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Clinical negligence

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Abstract

Clinical negligence may be tried under the civil or criminal legal system. Any General Medical Council proceedings are conducted separately. All cost time and money, and may be stressful for the patient and clinicians involved. In order to prove negligence, the claimant must prove the clinician had a duty of care, there was breach of that duty, and that breach caused injury. Interpretation of the law evolves as cases are heard in court and precedents are set. It is important for clinicians to keep up to date with developments in their specialty and good medical practice guidelines.

Keywords Bawa-Garba; duty of care; indemnity; informed consent; malpractice; Montgomery ruling; negligence; shared decision making

Royal College of Anaesthetists CPD Matrix: 1F01; 1F05; 1I04; 3J00

Learning objectives

After reading this article, you should be able to:

- define clinical negligence
- describe how the UK legal system works with regards to clinical negligence
- list some high profile legal cases and how they have changed practice
- explain how to reduce the risk of becoming involved in a negligence case

The UK legal system

The United Kingdom has several legal systems, one from each regional area, however the principles of each are broadly consistent. In all systems, negligence may be tried under the civil or criminal court system.

Civil prosecutions

Civil actions usually fall under tort law ('delict' in Scotland) and may result in damages being paid. A claim begins with a letter of claim being sent to the clinician. Ideally the claimant ('pursuer' in Scotland) will have already been through the service's complaints process, and the clinician's defence union will have been involved, so the claim is anticipated. Strict protocols with time limits are followed, and throughout the process the clinician and their defence union will consider whether to settle, usually without admitting liability. Almost 70% of claims are resolved without court proceedings.[1] If the decision is to defend against the claim, it will be heard in a Magistrate's Court (or Sheriff Court/Court of Session in Scotland), where a Judge will decide on the balance of probability if there was a negligent act and whether any compensation should be awarded. Following the decision, either party can appeal if they think the judge has made an error in reasoning or in applying the law. In the UK, the highest court the case may reach is the Supreme Court. The European Court of Human Rights may subsequently become involved, although following Britain's exit from the European Union it is unclear how this may change.

Criminal prosecutions

Criminal prosecutions for clinical negligence are much less common, but may result in a custodial sentence for the clinician. These matters arise most commonly when negligence has led to a death. The police will investigate the case. There are three conditions to be met to bring the case to trial.

1. The Crown Prosecution Service believe it to be in the public interest, and on the balance of probability they will be successful
2. The prosecution can prove beyond reasonable doubt (as opposed to on the balance of probability) that there was a breach in duty of care due to negligence and the negligence caused injury/death
3. The negligence was 'gross', which means that with regard to the risk of injury/death, the clinician's conduct was so bad in the circumstances as to amount to a criminal act.

Gross negligence manslaughter ('involuntary culpable homicide' in Scotland) was first defined in *R v Adomako* [1994]. An anaesthetist was caring for an intubated patient during ophthalmic surgery. The endotracheal tube became disconnected from the anaesthetic machine, which the anaesthetist failed to notice, and the patient died. The anaesthetist was given a suspended custodial sentence. In sentencing, the judge can balance with mitigating factors, and so most doctors, if convicted, will get a suspended sentence, as they are usually of good character and their probity unquestioned. The recent high profile case of Dr Bawa-Garba is discussed in Box 1.

General Medical Council referral

General Medical Council (GMC) referral is separate from legal proceedings. Not all civil prosecutions will be investigated by the GMC, but it is likely that criminal prosecutions will be. The GMC cannot open a hearing until criminal proceedings are complete. Approximately 80% of GMC referrals are closed without investigating, as they do not meet the GMC threshold, or are not matters they can investigate. Their process begins with information gathering, then two senior decision makers (one medical, one non-medical) review the evidence and decide on the next course of action. They may: conclude the case with no further action; issue a warning; agree to undertakings to address

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Bawa-Garba

The Criminal Case

In 2015 trainee paediatrician Dr Hadiza Bawa-Garba was convicted of gross negligence manslaughter and given a 2-year suspended custodial sentence. Jack Adcock, a seriously ill 6-year old boy died in 2011 while under her care. The clinical details of the case are likely to be familiar to most doctors, and are covered extensively elsewhere.[8] The judge, taking into account the circumstances of that day, noted failings 'were numerous, continued over a period of hours and included your failure to reassess … or seek assistance from senior consultants'. He went on to state that 'failures that day were not simply honest errors or mere negligence, but were truly exceptionally bad'.

GMC Referral and Medical Practitioners Tribunal

Dr Bawa-Garba was referred to the GMC and in 2017 the MPTS suspended her for 12 months, stating 'balancing the mitigating and aggravating factors, the tribunal concluded that erasure would be disproportionate'. The GMC subsequently took the MPTS (its own tribunal service) to court to appeal against the suspension, arguing that in the circumstances erasure was '… appropriate and proportionate, the reputation of the profession as a whole is more important than the interests of any individual doctor'. She was subsequently struck off; however, an appeal in 2019 ruled that she could return to work under supervision.

Personal Reflections

There was outcry among the medical profession as it was believed Dr Bawa-Garba's personal reflections in her e-portfolio had been used against her in court. Her defence union subsequently issued a statement to deny this. However, the consultants who gave evidence in court had been able to view the elements of her e-portfolio,[9] and her supervising consultant had notes from a reflective meeting with Dr Bawa-Garba that were used as part of his evidence. The GMC does not ask for reflections as part of its investigations, although it states that a doctor may provide them as evidence of insight and remediation. However, disclosure of personal notes may be required by law, and so clinicians should ensure any personal notes are anonymized as far as possible, and contain learning outcomes and future plans, rather than clinical details, which should be recorded in the patient notes.

Box 1

performance issues; or refer to the Medical Practitioners Tribunal Service (MPTS).

The MPTS is a statutory committee of the GMC, but is fully independent in its decision making and accountability. They hold a public hearing, and if they find a practitioner is impaired they can impose conditions on registration, suspend or erase from the register. Their decisions can be appealed in court.

The cost of clinical negligence

The quality and safety of clinical care has improved, but clinical negligence claims are increasing. NHS Resolution, the claims management service for NHS England, forecasts payouts to reach £3.15 billion in 2020–21, with the number of claims exceeding 10,000. Most of these claims are of low value, in 61% of cases the legal costs are higher than the damages paid out. However, the bulk of the cost is due to a smaller number of high value claims. Obstetric cases account for around 10% of the number of claims, but around 50% of the cost.[1] The NHS spend on maternity claims amounts to two-thirds of the total maternity services cost. Money meant to provide and improve care is instead being spent on compensation.

In addition to the financial cost, a clinical negligence claim can be a long and stressful process for both the patient and clinicians involved. While NHS organizations have indemnity for medical negligence claims to employees undertaking contracted duties, the British Medical Association strongly recommends individual doctors also have personal indemnity insurance as a member of a defence organization. NHS indemnity does not cover all situations, for example complaints, good Samaritan acts, voluntary work or General Medical Council referrals.

What is clinical negligence?

Professional negligence of any sort is the failure to take reasonable care to avoid causing injury to another person. The test to establish negligence is:

- The practitioner/organization had a **duty of care.**
- There was a **breach** of duty of care.
- The person suffered **injury.**
- The **cause** of the injury was due to the breach of duty of care.

Claims must be brought no later than 3 years from when the incident occurred, or when the claimant became aware of the injury. For children who suffer injury, the 3 year limitation starts when they reach 18 years of age. Negligence claims may be centred on injury due to investigation or treatment options, or issues related to consent.

Duty of care and breach of duty of care

The term 'duty of care' describes the standard of reasonable care or treatment that should be provided. This standard was first established with *Donoghue v Stevenson* [1932]. Mrs Donoghue found a dead snail in the bottom of a bottle of ginger beer. She fell ill. The House of Lords judged the manufacturer breached their duty of care. The concept was developed further in a medical context with *Bolam v Friern Barnet Hospital Management Committee* [1957]. During electroconvulsive therapy, a patient sustained fractures, a risk which he had not been warned about. The court ruled against the claimant as he could not prove that he would have declined the treatment. The judgement described an action as defensible if the clinician 'has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art'. In Scotland, *Hunter v Hanley* [1955] reached a similar conclusion.

While negligence arising from an investigation or treatment may still be judged in this way, with regard to consent issues, *Montgomery v Lanarkshire Health Board* [2015] legally changed the focus from the 'reasonable doctor' to the 'particular patient'. Mrs Montgomery was diabetic and had a vaginal delivery of a large baby who suffered shoulder dystocia and subsequent injury. She claimed had she been informed of the risks of

shoulder dystocia she would have chosen to have a Caesarean section. The judge ruled in her favour, and stated that a doctor is '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 ruling then elaborates on features the consent process should include:

- Reasonable **alternative** treatments for the particular case.
- What would happen if **nothing** was done.
- The material risks, which are:
  - risks which **a reasonable person in the patient's position** would attach significance to
  - risks which **that particular patient** would attach significance to; the significance of a risk may not be quantifiable and is likely to reflect a variety of factors relevant to that individual patient.

Critics[2] argue that it is difficult to identify what a particular patient would consider a material risk until that complication has occurred, and 'one cannot know with certainty whether consent is valid until a lawsuit has been filed and resolved'. They also question how the doctor can be expected to know what a particular patient would attach significance to, and note the difficulty in defining a 'reasonable person'.

However, the Montgomery ruling does align with the position advised by the GMC, which advocates a partnership with clear communication between doctor and patient. It also fits with the shared decision making model which has existed since the 1980s, but has become increasingly prominent and is seen as a step on from informed consent.[3] This process requires a number of consultations over time with clear, understandable dialogue around the range of options, with time for the patient to reflect, discuss with those important to them, and consider the best option. There are various decision aids available, and a Cochrane review[4] found they led to improved knowledge and more accurate risk perception in patients. While this approach is useful for high-risk patients considering major surgery, critics argue it is not practical for every patient within the time constraints of the health service.

In anaesthetic practice, most patients will be seen at a preoperative assessment clinic, and this is an opportunity to begin the consent process. In response to Montgomery, The Association of Anaesthetists published 12 recommendations in their guidelines on Consent. This includes using an evidence-based online resource or leaflet, but highlight that it remains the duty of the anaesthetist to ensure the patient understands that information.[5] By the day of surgery, the patient has usually already considered and consented to surgery, and while mode of anaesthesia and specific procedures, such as invasive monitoring, are regularly discussed with the patient, it is probably rare for anaesthetists to discuss specifics, such as size of epidural needle, or type of airway. Under *Montgomery*, this would be acceptable practice as long as the clinician feels they can reasonably argue that this information would not have any influence on the patient's decision making.

Standard of care

Bolam's 'responsible body of medical men' may now be interpreted as the standard provided in guidelines, such as those published by professional organizations, or those produced locally. However, it should be noted that guidelines may be deviated from if the clinician can argue that is in the best interests of the patient. Defence unions advise informing the patient that the practice deviates from the guidelines, and clearly documenting the reasons behind the decision.

Establishing what the standard of care was at the time of the incident is important. *Bolitho* v City and Hackney Health Authority [1996] established that alleged negligence must be judged according to the knowledge available at the time. This is particularly relevant in the context of unusual circumstances, such as the recent Covid-19 pandemic. Many of the medical defence unions, professional bodies and the General Medical Council (GMC) have published guidance regarding many aspects of care in the context of a pandemic, including working in other specialties, working in different ways (for example, telephone consultations), and concerns regarding refusal to treat in the absence of personal protective equipment. Any claims arising from work during the Covid-19 pandemic are likely to reference national and local guidelines from the time. The overarching principle in most of this guidance is to act in the patient's best interests, work within your competencies and document meticulously.

It is important to distinguish negligence from errors in judgement. Negligence can only occur if the individual has not acted at the standard expected of them. *Brady v Southend University Hospital NHS Foundation Trust* [2020] found in favour of the Trust, as despite an incorrect diagnosis, it was a reasonable diagnosis according to Bolam principles, and the clinician gave adequate advice. This may reassure doctors in training that they will be judged with reference to a reasonably competent person at the same level and specialty. If a doctor lacks relevant experience they are expected to ask advice and be supervised if required. This leads to consideration about who holds the duty of care. Is it the doctor in training or the supervising doctor/department? Some authors[6] have commented that the onus should be on the supervising department to ensure their trainees meet the standard expected, however the Bawa-Garba criminal case (Box 1) placed responsibility for negligence on the trainee doctor. Often in civil cases it is difficult to determine exactly who had duty of care, and as the health board has responsibility for the conduct of its employees, they often act as a single defendant.

Another consideration is precisely who the duty of care is owed to. This was tested by *ABC v St George's Healthcare NHS Trust* [2020]. ABC's father had been diagnosed with Huntington's disease. He was clear he did not want his family to know. His doctors knew ABC was pregnant but did not disclose the Huntington's diagnosis to her. She claimed if she had known she would have had a termination. One of the questions raised in the case was: did her father's clinicians have a duty of care towards her? The claim was dismissed, as the judge found the clinicians had no duty of care to ABC, and she did not prove she would have had a termination. However, the judge noted that 'duty of confidentiality to patients [is] not absolute', which may have implications for medico-legal cases in the future.

Causation

Once breach of duty of care has been established, to prove negligence the claimant must prove that the injury they suffered

How to avoid being involved in a negligence claim

- Put the care of the patient first
- Work within your competencies and seek advice when required
- Keep up to date with specialty and GMC guidance
- Communicate with your patient and colleagues: negative communication behaviour increases risk of litigation
- Document thoroughly, including patient refusals. It is easier to defend a claim if there are good, contemporaneous notes
- Determine and manage patient expectations, and ensure the consent process is patient focussed
- Deal with complaints timeously and apologize when necessary. An apology is not admission of liability
- Ensure personal reflections are anonymized as far as possible, and contain learning outcomes and plans for future professional development
- Cooperate with any investigations fully and honestly
- Look after yourself and colleagues; identify physical/psychological/drug/alcohol problems and seek help
- Be a member of a defence organization, and seek advice from them early

Box 2

was as a cause of the breach of duty. The basic test to establish causation is the 'but for' test; the injury would not have occurred 'but for' the clinician's breach of duty of care. It must also have been reasonably foreseeable at the relevant time that the behaviour would cause injury.

Currently, the law looks at causation in binary terms of probability; if the chance of something having happened is greater than 50%, then it is presumed that it would have happened. This is exemplified in *Gregg v Scott* [2005]. The claimant's cancer was initially misdiagnosed by the clinician. The delay reduced the claimant's chance of survival from 42% to 25%. As the initial chance of survival was less than 50%, the claim was denied. However, one of the judges did note that perhaps the law should be changed so that possible, rather than probable, causation may also be considered. Legally this is known as 'loss of chance', and is well recognized in contract law. Two of the judges in the Gregg case dissented in arguing that the law should recognize medical uncertainty, and it may be the law develops to recognize possibility instead of probability.

Chester v Afshar [2004] links causation with consent, and the patient's right to choose. Miss Chester underwent spinal surgery, which resulted in cauda equina syndrome, which she had not been informed about. Miss Chester claimed that had she known the risk, she would have chosen to defer the surgery to another day. This raises questions about the concept of risk and coincidence.[7] If she had chosen a different surgeon, or undergone the surgery at a different time, would the complication have occurred? The judges hearing the case had differing opinions; however, ultimately the clinician was found negligent in failing to allow the patient the right to choose.

It is not enough for the claimant to simply say they would have declined; they have to be able to point to extrinsic evidence of their particular circumstances that would have affected their particular decision. In *ABC v St George's Healthcare NHS Trust* [2020] described above, ABC failed to prove she would have terminated her pregnancy, as she subsequently chose not to inform her pregnant sister about their father's diagnosis.

There may be occasions when the patient is not fully informed of risk, for example when the patient declines to discuss risk, or where the clinician, on balance, feels the patient would be at risk of serious physical or psychological harm if the risks were discussed. In these cases, the Association of Anaesthetists Consent guideline recommends keeping clear documentation about any discussions, including with colleagues (Box 2). ◆

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