A systems approach to accepted standards of care: Shifting the blame

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SOAP BOX

Please cite this paper as: Glance DG. A systems approach to accepted standards of care: Shifting the blame. AMJ 2011, 4, 9, 490-494.
http://doi.org/10.21767/AMJ.2011.908

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Abstract

In healthcare, from a legal perspective, the standard of acceptable practice has been generally set by the courts and defined as healthcare professionals acting in a manner that is widely accepted by their peers as meeting an acceptable standard of care. This view, however, reflects the state of how practice "is" rather than what it "ought to be". What is ought to be depends on whether you take a "person" or "system" oriented approach to practice.

The increasing pressures of lack of money and resources, and an ever-increasing need for care are bringing pressure on the health services to move to a system approach and this is gaining acceptance both with clinicians and thus eventually the courts.

A systems-type approach to healthcare will, by necessity, embrace clinical protocols and guidelines supported by clinical information systems. It will also see blame for errors shifting from clinicians to the organisations that employ them.

This paper argues that a continued use of a person-based approach to healthcare, developed through an historical record of practice by individual clinicians, is no longer adequate defence in a case of supposed negligence.

When the healthcare system has codified clinical guidelines and digital data gathered across thousands of clinicians and their patients, it is possible to compute adequate levels of care and expect clinicians and the healthcare system in general to meet these minimum standards.

Future negligence decisions will rely on a systems-based best practice standard of care determined through evidence rather than opinion

Key Words
Medical negligence, health informatics, clinical protocols

What this article adds:

1. This paper argues that clinical practice will increasingly be guided and measured using clinical guidelines and protocols.
2. The clinical guidelines and protocols will set a level of acceptable standard of care that is and will be used increasingly by the courts in defending and prosecuting medical negligence cases.
3. A systems approach to errors and negligence will accompany this move and the adoption of clinical guidelines and protocols will necessitate the use of decision support and information systems.

Establishing a standard of practice: determining the height of the bar

In many countries, including Australia, legislation and the courts have established that an acceptable standard of care is one that would reasonably be considered proper by a responsible group of professionals skilled in that care. So, a medical practitioner will not be found to be negligent if the practitioner acted in a manner that was widely accepted by their peers as meeting an acceptable standard of care. This is a principle that is now legislated in most Australian states through variants of their Civil Liability Acts.[1-5]

The idea of "peer professional practice defence"[6] originally stemmed from the UK as a result of a 1957 English case of Bolam v Friern Hospital Management Committee.[7] Since then there have been variations on this ruling centring on the balance of determination of acceptable standards between peers and the courts.

A major issue with the determination of standard practice, especially when determined by peers, is that it is not

necessarily a reflection of how healthcare "ought" to be carried out but rather a reflection of the opinion of a particular group of professionals as to how it "is" carried out.[8] The courts usually reserve the right to decide that the current practice is irrational but they are not concerned with the ideal. The importance of this is twofold. First, the threat of legal action is an influencer of behaviour of both medical professionals[9] and healthcare organisations[10] and produces a feedback loop that can be either negative or positive depending on your perspective.[9] Second, the onus of liability resting on the individual or healthcare organisation is determined by whether it is the "person" or the "system" that is at fault.

The idea of dealing with medical errors from a "person" or "system" perspective was suggested by James Reason[11] who examined approaches to dealing with and limiting errors taken by high reliability organisations such as air traffic control centres, nuclear aircraft carriers and nuclear power plants. Reason started with the view that human errors are inevitable but in a systems approach to human errors the organisation places mechanisms around the humans to mitigate these errors and to be able to recover from them.

Acceptance of a systems approach: complexity, lack of resources, increasing need resulting in errors

Healthcare organisations would benefit from adopting characteristics of high reliability organisations in taking the approach that it is not the person who is ultimately at fault when an error occurs. The fact that errors occur in healthcare, and at a high rate, is not surprising. Like all aspects of human endeavour, healthcare generates an ever-increasing amount of information either explicitly or as a by-product of its activities. This patient data is not only about the health of the patient but also about how the patient has interacted with both health professionals and the organisations they work for. Health professionals are now expected to base their decisions of patient care on a more comprehensive view of all of the data collected at the same time as not missing critical information.

It is clearly the case that attempting to collect, analyse and interpret patient data in the modern context of healthcare and ensuring that this has been done in a systematic, comprehensive and timely way is not possible without the use of protocols and guidelines and clinical information systems to support their application. This is quite convincingly illustrated when examining adverse events in Australia's hospitals.

The Australian Institute of Health and Welfare reported[12] that in 2004–2005 there were 339,551 separations for which patients experienced an adverse event – this represents a rate of approximately 4.8% of all hospital separations. In the public sector this was 5.6% of all hospital separations. This compares to a study in the US from 1991[13] where adverse events occurred in 3.7% of all hospitalisations.

Interestingly, when looking at the reporting of sentinel events (adverse events that are analysed and reported by the hospital) there is a huge discrepancy in what is reported from adverse events experienced by patients. In Western Australia between 2004–2005 for example, there were 383,260 separations from public hospitals that would give approximately 19,163 adverse events but between 2004 and 2005 only 42 sentinel events were reported. In 2009–2010 only 47 sentinel events were reported.[14] In a study of coded data in Victorian hospitals, researchers were able to detect 4,375 sentinel events compared to 78 that were voluntarily reported.[15]

The consequences of not being able to process all of the data collected about a patient and process them in a timely fashion are clear. This can be seen in the area of review and follow-up of test results. In a review of studies examining test result follow-up, Callen, Georgiou and Westbrook[16] reported failure to follow-up inpatient tests in 20.04%–61.60% of all tests conducted and between 1%–75% of all tests conducted in the Emergency Department setting. They also reported a study reviewing closed malpractice claims where 16.5% of the claims involved missed Emergency Department diagnoses due to failures in test result follow-up.[17] The study by Callen, Georgiou and Westbrook[16] also included hospitals that used computerised physician order entry for ordering tests and processing the results and found a high failure rate to review and follow-up tests in these settings as well. So the utilisation of clinical information systems does not necessarily guarantee an acceptable standard of care.

Clinical protocols and guidelines

Following on from this, one would have thought that clinical guidelines and protocols and the use of electronic health systems would form the basis of accepted standards of care when looking at cases of negligence. But this is still not the case. In the US, there has certainly been the desire to be able to use a medical practitioner's adherence to a particular medical protocol or guideline as prima facie evidence of accepted standard of clinical practice. The US State of Maine trialled a project in which 20 practice guidelines were incorporated into state law. Essentially, following the guidelines would protect physicians from malpractice claims.[18] The results from this trial have so far

been inconclusive with only one litigation case bringing a guideline up as defence.[19]

In the UK and Australia it is unlikely that following a clinical guideline or protocol would be taken as sufficient evidence of following accepted practice[8] although an expert witness may call on protocols or guidelines in establishing accepted practice. This is indeed what does occur with a recent survey in the UK showing that a high percentage of lawyers were familiar with clinical guidelines and had observed them being used by both claimants and defendants in medical negligence cases.[31]

A case which did rest on the use of a protocol was the case of South Eastern Sydney Area Health Service v King[20] in which a paediatric oncologist, Professor Darcy O'Gorman-Hughes used an experimental treatment protocol in dealing with a malignant tumour on the spine and was deemed to have failed to keep himself aware of an important amendment to the protocol.

We posit, however, that the reason protocols and guidelines are not used in defence in medical negligence cases are because they are still not systematically used.

The fact that protocols or guidelines may not be admissible as evidence of current accepted practice in a negligence case may not be the relevant consideration in considering their place in healthcare. The resistance to protocols and guidelines has in the past been voiced as the medical profession maintaining the freedom to "exercise the art and science of medicine according to its traditions, standards and knowledge… without interference".[21]

Living with errors

There are always going to be errors in healthcare; the fact that after 20 years, the rate of adverse events in hospitalisations has not improved is evidence of this fact. To borrow another concept from the software industry, Yourdon[22] introduced the concept of "good enough" software. This recognised the fact that given constraints of time and money, software was never going to be perfect but that it actually did not need to be. Most users could live with the limitations of software that was in a permanent phase of development or "beta".

Given the constraints of time pressure and money and an ever-expanding need, healthcare is never going to be perfect and errors and adverse events will always be part of the system. This was the view of 97% of surveyed Australian GPs.[9]

Clinical information systems

Clinical information systems including decision support are capable of reducing errors and combined with protocols and guidelines provide healthcare's best chance of implementing a systems approach to the error problem. This is a view shared by world governments with Australia planning to spend AUD$470m by 2012[23], the UK government having spent between GB£1–GB£2 billion per year from 2002–2006 with GB£145 billion planned to be spent before 2016.[24] This is dwarfed by the US who were planning to spend US$100 billion before 2016 on eHealth.[25]

eHealth can reduce errors especially when combined with organisational change.[26-28] What it has the potential to do however is to provide data on the normative standard of practice of thousands of clinicians and their patients in such a way that not only can clinicians be alerted of potential deviations from this at the time of practice but this can also then be used as evidence that standard practice was followed. This approach has been taken in assessing conformance with drug prescribing protocols[29] and pathology test ordering[30] but is applicable in almost all areas of medicine.

Increasing need, fewer resources and escalating costs will drive healthcare even more aggressively into a more systematic of operation. This will involve the use of standardised approaches to care, systematic treatment of errors and their avoidance and the use of clinical protocols and guidelines supported by computerised clinical information systems. Not only will use of this approach act as a defence in cases of medical negligence but the opposite will also be true, not using this approach will potentially leave healthcare organisations and clinicians open to negligence claims simply because they are not meeting the current accepted standard of care.

The evolving systems approach

There is evidence that this trend is already under way. A recent survey in the UK showed that a high percentage of lawyers were familiar with clinical guidelines and had observed them being used by both claimants and defendants in medical negligence cases.[31] In the UK the Health Act 1999 imposes a statutory duty on NHS and Primary Care Trusts that healthcare provision is monitored and improved.[32] The systematic use of health information systems in bringing around increased efficiencies and reduced errors and litigation can be seen in the case of Kaiser Permanante's US$3 billion investment[33] in health IT. The business case was predicated on increased efficiencies amongst which were shorter stays, faster diagnosis, fewer errors and reduced litigation.

We have yet to see the use or lack of use of clinical information systems appear in medical negligence cases. But it is only a matter of time before these too are accepted as forming the accepted standard of care.

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ACKNOWLEDGEMENTS

The author acknowledges the input of reviewers of this article and early assistance provided by Catherine Russo.

PEER REVIEW

Not commissioned. Externally peer reviewed

CONFLICTS OF INTEREST

The authors declare that they have no competing interests

FUNDING

None

ETHICS COMMITTEE APPROVAL

Not Applicable