

Thursday, 15 October 2026

(10.00 am)

(Proceedings delayed)

(10.07 pm)

THE CHAIR: Ms Hyde.

MS HYDE: Good morning, Chair.

This morning, the Inquiry will hear from Dr Robert Reid, Deputy Director for Innovative Devices at the Medicines and Healthcare Products Regulatory Agency. He will speak to the MHRA's role in regulating medical devices and technology deployed in inpatient mental health settings.

We will then hear a read summary of written evidence provided by other bodies involved in the regulation and oversight of medical devices before hearing closing remarks from the Chair and Counsel to the Inquiry.

As with previous days, Chair, there may be aspects of today's evidence that are difficult to listen to. For some people it may not be possible to sit through two sessions and as with other days, anyone in the Inquiry room should feel free to leave at any time. I would like to take this opportunity to remind those engaging with the Inquiry that emotional support is available for all those who require it.

Present here again today are emotional support staff

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Inquiry. Is the first of those two statements dated 1 September 2026 and running to 21 pages?

A. Yes.

Q. Yes, we'll refer to that as the first statement.

Was the second statement dated 27 August 2026, running to 30 pages?

A. Yes.

Q. We'll refer to this as the second statement, and just for the sake of clarity, the second statement is dated before the first statement, but is it correct that the first statement was provided to the Inquiry first, but then only signed by you after the second statement was signed?

A. That's correct.

Q. Thank you. Are there any corrections that you wish to make to either of your statements?

A. No.

Q. Can you please confirm that both statements contain a Statement of Truth and that they have both been signed by you?

A. I can confirm that, yes.

Q. Are both the statements true to the best of your knowledge and belief?

A. They are.

Q. Are both of the statements you provided corporate

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from Hestia, an experienced provider of emotional support at these types of hearing. They are currently in this room and they can be identified by their orange-coloured scarves. There is a private room downstairs where anyone who needs emotional support can talk to Hestia support staff, and if you prefer, you can also speak to a member of the Inquiry team, and we will put you in touch with the emotional support staff.

For those following the hearing online, information about the emotional support available can be found on the Lampard Inquiry website. The "support" tab is near the top right-hand corner.

You can also contact the Lampard Inquiry team directly on contact@lampardinquiry.org.uk. We want everyone engaging with this Inquiry in whatever way to feel safe and supported.

Now, Dr Robert Reid.

THE WITNESS: Hello.

MS HYDE: Can you please read the affirmation.

DR ROBERT REID (affirmed)

Questioned by MS HYDE

MS HYDE: Thank you.

And would you please provide your full name.

A. Yes, Dr Robert Alan Reid.

Q. Dr Reid, you provided two witness statements to the

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statements in that you provided them on behalf of the Medicines and Healthcare Products Regulatory Agency?

A. Yes, that's correct.

Q. In relation to some of the matters that you comment on in your statements, have you had to rely on information provided to you by others within the MHRA?

A. Yes.

Q. Have you also had to go to relevant documents and draw on those for information in the statements?

A. Yes.

Q. Have you provided, with the statements, a range of exhibits that are relevant to the matters being considered?

A. I have, yes.

Q. Your statements and the exhibits will stand as part of your evidence to the Inquiry, and it will therefore not be necessary to ask you about every aspect of them but I will take you to any parts of them where necessary and will also put parts of the relevant documents up on the screens, including on the screen that's in front of you.

I would like to start by asking you about your role. Could you please confirm your job title.

A. Yes, so my job title is Deputy Director for Innovative Devices.

Q. And what does that entail?

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1 A. So I head up the team within the agency which is
2 responsible for developing and implementing regulations
3 as they apply to medical devices for the Great British
4 market.

5 Q. How long have you been in that role?

6 A. I've been in that role for around two and half a years.

7 Q. Were you employed by the MHRA prior to starting your
8 current role?

9 A. No, I was not.

10 Q. What steps have you taken to familiarise yourself with
11 the matters in your statement which preceded your
12 employment at the MHRA?

13 A. So I have familiarised myself with all of the exhibits,
14 the various email chains. I've spoken to those that are
15 still within the MHRA who were involved in those
16 discussions to familiarise myself with the exhibits and
17 the statements that were made.

18 Q. Will you therefore be able to assist the Inquiry with
19 all the matters set out in your statements, even where
20 they preceded your employment?

21 A. Yes, I hope to be able to.

22 Q. Thank you.

23 We will now turn to the matters that are set out in
24 your first statement relating specifically to the role
25 and regulatory remit of the MHRA. To begin, could you

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1 bring their products to market in GB.

2 We are then responsible for auditing -- designating,
3 sorry, and auditing third-party Approved Bodies which
4 undertake the pre-market conformity assessment of those
5 products, the higher-risk products, before they come to
6 market. So that involves assessing whether those third
7 parties have the required competencies, the required
8 processes, the quality management systems in place to be
9 able to assess products to those regulations that we
10 have set.

11 In addition to that, we will then audit those
12 organisations on an ongoing basis to ensure that they
13 maintain that capability.

14 Once a product is on the market the MHRA then has
15 responsibilities around vigilance, market
16 surveillance --

17 **THE CHAIR:** I'm going to ask you to speak just a little bit
18 more slowly, if you could. We have a stenographer
19 trying to keep a transcript.

20 **THE WITNESS:** Sorry.

21 **THE CHAIR:** Thank you.

22 A. So once a product is on the market, we then, as the UK
23 regulator, have responsibilities for monitoring the
24 safety and performance of those products on the market,
25 and taking compliance or enforcement action if safety

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1 please outline what the roles and responsibilities of
2 the MHRA are?

3 A. Yes. So the Medicines and Medical Products Healthcare
4 Regulatory Agency, the MHRA, is the UK's regulator for
5 medicines, medical devices, and blood components for
6 transfusion. The key responsibility of the MHRA is to
7 ensure that those products are safe, that they perform
8 as intended, they are of appropriate quality and
9 effectiveness. And we do this through a number of
10 means. And I'll focus here on the medical device
11 elements of what the MHRA does, that's the area that the
12 Inquiry's, I think, focused on and the area that I'm
13 most familiar with.

14 So the MHRA is responsible for setting, first of
15 all, the Regulatory Framework that manufacturers must
16 meet, that other parts of the supply chain for medical
17 devices must meet in order to bring those devices to
18 market within GB, and I make the distinction here
19 between the UK and GB because under the terms of the
20 Northern Ireland Protocol and the Windsor Framework,
21 Northern Ireland still applies EU law. So the
22 Regulatory Framework that we establish within GB is
23 for GB.

24 So we set those requirements the manufacturers and
25 the supply chain participants must meet in order to

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1 signals are reported or concerns are raised with regards
2 to those products.

3 **MS HYDE:** Thank you, and we'll consider those in a little
4 bit more detail shortly. But before we do so, it's
5 correct, isn't it, that the MHRA's remit relating to
6 devices extends only to medical devices? And is that
7 definition of a medical device found in the Medical
8 Devices Regulations 2002.

9 A. Yes, that's correct. So the MHRA's remit is for medical
10 devices, and as you say, the definition for medical
11 device is to be found in the UK MDR 2002.

12 Q. Thank you. And we've just brought the relevant part of
13 the regulations up on the screen. Does this tell us, in
14 summary, that: a medical device is an instrument,
15 apparatus, appliance, software, material or other
16 article, which, amongst other things, is intended by the
17 manufacturer to be treated for human -- sorry, to be
18 used for human beings, for the purpose of diagnosis,
19 prevention, monitoring, treatment or alleviation of
20 disease?

21 A. Yes, that's correct, along with alleviation or
22 compensation for an injury or handicap. And then the
23 parts (iii) and (iv) also of that definition.

24 Q. Thank you. And what does this provision tell us about
25 the MHRA's regulatory remit?

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1 A. So this ensures that the medical devices or the products
2 that come under the MHRA's regulatory remit are medical
3 devices. It defines those products that we will be
4 responsible for in terms of the pre-market requirements
5 and setting those out in regulation as well as those
6 post-market functions which I highlighted.

7 Q. Thank you. And would you agree that an important part
8 of the application of these regulations is the intention
9 of the manufacturer as to how the device is to be used?

10 A. Yes, it's a critical part of the assessment of the
11 qualification of a device as a medical device under the
12 regulations, and it's also important in defining the
13 classification of that device under the regulations.

14 Q. Thank you.

15 Can we take that document down, please.

16 You also tell us at paragraph 10 of your witness
17 statement, if we could pull that up on the screen,
18 please.

19 Paragraph 10, please.

20 You tell us that under:

21 "Under Regulation 7 of the 2002 ... Regulations,
22 general medical devices are classified into four classes
23 of increasing levels of risk ..."

24 And those are classes I, IIa, IIb or III, and does
25 that increase -- as those numbers go up does the

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1 Q. Would that risk classification, to your knowledge, take
2 into account matters such as potential psychological or
3 emotional harms associated with a device?

4 A. So the essential requirements which devices must meet,
5 to a degree, are related to the risk of the device. So
6 there will be relevant essential requirements within the
7 regulations that devices need to meet. One of those
8 requires manufacturers to have consideration of the end
9 users of that device and the safety of the device, given
10 the knowledge of those that would be using the device.

11 I don't think it specifically talks about the mental
12 health of those users.

13 Q. Thank you.

14 You've already mentioned Notified and Approved
15 Bodies. Can we now turn to consider those and how they
16 fit alongside the role of the MHRA. Firstly, what are
17 Notified and Approved Bodies?

18 A. Yes, so Notified Bodies are third-party organisations
19 that are designated by, under EU regulations, to conduct
20 pre-market conformity assessment as well as post-market
21 management of CE certificates for medical devices. So
22 these are bodies with a range of internal expertise
23 which is assessed and audited by competent authorities
24 within the EU to assure that they're able to undertake
25 the assessment of different codes of medical device.

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1 assessment of risk increase as well?

2 A. So the degree of oversight, the degree of assessment
3 increases with the increasing risk class. So as an
4 example, class I, the lowest risk devices, are able to
5 be self-certified by manufacturers to meeting regulatory
6 requirements, the essential requirements set out within
7 regulations.

8 Then as you move up through those risk classes, the
9 degree of oversight of the medical device and its
10 meeting of regulatory requirements increases.

11 Q. What kind of factors should be considered when assessing
12 the level of risk that is associated with a medical
13 device?

14 A. So the risk of the medical device will be based on, or
15 the categorisation of the risk of the medical device is
16 based on a number of different factors which are set out
17 within, as I said here, annex IX of the regulations.
18 These can include the length to which somebody is
19 exposed to the device; it can include whether the device
20 is invasive as it enters into the body through either an
21 open orifice or through transdermal means, for example.
22 So it takes into account both the intended purpose but
23 then the factors that are associated with that device
24 actually performing its function in order to then
25 provide that risk clarification.

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1 So they will have individual -- individual Notified
2 Bodies will have a scope of devices that they are able
3 to assess, and that's based on the coding of devices.

4 The Approved Bodies are the UK's equivalent of those
5 Notified Bodies. They are designated and audited by the
6 MHRA as the UK's competent authority, to ensure that
7 they have that expertise, the systems in place, the
8 quality management systems, in order to be able to
9 undertake those pre-market assessments and the
10 post-market functions that they perform once devices
11 have been certified.

12 But they essentially undertake the -- that
13 pre-market assessment of any device above class I, so
14 class IIa, class IIb and class III devices. If
15 satisfied that the manufacturer and the device meets the
16 relevant regulatory requirements, they will then issue
17 a certificate in the EU, a notified body will issue a CE
18 certificate, and in the UK, a UK-approved body will
19 issue a UKCA mark, and certificate.

20 Q. And what does the assurance mark that is assigned to a
21 medical device signify for regulatory purposes?

22 A. So it demonstrates that the device has been assessed to
23 meet the relevant regulatory requirements for that
24 particular device.

25 Q. Does the MHRA itself play any role in that assurance,

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1 marking and conformity assessment process?

2 **A.** No, other than setting the Regulatory Framework by which

3 Approved Bodies for the UK, or for GB, undertake those

4 assessments, we have no role in issuing certificates.

5 **Q.** Can you tell us more about the rationale for that

6 division of responsibilities?

7 **A.** So this, from a UK perspective, this goes back to us

8 having been part of the European Union. So the Notified

9 Body model within Europe was, I guess, the starting

10 point. When we left the EU we needed to establish our

11 own Regulatory Framework for a domestic route to market,

12 and there was a transposition of existing regulations

13 from European regulation into UK legislation. So, in

14 effect, we mirrored the European system.

15 I think the drivers for that system within the EU

16 reflect both the fact that there are 27 Member States,

17 it's a huge geographical and economic area. I think it

18 also reflects the fact that there are an estimated

19 500,000 types of medical device on the market, and

20 therefore, having a distributed model of regulation with

21 expert bodies that are able to assess specific types of

22 device and sharing that around, essentially, designated

23 and audited expert bodies, I think it's seen as a more

24 efficient way of regulating devices within such a large

25 market.

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1 scientific literature form an important part of

2 conformity assessment."

3 Does the conformity assessment process also involve

4 the Approved or Notified Body considering the clinical

5 evidence for a device, by which I mean evidence of its

6 clinical benefits?

7 **A.** Yes, as part of the file that will be pulled together by

8 the manufacturer to support the pre-market assessment,

9 there will be the inclusion of clinical evidence. What

10 that clinical evidence can be is set out in annex X of

11 the regulations. And here, it's slightly confusing,

12 from a -- well, very confusing, perhaps, from

13 a regulatory perspective, in that our regulations will

14 refer back to the EU regulations from which we've taken

15 our Regulatory Framework. So in that sense, annex X,

16 which sets out the clinical, what's required in terms of

17 clinical evidence, is annex X of the European directive.

18 **Q.** Would you expect that the conformity assessment process

19 includes claims -- assessment of claims made by the

20 manufacturer as to the clinical benefits of the device?

21 **A.** Yes. Any claims made by the manufacturer should be

22 supported by evidence, and I think in this case we had

23 a claim -- one claim in particular which we asked the

24 manufacturer to provide evidence on, and that led to a

25 change in terms of the claims that were being made.

15

1 **Q.** Thank you. In terms of the scope of the

2 assurance-marking process, and what is assessed, would

3 it include assessment of whether the device is safe for

4 use on or by patients?

5 **A.** So it should -- there is, as I mentioned, an essential

6 requirement for the manufacturer of the device to have

7 consideration of the end user of the device and the

8 environment within which it's used and how that could

9 impact upon the safety and efficacy of the device.

10 **Q.** And would that include any consideration of, perhaps we

11 might call them unintended uses of a device?

12 **A.** So I think ... I'm trying to recall the legal language.

13 I think, I'm not sure it talks specifically in that

14 particular essential requirement around unintended use,

15 however, I think that's something which, certainly when

16 we -- when we look at the guidance that we've produced

17 around digital mental health technologies, there is

18 a line within that guidance which refers to "reasonable

19 unintended use", or "reasonably perceived unintended use

20 of a product".

21 **Q.** Thank you, that is helpful.

22 In your second statement, if we could pull that up,

23 please. If we could turn to paragraph 26, in this

24 paragraph you tell us that:

25 "Clinical evaluation and supporting evidence such as

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1 **THE CHAIR:** What do you mean by "in this case"?

2 **A.** So in relation to the -- I think it was to do with the

3 activity monitoring function, the software.

4 **THE CHAIR:** So it's the Oxevision --

5 **A.** Yes.

6 **THE CHAIR:** -- activity? Yes.

7 **A.** Yes. There was a claim around reducing self-harm which

8 we asked for clinical -- for evidence to show that that

9 could be made, which I don't think was, from my review

10 of the documents, was not then something that could be

11 provided, and the company then made changes immediately

12 to its materials to remove that claim.

13 **THE CHAIR:** Thank you.

14 **MS HYDE:** We'll come on to look at that in a bit more detail

15 later but is it correct that the assessment of claims as

16 to clinical benefits occurs on an ongoing basis?

17 **A.** Yes. So once a product is on the market, there's

18 a requirement on the manufacturer to undertake

19 post-market surveillance activities. That includes

20 a clinical evaluation of the product, so ongoing

21 gathering of evidence to support the claims made for

22 that product.

23 **Q.** And where the body of evidence relating to the clinical

24 benefits of a product develops, how would that be

25 monitored by the MHRA?

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1 A. So that's monitored by the Approved Body that's
 2 issued -- or the Notified Body that will have issued the
 3 certificate. It will be the responsibility of the
 4 manufacturer to report to its Notified Body if there are
 5 any significant changes which would impact on the
 6 product's meeting of the essential requirements under
 7 the regulations.
 8 In addition, if there were any serious incidents
 9 associated with the product, then there are requirements
 10 for the manufacturer to report those to the MHRA.
 11 Depending on the nature of those incidents, there are
 12 time frames by which that reporting must be done.
 13 So if there is a public health impact, it's within
 14 two days of the incident being identified. If there is
 15 a death or possibility of death, then ten days, and if
 16 it's a serious incident, which could be deterioration of
 17 health, then it's 15 days.
 18 Q. We'll come on to the Vigilance System in more detail
 19 later, as well. But can I ask you this: how does the
 20 role of Approved Bodies and Notified Bodies in assessing
 21 claims as to clinical benefits sit alongside the role of
 22 organisations such as the National Institute for
 23 Clinical Excellence, which may also undertake similar
 24 evaluations?
 25 A. So the evaluations that are undertaken by the Approved
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1 of NHS England, and the role of the MHRA is summarised
 2 in the following terms in this email:
 3 "In very simple terms my understanding of the
 4 boundary of MHRA zone is when something is a medical
 5 device, you can only describe it doing what it is
 6 registered to do but they won't get into how effective
 7 it is at doing so (that is expected to be a clinical
 8 effectiveness assessment users/guideline issuers make).
 9 Or to put it another way, MHRA extremely good and strong
 10 at making sure a medical device is described as suitable
 11 for a particular use and doesn't do harm, but doesn't
 12 get into whether it does good."
 13 Is that a description that you would agree with?
 14 A. To some extent. I think the term "but it doesn't get
 15 into whether it does good" is slightly broad. I think
 16 I would describe it more as we -- and the medical
 17 device regulatory system, so I would include within that
 18 the role of the Approved Bodies, are responsible for
 19 ensuring that a medical device is doing what it is
 20 intended to do and has the evidence required to
 21 demonstrate that and that it is safe. So safe and
 22 effective, in essence.
 23 But what we don't then do is then compare that
 24 device to a similar device to say this is better than
 25 that. We are looking to ensure that the device has
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1 Body is in relation to the regulatory approval of the
 2 device. So does the device still meet the essential
 3 requirements? Is the intended purpose still the same?
 4 Does it still meet the requirements associated with the
 5 certificate that has been issued for that device? And
 6 if there are any changes in that, the Notified Body or
 7 Approved Body is able to withdraw that certificate or
 8 approach the manufacturer to ensure that there are
 9 changes implemented on the certificate.
 10 Other bodies will also look at clinical evidence,
 11 NICE was the example you gave, in order to support the
 12 work that they're doing. But that's not for regulatory
 13 approval; that could be for a health technology
 14 assessment in the case of NICE. It could be for further
 15 clinical assurance, in terms of procurement teams for
 16 those that are looking to use that technology within the
 17 healthcare setting.
 18 So the MHRA and the Approved Body, the focus there
 19 is on: does the product do what it's intended to do? Is
 20 it safe, and does it have evidence to prove that? We
 21 don't go into whether that should then be used within
 22 a healthcare setting.
 23 Q. Thank you. I'm going to turn up the document at
 24 NHSE028974.
 25 This is an internal email sent by Dr Frances Healey
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1 evidence to show that it does what it is intended to do
 2 and does that safely.
 3 Q. Thank you, that's very helpful.
 4 Can we now return to your first statement at
 5 paragraphs 15 to 17, which is on pages 5 to 6. At
 6 paragraph 17, just over the page, you tell us that:
 7 "After ... designation, the MHRA monitors UK
 8 Approved Bodies including by regular surveillance audits
 9 and by witnessing their compliance assessment of
 10 manufacturers."
 11 What does "witnessing their compliance assessment"
 12 mean in this context?
 13 A. So this is ensuring that they have the processes and the
 14 people, the expertise in place to be able to undertake
 15 those assessments. So whereas the MHRA are not
 16 undertaking an assessment alongside that assessment,
 17 it's more ensuring that the Approved Body has the
 18 required expertise, systems and processes in place to
 19 undertake that assessment.
 20 Q. So to what extent does the MHRA scrutinise the Notified
 21 or Approved Bodies' assessment of devices or
 22 manufacturers of those devices?
 23 A. So we will look at the assessments undertaken by
 24 Approved Bodies to ensure that they've been done in line
 25 with the regulations and that those Approved Bodies have
 20

1 both the expertise and, as I say, systems and processes,
2 to satisfy the regulatory requirements that apply to
3 those Approved Bodies.

4 **Q.** And what level of detail does that get into? I suppose,
5 another way of putting it would be: would the MHRA
6 exercise that role in relation to every conformity
7 assessment undertaken or by a sample, or at a higher
8 level?

9 **A.** It would be a sampling approach. As I mentioned before,
10 I think the sheer volume of medical devices on the
11 market mean that doing it product by product becomes
12 more difficult.

13 I think it is done on, again, a risk -- so as with
14 Approved Body review of products, there is a risk-based
15 element to this in terms of for higher-risk classed
16 devices there will be more of an oversight. For
17 lower-risk classed devices, more of a sampling approach.

18 **Q.** Thank you.

19 I now want to consider the registration of devices.
20 You tell us at paragraph 21 on page 7 that:

21 "All medical devices, whatever their assurance
22 marking, must be registered with the MHRA before being
23 placed on the market."

24 Can you help us, please, with the significance of
25 registration of a product as opposed to having an

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1 that mean, in summary, that a class I medical device
2 does not need to be subjected to an external assurance
3 process, but does need to be registered with the MHRA?

4 **A.** That's correct, yes. They -- I should be really clear
5 here that when I talked before about the level of
6 oversight, so a class I medical device manufacturer must
7 still have evidence to demonstrate that their product
8 meets the essential requirements of the regulations.
9 And if we, as the regulatory authority for GB, were to
10 come and knock on the door of a manufacturer of
11 a class I device and ask to see the evidence to show
12 that they meet those regulatory requirements, they need
13 to be able to give it to us. So although there's not an
14 external -- third-party external oversight in terms of
15 the pre-market conformity assessment, the level of
16 evidence required remains the same.

17 **Q.** Does that evidence need to be provided by the
18 manufacturer upon registering their product?

19 **A.** No, the manufacturer at the point of registration needs
20 to be able to upload their Declaration of Conformity or
21 their certificate, if granted by an Approved Body or
22 a Notified Body.

23 **Q.** But it's only if the MHRA were specifically to ask for
24 that evidence that it would come before you, as it were?

25 **A.** Yeah, if we had concerns raised about a product which

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1 assurance mark?

2 **A.** So registration of a product enables us to know, as the
3 UK regulator, to know what is on the market in the UK.
4 So any medical device coming to market in GB, regardless
5 of the route by which it has come to market, and by that
6 I mean there are several regulatory pathways through
7 which a device may enter the GB market, regardless of
8 that route, the manufacturer must register the device
9 with the MHRA.

10 If the manufacturer is based in the UK, then the
11 manufacturer can register that device. If the
12 manufacturer is not based in the UK, then they must
13 employ a UK-responsible person who will register that
14 device. The registration of the device enables us to
15 see not only what is on the market but also provides the
16 details of who we need to contact if there are issues
17 with that product on the market and we need to speak to
18 the manufacturer, or indeed through the UK responsible
19 person, the manufacturer.

20 **Q.** Thank you.

21 Now, we noted earlier that medical devices are, as
22 you say, stratified or categorised by risk level. And
23 you tell us -- you told us earlier, as well, that
24 class I medical devices do not require conformity
25 assessment but require self-assessment, in effect. Does

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1 led us to investigate that product, and that could be
2 safety signals, for example, which would warrant further
3 investigation or, indeed, compliance concerns which may
4 not be safety related but could be related to the way in
5 which the product is being marketed and manufactured
6 nonetheless, we would then expect to be able to see that
7 documentation.

8 **Q.** Thank you.

9 Turning to page 10 of your first statement,
10 paragraph 32, you tell us in the second sentence that:

11 "An MHRA authorisation or approval does not of
12 itself determine whether a product will be adopted,
13 commissioned, purchased or used within the NHS or by
14 a particular healthcare provider."

15 What other factors would you expect would be taken
16 into account when taking decisions as to medical device
17 deployment or commissioning?

18 **A.** First of all, I'll just correct something I've just
19 noticed, sorry, with that sentence, which is incorrect.
20 It states "An MHRA authorisation or approval". As
21 mentioned, we don't authorise or approve devices, that's
22 the Approved Body. So, sorry for that.

23 I think there are a range, and this is not an area
24 of my direct responsibility --

25 **Q.** Of course.

24

1 A. -- or expertise, but there will be a range of other
 2 types of evidence that would be reviewed by those bodies
 3 when considering whether a product should be used within
 4 a healthcare setting. NICE, as the health technology
 5 assessor, will look at, I think, value for money,
 6 whether the device is offering improvements on other
 7 pathways or potential products. Those then procuring
 8 the device may have their own assessments that will be
 9 undertaken in terms of both the healthcare outcome,
 10 economic, and any additional assurance or governance
 11 processes that they may want to go through.

12 Q. So do the MHRA's regulatory processes therefore take
 13 place in a context where you would expect that other
 14 kinds of checks, evaluations, risk assessments, and so
 15 on, would follow or would also take place?

16 A. The MHRA's regulatory process ensures that those devices
 17 which are available for others to choose to use or not
 18 meet the regulatory requirements relevant to those
 19 devices, that they are safe and they are effective. And
 20 that once on the market, we are maintaining oversight to
 21 ensure that continued effectiveness and safety.

22 The decision, then, to purchase and use the device
 23 is one for those other parts of the system. I would
 24 expect that they would be undertaking their own
 25 assessments relevant to their particular roles within

25

1 A. Yes, certainly. So one of the things that we are
 2 increasingly seeing, I think, with the rapid development
 3 of technology is the need to understand how these
 4 products are performing in the real-world environments.

5 The current regulatory process involves, you know,
 6 a pre-market assessment of a product which gives you
 7 a certificate to bring that product to market, and then
 8 a significant amount of post-market surveillance to
 9 understand how that product is functioning within the
 10 real world, and to continue to collect the evidence and
 11 data on that.

12 What we can do, and what we are looking at doing as
 13 the MHRA, is recognising that for some very innovative
 14 products, there may be opportunities to test the
 15 products within a tightly controlled regulatory
 16 environment ahead of the products having gone through
 17 a full conformity assessment. And in doing so, we are
 18 able to collect real-world evidence and real-world data
 19 on how those products perform, which can support the
 20 transfer, I guess, from that sandbox-type environment,
 21 that tightly controlled regulatory environment, to
 22 a full conformity assessment and for access to a wider
 23 population.

24 Q. Is that process something akin to a trial, or am
 25 I misunderstanding that?

27

1 that healthcare system.

2 Q. So MHRA registration and, where necessary, assurance
 3 marking, can they be seen as perhaps necessary but not
 4 sufficient for commissioning and deployment?

5 A. Sorry to interrupt. They are absolutely necessary. A
 6 product should not be available on the UK market unless
 7 it's registered with the MHRA and is approved from
 8 a regulatory perspective for use on the market.

9 Q. So necessary but not sufficient, I suppose is the right
 10 way around?

11 A. So necessary, but there may be further assessments that
 12 other parts of the system would want to undertake, which
 13 we don't. So we don't look at the health economics of
 14 a particular device against another device. We look to
 15 see whether that device is safe and effective.

16 Q. Thank you.

17 I now want to touch briefly on the MHRA's role in
 18 relation to emerging and innovative technologies.

19 Can we please pull up your second statement at
 20 page 13, and paragraph 52 at the bottom of page 13.

21 You tell us there that:

22 "The MHRA has an important role in supporting the
 23 safe and more rapid development of innovative and
 24 emerging medical technologies."

25 Can you tell us more about that?

26

1 A. No, it's very similar, and I guess the distinction is
 2 one whereby a clinical trial or a clinical investigation
 3 in relation to a medical device, or indeed a performance
 4 evaluation for an in vitro diagnostic device, will be
 5 the use of that device within a clinical study to gather
 6 the data which the manufacturer needs in order to
 7 demonstrate it's meeting all of the essential
 8 requirements.

9 This is a similar approach but rather than in
 10 a clinical study, this is in a controlled regulatory
 11 environment, referred to often as sandboxes, whereby we
 12 can derogate from some regulatory requirements to allow
 13 a product with very controlled parameters to be used to
 14 gather that information.

15 THE CHAIR: A dummy run, is it? Without the constraints of
 16 having to have a pre-existing authorisation, approval?

17 A. Yes, but it's done in a very, very tightly controlled
 18 way. So the product will still need to demonstrate
 19 safety, absolutely critically. And a level of
 20 performance. But this will allow us to, in certain
 21 circumstances, in very targeted areas, to be able to
 22 say: okay, well, we can allow this product within a
 23 sandbox environment, access to a very defined
 24 population, in order to gather further evidence of its
 25 real-world use.

28

1 **THE CHAIR:** Yes, I think I understand. Yes.

2 **MS HYDE:** Does that reflect a need to balance the
3 encouragement of innovation against a need to manage
4 potential risks to patient safety?

5 **A.** It absolutely does. As I say, the first consideration
6 will be safety. A product will still need to
7 demonstrate that it is safe before it will enter into
8 a sandbox. It's not a kind of open door in that sense.
9 It's a controlled, very controlled, environment in which
10 to test these products.

11 **Q.** Thank you. That's helpful.

12 I now want to consider in some more detail the
13 mechanisms you have already touched on by which the MHRA
14 manages potential risks to patient safety.

15 And returning to your first statement on page 11,
16 paragraph 40, you tell us that:

17 "The MHRA also exercises a range of post-market
18 regulatory and safety functions in relation to medical
19 devices once they have been placed on the market and are
20 in clinical use."

21 Turning over the page, you outline some of those.

22 Taking those in turn, the first is a Field Safety
23 Corrective Action, which you consider at paragraph 42.
24 Could you tell us more about those, please?

25 **A.** Yes, so if an issue has been identified with a product,
29

1 "The MHRA may also issue Device Safety Information
2 ... Medical Device Alerts ... or other safety
3 communications ..."

4 Under what circumstances might the MHRA consider
5 issuing those?

6 **A.** So I think this would be -- these are to healthcare
7 providers, and other relevant stakeholders. It would be
8 where we believe there is a need for a heightened
9 awareness of a particular issue that has been identified
10 through our own vigilance and surveillance actions.

11 **Q.** Once those communications are issued, do they specify
12 particular actions that should be taken?

13 **A.** The -- I think the DSI and the MDAs are more to raise
14 awareness. Again, I'm sorry, I can come back to you
15 with more detail on that. It's not something I know off
16 the top of my head, but my understanding is they're more
17 about raising awareness rather than action-oriented.

18 **Q.** Thank you.

19 You then -- you tell us on the next page, at
20 paragraphs -- on this page, you tell us about the Yellow
21 Card Scheme and vigilance reporting. Starting with the
22 Yellow Card Scheme, can you tell us how that operates?

23 **A.** Yes. So the Yellow Card Scheme is a portal, an online
24 portal, also an app that can be downloaded from the
25 Apple Store or the Android Play Store. It enables
31

1 then a manufacturer is required to take action to
2 address that issue. And the Field Safety Corrective
3 Action is a record, a note of that issue, and the action
4 that the manufacturer is taking to address it.

5 **Q.** And so that is an action that is driven by the
6 manufacturer and undertaken by them?

7 **A.** Yes.

8 **Q.** Are they required to report those to the MHRA?

9 **A.** Yes.

10 **Q.** Thank you.

11 The second mechanism you describe is a Field Safety
12 Notice. Could you tell us about that, please?

13 **A.** Yes, so this is a notice that would go out to all
14 affected customers of the manufacturer to highlight to
15 them the issue that has been identified and the actions
16 that have been taken to mitigate that issue.

17 **Q.** And does the MHRA play a particular role in the issuing
18 of those notices?

19 **A.** Yes, so the MHRA will review those notices to ensure
20 that they are providing enough information to customers
21 on the issue that's occurred.

22 **Q.** And would it do that before it's issued or after?

23 **A.** So it would be reviewed ahead of the FSN being issued.

24 **Q.** Thank you.

25 You then tell us at paragraph 44 that:
30

1 anybody, really, so healthcare professionals, patients,
2 the families of patients, the general public, to report
3 any concerns or incidents that they have with medical a
4 device that they are using, or that they are -- a family
5 member or somebody has used.

6 The data that is then collected via that Yellow Card
7 Scheme is analysed internally within the MHRA to look
8 for trends or safety signals associated with devices
9 which would then trigger further investigation of those
10 products.

11 **Q.** Is it a voluntary scheme?

12 **A.** It is a voluntary scheme.

13 **Q.** So is there, to your knowledge, any obligation on
14 healthcare providers to proactively contact the MHRA or
15 otherwise escalate concerns about a device?

16 **A.** There is no obligation, I think, other than the fact
17 that if, as a healthcare provider, you have concerns
18 about a device, this is the route by which you can
19 ensure those concerns are raised with the regulator.

20 I think the level of awareness and use of Yellow
21 Card is something which we, as an agency, are keen to
22 increase. And in our recently-published strategy in --
23 2030 Strategy -- we have a commitment to both work on
24 a more conversational interface for the Yellow Card
25 Scheme but also to seek to integrate into the NHS App,
32

1 and other secondary care electronic healthcare systems,
2 to both increase awareness and also usability of the
3 Yellow Card Scheme.

4 Q. Thank you.

5 Now, you outline later on in your statement that the
6 MHRA has received four reports through its Yellow Card
7 Scheme relating to Oxevision. To contextualise this,
8 can you tell us, roughly, how many reports are received
9 through the Yellow Card Scheme on an annual basis?

10 A. I don't have that number to hand, sorry.

11 Q. That's fine. Thank you.

12 You tell us at page 13 underneath the section about
13 the Yellow Card Scheme that manufacturers are under
14 reporting obligations, by virtue of the Medical Device
15 Vigilance System. What obligations do manufacturers
16 have, in terms of notifying the MHRA of adverse safety
17 incidents involving devices?

18 A. So these are post-market surveillance requirements which
19 we updated in June 2025 to provide clearer rules for
20 manufacturers in legislation as opposed to guidance
21 where they had sat previously. They require that
22 manufacturers have a post-market surveillance plan in
23 place and that that post-market surveillance plan is
24 implemented through a post-market surveillance system.
25 That system and the reporting requirements associated

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1 system for devices. We do have other routes for
2 reporting concerns. You've mentioned the Yellow Card
3 Scheme. We can also have direct contact with the MHRA
4 through usual kind of communication channels to raise
5 issues. But the manufacturers will know their product
6 very well. They are required by law to be monitoring
7 that product's use and identifying any issues with it.
8 And I think that's incredibly important and valuable for
9 us to ensure that the products are safe and effective,
10 and continue to be safe. And I think that's an
11 important distinction here, is there is the assessment
12 at a point in time for the pre-market conformity
13 assessment to say this product meets the requirements of
14 the regulations, but then there is a really important
15 ongoing monitoring of the product post-market to ensure
16 it still meets those requirements, and to understand if
17 there are any issues or concerns with its use in the
18 real world which may not have been identified prior to
19 conformity assessment.

20 Q. What enforcement powers does the MHRA have if, for
21 instance, it becomes aware that manufacturers have not
22 submitted reports of serious incidents to it either at
23 all or in a timely way?

24 A. So we have a number of enforcement powers which are set
25 out in the Medicines and Medical Devices Act where, if

35

1 with it require the manufacturer to notify the MHRA of
2 serious incidents as defined in the regulations with
3 their device within strict time frames depending on the
4 nature of those incidents.

5 Q. Do those obligations apply to all manufacturers with
6 devices registered with the MHRA, or do they depend on
7 the risk class?

8 A. No, they apply to all devices on the UK -- sorry, GB
9 market. They are also in harmonisation or very closely
10 aligned to the requirements in the European regulatory
11 system, which is important here because that applies in
12 Northern Ireland. So we don't have two very different
13 approaches to the way in which manufacturers are
14 required to follow the post-market surveillance
15 requirements.

16 Q. Thank you.

17 We can take that document down.

18 Now, the regulations, you've told us, place
19 reporting responsibilities on the manufacturer. Would
20 it be fair to say that the MHRA is partly reliant on
21 manufacturers to collate, analyse, and then share that
22 information with the MHRA in order to find out about
23 them in the first place?

24 A. I think post-market surveillance and the requirements on
25 manufacturers are essential to a functioning regulatory

34

1 we believe non-compliance with regulation has occurred,
2 we can take action. Just to take a slight step back,
3 I think our first approach or our approach is always in
4 the first instance to work with the manufacturer to
5 understand the nature of the non-compliance and to look
6 to address that through compliance mechanisms, through
7 actions taken by the manufacturer, and communicated then
8 to users through the Field Safety Notices and Corrective
9 Actions.

10 However, if a manufacturer continues to be
11 non-compliant, then we have powers, enforcement powers,
12 which would enable us to suspend or withdraw the product
13 from market within GB and also to require information is
14 provided by the manufacturer. So information notices,
15 withdrawals, suspensions, our powers that we have, if we
16 believe that non-compliance warrants that activity.

17 Q. Thank you.

18 Turning now to other sources of intelligence that
19 are available to the MHRA, returning to your first
20 statement at page 12, you tell us at paragraph 41 that
21 the MHRA might also take action after reports are
22 received through sources including inspections or other
23 safety investigations.

24 What kind of inspections or other safety
25 investigations are you referring to here?

36

1 A. So this could be inspections undertaken by other
2 regulatory authorities, it could be inspections
3 undertaken within the Trusts themselves through their
4 own governance processes. It could be inspections or
5 investigations, and I think in this context, this in
6 particular is -- or in this sentence, this is
7 particularly relevant: activities undertaken by
8 international regulatory colleagues.

9 So we, as the MHRA, participate in a number of
10 international forums for the exchange of safety
11 information.

12 Q. Would it include sources like CQC inspection reports, if
13 they were shared with the MHRA?

14 A. Yes, if they were shared, I think that would be
15 something we could look at.

16 Q. Would the MHRA routinely consider sources such as the
17 conclusions of inquests or Prevention of Future Deaths
18 Reports issued by coroners?

19 A. Yes, I think that would be something that we could
20 incorporate into the documentation that we look at.

21 Q. Are there any mechanisms maintained by the MHRA for
22 a proactively seeking out information from those
23 sources, or is it more reactive in that the MHRA will
24 consider those sources when they are shared with it?

25 A. I think it's more reactive in that we will respond to

37

1 Q. Thank you. That's very helpful.

2 I now propose that we move on to discuss Oxevision
3 and the MHRA's knowledge of, and engagement with, that
4 device. Starting at the beginning chronologically, you
5 tell us in your second statement, if we could pull that
6 up, please, at page 11, at paragraph 44 you tell us
7 that:

8 "In November 2017, following review of the
9 documentation submitted by Oxehhealth Ltd the MHRA issued
10 a 'no objection' determination on 4 October 2017 in
11 relation to the proposed clinical investigation
12 involving the Oxecam vital signs measurement software."

13 That letter is at MHRA025461. Could we pull that
14 up, please.

15 By way of context, what do you understand Oxehhealth
16 to have been seeking the MHRA's approval for at this
17 stage?

18 A. So when a manufacturer is pulling together the evidence
19 required to demonstrate that it meets the regulatory
20 requirements associated with its device, it may identify
21 gaps in that evidence, and in order to fill those gaps,
22 can undertake a clinical investigation; so a clinical
23 study which will have clear endpoints in terms of what
24 that study should be providing in terms of data. The
25 data then can be used in the conformity assessment

39

1 the information that's provided to us. However, we do
2 have regular interactions with a variety of -- other
3 regulators in other parts of the healthcare system at
4 which we would welcome these things being brought up or
5 being sort of highlighted to us. So I think it is
6 probably more reactive but there are routes and
7 mechanisms by which those issues can be raised.

8 Q. Would the MHRA see value in there being further
9 mechanisms available to it for the sharing of
10 information from the various sources of patient safety
11 intelligence?

12 A. Absolutely. I think the -- we recently had the
13 publication of a number of recommendations by a National
14 Commission on the Regulation of AI in Healthcare, so
15 this was focused on artificial intelligence and its use
16 in healthcare. But one of those recommendations was for
17 a system-wide approach to regulation and safety
18 management, and I think that's critical in particular
19 with some of these new technologies, where an
20 understanding of the way in which the technology will
21 impact the end user, the training requirements for that
22 end user, mean that it needs to be a more system-wide
23 approach, and that was something which was recommended
24 in the National Commission recommendations which we have
25 responded to, accepting all of those recommendations.

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1 application and actual process of assessment.

2 So this was -- sorry, step back. The regulations,
3 our regulations require that we are notified of proposed
4 clinical investigations, that we can assess those, and
5 have the ability to object to those going forward if we
6 see reasons to object to that study. If we issue no
7 objection, then the study can be undertaken.

8 Q. Thank you. And so this is a step that is taken with
9 a view to eventually achieving conformity assessment but
10 is not the same as registration or assurance marking?

11 A. That's correct. It's about us having oversight of those
12 investigations that are being proposed for a device and
13 checking or assuring that those -- that we have no
14 objections to the approach that's being proposed in that
15 investigation. The data that is then captured or
16 generated through the study forms part of the submission
17 to the Approved Body for the conformity assessment.

18 Q. Thank you. Now, at paragraph b of that letter it is
19 stated:

20 "We note your application was premature, because it
21 was submitted before all testing was complete ..."

22 Can you explain a bit about what that means?

23 A. So I can talk to what I understand the letter to mean.

24 Q. Of course.

25 A. I was not, as mentioned, directly involved. But I think

40

1 the drive is that there was still work ongoing on the
2 broader technical file for that product at the point at
3 which the application came for the clinical
4 investigation. So, as I mentioned, you would normally
5 think about where are the gaps in my evidence to support
6 the approval of this product? And then here's
7 a clinical investigation in order to fill those gaps.
8 I assume and I'm sorry, it's an assumption from reading
9 this, that that would be the case here.

10 Q. Thank you. That's helpful.

11 Turning to the next page, and appreciate that this
12 pre-dated your employment at the MHRA, the letter goes
13 on to note that the recipient, Oxehealth, appears:

14 "... to have started enrolment and some testing on
15 the subjects before MHRA issued the final 'no objection'
16 letter confirming the conditions have been met."

17 What is your understanding of the significance of
18 this?

19 A. So it should not have occurred. It's in breach of
20 regulatory requirements, and I think that's pointed out
21 in the letter. I don't know the reason why that
22 occurred, the history behind it, but I think we point
23 out quite clearly in the letter that that's not
24 something which should be occurring.

25 Q. And it's stated at the final sentence of paragraph c:

41

1 assessment, and upon a decision, would issue
2 a certificate, a Declaration of Conformity,
3 a declaration of compliance.

4 Q. Thank you.

5 And save for the -- a conditional 'no objection'
6 letter, is it correct that no one in the MHRA assessed
7 or otherwise evaluated Oxevision before it was placed on
8 the market?

9 A. That's correct. So we would have looked at the proposed
10 clinical study and objected or not to that, but then the
11 assessment, the pre-market assessment, is undertaken by
12 the Approved or Notified Body. The only time the MHRA
13 would look to make an assessment of a product itself,
14 and only power legally we have to do that, is through
15 something called an Exceptional Use Authorisation which
16 is usually employed if there is a humanitarian reason
17 for a device to be approved for use in patients in the
18 interests of health and protecting health. So these are
19 very narrowly used powers.

20 Q. Thank you. That's very helpful.

21 But before we break, which I propose we do in about
22 ten minutes, can we please consider the regulatory
23 status of different modules and features of Oxevision.

24 Returning to your first statement, and apologies
25 that we're jumping around rather a lot here, on page 14,

43

1 "We are considering whether this matter needs to be
2 brought to the attention of your academic institution."

3 Are you aware if that happened, or if any other
4 action was taken?

5 A. I'm not aware if that happened, no.

6 Q. Thank you.

7 We can take that document down.

8 Now, we've discussed this already, but that was then
9 followed by the conformity assessment process. And can
10 we turn up MHRA025447. Thank you.

11 Does this document, the Declaration of Conformity,
12 demonstrate that the British Standards Institution
13 issued certification to the Vital Signs device on
14 10 September 2018?

15 A. Yes, it does.

16 Q. Thank you. And that was carried out by the Approved
17 Body rather than the MHRA?

18 A. So that was carried out by the Notified Body under
19 European regulation.

20 Q. Thank you.

21 We can take that document down.

22 And does that reflect the regulatory division of
23 responsibilities that we discussed earlier?

24 A. Yes. So the Approved Body, or Notified Body in this
25 case, would undertake that pre-market conformity

42

1 at paragraph 54, you explain that some functions or
2 modules of the Oxevision system are classified as
3 medical devices for the purposes of the 2002 regulations
4 and others are not.

5 What does that mean, in terms of the MHRA's
6 regulatory remit over the product as a whole?

7 A. So the -- whether a product is qualified as a medical
8 device depends on whether it meets the definition that's
9 set out, and we discussed earlier in the regulations,
10 and the intended use of the product. And so those
11 things are taken together to look at whether elements of
12 the platform would be medical devices or not. And
13 applying those regulatory requirements to the different
14 elements means that in this case, the software element,
15 the Vital Signs, was deemed to have an intended medical
16 purpose. But if you were to take the component parts of
17 the platform, so it's an off-the-shelf camera, I think
18 off-the-shelf infrared components, the casing itself,
19 and you looked at the intended use of those individual
20 components, they would not have an intended medical
21 purpose.

22 That would mean that the -- under the regulatory
23 approach, the software is deemed as the element which is
24 a medical device, and it's that, then, that is subject
25 to regulatory requirements set out within the

44

1 regulations.

2 **Q.** Thank you.

3 We can take that document down.

4 I want to focus in particular on the regulatory

5 status of the Activity Tracker module which you consider

6 in your first statement.

7 Can we please turn up document 0XHE005087, and this

8 document is the Instructions for Use for the Oxevision

9 Activity Tracker.

10 Can we turn to page 4, please. There is the section

11 entitled "Intended Use". What this tell us is that:

12 "The Oxevision Activity Tracker is a software-based

13 Clinical Decision Support System for use by trained

14 healthcare professionals in hospitals, general care and

15 secured environments for the purpose of analysing data

16 to detect activity, posture, presence, and location of

17 subjects and other individuals."

18 It goes on to say in the third paragraph that:

19 "... [the] Tracker is not intended to replace

20 clinical care or direct in-person checks of subjects,

21 [but rather], it is intended to be used to augment

22 existing forms of monitoring ..."

23 And then in the fourth paragraph, we see that it

24 says:

25 "... [it] is not intended to be relied upon to

45

1 Activity Tracker was not considered by the MHRA to have

2 a medical purpose. Can you help us, please, with the

3 rationale underpinning that.

4 **A.** Yes. So the Activity Tracker was looked at by a team of

5 experts within the MHRA sitting within the software and

6 AI team to look at the intended purpose, look at the

7 Instructions for Use, to think about whether there was

8 an intended medical purpose within that by the

9 manufacturer and therefore would it qualify as a medical

10 device?

11 The outcome of those investigations was to say that

12 it was an Activity Tracker which is not in itself

13 a medical device, does not meet the definition of an

14 intended medical purpose as set out within the

15 definition of a medical device.

16 **Q.** Thank you.

17 Is it correct that the Activity Tracker was

18 originally registered as a medical device by Oxehealth

19 Limited?

20 **A.** It was registered, I believe, as a Class I --

21 **Q.** Yes.

22 **A.** -- self-declared medical device, yes.

23 **Q.** And what, in your view, can that tell us about the

24 manufacturer's intention for the product's use?

25 **A.** I think it tells us that the manufacturer,

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1 notify healthcare professionals of any immediate health

2 or safety hazards to subjects."

3 Now, does this, in your view, make clear that the

4 Activity Tracker was intended to be used by medical

5 professionals?

6 **A.** I think it makes clear that it's not intended to replace

7 clinical care --

8 **Q.** Yes.

9 **A.** -- which would be delivered by a medical professional.

10 **Q.** But in terms of the -- what this tell us about the

11 anticipated user of the device, who would that be, in

12 your view?

13 **A.** In my view, I don't think the statement itself is clear

14 on who the end user of the device would be.

15 **Q.** Okay. So --

16 **A.** Oh no, sorry. It's "intended to inform healthcare

17 professionals".

18 **Q.** Thank you. And does it also make clear, particularly in

19 the first paragraph, that it is intended to be used in

20 medical settings and it specifically notes "hospitals,

21 general care and secure environments"?

22 **A.** Yes.

23 **Q.** Thank you.

24 You can take that down, thank you.

25 Now, you note in your statement that the Oxevision

46

1 manufacturer's assessment of the product's use would, in

2 their opinion, be as a medical device.

3 **Q.** Right. But the MHRA, as you noted, took a different

4 view?

5 **A.** Yes. I think it was seen as a standalone software

6 element which was not -- did not meet the definition of

7 a medical device under the regulations. That was

8 the assessment undertaken by the team at the time.

9 **Q.** Thank you.

10 Can we please pull up document MHRA025471.

11 One second ... **(Pause)** Sorry, I don't think that's

12 the right document. Can we take that down. I'll return

13 to that later.

14 So is it correct that after the MHRA took the view

15 and communicated it to Oxehealth that the device was

16 deregistered with the MHRA?

17 **A.** Yes.

18 **Q.** Is the consequence of that deregistration and

19 non-classification of a medical device that the MHRA

20 does not have any regulatory role in relation to the

21 Activity Tracker?

22 **A.** Yes.

23 **Q.** Is there, to your knowledge, a different regulatory body

24 who would exercise some kind of patient safety oversight

25 function in relation to that device?

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1 **A.** So I think where you have a product which does not meet
 2 the definition of a medical device it would fall under
 3 general product safety requirements, which I think is
 4 with Trading Standards, I believe.

5 **Q.** So is the result that different functions of the same
 6 device are regulated by different organisations?

7 **A.** Yes. Which is not, I think, an uncommon occurrence when
 8 you're looking at perhaps platform technologies upon
 9 which other -- especially in the software space in which
 10 other functionalities are then built, that some of those
 11 functionalities may then meet the definition of
 12 a medical device, and require regulating as such,
 13 whereas perhaps the platform upon which it's built
 14 is not.

15 **Q.** Does this, in your view, create any risk of confusion
 16 or, I suppose, regulatory fragmentation?

17 **A.** I think there is, as I mentioned earlier, a need for an
 18 approach to some novel technologies, which is more of
 19 a system-wide approach to regulation that would
 20 incorporate different regulatory jurisdictions. And
 21 I do think that there are at times perhaps areas of
 22 overlap or areas where there is a very close
 23 relationship between the work of the regulatory bodies,
 24 and in those cases having a more system-wide approach
 25 would be a helpful outcome.

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1 clear on from an MHRA perspective as we look to the
 2 future, that areas such as definitions, such as
 3 classifications, they need to be things that we are
 4 continually assessing and continually evolving to
 5 reflect developments in technology.

6 There is also the way in which -- an important
 7 consideration is how we do that whilst also maintaining
 8 our remit as a regulator of medical devices, which is
 9 where I think it's important that we still have those
 10 boundaries between: this is a device, and this maybe is
 11 not a device. But where those boundaries lie, I think
 12 is something that needs to be continually assessed.

13 I also think there's a really important element
 14 here, which is around how we ensure that the end user or
 15 the population within which a particular technology is
 16 intended to be used is being accounted for more clearly
 17 in the approach that we're taking to regulation. And it
 18 fits, I think, with this kind of -- I've said it, and it
 19 sounds -- I'm saying it again, but the system-wide
 20 approach to regulation I think is important. And by
 21 "system" I would mean the MHRA as a regulator, NICE as
 22 HTA, other regulatory bodies, healthcare providers, and
 23 then, and most importantly, families and patients and
 24 the public, all of which I think form a role, or can
 25 form an important role in a system-wide approach to

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1 **Q.** Thank you.

2 One final question before we break. On Monday, this
 3 Inquiry heard expert evidence from Dr Francesca Denman
 4 on observations and the use of technology.

5 If we could turn up page 130 of her report, which is
 6 INQY028221, now, at the top of that page, one of
 7 Dr Denman's recommendations was that:

8 "It may be worth widening the scope of medical
 9 device regulation to allow it to cover technologically
 10 assisted interventions in mental health that are not
 11 currently captured."

12 And she states that:

13 "The current boundaries may not fit well [with] the
 14 nature of technologically assisted interventions on
 15 mental health ..."

16 What are your views of this recommendation?

17 **A.** So I think the first thing I think I would say is that
 18 regulation should not stand still. We need to make sure
 19 that we are evolving our Regulatory Framework to best
 20 address developments in technology and I think the case
 21 made here is valid. I think there are challenges that
 22 are posed by new technologies to existing regulatory
 23 approaches, that we need to be aware of those, and we
 24 need to be open to addressing those.

25 I think this is something that we have been very

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1 regulation.

2 **MS HYDE:** Thank you very much.

3 Chair, I suggest that's a convenient time for
 4 a break -- for 15 minutes?

5 **THE CHAIR:** Fifteen minutes.

6 **MS HYDE:** Thank you.

7 **(11.33 am)**

8 **(A short break),**

9 **(11.52 am)**

10 **THE CHAIR:** Ms Hyde.

11 **MS HYDE:** Thank you, Chair.

12 Dr Reid, I now want to consider your evidence about
 13 how the MHRA first became aware of and engaged with
 14 concerns relating to Oxevision.

15 And at paragraph 59 of your witness statement, which
 16 I don't propose we turn up, you explain that the first
 17 time the MHRA became aware of concerns relating to
 18 Oxevision was in April 2021, when you were contacted by
 19 the Patient Safety Team at NHS England.

20 Before we go to that email exchange, you've spoken
 21 about the need for a whole-system approach. How common
 22 is it for concerns about the safety of medical devices
 23 to be shared with the MHRA by other regulators?

24 **A.** It's quite a difficult question to answer. I wouldn't
 25 say it's a hugely regular occurrence but I think there

52

1 are, as I mentioned, those pathways and opportunities to
2 be able to do that in terms of sharing safety signals
3 and safety information across different parts of the
4 system.

5 **Q.** Thank you.

6 I'll take you to that email exchange now. It's at
7 MHRA025474. If we could start at the -- I think it's on
8 pages 7 to 8. Yes. Perfect.

9 Now, NHS England here states that it has concerns
10 about the device Oxevision manufactured by Oxehealth,
11 and it requests the Instructions for Use for the
12 technology.

13 Flicking up to the next page, which is
14 chronologically the next email, the response from the
15 Senior Medical Device Specialist at the MHRA is to ask
16 for some more information regarding concerns. And going
17 to the next page along chronologically --

18 **THE CHAIR:** What does IFU stand for?

19 **A.** Instructions for Use.

20 **THE CHAIR:** Thank you.

21 **MS HYDE:** On 4 May 2021 the Senior Medical Device Specialist
22 states that the MHRA:

23 "... [does] not keep IFUs of devices, and as we have
24 not had any concerns regarding this device, I will not
25 be able to provide any more information."

53

1 so we have transparency and traceability on individual
2 devices that are being provided to the market in GB.

3 **Q.** Thank you.

4 Now, we know the IFU was eventually provided to
5 NHS England. Now, can we move to an email that I think
6 is on page 1 of that document, sent on 27 May 2021 at
7 3.31. Here Ms Jennings of NHS England sends a list of
8 the NHSE's concerns that arise from those Instructions
9 for Use as well as its broader research.

10 Those are, in summary:

11 "There is misrepresentation between medical claims
12 on the website and the IFU using only the Vital Signs
13 tracker as a medical device; the website materials
14 suggest how it can be used to prevent falls, prevent
15 self-harm, monitor Covid patients."

16 It's then stated that:

17 "There is a high risk to patient safety if website
18 materials imply to patients or staff that there are
19 automatic alerting functionalities, which there are
20 not."

21 It's then stated that without access to the IFU,
22 that the MHRA provided to NHSE:

23 "This leaves users relying on website indications
24 which do not include warnings, cautions and
25 contradictions (sic)."

55

1 What is the -- does it remain the case that the MHRA
2 does not routinely hold IFUs for devices?

3 **A.** Yes, we don't currently hold IFUs for devices.

4 **Q.** Now, we've spoken about the significance of the intended
5 use of a product from the point of view of the
6 definition of "medical device". Considering that, would
7 it not assist the MHRA to retain copies of Instructions
8 for Use for devices that are registered with it?

9 **A.** I think it would. I think, again, it comes to the sheer
10 volume of products which are on the market and which are
11 registered. We have over 4 million products registered
12 with us on the hard database which would mean holding
13 4 million copies of Instructions for Use, needing to
14 make sure they're kept up to date, maintained, if there
15 are any changes. So yes, I think it could. We are
16 looking -- we have a large piece of legislation that
17 will be introduced into Parliament later this year which
18 is looking at registration in particular, and what
19 manufacturers are required to upload when they register
20 with us.

21 And I think as part of that work we can -- we have
22 been thinking about other information. So for example,
23 the introduction of unique device identifiers, these are
24 alphanumeric codes which are applied to individual
25 devices which are uploaded at the point of registration

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1 Then there is a concern relating to the safe fitting
2 of monitors to avoid ligature risk.

3 Was it the view of the MHRA that those were concerns
4 that warranted further action?

5 **A.** It was. And we followed up within NHSE&I and -- on
6 those specific concerns that had been raised.

7 **Q.** Thank you.

8 Can we take that document down.

9 This exchange was then followed by NHS England,
10 sending the MHRA a copy of its review of relevant data
11 from the National Reporting and Learning System. That
12 is at MHRA025443.

13 Now, page 1, in the section entitled "Trigger" we
14 see that this describes a trigger event involving
15 a patient who is in a room fitted with Oxevision, and
16 that patient was observed by a staff member using
17 Oxevision to conduct observations to have ligatured.
18 And that patient was found by staff unconscious and with
19 no discernible breathing or pulse.

20 What did MHRA understand NHS England's concern to be
21 in relation to this trigger event?

22 **A.** I think in relation to this trigger event it was the way
23 in which the device was being used within the healthcare
24 setting.

25 **Q.** Thank you. Looking ahead to page 3, in that first

56

1 bullet point, the report says:
 2 "Whilst some website materials might be read as
 3 implying can be set to alarm if patient in blind spot in
 4 room or risky areas (presumably near doors) more than
 5 x minutes, IFU suggest only settings are in bed/out of
 6 bed."
 7 Then beneath that it says:
 8 "Website might be read as implying falls prevention
 9 'algorithm' that alerts to sitting on side of
 10 bed/exiting bed and appears to require turning on once
 11 patient has settled in bed."
 12 And again, can you help us, please, with what the
 13 concern being expressed here was.
 14 **A.** I think it's a concern that there could be
 15 a misinterpretation of what the system is telling the
 16 healthcare professional in terms of the way it's being
 17 used by the healthcare professional, within the
 18 healthcare taking.
 19 **Q.** Thank you.
 20 Turning ahead to page 6 we see there is an appraisal
 21 of figures that were provided on Oxehealth's website and
 22 the document states:
 23 "Nothing found on website that could be source for
 24 the 66%/22%/15% figures, 88% figure may be from one of
 25 the single Trust pdfs undertaking surveys of staff but
 57

1 document, yes.
 2 **Q.** Thank you, and turning back to page 8, it says:
 3 "The CCTV 15 seconds of live video function", it
 4 states this function:
 5 "... was being used to conduct all patient checks
 6 and planned intermittent frequency checks for patients
 7 in their bedrooms (N=57)."
 8 Does that mean -- and I appreciate you may not know
 9 the answer to this -- that there were 57 such incidents
 10 identified?
 11 **A.** I would take that to mean that there were 57 incidents,
 12 yeah, with the "N=57", "N" would normally be the number
 13 of patients, or individuals.
 14 **Q.** Thank you. Now, there are several patient safety
 15 concerns addressed in this document. Would you agree --
 16 and in fact did the MHRA agree -- that these were
 17 serious concerns with the potential to have significant
 18 impacts for patient safety?
 19 **A.** Yes, I would say that the actions that we took
 20 subsequently would demonstrate that in that we met with
 21 NHSE&I, we pulled together an internal briefing document
 22 to share more broadly with our safety and surveillance
 23 teams within the MHRA and then followed up with
 24 a meeting with both NHSE&I and Oxehealth.
 25 **Q.** And we will consider those actions in some more detail.
 59

1 not clear which one."
 2 Does this show that NHS England expressed caution
 3 about Oxevision's claims as to the clinical benefits of
 4 the device?
 5 **A.** I think it shows they're expressing caution in terms of
 6 the clinical impact of the device.
 7 **Q.** Impact. Thank you. Thank you.
 8 Now, moving to page 11, we noted that this document
 9 considered a trigger event in which a patient was
 10 observed using a monitor rather than in-person
 11 observations. On page 11, towards the bottom of the
 12 page, it is stated:
 13 "In addition to the trigger incident, there were two
 14 additional reports of staff going to check the monitor
 15 to view the bedroom, rather than going direct to the
 16 bedroom, when patient noticed missing from communal
 17 areas. Whilst we can't be totally sure from incident
 18 reports, context suggested staff used the term 'monitor'
 19 or 'machine' to mean the screen in the staff office
 20 rather than an iPad they were carrying with them."
 21 So does this show that NHS England's analysis of
 22 patient safety data identified further incidents in
 23 which observations were carried out through monitors and
 24 not in person?
 25 **A.** That would seem to be what's being suggested in the
 58

1 Now, turning back to page 7, the report summarises
 2 the results of a search of the National Patient Safety
 3 Database, which it states generated 136 incidents.
 4 We heard from Mr Gareth Harry on behalf of
 5 NHS England on 5 October that the MHRA also has access
 6 to this database; is that correct?
 7 **A.** Yes.
 8 **Q.** Would the safety incidents that are summarised and
 9 analysed here, would those have been discoverable, as it
 10 were, by the MHRA, therefore?
 11 **A.** I believe so. It's not -- it's not something I have
 12 firsthand experience with. I would suggest that there
 13 would be many signals that would be in there and they
 14 would be interpreted based on the level of risk and a
 15 number of other factors in terms of further
 16 investigation.
 17 **Q.** But based on information that was available to the MHRA
 18 at this time in 2021, could MHRA have undertaken
 19 a similar analytical exercise itself?
 20 **A.** I don't know, if I'm honest.
 21 **Q.** You don't know. Thank you.
 22 Now, we can take that document down, thank you.
 23 But before we move on to consider the actions that
 24 followed in more detail, can you tell us whether this
 25 sort of analysis has been repeated by the MHRA since
 60

1 2021 or by another organisation and shared with the
 2 MHRA?
 3 A. Not that I'm aware of.
 4 Q. Do you consider it would be a helpful exercise to do so?
 5 A. Yes, I do.
 6 Q. Thank you.
 7 Next, I want to consider the specific post-market
 8 engagement that occurred between the MHRA and Oxehealth
 9 which you outlined in paragraphs 63 to 64 of your first
 10 statement. I don't propose we take it up.
 11 You tell us that this addressed marketing and
 12 website claims, the fitting and installation of
 13 equipment, reporting and management of incidents, data
 14 privacy and the Activity Tracker, which we've covered
 15 already. We now want to consider those other matters in
 16 a bit more detail.
 17 In summary, what were the MHRA's concerns about
 18 Oxehealth's marketing and website claims?
 19 A. So the key concern, I think, was around the claims made
 20 around preventing self-harm and the provision of
 21 advanced alerts, and whether there was the clinical
 22 evidence that would support making those claims for the
 23 device.
 24 Q. And were those concerns precipitated by, or triggered
 25 by, the NRLS analysis that we just went to?

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1 15 November 2021 at 3.11, do we see here that, after
 2 that meeting, the MHRA continued to have unanswered
 3 questions and concerns in relation to Oxevision and in
 4 particular those matters set out in questions 1 to 6?
 5 A. Yes.
 6 Q. Thank you.
 7 Now -- we can take that down, please.
 8 A response was provided to those questions on
 9 20 December 2021. That is document MHRA025435. Can we
 10 turn that up, please.
 11 This is a lengthy document and I don't propose we go
 12 through all of it but it's correct, isn't it, that this
 13 document did not answer all of the MHRA's questions and
 14 so there were further rounds of Q&A with Oxehealth, as
 15 it were?
 16 A. Yes, there were further communications with the company.
 17 Q. Thank you.
 18 Can we take this down and pull up NHSE028957,
 19 please.
 20 Thank you. If we can go to the -- if we can go to
 21 the next page of that document. Thank you.
 22 So we see here that the MHRA Senior Devices
 23 Specialist notes that the MHRA is working through that
 24 document, identifying further questions, and seeks the
 25 input of NHS England.

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1 A. So I think the concerns or the further investigation and
 2 the further action taken by the safety team at the time
 3 were triggered by the interactions that we'd had with
 4 NHSE&I.
 5 Q. Thank you. Now, we know that there then followed
 6 a series of engagement between the MHRA and Oxehealth.
 7 I want to look at that in a bit more detail now.
 8 Can we pull up NHSE028936, please.
 9 Turning to the first email chronologically, which --
 10 yes, that's the one. This is an email sent by the
 11 Senior Medical Devices Specialist to -- well, we don't
 12 know the subject. Do you know, and it refers to a
 13 meeting that took place on 27 October 2021; do you know
 14 who that meeting was with, in terms of the stakeholder
 15 rather than individual?
 16 A. I assume that this was a meeting between the MHRA and
 17 NHSE&I.
 18 Q. Can we go to the next email chronologically. Yes. So
 19 the response is from the Head of Engineered Compliance
 20 at Oxehealth. Can we take from this exchange that it
 21 was a meeting with --
 22 A. Yes.
 23 Q. -- Oxehealth? Thank you.
 24 So following that meeting, and if we could go to the
 25 next email chronologically, please, the email sent on

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1 Can we go to the first page again.
 2 In the paragraph starting "On page 7", Dr Healey,
 3 who we have mentioned previously, states:
 4 "On page 7 they seem to be claiming a technically
 5 [I assume that means a technicality] in relation to the
 6 self-harm functionality -- they are saying they are not
 7 claiming it reduces self-harm, simply sharing the
 8 experiences of clinicians who have found it does.
 9 You'll know ["you" being the MHRA] whether that does or
 10 doesn't count as making claims of medical purpose, but
 11 we're still concerned that isn't a claim supported by
 12 any evidence links on the site or in their answers
 13 here."
 14 We can take that down, thank you.
 15 Was that a concern that fell within the MHRA's
 16 remit?
 17 A. The claims that were being made and the concern that
 18 they weren't --
 19 Q. Indeed --
 20 A. -- substantiated? Yes.
 21 Q. Thank you.
 22 We know that there was a further round of questions
 23 and answers.
 24 Could we turn up NHSE028965, please. Thank you.
 25 So we see that Oxehealth responded to the further

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1 round of questions on 2 March 2022. Again, this is
2 a reasonably lengthy document, and I won't go through
3 all of it, but if we could turn to page 3, please.
4 Here, we have a note of the MHRA's concern in relation
5 to clinical benefit claims.

6 Was the concern, in summary, that there was
7 insufficient evidence on which to base the claim of
8 reducing self-harm and therefore this had implications
9 for the regulation of the device?

10 A. So I think the concern was that the claim required,
11 under the regulations, required literature -- sorry,
12 required clinical evidence, that could be literature or
13 study evidence, to demonstrate that that claim could be
14 supported. So the question was either: can that be
15 provided, or can the claim be removed?

16 Q. Thank you.

17 Do you know how Oxehealth responded in this
18 instance?

19 A. Yes, I think they made a change immediately to the
20 website, as far as I'm aware, acknowledged the
21 seriousness of the concern, and also addressed, I think,
22 in other materials, the concern around that particular
23 claim.

24 Q. I apologise, could you repeat that last sentence?

25 A. That they looked to address the concerns in relation to

65

1 Going to the response to that on page 1, here the
2 Lead Compliance Investigator for the Devices Compliance
3 Unit states:

4 "Firstly, just to check my understanding, it's the
5 software ('Vital Signs') which is measuring heart and
6 respiration rates that certified as a Class IIa device?
7 The location activity alerts relate to movement in the
8 room, which is monitored via optical sensors that use
9 algorithms to 'alert' carers to 'potential dangers'."

10 They suggest:

11 "I'd have assumed that the patient management system
12 as a whole would be classed as a medical device? But
13 perhaps not -- I know patient monitoring systems are
14 complicated and I always struggle getting my head round
15 them!"

16 Now, appreciating that this email was sent some time
17 ago, does this email indicate that there was at least
18 some uncertainty at the time about how the Regulatory
19 Framework as a whole applied to the Oxevision device and
20 the different modules thereof?

21 A. So I think it does suggest that there is someone
22 uncertainty around whether the Oxehealth device was
23 a system, would be characterised as a system under
24 Medical Device Regulations or the component parts would
25 be treated separately, effectively, and therefore only

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1 the claim.

2 Q. Thank you.

3 We can take that down, please.

4 Now, there was then, I think, further engagement
5 between MHRA and Oxehealth on this issue.

6 Can we turn up MHRA025425, please.

7 Thank you. If we could go to the first page -- the
8 first email chronologically, rather.

9 So this is an email sent by the Senior Medical
10 Device Specialist to a colleague within the MHRA on
11 13 April 2022. What is said there, amongst other
12 things, is that:

13 "... [Oxehealth] previously had on their website
14 that it [the device] reduces self-harm. However,
15 I pointed out to them that the claim has a medical
16 purpose, and there is risk that patients and users might
17 think that the system will be able to alert staff to any
18 self-harm attempts. They have now edited their material
19 and removed 'reduce'. However, the wording 'self-harm'
20 is still on their website."

21 So what was the residual concern expressed here
22 after those previous rounds of engagement?

23 A. The term "self-harm" in itself implied a medical
24 purpose.

25 Q. Thank you.

66

1 the Vital Signs module would be considered as a medical
2 device. The approach that had been taken by the company
3 and by the Approved Body was the latter and that was
4 the approach, I think, that the MHRA took at the time.
5 But I think this is a -- I mentioned earlier about the
6 importance of continual review of regulatory approach,
7 of definitional elements of that regulation, and I think
8 this is an example of an area where we need to be
9 thinking around when, and it brings in that: how will
10 this be used in the intended purpose? Is this a system
11 or is this individual components of the device?

12 Q. Thank you.

13 The other point I want to pick up from this email is
14 the paragraph beginning "Regarding advertising" and what
15 the Lead Compliance Investigator states here is:

16 "... annoyingly, we don't yet have the legislation
17 to allow us to take action against companies making
18 misleading claims about medical devices. There is
19 a section covering claims in the proposed future
20 regulations but these have only just gone through the
21 consultation phase so might be a little while before
22 they're in place (if agreed)."

23 So this email was sent more than four years ago.
24 Does the MHRA now have the power to take regulatory
25 action against companies in relation to their

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1 advertising as is suggested here?

2 **A.** So the large piece of legislation that I mentioned

3 earlier, which I think has about 160 provisions relating

4 to medical device regulations, is being laid in

5 Parliament before the end of this year. That will

6 introduce new requirements for manufacturers around

7 claims. I would highlight here that the process of

8 taking a policy through a consultation process, through

9 the legal drafting, in order to update legislation is

10 unfortunately quite a long one. So I appreciate that

11 it's been four years, but we are almost there with

12 regards to this being introduced to Parliament.

13 **Q.** Thank you, that's very helpful.

14 Can we take that document down, please.

15 Now, we know from your first statement at page 19,

16 which is at paragraph 64a, I believe -- apologies, it's

17 page 18. We see here that:

18 "Additional correspondence dated 27 May 2022

19 confirms that further changes to the website had been

20 made in response to MHRA's view on this matter."

21 We can take that down, please.

22 So was it at that stage that the MHRA was satisfied

23 as to the marketing claims being made on Oxehealth's

24 website?

25 **A.** So at that stage we took the, I guess the communication

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1 areas of engagement that you address in your first

2 statement. The first was the fitting and installation

3 of Oxevision equipment. You tell us that NHS England,

4 E&I, rather, considered that Oxehealth's guidance on the

5 fitting and installation of the technology needed to be

6 more robust regarding ligature risk. Could you tell us

7 a bit more about that?

8 **A.** So I think it was the suggestion from NHSE&I, there was

9 discussion around how the device was fitted into the

10 room, and who was responsible for fitting, and

11 therefore, were there sufficient instructions provided

12 to ensure that that device could be fitted safely to the

13 room?

14 These were concerns raised by NHSE&I that we engaged

15 with in terms of understanding, although the way in

16 which a device would be fitted would not be directly

17 within our regulatory purview.

18 **Q.** And would that be, to summarise, because fitting of

19 a device is not strictly a matter concerning the

20 inherent safety of the device?

21 **A.** I think -- well, it depends, I think, on the device.

22 **Q.** Thank you.

23 You tell us that the third area where MHRA had

24 post-market engagement with Oxehealth was in relation to

25 the reporting and management of incidents.

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1 to date and the actions that have been taken to date to

2 our Software Expert Advisory Group, which is a group

3 composed of external experts working in medical devices

4 and software, and were content, following presentation

5 to that group, that the company had addressed the

6 issues.

7 **Q.** Thank you. And by that stage, had it been more than

8 a year since NHS England first raised those concerns

9 with the MHRA?

10 **A.** I think it had, looking at the dates, yeah.

11 **Q.** And is the MHRA aware of how long the marketing claims

12 in question were on Oxehealth's website in total, but

13 before they were removed?

14 **A.** I don't know that off the top of my head, sorry.

15 **Q.** That's fine.

16 Now, after that change was made, did the MHRA

17 require Oxehealth to cascade the change to their

18 communications in any way, such as by contacting

19 existing customers?

20 **A.** Not that I'm aware of.

21 **Q.** Do you consider that, given the seriousness with which

22 both NHS England and the MHRA took this issue, it may

23 have been sensible to do so?

24 **A.** Yes.

25 **Q.** Thank you. I now want to turn to some of the other

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1 Can we turn up MHRA025423, please, starting with

2 the, I believe it's on the second page, an email is sent

3 from the Senior Medical Device Specialist on

4 10 February 2022 at 4.27.

5 In summary, this MHRA staff member expresses concern

6 about an incident, a safety incident involving Oxevision

7 which was not reported.

8 To summarise that, and turning, perhaps, to the next

9 page, was the concern here that a low pulse rate was

10 reported for a patient who was in fact tachycardic?

11 **A.** (No audible response).

12 **Q.** To contextualise this, what was the specific concern

13 being raised here in relation to reporting?

14 **A.** So the specific concern raised here in relation to the

15 reporting, there was a number of complaints which had

16 been received by Oxehealth from users of the device

17 which the company had assessed and concluded did not

18 meet the threshold for reporting to the MHRA. Upon

19 review of those complaints which were provided by the

20 MHRA by the company, our software specialist identified

21 one of those where we thought this was a significant

22 issue that should have been reported to the MHRA as

23 a serious incident.

24 **Q.** Thank you. And we see on this table that the rationale

25 recorded by Oxehealth was that "the patient could not

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1 have been harmed". That's in the third column.
 2 And then in the next sentence:
 3 "This particular patient was not suffering from any
 4 condition that could cause them serious harm."
 5 If we could turn -- actually, going back one
 6 second -- one step, you tell us that this information
 7 was provided by the manufacturer to the MHRA. In what
 8 context was it provided?
 9 A. It was after request from the MHRA for sight of those
 10 complaints.
 11 Q. And what prompted that request from the MHRA, the
 12 -- (overspeaking) --
 13 A. The initial conversation within NHSE&I and subsequent
 14 conversations have led to that.
 15 Q. Thank you. If we could go to the next email, thank you.
 16 This is the response from the Senior Clinical Adviser.
 17 Can you summarise that response, please?
 18 A. Yes, essentially they were highlighting that they
 19 thought there was a risk to the patient from this, that
 20 just because they were tachycardic, didn't mean they
 21 couldn't develop an acute condition, that that couldn't
 22 have happened during there, so that it was something
 23 which therefore should have been reported.
 24 Q. Thank you.
 25 We can take that document down, now.

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1 Was the MHRA aware of this?
 2 A. Yeah, my apologies, I was getting confused with the time
 3 frame. So we have full reports to the MHRA in relation
 4 to these pulse readings.
 5 Q. Thank you. That's very helpful. We can take that down
 6 now.
 7 You tell us next, in terms of the post-market
 8 engagement, that NHSE&I had concerns about data
 9 retention practices and informed consent. Do these
 10 issues fall within the remit of the MHRA as a regulator?
 11 A. These would fall under the remit of the ICO, the
 12 Information Commissioner's Office.
 13 Q. Thank you. Two final questions in relation to this
 14 post-market engagement that you outline.
 15 First, this programme of engagement appears to end
 16 in 2022. Was any consideration given, to your
 17 knowledge, of further follow-up or ongoing programme of
 18 engagement with Oxehealth?
 19 A. Not to my knowledge, but the company would be required,
 20 as mentioned at the start of my evidence session, to
 21 undertake post-market surveillance activities which
 22 would flag any -- or should flag any serious incidents
 23 relating to the products.
 24 Q. Thank you.
 25 Second question: viewed as a whole, having

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1 You tell us in your witness statement that following
 2 this exchange, Oxehealth was notified of MHRA's view and
 3 a Field Safety Corrective Action and a Field Safety
 4 Notice were issued.
 5 Did the MHRA consider taking any other actions at
 6 this time, such as enforcement action, for instance?
 7 A. No, because the company addressed the concern that was
 8 raised with them.
 9 Q. Thank you. Is the MHRA aware of issues with pulse rate
 10 readings recurring or being -- occurring since then?
 11 A. Not that I'm aware of, no.
 12 Q. Can I take you, please, to document BSI028561.
 13 This is the witness statement of Graeme Tunbridge on
 14 behalf of the British Standards Institution and what
 15 Mr Tunbridge tells us at paragraph 55(i), thank you, is
 16 that:
 17 "On 15 February 2023, Oxehealth Limited reporting to
 18 BSI that the Vital Signs software at one customer site
 19 produced erroneous constant pulse rate readings due to
 20 environmental power issues."
 21 And it states that -- in essence it reported:
 22 "... a constant pulse rate reading of 91 or 92 bpm
 23 that is different to patients' true pulse rate readings.
 24 All '34 rooms on this site' were affected over [a period
 25 of] 31 months."

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1 considered all of these exchanges, is this level of
 2 regulatory activity or engagement unusual, as far as the
 3 MHRA is concerned?
 4 A. No, I wouldn't say unusual. I think we -- where we are
 5 investigating safety of surveillance concerns or
 6 possible compliance issues, we will, as I mentioned at
 7 the start, initially look to engage with the company to
 8 understand the compliance concerns that have been raised
 9 and to address those through compliance activities
 10 through Field Safety Notices and Field Safety Corrective
 11 Actions. Taking further enforcement activity is
 12 available to us but would be triggered, I think, by
 13 those initial engagements failing to address concerns.
 14 Q. Thank you.
 15 Now, the final matter I wish to cover is
 16 recommendations. We have considered this idea of
 17 a whole-system approach already. I would also like to
 18 consider the challenges that regulators may face when, I
 19 suppose, keeping pace with the development of
 20 technology, which we've touched on already.
 21 You tell us in your first statement that the MHRA
 22 has a role in reforming the Regulatory Framework to
 23 address emerging and innovative technologies. Does that
 24 include identifying and potentially closing regulatory
 25 gaps that may become apparent?

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1 **A.** Absolutely. It needs to focus on where there are
 2 opportunities as well as challenges with the existing
 3 Regulatory Framework. So by that, I mean opportunities
 4 to develop an approach which, whilst absolutely focuses
 5 on safety, and efficacy, is also ensuring access for
 6 patients to devices which could have a significant
 7 impact on their care.

8 But equally, as we're doing that, we need to be able
 9 to identify where there may be challenges or gaps within
 10 the Regulatory Framework which could be highlighted by
 11 novel technologies or could be gaps which have been
 12 highlighted through particular incidents. So they
 13 absolutely need to be something that we're considering
 14 as we are thinking about our future Regulatory
 15 Framework.

16 **Q.** Thank you.

17 Now Mr Gareth Harry, on behalf of NHS England, was
 18 asked when he gave evidence on 5 October whether he
 19 recognised that there was a risk that enthusiasm for new
 20 technologies may come at the risk of patient safety.
 21 And he agreed this was a risk. Does the MHRA share that
 22 view.

23 **A.** I think it's a -- I don't think you can remove risk from
 24 anything and I think there therefore is a risk. I think
 25 we have to be -- we have to acknowledge that and we have

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1 And we heard from Mr Harry in NHSE that they, too,
 2 do not take responsibility for that latter clinical
 3 effectiveness, that that is a matter for individual
 4 providers, individual Trusts, notwithstanding the fact
 5 that devices such as Oxevision might be in a very large
 6 number of NHS mental health hospitals. Do you think
 7 there's a risk in that approach to ensuring that we get
 8 the best out of devices, that they're the most economic,
 9 that they are the most clinically effective, that they
 10 can be properly implemented?

11 **A.** I do. I think -- so first of all, coming back to the
 12 start of the question around clinical effectiveness,
 13 there is absolutely a requirement in the pre-market
 14 assessment phase for manufacturers to demonstrate the
 15 clinical effectiveness of their products. They need to
 16 be able to show, using evidence, that the product can do
 17 what they're claiming it can do.

18 **THE CHAIR:** Yes, sorry, that was my language.

19 **A.** And equally, in the post-market stage, they continue to
 20 collect evidence on that clinical effectiveness.
 21 I think --

22 **THE CHAIR:** I think we're talking about a wider clinical
 23 evaluation --

24 **A.** Yeah, adoption and uptake. And I think this has been
 25 a challenge, from a system-wide approach, for a long

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1 to think about how we are looking to encourage new
 2 technologies whilst also maintaining our role as
 3 a regulator which is ensuring the safety and
 4 effectiveness of devices which are -- which are coming
 5 to market in GB.

6 So I think that risk can be minimised through
 7 sensible approaches to the development of regulatory
 8 requirements, through full engagement with all of those
 9 that are impacted by the Regulatory Framework, and that
 10 goes from the manufacturer through to the healthcare
 11 system to the end user. And I think if we do those
 12 things correctly, we can minimise risks associated with
 13 new technology.

14 But I think there will be risks associated with
 15 existing technologies, with any new technologies. It's
 16 something that we just have to ensure that we are
 17 acknowledging and doing our best to mitigate and to
 18 minimise.

19 **THE CHAIR:** Can I ask whether you -- you've talked about the
 20 MHRA having responsibility for the safety and efficacy,
 21 as it were, of the device, but that the decision making
 22 about clinical outcomes, clinical effectiveness, whether
 23 it's actually going to do what is required in terms of
 24 caring for patients, is a matter for those who choose to
 25 procure the device or whatever it might be.

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1 period of time, that we have a regulatory approval
 2 process which gives you market access, but that doesn't
 3 lead to adoption and uptake of that product within the
 4 system because those decisions are taken elsewhere
 5 within the system.

6 Now, I think there is a dire need to kind of join up
 7 across that, especially as we're thinking about novel
 8 technologies, innovation, where we have an opportunity
 9 to identify really clear, clinical unmet needs within
 10 the healthcare system and then to work as a system to
 11 ensure that they are plugged quickly, safely, and
 12 effectively. But I don't think that's something that
 13 can be done by one part of the system on its own. So
 14 I think it's this system-wide -- that, I think, is
 15 incredibly important.

16 **THE CHAIR:** Thank you.

17 **MS HYDE:** That leads me quite nicely to the next question I
 18 wanted to ask.

19 Do you have any views on how information sharing
 20 between the different organisations with
 21 responsibilities in this space could be improved?

22 **A.** I do. I think there are -- we have a lot of data that
 23 sits within the system, but it's quite fragmented, and
 24 I think there are lots of attempts and as part of our
 25 2030 Strategy we're looking to work with the Health Data

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Research Service to better access the data that we know is held in other parts of the healthcare system that can inform the work that we do. So I think initiatives that aim to create a single data pool, effectively, and that would need to be very carefully governed and monitored to ensure confidentiality and protection of personal data.

But I think the benefits of being able to pull that disparate data together will be -- could be potentially transformative in terms of ability to identify issues, trends, and to react to those really quickly.

We know there's data that exists in registries which would be enormously useful for us in terms of doing our post-market work, but being able to access it, I think, is the key.

Q. Thank you. That's very helpful.

Are there any other matters that you would like to address this Inquiry on?

A. I think the first thing I wanted to say was to express my sincere condolences to the families affected by the incidents being investigated by the Inquiry, and to also, hopefully it's clear, but restate the MHRA's commitment to supporting the Inquiry in the work that it's doing.

I think there are a number of areas in which

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the healthcare providers themselves, by patients, by families. And that's partly because of awareness and I think it's partly because of ease of use. It's not, you know, it's not an easy system. Sometimes it seems like the most obvious thing would almost be a big red button that somebody can press to say, "There's something wrong with this" and we can then look to investigate. That's not the current case.

But as I said earlier, we are working through, or committed to working on making that more accessible and to raise awareness of the Yellow Card reporting, and I think that's something which will be really important in terms of addressing and picking up on some of the failings I think we've identified.

And then the final point we've talked about quite a lot that I wanted to make was around the joined-up approach and the system-wide approach which I think is something we've highlighted through several publications including the publication by the National Commission on the Regulation of AI in Healthcare, which called out, I think, many of these elements, the need for better post-market surveillance and reporting, the need for a system-wide approach to regulation and device safety, and the need to apply a kind of life-cycle approach, and by that I mean focusing not just on the pre-market

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evidence to the Inquiry, to my mind, have flagged as areas that we as a regulator and as part of a wider system should be considering as we move forward with our reviews of that regulatory environment.

The first of those, I think, is around the impact of technology and, increasingly, novel technologies in particular patient populations, and ensuring that we're understanding what the impacts will be within those patient populations. We have, as a regulator, an ambition to have patients at the heart of everything that we're doing, but I think there are areas where we can do better in terms of ensuring that the end user, that the patient, the kind of -- the user-centred design elements of medical device development and regulation are being considered more clearly.

And that can be through much clearer guidance from us, in terms of our expectations on manufacturers in that space, but I think it goes beyond just the manufacturer. I think that's a system, as I said, a system-wide approach.

I think -- we talked a little bit about safety signals and Yellow Card and the way in which we assess and have access to that data. And I think that's really critical. We have a system for reporting issues, but it's not used as much as it should be used, by, I think,

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conformity assessment but then how that device is actually used in practice in real-world situations.

So yeah, I would say those are the things that, certainly, from reading the evidence, have jumped out at me.

MS HYDE: Thank you very much, Dr Reid.

Chair, I don't have any further questions for the witness.

THE CHAIR: Neither do I, thank you.

MS HYDE: I propose that we take a break of 10 minutes to consider Rule 10s.

THE CHAIR: Thank you.

MS HYDE: And then return then.

THE CHAIR: Ten minutes.

(12.46 pm)

(A short break)

(1.02 pm)

MS HYDE: Thank you. We have some Rule 10 questions, Chair.

Firstly, Dr Reid, beyond those that we have already discussed, what limitations are there, if any, to the MHRA's ability to strike the right balance in relation to the regulation of emerging technology, specifically?

A. Sorry, could you repeat the first part of the question?

Q. Sure. Apart from those that we have discussed already, do you think there are any limitations to the MHRA's

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1 ability to strike the right balance in regulating
 2 emerging technologies in particular?
 3 **A.** I think it's a really good question. I think, in terms
 4 of limitations, I guess, we, to a degree, are limited by
 5 the resource and the expertise and the capability we
 6 have within the organisation, and I think that's why it
 7 is incredibly important we look outside of the
 8 organisation to engage with expertise that exists in
 9 other organisations, whether they be public bodies or
 10 others in order to be able to inform what we're doing,
 11 and that's the approach we take to any of our policy
 12 development, whether it's in relation to particular
 13 innovations or whether it's more broadly.
 14 The public engagement, the engagement with external
 15 stakeholders who will be impacted by those changes
 16 I think is critical.
 17 So in terms of specifically thinking about how we
 18 strike the balance between ensuring patients can access
 19 and benefit from novel technologies as quickly as
 20 possible, but to ensure that that's happening in a very
 21 safe way, I don't think that -- there's no kind of
 22 trade-off there. I think we -- you know, safety has to
 23 be number 1. We have to be absolutely certain of the
 24 safety of a device when we're looking at the regulatory
 25 approach. But that doesn't mean, I think, that we can't

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1 in June of 2025 around post-market surveillance, so this
 2 is the requirements that manufacturers must meet in
 3 order to continue to place the products on the market,
 4 work to address some of the concerns that we maybe had
 5 with post-market surveillance prior to those regulations
 6 coming into force, which was that many of the
 7 requirements were set out in guidance as opposed to
 8 legislation. So there was maybe an unlevel playing
 9 field in terms of how those guidelines were being
 10 implemented. By putting those requirements into
 11 legislation, I think we bring everybody up to the same
 12 standard.
 13 So I think the post-market surveillance regulations
 14 have been a step in the right direction, we'll continue
 15 to review those and to make sure they are delivering on
 16 the policy objectives that were, at the start, were
 17 driving that work.
 18 **Q.** Thank you.
 19 And the final question is about the Yellow Card
 20 Scheme. First, does the Yellow Card Scheme enable
 21 anonymous reporting?
 22 **A.** I ... it's a good question. I don't know. Perhaps
 23 I could come back to you on that. I know that when you
 24 go to fill in a Yellow Card it asks for details around
 25 name, address, and other information. I think some of

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1 look at novel, innovative approaches to regulation which
 2 maintain the safety whilst also allowing for more rapid
 3 access.
 4 **Q.** Thank you.
 5 Second question. You outlined in your evidence the
 6 regulatory engagement that the MHRA has had with
 7 Oxehealth. Has the MHRA, to your knowledge, ever
 8 received notifications from Trusts, family members,
 9 members of the public, whatever source, of any
 10 post-death investigations where Oxevision has been
 11 referenced?
 12 **A.** Not that I'm aware of.
 13 **Q.** Thank you.
 14 Next question. Are you satisfied that the current
 15 vigilance reporting system is sufficient to capture
 16 patient safety concerns, and if not, are there any areas
 17 where you think it could be improved in particular?
 18 **A.** So I think, as I mentioned in my evidence, I think there
 19 is a need to increase awareness of and ease of use of
 20 the Yellow Card system in particular, and that would
 21 enable members of the public, patients, their families,
 22 as well as healthcare professionals, anybody who has
 23 a concern with a device, to be able to report that to
 24 the MHRA.
 25 I think the new requirements that we've put in place

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1 that is optional but I'm not sure if it's -- if the name
 2 element is, and whether it's anonymised. But we can
 3 come back to you on that.
 4 **Q.** Thank you.
 5 I suppose it may be difficult to answer this, but
 6 has the MHRA considered there to be value in the option
 7 of anonymous reporting as a way of driving better
 8 engagement with that?
 9 **A.** I -- it's a difficult question to answer, because I'm
 10 not sure if it's an option that already exists, which
 11 I can -- we will come back to you on, if that's okay.
 12 **MS HYDE:** Thank you.
 13 I have no further questions, Chair.
 14 Thank you very much, Dr Reid. You may be stood
 15 down.
 16 **THE WITNESS:** Thank you.
 17 **THE CHAIR:** Can I also add my thanks to you for your turning
 18 up here and subjecting yourself to this evidence. It
 19 has been very, very interesting and very helpful. Thank
 20 you very much.
 21 **MS HYDE:** May we break for one hour, please, Chair?
 22 **THE CHAIR:** One hour.
 23 (1.08 pm)
 24 (The Short Adjournment)
 25 (2.10 pm)

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1 **THE CHAIR:** Ms Hyde.

2 **Summary of Regulators' Evidence**

3 **MS HYDE:** Thank you, Chair.

4 We will now hear a summary of evidence provided to
5 the Inquiry by other regulators, and this will be
6 published on the Lampard Inquiry website shortly.

7 In April and August 2026, the Inquiry sent requests
8 for evidence to healthcare regulatory and oversight
9 bodies in England requesting information concerning
10 their respective roles and responsibilities in the
11 regulation of healthcare technologies, including
12 Oxevision.

13 The Inquiry has already heard oral evidence from the
14 Medicines and Healthcare Products Regulatory Agency,
15 MHRA, and NHS England. This document summarises the
16 written evidence provide by other organisations relating
17 to oversight and regulation of healthcare technologies
18 in response to the Inquiry's Rule 9 Requests.

19 Those organisations are: the British Standards
20 Institution, BSI; the Care Quality Commission, CQC; the
21 Department of Health and Social Care, DHSC; and the
22 National Institute for Health and Care Excellence, or
23 NICE.

24 DHSC. DHSC's evidence is set out in the third and
25 fourth witness statements of William Vineall, dated

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1 by streamlining adoption pathways and working with the
2 MHRA on medical device regulatory reform. It does not,
3 however, become directly involved in managing concerns
4 raised about a particular device, and did not receive
5 any concerns relating to vision-based monitoring
6 systems, or Oxevision specifically.

7 DHSC's role does not directly encompass the
8 assessment, management and monitoring of risks and
9 patient safety implications of new technologies.
10 Rather, arms-length bodies, ALBs, such as the MHRA,
11 undertake these functions. They remain accountable to
12 the Secretary of State for Health and Social Care and to
13 Parliament in discharging their functions. DHSC does
14 not review or approve clinical or operational guidance
15 produced by ALBs as they operate to a statutory
16 independence.

17 Mr Vineall's statement then summarises the roles of
18 different health and care bodies.

19 Primary responsibility for overseeing NHS Trusts
20 lies with NHS England and the CQC. NHS England has
21 day-to-day responsibility for the delivery of NHS
22 services and is under a duty to monitor Trusts and
23 integrated commissioning boards in their performance.
24 The CQC monitors the quality and safety of NHS care by
25 way of inspections and reports, sharing concerns with

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1 20 May 2026, and 14 September 2026, respectively.

2 Mr Vineall is DHSC's Director for NHS Quality, Safety
3 and Investigations, a role he has held since 2020.

4 Mr Vineall outlines that DHSC's role in relation to
5 the use of technology and devices in healthcare is
6 "focused on setting the overarching policy framework and
7 strategic direction". This has been reflected in
8 a series of policy papers and strategies published in
9 recent years, including the UK's inaugural Medical
10 Technology Strategy, or the MedTech Strategy. The
11 MedTech Strategy set out the Government's priority areas
12 for medical technology and ambition to support the
13 delivery of products that are safe for all, clinically
14 effective, innovative, and sustainable. The MedTech
15 Strategy was followed in July 2025 by "Fit for the
16 future: 10-Year Health Plan for England". This plan set
17 out the Government's plan to reinvent the NHS through,
18 amongst other things, a shift from analogue to digital.
19 The plan emphasised the importance of driving innovation
20 in healthcare, and that regulatory bodies "must continue
21 to develop agile, risk-proportionate pathways for
22 evaluating and improving products".

23 In 2021, DHSC established a Medical Technology and
24 Innovation Directorate, the MTID. The MTID focuses on
25 removing structural barriers to adoption of technology

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1 other regulators, and taking regulatory action where
2 appropriate.

3 The MHRA is an executive agency of DHSC, whose role
4 is to regulate the UK medical devices market. Although
5 it is the responsibility of individual NHS Trusts to
6 procure, evaluate and deploy new technologies, the MHRA
7 ensures the safety, quality and effectiveness of medical
8 devices. It relies on Approved Bodies to assess the
9 regulatory compliance of devices.

10 Finally, Mr Vineall summarises the respective roles
11 of the Patient Safety Commissioner, NICE, the National
12 Institute for Health and Care Research, NIHR, and the
13 NHS Innovation Service all of which have supplementary
14 or advisory roles in relation to medical devices and
15 technology.

16 In relation to vision-based monitoring systems such
17 as Oxevision, Mr Vineall confirms that DHSC is "reliant
18 on the work of the ALBs such as the MHRA, CQC and
19 others, to provide the regulation, research and guidance
20 for the use of new technologies". Nonetheless, DHSC has
21 supported the work of ALBs in this respect. For
22 instance:

23 In June 2023, DHSC supported work by NHS England and
24 the NIHR to undertake a rapid review of the impacts of
25 surveillance methods on acute wards. This was followed

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by the publication of a further systematic review in November 2024.

DHSC policy and research leads engaged with HSSIB after it published its report, "Mental health inpatient settings: Creating conditions for the delivery of safe and therapeutic care to adults" in October 2024. This did not result in further research being commissioned.

In addition, DHSC recently published guidance for NHS Trusts on how to purchase medical technology. This guidance emphasised the importance of investing in technology, and urged a "fundamentally different approach to procurement that is applied consistently across the health service".

LIO approached DHSC "on several occasions to share information and seek discussions regarding its technology". This included seeking input in NHSE's rapid review and attending a meeting with a special advisor in DHSC, although it is not known what was discussed at this meeting.

DHSC has been made aware of concerns relating to the use of vision-based monitoring technology on several occasions. For instance, in January 2025, DHSC responded to written Parliamentary questions which raised concerns relating to the use of vision-based monitoring systems in inpatient settings, and the impact

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should a provider use technology such as Oxevision in a way that contravenes official guidance, this would be commented on by inspectors.

Mr Howarth was asked to comment specifically on CQC's published case study on the "Digital Care Assistant" technology, now known as Oxevision. His first statement outlines the following:

CQC published a series of case studies on its website in July 2019 relating to the potential of technology to drive improvements in the healthcare system under the umbrella of "Driving improvement through technology". Oxevision was one of the examples provided of "innovative uses of technology".

The publication of such case studies was driven by an internal decision on the part of CQC to showcase examples of healthcare providers "using technology in innovative ways to improve outcomes for people who use services", under the leadership of CQC's Independent Voice Panel.

Its objective in publishing the case studies was "to demonstrate the potential technology has to play a major part in how health and social care are provided, and improving health and care and that CQC welcomes innovation as long as it is not at the expense of quality".

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of Oxevision use in particular. In responses to both questions, the Parliamentary Under-Secretary of State at DHSC referred back to the NHS England rapid review.

CQC. CQC's evidence is set out in the first and second witness statements of Craig Howarth dated 1 June 2026 and 7 September 2026, respectively. Mr Howarth is a Deputy Director for Mental Health in the North region for CQC, having previously held the role of Interim Head of Inspection in the East of England region for Mental Health. This portfolio included oversight of Essex Partnership University NHS Foundation Trust, or EPUT.

Mr Howarth outlines that, in terms of emerging health technologies, CQC does not generally undertake independent analysis of any potential risks. This is because it is the responsibility of providers to make such decisions taking into account the evidence base. Nor does any assessment of the claims and assurances made by technology manufacturers fall within CQC's remit.

CQC would, however, analyse specific issues arising in relation to the deployment of technology on a case-by-case basis through inspections, through the discharge of its regulatory functions, and by reference to the CQC's Single Assessment Framework. Therefore,

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This reflects CQC's position that it will "encourage innovation and technology, including AI, where it benefits people and where the innovation supports high-quality, safe and equitable health and social care". However, CQC did not plan to complete any research on these technologies, or otherwise publish any commentary or conclusions on their use.

In November 2018, the CQC changed its planned approach to the publication of the case studies, deciding not to frame the case studies "as a cause/effect/a manual of how to improve".

CQC's Independent Voice Panel considered the "Driving improvement through technology" proposal in December 2018 and approved its progression. During discussion of the proposal, the panel asked CQC to consider the types of interventions being used by providers and whether these were having effects on service users and their privacy. It is not known how this comment was specifically addressed.

Mr Howarth emphasises that the CQC "does not endorse any particular product, supplier or service", and that the case studies were provided "as a basis for discussion". It was not considered that the case studies would be perceived as endorsements or encourage other Trusts to deploy the technology. Trusts were

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reminded to obtain their own professional or specialist advice.

The use of Oxevision by Coventry and Warwickshire NHS Foundation Trust was selected by CQC following an initial intelligence-gathering exercise. During its inspection report on the Trust in December 2018, CQC had noted the use of Oxevision in Coventry and Warwickshire as "outstanding practice", with staff identifying a reduction in falls since its deployment. The inspector who carried out the comprehensive assessment preceding that report recalled that they discussed the topical of consent to use Oxevision with the Trust. The inspector could not recall the details of that conversation, but believes that they were sufficiently reassured by CWPT's response that this did not prompt any additional probing nor any concerns.

The report was further subject to the CQC's usual sign-off process which includes review by its National Quality Assurance Group, albeit no mental health clinicians were involved in the CQC's determination that the use of Oxevision constituted outstanding practice.

Concerns were raised internally at the time that some of the case studies were presented in highly positive terms without there being a proper evaluation yet, or evidence from, CQC inspectors to rely on. It

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that CQC became aware of concerns relating to Oxevision in August 2023 when it was contacted by Stop Oxevision. Stop Oxevision raised concerns about what it described as "CQC's apparent endorsement of Oxevision". Following this contact, a series of meetings took place between Stop Oxevision and senior CQC figures, including then CEO Ian Trenholm. At a meeting in November 2023, Stop Oxevision raised concerns relating to consent, data protection, psychological impact on patients, and CQC's position.

In parallel, CQC engaged with NHS England which asked CQC to develop a policy position on the use of vision-based monitoring systems. This led to CQC developing its Brief Guide: Digital contactless patient monitoring technologies in mental health inpatient services, and an accompanying web page. CQC also commissioned independent evidence review into vision-based monitoring systems, complete in July 2025.

Separately to the above, Mr Howarth outlines several other relevant regulatory actions taken by CQC. These have been set out in previous evidence disclosed by CQC to the Inquiry. In sum, the action taken includes:

In October 2020, several management review meetings, MRMs, were held to consider the findings of CQC's 2022 inspection of EPUT, which, amongst other issues,

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was further noted that some of the examples included as case studies had "varying levels of evidence against them, in some cases pretty strong", to quote.

Mr Howarth states that a number of amendments were made to the draft case studies in response to these concerns. However, CQC did not undertake any assessments or analysis of its own, prior to the publication of the case study. The wording of the case study was also agreed in advance with Coventry and Warwickshire prior to publication.

Mr Howarth reflects on this process in his first witness statement and states that he "would have expected that CQC request data/information from the Trust to corroborate some of these statements in the report". While that information was requested, the Trust stated that research was still ongoing, and that the hypothesis that Oxevision helped to prevent falls was being explored.

Mr Howarth's view is that without such corroboration being provided, he would not agree with the assessment that the use of Oxevision represented outstanding practice. The case study is not currently on the CQC's website.

Beyond the consideration of Oxevision in the context of preparing that case study, Mr Howarth also outlines

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identified concerns with EPUT's processes for obtaining staff consent to the use of Oxevision. CQC noted, during that inspection, that several patients were not aware that cameras were installed in their bedrooms. There followed a process of engagement between CQC and EPUT, eventually resulting in CQC issuing a warning notice to ensure action was taken.

These steps are set out in further detail in the first witness statement of Stuart Dunn, dated 13 April 2026.

CQC inspected EPUT's acute wards for working age adults and Psychiatric Intensive Care units again in November and December 2024. The inspection report, dated 11 July 2025, considered that action had been taken to respond to its previous concerns. The report concluded that EPUT "ensured patients understood the use of the contact-free patient monitoring system and sought consent".

NICE. NICE's evidence is set out in the witness statement of Jonathan Benger CBE, Chief Executive of NICE, dated 13 May 2026. His statement is 15 pages long and accompanied by nine exhibits.

NICE was established in 1999 as a Special Health Authority, subsequently re-established as an arm's-length body of DHSC. Mr Benger's statement

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1 outlines that the role of NICE is to help ensure that
2 people have equal access to clinically and
3 cost-effective treatments by, amongst other things,
4 producing guidance and recommendations for health and
5 care practitioners, and providing independent assessment
6 of the evidence base for new health technologies. Its
7 statutory role and responsibilities are set out within
8 the Health and Social Care Act 2012 and regulations made
9 under that Act.

10 NICE produces several different kinds of guidance,
11 including guidelines. These are evidence-based
12 recommendations for health and care in England which
13 assist professionals to improve health and care services
14 with topics commissioned by NHS England.

15 Quality Standards. These documents set out priority
16 areas for quality improvement in health, public health
17 and social care, for the benefit of commissioners,
18 service providers, and practitioners.

19 And finally, health technology evaluations. These
20 are evaluations designed to provide recommendations on
21 the clinical and cost effectiveness of new and existing
22 medicines, health technologies, and treatment in the NHS
23 in accordance with NICE's technology appraisal and
24 highly specialised Technologies Guidance Manual.
25 Commissioners and NHS England are required to fund

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1 In May 2025, NHS England shared with NICE
2 a confidential market intelligence report on Vital Signs
3 monitoring technologies which made reference to concerns
4 relating to Oxevision. This was not a formal request
5 for NICE to assess Oxevision's effectiveness.

6 NICE has not undertaken any assessments of
7 Oxevision, and currently has no plans to evaluate it, or
8 similar vision-based patient monitoring systems for the
9 purpose of producing NICE Guidance.

10 BSI. BSI's evidence is set out in the witness
11 statement of Graeme Tunbridge, dated 24 September 2026.
12 Mr Tunbridge is the Senior Vice President of Global
13 Regulatory and Quality at BSI. Prior to joining BSI in
14 January 2022, he was the Director of Devices at MHRA.

15 BSI is organised as a global group of companies that
16 operates in several jurisdictions, the BSI Group. In
17 the UK, BSI is a company incorporated by Royal Charter
18 which acts as the UK's National Standards Body. The
19 activities of the BSI Group include standards
20 development, testing, inspection, certification, and
21 regulatory compliance services.

22 In the medical devices sector, BSI's activities
23 include operating as a conformity assessment body within
24 the European Union, the EU, and the UK, under the
25 applicable legislative framework.

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1 technologies recommended through health technology
2 evaluations. The processes that NICE follows when
3 evaluating health technology products are set out in the
4 HealthTech Programme Manual.

5 While NICE produces guidance on the effectiveness of
6 health technologies, it is not responsible for assessing
7 the patient care and safety implications of new
8 technologies that are deployed or proposed to be
9 deployed in the NHS. Its view is that primary
10 responsibility for such matters rests with the MHRA and
11 the manufacturer of the technology. Nonetheless,
12 Mr Bengier acknowledges the importance of patient safety
13 and states that NICE works closely with the MHRA to
14 ensure that NICE Guidelines remain aligned to the
15 regulatory status of individual healthcare products.

16 NICE has been made aware of concerns relating to the
17 use of Oxevision on two occasions.

18 In June 2024 NICE was contacted by a member of the
19 public raising concerns relating to the care of their
20 late partner at a mental health inpatient unit not in
21 Essex. Those concerns included that Oxevision, which
22 was in use on the ward, had not alerted staff to the
23 deceased's physical deterioration. NICE's view was that
24 it was not responsible for assessing the safety of
25 Oxevision, and no further action was taken.

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1 Specifically, prior to the UK's withdrawal from the
2 EU, BSI operated its medical device assessment and
3 certification business as a Notified Body under EU
4 legislation, which empowered BSI to assess and certify
5 compliance with EU Medical Devices Regulations. These
6 functions were discharged through its separate legal
7 group entity, BSI Assurance (UK) Limited. The MHRA
8 provided oversight of these functions.

9 Following the UK's exit from the EU, BSI Assurance
10 UK Limited became a UK Approved Body under the UK
11 Medical Devices Regulations 2002, or UK MDR. Approved
12 Bodies are designated and supervised by the MHRA.

13 BSI's conformity assessment activities include
14 assessment of a manufacturer's quality management
15 system, QMS, review of technical documentation, review
16 of clinical evaluation reports, and assessment of
17 post-market surveillance and vigilance systems.

18 Mr Tunbridge notes that BSI "does not undertake
19 independent product testing as part of the conformity
20 assessment process. Instead, it independently evaluates
21 the adequacy, relevance and sufficiency of the evidence
22 presented by the manufacturer against the applicable
23 regulatory requirements". Certification may be issued
24 if BSI is satisfied that the manufacturer has
25 demonstrated conformity.

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1 The manufacturer is responsible for generating,
2 maintaining and presenting information to demonstrate
3 compliance. The depth of BSI's assessment will depend
4 on a number of factors, including the risk
5 classification of the relevant device. Under both UK
6 and EU legislation, medical devices are classified
7 according to the level of risk they present, from low
8 risk to high risk: I, IIa, IIb, and III. The
9 manufacturer is responsible for applying the
10 classification rules which are determined by the
11 product's intended use.

12 Mr Tunbridge explains that higher risk devices are
13 generally subject to greater levels of individual
14 product assessment, whereas, under some conformity
15 assessment routes, particularly those for lower-risk
16 devices, certification may be based on assessment of the
17 manufacturer's QMS, together with sampling of technical
18 documentation from representative devices within
19 a product family. Therefore, conformity assessment does
20 not necessarily involve a product-by-product assessment
21 of every device covered by a certificate.

22 As to BSI's role in relation to wider patient safety
23 and regulatory oversight, Mr Tunbridge states that the
24 Regulatory Framework assigns primary responsibility for
25 patient safety and emerging risks associated with

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1 applicable regulatory requirements. These activities
2 may include QMS audits, technical documentation reviews,
3 review of post-market surveillance information, and
4 consideration of vigilance-related information submitted
5 by manufacturers. Information obtained through these
6 activities may result in additional assessment
7 activities, requests for information, review of
8 corrective actions, or, where appropriate, regulatory
9 action.

10 While BSI undertakes conformity assessment and
11 certificate activities as an Approved Body the MHRA acts
12 as the Competent Authority and regulator responsible for
13 market surveillance, enforcement and oversight of
14 Approved Bodies. In addition, MHRA exercises powers
15 relating to the investigation of emerging safety
16 concerns and may take direct regulatory action, when
17 necessary, to protect public health. BSI and MHRA,
18 therefore, fulfil complementary but distinct functions
19 within the overall Regulatory Framework.

20 As to the certification of LIO devices, the Oxecam
21 device was certified on 10 September 2018. The scope of
22 the certification covered "the design and manufacture of
23 standalone software used to measure heart rate,
24 respiration rate, and seeing monitoring on specified
25 hardware platforms". On 18 September 2018, BSI was

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1 medical technologies to the manufacturer and the
2 competent authority. Whilst BSI assesses whether
3 a device meets the applicable regulatory requirements,
4 decisions regarding procurement, deployment and the
5 broader clinical impact of a technology are generally
6 matters for healthcare providers and professionals. BSI
7 does not hold primary responsibility for assessing the
8 wider patient care implications of new technologies
9 deployed within healthcare systems, nor for determining
10 how they should be deployed.

11 Manufacturers are generally free to select any
12 appropriately designated Notified Body or Approved Body
13 within the relevant scope of designation when seeking
14 conformity assessment services. Consequently, no single
15 conformity assessment body has visibility of, or
16 responsibility for, all devices placed on the market,
17 nor for all devices deployed within the health service.

18 Similarly, BSI does not hold primary responsibility
19 for identifying and responding to emerging safety issues
20 at a population level once devices have been placed on
21 the market. Within the UK, these functions principally
22 sit with the MHRA.

23 BSI's responsibilities are the post-certification
24 surveillance activities it undertakes, which are
25 intended to verify continued compliance with the

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1 notified of a name change of the device to "Vital
2 Signs".

3 Following the UK's exit from the EU, on
4 5 September 2023, Vital Signs was certified as
5 a class IIa device. On 13 May 2025, the scope of the
6 certification was amended to include the Oxevision Sleep
7 System.

8 On 25 September 2024, Vital Signs and Oxevision
9 Sleep System devices were certified as class IIa devices
10 and the previous Vital Signs certificate was cancelled
11 on 14 April 2025.

12 As Oxevision Sleep System is a software-only medical
13 device, the only component of the overall product that
14 requires conformity assessment is the software element
15 of the product. BSI does not access the software or
16 test it as part of the conformity assessment. Instead,
17 BSI maintains specific processes and procedures for the
18 assessment of a software-only device, based on the
19 current state-of-the-art.

20 At present, this is assessed by reference to
21 BS EN 62304:2006, a standard which sets out a framework
22 of relevant life-cycle processes that are necessary for
23 the safety of the design and maintenance of medical
24 device software.

25 In relation to Vigilance System and safety concerns

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relating to Oxevision devices, Mr Tunbridge explains that the manufacturer is responsible for monitoring its devices after they are placed on the market and ensuring continued compliance with the regulatory requirements. Notified and Approved Bodies support vigilance by reviewing manufacturers' vigilance procedures, auditing how those procedures are implemented, assessing whether vigilance issues affect certification, and liaising with competent authorities where appropriate.

Notified Bodies and Approved Bodies are generally required to review the manufacturers' vigilance data during periodic surveillance audits, which typically take place annually.

Manufacturers must also submit vigilance data directly to BSI.

There were four incident reports for the Vital Signs device during the Inquiry's relevant period.

On 15 February 2023, Oxehealth Limited reported to BSI that the Vital Signs software at one customer site produced erroneous constant pulse rate readings due to environmental power issues. Oxehealth reported that "all power supplies were replaced and the software algorithm optimisation is planned". BSI reviewed and closed the incident with the actions taken by the manufacturer considered appropriate.

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into the pulse rate detection range when a pulse rate reading was not available.

Corrective actions were taken. BSI reviewed and closed the incident with the actions taken by the manufacturer considered appropriate, and no wider adverse trends noted.

In relation to the incidents reported in the 22 March 2022 and 19 December 2022 reports, Oxehealth initiated a Field Safety Corrective Action following which the MHRA issued Field Safety Notices.

Chair, might I suggest that we break now for ten minutes.

(2.48 pm)

(A short break)

(3.01 pm)

Closing statement by MR GRIFFIN KC

MR GRIFFIN: Thank you, Chair.

Chair, the evidence we heard from Mr Reid this morning brings us to the end of the in-person part of this interim recommendations hearing. Over the past two weeks, the Inquiry has made significant further progress in relation to these topics that earlier in the year you directed your team to explore as a matter of priority.

The oral evidence we have heard from witnesses and experts who came here to assist you in Chelmsford has

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On 19 December 2022, Oxehealth reported to BSI that its Vital Signs software produced incorrect pulse rate readings due to "intermittent instability in the output of the infrared illuminators caused by failing power supplies". The issue was proactively detected with no reported customer complaints, or health impacts on patients.

Oxehealth replaced defective updates.

BSI reviewed and closed the incident with the actions taken by the manufacturer considered appropriate, and no wider adverse trends noted.

On 3 November 2022, Oxehealth Limited reported to BSI that its Vital Signs software occasionally produced incorrect pulse rate readings for one specific patient. The occurrence rate was less than 1 in 1 million, and no user has taken a reading affected by the error.

The incident was deemed non-reportable, as the algorithm was performing as designed. BSI reviewed and closed the incident with the actions taken by the manufacturer considered appropriate, and no wider adverse trends noted.

On 22 March 2022, Oxehealth reported to BSI that its Vital Signs software erroneously reported a pulse rate of 50bpm for a patient who was actually tachycardic. The root cause was a very high breathing rate passing

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been supported by extensive written evidence and other relevant documentation that was disclosed to all core participants ahead of this hearing.

As previously outlined, the Inquiry will reconvene virtually next Tuesday, 20 October to hear oral submissions on behalf of the core participants who wish to make them.

That hearing will be live-streamed to the public via the Inquiry's YouTube channel in the usual way. The Inquiry looks forward to receiving constructive submissions on the topics of emergency response and resuscitation, and observations and the use of technology.

Equally, the Inquiry will consider with very great care the written submissions from core participants that will follow. We have firmly in mind, Chair, that we have not yet received those submissions and that you have a great deal to think about before making any decisions as to whether to make any interim recommendations.

May we take this opportunity, please, to pause and reflect on what we have learned during the course of this hearing. Whilst you've heard evidence in relation to two different topics, the evidence is purposefully dovetailed in parts, evidencing clear correlation

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1 between themes, for example the very rapid speed with
2 which a patient can deteriorate in a mental health
3 inpatient setting, underlining the need for a robust and
4 reliable system of observations to be in place.

5 In relation to emergency response and resuscitation,
6 we learned again that an increasing proportion of
7 cardiac arrests are what is known as secondary cardiac
8 arrests. This is very much the position in mental
9 health inpatient settings.

10 Secondary cardiac arrests are cardiac arrests that
11 take place at the end of the physiological process
12 following a trigger event. Those trigger events, often
13 known as special circumstances, incorporate many of the
14 sorts of incidents that take place on a mental health
15 inpatient ward, including, but not limited to, ligature
16 by suspension or self-strangulation, choking and
17 overdose.

18 Deterioration leading to secondary cardiac arrest
19 can also follow prolonged restraint situations and rapid
20 tranquilisation.

21 The Inquiry heard from Professor Jasmeet Soar, an
22 international expert in resuscitation. Professor Soar
23 told us that the best chance of saving a patient in
24 a medical emergency involving a secondary cardiac arrest
25 is to prevent that arrest taking place at all.

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1 EPUT witnesses told the Inquiry that the Trust
2 currently provides all registered staff, nurses in
3 particular, with Immediate Life Support training or ILS.

4 EPUT seeks to ensure that there is least one
5 ILS-trained registered professional available on each
6 ward for each shift.

7 This does not quite meet the Trust's Safer Staffing
8 Model of a 50/50 split between registered staff and
9 non-registered staff. Dr Suresh did not have an answer
10 for what would happen if that ILS-trained member of
11 staff was on a break or detained elsewhere in the middle
12 of the night.

13 We heard that it is for those who organise the
14 rosters to ensure the right numbers and skill mix, when
15 organising staff for each shift, and we were told that
16 those in charge of the rosters now have access to the
17 training records of those who may be allocated to the
18 shift.

19 We also learned, however, that lack of compliance
20 with initial training or refresher training is no bar to
21 engaging in patient-facing roles. Clinical judgement
22 and practical considerations will determine whether
23 a person should be allowed to work. Those will include
24 whether there are sufficient numbers of staff on any
25 given shift.

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1 It is his expert view that the person who arrives
2 first on scene has the best chance of saving a life.
3 And that they should be trained and equipped so they are
4 in the best possible position to do so. Time is of the
5 essence. Every second counts.

6 Dr Suresh, the Executive Chief Medical Officer at
7 EPUT, accepted Professor Soar's view that immediate
8 response is required within seconds, or certainly within
9 at least a minute. Interventions are time-sensitive.
10 With every minute that passes, an intervention becomes
11 less effective.

12 Over the course of its work, this Inquiry has
13 received evidence from bereaved families, from staff,
14 and through its investigation of its illustrative cases,
15 it has learned that there have been occasions at EPUT
16 when the first person arriving at the scene of a serious
17 emergency, the first responder, was a healthcare
18 assistant, or HCA.

19 Dr Suresh conceded that it does happen and agreed
20 that non-registered staff were often the first at the
21 scene.

22 Professor Soar told this Inquiry that in his view,
23 if it is possible that HCAs will be first on scene of
24 emergency, then HCAs must be put in the best possible
25 position to respond to that emergency.

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1 On the first day of this hearing, we heard evidence
2 from Ruth Bradley and Rebecca Lingard from East London
3 NHS Foundation Trust. Ms Lingard's evidence, in which
4 she outlined her own personal experience of
5 a resuscitation incident on an inpatient mental health
6 ward, brought to life for all of us quite how stressful
7 such an event is for those involved, including the staff
8 attending even when that emergency response is
9 successful.

10 This is because, as almost all the witnesses from
11 whom we heard impressed upon us, these sorts of
12 emergencies are relatively uncommon.

13 That's not to say, however, that preparation is any
14 less important. Professor Soar explained that because
15 staff are not training for an event that takes place
16 weekly, but for incidents that do not occur very often,
17 it is important not only for staff to be properly
18 trained, but also for staff to receive regular refresher
19 training, and to undertake regular simulations and
20 drills.

21 Moreover, staff confidence about engaging in an
22 emergency is absolutely key, particularly if there's to
23 be any chance of a successful response.

24 This Inquiry will need to consider very carefully,
25 therefore, the question of how all potential first

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1 responders to an emergency on a mental health inpatient
2 ward can be given that essential confidence, along with
3 the important knowledge and skills required.

4 During this hearing, we heard a range of views as to
5 whether or not ILS training is suitable for
6 non-registered staff such as HCAs. Nicholas Archer, who
7 is Head of Deteriorating Patient Pathways at EPUT, and
8 Dr Suresh, maintained EPUT's position that it is not
9 appropriate to provide ILS training to HCAs.

10 This position is based predominantly on the
11 assertion that some sort of additional anatomical
12 knowledge is required before a non-registered member of
13 staff can undertake ILS training.

14 This is despite evidence that until 2022, HCAs at
15 EPUT were provided with training, firstly in the form of
16 Enhanced Emergency Skills Training and latterly, in the
17 form of Grab Bag Training, which taught the very
18 elements of ILS that EPUT now maintains are unsuitable.

19 It is right to acknowledge, however, that Dr Suresh
20 stated EPUT would be prepared to consider the provision
21 of an additional module to address anatomical knowledge
22 so that HCAs could attend an ILS course, should such
23 a course be proposed by Mr Archer.

24 Professor Soar's experience was that non-clinical
25 staff do very well with ILS training, in fact, and that

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1 the Inquiry's examination of this topic has focused
2 minds.

3 Professor Soar expressed concerns that based on what
4 he has seen so far, the basic level of training proposed
5 by NHS England for most staff, including in mental
6 health settings, is probably set lower than at present
7 in the new proposal. Whilst he wished, quite properly,
8 to reserve any final opinion for when he sees something
9 more tangible down on paper, Professor Soar did observe
10 that the current proposals from NHS England seemed to be
11 directed at equipping staff to deal with primary cardiac
12 arrests as opposed to secondary cardiac arrests.

13 In light of all the evidence we have heard, Chair,
14 any such proposals may misunderstand the risks inherent
15 in mental health inpatient settings.

16 In terms of the emergency response and resuscitation
17 provision at EPUT, the actual service structure at EPUT,
18 as contemplated by RCUK Quality Standards for Mental
19 Health Inpatient Care, remains unclear.

20 Whilst seeking to explore the system for governance
21 at EPUT the Inquiry heard of the apparent involvement of
22 four Board members with engagement including a large
23 number of EPUT's governance groups and committees into
24 double figures, and lines of reporting that Dr Suresh
25 himself agreed could be reviewed to determine whether

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1 the pass rate is high. By way of illustration, as to
2 the contents of that training, Professor Soar explained
3 that he had provided much of the information from the
4 course, including detail of the ABCDE approach and the
5 all-important airway management to those of us in this
6 room during the hearing.

7 He described EPUT's practice of providing tools
8 based on ABCDE, such as EPUT's aide memoire relating to
9 assessing a critically unwell patient, and its
10 non-contact observation tool to non-registered staff
11 without giving them the requisite training, as something
12 of a "spray and pray" approach.

13 Asked to comment on Dr Adamson's position on behalf
14 of NHS England, that providing ILS training to HCAs,
15 thereby putting them in a position to respond
16 immediately to an emergency, would do more harm than
17 good, Professor Soar simply pointed out the inevitable
18 consequence and ultimate harm that would result from no
19 response at all.

20 It's right to say that NHS England's proposed
21 changes to mandatory training still appear to be a work
22 in progress, despite Mr Simon's initial evidence
23 indicating that he expected ministerial approval before
24 the end of December. It would appear from NHS England's
25 very recent increased engagement with the Inquiry that

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1 they might be made clearer, and more straightforward.

2 Dr Suresh told us that he is the Member of the Board
3 assigned to the resuscitation service but he was not
4 able to give us a direct answer as to whether there are
5 defined resources ringfenced for the resuscitation
6 service itself, as required by the RCUK Standards.

7 What also emerged from the evidence we heard is the
8 fact that EPUT do not appear to have been monitoring or
9 auditing their resuscitation service and resuscitation
10 incidents appropriately. This is despite the very clear
11 indication in the RCUK Quality Standards that they
12 should do so.

13 The Quality Standards requirements to monitor and to
14 audit are reflected to a certain extent in the current
15 EPUT policy CLP14. This document is a consolidation of
16 what were, previously, separate policy and procedure
17 documents.

18 We identified during the course of this hearing that
19 there is a requirement for three-yearly audits within
20 the policy. Dr Suresh told us that this did not mean
21 audits per se, but a more general review of the service
22 provision.

23 In any event, no three-yearly review document is
24 available from EPUT, despite the requirement being
25 included in each iteration of the policy since the

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merger in 2017.

We also learned that there have been no yearly reports, despite that also being a requirement set out in EPUT's CPR Policy. That, too, has been a requirement since the merger in 2017. Instead, Dr Suresh and Nicholas Archer told us that EPUT produce quarterly reports which provide the relevant information to EPUT's Quality Committee, having been given to that Committee from the Quality of Care Meeting. Those quarterly reports had not been provided to the Inquiry prior to last week.

So we asked EPUT for them.

The quarterly reports have since been supplied and have been disclosed to core participants today. Core participants will be able to see for themselves what is and is not included in those documents, and will be able to refer to them in submissions should they wish to.

We did hear, however, that EPUT are now beginning to audit if and when simulation training and drills are taking place, and to keep local records of which staff did not attend. The Inquiry learned from all relevant witnesses, without exception, that scenario training is extremely important for teaching staff core skills in relation to emergency response and resuscitation, for keeping those skills up to date, for identifying

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Ms Sheridan stated, she was looking for an alternative solution. We note that resolution was achieved shortly after the Inquiry focused its attention on this topic.

Chair, the more evidence we heard about the provision of emergency response and resuscitation at EPUT, the longer the list of Mr Archer's responsibilities became.

It was also apparent that, owing to possible deficiencies within EPUT's reporting systems and Datix, EPUT rely heavily on Mr Archer's institutional knowledge. It remains to be determined the extent to which this impacts EPUT's ability to properly identify incidents, to reflect upon them, and to draw learning which can be disseminated to others promptly.

We heard, for example, that the investigation and subsequent recommendations following the death of Jason Standing, who died in January 2022, took nearly two years to complete. In the meantime, other patients died in circumstances which appear to indicate the same systemic issues.

Indeed, in a joint witness statement submitted by Ms Sheridan with Dr Suresh on behalf of EPUT for this hearing, and in her oral evidence, Ms Sheridan appeared reluctant to accept that the circumstances relating to emergency response and resuscitation in some of the

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deficiencies and points for learning, and significantly, for providing the vital confidence that members of staff need if faced with an emergency situation.

Dr Adamson from NHS England referred to such training as "paramount". EPUT do not appear, for some time, to have had a clear understanding of whether, or the extent to which, scenario training was taking place within the Trust.

This led to a period of possibly 17 months on Willow Ward without simulations or drills taking place at all.

We heard a summary from a second statement provided to you from Louise Borton, a Matron at EPUT, that following various issues emerging from drills she took part in during June and August this year, a decision was made to increase their frequency at Basildon mental health ward to weekly.

Closer oversight should now be achieved, EPUT tell us, by the addition to their audits of a specific question relating to emergency simulations. This evidence gave rise to questions of why that action, which was identified following a SWARM huddle in June 2025, had only been completed in August 2026, some 14 months after the issue had first been identified.

The delay was apparently created by the failure to convene a meeting that was quorate, or because, as

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Inquiry's illustrative cases should be grouped. This is despite what are evidently similar issues. Again, it remains to be determined whether this approach reflects a continued reluctance on EPUT's part to see the bigger picture, and whether this in itself creates a barrier to learning.

As you are aware, Chair, EPUT have been asked repeatedly about the methods by which resuscitation events are reported and reviewed by the Trust. We learned that all incidents involving CPR should be recorded on Datix, including a completed Resuscitation Event Form. This does not appear to be failsafe for a number of reasons.

Mr Archer explained that the Datix entry system is not straightforward. Its reliability is largely dependent on the method by which a user inputs relevant information, including which dropdowns they use.

With regards resuscitation events, Mr Archer explained that incidents were often miscategorised when incorrect dropdowns were selected. Mr Archer told us that he hoped that he was aware of all resuscitation events, if not by Datix, by other means, such as being copied into emails reaching out to staff.

There is, on any view, an issue with the way Datix is being used and the data it generates is used by EPUT,

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1 which the Inquiry intends to look at in more detail.

2 Whilst we heard evidence from a number of EPUT
3 witnesses, who insisted that EPUT can retrieve various
4 information with the support of its Datix management
5 team, EPUT's complete and abject failure to respond to
6 what Dr Suresh agreed should have been a very
7 straightforward request for information relating to all
8 resuscitation events from 2017, post-merger,
9 demonstrates clearly that the system is not doing what
10 is intended for whatever reason.

11 The information provided to the Inquiry by way of
12 spreadsheet was, for reasons Dr Suresh accepted, but is
13 still not able to explain, completely unreliable.

14 Similar issues may have been revealed by evidence
15 the Inquiry heard yesterday about the reliability of
16 Datix reporting in the context of observations and the
17 use of technology. In a witness statement provided to
18 the Inquiry, EPUT stated that there had been over 1,400
19 incidents recorded by Datix in which Oxevision was said
20 to have played a role in bringing the incident to the
21 attention of staff.

22 That was recorded on 1,453 occasions via a relevant
23 tick box.

24 But the number was seen to reduce by over half when
25 the question was whether Oxevision was described in the

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1 responsibility rested with the individual Trusts and the
2 CQC.

3 Mr Harry provided evidence in relation to NHS
4 England's awareness of concerns relating to the use of
5 the Oxevision system in May 2021 and June 2022. This
6 gave rise to NHS England's formal letter to Trusts in
7 September 2023. Mr Harry told this Inquiry that he was
8 not aware whether Trusts reviewed their practices
9 relating to vision-based patient monitoring systems, or
10 VBPMS, following receipt of that letter.

11 Mr Harry also told us of existing concerns in
12 relation to Trusts' use of Oxevision, including current
13 concerns that ten Trusts using Oxevision appear not to
14 be using the system in line with NHS England's published
15 guidance, Principles for Using Digital Technologies in
16 Mental Health Inpatient Treatment and Care.

17 We heard this morning from Dr Robert Reid, Deputy
18 Director for Innovative Devices at the Medicines and
19 Healthcare Products Regulatory Agency, or MHRA, who
20 described the MHRA's jurisdiction in respect of medical
21 devices, and spoke about its oversight of new
22 technologies and its assessment of Oxevision.

23 Dr Reid expanded upon the remit of the MHRA in
24 regulating medical devices and ensuring their safety,
25 quality, and effectiveness, as well as how its role sits

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1 written narrative of the Datix reports. Zephon Trent's
2 evidence was that such data tells us something about the
3 use of Oxevision, but that he was unable to say, on the
4 basis of those Datix reports, whether the system was of
5 value or not.

6 I turn then, Chair, to what we have learned this
7 week as the Inquiry continued its examination of issues
8 relating to observations and the use of technology. We
9 heard evidence from Gareth Harry of NHS England on
10 Monday, 5 October, the first day of the hearing.

11 Mr Harry is NHS England's National Delivery Director
12 for Mental Health, Learning Disability and Autism and
13 his evidence covered NHS England's role in regulating
14 the use of technology in mental health services.

15 Mr Harry told the Inquiry that the responsibility
16 for the safe use of digital technology products rests
17 with the individual Trusts, and that NHS England
18 supports the safe use of technology through its
19 framework standards and policies.

20 Mr Harry did acknowledge that NHS England has wider
21 responsibility for the overall delivery of services, and
22 that it may, where systemic patient safety issues have
23 been reported, take action at a national level.

24 However, Mr Harry told us that NHS England does not
25 proactively monitor these issues, emphasising this

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1 alongside that of Notified and Approved Bodies. He
2 explained that the MHRA's role in this respect depends
3 on the risk classification of a product, and that its
4 principal functions include post-market vigilance,
5 whereby patient safety issues relating to devices on the
6 market are monitored and responded to.

7 Dr Reid provided evidence that the MHRA's awareness
8 of patient safety issues regarding Oxevision began in
9 spring 2021. This was when NHS England shared with the
10 organisation analysis of patient safety incidents
11 involving the technology. This led the MHRA to
12 undertake regulatory engagement with Oxehealth,
13 specifically focusing on the accuracy of claims being
14 made by the company about the clinical benefits of the
15 device in reducing self-harm.

16 There was further engagement relating to marketing
17 and other matters.

18 Dr Reid spoke of the benefits of introducing
19 a whole-system approach to patient safety and medical
20 device regulation, which would incorporate multiple
21 Government agencies as well as patients, family members
22 and others as key stakeholders.

23 The evidence of Mr Harry, Dr Reid, and the summary
24 of the evidence provided by the National Institute for
25 Health and Care Excellence, the Department of Health and

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1 Social Care, the CQC, and the British Standards
2 Institution, which has been read this afternoon,
3 highlight the complex regulatory oversight relating to
4 the deployment, implementation and use of technology in
5 mental health services.

6 We heard on Monday from Dr Francesca Denman,
7 a Consultant Psychiatrist with significant experience of
8 governance within NHS Trusts.

9 Dr Denman provided expert evidence to the Inquiry
10 relating to the role, function and efficacy of
11 observations, and the role of VBPMS in inpatient mental
12 health settings. Dr Denman also considered, from
13 a Chief Medical Officer's perspective, EPUT's adoption
14 and implementation of Oxevision.

15 Dr Denman provided her view on the development of
16 risk assessments within the period of the Inquiry's
17 investigation, in what she described as a move from risk
18 assessment to safety planning. She noted that the
19 attempts to stratify and formulate risk through
20 assessment were misleading, and failed to accurately
21 predict acts of self-harm and suicide.

22 She praised the unimpeachably sensible shift towards
23 the holistic and dynamic assessment of risk, which has
24 formally been in place since 2022.

25 Chair, this contextual understanding of the

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1 therapeutic engagement if such systems were to replace
2 in-person observations.

3 Dr Denman concluded that sole reliance on VBPMS
4 would therefore be inconsistent with responsible
5 practice in almost all circumstances. However,
6 Dr Denman recognised that there may be instances where
7 VBPMS provide benefits to patients, but emphasised the
8 need to recognise the use of Oxevision as the clinical
9 intervention for the individual patient, with its
10 appropriateness considered through an individualised
11 patient-centred approach.

12 Dr Denman identified the potential utility of VBPMS
13 in specific circumstances, including seclusion and
14 health-based places of safety where there may be risks
15 in entering a patient's bedroom. However, these
16 circumstances were identified as relatively uncommon and
17 Dr Denman stressed that reliance on remote monitoring
18 should not continue indefinitely, stating "We should be
19 working to repair that situation as fast as possible."

20 Dr Denman also provided her expert opinion regarding
21 the findings this year of the Parliamentary and Health
22 Service Ombudsman, the PHSO, relating to deficiencies in
23 EPUT's consent practice in respect of Oxevision.

24 Dr Denman's clear view is that observations,
25 including those performed using technology, constitute

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1 different approaches to risk management will assist you
2 in your assessment of issues across the full scope of
3 the relevant period.

4 Dr Denman identified an urgent need for further
5 research and academic analysis in relation to the role
6 of observations practice in general, in order to
7 consider what best practice looks like. Further, she
8 identified the enduring shortage of guidance
9 specifically for psychiatrists on observations, and
10 proposed this may be an area where further guidance
11 would assist clinicians.

12 Dr Denman's evidence emphasised the evidence
13 provided by Professor Soar as to the value and
14 importance of NEWS2 observations in monitoring
15 a patient's physical health. Dr Denman told you that
16 any measure that is not the NEWS2, for example just
17 pulse and respiration, must be treated with great
18 caution, and the NEWS2 should be preferred if at all
19 possible.

20 Dr Denman also underlined the important distinction
21 between different measurements to monitor a patient's
22 physical health and mental health observations.

23 With regard to the use of VBPMS, Dr Denman accepted
24 that the technology may provide useful information, but
25 warned of alarm fatigue and the risk of reduced

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1 a part of a patient's care to which the patient is
2 required to provide consent where they are able to
3 do so.

4 Chair, you, once again, invited Laura Cozens to come
5 and give evidence to the Inquiry on behalf of LIO.

6 During the course of her evidence, Ms Cozens
7 accepted the limits of the evidence base underpinning
8 the clinical utility of Oxevision, noting that there is
9 need for further research.

10 Ms Cozens' view was that this should run
11 concurrently with the deployment of Oxevision within
12 mental health inpatient units, so as not to miss out on
13 the potential benefits to patients. Ms Cozens accepted
14 that this represented a change in LIO's position,
15 particularly when contrasted to this time last year, and
16 which reflected the evidence and opinions provided by
17 the Inquiry's expert health statisticians in July.

18 Ms Cozens emphasised that the real-world experience
19 of clinicians who find Oxevision useful, while not the
20 same as a randomised control trial, was important, and
21 it is appropriate to have regard to it.

22 Ms Cozens maintained that the ability to conduct
23 remote observations at night was a benefit, so as not to
24 disturb sleeping patients. Ms Cozens also acknowledged
25 that the ability to conduct remote observations was not

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1 a replacement for in-person engagement by staff, and
2 that technology should be used to assist staff in
3 conducting observations. This should only occur after
4 discussion with the patient.

5 With regard to the benefits of Oxevision, Ms Cozens
6 developed her previous evidence to the Inquiry regarding
7 the specific settings in which LIO considered the
8 ability to take remote observations useful. These
9 include seclusion units, older adult wards, and
10 following rapid tranquilisation.

11 There are further savings possible, mainly through
12 the prevention of serious incidents, saving staff time
13 and cost in responding to serious incidents.

14 Ms Cozens stated that beyond this, it is not
15 envisioned by LIO that Oxevision would be used to reduce
16 the time actually spent by staff on observations;
17 further, that the system should not be used as
18 a replacement for in-person observations again.

19 With regard to NEWS2, the importance of which I've
20 already referenced when outlining Dr Denman's evidence,
21 Ms Cozens confirmed that Oxevision is able to take two
22 vital signs readings from patients remotely. These are
23 breath rate and pulse. It does not fulfil all the
24 functionalities of a full NEWS2 reading. Ms Cozens'
25 view was that information on breathing rates and pulse

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1 staff members were required to complete the OxeAcademy
2 training course with a 100% pass rate. And there were
3 competency checklists for new staff which were used at
4 ward level.

5 Following the initial training, Mr Trimble and the
6 Quality Matron undertook one further round of training
7 through refresher sessions based on staff feedback and
8 the requirements of the Standard Operating Procedure.

9 Mr Trimble told us that he was aware of instances
10 when Oxevision had generated inaccurate information.
11 Mr Trimble explained that when this happens, it may be
12 necessary to refresh the software. This was an issue
13 that had been raised recurrently as a point of feedback
14 from staff.

15 Mr Trimble was firmly of the view, however, that the
16 Oxevision system has saved lives. This view was based
17 on his interpretation of Datix reports and staff
18 feedback. Mr Trimble further explained that user
19 authentication had been introduced in The Lakes in
20 May 2026 and will be rolled out across the Trust
21 following clinical approval. This will provide an
22 important safeguard and accountability mechanism.

23 Mr Trimble also expanded on his view that clearer
24 national guidance on consent to the use of VBPMs should
25 be issued. Mr Trimble understands, through wider

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1 readings is capable of being of some assistance as well
2 as providing reassurance to staff.

3 Ms Cozens emphasised that she would expect Oxevision
4 to be used only with the consent of patients and that
5 this would be for the relevant organisation to
6 communicate with the patient around its use. This would
7 include being told how the system works.

8 As with our resuscitation topic, the Inquiry went on
9 to consider how Oxevision was and is utilised at EPUT,
10 alongside EPUT's observation practices more generally.
11 The Inquiry heard evidence on Tuesday afternoon from
12 Derrick Trimble, a project manager at EPUT involved in
13 the deployment and ongoing use of Oxevision at the
14 Trust.

15 Mr Trimble gave evidence about his role in relation
16 to the rollout of Oxevision on EPUT wards. This
17 included the part he had played in drafting the
18 technical elements of Standard Operating Procedures.
19 Mr Trimble said his role was limited to project
20 management of the introduction of Oxevision. Mr Trimble
21 is not a clinician, and he told you that he was not
22 a decision maker, in relation to the decision of the
23 Trust to procure the technology.

24 As to how staff are trained and helped to gain an
25 understanding of the system, Mr Trimble explained that

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1 conversations in the sector, that there is significant
2 variation between the approaches adopted by different
3 Trusts. Mr Trimble considered that having greater
4 structure and guidance would be helpful.

5 Yesterday, Chair, the Inquiry heard evidence from
6 Dr Kallur Suresh again, and Mr Zephan Trent, who is
7 Executive Chief Digital and Information Officer at EPUT.

8 Mr Trent's and Dr Suresh's evidence touched upon
9 broad aspects of observation practice at EPUT, in
10 particular the role of the Oxevision system. Their
11 evidence covered not only historic use of the system at
12 EPUT, but recent changes in practice, mandated by
13 revisions to the Standard Operating Procedure or SOP in
14 June of this year.

15 The Inquiry heard evidence regarding the need to
16 obtain patients' consent for the use of Oxevision. EPUT
17 now accepts that patients should have been required to
18 provide explicit consent on an opt-in basis from the
19 first time the system was deployed. Whilst that form of
20 consent is required by EPUT's most recent SOP, it was
21 accepted that there had been internal inconsistencies in
22 previous versions of the SOP, and that informed consent
23 had not always been obtained.

24 That was a view echoed by the PHSO, whose findings
25 have been accepted by EPUT.

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1 In terms of potential changes in the future,
2 Dr Suresh supported Dr Denman's view that there may be
3 value in having an identified Board member with
4 responsibility for consent. Zephani Trent further told
5 you that he found the Inquiry's consideration of
6 technology and patients' consent to be timely, given the
7 current focus of the healthcare system on the role of
8 technology.

9 Another theme which arose from yesterday's evidence
10 was the limited support and guidance available to a
11 Trust seeking to deploy a new technology. We heard from
12 Mr Trent of an expectation that NHS Trusts will look at
13 the opportunities available with regards to technology,
14 for example when implementing the NHS 10-Year Plan.

15 Notwithstanding that expectation, the evidence of
16 both Dr Suresh and Mr Trent was that the practical
17 support provided to Trusts when evaluating, piloting and
18 deploying new technologies is, at present, limited.

19 Dr Suresh gave his opinion that there should be
20 evaluation of emerging technologies at a level above
21 that of individual Trusts. Mr Trent told the Inquiry
22 that once new technologies are rolled out, there were
23 opportunities for the NHS to learn of issues and improve
24 practice more systematically and draw on multiple
25 providers' experience.

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1 The system may also confer benefits at nighttime by
2 virtue of allowing for reduced disturbance of a sleeping
3 patient. Their evidence as to the system's role and
4 proper purpose echoed many of the features of
5 Dr Denman's evidence.

6 Lastly, I want to say something about the evidence
7 heard concerning the rollout of Oxevision at EPUT.
8 Mr Trent's evidence was that the deployment of Oxevision
9 was done with a clear strategic intent to improve
10 patient safety. However, Mr Trent accepted Dr Denman's
11 expert opinion that the specific benefits by which that
12 ambition would be realised had not been identified.
13 Mr Trent went on to accept that a fuller analysis of the
14 potential risks associated with the use of Oxevision
15 should have been undertaken by the Trust at an earlier
16 stage; further, that there was a lack of lived
17 experience involvement in consideration and
18 implementation of the system.

19 Mr Trent gave evidence of his own experience of the
20 value of constructive challenge from those with lived
21 experience, and he conceded that it should have been
22 sought sooner.

23 The EPUT Board recognises that the Trust should have
24 done better in the past.

25 Chair, as I stated at the outset of this closing

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1 Turning to the functions of the Oxevision system,
2 Dr Suresh's evidence was that the Oxevision Vital Signs
3 function conferred limited benefits. When asked whether
4 there was any reason for the frequent checks of heart
5 rate and respiratory rate using that feature, which had
6 been seen to have occurred at EPUT, he responded "All
7 other things being equal, probably not."

8 His evidence was that, at its most basic, the Vital
9 Signs device can inform a clinician whether a patient is
10 alive, and may alert them to carry out a more rigorous
11 assessment if either the pulse or respiratory rate are
12 found to be elevated.

13 Mr Trent's evidence was similar. He accepted that
14 it was difficult to conclude that the Oxevision system
15 was having an impact on ligature incidents from EPUT's
16 own analysis of its self-harm data. He further accepted
17 that there were deficiencies in the Trust's approach to
18 that data analysis, and explained the improvements made
19 by EPUT in respect of its data interpretation since.
20 Both witnesses provided evidence as to the benefits of
21 the system, including its potential use in settings,
22 where the risk to both patients and staff is higher,
23 such as health-based places of safety and seclusion
24 suites, as well as older adult wards where, for
25 instance, there may be an elevated risk of falls.

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1 statement, the Inquiry looks forward to receiving
2 submissions from the core participants on these two
3 important issues. Thereafter, you will consider
4 everything you have read and heard to determine whether
5 there are ongoing risks to the safety of current
6 patients, and whether interim recommendations are
7 required.

8 The Inquiry will then move on to examine further
9 substantive themes in 2027. We will begin in January by
10 considering issues relating to assessments
11 pre-admission, safeguarding, and sexual safety.

12 The Inquiry hopes to release its first tranche of
13 disclosure in relation to those thematic areas in the
14 near future.

15 That announcement having been made, may I once again
16 take this opportunity to thank all of those who have
17 engaged in this hearing.

18 Chair.

19 **THE CHAIR:** Thank you, Mr Griffin.

20 **Closing remarks by THE CHAIR**

21 **THE CHAIR:** So we've now come to the end of the October
22 hearing, and I am grateful to everyone who has given
23 evidence over the past two weeks, and to all those who
24 have helped the Inquiry examine the important and
25 difficult issues we heard about last week and this.

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1 I would particularly like to thank the experts for
2 their participation and their time. Their evidence has
3 helped the Inquiry examine specialist and technical
4 issues in relation to emergency response and
5 resuscitation, and in relation to observations and the
6 use of technology in detail.
7 Although we've not heard directly from bereaved
8 families during this hearing, they remain at the heart
9 of this Inquiry's work. I recognise that hearing some
10 of the evidence in great detail may have been
11 distressing, particularly for those with personal
12 experience of the issues under investigation and
13 I remain very grateful for their efforts in engaging
14 with the Inquiry.
15 As I've said at the start of the hearing, I will
16 consider all the evidence gathered by the Inquiry in
17 relation to the topics we've considered at these
18 hearings with care, objectivity, and complete
19 independence. This includes the evidence heard during
20 this hearing, as well as the submissions to be made at
21 the virtual hearing on Tuesday, and the written
22 submissions that follow at the end of this month.
23 I am grateful to core participants and their legal
24 representatives for their assistance to the Inquiry.
25 My team and I will continue to review all evidence

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1 carefully and in its full form before I reach any
2 conclusions about the appropriate next steps.
3 It only now remains for me to thank everyone at the
4 Chelmsford Civic Centre, who have looked after us during
5 the course of this hearing, that includes the security
6 team, the management, and hospitality team here, and the
7 technical team, RTS. I also want to thank our
8 long-suffering stenographer Louise Pepper, and our
9 excellent evidence handler, Sarah Killingback.
10 Above all, as ever, my thanks are to my Secretariat
11 Team, my solicitor team, and my counsel team. I'm very
12 grateful to you all. Thank you very much indeed.
13 **MR GRIFFIN:** Chair.
14 **(3.56 pm)**
15 **(The hearing concluded)**
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