[Amelia:

So we're going to spend the next twenty minutes or so taking you through the law on consent and how the law has developed, and then look at some recent case law to see how the courts are applying the law very up to date and some of the issues that commonly arise, and finally, some of the practical implications of this. So what that means in terms of takeaway messages.

In the interest of time, I should say that we're not going to look at any issues relating to patients who lack capacity to make decisions on specific treatments. So we're going to focus on capacitous patients. And I thought before we get into the law, we just have a look at some of the key principles, just remind ourselves. Some of this has already been discussed this morning, but consent must be given voluntarily by a patient who is appropriately informed and we're going to look at what that means. What does it mean to be appropriately informed?

The clinician must explain the procedure or treatment in terms that a patient can understand, and the point that Helena made around looking at the format of that information, how is it provided? That will include the use of language and how you communicate verbally in language, in language that a patient can understand, avoiding medical jargon, looking at any potential barriers to understanding. Some of those issues have been mentioned already, but really importantly, I'm going to come back to that, checking the patient's understanding. Have they have they actually understood, not assuming a level of understanding?

There's been some discussion already about documentation and we're lawyers, so we love documentation, but I recognise that there was a bit

of a tension there between, you know, as the lawyers retrospectively, what we're looking at and what you're doing in the field. But it is really, really critical. You know, a consent form is important, but it really just demonstrates that a patient can write their name. It isn't a detailed account of the discussions that you've been having. And one of the phrases that's been coming up a lot this morning is 'meaningful dialogue' and that is what we're looking for as lawyers in the notes and it is going to protect you in terms of showing what discussions you've had about risks and benefits with a particular patient.

So just by way of background, and I'm not going to spend too long on this, but I think it is important when we come on and look at some of the other issues that arise in terms of consent. Some background to the legal test and some laws already been discussed this morning in the Australian case of Rogers and Whitaker. But for many years, the duty for determining, sorry, the legal test for determining the duty to provide information to a patient was determined by the Bolam test and I think some of you will be familiar with that.

But essentially it's a peer review test, and if a clinician acts in accordance with a responsible body of medical professionals in the same way that they would do, they will not have breached their duty of care in that respect. So if you could show through expert evidence that you had discussed the same risks and benefits of a procedure with a patient as your peers would have done, the same responsible body of peers, then you would not be deemed to have breached a duty of care and consent would have be deemed to be valid. That test was amended subsequently with a caveat in the Bolitho case. So that test and whether or not you have acted in accordance with a responsible body of medical professionals has

to withstand logical analysis. But the focus, very much historically, was on the doctor knows best. So medical paternalism and that trumped patient autonomy.

That continued until a case called Sidaway, which did not change the law, but there was an important dissenting judgment from Lord Scarman in that case, who, his view was that the Bolam test should not apply to the issue of informed consent, so that a doctor should have a duty to tell the patient the inherent material risks in respect of the treatment that's proposed. And after that case, the paternalistic view, the sort of 'doctor knows best' view, that really did cease to, It was evident that it didn't reflect reality. And indeed importantly did not, did not align with the GMC guidance. So the law was at odd odds with that.

You want to say something else about?

[Jonathan:
It's just interesting hearing about Australia before, because it's not the only common law jurisdiction that's sort of moved away from this test for some time. In the USA, they've had a prudent patient test for about 50 years now, since the early 1970s. So doctors have to disclose any material risks inherent in a proposed line of treatment. And that involves, well, what would a prudent patient understand?

It's similar, you've heard about how the law has developed in Australia moving away from the Bolam test in the kind of early 1990s. Very similar position in Canada as well, actually, in the early 1980s. So to an extent, for quite some time, the law in this country has been kind of behind the law in other Commonwealth common law jurisdictions. Yeah.

[Amelia:

So, yeah, it wasn't in fact, until 2015, the law actually changed and aligned with the GMC guidance. And Montgomery has already been mentioned. I suspect all of you in the room will be familiar with the case, but I thought it would be remiss not to mention it and just run through the brief facts.

The case relates to the birth of Nadine Montgomery's son, Sam, in 1999. Nadine Montgomery had diabetes and she was of short stature, and she was aware that there was a risk she was carrying a larger than average baby. But the consultant obstetrician who was responsible for her care did not inform her about the risks of delivering a large baby, including the risk of shoulder dystocia and the potential consequences of that. And she did not discuss the option of having a Caesarean section with Nadine rather than a vaginal delivery. In the end, the delivery was difficult and Sam was born with a brachial plexus injury and cerebral palsy following the occurrence of shoulder dystocia.

And the Supreme Court found in favour of Nadine Montgomery and that there had been a breach of duty by the consultant for failing to inform her of the risk of shoulder dystocia and also the alternative of having a caesarean section. Nadine Montgomery was able to show that she had raised numerous concerns during the course of her pregnancy and that had she been aware of the option of having a caesarean, she would have opted for that, avoiding the injuries to both her and her son. And she was awarded over five million pounds in damages.

There's a fantastic film on the NHS resolution website. I've got a link at the end of the slides, which documents Nadine Montgomery talking about

her experiences and her story and she makes it very clear that for her, it wasn't about blame. It was about understanding what had happened to her, what had gone wrong, and making sure that nobody else went through the same experience as her. So I commend that to you.

So just cracking on, in terms of the legal test following Montgomery. So the law is now in line with the GMC guidance. Clinicians have a duty to take reasonable care to ensure that patients are aware of, or a patient is aware of, a material risk involved in a recommended treatment and of any reasonable alternative or variant treatments. And we're going to just unpick that a little bit and try and make it as practical as possible.

So what are material risks? What does it mean?

It's a two-stage approach involving both an objective and a subjective assessment. So the objective part of this: What risks would a reasonable person in the patient's position be likely to attach significance to? And then the second part, the subjective bit: what risks should a clinician reasonably be aware that an individual patient would be likely to attach significance to?

And this is the dialogue point. This is the part where you need to understand what is significant to your individual patient in front of you. Because in order to understand what's significant to them, you need to know about them, their lifestyle, their characteristics and their future aspirations. So this is the meaningful dialogue. It's fact sensitive and every patient will be different. So a small risk of serious harm may be something that most people would attach significance to,

particularly if it is an elective procedure, non-urgent or purely cosmetic.

By contrast, a relatively large risk of minor harm might not be expected to weigh heavily in the minds of most patients, especially if the treatment is vital or strongly indicated. And a risk, however, remote might be of particular significance to somebody whose livelihood would be significantly affected if the risk materialised. So the good example that we often use in our cases, surgery where there's a small risk of damage to the vocal cords, would be a particular significance to somebody who needs to use their voice in their in their career. So a singer or a nursery worker, teacher, that sort of thing.

I'm gonna hand over to Jonathan. He's gonna talk to you about reasonable alternative treatment options.

[Jonathan:
So I think the issue that arose pretty soon after the Montgomery decision is: what does a reasonable alternative' or 'variant treatment options' really mean? How far do the clinicians have to go? Do you have to discuss all the possible options or can the doctor exercise reasonable clinical judgment over what is discussed?

And one of the first cases after, that dealt with this issue directly, is the case of Bailey in 2017. So the claimant had suffered a DVT and she claimed she should have been advised of all of the possible treatment options, including options that were only available outside the UK. And this one, it's specifically that she should have been advised of something called an 'Illeophermeral venous stent'. I'm sure the medics

know more about that than me, but my understanding, certainly at the time, is that that was quite an experimental treatment. There were some papers available that had shown that it was useful, but it wasn't regularly being used and it was only common in a few centres in the USA. So the issue that the court had to decide is 'how far do you have to go and do you have to advise about experimental treatments, things that aren't commonly available in the NHS?'

The judge, and this is just the first instance, the decision at the time, really decided really there have to be some limits. We don't have to go that far. And he set out some a variation on that test as set out in bullet points on that slide. This has now been followed up by another really significant Supreme Court case that came out at the end of last year, this is a case called McCulloch. And I think it's a really helpful case. It's a very pragmatic decision by the Supreme Court.

So Mr. McCulloch had died having suffered a cardiac arrest and it was claimed that his death was caused by the negligence of the cardiologist. And the particular issue was whether the cardiologist was required to discuss an option, and in particular, an option of using non-steroidal, of him starting non-steroidal anti-inflammatories. There's a very pragmatic answer to that. It goes a step further than Bailey. The answer is that the cardiologist wasn't negligent because she could exercise a reasonable clinical judgment not to offer that option. And what this means is that in the future, this issue about the extent of the options that you need to offer the patient is going to be ultimately determined by the courts on expert evidence about what is reasonable. So you can see the sort of return of the Bolam test, a bit, back into this, into the issue of what options the patient can reasonably be provided with.

[Amelia:

So, we're going to have a look, Johnathan is going to talk to you in a minute about causation, just very briefly but we thought it would be useful just to talk about some recent cases and sort of illustrate how the courts are applying some of these principles. Obviously, every case is different, but it just gives you an idea of as to how the courts are applying the law in this area.

So there was a case last year, CNZ, um which was a birth injury claim actually related to a delivery in 1996., which gives you an idea as to how some of how long it takes some of these cases to go to trial and to be brought, and emphasises the importance of documentation. If you think you'd be able to remember, I can't remember what I was talking about last week, let alone in 1996. So the case is really significant because it sort of shows you that the courts will apply Montgomery, which was decided by the Supreme Court in 2015, retrospectively.

So in this case, in 1996, it was deemed to have been reasonable and a reasonable alternative option to offer the claimant in that case as Caesarean section. So it's been not just looking at instances post 2015, although the majority will be. Jonathan's mentioned, in the case of Bailey, the sort of experimental treatment. And there was a case last year called Snow and Royal United Hospitals of Bath, where a gentleman had rectal cancer and there was a new laparoscopic technique to treat that, involving approaching the pelvis from above rather than underneath, which was a new procedure and hadn't been performed very many times. and he was successful in his claim. The court found multiple breaches of consent duties in that case. There had been some NICE guidance, which

hadn't been provided to the claimant. There was also some NICE evidence on how effective that procedure was, and that also hadn't been discussed with the claimant. And the claimant hadn't also been told in that case, that the surgeons who were doing the procedure, had only done it twice before. So these are really key issues to discuss with patients, but particularly in respect of a new procedure.

[Jonathan:
Okay, so one of the one of the other issues that's followed Montgomery is the extent to which, if there is a breach of duty, if we haven't warned the patient of the risks appropriately, how much further does a does the patient have to go in order to bring a successful claim? And in particular, does the patient then have to go on and also establish that, if they had been warned of the risks that they weren't warned of or were given alternative options that they weren't, would they then have gone on and done something different? So what lawyers always referred to as causation.

Interestingly, it's a subject that's gone before the, not the Supreme Court, but to the court of appeal four times on four different cases since Montgomery. And on each case, people have argued essentially that Montgomery is such a widespread change of the law that in fact, it's produced a situation where there's a standalone right to damages. So just because you haven't warned of the risk, that entitles a patient to recover damages. That is on each occasion, that's it's very clear that that's not the case.

So it isn't enough for there just to have been a failure to warn of the risks. The claimant must also establish causation. So I've kind of

referred to a case there called Diamond. It's a hernia repair operation. The claimant wasn't given the option of a suture repair as an alternative to the mesh repair, she in fact, had. But the court weren't convinced that if she had, that she would have taken the option of a suture repair otherwise.

Okay. So I think these the issue of causation is always going to turn on factual evidence, predominantly the claimant's factual witness evidence about what they would have done otherwise.

[Amelia:
Right, we've got some summary slides now, which you'll be very pleased to hear about, given that we've got not very long left. So I've divided these into three set points. Communication. What does this all mean? Work in partnership with your patients, and there needs to be this genuine dialogue, the sort of key takeaway really. And, you know, to what extent are the patients understanding the information you're providing them with? Check. Check that.

There's a case I'm not going to go into it in any detail, but Mordel v Royal Berkshire NHS Foundation Trust. The claimant's first language was Polish, but she spoke, seemed to speak quite good English and seemed very reasonably fluent. But in evidence, the judge decided that although her English was, sorry, although she was reasonably fluent, there were occasions when she failed to understand what was being put to her in the course of the evidence that she gave at the trial. And the court decided that the sonographer in that case, who hadn't told her about the information needed to decide on a screening test for down syndrome, hadn't insured herself that the claimant understood the essential

elements and purposes of scanning for down syndrome. So she hadn't done that. And he accepted that in that case, the claimants thought that the question that she was being asked when she was asked, 'do you want the screening for Downs' was whether she wanted a child with Downs. So there was a sort of nuance, she was in the moment in that situation and she'd misunderstood the question, so she replied, 'no', didn't have the screening test.

Record keeping and documentation. Document your discussions carefully. You know, it's really, really important. Patient information leaflets are super useful to support that discussion, but as has already been said, do not supplement the need for the conversation to be had with your patients. I need to mention the case of Biggadike there. This is actually a case that, where EIDO leaflets were used, it's a case against two defendants. The case against the first defendant was unsuccessful. The clinician had used the EIDO leaflets, which were described as gold standard and the clinician in that note, had documented that the leaflets had been given simply by referencing a tick box to that. 'EIDO leaflets given' and a tick box. So that was evidence there that the patient had seen those leaflets. So if you are giving out patient information leaflets, document it, so that it's very clear.

And then just a sort of a final slide on litigation risk and how to sort of mitigate the risk of claims against you, although it's not possible to completely avoid it. Keep up to date with GMC guidance and current developments in the law in this area. Getting it right first time, I don't know, I presume people are familiar with that program, but they are actually releasing some standardised consent form following a pilot next year and there's going to be some new principles and guidance coming out

was my understanding, next year with a collaboration with NHS England GIRFT, GMC, Patience Association and the Royal College of Surgeon.

And having these conversations with patients makes it less likely that patients are going to feel angry if something doesn't go as planned, because they're going to know about those risks and if complications do arise, it may reduce the risk for litigation. So, I hope that was helpful.

I think we might have a little bit of time?

[Simon:
Yep, thank you very much. Do we have any questions? We will bring the microphone to you. I always find it very scary when I listen to the legal side of it but, a question from over there.

[Martin:
My name is Martin, one of the Vascular surgery registrars at QMC. When consenting as trainees, I mention that I may be doing part of the operation, the whole of the operation. Just coming back to your slide on new techniques and competence level. Quite often, I won't know how much of a procedure I'm going to be doing, whether my boss will be directly in the room for all of the procedures, some of the procedure. How do you mitigate that and consent for that? Because I say, I'll do the parts of the procedure that I'm competent in, I may do something with my boss that'll supervise me directly, but it's a difficult thing to consent for when you don't know what you're gonna find when you get when you go in.

[Amelia:

I mean I think it is difficult. I think I think talking to the patient openly about the fact that there is going to be this approach with your consultant as well, whereby they will be supervising you and that you will be doing the bits that you are competent to do and explaining sort of the risks around that in terms of, you know, as you would do ordinarily and documenting that, I think is what you can do.

I don't think there's a sort of way you can go any further than that because you can't sort of stop the operation and wake the patient up and then sort of, you know, say ‘right, now I'm going to take over’ so I think you just need to be open about the fact that there may be, you know, it may not be clear when you're having the conversation as to which bits you're doing, but there is gonna be this joined up approach. The consultant is ultimately responsible for ensuring the patient has been properly consented and been provided with all that information and they should be happy that, you know, that is something that the patient understands following their discussion with you and is happy to proceed on that basis. And if they're not, then, obviously, you know, the procedure has to take place as they wish, you know, from having all the information in front of them.

I Don’t know whether?

[Jonathan:

It’s fine.

[Simon:

I think you know, we're moving into the realms of robotic surgery and, you know, it's really important that our consultants are being proctored by experts who've developed that technique, and that has to come into the consent process as well, you know. Having only done one or two of these and then doing them on your own is a risk, isn't it?

Yes, a question there.

[Brian:
So, I'm Bryoney Lovett. I'm a colorectal surgeon. I say to patients that the person doing their operation will be competent to do that operation and in delegating permission to operate, I only allow my trainees and my locally employed middle grade, sorry, resident doctors to do procedures for which they've been signed off at level four. And level four is the level expected of a doctor on the first day of consultant practice.

[Simon:
Okay. So what about actually teaching people new techniques?
Because we have to train as consultants, don't we? Sorry, another question.

[Charles:
I'm Charles Ranaboldo, I'm a general surgeon, vascular surgeon. We've talked to the patient, you've explained the risks, the benefits, you've given them the leaflet, and you get to the day of the operation. And Mrs. Jones sits there all in her dressing gown and you ask her, have you read the leaflet? Did you understand it? Have you got any questions? And she goes, ‘oh no, dear, I' didn't do that’. Where are you then, in terms of proceeding?

[Jonathan:

Well, I think you've had the discussion previously and you've provided them with the information. I don't think, it's not like a tick box where you can only do the operation if of all these things have been done. So I think that it needs to be regarded as a holistic process across all of that. And certainly you've given you've given the patient the opportunity to read that leaflet.

[Charles:

She's had it, but she's not cognisant of its content.

[Jonathan:

Yes It's difficult isn't it, I can see.

[Charles:

That's the real issue here, is about cognisance of information.

[Simon:

Yeah, and of course, we all know that there are some patients who like to bury their heads in the sand and choose not to read the information. The previous GMC guidance had a statement, something like, 'you should not withhold information for fear of upsetting the patient' and I think it is a very difficult scenario, particularly on the day of surgery. But I think are certain bits of information you have to, they have to understand the main risks, you know, the risk of death or whatever. It's a tricky one, but we've got a couple more hands up -

[Amelia:

-I would just add to that sort of, I'm a risk management lead. So, you know, if you have any concerns that the patient in front of you on the day, even if they've had all the information, if they are unsure, that you don't think that they understand fully the risk, then I think the answer has got to be that you don't go ahead. And you discuss the risks of that with them, but it's more important that they have the time and reflection to actually go away and understand it, so I just wanted to.

[Charles:

You're pushing against competence, when there's competence wavering.

[Amelia:

Yes, no, I appreciate that.

[Simon:

Okay, let's have another question there.

[Manoj:

I'm Manoj Shenoy, I am one of a paediatric neurologists and paediatric surgeons here in Nottingham. So sometimes a parent that we see in clinic would say that, 'we want *you* to operate on the patient.' Now, I do take on what our colleague said and the person in front of me, and it becomes an ethical issue as such, because on the consent form it says that, you know, you can't specify who's going to operate. And as the consultant would say, 'well, I will do the procedure.' And it puts you in a very awkward situation. How do you handle that?

[Amelia:

Sorry, was that an example where a patient doesn't want a particular?

[Manoj:

I deal with children, so it's a parent that says to you that, you know, 'I don't want a trainee to operate.'

[Amelia:

Okay. I think you have to listen to the patient and understand what those concerns are around, you know, what concerns they have. You know, are the risks of a trainee properly supervised by their senior in terms of doing the procedure? what are the increased risk? But I think, you know, again, I think the answer is that you can't proceed with a procedure that is being done by somebody that patient is not happy, in terms of sort of the consent side of things and the risk. But this is why the dialogue is so important, to get the patients to understand and be, you know, happy that the procedure is going to be performed competently by somebody who has that experience and competence to do so.

I don't know whether you've got anything to add?

[Jonathan:

I entirely agree.

[Amelia:

I understand. I understand with it's very easy for us to say this, and you're, you know, it's not easy when, you're you know, in the middle of it all, but that's the sort of, if you are challenged about it, if something goes wrong and you're challenged, it's going to be very difficult to then manage that after the event. And obviously, you know, you want to try and avoid that.

[Simon:

Okay, thank you very much. We're gonna have to move on.

[End of transcript]