INFORMED CONSENT - Episode 1

PRESENTER: In 2015, almost 60 years of conventional medical practice was legally challenged in a landmark case regarding consent to treatment.

LESLIE HAMILTON: This is a change in the law. There's no debate about that, the judges have been very clear. It was a Supreme Court case, of seven judges being unanimous which is almost unheard of.

CLARE MARX: In the past, we as surgeons were there to deliver the surgery. Now what we are suggesting is that we should be there to have the conversation which will assist the patient in making the decision as to whether the procedure is the correct thing for them.

PRESENTER: I'm Murray Anderson-Wallace and in the next three podcasts I will be exploring the legal, ethical and practical implications of the judgement, and discussing the new guidance produced by the Royal College of Surgeons on "Consent: Supported Decision-Making"

LESLIE HAMILTON: The law is now very clear and from the legal point of view we have to comply, but there is evidence to show that patients are more satisfied, there's a reduction in complaints and there are certainly fewer medical legal cases.

PRESENTER: That was Leslie Hamilton, a Director of Professional Affairs and Council Member of the Royal College of Surgeons.

LESLIE HAMILTON: Yes, the Bolam Test goes back in fact to 1957 and was about consent, but the judge said, and it's a very famous judgement: 'The doctor's not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of medical men skilled in that particular art'. So in other words, we as doctors could decide what we told patients, and if other doctors didn't disclose risks to patients, then we didn't have to either. So we were allowed to decide what the patient would be told. That was followed up by a case called 'Sidaway' where one of the five judges in the law lords

objected to the fact that doctors should be allowed to decide, and he raised the issue whether patients should be allowed to decide what they were told.

And so that was the first step along the way; there have been a number of cases since but Montgomery has really now sealed that and come the full circle. And the judges pointed out that they're not saying anything in Montgomery that the GMC haven't laid down in good medical practice, which we should have been following.

PRESENTER: But how big an issue is this for practising surgeons and what are the real risks?

LESLIE HAMILTON: If you talk to the medical defence organisations, 60-70% of cases have an element of consent difficulties in them. I'm already hearing and seeing cases coming through the clinical negligence system of solicitors referring to the Montgomery judgement so I think it will be an increasing issue, and that's why the College wants to produce this guidance so that we're ahead of the game.

PRESENTER: The judges identified the need for surgeons to specifically focus on how risks are presented to patients.

LESLIE HAMILTON: They said a material risk has to be disclosed to the patient, and they made the point that they can't be reduced to percentages; in the past we've said, 'if it was more than 1% or if it was very serious then you would tell the patient' but the judges made it clear that not only was the nature of the risk an issue, but the effect on the life of that patient, that particular patient, if it occurred, and the importance to the patient of the benefits of the treatment, and the alternatives available.

PRESENTER: The dramatisation that follows is based on two real medico-legal case studies involving consent. It aims to explore the principles of the Montgomery judgement and illustrate the important shifts in practice that are now required to work within the law.

Piano Intro. We hear background noise of hospital waiting room. A door closes.

SURGEON: Glad we could meet again Mr Roberts to talk these things through. And this is…

MR ROBERTS: Claire, my daughter.

CLAIRE: We've all been really worried about him. And you're a bit of a worrier too, aren't you Dad? But it's time to put a stop to all the pain he's been suffering with the angina.

MR ROBERTS: Naturally I worry - I mean, 'open heart surgery' - it's a big thing isn't it?

SURGEON: Of course it is, but it's very routine these days and really nothing to be worried about.

CLAIRE: I think you did one for my mother-in-law, last year? Mrs Henderson?

SURGEON: Yes, I do lots of these operations.

CLAIRE: A triple by-pass. She recovered really well.

SURGEON: Well, that's one of the options we have before us today. Mr Roberts, you are 78?

MR ROBERTS: 79 actually

SURGEON: (shuffles papers) According to your notes you are in generally good health for your age, but your scan has shown us that these heart problems are now life-threatening. Now we have two main options in front of us - three if you count doing nothing at all, which I really can't recommend in your case. The first option involves major surgery – where in effect we replace the affected arteries in your heart with some that we harvest from your leg – the second is Percutaneous Coronary Intervention - often referred to as Angioplasty.

MR ROBERTS: Now I've heard of that but I'm not really quite sure what that means.

SURGEON: Angioplasty is when we widen your arteries using what is basically a balloon - a balloon catheter - which is carefully inserted into your arteries, inflated to widen them, then deflated and withdrawn. I should say however, our multi-disciplinary team have discussed the matter and our conclusion is that although Angioplasty would help with the angina pain, surgery will give you the chance of living longer.

MR ROBERTS: So when you say surgery, you mean a heart bypass?

SURGEON: Yes. We bypass the blockage in your heart by using a long vein taken from your leg. There's also another approach called - Total Arterial Revascularisation - that's TAR for short - where we use arteries from your chest and arm, and that is my preferred approach in cases like yours.

MR ROBERTS: I…I'm not so sure about…

CLAIRE: I think that's what Phil's mum had done. It's not really as bad as it sounds.

MR ROBERTS: Well I was going to say I'd rather have the balloon thing… B…But if you say I would live longer…

SURGEON: PCI is certainly less invasive but if you want to go that route then you need to discuss the detail with your cardiologist, not me. Surgery, however, would increase your chance of living longer. Nothing is guaranteed, of course, but survival rates are 97%.

CLAIRE: That sounds good, doesn't it Dad? 97%!

MR ROBERTS: I…I suppose so.

CLAIRE: Don't say it like that Dad. You can't just give up if there's an operation that will help you live longer, surely?

SURGEON: I don't want to underplay the seriousness of the procedure. It is a major operation - and there are chances of complications, like wound infection; about 5% experience bleeding requiring a return to theatre and there is also a small chance of having a stroke. Some people also find the recovery quite challenging but overall, it is regarded as a very safe and effective procedure – I do three or four of them a week sometimes.

CLAIRE: What do you think, Dad?

MR ROBERTS: Well, I'm not sure… I really don't like the thought of being out of action for a long time…(pause) But if that's your recommendation, doctor, and if you think it's the best thing Claire – I mean it would be good to see the kids grow up, you know how much I love playing with them now...

CLAIRE: I know – and they love it too Dad!

MR ROBERTS (pause) Alright, I suppose so… yes!

SURGEON: Excellent. So we will proceed then with Total Arterial Revascularisation and I'll book you in just as soon as I can.

CLAIRE: That's great. I'm sure we've made the right decision.

Piano Music Outro

PRESENTER: I asked senior figures at the Royal College of Surgeons for their opinions on this case study, particularly to comment on whether it meets the new legal requirements established by the Montgomery judgement. Clare Marx, President of the Royal College of Surgeons.

CLARE MARX: He accepts the daughter coming along and pushing her father, but actually the surgeon might try and make sure that the daughter doesn't push too hard because she doesn't have any knowledge at all apart from the mother-in-law who was lucky enough to have a good outcome.

PRESENTER: Sue Hill is a Consultant Vascular Surgeon and Council Member.

SUE HILL: The family will be worried about what's wrong with their relative, the surgeon will be trying to clarify everything, but might come from a position where he or she feels the patient **should** have surgery, and the patient themselves then find themselves badgered from both sides. It's very subtle.

LESLIE HAMILTON: It's certainly very clear in the Medical Capacity Act the patient has to make a decision free of the inference of anybody else, to be acting voluntarily, so that's very clear from the capacity side. From the practical point of view, as the surgeon you want a relative or some support there for the patient in clinic as there's a lot to take in; you want them to feel they've got some support and to be able to discuss afterwards what was actually said. And it's a balance between not allowing undue influence and the patient making the wrong decision, and that's again a question of surgical judgement and communication skills.

What would be better would be more explanation of the alternatives, of angioplasty, and can't pass the bloke off to the cardiologist under Montgomery; maybe not jump in at the beginning with the MDT recommendation, keep that to the end

when the patient's trying to weigh up the options; and if they say to you 'what would you do', that is when you bring in the MDT and say, 'well actually, we have discussed your case and we think for the following reasons surgery would be better. But then he didn't go into the morbidity associated with TAR, and didn't find out about the patient's lifestyle and what was important to him.

CLARE MARX: And he uses very, sort of, emotive language: 'This is life-threatening now'; well, what is the risk to his life right now? Is it 5% in a year? If it's 5% in a year and the risks of surgery is 5% in a year then how about playing off that balance?

PRESENTER: Would this have passed the Bolam test?

LESLIE HAMILTON: Oh yes. This to me is a good reflection of what I think happens normally. You know, you throw a bit of information at the patient and say 'here, sign the form', or not even sign the form, you wait til they come into hospital.

PRESENTER: Would it pass Montgomery?

LESLIE HAMILTON: No, for the reasons we've talked about.

CLARE MARX: I think it passes the Bolam test, because the Bolam test says 'what would any other reasonable doctor in the same situation do' and the answer is, 'I'd tell him he's got life-threatening vascular disease and his best option is to have some surgery, and I've told him what the risks are, so …'. It doesn't pass the Montgomery test though.

PRESENTER: Clearly the legal context has changed – it is the law now. To what extent do you think that will be the motivator for surgeons to change their practice?

CLARE MARX: Well there's a danger in that because if something is the law, and if somebody doesn't want to change, what they will do will say 'it is the law that I tell you this and that we have this conversation' and that is going to be really counter productive. So the law has changed, yes, but unless I really understand why that had to happen, then I'm never going to make the changes that I really need to make this a valid process.

PRESENTER: So, if expensive and career limiting litigation is to be avoided, surgeons need to make subtle but important changes to their practice.

But what do these changes look like, what are the benefits beyond the law and how should surgeons deal with the inevitable dilemmas that will accompany these changes?

In our next podcast, we'll examine these questions, learn how Mr Roberts' surgery went and explore the implications for our fictitious surgeon.

END OF EPISODE 1

END CREDITS

Mr Roberts was played by Lionel Guyett, Clare by Hilary Greatorex and the Surgeon was Simon Snashall.

Interviewees were Clare Marx, Leslie Hamilton and Sue Hill.

The series was presented by Murray Anderson-Wallace and written and produced by Murray Anderson-Wallace and Roland Denning. Professional advisors were Leslie Hamilton and Katerina Sarafidou. The Production Manager was Lesley Davis.

'Informed Consent' was an Anderson-Wallace production for the Royal College of Surgeons of England.