Medico-legal issues in gynaecology

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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 proximate causes such as poor decision-making or to remote causes such as destitute safety culture in the organization, 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 organization and delivery of care. In other cases, the harm is attributable to sub-standard 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).

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 recognized 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 realized 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 recognized 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. It does this largely through the Clinical Negligence Scheme for Trusts (CNST).

CNST

This scheme, funded by member trusts, provides an indemnity to members and their employees in respect of clinical negligence claims arising from events that occurred on or after 1st April 1995. The CNST provides incentives for trusts to reduce patient safety incidents and litigation through attainment of risk management standards. Some of these standards, such as those relating to patient identification, consent, infection control, record keeping and transfer of care between professionals, cover areas that feature regularly in gynaecological cases proceeding to litigation.

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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 case. On the basis of these reports a Letter of Response is drafted, 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 counterschedule. 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 and are essentially the same as previously reported. 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.

Open gynaecology claims by cause as at 31/01/2012 (NHSLA)

Cause	No. of claims	%
Wrong diagnosis	146	20
Intra-operative problems	119	17
Inappropriate treatment	98	14
Failure/delayed treatment	65	9
Failure/delayed diagnosis	58	8
Failure to obtain valid consent	39	5
Failure to recognize complication	31	4
Operator error	22	3
Failed sterilization	14	2
Failure to perform operation	11	2

NHSLA, National Health Service Litigation Authority.

Table 1

Open gynaecology claims by injury as at 31/3/07 (NHSLA)

Injury	No. of claims	%
Bladder damage	215	30
Additional/unnecessary operation(s)	126	17
Unnecessary pain	78	11
Bowel damage/dysfunction	34	5
Infertility	24	3
Psychiatric/psychological damage	24	3
Cancer	21	3
Advanced stage cancer	13	2
Perforation of viscus	18	2
Incontinence	16	2
Fatality	16	2
Unwanted pregnancy	15	2

NHSLA, National Health Service Litigation Authority.

Table 2

Consent

All patients undergoing treatment should be given appropriate information on the nature and purpose of the treatment, benefits,