An organisation with a memory

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ABSTRACT – Patient safety has been an under-recognised and under-researched concept until recently. It is now high on the healthcare quality agenda in many countries of the world including the UK. The recognition that human error is inevitable in a highly complex and technical field like medicine is a first step in promoting greater awareness of the importance of systems failure in the causation of accidents.

Plane crashes are not usually caused by pilot error *per se* but by an amalgam of technical, environmental, organisational, social and communication factors which predispose to human error or worsen its consequences. In healthcare, the systematic investigation of error in the administration of medication will often reveal similarly complex causation. Experience and research from other sectors, in particular the airline industry, show that the impact of human error can be reduced if the necessary work is put in to detect and then remove weaknesses and vulnerabilties in the system.

The NHS is putting in place a comprehensive programme to learn more effectively from adverse events and near misses. This aims to reduce the burden of the estimated 850,000 adverse events which occur in hospitals each year as well as targeting high risk areas such as medication error.

KEY WORDS: adverse events, healthcare, medical error, patient safety, quality

The context for the provision of healthcare in developed countries is changing. Policies which seek to ensure the quality and safety of services for patients need to take account of factors such as:

- the shift to a more primary care centred model of care
- the growth and complexity of clinical workload
- the ageing of the population
- the balance between centralisation of specialised services and public expectations for more convenient and local access to services.

Clinical governance[1,2] was introduced as a way of ensuring that the statutory duty of quality[3] placed on all providers of NHS services was implemented at local level. Clinical governance is the way in which local services can assure, and seek ways to improve, the quality of their services, putting in place the systems, networks and staff competencies necessary to do this. It is an organisation-wide programme which aims to build effective teams, bring about cultural change and create a truly patient-centred approach to care.

Patient safety is an important strand of this programme of clinical governance. Safety is a vital consideration in any service industry in which there are potential risks as well as benefits to those receiving the services. However, compared with other industries (eg airlines), healthcare has given less attention to safety. This deficit is starting to be rectified as reports in the UK[4] and the USA[5] have identified patient safety as a core element of healthcare.

This article sets out the main concepts and issues in this field and describes the work that needs to be done to make improved patient safety a realisable goal.

Failures in standards of care

The NHS was dogged by a series of high profile failures in standards of care during the 1990s, varying from the widely publicised problems in the children's heart surgery service in Bristol[6] to concerns about the conduct and competence of individual doctors[7]. These so-called 'medical scandals' undoubtedly served as a turning point in public and professional attitudes towards poor standards of care in a publicly funded health service.

Tolerance of poor standards on the grounds that it is difficult to recognise such problems and that there are inadequate procedures to deal with them was no longer an acceptable justification. Sustained national media coverage of such local service failures added urgency to the task of introducing comprehensive clinical governance arrangements in every NHS organisation. Cultural transformation is a core element of the change required under clinical governance. The existence of a non-patient-centred 'club culture' was highlighted as a predisposing feature of the dysfunctional and poor quality services described in the public enquiry into the events in the Bristol children's heart surgery service[8].

High profile service failure was also the driving force behind new NHS policies to deal more effectively with poor practitioner performance[9] and the

introduction of a five-yearly 'revalidation' of a doctor's licence to practise[10].

The challenge in quality improvement is to shift the quality curve to the right (Fig 1) so that patients will receive a higher quality of care in more local NHS hospitals and primary care services. This will be most effectively achieved by 'shifting the mean' – ensuring that good mechanisms for quality assurance and quality improvement are in place everywhere. It is also important to make safety a wider issue. An important part of this is to learn more effectively from things that go wrong.

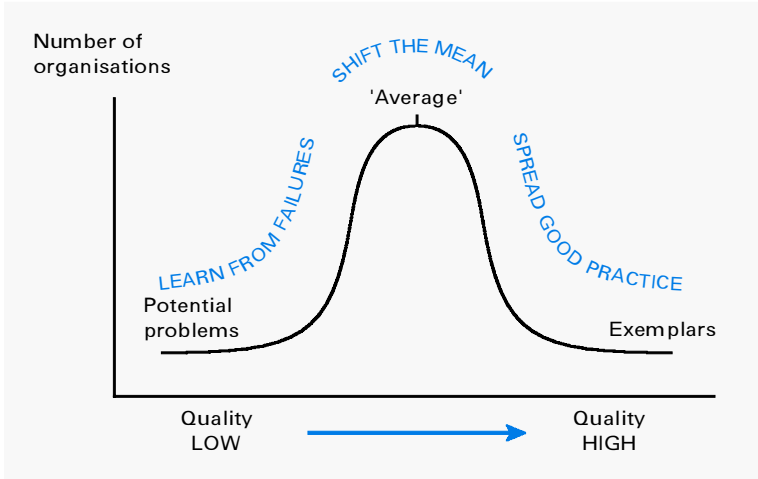

Fig 1. Variation in the quality of health organisations[1].

Thinking about safety

In January 2001, a teenager undergoing maintenance therapy for leukaemia received an intrathecal injection of vincristine sulphate[11]. Meant for intravenous injection, it was given intrathecally in addition to another drug correctly intended for administration by the intrathecal route (Fig 2). As a result, the teenager died and the attendant media headlines ('Cancer boy dies after blunder over injection', 'Drug blunder teenager dies') made familiar and depressing reading. Some 13 similar cases have been reported in the medical literature since 1985[12].

This event was important for several reasons. It was a very rare occurrence, yet catastrophic in its impact on the patient, his family and the clinical staff involved, and an example of how human error occurring in a weak system is the common explanation for most 'accidents' or 'adverse events' in healthcare and other sectors. The investigation into this intrathecal injection 'error' was undertaken by a non-health investigator with experience in establishing the cause of railway and other disasters. He identified some 40 systems failures[13]. What killed the teenager was not human error *per se* but human error in a weak system:

- a weak safety culture
- weak operational practices
- weaknesses in the presence of protocols and training
- weaknesses in communication
- serious weaknesses in the packaging and design of drugs and equipment.

In short, there were comprehensive systems weaknesses.

Action is in hand to try to eliminate these risks entirely through standardisation on safe practice[14,15]. The example of the intrathecal injection error remains a good test for a new approach to risk and safety in the NHS. If it is possible to eliminate a rare catastrophic event entirely, it should also be possible to reduce the occurrence of more common adverse events.

Catastrophic events in healthcare where people are killed or seriously injured also happen in aviation, on the railways, in the nuclear and chemical industries, in factories and workplaces. Research and best practice experience outside healthcare have shown that big improvements in safety are not made by telling people to take care but by understanding the conditions that provoke error[16,17].

Extensive study in the non-health field has shown that there is usually no simple cause for most unintended failures but a complex interaction between a varied set of elements, including human behaviour, technological factors, socio-cultural factors and a range of organisational and management weaknesses. This was the 'cause' of the intrathecal injection death and of major accidents such as the Kegworth air crash (Box 1).

This view of accident causation compares the risks of something going wrong with the holes in slices of a Swiss cheese (Fig 3). The solid parts of the slices are the system's defences, the holes are the vulnerabilities. Unlike the holes in a real Swiss cheese, those in the imaginary cheese – the organisation's system – are constantly opening, closing and shifting position. Danger arises when a set of holes lines up. Some of the holes (the risks) are caused by unsafe actions committed by individuals: slips, lapses, mistakes or violations of procedures. However, many more are due to so-called 'latent' conditions, factors in the system which create preconditions for failure: lack of training,

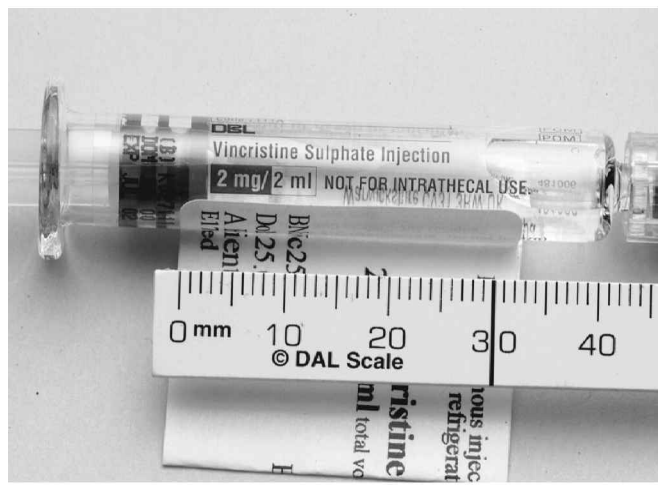

Fig 2. Pre-filled syringe containing vincristine sulphate illustrating the warning that it is not for intrathecal use.

Key Points

- **Patient safety is an important strand of clinical governance which was introduced as a way of ensuring the statutory duty of quality placed on the NHS**
- **Medical error is a large and previously mostly unrecognised cause of avoidable mortality and morbidity**
- **The NHS is putting in place a comprehensive programme to learn from adverse events and near misses**
- **The cornerstone of the new programme of patient safety will be a system of reporting, recording, analysing and learning from errors**

poor equipment, absence of procedures. They may not be recognised, but when human error occurs in combination with these latent conditions a serious incident can occur.

The importance of the Swiss cheese analogy is that it helps to increase awareness of the conditions which predispose to error (or worsen the likelihood that an error will be serious). It encourages systems thinking and a preventive approach based on risk management.

Box 1. The Kegworth air crash

In 1989, 47 people died when a British Midland Boeing 737–400 aircraft crashed on to the M1 motorway in Leicestershire. The immediate act precipitating the crash was the shutdown by the crew of the wrong engine following an engine fire. The pilots were criticised for acting too quickly and for failing to assimilate information from their instruments.
The official accident report made a number of recommendations concerning changes to the aircraft as well as pointing to the faults of the pilots and cabin staff. The media, though, used the shorthand of 'human error' to describe the event.

In fact, this accident illustrates how systems failure can occur at a number of levels:

- technical component failure, in this case resulting from the fracture of the engine fan blades
- poor cockpit and instrumentation design: in this case, the specific nature of the failure was not identified by the aircraft's warning system which failed to provide the pilots with unambiguous information concerning the nature of the incident
- poor fault-finding protocols
- inadequate pilot training
- communications failures

Size and nature of the problem of medical error

The epidemiology of medical error and patient safety more generally is still an under-researched field[18]. Such data as exist suggest that medical error is a large and previously mostly unrecognised cause of avoidable mortality and morbidity.

Studies in the USA, Australia and the UK have suggested a level of adverse events amongst hospital inpatient admissions of 3.7–16.6%. The percentage of hospital inpatient episodes leading to unintended harm is 3.7% in the USA[19], 16.6% in Australia[20] and 10% in the UK[21] (broadly equivalent to 850,000 hospital admissions per year in the UK), with about half being preventable in the latter two countries. Worldwide, it is estimated that around a quarter of all adverse events are due to medication error alone[22]. Existing information systems in the NHS are fragmented and give an incomplete picture of the size of the problem. Individual sources of risk continue to provide powerful illustrations of the scale of the challenge in improving patient safety.

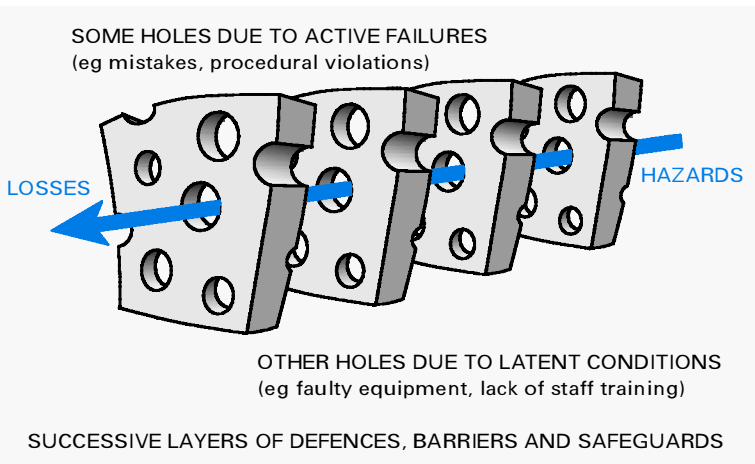

Fig 3. The Swiss cheese model of accident causation (adapted from the work of James Reason[17]).

Infusion pumps

One example is the use of infusion pumps to administer therapy which has grown enormously in the last 25 years. The number of reported adverse incidents associated with these devices is of concern since many result in patient harm or death, primarily from irreversible overdose. In the USA, at least 418 patients have died and 1,356 others injured since 1995 in adverse incidents involving infusion pumps. In a similar period in the UK there were 1,266 and 1,405 reports involving infusion pumps and administration sets, respectively, with 39 deaths and 145 injuries involving infusion pumps. Action by the Medical Devices Agency appears to have improved safety. The number of pump fatalities fell from 11 in 1995 to four in 2000 (Fig 4). These four deaths have not been remarked on, whilst deaths in other fields such as rail safety provoke a major public debate.

Steps taken to reduce risk include:

- giving users information and advice through publications and study days
- evaluating and publishing findings on new devices
- where appropriate, taking up necessary issues with manufacturers so that the potential for adverse incidents to occur with devices was reduced.

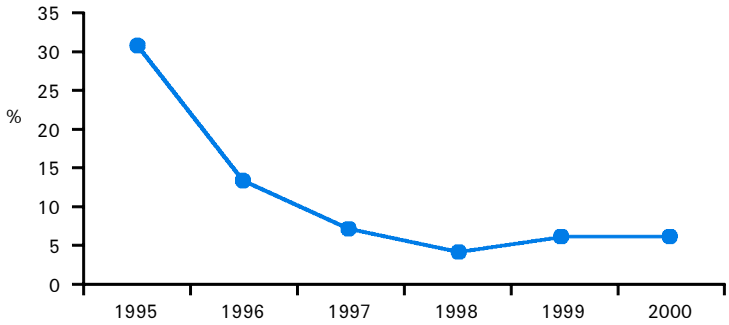

Fig 4. Percentage of infusion pump fatalities compared with all reported fatalities associated with medical devices (UK).

Packaging and labelling

Other therapeutic agents administered intravenously pose a risk because of similarities in packaging and labelling. Various agents that might be used in an anaesthesia setting (eg 10 ml vials) all look similar; injection of the wrong one in the wrong circumstances can cause harm (Fig 5). Colours on labels are at the whim of manufacturers.

A working group of the Committee on Safety of Medicines has reviewed all published evidence related to medication errors in which aspects of the labelling and packaging of medicines were implicated as a causative factor. A series of principles was agreed for the development of best practice guidelines for industry[23].

Blood transfusion

Blood transfusion errors remain a rare, but important, potentially avoidable source of patients' lost lives. This source of error has been the subject of a special reporting scheme: the Serious Hazards of Transfusion (SHOT). For the fourth consecutive year the single most important cause leading to mistakes in transfusion was failure of some aspect of the bedside check procedure immediately before administering the transfusion. Contributory factors were also similar to those in previous reports, for example:

- confusion over patients with the same or similar names
- checking carried out remote from the patient's bedside
- interruption between completion of the checking procedure and administration of the transfusion
- failure to note discrepancies between compatibility and donation labels where a preceding laboratory labelling error had occurred.

Missing wristbands or other formal means of patient identification contributed to bedside errors in 10 instances. Multiple errors contributed to bedside administration errors in 94 cases,

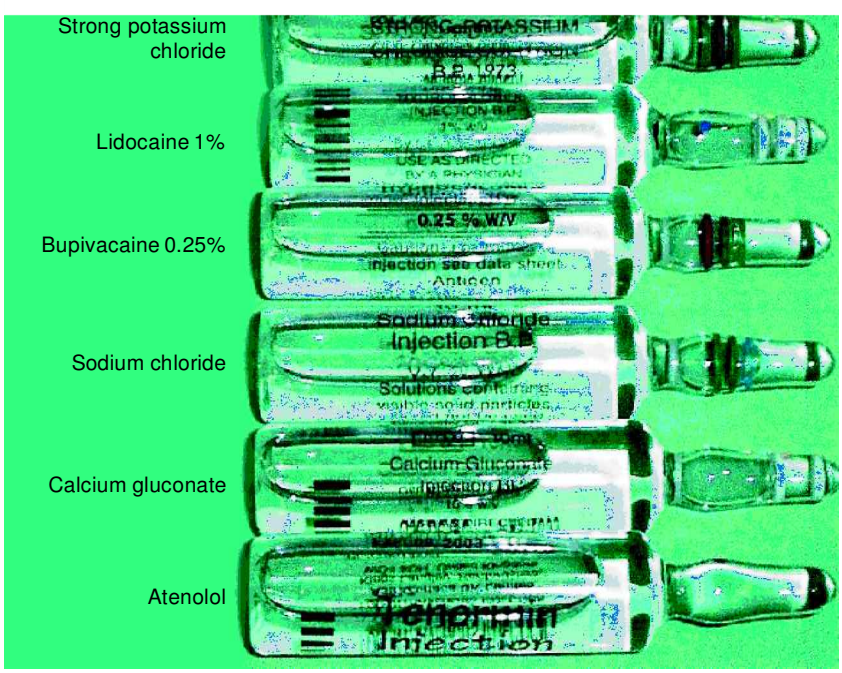

Fig 5. Injectable materials which are not always easily distinguishable.

Table 1. Expectations of a service that is working well.

- Serious failures of standards of care are uncommon
- Serious failures of a similar kind do not recur on a future occasion
- Incidents where services have failed in one part of the country are not repeated elsewhere
- Systems are in place which reduce to a minimum the likelihood of the occurrence of serious failures in standards of care
- Attention is also paid to monitoring and reducing levels of less serious incidents and near misses
- The culture in health organisations encourages openness in reporting, and values learning from error rather than retribution

indicating that problems still exist at all levels in the transfusion chain[24].

Learning to learn

A major strategy document on patient safety in the NHS, *An organisation with a memory*[4], was published in 1999. It painted a stark picture of an NHS that had no systematic way of identifying error, learning from its causation and reducing risk for future patients. Existing systems of adverse events recording are incomplete and fragmented. This publication set out a plan to transform this situation into a service that is working well (Table 1) by:

- gaining the commitment of all NHS staff and the boards of NHS organisations
- creating a culture in which staff feel they can report errors, mistakes and adverse events without fear of retribution
- establishing a clear national and local mechanism for identifying adverse events and near misses, reporting them, and analysing trends and patterns
- learning lessons to reduce risk and prevent future harm to patients
- setting targets in certain key high risk areas
- calling for a systematic programme of research.

The implementation of a comprehensive programme of patient safety within the NHS has involved the establishment of a National Patient Safety Agency whose main responsibilities are to:

- collect and analyse information on adverse events from local NHS organisations, NHS staff, patients and carers
- assimilate other safety-related information from a variety of existing reporting systems and other sources in this country and abroad
- learn lessons, and ensure they are fed back into practice, service organisation and delivery
- produce solutions to prevent harm where risks are identified, specifying national goals and establishing mechanisms to track progress.

The cornerstone of the new programme of patient safety will be a system of reporting, recording, analysing and learning from errors. The pilot phase of the new adverse event and near miss reporting system covered 28 sites across the NHS and was completed at the end of March 2002. It is intended to introduce it more widely after formal evaluation.

Table 2. How are we doing on patient safety? Examples of some questions a health organisation could ask itself.

- Are patient safety and quality key objectives for the organisation and considered by the Board?
- Can you indisputably demonstrate that your service is becoming safer for patients year in year out?
- Can the management and clinical teams show you examples of where, through analysing something that has gone wrong, care of future patients will be much safer?
- What is your organisation doing to reduce the risk of medication error (which accounts for a quarter of all harm to patients)?
- Pick the worst three errors you have heard of and ask managers and professional staff if they could happen in your organisation
- If something serious happened, would the culture of your organisation be to cover it up or learn from it?
- Are patients actively involved in activities to improve safety and reduce risk?

Integrating patient safety within an NHS committed to developing clinical governance in every local hospital and primary care service goes beyond establishing a reporting system for medical error (though this is important). It involves changing the culture so that there is an ethos of reporting, anticipating and combating risks, of learning from things that go wrong, and of moving away from an approach based on blame and retribution (Table 2).

Safety consciousness at both an individual level and an organisational level represents a profound change for the NHS but one which offers exciting opportunities to benefit patients in the future.

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