[Ben:

Good morning, everybody.

So I think there's seven principles of consent we're going to come back to time and time again with the GMC guidance there. So if I just move on slightly and actually put a slide that I think you'll recognise from earlier on, it's decision-making and consent. And I'm just going to look around the room now and say that, sort of ten years of experience in this space has shown that I think a lot of clinicians equate consent with a yellow form, with a consent form, whereas actually it's about decision-making. It's about that dialogue with the patient.

So it's an implicit part of every healthcare interaction. It's part of an ongoing dialogue with a patient with the medical notes providing that record of shared decision-making, that valid basis for ongoing treatment. And I think in this day and age with the retrospective scrutiny that we all deal with, it's a coherent narrative and ultimately a timeline that gets unpicked in the future. So I think it makes that very important point that it's about every healthcare interaction. It's about every entry in the medical notes. And I think that sometimes the medical notes have that very perfunctory function and we don't actually always remember that it's a legal record. It's a record of that ongoing conversation with a patient.

So, sorry to digress slightly, but this is the background to the peer review and I think most of you will be aware of it. That medical decision-making is complex and nuanced is a subjective assessment that we make often; the risks, benefit and probability of various outcomes in our patients because every patient is different. It's an individualised assessment. And I think we also recognise that our decision-making is perspective and dynamic. It's not a retrospective thing. It changes, the circumstances change as Simon alluded to there with the sort of gap between referral and listing for an operation in reality. And it's very difficult, I think, sometimes to communicate that risk and uncertainty to our patients. And I think again, looking around the room, I think sometimes we're not always sure of the exact risks in that individual patient. And we are, you know, it is very difficult to communicate the uncertainty we often have about the right way forward. And I think that that's a very important new answer to these conversations that we have.

So, anyone in the room, any takers for who this gentleman is here? William Osler.

So they've a rich source of quotations for any sort of Medical-legal or medical thing, eminent physician set up John Hopkins University in the sort of late, latter part of the 19th century. "Medicine is a science of uncertainty and an art of probability" and I think for me that frames the complexity of the decision-making that we deal with.

"Variability is the law of life and as no two face is the same, so no two bodies are alike and no two individuals react alike and behave alike under the abnormal conditions, which we know as disease". So I think that very powerfully encapsulates the individual circumstances aspect and probably alludes to the materiality of it. We can't really talk about standardised risk. We've got to look at that individual patient in front of us.

So, you know, some of you will remember the sort of doctors of the B series from the early 90s. Quotation from Peter Richards, then dean of Medicine. "Medicine is about making decisions on incomplete evidence, changing them in light of experience and sometimes living with the consequences of your wrong decisions". I think as clinicians, we all recognise that sentiment. And for me that encapsulates the sort of essence of what we should be capturing in that dialogue with our patients moving forward.

So there is a purpose to this and it's getting to the peer review. I think one thing that we're all very conscious of, it sometimes feels that there's a there's a dichotomy between medical and legal decision-making.

So, legal, always retrospective, they've got all the facts that are required. Medical, often prospective, dynamic. Legal, based on certainty and facts or certainly expert opinion. Medical, uncertainty, probability, changing conditions, complete information versus incomplete information, individual versus that concept that you've got a collective of patients that you're looking after, adversarial versus collaborative.

I think it's fair to say that you've got to see all the patients in your clinic, all the patients on your ward round. And I think the important thing for me at the bottom, that legal reasoning is often about the process followed in that decision-making, whereas sometimes, I think as clinicians, we can be accused of being outcome based. You know, if we get the patient on the right treatment, and the outcome is okay, quite often the process is never analysed.

So I'm sorry to digress there.

Our courtroom versus the Supreme Court with all the expert witnesses, all of the information required.

I won't dwell too much here, but we broaden the remit of our consent group to look at the decision-making aspect and actually now, we digress into end of life decision-making and also the triangulation with training around the mental capacity act, recognising that it is all decision-making. It's all part of a consent process and that dialogue with the patient.

So when we set up the group in 2017, we asked, "how can you measure the quality of that consent dialogue?, that consent process?" And most organisations relied on consent form audits as a surrogate marker. So summary format, tick box approach sort of to an extent, further context often required and no evidence of that preceding dialogue that Simon mentioned earlier in the outpatient clinic or within the ward round where it's not recorded or documented in the notes. And it's those missed opportunities for that dialogue.

So we ask, you know, what tool could we look at? So we went with peer review. So why peer review? it allows you to assess that two stage model that we all look for, or at least two-stage, in those consent conversations. And it allows an assessment to be made of that two-way conversation, that process of shared decision-making. And moving down the left-hand side there, the beauty of the peer-reviewed process is the relevant expertise is built into the process because it's undertaken by clinicians who are skilled in that particular procedure, that particular treatment. It allows for reflection on our own practice when we're undertaking those exercises and I think something important, with a

assistant medical director hat on, would be the process of normalising that process of review and reflection.

And I think that's something we've been slow off the mark about, especially as consultants or in actually accepting that that's an integral part of our professional development and something we have to embrace moving forward, given the increased scrutiny. It facilitates a focus specialty-based discussion. It allows discussion of key messages and it facilitates a consistent approach to that consent process where we're confronted with pulled lists and in our case, quite often regionalised services, where a patient may be operated on an a centre removed from where the outpatient consultation is happening, and also as Simon mentioned earlier, the concept of delegated consent. 'How do we provide that assurance about that delegated consent process?'. And I think from an organisational perspective, it allows us to provide greater assurance of those consent processes rather than the consent form as a surrogate. It allows us that at an organisational level to monitor trends and target intervention where particular patterns emerged. So that's why we went with peer review.

I'm not going to dwell too much on the methodology because it was incredibly simple. So the 'Who', specialty or clinical governance groups, coordinated by the leader of that MDT. Clinical judgment ordinarily would be a senior clinician just in terms of the clinical judgment required in what is a qualitative assessment of the consent process review of the medical notes. For 'How', retrospective review using the consent tool that we developed. The 'What', looking at the informed consent process, largely an elective setting, patients aged over the age of sixteen, I won't dwell on too much of the details. We used twenty sets of case notes and we used the three-month window for the initial rounds of peer review that we organised. 'Where', a review of surgical specialties and also broadening the remit slightly into interventional radiology, interventional cardiology and dermatology. And I can see that I'm rapidly running out of time there.

So some comments about the two-stage process, shared decision-making. If I just briefly allude to their consent standards, nothing surprising there, look at the consent form, looking for that two-stage consent process, looking at that consent dialogue, and actually looking at that

conversation around risks and benefits. So if I just skip to the end now for the purpose of time here, I'm happy to share the methodology, so looking for a ninety percent compliance with those standards, looking at the provision of a patient information leaflet was a crucial part of that conversation, development of an action plan, the idea that was discussed.

The key messages were: procedure specific leaflet only provided in forty percent of cases based on two cycles of this audit across Wales. Version of leaflet provided only recorded in twenty-five percent of cases. And one of the interesting things for me, not all appropriate and available treatment options discussed in more than twenty percent of cases. So that seemed to be where the dialogue fell down, was the discussion of the alternative treatments, including no treatment. And I think the crucial thing for us, which is something we may all recognise, is decreased engagement in the second cycle of the peer review. That's something I think we're finding, certainly in Wales, is that clinical capacity and various other factors are affecting engagement currently.

So feedback, very well received nationally, very valuable organisational tool, and it was the educational value of the exercise that I think was the big take-home for us and the element of reflective practice. And I think it's the educational value of this, above and beyond the quality improvement, I think is crucial. So thank you very much.

## [Simon:

Do you want to come up?

Great, thank-you very much, do we have some questions for Ben and Jonathan?

## [Anne:

My Name is Anne Davidson and I work for NHS blood and transplant which is the blood service for England, but I do work very closely with the blood services across the UK and Ireland. What I'm very interested in is, one: does everybody in the UK have access to your consent E-learning module?

# [Simon:

Does everyone have access to your consent E-learning module?

## [Jonathan:

Yeah absolutely. Everybody's got access and very much encouraged to participate and some health boards have made it part of their mandatory training program and we actually use it as incentive scheme to reduce the contributions to our Welsh risk pool fund by health boards with high numbers of take-up. It's accessible via our ESR platform and for our primary care colleagues, there's a system called 'learn at Wales', which looks remarkably like ESR but it's for primary care.

## [Anne:

Is that UK wide though? Can everybody in the UK?

### [Jonathan:

No specifically for the NHS in Wales. That E-learning package was specifically for Wales. It is technically accessible on ESR in England and obviously much of the law is comparable to England and Wales.

#### [Helena:

Ben, does your audit take into account patient preference for format of information and format of form? Because as a patient representative we find that's quite an issue, that patients can't actually access the information.

### [Ben:

If I'm honest it probably falls outside the remit of this audit, I mean I've struggled with what we call it. I've tended to go with a peer-review assessment. For me the emphasis was on the decision-making process undertaken by our clinicians because, what I think we were looking at was managing the risk and I think there's a recognition that, I personally think we are very outcome driven as clinicians, which gets back to the nub of the patient experience that you're alluding to there. And I think where we're more cited and mindful of the process, we're more likely to, if you like, allow for the patient experience in that process.

So for me it was about emphasising the dialogue and the process, probably without directly looking at the patient information forum because I'll give you a very honest answer. In the majority of cases the patient information leaflet wasn't being provided and I think there is a tendency still to look at consent as a flat blanket, so you know, I'll state you some risks which my or may not apply to you, I've given you the

information, you've been consented and I think it's getting that message across to clinicians that there needs to be a meaningful dialogue. And above and beyond that there needs to be documentation of that process that was undertaken and for me, the reason why I used two thirds of my presentation on that decision-making process is, we changed the name of the group and there's been a shift in emphasis into decision-making. And that for me is recognition that you know, it's about more than what we call consent to a procedural treatment.

It's actually an implicit part of every consultation and if I'm honest, the direction that Jonathan and I were taking about this morning, there's a pressure nationally and we have the ability to network nationally to, if you like, diversify into end of life decision-making and treatment escalation planning. Because when you look at the sources of scrutiny and you look at the sources of the patient experience line, that's where we're seeing the bulk of the concerns and incidents from our medical examiner service, which is national in Wales, and also from individual patient concerns so very much recognising the experience but I think that we are in the dark ages a little bit, as clinicians, and we need to recognise that it's a process that is not outcome determined predominantly, it's about the process undertaken with the patient.

### [Simon:

I think, you're not alone in having audits which are performed pretty badly and we've done audits in Nottingham. I sit on the consent committee, and time and again the resources that are available to the clinicians aren't being used and that's such a shame, and of course it's a risk.

We're gonna move on, so thank-you guys for that presentation.

(Round of Applause)

[End of Transcript]