Medico-legal issues in gynaecology

Leroy C Edozien

Abstract

Gynaecologists, like other healthcare professionals, have a legal obligation to adhere to a reasonable standard of care while acting in their professional capacity (the 'duty of care'). A breach of this duty, whether due to an individual's actions such as poor decision-making or corporate causes such as destitute safety culture in the organisation, could lead to litigation. This review discusses the burden and causes of litigation in gynaecology and outlines the process taken by a medico-legal claim.

Failure to diagnose, intra-operative complications, unnecessary surgery, consent issues, poor supervision and retention of foreign bodies are common causes. An illustrative case study is presented and some ways of reducing the risk of litigation are recommended.

Keywords clinical negligence; medico-legal; patient safety; risk management; safe practice

Introduction

Sometimes patients suffer harm, physical or psychological, from care that was intended to heal them. In some cases, this is due to human error or to defects in the organisation and delivery of care. In other cases, the harm is attributable to substandard care associated with technical incompetence, poor decision-making or departure from accepted clinical practice. Whatever the underlying cause, litigation may follow. In this article, the burden and causes of litigation in gynaecology are discussed and the process taken by a medico-legal claim is outlined. Recommendations are made to reduce the risk of litigation.

Clinical negligence

Gynaecologists, like other healthcare professionals, owe a 'duty of care' to their patients. The duty of care is a legal obligation to adhere to a reasonable standard of care while acting in a professional capacity.

When a case goes to litigation, the question arises whether this duty of care has been breached. To determine this, the court relies on the evidence of expert witnesses. In turn, expert witnesses will take account of national and local evidence-based guidelines and conventional practice when advising on the standard of care provided. The courts will apply the principle that states that a doctor is not negligent if he/she acts in accordance with accepted medical practice at the time, even though there may be doctors who hold a contrary opinion (the Bolam test); however, the court must be satisfied that exponents of that practice could demonstrate that their opinion had a logical basis (the Bolitho test).

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The duty of care may be breached by a failure or delay in diagnosis or treatment, failure to advise or to provide adequate information, administering a wrong treatment (including performing the wrong surgery), or performing an inappropriate operation.

The breach of duty, whilst regrettable and unacceptable, will not in itself be enough to establish a case of clinical negligence. The claimant has to show that the breach caused an injury; in other words, it must be shown that but for the breach of duty the injury would not have occurred (or would not have been as severe). This is known as 'causation'. If causation is established, the court will grant compensation for losses that the claimant has suffered as a result of the injury, provided that such losses are recognised by the court as deserving of compensation. The compensation comprises a sum for the 'pain, suffering and loss of amenity' caused by the injury and another sum covering the financial losses and extra expenses caused by the injury.

For most cases in gynaecology, the claim has to be brought within 3 years of the injury, or within 3 years of the time when the patient realised or could reasonably have known that she had suffered an injury attributable to her treatment. This rule of limitation does not apply if the patient is a child (the 3-year period starts on her 18th birthday) or if the patient has a recognised mental illness.

NHS indemnity

Gynaecologists working under a contract of employment with the National Health Service (NHS) — unlike those working in the private sector or colleagues in countries like the USA — do not have to worry about being sued in their personal capacity. This is because they are indemnified by their employer for any alleged negligence in the course of their employment. NHS indemnity also covers locums and academic medical staff holding an honorary contract who have a duty of care to the NHS patient. This indemnity has implications for pattern of care because clinicians working under the fear of litigation are often accused of practicing 'defensive medicine' — that is, practicing an interventionist style of medicine in a bid to avert litigation.

Claims against NHS Trusts are handled by the NHS Litigation Authority (NHSLA). Apart from handling claims, the NHSLA has a statutory duty to help improve the quality of patient care by assisting NHS bodies with risk management.

Litigation: life-cycle of a claim

Most gynaecologists would at some point in their career have to address a complaint filed by a patient about their care. Sometimes it is anticipated that this complaint would be followed by litigation. At other times, the complaints route is not followed and the first indication of imminent litigation is a letter from a solicitor requesting for the patient's medical records. The solicitor passes the records to an expert witness for a report on breach of duty and causation (see above). If the report suggests that there is a claim, the solicitor writes a Letter of Claim setting out the facts of the case, the alleged sub-standard care and the resultant injury. The NHSLA obtain reports from the clinicians who looked after the patient and solicitors commissioned by the NHSLA instruct an expert witness to write a report on the

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case. On the basis of these reports a Letter of Response is drafted written, which sets out which aspects of the claim are agreed and which ones are repudiated. Negotiations and mediation usually follow. In the cases where contentious issues remain unresolved, formal legal proceedings start. The claimant files Particulars of Claim and the NHSLA files a Defence. Statements of witnesses of fact and reports of expert witnesses are exchanged between both parties, as are a schedule of the financial losses sustained as a result of the injury and the defendant's counter schedule. In the small number of cases that remain unresolved at this stage, trial begins. Only about 4% of cases reach the courts.

Burden of claims in gynaecology

Obstetrics steals the limelight from its twin sister when it comes to litigation statistics but gynaecology has its own fair share of medico-legal claims. Between 2001 and 2011, the NHSLA received 3757 claims relating to gynaecology, and paid out a total of £189 million on gynaecology claims. During the same period, there were 9035 new obstetric claims and the total amount paid out on obstetric claims was £2824.6 million. In the NHSLA's books, gynaecology accounted for 4% of open claims by specialty as of 31 March 2011 (obstetrics 20%; orthopaedics 13%; accidents and emergencies 12%; general medicine 6%; general surgery 8%; and paediatrics 5%).

These figures, however, do not tell the whole story. Firstly, most patients in other adult specialties are older persons with major health problems, higher levels of morbidity and lower expectations. Gynaecology patients, bar those with cancer, are mostly healthy younger women seeking better quality of life through fertility treatment or fertility control, regulation of the menstrual cycle, treatment of non-life-threatening infection or treatment of pelvic floor dysfunction. Their expectations of a good outcome are relatively high. Secondly, the litigation statistics are the tip of the iceberg — many victims of patient safety incidents do not proceed to litigation. Thirdly, no matter how small the fraction of payments for gynaecological claim, this is money that should have gone into patient care.

Causes of claims

The common causes of claims in gynaecology are shown in Table 1. The distribution of claims by type of injury is shown in Table 2. More specific examples of incidents that lead to claims are given in Table 3. Many claims arise from patient safety incidents occurring in the operating theatre. These include injuries to viscera — bladder, bowel, ureter, major blood vessels — and the problems that flow from an allegedly unnecessary operation. Some of these incidents are the result of human error on the part of the gynaecological surgeon; others have their roots in systemic deficiencies — such as poor safety culture, inadequate staffing, absence of supervision and poor team work. Although only 4.5% of cases have been classified as failure to obtain consent, it is likely that many of the cases of unnecessary surgery were consent cases — the patient arguing that had she been given adequate information about the benefits and risks, she would not have agreed to undergo the operation. In the next few paragraphs some of the common causes of claims are discussed further.

Consent

All patients undergoing treatment should be given appropriate information on the nature and purpose of the treatment, benefits, alternatives and risks, and the consent process should comply with professional and legal standards. The emphasis here is on consent as a process, not merely obtaining the patient's signature on a consent form. Consent should be seen not as an end in itself but a means to responsible participation by patients in their own care and a means to a mutually rewarding relationship between clinician and patient. All too often clinicians equate consent with the signing of a form or consider consent primarily as protection against litigation. The signatures on a form are not a substitute for a proper discussion of the proposed intervention and engaging the patient in decision-making about her own care. Guidance in this regard has been provided by the Royal College of Obstetricians and Gynaecologists and the General Medical Council.

The decisions of the apex court in *Chester v Afshar* and *Montgomery v Lanarkshire Health Board* emphasise the need for gynaecologists and other surgeons to pay attention to consent, engage with the patient, and document consent discussions adequately.

Miss Chester underwent surgery in the hands of the neurosurgeon Mr Afshar to remove three protruding intervertebral discs that were causing back pain and had not responded to conservative management The operation carried a 1–2% risk of cauda equina syndrome developing. Unfortunately, this risk materialised. Miss Chester alleged — and this was contested by the defence but accepted by the trial judge — that Mr Afshar did not warn her of the risk of paralysis. Expert witnesses testified to the effect that there had been no negligence in performance of the surgery. The defence argued that even if the surgeon had failed to warn the patient of the risk of cauda equina syndrome, there was no evidence that, had she been given this warning, Miss Chester would never have had the operation. This argument followed the traditional principle of causation described above — that unless a claimant can prove, on the balance of probabilities, that the defendant's sub-standard care caused her injuries, the claim fails. The House of Lords, by a majority of 3:2, modified this principle and decided in favour of the claimant. The majority held that not informing Miss Chester of the risk of cauda equina syndrome denied her the chance to make a fully informed decision — and this fundamental right to make an informed decision deserved protection. This means that gynaecologists must pay particular attention to consent and remember that the usual principle of causation may not necessarily apply in these cases. The case also draws attention to the importance of fully documenting consent discussions.

Nadine Montgomery had diabetes in pregnancy and was carrying a macrosomic baby. She was keen to know the risks associated with macrosomia, but information on the risk of shoulder dystocia was withheld from her because it was feared that she would request for an elective Caesarean delivery. The risk materialised, and her baby suffered hypoxic brain injury and obstetric brachial plexus injury. Although medical expert opinion furnished by the defendants stated that the risk of shoulder dystocia would not necessarily be disclosed as a routine, the court held that the appropriate test is what risk a reasonable patient would want to be informed of. The UK Supreme Court

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