I think there is an issue 16

17 once we have seen what the Inquiry reports on that we

18 need to look at.

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19 Our guidance has been pretty well received and was 20 quite -- I think considered quite good but we last updated it when we took over the responsibility in 2018 21 22 so obviously as and when the Department decides that 23 that needs to be looked at again, this is an issue that

24 we need to address in that.

> Topic 11, my final topic, the tracking and 176

implementing of Inquiry recommendations?

A. Yes.

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3 Q. And your reaction to me providing you with 4 that title suggests that this is a topic that you may 5 have something to say upon?

Yes, yes. So what have we heard here and in other places? That there is a lot of recommendations and we need to do something better to organise ourselves in the response. That's kind of the gist of the 10 argument, isn't it; is that fair?

Precisely so.

12 What I would say is this is an issue the 13 government recognises. There is a House of Lords report from September making that very point which is due to be responded to very shortly I think in the next several 16 weeks. We did a piece of work through HSSIB through 17 Rosie Benneyworth who was here last week and I think spoke about it sort of positing the issue that we have 18 19 a lot of different activity coming into organisations 20 the point from earlier recommendations and we need to do something to corral that better. Our minister's 22 response in September was to crack on with the thinking

23 about that when the report came out. 24 We have done some preliminary work on that, the 25 Dash Review is looking at this issue and I think is

in the Department. I recognise that we need to look at this issue in the round, I don't think the present position is untenable but I think everybody agrees there is room for good improvement and we certainly want to be a part of that.

Q. One of the pieces of work which the Department engaged with was the schedule created by this Inquiry into previous recommendations?

A. Yes.

10 And that identified a very large number of Q. recommendations and provides a line by line commentary 11 upon whether it's been implemented, rejected and so on. 12 And your Department contributed to the Inquiry's 13 14 understanding of each of those; is that right?

That's correct.

16 Q. In terms of taking a step back, you have been a civil servant in the Department of Health and Social 17 Care for a very long time? 18

A. Yes.

Q. When you looked at that document, were you surprised at where the balance lay in terms of recommendations being implemented or not or did it accord with what you were expecting that piece of work to produce?

> A. Well, what I expected to show which certainly 179

going to say something about it in its forthcoming 1 report. So that should give us the basis alongside the HSSIB report and whatever the Government at Cabinet 3 Office level comes out with to take it forward. 4 5 I think the description that somebody said that

6 this was untenable, I don't recognise it as untenable 7 because there is quite a lot of things from Inquiry recommendations that we implement, like HSSIB, like 8 Medical Examiners, like Fit and Proper Person Test. 9 10 But I do recognise that at the local level people

feel there are a lot of recommendations coming on to 11 them although I note that Jane Tomkinson said precisely 12 the opposite when she was asked about it the other day 13 so it is not everyone's view, but there is a view there 14 is quite a lot coming down the line. I also think there 15 16 is the question about how we track Inquiry 17 recommendations.

18 I do actually think we track Inquiry 19 recommendations quite carefully but I think there is the 20 question of returning to the efficacy of things once you have either implemented them or either implemented but 21 22 still ongoing is going to be important.

23 So I suppose in summary there is a pipeline that 24 I think will establish a clearer Government position on this issue. There's some preliminary work we have done 178

when we did our returns to you showed was that we had implemented quite a number of Inquiry recommendations 2 3 and there was a set that was implemented ongoing. So 4 there was further work to do to continue with their

5 implementation but they had been taken forward. And 6 that they were a small number that had either been

7 superseded or had been disagreed with which the 8

Government is able to do.

I think the thing that did strike me is that there 9 10 was quite some commonality in the recommendations that 11 come forward. So we have to ensure that our solutions, 12 you know, have a longevity that mean issues don't 13 continue to come up.

I do think going back to my earlier theme it is 15 important that in implementing recommendations, you know there is an expectation on the front line that they will 16 17 take them forward in a serious manner and we do still have an issue at the moment that there is too much 18 difference between how people do things, which I think 19

20 comes back to the previous discussion about cultures and

21 boards.

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22 So I don't think -- I don't think I was 23 particularly surprised by what I found. I think my two 24 learning points are if we are still having quite a lot of Inquiries that are saying the same thing, we need to 25

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have a hard look at some of our solutions, that is the first thing and probably a statement of the obvious.

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And the second thing I would say is that you get to a point with recommendations that they cease to add value, so sort of honed and focused recommendations I think are the things that hold the Government best to account rather than sort of a voluminous list.

MR DE LA POER: Mr Vineall, thank you. Those are my questions. There is permission for one of the CP representatives to ask you some further questions.

LADY JUSTICE THIRLWALL: Mr Baker.

Questions by MR BAKER

MR BAKER: Thank you, my Lady.

Mr Vineall, I ask questions on behalf of two of the Family groups. Can you hear me clearly enough?

Yes, now I can hear you fine.

17 At a number of points in your witness statements you refer to a need to establish 18 19 a transparent patient safety culture within the NHS. In 20 this sense when you talk about transparency, are you 21 talking about a system which is candid with those who 22 are harmed?

A. Candid with those who are harmed and candid about the problems that arises from those harms in order that you can learn better for the future and hopefully

So we have got -- we have still got pockets where I don't think it works properly and, you know, my personal evidence of that is some of the issues that have come up in this Inquiry are not unfortunately that dissimilar from what came up in the first Mid Staffs Inquiry when I was sort of sitting on the other side of the desk and that was 15 years ago.

So we have got some things that are, you know, long, long term problematic, I think I don't think they are systemic to the NHS as a whole at all. But we have got pockets of problems where it appears that people don't recognise the generality of messages from an Inquiry even though they may be focused on one institution.

I mean, there must be some aspect of either generic NHS culture or deviant NHS culture which has a major problem with transparency because it keeps coming up over and over again in the Inquiries?

That's a good question.

What would I say to that? I would say that there is a -- there is a difficulty that in some places, be that on the clinical or the managerial side, people feel it is a weakness to say that we have got something wrong.

> Q. Yes.

diminish the number. 1

2 So a healthy patient safety culture is one 3 that confronts the issues that cause patient harm, is 4 upfront about them and is clear with those who are 5

Yes, and has all of those things I think sort of supported energetically by its board and the way it behaves and indeed the information it receives at the board.

10 Yes, and I don't need to take you to it but it is paragraph 123 of your first witness statement, you 11 talk about measures being put in place to foster 12 13 a transparent safety culture since 2012.

14 Am I to understand that it would be fair to say that there are still -- there is still progress to be 15 16 made in taking the NHS to a transparent safety culture?

17 I think there is still progress to be made. 18 I think it is very good in some places. I think it has 19 improved overall because we didn't have things like 20 candour any more and all the -- you know, we haven't quite got there with the duty of candour, we are part of 21 22 the way there. But the unfortunate thing is you do 23 see -- well, one, you see a number of Inquiries but probably more pertinently, the Inquiries that you see 24

don't come up with dissimilar problems.

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1 And I think in other walks of life, we have moved away from that and we are moving away from it in 2 3 the NHS, but we need to go a bit faster.

4 And we do have some problems -- and I think this is 5 a case in point -- where when you have got a problem, 6 you do everything to try and solve the problem other 7 than absolutely face up to it.

> Q. Yes.

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And of course if you absolutely face up to it, you usually end up in a better place in due course. 10

11 And we have done, we, the Department, over the 12 years have done a lot of work externally to try and push 13 people to do that with regulators and inspectors and 14 champions and all of those things, but there is also a point that you need the organisation to take -- to 15 take on its responsibility. 16

17 And if I can give you one example of positivity from recent Inquiries to illustrate that. We have got 18 an Inquiry that's finishing quite soon, the David Fuller 19 20 Inquiry, into the man who was, you know, a necrophiliac 21 in the mortuary and is now in prison.

22 And the first part of the Inquiry was into the 23 hospital and it said to the hospital: you made quite 24 a lot of mistakes here and you should have picked up on this chap sooner and why did he have his own access to a

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1 swipe card to the mortuary and things like that.

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This had all happened over a period of years going back to the, you know, 90s or 80s; a long time. And the Maidstone and Tunbridge Wells Trust said: Yes, okay, there is a problem here. We need to address it.

So the first report had 16 recommendations for the Trust and we published the response some time last year I think in the autumn and they had done them all. Now, when I went down to the Trust what struck me was that they were pretty open about learning from their mistakes and they thought it was an issue to resolve and in resolving it, it would be for the betterment of the Trust overall.

So there are lots of good practice like that and I think, it's a generality, but I think if you had had that similar incidence 30 years ago in another part of the NHS they probably wouldn't have responded in as open a way. They would have thought it's an appalling story.

So there is work to do, but there are good signs of progress.

Q. It's clear that the Department at least recognises some of the issues or indeed promotes the issues because you have the duty of candour being put in place, you have whistleblowing protection being put in place?

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statements, to having boards that are, you know, curious rather than looking for security, as the board in this instant wasn't, are sensitive about quality of patient care, do listen to patient stories, aren't defensive and don't enable tribalism amongst their different groups of professionals, which clearly was the case here.

And I think, you know, we have got -- we have got to get boards to do more work to look at their culture themselves.

We promulgate, we exhort, we set policy, we
encourage. Our ministers can use their political
position, we can use our official position in terms of
issuing guidance, but in the end you are sending it out
to a group of people who are responsible for an
organisation that isn't something you're in day-to-day

16 charge of.
17 And maybe one of the solutions in a sense, going
18 back to what I was saying earlier today, is that if you
19 had a more structured programme of training both for
20 managers and clinicians, in some of these governance
21 issues you might greater openness because there are lots

22 of people, including the evidence you've seen,

23 Judith Smith, Michael West, who make clear that if you

24 have the right culture and the right governance you

25 probably get better patient outcomes.

A. Yes.

2 Q. But I think you have read through the 3 transcript of Jane Tomkinson's evidence?

A. I have.

5 Q. She very candidly accepted that despite all of 6 that regulation, an instruction coming down to the Trust 7 it's just ignored in this, in this case. It appears to 8 be just bypassed. I mean, that's a cultural issue. How 9 do you deal with that? Is that through better 10 regulation of managers?

A. Well, I think manager regulation, for all the reasons that I have said, would help and no doubt it would help in relation to this. It's pretty odd that we've got a significant group of professional people who aren't regulated. I mean that's anomalous as Dr Kingdon said.

17 I think there is a point, and it was always the
18 kind of contrary criticism of what we did, was that you
19 can carry on regulating people as long as you want but
20 actually for some people it won't shift the dial.

21 I think regulation absolutely has a role. We were 22 right to do all the things we did. But there comes 23 a point at which you have got to generate some of those 24 things from within.

And I think it does come back, as we said in these

So there is more we can do. But there is also more the NHS can do and I think NHS England, you have, they have been pretty, pretty enthusiastic in taking forward the leadership and development and training programme.

But as Jane said there's a point at which you have to get, you know, a sensible reception from the other side. And, you know, with somebody like her at the helm you are obviously going to get it because she recognises the issue. You do have some places where the whole

10 thing is a bit intractable and we have to do more to

11 make sure that that stops.

12 Q. Yes. If I can come on, very briefly, to13 candour as it interacts with patient safety reporting.

A. Yes.

15 **Q.** So there is an anonymous patient safety 16 reporting system NRLS, which allows patient safety

17 issues to be reported to a central database as

18 I understand it?

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19 **A.** Yes.

20 Q. That's correct?

21 A. What did you say the acronym was?

22 Q. NRLS.

23 A. Yes. Well, it -- the National Reporting and

24 Learning Service.

Q. Yes. Now, what is done with the information

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that is deposited in the NRLS? 1

Well, the NRLS was the scheme we had until, you know, just a couple of months ago, which was the main point of reporting for Trusts into NHS England for patient safety incidents and that used to have -- a cut of that data was analysed centrally to look for patterns of care. But that now has been moved into the Learning from Patient Safety Events, which is a more sophisticated database, with machine learning that gives my colleagues in NHS England who run patient safety more larger real-time data that allows you to give messages back out to the NHS about patterns of particular care.

So in a sense that is a -- it's a sophisticated data management function which has just been recently upgraded. It obviously is dependent on, on sensible reporting and one of the issues we saw here was the whole sort of knowledge of Datix and all of those things --

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Q. Yes

-- was a little bit different between A. different people and so it wasn't exactly clear what was being reported when.

But Datix is something that's reported internally within the Trust and isn't --

25 A. Yes.

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NHS England is to look at the, you know, totality of the data and work out if there are any patterns.

But I mean in a sense, as I was saying to you before, it's incumbent on the organisation locally to have an understanding of reporting procedures and to understand issues that are of concern.

In some places, you have low reporting because people aren't sufficiently engaged in the process. In other places, you have high reporting because people are zealous about patient safety incidents and often high reporting is an example of better learning.

So the precise numbers don't indicate in a sense how good or bad an organisation is. They just tell you about whether they are open about their mechanisms or

But these central reporting systems, are they just a big warehouse where people send their concerns and they are collated by statisticians and data analysts?

19 20 A. I don't think they are just a warehouse 21 because, we try, because I mean --

> Q. I don't mean a literal warehouse.

23 A. No, I know, I know you don't. I don't think 24 they just languish in the warehouse, I think that's your point because NHS England do send the details and the 25

Q. -- isn't anonymous?

A. Yes.

3 Q. Whereas, so if you were to write down on 4 a Datix, "I am concerned that Nurse Letby is attacking patients", then you would have to fill that Datix in.

6 The Trust would see that, it's not an anonymous

7 reporting. Whereas NRLS and its successor adopted as their models the aviation reporting system in the US 8

9 where people could anonymously report safety issues --

Α. Yes.

11 Q. -- and they would be acted upon.

12 Now, I looked at the NRLS data published online

13 through its website and the most recent published

information was from 2022 and it records in the period 14

between April 2021 and March 2022 over 90,000 incidents 15

16 were coded as patient abuse by staff or third party.

17 Now, I'm assuming by far and away the vast majority 18 of those are by third party rather than by staff. But 19 is anything done with that information? If somebody in

20 this case had reported a safety incident relating abuse

by staff, would anybody have done anything in response 21

22 to that?

23 Well, you would have expected somebody to do 24 something locally about because clearly the reason for reporting into NRLS and then eventually back to

information back out to the NHS and I was referring this

morning to the fact that we did get a presentation about 2

3 how more better data could be produced in real-time as

4 a result of these new systems and it was, it was quite

5 persuasive that there will a lot more to learn more

6 quickly.

7 So I think and, you know, the replacement, LFPSE 8 and PSIRF, are very popular in the NHS and people think they've, you know, they have improved arrangements also 9 not just in terms of the quality of the information but 10 in terms of the time taken and the efficiency that goes 11 12 with it.

13 But in terms of a concerned member of staff 14 in, for the sake of argument, the Countess of Chester Hospital, who wishes to report something centrally for 15

somebody to take action and help them because nothing 16

17 has been done locally, there isn't a mechanism, is

18 there, they have to use a Datix?

19 Well, the mechanism, the mechanism is intended 20 to get you the global and if you like the larger-scale

learnings. I mean if somebody had a concern like that 21

22 locally you would expect them to raise it through the

23 normal routes anyway and for the organisation to be, you

24 know, open and sensitive enough that they were going to

25 respond to it.

- Finally on a linked topic, the Inquiry heard Q. evidence from Dr Rosie Bennyworth from the Health Services Safety Investigations Board and in particular I asked her questions about protected disclosures --
 - Α.
 - Q. -- in the context of their investigations.
- Α. Yes

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- Now, isn't there a tension between systems Q. which have the effect of reducing transparency and the need for candour with those who are affected by the incidents?
- Yes. So and, and the bit she didn't answer was the bit about why did we set up HSSIB in that way.

So the reason we set up HSSIB in what way was because we had a problem with people speaking up as discussed earlier and seen in this Inquiry and we knew from the aviation industry that their sort of black box approach of having the totality of the evidence in that case in relation to a flight or a crash we might do well to replicate that for the purposes of learning and that that would encourage people to come forward. So there would be a greater transparency and openness about people's contribution and engagement.

But because we established HSSIB for the purposes of, I mean, literally not just in terms of the phrase

do so. So that -- that's the logic of HSSIB.

But it's possible, isn't it, to be told information by somebody to accept it as credible and to use it as part of your decision-making as to what happened and for that to be communicated to the injured parties without revealing who gave you that information or indeed --

A. Yes, it is. And I mean, you know, the duty of candour is predicated on being open about information with people and --

O. That's owed by the Trust to the injured person, not by the HSSIB to the injured person?

Yes, that's right, the HSSIB is in a different framework for its investigations so that's a small subset. The duty of candour we have just explained.

And -- and of course there is, you know, NHS Resolution, our litigation organisation, litigation and safety learning organisation, makes very clear that saying sorry is not an admission of guilt and people should be encouraged to do that.

20 21 So from all angles we are trying to get to 22 a position of greater openness whether it's through 23 candour, regular interaction, whether it's through the 24 point at which something may turn into a case for litigation or may not and then I think separately from 25

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"learning rather than blaming" and not for litigation 1 2 purposes that would be sealed unless the GMC or 3 a Coroner or, in exceptional circumstances, the PHSO 4 gave a court order to access it because you are always going to have the rare exceptions. So that was the way 5 6 we set up HSSIB.

7 HSSIB is a learning organisation and we thought 8 that that was the best way to generate more learning. 9 You know, the trade off on the guid pro guo is that for 10 the outside world there isn't the transparency about the precise details and events. On the other hand, the 11 findings of the investigations are absolutely 12

13 promulgated across the NHS. 14 So it's an approach. It doesn't cover all patient safety incidents. It isn't the way we would, you know, 15 16 expect people to behave in the NHS. We would expect 17 them to talk and talk openly. But I think it's there for a purpose because we had uncovered in a number of 18 19 investigations, including Morecambe Bay, which is really 20 where the recommendation came from, although the idea 21 had been mooted by one or two people previously, that 22 that was a good way forward to get out of this bind 23 where a family has a Serious Incident that they want investigating, we want to investigate it for the 24 purposes of learning and we can't get right evidence to

1 those two we have got the approach to HSSIB which is for 2 the purposes of safety learning.

3 Q. Yes, but there at all stages has to be 4 candour --

5 Α. Yes, I mean there has to be candour with a --6 with a big and a small C and, you know, I mean clearly 7 the evidence from this Inquiry is that there were quite 8 a lot of instances where there wasn't candour of any kind --9

Q. Yes.

10 11 Δ -- and that was -- that contributed to the set of problems. I have found in doing this job for 12 13 a number of years that there are two things that usually 14 go on where there's a problem. One is can you actually sort out the problem, why it happened and explain it to 15 the small I injured party, and the second one is people 16 17 feel nervous about that and therefore they engage in behaviour that isn't transparent and you have an even 18 worse job to try and unpick what was actually the truth 19 20 because somebody has been a bit evasive or difficult about it and I think if -- we are desperate to drive the 21 22 latter out of the system so that we can concentrate on 23 the former.

24 MR BAKER: Yes, thank you. My Lady, I'm sorry if 25 I have gone slightly over time.

1 Questions by LADY JUSTICE THIRLWALL that that's how you described what they could include 1 2 LADY JUSTICE THIRLWALL: Thank you very much indeed 2 and you began with: difficulty defining the skills and 3 Mr Baker. Is there anyone else? No. Thank you. 3 competencies required of senior managers who are less 4 Just one or two from me if I may, Mr Vineall. 4 easily and clearly delineated than the clinical 5 competencies which are less clearly delineated and 6 LADY JUSTICE THIRLWALL: I think in the Terms of 6 knowledge needed for clinical health professions. 7 Reference I am asked to look at the accountability of 7 I understand the point that you are making, it's 8 managers. We have rather focused on regulation of probably not a reason not to regulate. I think the 9 managers not least because the consultation that has 9 point really is that it is not entirely clear what is 10 come out which is obviously a subset of 10 expected of managers and what they actually achieve. 11 accountability --Some managers, you can see a really good one when they 11 12 A. Yes. are working, but when you try and define what that is in 12 13 LADY JUSTICE THIRLWALL: -- and may be thought to 13 advance presumably it's quite difficult since that be a very sort of physical demonstration of how you hold 14 argument was even one that was potentially something 14 people accountable. When you wrote your -- I think it that you could have thought people might raise. 15 15 16 may have been your second statement --16 Yes. So two parts to that; is the point in 17 Yes. 17 255 Part A insurmountable? No. That was written under 18 LADY JUSTICE THIRLWALL: -- or it may have been the previous government. 18 19 your first. I'm sorry. 19 LADY JUSTICE THIRLWALL: No, I understand that. 20 About manager regulation. 20 The current government is pretty clear that, 21 LADY JUSTICE THIRLWALL: Yes, at page 255, at that 21 you know, we can find ways through these things. LADY JUSTICE THIRLWALL: But on that first point, 22 point you were sort of setting out what the arguments 22 23 against regulation might be. 23 is the way through or is one way through to be very 24 Yes 24 clear about what a good manager looks like to use that 25 LADY JUSTICE THIRLWALL: Or could be. I noticed horrible phrase? 198 1 No, I think it is, and that's why when the 1 LADY JUSTICE THIRLWALL: Perhaps in an ideal world, 2 Secretary of State was here in Liverpool, you know, in 2 we would have had managers whose role and scope was well 3 his speech in November which just preceded the 3 understood by everyone and you would have had good 4 announcement that -- the manager regulation wasn't 4 managers. Then the question of regulation would have 5 announced at the same time, he was making the case, as 5 arisen. But what we are doing now is thinking if we want 6 he said not always terribly popular, that we need more 6 to regulate, then in order to do that, we have to take 7 managers and we need better managers and a corollary of 7 those prior steps. I am not saying that that's not 8 having better managers is that you have better training; 8 a good idea, but that is how we have got here, isn't it? 9 Yes, yes. I mean, the other way, or maybe the hence the very senior manager pay framework, hence the 9 leadership development programme that NHS England is way I put it is we are doing it in a sense the other way 10 10 11 doing, hence the work he has asked General Sir Gordon 11 round; that we have got management in different formats 12 and now we are saying: Let's regulate it. Whereas what Messenger to do on talent management. 12 13 So I think there is strong recognition from this 13 you usually do when you establish a profession or 14 set of ministers that if you are going to regulate 14 a group is as they develop you regulate in lockstep. effectively you have to have both the fence of the The Royal College of Physicians was established in 15 standards that you are regulating against and you need contradistinction to quackery and they said: Right, 16 16

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an infrastructure and a framework which is going to

Helené Donnelly point: it's fine to regulate managers

but please can they be given the right support so that

have to have the right people in post, don't you?

You do have to.

And we don't have that description at the moment.

LADY JUSTICE THIRLWALL: Yes. But first of all you

enable people to deliver that; a bit like the

they can do the job properly.

before I came here -- there are identifiable groups of people. There's the people who do the general management training scheme, a tiny number, the elite; they've been there since 1956, Judy Smith said. LADY JUSTICE THIRLWALL: Yes, we've heard evidence some about that.

Now for management, I think -- I thought about this

we're not quacks, we are doctors and then we'll go from

1 A. So 1. 2) there are the group of people a lot
2 of whom have been to the Inquiry and who I have seen
3 throughout my career in the NHS which is people who
4 started as clinicians, often but not always nurses, who
5 become managers and doctors who become managers and
6 become Chief Executives, there's a second group.

There's the group of people who are a lot of people in the health service -- who would have been me if I hadn't moved from the NHS into the Department -- who start off at the ground floor and work their way up and maybe don't go through as many schemes but still become managers. And then obviously there's the group of people who come in later in life.

people who come in later in life.
A lot of people when we, you know, introduced the
Trust movement in the early '90s there were quite a lot
of people who came in from large organisations,
including the Armed Forces because they had an
understanding of structures and systems. There is, you
know, there is the faculty of management and leadership

20 in medicine which has quite long established and quite
21 good rubrics for what a decent manager who's come from
22 clinical life looks like.

LADY JUSTICE THIRLWALL: Sorry just to cut across you, but what's clear is there are lots of routes into management.

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who feel that they are in the ascendant. That's a verygeneral observation.

A. Yes.

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LADY JUSTICE THIRLWALL: But it certainly is not 4 5 an observation I think one would have made 20 years ago. 6 So there has been that shift. I think it probably goes 7 to the question of culture, the sort of understanding 8 and mutual respect of the qualities of the other person. 9 I mean, it doesn't just go to managers and doctors or 10 nurses or whoever. But there needs to be that understanding what the other person is doing, respect 11

12 for what they are doing and then a collaborative13 approach, which I know is very easy to say, and I think

14 it's much harder to actually achieve or seems to be?

A. I think that's important, very important. And
I mean it was interesting that Gordon Messenger said in
his original report in the summer of 2022 that to him,
coming from the Armed Forces, he thought the NHS
appeared like of federated ecosystem, which was a great
phrase. And then he followed on by saying: in which
managers don't feel they have the right profile, in

22 which the medical culture can be sometimes a little bit

23 difficult to get on with, in which people aren't always

24 respectful of one another and in which across the piece

25 equality, diversity and inclusion is not what it should 203

1 A. Well, but there are lots of groups, there are

lots of groups who are there already and there are lots

3 of routes. So your point which is we are sort of

4 regulating but we have already got quite a lot of the

5 groups in place they need to inform how we do that

6 regulation.

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LADY JUSTICE THIRLWALL: Yes.

A. That's the point that was --

9 LADY JUSTICE THIRLWALL: Yes. No, I understand.

10 A. -- that the sort of posited point I was

11 making.

12 LADY JUSTICE THIRLWALL: I understand that. The

13 other thing which unsurprising you haven't referred to

14 but what I think is certainly something to be considered

15 is historically the sort of resentments or tribalism,

16 call it what you will, between the clinicians on the one

17 hand, the managers on the other, the first thinking that

18 the second are seeking to sort of take over --

19 **A.** Yes.

20 LADY JUSTICE THIRLWALL: -- and the second thinking

21 they are being talked down to to put it --

22 A. That's a good summary.

LADY JUSTICE THIRLWALL: I think, it is my

24 observation that that has rather changed so that it's

25 now the doctors who feel talked down to and the managers

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1 be and not what it is in other walks of life. So ...

LADY JUSTICE THIRLWALL: Yes. I mean we obviously

3 heard his evidence about that. It's not very

4 surprising.

A. Yes. So we have got a bit of an issue across

6 the piece that the cultures aren't talking to each

7 other.

8 LADY JUSTICE THIRLWALL: Can I just ask a sort of

9 supplementary question. Sorry, I don't mean to cut

10 across you.

11 A. That's all right.

12 LADY JUSTICE THIRLWALL: You can always finish off

13 if you want to.

14 A. No, I've finished more or less.

15 LADY JUSTICE THIRLWALL: But we have a situation

16 where you have got the graduate scheme --

A. Yes

18 LADY JUSTICE THIRLWALL: -- which you described as

19 an elite scheme and Professor Smith talked about, you

20 know, it's not quite fair that people who come in in

21 a different way don't have those same opportunities.

Well, irrespective of whether it's fair or not it's

23 the way it is. But, is there not a way of providing the

24 same quality of training for people who come in via

25 different routes, the people in those different groups

1 that you were identifying?

- 2 A. Yes, I agree with that and she's quite right,
- 3 which is if you are not, you know, through that elite
- 4 route which exists in all sort of equivalent
- 5 multi-national organisations -- they all have graduate
- 6 schemes for the top people, don't they -- you need some
- 7 structures for all the rest of the people who are coming
- 8 in. And I noticed, you know, what is
- 9 Sir Gordon Messenger was saying was you need to do this,
- 10 you know, you need middle management and early entry and
- 11 mid-career points just like you would have in any other
- 12 large organisation.
- 13 So we do need to do all of that work and
- 14 NHS England, you know, are starting out on some of these
- 15 things; a management training programme, they have
- 16 obviously got the leadership competency framework for
- 17 boards so they have got the top-end stuff. So we do
- 18 need to do that.
- 19 And I think you could end -- we would hopefully end
- 20 up with a virtuous circle where we have regulation of
- 21 managers so people know what it means to be a manager
- 22 and we have training structures that support people to
- 23 become better managers. And that way both doctors and
- 24 the general public and anybody else understand that
- 25 management is a reputable profession.
 - 205
- 1 of Conduct not regulation because it's not a profession,
- 2 whereas you have put it: it's a lot of professionals,
- 3 but there isn't a sort of recognised --
- 4 A. There isn't recognised --
- 5 LADY JUSTICE THIRLWALL: -- management.
- 6 A. I mean, I didn't agree with -- I mean his
- 7 point was slightly, I think he said you shouldn't
- 8 regulate managers because you can't define them as
- 9 a profession. Now, I'm not --
- 10 LADY JUSTICE THIRLWALL: Yes, that's absolutely
- 11 what he said, yes.
- 12 A. I am not persuaded about that.
- 13 LADY JUSTICE THIRLWALL: Yes.
- 14 A. We know what the NHS is.
- 15 LADY JUSTICE THIRLWALL: That's why we go back to
- 16 the point we made about what you want them to do.
- 17 A. Management has existed for 100 years and you
- 18 can pretty well explain what it is; systems in
- 19 organisations and pulling things together and making
- 20 something from component parts.
- 21 We have, the point I was making to you, we have
- 22 a number of different professional management groups in
- 23 existence at the moment. It cannot be impossible to
- 24 draw that into a structure for, you know, a profession
- 25 of management that is properly regulated both at the top 207

- 1 And if there have been situations where there's
 - been this movement round to one person feeling they have
- 3 the upper hand to the other person feeling they have the
- 4 upper hand, we can end that and agree that we all need
- 5 to be on the level. That's where you want to get to.
- 6 You know, my experience of working with clinicians
- 7 is, you know, they're good, clever and decent people to
- 8 work with
- 9 I think when you get difficult situations or
- 10 extreme situations, like the one we have been talking
- 11 about here, you do get a reversion to that tribalism and
- 12 we do unfortunately see that in the worst cases that
- 13 I was just discussing previously and we sometimes see
- 14 that through boards and through the leadership of those
- 15 groups and organisations, and we really need to be
- 16 moving away from that.
- 17 LADY JUSTICE THIRLWALL: Regulation of managers may
- 18 be one way of doing that, but it's not all, is it?
- 19 **A.** Regulation of managers is a component part of
- 20 that.

21

24

25

- LADY JUSTICE THIRLWALL: Yes.
- 22 A. Regulation of managers is there because it's
- 23 anomalous that we don't have it.
 - LADY JUSTICE THIRLWALL: I think Mr Jarrold said
- rather wisely was that actually what you want is a Code
 - 20
- 1 level where it paradoxically is probably slightly easier
- 2 to do it --
- 3 LADY JUSTICE THIRLWALL: Yes.
- 4 A. -- and through the routes coming down.
- 5 I just, you know -- we can do that.
- 6 You know, that's what we are intending to do.
- 7 LADY JUSTICE THIRLWALL: Yes. What about at the
- 8 levels of ward managers, which is a different role and
- 9 a more circumscribed role, but what is the thinking
- 10 behind what the standard should be for people in those
- 11 situations? Because that has the ability, doesn't it,
- 12 to make people's lives quite difficult?
- 13 A. Yes. I don't -- I don't think I have as
- 14 knowledgeable an answer to that. The only answer
- 15 I give, which is a little bit packed but is true, which
- 16 is we are asking, well, we are asking within the
- 17 consultation at what level regulation of managers should
- 18 apply; top, middle, right down to the bottom end.
- 19 And there is a very important question about what
- 20 we do in terms of those people who, if you like, are
- 21 double qualified; some of the people who have been here
- 22 who started off as clinicians and became managers. Do
- 23 we write management into their clinical practice or do
- 24 we have something that sits across the two?

LADY JUSTICE THIRLWALL: Yes.

So I think, you know, we need -- there's, I mean the consultation has a lot of detailed questions quite a lot of which are about scope and level.

LADY JUSTICE THIRLWALL: Yes.

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Because 1) we need to make sure we include the right people and, secondly, we need to ensure that the nature of the regulation is proportionate, right-touch regulation, which is a bit jargonistic --

LADY JUSTICE THIRLWALL: It is.

10 -- but it's the point about be common-sensical in how far, you know, in the structures you use to 11 regulate people. You know, one of our professional 12 organisations, the Health and Care Profession Council 13 holds accredited registers for new professions. 14

So I'm not saying in saying any of that that that's 15 16 the way we are going to go with management regulation. 17 But I am saying that proportionate regulation does exist from those emerging professions that that organisation 18 19 looks after to the sort of, you know, most sophisticated 20 brain surgeon who works for the Royal College, you know, who has some regulation through the GMC and the 21

23 So you have got to be sensible and obviously 24 whenever you regulate something and you are starting off, you have got to have some ability to bring on 209

Royal College of Surgeons.

I am now going from memory, but in the front of the consultation document we pointed out where certainly in setting up infrastructures costs would be likely to fall to government. I think that that's as much as we said.

LADY JUSTICE THIRLWALL: I'm just thinking about the resentments and the opportunities for things to be done a bit better.

8 It would be -- it seems an obvious human response, 9 that if one group is not having to pay for their regulation and the others are, I think that's just 10 a very easy way of making people feel resentful, leaving 11

aside questions of pay and hours and how long they have

13 had to work to get there, et cetera, et cetera.

There's a lot to think about --

15

16 LADY JUSTICE THIRLWALL: -- as I know you know. A 17 separate question --

18 So a plea for consistency there, I think is what you were saying. 19

20 LADY JUSTICE THIRLWALL: Yes, consistency across 21 the piece.

22 A separate and different question. I don't want to 23 take a long time over the memorandum of understanding.

24

25 LADY JUSTICE THIRLWALL: The December 24 document. 211

people who are mid-career into that and you don't want 1

2 to introduce it with such sort of -- so much

3 infrastructure that it's off-putting to getting people

4 to come in and you know starting that career.

5 So, you know, how you land and introduce this thing 6 you have to be careful about.

LADY JUSTICE THIRLWALL: Yes, but if someone wants 7 8 to be a doctor or a nurse they are not put off by the

9 fact that they're going --

10 No, no, I am not saying they are not put off. But you just make sure, if you are going from having 11 nothing at all to something, you have to make sure the 12 something is of the right proportion. 13

14 LADY JUSTICE THIRLWALL: Yes.

15 And, you know, it isn't sort of, you know, 16 extreme.

17 LADY JUSTICE THIRLWALL: Yes. Understood.

18 Then doctors and nurses I think pay for their 19 regulator, don't they?

20

Yes. Α.

21 LADY JUSTICE THIRLWALL: I'm sorry I have not had a chance yet to read the consultation. But is that part 23 of the picture, that managers will have to pay for their 24 regulation?

> Α. Well, no decision has been made on that and 210

1 But just really to make the observation there is no

2 reference anywhere to the question of safeguarding, you

3 know, what you do in a situation where the harm is being

4 done or you suspect, on whatever basis, you suspect that

5 harm is being done to a child and there is no reference

6 to that. Was that, as far as you know, a deliberate

7 omission?

25

8 I don't know, but we can take it away and look 9 at it.

10 LADY JUSTICE THIRLWALL: Yes. It seems to me 11 because the guidance there is very clear as to what has

to be done in whatever the situation, including to 12

healthcare professionals, to everyone. So it may be it 13

14 may have been an oversight, but if you wouldn't mind,

would you be able to just do a short couple of 15

paragraphs on whether or not it was omitted 16

17 deliberately?

19

18 Yes, we'll send that to you.

LADY JUSTICE THIRLWALL: Just to finish that off.

20 Definitely.

21 LADY JUSTICE THIRLWALL: Thank you very much.

22 Does anybody want to ask anything arising out of

23 that? No.

24 Happily, it's 29 minutes past 4 so we finished on

25 time. Thank you very much indeed, Mr Vineall, for

1	coming to give your evidence. You are free to go.	1	INDEX	
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3	MR DE LA POER: I believe so, my Lady, yes.	3	PROFESSOR SIR DAVID SPIEGELHALTER	
4	LADY JUSTICE THIRLWALL: 2 o'clock tomorrow. Thank	4	(affirmed)	
5	you all.	5		
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7	(The Inquiry adjourned until 2.00 pm,	7		
8	on Thursday, 16 January 2025)	8	Questions by MR SKELTON	5
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