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

their orange-coloured scarves.

There is a private room downstairs where anyone who needs emotional support can talk to the Hestia staff. If you prefer, you can speak to a member of the Inquiry Team, who are wearing purple lanyards, and they will put you in touch with them.

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

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

PROFESSOR CHRISTL DONNELLY (affirmed)

DR MARIA CHRISTODOULOU (affirmed)

Questioned by DR HAYES

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

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

DR CHRISTODOULOU: I have a BSC in mathematics and

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

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

DR CHRISTODOULOU: I am a Chartered Statistician, yes.

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

PROFESSOR DONNELLY: Yes.

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

PROFESSOR DONNELLY: Yes, I am.

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

PROFESSOR DONNELLY: That's in 2026.

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

PROFESSOR DONNELLY: Yes.

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

PROFESSOR DONNELLY: Yes.

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

PROFESSOR DONNELLY: Yes.

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

DR CHRISTODOULOU: Yes, I am.

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

DR CHRISTODOULOU: Yes, I was.

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

DR CHRISTODOULOU: That is correct.

PROFESSOR DONNELLY: Yes.

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

DR CHRISTODOULOU: Yes.

PROFESSOR DONNELLY: Yes.

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

DR CHRISTODOULOU: Yes.

PROFESSOR DONNELLY: Yes.

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

report to the Inquiry entitled "Report on Oxevision evidential base and case study methodologies"?

PROFESSOR DONNELLY: Yes.

DR CHRISTODOULOU: Yes.

Q. Is that report dated 24th June 2026?

DR CHRISTODOULOU: It is.

PROFESSOR DONNELLY: It is.

Q. Was that report produced after you were instructed by the Inquiry to critically appraise the scientific evidence base underlying the use of Oxevision in mental health settings?

DR CHRISTODOULOU: Yes, it was.

PROFESSOR DONNELLY: Yes.

Q. Were you provided by the Inquiry with 50 research papers which described the use of the Oxevision system for that purpose?

DR CHRISTODOULOU: It was 45. 45 papers (overspeaking) --

Q. 45?

DR CHRISTODOULOU: Yes.

PROFESSOR DONNELLY: Yes.

Q. I'm grateful.

Do you have a copy of the report in front of you?

DR CHRISTODOULOU: Yes, we do.

PROFESSOR DONNELLY: Yes.

Q. Is that report 46 pages long?

PROFESSOR DONNELLY: Yes.
DR CHRISTODOULOU: Yes, it is.
Q. Can you turn to page 35. On page 35 do we see both your signatures?
PROFESSOR DONNELLY: Yes.
DR CHRISTODOULOU: Yes.
Q. Can you confirm that you both contributed to that report and that it is true and accurate to the best of your knowledge and belief?
PROFESSOR DONNELLY: Yes, it is.
DR CHRISTODOULOU: Yes.
Q. When drafting your report, did you understand that your duty was to assist the Chair to the Inquiry on matters properly falling within your expertise?
DR CHRISTODOULOU: Yes.
PROFESSOR DONNELLY: Yes, we did.
Q. I'm going to ask you questions about parts of that report. Please both of you respond as you see appropriate.
DR CHRISTODOULOU: Thank you.
Q. I want to start by discussing in fairly basic terms some general concepts relating to scientific studies so that we can better understand the detail of your report. I'm going to ask you what the terms "hypothesis", "comparison groups," "confounding" and "peer review"

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

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

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

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

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

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

DR CHRISTODOULOU: Indeed.

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

testing a hypothesis?

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

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

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

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

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

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

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

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

DR CHRISTODOULOU: In the other group --

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

DR CHRISTODOULOU: Exactly.

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

DR CHRISTODOULOU: Yes, we do.

Q. Another phenomenon that we see referenced in your report

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

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

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

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

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

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

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

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

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

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

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

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

THE CHAIR: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR CHRISTODOULOU: Could you repeat the question, please?

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

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

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

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

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

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

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

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

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

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

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

PROFESSOR DONNELLY: So randomised control trial is

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

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

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

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

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

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

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

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

have a relatively appropriate strength for the comparison to happen.

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

DR CHRISTODOULOU: To my understanding, no.

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

Q. Not within the papers we provided you?

DR CHRISTODOULOU: No.

PROFESSOR DONNELLY: Of Oxevision for mental health inpatient settings.

DR CHRISTODOULOU: Yes.

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

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

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

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

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

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

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

PROFESSOR DONNELLY: Yes. So to quote from them:

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

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

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

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

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

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

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

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

report, have you provided an executive summary?

DR CHRISTODOULOU: Yes, we have.

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

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

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

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

DR CHRISTODOULOU: Broadly, yes.

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

purpose?
DR CHRISTODOULOU: We try to find themes that connected the studies so that the narrative is coherent.
Q. Now, the first of those sections, does that look at economic evaluations performed in respect of vision-based patient monitoring systems?
DR CHRISTODOULOU: It does.
PROFESSOR DONNELLY: *(The witness nodded)*.
Q. But is it correct to say that when considering the conclusions which can be drawn from those economic evaluations, you have to have one eye on the assumptions that fed into them?
DR CHRISTODOULOU: That is correct.
Q. Accordingly, I'd like to take your report out of turn, if I may, and start with Section 2 rather than Section 1. Is it correct that Section 2 of your report looks at Oxevision and related systems across a range of mental health inpatient settings?
DR CHRISTODOULOU: That's correct.
Q. And in total, in Section 2, did you review 15 studies?
PROFESSOR DONNELLY: Yes.
DR CHRISTODOULOU: Yes.
Q. And starting at page 15 of your report, do we find from paragraphs 2.4 to 2.18, individual summaries of each of those studies?

DR CHRISTODOULOU: Yes.
PROFESSOR DONNELLY: *(The witness nodded)*.
Q. And at paragraphs 2.1 to 2.3 do we see your overall appraisal of this part of the evidence base?
DR CHRISTODOULOU: That's correct.
BY PROFESSOR DONNELLY: *(The witness nodded)*
Q. In very broad terms, is Section 2 where we would look if we wanted to consider whether the Oxevision system is having an impact of any sort on the outcomes for patients who are subject to its use?
PROFESSOR DONNELLY: Within mental health settings, yes.
Q. I don't intend to take you to each and every one of those studies, I'm sure you'll be grateful to hear. The Inquiry has and will consider your report in its entirety, but I would like to take you to some specific studies just so that we can look at their results, their potential limitations and the strengths of the conclusions that can be drawn from them.

Can we start with the first Ndebele study from 2022, which is a study, I believe, from Coventry and Warwickshire Partnership NHS Trust, and you discuss this at paragraph 2.6 on page 16 of your report.
DR CHRISTODOULOU: Yes.
Q. I'll give you time to turn to it. Can you explain the methodology of this study? What was going on?

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

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

DR CHRISTODOULOU: That's correct, yes.

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

DR CHRISTODOULOU: That's correct, yes.

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

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

Q. And what were the findings of this study?

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

PROFESSOR DONNELLY: But that was non-significant.

DR CHRISTODOULOU: That was non-significant.

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

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

significance later.

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

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

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

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

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

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

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

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

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

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

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

DR CHRISTODOULOU: Yes, caution is advised.

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

DR CHRISTODOULOU: That's correct.

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

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

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

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

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

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

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

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

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

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

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

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

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

PROFESSOR DONNELLY: Indeed.

THE CHAIR: -- it is received?

PROFESSOR DONNELLY: Yes.

THE CHAIR: Yes.

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

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

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

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

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

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

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

important to acknowledge those.

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

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

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

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

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

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

DR CHRISTODOULOU: Yes.

PROFESSOR DONNELLY: I do, yes.

Q. What did this study look to evaluate?

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

Q. And what were the findings of this study?

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

annualised moderate severity falls.

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

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

DR CHRISTODOULOU: Yes.

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

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

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

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

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

yeah.

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

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

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

DR CHRISTODOULOU: Yes.

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

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

Q. Yes.

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

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

Q. So --

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

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

I can see you nodding.

DR CHRISTODOULOU: Yes, that's correct.

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

DR CHRISTODOULOU: That's correct.

PROFESSOR DONNELLY: *(The witness nodded)*.

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

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

DR HAYES: Yes, perfect.

THE CHAIR: Ten minutes. Thank you.

(11.06 am)

(A short break)

(11.30 am)

THE CHAIR: Mr Hayes.

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

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

DR CHRISTODOULOU: Yes, it is.

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

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

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

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

Q. What was this study seeking to examine?

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

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

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

Q. Is it --

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

Q. And what is the consequence of that?

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

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

PROFESSOR DONNELLY: Indeed.

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

DR CHRISTODOULOU: That's correct.

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

DR CHRISTODOULOU: That's correct.

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

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

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

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

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

DR CHRISTODOULOU: That's correct.

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

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

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

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

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

DR CHRISTODOULOU: That is correct.

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

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

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

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

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

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

DR CHRISTODOULOU: That's correct.

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

DR CHRISTODOULOU: That is correct.

Q. And was that result statistically significant?

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

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

Can we bring up OXHE020520 at page 5, please.

PROFESSOR DONNELLY: Yes, so there, what we see plotted is, we have on the left the data from observational wards, so those are the wards in which they had the vision-based system, and then we had the control wards, those are the comparison ones. The y-axis, which is the vertical axis, is -- gives you a number which is the rate of self-harm incidents, so how often that happens. And so if we look purely at the -- so -- and to add to that, then the colours, the difference between black is for the baseline period, grey is for the active period.

So if we just look at the two boxes on the left, that shows us the difference between observational wards and base lines, so before, and in grey, after the implementation of that. So you see a reduction. And that relates to the 22%.

So how do we get to 40 -- or how did they get to 44 per cent? And that is because that is a combination of that 22 per cent reduction, so the reduction inside the observational ward, and what was happening in the control wards, and you see that what happened in the control wards is that there was an increase between the baseline period and the active period. So incidents of self-harm actually increased that rate in the control wards, so in the absence of this intervention.

Now, if the control or comparison wards were exactly

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

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

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

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

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

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

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

DR CHRISTODOULOU: That is correct.

Q. And can we pull that up. It's INQY024285 on page 1.

Can we move over to page 2, please.

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

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

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

PROFESSOR DONNELLY: They calculated an alternative way of

doing it, yes.

DR CHRISTODOULOU: Yes.

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

Q. In respect of the way the data was presented in the Ndebele paper, Chua says this:

"Comparing a reduction in ward A with an increase in ward C exaggerates the apparent effect. The two directions of change are not directly comparable and doing so risks overstating the benefits of Oxevision."

In your view, is that a fair statement?

DR CHRISTODOULOU: That's a fair statement.

Q. Is there any benefit in presenting the data using the relative risk that was employed in the Ndebele paper to get to the 44 per cent figure?

DR CHRISTODOULOU: Again, every method has its benefits in the correct context. So for example, communication and how intuitive something to understand and how to contextualise data from multiple wards in one number. That is intuitive and easy to communicate. On the other hand, it is easy to decontextualise once we bring so much information into a single number and that may be the primary issue that we're dealing with here.

Q. Is there a risk that when you take data out of context it can be misleading, even if inadvertently?

DR CHRISTODOULOU: Taking data out of context is always

a dangerous thing to do.

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

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

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

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

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

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

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

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

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

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

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

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

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

DR CHRISTODOULOU: That's correct.

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

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

Q. What did they look at in this study?

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

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

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

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

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

THE CHAIR: Not comparing like with like?

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

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

heterogeneity?

DR CHRISTODOULOU: Not formally, to my understanding.

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

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

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

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

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

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

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

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

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

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

DR CHRISTODOULOU: Mm-hm.

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

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

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

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

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

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

DR CHRISTODOULOU: It does.

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

DR CHRISTODOULOU: *(The witness nodded)*.

Q. And should be afforded relatively low evidential weight?

DR CHRISTODOULOU: And I think they say themselves that adding more studies with stronger methodological controls will assist in understanding the system better.

Q. The final two papers I want to discuss in this section of your report are the systematic reviews. One is by Griffiths et al, and you discuss this at paragraph 2.13 of your report. The other one is or was undertaken by SQW for the Care Quality Commission and that's discussed in the following paragraph.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

moderate or low quality.

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

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

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

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

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

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

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

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

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

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

Q. Can I turn to your conclusions on Section 2 as a whole, which is set out, I think, at paragraph 2.1 to 2.3 of your report. Overall, did you summarise your view as:

"The evidence provides low to moderate support for the hypothesis that vision-based patient monitoring systems may contribute to improvements in some safety outcomes but substantial uncertainty remains regarding the size, causality, generalisability and acceptability of these effects."

DR CHRISTODOULOU: That's correct.

PROFESSOR DONNELLY: Yes.

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

you what you mean by acceptability?

DR CHRISTODOULOU: When we do not include more extensive qualitative research that would bring in, for example, the experience of the people working on the wards or the people being in the wards as patients, then that gives us our very numbers-focused understanding of the situation, which does not capture the entirety of the context, where the numbers were generated. Again, it's about providing context to the numbers.

Q. Is one thing that might be missed because of that whether or not the interventions, whether or not Oxevision, even if it does have an effect, is acceptable to patients, whether or not they will allow it to be used?

DR CHRISTODOULOU: Are you asking about whether consent was sought in the studies, or ...?

Q. No, what I'm asking is: in the absence of lived experience data and qualitative data, is there a risk that whether or not the intervention is acceptable to patients will be lost?

DR CHRISTODOULOU: Yes, we will not have any way of recording what they believe will be the appropriate implementation of the method.

PROFESSOR DONNELLY: Lived experience can also inform people who are considering an intervention in how they

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

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

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

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

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

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

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

DR CHRISTODOULOU: That's correct.

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

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

DR CHRISTODOULOU: That's correct.

PROFESSOR DONNELLY: Indeed.

Q. Can I ask about economic evaluations generally, then. How do they go about this task of working out whether or not the system would result in costs or savings?

DR CHRISTODOULOU: The type of economic evaluations that we

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

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

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

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

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

DR CHRISTODOULOU: That is correct.

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

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

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

a criticism of these, it's just reality.

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

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

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

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

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

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

DR CHRISTODOULOU: That's correct.

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

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

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

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

PROFESSOR DONNELLY: So to use the words of the authors, so:

"This early analysis indicated that the vision-based system is likely to be cost saving within both settings examined ..."

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

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

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

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

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

Q. You said at paragraph 1.4 that:

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

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

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

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

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

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

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

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

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

Can I bring up table 2 of OXHE020518.

If we look at this table, it says:

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

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

Is that the confidence interval?

DR CHRISTODOULOU: That's the confidence interval.

Q. What does that confidence interval tell us about the precision of this input?

DR CHRISTODOULOU: It is a rather wide confidence interval but the part that is the most obvious thing to observe is that it includes both a minus and a plus number, it means that it includes zero. Now, I need to bring to your attention the phrasing of this statement, it says "reduction in one-to-one observation" that means a positive number means a reduction, and a negative number means an increase. So the confidence interval includes both reduction up to 36%, and an increase to minus 13%.

PROFESSOR DONNELLY: That means that if you were thinking about it in terms of hypothesis testing, if your null hypothesis was that there was no change in one-to-one observation hours in this context, then you would not reject. So the data has not convinced you to reject that null hypothesis.

Q. So again, when we're talking about this reduction in one-to-one observation hours being cost saving, that's a conclusion that we need to treat with caution?

PROFESSOR DONNELLY: Indeed.

DR CHRISTODOULOU: *(The witness nodded)*.

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

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

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

DR CHRISTODOULOU: They did.

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

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

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

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

Is that a stronger conclusion than the data really allows?

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

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

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

So that's a more cautious statement.

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

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

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

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

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

DR CHRISTODOULOU: That's correct.

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

DR CHRISTODOULOU: Yes, that's correct.

Q. And so --

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

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

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

PROFESSOR DONNELLY: And they note in their conclusion:

"However, this is based on a single-centre observational before-and-after study."

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

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

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

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

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

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

PROFESSOR DONNELLY: So --

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

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

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

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

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

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

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

DR CHRISTODOULOU: Yes.

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

less, as well?

DR CHRISTODOULOU: Of course.

PROFESSOR DONNELLY: Yes.

Q. At paragraph 1.5 you conclude that "The base case conclusion is highly fragile." Can I ask what you mean by that?

DR CHRISTODOULOU: By that, we mean that if we have such difference in magnitude that is connected to a single estimate with quite high levels of variability like the confidence interval we saw, it means we are very uncertain as to what actual economic benefits we would be seeing in a real-life situation because remember this is an estimate that comes from a model rather than an actual realisation that was captured in real world.

Q. Final question on this paper. Is it correct that both this and the other Malcolm study were funded by Oxehealth?

DR CHRISTODOULOU: The -- Oxehealth funded the research institute that the researchers were based at, yes.

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

PROFESSOR DONNELLY: Yes, so it says that the authors are employed by York Health Economics Consortium, and that consortium was funded by Oxehealth to develop the economic model and manuscript.

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

independence as we saw or we discussed earlier?

DR CHRISTODOULOU: It would be similar concerns.

PROFESSOR DONNELLY: -- (overspeaking) --

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

THE CHAIR: That's fine, thank you very much, Dr Hayes. Forty-five minutes.

(12.31 pm)

(The Short Adjournment)

(1.15 pm)

(Proceedings delayed)

(1.20 pm)

THE CHAIR: Dr Hayes.

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

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

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

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

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

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

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

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

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

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

DR CHRISTODOULOU: Yes, we did.

Q. Can you explain the reasons that the article was

retracted?

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

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

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

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

DR CHRISTODOULOU: Can you repeat the question, please?

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

the evidence pool, in effect?

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

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

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

DR CHRISTODOULOU: Yeah.

THE CHAIR: Thank you.

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

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

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

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

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

Can I have on screen OXHE020526 at page 2.

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

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

Is that usual practice?

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

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

published?
DR CHRISTODOULOU: That would imply that if there is disagreement, for example, between what the authors are presenting and what the external party feels should be published then that may say that this is not allowed to go to publication.
Q. Can I turn to the York Health Economic Consortium analysis, this is at paragraph 1.6 of your report.
Now, is this the fourth and final economic analysis that you were provided with?
DR CHRISTODOULOU: It is.
Q. And is it correct to say that it also showed that there was a possibility for economic benefits to be realised by deployment of the Oxevision system?
DR CHRISTODOULOU: It does.
Q. Is it also correct that the analysis in this paper is subject to the same considerations that we discussed in relation to the two Malcolm papers?
DR CHRISTODOULOU: Yes, and furthermore, that particular analysis, because it's at an earlier stage, as we understand it, does not have any measures of uncertainty, which the Malcolm paper does, that's how we saw the confidence intervals being quite wide. Here we do not have that in the same way, and they also stated that they, I believe, had no full access to the data to

begin with. Here, yes.

PROFESSOR DONNELLY: Yes, the data analysis was carried out by Oxehealth, and the York Health Economics Consortium has not had a view of the data used for the analysis.

Q. What is the significance of that?

PROFESSOR DONNELLY: That gets us back to the same thing that happen with the previous paper. That the people who -- the authors of this report were not given access to the full data so that they might have not been aware of all the patterns that were there.

Q. So the assumptions made in them, they weren't able to interrogate properly the assumptions that were deployed in the model?

DR CHRISTODOULOU: *(the witness nodded)*

PROFESSOR DONNELLY: Indeed, they would be taking it on good faith from the estimates and summaries that were provided to them.

Q. Does the fact that the uncertainty analysis wasn't provided in this paper in the same way as it was the Malcolm papers, does that mean that we have to be even more cautious in relying on the data from this paper when considering what economic benefits may or may not be realised?

DR CHRISTODOULOU: That is correct.

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

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

DR CHRISTODOULOU: They do.

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

DR CHRISTODOULOU: That's correct.

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

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

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

DR CHRISTODOULOU: That's correct.

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

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

change, the overall benefits will alter.

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

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

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

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

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

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

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

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

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

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

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

effectiveness."

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

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

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

DR CHRISTODOULOU: Exactly.

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

Is that correct?

DR CHRISTODOULOU: Yes.

PROFESSOR DONNELLY: Yes.

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

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

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

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

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

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

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

DR CHRISTODOULOU: Yes.

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

PROFESSOR DONNELLY: *(The witness nods)*.

DR CHRISTODOULOU: That's correct.
Q. Is that a statement to the effect that these publications are not empirical data themselves?
DR CHRISTODOULOU: Empirical data is always in relation to a specific question. There would not be empirical data for the mental health setting on Oxevision but there would be contextual information for the system, or for the different settings that they're evaluating.
Q. So they don't provide evidence as to whether Oxevision can improve safety or patient outcomes or patient experience or whether or not they represent value for money in mental health settings?
PROFESSOR DONNELLY: Indeed, they don't address that. In some cases they talk about the potential for digital approaches, often more generally than one specific one, but it's in general terms in talking about, you know, what the future may bring in many cases.
Q. So does it follow that in terms of study methodology or statistical analysis in these papers in Section 4, there's relatively little for us to invite your comment upon?
DR CHRISTODOULOU: I believe so.
PROFESSOR DONNELLY: (*The witness nodded*).
DR HAYES: Chair, that concludes my questions. Do you have any further questions?

THE CHAIR: I don't.

Thank you, Dr Hayes.

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

THE CHAIR: Yes, 15 minutes. Thank you.

(1.39 pm)

(A short break)

(1.57 pm)

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

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

Questioned by MS SCOLDING KC

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

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

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

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

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

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

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

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

Q. Okay, thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

PROFESSOR DONNELLY: Sorry, could you repeat the question?

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

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

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

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

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

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

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

MS SCOLDING: Thank you very much. Those are all my questions. Thank you, very greatful.

MR GRIFFIN: Thank you, Chair.

If Ms Campbell could come forward.

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

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

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

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

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

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

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

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

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

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

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

culture measured as outcomes?

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

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

I think it would be impossible for one study to

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

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

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

Q. Professor, do you agree with that answer?

PROFESSOR DONNELLY: Yes.

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

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

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

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

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

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

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

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

DR CHRISTODOULOU: This is outside our area of expertise. This is something that somebody with a background in ethics would be able to answer.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Q. Within the mental health setting.

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

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

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

Q. Okay --

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

MS CAMPBELL: I will of course.

Would it have been important or helpful to have

reflected --

DR CHRISTODOULOU: It would have been informative.

MS CAMPBELL: Thank you very much.

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

Questioned by MS MISRA KC

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

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

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

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

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

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

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

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

PROFESSOR DONNELLY: Yes.

DR CHRISTODOULOU: Yes.

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

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

PROFESSOR DONNELLY: Yes, there were certainly cases --

DR CHRISTODOULOU: There were --

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

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

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

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

PROFESSOR DONNELLY: What we looked at in Section 2.

DR CHRISTODOULOU: Yes.

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

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

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

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

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

that would be very helpful, if you feel able.

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

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

DR CHRISTODOULOU: Did not.

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

Q. Thank you very much.

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

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

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

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

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

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

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

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

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

So:

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

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

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

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

DR CHRISTODOULOU: I believe that's correct.

Do you have a ...?

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

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

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

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

DR CHRISTODOULOU: That's correct.

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

Q. The two go hand in glove?
PROFESSOR DONNELLY: Yes.
Q. I understand. Thank you. The next one, again, is that your report seems to suggest that there was no evidence that could be given even moderate weight in support of the acceptability -- and I use your definition from the report -- of Oxevision in the inpatient mental health context?
DR CHRISTODOULOU: Yes, that's correct.
PROFESSOR DONNELLY: Yes --
DR CHRISTODOULOU: That's correct --
PROFESSOR DONNELLY: There is little focus on that --
DR CHRISTODOULOU: Very little focus on that. That's correct.
Q. Thank you. And again my fourth proposition: there was no evidence that could be given even moderate weight in support of the economic value of Oxevision in the inpatient mental health context?
PROFESSOR DONNELLY: So we -- I mean, there we talked about the evidence being limited. I mean we have these calculations, we've talked about the fragility of some of these results, that they rely on estimates. So the economic evaluation is always going to be dependent on the strength of the estimates that go into that and when they are uncertain, particularly the economic ones seem

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

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

Q. Thank you.

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

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

DR CHRISTODOULOU: -- (overspeaking) --

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

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

DR CHRISTODOULOU: *(The witness nodded)*.

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

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

MR GRIFFIN: Thank you.

Ms Bartlam, please.

Questioned by MS BARTLAM

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

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

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

In relation to the economic evaluations of

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

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

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

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

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

DR CHRISTODOULOU: Yes.

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

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

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

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

DR CHRISTODOULOU: You mean the reason it was believed?

Q. Yes.

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

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

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

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

these economic evaluations as a basis for introducing Oxevision?

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

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

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

Q. Thank you.

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

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

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

proceedings.

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

DR HAYES: No further questions from me, Chair.

THE CHAIR: I have no further questions.

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

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

DR CHRISTODOULOU: Thank you.

PROFESSOR DONNELLY: Thank you.

(2.39 pm)

(A short break)

(2.50 pm)

THE CHAIR: Ms Harris.

Closing statement by MS HARRIS KC

MS HARRIS: Thank you, Chair.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

carers in risk assessments.

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

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

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

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

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

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

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

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

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

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

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

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

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

them", she said.

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

And she was asked the question:

"What about things like copying and pasting?"

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

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

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

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

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

Evidence that was echoed by Louise Borton.

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

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

patient'."

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

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

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

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

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

Finally, Chair the staff evidence gave rise to

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

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

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

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

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

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

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

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

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

Mr Scott accepted that EPUT's actions had delayed

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

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

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

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

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

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

Chair, this week the Inquiry turned its attention to

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

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

In respect of this topic, Chair, the Inquiry intends

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

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

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

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

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

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

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

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

In contrast, having piloted Oxevision, we learnt

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Taken together, the expert evidence has provided the Inquiry with something of a wider national importance. Rather than asking simply whether technology can be deployed, the evidence has consistently returned to a more fundamental question: what genuinely improves patient safety, therapeutic care, and patient experience within mental health inpatient services? And that broader question lies at the heart of this Inquiry.

Chair, you have asked that your team considers the evidence with you before you make any final decisions as to what additional information would assist you on this issue. You have already indicated, however, that you would be assisted at least by hearing further evidence from EPUT around their use of technology in this way and from LIO, formerly Oxehealth, in response to the evidence which has been heard during this hearing.

The reframed Interim Recommendations Hearing in October will therefore provide an important opportunity to examine these two issues further, not only in the context of Essex, but in light of wider national practice and evidence. The next hearing will be at the Civic Centre in Chelmsford and in the meantime, Chair, your team will continue the important work of this Inquiry without break.

We continue to do whatever is necessary to uncover systemic failures in Essex, to assist you in meeting your Terms of Reference, and to make meaningful recommendations. Details about future hearings and further tranches of disclosure will follow.

Chair, throughout these hearings we have heard from bereaved families, frontline staff, senior leaders, other NHS providers and independent experts. And those different perspectives have repeatedly converged around

the common themes. And that convergence is significant.

It enables this Inquiry not only to examine what happened in Essex, but also to identify the wider lessons capable of improving mental health inpatient care nationally, where required.

Closing remarks by THE CHAIR

THE CHAIR: Thank you very much, Ms Harris, I'm very grateful.

We have now come to the end of this hearing and I'm grateful to everyone who has provided evidence over the past three weeks. It takes courage to talk about challenging experiences and sensitive topics in a public forum such as this, so once again, I would like to thank the bereaved families who have given evidence so openly about those who died.

I also recognise the potential difficulties that staff witnesses may face in giving evidence to a public Inquiry. Evidence from staff is essential if my team and I are to understand the realities of working on a mental health unit. Staff evidence received so far has given me an invaluable insight into what used to happen on inpatient wards in Essex, what still occurs, and what may be considered good practice, what is bad practice, and the potential pressures faced by many NHS mental health staff.

All the evidence at this hearing has given me a lot to think about, and matters that I and my Inquiry Team will want to consider most carefully.

I am grateful for the assurances set out in EPUT's Position Statement, supported by board members, that EPUT will (a) respond to the Inquiry's requests for information and documents within a reasonable timeframe, and (b) that EPUT are substantially on track to deliver the deadlines set by the Inquiry.

These assurances were confirmed in evidence given by Paul Scott, the former Chief Executive Officer, and Loy Lobo, the Acting Chair of EPUT's Board of Directors. Nevertheless, as Ms Harris has outlined, since providing that evidence to the Inquiry only two weeks ago, EPUT has given me cause to issue a pre-emptive notice under Section 21 of the Inquiries Act to ensure prompt compliance with a request for information.

I am hopeful, however, that from hereon, EPUT will be able to adhere to the assurances they provided during this hearing and that they won't disappoint me further in this respect. I would stress, though, that where I am concerned that deadlines will not be met, jeopardising the effective running of the Inquiry, I will continue to use the statutory powers which exist under Section 21 of the Inquiries Act to ensure prompt

compliance.

To undertake our investigations thoroughly we need information to be shared with us, and shared promptly by all information providers, but particularly by EPUT.

As Ms Harris has indicated, the next public hearing will be held in October in Chelmsford in Essex, where we will hear further evidence about the use of technology on inpatient wards and current practices around resuscitation. I will then consider whether to make interim recommendations on these areas of concern.

My ambition for this Inquiry is to improve mental health inpatient care for everyone. First and foremost for patients, but also for their families and for the staff working on inpatient wards, the majority of whom, I believe, want to do the best they can for those in their care.

My focus is on making recommendations that will have long-lasting impact on mental health inpatient care, both in Essex and beyond. Wherever possible I will extend the recommendations to make them national, so that the evidence provided to this Inquiry, the investigations undertaken by it, and the findings made can have the widest, positive impact possible and help to improve mental health inpatient care across the whole country.

It only remains now for me to thank everyone here at Arundel House who have looked after us during the course of these hearings, that includes the security team, the management and hospitality team here, and the technical team, RTS. I also want to thank our long-suffering stenographer, Louise Pepper, and our evidence handler, Amanda Shadbolt.

Above all, my thanks, as always, are to my Secretariat, my solicitor team, and my counsel team. I'm very grateful to you all. Thank you very much indeed.

(3.25 pm)

(The hearing adjourned until a future date in October)

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