[Karen:

Thanks, Julie, and thank you very much for giving us the opportunity to come here and talk to you about our experience with the digital platform within breast surgery in Nottingham. Excellent. These are our conflicts of interest so we've been involved in producing the breast leaflets for EIDO and our breast units received some fee for that and we've also had fee for conferences.

So just a little bit of background. So my interest in consent started about 12 years ago when I first came into this role and I was working with a breast surgeon one day. He's one of our consultant surgeons and it was a normal day in theatre, ready to see the patients before the day's operating began. And we were seeing the patients. If anybody knows any breast surgery, they would understand that seeing patients for marking up in the morning, particularly if they're having a non-oncoplastic procedure where they're having the breast cancer removed and also the breast reshaped at the same time, can take time to mark the patients up. We also got the patient to sign their consent form at that time.

So this was a very busy time, so often taking up to about 15 minutes, I would say, a patient. And we had four or five patients to get through and the list. And there was one particular patient who saw the surgeon and the surgeon hadn't seen the patient prior to the day of surgery. And the consultant was very experienced, and he felt that there was a better surgical option for the patient, so rather than just having the cancer removed on one side of the breast, have the cancer removed, but also to reduce both breasts at the same time. And I remember seeing the look on the patient's face and she was completely overwhelmed. And at that point, I just thought, ‘there's got to be a better way of doing this.’

And so all of this can coincided with me needing to complete a dissertation for my masters project. And so we carried out a service evaluation into the informed consent process. We've heard today about consent guidance and particularly that we should, it’s a process, and that we should be taking the consent or getting the consent form signed, probably a few days before the operation itself to give the time for the patient to be able to ask any questions. So our main concerns were about

timing of the consent. We looked at moving, getting the patients to sign their consents. But then we had issues with manpower. How do we staff those extra clinics to take that extra consent? And also logistically, how do we get the consent form to where it needs to be on the morning of surgery? So the service evaluation, the methodology I used was for focus groups. So I had three focus groups, five consultant breast surgeons in there. There was a group with three junior doctors. And when I say junior doctors, they were all at SPR level and above. We also had a patient group and these are patients that had all had breast surgery in the previous year.

So I thought I'd just share with you a few of the comments from my dissertation. So it was a qualitative piece of work and I'll just let you read those.

[indistinct voice speaks up]

[Karen:
Sorry, of course, yeah, I'll read them both because they sort of go together.

So I think to a certain extent, you need some explanation. A little bit more to say what might happen, not just, you know, d-d-d-d But they really haven't got the time, really. Your mind is not really processing yet. You know, they come up with all of these things and it's just a blur.' And then 'it's a bit like a spiel sometimes. You know on the television, when they're going to arrest somebody and then they say the whole thing, don't they? It's a bit like that. And they're just going through the motions as they are saying it rather than actually explaining it and making sure that it's been understood.' So quite clearly from our patients, we weren't providing them with the best service when it comes to giving them that information and taking the consent.

And these were some quotes from the medical staff and these are both consultants and our junior doctors.

So 'I think it', so consenting and marking, 'can be quite rushed on the morning of surgery.' 'I don't think it's necessarily a particularly comprehensive consent', 'and I think that we are not being realistic to

say that this is proper informed consent. It's just not.' And 'how valid is our consent on the day? I do have concerns about that.' And 'I find it really difficult, especially in the confines of the NHS, you literally just have to say, look, these are the facts relating to this operation.'

So they're quite concerning quotes, so we knew that we needed to change And then we had the opportunity to work with EIDO. So I'll hand over to Lisa now.

[Lisa:
So as you've already heard from Simon, oh! Sorry. (chuckles)

The EIDO pilot, the EIDO system was already available in the trust for patient information leaflets, but we weren't using it for breast. So the first step was to get all of the breast leaflets up to date, and I think it's fair to stay there were a few procedures missing, it hadn't been updated for a little while, and that process is now in place and we're regularly reviewing them. That worked out really well over COVID times. We could start using electronic information to send out to our patients as we developed them.

Then volunteers were requested for a trust pilot as a result of an incident review in the trust, and breast being a very complex specialty in terms of the procedures. And by that, I mean, we often stack procedures, so we will do something to the breast to remove the cancer, something to the armpit to, what we call a staging procedure, and then something reconstructive as well. And we often, could end up doing different things on different sides as well to give symmetry, so often can end up with four or five procedures stacked. So we were selected as one of the more complex specialties where our procedure consent is more complicated.

We worked with patient volunteers from our support group, so the previous patients who've been through the breast cancer pathway but got enough distance to look at it, without being so emotive for them. And we got them to test the test environment with us and we made lots of changes and EIDO were really accommodating at letting us make changes to make it work for our patients. Some of those things involved including email addresses, more patients than we thought were happy to use electronic

systems, but they wanted it direct to email so they could load it on a big screen rather than getting it by text and having to transfer it to their email because they weren't so Sappy that they knew how to get it onto their computer.

As for the test pilot, we've used an external system, which isn't integrated and has had its challenges and we'll talk about those. Simon's shown you the process, but it's a very intuitive system to use as clinicians, much more intuitive than a lot of the NHS systems we use. You put your patient's details in, or find them in the system, and you start your consent process. You type in your procedures and click on the relevant leaflets or relevant procedures as they come up and confirm the laterality for them and you can stack many procedures and you can add treatment options so there's a generic leaflet about treating invasive breast cancer and all the possible treatment options that might be applicable, and we've got the same for non-invasive cancer as well. We add any patient specific information, so there's an option to add specific information, so for us, we use mesh procedures to support implants and they're often animal derived, but there are synthetic ones available. So that's one of the things that we often record after discussing with our patients is that this patient specifically wants no animal derived products. We can add patient specific risks, so for those who are on blood thinners to treat a recent clot, we can document that their risk of a clot is much higher than for the average population that's quoted in the consent data and that they are increased risk of rebleeding as well.

We took the approach that we wanted to complete the clinician consent statement and where possible, send this through to the patient to review it at home. So our process is we have one results appointment and then often we have one surgical planning appointment, but feedback we get from breast cancer patients all the time is that they're absolutely overwhelmed with information. It's on a 28-day pathway in general and it's very tight and so doing more in the clinic just felt too much, both for us and for the patients. It does mean we can go through the system in clinic with a patient if they want to do it in the clinic, but actually for the vast majority who've taken us up on this, they've had the link to work through at home.

So in our pilot, it was slow to start like any new system in the NHS, it snowballed and it started very slowly. We've offered 145 patients e-consent. We were a little limited at the start, not all the procedures were on that are on now for breast, and it has expanded the procedure library. And in addition, it only really worked at the start when me or Karen who were very motivated, were in the clinic. We've now got some advocates, some of whom are here, like Ruth our senior trainee. Of those 145, 66 have either completed their e-consent and it's been successfully used in theatre, or are awaiting the date of surgery but have completed their consent ready.

Sixteen, so only just over 10%, declined electronic consent. A few had no email or no suitable device to view it on. A few said they preferred printed or face-to-face, and we have been printing off from the EIDO system to facilitate that. A couple admitted to limited literacy. The ones who are 'reason not clear', we've already mentioned earlier this morning that there is some shame about not admitting to a lack of literacy, and that may, those women declined to give a reason and that may account for those. And we had a few where the main language was not English. We've had quite a few unsuccessful consents. Mostly at the start, it's got less and less. There are half where the patient either didn't complete or start the e-consent process.

Now, there was emails coming up from EIDO that have sometimes gone to spam, and where we've had manpower, we have rung people up and reminded them to look in their spam folder and that might account for some of those. We also found that as people were coming through the breast clinic, they were then going to pre-op who were telling them, 'oh, no, we don't, you get preop done, you get consented on the day for breast.' and so we do wonder if that played a role early in the pilot.

Another quarter, so that's the top left quarter, were failures on the part of the hospital. So we failed to screen them properly. We thought we'd screened for language, but one of them didn't speak, although they spoke enough to communicate in the clinic, they couldn't manage with the written text. A clinician failed to initiate the consent section. We had a few cases where it was declined to be used by theatre teams, and that was all very early on and it was teams who were new, who didn't normally work with breast and declined to use it because I hadn't seen it before.

And the patient evaluation. We had, so everyone who's completed the electronic consent or accessed it, was sent an evaluation survey and we got 22 responses. I'm going to be quite quick through these, but I think agree is yellow, strongly agree is green, neutral is orange, and you'll see there's quite a theme as we've gone through. The digital platform was easy. Everyone reported receiving benefits who answered the question. Both PDF by email and digital accounts for the 21 who use the system and then printed is another five, so they were getting printed information as well as the digital information.

'Consent process used visual aids, and did they find them useful?' The vast majority felt they were useful, one was neutral. 'Adequate time and opportunity to consider the information presented.' Again, it's very rare in medical feedback that you get all agree or strongly agree and no disagrees. 'Consent process provided information in a way I could easily understand.' 'A good understanding of the benefits of the procedure.' 'Information on the alternatives, including the option of doing nothing.' In cancer surgery I think we, it's very brief the discussion about doing nothing, because most of the patients we're talking to do understand that can some treatment is indicated for cancer, but we're not very good at documenting that because of the knowledge that inherently comes as part of our conversation but this way it is documented and recorded.

'The patients felt comfortable asking questions and they felt they had access to the clinician, despite us sending this electronically to do at home', and we did use the section where patients can record the questions, but we only manage those questions face to face or by telephone, not across the electronic platform. So, important for me was 'did the patients feel involved with this electronic remote system where we're not seeing the patient face to face?' and they all agreed or strongly agreed and one was neutral. 'The patients felt empowered' and 'would the patients go digital again?'. Everyone who replied, and I accept that this is a potentially biased response, but everyone who replied said they felt happy that they would do that again as well.

We gave free text option and it's a really simple process. It didn't time out, broke the items to read up individually so it wasn't overwhelming. And patients can go into it and leave it and come back to it. And that's

a really, in our patient groups when we're working through how to use the system, that was really good feedback that patients wanted time to break it up. And all fine.

I'll Pass over to Karen.

[Karen:
Thank you. So we also sent questionnaires out to colleagues as well, so we could get their opinions of the EIDO system. So this is just demonstrating the responses that we had. So we had four consultant surgeons, one surgical doctor, three ACPs, strangely enough being I'm one of them, an anaesthetist, oh sorry, five anaesthetists. Which was really good, and it was really good to get the theatre aspects from you know, their feedback from the theatre teams as well. But unfortunately, we had no ODPs or scrub team, two admin staff and they'll be the two admin staff that input all of the patient details on the EIDO system for us.

'So what was your involvement with digital consent?' So most were completing 'in-theatre consent checks', and I suppose that's because we also have the anaesthetists on there as well with that. 'Accessing consent documents', so nine involved with that. 'Creating consent forms', 'obtaining consent from patients' and 'sending the digital information to patients'.

So, 'Did you did you feel your patient received adequate informed consent?' So overwhelmingly, we can see. Yes. Three, not applicable and that was because they were anaesthetists that were answering that question, that's why it's not applicable.

'How does digital informed consent compared to paper-informed Consent?' and people either felt that digital was better or it performed the same as paper. So, 'How easy did you find the process?', so the actual process of using the system. The majority has said 'somewhat easy', followed by 'very easy.' Nobody said 'somewhat difficult' or 'extremely difficult', which is reassuring.

'Did you find that using digital consent saved time and improved the process on the morning of surgery?', and this was something that was really important for us as I alluded to earlier, it could take up to 15

minutes to consent a mark a patient for surgery. And again, yeah, the vast majority said ‘yes, it did improve time.’ And ‘Was the consent form available in digital health records on the day of surgery?’ and either ‘always’ or ‘sometimes’.

[Lisa:
I'll just add that we've addressed that. There was a mis-filing, technical issue of mis-filing in our electronic record initially, which has been sorted. So that's no longer a problem.

[Karen:
Thanks, Lisa.
‘Was the equipment available to you to access digital consent?’ So 12 have said ‘yes’, and two said ‘no’, however I think there was a bit of a lack of understanding that actually there are iPads that we use in theatre and we can access the health record, our digital health record through that. And I think there was a bit of a lack of awareness and probably our communication, really I suppose as well, to the theatre staff and perhaps in these tests that they didn't realise they could access that on the digital…Yep (Chuckles). They didn't realise they could access the digital consent on their iPads.

‘Did the consent have to be redone? So overwhelmingly ten ‘never’. One had to be redone digitally and one had to be redone on paper, and there were three ‘unknown’. So again we put free text box, so ‘are there any procedures missing from the program?’. ‘Nothing that I have noticed’, ‘revision of breast reconstruction’, ‘auxiliary node sampling’, duct excision, and ‘fat grafting’.

[Lisa:
Two of those are already addressed and have been dealt with and the others are in progress.

[Karen:
‘Do you think any changes are needed to the process?’ So, ‘it's a great tool. I hope it gets used more widely’, that was from one of our consultant anaesthetists. ‘The biggest issue is ensuring that the patients has sent the link for the consent form prior to the surgery date, and this is very dependent on clinician involvement.’ ‘Text or

email prompt to remind patients to complete e-consent', We'll have to have discussions about whether or not that's possible. And 'I think digital consent is much easier and it saves time on the morning of surgery.'

'Do you think there are any changes needed to the process?' Electronic consent has performed well in my experience. 'Integrating into theatre routine that the patient's consent form is accessed by surgical or scrub team to prevent delays.' And I think that was probably an early, quite early issue, but we've addressed that issue as well. And now the theatre team, in theatres that we usually operate in, are well used to this process. 'Time consuming, adding the patient details in in-clinic.'

[Lisa:
That's just an issue for the pilot whilst it's not integrated.

[Karen:
And consent forms should be logged in DH-Isla consent section and as Lisa's already alluded to, that's now been addressed as well. And any additional comments, 'all consent should follow this process.' 'A recent feature to resend the link really helpful', and 'its ideal that the patients sign their consent in advance of their procedure date in accordance with nice guidance.' 'Ideally have iPads in theatre to confirm consent' and again, as I've already said, we actually have got the iPads in theatre.

[Lisa:
Just one slide on challenges and then we're done. So uptake for anyone in the NHS engagement, with digital systems that are not integrated, is really difficult. You're learning yet another system, another login, and we had big variability between clinicians. But it does, like anything if you persevere, it snowballs and you get a few people using it and a few more people become advocates and then it does spread. It's common in breast to stack the procedures and that was an added complexity for EIDO to work with as well, but they were really good at working that with us.

We had some technical issues. It was mis-filing not into the consent section of our electronic record so, and ensuring mobile numbers or email addresses are available and validated as well and checked. You'd be

surprised how many times it's not right, even though the patient's been asked it at their check-in at reception, so double checking. Our take-home message was that EIDO has enabled breast to move away from consenting patients on the morning and that the patients gave really good feedback, which I've already been through, so I'm not going to highlight that again.

And a little thank you to everyone. Thank you.

(Round of applause)

[Julie:
Thank you, Lisa and Karen. It was a fantastic presentation. Do we have any questions? We've got a few minutes.

[Unnamed attendee:
Operationally, especially in theatre, how are you coping with the dual economy of both paper and e-consent?

[Lisa:
So usually at the at the huddle at the start of the day, we'll mention which patients have got electronic consent. Most of our patients are cancer and most of the cancer procedures are on the system now. Some of the revision procedures are not, but most cancer is on there now. but we do discuss it at the at the huddle, which ones will be consent, which ones we've checked in the morning are electronic.

[Julie:
Any other questions?

[Unnamed attendee:
Can you hear me? Hi, thank you so much. That was really interesting. I've just got a slight red flag and I was chatting with Simon about this earlier. I happen to be, for my sins, on the horizon Europe ethics review for the European Commission research. And one of the things that that people are concerned about is, okay the system may be 'secure', air quotes. But however, it's when the information is passed from the patient to you that people have concerns. For example, is their Wi-Fi secure? And I'm just wondering when you went to your ethics committee to get consent

to do this research, did they have any issues or concerns about data privacy? Thank you so much.

[Lisa:
So we did do a full risk assessment with the help of some of the IT governance team at the hospital. Yes, there were concerns, but equally we're using other digital platforms all the time. Patients are, there is information about what information will be passed, in the in the entrance to the portal.

[Same attendee:
Yeah, but I'm talking about when the information goes from the patient to you, you know when it goes through the internet and up to satellites and wherever it is. It's just a lot of people, I'm just being devil's advocate perhaps slightly, that a lot of people are really concerned about what happens to that information en route to you and how are you able to mitigate that? Thank you.

[Lisa:
There is a technical statement which Matt is probably going to tell you about now.

[Same attendee:
Thank you.

[Matthew:
Yeah well, as was mentioned, there is a full information security process to go through to make sure data is encrypted and securely stored in transit, as well as whilst it's stationary. We use clinical safety process, The Safehand guys who are here, give us that clinical safety officer input. So there's a really rigorous process to go through. And then we obviously go through the process with NHS England around getting DTAC certification and the data security protection tool kit certification. So security is crucially important for this process and it's been built in from the design upwards.

[Bryony:

Just to ask what you're doing with the patients who don't engage with the platform? Do you then can send them on paper on the day or do you call them up before the day of surgery?
[Lisa:

So there's a reminder system built into EIDO as well that sends a prompt, but we have been phoning some patients when we've got manpower. As this is a pilot, the business continuity plan was built into AESOP and that was always, we've always got the paper option on the day, which is what we were doing before. Again, there's lots of non-ideal things about that, but that was what we were doing before. So we reverted to that.

But yes, we have been trying to phone patients, even just our bookings clerk has been phoning patients and just saying, 'have you seen the email? Have you responded, could you go on it?'. And you can obviously go on and see, if they've started it, there's a good chance they might finish it, if they're making progress.

[Julie:
Okay, I think that's all the questions we've got time for, but thank you very much Lisa and Karen, that was a really fantastic presentation.

(Round of applause)

[End of Transcript]