ARE PATIENTS SAFE WITH THE NHS?

MEETING OF THE PARLIAMENTARY AND SCIENTIFIC COMMITTEE ON MONDAY 20TH NOVEMBER

In a recent report into safety aspects of the National Health Service the House of Commons Public Accounts Committee commented, "Every day over one million people are treated successfully by the NHS. Although patient care is generally of a high standard, the scale and complexity of patient interventions means that patients can sometimes suffer unintended harm and official estimates show that one in ten patients admitted to NHS hospitals is unintentionally harmed. There were 940,000 reports of incidents and near misses last year, which include blunders ranging from medication errors and drug interactions to missing emergency equipment and the wrong limbs being amputated. Even more patients are at risk since this does not include 300,000 reports of hospital-acquired infections each year including MRSA. Around 50 per cent of all actual incidents might have been avoided if NHS staff had learned lessons from previous ones. There are big differences between similarly-sized trusts in the number of incidents reported. Massive under-reporting of deaths and serious incidents means the NHS has no idea how many people are dying each year from patient safety incidents."

Nevertheless these startling statistics are not significantly different from those reported in several other developed countries. So how can the further application of science, technology and engineering help to improve a situation arising predominantly as the result of human failure?

Are Patients Safe with the NHS?

Bill Murray OBE
Acting Chief Executive, National Patient Safety Agency

A healthcare system involves often very complex technology, consultations with different individuals at different locations and the end result may mean a variety of medication to be taken at specific times or intervals. These multiple interactions have to combine seamlessly to result in an improvement of the patient's condition. Given this complexity, preventing error and harm within these systems is an increasingly important challenge for many modern health services across the world.

Patient safety is an international concern and broadly similar levels of patient safety incidents have been found across healthcare systems in developed countries. The most detailed information on the frequency of incidents in the developed world comes from a number of studies which used a review of patients' notes to identify events that caused harm.[1-10] It should be noted however that these studies have used broad definitions of adverse events.[11]

In recognition of the scale of adverse events or error within healthcare systems, the World Health Organisation has launched the World Health Alliance for Patient Safety, led by our Chief Medical Officer Professor Sir Liam Donaldson, to tackle and prevent unintended harm to patients.

As part of the drive to improve the quality of care in the NHS, the National Patient Safety Agency (NPSA) was established in July 2001 to help the NHS learn from its mistakes so that it can improve patient safety. The blueprint for the NPSA was described in the Government report *Building a safer NHS for patients – Implementing an organisation with a memory*.[12] The report highlighted that the Agency's first step towards improving the safety of patients and understanding medical error was to help the NHS learn from what goes wrong. The NPSA was charged with creating a central repository for information about patient safety incidents and finding a way to interrogate the data to identify trends and hotspots. This intelligence would inform a programme of work.

The NPSA developed the National Reporting and Learning System or NRLS, the first national reporting system for patient safety incidents in the world. The system covers England and Wales and integrates into existing NHS local reporting systems. This has minimised disruption to NHS staff; they only report to their local system with the data uploaded to the NPSA regularly. The NRLS collects information spanning the breadth of the NHS; Figure 1.0 breaks down the source of incident reports as at September 2006.

Those NHS organisations that do not have a local risk management system can report directly to the NPSA through an electronic reporting form (eForm) on the internet.

Number of incidents to end of September 2006		
Acute/general hospital	72%	701,874
Ambulance service	0%	3,579
Community and general dental service	0%	283
Community nursing, medical and therapy service (incl community hospital)	10%	96,442
Community optometry/optical service	0%	12
Community pharmacy	0%	2,809
General practice	0%	4,105
Learning disabilities service	3%	29,801
Mental health service	14%	135,751

Figure 1.0 Breakdown of care settings reporting to NRLS (November 2003 to September 2006)

The primary purpose of an incident reporting system is to help make healthcare safer for patients. Incident reporting typically involves staff actively recording information on events that lead to unintended harm or potential harm to patients. Most incidents involve a complex interplay of individual, team, technical and organisational factors. Although each incident is unique, there are likely to be similarities and patterns which may otherwise go unnoticed if incidents are not reported and analysed.

Systems to collect data on errors in other industries, such as the aviation and petrochemicals industry, have found that a commitment to confidentiality increases reporting levels. The NPSA chose to take this approach and does not request information about the names of staff or patients involved in reported incidents.

How is this information used to improve patient safety?

Incidents reported by staff to the NRLS provide a national picture of patient safety in England and Wales. They help the NPSA identify new patient safety concerns and recognise those that are causing the greatest harm to patients. All NHS trusts have reported incidents to the NRLS and reporting to the system is increasing.

The NRLS currently contains over one million incident reports – it is important to note that high incident reporting rates do not equate to unsafe care: organisations with a strong reporting culture and effective local mechanisms for investigating incidents would be expected to report more. The majority of reports in the NRLS relate to patients suffering no harm – a breakdown is given in Figure 2.0.

No harm	665,673	68.2%
Low	244,420	25.1%
Moderate	52,821	5.4%
Severe	9,091	0.9%
Death	3,837	0.4%

Figure 2.0 Breakdown by degree of harm of NRLS reports (November 2003 to September 2006)

Themes and trends are analysed and solutions to broad and general themes developed. The NPSA has issued 16 safety solutions in the form of alerts as well as a range of advisory reports to promote safer care for patients, for example, the award winning cleanyourhands campaign to improve hand hygiene amongst healthcare staff. We recommended placing alcohol based handrubs close to every patient for speedy and effective cleansing and encouraged patients to ask staff if they had cleaned their hands. This campaign is one of the central planks of the government's strategy against healthcare associated infection. We have trained over 8,000 NHS staff in the incident investigation technique of "root cause analysis" to ensure maximum understanding – and learning – from things that go wrong. This training has in turn been cascaded down to more than 47,000 front line staff.

In summary

The NPSA was established to help the NHS learn from its mistakes.

Through the National Reporting and Learning System the NPSA receives reports about patient safety incidents from NHS organisations throughout England and Wales. The majority of these reports come directly from local information systems.

Local NHS organisations continue to have primary responsibility for investigating and acting on local patient safety incidents.

Clinical teams review all reported deaths.

Computerised data analysis tools help identify potential clusters, patterns and trends across these reports.

The reports help the NPSA learn from incidents and develop interventions to reduce risk for patients.

The NPSA regularly publishes a quarterly breakdown of NRLS data on its website.

The NRLS feeds back analysis and benchmarking to the NHS to allow organisations to better understand their safety profile.

REFERENCES

1 Brennan TA et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med* 1991;324:370–6.

2 Leape LL et al. The nature of adverse events in hospitalised patients. Results of the Harvard Medical Practice Study II. *N Engl J Med* 1991;324:377–84.

3 Wilson RM et al. The Quality in Australian Health Care Study. Med J Aust 1995;163(9):458–71.

4 Wilson RM et al. An analysis of the causes of adverse events from the Quality in Australian Health Care Study. *Med J Aust* 1999;170:411-5.

5 Thomas EJ et al. Incidence and type of adverse events and negligent care in Utah and Colorado. *Med Care* 200;38:261–71.

6 Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. BMJ 2001;3;322(7285):517–9.

7 Davis P et al. Adverse events in New Zealand public hospitals I: occurrence and impact. *N Z Med J* 2002;13;115(1167).

8 Davis P et al. Adverse events in New Zealand public hospitals II: preventability and clinical context. *N Z Med J* 2003;116:U624.

9 Baker GR, Norton PG, Flintoft V. Canadian adverse events study. CMAJ 2004;171:834.

10 Schioler T et al. Danish Adverse Event Study. Incidence of adverse events in hospitals. A retrospective study of medical records. *Ugeskr Laeger* 2001;163:5370–8.

11 Figure available at http://www.scienceinparliament.org.uk/sip.asp

12 Department of Health. Building a safer NHS for patients. Copies can be obtained from the Department of Health, PO Box 777; doh@prolog.uk.com Also available at: http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPAmpGBrowsableDocument/fs/en?CONTENT_ID=4097460&chk=gngr/O

Are Patients Safe with the NHS?

Professor Tom Treasure MD MS FRCS
General Thoracic Surgeon, Guy's Hospital

I open by rising to the bait. The title I have been given carries within it the implication that it is the NHS specifically, rather than the delivery of health care services in general, which is associated in some way with lack of safety. Hospitals are high risk places in any country and in any system. Sick and dying people are gathered in and doctors with strong medicines and sharp instruments do things to them. The challenges are to keep the risk of interventions to the minimum, to maintain high standards of expertise so that we deliver the most good to the most people, and to avoid additional illness such as MRSA infection caught in hospital. The range of quality of care in the United States is much wider: at one end no effort or expense is spared to the point of inappropriate over treatment while at the other end, there are many who go without[1]. In Britain, most health care is delivered within a national service and part of the equity of care in which we believe is that we should be able to maintain uniformly good standards. As a short answer, it might be said that patients are safer with the NHS than they would be without it.

In this presentation I illustrate some of what has been achieved in cardiothoracic surgery by collection of data about surgical outcomes. I will touch upon the use and abuse of data – apart from anything else that might be said of routine data collection, it is inefficient as a means of picking up comparatively poor practice. I will then look at another way of capturing the knowledge and experience of the whole of the medical profession to identify recurring features of care which could be improved. This is the work of the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) which I chair.

Cardiac surgery from its inception lent itself to counting. Because of the need for the very expensive heart lung bypass machinery and the expertise to run it, cardiac surgery was centralised on relatively few sites. Each operation was a major event and death was both common enough and unequivocal evidence of failure to achieve the objective. It was the surgeons (through the Society of Cardiothoracic Surgeons of Great Britain and Ireland or SCTS) who collected the data and circulated the anonymised results so that we could reflect on our practice in comparison with pooled national data[2]. That has continued and has become increasingly sophisticated but the secrecy has had to go. Both hospitals and surgeons have now to be identified[3,4].

In order for the outcomes to be used for fair comparisons risk adjustment was essential and if we were to pick up slipping practice, the data would have to be regularly scrutinised. We devised and put into widespread use means of displaying risk adjusted outcomes case by case[5]. But what rules should we set to trigger an investigation? The problem is inherent in proper use of statistics. To explain I will use an analogy. A domestic burglar alarm can be set up so that every passing car, gust of wind or stray cat will trigger an awful noise and wake up all the neighbours. Alternatively, it might be set so it will only trigger when an intruder has actually gained access to the safe. In cardiac surgery very sensitive setting to trigger an alert at the first hint of possible trouble results in many teams being subjected to scrutiny at a level which disrupts the service. The consequence is that to avoid this unhappiness and disruption, surgeons may well practise defensively, denying surgery to the "riskiest" patients, the very patients for whom surgery would make the biggest difference, that is to say between life and death. On the other hand, to wait until the conventional statistical tests prove beyond reasonable doubt that there is poor practice requires many deaths maybe over a period of years.

So far I have referred to cardiac surgery and to the counting of deaths but when death is a rare outcome (for example after cleft lip and palate surgery) other measures

much more difficult to capture and quantify must be used. In palliative care of terminal cancer, death is the expected outcome; it is comfort and dignity while dying that is the index of the quality of care. A process based on counting deaths cannot discriminate quality of practice in any but a few clinical circumstances.

While of limited value in measuring quality, these data do have some value in studying process. We have used the Society of Cardiothoracic Surgeons' data to explore practice in non-cardiac thoracic surgery. For the very common condition of pneumothorax (a collapsed lung) we were able to show a concerning variation in implementation of the new "keyhole" technology to replace major surgery[6]. A review of practice subsequently shows an increase in the proportion from 57% in 2000-2002 to 73% in 2003-2005. We have also explored the interaction of process and outcome to see if the number of lung cancer operations a surgeon performs affects the perioperative death rate[7]. The data themselves do not flag up any concern. It is their analysis, interpretation and dissemination for comments that help to promote safer care.

I will turn now to a fundamentally different approach. The National Confidential Enquiry into Patient Outcome and Death does not collect data routinely. We receive from any individuals or groups suggestions about aspects of care that might merit investigation. These are openly discussed by a steering group of about forty people, representing all aspects of health care but largely nominated by Royal Colleges and other organisations. The topics for study emerge from an awareness that some aspect of care is not going well and should be done better. A study is then carefully planned to investigate this area of practice. I will give three examples.

The confidential enquiry first made its mark when it reported on the deaths associated with night time surgery. At the time it was the norm for patients requiring urgent surgery to join an inpatient queue waiting to be operated upon. It was not uncommon for this list to start well into the evening when all the day's work was finished and the night nursing staff came on. However the doctors did not change shifts. It was usual for the trainee surgeons who had been working all day and would work again tomorrow to be doing these operations in the small hours of the morning, with the help of equally junior and exhausted anaesthetists. That this was wrong did not require sophisticated statistical analysis and certainly could not have been subjected to a randomised trial. The documentation that it was happening and was commonplace was enough to lead to the "NCEPOD theatre" to be staffed by consultants operating in normal waking hours.

In 2004 we reported on the practice of inserting feeding tubes through the abdominal wall into the stomach (percutaneous endoscopic gastrostomy or PEG). Of 719 instances the expert panel regarded nearly a fifth as futile and 43% were dead within a week from their underlying condition. Again description of the practice and reflection upon it was enough to make the point that this was not appropriate care.

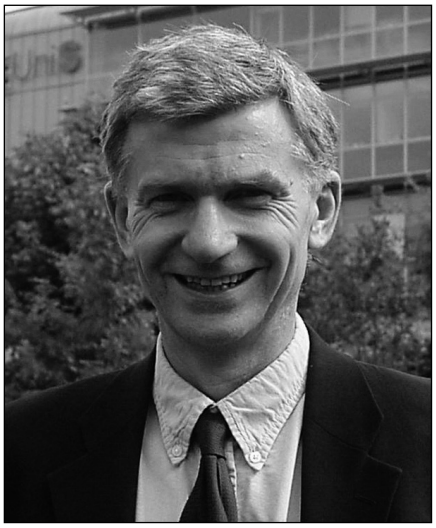
In 2005 we published an investigation of repair of abdominal aortic aneurysm, the commonest major vascular operation. It may be done as a planned operation or as an emergency. We found that a fifth of these operations are done in hospitals doing fewer than 30 a year and by surgeons doing fewer than fifteen a year. This is surgery for which surgeon and hospital numbers affect the likelihood of surviving.[8;9]

Much as I love dealing with data, and I am committed to randomised trials when appropriate, there are times for other methods[10]. Routinely collected and complete databases are a rich source for analysis but they are set up at a particular point in time with a finite number of fields and count the countable. NCEPOD on the other hand captures the amalgamated sense that things are not well in an area of practice and sets out to investigate the specific problem and to report on it, whilst also disseminating instances of excellent practice. Patients and doctors are protected by careful attention to confidentiality. We do not seek whistle blowers or scapegoats. NCEPOD captures much of what is hard to count and may be impossible to measure.

References:

1. Lamm RD. The Brave New World of Health Care. Golden, Colorado: Fulcrum Publishing, 2003.
2. English TA, Bailey AR, Dark JF, Williams WG. The UK cardiac surgical register, 1977-82. Br.Med.J.(Clin.Res.Ed) 1984;289:1205-8.
3. Keogh B, Spiegelhalter D, Bailey A, Roxburgh J, Magee P, Hilton C. The legacy of Bristol: public disclosure of individual surgeons' results. BMJ 2004;329:450-4.
4. Treasure T, Gallivan S. Publishing Individual Mortality Rates. In Lugon M, Secker-Walker J, eds. Clinical Governance in a Changing NHS, pp 157-74. London: RSM Press, 2006.
5. Lovegrove J, Valencia O, Treasure T, Sherlaw-Johnson C, Gallivan S. Monitoring the results of cardiac surgery by variable life-adjusted display. Lancet 1997;350:1128-30.
6. Sedrakyan A, Van Der Meulen J, Lewsey J, Treasure T. Variation in use of video assisted thoracic surgery in the United Kingdom. BMJ 2004;329:1011-2.
7. Treasure T, Utley M, Bailey A. Assessment of whether in-hospital mortality for lobectomy is a useful standard for the quality of lung cancer surgery: retrospective study. BMJ 2003;327:73.
8. Birkmeyer JD, Siewers AE, Finlayson EV, Stukel TA, Lucas FL, Batista I et al. Hospital volume and surgical mortality in the United States. N.Engl J Med 2002;346:1128-37.
9. Birkmeyer JD, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. Surgeon volume and operative mortality in the United States. N.Engl.J.Med. 2003;349:2117-27.
10. Treasure T. The evidence on which to base practice: different tools for different times. European Journal of Cardio-thoracic Surgery 2006;30:in press.

Patient Safety, Systems Design and Ergonomics



Professor Peter Buckle
Robens Centre for Health Ergonomics, University of Surrey

Introduction

The health service is a highly pressured complex system where the potential for error and accidents is ever present (Clarkson et al 2004). The scope for error in all parts of the system is high, although research studies have tended to focus on only limited components of this complex system.

Design is a structured process for identifying problems and developing, testing and evaluating user focused solutions. Application of the design process to healthcare could generate products, services, processes and environments that are intuitive, simpler, safer to work within, easier to understand and more efficient to use. By contrast, design that does not follow such a structured approach is likely to be confusing, less effective and potentially dangerous to medical staff or patients.

The importance of effective design thinking in healthcare is now starting to gain recognition (Bristol Royal Infirmary Inquiry, 2001; Department of Health, 2001). Three years ago we undertook a study for the Department of Health and the Design Council. It sought to deliver ideas and practical recommendations for a design approach to reduce the risk of medical error and improve patient safety across the NHS. The full investigation included the development of baseline information, including examples of international best practice on the efficacy of a design-led approach to patient safety. This paper seeks to demonstrate the importance of this approach and the need for further investigation and funding.

Systems Engineering, Ergonomics and Error

Ergonomists and systems engineers have long since recognised that enhancing performance requires an emphasis on design (or re-design) at a systems level. In typical work systems this includes a consideration of people, equipment, jobs, tasks and the socio-technical context of the work. Those involved with such design have traditionally examined the system goals, the allocation of functions and tasks (eg to teams, individuals, equipment, IT), the equipment design, the interactions between sets of equipment and groups of people, the work organisation and the job design.

A recent model (fig 1) (Moray, 2000) enables the various levels of the system to be conceptualised for the purpose of understanding, interpreting, evaluating, information collection, and design purposes. The relevant information needed to reduce error in the design of equipment to be used by humans is readily available. Each level of the system can be considered with respect to medical error.

Physical devices: At the centre of the system is the physical device or tool being used. There are many illustrations and examples of errors and difficulties associated with the use of equipment (see Obradovich and Woods, 1996.)

Factors affecting the individual: Omissions (ie the failure to carry out some of the actions required to achieve a desired goal (Reason, 1990)) are a common source of error. The role of such errors is evident when considering the giving of drugs to the wrong patient. Understanding why omissions occur (eg what aspects of drug administration require high levels of attention) may lead to improved design of products and work organisation that reduce the probability of such errors occurring. Blaming the individual who made the error is rarely a successful way of dealing with the cause and may make it more likely to happen again.

Physical environment: The physical layout of, for example, an operating theatre may increase the likelihood of errors. Noise levels in working environments may cause messages to be misunderstood and can lead to interruptions.

Team and group behaviour: In healthcare, most people work within a team and so a consideration of factors such as communication, supervision and responsibility is required. Absence of, or poor, communication between and within teams is likely to contribute to errors. For example, in a hospital setting the most junior medical officer is usually called upon to take a patient's medication history on admission. These doctors are often called upon to prescribe drugs and do so without asking questions under the assumption that this is the correct procedure. In some instances supervision is seen as inadequate and other issues, for example, overlapping responsibilities between teams also contribute to errors (Dean et al, 2002).

Traditionally, information flows vertically through a hierarchy and orders are sent from the top down with the expectation that lower

levels will implement them (West, 2000). Adverse events can occur because individuals of lower status experience difficulties challenging decisions of a person of higher status.

Organisational and management behaviour: Although factors affecting individuals have been highlighted there is limited value in focusing on individual activity, as this tends to perpetuate a blame culture. The focus needs to widen to include systems issues underlying the problems that are present in any complex work environment. System failures are sometimes difficult for "front line" staff to recognise because the decisions underpinning these systems may have been made in the past by those at a higher level of the organisation (Leape et al, 1995). System changes to reduce errors suggested include adjusted work schedules simplifying work systems and enlisting the help of frontline personnel.

Legal and social pressures: The behavioural options available to those working in a system may be tightly constrained by regulatory rules. For example, only certain drugs may be administered or procedures undertaken. As systems become more complex, the task of regulating becomes ever more difficult. For example, how do regulators cope with the issues that arise when multiple pieces of equipment are used conjointly (eg in intensive care units) or when "intelligent" software is embedded within drug delivery systems, thereby blurring the boundaries between equipment design and clinical decision-making?

Relationship between elements within complex systems: There is an added level of complexity that occurs when elements are linked. Our research (Buckle et al, 2006) has demonstrated that stakeholder groups rarely have any clear idea of what happens "further down the chain". Thus drug wholesalers have little idea of the problems, and potential medication errors, they cause for high street pharmacists with the way medication is packed and delivered. Worse, drug manufacturers rarely consider the difficulties they generate for patients who attempt to adhere to their medication despite often being unable to distinguish between the medications because of confusing packaging, tiny font size and hard to access tablets. Those prescribing are often unaware of the enormous complexity of having to manage 10 or more medications in complex treatment regimes.

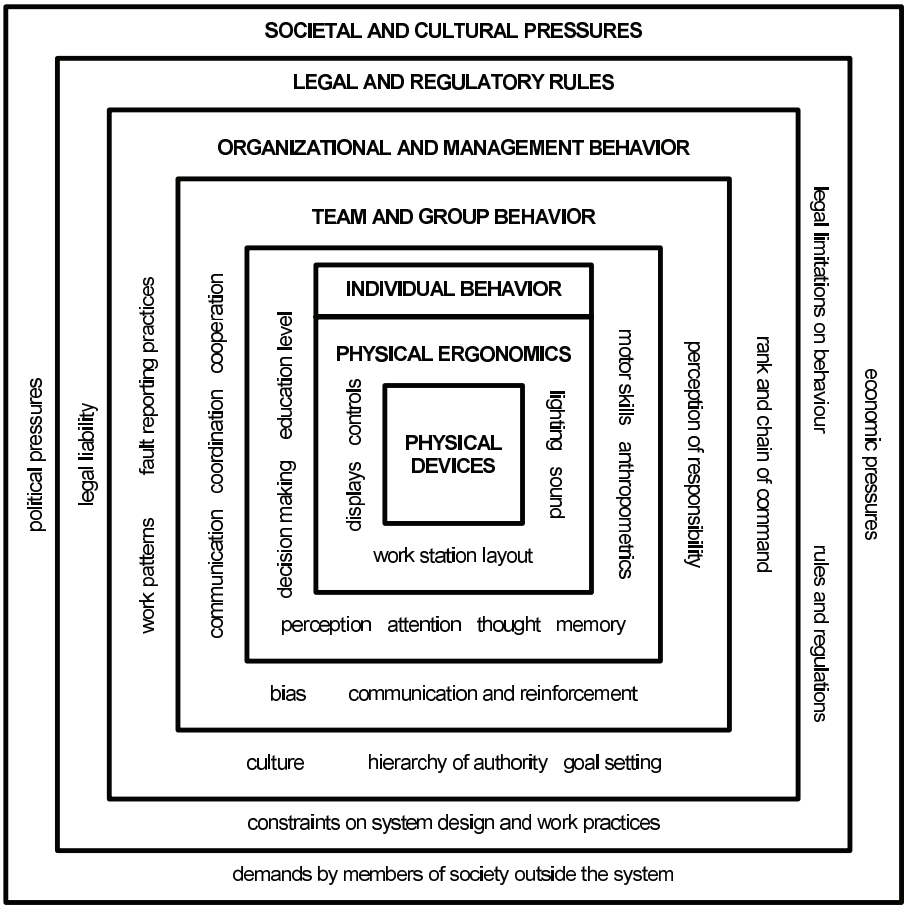


Figure 1. Ergonomics as the study and design of socio-technical systems (Moray, 2000)

Discussion

A key finding of the research has been that the "big picture" understanding is missing in the health care sector. The highest priority must be attached to remedying this without delay.

Mapping the "system" is a central focus for complex and intricate systems. As the interfaces between stakeholder groups become apparent, then so does the potential for error. Such mapping exercises have led to the development of a model to serve as a template for future systems design (see Cambridge, Surrey and RCA, 2003).

The need for risk assessment to include the intended user is essential, as is the need to learn from errors.

References available at http://www.scienceinparliament.org.uk/sip.asp

In discussion the following points were made:

Litigation in general does not deter doctors, but is undoubtedly increasing pressure on the system. More emphasis is required on the need for better prescribing as many young doctors are uncertain about their ability to prescribe correctly due to the lack of sufficient training in this area. However the view was expressed that one should never train someone for a system which is intrinsically unsafe. The lack of a language requirement for NHS Doctors who were trained elsewhere in Europe was thought to introduce unnecessary risks of misunderstanding due to the lack of relevant skills with the English language. Good medical practice varies between hospitals, between wards and between shifts on wards and is therefore difficult to manage across the NHS. Regulation is needed to ensure standardisation of medical equipment, especially that which is used in life threatening circumstances, in order to reduce the risks of accidental misuse.