

An introduction to clinical risk management

“Accidents hardly ever happen without warning. The combination or sequence of failures and mistakes that cause an accident may indeed be unique, but the individual failures and mistakes rarely are”.

Risk management has recently become something of a buzzword in the National Health Service (NHS), although it has been recognised within the business world and industry for a long time. For many years, the aviation industry has learnt detailed lessons from its disasters and near misses to try to make flying safer. Medicine and allied professions can use risk management to achieve the same end.

Risk management is something that will have a significant impact on the NHS in the near future and will be rapidly implemented, even faster than it was in the aviation industry. As with clinical governance in general, clinical risk management will inevitably affect all clinicians in the NHS. Hospital optometrists will no doubt be affected by these changes before their community general practice colleagues.

Those in community practice, however, will not escape the influence of these changes in the fullness of time. As is so often the case, the most readily available information is derived almost exclusively from the secondary care sector with very little from primary care sector.

The aims of this article are to:

- explain what is meant by clinical risk management;
- explain the background to clinical risk management and how it has come into existence in the NHS;
- outline how it is likely to affect optometrists and other healthcare professionals in general and hospital optometrists in particular;
- suggest action plans for optometrists to start preparing for the implementation of clinical risk management; and
- briefly discuss the effect this is likely to have on everyday clinical practice.

Background

Clinical governance can be defined as - “the framework through which NHS organisations are accountable for continuously improving

the quality of their services and safeguarding high standards of care by creating an environment in which excellence in healthcare will flourish”.

Clinical risk management is a key component of clinical governance. The consultation document, “A first class service”², subsequent to the government’s White Paper, “The new NHS – Modern and dependable”³, places clinical risk reduction programmes and critical incident reporting as some of the main components of clinical governance.

Risk management in the context of the NHS is a broad subject covering both clinical and non-clinical services⁴. It can be described as the systematic identification, assessment, prioritisation and reduction of risk to patients, staff and members of the public². Management of clinical risk tends to be associated with the cost of clinical negligence which, for the NHS, is currently around £400 million annually⁵.

The implementation of risk management was included in the NHS Plan, published in July 2000⁶. In June 2000, a key document was published entitled, “An organisation with a memory”⁷, which was a Department of Health report by a panel of experts on learning from adverse events in the NHS. This was chaired by Professor Liam Donaldson, Chief Medical Officer. This document has attracted a great deal of interest both nationally and internationally. It has been described as a landmark report that was courageous in labelling the problem of medical errors as, “pervasive, consequential and pledging progress to address the issue”. The report acknowledged that there had been little systematic learning from adverse events and service failure in the NHS in the past. “An organisation with a memory” drew attention to the scale of the problem of potentially avoidable events that result in unintended harm to patients (**Table 1**). The report proposed solutions based on developing a culture of openness, reporting and safety consciousness within NHS organisations. It proposed that a mandatory national reporting system should be introduced to identify adverse events in healthcare, including specified near misses, to gather information as to their causes, to synthesise, learn and act to prevent similar events occurring and reduce risk (**Tables 2 and 3**).

The recommendations from this report were subsequently fully accepted by the government (**Table 4**). Following on from this report, “Building a safer NHS for patients” was published in February 2001 in which the government set out its plans for promoting patient safety as part of the NHS Plan. Patient safety was placed in the

Table 1

“An organisation with a memory” - executive summary

- Majority of NHS care is of high standard
- Rarely, serious failures occur with devastating consequences and are very distressing
- Most have a familiar ring
- Most could be avoided if only previous lessons had been learnt

Table 2

“An organisation with a memory” - the problem every year in the NHS

- 400 people die or are seriously injured in adverse events involving medical devices
- ~10,000 adverse drug reactions reported
- ~1,150 people in recent contact with mental health services commit suicide
- ~28,000 written complaints received re: treatment
- NHS pays out £400 million per year on clinical negligence claims
- Potential liability of ~£2.4 billion
- 10% of all admissions result in harm to patients due to adverse events
- Cost to the NHS £2 billion a year in additional hospital stays alone excluding wider costs
- Some specific, relatively infrequent, but very serious adverse events happen time and again over a period of years
- Usual response has been to apportion blame

Table 3

“An organisation with a memory” - summary of conclusions

- Unified mechanisms for reporting and analysing when things go wrong
- A more open culture, in which errors or service failures can be reported and discussed
- Mechanisms for ensuring that, where lessons are identified, necessary changes are put into practice
- A much wider appreciation of the value of the system approach in preventing, analysing and learning from errors

context of the government's NHS quality programme and highlights key links to other government initiatives. This will hopefully enhance existing mechanisms for improving quality of care and promoting patient safety by harnessing learning throughout the NHS when something goes wrong.

Clinical risk management Changes in perspective

Over the past decade, there have been a number of events that have had a significant impact on the NHS and help to explain why various changes are now taking place and why risk management within the NHS has become such a high priority.

These include:

Crown immunity for hospitals

This was lost in 1990 and replaced with Crown indemnity, to replace clinical negligence cover by medical defence organisations. Incredibly, until this time hospitals were immune from prosecution over accidents that occurred on the premises.

Health and Safety Executive (HSE)

In a landmark case in 1996, Norfolk Health Care Trust was fined by the HSE for breaches of health and safety law. This was because the hospital had failed to prevent a patient, undergoing a routine cardiac angiography, from accidentally being injected with air instead of radioactive plaque dye. The patient subsequently died as a direct result of this medical error. This ruling had major implications for NHS trusts across the country as it highlighted the possibility that prosecutions under health and safety law could now be brought in relation to clinical accidents.

Human Rights Act

This made it a legal responsibility to respect human rights in public service. Even a non-negligent act may still breach the Human Rights Act. For example, take this hypothetical scenario where a person presents to an accident and emergency department with chest pain. The attending doctor undertakes their examination and performs all the tests he considers appropriate to make a diagnosis in line with currently accepted practice. Following this medical examination, he concludes that there is no serious problem and sends the person home. On returning home, the person subsequently has a massive heart attack and dies. A doctor would not be guilty of negligence if he has acted "in accordance with the practice accepted as proper by a responsible body of medical men skilled in that particular art". This is referred to as the "Bolam" principle and has been applied in the courts in medical (and optometric) negligence cases ever

Table 4

"An organisation with a memory" - summary of recommendations

- Introduce a mandatory reporting scheme for adverse healthcare events and specified near misses
- Introduce a scheme for confidential reporting by staff of adverse events and near misses
- Encourage reporting and questioning culture in NHS
- Introduce a single overall system for analysing and disseminating lessons from adverse healthcare events and near misses
- Make better use of existing sources of information on adverse events investigations and inquiries
- Improve quality and relevance of the NHS adverse events and investigations and enquiries
- Undertake a programme of basic research into adverse healthcare events in the NHS
- Make full use of the new NHS information systems to help staff access learning from adverse healthcare events and near misses
- Ensure important lessons are implemented quickly and consistently
- Identify and address specific categories of serious recurring adverse healthcare events

since the 1950s. The courts can, however, still judge whether a certain practice or line of treatment, which may cause harm to a patient, should not be regarded as acceptable simply because a group of medical experts accept that a particular treatment is common practice. Conversely, under the "Bolitho" ruling, the courts may even decide that a certain practice or line of treatment is an acceptable defence, if only supported by a minority of experts. This is providing that, in the court's view, the defence is "logically supportable"⁸. In addition to the Bolam principle, for a successful negligence claim, the litigant would also have to establish that a duty of care was owed and that there was a causal link between the alleged negligence and harm sustained.

If we assume, however, that the doctor was not found guilty of negligence, the dead person's relatives could still, theoretically, sue the hospital as a public organisation, under Article 2 of the Human Rights Act, for not safeguarding the dead person's right to life.

In recent years, there have been a significant number of cases in the NHS that have brought about a crisis of confidence. Examples include the Bristol Royal Infirmary children's heart surgery enquiry, the GP Harold Shipman, the Alder Hey body parts scandal, the gynaecologist Rodney Ledwood,

Richard Neale and the Professor van Velzen scandal.

Accident investigation

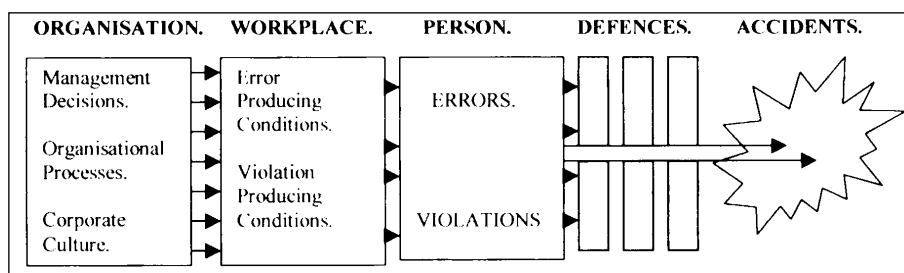
In the past, accidents have been more thoroughly investigated in industry and transport. Examples include the oil platform Piper Alpha disaster, the Paddington rail enquiry and the sinking of the passenger ferry Herald of Free Enterprise in 1987. Until very recently, this was in complete contrast to clinical practice with the exception perhaps of Anaesthesia^{9,10,11}.

The vast majority of healthcare professionals are committed to providing a service to the highest standards and quality. Despite this, human error accounts for some 70% of accidents and equipment failure for around 15-20%. Other factors such as poor equipment design, lack of appropriate policies and procedures and lack of proper training account for the remaining 5-10%⁵.

Any healthcare professional involved in an incident with a patient, will recognise that it is seldom the case that a single isolated event was the cause. It is more likely to be a constellation of numerous factors, many perhaps outside the direct control of the healthcare professional, that led to errors being made. This can be summarised by James Reason's model of organisational accidents (**Figure 1**).

Figure 1

Modelling organisational accidents by James Reason (by kind permission of BMJ Publishing)



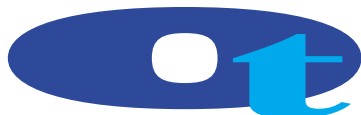


Table 5

Example of the main elements of an incident/near miss form¹²

Reporting officer	
Date of report	
What happened? (Location)	
Where did it happen? (Date and time)	
Why did it happen? (Underlying root causes)	
What action was taken? (Immediate and longer term)	
What impact did the event have? (Harm to patient, others, the organisation)	
What factors did, or could have, minimised the impact of the event?	

Table 6

Suggested ways to address risk management requirements

- Optometry clinical risk assessment, e.g. the theoretical risk of vCJD and contact lenses or the real risk of not, e.g. using mydriasis in all diabetics attending for retinopathy screening?
- Keeping comprehensive legible case records and avoiding abbreviations
- Extending scope of practice only after accreditation to undertake extended roles
- Introduce competency-based assessments for all staff in specific clinical tasks
- Introduce professional development profiles for all staff, in addition to professional development plans
- Introduce reflective diaries and use these in staff discussion forums on clinical management of interesting or complex cases
- Act on lessons learnt

In Justice Sheen's report¹³ into the Herald of Free Enterprise disaster, for the first time a distinction was made between active human failures, that is, someone did not shut the bow doors properly, and latent human failures. These are the inadequate organisational policies or inappropriate decisions that moulded the environment that enabled the active failures to thrive. Even the best of us make mistakes and so it is important to ensure defences are in place to make these mistakes due to human fallibility less likely.

Interestingly, "An organisation with a memory" uses very similar language to that in the Sheen report and discusses its findings in terms of⁷:

- "Active failures" - these are defined as "unsafe acts" committed by those at the sharp end of a system, which are usually short lived and often unpredictable; and
- "Latent conditions" - which can develop over time and lie dormant before combining with other factors or active failures to breach systems' safety defences. "These are long lived and, unlike many active failures, can be identified and removed before they cause an adverse event".

Identifying risks and incident reporting

It has been estimated that for every major injury in the NHS there are 25 minor injuries and 300 near misses.

An adverse incident may be defined as any occurrence which is not consistent with the routine care of the patient or the routine operation of the institution⁵.

A near miss can be defined as an occurrence, which but for luck or skilful management would in all probability have become an incident⁵.

Clinical risk management, with these human factor concepts as its foundation, aims to achieve four principle objectives⁵:

1. Identification of organisational, system failures or defence inadequacies. This is so that managers can act to remedy the situation before an accident occurs. Pro-active analysis of incident data would help reduce risk, that is, analysing what is likely to go wrong. This may also help identify what the costs are of getting things right versus getting things wrong.
2. The prompt collection of all relevant records as soon as possible after an accident.
3. Provide early warning of possible claims. Incident reporting allows up-to-date information to be used to decide whether an organisation, be it a trust or even an optometric practice, should consider fighting or settling any clinical complaint. Where an incident has occurred, honesty with the patient is always the best strategy. However, liability should never be admitted without first seeking expert legal advice and support from their professional indemnity insurers. This is also about controlling the risk and finding ways of reducing the risk.
4. Early incident reporting and analysis enables lessons to be drawn. This is through an objective assessment of all the active and latent human failures surrounding a particular event.

Incident and near miss reporting should never be about discipline, covering things up or creating complex arguments to defeat claimants.

What to report

An adverse patient incident (Table 5) is any event or circumstance that could have or did lead to unintended or unexpected harm, loss or damage.

Adverse event or near miss is distinguished by whether or not the incident actually resulted in harm, loss or damage.

An incident/near miss is considered clinical if clinical action or the exercise of clinical judgement would have prevented or reduced the impact of an incident.

Currently a new independent body, the National Patient Safety Agency, is being

established. Its main purpose will be to improve patient safety and reduce risk of harm by setting up a national reporting system to collect and analyse information on adverse events within the NHS. Other safety related information would be assimilated in order to derive lessons learnt. Where possible, solutions to prevent harm will be published along with national goals and methods of monitoring progress. By the end of 2001, 60% of all trusts will have reporting systems in place to feed information into this new agency. This will include all NHS trusts by the end of 2002.

Planning for the implementation of clinical risk management

It is predicted that the full implementation of clinical risk management in the NHS is going to be very fast indeed. Undoubtedly, it has the potential to produce masses of extra paper work for all healthcare professionals. The challenge for the organisation will be to create a system in which the demand for paper work is proportional to its value in reducing risk.

Certain aspects of clinical risk management have, however, already been implemented.

Examples include:

1. Current use of incident report forms in many NHS organisations with a vertical reporting structure leading up to the chief executive who takes ultimate responsibility for risk management.
2. Adherence to several legislative standards, e.g. HSE "Reporting injuries, diseases and dangerous occurrences" (RIDDOR 1985) and "Control of substances hazardous to health" (COSHH 1990)³³.
3. Use of assessment scales in clinical practice, e.g. Snellen visual acuity, Glasgow coma scales or Norton and Waterloo scales for pressure sore vulnerability in nursing.
4. Quality assurance in healthcare and clinical audit programs.
5. Introduction of continuous professional development and staff appraisal.
6. Staff training and continuing education requirements.
7. Production and publication of various codes of ethics and clinical practice guidelines.

In the future, it is quite likely that the College of Optometrists will prepare advice and guidance on risk management specifically for optometrists. The AOP Hospital Optometrists Committee (HOC) is also looking at ways of how they may be able to assist the College in this work.

Other strategies that optometrists in

particular could use in order to address risk management issues in the future are summarised in **Table 6**.

The most challenging aspect to the implementation of successful, effective risk management is going to be the required change in culture within the NHS from "blame" to "openness". Understandably, staff are not initially going to believe their managers, that if they make a mistake, they are not going to be automatically punished or face disciplinary procedures.

Conclusions

Introducing a non-punitive approach where, for example, staff do not fear for their jobs, will take time to build up the required trust. Real change will only occur when all staff groups are perceived to be treated fairly and equally, whether they are doctors, nurses or other healthcare professionals. Currently, in disciplinary matters this is not always the case, particularly where different staff groups are involved in the same incident. For example, a junior doctor may get away with a castigation from their consultant, whilst the nurse or other healthcare professional may well face formal disciplinary charges.

Developing a pro-active safety culture through collaborative working is also important. This is where risk management is seen by staff to be worthwhile and not another instrument of control or yet more hurdles to cross. Successful risk management will also depend on good co-operation and communication between healthcare practitioners and management, who should also demonstrate commitment to the process.

Looking at ways to keep paper work to an absolute minimum and reduce disciplinary stigma will help encourage staff to report incidents and near-misses from which valuable lessons can be learnt and acted upon.

Finally, this article has concentrated on how risk management will be developed mainly in a secondary healthcare setting, where settlements for negligence claims comes out of the overall NHS budget. In primary care, however, negligence claims are settled by the various defence bodies, e.g. MDU, AOP. This is by means of professional indemnity insurance. Those of us working in community general optometric practice should therefore remember that where a mistake has been made or a complaint received, the optometrist should never, under any circumstances, admit liability without first seeking expert legal advice and support from their professional indemnity insurers. For many optometrists, this is the AOP legal team.

About the author

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References

1. Quote by Mike O'Leary, British Airways Executive, in Building a safer NHS for patients 2001; 1: A new focus on patient safety, pp 1-4.
2. Department of Health. A first class service. Quality in the new NHS. Health Services circular 1998/113.
3. The Stationery Office. The new NHS. Modern and dependable. 1998, London.
4. Roy R. Risk management. *Nursing Standard* 1996, 10;18: 51-56.
5. Lugon, M and Secker-Walker, J. Clinical governance – making it happen. *Royal Society of Medicine Press* 1999, pp 77-92.
6. The Stationery Office. The NHS Plan 2000.
7. The Stationery Office. An organisation with a memory, June 2000.
8. Cooper JB, Newbower RS, Kitz RJ. An analysis of major errors and equipment failures in anaesthetic management; considerations for prevention and detection. *Anaesthesiology* 1984; 60: 34-42.
9. Gaba DM. Human error in anaesthetic mishaps. *Int. Anaesthesiol. Clin* 1989; 27: 137-147.
10. Runciman WB, Sellen A, Webb RK, et al. Errors, incidents and accidents in anaesthetic practice. *Anaesth. Intensive Care* 1993; 21: 506-519.
11. Reason JT. Understanding adverse events: human factors. In: Vincent CA ed. Clinical risk management. London. *BMJ Publications* 1995.
12. Sheen Mr J, MV Herald of Free Enterprise. Report of Court No. 8074 formal investigation. London. *Department of Transport* 1987.
13. Craig S. Working collaboratively – risk assessment
14. University of Sunderland, MSc dissertation in Advanced Nursing Practice. February 2001.