Litigation and the practitioner part 5

In the latest in his series looking at the legal framework within which eye care practitioners need to operate, Dr Nizar K Hirji discusses issues around informed consent and disclosure (C54895, one distance learning CET point for optometrists, dispensing opticians, contact lens opticians and therapeutic optometrists.)

This series of articles is concerned with key areas of accountability of the optometric/optical practitioner in England. However, many aspects have similarities, or indeed apply to other parts of the UK, and to business registrants of the General Optical Council (GOC). It is not a substitute for formal legal counsel.

This article will consider practitioner accountability for patient consent and disclosure, and its transformation from peer-view 'consent' into patient-view 'informed consent' over a period of 58 years as a result of court judgements handed down on seven landmark cases from 1957 onwards. In seeking to understand this metamorphosis it is necessary firstly to introduce the notion of a 'disclosure claim'. This arises when a patient alleges that had they been informed about the risks associated with a particular procedure, intervention or treatment option, they would have declined it, delayed it, or selected an alternative, given the choice. This is different to other clinical negligence claims in that determining what information to provide to the patient does not involve use of clinical skills.

FROM PEER-VIEW 'CONSENT' TO PATIENT-VIEW 'INFORMED CONSENT'

To establish the standard of care for diagnosis, treatment and disclosure, the courts have relied on professional/expert opinion. Expert opinions are normally sought and a decision is made based on what is considered to be the standard of care that would be delivered by a competent practitioner in the field. This was so in the landmark case of Boulas v Friern Hospital Management Committee which established in 1957 the 'Boulas test' and the principle that a healthcare practitioner 'is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art. Putting it another way round, a doctor is not negligent if he is acting in accordance with such a practice, merely because there is a body of opinion that takes a contrary view.' The practitioners (defendants) in this case, did not warn John Boulas (the plaintiff), who underwent electro-convulsive therapy (ECT) without any muscle relaxants or any form of manual restraint, of the risks involved in the treatment. As a result, he suffered violent spasms and fractured his hips during the ECT. Expert witnesses gave evidence that the use of ECT without relaxant drugs and no restraints was competent and recognised practice in the discipline. The defendants took the view that it was not desirable to warn patients of the risk unless they asked about it, while the expert witness for the plaintiff took the view it would not be right not to warn a patient of the risk of fracture. As a result, the judgement was for the defendants. This became the litmus test for all future cases where the standard of care for diagnosis, treatment and disclosure, including consent information and advice given, was in question – also referred to sometimes as the 'peer-view'.

The second landmark case was that of Sidaway v Bethlehem Royal Hospital Governors and others, where Mrs Sidaway, who suffered from persistent pain in her neck and shoulders, was advised by a surgeon employed by the defendant hospital governors to have an operation on her spinal column to relieve the pain. In the course of the operation Sidaway suffered some injury to her spinal cord which resulted in her being severely disabled. She brought an action against the hospital governors and the surgeon's estate. Unable to succeed in a claim based on negligent performance of the operation, she contested that the surgeon...
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There has been a shift towards giving the patient enough information to make an informed choice

had been in breach of his duty to her to warn her of the risk of damage to the spinal cord for the procedure (less than 1%), with the result that she had not been in a position to give ‘informed consent’ to the operation. Applying the Bolam test, the appeal on February 21, 1985, by the House of Lords, was dismissed. English law at that time did not recognise the doctrine of ‘informed consent’. However, a dissenting view held that ‘whether in the particular circumstances the risk was such that this particular patient would think it significant (if she was told it existed) – a proposition that the patient should be deciding, if a risk was significant. However, the use of Bolam test for diagnosis, treatment and disclosure sustained.

The case of Bolitho v City and Hackney Health Authority allowed some refinement of the Bolam test by the Court of Appeal in 1997, and moved from simply peer view to expert views that must withstand logical judicial analysis and greater scrutiny. Bolam modified by Bolitho, gave healthcare practitioners the liberty to decide what information they disclosed to patients.

In the fourth landmark case, Pearce v United Bristol Healthcare NHS Trust, Mrs Pearce gave birth to a stillborn baby. She had asked her medical consultant for induced labour or a caesarean section but was advised to let nature take its course, and for her to have a normal birth without any medical intervention. Her consultant explained that it would be very risky to induce the birth, and that it would take longer for her to recover if she had a caesarean section. She accepted this advice. The consultant however had failed to tell her that there was a small but increased risk of stillbirth (0.1-0.2%) as a result of the delay in induced labour. His Honour Judge Burrell QC, sitting at the Law Courts in Bristol, on 26 November 1996 dismissed a claim for negligence brought by Mr and Mrs Pearce in respect of the stillborn baby having applied the Bolam test. Mrs Pearce appealed and the Court of Appeal held that ‘if there is a “significant risk” attached to a particular treatment or course of action, which would affect the judgment of a reasonable patient, then in the ordinary course, the doctor is responsible for informing the patient of that risk’. It was additionally held that ‘Had the patient been informed of the risk she would, as far as could be ascertained from the evidence, reluctantly have agreed to follow the advice of the doctor and wait for a natural labour and delivery’. The plaintiff had failed to prove the surgeon was in breach of any duty of care, and in the circumstances, the Court of Appeal in January 1998 dismissed the appeal. Nevertheless, there was, in this case, an explicit departure from the Bolam test towards the patient’s prerogative regarding risk disclosure.

In the case of Chester v Afshar, the neurosurgeon failed to warn Carole Chester of the small risk of nerve root injury and possible motor and sensory impairment, inherent in her back-surgery even if correctly completed. Even though the risk was not increased by the failure to warn, and even though Chester had not established that she would never have had an operation carrying the same risk, the surgeon was held negligent in failing to warn the patient of the 1% to 2% risk of damage to the nerve. This was an unequivocal judgement by the Court of Appeal in May 2002, that even small risks must be declared, and that it was for the patient to weigh-up the importance of that risk to them, and not the practitioner. This decision also made it clear that a failure to recognise that the patient has the right to make decisions about their treatment would attract liability even if that failure has not caused any harm.

In Birch v University Hospital NHS Foundation Trust, Janet Birch, a poorly controlled type 1 diabetic was admitted via her GP into Watford General Hospital on June 18, 2003. She had a gradual onset headache behind her right eye with associated nausea, some swelling around her right eye, and painful 3rd nerve palsy. She was diagnosed with a pupil sparing 3rd nerve palsy by the attending honorary consultant Dr Giovanni on June 20. He also requested an MRI to exclude either a posterior communicating artery aneurysm or cavernous sinus pathology. However, Mrs Birch was transferred late on June 20 to the National Hospital for Neurology and Neurosurgery at Queen Square, London, a tertiary referral centre, for
further investigation since an MRI was not made available at Watford. The next day around lunchtime, a cerebral catheter angiogram was performed on Mrs Birch at Queens Square to rule out the possibility of an aneurysm after details of the procedure were explained to her, including the 1% risk of stroke along with other risks, and a consent form completed for the intervention. However, Mrs Birch was not informed of the comparative risks associated with the alternative procedures of MRI as recommended initially by Dr Giovanni, and the cerebral angiogram which was in fact performed. Unfortunately, Mrs Birch suffered a stroke which experts agreed was caused by the cerebral catheter angiogram at the defendant’s National Hospital for Neurology and Neurosurgery, on June 21, 2003. As a result, she was disabled, with weakness down the left side of her body, her left arm and hand lacked function, she could not carry, had difficulty with her personal care and dressing, and could not do housework. Having heard the evidence, including five expert witnesses, and in the course of the trial, referral to some 34 articles or extracts from the medical literature, Justice Cranston, applying the Bolam test modified by Bolitho, and taking into consideration relevant antecedent cases, adjudicated that ‘the decision to choose catheter angiography over MRI because of the Queen Square view that the MRI available was not adequate to provide a definite diagnosis, stands up to logical analysis’. He further went on to conclude that ‘Where Queen Square fell down was in failing to discuss with Mrs Birch… the imaging methods and their comparative risks. For that reason, the defendant is liable to her for breach of duty’. This is a judgement that obliges practitioners to disclose benefits and risks between alternative procedures, treatments, etc. so patients can make informed decisions about options available.

This approach was then ratified in the landmark case of Montgomery v Lanarkshire Health Board when Mrs Montgomery, an insulin dependent diabetic of small stature (5 feet in height) was in 1999 expecting her first baby. As a result of her diabetes it was likely that her baby was going to be large. This risk of shoulder dystocia was 9-11% in diabetic mothers, but the consultant obstetrician and gynaecologist failed to warn her on the grounds that the probability of a grave complication for the baby was 0.2% of a brachial plexus injury, and less than 0.1% of the umbilical cord becoming trapped and occluded, causing prolonged hypoxia, resulting in cerebral palsy or death of the baby. The same consultant also failed to give Mrs Montgomery the choice of a caesarean section. As a result of complications during the delivery, the baby was born with severe disabilities. The Supreme Court ruled that it was incumbent on the consultant obstetrician and gynaecologist to advise Mrs Montgomery of the substantial risk of shoulder dystocia, and the very small risk of catastrophic injury resulting from the deprivation of oxygen during delivery, if a vaginal delivery were attempted, and to discuss with her the alternative of a caesarean section. The Bolam test was regarded inappropriate with respect to consent and disclosure, and the appeal was allowed. The doctrine of patient-view informed consent, in 2015, finally arrived unequivocally into English law with risk disclosure becoming entirely patient-centred.

WHY IS INFORMED CONSENT A BENEFIT TO CONTEMPORARY OPHTHALMIC PRACTICE?

There are two fundamental reasons – one from the patients’ perspective and the other from the practitioners’ perspective as follows:

- It empowers patients to decide what is (or is not) going to be done to them, weigh up the risks and benefits of options available, and choose a particular course of action.
- It provides practitioners with a defence to a criminal charge of assault, battery, trespass to the person, or a civil claim.

It would not be out of place at this juncture, to explain that an assault is intentionally or recklessly causing another to apprehend immediate and unlawful violence, whereas battery is the intentional or reckless infliction of unlawful force or recklessly applying unlawful force to another. In practice this means acting (e.g. touching the patient) or conducting an ‘invasive’ procedure without consent or an incorrect procedure (e.g. administering an eye drop in the incorrect eye) with consent.

The importance of this is illustrated by reference to a case in dentistry. In Appleton v Garrett a dentist was sued for negligence and trespass, for general and aggravated damages by Appleton and others, in relation to unnecessary dental treatment undertaken for financial gain. Negligence was admitted but claimants also succeeded in action for ‘trespass to the person’ (which includes battery) and were awarded aggravated damages.

The duty of care for practitioners after Montgomery includes providing patients with comprehensive information about all aspects that may have an impact on the patient’s decision, including treatment options, advantages, disadvantages, risks, and answers to all the patient’s questions. This is so as to be satisfied that the patient has proper and complete information to consent, or decline a particular course of intervention or action. Should a patient ask a question that the practitioner cannot answer, then this question must be referred to someone who can. Guidance from professional bodies, regulators and the NHS already provides plenty of advice to practitioners of what good practice, in terms of informed consent means and requires, for adults and children, with and without capacity.

Practitioners may argue that disclosing and discussing small but more serious risks of potential consequences with some diagnostic and treatment options might unduly alarm patients and may even put them off; but Montgomery means that it is no longer up to the practitioner to decide if a risk or question is rele
You would want to know all the risks ahead of time

vant – it is the patient's prerogative. It may be that risks are very rare and may never come to pass in the patient's or the practitioner's lifetime, but nevertheless they have to be raised. Thus all discussions with patients including details in patient information leaflets (where appropriate), have to be up-to-date and contain key facts together with known risks, even if small, of any diagnostic techniques to be conducted, or treatments that practitioners provide and alternatives. For example, during discussions (and in any patient information leaflet) regarding contact lens options, there needs to be an explicit caution about the potential risk of sight-threatening microbial keratitis with different types of contact lenses and modalities of wear. Although rare, this severe complication of contact lens wear is known to have an annualised incidence of 4.2 per 10,000 (0.042%) and varies with type of lens and modality of wear, eg the annualised incidence of microbial keratitis in daily soft contact lens wear is 1.9 per 10,000 (0.019%) and in overnight soft contact lens wear, 19.5 per 10,000 (0.195%). It is for the patient to decide if this small risk is material to them or otherwise. Patient information leaflets should be and could be used more imaginatively to give patients explicit information about a variety of ophthalmic practice activities like personal data handling/processing by the practice, examination or diagnostic procedures, treatment options, associated risks, etc. Patients could be supplied with these information leaflets to 'pre-read' and then given an opportunity to ask questions and discuss opting out if they so wish, from parts they consider to be unacceptable to them before any formal consultation or attendance at the practice. It is important, however, that patients are not swamped with technical information but are provided with information they can easily digest. Additionally, it is useful to use terminology the patient can relate to when obtaining consent, eg the risk of precipitating an angle closure attack is one in 20,000 when using topical mydriatics for diagnostic purposes. This could be explained as 'perhaps up to five people out of a full Wembley Stadium (90k) might get a pressure reaction with dilating drops'.

In the wake of the Montgomery judgement and the antecedent cases, it is incumbent on practitioners to disclose available alternatives to patients and the different risks and benefits associated with each option or course of action. This disclosure should be based on the best available and up-to-date evidence. It is not unusual for patients to be happy to be led by the practitioner's recommendations based on their best evidence-based knowledge and professional judgement. However, where a decision is made to proceed with a riskier option (eg, overnight use of ortho-k contact lenses for myopia control) and something untoward happens, the patient may take the practitioner to task regarding disclosure of risks, benefits, and informed consent.

Montgomery fundamentally shifts the position with regard to information giving and consent from 'personal view of consent, to patient view of informed consent. The safest practice is to fully disclose the best evidence-based risks, benefits and alternatives of a particular diagnostic and/or treatment option, and let the patient decide the course of action.

The next and last article in this series will cover defensive practice to avoid the potential of litigation and how to be better prepared if taken to task.

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