[Bryony:

Thank you very much. I just wanted to answer that question about the MDT. The MDT, it's 'no decision about me without me' is the mantra of an MDT, and when you come out of an MDT with an MDT recommendation, it's not a decision. It's just to facilitate the consultant discussion with the patient.

So, on that note, I've been asked to talk about implications for surgery and patient safety. My declarations are that I'm the medical director for surgery for mid-South Essex Foundation Trust, which is an accumulation of three hospitals in Essex, Basildon Southend and Brimfield or Chelmsford, for those of you who know Essex. I'm also an elected member of the RCS England Council, and I'm an EIDO Leaflet user and promoter. Okay.

So, the question I got was slightly different, but I thought I'd look at consent from my point of view. And the first time I was asked to give consent or take consent, I was a house officer, and I'll tell you how old I am, 1988, Some of you were not born, but I was sent to take consent from a man at the end of the ward who needed to have his leg amputated because it was so painful. It will not surprise you to notice that he refused to give me consent, because I had absolutely no idea how to do the operation. I didn't really know what it involved, I wasn't able to convince him that having his leg removed was going to be to his benefit. And I think it was probably the patient in the next bed who persuaded him that it was a good idea, because he'd had it done last week (Audience laughs). Fortunately, the registrar who did know how to do the operation went back and took consent.

I disagree with consent on the day. Consent is a process. It starts with the diagnostics. So I do endoscopy, if I see something in endoscopy that looks like a cancer, I'm gonna tell the patient that at the time, I'm not gonna say it is a cancer because that's not fair. But they're looking at the screens the same as I am when I'm doing an endoscopy. So it might be a cancer, you need to have these investigations, this is the process that's going to start. But consenting on the day of surgery is a complete waste of time. The patient's completely terrified. They've turned up, which is effectively implied consent. They do sign a form, but that is not consent, consent is the process that went on before that. They might have a few final questions like, 'are you going to do the operation?'

Patient information leaflets. When I started writing my own when I was appointed as a consultant, I have a fantastic lap-chole leaflet, which is very similar to the EIDO one which I now use. My diagram is better, and I draw on it for the individual patient. This week I did an endoscopy list in my NHS trust, which doesn't use EIDO endoscopy leaflets, but uses those little sticky labels that are too small for the patient to read, with all of the risks on the sticky label. So we've already talked about the Montgomery ruling, so you're familiar with it. It's about giving informed consent of material risk to the patient, that are relevant to them. So I'm not going to dwell on that again.

But it's important that the doctor, the test of materiality, is the really important thing for a doctor. In the circumstance of a particular case, what would a reasonable person in the patient's position want to know? And what importance would they attach to that risk? Someone alluded to being an ENT surgeon. My step-god-grandmother was an opera singer and you know clearly for her having surgery on her vocal chords is really,

really important, less important for me as a colorectal surgeon. So it's important to understand your patient and their particular attitude to risk. I think the most important thing about Montgomery is the shift in focus of consent towards the specific needs of your patient and being aware that any risk that an individual patient, not the doctor, might consider, is really important. And I as the doctor, am no longer the sole arbiter of making that decision for the patient, or even deciding what I think might be a material risk for them.

So the core implications for surgeons are that consent is patient specific. You need to know your patient. I'm really nosy, I want to know what everyone does for a living, mainly because I want to know if they might be helpful for me, if they're gonna mend my car or advise me on my architecture. But it's really just because I wanted to understand what they might know already, or what they're thinking, or what their beliefs and background might be. It's important that I make sure the patient is fully informed of the procedure and its consequences. But I also know about alternative treatments, some of which I may not offer myself. So an alternative treatment for the patient may involve them going to another hospital or seeing another specialist, or another person in my department.

A consent form isn't a decision-making record, and that's been alluded to. The importance of documentation, contemporaneous documentation. And I was criticised a long time ago by a patient's relative in a complaints procedure that, I wasn't actually the culprit, I was the medical director, meeting this man who said “why don't you write down as you go along?” And this was a patient whose cardiac arrest had not been documented as it was happening, and the medical registrar had gone off

later to write and come back and written in the notes ‘in retrospect’. This man didn't like ‘in retrospect’ because he was a police officer, and if you're a police officer, it all has to be contemporaneous or it didn't happen.

Communication skills are really important, and time pressures. You know, we need to take time to consent people for what can be life changing decisions and better technology can help with that, but it can also take longer. NHS Resolutions will tell you that the blue line, the percentage of claims relating to consent, has gone up to almost 12% of complaints are about consent. The green line is a good one for surgeons because that actually shows that the number of complaints against surgeons has gone down. But the cost to the NHS, my trust is currently in what we would previously call ‘financial special measures’, which means we don't have any paper anymore. But that figure on the right hand side of 7 million pounds cost of litigation to the NHS, I would really like to have that money in my budget.

So, as with all talks these days, I went to chat GPT and asked them what the patient's safety benefits of informed consent were. And in the second paragraph, you'll be pleased to see that apparently informed consent prevents ‘adverse events’, and I was very interested to explore this. The general medical council has provided seven principles of consent, which was spoken about earlier. The College of Surgeons went three better, but in fact, they can't count because the last one, 10A, is making a decision-making record, and that was also alluded to, the importance of documenting the whole process of consent and writing it down, and putting it in the letter to the GP.

So, I'm a colorectal surgeon and B.R.A.N is extremely important to me. The college says that you must use BRAN in your consent process, and that is the benefits of the procedure that you're proposing, the risks of the procedure that you're proposing, the alternatives to that procedure, including the 'do nothing' option. I think it's really important that we remember that. Surgeons are simple people. I can't remember ten and a half points, but I can remember four, particularly if it's BRAN.

This allows patients to make decisions that align with their preferences and values, to refuse treatments that they're perhaps not comfortable with, to avoid unwanted procedures, to say no they don't wish to have anything done, to ask appropriate questions and to voice their concerns. And it's really important that you involve their families. Because when a patient has a complication, particularly one that puts them into ITU, the people who you are going to be talking to are not the patient, they are the families. And they need to understand the risks, benefits, options of that procedure before you're having that difficult conversation with them when something hasn't gone to plan.

Enhanced communication, which comes out of informed consent, fosters a much better understanding of the treatment, and from Australia, we learned about trusting your doctor. I think you've really got to trust your surgeon. Surgery is effectively assault with permission. So you gotta trust the person who's holding the scalpel. The patient and their families have to have clear expectations what you can achieve, the potential complications, what their expected outcome is, what your expected outcome is, and that may actually help them to manage their own risks. So we now put patients into prehabilitation programs. I teach patients to do what's called 'stand to sit' or 'sit to stand' exercises,

I do them with them in the consent process. We all stand up and sit down out of the chair 20 times, three times a day, every time you boil the kettle, to improve your fitness to reduce your risks of dying as a result of the life-saving operation that I'm potentially offering you. And I think you have to engage with your patients so that they really understand how they can mitigate their own risk.

Shared information actually usually results in information flowing the other way. It's amazing how often patients don't tell you things, like they're on an anticoagulant, or they're taking St John's-wort, which also increases your bleeding time. You know, you need to know these things and patients won't tell you unless they trust you and if they think you're interested in them. ‘What does fully informed really mean?’ We talked about material risks. I'm not sure I still fully understand all of the material risks that I should discuss with the patient, and we can talk about that over lunch. We've alluded to percentages. One in five, that's 20% of the population. ‘Do you not understand what a percentage is?’ How are they going to understand when you tell them they have a one percent risk of something happening? So I like these particular type of boxes. I think that they're much easier to understand for patients. I couldn't find a decent surgical one, which perhaps says everything. Giving people a long list of potential complications or questions to ask on the back of a form they can't read, doesn't improve understanding. It just increases confusion. And I think it's really important that when you go into a consent discussion with a patient, that you're really clear about what information you're trying to impart to them, and you're confident about what you're saying. Don't consent for someone for something that you don't know how to do.

Empowerment and trust. Patients must have a voice in their care, and I think trusts generally do recognise the importance of involving patients. In the Royal College of Surgeons of England, we have patient involvement in every aspect of what college does, lay involvement in exams, communication skills at MRS level. It's a really important part of our service, because otherwise, we're not treating the patients that we look after if we don't include them in our discussions and our plans. I mean my trust website is impregnable, and I'd really like help with sorting it out from our patient advocates. But they're more likely to ask questions if they trust you, if they believe you're going to listen to their question, and that will engage them in their treatment, and then they'll take steps to ensure their own personal safety by the choices that they make.

Informed patients feel respected and they're much more likely to collaborate with you and adhere to safety protocols, or even to listen when you say, 'if this happens, call this number and we will see you', not 'turn up in A&E and wait for four and half hours to be sent home'. You've got to give them clear advice and guidance that they're gonna hear and they're gonna believe it's gonna happen. When we started our ambulatory service, I used to say to patients, "if you go home, this and you know, your CT scan will happen tomorrow" and they say, "I'm not going home because it won't happen tomorrow". And I go, "I promise it will happen tomorrow", and "I had to bend over backwards to make it happen tomorrow", but now they're prepared to go home because they know it will happen tomorrow. That's a very big change in patients' willingness to follow instructions because they believe that what you've said is gonna happen, will happen.

Informed consent results in better post treatment outcomes. Patients know what to expect. They're informed about the potential risk. They're much more likely to report them in the post operative period and they'll follow the instructions. So my patients go home with Inhixa for 28 days, and they're taught how to inject it, or someone else is taught how to inject it. But they know why they're taking it and why they're wearing their TED stockings and then they're more likely to keep them on even though it's 40 degrees outside. And they're also alert to complications. So if they listened and you've given good instructions, they will look out for wound infection and then they will report it. They'll seek medical help earlier.

I'm a colorectal surgeon, I have a team of colorectal nurses who are always contactable, and stoma nurses, who are another good way back into the hospital. Patients will call them and say, 'this has happened, what do I do?' and then you can see them and you can reduce adverse outcomes by doing that. But consent does not prevent errors. Patients and surgeons are human, complications, I prefer to call them 'adverse events' and not 'errors', will happen and you have to live with them if you feel that you were responsible for that procedure. Remember that surgeons and allied healthcare professionals do not set out to cause harm to their patients. That's not what we're trying to do, and I don't believe the consent form is about stopping you suing me either. But patients may choose not to go ahead. And that will reduce the risk to them of that procedure because they didn't have the procedure, but there will be complications of whatever else they choose to have done.

'Does informed consent reduce your legal and ethical risk?' I think it demonstrates that you've considered your patient's autonomy and the right

to make their own healthcare decisions, provided you make contemporaneous notes and you write them in the medical record, and they're legible. ‘Does it align your medical practice with ethical standards?’ I hope so, and the fact that you're here in this room means that you're interested in this whole subject. It records evidence that the patient is fully informed before they agreed to treatment, provided it was in text that they could read, and they were given time to consider it. And it does create a record that can be referred to in case of disputes, and we've heard of successful defence claims where the medical record has been clear and contemporaneous. And it reduces the chances of conflict, misunderstanding, or perceived violation of patient rights. And yes, it does protect you from legal risks. If you can demonstrate as a trust that you have a good consent process, it reduces your insurance costs as a trust because we no longer have crown indemnity. Each trust pays for its own insurance. So if you can show good medical note keeping and consent processes, it actually reduces your premium, much as it does your car insurance if you don't crash on a regular basis.

I was once told that the only way to avoid complications was not to operate, and if you've not had any complications, you've not done enough operating. But not operating may result in other complications. So there is always a balance as to which you're going to choose. So, the Royal College of England’s perspective on this is that 80% of cases in invited review mechanism, where we reviewed hospitals and doctors, are related to poor communication, teamworking and shared decision-making rather than actual technical skills. We have consulted with our membership, supported by the GMC with local workshops in London, that's where the college is. With Barts and Guy's and Thomas’, highlighting issues around lack of time to consent, delegating consent to other people and the challenge of what

is materiality. There have been some relevant inquiries and tribunals, such as Patterson and Dixon, resolution data which, I think we're gonna hear about later because there's a chap from NHS resolution going to speak, does show really mixed methods in the consent for general surgery, and we need to standardise how we teach people to take consent and what they should document. And we should work with partners such as the GMC.

Dixon failed to communicate material risks in patients for whom he used artificial mesh for prolapsing bowel. He didn't offer alternative treatments because he was single minded that mesh was the way forward and he failed to allow adequate reflection period for the patient, which we heard should be at least 14 days because this isn't a life threatening procedure. 'What should the information sharing content be? What is the material risk?' and I think that's where the EIDO leaflets come into their own in providing patients with a good background of information, and then the consultant has to tailor their conversation with the patient based on the patient's own understanding and background. But you need enough time, and that may mean the patient coming back to outpatients, which in a pressured NHS, is really difficult. Delegating consent, again, only delegate consent to somebody who can actually do the procedure. Don't delegate it to someone who's junior, but you've got to teach your junior colleagues how to take consent. So take them with you. make them sit in with you when you're taking consent, and ask them to give you peer critique as well. It's always good to get reverse mentoring from your younger colleagues. And pulled operating lists, I have a problem with these because patients can actually choose not to be on a pulled list, which means you don't get a random surgeon on the day who should be able to do the procedure, but maybe didn't consent you. Most of my patients don't want to be pulled.

Refection period. We've talked about ‘how long should the reflection period be?’ ‘How much time is appropriate?’ ‘Does a patient with learning difficulties need longer?’ ‘Do they want to consult with another patient advocate?’ You know, everyone is different, so you allow your patients the appropriate amount of time to make their decision.

Over reliance on signing the form is, we've already said that you might as well not have a form. You have to have a form to say someone signed it, but it's not actually a very useful piece of paper in the medical record. I think it's much better to have written notes, something in the GP letter that you've dictated about that particular patient. There's an inconsistent approach to the consent process across different hospitals and we’re now one big trust, so one of my jobs is to try and standardise everything. And I'm still working on it.

Complex consent. I work with the plastic surgeon doing abdominal wall reconstructions. Those are complex operations with complex anaesthetics. Recently, when we introduced EIDO leaflets, the anaesthetist said “no, we don't need leaflets, we just give anaesthetics.” I said “Well you do lots of things to the patients, you actually need to include consent for anaesthesia.” And I've watched the EIDO anaesthesia library grow, and I'm looking forward to our anaesthetist actually using this.

So what next? The college is implementing new guidance, training teams on e-consent. I'm very interested in the Welsh consent. I'd love to get hold of that, please. Lobby for time for consultants in outpatient clinics to actually talk to their patients properly, and I consent my colorectal cancer patients outside the MDT and outside clinic. We have a separate

room with nice sofas, nice pictures, all of the leaflets, a window. I can leave and leave the patient with the colorectal nurses they can have as long as they like. Local policies on addressing adequately the issues around delegation of consent and pulled lists. I think we haven't sorted this out yet. And obviously the college has a partnership with EIDO, which is partly why I'm here to support these information leaflets. And there's college guidance on consent, there's the e-learning modules, although at the moment you have to pay for that, which I'm not quite sure about. And guidance on remote consultations and how to manage video consultations. And under development is the guidance as I said on the consent checklists and a consent process map. So lots going on at college.

What's going on in my trust is that we have just started electronic consent in our breast units. I thought I'd talked to you very briefly about that journey. We have purchased our new electronic patient record, which is Cerner. We've called it 'Nova' and within that we will have an electronic consent process, we're trying to go paper free while supporting our less digitally competent patients and colleagues. The e-consent system is part of the EIDO offering, and I'm very pleased to have used the library for many years, but to have only recently gone through the digital consent discussion. It's taken us about 18 months, I think. But last month we used 907 EIDO leaflets in multiple specialties and in multiple languages over the last year. We have a big immigrant population, many of whom English is not their first language. So we've been through a process of mapping our consultation and once we've identified the need for surgery, discussed the pros and cons, we provide written information, usually in the form of an EIDO leaflet documented with its number in the record, give the patient a chance to think about

consent. And we've discussed whether you should not be allowed to go onto a waiting list until you've actually consented for a procedure. That has some logistical difficulties with the waiting list organisation, but really, if you're not gonna consent for the procedure, why should you be on the waiting list? You need time to think.

Pre-admission, and you'd have chance to review the information at home, discuss it with other people. Confirm your consent prior to surgery on the electronic platform, ask questions, and then be admitted, and on the day you have a final chance to agree that you want to go ahead on the day. And when you will meet the surgeon, hopefully the surgeon doing your procedure, but then it gets checked when you get to theatre, the nurses check that you are having the right operation and that you understand, and if they actually challenge, that's if they don't feel the patient can explain their operation. I've started asking my patients a new question, which is, 'it's lovely to see you today. I know you've come in for your surgery. When you went to the pub last night to see your friends, what did you tell them that you were going to have done today?' And it produces some interesting responses. Some people don't go to the pub clearly. I think I couch my question according to how much and how well I know the patient, but that's the that's the essence of the conversation. 'Can you explain to somebody else what I'm going to do to you and why?'

The porter walks the patient to theatre usually and has a long chat with them on the way, about what they're having done and have they got any concerns and will also flag up those concerns. It might seem quite late, but sometimes that little nugget of concern comes out, because the porter is somebody they feel they can trust in a different way. In the anaesthetic room we check again, that it's the right side, it's marked,

and the WHO checklist is our final sort of port of call to make sure we are doing the right thing to the right patient, and they have signed a consent form that says the same thing.

So this is an EIDO employee, Rich, with my breast surgical colleague on the first day of our electronic patient consenting launch in our breast unit. So I hope to come back next year and tell you how we got on. This is our timeline, I think it just shows that it takes a very long time to get people to engage with a process such as this. There have been laggards, there have been people who haven't quite done their training, possibly in the hope that we wouldn't go ahead but we went ahead anyway and said “right, now you really got to train.” And one of my biggest laggards found me in the corridor and said “you know that that EIDO e-consent process, it's amazing. Why haven't we done it before?”

(Audience laughs)

Okay? So we're a little bit behind. We've engaged our clinicians. They use the paper leaflets in one of my trusts, they still print them off and give them to patients, but we're getting there. We've under undertaken a review of our own consent policy. It will be on our website for patients to look at. We've completed our governance requirements in terms of changing the way we run our consent. We've gained all of the necessary approvals from IT governance, etcetera. We did a little pilot with four or five patients in Breast and ENT. ENT aren't quite ready yet but they will follow from the breast surgeons, and it's November, not September, but we have actually started to use it.

(Round of applause)

[Matthew:

Thank you very much Bryony, do you want to take a seat?

We did have one question sent in and I think you've actually covered it very well in your roadmap just there. It was about 'can patients consent to their treatment during the clinic appointment and then reconfirm on the on the day of the appointment?' And I think that's well covered in the roadmap as absolutely something that happens.

So are there any other questions or comments?

[Unnamed attendee:

Thank you very much. That was a nice presentation. I like the timeline of when you see them in clinic and then the next meeting, et cetera, et cetera. I work in a very, very busy university hospital. We operate on about 10 to 20 patients as an emergency every day, at least. How about the consent in an emergency setting when patients are under a huge amount of pain killers and they are unwell, etcetera, etcetera. And under the pressure of time and there are 20 patients waiting outside to be seen, and you're short of staff and theatres are rushing, you know? You know how busy it is and it just becomes a very, very challenging situation and actually finding it that, you're trying to help a patient as much as you can and their litigation comes later, this is very disheartening and frustrating.

[Bryony:

I'm not sure I can answer all of those questions. (Audience chuckles)

Reflecting on the e-consent in the breast unit, we've chosen a very contained environment with a small number of surgeons who do a relatively small number of procedures. ENT are going to be next. But in the meantime, I was talking last night and suggesting to Simon, that I think the next group I want to trial are emergency appendectomies. One procedure in an emergency setting where I will have an opportunity to educate all of the middle grades, the resident doctors, the consultants across the spectrum of emergency care and all of the nurses who work in the same day emergency care, surgical referrals unit. Because like you, I can see that emergency surgery is a very different setting from elective care.

And I've thought that rather than trying to launch it into emergency surgery as a whole, I did think about laparotomy and in fact, I use the EIDO laparotomy leaflet for laparotomy patients. And I think those are the patients who have the most major surgery, with the least warning, and the most consequences. And actually I had an emergency caesarean section a long time ago and I remember absolutely nothing about the consent process apart from 'please just hurry up and get this baby out' and I think they assumed I knew something about it because I can do a Caesarean section, but that's not the point. The point is that you sign up for a laparotomy. You're in extremis, you're full of morphine. You're told that there's a, well, there's a 10% percent chance you might die as a result of the operation, because that's what NELA says, but there's a 90% chance you might die if you don't have the operation. So there's no question you're going to sign the form, but then you wake up afterwards and the reality is that you don't remember anything about it. You know nothing about the potential consequences because no one, if they did explain them

to you beforehand, you don't remember them and I think with laparotomy, the really important thing is the post-operative information leaflet about what we did, why we did it, and then what the risks are to that. And the great thing about EIDO is those sort of blocks of information in leaflet, so you can you can build a more bespoke laparotomy leaflet potentially for patients. So I don't think that's answered your question, but I've got some thoughts.

[Unnamed attendee:

Just in regards to your e-consent process, if your patient fails to consent legitimately, because they don't want to go ahead with the procedure electronically and remotely, how are you not classing that as a DNA?

[Bryony:
We have talked about this. If a patient doesn't consent in a period of time, then it does flag back through the EIDO e-consent system to you, and then you offer them the opportunity to come back and have another conversation. It's not a DNA, it's just they haven't made a decision and there's also a facility on E-consent, which we've talked about whether we include or not, for them to ask questions. And we decided that we don't want to enter into an electronic conversation or a dialogue with the patient. If they have questions, then we will bring them back for another consultation. I think the most important thing is to give the patient enough information in advance that's material to them, for them to make a decision. E-consent doesn't replace a face-to-face patient centred conversation.

[End of Transcript]