Changes to the law on consent following Montgomery *vs* Lanarkshire Health Board

The Supreme Court's determination on Montgomery (AP) (Appellant) v Lanarkshire Health Board (Respondent) (Scotland) [2015] clarified UK law on consent. It is for the informed patient to determine which intervention, if any, they will undergo. All doctors must meet this standard and may need to reassess their practice to do so.

In medical interventions, conflicts may arise because of the mutual incompatibilities within the elements of doctors' ethical duties: patient autonomy, justice, non-maleficence ('do no harm') and beneficence ('do good') (Foster, 2010). The patient needs to understand this: '…what patients want most in... their doctors is to be able to trust them... and that for a patient to trust a doctor, the patient must know that nothing is being withheld that should be spoken' (Foster, 2010).

Mrs Montgomery, a small of stature type 1 diabetic mother, was recognized to be at 9–10% risk of shoulder dystocia and was managed as a high-risk pregnancy with planned vaginal delivery. Labour was induced but became arrested and was pharmacologically augmented. With forceps applied the baby's shoulder became impacted with half of his head outside the perineum.

The obstetrician, who had never dealt with this situation before, initially attempted the Zavanelli manoeuvre under emergency general anaesthetic but was unsuccessful. Forceps were re-applied with 'significant traction' without effect. An attempt at symphysiotomy was compromised as no scalpels with fixed blades were available, and the blades became detached before the division of the joint had been completed. Eventually vaginal delivery with forceps was achieved. The baby was asphyxiated and required resuscitation, and now suffers from a brachial plexus injury and cerebral palsy (Montgomery (AP) (Appellant) v Lanarkshire Health Board (Respondent) (Scotland) [2015]).

Initial litigation

An action in civil litigation began, alleging:

1. Failure to respond appropriately to the abnormalities on the cardiotocograph tracing and deliver the baby by caesarean section
2. Failure to properly discuss risks.

The obstetrician said '[our] practice was not to spend …any time at all, discussing potential risks of shoulder dystocia… because… the risk was very small… if the condition was mentioned, most women will actually say, "I'd rather have a caesarean section" …it's not in the maternal interests for women to have caesarean sections' (Montgomery (AP) (Appellant) v Lanarkshire Health Board (Respondent) (Scotland)[2015]).

Mrs Montgomery had not asked 'specifically about exact risks'. If she had done, she would have been advised about the risk of shoulder dystocia, and cephalopelvic disproportion (the baby's head becoming stuck) and she would have been given an elective caesarean section if she wanted one.

The action failed on both counts before Lord Bannatyne in the Outer House of the Court of Session in 2010.

Appeal hearing

A subsequent appeal was heard by Lords Eassie, Emslie and Hardie in an Extra Division of the Inner House in 2013, regarding the failure to discuss risk. This upheld the views of Lord Bannatyne who had applied the Bolam test – whether the omission to discuss those risks constituted a breach of duty depended on whether the omission was accepted as proper by a responsible body of medical opinion '…*skilled* in that particular art' (author's emphasis).

Mrs Montgomery was able to appeal to the Supreme Court because she disagreed that Bolam was the correct test on the grounds that properly discussing risk had nothing to do with the standard of an obstetrician's skill.

The case was heard on 22 and 23 July 2014. The Supreme Court heard submissions from Andrew Smith QC on behalf of the General Medical Council as interveners (Montgomery (AP) (Appellant) v Lanarkshire Health Board (Respondent) (Scotland)[2015]). (In law, intervention allows someone who is not a party – an intervener – to join ongoing litigation, if the judgment may affect the rights of non-parties.) He set out the position (Montgomery (AP) (Appellant) v Lanarkshire Health Board (Respondent) (Scotland)[2015]) from the General Medical Council's (2013) *Good Medical Practice* that a doctor has a professional and ethical duty to fully advise a patient of the options for treatment, the risks of each option and the benefits of the option, and it was then for the patient, not the doctor, to advise which option he/she wished to choose.

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Nine months later, seven Lords of the Supreme Court delivered their saltatory judgement, unanimously contradicting the previous four legal Lords.

Lady Hale, and Lords Neuberger, Kerr, Clarke, Wilson, Reed and Hodge set out the correct position, in relation to the risks of injury involved in treatment, as:

- An adult person of sound mind is entitled to decide
- The doctor is under a duty to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative.

The test of materiality is:

- Whether a reasonable person in the patient's position would be likely to attach significance to the risk, or
- The doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.

They made three important further points:

1. Whether a risk is material cannot be reduced to percentages… The significance of a given risk depends on:
   a. Magnitude
   b. Nature of the risk
   c. The effect which its occurrence would have upon the life of the patient
   d. The importance to the patient of the benefits (of) the treatment, the alternatives and the risks (of) those alternatives
   e. The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient.
2. The doctor's role involves dialogue… to ensure that the patient understands the …condition and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision.

   This role will only be performed if the information provided is comprehensible, not by bombarding the patient with technical information which she cannot grasp, let alone by routinely demanding her signature on a consent form.
3. It is important that the therapeutic exception (avoiding discussions that might cause harm) should not be abused. The patient should make the decision whether to undergo a proposed course of treatment: it is not intended to subvert that principle by enabling the doctor to prevent the patient from making an informed choice where she is liable to make a choice which the doctor considers to be contrary to her best interests.

The written judgement of the Supreme Court is clear and understandable and sets a new standard for explanations of the difficult concepts surrounding consent by professionals to the general public. This is particularly important as those concepts were so difficult that their fellow professionals – including four Scottish judges apparently – did not fully grasp them.

Solutions to this problem were suggested by the 2009 Ernst Strüngman Forum Better Doctors, Better Patients, Better Decisions (www.esforum.de/forums/esf06_healthcare2020.html). A key issue for that forum was to address the problem of literacy in health care and its impact on the health-care system. The suggestions on how this could be improved start from the premise that for individuals to fully participate in their health care requires informed patient choice to be the standard for determining preference in medical intervention. This chimes in harmony with the Montgomery determination.

Presenting information

By setting out accurate, clean, clear information, shared by both doctor and patients, a knowledge-based decision is promoted and the misinformation caused by bias, unconscious ignorance, conflict of interest and statistical illiteracy that could adversely influence both doctor and patient is overcome. This assists in promoting active patient participation and shared decision making which democratises the clinician–patient relationship. This by putting both parties on an equal footing as far as understanding of the data is concerned. This is mandatory for consent to be valid and informed.

A practical example is a facts box (*Figure 1*) (a summary of the best available evidence such as from meta-analyses or from randomized control trials used in the Food and Drug

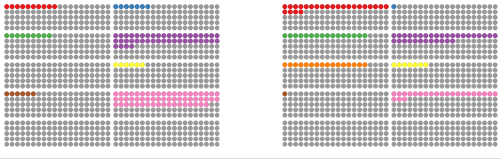
Figure 1. Hysterectomy; comparing abdominal surgery with laparoscopic surgery. This fact chart (created using pre-release Factarray software) sets out information to allow a patient to choose between hysterectomy via an abdominal route (control group) or by laparoscopic surgery (comparison group) route. Data from Royal College of Obstetricians and Gynaecologists (2009), Aarts et al (2015).

Hysterectomy; comparing abdominal surgery with laparoscopic surgery

What is this treatment for?	Surgical removal of the womb +/- cervix
Who might consider using it?	women suffering from: abnormal bleeding, fibroids, pelvic pain
Other things to consider?	symptomatic treatment, medical treatment, targeted radiological, laser or surgical treatment

Hysterectomy prevents menstrual bleeding, pelvic pain may not be abolished. Women who are; obese, have significant pathology, have undergone previous surgery or with pre-existing medical conditions are at increased risk of complications. Three out of four women are pleased or delighted with the outcome of hysterectomy. Return to normal activities is 14 days for laparoscopic hysterectomy and 36 days for abdominal hysterectomy. The risk of death is 3 women in every 10,000.

1. https://www.rcog.org.uk/globalassets/documents/guidelines/consent-advice/ca4-15072010.pdf
2. http://www.cochrane.org/CD003677/MENSTR_surgical-approach-hysterectomy-benign-gynaecological-diseases



urinary tract/bladder injury	10	24
bowel injury	7	1
vascular injury	9	16
bleeding requiring transfusion	44	32
fistula	0	16

Administration's approval process) to summarize issues combined with an icon array. An icon array (Schwartz et al, 2007) is an abacus-like pictograph, requiring minimal mathematical skill to interpret accurately, that summarizes data on benefits and harms inherent in treatment.

Fact boxes communicate the best available evidence contrasting important pros and cons. They assist those without medical or statistical knowledge to make competent decisions.

Icon arrays increased accuracy of understanding risk reduction, perceived seriousness of risks, and perceived helpfulness of treatments in both low- and high-numeracy people (Galesic et al, 2009).

The General Medical Council (2015) has updated its website as a result of this change in the law. Unsurprisingly – as the Supreme Court's decision was made with the assistance of the General Medical Council as an intervener – little update was needed from its existing advice.

The Royal College of Obstetricians and Gynaecologists has (at the time of writing) made no response. It is likely that this case will influence consent in the future and NHS trusts will need to consider how their practice will change. Fact boxes and icon arrays may prove to be a solution to the challenges in communicating risk posed by Montgomery - once their position has been properly assessed from indemnity and legal perspectives. **BJHM**

Conflict of interest: Mr L Clearkin is Medical Director of Renuntiabo Ltd the parent company of Factarray. He stands to benefit financially from this product.

KEY POINTS

- The 2015 Montgomery determination clarified UK law and set new standards for consent to medical intervention.
- Doctors now need to ensure that patients understand the material risks of any medical intervention that they face.
- Material risk communication is demonstrated.

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