Introduction

In 2014/15, the NHS dealt with 1 million patients every 36 hours. 16 million people were admitted to hospital, and almost 10 million patients had operations. 22 million people attended Accident and Emergency departments. Serious incidents were reported in 0.5% of that activity and medical negligence claims were made in 0.05% of that activity. 150,000 doctors, 377,000 nurses and 156,000 associated staff, cared for these patients and 37,000 managers managed the service. All of those people went to work each day with the aim of helping people, and not intending to do harm. Errors do happen, albeit rarely, but the consequences can be serious for all involved.

Tonight, I want to consider how important are the cultures of our health and legal systems in both identifying serious medical error and mitigating present and future risk. For simplicity and because of time, most of my comments will refer to medical staff and their employers. The exam questions are these; does our current system of medical negligence litigation adequately compensate victims of error, help or hinder improvements in medical safety, and are there better ways to achieve those goals? And, is the NHS capable of both learning from events and then ensuring that the necessary changes are both put in place and sustained by appropriate discipline?

Imagine you have had to go to hospital for an operation to remove your right kidney. The members of the team are each charming and, as far as you can tell, have been very clear about the risks and benefits of the treatment. You sign the consent form, have a sleepless night and in the morning are prepared for the operating room; you are anaesthetized and have your operation. Whilst you are waking up in the recovery room, the surgeon asks to see your partner, and tells them that, sadly, they had removed the wrong kidney by mistake and so you will need dialysis and a later kidney transplant. Your life expectancy is reduced.

This is known as 'wrong site surgery' and is a 'never event'. Never events should of course never happen, but they do, albeit rarely (326 times in 2014/15). It did happen, and now your life is ruined. You will need dialysis three times per week, a complex diet, lots of drugs, the stress and emotion of transplantation, and the anti-rejection therapy associated with it. You might lose your job. You will have to change your activities. You will lose income, yet incur significant costs.

If something like this happens, one would rather hope that there would be equally important consequences.

• Somehow you will be compensated; certainly by having any additional costs covered, and perhaps loss of income or life chances. After all, it wasn't your fault.

• The exact cause(s) of the disaster will be investigated, identified and reported.

• The individuals involved will learn the lessons, and the message will be spread effectively through the NHS so that the error does not happen again.

• All involved will receive support; they will probably need it.

Duties

There are some clear duties which medical staff have towards you as a patient, and which have their basis in Law. First, there is a Duty of Care. I will go into this in a little more detail in a moment. Secondly, and following on from the Francis report into the Mid-Staffordshire scandal[i], there is a Duty of Candour (www.cqc.org.uk/content/regulation-20-duty-candour). Whilst a duty of candour has long been an ethical duty of doctors, incorporated into the General Medical Council's Duties of a Doctor (www.gmc-uk.org/guidance/good_medical_practice.asp) by Sir Ian Kennedy some 30 years ago, new legislation obliges organisations as well as doctors to disclose details of ‘moderate to severe’ harm to patients, and to provide an apology[2]. Criminal sanctions can be applied to those who fail so to do. The background to the introduction of this duty is well summarised in Sadler and Stewarts ‘thought paper’ on transparency, describing themes which emerged from the Mid-Staffordshire inquiry by Francis and the report by Don Berwick in the same year (2013). In mid-Staffordshire there was;

• A repressive,opaque leadership culture and a lack of transparency throughout the organisation and a failure to respond to outside pressure

• Marginalisation of those clinical staff and others who raised issues or complained

• Dominance of financial consideration over quality of care and safety
**Serious Incidents and their Investigation**

As Sir Cyril Chantler has said [v], "Medicine used to be simple, ineffective and relatively safe. Now it is complex, effective and relatively dangerous." When a serious incident occurs in the NHS, it must be investigated to ensure that its cause is identified and to determine if it can be prevented in the future. The investigation takes place at local level in the relevant Trust[3] following defined processes (https://www.england.nhs.uk/patientsafety/serious-incident/). For serious incidents (SIs), the time scales are also defined, and affected families should be kept both informed and (at best) involved throughout. Serious incidents refer usually to errors of commission; something bad was done. Currently, they do not include errors of omission such as non-diagnosis, mis-diagnosis, late diagnosis or other delays in treatment. The findings of investigations into serious incidents are reported back to NHS England Commissioners[4], who have the responsibility to distribute those findings and ensuring that 'any learning is embedded'. Commissioners must also publish the summary findings of investigations and collate national information.

The investigation process involves something called 'Root Cause Analysis' [5], and requires collation of hard evidence from the notes and other records of the patient, and written statements from all involved. It is supported by trained staff, and led by a relevant manager, usually, but not always, a clinician. There is quite considerable local variability in both the quality and effectiveness of investigation, and the subsequent reports. The process is designed to be supportive and helpful, but in my experience it is incredibly stressful for all those concerned and is extremely time consuming. It can feel like a trial, and a trial that extends over weeks, during which time people still have their day jobs to do. Those involved are often extremely anxious; primarily because of concern for the victim, but also because they fear that they themselves will be blamed for something, and that this will affect their current job, promotion chances or other career opportunities. It is not surprising that fear of blame is profoundly embedded in healthcare workers; there are many examples of medical staff being suspended early in the investigation process, with Trusts taking the view (probably themselves for fear of litigation or financial penalty[vii]) that it is better to have that person out of circulation, just in case they did turn out to be at fault.[6] This tends to be exacerbated by the nature of the internal investigation. Often the appointed lead clinician or manager acts like a prosecutor rather than a disinterested analyst of the events and that adds to the feeling that blame is being apportioned.

I hope that the establishment of the Independent Patient Safety Investigation Service (IPSIS), due to operate from April 2016, will help improve the processes (including the variation between centres) and outcomes (https://www.gov.uk/government/groups/independent-patient-safety-investigation-service-ipsis-expert-advisory-group).

**Blame**

A culture of blame is not limited to healthcare, where it describes a culture that 'names, blames and shames' those who make medical errors. The UK in general has a very prevalent 'Blame Culture' [vii]. We see it every day in the headlines of newspapers, and in the general search for a culprit. One hears it expressed as a common question on the Today programme on Radio 4: "who is to blame for this?" Individuals at the sharp end of practice are seen as the problem, rather than other (often larger) systemic or latent issues (e.g. equipment design, workplace conditions, training, etc.) described by Reason[viii].

Many of us grew up in a system that thrived on distributing blame, and usually that blame ended up with the newest, youngest or most vulnerable member of staff. Such behaviour was the norm, and seen almost as a rite of passage. In retrospect, it was institutionalized bullying, and common to many organisations at the time. Sadly, such behaviour still occurs, and we read about it frequently in relation to banks, city law firms and, allegedly, Sports Direct!

Things are better in medicine now, but the fear remains, and that fear can limit our ability to get to the truth. I have visited hospitals throughout the world, and been horrified, in some, at the way in which blame is handed around at meetings. It makes the person being blamed insecure, and nervous of contributing. One wonders whether they will ever raise an important issue again. In medicine, individuals can (and often do) become fearful of potential errors and become over-cautious, practicing what has been called defensive medicine, characterized by over-testing (I must not miss anything) and by choosing not to treat the most complex, and therefore riskiest, patients (too dangerous, something might go wrong). It is not surprising in such a culture that
individuals become resistant to reporting errors, meaning that incidents are not investigated, underlying causes may not be exposed and no learning can occur for others. Unreported errors mean that the true incidence of harm may be worse than what we think it is. Lucian Leape said in testimony to Congress [ix], "The single greatest impediment to error prevention in the medical industry is that we punish people for making mistakes". As was said in the Pennsylvania Safety Collaborative Report in 2001 [x], “Many organisations need to break out of the "blame and train" mentality that punishes individuals for errors and rarely looks beyond to underlying job designs or system malfunctions. In these environments, personnel tend not to report errors they can hide, and are hesitant to discuss them. As a result, voluntary reporting (such as the standard event report) typically identifies fewer than 5 percent of the errors that actually occur.”

A blame culture increases the pressure on the so-called 'second victims' [xii] of medical error; the healthcare givers who themselves have been traumatised by the event, and who experience many of the same emotions as the victims and their families, up to and including severe post-traumatic stress disorder. The signs and symptoms these second victims show are similar to those in acute stress disorder, including initial numbness, detachment, and even de-personalisation, confusion, anxiety, grief and depression, withdrawal or agitation, and re-experiencing of the event. They may also suffer shame, guilt, anger and self-doubt. Some healthcare workers leave their profession and a few even commit suicide because of the experience, and the whole can be compounded if the case goes to litigation[xii]

Some have even suggested [xiii] that there is a 'third victim', namely the healthcare organisation in which the event took place. It may suffer bad publicity, deterioration in morale and become unable to work with its staff to make necessary changes. As we have seen, the organisation may demonstrate knee-jerk reactions to incidents resulting for example in suspension, which end up amplifying the problem. Both the second and third victims may be so severely affected that they cease to be able to carry out their work, wasting years of training or organisational development.

Learning from Investigations

Back to your missing kidney! Once the Trust's investigation is complete, you should receive, in due course, some sort of explanation as to what went wrong and an indication of what will happen to prevent such accidents happening in the future. These reports are long, and sadly often difficult to read, either because of an excess of technical terms or acronyms, or because they are written in an impersonal or clumsy style which can alienate victims or their families. Because it will end up in the public domain, the report is likely to include terms like 'the patient' or 'the child' rather than real names. They can seem cold and distant, and it is crucial that families are helped to understand. A 'personalised' version of the report, with a summary in plain English, helps.

I want to remind you that the NHS is not quite the uniform an organisation we are led to believe. Sequential reforms have left us with a complex system in which the Department of Health sets policy and distributes money to Commissioners, led by NHS England, who buy services from the semi-independent provider organisations called hospital trusts, some of which (called foundation trusts) have theoretically greater financial freedoms. Each has its own CEO and Board of Directors. The whole system is regulated: financially by Monitor (https://www.gov.uk/government/organisations/monitor), and for ‘quality’ by the Care Quality Commission (http://www.cqc.org.uk).

Once the local investigation report gets to the Commissioners, how confident can we be that the lessons emerging from it are spread throughout the system and appropriate preventative actions taken? The commissioners collate various performance measures and the findings of serious incident reports from those organisations in which they occurred are sent out to other Trusts, where the most obviously important findings will be discussed at Trust Board level, and instructions issued to change processes etc. However, most do not get that far and it is left to local safety leads, medical and nursing directors to do the best they can to make changes. This results in very patchy implementation and can offer little assurance to the NHS Board itself, or to the wider public, that the underlying error will not happen again. This is partly because of the triumph of localism over centralism, but also because there remain few standard operating procedures in place in medical practice and even less standardisation of processes. It can be incredibly hard to change the behaviour of local physicians based on a mistake that happened somewhere else. "That could never happen here" is a common refrain.

Compensation and Litigation

We have established that the NHS has a duty to investigate and report serious incidents, and to do so promptly.

But how in England does the victim of such an incident get new expenses covered and/or obtain additional financial compensation? Fortunately, the NHS (at present) provides free health care for all so, in theory, the future medical needs of a victim of medical accident should be covered in the same way they are for the rest of the population, unlike, say in the USA, where medical expenses may be massive. The NHS provides basic care, and you are unlikely to get better services just because the NHS harmed you. However, the only way to get any kind of financial compensation at present, it is necessary to take legal action[xiv] by making a claim of medical negligence.

Our system is based on TORT law and concerns civil rather than criminal wrongs. Tort is not enforced by the police, and one party must sue another (say the hospital concerned), any trial being held in front of a judge, and
rarely a jury. Tort derives from the Middle English for injury, and ultimately from the Latin ‘torquere’, to twist. A wrong must be done by someone, or an organisation, to someone else. For liability under negligence, a duty of care must be established, owed to individual concerned. Whilst there is academic argument about what a duty of care really means, it is reasonably obvious that a surgeon, for example, has a duty of care to her patients. The legal definition of duty of care is not as simple as the phrase implies and is discussed at length in Kennedy and Grubb pp. 414-415 and by McBride. These arguments are beyond the scope of this lecture. However, for negligence to be proven against an individual or organisation, the following must exist:

- A duty of care
- A breach of that duty
- That breach causing material harm (injury)
- The harm must not be remote (in time) from the breach of duty

Thus our hypothetical patient who has had the wrong kidney removed would have to seek legal advice, and via the advisers, seek to prove all the above elements, probably ending up in litigation. Bismark and Dauer quoted in Cave suggest that there are four motivations to medico-legal action:

- Restoration, including financial compensation or some other intervention to ‘make the patient whole again’,
- Correction, such as a system change or competence review to protect future patients,
- Communication, which may include an explanation, expression of responsibility, or apology; and
- Sanction, including professional discipline or some other form of punitive action.

Of course, you may be advised that you don't have a strong enough case to proceed, if it seems unlikely that negligence can be proven. You may still have significant costs to meet during your life, yet if you had happened to be in hospital lying next to a patient who suffered the identical consequences from a medical error, and in whose case negligence could be proven, then that patient may receive compensation, but you would not despite the consequences of the event being identical, and this may seem like a profound iniquity.

Prior to 1990, individual hospital doctors had to be named in suits. In that year, the then Health Authorities took over responsibility for negligence attributable to medical and dental staff of hospital and community services (Health circular (England) HC(89)34 – Claims of medical negligence against NHS hospital and community doctors and dentists). GPs and those in private practice are not covered by this system and usually take out additional insurance cover.

In negligence litigation, the duty of care is assumed, but what constitutes a breach of that duty may be contentious. The removal of the wrong kidney is a pretty obvious breach, but what if the treatment or event that caused the injury is more controversial? Say, for example, that brain damage occurred after open-heart surgery. The cause may be very difficult to work out, and the scientific background confusing or even contradictory. Many clinicians would argue that such brain damage is a recognised complication (always a dangerous and non-self-critical term), others would question the details of the techniques used during surgery. In the UK, the judge's ability to determine, whether or not the duty of care was broken is going to depend on the views of expert witnesses. In the USA, such determinations are left to the jury, and this has an enormous impact on damage settlements. Experts' views, like the rest of the population, differ. But the experts' views are usually expressed loudly (and in public) and differentiating truth from fallacy may be difficult.

Over the last 60 years, the English Courts have used the Bolam test (developed from the judgment in Bolam v Friern Hospital Management Committee: 1957, 1 WLR 582, 587). In 1954, Mr Bolam was to have Electro-Convulsive Therapy at Friern Hospital. He agreed. He was neither given muscle relaxants nor restrained, and he fractured his hip. He sued the hospital for not giving him relaxants, for not restraining him and for not warning him of the risks. He lost. In judgment, Judge McNair said that what was common practice in a particular profession was relevant to the standard of care required. A person falls below the appropriate standard, and is negligent, if he fails to do what a reasonable person would do in the circumstances. Re-worded, the Bolam test states that 'if a doctor reaches the standard of a responsible body of medical opinion, he is not negligent'. Thus it is not surprising that so many cases hang on the expert medical opinions sought by both sides.

The Bolam test has undergone several challenges over the years, but its interpretation was most modified by the Bolitho case in 1997 (Bolitho v City and Hackney Health Authority: 1997, 4 All ER 771). In this case, which was about a two year old boy whose airway were blocked causing a cardiac arrest and brain damage, there was disagreement between experts with five of them saying that one treatment, airway intubation, should have been carried out and one of them disagreeing. The House of Lords subsequently held that there would have to be a logical basis for the decision not to intubate, which would involve the weighing of risks against benefit to reach a defensible conclusion. The judge should be able to choose between two bodies of expert opinion and to reject an opinion which was 'logically indefensible', thus allowing the court to set the law rather than the medical profession and essentially doing away with the responsible minority concept embedded in Bolam. Bolitho, though, remains a last resort in most cases, with judges preferring to see clear opinions from the experts.
Quality of Evidence

So your case proceeds, and the outcome is dependent on both the quality of evidence and the opinions of medical experts. (And, of course, on the quality of your lawyers). But how reliable is the evidence before the court? Clearly for something as clear-cut (if you will excuse the pun) as having the wrong organ removed, the evidence should be pretty clear. But in my experience as an expert witness, the evidence is usually far from clear. And in many ways it is getting less clear.

When a case goes to court, the medical records of the patient become a key element in determining the outcome. And of course they form the basis of internal investigations as well. You might think that the records would be a perfect source of relevant data, but in fact they can be anything but. For generations, medical records (the notes) have essentially been a paper-based narrative, with daily records being kept by medical staff and a (usually) separate nursing record being similar. Observation charts (of the type you see on clipboards at the end of the bed) and ICU records are also stored, but separately, as are all blood test results and imaging. Each component of these will contain clues as to what happened, but there are many hazards in relying on them.

Doctors' handwriting is notoriously bad, and their completeness of record keeping is highly variable. Nursing records are more reliable, but often exclude strategy and analysis of decisions made. People on the whole are good at writing down what they did, but not why they did it or what they rejected in coming to the decision. Notes are often brief (people are busy and may be rushing), obviously written after the event (and thus 'filtered' by the writer) and riddled with acronyms. Times and names may not be recorded properly, and building a timeline of events can be extremely time-consuming. People are employed full-time in large trusts to do this.

Sorting out biochemical, microbiological and imaging data used to be a nightmare, but these have been maintained electronically for several years now, and it is getting easier. The digital revolution should have helped the review of medical records in general, but sadly that is not the case. The medical record has become rather a complex organism, and in most hospitals the patients' record has to be 'reconstituted' from data held on multiple systems, often with different time codes. This latter may not matter if events happen over days, but if you are investigating the effect of a drug, then the exact time of delivery and effect become critical. However, the loss of paper records has made it much more difficult to follow the narrative of a patient's illness, especially as the reduction in junior doctors' hours means that handovers occur more frequently and note-keeping styles change with each shift.

Events that lead to poor outcomes may last only seconds or minutes, especially in the operating room or ICU. Whilst those events are happening, people are doing their best to solve the problem and save the patient. They are not writing down what they are doing, and it is very unusual to have enough staff around to be able to have a note taker and clock-watcher. The notes therefore become summaries if what happened, written later, from memory, when things calm down. They are an interpretation of events. Even matching graphical data from the multiple monitoring devices is challenging. Too rarely do they have a standard time code. Video and audio records, as in a cockpit voice recorder, are almost never available, and thus the story of events is slow and complex to construct, particularly as the statements of staff will also reflect their different perspectives.

It is the job of lawyers and the court to sort this out, and considerable time is spent in doing so. Huge boxes of records are transported and reviewed by solicitors, barristers, judges and experts. Multiple meetings are held to pore over minutiae or inconsistencies and further opinions may be sought, and the whole is re-run if the case goes to court. There is no wonder it is expensive.

The people involved in this retrospective investigation of error have the benefit of time and are trained in the forensic approach. They are, if you like, analysing the consequences of risk at leisure, whilst the people carrying out the medical treatment usually have to take risks at relative speed. I have often seen doctors castigated in court for poor record keeping, only to defend themselves by arguing that they were trying to look after the patient and did not have time or emotional energy to write down all the details. They did not expect to end up in court.

Managing patients is rarely straightforward; each one is a different. Doctors and nurses have to make hundreds of decisions per day. Darst [xxi] et al (2010) in followed 10 paediatric cardiologists around Boston Childrens' Hospital and found that they were each making an average of 158 clinical decisions per day, often only on the basis of experience and anecdote, rather than hard evidence in the medical literature. It is hard enough to look up the literature in real time and harder to find time to write down the rationale for every single decision. Certainly the options that are rejected are rarely recorded, so the lawyer or investigator looking backwards at a case through the retrospectoscope cannot easily imagine the blind ending branches of the decision tree, and will have to rely on the statements (made from memory) of the participants. It is far from perfect.

Costs

The whole process is intimidating for everyone involved, except for the lawyers on whose turf the battles are fought. It can take years for cases to be resolved, and the emotional stress on those involved is considerable. The costs of litigation are enormous. The NHS in England has within it a non-profit organisation, called the Litigation Authority (NHSLA), which manages negligence and other claims on behalf its members. It is supposed
“to minimise the overall costs of clinical negligence...to the NHS and thus maximise the resources available for patient care by defending unjustified actions robustly and settling justified actions efficiently”. The NHSLA has to set aside funds to settle claims in the NHS. The sums involved are staggering. As of July 2015, the NHSLA had set aside (however they do that) £28.6 billion! This represents a 10% rise in one year, and is equivalent to about 25% of NHS England's commissioning budget[xxiii]. These are vast amounts of money, and must come from somewhere. The NHSLA hosts the Clinical Negligence Scheme for Trusts (CNST), which gathers contributions (premiums) from its members to cover them and their employees in case of claims. Recently, premiums have been loaded to reflect the Trust's previous and current claim history, making maternity and paediatric services particularly vulnerable to increased costs because the patients involved are so young, and they, and their families, have a whole lifetime of costs ahead of them.

Most doctors and all GPs belong to a separate professional indemnity scheme such as those run by the Medical Defence Union (http://www.themdu.com/) or Medical Protection Society (http://www.medicalprotection.org/). General Practitioners and those doing private practice are not covered by the crown indemnity scheme. Most hospital doctors choose to be covered, either because they have some private practice or because they don’t trust the NHS scheme to fight their corner, given the financial imperative given to the NHSLA from Parliament to minimise costs and payments. Doctors also join indemnity schemes to ensure they have financial protection in the event if GMC proceedings or for criminal proceedings, such as manslaughter, neither of which circumstances is covered by the NHSLA. The costs of professional indemnity are considerable, and may be £10s of thousands per year out of net income, depending on the specialty. In 30 years of practice as a paediatric cardiac surgeon in England, I have paid (approximately) an astonishing £500,000 from my net income to one of these organisations, and have never claimed. These costs, which are rising at similar rates to the other indemnity schemes, have been suggested as one of the causes for so many doctors leaving high risk specialties, the country or medicine altogether. In fact, most doctors in both general practice and hospital work do take out additional insurance cover, with the MDU, MPS or other smaller organisation, and anecdotally 70% of doctors have had to contact their indemnity organisation at least once. Astonishingly, 14% of those doctors appearing before the GMC (costs of which are not recoverable via the NHSLA) have no such cover (Professor Terence Stephenson, personal communication). Such people could (and do) lose their houses; costs can easily exceed a lifetime’s contribution to the MDU or MPS.

That there is so much money in the litigation business accounts to some extent for the existence of so-called ambulance chasing law firms that specialise in personal compensation and which advertise their service in the foyers of many hospitals. Legal aid use to be available to claimants in medical negligence cases, but in an attempt to reduce Government costs, such funding ceased some years ago [xxiv], and the ‘no-win, no-fee’ schemes began to proliferate, in which the law firms advertise to investigate your claim and pursue it if there is a reasonable chance of victory. Their fees were limited a couple of years ago, but it has yet to have an effect on the overall costs of litigation.

I have stated that people would expect to have the costs of the harm done to them met in some way. But we all get free health care in England anyway, so should the settlement cover just the basic costs, or provide for improved benefits over what NHS provides for all of us? Should it cover loss of earnings over life for you and your carers or pay for holidays, which will be more complex to arrange than before? New housing perhaps? Should there be punitive damages recoverable from those who did the harm (this is not possible in the England at present)? What are the limits of liability? And anyway where should the money come from? It will of course come out of the health budget one way or another, thus potentially taking resources away from other vital services, threatening the core principles of distributive justice.

The scale of settlements in complex cases, especially involving children, highlights some of these points. In 2010, a terrible event occurred where I work, at The Great Ormond Street Hospital for Children. That event severely and permanently affected a 10-year-old little girl’s life. She was having high-risk treatment for a complex congenital anomaly of the blood vessels in her brain. Treatment involved the injection of glue into the abnormal cluster of vessels via tiny catheters passed from the groin blood vessels. The people who can do this are few and far between and extraordinarily highly trained. During the procedure, the operator was handed a syringe containing the glue, rather than the radio-opaque dye he wanted in order to show up the blood vessels clearly on X-ray. Important blood vessels were blocked and she suffered permanent brain damage.

It was an incredibly simple mistake, yet there were many factors leading up to the ultimate catastrophic injection of the wrong substance. The glue and the radio-opaque dye are both clear fluids. They have to be drawn up into syringes in advance, but not too far in advance, since they may both be needed in a hurry. The syringes are identical, in size appearance and injection mechanism. The operator is focused on the images on the X-ray screens that allow him skillfully to navigate the fine catheters into place. He asked for the syringe with radiopaque dye, and was given the one with glue in error. The syringe was not labeled. Fault could be laid at the door of manufacturers, nurses, assistants, operators and the institution involved.

If the little girl involved lives until she is my age, the settlement of her case (which took 4 years) and a court case is likely to cost the NHS Litigation Authority £24 million. GOSH contributions to the CNST have increased dramatically over recent years; 17% alone in the last year to over £6million this. Such costs will continue to rise unless the system changes again.
The operator involved in the case, a world leader in the field who had saved many, many lives and been truly innovative, has returned to his home in New Zealand, where he now runs a farm and is doing less complex work. I wrote to him and asked him how he felt now, 6 years later. This was part of his reply:

"I was greatly impressed with the rigor with which the two QC’s dissected the argument. It would have been close to impossible to hold a position that one didn’t believe to be true. It left me reassured by the legal process. Were it not for the cost, I would argue that litigation of doctors should be encouraged, to subject us to maximal external scrutiny, and ensure rational practice. If anything, the glue debacle delayed my departure, because I felt I could not run away from it."

The Wednesday after it happened, when I next had a list at GOSH, as I left my house I decided I couldn’t do it, went back inside and back to bed, and tried to fall asleep. Someone phoned me and said there was an acute vein of Galen malformation in heart failure. I reluctantly got up, went in and successfully embolised it.

Had it not been for a case that I had to perform arising reasonably close to the glue debacle, I am not sure I would ever have been able to perform a case again, as the longer I festered the worse it got. For the first year, it destroyed my procedural fluidity, because I was subjecting even the simple parts of a procedure (e.g. arterial puncture) to excessive scrutiny.

After a few years I think the net effect on me as a doctor was probably positive. It made me take a much more global view of risk rather than focussing on technical excellence.

On a personal level, it still causes me pain, and I will never forgive myself for allowing it to happen. This is not to say that I feel I am solely responsible; I accept that I was part of a system that failed, but I was leading that team and I injected the glue."

He is clearly a ‘second victim’, and his rare skills are now lost; not just to us at GOSH, but to the innumerable potential patients he might have helped. I have absolutely no doubt that the lovely little girl involved needs help, but was this, medical negligence litigation, the best way to get that help? If clinical practice has been universally altered to improve labeling, syringe design and to introduce colour coding, then perhaps it is worth it. I have no evidence that this has happened, but certainly intra-procedural checks in the UK at least are much more robust.

Alternatives to Medical Negligence Litigation

Do these huge settlements really change the likelihood of adverse events happening again happening again? Are these increases in costs sustainable? Do they satisfy the public's ideas of how to reduce of error; views which may be at odds with those of the profession? [xxv]

In 2003, Liam Donaldson, then the Chief Medical Officer, published [xxvii] proposals to reform clinical negligence in the NHS. He described the system at the time as complex, unfair, slow, costly, unsatisfactory for families and encouraging defensiveness and secrecy. Such criticism continues[xxvii]. Many people, myself included, have argued in favour of a transparent, patient-led, outcome-driven NHS. The inadequacies of the clinical negligence system highlighted by Donaldson[xxviii] do not facilitate achieving that goal, and indeed may result in what Keren-Paz has described[xxix] as an 'asymmetric system' damaging the doctors and hospitals without significantly benefitting the patient/victim.

Donaldson recommended a fast track clinical negligence system (discussed in more detail in Cave [xxx]), which would not only deal with compensation but also emphasise correction and communication as defined by Bismark and Dauer[xxxi]. The NHS Redress Act was enacted in 2006, and proposed a redress package that must include an offer of compensation, an explanation, an apology and a report of action taken to prevent similar occurrences. The package could be accepted with the waiver of the right to sue, or rejected. It proposed a consensual, not judicial, process during which legal rights were suspended. The Act fell short[xxxii] of the CMOs recommendations and necessary secondary legislation was not passed, despite support from the appropriate select committee of the House of Commons, and the Act has fallen into abeyance through lack of political will.

Donaldson had also drawn attention to the damaging implications of clinical litigation on both claimants (process too slow, poor information and inappropriate redress) and defendants (stressful, career damaging and expensive). He judged the process to be too expensive and, with the subsequent financial crisis, recession and austerity programs, a drive to cost reduction has dominated government thinking. As Cave [xxxiii] points out, "whilst the cutting of costs of clinical negligence litigation is a worthy goal, ignoring patients’ interests will result in damaged confidence in NHS redress and will ultimately necessitate[7] further reform".

As Studdert and Brennan [xxxiv] state, when mistakes are (or may be) the subject of litigation, physicians and institutions strive to cloak them in confidentiality, forgoing opportunities to learn from the problems that lawsuits can sometimes help to illuminate. Only part of the truth will out.

No-Fault Compensation Schemes

Such arguments of excess cost, failure to satisfy the public and ineffectiveness in altering physician behaviour have been oft repeated since Donaldson's report, and have led many to reconsider the advantages of No-Fault Compensation Schemes [8]. No-fault schemes have been adopted in several countries around the world, notably
New Zealand, the Nordic countries and in a limited way in some US states. Although it is still necessary to prove causation, no-fault schemes work in the principle that there is no need to prove negligence to be eligible for the payment of financial compensation. Farrell et al[xxxv] have summarized the common features of no-fault compensation schemes, and these are:-

- All have eligibility and threshold criteria which must be satisfied before cover is accepted
- There are limitations on the extent of cover and there may be caps on certain types of compensation, e.g. for pain and suffering
- Levels of compensation tend to be lower than negligence claims brought under tort-based systems
- Access to the courts is often restricted
- There is a comprehensive national social welfare/insurance system in place

The advantages and disadvantages of such schemes are summarized in the following table, also derived from data in Farrell et al [xxxvi]. A short summary of advantages and disadvantages of No-Fault systems is provided by Norrie and Hendry.[xxxvii]

<table>
<thead>
<tr>
<th>ADVANTAGES</th>
<th>DISADVANTAGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principled, comprehensive, fair and</td>
<td>Very expensive, especially for large</td>
</tr>
<tr>
<td>adequate, efficient and reflective of</td>
<td>national populations</td>
</tr>
<tr>
<td>community responsibility</td>
<td>High rate of rejection as eligibility</td>
</tr>
<tr>
<td>Wider eligibility than for negligence</td>
<td>criteria may be tight</td>
</tr>
<tr>
<td>cases under tort</td>
<td>Fails to promote institutional or professional accountability, and removes disincentive to unsafe practice. There is little evidence that learning from medical error is enhanced</td>
</tr>
<tr>
<td>Increased scope for data collection to</td>
<td>May result in increased volume of claims</td>
</tr>
<tr>
<td>improve safety</td>
<td>Causation still has to be established. Difficult enough under tort systems, and may be worse under no-fault schemes</td>
</tr>
<tr>
<td>Easier access and understanding of</td>
<td>Lower rates of compensation, may be set below the financial needs of the victim</td>
</tr>
<tr>
<td>process for patients</td>
<td>Schemes may not include important elements such as explanation, apology and accountability of healthcare workers</td>
</tr>
<tr>
<td>Reduced time and costs compared with tort</td>
<td>Only works well if social security systems well-funded</td>
</tr>
<tr>
<td>systems</td>
<td>Lack of access to courts could conceivably infringe human rights and may encourage victims to seek redress via the criminal law</td>
</tr>
<tr>
<td>Earlier resolution without the need to</td>
<td></td>
</tr>
<tr>
<td>involve the court</td>
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<tr>
<td>Reduced pressure on healthcare workers, both</td>
<td></td>
</tr>
<tr>
<td>psychologically and financially</td>
<td></td>
</tr>
<tr>
<td>Symbiosis with existing social security systems</td>
<td></td>
</tr>
<tr>
<td>Avoidance of court reduces cost, distress</td>
<td></td>
</tr>
<tr>
<td>and administrative burden for everyone</td>
<td></td>
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</tbody>
</table>

The system in New Zealand, managed by the Accident Compensation Corporation (ACC), has been in place since 1974 and is perhaps the most studied. Covering personal injury generally, it was established 'to enhance the public good', and minimize both the incidence and impact of injury in the community. The treatment injury account is one of seven retained within the ACC. Public trust and confidence in the system stands (2014) at 60% for levy payers and amongst clients at 76% [xxxviii]. The details of the system are too complex to be covered effectively in this lecture, but if you are interested you can read much about them in these references[xxxix][xli], which also analyse[xlii] the systems in the Nordic countries in a little more detail. Despite wider eligibility than under tort-based systems, there remains the potential for iniquity. Two people may end up with the same injury, one caused through injury and one through illness, but they will have totally different compensation trajectories, favouring the individual damaged by injury. It has been described[xliii] as a system that 'stops short of providing full social insurance'.

The relative success and acceptability of no-fault systems in Scandinavia and New Zealand, and the comparative dislike of the medical negligence system in the UK, have led many authorities[xlii] [xl] to suggest that we should introduce such a system here. However, whilst it is very attractive to many of us, the cost of such a system is likely to pose an insurmountable barrier[xlv]. All the countries which successfully have adopted no-fault compensation have relatively small populations: the size of the fund needed to provide cover for the people remains relatively small, although even then it tends to struggle to meet demand[xlv]. It becomes even more of a difficult construct in the context of government policy which is aimed at reducing the proportion of spending allocated to public services towards 35% of GDP and the very existence of current concepts of welfare and social support are being called into question. To create an adequate sized insurance fund to underwrite a no-fault compensation scheme seems impossible at present. Further, our politicians seem to remain unconvinced that no-fault is an effective way to influence behaviour, preferring to make at least organisations cough up in proportion to the injury or incidence of claims.[xlvii] I think it is easy to understand why politicians might take this
view. They are much more likely to deflect criticism of the core system (and latent system failures), for which they hold overall responsibility, towards the local front line services, thus potentially avoiding media criticism and adversely affecting their chances of re-election.

So, if the current system has significant disadvantages, and no-fault compensation is unaffordable, what else could we do?

As Sohn points out [xvii], even in the USA where litigation is a national sport, only a fraction of the >$100 billion spent annually on medical negligence litigation actually ends up with the patient, most goes to lawyers and costs. The simplest, and most obvious, approach would be simply to place a cap on the non-economic damages (e.g. pain and suffering, etc.) associated with medical negligence.[xviii] Caps on non-economic damages affect what lawyers can recover (billable hours), and did effectively reduce costs (and length of trials) in California following the introduction of the Medical Injury Compensation Reform Act (MICRA)[xlix]. It also seemed to have an effect on decreasing the costs associated with physicians ordering unnecessary test as part of ‘defensive medicine’. Overall medical expenditure decreased by between 5 and 9%. Caps were not to be included in the recent Obama-care reforms in the USA. Capping has proved effectively impossible across most of the USA because of the constitutional right to a jury trial and the right of the jury to impose punitive damages. Thus in the US, negligence associated costs are ruinous, both to the individual and the healthcare system. In the UK, punitive damages are not paid under medical negligence law. Here, the Judicial College publishes defined categories of payment (damages) for types of injury. These are included in the Guidelines for the Assessment of General Damages for pain and suffering and ‘loss of amenity’[li]. For example, awards for tetraplegia are in the range £230,000 to £285,500 in addition to the costs of care through life. This money thus does comprise damages, recoverable via the NHSLA from the plaintiff.

**Alternative Dispute Resolution**

Another system proposed in the USA has been the Alternative Dispute Resolution (ADR), referring to a range of dispute resolution techniques aiming to resolve conflicts outside the courtroom. These include strategies of early apology, mediation and arbitration, and they vary in both nature and formality. Interestingly, mediation has had excellent success in both cost-containment and satisfaction for both sides where it has been tried, notably at the Universities of Drexel and Pittsburgh. These centres reported successful resolution of conflicts in 85% and 88% of cases respectively, and Pittsburgh saved $1 million in the first year ( [http://www.physiciansnews.com/2005/11/13/malpracticecasealternativedisputeresolution/](http://www.physiciansnews.com/2005/11/13/malpracticecasealternativedisputeresolution/) ). Arbitration proved to be more acrimonious and expensive, and even a successful defense could cost $100,000.

An additional obstacle to more widespread use of ADR in the USA has been the associated compulsory reporting of outcomes to the US National Physician Database (NPDB), which physicians believed had potentially damaging effects on the physicians’ reputations, hence reducing their willingness to take part. In America, physicians tend to come out well at jury trials, so missing out on the opportunity of such a trial was also not attractive to them.

In the UK, we do have ADR in the form of mediation. The parties in a negligence case are obliged to consider whether mediation is appropriate, and they must declare this consideration. Implicit in the civil procedure rules is that if it is appropriate, then you should do it. Similar procedures have are very successful in other parts of the law, but in medical law the claimants have often wanted a payout and mediation has failed. Claimants would rather have their day in court and allow a judge to decide the payout.

However, since 2000 and after the Woolf report [10], when cases have been thoroughly worked up for trial, but sometime before trial is likely, the parties are obliged to meet to see if they can settle the case. Usually these so called Round Table Meetings take place in Chambers, between the opposing legal teams, with the victim in other room or available by phone. The meetings usually take hours and everyone is genuinely tries to settle the case. Only 1-2 % of cases now actually get to court.

**Health Courts**

The USA has also begun to consider the use of Health Courts. These are specialised tribunals at which medical malpractice cases would be decided by medically savvy judges or tribunals, rather than juries. In practice, this is not dissimilar to the English system and is thought to have the potential to discourage frivolous litigation in pursuit of punitive damages. In the USA, there are objections to these courts as they may infringe the constitutional right to a jury trial. Various ‘workarounds’ have been suggested, but remain to be adjudicated.

So here you are, left with no functioning kidneys, an increased cost of living and probably a reduced income. Your only recourse it seems is to take legal action, perhaps helped by a no-win, no-fee firm. It will cost a great deal (our most senior judge, Lord Chief Justice Thomas, last week warned, in the introduction to his annual report [l], that civil justice is now unaffordable to most) but you will almost certainly win, probably by settlement out of court. However, few cases are so easy to resolve as removing the wrong organ. Most are quite nuanced, and both expert opinion and legal argument will be engaged. It is far from clear that there will be any lasting change to NHS systems as a result of such litigation. However, last week the first case of corporate manslaughter came to Court with Maidstone and Tunbridge Wells NHS Trust as defendants, accused of failing to ensure adequate training and supervision of two anaesthetists under whose care a 30 year old woman died during a caesarian section. It is certainly possible that court cases such as this will change behaviour of Trusts,
and force them to put patient safety higher up their corporate agenda. It is remains unclear whether the learning from such litigation will spread throughout the incredibly complex NHS organisation and result in clear actions in order to prevent it happening again.

**Local Prevention**

There is perhaps another way to think about all this. And that is to go back to one of the basic tenets of medicine. Prevention is better than Cure. Much of what we do in healthcare carries risks, and better understanding of how we might mitigate those risks, and a genuine sense of accountability, backed up by consequences at local level may be more effective in making healthcare safe than any amount of litigation. Employers MUST encourage staff to report incidents and support them to do so. A safe culture requires this. This balance between a “No Blame Culture” and accountability has been considered by several people, notably James Reason, who argued for a Just Culture (rather than a blame culture) in which it was recognized that some unsafe acts, both of commission and omission, are genuinely unacceptable and those committing them should be subject to sanction, even if the overriding culture of the organisation was non-punitive. Marx (quoted in Wachter et al [lvii]) also promoted a just culture, differentiating ‘blameworthy’ from ‘blameless' acts. Some things are, simply, worthy of blame.

Most errors are committed by good, hardworking people trying to do the right thing at the right time. However, there are situations in which the actions, inactions or behaviour of individual physicians pose a clear risk to patients. Some of these behaviours, actions or inactions would be better challenged locally and corrected, before they escalate into harm, rather than wait until injury has occurred and litigation results. Doctors are not very good at being told what to do; they do not feel like, or often behave like employees. They tend to say they work AT, for example, Great Ormond Street rather than FOR Great Ormond Street. They are frequently sure they know better than the system, and they certainly seem to resent being managed by 'managers' rather than their peers. Even their peers struggle to manage them!

Despite clear evidence that those who repeatedly cause minor harm or who have low-grade behavioural issues gone on to become serious 'offenders' ending up in court or before regulatory authorities, we have failed to create real accountability or real performance management at local level in the way that true high reliability organisations have done. Doctors remain subject only to relatively weak peer enforcement through medical staff structures [ili]. The recent (2012) introduction by the General Medical Council of a process of Revalidation (http://www.gmc-uk.org/doctors/revalidation.asp), based on a combination of appraisal and some limited performance data, has gone some way towards ensuring that all doctors are up to scratch, especially since there is a local Responsible Officer who has to sign off that doctors are competent to do the work.[ll] The reactions from Responible Officers, the senior doctors running the system within organisations, have been overwhelmingly positive, with many reports that the process has introduced rigour and tangible improvements in clinical governance. The GMCs process of physician revalidation is regarded as one of the most comprehensive and ambitious, schemes in the world. However, within smaller sections of many organisations, say a department, performance management remains weak. It is hard to discipline a life-long colleague when you have to work with him or her every day, and few doctors are trained in the skills required to do so. In my view, they should be.

Better training at medical school in both human factors and systems engineering would go some way to helping doctors understand the importance of day to day discipline, and discipline without consequence is of little benefit. Nobody wants to punish someone for a single error, unless it is both deliberate and egregious. For example, hand-washing is recognised as a way of preventing infection, yet doctors are usually the worst offenders in hospitals when it comes to maintaining high rates of hand washing. It is rare to get hand washing rates amongst physicians above 70% [liv]. Everyone forgets to wash his or her hands on occasions. However, what if someone repeatedly does not wash his hands; what should be done then?

Even more seriously, surgeons do not like to be told to use a checklist, even though it has been proved to help; wrong site surgery still happens (there were 326 cases in England last year). Surely there should be some sanction then? Wachter and Provonost [lv] propose a sliding scale of sanctions for ‘offenders', for example losing access to the operating room for increasing periods of time. This would be effective in the US[lvi] where that equates to income, but it might equate to an offer of holiday time in England! Gerry Hickson in Nashville has carried out a great deal of work in improving local accountability, based on a series of escalating ‘difficult conversations' and it has proved very effective wherever it has been applied in the USA. All complaints (even apparently trivial) and performance data relating to a physician (including feedback data from patients) are collected and used as the basis for these conversations. Hickson estimates that at each stage about half of those subject to such a conversation will correct their behaviour or performance, effectively rehabilitating them, importantly before a major accident or litigation. It has not been so easy to get off the ground in the UK. Lack of awareness or engagement by human resource departments together with the complexities of the consultant contract and its associated life-time tenure pose real challenges. You can see Gerry Hickson talking about some of his work at the Risky Business website (http://www.risky-business.com/results.php?key=hickson).

We cannot just impose local discipline by dictat. Doctors do not respond well to that and as Thomas Lee and Toby Cosgrove put it ‘any ambitious strategy that they do not embrace is doomed'[lvii]. The changes that are occurring currently in medicine are profound, and doctors are being told that they must accept new organisational structures, ways of working, payment models and, simultaneously, performance goals. It is not
surprising they are anxious. Lee and Cosgrove[viii] describe them as being in the classic stages of grief, including denial, anger and outbreaks of rage! Doctors always claim to put the patient first, and that remains the best ‘lever’ for engaging them in change. But there are undoubted elements of self-interest, for example remuneration and job security, which must be acknowledged, and many organisations around the world use these as levers to ensure that doctors do what is required.

In many US hospitals pay is directly related to performance, both in terms of quantity and quality. It is also common to have contracts that are reviewable at regular intervals (often annually), and continuation of contract is possible only on the basis of detailed performance reviews, including safety data. Such reviews would concentrate the mind wonderfully, and do not seem to me to be fundamentally unfair. Our revalidation programmes are better than nothing, but far away from such local control. It seems pointless to leave quality and discipline to national bodies, when there is plenty of opportunity for local surveillance, quality assurance and control.

Many medical directors with whom I have discussed the topics covered in this lecture have commented on the lack of help they get from the Human Resources Departments in their Trusts. HR seems to be populated by a different tribe (as I am sure they would say about medics). It is incredibly rare to see doctors disciplined locally and even rarer to see them dismissed. The processes are byzantine, slow (up to 5 years in my experience) and often amount to death by paper. The costs of such actions are enormous (millions), and in the current financial climate a disincentive to taking action. Turnover of HR staff is high, and continuity of case management difficult. The doctors’ union, the British Medical Association, and their defence organisation if they are in one will rightly be fighting for the doctor, yet records relating to individuals are often inadequate and cases can collapse because of lack of information relating to known, but inadequately recorded, past events or complaints. All can be improved, and must, if we want to raise standards and avoid harm and litigation.

I suggest that it is at this local level that we will find the answer to the rapidly rising cost of medical litigation. Safety must be made paramount, and we must find a way to create a balance between a no blame culture, which supports investigation of incidents in an open and honest way, and a just culture, embracing a system of accountability for ones behaviour and actions subject to sliding scales of sanction. Negligence will occur, as it does in all fields of human activity. However, it should be prevented wherever possible, and whenever it does occur we should find ways of hastening the compensation of victims.

I began the preparation for this lecture with the assumption that I was going to come down on the side of no-fault compensation. If such a system was comprehensive enough and lessons genuinely could be learned, I would still favour that over the lottery, expense and potential unfairness of litigation. The evidence suggests that it would be financially impossible to introduce such a system in England at present. However, if we can control the rate of harm by making it safer at local level, then the costs may be come low enough to permit the establishment of a no fault scheme. Litigation should be used for some; some things are blameworthy, and organisations may be moved to change behaviours by a manslaughter charge. A forensic approach, managed by those skilled in it definitely has its place, but the costs are prohibitive of routine use. As the radiologist involved in the £24 million case at GOSH told me: “It left me reassured by the legal process. Were it not for the cost, I would argue that litigation of doctors should be encouraged, to subject us to maximal external scrutiny, and ensure rational practice”.

In my last lecture, I drew your attention to the human factors so crucial to making both aviation and medicine safer. I emphasised the frequency with which medical errors occur, and how medicine remains a relatively low-reliability organisation. I discussed how medicine is more complicated than flying and has more potential for human error because it is so labour intensive with so many interactions. Human error is inevitable. I want to finish with a little demonstration.

I am clearly aware that some lawyers may have been attracted to attend tonight by the title of my talk. Please would you put up the house lights for a moment? Are there any lawyers here? I need 7 people to come up on stage with me, and it would be perfect if some could be lawyers.

Thank you.

Demonstration of copying

Concluding Remarks

We all make errors. It is how we learn from them that matters. That, and not making the same mistake twice. What I have learned from this work is this:-

- Errors are frequent, negligence is not
- Only those suffering harm form negligence are compensated
- Repeated errors are a warning of greater harm to come
- Managing negligence is costly in all respects, yet litigation 'shines a light'
No-fault compensation is fair and logical, but currently too expensive to implement.

We must encourage local actions to reduce harm, cost and the repetition of error.

Reporting and investigation are helped by a no-blame culture, but in the end some blame needs to be attributed in serious cases, and litigation does seem to help. The culture and practice of organisations MUST put safety first, and discipline of oneself, and by one's employers, is required incorporating more sophisticated performance management, minimising the need for litigation.

'To blame or not to blame' was probably the wrong the question. Both are appropriate. 'How do we make it safer' is the correct question, and I hope I have suggested some answers which move you.

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[1] The General Medical Council is an independent body with which all doctors must be registered (at their own expense) in order to care for patients. It sets standards, maintains records and can take action to prevent doctors putting the safety of patients or public confidence in doctors at risk (www.gmc-uk.org)
[3] An NHS Trust is an organisation within the English NHS to deliver care. They were first set up in 1990 and are in effect public sector corporations. There are several types of Trust; NHS hospital trusts, mental health trusts, ambulance service trusts and community health trusts. Each may apply for Foundation Trust status which theoretically gives them greater financial and managerial freedom.
[4] Commissioning in the NHS is the process of planning, agreeing and monitoring services. Commissioners are the people who manage That process on behalf of the Department of Health. More detail can be found here https://www.england.nhs.uk/commissioning/
did not return to work. Many of these suspensions were not related to errors per se, but to ‘personality clashes’ within teams or with managers. A representative of the Medical Protection Society (Dr. Gerrad Panting), which advises and supports doctors, said at the time of the NAO report “suspension is seen as a condemnation of the doctor’s practice. The longer the doctor is suspended, the harder it is for him or her to get back to work because of the inevitable decrease in professional skills and confidence”[6]. These comments hold true today.

[7]My emphasis
[8]A detailed, and easy to read, review of the subject is available at http://www.gov.scot/Topics/Health/Policy/No-Fault-Compensation

References

[xlvi] Campbell D. Hospitals could have to pay for errors that kill or cause injury, says Hunt. The Guardian 2013.


