[Vivienne:

Thank you very much. I'm delighted to be here. This is only the second time I've been able to attend an EIDO conference, so I'm really pleased to see so many people, it's a great delight. We've heard a great number of things from which we can be optimistic. I hope I'm not going to tell you anything that's too depressing. But I want to look at consent in the broader context and looking back through one of the public inquiries in particular, to see how things have been really, very sad over the years and we're now emerging from that, thanks to technology. I didn't understand all the acronyms, I have to confess, but it sounded very good.

Well, consent is clearly central to anything that happens in healthcare. It's almost like a sort of spider's web, wherever you go as a patient. Patients entering A&E are owed a duty of care by receptionists. So that the Supreme Court unanimously decided in 2020 that a man called Michael Darnley, who had a stroke because he was misinformed by a hospital receptionist, as he went into A&E that he'd have to wait for between four and five hours before he would be seen. So he left, with a terrible head injury, which should have been seen and treated. In fact, he would have been seen sooner had he left and had a really massive stroke and was awarded a large amount of damages. Having said that, of course, damages should be paid. Compensation should be paid to people who have been injured as a result of negligence. That is the way our system works. It's not the same in every country in the world.

But recently, and this is a cause of optimism, over the last year there's been a spate of cases in which people who have exaggerated their symptoms. To the extent that you know, they say they can't walk and there they are, photographed Hang gliding on their social media. So you know,

those cases are now really, very prominent and people like that who, in that case a man wanting 6.5 million pounds, got nothing. Not only did he get nothing, he had to pay back his interim payment of compensation. And of course, he didn't get his costs. So in some respects, things are improving as far as getting a grip on the high levels of compensation that have been paid out of, what is the same part as patient care is being provided.

So these are all, this is just a list of all the occasions when consent is important. We have been focusing today on adults who have capacity, which is great. It's wonderful. They can actually give informed consent, properly informed consent on most occasions now, but there are many other people who don't have that capacity. Not only people living in digital poverty, those people who lack capacity, we haven't heard much. We did hear mention of children at one point, which of course is great. People are under 16, and then between 16 and 18. Obviously, surgery is crucial to many of you here and consent for that is really, really important. But sometimes things go wrong even there.

In fact, I once advised someone who'd been, she'd had a great shock. She didn't get any compensation for this, but she went down for a mastoidectomy and guess what was written on the form. And she only realised just as she was waiting to go into the theatre, someone had written mastectomy. Obviously you know, an ENT surgeon couldn't do much about a mastectomy, (audience chuckles) but she made a complaint and quite rightly. So of course, there's emergency care, there's fertility treatment, all of these other things. Pregnancy, and we'll be hearing a little bit about that towards the end. End of life care, that's all over the media at the moment. Massive issues there, ethical issues as well as

legal issues. Then primary care. We haven't heard a lot about primary care, although it has been mentioned and then there's public health, all this stuff about vaccinations, and of course, that was very important during the COVID pandemic, public health regularly in the news. Care homes, massive area, hugely important because many people living in care homes have lost capacity. They may once have been able to be computer whizzes, but they are no longer.

And problems there with things like covert medication, people with powers of attorney. And I speak from experience there because my mother's 102, living in a care home and sort of, in and out of capacity if you like. And then there's mental health. How much do people really understand about the relationship between the mental capacity act and the mental health act? Very important. Clinical trials. We've had mention of clinical trials today. Very important area. And there are moves afoot actually to improve things as far as clinical trials go because in a way, it is the most important time, the crucial time for a patient to be properly consented. And then organ donation, huge. And of course, there's resource allocation. People who want the very, very expensive treatments and can't always get it.

And we've heard how important good communication is. Many a time you can hear a judge in court, those few who are lawyers, you will hear a judge ripping a doctor apart verbally, of course, orally. Because they have lied in communicating with patients. Or they've changed or altered the patient records, and not only doctors, other healthcare professionals. It's really important that they should know and understand that the best evidence is contemporaneous written evidence, and that's come over very clearly today from almost every speaker. So that is where, of course,

digital systems are extremely helpful. But, you know, documentation is very important at hand over time, or when a patient is discharged, going to their community. And of course, in terms of medicines reconciliation. When people go, they leave hospital and their GP doesn't know what medication they've left on.

So it's fundamental throughout the patient journey and where do we find out about how successful people are at consenting patients? We can find out from the law reports and we've had some very good explanations, some very clear explanations today, from the legal people who have been present about the latest case law. And that can be found in law reports, of course. Annual reports issued by NHS resolution, and the Welsh and Scottish and other equivalent organisations. The defence organisations, ombudsmen's reports. There's all sorts of sources where you could find out. It would be impossible, actually, to gather all this information into one place. But I won't go into that any further.

I want to look more deeply. Where can we find these deeper insights? Looking not so much broadly across the NHS and what goes on and private healthcare, of course. But where can we find these deeper insights into consent? Now, the problem we have is that litigation does not always unearth the truth. Because the system we have in this country, and it's in Australia, Canada, India, USA really, well, it's a bit mixed in the USA, but it's common law. The system based on English common law. Because the countries that this country colonised, dare I say it, years ago took with them and planted in those countries the legal system that they took. And it's known as English common law. There's another system called civil law, which operates in a different way. Now, the main thing about our system is that good advocates can win a case. And, you know, if you just

take Lucy Letby case, I know there's a lot of talk about that in the media at the moment as to whether she was guilty or not. That case was absolutely horrifying, but she was not called. Her team did not call her to give evidence at her trial, which would have been her right. That's because it was a decision of her lawyers. The judge is neutral in a case like that and in civil cases of clinical negligence cases, you've heard the judge is neutral. The court is neutral and it's for the advocates to prove the case. The person bringing the case must prove the case. If it's a criminal case, it used to be said 'beyond reasonable doubt'. But you know, the jury or whoever is judging, has to be satisfied so that they're sure, which is I think, rather more difficult to understand than beyond reasonable doubt. Never mind.

In a civil case, like a negligence case, the case has to be proved on a balance of probabilities. It has to be more likely than not that the clinician was negligent or whatever. So it's a matter of, it's not really getting the truth. Sometimes you know somebody's lying. It's, I shouldn't say this, but you know, fibbing perhaps, is a bit of a euphemism for it. And yet, they get away with it, as it were. So the only ways of establishing the truth is to use an inquisitorial procedure, not an adversarial procedure, an inquisitorial procedure is used in those other countries that have civil law systems based on, originally on Roman law, but places like France, Germany, Japan, and so on. And inquisitorial procedure is quite different.

I apologise to any lawyers of here because it's going to sound like an oversimplification. But basically the judge is in full control, can order people to come and give evidence. And really, it's up to, and if you take an inquest for example, which in this country uses an inquisitorial

procedure, as the name suggests. The judge will say, “well, I want to speak to all these different people. They've got to come and give evidence on oath.” And all sorts of things come out in inquests. I mean, when I was in practice, present during an inquest at which a man had committed suicide, very sadly. And he had a wife and three children, and a partner with whom he was living as well. So he had two households, if you like, but neither knew about the other. So he told, and all of this came out in the inquest, that he told the wife that he was doing a very important job for Mercedes and he was having to go to Germany and drive cars back. I don't know, I can't remember what he told his girlfriend, his partner. But you know that sort of thing, you'd never get coming out really, in a normal trial if it is adversarial.

So the other area in our law in which we have inquisitorial procedure, that is, seeking the truth, is the public inquiry. And other inquiries, you know, many of you here who are lawyers, will have carried out investigations into things that have gone wrong in health. That is something that I do from time to time. And you have great scope to speak to witnesses. ‘Well, I think I ought to hear from that nurse who observed allegedly that procedure’ or you know, those are the sort of things you can seek, that's the way in which you get at the truth. So internal inquiries within health boards and trusts, and external inquiries where someone else is commissioned, someone like Donna Ockenden, a very famous midwife who's done a lot of that. So the aim then is to establish, what I would say, is the truth. And there's quite a lot of case law, which I won't dwell on.

Coroners’ inquests seek the truth about by investigating certain deaths where the circumstances are unclear or unknown, or there's been a violent

death say, or an unnatural death. And they then in an inquest, the coroner, aims to discover: who the deceased was, where and when they came about their death, and how the death occurred. And as the law is progressing, the coroner is becoming able to extend the scope in certain cases of inquests. I won't dwell on that. What I want to talk about mostly are public inquiries. And public inquiries are usually major investigations into matters of really important public interest, usually convened under an Act of Parliament called the Inquiries Act 2005, by a government minister and they can be given special powers. It depends on their terms of reference as to what powers they have.

But for example, the chair of the inquiry can compel people to come and give testimony under oath, and they can ask for all sorts of evidence because they're there to find out actually what did happen. And each inquiry is led by a panel with a chair person, usually legally qualified. Very seldom do they have one who's not, usually a very eminent judge. And the public inquiry begins when its terms of reference are set out, covering all sorts of questions that the inquiry is going to address and the good news about them, is that they raise the profile of large-scale scandals in a coordinated way. And the other thing is that they investigate very thoroughly. Hardly a stone is left unturned. They attract media interest. So you know, the COVID inquiry, which is currently ongoing, is from time to time, picked up by the media and reported on. And it’s still got a long way to go, of course. And they draw attention to serious errors on the part of public bodies

They also encourage victims of bad practice to come forward, people who didn't know they might have a claim somewhere because of something that happened to them. And they save time and money for litigants by, you

know, someone else is unearthing all the evidence for them as it were. And they make valuable recommendations, although these are not necessarily always followed up. However, there are certain drawbacks, very, very time consuming. The infected blood inquiry has taken six years and it's covered a huge geographical area. The whole of the UK, right back to 1948, but mainly for focusing on events between 1970 and the 1990s. And in the course of these long inquiries, you might have the chairperson dying or staff leaving, going on to more interesting things. They can become adversarial, although they're not meant to be. And their recommendations, sadly, are not always implemented.

So the government is currently reviewing them. They announced a couple of months ago that they're going to review these very expensive time consuming inquiries. And there's an example of a few historical, recent and current. One in the 1970s, it's about a hospital in Cardiff, the Bristol inquiry when Ian Kennedy investigated deaths of babies undergoing surgery in Bristol, Royal Infirmary. The Shipman inquiry, I know you know all about that. That was very long-winded, it produced three reports. Dame Janet Smith did a wonderful job there. A lot of that was about consent, a lot of the Bristol inquiry was about consent or the lack of it.

Grenfell Tower has recently been in the news and of course, the Lucy Letby inquiry has now just been set up. Now, I know that print is probably too small for you and I apologise, but you will have copies of these. I want to talk about the infected blood inquiry then, and it was Sir Brian Langstaff, who's the chairman, presenting findings in 2024 after six years of inquiry. And more than 4,000 statements, vast, vast inquiry. Around 30,000 people had been given contaminated blood and

tissue. And, you know, you can imagine the extent of trying to identify who they were, whether they were still alive, most of, an awful lot of them have died. Who their relatives were, because the relatives were affected. You know, you don't have a tragedy happen to one person in a family without the whole family, really, the closest family being affected too. And the main findings were, and I'm focusing mainly on consent, were that there was profoundly unethical lack of respect for individual patient autonomy. And of course, consent stems from autonomy.

Closely related to that, was this idea that clinicians should have clinical freedom. They ought to be allowed to, and the word 'experiment' was used on patients. And many patients were experimented on by these by the use of these blood products, without being informed at all that they'd come from prisoners in America, for example. So clinical freedom enabled clinicians to, as it were, get away with doing things that were unethical. But on top of that, there was reluctance on the part of managers and you know, senior civil servants and even ministers to interfere with what was going on, even though they knew. And damage was caused also by the lack of candour. I mean, terrible things were happening to these people, and nobody apologised or explained or said, "look, we made a mistake."

Now, it was way back in the 2001 inquiry into the Bristol baby scandal, that Sir Ian Kennedy recommended that there should be a duty of candour. It took a very, very long time for that recommendation to be followed up. But there were all sorts of failings in the processing of blood. You know, it was being done in sort of in people's back gardens in sheds in some instances. And despite the discovery of known risks, many, many examples of poor treatment and lack of consent could be found And this

was all going on at a time when we were listening to all kinds of government strategies and you know. Health boards, trusts were putting out their latest strategy on putting patients at the centre, and we've heard a lot about that today. Respecting patients, which you know. That all goes with the basic ethical principles, of course, autonomy and respect for persons.

And so, you know, the courts at the time were developing law on consent. And yet all this stuff was still carrying on. So extremely unethical practices and I'm going to focus on one tiny part of this huge, huge, massive report, which I did try to boil down for something I was writing and I just gave up in the end. It was too big. I just picked out certain things. But there was a school at which people with haemophilia were being educated. Only about 30 of the people attending that school, apparently over the years, there had been about 122 pupils there between 1970 and 1987, are still alive.

But the report points out that what happened there, both illustrates and highlights the nature of, and many of the reasons for the national treatment disaster, which was infected blood. And Rishi Sunak, when the when the report came out, said it was the biggest disaster that had ever occurred in the NHS since it was founded. So extremely unethical practices were found in the course of clinical trials. Boys were being pulled out of class, 'oh can you just go in and you've got to have an injection, or a blood transfusion' and many of these were young people who were Gillick competent, but they weren't told what was going on and their parents were not told either. And it both illustrates and highlights many of the reasons why it was such a terrible disaster.

So lots of areas of wrongdoing were identified, and evidence from the few people who survived has been absolutely devastating. It's a long report, but it's worth reading to understand how and why this was ever allowed to happen. And it's, of course just said in the inquiry and one of the findings, was that it has long been recognised that informed consent is essential before a person can be entered into a clinical trial. And that particular care should be taken when children are being considered as trial subjects. It's also good practice, as stated in all the protocols and so on, to stop a trial when it becomes apparent, the trial subjects are suffering harm. Obviously, the most basic principles of law and ethics were flagrantly flouted at Treloar's.

One of the things that had been recommended by Sir Robert Francis in the mid staffs inquiry was that there should be a criminal offense of wilful neglect. That criminal offense was created in 2015 in the criminal justice and courts Act, section 15, and wilful means reckless for the purposes of that act. There are instances now, of prosecutions for people who have been guilty of wilful neglect of patients in clinical trials, by not fully informing them of what was going on.

There have been lots of other inquiries that have highlighted issues about consent. The maternity services, loads of inquiries there. The Ockenden review, the East Kent hospital’s NHS foundation. That's another one that’s awful. A report of the all parliamentary group on birth trauma. And that particular report is again, quite shocking. Again, you will have the slides. It's too long a story to tell.

Poor communication throughout. Findings of not asking for consent, a lack of informed consent about risks and complications, women being mocked when they were in labour and asking caesarean sections or pain relief. You know, anyone who's ever been in labour will know, and I've done it six times so I can tell you. You want pain relief. You don't want to be laughed at because you ask for pain relief. And you don't want to be told, "oh it's quite normal dear". So I'm not going to go on with this. I'm only going to tell you that there are some good things. Oh, Derby, there's one gone on in Derby as well recently.

I'm only going to tell you that the Maternity Alliance has called for a public inquiry into these maternity cases because there are so many of them now. But the good thing about it is that recommendations have been made and acted upon far more quickly because these are small independent inquiries. They are not like these huge public inquiries taking years and they're not as expensive to carry out. So we know that there's a lot of racism going on in maternity wards, but the conclusion, you'll be pleased to know it's the conclusion now. (audience chuckles)

Despite consent being central to good practice, and we all know how important it is, and high quality care. Many examples of bad practice on consent have been revealed and we know about them, and recommendations have been made to improve them.

So I hope that what you've heard today from EIDO, and from many of the other presenters, will you know, resonate and you can take it back to wherever you're from and implement, because good things can happen.

Thank you very much.

(Round of applause)

[Simon:

Are there any final questions for Vivienne? Yeah, one at the back.

[Ben:

Hi, Vivian. It's Ben Troke from Wakeman's solicitors. Not a question, but a comment since you mentioned the duty of candour, just to flag up that today, a concern about um sometimes a lack of openness about patient safety issues and concerns. As a result of that, the government has published proposals today for changes in the regulation of NHS management and potentially introducing an individualised duty of candour for professional NHS management and execs. Alongside the GMC, NMC clinical duty and the statutory duty of care, sorry, statutory duty of candour in the CGC regulations that only applies to organisations. So that's just been published today and is out for consultation till the 18th of February.

[Vivienne:

Thank you. That's great. I haven' time to look that up. I usually pick these things up on a daily basis, but not that one. Thank you. Thanks, Ben.

[Simon:

Okay, thanks for that. Any other comments or questions? The question is what about those are aren’t included in?

[Unnamed attendee:

If they are unable to consent to treatment are they included in the digital consent thing with EIDO?

[Simon:

So, obviously, if a patient doesn't have the technology to consent digitally, then as Julie said earlier, we have our paper versions of the information that we can give to patients and they will use the traditional paper consent. I don't think we're ever going to completely replace that because of the reasons you just said. But we can also, for patients being consented in hospital, we can use the iPads with them and lead them through that. So, you know, we can provide the technology for them. They just need to be able to read it.

[Vivienne:

So can I just add to that? People who lack capacity. Is there any way of training the people who have powers of attorney for them, for medical decision-making? Does EIDO offer a service to people like that?

[Simon:

So we for patients who lack capacity, then we would go to consent form two, which is the two doctor sorry. Consent form four, which is the two doctor consent. Obviously other members, people with power of attorney can for medical matters, do have the legal right to do that.

[Vivienne:

They need to yes, but you know, it's very important to give them some information about all of that.

[Simon:

Yeah, so we could actually provide it to people who have that legal right. Absolutely we can provide that.

[Vivienne:

Get onto the court of protection, tell them.

[Simon:

Okay. (Chuckles)

[End of Transcript]