Case in point: what can we learn from litigation?

Just sign here: the intricacies of consent in the post-Montgomery era

The consent process is a vital part of the patient pathway and is far more than just getting the patient to sign on the dotted line. In my work in litigation I often see issues around informed consent resulting in complaints and potential clinical negligence claims.

We have a duty of care to the patient to engage with them and we need to undertake our work in partnership with them. Cataract surgery, one of our most common operations, is arguably one of the safest procedures carried out within the NHS. When things go well patients do not complain and in the vast majority of cases this is the case, but we are all painfully aware that sometimes things can and do go wrong.

I liken the surgery to a bridge we guide the patient over. There is a chasm beneath with some stormy waters they could fall into. The vast majority get over it without a problem but it does not take away from the necessity to fully inform the patient of the dangers involved. If I crossed a bridge only to be told afterwards that 1 in 100 people who did so fell and lost their lives I would not be happy. Even having already crossed it safely I would be aggrieved at the loss of choice. Patients need to enter the process with open eyes (pun intended).

Whatever our attitudes to consent were, the pivotal Montgomery case in 2015 was a landmark for informed consent in the UK and significantly changed the playing field for us as clinicians.

Montgomery vs. Lanarkshire had nothing to do with eyes, but the implications of it are important for all specialities. It involved the case of Nadine Montgomery, a woman with diabetes and of small stature. She was pregnant and delivered her son vaginally. He sadly experienced complications owing to shoulder dystocia resulting in hypoxic brain damage with consequent cerebral palsy. Mrs Montgomery brought a claim against Lanarkshire Health Board, alleging that she should have been advised of the 9-10% risk of shoulder dystocia associated with vaginal delivery notwithstanding the risk of a grave outcome was small (less than 0.1% risk of cerebral palsy).

The case and judgment centres around the fact that her obstetrician had not disclosed the increased risk of this complication in vaginal delivery, despite the mother specifically asking if the baby's size was a potential problem. Montgomery sued for negligence, arguing that, if she had known of the increased risk, she would have requested a caesarean section. She was effectively deprived of choice.

The Supreme Court found in her favour in March 2015. It established that, rather than being a matter for clinical judgment to be assessed by professional medical opinion, a patient should be told whatever they want to know, not what the doctor thinks they should be told.

The final judgment should be read and absorbed by us all: "An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, 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."

It was a clear boost for patient autonomy over medical paternalism and I believe it was something we already adhered to, or at least should have been adhering to.

Clearly, we have now moved from the 'reasonable doctor' to the 'reasonable patient' test as the marker for consent.

From a legal perspective, prior to Montgomery, the Bolam test [1] in England was used to determine what should be disclosed. This tested whether a doctor's conduct would be supported by a responsible body of clinicians. So, previously if a responsible body of clinicians felt that the amount of information provided was reasonable and what they would have done, it was acceptable in law.

In ophthalmology, we are fortunate in that we are rarely in an emergency situation which requires rapid consent. Most of the time we operate electively and patients have time to consider their options and the risk involved.

We are, however, challenged by the delicate and specific nature of the eye and eye anatomy. Patients understand the concepts of broken bones, gall stones and complications such as deep vein thrombosis, infection and scars. They understand that they can bleed from an abdominal procedure and that in cancer procedures sometimes it is impossible to clear away the disease, but what do they understand by the term posterior capsule (PC) rupture? Do they truly understand what it is all about and how do we educate them to give them true informed consent without teaching them and testing them on the anatomy of the eye?

We also have an elderly population who may not understand everything we tell them. And there lies the rub of generalisation and paternalism in our profession. We should move away from the classification of elderly and really assess the individual patient and their level of understanding and need to understand.

Despite my best efforts to consent patients and my explanation about "the clear cellophane type bag around the lens that can sometimes rupture and allow the jelly at the back to come forward or even worse allow the lens to fall to the back" and what I consider a great explanation about how I "break the lens up with ultrasound and suck it out with a vacuum" I still get patients on the table asking "what are you actually doing" and "Oh, I thought it was just a membrane you peeled away".

We have a duty to educate patients and inform them about what we are going to do and what the possible complications are. Furthermore, it is vital that we engage with the patient on their level. Many of our patients are old and we do need to make a judgment on how much they will comprehend, but that should be an active judgment based on the individual patient, their needs, their understanding and their particular circumstances. It is an active process and not a passive one.

Always remember that a patient cannot consent to negligent treatment and so if visual loss is on the consent form and the patient loses vision due to a breach of duty then the consent becomes meaningless.

So what do we discuss with our cataract patients? Clearly our aim is to improve their vision and the important thing is that they know this is not guaranteed. But what is important to them?

Doctors must now ensure that patients are aware of any 'material risks'. Loss of vision is clearly important and a material risk. Infection, loss of the eye and blindness are complications that can have a devastating impact on the patient. The need to return back to theatre for another remedial procedure is clearly of significant psychological impact, as well as detrimental impact on the eye and so should be explained. This is the minimum we should be informing our patients about, but what about posterior capsule rupture and the need for YAG laser treatment at a later date? The former is thankfully rare (circa 2%) and the latter more common (circa 25%). The visual outcomes are good if appropriately managed in both circumstances so are they material risks and something patients need to be informed about? Will patients absorb and understand these concepts and risks enough to be truly informed?

One prospective survey study by Tan and colleagues [2] investigated 100 patients' preferences for information and discussion prior to routine cataract surgery. Of the entire group of 100, 32 did not wish to know "anything at all" about risks and would prefer to leave decision-making to their ophthalmologist; 22 were interested only in knowing their overall chance of visual improvement; and 46 welcomed a general discussion of possible complications, of whom 25 went on to enquire about specific complications. Of these 25, 18 wished to be informed of posterior capsular rupture, 17 of endophthalmitis, 16 each of dropped lens, retinal detachment and corneal clouding, and 15 of bleeding, sympathetic ophthalmia, and PC opacification.

In the era of informed consent and respecting patient autonomy should we be forcing the third of patients who do not wish to know "anything at all" about the risks to listen to us as we relay what could go wrong but probably wouldn't? The answer is yes, naturally, but who are we protecting, the patient or ourselves? Are we writing things on the consent form purely to point to it later if things do go wrong or are we truly engaging in the process and ethos of consent? Sadly, in my practice it is a bit of both, but it is something I, and I would encourage you also to reflect upon.

References

1. Bolam v Friern Hospital Management Committee (1957) 1 WLR 582.
2. Tan LT, Jenkins H, Roberts-Harry J, Austin M. Should patients set the agenda for informed consent? A prospective survey of desire for information and discussion prior to routine cataract surgery. *Ther Clin Risk Manag* 2008;**4(5)**:1119-25.

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