

Thursday, 23 July 2026

(10.00 am)

(Proceedings delayed)

(10.08 am)

THE CHAIR: Mr Hayes.

DR HAYES: Good morning, Chair.

This morning, the Inquiry will hear from Professor Christl Donnelly and Dr Maria Christodoulou, expert statisticians from the University of Oxford. They will be giving evidence as to the strength of the evidence base underlying use of the Oxevision system.

This afternoon the Inquiry will hear closing submissions from Rebecca Harris KC summarising the evidence heard in these July hearings.

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 the full session. As with other days, anyone in the Inquiry room should feel free to leave at any time.

May I take this opportunity to remind those engaging with the Inquiry that emotional support is available for all who require it. Present here again today are emotional support staff from Hestia, an experienced provider of emotional support at these types of hearing. They are currently in this room and can be identified by

1 their orange-coloured scarves.

2 There is a private room downstairs where anyone who
3 needs emotional support can talk to the Hestia staff.

4 If you prefer, you can speak to a member of the Inquiry
5 Team, who are wearing purple lanyards, and they will put
6 you in touch with them.

7 For those following the hearing online, information
8 about the emotional support that is available can be
9 found on the Lampard Inquiry website
10 @lampardinquiry.org.uk. The "Support" tab is near the
11 top right-hand corner. We want everybody engaging with
12 the Inquiry in whatever way to feel safe and supported.

13 Chair, we are ready to hear from today's witnesses
14 if they could please take the affirmation.

15 **PROFESSOR CHRISTL DONNELLY (affirmed)**

16 **DR MARIA CHRISTODOULOU (affirmed)**

17 **Questioned by DR HAYES**

18 DR HAYES: Taking it in turns, can you please provide your
19 qualifications.

20 PROFESSOR DONNELLY: My background is that I have a BA in
21 mathematics from Oberlin College, an MSC in
22 biostatistics from Harvard University and a DSC --
23 that's a Doctor of Science degree -- from Harvard
24 University, again in biostatistics.

25 DR CHRISTODOULOU: I have a BSC in mathematics and

1 statistics from Imperial College London, a BSC in
2 biological sciences from Imperial College London, an MSC
3 in Taxonomy and Evolution from the University of Reading
4 a PHD in biological sciences from the University of
5 Reading.

6 Q. Dr Christodoulou, is it also correct that you are
7 a chartered statistician of the Royal Statistical
8 Society?

9 DR CHRISTODOULOU: I am a Chartered Statistician, yes.

10 Q. Turning back to you, Professor Donnelly, is it correct
11 that you are a Professor of Applied Statistics in the
12 Department of Statistics at the University of Oxford?

13 PROFESSOR DONNELLY: Yes.

14 Q. Are you also a Professorial Fellow at St Peter's College
15 at the University of Oxford?

16 PROFESSOR DONNELLY: Yes, I am.

17 Q. Do you hold the following fellowships: in 2016 (sic) you
18 were elected as Inaugural Fellow for the Academy in
19 Mathematical Sciences?

20 PROFESSOR DONNELLY: That's in 2026.

21 Q. 2026. And in 2016, were you elected as a fellow of the
22 Royal Society?

23 PROFESSOR DONNELLY: Yes.

24 Q. In 2015 were you elected as a Fellow of the Academy of
25 Medical Sciences?

1 PROFESSOR DONNELLY: Yes.

2 Q. And were you awarded a CBE for services to epidemiology
3 and the control of infectious disease in 2018?

4 PROFESSOR DONNELLY: Yes.

5 Q. Dr Christodoulou, are you a senior statistical
6 consultant at Oxford University Statistical Consulting?

7 DR CHRISTODOULOU: Yes, I am.

8 Q. And prior to that, were you a post-doctoral researcher
9 in biostatistics at the University of Oxford?

10 DR CHRISTODOULOU: Yes, I was.

11 Q. Is it correct to you that say you both have expertise in
12 statistics including those statistics relevant to
13 scientific and epidemiological studies?

14 DR CHRISTODOULOU: That is correct.

15 PROFESSOR DONNELLY: Yes.

16 Q. Do you have expertise in experimental design and data
17 handling?

18 DR CHRISTODOULOU: Yes.

19 PROFESSOR DONNELLY: Yes.

20 Q. So do you feel qualified to comment on the general
21 principles underlying the design and analysis of
22 scientific studies?

23 DR CHRISTODOULOU: Yes.

24 PROFESSOR DONNELLY: Yes.

25 Q. Is it correct that together, you provided an expert

1 report to the Inquiry entitled "Report on Oxevision
2 evidential base and case study methodologies"?
3 PROFESSOR DONNELLY: Yes.
4 DR CHRISTODOULOU: Yes.
5 Q. Is that report dated 24th June 2026?
6 DR CHRISTODOULOU: It is.
7 PROFESSOR DONNELLY: It is.
8 Q. Was that report produced after you were instructed by
9 the Inquiry to critically appraise the scientific
10 evidence base underlying the use of Oxevision in mental
11 health settings?
12 DR CHRISTODOULOU: Yes, it was.
13 PROFESSOR DONNELLY: Yes.
14 Q. Were you provided by the Inquiry with 50 research papers
15 which described the use of the Oxevision system for that
16 purpose?
17 DR CHRISTODOULOU: It was 45. 45 papers (overspeaking) --
18 Q. 45?
19 DR CHRISTODOULOU: Yes.
20 PROFESSOR DONNELLY: Yes.
21 Q. I'm grateful.
22 Do you have a copy of the report in front of you?
23 DR CHRISTODOULOU: Yes, we do.
24 PROFESSOR DONNELLY: Yes.
25 Q. Is that report 46 pages long?

1 PROFESSOR DONNELLY: Yes.

2 DR CHRISTODOULOU: Yes, it is.

3 Q. Can you turn to page 35. On page 35 do we see both your
4 signatures?

5 PROFESSOR DONNELLY: Yes.

6 DR CHRISTODOULOU: Yes.

7 Q. Can you confirm that you both contributed to that report
8 and that it is true and accurate to the best of your
9 knowledge and belief?

10 PROFESSOR DONNELLY: Yes, it is.

11 DR CHRISTODOULOU: Yes.

12 Q. When drafting your report, did you understand that your
13 duty was to assist the Chair to the Inquiry on matters
14 properly falling within your expertise?

15 DR CHRISTODOULOU: Yes.

16 PROFESSOR DONNELLY: Yes, we did.

17 Q. I'm going to ask you questions about parts of that
18 report. Please both of you respond as you see
19 appropriate.

20 DR CHRISTODOULOU: Thank you.

21 Q. I want to start by discussing in fairly basic terms some
22 general concepts relating to scientific studies so that
23 we can better understand the detail of your report. I'm
24 going to ask you what the terms "hypothesis",
25 "comparison groups," "confounding" and "peer review"

1 mean in practice. After that, I'm going to ask you some
2 questions about different types of study design, and in
3 particular before and after studies and randomised
4 control trials.

5 Starting with hypotheses, then. Is it correct to
6 say that, at a very simple level, a scientific study
7 will start with a hypothesis that it intends to test?

8 DR CHRISTODOULOU: Yes. A hypothesis, and it's part of
9 hypothesis testing, would begin with the default
10 scientific theory, often called the null hypothesis and
11 that's generally representing the absence of an effect
12 or a finding of interest.

13 Q. So can we, to give that some context, if we were looking
14 at the sorts of papers that we've been looking at in
15 your report, the null hypothesis would be that the use
16 of the Oxevision system has no impact on, say, self-harm
17 rates?

18 DR CHRISTODOULOU: There would be no difference in the two
19 groups, if one of them is a ward with Oxevision and the
20 other one without Oxevision, we would be finding no
21 difference between them. That's the null hypothesis.

22 Q. And the alternative hypothesis would be that there is
23 a difference between those two wards?

24 DR CHRISTODOULOU: Indeed.

25 Q. In general terms, then, how do researchers go about

1 testing a hypothesis?

2 PROFESSOR DONNELLY: So collecting evidence. So it depends
3 on the type of study. So there could be a primary study
4 in which data are collected, and so then they have to go
5 about setting up the methods and the methods will be
6 deciding the population of interest, the methods that
7 they will use for measurement of that data, and other
8 things about the design, the detail of how that will be,
9 it may be time period, it may be how many individuals
10 are studied or how many wards. They will then collect
11 data and analyse that data.

12 There can be other sorts of studies that are looking
13 at secondary analysis of other people's data. That may
14 be one dataset that's already been collected and you are
15 re-analysing it, perhaps through a different lens. Or
16 it could be a meta analysis. That is where you look at
17 several studies that have tried to estimate the same
18 sort of parameter, and then look to see how consistent
19 they were and whether or not those come together to have
20 a consistent story.

21 Q. So at the most basic level, you just try to collect data
22 to see if you can establish if there's a link or not
23 a link between two or between an exposure and the
24 results that you observe?

25 PROFESSOR DONNELLY: Yes, and so then with that data, we

1 would do typically a statistical test, and that would be
2 a test of the null hypothesis. So the null is that
3 there is no effect and we'd be looking to the data to
4 see if there's evidence to convince us otherwise.

5 Q. When you are looking -- or one thing we will hear about
6 over the course of your evidence, is comparison groups.
7 How do comparison groups help in testing a hypothesis?

8 DR CHRISTODOULOU: Comparison groups help us understand what
9 are general characteristics of the population we're
10 observing and what are characteristics that may be
11 associated with the intervention that we have
12 implemented. They give us a benchmark so we can look
13 against and say: this is the expected behaviour and this
14 may be a divergence from that behaviour.

15 Q. And the divergence -- you'd be looking for the
16 divergence in the other group --

17 DR CHRISTODOULOU: In the other group --

18 Q. -- to see if there was an impact of whatever that group
19 was exposed to?

20 DR CHRISTODOULOU: Exactly.

21 Q. Do we also see comparison groups being referred to in
22 both your report and in the medical literature as
23 control groups?

24 DR CHRISTODOULOU: Yes, we do.

25 Q. Another phenomenon that we see referenced in your report

1 is something called confounding, can you help us with
2 that? What is confounding?

3 PROFESSOR DONNELLY: So confounding would be if you have two
4 variables that are both changing at the same time. So
5 for example, if you had an intervention you might have
6 one ward where you say: okay, I'm going to bring an
7 intervention here, and the other ward I won't, and we'll
8 compare those. If, at the same time, one ward had
9 a staffing issue and the other one didn't, then those
10 two things would be confounded. So if we see systematic
11 differences we don't know if it is because of our
12 intervention that we are looking to test or if we're
13 seeing in part or fully the effect of this other issue,
14 which is perhaps a staffing challenge.

15 That is the reason why you'd like to have multiple
16 replicates so you wouldn't just like to have one ward
17 compared with another; you'd like to have several wards
18 in each group, and you would like to have them be
19 representative of whatever population you would like to
20 extrapolate the results to.

21 Q. In principle, therefore, is it necessary for studies to
22 try and control for confounding variables?

23 DR CHRISTODOULOU: It is a very important part of
24 experimental design, to try and understand what are
25 potential confounders and try to design in such a way

1 that even for confounders we do not anticipate to at
2 least have a buffer against them.

3 Q. Can I ask you about the process of peer review in
4 scientific literature. What is meant by peer review?

5 DR CHRISTODOULOU: Peer review is the process that is used
6 in scientific publications to pass a certain level of
7 quality control before something becomes available for
8 other researchers. So when somebody completes a study,
9 the group writes it up, it is submitted to a journal,
10 and the journal passes from an editorial desk, who
11 assesses whether this is appropriate for the journal
12 scope and for the level that the journal is trying to
13 reach, and then that goes through to peer review. Peer
14 review is when subject experts are called in to assess
15 the work and give feedback. First, whether this is
16 appropriate for the publication that we're looking into.
17 And second, whether there are any amendments that need
18 to happen.

19 At that stage, the publication, the manuscript, can
20 go back to the research group and they can edit it and
21 review it or write a rebuttal letter back to the editor
22 if they feel some of the amendments requested are not
23 reasonable or there are other reasons why they cannot be
24 done. And that passes through various cycles up until
25 the stage where the reviewers and the journal are happy

1 to publish this paper. This is the main part of peer
2 review.

3 THE CHAIR: Are there any recognised, common standards for
4 peer review? For instance, the numbers of other
5 academics who might be invited to comment? Are there
6 sort of guiding principles?

7 DR CHRISTODOULOU: There are common practices. It is very
8 rare to have fewer than two reviewers. Usually three,
9 I would say. But quite often in specific studies, some
10 journals have started incorporating expert reviewers for
11 specific components of the work, for example if a work
12 is done on a medical paper, some journals also include
13 a statistical reviewer, which is a separate step, so
14 they can see the statistical rigour but also the
15 biomedical or medical rigour. That is not practised
16 everywhere but it is a practice that is becoming more
17 and more common.

18 THE CHAIR: Thank you.

19 PROFESSOR DONNELLY: To elaborate further, so Maria was
20 talking about the process to publication, but of course
21 there's the possibility that the peer review process may
22 decide that this is -- lead the editors to conclude this
23 is not appropriate for the journal. Now that may be
24 because of what is seen as flaws or weaknesses in the
25 study or it may be because the process, depending on the

1 journal, that this just isn't a high enough priority
2 area for them.

3 The pressures on journals are different now because
4 a lot of them are electronic so there's less issue with
5 space, but when it was print journals it was like if we
6 published this paper, then we can't publish a different
7 one, because there's only a certain number of pages.

8 So that will go through. And it's also the case
9 that now, some journals online are making the peer
10 review information available. So sometimes it is
11 a policy of the journal. Sometimes it is an option for
12 the journal, and so if it is the case that a journal
13 could insist that all peer review reports so you see --
14 go online, you can see the original version that was
15 submitted, you can see the reports that were produced by
16 the peer reviewers who might or might not be named.
17 Then you can see the reply from the authors as well as
18 the amendments they have made.

19 So some journals allow you to see this whole
20 behind-the-scenes process so you can understand what's
21 gone through. Other ones, it's just: here's the version
22 of record, this is where we are.

23 And I would add there's an additional thing in
24 publishing which is called the pre-print which has
25 become increasingly common, which is -- a pre-print

1 allows people to upload their work before it's submitted
2 and so it hasn't undergone peer review and so there's
3 med archive, bio archive, various venues for this. This
4 has been done in physics, for example, for a long time.
5 And that allows people to alert the community to "These
6 are my ideas and findings" but then to be able to speak
7 about them more freely without being worried that
8 somebody in the audience might go off and publish faster
9 than you can.

10 So the literature has a range of different options
11 available. If somebody pre-prints results, they can
12 then subsequently, and usually do, send it for peer
13 review. So then there will end up being multiple
14 versions of the same type of research and you can see it
15 evolve.

16 Q. I have been asked for the benefit of the stenographer to
17 ask if we can all slow our note of speech slightly.

18 Is it nevertheless possible, notwithstanding that
19 peer review process, for papers to be published which
20 contain important methodological limitations or even
21 errors and that they would still be published? Is that
22 something that we do see?

23 PROFESSOR DONNELLY: Yes, and so there are -- the goal is to
24 weed out any issues, identify them in the process of
25 peer review, but you only have a number of peer

1 reviewers and they may not have expertise or the full
2 knowledge of everything that might be there.

3 Similarly, even an author might realise afterwards,
4 actually, there was a typo in something we produced and
5 if it's important -- so someone can alert the journal.
6 That could either be the author realising, oh, we
7 actually made a mistake and that number is not correct,
8 here's the correction, or someone reading the paper who
9 identifies something can ask the editors to look at it,
10 if they're concerned that there's an issue there.

11 That can lead to corrections, which is a --
12 important but a relatively minor thing, and say, okay,
13 the paper primarily stands, here's just a correction,
14 and online you would see a link to -- if you find the
15 primary paper: here's a link to the correction. So you
16 would see both of those things.

17 In a more extreme case, it could lead to
18 a retraction, and that is the journal saying, through
19 the editors, "We retract this", so retrospectively
20 saying it was something that shouldn't have been
21 published under the banner of our journal.

22 Q. How often do you -- or is it seen that there is a need
23 to retract studies after the process of peer review? Is
24 that something that happens relatively frequently or is
25 it an uncommon occurrence?

1 DR CHRISTODOULOU: It is not overall a common occurrence but
2 it is also discipline dependent. Some disciplines are
3 more prone to retractions than others but overall it is
4 something that we try to build peer review, to stop
5 doing, to not have.

6 Q. Is it, given that errors can still get through that peer
7 review process, is it important that readers of studies
8 seek to independently interrogate them with an open
9 mind, rather than adopting the conclusions at face
10 value?

11 DR CHRISTODOULOU: Could you repeat the question, please?

12 Q. Yeah. Is it important when you're looking at a study to
13 interrogate its methods yourself rather than just to
14 assume that the conclusions are valid?

15 DR CHRISTODOULOU: It is, and that is the primary reason why
16 most journals in their publications they have a method
17 section where they explain how the data were collected,
18 how they were handled and sometimes supplementary
19 methods to give us a little bit more insight. Now, with
20 the use of code, they also often connect to what
21 analysis was done and we can look through the code,
22 which means that researchers interested in that
23 particular work, they can look through it and try to
24 understand exactly what happened to make sure that that
25 aligns with their understanding of the system.

1 Q. There are a couple of types -- different types of study
2 that we see referenced in your report so can I ask
3 first, what is a before-and-after study?

4 PROFESSOR DONNELLY: So as the name implies that's going to
5 be a comparison of outcomes that happen before an
6 intervention and outcomes that happen after. So, for
7 example, you might have the rollout of a change and so
8 then you look to see what the rate of occurrence of some
9 outcome of interest was before the period, and after.

10 The risk with that is, as we mentioned with
11 confounding, other things might change. So over time
12 you might have a change in the way a certain medication
13 is delivered that's totally separate from what your
14 primary intervention of interest is. And so it has
15 that, if they're not concurrent, you may have concerns
16 that you're seeing a difference in the before period and
17 the after period but there could be multiple things that
18 changed. So attributing a difference in
19 a before-and-after study is -- it's a weaker result than
20 if you have concurrent controls, usually.

21 Q. What would the advantage of a before-and-after study be,
22 then, if it doesn't have that methodological benefit?

23 DR CHRISTODOULOU: To start with it, they're quite
24 intuitive. It is an intuitive way for us to understand
25 the system, we see what happened before, and what

1 happened after. So that is an advantage. It's
2 intuitive, so that's easy to communicate. It is also
3 much easier to implement than trying to have a fully
4 randomised control study, which takes a lot of work and
5 takes a lot of design, time and effort. It is
6 convenient overall, and it has an ease of communication.

7 PROFESSOR DONNELLY: Yeah, so the people who would be --
8 could consent to take part in the study, one of the
9 reasons why people might be consenting to be in a study
10 is the opportunity to have the intervention if they
11 think it would be useful and so if it's
12 a before-and-after study then everybody is getting the
13 chance to benefit from that as opposed to if you have
14 a concurrently controlled study: well, you agreed to
15 take part in the study and then you could be, for
16 example, randomised to either standard of care or
17 getting the intervention.

18 So sometimes a study will have two arms. One is
19 getting the intervention soon, and one is getting the
20 intervention later. And so that allows for the
21 opportunity that everyone can take part. So it just
22 depends on the specifics, what's the most appropriate.

23 Q. You have already touched on this slightly, but can I
24 just ask, what is a randomised control trial, then?

25 PROFESSOR DONNELLY: So randomised control trial is

1 a particular sort of study. Now, it's not to say that
2 every randomised control trial has exactly the same
3 design, they don't. But, in general, so the
4 randomisation is that process through which the research
5 team will randomise the units of study. Now, the unit
6 of study could be a ward, the unit of study could be an
7 individual or a room, and that will be randomised to the
8 comparison or the intervention.

9 And the reason for that randomisation is to protect
10 us from confounding. We would like the groups to be
11 comparable to each other. There are things that we can
12 record and later potentially adjust for, in case they
13 worked. For example, it might be that we happened to
14 have more older people in one group than another, more
15 men than women, and so on. But if we randomise, that
16 helps protect us against the things also that we haven't
17 measured, because there can be differences between the
18 groups and if it's not something that we are able to
19 measure or we didn't measure it, randomisation should,
20 if the groups are large enough, balance those out.

21 Then the controlled is simply that we have that
22 comparison group, that we're able to make the
23 calculations in one group and compare them with the same
24 calculation in another. And so that allows us to
25 collect evidence, to look at -- and by randomising, that

1 strengthens the evidence. Then we're more likely -- it
2 doesn't mean that there couldn't be things that still
3 creep in and are unexpected in terms of our design, but
4 that is -- gives us the best possible chance of
5 detecting an effect that truly can be attributed to our
6 intervention.

7 THE CHAIR: Presumably, the larger the number of randomised
8 items you choose, the less danger of confounding; is
9 that right?

10 PROFESSOR DONNELLY: Yes, in general that would be the case
11 but sometimes people talk about big data. You need to
12 be a little bit careful that you're still collecting --
13 you're measuring things with high quality and carefully.
14 So there can sometimes be a trade-off between a really
15 big study in which case you don't have such detailed
16 information, or a somewhat smaller study but you have
17 more detail on the individuals, and that is a trade-off
18 that will have to be made for any research team as well
19 as, of course, resources.

20 DR HAYES: I think you led me to my next question, which is:
21 what are the potential downsides of doing a randomised
22 control trial?

23 DR CHRISTODOULOU: They are quite laborious. They need
24 extensive design. They need resources. They need quite
25 a large group of units to be included for it to actually

1 have a relatively appropriate strength for the
2 comparison to happen.

3 Q. Is it correct to say that there have been no randomised
4 control trials of Oxevision?

5 DR CHRISTODOULOU: To my understanding, no.

6 PROFESSOR DONNELLY: Indeed, that's my understanding, as
7 well, yes.

8 Q. Not within the papers we provided you?

9 DR CHRISTODOULOU: No.

10 PROFESSOR DONNELLY: Of Oxevision for mental health
11 inpatient settings.

12 DR CHRISTODOULOU: Yes.

13 Q. In principle could a randomised control trial be
14 undertaken for an intervention like Oxevision?

15 PROFESSOR DONNELLY: It could be indeed. It would be
16 possible to randomise that. You would need to -- the
17 person would need to -- or the team who are setting up
18 the trial would need to consider whether or not they
19 were randomising individuals for their stay or setting
20 up particular rooms.

21 There could be issues, for example, that some rooms
22 have different facilities than others and that would
23 need to be considered. But it would be possible to do
24 that, and you could have individuals who were -- when
25 they came in and consented to taking part in the study,

1 could be randomised to then this standard of care, which
2 is not to have it, or to have Oxevision (unclear).

3 There would need to be consideration of whether or
4 not -- it would depend on what the study was looking
5 for. Would the presence of Oxevision then mean that
6 there were fewer in-person visits to the patient, and
7 checks? So would the Oxevision checks that were
8 possible, for example, on the location of the individual
9 or in terms of their heart rate, would those replace
10 ones that would otherwise be done by a person, and that
11 depends on the particular scope of the trial.

12 DR CHRISTODOULOU: To add to this, when a study like that is
13 designed, it is not a small team that needs to design
14 it; it's a multidisciplinary team that will have to come
15 together because it's not just about statisticians
16 setting up the steps; you need to bring in experts for
17 a variety of disciplines from mental health disciplines,
18 from patient experience, and the quality of care that
19 they are receiving. So a lot of components need to come
20 together before a study like that can be designed, which
21 adds to the laboriousness.

22 Q. One of the reports I will ask you later is by
23 Buckley et al. Was a randomised control trial something
24 that they themselves recommended at the end of their
25 study?

1 PROFESSOR DONNELLY: Yes. So to quote from them:

2 "A key limitation is that the data was sourced from
3 quasi experimental studies which compared the
4 differences in outcomes before and after the
5 implementation ... as opposed to randomised control
6 trials."

7 So they go on to acknowledge that it's possible that
8 confounding variables could have influenced the results,
9 and so they say that the evidence base would benefit
10 from a randomised trial. They talk about a specific
11 sort, which is a cluster randomised trial. That could
12 be when you -- a cluster could be a ward, for example,
13 of patients. So that's -- when I talked about the unit
14 of analysis, you -- the unit could be the ward and that
15 could be a cluster, but they were recognising there the
16 limitations of the study.

17 And that is best practice to -- when you go through,
18 in a paper, usually you have the introduction where you
19 say why this is important, why you've done the study,
20 what past results have been found that are relevant.
21 You lay out the methods for your -- any data collection
22 as well as the statistical methods that you're going to
23 undertake. The results, that's when you say what -- how
24 the data looked, and what the results of your analyses
25 were.

1 Then you go into a discussion section. You may have
2 a separate subsection for limitations, they do here.
3 But that is an important process in the discussion of
4 putting things into context, and if you don't mention
5 the limitations of your own study, peer review will be
6 rightly pointing that out: that no study is going to be
7 fully comprehensive and perfect and the only one piece
8 of evidence that's needed. So it's important for the
9 team to have been, you know, introspective in both the
10 limitations by design as well as any other unexpected
11 events that happen. And so it's a good thing to, you
12 know, acknowledge the limitations of your study and say
13 what might be done.

14 Often, very large trials can be done
15 internationally, and that's important as well, because
16 if they're looking at a fundamental question of does
17 this drug help, it may be important to see how it
18 performs in different healthcare systems.

19 And so on a smaller scale, that might be involving
20 different NHS Trusts, and different hospitals within
21 those Trusts. Because the scope of the study may mean
22 that the scope of the findings are limited.

23 Q. Can I ask for a document to be put on screen, please.
24 It's INQY025968. At page 5.

25 This is your own report. Now at page 4 of your

1 report, have you provided an executive summary?

2 DR CHRISTODOULOU: Yes, we have.

3 Q. And at the end of that summary did you say this of the
4 evidence base in support of the use of Oxevision:

5 "In conclusion, the current evidence provides only
6 limited and cautious support for the use of Oxevision
7 and related [vision-based patient monitoring systems] in
8 mental health inpatient settings. It suggests that the
9 technology is technically feasible and may have
10 potential operational applications, but it does not
11 provide strong, independent evidence of clinical
12 effectiveness, improved patient safety, acceptability or
13 cost-effectiveness in mental health inpatient settings.
14 Further independent randomised adequately controlled
15 research would be needed before stronger conclusions
16 could be drawn."

17 I would like to have a look at some of the -- or in
18 greater detail at some of the studies that you evaluated
19 in your report to see how you came to that conclusion.

20 Can I ask or start by asking about the structure of
21 your report. Is it correct to say that you divided it
22 into four broad sections?

23 DR CHRISTODOULOU: Broadly, yes.

24 Q. And do each of those sections consider studies which are
25 either of a similar nature or which have a similar

1 purpose?

2 DR CHRISTODOULOU: We try to find themes that connected the

3 studies so that the narrative is coherent.

4 Q. Now, the first of those sections, does that look at

5 economic evaluations performed in respect of

6 vision-based patient monitoring systems?

7 DR CHRISTODOULOU: It does.

8 PROFESSOR DONNELLY: *(The witness nodded)*.

9 Q. But is it correct to say that when considering the

10 conclusions which can be drawn from those economic

11 evaluations, you have to have one eye on the assumptions

12 that fed into them?

13 DR CHRISTODOULOU: That is correct.

14 Q. Accordingly, I'd like to take your report out of turn,

15 if I may, and start with Section 2 rather than

16 Section 1. Is it correct that Section 2 of your report

17 looks at Oxevision and related systems across a range of

18 mental health inpatient settings?

19 DR CHRISTODOULOU: That's correct.

20 Q. And in total, in Section 2, did you review 15 studies?

21 PROFESSOR DONNELLY: Yes.

22 DR CHRISTODOULOU: Yes.

23 Q. And starting at page 15 of your report, do we find from

24 paragraphs 2.4 to 2.18, individual summaries of each of

25 those studies?

1 DR CHRISTODOULOU: Yes.

2 PROFESSOR DONNELLY: *(The witness nodded)*.

3 Q. And at paragraphs 2.1 to 2.3 do we see your overall

4 appraisal of this part of the evidence base?

5 DR CHRISTODOULOU: That's correct.

6 BY PROFESSOR DONNELLY: *(The witness nodded)*

7 Q. In very broad terms, is Section 2 where we would look if

8 we wanted to consider whether the Oxevision system is

9 having an impact of any sort on the outcomes for

10 patients who are subject to its use?

11 PROFESSOR DONNELLY: Within mental health settings, yes.

12 Q. I don't intend to take you to each and every one of

13 those studies, I'm sure you'll be grateful to hear. The

14 Inquiry has and will consider your report in its

15 entirety, but I would like to take you to some specific

16 studies just so that we can look at their results, their

17 potential limitations and the strengths of the

18 conclusions that can be drawn from them.

19 Can we start with the first Ndebele study from 2022,

20 which is a study, I believe, from Coventry and

21 Warwickshire Partnership NHS Trust, and you discuss this

22 at paragraph 2.6 on page 16 of your report.

23 DR CHRISTODOULOU: Yes.

24 Q. I'll give you time to turn to it. Can you explain the

25 methodology of this study? What was going on?

1 DR CHRISTODOULOU: So in this study they reported the
2 findings from a before-and-after study without controls
3 and it was using Oxevision, to evaluate Oxevision in
4 a single male PICU.

5 Q. Is it correct that the study was installed in 12
6 bedrooms on that PICU ward?

7 DR CHRISTODOULOU: That's correct, yes.

8 Q. You said it was a before-and-after study. Did they look
9 at incident data from 31 patients over a period of
10 12 months before and then 12 months after the
11 implementation of Oxevision?

12 DR CHRISTODOULOU: That's correct, yes.

13 Q. What was this study trying to examine, predominantly?

14 DR CHRISTODOULOU: They were trying to examine whether there
15 were any reduction in all assaults and in rapid
16 tranquilisations that were related to assaults.

17 Q. And what were the findings of this study?

18 DR CHRISTODOULOU: They reported a reduction in all
19 assaults, a reduction in rapid tranquilisations and some
20 reduction in bedroom assaults.

21 PROFESSOR DONNELLY: But that was non-significant.

22 DR CHRISTODOULOU: That was non-significant.

23 PROFESSOR DONNELLY: So that would mean a sort of trend but
24 not statistically convincing.

25 Q. I'll come back to the concept of statistical

1 significance later.

2 Was it your view that this study had some
3 methodological limitations, then?

4 DR CHRISTODOULOU: The study didn't have a control. It was
5 also quite small in size, which made it quite difficult
6 to extrapolate from those findings. It had no
7 adjustments or randomisation, so we couldn't adjust for,
8 for example, patient mix. That may be different in the
9 before and after. Some of the methodological steps that
10 were taken to correct for this would not have overcome
11 the limitations of the design.

12 PROFESSOR DONNELLY: Could I note, then, again in the way
13 that I was mentioning before, there is mention by the
14 authors of limitations in the very last paragraph:

15 "Although this analysis was limited in its sample
16 size and lacked a controlled cohort ..."

17 And then they go on to say the data indicated these
18 reductions. But they were acknowledging that it was
19 a limited study but what they point out is that it was
20 as they understood it, the first analysis of the impact
21 of such a system within an inpatient setting of this
22 sort.

23 Q. We've already touched on this but can I just ask, what
24 is the consequence of a study having a small population
25 that it looks at?

1 DR CHRISTODOULOU: The size of the population will connect
2 with how easy it is to describe the overall patterns
3 we're expecting to see outside that population. The
4 smaller the group, the less likely it is for us to be
5 able to capture the variability that exists outside that
6 environment. So it makes it a lot harder for us to step
7 outside that very specific setting and make some more
8 general claims, which is normally the aim of those
9 studies.

10 Q. Overall, what were your conclusions about the strength
11 of this study?

12 PROFESSOR DONNELLY: So I think it was a preliminary study,
13 and in that sense, was useful for people to see a sort
14 of proof of concept of how this could be done. But due
15 to the limitations in both scope and structure of the
16 study, it produces some evidence, but it's not overly
17 convincing so we would say it's low evidential weight
18 but it's a starting point and I think -- that is
19 important in the scientific process to get started and
20 for someone to say: okay, this is possible. And, you
21 know, as they acknowledged, there are limitations to the
22 study but things could go on from there.

23 DR CHRISTODOULOU: Scientific discovery is incremental.
24 This is a first starting point. It's hypothesis
25 generating.

1 Q. Is it correct to say that those limitations you've
2 identified would mean that we'd have to be particularly
3 cautious in extrapolating the results of this study out
4 to a much larger population?

5 DR CHRISTODOULOU: Yes, caution is advised.

6 Q. There is one other point I would like to pick up in this
7 first study. Is it correct that two of the authors were
8 employed by Oxehealth and that an Oxehealth contributor
9 assisted with data compilation and analysis?

10 DR CHRISTODOULOU: That's correct.

11 Q. Can I just talk about independence in research
12 generally. Why is it relevant if a publication was
13 either funded by Oxehealth or based on data supplied and
14 analysed by Oxehealth or produced by organisations that
15 were commissioned by Oxehealth?

16 PROFESSOR DONNELLY: So independence is one thing that you
17 would aim for in the strongest (unclear) evidence,
18 because you would like people not to have that sort of
19 skin in the game. So you would like the scientists who
20 are undertaking the study not to benefit if a particular
21 outcome happens.

22 There are various approaches that can be taken to
23 reduce those risks. One of them is, for example, that
24 you can pre-register your analysis plan of a particular
25 study. So it's possible. And that gives a date stamp

1 where the research team has said, "This is how we're
2 going to analyse our data." And that means that when
3 readers look at the analysis later, and you might then
4 undertake additional analyses because of things that
5 arose in patterns that you saw, but your primary
6 analysis is one that you pre-specified before you saw
7 the data. And that reduces the risk of someone, even
8 with good intentions, looking at the dataset and then
9 deciding, within the range of possible approaches, to
10 take one that might make it look better.

11 Now that's not to make any particular -- you know,
12 I'm not making accusations to any individuals, but when
13 you have people with conflicts of interest, it is of
14 particular concern when readers or stakeholders are
15 evaluating the evidence.

16 It is important to say, so the link to Oxehealth is
17 made clear. So it lists Oxehealth as the employer of
18 two of the authors and as you said, it mentions someone
19 who contributed from Oxehealth for data compilation and
20 analysis.

21 Q. Are those sorts of arrangements uncommon or are they
22 relatively frequently observed?

23 PROFESSOR DONNELLY: In my experience, you often see people
24 from a drug company, for example, collaborating with
25 other people to have a study of effectiveness. That

1 could be for a vaccine, that could be for a therapeutic
2 drug. In the -- when you're going for a sort of
3 clinical trial that would lead to certification of
4 a drug or sort of approval from the US Food and Drug
5 Administration or from the equivalent in the UK, you
6 would need to have several safeguards in place that
7 would make sure the study was done as originally planned
8 so that you pre-specify that analysis plan and that's
9 critical and then it was done.

10 Often there would be -- that analysis would be done
11 by someone blinded to which group was which. So they
12 would, for example, know, you know, I might have worked
13 with a team that collected the data. We send it to
14 Dr Christodoulou, for example, and she would just see
15 group A and group B and then have the data. And not
16 know which was the intervention and which was the
17 comparison group. And that's an extra control that
18 comes in, that's blinding. So in that case, she's
19 blinded to which of these groups and that just gives an
20 extra level of protection from any potential bias that
21 might come in.

22 That bias is not at all people changing the data or
23 sort of misrepresenting the results, but just in the
24 possibility of, you know, it might -- you know, it's
25 human nature to want to show things that would have

1 a benefit, like you hope that this could make things
2 better. And so that desire to see success, if that's
3 how you've defined it, could mean that you were, you
4 know, you might just be tempted to make one decision
5 rather than another. So if you're blinded and see them
6 as group A and group B, there's not that temptation.

7 THE CHAIR: It's also significant, presumably, for
8 perception of the work and how --

9 PROFESSOR DONNELLY: Indeed.

10 THE CHAIR: -- it is received?

11 PROFESSOR DONNELLY: Yes.

12 THE CHAIR: Yes.

13 DR HAYES: Is it necessary to attach less evidential weight
14 to studies which are authored or funded or influenced in
15 some way by the manufacturer of a product? Or is that
16 going too far?

17 PROFESSOR DONNELLY: I think it depends on the context and
18 exactly how it was undertaken. I mean, there are many
19 very good studies that have people employed by or, you
20 know, or that it was commissioned by a company, but it's
21 a matter of how it was undertaken and what protections
22 were there.

23 There is also -- can be a data safety and monitoring
24 board and those are people who can be brought in and
25 those are independent. Often they're unpaid, so they're

1 volunteer positions to make sure they have even indirect
2 interest. For example, if this study went longer, maybe
3 the board would meet more often and they might get more
4 pay. That's completely obliterated if those are
5 volunteers.

6 So then they look at, in a structured way, look at
7 the data as it's collected and make a decision on the go
8 or no go for the rest of the trial. They would be
9 important if any safety concerns came up for them to
10 evaluate it.

11 Q. Can I ask about conflict of interest declarations. Is
12 it correct to say that the declaration of conflicts of
13 interest is regarded as important in the appraisal of
14 scientific research?

15 PROFESSOR DONNELLY: Indeed, and that can be -- the most
16 obvious declaration of potential conflict of interest is
17 when you say your address. This is the institution or
18 institutions in which you're affiliated. But then you
19 have often a separate section for conflicts of interest
20 in which you can explain, for example, who funded the
21 study. It might also not just be who funded the study
22 but who funds those researchers in other work. And so
23 often, in my own research I say: okay, I have this
24 research grant, I have that research grant. And just
25 even though they didn't fund that specific study, it's

1 important to acknowledge those.

2 DR CHRISTODOULOU: The additional component is that although
3 affiliations are particularly important to make clear
4 and be transparent, some journals have a blinded peer
5 review process which means those are removed from the
6 peer reviewers. The peer reviewers don't know the
7 affiliation of the authors which is why the conflict of
8 interest statement needs to align with the affiliations
9 that they've declared so that the peer reviewers are in
10 full view of all the potential conflicts.

11 Q. You've already sort of covered this, but why is it
12 necessary for people looking at a study to be alert to
13 potential conflicts of interest?

14 DR CHRISTODOULOU: Because it is important to know that if
15 somebody may have some even implicit bias in presenting
16 a finding, the reviewers can double check that
17 everything has been done as it should have been.

18 PROFESSOR DONNELLY: I think it's important in that sort of
19 realising that, you know, the writing of the paper even
20 as statisticians, people who are very number focused,
21 that, of course, there is the -- so you can have
22 a pre-registered analysis plan, then you do the
23 analysis. There's still how you write up and interpret
24 those results. And it's important for people to realise
25 if there would be any conflicts of interest in how you

1 might -- and spin would be too much but, you know, in
2 any way that I might write up a result versus
3 Dr Christodoulou, we might just choose different words
4 and it's important for people to realise whether or not
5 there was any potential motivation to present things in
6 a slightly better light.

7 Q. Can I turn now to the Wright and Singh paper, which
8 I think is another study from Coventry and Warwickshire
9 Partnership NHS Trust and you've covered this at
10 paragraph 2.7 of your report. Do you have that in front
11 of you?

12 DR CHRISTODOULOU: Yes.

13 PROFESSOR DONNELLY: I do, yes.

14 Q. What did this study look to evaluate?

15 DR CHRISTODOULOU: Again we have a before-and-after study.
16 So it's a similar design to the previous one and we are
17 looking at the use of the vision-based system in two
18 dementia inpatient wards. We have it installed in 12 to
19 24 bedrooms and what they were trying to look into is
20 how nighttime falls compared across the 12-month
21 baseline and the 22 months after the installation
22 period.

23 Q. And what were the findings of this study?

24 DR CHRISTODOULOU: They reported a reduction in nighttime
25 falls, a reduction in A&E admissions, and a reduction in

1 annualised moderate severity falls.

2 Q. Did they also identify a reduction in levels of enhanced
3 observations?

4 PROFESSOR DONNELLY: I don't -- looking at this, I see
5 number of falls, nature of the fall, severity of the
6 fall, visits to -- visits by emergency services, and
7 visits to A&E. The costs of enhanced one-to-one
8 observations were analysed before and after the system
9 was installed.

10 DR CHRISTODOULOU: Yes.

11 Q. If we -- if you turn to the top of page 4, the column at
12 the top left below figure 5?

13 PROFESSOR DONNELLY: Yes, yes, so that looks at the data on
14 the cost of enhanced observations. So the observational
15 hours were reduced by 71 per cent, it says, after the
16 system became operational.

17 DR CHRISTODOULOU: They did, however, report a policy change
18 during the collection of the data which makes them
19 refrain from analysing this further so it's difficult to
20 draw conclusions from this.

21 Q. Would it be fair to say that that reduction in
22 observational hours should be given relatively low
23 evidential weight?

24 DR CHRISTODOULOU: We need to be very cautious because of
25 the potential compounding that they clearly stated,

1 yeah.

2 Q. If we go back to the sort of principal headline findings
3 that you brought our attention to relating to nighttime
4 falls and A&E admissions and the like, what was your
5 view as to the strength of those conclusions?

6 DR CHRISTODOULOU: The design by itself, the fact that it
7 was quite small in size, and the difference in the
8 periods that we're measuring make it difficult for us to
9 associate a high burden of evidence with this. It is on
10 the low side of evidence. It needs to be examined much
11 further before we can establish this.

12 Q. You talk there about the size of the study.

13 DR CHRISTODOULOU: Yes.

14 Q. Were there other limitations that reduced the confidence
15 that could be placed in its conclusions or mean that you
16 have to treat them with caution at least?

17 DR CHRISTODOULOU: Are you asking if there are other
18 limitations other than the sites?

19 Q. Yes.

20 DR CHRISTODOULOU: Yes, the before and after is always a
21 concern for confounding. They themselves experienced
22 one of the effects of confounding when they were trying
23 to understand the lowering of staff time. The absence
24 of a control makes it very difficult for us to be able
25 to assess how similar the situations were before the

1 implementation and after. So no controls and
2 randomisation and the size of the study makes it
3 a difficult study to extrapolate, but a starting point.

4 Q. So --

5 PROFESSOR DONNELLY: This is, again, where there's
6 a limitation section in the paper so these are things
7 that the -- the authors are aware of the study only took
8 place in two wards in a single hospital and also that
9 they only looked at falls in bedrooms at nighttime, so
10 the scope of it was limited, but that is where they --
11 where the Oxevision had been installed. So in that
12 sense, it makes sense. But they are -- and then they
13 noted this about operational changes that affected their
14 ability to look at impacts of Oxevision in this way.

15 Q. So would it be correct to say that, again, this is
16 a paper that perhaps ought to be treated with a degree
17 of caution?

18 I can see you nodding.

19 DR CHRISTODOULOU: Yes, that's correct.

20 Q. And that whilst it may provide an early signal of
21 a possible association between the use of the technology
22 and reduced falls, one needs to be cautious about
23 generalising those effects to a greater population?

24 DR CHRISTODOULOU: That's correct.

25 PROFESSOR DONNELLY: (*The witness nodded*).

1 DR HAYES: Chair, that concludes my questions in respect of
2 that particular paper. Now might be an opportune moment
3 to break before we move on to another topic.

4 THE CHAIR: How long do you want? Ten minutes?

5 DR HAYES: Yes, perfect.

6 THE CHAIR: Ten minutes. Thank you.

7 **(11.06 am)**

8 (A short break)

9 **(11.30 am)**

10 THE CHAIR: Mr Hayes.

11 DR HAYES: The next study that I would like to look at with
12 you both is a paper by Ndebele from 2024 and an
13 associated paper by Chua et al. That, you discuss at
14 paragraph 2.9 of your report on page 17.

15 Is this another study that was performed at Coventry
16 and Warwickshire Partnership NHS Trust?

17 DR CHRISTODOULOU: Yes, it is.

18 Q. Is there any significance in the fact that the three
19 studies we've looked at so far, and I appreciate there
20 were other studies done, but it does appear that several
21 of them are done in the same Trust. Does that have any
22 effect when interpreting them?

23 DR CHRISTODOULOU: In what sense does it have an effect?

24 Q. In -- does it have -- is there a limitation in multiple
25 studies being undertaken in the same Trust?

1 DR CHRISTODOULOU: It would give us information about that
2 Trust and it would give us multiple points of
3 information for that Trust. It may not give us any
4 information about how this would generalise to other
5 Trusts.

6 Q. What was this study seeking to examine?

7 DR CHRISTODOULOU: There -- it was another before-and-after
8 study of the vision-based system. In one female and one
9 male inpatient mental health ward. We looked at the
10 wards with the vision-based system implemented and some
11 control wards. They used the routine incident reporting
12 system that has already been in place, and they were
13 trying to assess the bedroom self-harm and ligature
14 rates before and after implementation.

15 Q. One of the limitations of the studies we looked at
16 previously was that they didn't have a control. So to
17 what extent does the presence of a control in this study
18 relieve those concerns?

19 DR CHRISTODOULOU: Presence of a control is very useful.
20 The control should be used for us to assess whether the
21 intervention ward is behaving in a different way to the
22 control ward for the reasons we discussed earlier in
23 terms of confounders, for example. So that is an
24 improvement in the design.

25 Q. Is it --

1 PROFESSOR DONNELLY: Sorry. I just want to say, it is
2 acknowledged by the authors that this is
3 a non-randomised study. So it has controls. But the
4 choice of where to put Oxevision and where not to is not
5 randomised.

6 Q. And what is the consequence of that?

7 PROFESSOR DONNELLY: Well, if it's such a small sample size
8 even if it were randomised, you would still have
9 concerns, but there may have -- we don't know the
10 reasons why they chose those particular wards to put the
11 intervention and it may mean that they are -- may be
12 dissimilar to the control wards in some particular way
13 that will have motivated that choice.

14 Q. And even if it didn't motivate the choice there could
15 still be differences between those wards that would
16 impact on the results?

17 PROFESSOR DONNELLY: Indeed.

18 Q. Is it correct that this is another single-site study
19 with a small number of participants and that those same
20 limitations we discussed earlier therefore applied to
21 this study?

22 DR CHRISTODOULOU: That's correct.

23 Q. And do we again see that Oxehealth employees are
24 involved in the study?

25 DR CHRISTODOULOU: That's correct.

1 Q. Can I ask about the results of this study. What was the
2 headline result of this study?

3 DR CHRISTODOULOU: They reported a 44 per cent relative
4 reduction in bedroom self-harm and a 48 per cent
5 relative reduction in bedroom ligatures compared to the
6 control wards.

7 Q. So in simple terms, were they looking at the rate of
8 self-harm on the wards with Oxevision and the control
9 wards, and comparing the two?

10 DR CHRISTODOULOU: Yes, they would bring those together to
11 see how, how the numbers would change.

12 Q. Now that 44 per cent relative reduction in bedroom
13 self-harm and 48 per cent relative reduction in bedroom
14 ligatures, that was something that I believe was
15 statistically significant; is that correct?

16 DR CHRISTODOULOU: That's correct.

17 Q. Can I ask you to explain this concept of statistical
18 significance in fairly basic terms?

19 DR CHRISTODOULOU: Earlier we discussed the idea of the null
20 hypothesis, this default scientific premise where
21 nothing interesting, nothing different is happening
22 between the groups.

23 When the data we have collected is as extreme as the
24 data we collected or even more extreme and that is
25 associated with a small probability, then we're saying

1 it's less likely that it was generated by that default
2 assumption that nothing interesting is happening. If
3 the probability of our data coming from that default
4 assumption is very small, then it means it's not very
5 likely.

6 Q. Is it correct to say that when a result is statistically
7 significant, it's one in which the observed effect is
8 unlikely to have occurred by random chance?

9 DR CHRISTODOULOU: That is correct.

10 Q. Can I ask you about confidence intervals. What does the
11 spread of a confidence interval tell us about the -- or
12 how does that influence our interpretation of a study's
13 result?

14 DR CHRISTODOULOU: Any measurement we take is subject to
15 uncertainty. There is a lot that could be happening to
16 be going into our estimates. That uncertainty can be
17 represented by a confidence interval around it. If that
18 confidence interval is wide then we believe that our
19 estimate is not as precise. If the confidence interval
20 is narrow, we have -- I believe that our estimate is a
21 lot more precise. If the confidence interval we have
22 contains within it the zero effect between the two
23 treatments, then that's connected to a P value that's
24 not significant as well.

25 Q. So where the confidence interval is wide, you have

1 greater precision in your measurements; is that a fair
2 statement?

3 DR CHRISTODOULOU: When a confidence interval is wide you
4 have less precision in your measurement; when
5 a confidence interval is narrow, you have more precision
6 in your measurement.

7 Q. Is it correct that, in this study, they also looked
8 solely at the reduction in self-harm that was seen on
9 the Oxevision ward before and after the system was
10 deployed?

11 DR CHRISTODOULOU: That's correct.

12 Q. And did that show that rather than a 44 per cent
13 reduction, the reduction was closer to 22 per cent?

14 DR CHRISTODOULOU: That is correct.

15 Q. And was that result statistically significant?

16 DR CHRISTODOULOU: It was not statistically significant and
17 the confidence interval was wide to include both values
18 of increased and decreased self-harm.

19 Q. Can we try to unpick how it can be the case that there
20 can be two results that appear to be in tension in this
21 study: one is a 44 per cent relative reduction in risk
22 and one is a non-significant 22 per cent reduction
23 between before and after the system was deployed. I'd
24 like to try to understand that more, if I can.

25 Can we bring up OXHE020520 at page 5, please.

1 PROFESSOR DONNELLY: Yes, so there, what we see plotted is,
2 we have on the left the data from observational wards,
3 so those are the wards in which they had the
4 vision-based system, and then we had the control wards,
5 those are the comparison ones. The y-axis, which is the
6 vertical axis, is -- gives you a number which is the
7 rate of self-harm incidents, so how often that happens.
8 And so if we look purely at the -- so -- and to add to
9 that, then the colours, the difference between black is
10 for the baseline period, grey is for the active period.
11 So if we just look at the two boxes on the left,
12 that shows us the difference between observational wards
13 and base lines, so before, and in grey, after the
14 implementation of that. So you see a reduction. And
15 that relates to the 22%.
16 So how do we get to 40 -- or how did they get to
17 44 per cent? And that is because that is a combination
18 of that 22 per cent reduction, so the reduction inside
19 the observational ward, and what was happening in the
20 control wards, and you see that what happened in the
21 control wards is that there was an increase between the
22 baseline period and the active period. So incidents of
23 self-harm actually increased that rate in the control
24 wards, so in the absence of this intervention.
25 Now, if the control or comparison wards were exactly

1 comparable to the observational wards, you might have
2 expected, well, in the absence of bringing in this
3 vision-based system it would have also seen an increase.
4 And that's where the 44 per cent comes in. It sort of
5 says what we would have expected had they been behaving
6 like the control wards. But if we just look at the
7 observational wards themselves then we see the reduction
8 that was observed there of the 22 per cent.

9 And it's that comparability question. If the people
10 looking at this study, one thing would be what, you
11 know, immediate question is: why did that increase?
12 What happened in the control wards? And that's
13 something that would -- was probably out of the scope of
14 this, as they set up the data collection to begin. But
15 that's something you would want to understand, is why
16 did that actually increase?

17 It could have been just it was by chance the number
18 and combination of patients that were in inactive period
19 were behaving differently than the baseline period or it
20 could have been affected by external factors. We don't
21 know.

22 DR CHRISTODOULOU: It requires further examination when we
23 see something like that in the control wards. We need
24 to understand what is happening, to the best of our
25 ability, before we use it for a relative estimate.

1 Q. Is that because the statistically significant change in
2 the relative rates is in part being driven by an
3 unexplained increase in the control ward?

4 DR CHRISTODOULOU: The relative per cent of the change is
5 a ratio. On the top we have the observation ward and on
6 the bottom we have the control wards, and that ratio
7 will change if you increase what goes in your
8 denominator or if you decrease what's going in your
9 denominator at the top and at the bottom.

10 Q. Now, this, the approach to the way the data was used in
11 this paper was subject to criticism in a paper by Chua.
12 Is that correct?

13 DR CHRISTODOULOU: That is correct.

14 Q. And can we pull that up. It's INQY024285 on page 1.
15 Can we move over to page 2, please.

16 Now is it correct that Chua observed the true change
17 in self-harm on the Oxevision wards to be that
18 22 per cent figure that you've discussed previously?

19 DR CHRISTODOULOU: I don't believe they observed it
20 themselves. I believe that they used the data that was
21 available from the Ndebele study.

22 Q. Yes, so their interpretation of the same data was that
23 the true figure was 22 per cent rather than the
24 44 per cent relative reduction.

25 PROFESSOR DONNELLY: They calculated an alternative way of

1 doing it, yes.

2 DR CHRISTODOULOU: Yes.

3 PROFESSOR DONNELLY: So that's looking at the ratio.

4 Q. In respect of the way the data was presented in the

5 Ndebele paper, Chua says this:

6 "Comparing a reduction in ward A with an increase in

7 ward C exaggerates the apparent effect. The two

8 directions of change are not directly comparable and

9 doing so risks overstating the benefits of Oxevision."

10 In your view, is that a fair statement?

11 DR CHRISTODOULOU: That's a fair statement.

12 Q. Is there any benefit in presenting the data using the

13 relative risk that was employed in the Ndebele paper to

14 get to the 44 per cent figure?

15 DR CHRISTODOULOU: Again, every method has its benefits in

16 the correct context. So for example, communication and

17 how intuitive something to understand and how to

18 contextualise data from multiple wards in one number.

19 That is intuitive and easy to communicate. On the other

20 hand, it is easy to decontextualise once we bring so

21 much information into a single number and that may be

22 the primary issue that we're dealing with here.

23 Q. Is there a risk that when you take data out of context

24 it can be misleading, even if inadvertently?

25 DR CHRISTODOULOU: Taking data out of context is always

1 a dangerous thing to do.

2 PROFESSOR DONNELLY: I think it's worth noting that it's
3 a matter of scale here. So if there had been a large
4 number of intervention wards and a larger number --
5 a large number of control or comparison wards, if we
6 systematically saw increases in self-harm in the control
7 wards, that would be alarming, just full stop, wanting
8 to understand that. But it would also make you much
9 more impressed with a 22 per cent reduction because then
10 you would have had reason to think that that 22 per cent
11 reduction would have been an increase, had it not been
12 for this vision-based intervention.

13 So it's a matter of scale, but it's -- in the
14 absence of a larger study when you just have a small
15 number of wards, seeing an increase like that and not
16 understanding why means that, you know, it's doing a lot
17 of the lifting here to get to that 44 per cent. And it
18 was -- yeah, again to quote the Chua editorial:

19 "Absolute rate changes provide a more tractable
20 account than relative risk changes as the latter can be
21 misleading."

22 And it depends very much on context and scope of the
23 trial, and Ndebele did say that non-interventions in
24 comparison wards were based on similarity of the patient
25 cohort, ward size, and clinical ways of working. But

1 that's a very multifaceted thing. And when it's such
2 small numbers of wards that you're dealing with, you
3 risk that chance could be against you, or something
4 unexpected could happen.

5 Q. Can I turn now to consider two studies by Kekic et al,
6 you discuss the key one at paragraph 2.12 of your
7 report.

8 First, is it correct to say that Kekic has published
9 two articles or two studies?

10 DR CHRISTODOULOU: The second study, the one dated 2026, is
11 an extension of the original study that was published in
12 2023, and was retracted.

13 Q. And was the first of those retracted after publication
14 because the authors had failed to declare, in the
15 relevant conflicts of interest section, that some of the
16 authors were employed by Oxehealth?

17 PROFESSOR DONNELLY: Yes, there was an investigation by the
18 editors, and it was confirmed that while the authors had
19 reported their employment status when -- in the section
20 where they gave their personal affiliation, they didn't
21 also put it in the conflict of interest section. And
22 because the journal uses a double-blind process, so the
23 reviewer, those peer reviewers, when they received the
24 publication, because they didn't see the names or the
25 affiliations of the authors, then there was nothing in

1 the conflict of interest they didn't realise this
2 potential conflict of interest. It was unseen to them.
3 And so that led, then, to a review and the decision by
4 the editors for a retraction.

5 And it must be said that the note about that notes
6 that Dr Kekic, the first author, disagrees with the
7 retraction on behalf of all authors.

8 Q. You just said that then the data from that paper was
9 taken and added to, and then forms the 2026 studies; is
10 that correct?

11 DR CHRISTODOULOU: That's correct.

12 Q. Was this a study that was performed across multiple
13 Trusts?

14 DR CHRISTODOULOU: So these studies are meta analysis, so
15 they take results that have been collected in different
16 studies and they bring them together to analyse them all
17 together, and understand whether there is any signal
18 that we can capture by bringing all this together.

19 Q. What did they look at in this study?

20 DR CHRISTODOULOU: So in this study they looked at incident
21 reporting data from six NHS Mental Health Trusts. They
22 looked at changes in self-harm, falls, assaults,
23 physical restraint and rapid tranquilisation, after the
24 implementation of the platform.

25 Q. One of the criticisms that has been levelled at some of

1 the other studies we've looked at is that they're small
2 or single-centred. Are those concerns alleviated to any
3 extent in this study?

4 DR CHRISTODOULOU: In general, meta analysis try to deal
5 with, among other issues, this problem: the problem that
6 a lot of smaller studies may be providing evidence that
7 can be seen only if we put all of them in one place and
8 analyse them all together. The principal problem that
9 this kind of analysis may have is that every single
10 study has its own quirks, which means they may not be
11 comparable or it may not be possible for us to get the
12 right effect estimate, the right estimate from all of
13 them, because some of them are too different to include
14 in the same place. We are comparing things that are not
15 exactly comparable.

16 Q. So you're, to put it in slightly blunt terms, I suppose,
17 putting things together that aren't the same but trying
18 to get them to -- trying to get to a conclusion that
19 they're all pointing in the same direction?

20 THE CHAIR: Not comparing like with like?

21 DR CHRISTODOULOU: That would be a main issue. So we need
22 to first assess how similar, how homogenous the things
23 we are looking into are before we can do this kind of
24 analysis.

25 DR HAYES: Did the authors of this study do an assessment of

1 heterogeneity?

2 DR CHRISTODOULOU: Not formally, to my understanding.

3 Q. Does that limit the weight that can be put on the
4 findings of the study?

5 PROFESSOR DONNELLY: They do provide tables. So there's
6 supplementary information that is provided, so that if
7 you were interested you can see these changes and how
8 they varied, depending on which Trust. And so on. And
9 then there's even additional data by ward. So you can
10 look at the variation there. So that is available to
11 look at. And that is an online supplement of
12 information which is a common way to do things these
13 days.

14 Q. Overall, what did the study identify in respect of the
15 benefits that may be associated with Oxevision?

16 PROFESSOR DONNELLY: So they were quite cautious in the way
17 that they -- in drawing the conclusion:

18 "This research highlights a promising association
19 between the use of a contactless patient monitoring
20 platform and reductions in safety events in inpatient
21 mental health settings."

22 So that is acknowledging that it's an association
23 rather than being able to prove causation given the
24 structure of the data that were there. And then it
25 specifically says that:

1 "Further studies with stronger methodological
2 controls are needed to validate the findings."

3 So it's, again, a step in the building of the
4 evidence database -- on which people can rely, but
5 again, we're sort of trying to work toward a situation
6 where you have replication and you have analyses of data
7 where we have replicates, we have multiple Trusts,
8 multiple wards within that, and ideally, you would like
9 a range of ward types if you're thinking of rolling this
10 out to a wider population.

11 Q. I think, at paragraph 2.12 of your report you say:

12 "However, important methodological limitations
13 substantially affect interpretation of these findings."

14 DR CHRISTODOULOU: Mm-hm.

15 Q. And is that a reflection of the same sort of limitations
16 that we've discussed previously, so each one of the
17 individual studies that were looked at were relatively
18 small, they were before-and-after studies?

19 DR CHRISTODOULOU: When conducting any analysis what the
20 input is and the quality of the input would be impacting
21 the reliability of the result. If there are concerns
22 about the original data-gathering processes in the
23 component studies, those would be entered in the meta
24 analysis. They could be minimised because they become
25 just one piece of evidence but they're still present.

1 So these are -- concerns that are in earlier studies and
2 brought in to the study will still be present.

3 Q. How did those concerns about the initial studies impact
4 the weight that you thought should be given to the
5 findings in this study?

6 DR CHRISTODOULOU: The method of the use specifically is
7 assuming that the estimate we're trying to capture in
8 all the study components is the same, but just a little
9 bit of uncertainty surrounding it. This is a relatively
10 strong assumption to make, especially since the
11 component studies have limited samples themselves. We
12 cannot verify that assumption from where we are right
13 now and it is quite difficult for us to put high burden
14 of evidence to this when we know that the original
15 components may have issues and the main assumption that
16 they all bring in the same estimate and signal into the
17 analysis, and they're all comparable, is something we
18 haven't tested.

19 Q. So whilst it was -- whilst it built on those previous
20 papers we discussed --

21 DR CHRISTODOULOU: It does.

22 Q. -- would it be correct to say that it still needs to be
23 treated with caution?

24 DR CHRISTODOULOU: *(The witness nodded)*.

25 Q. And should be afforded relatively low evidential weight?

1 DR CHRISTODOULOU: And I think they say themselves that
2 adding more studies with stronger methodological
3 controls will assist in understanding the system better.
4 Q. The final two papers I want to discuss in this section
5 of your report are the systematic reviews. One is by
6 Griffiths et al, and you discuss this at paragraph 2.13
7 of your report. The other one is or was undertaken by
8 SQW for the Care Quality Commission and that's discussed
9 in the following paragraph.

10 Can I start first with: what is a systematic review
11 and how does it differ from the other studies we've been
12 looking at?

13 PROFESSOR DONNELLY: So a systematic review is systematic by
14 design so that is that you specify a search criteria
15 that you're going to use to identify relevant studies.
16 So it doesn't involve the researchers sitting down and
17 thinking: oh, what are the people -- the papers that
18 I know, or studies that have been done by someone I've
19 heard of?

20 You systematically go through a database with search
21 terms that will identify relevant studies. You then
22 have inclusion and exclusion criteria, that those should
23 be specified, and that will allow you to choose what you
24 will include and exclude. Some might have to do with
25 scope. Some might have to do with the type of study.

1 So you might be saying, okay, I want to look at things
2 that measure impact on assaults. You might want to do
3 impacts on self-harm. But you might decide that
4 although it's important, it's out of scope to look at
5 qualitative studies.

6 So once you do that then you have criteria that you
7 go thorough. Often there are multiple authors that will
8 independently evaluate the studies, both conduct the
9 search and decide on the inclusion and exclusion. And
10 so then you can go back, and if they disagree, have a --
11 they either have a discussion or have a third party come
12 in and they all decide together what the judgement is.
13 And that gives you then a good snapshot at that point in
14 time of what the relevant database was.

15 So again, it doesn't mean that you can't use one
16 flawed study to cancel out another one and say they're
17 all going to average because there might be errors that
18 made them systematically biased in a particular way.
19 But it allows you to go through and then evaluate those
20 studies.

21 So in a systematic review sometimes you will have
22 several studies that are similar enough in design and
23 the parameter that they're trying to estimate, for
24 example reduction in assault incidents or self-harm
25 incidents, that allows you to then combine and get

1 a single estimate, and evaluate how much that
2 estimate -- did it vary more than we would expect it by
3 chance between the different studies? Or it may be more
4 qualitative, that you're combining these things and
5 saying: okay, these are different ways of looking at the
6 same type of problem but not directly comparable.

7 And then you go through and systematically evaluate
8 those studies and bring together the data, the state of
9 play at that point.

10 Now, it's one snapshot in time because there will
11 continue to be new studies but it's really useful to
12 have someone who's evaluating the data systematically,
13 drawing together these strands of evidence and bringing
14 them together.

15 Q. Is it correct that the authors in this systematic review
16 performed a review of surveillance-based technologies in
17 inpatient and acute mental health settings? Is that
18 what they set out to do?

19 DR CHRISTODOULOU: Yes, they performed a systematic review
20 on those -- (overspeaking) --

21 Q. And when they undertook that task, what did they
22 identify? What were the findings?

23 DR CHRISTODOULOU: They studied 32 studies that actually met
24 the inclusion criteria. And they looked into both
25 qualitative and quantitative studies. We have been

1 talking extensively about quantitative studies but
2 qualitative studies are also particularly important
3 because they can bring in lived experience a lot more
4 extensively.

5 And for the quantitative studies they looked at the
6 similarity or the heterogeneity that we were discussing
7 on the previous paper, carefully, and decided not to
8 conduct the meta analysis because they found the data
9 that were present to be too different to bring together
10 into a single analysis. They felt that the current
11 level of evidence, as of the time of publishing, which
12 was in 2024, was limited and they -- there was
13 insufficient evidence, as they say themselves, to
14 suggest that surveillance technology in inpatient mental
15 health settings are achieving their intended outcomes
16 such as including safety and reducing costs. That was
17 one of the main conclusions.

18 Q. Was that conclusion echoed in the second systematic
19 review?

20 DR CHRISTODOULOU: The second systematic review was a rapid
21 review, which means they had a more condensed time to do
22 the review and present their findings. They still used
23 specific standards to ensure that they were following
24 the appropriate steps, and they do echo that the
25 evidence is limited and some of the studies are of

1 moderate or low quality.

2 Q. Did the SQW review also note that much of the evidence
3 base was polarised in that it was either produced by an
4 organisation with an interest in vision-based patient
5 monitoring systems or by organisations campaigning
6 against its use?

7 DR CHRISTODOULOU: They do bring that there conflict of
8 interest that could be in some of the results, and
9 the -- counter interest in them.

10 Q. Did it also note that lived experience evidence in this
11 field was limited and so much of the evidence focused on
12 clinical efficiency rather than patient outcomes or
13 experiences?

14 DR CHRISTODOULOU: They do, and the systematic review by
15 Griffiths et al also mentioned that lived experience is
16 a lot more limited than it ought to be.

17 PROFESSOR DONNELLY: I'd just like to clarify there when you
18 say patient outcomes, so in some sense a patient
19 outcome, a self-harm incident is a patient outcome. So
20 it's just -- so there would be, you know, patient --
21 relevant patient data is being analysed in the
22 quantitative studies but it's this fuller picture that's
23 often not being gathered.

24 Q. Is that fuller picture -- was that picture limited by
25 the absence of lived experience data?

1 DR CHRISTODOULOU: Yes, many studies do not include any
2 lived experience or any interviews from patient and
3 staff.

4 Q. And is the absence of that a prominent feature of the
5 evidence base relating to Oxevision?

6 DR CHRISTODOULOU: It is a very common feature but it's not
7 always. There are some papers that do include some
8 interviews.

9 PROFESSOR DONNELLY: And the SQW report specifically
10 supplements it with interviews, so they specifically --
11 and it's 11 stakeholders which is in some sense a small
12 number but they would be in detail.

13 Q. Can I turn to your conclusions on Section 2 as a whole,
14 which is set out, I think, at paragraph 2.1 to 2.3 of
15 your report. Overall, did you summarise your view as:
16 "The evidence provides low to moderate support for
17 the hypothesis that vision-based patient monitoring
18 systems may contribute to improvements in some safety
19 outcomes but substantial uncertainty remains regarding
20 the size, causality, generalisability and acceptability
21 of these effects."

22 DR CHRISTODOULOU: That's correct.

23 PROFESSOR DONNELLY: Yes.

24 Q. We've touched on the limitations in respect of causality
25 and generalisability as we've gone along but can I ask

1 you what you mean by acceptability?

2 DR CHRISTODOULOU: When we do not include more extensive

3 qualitative research that would bring in, for example,

4 the experience of the people working on the wards or the

5 people being in the wards as patients, then that gives

6 us our very numbers-focused understanding of the

7 situation, which does not capture the entirety of the

8 context, where the numbers were generated. Again, it's

9 about providing context to the numbers.

10 Q. Is one thing that might be missed because of that

11 whether or not the interventions, whether or not

12 Oxevision, even if it does have an effect, is acceptable

13 to patients, whether or not they will allow it to be

14 used?

15 DR CHRISTODOULOU: Are you asking about whether consent was

16 sought in the studies, or ...?

17 Q. No, what I'm asking is: in the absence of lived

18 experience data and qualitative data, is there a risk

19 that whether or not the intervention is acceptable to

20 patients will be lost?

21 DR CHRISTODOULOU: Yes, we will not have any way of

22 recording what they believe will be the appropriate

23 implementation of the method.

24 PROFESSOR DONNELLY: Lived experience can also inform people

25 who are considering an intervention in how they

1 communicate with the patient population. So it's not
2 just -- I mean, something not being acceptable may be
3 a function of what you understand about it, and
4 understanding only some components of it.

5 So the benefit of getting the views of staff as well
6 as patients who are there is to actually understand how
7 people perceive it, to understand whether or not they're
8 only understanding one component and whether or not
9 they're -- they have a fully rounded view. Because it
10 may be that people have a misunderstanding of how it's
11 working or why it's there. And that engagement may
12 actually improve things for everyone.

13 DR CHRISTODOULOU: And it could be that it's not
14 a misunderstanding but it is something that they -- that
15 the creators of the technology had not considered, which
16 means they can make an improvement. It gives everybody
17 the opportunity of engaging more fully with the process.

18 Q. I'd like now to turn to Section 1 of your report, which
19 commences at page 11.

20 What sorts of study do you consider at Section 1 of
21 your report?

22 DR CHRISTODOULOU: We looked at four studies that were
23 examining the economic impacts that may be associated
24 with the implementation of the vision-based monitoring
25 system.

1 Q. Now, is it correct that these studies do not, in and of
2 themselves, actually seek to evaluate whether or not the
3 system confers a benefit on patients; they're purely
4 looking at the economic savings that may be realised if
5 the system is deployed?

6 DR CHRISTODOULOU: That's correct.

7 Q. There are four studies in this section. Information
8 about each study is set out at paragraphs 1.4 to 1.7 of
9 your report, and I think your general observations are
10 at paragraphs 1.1 to 1.3.

11 But, in summary, was it your view that this body of
12 evidence may be regarded as providing low to moderate
13 strength evidence regarding the potential economic
14 implications of Oxevision. It identifies plausible
15 mechanisms through which financial savings could be
16 achieved but does not provide robust independent
17 evidence that equivalent savings will be realised
18 consistently across NHS mental health services in
19 routine practice.

20 DR CHRISTODOULOU: That's correct.

21 PROFESSOR DONNELLY: Indeed.

22 Q. Can I ask about economic evaluations generally, then.

23 How do they go about this task of working out whether or
24 not the system would result in costs or savings?

25 DR CHRISTODOULOU: The type of economic evaluations that we

1 have examples of here is based on a model, a model of
2 what the costs are going to be and what costs could be
3 reduced or increased after the implementation of an
4 intervention. So one of the first steps would be to try
5 and ensure that we have a clear understanding of all the
6 outgoing costs that are connected with the unit of
7 study, for example ward or an NHS Trust.

8 Once this is done, what they need to be doing is
9 they need to be finding what changes are going to be
10 happening after we've implemented our intervention. So
11 they need to get an understanding of how the
12 intervention is impacting the specific components of
13 their model. After doing that, what they are doing is
14 a comparison, a comparison of what the costs would be if
15 we have the intervention implemented versus the costs if
16 we don't have it.

17 It is a model and not something that's tested in
18 a real-life situation so that is fundamentally different
19 to what we're looking into in the Section 3 studies,
20 where they are entering a ward and they're trying to
21 take those measurements and they're looking at real
22 events. But it is informed from those studies. So
23 those studies will be the input into those economic
24 models.

25 Q. So at a very basic level, they take estimates of

1 assumptions about the cost of the system, the outcomes
2 that will happen if a system is or isn't deployed and
3 the costs of the results, so self-harm incidents,
4 et cetera, and try to work out whether or not there's an
5 economic saving?

6 DR CHRISTODOULOU: That is correct.

7 Q. Does it follow, therefore, that these models are only as
8 good as those inputs that feed into them?

9 DR CHRISTODOULOU: All models are as good as the inputs we
10 feed into them.

11 PROFESSOR DONNELLY: And also I think it's worth deciding
12 that some decision always has to be made on what the
13 scope of what you're considering. For example, if you
14 have prevention of a self-harm incident. So that would
15 have economic benefits in terms of not having to call
16 out emergency services, but there would also be
17 potentially less disruption to the friends or family of
18 the person if they were to come and visit more and have
19 to provide more support, which none of those additional
20 sort of significant others are considered in this. And
21 I think that that's because it's difficult to do that,
22 but it's always the case that when you have an economic
23 impact that you have -- it has a defined scope, and
24 there will almost always be cases where there are
25 knock-on effects that are not considered. That's not

1 a criticism of these, it's just reality.

2 But -- so even with -- but within that scope, then
3 they have to rely on other studies for what is the
4 reduction that you might see in self-harm events or in
5 assaults, and then that feeds into the (unclear).

6 And then a key one of these was also the reduction
7 in staff time that was needed for one-to-one monitoring
8 of patients.

9 Q. Let's take a look at some of these in a bit more detail
10 because, as I understand it, if you're trying to
11 interrogate the conclusions of these studies, then you
12 have to look at those inputs and -- that went into the
13 studies to work out whether or not the -- or the
14 strength of the conclusions that are drawn.

15 The first point relates to the generalisability of
16 these studies, though. At paragraph 1.1 of your report
17 you say that:

18 "This group of publications examines the potential
19 economic impact of Oxevision within NHS mental health
20 inpatient settings including acute adult wards, older
21 adult services and Psychiatric Intensive Care Units."

22 Is it correct that those were the only settings that
23 were looked at across these papers?

24 DR CHRISTODOULOU: That's correct.

25 Q. So does it follow that you would have to be cautious

1 about extrapolating the findings from these models to
2 other settings? So CAMHS wards, or forensic wards,
3 wards for patients with learning disabilities, those
4 kind of settings?

5 DR CHRISTODOULOU: Extrapolating, you always need to make
6 sure that you have enough evidence to be able to do so,
7 and going to something such as completely different type
8 of ward would be something to be done with a lot of
9 caution.

10 Q. Can I go to the first study by Malcolm et al. You
11 discuss this at paragraph 1.4 of your report on page 11.
12 What did this study conclude?

13 PROFESSOR DONNELLY: So to use the words of the authors, so:
14 "This early analysis indicated that the vision-based
15 system is likely to be cost saving within both settings
16 examined ..."

17 And the "both settings examined" were an acute adult
18 ward and an older adult mental health hospital.

19 Q. Did they conclude that the key driver of those savings
20 was a reduction in the level of one-to-one observations?

21 PROFESSOR DONNELLY: Yes, that was the key cost savings that
22 was there.

23 Q. And was it the case that those savings would be cash
24 generating because they were likely to be undertaken by
25 agency staff?

1 PROFESSOR DONNELLY: So it was a matter of reducing -- what
2 they found was they had an estimate of the reduction in
3 one-to-one observation hours. In terms of how that
4 realised, I think it was talking about the reduction of
5 per patient, per year.

6 Q. You said at paragraph 1.4 that:

7 "The acute adult model is particularly fragile, the
8 assumed 20 per cent reduction in one-to-one observation
9 hours was not statistically significant and when
10 one-to-one observations were excluded in the scenario
11 analysis, the intervention was no longer cost saving."

12 Can we just consider that in a little more detail.
13 Where did the assumption that there would be
14 a 20 per cent reduction in one-to-one observations come
15 from?

16 DR CHRISTODOULOU: So this is part of the input in the model
17 and one of the limitations that they acknowledge is that
18 they -- this is an early study that they were conducting
19 which means they were using data that were, at that
20 time, some of them published, some of them still
21 unpublished. And they were informing their estimates
22 from some internal other estimates that had been
23 provided to them before those had gone through peer
24 review.

25 Q. Does the fact that some of those inputs were unpublished

1 and hadn't gone through the peer review process that we
2 discussed earlier mean that they should be treated with
3 caution?

4 DR CHRISTODOULOU: One of the things that is a reality in
5 scientific publication is that the peer review cycle is
6 very variable, and something being unpublished doesn't
7 mean it hasn't been completed and in peer review for an
8 extensive period of time. The main challenge that this
9 raises is the fact that we as readers cannot go to that
10 study and assess the validity of an assumption. So we
11 are bringing the caution not because the study is itself
12 unpublished and that says something about the quality of
13 that study, but it tells us that we cannot assess that
14 quality, to be able to see how valid that assumption is.

15 Q. So you can't interrogate that underlying data as the
16 reader?

17 DR CHRISTODOULOU: As the reader, you want to have the
18 ability to look to that reference and actually examine.

19 Q. We talked previously about this concept of statistical
20 significance.

21 Can I bring up table 2 of OXHE020518.

22 If we look at this table, it says:

23 "Reduction in one-to-one observation hours from
24 VBPM, " and it says 20%.

25 Below, we see brackets that say, "Minus 13% to 36%."

1 Is that the confidence interval?

2 DR CHRISTODOULOU: That's the confidence interval.

3 Q. What does that confidence interval tell us about the

4 precision of this input?

5 DR CHRISTODOULOU: It is a rather wide confidence interval

6 but the part that is the most obvious thing to observe

7 is that it includes both a minus and a plus number, it

8 means that it includes zero. Now, I need to bring to

9 your attention the phrasing of this statement, it says

10 "reduction in one-to-one observation" that means

11 a positive number means a reduction, and a negative

12 number means an increase. So the confidence interval

13 includes both reduction up to 36%, and an increase to

14 minus 13%.

15 PROFESSOR DONNELLY: That means that if you were thinking

16 about it in terms of hypothesis testing, if your null

17 hypothesis was that there was no change in one-to-one

18 observation hours in this context, then you would not

19 reject. So the data has not convinced you to reject

20 that null hypothesis.

21 Q. So again, when we're talking about this reduction in

22 one-to-one observation hours being cost saving, that's

23 a conclusion that we need to treat with caution?

24 PROFESSOR DONNELLY: Indeed.

25 DR CHRISTODOULOU: *(The witness nodded)*.

1 PROFESSOR DONNELLY: So the conclusion on that specific
2 reduction is that, you know, there's a lot of
3 uncertainty about that, and for cost saving to rely on
4 that particular line item, as it were, is as uncertain
5 as this specific result is.

6 So it's possible that there could have been, you
7 know, within this confidence interval a need to increase
8 one-to-one observation hours, in which case, you know,
9 that -- you don't see a saving there at all. You
10 actually see an increase there as well as other places.

11 Q. Did the authors of this study perform an analysis using
12 only those results which were statistically significant?

13 DR CHRISTODOULOU: They did.

14 Q. And when they did that, what were the results, in terms
15 of cost saving?

16 DR CHRISTODOULOU: They didn't find the same cost savings
17 that they had found before. Those didn't materialise.

18 Q. Can I go to the bottom of page 9 of this document,
19 please. Now this is the discussion section. And they
20 say:

21 "The introduction of [vision-based patient
22 monitoring] to supplement standard care was shown to
23 save costs when evaluated in acute adult wards ..."

24 Is that a stronger conclusion than the data really
25 allows?

1 DR CHRISTODOULOU: I don't believe it's as cautious as it
2 could be. It doesn't contextualise it appropriately.
3 In some situations they did demonstrate to save costs
4 but it wasn't contextualised on the fact that this was
5 based on estimates that were not necessarily showing
6 a reduction on those.

7 PROFESSOR DONNELLY: And I think you will see the authors
8 using different terminology elsewhere. For example, if
9 you go to the conclusions, which is the next page:

10 "The results of the current early analysis suggest
11 that augmenting standard care with a vision-based system
12 produces cost savings."

13 So that's a more cautious statement.

14 Then finally, in the "Results and Conclusion" in the
15 abstract, an abstract is a short version of the paper,
16 usually published at the beginning, often that's
17 structured, in this case it is, so under "Results and
18 Conclusions", they say:

19 "This early analysis indicated that the vision-based
20 system is likely to be cost saving."

21 Now, that is not a set of wording that we would say
22 is statistically based on what's here, so we don't have
23 a likelihood of whether or not this would be realised.
24 I think that what they're reflecting there is that their
25 estimate of a 20 per cent reduction leads to an estimate

1 of a reduction in costs, but as we've shown, we're
2 uncertain about the 20 per cent reduction to the point
3 that it might not be a reduction at all, in which case
4 that would mean that there wasn't cost savings.

5 Q. Can I move on to the second study by Malcolm et al.
6 That is discussed at paragraph 1.5 of your report on
7 page 12. Is it correct that this essentially was
8 a similar economic analysis but the study -- as the
9 study we were just looking at, but it was looking at the
10 economic benefits of Oxevision in Psychiatric Intensive
11 Care Units instead?

12 DR CHRISTODOULOU: That's correct.

13 Q. Did the data on clinical effectiveness in this study
14 derive from a single unpublished before-and-after study?

15 DR CHRISTODOULOU: Yes, that's correct.

16 Q. And so --

17 DR CHRISTODOULOU: At the time unpublished, (unclear).

18 Q. And so do the same issues, in terms of single-site,
19 small studies that we looked at previously apply to this
20 input?

21 DR CHRISTODOULOU: Everything would transfer over as
22 a similar concern.

23 PROFESSOR DONNELLY: And they note in their conclusion:
24 "However, this is based on a single-centre
25 observational before-and-after study."

1 So observational is as opposed to experimental, so
2 observational is observing things as they occurred as
3 opposed to what you -- like an example of an
4 experimental study is a randomised control trial. And
5 that's where you're randomising the treatments to these
6 things and therefore it's an experimental study.

7 Q. Then we look at the confidence intervals in this study,
8 we see that the base case reduction in one-to-one
9 observations is 7 per cent but the lower bound
10 confidence interval is minus 41 per cent; is that
11 correct?

12 PROFESSOR DONNELLY: Yes, so that represents a 41 per cent
13 increase.

14 Q. Does that highlight exactly the same issues that you
15 just discussed in respect of the previous study when
16 talking about wide confidence intervals and confidence
17 intervals across zero?

18 PROFESSOR DONNELLY: Indeed, and this one's even wider.

19 Q. In this study, when the authors restricted their
20 analysis to those assumptions that were statistically
21 significant, what happened to the economic savings?

22 PROFESSOR DONNELLY: So --

23 DR CHRISTODOULOU: When they restricted it only to the
24 significant results, the actual magnitude of the
25 economic benefits that they had originally established

1 decreased substantially. So it would go, for example,
2 from the total cost of occupied bed day, it went to --
3 there was no difference between the standard care and
4 the standard care with the vision-based system, and in
5 the original, the cost savings would have been at the
6 £18, and then expanded to the average-sized ward per
7 year, the overall savings in this new scenario that
8 excludes one-to-one observations is reduced to £1,140 as
9 opposed to £72,000.

10 Q. Can I look at another one of the assumptions that they
11 used in this study. Is it correct that they assumed
12 that the cost of staff to conduct one-to-one
13 observations per hour was £30 an hour?

14 DR CHRISTODOULOU: That is the one for the nighttime
15 observations, yes.

16 Q. And would it follow that if in fact the staffing costs
17 were less than £30 an hour, then the economic benefits
18 would be reduced?

19 DR CHRISTODOULOU: Can I clarify what you mean by staffing
20 costs? Because I suspect they mean the cost to the
21 employer rather than the actual salary of the staff.

22 Q. Yes, if the hourly rate cost to the employer was less,
23 then --

24 DR CHRISTODOULOU: Yes.

25 Q. -- the economic benefit would be -- commensurably be

1 less, as well?

2 DR CHRISTODOULOU: Of course.

3 PROFESSOR DONNELLY: Yes.

4 Q. At paragraph 1.5 you conclude that "The base case

5 conclusion is highly fragile." Can I ask what you mean

6 by that?

7 DR CHRISTODOULOU: By that, we mean that if we have such

8 difference in magnitude that is connected to a single

9 estimate with quite high levels of variability like the

10 confidence interval we saw, it means we are very

11 uncertain as to what actual economic benefits we would

12 be seeing in a real-life situation because remember this

13 is an estimate that comes from a model rather than an

14 actual realisation that was captured in real world.

15 Q. Final question on this paper. Is it correct that both

16 this and the other Malcolm study were funded by

17 Oxehealth?

18 DR CHRISTODOULOU: The -- Oxehealth funded the research

19 institute that the researchers were based at, yes.

20 Q. And does that give rise -- (overspeaking) --

21 PROFESSOR DONNELLY: Yes, so it says that the authors are

22 employed by York Health Economics Consortium, and that

23 consortium was funded by Oxehealth to develop the

24 economic model and manuscript.

25 Q. And does that give rise to similar concerns relating to

1 independence as we saw or we discussed earlier?

2 DR CHRISTODOULOU: It would be similar concerns.

3 PROFESSOR DONNELLY: -- (overspeaking) --

4 DR HAYES: Chair, it is suggested that we may stop now for
5 a 45-minute lunch break.

6 THE CHAIR: That's fine, thank you very much, Dr Hayes.

7 Forty-five minutes.

8 **(12.31 pm)**

9 **(The Short Adjournment)**

10 **(1.15 pm)**

11 **(Proceedings delayed)**

12 **(1.20 pm)**

13 THE CHAIR: Dr Hayes.

14 DR HAYES: Can I start just by returning to a point that we
15 were dealing with in respect of the first study by
16 Malcolm et al before lunch.

17 Can I have on screen OXHE020518, please, at page 6.
18 And can we just zoom in on the top half. If we look
19 here at where it says, "One-to-one observation hours" on
20 the left-hand side, at the bottom it says:

21 "Proportion of one-to-one observation hours that is
22 cash releasing."

23 And there is a footnote for note 8, do you see that?

24 Can we go to the bottom of this table and then if we
25 look at footnote a, it says:

1 "Cash-releasing savings refers to savings that bring
2 in an in-year monetary return without changing safe
3 staffing levels (eg through reduction in agency staff
4 while maintaining safe staffing levels)."

5 Was the way in which cash savings were realised by
6 reduced observations in this paper that there would be
7 a decreased requirement for agency staff?

8 PROFESSOR DONNELLY: I think, as -- I mean, the "eg" is, for
9 example, and that's what they've used there. Obviously,
10 they have to make sure that safe staffing levels are
11 maintained throughout, and it would depend on how
12 reliably that reduction could be seen, whether or not
13 they could count on that.

14 So obviously you couldn't just pay people
15 20 per cent left if they didn't have to do as many
16 observations. So it was a matter of how many agency
17 staff were in use. If there wasn't agency staff used to
18 begin with, it might be hard to realise that full
19 reduction.

20 Q. Can I turn now to the paper by Buckley et al. You cover
21 this at paragraph 1.7 of your report on page 13. Did
22 you identify that this study had been retracted on
23 15 July this year?

24 DR CHRISTODOULOU: Yes, we did.

25 Q. Can you explain the reasons that the article was

1 retracted?

2 DR CHRISTODOULOU: So the reasons the article was retracted
3 are described on the retraction note that was published
4 on 15 July 2026. And the editorial team stated that
5 there were aspects of the study design that they felt
6 were not adequately justified, and those included
7 inconsistencies in data sources for clinical parameter
8 model inputs, selection of some specific assumptions and
9 inputs, and data restrictions such as that the authors
10 did not have access to the clinical data from all five
11 studies that informed the model inputs.

12 They also felt that there may have been bias in the
13 selection of modelling the data and the risk of bias in
14 modelling the data in view of competing interests was
15 not adequately addressed by processes used to evaluate
16 data sources or in the analytical approaches to evaluate
17 uncertainty.

18 They did not report any sensitivity analysis, or the
19 details of the model developed in the study and the
20 above made them decide to retract the article. The --
21 all authors agreed with the retraction.

22 Q. Now this article has been retracted, does it follow that
23 no real weight should be placed on its conclusions?

24 DR CHRISTODOULOU: Can you repeat the question, please?

25 Q. Now the article has been retracted, has it fallen out of

1 the evidence pool, in effect?

2 DR CHRISTODOULOU: When an article is retracted it remains
3 in the public domain, it is labelled as "retracted"; it
4 is not removed for us not to know what has happened. We
5 can still see the work that they did and how they
6 presented it. The fact it's been retracted is telling
7 us that some of the assumptions did not pass the
8 criteria or some of the methods used did not pass the
9 criteria of the journal and we need to take this into
10 consideration.

11 THE CHAIR: And would we be right to place no evidential
12 weight on it?

13 PROFESSOR DONNELLY: You'd have to use considerable caution
14 when relying on that.

15 DR CHRISTODOULOU: Yeah.

16 THE CHAIR: Thank you.

17 PROFESSOR DONNELLY: Perhaps it would be useful for me to
18 explain what a sensitivity analysis is, since that was
19 mentioned. So a sensitivity analysis is a general term
20 that is looked at to show the robustness of a result.

21 So in a sensitivity analysis you might change the
22 structure of the model, in certain ways. So that could
23 be variation in parameters, so, for example, what
24 proportion of one-to-one observation you reduce, but you
25 might also structurally change the model in a different

1 way. It's not specific to a particular way of doing it
2 but it means, you know, looking at the robustness of the
3 conclusions.

4 DR CHRISTODOULOU: And it was also done in multiple
5 publications. For example, the two Malcolm et al papers
6 have sensitivity analysis for when they removed the
7 one-to-one observations to see how that changed their
8 estimates.

9 DR HAYES: There's one final point I'd like to consider in
10 respect of this article.

11 Can I have on screen OXHE020526 at page 2.

12 We see on the left here where it says, "Funding" and
13 "Competing interests" a statement to the effect that:

14 "Oxevision were jointly involved in the decision to
15 publish and reviewed the final manuscript."

16 Is that usual practice?

17 DR CHRISTODOULOU: It is not usual practice to do this when
18 none of the authors are included in, so it's -- the
19 authors can come to the decision of publishing the
20 manuscript. If somebody external to the authors has
21 input on that decision, that could be a conflict of
22 interest that we need to be aware of.

23 Q. What is the -- it may be obvious but what is the issue
24 that arises if people who aren't authors to the paper
25 are making a decision as to whether or not it should be

1 published?

2 DR CHRISTODOULOU: That would imply that if there is
3 disagreement, for example, between what the authors are
4 presenting and what the external party feels should be
5 published then that may say that this is not allowed to
6 go to publication.

7 Q. Can I turn to the York Health Economic Consortium
8 analysis, this is at paragraph 1.6 of your report.

9 Now, is this the fourth and final economic analysis
10 that you were provided with?

11 DR CHRISTODOULOU: It is.

12 Q. And is it correct to say that it also showed that there
13 was a possibility for economic benefits to be realised
14 by deployment of the Oxevision system?

15 DR CHRISTODOULOU: It does.

16 Q. Is it also correct that the analysis in this paper is
17 subject to the same considerations that we discussed in
18 relation to the two Malcolm papers?

19 DR CHRISTODOULOU: Yes, and furthermore, that particular
20 analysis, because it's at an earlier stage, as we
21 understand it, does not have any measures of
22 uncertainty, which the Malcolm paper does, that's how we
23 saw the confidence intervals being quite wide. Here we
24 do not have that in the same way, and they also stated
25 that they, I believe, had no full access to the data to

1 begin with. Here, yes.

2 PROFESSOR DONNELLY: Yes, the data analysis was carried out

3 by Oxehealth, and the York Health Economics Consortium

4 has not had a view of the data used for the analysis.

5 Q. What is the significance of that?

6 PROFESSOR DONNELLY: That gets us back to the same thing

7 that happen with the previous paper. That the people

8 who -- the authors of this report were not given access

9 to the full data so that they might have not been aware

10 of all the patterns that were there.

11 Q. So the assumptions made in them, they weren't able to

12 interrogate properly the assumptions that were deployed

13 in the model?

14 DR CHRISTODOULOU: *(the witness nodded)*

15 PROFESSOR DONNELLY: Indeed, they would be taking it on good

16 faith from the estimates and summaries that were

17 provided to them.

18 Q. Does the fact that the uncertainty analysis wasn't

19 provided in this paper in the same way as it was the

20 Malcolm papers, does that mean that we have to be even

21 more cautious in relying on the data from this paper

22 when considering what economic benefits may or may not

23 be realised?

24 DR CHRISTODOULOU: That is correct.

25 Q. Can I take the three economic analyses or -- actually,

1 all four of them. They look at or they incorporate into
2 their models a consideration of bed occupancy; is that
3 correct?

4 DR CHRISTODOULOU: They do.

5 Q. And the reason for that is that you would get more
6 benefits from the system if your beds were occupied 100
7 per cent of the time than if 50 per cent of them were
8 empty; is that correct?

9 DR CHRISTODOULOU: That's correct.

10 Q. Does it follow that a similar adjustment therefore would
11 be required in respect of patients that may not consent
12 to use of the system?

13 DR CHRISTODOULOU: Can I clarify, are you asking that if
14 something is implemented but then patients elect not to
15 use it, then that would mean that the benefits that are
16 associated with the estimate would not be accurate, for
17 the reduced usage?

18 Q. Yes, that's the point I am getting at.

19 DR CHRISTODOULOU: That's correct.

20 Q. And if patients ultimately chose not to consent to use
21 of the system then the economic benefits will be
22 reduced.

23 DR CHRISTODOULOU: It's very similar to the idea of when
24 looking at the staff costs, if the numbers that are used
25 to estimate the overall cost, if any of the multipliers

1 change, the overall benefits will alter.

2 PROFESSOR DONNELLY: I should add, though, a consideration
3 would be that we wouldn't be aware of what the contract
4 is for the costs. So there would be, like, a licensing
5 fee, for example, and whether or not that licensing fee
6 depended on its actual use or whether or not it was
7 licensed, so while it's in the room it's being paid for.
8 So we don't have access to the details of that and
9 I imagine they might be considered commercial,
10 confidential, but whether or not the costs change as
11 well as the benefits would be important in looking at
12 what the impact was.

13 Q. Can I ask about your overall conclusions in respect of
14 these papers, the economic analyses. How would you
15 summarise the evidence base in support of the
16 proposition that the deployment of the Oxevision system
17 will generate savings for Trusts that deploy it?

18 PROFESSOR DONNELLY: I think that first we have to see that
19 the -- the outputs can only -- it can't be any stronger
20 than the inputs and so the inputs in terms of the
21 estimates of benefits in terms of both reductions in
22 one-to-one monitoring as required by staff, and the
23 reductions in, for example, ligature incidents or
24 self-harming more generally, to the extent that those
25 are uncertain, that uncertainty carries through. And

1 then we have additional assumptions that are brought in
2 in terms of economic costs. So those things.

3 And to the extent that we don't have a rigorous
4 sensitivity analysis to look at how robust these things
5 are, there is considerable uncertainty. So I think that
6 these things provide suggestions that there could be
7 cost savings in the wards in which they had looked at
8 them, but I would say it's not convincing evidence.

9 DR CHRISTODOULOU: The evidence is limited. We will need to
10 see more evidence to be able to assess that.

11 Q. And presumably that uncertainty and the limitations on
12 that evidence are greater, the more that the environment
13 in which you're deploying the system differs from those
14 in the research papers?

15 DR CHRISTODOULOU: It would involve extrapolation in
16 environments we have not tested so we wouldn't be able
17 to tell how different or how similar they would be.

18 Q. I'd like to go quickly to Sections 3 and 4 of your
19 report.

20 Section 3, I believe, commences at page 22 of your
21 report, where you say:

22 "This body of evidence primarily addresses the
23 technical feasibility, measurement performance and
24 practical implementation of non-contact video-based
25 physiological monitoring rather than its clinical

1 effectiveness."

2 So is it correct to say that in this third section
3 of your report you reviewed studies which looked at how
4 well Oxevision performs in its role as a measurement
5 device?

6 DR CHRISTODOULOU: We were looking at the system and some of
7 the references are more historical on the development of
8 the system, so earlier levels of this particular set-up.
9 It wasn't necessarily everything that resulted in what
10 is Oxevision, but we saw this idea of the camera set-up
11 trying to monitor specific vital rates.

12 Q. Specifically a patient's heart rate and breathing rate?

13 DR CHRISTODOULOU: Exactly.

14 Q. So these studies are focused on whether or not the
15 system can accurately measure those parameters.

16 Is that correct?

17 DR CHRISTODOULOU: Yes.

18 PROFESSOR DONNELLY: Yes.

19 Q. What it doesn't provide is an assessment of whether
20 measuring those parameters in turn confers a benefit on
21 patients in terms of their outcomes?

22 PROFESSOR DONNELLY: Indeed, the ones in this section were
23 not set out to do that in the first place, and in some
24 cases they involve populations that are very --
25 neonates, for example, which is a very important

1 question in and of itself but doesn't translate directly
2 to impact here.

3 Q. What were your conclusions as to how effective and
4 accurate Oxevision could be said to be in terms of
5 measuring heart rate and respiratory rate amongst
6 psychiatric inpatients?

7 DR CHRISTODOULOU: The primary technical validations that we
8 reviewed in different contexts demonstrate that under
9 specific conditions the measurements can be comparable
10 to measurements taken in ward from observations, but
11 these conditions would involve, for example, absence of
12 movement when the measurement is taken, multiple points
13 being available for that measurement. It was within
14 a specific range of skin tones. Anything else --

15 PROFESSOR DONNELLY: Tattoos can be an issue as well, so
16 depending on what skin is available for observation.

17 Q. So did you determine ultimately that, whilst it was
18 capable of performing those measurements, there were
19 those limitations that you just discussed?

20 DR CHRISTODOULOU: Yes.

21 Q. Finally, Section 4. Digital health. Is it correct to
22 say that these papers are, as you say at paragraph 4.4,
23 contextual evidence rather than evidence of
24 effectiveness?

25 PROFESSOR DONNELLY: (*The witness nods*).

1 DR CHRISTODOULOU: That's correct.

2 Q. Is that a statement to the effect that these

3 publications are not empirical data themselves?

4 DR CHRISTODOULOU: Empirical data is always in relation to

5 a specific question. There would not be empirical data

6 for the mental health setting on Oxevision but there

7 would be contextual information for the system, or for

8 the different settings that they're evaluating.

9 Q. So they don't provide evidence as to whether Oxevision

10 can improve safety or patient outcomes or patient

11 experience or whether or not they represent value for

12 money in mental health settings?

13 PROFESSOR DONNELLY: Indeed, they don't address that. In

14 some cases they talk about the potential for digital

15 approaches, often more generally than one specific one,

16 but it's in general terms in talking about, you know,

17 what the future may bring in many cases.

18 Q. So does it follow that in terms of study methodology or

19 statistical analysis in these papers in Section 4,

20 there's relatively little for us to invite your comment

21 upon?

22 DR CHRISTODOULOU: I believe so.

23 PROFESSOR DONNELLY: *(The witness nodded)*.

24 DR HAYES: Chair, that concludes my questions. Do you have

25 any further questions?

1 THE CHAIR: I don't.

2 Thank you, Dr Hayes.

3 DR HAYES: Can we now perhaps have 15 minutes to make final
4 arrangements for the Rule 10 process for the Core
5 Participants?

6 THE CHAIR: Yes, 15 minutes. Thank you.

7 **(1.39 pm)**

8 **(A short break)**

9 **(1.57 pm)**

10 MR GRIFFIN: Chair, we've now reached the stage where we'll
11 have questions from Recognised Legal Representatives of
12 certain Core Participants, and we'll follow the process
13 that we followed yesterday.

14 May I ask again, therefore, that before asking
15 questions, each advocate introduces themselves first.
16 Thank you very much.

17 **Questioned by MS SCOLDING KC**

18 MS SCOLDING: Good afternoon, Professor Donnelly,
19 Dr Christodoulou. I am Fiona Scolding and I'm asking
20 questions on behalf of Oxehealth Limited, trading as
21 LIO.

22 The first question I wanted to ask you is about
23 observational evidence and observational evidence in
24 respect of clinical research. Would you agree that
25 there are very many studies which are carried out which

1 are observational in nature, and whilst their weight may
2 well be less than the randomised control trial, they are
3 frequently used by clinicians and others within
4 inpatient and outpatient settings to approve, or
5 otherwise, various forms of treatment?

6 PROFESSOR DONNELLY: Yes, it is quite common to have
7 observational data, and those are important. In
8 informations -- in implementation studies in particular,
9 so we're wanting to see, okay, as this is rolled out how
10 has it gone? That is a -- one of the lines of evidence,
11 but the experimental evidence is also very strong and
12 those two together can be complementary.

13 Q. Can I ask in particular about studies within mental
14 health settings and the ethical difficulties there can
15 sometimes be in running randomised control trials? Now,
16 my understanding, which may well, and is highly likely
17 to be, imperfect, is that you can only really run
18 a randomised control trial if you're not clear whether
19 there is any ethical benefit to the treatment or not.
20 So if you're absolutely clear that the treatment is
21 useful or will be useful, you wouldn't be undertaking
22 a randomised control trial because it wouldn't be
23 ethical for those not in the -- you know, who get the
24 placebo effect -- not to have the benefit of the
25 treatment. Does that therefore make it more difficult

1 in mental health settings for there to be randomised
2 control trials? Do you have any views or observations
3 about that?

4 PROFESSOR DONNELLY: I mean if there were compelling
5 evidence that there was something that was beneficial
6 then yes, you would need to consider very carefully the
7 ethics of not implementing that. Obviously if there
8 resources -- if you saved resources here, you might be
9 able to use them in a different way to patient benefit.
10 But this is -- yeah, that's different than the case
11 where you are not yet certain what the benefit could be
12 to patients.

13 DR CHRISTODOULOU: To add to this, it is particularly
14 important when you're thinking of all these large
15 studies, to really think about how multidisciplinary
16 they are. So there is always an ethical component,
17 there would always be -- or there should always be
18 experts in ethics involved in this decision making so
19 it's not just about the statistical design, it's about
20 the statistical design, the ethics, the impact to the
21 patients, so bringing it all together. These can be
22 designed but they need to be designed cautiously.

23 Q. Okay, thank you.

24 And in particular, one of the concerns that you have
25 really about all the data and the information and the

1 studies is their relatively small size. Would you agree
2 that it's frequently difficult to get large-scale
3 studies, particularly in respect of mental health
4 settings, because simply there are fewer mental health
5 beds than there are physical health beds within the NHS
6 in the United Kingdom, or is that something that you
7 haven't seen as a particular problem?

8 PROFESSOR DONNELLY: Certainly it's the case that the
9 patient population is smaller and so therefore there
10 would be (unclear) but I think it's still important to
11 consider the range of settings that you might consider
12 rolling an intervention out into, and so to make sure
13 that they're represented but the -- and it is inevitably
14 the case and statisticians will always go to, you know,
15 of the smaller the sample size, the more uncertainty
16 you're left with. So it's that trade-off between these.

17 Q. But again, would you agree that there are relatively
18 few, other than for new drug treatments, for example,
19 for mental health, you know, antidepressants or
20 something like that, there are relatively few very
21 large-scale studies in respect of mental health
22 treatments within the UK?

23 DR CHRISTODOULOU: That may be saying more about how we are
24 designing studies for mental health rather than about
25 how -- what the problem is about the size of the mental

1 health population. So that would be a completely
2 different issue to address.

3 Q. Okay. You identify that further randomised controlled
4 research would be needed and, of course, I think we
5 accept that that is the gold standard in terms of
6 assessing the efficacy and, you know, the efficacy of
7 medical care. Is it something which is particularly
8 difficult to implement within a mental health setting,
9 do you think?

10 PROFESSOR DONNELLY: I think there would be challenges that
11 would require, as Dr Christodoulou mentioned, an
12 interdisciplinary approach to study design and careful
13 consideration of ethics as well as informed consent, and
14 understanding who could consent in which cases depending
15 on the severity of the cases. There would undoubtedly
16 be challenges, but, you know, proactively working with
17 people might actually generate more buy-in that people
18 felt empowered to take part in the study and to help
19 improve the evidence base for their treatment.

20 Q. You talk about the ethical complications. Would you
21 mind just expanding slightly on what you mean by that?
22 Is it largely issues to do with capacity and ability to
23 have informed consent?

24 PROFESSOR DONNELLY: Yes, I believe that and also the
25 trade-offs with privacy, and understanding that.

1 Q. I lastly just wanted to ask you a few questions about
2 the independence and funding. Now, as you've quite
3 properly set out, Oxehealth funded or funded the
4 researchers to carry out a significant amount of this
5 research, that is not necessarily that unusual or that
6 infrequent in the context of clinical research; is that
7 right?

8 PROFESSOR DONNELLY: That is correct but there are often
9 controls that are put in place to make sure that there's
10 either blinding in the analysis, or an independent data
11 safety monitoring board that help reduce the risk of
12 bias creeping into that calculation.

13 Q. There is also some discussion in your report about the
14 fact that the Oxehealth data, even if the individuals
15 weren't funded by Oxehealth, that the data -- their data
16 was used. But given that they are the people who are
17 generating the data, is there anything implicitly wrong
18 with that, providing that the individuals who are
19 undertaking the research understand either the limits of
20 that data or have an opportunity to see the raw data in
21 whatever format?

22 PROFESSOR DONNELLY: Sorry, could you repeat the question?

23 DR CHRISTODOULOU: Can you clarify whether you're asking if
24 somebody generating the data and somebody else using it
25 is a problem?

1 Q. Yes, yeah. So if Oxehealth generated the data but
2 somebody then analysed it who was separate to Oxehealth,
3 would that be ethically problematic?

4 DR CHRISTODOULOU: They would need to be fully in control
5 and understanding of how the data were generated and
6 present that, as well, with a description of the data
7 because that gives a lot of insight.

8 Q. Yes. Because you would need to see the raw data that
9 was underlying whatever might be produced --

10 DR CHRISTODOULOU: Not just the raw data but how the data
11 were collected. That is a particularly important
12 component, and the bigger problem with second hand use
13 of data, which is very common --

14 Q. Yeah, I was going to say that is very common within
15 clinical research, isn't it?

16 DR CHRISTODOULOU: It is very common, but the biggest issue
17 with this is the fact that when you don't see how the
18 data were generated and collected, a lot of bias that
19 may have come in that the researchers collecting it did
20 not realise was there is not visible to you anymore.

21 MS SCOLDING: Thank you very much. Those are all my
22 questions. Thank you, very grateful.

23 MR GRIFFIN: Thank you, Chair.

24 If Ms Campbell could come forward.

25

Questioned by MS CAMPBELL KC

MS CAMPBELL: Good afternoon, Professor; good afternoon, Doctor. My name is Brenda Campbell and the questions I ask are asked on behalf of the families of Christopher Nota, of Edwige Nsilu, and of Sophie Alderman, who all died and I also represent the campaign network Stop Oxevision.

And you've helpfully introduced us to a number of statistical concepts of confidence intervals, statistical significance, heterogeneity and so on, as well as methodological flaws in papers, and against that background in fact you were asked this morning about how important it is that readers of the study perhaps don't accept what they're reading at face value or assume that its conclusions are valid. And I want to ask you a few more questions about how that works in practice, if I may.

In your experience, is it reasonable to expect that many NHS managers or policymakers or commissioners, so the people who are making decisions about the adoption of new healthcare technologies, will not necessarily possess the statistical training or be alert to the methodological flaws that you've alerted us to in the course of your evidence?

PROFESSOR DONNELLY: I would expect most of them would not

1 have much statistical training. They may have
2 experience reading other studies, but yeah, they would
3 be relying usually on the summaries, I would have
4 thought.

5 DR CHRISTODOULOU: But access to expertise is available.
6 Expertise is available for people to access,
7 statisticians exist.

8 Q. Against that background, I suppose my next question is,
9 well, how important, therefore, is it for authors and
10 researchers to clearly and accurately communicate in
11 their papers any surrounding uncertainties or any
12 limitations to their findings so that non-specialist
13 readers are not inadvertently misled?

14 PROFESSOR DONNELLY: That's something I would say, as
15 a scientist, not just as a statistician, that we all
16 strive to do: to explain our studies clearly, both what
17 we -- our motivation and what we intended to collect,
18 the data that we saw in -- with -- which may include
19 missingness, through no fault of our own. Some bits of
20 it -- there may be other limitations to that, and to go
21 through it and, you know, clearly when drawing
22 conclusions, try to, as objectively as possible, say
23 what the strengths and limitations are.

24 And so I highlighted in the evidence earlier
25 instances where limitations were acknowledged by the

1 authors, and I think that's to their credit to do that.
2 But it's something that you always have to do when
3 reading a paper to make sure that you're keeping in mind
4 the possibility that, you know, this may not be
5 applicable to the situation you're considering.

6 DR CHRISTODOULOU: Adding to this, our discipline is one of
7 those that is used by a lot of other disciplines and not
8 everybody using statistics is necessarily an expert in
9 all the statistical concerns or issues that may arise in
10 the experiments, so it's possible that for some of these
11 limitations the researchers are not aware that there are
12 limitations. This is why peer review is important and
13 sometimes reviewers can catch these things, but things
14 do go through.

15 Q. Thank you. I want to ask you about an observation that
16 you then make at page 7 of your report. It's in the
17 early stages. And you state that:

18 "A high-quality evaluation of Oxevision would
19 ideally examine unintended consequences, including
20 patient experience, staff workload, therapeutic
21 relationships, and ward practice."

22 And I wanted to ask whether, in the Oxevision
23 studies that you reviewed at the request of the Inquiry,
24 to what extent were those staff-patient contexts or
25 therapeutic engagement observation practices and ward

1 culture measured as outcomes?

2 DR CHRISTODOULOU: Some studies included interviews with
3 staff. Some included interviews with patients. There
4 was a qualitative study that included patient advisors
5 to help focus the thematic analysis that was conducted.
6 It is a very varied selection of engagement that
7 happened with the various members of the communities.
8 And I think that the statement here is saying that
9 increasing the engagement will be beneficial in
10 understanding the context in which the data are
11 (unclear).

12 PROFESSOR DONNELLY: And it's worth noting in the things
13 that you listed something like staff workload is much
14 easier to quantify and think about the dimensions of
15 that than the patient experience, which is inherently
16 very multifaceted and will vary over time within -- so
17 these things are challenging, but integration and
18 consideration of lived experience from the outset, can
19 help researchers decide what they, you know, what
20 components to include. But it is very challenging, and
21 the scope of trying to include all of these things may
22 be tricky but it's important they are considered and
23 a very conscious choice is made over what components
24 that they are able to address in a particular study.
25 I think it would be impossible for one study to

1 address everything in sufficient detail. That's why we
2 look for the evidence base.

3 Q. In the round -- in fact that may, in part, answer my
4 next question, which was: if studies, for example,
5 report reduction in enhanced -- sorry, in observation
6 hours or in staffing costs, but do not at the same time
7 measure whether patients received less face-to-face
8 therapeutic engagement or whether ward safety or
9 practice had changed, does that create a limitation, in
10 terms of the interpretation of the outcome of the study?

11 DR CHRISTODOULOU: It doesn't give the complete context in
12 which the data are generated. As for a limitation,
13 limitation is always in relation to the question it's
14 trying to answer. If it's answering a very specific
15 question, then that technically wouldn't be
16 a limitation. But if you're trying to understand the
17 system as a whole, then it can lose part of the context.

18 Q. Professor, do you agree with that answer?

19 PROFESSOR DONNELLY: Yes.

20 Q. Thank you. Just to explore that then a little bit
21 further. Can an economic model properly treat, for
22 example, reduced observation hours as a saving without
23 also considering possible patient-centred disbenefit
24 such as that reduced engagement or increased stress or
25 the trade-off in privacy that you mentioned in your

1 evidence just now, Professor. Can an economic model
2 properly consider one without the other?

3 PROFESSOR DONNELLY: Well, it, you know, they decided what
4 variables they wanted to include, and obviously there
5 are additional variables. You know, reduction in
6 one-to-one observation could be beneficial in multiple
7 ways to the patient if they were able to sleep the night
8 through without being interrupted. You could imagine
9 getting better sleep would be -- on the other hand if
10 they then went longer without seeing someone in
11 a particular context, that someone might feel that they
12 weren't being monitored properly. So it would depend
13 very much on the context.

14 And I think it would be a matter of the studies
15 having to be done within the clinical context and
16 measure these things than for the economics as usually
17 the next layer. So until those original studies are
18 done, it would be difficult or impossible for the
19 economist to incorporate them correctly.

20 Q. Thank you. You go on in your report, and this is
21 specifically at paragraph 2.3, but I can address what it
22 is that you identify. In the middle of that paragraph
23 you refer to "unresolved issues around privacy, dignity,
24 consent, surveillance, data governance, anxiety and
25 therapeutic relationship."

1 The Inquiry has heard evidence from Hat Porter who
2 is a researcher and representative of Stop Oxevision and
3 they gave detailed evidence about, for example, the use
4 of opaque language in promoting the technology of
5 Oxevision such as calling it an optical sensor, by way
6 of example, and about reliance on posters to provide
7 information about its function, and they also raise
8 concerns about issues of implicit consent and lack of
9 understanding about what the system actually does and
10 about uncertainty in terms of the recording and data
11 sharing via the cameras.

12 And really, my question focuses on the concept of
13 acceptability that you told us about. From an
14 evidential perspective, can patient acceptability be
15 inferred, from, for example staff or operational or
16 organisational support, or does it in fact require
17 direct evidence from patients and from those affected
18 groups?

19 PROFESSOR DONNELLY: I would say this is not my specialist
20 area.

21 DR CHRISTODOULOU: This is outside our area of expertise.

22 This is something that somebody with a background in
23 ethics would be able to answer.

24 Q. Okay. Perhaps, Professor Donnelly, can I ask it in this
25 way: you told us in your evidence this morning that

1 something not being considered acceptable may be
2 a function of what the user -- the person understands
3 about it, and how that has been communicated to them.
4 But is the opposite also true: that something being
5 presented as acceptable may be a function of a lack of
6 understanding or a miscommunication of what a system in
7 fact does?

8 PROFESSOR DONNELLY: Certainly if someone were presented
9 with incomplete information, then their decision about
10 what is acceptable or not might not be the same one they
11 would reach if they had full information. But it's
12 coming from an area that's highly technical and thinking
13 about how to explain statistical concepts within this
14 setting, we had to use particular language that we
15 thought would be both informative and understandable.
16 I can imagine it's challenging to figure out exactly how
17 to describe all of these things, but it's something that
18 would need very careful thought and you can imagine the
19 involvement of people with lived experience could be
20 very informative in developing that.

21 Q. Thank you. In fact, I want to ask you, then, about some
22 of the methodology for exploring lived experience.

23 You considered a paper at paragraph 2.8, and that's
24 the Dewa et al paper, where the methodology for
25 exploring lived experience, staff experience, and

1 implementation issues was considered by you, and you
2 observed that the study is strengthened by that
3 meaningful patient and public involvement. Overall, did
4 you see that same methodology adequately replicated
5 across the Oxevision studies that you reviewed?

6 DR CHRISTODOULOU: No, this was a qualitative study and
7 there weren't that many qualitative studies in the
8 bundle to begin with. There was -- some of the
9 qualitative studies had included components of staff
10 interviews or patient views, but the evidence that we
11 see in this particular paper was focused on creating the
12 themes around the, for example, the patient advisors,
13 that they had, and so this is a particular design, and
14 it was clearly described and it was very easy to follow,
15 even from our quantitative perspective.

16 Q. Thank you. It may be that you've answered this to some
17 extent already but perhaps if I can ask it in this way:
18 how significant is that lived experience evidence in
19 assessing the perceived safety benefits and considering
20 concerns about privacy, dignity, patient disbenefits,
21 increasing, for example, paranoia and distress, and
22 evaluating issues around consent?

23 PROFESSOR DONNELLY: I think lived experience is very
24 important in not just mental health; any time that
25 you're dealing with patients, but especially in a mental

1 health setting. It would need to be considered very
2 carefully and obtained in a way that is useful and in no
3 way distressing to the people involved.

4 But -- and they can -- by involving them in the
5 co-production of a study, that can help. So that's very
6 different from sort of engaging with them after the
7 study has been done about how it's communicated.

8 Now, if a study has already been done, even that
9 communication is better than not doing it at all. But
10 if it -- if there can be engagement with patients at the
11 outset, that will help you design a study that should
12 answer the most important questions. And the most
13 important questions could be different, depending on
14 different perspectives.

15 DR CHRISTODOULOU: Can I add to this, that the -- quite
16 a lot of the work we do in statistics and quite a lot of
17 the work we discuss relies on context. We cannot
18 exclude a component from this context and the lived
19 experience is one of those components. It needs to be
20 included so that we have a more complete picture.

21 Q. Thank you. I suspect I may be up against the time limit
22 so I'll move on, if I may, to my last set of questions.

23 And I want to return for a moment to Hat Porter's
24 evidence because they gave evidence about disability,
25 about learning disability, neurodivergence, women,

1 transgender patients, about trauma, skin tone, scarring,
2 some of which you've mentioned in your evidence. Is, in
3 the technical validation studies that you reviewed, to
4 what extent was performance assessed across, for
5 example, different skin tones or scarring or tattoos?
6 And was it adequate?

7 DR CHRISTODOULOU: In the context of, for example -- are you
8 referring to the haemodialysis examples, or are you
9 referring within the mental health?

10 Q. Within the mental health setting.

11 DR CHRISTODOULOU: So a lot of the characteristics of the
12 patients are summarised by conditions rather than
13 characteristics such as skin colour, tattoos, or past
14 experience that may be informing the current experience.

15 Q. So where validation studies lack consideration, for
16 example, of diversity in skin tone, it may be --

17 DR CHRISTODOULOU: To be honest with you, I don't know.
18 They didn't report it so I don't know whether it lacked
19 it but it wasn't reported.

20 Q. Okay --

21 MR GRIFFIN: Can I say that's now over 15 minutes. If
22 there's a short follow-up question, by all means, but
23 would you bring it to an end.

24 MS CAMPBELL: I will of course.

25 Would it have been important or helpful to have

1 reflected --

2 DR CHRISTODOULOU: It would have been informative.

3 MS CAMPBELL: Thank you very much.

4 MR GRIFFIN: If Ms Misra would come forward, thank you.

5 **Questioned by MS MISRA KC**

6 MS MISRA: Good afternoon. If I could start by introducing
7 myself, my name is Eleena Misra and I'm counsel
8 instructed by Hodge Jones & Allen. We have the largest
9 cohort of bereaved families and lived experience
10 clients.

11 I would like to start by asking you about conflicts
12 of interest, if I may, which I know you've already
13 touched upon to some degree today. And by that, and
14 just to frame my question as accurately as I can, when
15 I'm talking about conflicts of interest, I'm talking
16 about actual or potential conflicts which, in my
17 definition for this question, would include authors
18 having a direct financial interest in Oxehealth, being
19 a founding member, being an active director or an
20 employee of Oxehealth, or where the source of funding is
21 Oxehealth which I think are different scenarios we've
22 covered.

23 And I wanted to ask you about the proportion of
24 studies in your review in which there was an actual or
25 potential conflict of interest. So, in some cases, the

1 authors had, as I understand it, set out clearly
2 a conflict of interest in the relevant box, if I can put
3 it that way, and in other cases it may have been
4 self-evident from just knowing who the authors were or
5 their connection or institution.

6 So I wonder if I could ask you whether you could
7 comment on the proportion of papers that you reviewed in
8 which there was a conflict of interest, actual or
9 potential?

10 DR CHRISTODOULOU: Can I ask for a clarification on your
11 definition. Some of the documentation we reviewed is
12 historical. So it's on the development of the
13 technology and somebody may have gone on to be involved
14 in Oxehealth, but at the time that they did that work,
15 and they published that paper, Oxehealth, for example,
16 was not part of the work experience. Is this something
17 that would be considered in the conflict of interest?

18 Q. No, so I think in absolute fairness in answer to that
19 question, I'm talking about aware at the time of the
20 work in question, the study, there was a live conflict
21 of interest, actual or potential?

22 DR CHRISTODOULOU: As a percentage we would say about
23 a third?

24 PROFESSOR DONNELLY: Yes.

25 DR CHRISTODOULOU: Yes.

1 PROFESSOR DONNELLY: We went through and identified that and
2 that is actually very similar to what was reported in
3 the Griffiths review. If you look at that. So that
4 looked at 32 studies and that was looking at inpatient
5 and acute mental health settings and they identified
6 nine studies, that was 28 per cent that declared
7 a conflict of interest.

8 Q. Thank you very much. So I think, certainly from my
9 client base, looking at the -- looking at 44 papers, it
10 appeared that more than half involved someone who may
11 have had a connection but as you say, that may have been
12 subsequent to the actual study that was done. Thank you
13 for that.

14 PROFESSOR DONNELLY: Yes, there were certainly cases --

15 DR CHRISTODOULOU: There were --

16 PROFESSOR DONNELLY: -- where individuals were later listed
17 as having association with Oxehealth but on some of the
18 earlier papers they hadn't been.

19 Q. Thank you very much for that. So following on from
20 that, can I ask you about those papers in which there
21 was an actual or potential conflict of interest at the
22 material time. Did you observe there to be any
23 differences in terms of those papers' findings, in other
24 words whether they were pro or anti the use of Oxevision
25 and the objective strength of their conclusions? Were

1 there any trends in this regard that you were able to
2 discern?

3 DR CHRISTODOULOU: So we found that the four papers we
4 looked at from the economic perspective, all four had
5 conflicts of interest that was declared. In the ones
6 within the vision-based, one-third of them had
7 a conflict of interest, declared, and those were some of
8 the papers -- (overspeaking) --

9 PROFESSOR DONNELLY: What we looked at in Section 2.

10 DR CHRISTODOULOU: Yes.

11 From the ones that looked at the more technical
12 components or the development of the technology, we
13 found six papers in that section, Section 3., and in
14 that section it was a variety of studies. It is quite
15 diverse to try and bring in together.

16 I'm not sure I'm answering your question very
17 clearly right now, but are you asking more specifically
18 about the first two sections as a focus or overall
19 whether --

20 Q. Overall. If you're able to comment.

21 DR CHRISTODOULOU: With the addition of the third section,
22 this is difficult to comment because they are quite
23 varied in that third section. So I would find that hard
24 to comment.

25 Q. If you're able to comment, then, on the other sections

1 that would be very helpful, if you feel able.

2 DR CHRISTODOULOU: With the economic benefit ones, all the
3 papers we reviewed presented an economic benefit, all
4 four had conflict of interest. The papers that we
5 reviewed on the vision-based monitoring system, they
6 found a decrease in harmful events to the patients.

7 PROFESSOR DONNELLY: We didn't note a systematic bias.

8 DR CHRISTODOULOU: Did not.

9 PROFESSOR DONNELLY: But its' -- there are different outcome
10 variables so you wouldn't expect the estimates to --
11 even if everybody had done exactly the same approach,
12 you wouldn't expect them to be exactly the same. So for
13 the limited number we have, yeah, we aren't able to
14 detect something here.

15 Q. Thank you very much.

16 In particular, if I move on now to the importance or
17 weight you give to independence in terms of statistical
18 reliability, and in particular, in the case of published
19 studies which you have reviewed that have now been
20 retracted, of which I think we know there are now two,
21 one of which Mr Hayes took you to earlier, I wanted to
22 ask you about whether your determination of how much
23 weight those should be given has been affected at all.

24 And if it assists you, just to anchor this to some
25 earlier evidence, it was paragraph 1.7 at page 13 of

1 your report which was one of the examples we looked at.
2 And I wondered if I could ask you whether your
3 assessment of weight has been affected by knowledge of
4 reports having -- publications, rather, having been
5 retracted since the time of your report or becoming
6 aware since the time of your report?

7 DR CHRISTODOULOU: I think the -- one of the things with
8 retracted papers is that there is always a possibility
9 for somebody to resubmit and get published if they feel
10 they can amend to those issues. We don't know whether
11 this is something they can amend, and represent again.

12 The absence of ability to actually view the original
13 data and try to understand the original data that
14 Buckley et al have presented as a limitation, and that
15 was one of the reasons for retraction, that is a problem
16 that impacts the evidential weight, yes. But overall,
17 this could be something that is rectified, if they get
18 access to it and they stand by their results, which is
19 something we don't know and something that we saw, for
20 example, in Kekic et al, they presented the same paper
21 enhanced with more information.

22 Q. So would it be fair to say, if I were to take you to the
23 very concluding sentence at paragraph 1.7 of your
24 report, where, in relation to the Buckley publication
25 which has been retracted you say that:

1 "Overall the paper should be given low-to-moderate
2 evidential weight."

3 Is it fair to say that that conclusion is of itself
4 up in the air, given the status of that publication and
5 because you don't know whether any of the errors can be
6 dealt with?

7 DR CHRISTODOULOU: Yes, and if we carry on reading that
8 sentence, it's that a very cautious interpretation of
9 these should be used anyway.

10 So:

11 "... its conclusions require cautious interpretation
12 because of confounding, limited statistical uncertainty
13 reporting, restricted data access and
14 conflict-of-interest concerns."

15 Q. Thank you very much. It was already a cautious
16 conclusion, as it were. Thank you.

17 I just want to conclude, if I may, by just ensuring
18 that we've all carefully understood the important
19 conclusions of your report. I wonder if I could just
20 put to you in summary whether I'm right in saying that
21 there was no evidence that could be given even moderate
22 weight in support of the following propositions:

23 So, first of all, the clinical effectiveness of
24 Oxevision in the inpatient mental health context.

25 DR CHRISTODOULOU: I believe that's correct.

1 Do you have a ...?

2 PROFESSOR DONNELLY: So we have that overall the evidence
3 provides low to moderate support for the hypothesis that
4 it may contribute to some safety outcomes.

5 Q. Thank you. And again, there's no evidence that reaches
6 even moderate weight in support of the proposition that
7 the safety of Oxevision -- of the safety of Oxevision in
8 the inpatient mental health setting or context.

9 PROFESSOR DONNELLY: I think I may have confused the two
10 things, sorry. I think that may have been what I just
11 replied to. Can we go back to your previous question so
12 I make sure I understood it.

13 Q. Of course, Professor. So the first proposition I put to
14 you, just to ensure that we had understood correctly,
15 your conclusion was that there was no evidence that
16 could be given even moderate weight in support of the
17 clinical effectiveness of Oxevision in the inpatient
18 mental health context?

19 DR CHRISTODOULOU: That's correct.

20 PROFESSOR DONNELLY: So -- I mean -- yeah, in that case I'm
21 not sure how we would separate clinical effectiveness
22 and safety, because obviously if someone is self-harming
23 it would improve their situation clinically and also be
24 an improvement in safety. So I wouldn't see those as
25 separate issues.

1 Q. The two go hand in glove?

2 PROFESSOR DONNELLY: Yes.

3 Q. I understand. Thank you. The next one, again, is that

4 your report seems to suggest that there was no evidence

5 that could be given even moderate weight in support of

6 the acceptability -- and I use your definition from the

7 report -- of Oxevision in the inpatient mental health

8 context?

9 DR CHRISTODOULOU: Yes, that's correct.

10 PROFESSOR DONNELLY: Yes --

11 DR CHRISTODOULOU: That's correct --

12 PROFESSOR DONNELLY: There is little focus on that --

13 DR CHRISTODOULOU: Very little focus on that. That's

14 correct.

15 Q. Thank you. And again my fourth proposition: there was

16 no evidence that could be given even moderate weight in

17 support of the economic value of Oxevision in the

18 inpatient mental health context?

19 PROFESSOR DONNELLY: So we -- I mean, there we talked about

20 the evidence being limited. I mean we have these

21 calculations, we've talked about the fragility of some

22 of these results, that they rely on estimates. So the

23 economic evaluation is always going to be dependent on

24 the strength of the estimates that go into that and when

25 they are uncertain, particularly the economic ones seem

1 very sensitive to the reduction in one-to-one
2 observations, and the savings that that might generate.

3 DR CHRISTODOULOU: In each of those summaries, it is -- we
4 have either low, very low, or low to moderate, in the
5 case of Buckley, which we may need to review.

6 Q. Thank you.

7 So the last proposition for clarity and indeed my
8 last question to you this afternoon, is that it seems
9 your report would suggest that there is no evidence that
10 could be given even moderate weight in support of the
11 disbenefits of Oxevision being outweighed by the
12 potential benefits.

13 PROFESSOR DONNELLY: I think it would be -- I think that's
14 not a statistical question.

15 DR CHRISTODOULOU: -- (overspeaking) --

16 PROFESSOR DONNELLY: Because the benefits and the
17 disbenefits are on different scales. Right? They're
18 different quantities. So if you talk about sort of
19 concerns about privacy and dignity versus -- which
20 obviously you would want to maximise but you also want
21 to keep people as safe as possible and have as few
22 adverse events. So I don't think there would be ever,
23 no matter what the study, one answer to that question
24 because it will be a balance between those different
25 components.

1 Q. So there may be a form of holistic assessment that is
2 really outside the field of statistics altogether?

3 DR CHRISTODOULOU: *(The witness nodded)*.

4 PROFESSOR DONNELLY: Yes, and that's where people bring in
5 the qualitative research, but the qualitative research,
6 by definition, won't give you a number where you decide,
7 well, it's high enough and that's the threshold. So
8 these things are -- that's where human judgement will
9 come in.

10 MS MISRA: Thank you very much for your answers to my
11 question and that concludes my questioning. Thank you
12 very much.

13 MR GRIFFIN: Thank you.

14 Ms Bartlam, please.

15 **Questioned by MS BARTLAM**

16 MS BARTLAM: Good afternoon, Professor Donnelly, good
17 afternoon Dr Christodoulou, good afternoon, Chair.

18 My name is Chiara Bartlam and I ask questions on
19 behalf of the charity INQUEST. INQUEST has expertise in
20 stated-related deaths and investigations.

21 I've just got a series of questions to ask you about
22 these estimated cost savings, if I may and of course if
23 anything is outside the area of your expertise, please
24 do say, as you have done already.

25 In relation to the economic evaluations of

1 Oxevision, we've already heard mention of a potential
2 saving of around £72,000 per average-sized ward in
3 a year. That came from the second Malcolm et al study
4 in 2022. Would you agree that on the face of it, these
5 estimated cost savings are potentially substantial?

6 DR CHRISTODOULOU: Can I clarify whether you are asking
7 whether the 72,000 estimate is a substantial estimate?

8 Q. Yes, in terms of the way it's framed -- sorry, not about
9 the estimate itself. In terms of the way these figures
10 are framed by the authors of the report, would you agree
11 that they're framed in a way that these are substantial
12 savings to be made?

13 DR CHRISTODOULOU: They are presented as substantial
14 savings, yes.

15 Q. And you've also, you've said already in your evidence
16 that these savings were highly dependent on reductions
17 in one-to-one observations?

18 DR CHRISTODOULOU: Yes.

19 Q. Would you agree that in principle the only way that any
20 savings in one-to-one observations could be directly
21 attributable to Oxevision use is if fewer one-to-one
22 observations were required while it was being used?

23 DR CHRISTODOULOU: Something being directly attributable to
24 one thing contains a concept of causality, and that
25 requires a lot stronger experimental design to be

1 placed, that we can completely discount all other
2 sources, anything other than that would make it very
3 difficult for somebody to say specifically: this is the
4 only cause for it.

5 Q. And did you get any sense from the papers as to why
6 Oxevision was said to possibly result in a reduction in
7 one-to-one observations, either directly or indirectly?

8 DR CHRISTODOULOU: You mean the reason it was believed?

9 Q. Yes.

10 DR CHRISTODOULOU: I believe that would have to do with ward
11 practice and how it was used, which is outside our
12 actual area of expertise.

13 Q. Of course. And this Inquiry has been repeatedly told
14 that Oxevision should not be used to replace one-to-one
15 observations. Does any of the material you've reviewed
16 make that clear?

17 DR CHRISTODOULOU: I believe they're saying that it is in
18 addition to standard care in the materials. For example
19 if you look on the summary results, table 5 in the paper
20 you mentioned, the estimate is standard care versus the
21 vision-based system, plus standard care. So that's the
22 statement they're making.

23 Q. And finally, from me, you've obviously referred to the
24 fragility of the results in the economic evaluations.
25 What is the risk if a mental health Trust relies on

1 these economic evaluations as a basis for introducing
2 Oxevision?

3 DR CHRISTODOULOU: I think that's beyond my expertise,
4 because that would contain a lot of other disciplines
5 that would have a say on what the risk would be.
6 Because there could be a risk in a multitude of ways.
7 I would not know that.

8 Q. Would you agree that one of the obvious risks is that
9 they might think it produces a cash saving when in fact
10 it might not?

11 DR CHRISTODOULOU: It's possible. I don't know how they
12 would be reviewing this evidence. When I'm reviewing
13 it, I have a different lens to how they will be
14 reviewing it.

15 Q. Thank you.

16 PROFESSOR DONNELLY: And at it's most superficial level,
17 that seems like the risk is that, you know, they would
18 be expecting -- you know, could be expecting this 74 --
19 or, sorry, 72,000, and then not realise that. And as
20 we've shown, the uncertainty in -- particularly in the
21 reduction of one-to-one hours, means that that might be
22 realised or it might not.

23 MS BARTLAM: Thank you. I have no further questions.
24 Thank you, Chair.

25 MR GRIFFIN: Chair, that forms the end of this stage of

1 proceedings.

2 I'll hand back over, if I may, to Mr Hayes.

3 DR HAYES: No further questions from me, Chair.

4 THE CHAIR: I have no further questions.

5 DR HAYES: That concludes the evidence. May we have ten
6 minutes to prepare for closing submissions?

7 THE CHAIR: Before we do, though, can I thank you both very
8 much, both for your written report and for your evidence
9 here today, which has been admirably clear and extremely
10 illuminating. Thank you very much.

11 DR CHRISTODOULOU: Thank you.

12 PROFESSOR DONNELLY: Thank you.

13 **(2.39 pm)**

14 **(A short break)**

15 **(2.50 pm)**

16 THE CHAIR: Ms Harris.

17 **Closing statement by MS HARRIS KC**

18 MS HARRIS: Thank you, Chair.

19 Chair, the evidence we've heard today brings us to
20 the conclusion of this public hearing.

21 On behalf of the Inquiry Team, may I say once again
22 how grateful we are to all those witnesses who have come
23 before you to give evidence at this hearing.

24 Before we close these proceedings today, I would
25 like to reflect on that evidence and the recurring

1 themes that have emerged across witnesses,
2 organisations, and documentary material during the
3 course of the hearing.

4 Chair, whilst the Inquiry's investigations are
5 rooted in Essex, the issues explored during this hearing
6 may reach well beyond one county or one provider. The
7 evidence has engaged questions which resonate across
8 mental health inpatient services nationally, how
9 patients and families are heard; how staff are supported
10 to deliver safe therapeutic care; how organisations
11 learn from harm; and how innovation and technology
12 should be deployed safely. And that broader perspective
13 is reflected in your Terms of Reference.

14 We offer particular thanks again, Chair, to those
15 bereaved families who felt able to come forward to share
16 with us their experiences and their suggested
17 recommendations for change. We thank them for their
18 courage and their clarity in doing so.

19 Echoing the evidence of other families who we've
20 heard from, Lynne Breaker-Rolfe spoke of not being
21 listened to and of being excluded almost entirely from
22 decisions in relation to her husband Roy's assessments,
23 care, treatment and discharge. She described being
24 prevented, in effect, from explaining to clinicians in
25 clear terms what she knew: that Roy presented

1 a continuing danger to himself, because she was not
2 afforded the opportunity to speak to clinicians
3 separately, away from him.

4 Lynne told us about the crucial window of time in
5 which her husband's symptoms of psychosis would have
6 been clear for all to see, but the window was missed,
7 which allowed him to mask, to tell those assessing him
8 that all was well, to be sent away and for the cycle to
9 repeat itself.

10 And Lynne said this: "I could have done with some
11 help. I do understand that Roy's mental health problems
12 may not have been solvable, but they might have been
13 able to help him or to live a longer life, and normally,
14 just to listen and to try and help."

15 Two bereaved mothers, Lisa Wolff and Victoria
16 Sebastian, gave harrowing evidence of their long and
17 dedicated efforts to secure appropriate care and
18 treatment for their daughters. They spoke of
19 fundamental, enduring failures by the Trust and its
20 systems and staff to recognise autism, to understand its
21 impact on their daughters, and to shape care and
22 treatment accordingly.

23 Lisa Wolff described her urgent concerns being
24 ignored, dismissed and laughed at by those responsible
25 for her daughter's care, with complete denials from

1 staff that any diagnosis of autism had even been made
2 despite Abbigail's diagnosis being there in the records
3 to be seen.

4 We heard of instances of bullying and violence
5 towards both Abbigail Smith and Elise Sebastian on the
6 mattered; restrictive practices on CAMHS units that
7 appeared to reinforce or worsen cycles of self-harm;
8 failures in observation, falsification of records, and
9 wholly inadequate risk assessments; safeguarding
10 failures, failures in basic recordkeeping and the
11 prescription of medication; unexpected periods of leave
12 or discharge, and an absence of advice or guidance or
13 support to those in the patient's home.

14 Lisa Wolff and Victoria Sebastian also added their
15 voices to the families who have given evidence before
16 them, describing how no one listened to them, and to
17 their repeatedly expressed fears that their daughters
18 were unsafe.

19 Much of what was said by those families was also
20 echoed in the evidence given by members of staff over
21 the first two weeks of this hearing. We began to see
22 and hear the duty of candour emerge, with many staff
23 sharing their concerns openly and unreservedly. We also
24 thank those members of staff who came here and provided
25 detailed and candid evidence. The Inquiry does not

1 underestimate the challenge of being asked to provide
2 evidence to you, Chair in the context of a public
3 inquiry.

4 The Inquiry heard from staff both past and present
5 working across a range of roles and levels of seniority:
6 a healthcare assistant, an undercover healthcare
7 assistant, ward staff, ward managers, clinical leads and
8 two retired senior nurses. Whilst each witness spoke
9 from their own experience, there was notable consistency
10 in many of the themes that emerged. And those themes
11 included the following: firstly, minimal family
12 engagement.

13 A number of the staff accounts reflected the
14 families' experiences. Stuart Ayris candidly explained
15 how it was only years later, when working in a community
16 role, that he realised how little families had been
17 involved in the care provided during his time at the
18 Linden Centre. He told you that staff had only been
19 getting half or two-thirds of the picture. And
20 furthermore, whilst Chloe Cawston stated that she was
21 now very passionate around engaging families, she
22 acknowledged that as a Trust EPUT hadn't always done
23 their best in terms of engaging with family. Louise
24 Borton agreed that owing to staffing pressures it was
25 not always routine practice to involve patients and

1 carers in risk assessments.

2 And it was particularly striking that all staff
3 witnesses spoke of staffing pressures; understaffing,
4 principally, with failures to ensure an appropriate
5 skill mix on the ward at any given time, and with heavy
6 reliance on bank and/or agency staff, which was
7 described by Louise Borton as resulting in a very
8 challenging environment to work in.

9 Brian O'Donnell explained that it was not possible
10 to raise concerns about staffing levels even when things
11 were not safe. The response would be "We can't get more
12 staff, you need to get on with it."

13 Zoe Bunting considered that staffing levels had
14 influenced decisions such as observation levels.

15 Staffing pressures also resulted in lack of
16 therapeutic engagement with patients, according to
17 Beverly Switzer, who gave evidence that patients would
18 be upset so that -- that there were not activities, so
19 she would -- "We'd try", she said "as healthcare
20 assistants, to put something else in place. But
21 obviously with shortage of staff and everything it's not
22 always possible to give them that engagement in that
23 way."

24 A number of the staff witnesses spoke to the tension
25 between operational pressures and therapeutic engagement

1 especially when undertaking observations. Louise Borton
2 considered that staff understanding of trauma-informed
3 care had been really poor until around 2023, and whilst
4 there was now a greater focus on therapeutic engagement,
5 previously it had been about keeping people alive.

6 We heard of concerns reported in relation to
7 inconsistency and/or a lack of support for staff from
8 managers and senior leadership, with an effect on ward
9 culture. Dawn Low told us about what she perceived to
10 be a severe lack of leadership and support, describing
11 the working environment for staff as "absolute chaos."

12 Ian Arthur described senior management at one stage
13 as "remote and disengaged", with Stuart Ayris describing
14 his experience of management throughout his time at NEPT
15 and EPUT as "conflict driven", "arrogant", and
16 "aggressive".

17 It was also a common theme across the staff evidence
18 that those who spoke up felt that management had
19 suppressed their concerns. Stuart Ayris considered that
20 his career had been impacted as a result of the concerns
21 he had raised in the mid-to-late 2000s, ultimately being
22 accused of putting patients at risk and being moved to
23 another role, he said.

24 Particularly concerning was the similarity between
25 accounts separated by almost two decades, when we heard

1 Brian O'Donnell describe a similar sense of being
2 treated like a "troublemaker" 20 years later, also for
3 raising concerns, and whilst Zoe Bunting felt well
4 supported by her Service Manager, she did not, she said,
5 "have the confidence that, actually, if the Service
6 Manager spoke to the Matron, that that would have the
7 desired effect. In fact, [she said] I think it probably
8 could have made my life a little bit more
9 uncomfortable."

10 And this was part of a picture, according to
11 Stuart Ayris and Brian O'Donnell, whereby EPUT and its
12 predecessor Trusts were focused on perception and
13 statistics and, very worried about their reputation,
14 blaming individuals for systemic issues and moving them
15 on, reflecting a general lack of care, understanding and
16 compassion. Several witnesses described what they
17 perceived to be an organisational focus on performance
18 metrics and reputation at the expense of openness,
19 learning and improvement.

20 Staff witnesses acknowledged deficiencies with
21 recordkeeping, particularly around observations, with
22 Louise Borton being "aware that there were concerns
23 about recording of observations within the Trust, about
24 observations being recorded after the time that had been
25 sort of time stamped, I guess, when you were writing

1 them", she said.

2 Chloe Cawston also conceded that "When we've had
3 vacancies across the wards, inpatient in particular, you
4 can see that that does have a knock-on effect on the
5 clinical records being updated in a timely manner and
6 then I guess as well thinking about clinical demand at
7 the time."

8 And she was asked the question:

9 "What about things like copying and pasting?"

10 And she said, "Yeah, so I've witnessed copy and
11 pasting - I've seen that in care plans."

12 All witnesses spoke to problems with observations
13 more generally and some raised concerns about and
14 challenges with, the use of technology. Brian O'Donnell
15 talked of difficulties with observations, missed
16 observations, and risk management, highlighting the
17 practical impossibility on occasions of checking on all
18 patients at the levels set for those patients within the
19 allocated time.

20 In relation to Oxevision, Zoe Bunting referenced
21 a complete lack of training before it was implemented in
22 the pilot phase, so she familiarised herself, she said,
23 with the system by speaking to colleagues. Chloe
24 Cawston had some positive remarks to make in relation to
25 the use of Oxevision:

1 "I think in terms of monitoring the physical health
2 care it's good and also in terms of supporting with
3 monitoring the sleep patterns, it's good ... Obviously
4 the limits would be potentially when staff have misused
5 Oxehealth", she said, but agreed "it shouldn't be
6 a replacement for the in-person checks."

7 Whilst Brian O'Donnell appeared to be in favour of
8 at least some use of Oxevision, Zoe Bunting stated that
9 her personal view was that the benefits are minimal.
10 She considered the only clear benefit was that it
11 reduces the scope for retrospective entry of
12 documentation, but considered it was directly contrary
13 to the principle of least restrictive practice and
14 intrusive.

15 Evidence that was echoed by Louise Borton.

16 And some of the evidence we heard suggested
17 a disconnect between the intended purpose of Oxevision
18 and what it was actually used for on the ground, often
19 owing to staff lack of knowledge and understanding of
20 the system. Dawn Low was not aware of what it was until
21 she had done a number of shifts. She said:

22 "I think they were just carrying on and ignoring
23 it. I didn't even -- it was -- the noise was constant
24 so there was no -- there was no reference to 'The
25 Oxevision's activated, we need to go and check on the

1 patient'."

2 Beverly Switzer also explained that the only
3 training she received on Oxevision was in the form of
4 another HCA showing her how the system worked. She did
5 not ever recall being provided with a copy of the
6 Trust's Standard Operating Procedure and she confirmed
7 that she used the system to undertake level 2
8 observations, including those that she was required to
9 undertake in relation to Adam Steel.

10 A recurring theme throughout the evidence was that
11 technology cannot remedy deficiencies in staffing,
12 supervision, training, or therapeutic engagement.

13 In relation to substance use, Chair, we heard from
14 Stuart Ayris that:

15 "People were just referred to as an 'alcoholic' or
16 a 'druggie', or whatever. No thought was put into how
17 that person came -- why that person takes that amount of
18 alcohol, why that person takes that amount of drugs, and
19 the trauma that may have led to that."

20 There have long been deficiencies in the treatment
21 of those with drug and alcohol dependency, it would
22 appear, described by Louise Borton as a fragmented
23 approach at discharge with care and treatment outsourced
24 to other organisations.

25 Finally, Chair the staff evidence gave rise to

1 questions of whether senior management and governance
2 processes at EPUT facilitate candour and learning or
3 whether they instead represent defensive and
4 bureaucratic systems focused on protecting
5 organisational reputational risk. Louise Borton
6 expressed her concerns about learning not being shared
7 more widely. She said:

8 "I think it's such a huge organisation. There are
9 so many staff that need information to be cascaded to,
10 I don't think there's effective means to share that
11 learning. Yeah, I think it's a huge organisation.
12 I don't know whether we've got the oversight to ensure
13 that learning is embedded consistently across the
14 organisation."

15 And Brian O'Donnell explained how only last week
16 he'd been with the CQC when they had identified Datixes
17 from which there could be learning, but he said they're
18 often seen as a bit of a chore and there are often
19 missed opportunities for learning as a result.

20 Separately, Chair, the Inquiry listened with concern
21 to the issues raised by Brian O'Donnell with regard to
22 EPUT's current approach to Datix reports and the 4,000
23 reports he referred to that he was asked to deal with.

24 And I can confirm, Chair, that this evidence will
25 form an important strand of the Inquiry's ongoing

1 investigations into incident reporting, organisational
2 learning, and governance at the Trust and will inform
3 the Inquiry's review of how concerns are being addressed
4 and how lessons are being learned.

5 Taken together, the staff evidence did not simply
6 describe individual instances or isolated operational
7 difficulties. Rather, it identified recurring themes
8 relating to staffing, culture, recordkeeping,
9 governance, speaking up, family involvement and
10 organisational learning. Whether those themes
11 ultimately translate into systemic failings will be
12 a matter for your conclusions at the end of the Inquiry.
13 They nevertheless represent important lines of
14 investigation which fall squarely within your Terms of
15 Reference and which the Inquiry will continue to
16 examine.

17 Chair, at the start of this hearing, you heard
18 evidence from Paul Scott, EPUT's former CEO, and from
19 Loy Lobo, EPUT's Acting Chair of the Board of Directors.
20 They spoke about EPUT's failure to engage adequately
21 with the Inquiry over a sustained period of time.

22 Admissions as to those failures to engage were made
23 by EPUT within their written Position Statement and by
24 both Mr Scott and Mr Lobo in their oral evidence.

25 Mr Scott accepted that EPUT's actions had delayed

1 the work of the Inquiry and interfered with the
2 Inquiry's plan for work, including progress of its
3 investigative work and hearings. He accepted that EPUT
4 should have informed the Inquiry sooner when deadlines
5 were in jeopardy and often fell short in this regard.
6 He accepted that EPUT had made an error in not setting
7 themselves up better at the outset, to support the
8 Inquiry. He further accepted that confidence now needs
9 to be rebuilt between EPUT, the Inquiry and bereaved
10 families.

11 Mr Scott went on to give many assurances to you,
12 Chair, an assurance that Inquiry deadlines will not be
13 missed without prior agreement of the Inquiry. An
14 assurance that EPUT will make resources available to the
15 Inquiry team as there is no financial bar to engagement.
16 An assurance that EPUT's Inquiry Project Team is now
17 sufficiently resourced to deal with anticipated
18 increased demand in relation to evidential requests. An
19 assurance that EPUT can now meet the deadlines set by
20 the Inquiry and serve the Inquiry's needs. An assurance
21 of strong confidence that EPUT will respond to the
22 Inquiry's requests for evidence within a reasonable
23 timeframe, as requested by the Inquiry.

24 Mr Scott caveated his assurances. He stated that
25 the new processes and systems need constant attention

1 and testing to ensure demands can be met in the future
2 and suggested an external audit to test the new system.
3 On behalf of the board, Mr Lobo adopted the evidence of
4 Mr Scott in its entirety -- written and oral.

5 Chair, as I stated at the outset of this hearing, a
6 lot of this work takes place in the background, away
7 from the public eye. And this has also been the
8 position throughout the course of this hearing.
9 Unfortunately, Chair, in recently received
10 correspondence, EPUT have once again indicated that they
11 will not meet an Inquiry deadline. And whilst the
12 Inquiry acknowledges the transparency in that
13 communication, you have been concerned again about
14 further delay, and you determined last Friday that it
15 was necessary to issue a further Section 21 Notice to
16 EPUT to secure important evidence by the proposed
17 revised deadline.

18 In order to undertake our investigations thoroughly,
19 Chair, we need information to be shared with us promptly
20 by all material providers. The Inquiry hopes that these
21 latest challenges reflect only that EPUT's new processes
22 and systems referred to by Paul Scott are still at their
23 early stage of implementation and that this is not
24 indicative of wider, ongoing compliance issues.

25 Chair, this week the Inquiry turned its attention to

1 the topics you consider require more immediate
2 attention, on the basis that there may be issues
3 relating to the safety of current patients and we will
4 return to these topics at the Inquiry's hearing in
5 October, following which you will consider whether there
6 is an evidential basis for you to make any interim
7 recommendations in either subject.

8 On Monday, having already heard evidence from
9 bereaved families and staff on the topic, we heard
10 evidence in relation to the provision of emergency
11 response and resuscitation on mental health inpatient
12 units. We learned that there are significant challenges
13 in responding to the type of emergencies that arise in
14 mental health inpatient units, and that the window of
15 opportunity to improve outcomes is small. We learned
16 how important it is for those who may be first on the
17 scene to be equipped with the right skills and resources
18 to identify and deal with the situation as they find it.
19 We also learned how clarity in process and systems are
20 key. The evidence reinforced that mental health
21 settings present distinct clinical challenges which
22 demand systems specifically designed for those
23 environments rather than assumptions that are imported
24 from acute healthcare.

25 In respect of this topic, Chair, the Inquiry intends

1 to obtain focused assistance in relation to the issues
2 surrounding resuscitation in special circumstances,
3 whilst also exploring the reality of the day-to-day
4 workings and challenges of present-day mental health
5 units. We will explore the evidence from EPUT and from
6 the other providers relating to emergency response and
7 resuscitation on their wards.

8 Chair, this hearing has also demonstrated one of the
9 strengths in this Inquiry's approach. Because whilst
10 our focus remains firmly upon events in Essex, we have
11 deliberately tested evidence against experience
12 elsewhere. And that is why you have heard from
13 providers beyond Essex, from independent experts and,
14 today, from leading statisticians. Their evidence
15 assists not only in understanding what happened
16 historically, but also in identifying what safe mental
17 health inpatient care should look like today and in the
18 future.

19 Importantly, the evidence from other Trusts in
20 relation to Oxevision and the use of technology,
21 demonstrated that there is no settled national consensus
22 regarding the deployment of vision-based patient
23 monitoring systems. Different organisations considering
24 similar technology have legitimately reached different
25 conclusions and that diversity of practice reinforces

1 the importance of the careful evidence-led approach this
2 Inquiry has adopted before reaching any conclusions or
3 recommendations.

4 We have heard further important evidence about
5 observations on mental health units, and at some points,
6 highly technical evidence about the use of technology to
7 undertake those observations and this has involved
8 focusing, once again, on the use of Oxevision.

9 On Tuesday we heard from two Trusts outside of Essex
10 who had both trialled Oxevision but had come to
11 different decisions as to its deployment. If used
12 correctly at Tees, Esk and Wear Valleys NHS Foundation
13 Trust, also known as TEWV, it has a narrow stated remit,
14 measuring vital signs at night and issuing various
15 alerts at night. Monthly usage reports in 2024 revealed
16 that Oxevision was also being used in the day however.
17 Although Ms Devanney stated that we would not see that
18 sort of data now.

19 We learned that the TEWV consent model is opt out,
20 but that patient decisions can be overridden by the
21 multidisciplinary team.

22 TEWV are currently undertaking a review of
23 Oxevision, during which all options will be considered,
24 including the possibility of not using Oxevision at all.

25 In contrast, having piloted Oxevision, we learnt

1 that Leicestershire Partnership Trust, also known as
2 LPT, their decision was ultimately not to deploy
3 Oxevision on the grounds that the evidence base was not
4 there and because LPT was already using alternative
5 technology addressing certain areas covered by
6 Oxevision.

7 Chair, yesterday you heard a day of evidence from
8 Jill Archibald, a Consultant Nurse who assisted you as
9 an expert witness. Ms Archibald has provided the
10 Inquiry with her report entitled "Observation and
11 engagement and the use of vision-based monitoring".

12 And Ms Archibald's view was that, "Ultimately,
13 observations are most effective when they remain human,
14 relational, and patient-centred, rather than becoming
15 purely procedural or surveillance based."

16 "Observations can and do save lives", she said, "but
17 it really does boil down to the quality of them and the
18 relationship you have with the patient."

19 Ms Archibald went on to say that she welcomed
20 assistive technology:

21 "My experience of Oxevision in practice", she said
22 "is that for it to be effective you almost have to put
23 Oxevision on observations. So somebody is assigned to
24 have that portable device that would alert, and so that
25 member of staff has to respond to those alerts. So in

1 my experience it's not saved time. It's added an extra
2 layer of work on, but what it has done is give us an
3 insight into what is going on inside patients' bedrooms
4 when we're not there. That is what it has given, but
5 you've got to balance is that absolutely necessary."

6 Ms Archibald has made five recommendations to the
7 Inquiry within her report in relation to the use of
8 Oxevision on inpatient wards.

9 Firstly, that the use of Oxevision should be
10 clinically justified, appropriate and consent based.
11 Secondly, that staff access should be individually
12 logged, and auditable. Thirdly, there should be clear
13 national standards on the minimum response to VBT and
14 VBPMS alerts. Fourthly, audits should include patient
15 and family experience. And fifthly, observations
16 engagement and VBPMS training should be face-to-face and
17 competency based.

18 Ms Archibald confirmed during her oral evidence that
19 she cannot see a direct link between the use of
20 Oxevision technology and an improvement in care for any
21 of the patients within the illustrative cases that she
22 has reviewed.

23 Finally, Chair, we heard today from
24 Professor Christl Donnelly and Dr Maria Christodoulou,
25 the Inquiry's expert health statisticians, who together

1 provided their opinion on the evidence base in support,
2 or otherwise, for the use of Oxevision on mental health
3 inpatient units.

4 In summary, Professor Donnelly and Dr Christodoulou
5 concluded that the current evidence provides only
6 limited and cautious support for the use of Oxevision
7 and related VBPMs in mental health inpatient settings.
8 The evidence available suggests that the technology is
9 technically feasible and may have potential operational
10 applications, but it does not provide strong independent
11 support for clinical effectiveness, improved patient
12 safety, acceptability or cost effectiveness in mental
13 health inpatient settings.

14 Professor Donnelly and Dr Christodoulou are of the
15 view that further independent, randomised and adequately
16 controlled research would need to be undertaken before
17 any stronger conclusions could be drawn.

18 Taken together, the expert evidence has provided the
19 Inquiry with something of a wider national importance.
20 Rather than asking simply whether technology can be
21 deployed, the evidence has consistently returned to a
22 more fundamental question: what genuinely improves
23 patient safety, therapeutic care, and patient experience
24 within mental health inpatient services? And that
25 broader question lies at the heart of this Inquiry.

1 Chair, you have asked that your team considers the
2 evidence with you before you make any final decisions as
3 to what additional information would assist you on this
4 issue. You have already indicated, however, that you
5 would be assisted at least by hearing further evidence
6 from EPUT around their use of technology in this way and
7 from LIO, formerly Oxehealth, in response to the
8 evidence which has been heard during this hearing.

9 The reframed Interim Recommendations Hearing in
10 October will therefore provide an important opportunity
11 to examine these two issues further, not only in the
12 context of Essex, but in light of wider national
13 practice and evidence. The next hearing will be at the
14 Civic Centre in Chelmsford and in the meantime, Chair,
15 your team will continue the important work of this
16 Inquiry without break.

17 We continue to do whatever is necessary to uncover
18 systemic failures in Essex, to assist you in meeting
19 your Terms of Reference, and to make meaningful
20 recommendations. Details about future hearings and
21 further tranches of disclosure will follow.

22 Chair, throughout these hearings we have heard from
23 bereaved families, frontline staff, senior leaders,
24 other NHS providers and independent experts. And those
25 different perspectives have repeatedly converged around

1 the common themes. And that convergence is significant.

2 It enables this Inquiry not only to examine what
3 happened in Essex, but also to identify the wider
4 lessons capable of improving mental health inpatient
5 care nationally, where required.

6 **Closing remarks by THE CHAIR**

7 THE CHAIR: Thank you very much, Ms Harris, I'm very
8 grateful.

9 We have now come to the end of this hearing and I'm
10 grateful to everyone who has provided evidence over the
11 past three weeks. It takes courage to talk about
12 challenging experiences and sensitive topics in a public
13 forum such as this, so once again, I would like to thank
14 the bereaved families who have given evidence so openly
15 about those who died.

16 I also recognise the potential difficulties that
17 staff witnesses may face in giving evidence to a public
18 Inquiry. Evidence from staff is essential if my team
19 and I are to understand the realities of working on
20 a mental health unit. Staff evidence received so far
21 has given me an invaluable insight into what used to
22 happen on inpatient wards in Essex, what still occurs,
23 and what may be considered good practice, what is bad
24 practice, and the potential pressures faced by many NHS
25 mental health staff.

1 All the evidence at this hearing has given me a lot
2 to think about, and matters that I and my Inquiry Team
3 will want to consider most carefully.

4 I am grateful for the assurances set out in EPUT's
5 Position Statement, supported by board members, that
6 EPUT will (a) respond to the Inquiry's requests for
7 information and documents within a reasonable timeframe,
8 and (b) that EPUT are substantially on track to deliver
9 the deadlines set by the Inquiry.

10 These assurances were confirmed in evidence given by
11 Paul Scott, the former Chief Executive Officer, and Loy
12 Lobo, the Acting Chair of EPUT's Board of Directors.
13 Nevertheless, as Ms Harris has outlined, since providing
14 that evidence to the Inquiry only two weeks ago, EPUT
15 has given me cause to issue a pre-emptive notice under
16 Section 21 of the Inquiries Act to ensure prompt
17 compliance with a request for information.

18 I am hopeful, however, that from hereon, EPUT will
19 be able to adhere to the assurances they provided during
20 this hearing and that they won't disappoint me further
21 in this respect. I would stress, though, that where
22 I am concerned that deadlines will not be met,
23 jeopardising the effective running of the Inquiry,
24 I will continue to use the statutory powers which exist
25 under Section 21 of the Inquiries Act to ensure prompt

1 compliance.

2 To undertake our investigations thoroughly we need
3 information to be shared with us, and shared promptly by
4 all information providers, but particularly by EPUT.

5 As Ms Harris has indicated, the next public hearing
6 will be held in October in Chelmsford in Essex, where we
7 will hear further evidence about the use of technology
8 on inpatient wards and current practices around
9 resuscitation. I will then consider whether to make
10 interim recommendations on these areas of concern.

11 My ambition for this Inquiry is to improve mental
12 health inpatient care for everyone. First and foremost
13 for patients, but also for their families and for the
14 staff working on inpatient wards, the majority of whom,
15 I believe, want to do the best they can for those in
16 their care.

17 My focus is on making recommendations that will have
18 long-lasting impact on mental health inpatient care,
19 both in Essex and beyond. Wherever possible I will
20 extend the recommendations to make them national, so
21 that the evidence provided to this Inquiry, the
22 investigations undertaken by it, and the findings made
23 can have the widest, positive impact possible and help
24 to improve mental health inpatient care across the whole
25 country.

1 It only remains now for me to thank everyone here at
2 Arundel House who have looked after us during the course
3 of these hearings, that includes the security team, the
4 management and hospitality team here, and the technical
5 team, RTS. I also want to thank our long-suffering
6 stenographer, Louise Pepper, and our evidence handler,
7 Amanda Shadbolt.

8 Above all, my thanks, as always, are to my
9 Secretariat, my solicitor team, and my counsel team.
10 I'm very grateful to you all. Thank you very much
11 indeed.

12 **(3.25 pm)**

13 **(The hearing adjourned until a future date in October)**

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I N D E X

PROFESSOR CHRISTL DONNELLY (affirmed)2

DR MARIA CHRISTODOULOU (affirmed)2

 Questioned by DR HAYES2

 Questioned by MS SCOLDING KC93

 Questioned by MS CAMPBELL KC99

 Questioned by MS MISRA KC111

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