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focus

Consent: The reasonable patient

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Where does consent sit within the surgical care pathway when it is becoming increasingly probable that it may take longer to go through the consent process than to undertake the procedure[1]?

Consent derives from the principle of autonomy, the purpose of which is to gain agreement to provide care. It is required and given in many different forms, dependent on circumstance and context; taking blood pressure, blood testing, biometry, administering eye drops, injection, laser, cataract surgery all having implications for the patient. Not all will have a written consent form, some may be verbal or be implied.

The UK Supreme Court in the recent judgement of Montgomery v Lanarkshire[2] emphasised the role of the individual patient's risk and attitudes as well as the amount, timing and delivery of relevant information to gain a valid consent for any procedure.

Historically the legal test within the English jurisdiction has been somewhat paternalistic and based on Sidaway v Bethlem Royal Hospital Governors1985[3] when it was determined unnecessary to warn a patient of every risk. However, it did establish that there was a duty to provide patients with sufficient information about the nature of the procedure, its alternatives, and any common or serious potential consequences to reach a balanced judgement. It also made clear the doctors' duty to answer any questions in relation to the procedure and its risks truthfully and fully.

In deciding the case the Bolam[4,5] principle was to be applied.

> *'A doctor is not guilty of negligence if he has acted in accordance with a practise accepted as proper by a responsible body of medical men skilled in that particular art.'*

English law was settled by not taking the approach of other jurisdictions of 'informed consent' or 'prudent patient' but accepting the approach of the 'reasonable doctor'.

However several judgements[6,7] since Sidaway suggested that we were moving away from 'the doctor knows best' approach to that of the patient's perception and attitude to risk.

Rogers v Whittaker[8], although an Australian case, is particularly relevant and concerned the development of sympathetic ophthalmia in an only seeing eye following an operation on the non-seeing eye which resulted in total blindness. The risk of such a complication was considered to be 1 in 14000. The patient had been particularly concerned about the possibility of any effect on the good eye but the treating surgeon repeatedly failed to warn the patient of such despite being asked. The Court was of the view:

> *The Law should recognise that a medical practitioner has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.*

The General Medical Council has long promoted a patient orientated decision making approach as set out in 'Consent: patients and doctors making decisions together'[9]; the RCOphth Cataract Surgery Guidelines (2010)[10] reflect these principles.

In 2014, in a complex case regarding consent for laser refractive surgery[11] the judge highlighted the timeline of the process and how little time was spent in discussion around consent and noted:

> *…If a lay person is receiving a fair amount of technical information delivered swiftly, it is not easy for them to grasp detail. It might look good on a printed page later, but may well not impress itself in the mind of a lay person…*

He went on to suggest that printed electronic notes, which appeared generic, could not be relied upon.

The law caught up with the GMC guidance this year with the Judgement in Montgomery v Lanarkshire Health Board[12]. This is a salutary tale in which an expectant mother with a high risk delivery was not given sufficient information on the risks of a vaginal delivery or the alternative of an elective caesarean section. During vaginal delivery there was delay due to obstruction from shoulder dysctocia with resultant hypoxic brain injury.

The Court considered that since Sidaway the doctor-patient relationship as described then

> *…has ceased to reflect the reality and complexity of the way in which healthcare services are provided or the way in which the providers and recipients of such services view their relationship…patients are now widely regarded as persons holding rights, rather than as the passive recipients of care…*

The conclusions and effect of Montgomery is that consent is an integral part of the care pathway and requires that it is not a generic tick box exercise;

Consent Requirements

1. Consent starts at the first consultation and is a progressive and longitudinal process
2. Appropriate patient information leaflets/ web/ videos that the patient can access prior to discussion
3. A clear outline of the issues requiring treatment and possibilities with a patient centred discussion of the following:

a. options including that of alternatives and of no intervention

b. the associated risks in manner that the patient understands, and not simply a list of statistics or probabilities

c. awareness of how such risks would impact on the individual, and their approach to risk

4. A dialogue resulting in a patient centred decision

5. Opportunities for the patient to ask further questions should be available

6. Consent is not given under duress – that might be for instance time constraints and there should be a 'cooling off' period.

7. Contemporaneous documentation of such the discussion at each stage of the process from investigation, diagnosis, treatment and follow up.

As a specialty we have achieved, through innovation and by necessity, commendable efficiency with pooled lists, patient information sheets, delegated assessment and consent, new procedures and greater productivity. However, in doing so it may appear that consent has become a tick box exercise, based largely on generic information rather than the risks and benefits for the individual patient involved. Having lost that 'time' it will be very difficult to get it back without seeming loss of such efficiency. But,

> *Consent is an opportunity to guide the patient to the right decision for them, and also dispel any unrealistic expectations concerning the procedure. Ultimately it is an opportunity to create a relationship of openness and trust between doctor and patient, which may help if operative complications are encountered. With high health-care expectations, a poorer than expected outcome may lead to surprise and subsequent anger: good patient education, during the informed consent process, is the surgeon's chance to forge a relationship with the patient and make sure that the patient's expectations are realistic.*[13]

We have to take surgery off the 'treadmill', consent is an integral part of that surgery and it should be inculcated into surgeons that it is not an add-on and like surgery itself cannot be rushed.

Naturally there are concerns about having to tell patients about every eventuality. This is not what either the GMC or Montgomery says. It is about tailoring the consent to the individual; subsequent judgements have confirmed this[14]

> *…In my judgment the decision in Montgomery affirms the importance of patient autonomy, and the proper practice set out in the GMC Guidance… It is not authority for the proposition that medical practitioners need to warn about risks which are theoretical and not material…*

Whilst the issues of resources - 'no time', 'no money' - remain, the courts are very unlikely to accept these as admissible defence. There are further implications which are often not touched upon and should be carefully considered;

- Standard basic information leaflet which directs to further information: each trust often has its own leaflets with variable information and often without direction to other resources – such as NHS Choices which has videos. It is clear that written information is very important as discussions around consent are remembered variably[15] and are better understood with videoed information [16]

- Alternatives that one does not undertake or are not available on the NHS such as 'premium' intraocular lenses; i.e. 'surgical alternatives' require additional discussions

- Who should and is qualified to take the consent and can it be delegated?

- Who is doing the operation; e.g. a trainee? [17, 18]

The Montgomery judgement has laid bare that which we should have already been doing as so very clearly set out in the GMC guidance; personalising consent to the individual and in doing so finding out their attitudes and concerns about any particular procedure and its alternatives.

> *'Montgomery will be proclaimed as the death knell of medical paternalism. But it is not. The death actually occurred a long time ago: Montgomery is just a very explicit and very belated obituary.'* [19]

Disclosure

Mr Newman acts as a paid expert witness and undertake medical legal reports for both claimant and defendant in the family, civil and criminal courts.

Mr Newman is the Honorary Secretary of The Royal College of Ophthalmologists.

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