Medico-legal claims against English radiologists: 1995–2006

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ABSTRACT. A list of claims against radiologists from 1995–2006 was obtained from the NHS Litigation Authority. It shows a total of 440 claims. The largest number of claims (199) related to delayed or missed diagnoses of cancer, and 73 claims related to breast radiology. There is a trend for a mild increase in the number of claims each year. 30 claims were made after a false-positive diagnosis of cancer. Just under £8.5 million has so far been paid in damages, with a further £5 million in legal fees. A claim for multiple missed diagnoses of breast cancer led to a pay-out of £464 000 (£673 000 after legal fees); the largest sum awarded following a delay in the diagnosis of an individual cancer was £300 000. The subtle legal distinction between error and negligence is reviewed here. The reason why breast radiologists are more likely to be sued than any other type of British radiologist is also discussed, along with the implications for UK radiological practice, particularly in light of the recent Chief Medical Officer's report on revalidation. A method is proposed that may protect radiologists from allegations of clinical negligence in the future.

Received 4 November 2008

Revised 27 January 2009

Accepted 28 January 2009

DOI: 10.1259/bjr/61782960

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The NHS Litigation Authority (NHSLA) coordinates and collates claims against health professionals in the English NHS. As such, it is ideally placed to provide data to inform research into clinical negligence claims. A study of the range and type of claims is likely to provide data that would inform Trusts and radiologists of high-risk areas, and this should permit allocation of resources to reduce errors and claims in those areas.

Methods

The NHSLA sent the author, on request, a spreadsheet listing claims concerning radiologists since the inception of the Clinical Negligence Scheme for Trusts (CNST) in 1995. The data were analysed as part of a dissertation for an LLM degree [1]. The spreadsheet was designed as a claims management tool and not for research purposes, and some data are incomplete. In particular, some descriptions of the causative event are unclear; for example, several items are listed only as “delayed diagnosis of cancer”. In addition, before 2002, English Trusts were responsible for the management and cost of claims below the CNST excess, ranging from £10 000 to £500 000 per Trust, and not all of these claims were notified to the NHSLA. It must also be noted that further claims may yet come to light, as the limitation period has not yet expired. This holds true particularly for more recent years, as many claims are not made until years after the alleged negligence took place.

Results

Table 1 summarises the claims made (and Table 2 provides a glossary of terms used). The largest number of claims (199) concerns delayed or missed diagnoses of cancer, and 73 of these relate to breast radiology. In contrast, only 27 claims relate to any variety of abdominal cancer, and 32 to lung cancer. The second most common cause for claims is skeletal radiology, amounting to 124 claims; the great majority of these followed missed diagnoses of a fracture following trauma. 30 claims were made for false-positive diagnoses, of which 23 alleged false-positive diagnoses of cancer, often leading to an unnecessary operation or chemotherapy. Just under £8.5 million was paid in damages, and a further £5 million in legal fees. A claim for multiple missed diagnoses of breast cancer led to a pay-out of £464 000 (£673 000 after legal fees); the largest sum following a delay in diagnosis of an individual cancer was £300 000. There is a suggestion that claims are becoming more common: from 1995 to 1998/9, fewer than 30 claims a year were made against radiologists but, since 2001/2, the number of claims has ranged from 48 to 60.

Discussion

If a patient dies or is harmed during medical treatment, there is a common response to try and apportion blame to one of the doctors involved. This is part of the human grief reaction: feelings of anger or blame commonly follow on from initial denial or disbelief [2]. It is as difficult to suppress the instinct to blame as it is to prevent slips and lapses from occurring. There can be no doubt that many patients are harmed by medical mistakes each year. Harpwood [3] quotes the Royal Commission on Civil Liability and Compensation for Personal Injury that “between 1973 and 1975, there

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Table 1. Causes of claims against radiologists from 1995/6 to 2005/6

Cause of claim	No. of claims
Total number of claims	455
Missed/delayed cancer	199
Breast cancer	72
Bronchial cancer	32
All abdominal organs cancer	27
Unspecified cancer	16
Musculoskeletal	124
Missed fracture/dislocation	95
Antenatal ultrasound	17
Brain	29
Vascular	12
Chest	12
Others/miscellaneous	71

were 36 000 injuries caused by medical care, of which 13 000 were due to medical complications". The tort of clinical negligence occurs when a patient comes to harm owing to an act or omission by a healthcare professional, which is judged to represent a failure of a duty of care [4]. Despite the large number of errors committed in the NHS, few clinical negligence cases come to court. According to Harpwood [3], there was a slow increase in the number of claims against doctors from 1950 to 1970, and a more rapid increase thereafter. She quotes the Pearson Report [5], saying "by 1978, there were approximately 500 claims against the NHS each year". By 2006, the number of claims had gone up by 1200%. Fenn et al [6] estimated that there were nearly 7000 clinical negligence claims in 1991. In 2005/6, the Compensation Recovery Unit showed a total of 9321 cases in the UK.

Data from the National Audit Office in 2005 [7] found the following:

- 974 000 reported incidents and near misses;
- 10.8% of patients experience adverse events, of which half were preventable;
- at least 2181 deaths from adverse incidents, almost certainly a major underestimate;
- £423 million paid in claims, with £2 billion set aside for outstanding claims.

The great majority of errors do not result in a legal action for negligence — Harpwood estimates a rate of 7% [7] — but the annual cost to the NHS in 2004/5 of clinical negligence claims was £502.9 million [7].

Errors in radiology

Reason's [8] book on error has become the standard text. He considers an error to have occurred when a desired outcome is not achieved, excluding the intervention of chance. Merry and McCall Smith [9] consider that the definition of error must focus on intention rather than outcome, because some errors do not alter outcome unfavourably and near-misses, for example, deserve attention. Their book, "Errors, medicine, and the law" [9], is highly recommended reading for all doctors. Green

[10] divides errors between three main groups: errors of perception, errors of intention and errors of execution. Errors of perception account for the majority of radiological errors. A perceptual error is in fact a complex mix of three different factors. A radiologist must have sufficient *knowledge* to be able to search for an anomaly; having *perceived* it, he or she must make a *judgement* as to whether it is a normal variant, a pathological lesion or an artefact. An error in any of these elements may lead to a wrong report. Knowledge, perception and judgement are three different cognitive skills, all of which are subject to failure. The causes of such failure have been investigated extensively [11–18], but they remain part of the human condition and can never be eliminated. Psychological processes such as "satisfaction of search" [19], "search for meaning" [20] and the "cocktail party effect" [21] explain both the logical leaps that can lead to a diagnosis and why perceptual errors are intrinsic to these processes.

All radiologists are aware of the frailties of perception and do their best to avoid perceptual errors but, unfortunately, an over-eager search of an examination can lead to false-positive diagnoses [22]; *e.g.* at least 10% of lesions reported as cancerous on mammography turn out to be benign [23]. Apart from the obvious morbidity that may accompany false-positive diagnoses, NHSLA data show that radiologists are also sued for these errors. It is, after all, very hard to explain to a judge why a specialist radiologist failed to notice an abnormality that is obvious, even to the judge. The fact that all radiologists sometimes miss "obvious" lesions is accepted in the radiological community. Such errors are at the heart of the complex cognitive processes of perception.

The process can be likened to a "spot the difference" puzzle. Two people doing the same puzzle will find the differences in a different order to each other. A difference hidden to one observer will be readily apparent to the other, and *vice versa*. But once the answers are revealed, neither observer will be able to explain why they could not find the "obvious lesion". And every time the puzzle is reviewed, the previously obscure differences will stand out as readily apparent.

Berlin [17, 24–27] has written extensively in the American literature regarding errors in radiological interpretation but, as he points out, the error rate has not changed significantly over the last 50 years since Garland wrote on the accuracy of diagnostic procedures in 1959 [28]. A second viewing of the same film by the same radiologist will result in a different report in as many as 20% of occasions [12], and Goddard et al [29] reported discrepancy rates of as high as 20% between reports, where the alternative reports would cause clinically significant changes in the patients' management. Berlin [27] states that, where a study reveals an abnormality, discrepancy rates between radiologists average 30%. If all films are taken into account (bearing in mind that most will be normal), the discrepancy rate is ~4%.

Berlin [27] aptly quotes Robinson [30]: "although technology has made enormous progress in the last century, there is no evidence for similar improvement in the performance of the human eye and brain".

Can all of these errors be negligence?

Table 2. Glossary

Causation	For a negligence claim to appeal, legal and factual causation must be demonstrated; there must be a causal and direct link between the failure of a duty of care and the harm suffered
Defendant	The person against whom allegations are made
Negligence	The tort of negligence occurs when someone comes to harm as a direct result of another person's failure of a duty of care
Plaintiff	The person who complains, more commonly now referred to as the claimant
Prima facie	On face value
Strict liability	A legal position which reverses the burden of proof: the defendant is presumed guilty unless he can prove otherwise
Tort	In English common law, a tort is a "wrong" for which the injured party is entitled to seek redress. Negligence is a tort, as is libel or assault. The common law system deals with many torts that are not subject to criminal law. If someone has been wronged, it is the purpose of common law to make the defendant liable to pay compensation, in order to return the claimant to where they would have been if it were not for the tort
Implied consent	Consent given without signing a form — a patient who holds out his arm for a blood test is giving implied consent

Recent changes in the law

Clinical negligence occurs when a patient comes to harm as a direct result of a doctor failing in his or her duty of care [4]. In order for a claim for negligence to succeed in the courts, each of these components has to be in place. As a doctor's duty of care to the patient is seldom questioned, negligence cases usually turn on whether the doctor failed in his duty, and on issues of causation.

Perhaps surprisingly, very few medical negligence cases succeed in court. According to the Royal Commission on Civil Liability and Compensation for Personal Injury [31], only 35% of claims are successful, compared with a rate of 60–80% for other negligence claims reaching court. This has been the subject of much academic debate among the legal profession [32] and, for many years, lawyers have been seeking to redress the balance (as they see it) to enable more patients to recover damages from doctors after an adverse event.

As recently as 2001, Lord Woolf [33] wrote that he considered that the courts had been too deferential to the medical profession, and that this balance was changing.

Why do most clinical negligence cases fail? Most often, it is the issue of causation. The law has always required a direct and absolute connection between the failure of duty and the harm caused. In the medical setting, it is often difficult to separate out other natural causes of harm. A surgeon was found not guilty of manslaughter when a patient died after removing their healthy kidney instead of the diseased one because the final cause of death was pneumonia, not renal failure; the causal link between the wrongly performed operation and death was not strong enough. However, recent changes in case law have combined to weaken the defendant doctor's position.

In *Bolitho vs City and Hackney Health Authority* [34], the House of Lords seriously damaged the Bolam defence whereby a doctor could not be found guilty of negligence if he could show that a body of medical opinion agreed with his or her management. Although a detailed discussion of this case is outside the scope of this article, the Law Lords decided with a majority verdict that, in order for a medical opinion to valid, it must be "reasonable, responsible, and respectable", and

be able to withstand logical interrogation. In other words, judges can, in some circumstances, dismiss a Bolam defence if they consider it illogical. It is no longer sufficient for a defendant to show that other doctors agree with him: these doctors must now defend their position. For example, it may not be possible to justify an opinion that conflicts with National Institute for Clinical Excellence (NICE) guidelines [35].

In the context of a claim against a radiologist, it may be difficult for a colleague to defend a radiologist who, in a perceptual error, has missed a cancer. Will the judge find that to miss a lesion, so often obvious in retrospect, even to the judge, is compatible with logic?

Chester vs Afshar [36] concerned a patient who suffered a permanent paraparesis after a lumbar spine operation. It was accepted by the courts that the operation was carried out skillfully, and that paraparesis was an accepted risk of the procedure. However, the courts found that the surgeon had failed in his duty of care in failing to properly warn the patient of this risk. It is only fair to say that the surgeon disputed this finding, but the issue of consent was not further discussed by the time the case came to the House of Lords. In the past, the issue of causation in this situation would mean that the claimant would have to prove that he or she would not have undergone the surgery if warned of the risk, but the patient in this case said that she would have had the (highly necessary) operation, but would have delayed it until a later date. In finding for the claimant, Lord Steyn broke the previously impregnable link between incident and causation. He said "I am glad to have arrived at the conclusion that the claimant is entitled in law to succeed. This result is in accord with one of the most basic aspirations of the law, namely to right wrongs. Moreover, the decision announced by the House today reflects the reasonable expectations of the public in contemporary society".

In other words, his decision was influenced by public expectation and was, in the authors' opinion, a policy decision to move forward the law of negligence. He quoted with approval the commentary by Professor Paul Honore on a similar Australian case [37]. Honore specifically endorsed the use of policy and corrective justice to make a defendant strictly liable, to make sure that justice is done, and to vindicate a plaintiff's rights, even in the absence of causation. The term "strict

liability" has not previously been used in UK clinical negligence cases, and in a legal sense it means that, after an accusation of negligence, the burden of proof falls upon the defendant to prove that there was no negligence, rather than on the claimant to prove that there was. Reversing the burden of proof in medical negligence cases has long been an aim of pro-patient charities like Action against Medical Accidents (AvMA), but such a departure would bring a sea-change to the world of medical negligence.

How does this ruling affect a radiologist? Take for example a patient who suffers harm after a missed diagnosis of breast cancer. The patient may have been seen by two or three doctors who did not find a breast lump. Microcalcification on a mammogram might have been interpreted as benign, or just missed. But when the patient returns 6 months later with advanced cancer and a large palpable lump, it is only the radiological examination that is available for re-evaluation. If a clinician failed to notice a small lump, his or her judgement can never be questioned. But the radiologist's judgement is permanently recorded and ready for retrospective analysis. In the knowledge of the outcome, it is very easy for any number of experts to demonstrate an abnormality to the judge, and explain that such an appearance must be considered as evidence of malignancy. Having been shown the differences between two pictures, it is easy to demonstrate them to a third party.

Faced with the patient who has suffered and an "obvious" lesion on the mammogram, can a judge be made to understand the vagaries of radiological interpretation? Outcome and hindsight bias are two factors that work against the defendant radiologist. These are psychological factors inherent in us all, making us judge more harshly an incident once we know of a bad outcome and the eventual confirmed diagnosis. Hindsight is a powerful psychological tool, and Fischhoff and others [38, 39] have demonstrated that knowledge of the outcome of an event influences how it is assessed in retrospect [26, 40, 41].

Following Lord Steyn in *Chester vs Afshar* [36], does it not fit a policy of corrective justice and the expectation of society to find the radiologist guilty of negligence and compensate the patient — to right the wrong? Although root cause analysis of adverse events often shows that an incident is either due to system failure or a culmination of small events [42], it is often the radiologist who is left holding the smoking gun.

Error or negligence?

Is it possible for a doctor to make an "honest mistake", or is every slip or lapse made by a doctor to be interpreted as a failure in a duty of care? Is there evidence in English law that doctors who make perceptual errors are punished for the sort of mistake that every radiologist makes every week?

From the NHSLA data presented above, it is clear that some areas of radiology are particularly at risk. In Cardiff, mammography represents 1.4% of radiological work (Cardiff and Vale NHS Trust and Breast Test Wales, personal communication), but the NHSLA data show that 16% of claims against radiologists involve

breast radiology. In contrast, musculoskeletal radiology accounts for 28% of claims, but this is roughly appropriate to the number of musculoskeletal examinations performed. Breast cancer is approximately as common as lung cancer, but far fewer claims have been made after delayed diagnosis of bronchial carcinoma.

There are only two possible explanations for this disparity: either breast radiologists are careless doctors who are more likely to practice negligently than others, or breast radiologists work in a field that is subject to a particularly difficult perceptual task. It is submitted that the latter explanation is much more likely.

It does not fit natural justice that one group of doctors should be held more accountable to the law than others practising in the same department, doing similar work, with a similar degree of care. But how can a doctor accused of negligence after missing a cancer demonstrated in retrospect defend himself in court?

Possible solutions

The issue needs to be addressed from more than one angle. Firstly, radiologists themselves need to be aware of the cognitive and psychological processes inherent in the perceptual tasks of radiology reporting. In the author's experience, these processes are poorly taught in training programmes but, to a limited extent, forewarned is forearmed.

It is then necessary to educate our colleagues, the judiciary and the general public in the difficulties of radiological interpretation, and even to publish the number of mistakes made every day in Radiology departments. A major factor in a claim being brought is that, once a cancer is missed and the patient tries to find out what went wrong, the perceptual error will often be obvious even to the lay person, who cannot understand how an expert could miss such an obvious thing. The error is *prima facie* evidence of negligence.

However, the law could not, should not and will not allow radiologists a blanket defence of "common perceptual error", which might allow a careless doctor to practise recklessly. If we are to convince others that we do not act negligently, then we must supply evidence of careful and safe practice, and publish the evidence for our peers and our patients to read.

Quality control

There is some evidence in law that robust quality control mechanisms can protect against allegations of negligence, albeit from consumer protection law, where strict liability is the norm [43]. It is proposed that radiologists should build a revalidation portfolio based on a consistent, coherent and regular peer review of his or her reports. This would accrue over time to be a database of hundreds, and eventually thousands, of cases that have been verified. A small number of reviewed cases each week would quickly build into a significant bank of evidence, demonstrating that the doctor maintains his knowledge and skills. The reviewer would have to have the same area and level of specialisation and, when the doctor works in a particularly unusual speciality, periodic external peer review

might be required. Of course, many radiologists already do this, but by no means do all formalise peer review.

In breast screening, national audit programmes are in place, and national audits are the norm in pathology. An element of external peer review would avoid allegations of collaboration between colleagues. The specialist groups within the Royal College of Radiologists could play a role in distributing anonymised test cases on digital media or through a web-based system, which would provide an element of external review for all.

The recent report published by the Chief Medical Officer [44] indicates that all doctors practising in England will have to reapply for a licence to practise every 5 years, and that the application must be supported by evidence from audit and clinical governance. Peer review of radiology reports will soon become mandatory. Radiologists should embrace it, ensure that their job plans contain time for peer review, which need not be an adversarial process, and use the data as evidence of safe practice.

It is the nature of statistics that 49% of radiologists will be below average on each test, and this would have to be taken into account, most simply by incorporating several "rounds" of review before releasing results into the public domain. The great majority of radiologists will be at (or close to) the average, but inevitably some radiologists will be shown to be performing poorly in one or more areas. This needs to be identified for the public good, and such doctors should undergo retraining or redeployment into other areas. It is also likely that some areas of radiology will be shown to have a relatively low error rate, and others a higher one. Perhaps mammography will be one of the latter. In this case, Trusts will need to consider whether all of these examinations should be double-reported in order to reduce error. Perhaps patients should insist on it.

Public information

Doctors have been accused of cultivating a reputation for infallibility [45], and it is submitted that the view of a doctor as someone who does not make mistakes is unhelpful to both patients and the profession. On the one hand, patients need to be able to trust their doctor, and believe that the doctor will help to cure them but, on the other hand, if a patient has a mammogram which is incorrectly reported as normal, then she might be reassured falsely and may ignore symptoms of early cancer. All the psychological evidence states that doctors make errors, and it seems that radiologists are particularly prone to errors of perception: this fact should be made public. There is growing evidence in the USA of a general and judicial awareness of the inevitability of human error [20, 46, 47].

One of the reasons why claims against radiologists are made is the public perception that a specialist radiologist should see and report all abnormalities on radiological images, particularly when these are "obvious" and can be seen in retrospect by even a lay observer.

Surgeons and other doctors who perform practical procedures, such as cardiologists or interventional radiologists, will never carry out a procedure without discussing the risks of the procedure, and the likelihood of success or failure, with the patient. This establishes a

personal relationship between clinician and patient, and limits expectations. The signed consent form has weight in law if it is agreed that, in signing the form, the patient has understood the nature and purpose of the procedure, together with its attendant risks and benefits. In diagnostic radiological examinations, however, consent is implicit. There is no direct doctor-patient relationship, and no understanding by the patient of the complexities of radiological diagnosis.

It is clearly impractical for a radiologist to meet every patient who comes for a radiograph. However, it would be possible to manage patients' expectations by a carefully worded information leaflet which, in the case of mammography, would intimate the difficult nature of mammography reporting and emphasise the need for a patient to discuss the result of her test in the light of her symptoms and signs. It would be entirely feasible to publicly display the audit results of the reporting radiologists either in the department or within the leaflet. This might take the form of:

"The radiologists who will report your mammogram are Dr Smith and Dr Jones. Together, they have 14 years of experience in diagnostic mammography, and they will take all appropriate care in looking at your films. Both Dr Smith and Dr Jones undergo regular training and assessment to maintain and test their skills, and internal and external peer review of their work has shown that their accuracy in reporting mammograms is very similar to that of other doctors in their field. However, no human being is perfect, and some abnormalities could be overlooked, and so if you develop, or are worried by, any symptoms, then it is important that you discuss these with your doctor, who can ask us to review your films whenever appropriate."

Many doctors would find such directness initially difficult and disturbing, and inevitably predictions would be made that such openness would surely lead to more claims and not fewer. However, limited evidence from Kentucky suggests otherwise [48]. The initial public response might also be unfavourable. Some patients would not want to hear of their doctors' mistakes, and there would be a risk that some would not attend screening examinations owing to a loss of confidence in the accuracy of the system. It is submitted though that informing the public and limiting unrealistic expectations would go a long way to reducing claims caused by a lack of understanding of the nature of radiology, and this view has some support in the USA [25]. Lord Steyn's dictum in *Chester vs Afshar* indicated that a judgement against the surgeon was in keeping with public expectation. To modify public expectation, therefore, should provide some protection in a clinical negligence claim.

No-fault compensation?

On the face of it, a no-fault compensation system would be ideally suited to a situation where a patient has been harmed as a result of a medical error but where it has been demonstrated that the error was not a negligence

one. The NHS Redress Act (2006) goes some way along the road to compensating patients for medical accidents, but it has important limitations. Firstly, the opening paragraph of the Act makes it clear that it is not a no-fault system — a qualifying liability in tort is required [49]. Secondly, there is a limitation to the quantum of compensation at £20 000 [50], and the NHS data demonstrate that compensation for a delayed or missed diagnosis of cancer can be many times that amount. Thirdly, the Act does not include a “duty of candour”, despite this being one of the proposals in the preceding White Paper “Making Amends” [51]. AvMA has campaigned strongly for a statutory duty of candour in the NHS, and it is submitted that such a duty would, in the long term, be beneficial to doctors and patients alike.

Caldwell and Seamone [20] have proposed in the USA that a legal defence of “excusable neglect” exists, and that this should apply to radiological errors of perception. The author proposed in an LLM dissertation [1] that, in exchange for accepting a statutory duty of candour and embracing peer review and audit, a similar defence of “non-culpable error” be adopted by the courts in English medico-legal cases where a defendant doctor has proved safe practice by audit and peer review, but has made a perceptual error, resulting finally in harm to a patient. Bringing patients who have suffered as a result of such an error within the remit of the NHS Redress scheme would seem a just and reasonable result.

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