

Medicolegal principles in ophthalmology

**Amar Alwitary FRCOphth MMedLaw Consultant
Ophthalmologist and Safety and Learning Special Advisor
to NHS Resolution.**

Between 2010/11 and 2017/18, NHS England paid £129 million in damages and legal costs related to ophthalmology¹. Delayed diagnosis and treatment, and failure to perform tests were the costliest errors, followed by intraoperative problems, operator error and failures of consent (Table 1). Of 1,510 claims, 972 (64%) were settled with damages paid.

We all have an important role in reducing errors and ensuring we practice at or above an acceptable standard. This article discusses the important medico-legal principles of negligence and consent and considers how they can be applied to ophthalmology.

Negligence and Posterior Capsule Rupture

Posterior capsule rupture (PCR) and/or vitreous loss are common complications of cataract surgery, occurring in 1.4% of the more than 180,000 procedures recorded in the 2018 National Ophthalmology Database Audit (NOD)². Although PCR is a recognised complication of cataract surgery, it can lead to litigation. However, is it negligent to accidentally rupture the posterior capsule and has a surgeon breached their duty of care if they cause this complication?

The Bolam test is used as a marker for negligence. Bolam v Friern Hospital Management Committee³ is a case that lays down the typical rule for assessing the appropriate standard of reasonable care in negligence cases. As doctors, we represent ourselves as having more than average skills and abilities and this legal test expects us to adhere to standards which must be in accordance with a responsible body of opinion, even if others differ in opinion. In other words, the Bolam test states that “if a doctor reaches the standard of a responsible body of medical opinion, he is not negligent”.

So how could we apply the Bolam test to PCR? It is self-evident that PCR is not a “practice accepted as proper by a reasonable and responsible body of surgeons”, however, damage to the capsule is accidental. The proper test should be whether the ophthalmologist exercised reasonable skill and care, which, on the balance of probabilities, we usually do. We have no motive to do anything but avoid a complication.

So how do we determine whether the surgeon who ruptured the posterior capsule exercised reasonable skill and care? It is practically impossible to do so, and thus we need to rely upon proxy measures such as complication rates compared to surgical benchmarks. The Royal College of Ophthalmologists assists us by publishing benchmark data and more recently facilitating the NOD². The College was commissioned by the Health Quality Improvement Partnership (HQIP) and funded by NHS England and the Welsh Government to manage the NOD as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP).

The NOD prospectively collects, collates and analyses a standardised, nationally agreed cataract surgery dataset from almost all centres providing NHS cataract surgery in England & Wales to update benchmark standards of care and provide a powerful quality improvement tool. This database provides invaluable data which allows surgeons to compare complication rates to their peers. By benchmarking ourselves against NOD data we can prove to our peers and potentially to the Courts that we operate with reasonable skill and care. It is essential that we continue to cooperate with NOD and facilitate data collection, but it is also important that we have in place robust local audit processes to assess outcomes and complications.

Does Bolam always prevail in other aspects of care?

It is hoped that the courts will appreciate that the Bolam test cannot be used reliably for surgical complications however there

Primary cause of claim	2010/11	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18
Equipment malfunction	5							
Fail / delay treatment	31	25	28	30	31	29	43	38
Fail to follow up	6				8	5	11	9
Fail to recognise complication	6		6					
Fail to warn / informed consent	5	9		6	5	5	6	
Delay in performing operation		5				13		
Failure / delay diagnosis	15	12	17	18	25	16	23	28
Inappropriate treatment				6	11	11	14	12
Intraoperative problem	12	9	10	9	8	12	13	17
Operator Error				9	10	13	16	14
Medication Errors							5	5
Error with agent, dose, route							5	5
Failure to perform tests						8		8

Table 1. Most common causes of successful claims made against NHS England ophthalmology services between 2010 and 2018 (NHS Resolution). Cases where less than 5 claims were made in a particular category are not shown.

are other scenarios when the Bolam test may fail to clinch a verdict. An example of this is the on-going concern over the use of Hydroxychloroquine (HCQ) at levels above the recommended dosage per weight recommendations.

The 2009 RCOphth guidelines (updated in 2018) recommended a maximum safe dose of 6.5 mg/kg/day of ideal body weight⁴. Recent studies in the UK examining patients treated with HCQ for at least five years have revealed that in up to 40% of cases the recommended dose was exceeded. Furthermore, between 2007 and 2016, the percentage receiving more than the recommended dose did not seem to decline, with one study showing even by 2011 over 50% of patients to be taking 400mg of HCQ daily⁵.

If a patient developed toxicity from an excessive dose of HCQ and lost vision in 2011 would the prescribing clinician have breached their duty of care? The Bolam test would suggest not, despite the failure to adhere to the appropriate guidance, as a responsible body of physicians were overdosing their patients and therefore the practice of that clinician would not have differed from those of his/her peers. Does the profession's failure to adhere to guidance protect the clinician from criticism? It is unlikely that the Court would look favourably on this argument, but it has not yet been tested.

Bolam surrenders to Montgomery

An area where Bolam has certainly been supplanted regards consent to treatment. In a 2015 case, Mrs Montgomery, a type 1 diabetic of small stature, went into labour complicated by shoulder dystocia. Her baby developed hypoxia, leading to cerebral palsy. Her attending obstetrician had failed to warn her of the risks and did not offer caesarean section, which might have prevented this. This was despite being specifically questioned about the risks by the Claimant. The Supreme Court ruled in favour of Mrs Montgomery despite attempts to defend her treatment based on the Bolam test.

The court based its decision in part on GMC guidance on consent, which advises doctors to 'tailor your approach to discussion with patients according to (a) their needs, wishes and priorities, (b) their level of knowledge about and understanding of their condition, prognosis and treatment options, (c) the nature of condition, (d) the complexity of treatment and (e) the nature and level of risk associated with investigation/treatment'. Prior to Montgomery, the Bolam test was used to determine what should be disclosed. This tested whether a doctor's conduct would be supported by a responsible body of clinicians. We have now moved from the 'reasonable doctor' to the 'reasonable patient' test as the marker for consent.

How do we apply the principles of Montgomery to patients attending for cataract surgery?

The NICE Cataract Surgery Guidelines⁶ do not offer much assistance as to what we should be telling patients prior to cataract surgery, simply stating that they should be informed of "possible risks and benefits". So what would a 'reasonable patient' need to know?

A recent prospective survey⁷ investigated 100 patients' preferences for information and discussion prior to routine cataract surgery. 32% of patients did not wish to know anything at all about risks and would prefer to leave decision making to their ophthalmologist. In the era of Montgomery is it acceptable to simply tell these patients nothing about potential risks of surgery, or should we be forcing patients who do not wish to know to listen as we relay what could go wrong? The answer is that although we need to make an active judgment about how much a patient wants to know and how much they comprehend, we also need to make sure patients are aware of any "material risks", even if they would prefer not to know. We must

discuss pros and cons of surgery and also always discuss the option of conservative non-surgical treatment. We should truly engage in the process and ethos of consent.

Whereas patients are likely to understand complications such as blood clots, infections and scars, conveying information about complex ophthalmic procedures or complications such as posterior capsule rupture is more challenging. It is nevertheless our responsibility to clearly relate information at a level, and using a format, patients can understand, which will be different for each patient.

It is also important to appreciate that a patient cannot consent to negligent treatment and so if visual loss is discussed as a complication, but the patient loses vision due to a breach of duty, then the consent becomes meaningless. It is not a protective umbrella which negates breach of duty.

In summary, awareness of the common causes of litigation is likely to help identify common preventable failings. Failures to warn and failures of consent represent a common cause of successful claims, in addition to intraoperative problems. We must make ourselves aware of the medicolegal playing field we may reluctantly enter and do our utmost to consider our practice in the harsh light of legal scrutiny both to protect our patients and ourselves.

References

1. https://resolution.nhs.uk/wp-content/uploads/2019/03/FOI_3684_Ophthalmology.pdf
2. <https://www.nodaudit.org.uk>
3. Bolam v Friern Hospital Management Committee (1957) 1 WLR 582.
4. Bourke BJ, Jones S, Rajammal AK, Silman A, Smith R. Hydroxychloroquine and ocular toxicity recommendations on screening. The Royal College of Ophthalmologists in association with The British Society for Rheumatology and the British Association of Dermatologists. 2009.
5. Jorge AM, Melles RB, Zhang Y, Lu N, Rai SK, Young LH, Costenbader KH, Ramsey-Goldman R, Lim SS, Esdaile JM, Clarke AE, Urowitz MB, Askanase A, Aranow C, Petri M, Choi H. Hydroxychloroquine prescription trends and predictors for excess dosing per recent ophthalmology guidelines. *Arthritis Res Ther*. 2018 Jul 5;20(1):133.
6. Cataracts in adults: management NICE guideline [NG77] Published date: October 2017
7. 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 Oct;4(5):1119-25.

Andrew Tatham

Editor, Focus

Visit www.rcophth.ac.uk/standards-publications-research/focus-articles/ for references relating to this Focus feature