The purpose of this talk is to discuss the recent Scottish decisions on the question of informed consent following the radical change in the law resulting from the decision of the Supreme Court in Montgomery -v- Lanarkshire Health Board 2015 UKSC 11.

At the outset I should perhaps acknowledge the irony of my giving this talk. Two years ago, I stood here after the hearing in Montgomery but before the judgement had been issued, and suggested that whilst I believed that Mrs Montgomery's appeal was likely to be successful, I did not think there would be a change in the law. This was because not one of the seven justices had asked any of the four senior counsel about why the law should or should not be changed. The inference I drew, wrongly, was that, having studied the voluminous written cases and the authorities, American, Canadian, South African, Australian, New Zealand, English and Scottish, they did not intend to do so. How wrong can you be? The correct inference was that they clearly had already decided that the law had to be changed.

For my part, I have no great difficulty with the bases for the change in law but I remain of the view that, purely on the basis of the factual evidence, the decision is a somewhat troubling one. In the particular circumstances of that case, there is something of an air of unreality about the final decision. For those who are sufficiently interested, there is an interesting article by Professor Montgomery in the Journal of Medical Ethics entitled "Montgomery on informed consent: an inexpert decision?" In mitigation, all of the criticisms which the author make of the Supreme Court's treatment of the evidence, were addressed by me at the hearing but to no avail. However inapt the facts of the case may or may not have been, the Supreme Court clearly had an agenda and their lengthy decision is the result.

I am sure nearly all of you in this room will be aware of the change. Previously the test for whether a clinician was guilty of professional negligence in the dissemination of information to a patient was the traditional Hunter -v- Hanley test subject of course to the Bolitho override.

I say essentially because in the previous House of Lords decision in Sidaway -v- The Board of Governs of the Bethlam Royal Hospital 1985 AC 871, the four judges in the majority approached the question in slightly different ways although with some overlap. In Montgomery the Supreme Court was asked to depart from the majority decision in Sidaway and to endorse the dissenting judgement of Lord Scarman. That is what they did. The essence of the decision is to be found in paragraphs 87, 89, 90 and 91.

Thus the question of whether a doctor is negligent in the dissemination of information is ultimately to be judged by the Court, not exclusively by reference to the evidence of medical experts as to acceptable and normal practice. The test, put very simply, is rather to consider what the reasonable patient might wish to know and it is for the Court to assess that.

How then has this new approach been applied and what lessons can we learn from such decisions as there are?

The first is a case in which Robin Clelland and myself appeared for the Defenders, KR -v-Lanarkshire Health Board 2016 SCOH 133, a decision of Lord Brailsford dated 16th September 2016.

This was another case where the Pursuer gave birth to a brain damaged child and sued the Defenders on the basis of the alleged negligence on the part of the obstetrician in charge of her labour. As so often the allegations of negligence were largely predicated upon an interpretation of the CTG trace. The expert led on behalf of the Pursuer considered that the CTG was abnormal, a matter disputed by the Defenders' experts. In essence the Pursuer's grounds of fault were five in number and were as follows:-

- "(1) It was the duty of Dr O, the registrar who attended at 1600 hours to call for the advice of a consultant who would have initiated a Caesarean procedure.
- (2) Further, she had a duty when she attended at 1645 to have commenced delivery by C section at 1645 hours.

- (3) Further, it was the duty of Dr O to have commenced the delivery by C Section following her review of the First Pursuer at 1720 hours.
- (4) Further, it was the duty of Dr O to have commenced delivery by assisted vaginal delivery (given full dilation) or by C Section at or around 1822 hours in consequence of the prolonged deceleration which commenced at 1818 hours and not to have elected to do a FBS in these circumstances.
- (5) Further and in any event at each of her attendances with the First Pursuer at 1645, 1720 and 1818 hours, Dr O failed in her duty to discuss with the First Pursuer the non reassuring features, and the options, including urgent delivery by caesarean (or assisted vaginal delivery at the later time) to enable the First Pursuer to make an informed decision about, and to give her informed consent to, the continuing progress of her labour."

Lord Brailsford was not satisfied that the Pursuer had established negligence in relation to the first three claims, but found negligence established in relation to the fourth and fifth ground. A reclaiming motion has been marked and the cause is currently sisted to enable the Pursuer's legal aid certificate to be amended. We do not know what the Inner House will make of this and we are not today concerned with the fourth ground of fault. In relation to the fifth ground of fault, i.e. the consent case, the factual background was as follows. At about 1818 the CTG showed a sudden slowing of the foetal heart rate down to 59 bpm, starting at about 1817 and recovering spontaneously at 1820 to 125 bpm. The slowing of the foetal heart rate therefore lasted for 3 minutes. The NICE / RCOG Guidelines classify a foetal bradycardia as a slowing of the foetal heart rate for longer than 3 minutes. The registrar recorded the CTG at about 1825 and did an FBS to reassure herself that the foetus was healthy. The FBS was normal. The contention was that, upon the manifestation of this bradycardia, there ought to have been a discussion with the mother to discuss her options. There was no discussion at that stage. Lord Brailsford considered that, at that stage, i.e. at about 1825 there were two alternative approaches to the management of labour, firstly to proceed to immediate vaginal delivery or secondly to obtain a FBS and, providing these were satisfactory, proceed to stage 2 of delivery.

I now quote *verbatim* what Lord Brailsford says about this:- "In my view these alternatives should have been explained to KR and the risks associated with each also explained. Had this been done KR would have been provided with sufficient information to permit her to make an informed choice as to which course she opted to take. The fact that this approach was not taken renders this case, in my opinion, fairly within the ratio of Montgomery. I am accordingly satisfied that the Pursuer has established this part of her case."

I wonder if this is right. At the very least there are a number of difficulties with this. On the face of it Lord Brailsford seems to be saying no discussion = negligence = success for the Pursuer. The most obvious problem with this is that it ignores altogether the question of causation.

For a fuller understanding, it is probably necessary to rewind a bit. One of the allegations of negligence was that a caesarean section ought to have been performed at 1645. At 1645 the midwife noted "meconium stained liquor". The Pursuer gave evidence that she heard the registrar say to the midwife that there was "meconium stained liquor". She claimed that, upon hearing this, she sat up in a panic, she knew the baby was distressed and that she needed a caesarean section. The evidence of the Pursuer and her mother, who was present, a little confused but essentially it came to the Pursuer saying "I need a caesarean section". This account was not accepted by the registrar nor the midwifery staff. The Pursuer's account was expressly rejected by the Lord Ordinary.

It is important to know that in relation to the events at about 1645, the Pursuer was asked in examination in chief the following question:- "If offered a C/S at this time what would you have done?" Answer: "yeah I would have done it". The next question was "How can you be clear that you would have taken a C/S?" Answer:- "As I knew she was distressed". According to my notes/recollection, the Pursuer was not asked what she might have done at 1825. The matter was not explored in cross examination. There was no evidence as to what a conversation as to options at about 1825 might have entailed.

Lord Brailsford simply does not address the question of causation. In my view what is necessary before the Court can determine both the question of negligence and the question

of causation is firstly an appreciation of whether there is a material risk, i.e. one that a reasonable prudent patient would wish to know about. That will involve medical evidence. As the Supreme Court acknowledged (at para 83) the existence of risk is a matter falling within the expertise of members of the medical profession. Secondly it will be necessary to know what content the desired conversation would have had. If there are two courses of action it would, in my opinion, be necessary to know what information would be given to the patient, the risk and benefit of both courses being explained. I suggest that it would probably be necessary to know what advice the doctor would have given. It is all very well to say that there are two options and that the Pursuer ought to be given the chance to chose between them. But if once all is known about these two options by way of risks and benefits and the advantages of one course over another are objectively clear, and if it be the case that, whilst the decision is ultimately one for the patient the doctor would in fact have recommended one course over another, then that surely is something that the Court should be aware of to enable it to come to a view on what is likely to have happened if the desired conversation had in fact taken place.

In KR there was no evidence of what the necessary discussion would have covered. So, in KR, if there had been a discussion which would have resulted in KR agreeing to the labour continuing, then the failure to have the discussion has no causative effect. We will never know what the Pursuer might have done because the matter was simply not explored.

There was a different approach and a different outcome in Iain Britten -v- Tayside Health Board an unreported decision of Sheriff S G Collins QC, sitting in Dundee Sheriff Court dated 28th September 2016. Here the Pursuer was a man who suffered from bipolar disorder. He had suffered from this disorder since 1990 and was hospitalised then and in 1995 and 1997 on each occasion for about 3 months. He was successfully treated following his hospitalisation in 1997 and his condition had stabilised. By 2005 (the date of the alleged negligence) he had had no further relapse and had been psychiatrically very stable for nearly 8 years.

In 2001 he began to experience pain, photophobia and inflammation of the left eye. He was diagnosed with uveitis. He was successfully treated with topical steroid eye drops. In

February 2003 he had a recurrence and was again successfully treated with steroid eye drops.

In January 2005 the Pursuer experienced further problems with his eye. Put short, there were two possible means of treatment. Continued treatment by way of eye drops was no longer appropriate given the deterioration in his condition. Treatment by way of oral steroid was, then and now, the standard recommended treatment for the condition. It was the treatment most likely to be effective to resolve the condition and so preserve sight in the eye. However, treatment with oral steroids is recognised as being associated with adverse psychiatric events which occur in 5 to 15% of cases. The fact that the Pursuer had a history of bipolar disorder and was taking Lithium to regulate his condition did not make treatment by oral steroids inappropriate in January 2005. Treatment by oral steroids is standard recommended treatment for sight threatening uveitis. The alternative means of treatment was steroid injection. Administration of steroids by injection is thought to carry a lower risk of precipitating an adverse psychiatric event than taking oral steroids. Steroid injection, as you might imagine, however carries other serious risks.

The Sheriff held that the Pursuer was not advised by the treating doctor of the possibility of treatment by steroid injection as an alternative to treatment by oral steroids. He was not advised of the relative risks or benefits as between these two treatments. The Pursuer took the oral steroids. About a month later he became agitated and panicky. He became increasingly mentally unwell and in late February 2005 was admitted to a mental hospital, initially as a detained patient, where he remained until discharge in mid April 2005.

The relapse in the Pursuer's bipolar disorder was caused by the oral steroid treatment which he received in January and February 2005. The Sheriff however held that had the Pursuer been told that treatment by steroid injection was available as an alternative to treatment by oral steroids, and had the potential risks and benefits of these two treatments been fully explained to him, he would still have chosen to have treatment by way of oral steroids, as was in fact prescribed for him.

How did the sheriff reach this conclusion? At page 23, Sheriff Collins opined "It seems to me that the question of whether an alternative treatment is or is not reasonable must be a matter for the court to assess on the basis of the evidence presented to it. That will include the views of the medical experts, but also the evidence of the Pursuer, so as to determine whether a reasonable person, in the Pursuer's position, might reasonably consent to such treatment". I respectfully agree with that.

At the outset of his decision (at page 51, para. 81) Sheriff Collins states "Seeking to apply the principles derived from Montgomery in the present case, it seems to me that in order to succeed in his claim the Pursuer has, in summary, to establish (1) that he was not properly advised of the risks to his mental health of treatment with oral steroids at the material times; or (2) that steroid injection was a reasonable alternative treatment which was available, but (3) the Pursuer was not advised of this alternative nor of the potential and relative risks and benefits of such treatment vis a vis treatment by oral steroids; and in either case (4) that treatment by oral steroids caused the relapse in his bipolar disorder and so caused him loss, and (5) that but for the failure to properly advise him of the availability of treatment by steroid injection and the potential and relative risks of such treatment he would not have consented to treatment by oral steroids and so would not have sustained this loss". Again, I respectfully agree.

Unlike KR, there was considerable discussion (a) about the risks and benefits of the two alternatives (b) what the desired discussion would have entailed and (c) a detailed examination of the Pursuer on the question of what would he have done had the desired conversation taken place and why. Essentially the Sheriff concluded that, notwithstanding the Pursuer's clear assertion that he would have opted for steroidal injection, all the evidence strongly suggested otherwise. It is unnecessary for today's purpose to examine the actual evidence. Rather I commend Britten to you, not for the result which is immaterial, but rather for the approach which I would suggest is the correct one.