

IMPROVING PATIENT SAFETY: Insights from American, Australian and British healthcare

Based on the proceedings of a joint ECRI and Department of Health
conference to introduce the National Patient Safety Agency

edited by

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Paul Barach M.D. is board-certified in Anesthesiology and Intensive Care medicine, all at the Massachusetts General Hospital (MGH). He received his B.Sc. and MD degrees, *Cum laude*, from the Hebrew University Hadassah Medical School in Jerusalem where he grew up. He completed a Masters degree in Public Health, with emphasis on Injury Epidemiology and biostatistics, and was a simulation instructor at the Harvard Center for Medical simulation. He spent 5 years in the Army focusing on quality assurance of resuscitation, incident reporting and analysis, safety science, team training, and simulation of adverse events. After joining the staff at the MGH, he was recruited last year to direct the Center for Patient Safety at the University of Chicago. He is member of the Harvard Kennedy School Executive Session on Medical Error and Patient Safety, the Massachusetts Coalition for the Prevention of Errors, and is on the Board of Examiners of the Malcolm Baldrige National Quality Program. He is member of the Robert Wood Johnson Scholars faculty, and advisor to the Veterans Administration taskforce on adverse event reporting. He has authored or co-authored 35 peer-review articles, 9 book chapters, and is guest editor for the Annals of Internal Medicine and for the British Medical Journal. He is presently funded by the National Institute for Health (NIH) to study the design and implementation of adverse event reporting systems, simulation, team training and patient empowerment to improve safety. He has recently been appointed as co-editor of the BMJ Journal of Quality & Safety in Healthcare.

Nick Barber is Professor of Pharmacy and Head of the Centre for Practice and Policy at The School of Pharmacy, London. A pharmacist and a former lecturer in pharmacology, he previously ran hospital pharmacies at the National Heart Hospital and Oldchurch General Hospital. He returned to academia when he joined the School in 1990, in a joint position in which he was also Regional Director of Clinical Pharmacy. He became a Professor in 1992. His research is broadly into the rights and wrongs of medicines use, and the ways in which pharmacy services can improve matters. Deeper themes in his work are risk, and the patient's perspective. He has worked with a philosopher on the question of 'what is good prescribing', and on values in pharmacy. He has been part of a large multi-disciplinary study on doctor-patient communication about medicines, which has shown the problems that ensue from poor communication. Patient compliance with medication is a related theme, and he is currently studying whether human error theory can explain non-compliance. His work on error has run over the last decade, and includes study of drug administration errors in hospitals and prescribing errors.

Stuart Emslie is Head of Controls Assurance at the Department of Health where he is responsible for aspects of policy relating to governance, risk management and internal control across NHS organisations in England. He is a Chartered Mechanical Engineer by profession, a former academic at the University of Strathclyde in Glasgow, and a Fellow of the Institution of Occupational Safety & Health. He has a professional interest in incident reporting and patient safety. In 1997 he won the Institution of Occupational Safety and Health and Zurich Municipal Safety Trophy for 'a major contribution to safety in the public services' by 'putting patients before paperwork'. This was awarded for his contribution, as technical director, to the development of a national incident recording and information system (IRIS – part of the NHS's Safecode software, © Crown Copyright), funded by the four UK Health Departments and the NHS. In his work to support the developing patient safety agenda at the Department of Health, Stuart contributed to *An Organisation with a Memory*, was a key contributor to *Building a safer NHS for patients*, with particular responsibility for developing the blueprint for the new national system for learning from adverse events and near misses, and was principal author of the draft pilot guidance *Doing Less Harm*.

Lord Hunt of Kings Health OBE was appointed Parliamentary Under Secretary of State for Health (Lords) on 29 July 1999. He was appointed a life peer in July 1997 and in 1998 became a Government Whip and spokesperson in the House of Lords on Education, Employment and Health. He was joint chair of the All Party Primary Care and Public Health Group from 1997 to 1998 and Vice-Chair of the All Party Group on AIDS from 1997 to 1998. He was the first Chief Executive of the NHS Confederation, and previously Director of the National Association of Health Authorities and Trusts (NAHAT) from its formation in 1990. Before that he was Director of its predecessor organisation, the National Association of Health Authorities (NAHA) from 1984 to 1990. Lord Hunt's NHS career began in 1972 when he joined Oxford Regional Hospital Board as a works study officer, moving to Nuffield Orthopaedic Centre as hospital administrator in 1974. Between 1975 and 1978 he was Secretary to Edgware/Hendon Community Health Council before joining NAHAT in 1979 as Assistant Secretary. He was President of the Family Planning Association from 1997 to 1998 and Co-Chair of the Association for Public Health from 1994 – 1998. From 1980 – 1982 he was a member of Birmingham City Council and a member of Oxford City Council from 1973 – 1979.

David Jefferys is the Chief Executive and Director of the Medical Devices Agency of the Department of Health. He is a physician by training who joined the Department of Health in 1984 after a career in clinical and academic medicine. He was most recently the Director of the licensing Division of the Medicines Control Agency of the Department of Health and the UK delegate to the Committee on Proprietary and Medicinal Products. He has published and lectured extensively on regulations and especially on medicines regulation. He is also a Professor of medicine at the University of Newcastle.

Kirstine Knox was, at the time of this ECRI/DH conference, policy and project manager at the Department of Health with responsibility for managing the implementation of *An Organisation with a Memory*. She led a team that successfully bridged the gap between policy development and implementation in procuring an IT solution and associated services for the new national system for learning from adverse patient incidents. She enlisted the enthusiastic support of a network of regional pilot sites and also helped establish the National Patient Safety Agency. She was a key contributor to *Building a safer NHS for patients*, with particular responsibility for developing the outline patient safety research agenda, and contributed to the draft pilot guidance *Doing Less Harm*. Prior to her patient safety role, Kirstine led a cancer research group at the University of Oxford before joining the Strategy and Policy Unit of the Department of Health's Research and Development Directorate. Kirstine is currently Strategic and Scientific Director of the National Translational Cancer Research Network (NTRAC) based at the Oxford Radcliffe Infirmary.

Martin Pickstone is a scientist with substantial experience in many fields - academic and applied research into fluid flow for the chemical industries, product design/development, labour-market economics and research into organisational performance. He joined the Royal Postgraduate Medical School (now part of the Imperial College Faculty of Medicine) in 1992 and specialised in the assessment of risks associated with technology-assisted clinical procedures and in developing countervailing educational, training and management methods. He was responsible for the development and national trial of competence training so that nurses would use infusion equipment safely - a first for the NHS. Later he established a specialist consultancy and has collaborated with ECRI on several projects. Martin Pickstone has a PhD in Polymer Physics, a BSc in Chemistry, a Diploma in Materials Science and a Diploma in Management Studies. He is an Honorary Research Fellow at the Imperial College Faculty of Medicine.

Chris Quinn is a registered nurse, qualifying in 1980, with experience in Critical Care and as a Clinical Teacher. Chris is currently the Medical Devices Officer and Risk Manager working for the Newcastle upon Tyne Hospitals NHS Trust. He has a Masters Degree in Business Administration (MBA) as well as a Post Graduate Diploma in Management Studies. Chris has lectured nationally and internationally on medical devices management and has published extensively on this subject. Medical device management is one of his main areas of expertise, particularly in relation to the establishment of equipment libraries, procurement and training schemes. Chris also is an active member of his Trust's Risk Management and Professional Development Team. He is one of the leads for the Clinical Negligence Scheme for Trusts (CNST) assessments as well as contributing to ongoing Controls Assurance standards maintenance and development. Chris has an extensive network of contacts and has carried out work for many national

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June Raine qualified in medicine at Oxford University in 1978 and undertook postgraduate research leading to an MSc in Pharmacology. After general medical posts and membership of the Royal College of Physicians (MRCP), she joined the then Medicines Division in 1985 and has worked in several licensing areas including the Review of Medicines, New Drugs and Abridged. From 1992 she acted as Principal Assessor to the Medicines Commission. Since 1994, when the Post Licensing Division was formed, she has had responsibility for variations, renewals, change of legal status and advertising. In October 1998 she took on the leadership of the Division following the death of its first Director, Dr Susan Wood. She was formally appointed Director in June 1999.

Rory Shaw is the first Chairman of the National Patient Safety Agency. Professor Shaw is also the Medical Director of the Hammersmith Hospitals Trust, comprising Hammersmith, Queen Charlotte's and Charing Cross. Professor Shaw has a particular interest in Clinical Governance and how IT can support the implementation of clinical governance. Professor Rory Shaw originally qualified from St Bartholomew's Hospital Medical School in 1977. He undertook postgraduate training at the Brompton and St George's Hospitals. He obtained an MD following a period as Wellcome Research Fellow in the Department of Allergy and Clinical Immunology at the Brompton. He was a Senior Registrar in Respiratory Medicine at St Mary's Hospital and an MRC and Royal College of Physicians travelling fellow at the National Jewish Centre for Immunology and Respiratory Medicine in Denver, Colorado. Following his return as a Senior Lecturer and Consultant in Respiratory Medicine at St Mary's, he undertook a part time executive MBA at the Imperial College Management School. He has subsequently played an important role in the development of Undergraduate Medical Education within the new Imperial College Faculty of Medicine as Director of Clinical Studies and Director of the Medical Education Unit. He has also continued his research interests in the area of tuberculosis.

Bill Runciman is Head of the Department of Anaesthesia and Intensive Care at the Royal Adelaide Hospital in South Australia and is Professor of Anaesthesia and Intensive Care at the University of Adelaide. He is also President of the Australian Patient Safety Foundation (APSF), which is a non-profit independent organisation dedicated to the advancement of patient safety. The APSF provides leadership in the reduction of harm to patients in all health care environments, through its incident management system AIMS. Bill has published extensively on a range of patient safety matters including anaesthesia safety, iatrogenic injury generally, development of coding and classification systems, systems issues, and problems with medical equipment.

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Dedications

To my parents, Ian & Lilian – Stuart Emslie.

To my parents, Bill & Hilda – Kirstine Knox.

To Aunts Nancy, Ray, Yetta and Frances – Martin Pickstone.

Abbreviations and acronyms

ADR	Adverse Drug Reaction
ADROIT	Adverse Drug Reactions On-Line Information Tracking
AIMS	Australian Incident Monitoring Study
ALARM	Association of Litigation and Risk Management
APSF	Australian Patient Safety Foundation
AS/NZS	Australian/New Zealand Standard
BMJ	British Medical Journal
BUPA	British United Provident Association
CB	Companion of the Order of the Bath
CBE	Commander of the Order of the British Empire
CHI	Commission for Health Improvement
CNST	Clinical Negligence Scheme for Trusts
CSM	Committee on Safety of Medicines
DH	Department of Health
ECRI	Emergency Care Research Institute
ENT	Ear, Nose and Throat
ESU	Electro-surgical Unit
FDA	Federal Drug Administration
GHTF	Global Harmonization Task Force (Medical devices)
GOC	Generic Occurrence Classification
GP	General Practitioner
HR	Human Resources
HSE	Health and Safety Executive
IT	Information Technology
IV	Intra-venous
ICD-10	International Standard Classification of Diseases Version 10
ICU	Intensive Care Unit
IOM	Institute of Medicine
ITU	Intensive Therapy Unit
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
JSC	Johnson Space Center
MCA	Medicines Control Agency
MD	Doctor of Medicine
MDA	Medical Devices Agency
MRC	Medical Research Council
NASA	National Air and Space Administration
NHS	National Health Service
NICE	National Institute of Clinical Excellence
NPSA	National Patient Safety Agency
OBE	Order of the British Empire
OR	Operating Room
OWAM	Organisation with a Memory
PCT	Primary Care Trust
RIDDOR	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations
SIC	Statement on Internal Control
TTA	'To Take Away'
UK	United Kingdom
US	United States
USA	United States of America
VA	US Department of Veteran's Affairs
VHA	Veterans Health Administration

Foreword

One guarantee that we cannot give patients is that they will not be harmed by the system meant to look after them. Individual stories of suffering caused by the healthcare system - whether told by the patients and families who have suffered or by the healthcare professionals involved - are moving and can be terrifying¹. The epidemiology of this silent epidemic is currently being unravelled and the figures are startling. About 10% of patients admitted to hospital will be harmed, half of which is considered preventable. Of these, some 6% will suffer permanent disability and 8% will die. In many instances this is put down to 'medical error'. But each year in the UK, for example, over 5,000 people die as result of a hospital-acquired infection². None of this is new. What has changed, however, is that the problem and its extent are being recognised and, most importantly, is now being openly discussed and addressed.

High profile cases and individual anecdotes jolt us out of complacency and place an 'urgent' tag onto the problem. These are important in helping stir attitudes. But the problem goes way beyond those stories that hit the headlines. There are many instances of iatrogenic harm that we simply do not hear about. And sometimes errors are made that result in near misses that both patients and healthcare professionals are either not aware of, or do not consider worthy of reporting. To implement effective solutions we need to report all incidents, understand how and why they occur and we need to change healthcare and professional culture.

Patient safety has, of course, been a concern in the NHS for some time. The Medical Devices and Medicines Control Agencies, for example, have, between them, over 70 years accumulated knowledge and expertise in their respective domains. However, few working in the NHS are aware of their existence let alone their important work. But publication of *An Organisation with a Memory*³ and establishment of the National Patient Safety Agency have signalled that improving patient safety is now an important and explicitly stated priority for the NHS as an organisation and for everyone associated with it. This message was reinforced by the Minister responsible for patient safety and quality in England, Lord Hunt of Kings Heath OBE, who introduced the National Patient Safety Agency at a joint ECRI and Department of Health conference in London on 10 October 2001. The message was further reinforced both by the NHS Head of Controls Assurance at the Department of Health, and by the Chairman of the National Patient Safety Agency, who jointly chaired the conference. This was a sell-out event, suggesting that many people working in the NHS are now concerned with finding out how to make healthcare safer.

The conference included presentations from the Medical Devices and Medicines Control Agencies who outlined some of their crucial work. Patient safety is an international problem and speakers from the USA and Australia indicated just how much the NHS can learn from work in other healthcare systems. All of the conference

presentations contained important messages and I am delighted that these have been compiled as this publication and made available by ECRI and the Department of Health to many more than were able to attend the conference.

This publication indicates the breadth of the work to improve patient safety already underway. We know the extent of the problem; we understand some of the causes; and we are beginning to grapple with potential solutions. If we can convey the emerging lessons to those working in healthcare - both in management and in clinical practice - and persuade them to make the necessary changes to professional practice and organisational behaviour, then we will make healthcare much safer. We will then be able to demonstrate a waning of this iatrogenic epidemic.

Dr Fiona Moss

Editor

Journal of Quality & Safety in Health Care⁴

¹ *Medical Mishaps – Pieces of the Puzzle* edited by Marilyn Rosenthal, Linda Mulcahy, Sally Lloyd-Bostock. Open University Press. ISBN 0-335-20258-6

² *The Management and Control of Hospital Acquired Infection in Acute NHS Trusts in England*. HC 230 Session 1999-00, Feb 2000, London. The Stationary Office

³ *An Organisation with a Memory* www.doh.gov.uk/orgmemreport

⁴ www.qualityhealthcare.com

Summary

Introduction

This publication is based on the proceedings of a conference to introduce the National Patient Safety Agency held in London on 10th October 2001. All speaker presentations were audio-recorded and abridged transcriptions prepared for subsequent editing by speakers (alternative contributions for publication were sent in a few cases). Where appropriate the editors have added relevant footnotes which are hopefully useful for readers. Part four consists of annexes - the editors' assessment of key messages from each speaker, a transcript of the conference question-and-answer sessions, a summary of post-conference feedback and further sources of information. Both ECRI Europe and the Department of Health provided valuable help to the editors during the preparation of this publication.

The ECRI/DH conference to introduce the new National Patient Safety Agency

The National Patient Safety Agency has been established to help transform the NHS into a safety-conscious organisation that learns continuously from mistakes involving patients. The conference was mounted by ECRI Europe with support from the Department of Health and dealt with four themes:

1. The scale and consequences of inadequate patient safety in the NHS and in global healthcare.
2. Case studies of successful incident reporting systems.
3. How senior managers should treat frontline staff so that the organisation learns to be both more safety-conscious and safer - and how frontline doctors should treat their patients.
4. Case studies of organisational change and safer healthcare.

The scale of the problem

Research has shown 10.8% of NHS patients experienced an adverse event, half of which were potentially preventable and a third of which led to either serious complications or death. Lord Hunt and Professor Rory Shaw both use this study to project annual totals of 400,000 preventable adverse events and 34,000 deaths. More than a thousand mental-health patients commit suicide each year. Dr Paul Barach

points out that there are more deaths in UK healthcare ‘accidents’ than in any other kind of accident including those on the roads. This lack of safety is a very expensive diversion of healthcare funds, quite apart from the ensuing distress for patients, relatives and frontline staff. The UK annual sums are huge as exemplified by: prolonged hospital stays - two billion pounds, hospital-acquired infections - one billion pounds, claims for medical negligence - five hundred million pounds (the backlog is several billion pounds). Professor Bill Runciman says of Australian healthcare ‘Without re-design the system will continue with relentless inefficiency to kill 10,000 patients and generate 500,000 adverse events’ The picture is no better in the US.

Unsafe healthcare practices resulting in Adverse Drug Reactions (ADRs) compound the problem. Dr June Raine summarises recent UK research, which shows that ADRs cause 5.5% of hospital admissions, of which two-thirds may be potentially avoidable. She also points out that ADRs are one of the leading causes of deaths in the US. Anticoagulants cost the NHS an estimated one million pounds *daily* and are a major problem in healthcare everywhere. Here are some examples: patients who should be on Warfarin and are not and have an embolic stroke; those who are on Warfarin but bleed; and patients who wrongly receive the drug. Failure to use Heparin peri-operatively is also known to be associated with an increased rate of thromboembolism. Professor Bill Runciman sets out the following key Australian facts that should alert all of us - anticoagulants cause: one-third of preventable adverse drug events, one-third of deaths associated with adverse drug events and are number three on the list of drug-related admissions.

Dr Joel Nobel cautions against the uncritical acceptance of data on patient harm and exemplifies his advice with an extraordinary case study. During the 1960s spurious research, falsified data, charlatans, gullible biomedical engineers, and imaginative media types ushered in America’s first widespread patient safety campaign, flawed reporting systems, and poorly considered medical device regulations. Hundreds of millions of dollars were spent by hospitals defending patients and themselves from a risk that had been immensely exaggerated. To this day, disproportionate efforts are expended by biomedical and electrical engineers focused on the electrical safety of medical devices. Yet the real risks are mechanical problems. Plumbing, gas-line mix-ups, and failure to connect ventilators properly to patients are examples. Patients have died because oxygen and nitrous oxide lines have been interchanged during construction or renovation. Furthermore, about 50% of adverse incidents have been caused by operator error, which needs to be remedied through training and human factors design - areas that get inadequate attention.

Case studies of successful incident reporting systems

Five incident reporting systems are discussed: ECRI, Medical Devices Agency, Medicines Control Agency ('Yellow Card Scheme'), Australian Patient Safety Foundation and the US Veterans Health Administration. The discussions are interlaced with three issues: the earliest possible detection of a problem from the smallest number of reports, the rapid detection of rare events and the comprehensive reporting of all events. Dr Joel Nobel advances the counterintuitive argument that the comprehensive collection of similar reports diverts the system's managers towards data collection and analysis and away from corrective action and feedback to reporters. As little as a single report can be enough to trigger investigation and establish cause. By contrast both the Medical Devices and Medicines Control Agencies have striven for many years to increase reporting volumes from as many different healthcare occupations and organisations as possible - and now from patients. Dr June Raine (Medicines Control Agency) points out that ADRs must be monitored throughout the drug's lifetime on the market. Dr David Jefferys explains that there is a substantial transfer of complex medical devices from acute to primary and community care; hence reports must be collected from the latter sectors. Professor Bill Runciman explains and exemplifies why the numbers and sources of reports together aid the early detection of accurately characterised rare events. He emphasises that common definitions of event types must be used. Dr Jim Bagian (US Veterans Health Administration) argues that the number of reported accidents and near misses is both a measure of staff morale and safety-consciousness citing impressive supporting evidence. Mr Stuart Emslie shows how future incident reporting, incident grading and root cause analysis in the NHS fit naturally into the Governance and Controls Assurance agendas. He explains why root cause analyses are organised common sense that many staff are capable of doing.

The treatment of staff and the participation of patients

The willingness of staff to freely report accidents and particularly near misses is a prerequisite of safer healthcare. Lord Hunt, Stuart Emslie and Professor Rory Shaw all emphasise that healthcare systems are at fault and that the practice of blaming frontline staff does not improve patient safety and is wrong. Dr Joel Nobel reminds senior managers that rapid feedback to reporters sustains their morale and commitment. However Dr Jim Bagian argues that the common term 'blame-free' to describe the correct organisational environment will only invite public opprobrium and should be replaced by 'blame-worthy'. The Veterans Health Administration defines only intentionally unsafe acts as 'blame-worthy' and all else is placed in the confidential reporting system. Professor Bill Runciman uses the term 'just culture' in which there is a firewall between the two kinds of procedures: those for accountability and discipline and that for learning. Managers of the former should never control the latter. The reporter should always be protected, have the right to anonymity and information should always remain confidential - especially from lawyers. Dr Jim Bagian reminds senior managers that the risks for patients come before those of the organisation. Dr

Paul Barach explains why healthcare should learn the teamwork of high-reliability organisations (special forces, aviation and space flight). These lessons will be hard: egos are sacrificed for the good of the team, safety before hierarchy and radical changes to the educational curricula of healthcare occupations. Continuous in-service training is a must. Doctors need to trust patients with information and encourage them to take responsibility for their own care.

Case studies of organisational change and safer healthcare

Dr Kirstine Knox explains how her Department of Health team supported pilot sites for the NHS incident reporting scheme to obtain the prompt reporting of adverse events and near misses. Examples from primary care, mental health and the acute sector are given. Professor Nick Barber analyses why Pharmacies have always had the organisational culture that encourages reporting, safety and high quality that are so lacking in much of the NHS. Dr Martin Pickstone and Mr Chris Quinn show how the lessons of industrial safety management and training have been successfully used in intravenous therapy services. Mr Chris Quinn also cites preliminary evidence that as safety-consciousness takes root so the number of serious infusion incidents drops sharply. Both Professor Bill Runciman and Dr Jim Bagian provide case studies of the practical benefits of their incident reporting systems.

Part I – Improving patient safety: Tasks for the NHS

1

Patient safety – A major Government priority

Lord Hunt of Kings Heath OBE

Parliamentary Under Secretary of State for Health (Lords)

Introduction

Ensuring the safety of *everyone* that comes into contact with health services is one of the most important challenges facing healthcare today. The importance of patient safety in particular is an issue of crucial concern, reflected in the size and breadth of the audience. I'm told that I could easily have been speaking to 800 people today if only there was the space! Welcome to all of you.

And I'd like to extend a particularly warm welcome to our international speakers and delegates. Their presence here today signifies that patient safety is a global issue. There is much that we can learn from each other internationally in the drive to reduce future risks for patients in healthcare.

In our own country, the Government has set out a ten-year modernisation strategy for the NHS. One of the main aims of this is to bring about major and continuing improvements in the quality of clinical care delivered to patients across the NHS. Patient safety is an integral part of this drive for quality.

An organisation with a memory

Last year an expert group on learning from adverse events in the NHS, chaired by the Chief Medical Officer, set out its findings in the internationally acclaimed report - *An Organisation with a Memory*¹. This report concluded that if the NHS was to successfully modernise its approach to learning from failure, four key areas must be addressed:

1. unified mechanisms for reporting and analysis when things go wrong
2. a more open culture, in which errors or service failures can be reported and discussed
3. mechanisms for ensuring that, where lessons are identified, the necessary changes are put into practice; and
4. a much wider appreciation of the value of the system approach in preventing, analysing and learning from errors.

¹ www.doh.gov.uk/orgmemreport

The expert group believed that only if these four conditions were met could the NHS develop the modern and effective approach to learning from failures that it so badly needed. The report set out ten key recommendations - which were all accepted by the government. In the process, patient safety became a key component of the NHS plan² and a major strand of the NHS quality and clinical governance agendas.

Patient safety and the NHS

Today our focus is on patient safety and with good reason. Research carried out in this country and independently in Australia and America suggests that 1 in 10 patients admitted to hospital suffers an adverse event. Now, some adverse events will be inevitable complications of treatment. But at least half of these events are thought to be preventable. That's 1 in 20 patients suffering a preventable adverse event. And the research further suggests that 8% of these 1 in 20 patients will die as a consequence.

Today our focus is statistics. There are about 8.5 million hospital admissions each year in the NHS. Based on current evidence of 1 in 20 patients experiencing a preventable adverse event, and an 8% mortality rate we could be looking at over 400,000 events in the NHS each year that leave over 34,000 patients dead.

The picture is no better internationally. In Australia, for example, the estimate is 10,000 patient deaths attributable to adverse events. In America, the estimate is anything up to 98,000 patient deaths every year. The point is that we do not know if these estimates are correct - but even if they are only half right, we are still looking at a huge-scale problem for the NHS and other healthcare systems. Through the new National Patient Safety Agency, we will get a better picture of what is happening across the NHS and elsewhere.

But it's not just the harm to patients that we need to consider. There's the knock-on anguish of families, loved ones and friends. There's the distress caused to the staff involved who have to deal with adverse events. And there's the financial implications, which add tremendously to the pressures on the NHS, limiting its ability both to treat more patients and to provide higher quality services. Let me give you some hard figures.

We know that adverse events involving prolonged hospital stay alone costs in excess of £2 billion every year. That's around 5% of annual NHS spend. Hospital acquired infections, a very specific type of adverse event, costs a further £1 billion a year. And claims for clinical negligence cost around £500 million every year (and rising) and there are outstanding claims in the system that amount to several billion pounds. Just think how much more good the NHS could achieve if only we could reduce the incidence of preventable harm to patients.

² www.doh.gov.uk/nhsplan

Learning from experience

But how can we start to achieve this? Well, what's most definitely *not* the answer is to respond to adverse events with blame. Instead, when something goes wrong we should learn from the experience and, through that learning, strive to reduce the risk to future patients - not just locally, but across the NHS, and throughout healthcare generally, nationally and globally. Hence the need for a National Patient Safety Agency – collecting and analysing key information from local organisations and from other sources - providing relevant and timely feedback to organisations and clinicians to help them improve patient safety.

So *learning from experience* is the answer. And to unlock the learning from adverse events we are looking for the real reasons - the *root causes* that lie behind these events. Root cause analysis is the key to learning. And so to prevent adverse events in healthcare, it is necessary to get at and eliminate root cause. Root cause analysis is a structured investigation that aims to identify the true cause of a problem and the actions necessary to eliminate it. It is not about blaming individuals for poor performance. It is about gathering the appropriate information and keeping asking why something happened. It is about drilling down into the underlying management and organisational factors – the *systemic* factors - that allowed the event to occur.

Improving systems in healthcare

An increasing body of evidence is pointing to the fact that in the majority of instances, it is not bad or poorly performing healthcare professionals that are directly responsible for adverse events. Rather, the fault lies in the systems in place to support the delivery of safe, quality health care. Consequently, improvement strategies that focus on blame are misguided and do not work. Instead, we need to concentrate on dysfunctional systems.

Of course we must recognise that whilst systems make things happen, it is people that make systems work. And people design systems in the first place. So I'm not advocating that at the end of the day people are not held accountable when things go wrong. But we need to move the balance from one of blame to one of organisational accountability, openness and, as far as is possible, prevention. We need to accept that we are responsible for implementing and maintaining sound systems for the delivery of safe patient care and treatment, and we must take these responsibilities seriously. And, taken to its eventual conclusion, root cause analysis may indeed, in some cases, highlight where we can improve our own national policies

Pulling it all together and delivering - the NHS quality agenda

Patient safety is an integral part of the NHS quality agenda. Improving quality is the lynchpin of this government's drive to modernise the NHS. This agenda contains four distinct components.

Firstly, setting clear national standards – such as those set out in national service frameworks³, NICE standards⁴, Controls Assurance standards⁵, and so on.

Secondly, effective local delivery through clinical governance, supported by the NHS Modernisation Agency, which incorporates the Clinical Governance Support Team⁶ headed by our NHS Director of Clinical Governance, Professor Aidan Halligan.

Thirdly, strong monitoring mechanisms through the Commission for Health Improvement⁷, and the performance assessment framework⁸.

And *finally*, measures for increasing patient and public involvement, such as:

- Patient advocacy liaison services
- Reform of the NHS complaints procedure; and
- Patient surveys

This agenda is underpinned by the Health Act 1999, which places a statutory *duty of quality*⁹ on all NHS organisations that provide direct patient care. It is through the quality agenda that we will improve patient safety. And it is through consideration of patient safety issues that we will help improve quality in the NHS. The two issues are inextricably linked. Safety and quality go hand in hand. Safety and quality are now major priorities for the NHS and everyone associated with the NHS. And improving safety and quality is a key objective for all NHS organisations. An objective that will be delivered through sound clinical governance aimed at delivering safe, high quality, accountable care in open and questioning environments.

Concluding comments – the National Patient Safety Agency

Let me conclude and summarise by saying to you the following. In an organisation as complex as the NHS, things will sometimes go wrong and patients will suffer unintended harm. But when this happens the response should not be one of blame, but

³ www.doh.gov.uk/nsf

⁴ www.nice.org.uk

⁵ www.controlsassurance.info

⁶ www.cgsupport.org

⁷ www.chi.nhs.uk

⁸ www.doh.gov.uk/nhsperformanceindicators

⁹ www.hmsa.gov/acts/acts1999/19990008.htm

of learning, a drive to reduce the risk of harm to future patients, and a concern for staff who may suffer as a consequence.

Improving patient safety is a major Government priority. It is an issue that, properly addressed, will reap tremendous benefits both in terms of a reduction in unintended harm to patients and a reduction in unnecessary financial costs associated with such harm. Properly addressed, improvements in patient safety will contribute significantly to improving quality for NHS patients. But NHS staff cannot effectively improve safety and quality all on their own. We need the help and support of national initiatives and bodies. And this is why we have established the National Patient Safety Agency¹⁰.

The National Patient Safety Agency is here to help. It is a learning organisation. An organisation you can turn to for help, and one that will provide timely and relevant feedback on key patient safety issues that will assist us all in our efforts to improve safety and quality in the NHS. Efforts that will help us in Government with modernising the NHS. Indeed, the very nature of the NHS gives us the opportunity to implement an integrated, comprehensive approach to patient safety across our *national* health services - an option not available in many other countries. And so I am looking to the new National Patient Safety Agency to become an international focus for excellence in improving patient safety. But to do that it has got to establish itself as an organisation of excellence and high quality.

In the past we have assumed that good intentions and hard work have increased the safety of our patients. The statistics appear to tell a very different story. The NHS does a tremendous amount of good. But we can all learn to do better. For the sake of patients, we must apply a more rigorous and open approach to improving safety. We need to create learning organisations in which we all learn from errors, mistakes and failures. Learning is the answer to the question of patient safety. And the National Patient Safety Agency is the engine for learning.

¹⁰ www.npsa.org.uk

2 Building a safer NHS for patients

Mr Stuart Emslie
Head of Controls Assurance
Department of Health¹

Introduction

This Keynote Address has a different emphasis to that which was to have been given by the Chief Medical Officer, Professor Liam Donaldson, who unfortunately cannot be here today because of business abroad. I am going to talk in his place about two inter-related topics - patient safety in the context of the wider NHS Governance and Controls Assurance agendas, and the proposed new national system for learning from adverse patient incidents to be implemented by the National Patient Safety Agency.

Background

In his introductory address, the Minister, Lord Hunt, stressed that the goal of improving patient safety can only be achieved through a fundamental change in NHS organisational culture. Kaiser Permanente, a large American healthcare organisation, has aptly stated the task that we all face²:

“We live in a culture that manages error by looking for people to blame; that silences admission of errors; and that focuses on the ‘sharp end’ (i.e. the clinician) instead of working at to improve the systems we’ve created. We must foster responsible reporting and focus on the ‘blunt end’ (i.e. the system) to build more error-proof systems. Our organization faces the challenge of permanently changing our culture to embrace the new paradigm.”

Evidence already exists that the practice of scapegoating frontline doctors and nurses - much abetted by the media - is wrong and does not help patients. For instance, the Joint Commission on Accreditation of Healthcare Organisations (JCAHO) in America has a *sentinel event* scheme that requires accredited healthcare organisations to both report and subject serious incidents to root cause analysis. Figure 2.1 presents a summary of the root causes of sentinel events reported to the JCAHO³.

¹ Any views expressed are the author’s and are not necessarily those of the Department of Health.

² www.kaiserpermanente.org/medicine/permjournal/sum01/PatientSafety.html

³ www.jcaho.org Readers will note that these are not *true* root causes, but should more appropriately be described as *underlying contributory factors* in accordance with the information presented in figure 2.5 in this chapter.

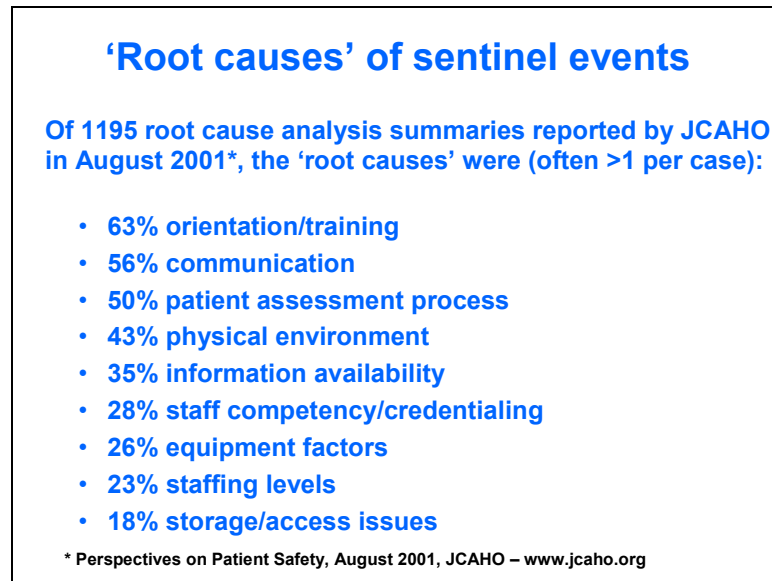


Figure 2.1 The root causes of sentinel events

There are two key lessons in figure 2.1. Firstly, the causes identified cannot be blamed on frontline clinicians. Secondly, there is often more than one cause associated with an event, which means that most serious incidents cannot be blamed on one person. In other words these are *systemic* causes, and improving systems is a *management* responsibility.

I believe we need to better *manage* healthcare. The NHS is a very complex organisation whose spending on *management* is around 3-4% of running costs. In contrast, commercial companies, much less complex than many NHS organisations, spend, perhaps, 15-20% of their running costs on management to ensure that their goods or services are safe and of satisfactory quality. I believe we need to educate the media and the public to understand the need for investment in *management*. Management needs to be seen not as a *cost*, but as something positive that adds value to healthcare processes. This does not necessarily mean more managers, but it does mean ensuring that good *management* and improving *systems* is given greater investment priority.

The importance of *management* was recently highlighted by the Secretary of State for Health in England, Mr Alan Milburn⁴:

"The crucial ingredient that makes or breaks a hospital.....is about how well the hospital is organised and how well it's managed."

Based on the evidence provided to-date through root cause analysis, one could argue that under-investment in adequate levels of healthcare management is a significant

⁴ As reported in the *Health Service Journal*, 27 September 2001. www.hsj.co.uk

factor in the high incidence of preventable harm to patients. In addition, as Lord Hunt has already said today, we are also incurring very substantial financial losses that could be better spent doing more good for patients. We must remember that it is not just about the safety of patients. It is about staff, visitors and others who are affected by the activities of healthcare organisations. And financial losses are not confined to those associated with patient safety. Other losses, which could conceivably be cost-effectively minimised through investment in sound healthcare management include: staff absence, fraud, theft, drug wastage, and general inefficiency. Management and legal costs are often also incurred in patching-up things that should never have gone wrong in the first place.

All of us, collectively, that's clinicians, managers, civil servants and ministers, are responsible for managing healthcare in this country. But how can the NHS be managed better? Fundamentally, I believe it is about ensuring good governance and internal control within our healthcare organisations and across the NHS as a whole.

Governance and Controls Assurance – managing the NHS better

Governance can be defined as 'the system by which an organisation is directed and controlled, at its most senior levels, in order to achieve its objectives⁵ and meet the necessary standards of accountability, probity and openness'⁶. In line with best governance practice in the private sector, all organisations should maintain a *sound system of internal control* and provide assurances as to its effectiveness. NHS organisations are no exception. The system of internal control should include an effective risk management process, embedded at all levels throughout the organisation. Fundamentally, systems of internal control exist to help ensure the risk of failure to meet objectives is minimised.

But what exactly do we mean by a sound system of internal control? The model presented in figure 2.2 provides a generic framework that can be applied to whole healthcare organisations, or to component parts such as directorates or departments, and forms the basis of the Controls Assurance standards issued by the Department of Health. The model can also be applied to individual key objectives or to areas of significant risk. For example, you could apply the model to establish the system of internal control for, say, clinical governance, medicines management, medical devices management, infection control, and so on.

Let us now look at the model in some detail as it might be applied to a whole organisation (to reduce complexity you might prefer to do this on a directorate or department basis and aggregate the results).

⁵ The objectives of most healthcare organisations include provision of safe, high quality patient care.

⁶ See Controls Assurance core standard on Governance, available at www.controlsassurance.info.

Firstly, you need to know your *objectives*. This might be as straightforward as ‘providing high quality care to patients in a safe, open and questioning environment’. Or you might have an overall aim with a set of key objectives (preferably no more than five or six). Whatever they are, write them down and understand them.

Secondly, you need to know who your *stakeholders* are both within and outside your organisation. There are likely to be many stakeholders and they will typically include patients, staff, local consumer groups, Strategic Health Authorities, regulatory bodies and the Department of Health, to name a few. Whoever they are, write them down.

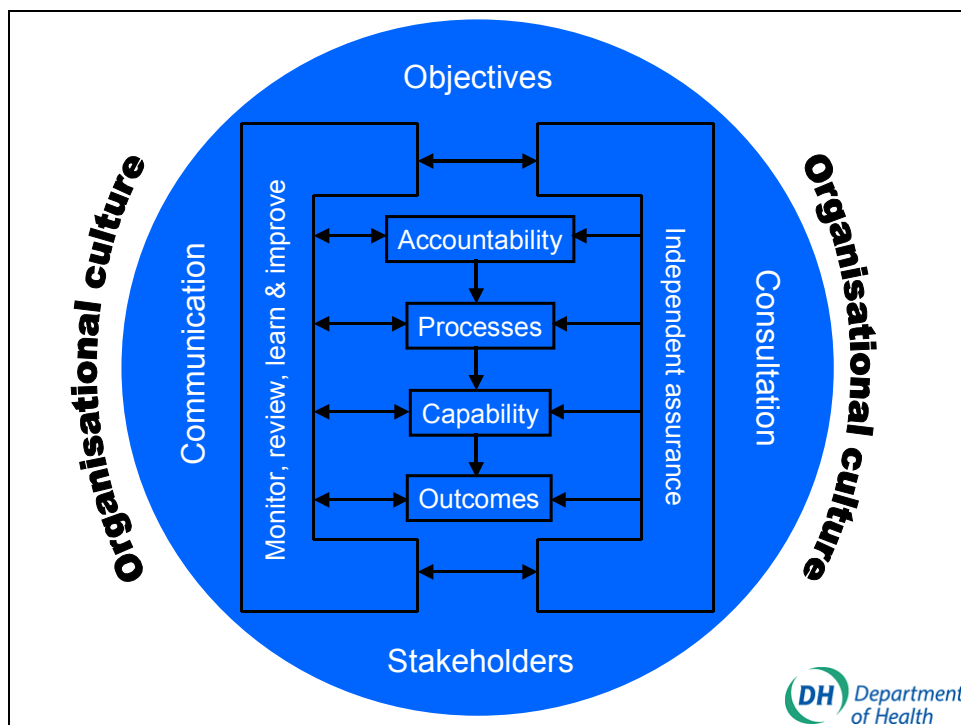


Figure 2.2 Generic framework model for an NHS system of internal control

Then start fleshing out the core of your system of internal control. Start with *outcomes*. Write down what outcomes, or results, either in general or specific terms, you want to achieve in relation to meeting your objectives. This may take some time to establish properly, and could become quite detailed, involving a range of key performance and risk indicators. Fundamentally you will want to ensure you have good outcome indicators that will be capable of showing performance improvement, including risk reduction and safety improvement. Such indicators might include mortality and morbidity rates, infection rates, staff turnover, and adverse patient incident rates. A range of key performance indicators has been developed as part of the NHS

Performance Assessment Framework⁷. The NHS Controls Assurance Support Unit is working on key internal control indicators⁸.

With clarity over objectives, stakeholders, and outcomes, you then need to define the key *accountability* arrangements within your organisation. Who is responsible to whom, and for what? Include any committees or other groups with responsibility for specific issues. Start with the board and work down. Produce an organisation chart that clearly shows the accountability arrangements.

Next define the key *processes* you have in place to produce the outcomes you want. Include in this your risk management process, which should conform to the requirements of the Australian/New Zealand risk management standard outlined later in this chapter.

Then set down the *capability* required to meet your objectives. Capability can be expressed in many ways – leadership is crucial, but also important are financial and human resources, physical resources such as buildings and equipment, and staff attributes such as specific knowledge, competence, skills and expertise, and so on.

Now define the arrangements you have to have in place for management, including the board, to *monitor and review* all aspects of the system of internal control – to *learn* from identified weaknesses, and to *improve* the system where necessary.

Monitoring and review processes will also look at the work carried out by those individuals, functions and organisations providing aspects of internal or external *independent assurance*. Within your organisation, this might include internal audit and clinical audit, specialist risk and safety personnel who are in a position to provide truly independent assurances, and so on. Externally, this might include external auditors, professional colleges, the Commission for Health Improvement, accreditation bodies, the NHS Litigation Authority and various regulatory bodies, such as the Health and Safety Executive. Write them all down and make sure their reports and any other communications with you are properly taken into account as part of monitoring and reviewing your system of internal control.

Finally, set down your arrangements in place for *communication* and *consultation* with both internal and external stakeholders.

You have now defined your system of internal control, which should be documented and maintained up-to-date. The system includes a risk management process that will help ensure you meet your objectives by minimising risks of all kinds. And the system operates within, influences, and is influenced by the *organisational culture*. All that remains is for your organisation, through the Chief Executive and Board, to provide a

⁷ www.doh.gov.uk/nhsperformanceindicators

⁸ www.casu.org.uk

public assurance on the overall system of internal control. This is the essence of the NHS Controls Assurance project, which requires a *Statement on Internal Control* to be included in your organisation's annual report and presented alongside the statutory audited annual accounts.

Controls Assurance is no more than a process by which NHS organisations demonstrate that they are doing their reasonable best to *manage* themselves so as to meet their objectives and protect patients, staff, visitors and other stakeholders against risks of all kinds⁹. It is built on best governance practice. The process is about ensuring that the organisation maintains a sound system of internal control covering all controls, including financial, organisational and clinical controls, and risk management. The output from this process is the Statement on Internal Control (SIC)¹⁰.

So, Governance is the system by which organisations are directed and controlled, and NHS organisations need to maintain sound systems of internal control. Controls Assurance is the process by which a Chief Executive, on behalf of the Board, provides an assurance that their organisation has a sound system of internal control in place across all its functions and activities, and by which key risks in relation to objectives are identified and managed. The key, therefore, to all of this is *risk management*. Good governance and effective internal control needs to be based on a sound risk management approach.

Managing risk in the NHS

The management of risk in the NHS is based on AS/NZS 4360:1999 – a risk management standard published by Standards Australia¹¹. The standard contains a generic risk management process and methodology (Figure 2.3) and has been adopted by the Department of Health for the NHS¹² to cover all risks – clinical and non-clinical. Standards Australia has recently produced guidance on implementing the standard in healthcare, assisted by the Department of Health and the NHS¹³. Standards Australia has also kindly assisted the Department of Health in the production of an e-learning CD-ROM – *Corporate Governance and Controls Assurance* – which is included in your handout folder today. The CD-ROM is freely available to NHS organisations through the Department of Health's Controls Assurance Team¹⁴.

⁹ See HSC 1999/123 and associated guidance available from www.controlsassurance.info

¹⁰ See latest guidance on *the Statement on Internal Control for 2002/2002 and beyond* available from www.controlsassurance.info

¹¹ AS/NZS 4360: 1999 – *Risk management*. www.standards.com.au and www.riskmanagement.com.au

¹² www.controlsassurance.info

¹³ HB 228:2001 - *Guidelines for managing risk in the healthcare sector*. www.standards.com.au

¹⁴ CAP@doh.gsi.gov.uk

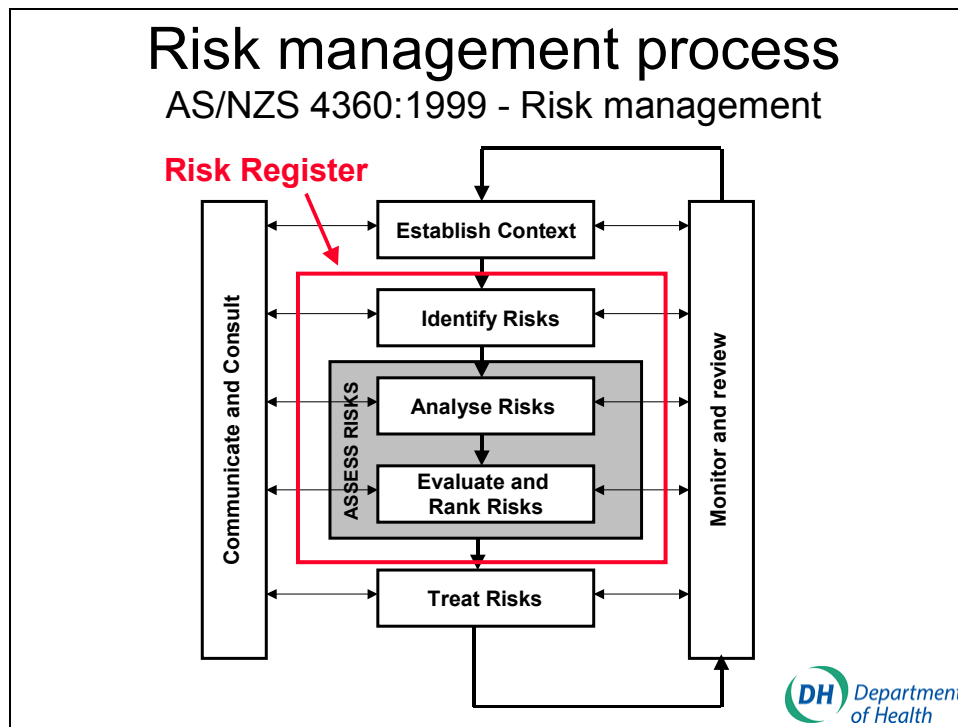


Figure 2.3 AS/NZS 4360:1999 Risk management process

The proposed new national system for learning from adverse patient incidents

The National Patient Safety Agency is an essential piece of the NHS Governance and Controls Assurance jigsaw and should assist in determining how effective an organisation's system of internal control is in meeting patient safety objectives. The Agency's core purpose is to implement, operate and oversee all aspects of the new national system for learning to improve patient safety by reducing the risk of harm.

Figure 2.4 is taken from our recent publication *Building a safer NHS for patients*¹⁵ and illustrates, schematically, the blueprint for the new national system for which the National Patient Safety Agency will be responsible. In essence, all organisations providing care and treatment to NHS patients will be required to report standardised information on selected adverse patient incidents to the NPSA. The NPSA will maintain a *repository* of information for learning. This information will not be restricted to adverse incidents. It is expected that a lot of the learnings available from a range of existing sources, including research results and international sources, will be assimilated together with incident information to produce timely and relevant feedback. This feedback is crucial to the success of the Agency in helping create positive change in clinical, management and organisational practices for the benefit of patient safety and service/clinical quality improvement.

¹⁵ www.doh.gov.uk/buildsafenhhs

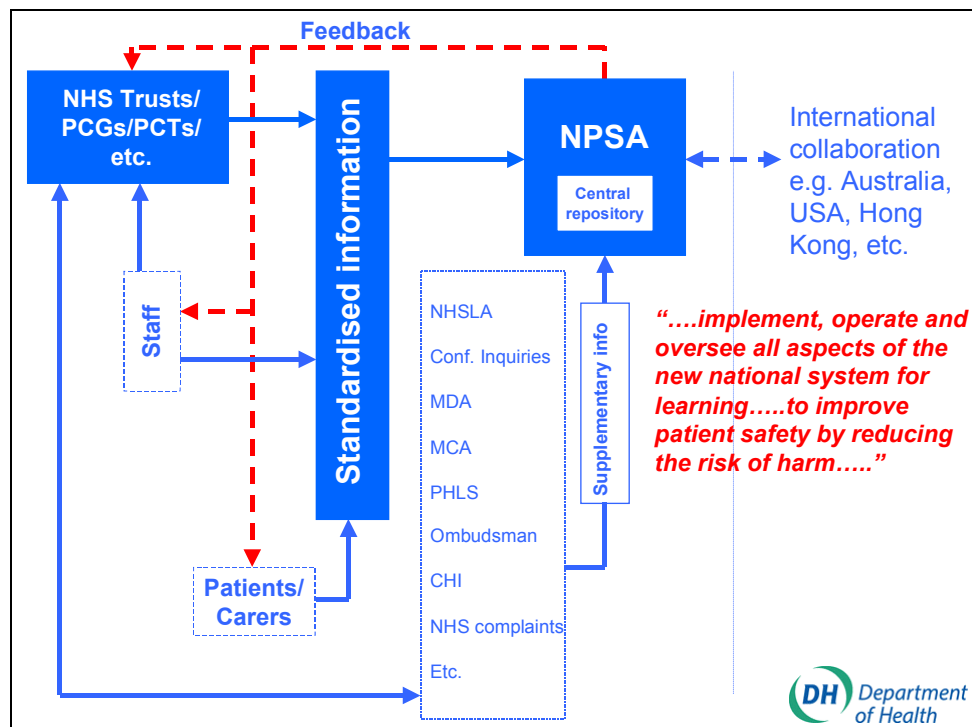


Figure 2.4 Blueprint for the new national system for learning

Detailed local requirements for reporting, analysing and learning from adverse patient incidents

Our latest guidance, *Doing Less Harm*¹⁶ sets out key requirements (Box 2.1) for healthcare providers for improving the safety and quality of care through reporting, analysing and learning from adverse incidents involving NHS patients - and arriving at a suitable title for the guidance was in itself an interesting exercise!¹⁷ Much of the guidance is aimed at, in the words of Lord Hunt, changing the culture in healthcare from “one of individual blame to one of organisational accountability.” I like to think of this as promoting a *no-blame*¹⁸ or *just culture*¹⁹.

¹⁶ www.npsa.org.uk

¹⁷ After much debate, it was decided to adopt a title that represented the core objective of the content of the publication and gave a clear signal to all, particularly the public and the media, that we are committed to *doing less harm*. And we’re committed in a way that, as Lord Hunt stated, ensures we shift the balance, when things go wrong, from individual [frontline] blame to organisational accountability and, ultimately, perhaps partly attribute causation to national policies. After all, very few, if any, healthcare professionals go to work to deliberately harm patients!

¹⁸ The term *no-blame* can be too easily misinterpreted as implying exoneration and escape for perpetrators of deliberate acts or for those who repeatedly underperform. For this reason, I prefer to use the term *just culture*.

¹⁹ There is significant interest in promoting the concept of a *just culture*. An excellent primer on *Patient Safety and the “Just culture”* written for healthcare executives can be freely downloaded from www.mers-tm.net

Box 2.1 – The ten key requirements contained in *Doing Less Harm*

1. All individuals involved directly or indirectly in patient care are aware of what constitutes an adverse patient incident.
2. The incident is managed and reported to a designated person, or persons, in accordance with local arrangements.
3. All serious incidents are reported immediately to a locally designated person, or persons, and, where appropriate, information on these incidents is fast-tracked to relevant external stakeholders.
4. All reported incidents are graded according to the actual impact on the patient(s), and the potential future risk to patients and to the organisation²⁰, and reviewed to establish stakeholder-reporting requirements.
5. Adverse patient incidents are subject to an appropriate level of local investigation and causal analysis and, where relevant, an improvement strategy is prepared.
6. Incidents graded as red, are reported to the National Patient Safety Agency within 3 working days of the date of occurrence. For category red *adverse events only* (i.e. where serious actual harm has resulted), this information is also reported within 3 working days to relevant Regional Office²¹ of the Department of Health.
7. For all category red incidents, a full root cause analysis is undertaken by the local organisation and reported to the National Patient Safety Agency within 45 working days of occurrence of the incident. For category red *adverse events only* (i.e. where serious actual harm has resulted), this information is also reported within 45 working days to the relevant Regional Office of the Department of Health.
8. Where appropriate, the organisation co-operates with the Department of Health to establish the need for an independent investigation or inquiry, and also co-operates with other stakeholders who might be required to undertake investigations and/or inquiries into the circumstances surrounding a particular adverse patient incident.
9. Aggregate reviews of local incident data/information are carried out on an ongoing basis by the organisation and the significant results communicated to local stakeholders. Aggregate review reports are sent to the National Patient Safety Agency on a quarterly basis.
10. Lessons are learned from individual adverse patient incidents, from local aggregate reviews and from wider experiences, including feedback from the National Patient Safety Agency, other agencies/bodies, and benchmarking. Improvement strategies aimed at reducing risk to future patients are implemented and monitored by the organisation. Where appropriate, local staff learn lessons and change practice in order to improve the safety and quality of care for patients.

²⁰ See figure 4.7 in Professor Rory Shaw's chapter.

²¹ Regional Offices have been abolished and many of their functions have been taken on by the new Strategic Health Authorities. This requirement will, therefore, change. Refer to the latest guidance from the NPSA (www.npsa.org.uk) for information.

Root cause analysis – the key to learning

As Lord Hunt said this morning, the key to learning is *root cause analysis*, which is:

“A structured investigation that aims to identify the true cause of a problem and the actions necessary to eliminate it. It is not about blaming individuals for poor performance. It is about gathering the appropriate information and keeping asking why something happened. It is about drilling down into the underlying management and organisational factors - the ‘systemic’ factors - that allowed the event to occur.”

There is an old Chinese proverb that says that to get rid of a weed you must dig up the root. And so, to eliminate adverse incidents you must establish and eliminate the root cause, or causes.

Root cause analysis is not rocket science. It is a straightforward, systematic process that aims to arrive at *why* an incident occurred and the actions necessary to prevent recurrence. In many instances it need not take significant time and effort to conduct a suitable root cause analysis. At the simplest level, it is about getting the right people together to constructively and openly look at the sequence of events leading up to an incident in order to determine underlying systemic causes.

Figure 2.5 is based on the ‘clinical incident investigation protocol’ referred to in *Doing Less Harm*, which was developed by University College London and the Association of Litigation and Risk Management (ALARM)^{22 23}. It shows the relationship between root causes, immediate causes, underlying causes and contributory factors. Following the causal chain in some instances may well, as the Minister said, reveal some root causes as being policy-related for which the Department of Health or an Agency or other authoritative body might be considered responsible.

²² University College London & Association of Litigation and Risk management (ALARM). *A protocol for the investigation of clinical incidents*. Royal Society of Medicine Press, 1999. Telephone (44) 0207 290 2968.

²³ *How to investigate and analyse clinical incidents: Clinical Risk Unit and Association of Litigation and Risk Management Protocol*. Charles Vincent *et al.* BMJ Volume 320 – 18 March 2000. www.bmj.com

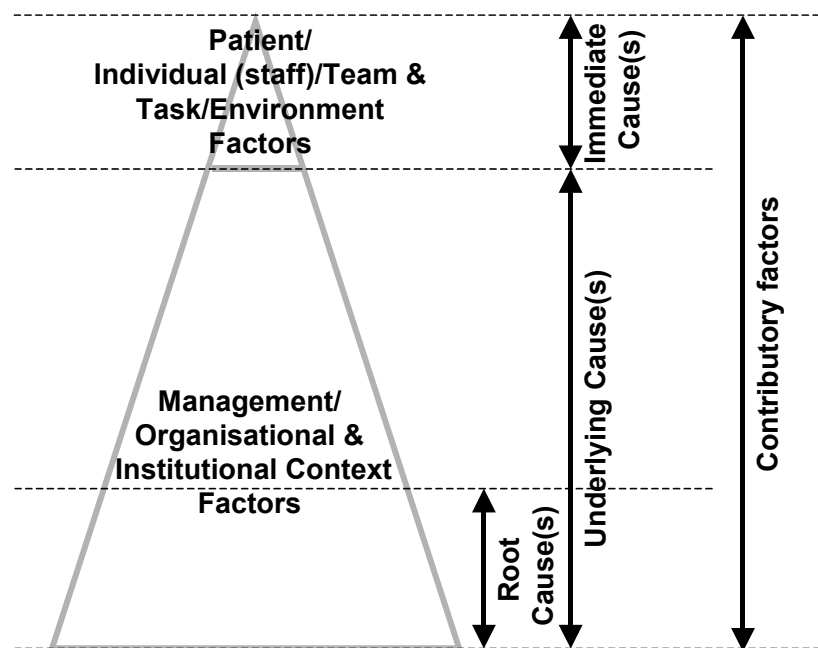


Figure 2.5 Incident causation

Concluding comments

There are many sources of learning in the field of patient safety. One exciting new publication I would particularly like to draw your attention to is the *Journal of Quality & Safety in Health Care* from BMJ Publishing. This is a revamp of the Journal of Quality in Health Care²⁴. Its editor-in-chief is Dr Fiona Moss, who is with us today, and Dr Paul Barach, one of our speakers this afternoon, is co-editor.

I would like to thank ECRI for organising this conference for the Department of Health and for inviting me to jointly chair the day along with Professor Rory Shaw. This is an extremely important event in the ongoing development of the patient safety agenda in Britain and globally. I am only sorry that not all of those who wanted to come to this conference were able to attend. But I'm pleased that there will be a publication produced based on the conference that will be downloadable from the ECRI website²⁵.

In my talk I have outlined out the proposed new national system for learning from adverse patient incidents and set this in the context of the wider NHS Governance and Controls Assurance agendas.

To succeed it is vitally important that we all work together - the NPSA, the Department of Health, other agencies and bodies, international organisations, commercial

²⁴ www.qualityhealthcare.com

²⁵ www.ecri.org

organisations and, of course, the managers and frontline clinicians who are the people out there making the difference - to achieve safer, higher quality care and treatment for patients. Improving safety and quality are major priorities for the Government and the Department of Health, and for the NHS as an organisation and for everyone associated with it. And the National Patient Safety Agency will provide support to NHS organisations and healthcare professionals in making the objective of improving patient safety a real priority. Thank you.

3 Emerging lessons from implementing *An Organisation with a Memory*

Dr Kirstine Knox
Strategic & Scientific Director
National Translational Cancer Research Network
formerly Policy and Project Manager, Department of Health¹

Introduction

It has been a privilege to have been involved in the implementation of *An Organisation with a Memory* (OWAM²) and to see the vision outlined in OWAM translated into a new national system for learning from adverse incidents involving NHS patients. To have led the team that has worked so hard over the past six months to establish evaluations of the new system at selected pilot sites has been particularly rewarding. And it is a great pleasure to see that work realised in the birth and introduction, for the first time here today, of the National Patient Safety Agency.

Overview

I am going to set out today the emerging lessons from the pilots and evaluations, which started in August 2001 and will continue under the management of the National Patient Safety Agency from November 1.

Our preparations for this work began late last year by consulting experts in patient safety both in the UK and abroad. Leading patient safety proponents like Bill Runciman, Paul Barach and Jim Bagian, who are speaking here today, have been particularly generous with their time, advice and information. Our job was to learn from the experts and to establish a detailed specification, with supporting guidance and rollout plan, for a national system for learning from adverse patient incidents. The system will be progressively implemented by the National Patient Safety Agency across the NHS, and across non-NHS organisations providing services to NHS patients, commencing early 2002. We were fortunate to have on our team Stuart Emslie, Head of Controls Assurance at the Department of Health who has previously delivered, and won an award for, a major national incident recording and information system funded by the UK Health Departments and the NHS.

¹ Any views expressed are the author's and are not necessarily those of the Department of Health.

² www.doh.gov.uk/orgmemreport

A blueprint for the new national system

In designing the new national system, we started with the premise that the National Patient Safety Agency would operate a system that demonstrably contributes to improvement in patient safety in the NHS. We wanted to avoid, at all costs, the national system ending up as nothing more than an exercise in data collection. Figure 3.1 depicts the relationship between the Agency and the NHS in terms of information flows.

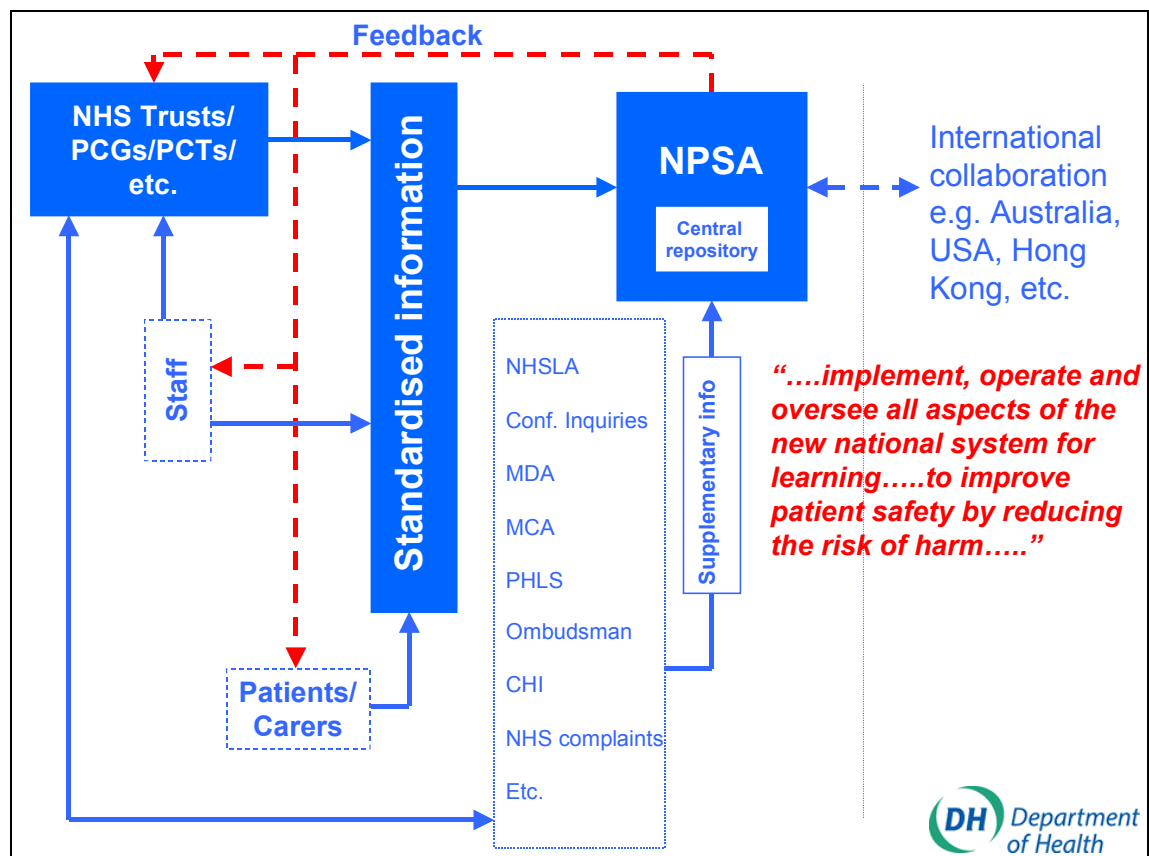


Figure 3.1 Blueprint for the new national system for learning

We wanted the National Patient Safety Agency to assimilate the evidence needed to advise Ministers, the Department of Health and organisations providing services to NHS patients about the key problems and, most importantly, potential solutions. Some of this advice may prove, to some, to be more than a little uncomfortable! If, as many, including Stuart Emslie, allege that the fundamentally key problem that needs addressing is how we *manage* the NHS, then incontrovertible evidence from the National Patient Safety Agency must be used to help improve systems to make a real difference for patients.

Modern policy development and implementation

When we started to design the new national system and to establish the pilots and other evaluations, we were determined to belie the opinion that some - sometimes justifiably - hold of the Department of Health that it is sometimes unable to properly devise and implement policies that the service wants, needs, owns and can use. Modern policy development and implementation needs to be undertaken by individuals and teams with the requisite leadership and enthusiasm for the subject, in addition to detailed technical and policy development and implementation knowledge and understanding. Proper involvement of those at the frontline of healthcare delivery is essential if there is to be a sense of ownership and commitment to the cause.

I think the OWAM implementation team can be justifiably proud of its achievements over the last year. We have used existing building blocks of experience and competence at the frontline. Many of you collect incident reports to the standards already required by the Controls Assurance project³ and by the Clinical Negligence Scheme for Trusts⁴. We have learned from this and what we will be asking you to do next year is to build on what you already have been doing by giving the reports to the National Patient Safety Agency. We will not ask you to replace local IT systems and thus discard the significant investment you have made in both people and technology. Rather, the IT underpinning the new national system is being designed to take the data out of local software systems.

We have extended the principle of learning from local experience to the national and international levels. So the pilots and evaluations build on the knowledge and expertise of other agencies and bodies that collect and analyse information on adverse patient incidents. The Medical Devices and Medicines Control Agencies in the UK are examples. We hope that the National Patient Safety Agency will not supplant other UK reporting agencies, but will, rather, be an over-arching conduit for lessons and solutions to be taken to Ministers and to the NHS. We have collaborated closely with: ECRI, the Australian Patient Safety Foundation (APSF), the Centre for Patient Safety in Chicago, the Hong Kong Hospital Authority, the US Veterans Health Administration, and with other bodies and individuals. Patient safety is a global challenge and I believe that the NHS and our patients can benefit greatly from the growing international collaboration that is represented here at this conference.

³ www.controlsassurance.info

⁴ www.nhs.uk

Procuring the pilot national software for the central repository

Once we had designed the system, and before we began piloting at local sites, we had to decide which software should be used to underpin the pilots of the new national system. For many reasons this was an incredibly sensitive area. Working closely with Kevin Treeby, who is Head of procurement at the Department of Health, and whose pragmatic, common sense approach came to be much valued, we tendered for a supplier under strict European procurement rules. From a shortlist of six organisations – APSF Consortium, Datix, Marsh, Rebus, Safecode and SAS – a selection panel unanimously chose (using very extensive and stringent criteria) the Australian Patient Safety Foundation Consortium. The Chief Medical Officer, Ministers and the Permanent Secretary subsequently approved that decision in August this year.

The APSF Consortium - which comprises the APSF⁵, the UK company Safecode Ltd.⁶, and the Australian company Clinical Risk - has been working since August to install software and systems which will allow reports from the pilot sites and other Trusts to be transferred electronically to the central *repository*. In the meantime, until the issues around electronic reporting are resolved, we have been collecting information from pilot sites manually. Some examples of near misses and adverse events collected in the few weeks we have been up and running are briefly described below.

Examples of near misses:

- ❑ *Report 1:* the air supply to ventilators in the ITU was cut off without warning by building work that was being done next door. All the children then had to be ventilated by hand.
- ❑ *Report 2:* children's weights were mixed up prior to anaesthesia because the records were disorganised. "This happens all the time."
- ❑ *Report 3:* no laboratory staff were available to process a very urgent blood sample; all the staff were at a meeting.
- ❑ *Report 4:* an ambulance was unable to find the hospital labour suite. "This kind of problem was reported ten years ago."
- ❑ *Report 5:* a records problem lead to the potential amputation of the wrong finger; incidents like this have been seen over and over again.

⁵ www.apsf.net.au

⁶ www.safecode.co.uk

Examples of adverse events

- ❑ *Report 1:* a heroin addict died of an overdose, but might have been saved had the paramedics been carrying Narcam. This case demonstrates important lessons. The root cause of this event was identified quickly and easily just by getting the right people round a table. A single case can highlight a problem about which GPs and paramedics are aware but for which no national protocol exists. If the recommendations in the report are taken up either by the Department or the National Patient Safety Agency then changes in national and local policies will follow.
- ❑ *Report 2:* despite regular observations, a mental health in-patient was found to be dead when examined closely. The (unconfirmed) root cause was the absence in the protocol of direct contact with the patient during observations. Hence people only looked through the observation window.
- ❑ *Report 3:* a mixed-up theatre list caused the wrong patient to be given an ophthalmic skin graft.

Our preliminary work, from which these examples have been drawn, has demonstrated that there are preventable adverse events in primary care, mental health services and the acute sector. Furthermore near misses outnumber adverse events by the amounts predicted by Heinrich - the pioneer researcher into industrial accidents⁷. The preventive actions that can be taken by clinicians and managers prevent or minimise the likelihood of recurrence and are simple and inexpensive. And the Narcam case demonstrates the potential for changes in national policy - in this instance, to prevent death by overdosing. However, what must be emphasised above all else is that these are examples for which *the system* and not frontline healthcare professionals is responsible. As Lord Hunt and Stuart Emslie have stressed today, systems are the responsibility of management and we need to better *manage* healthcare.

The pilot site communities

The OWAM project has twenty-six pilot sites in England, including one private healthcare organisation, BUPA⁸, which are grouped into three communities: West Midlands, Northern & Yorkshire and London. The term *community* is used rather than *region* because acute, primary, mental health and ambulance trusts all participate. It would have been easier for us to involve only acute trusts where incident reporting has been well established for several years, but much less valuable from a learning viewpoint. The London community is slightly different from the others because it has major hospitals outside London such as Addenbrooke's. A further two pilot sites have been proposed in Wales.

⁷ See *An Organisation with a Memory* – www.doh.gov.uk/orgmemreport

⁸ www.bupa.co.uk

How we are supporting the pilot sites

We have been supporting the pilot sites through a range of co-ordinated activities. For example, OWAM team members have visited sites every three weeks since June. This has contributed substantially to system design, guidance formulation and the establishment and operation of the pilot activities. The Department has now issued the draft guidance *Doing Less Harm*⁹ and we hope that through our continued interaction with frontline staff that the guidance reflects rather than supplants frontline experience.

We have a very basic website www.npsa.org.uk, which is now operational and you'll note that we have, at least for the purposes of the piloting activities, branded the NPSA differently to a conventional Special Health Authority. This was to give it a sense of individual identity in line with the objective outlines in the OWAM report that the new national body should be perceived to be independent. Pilot sites members will be sent an interactive CD-ROM that has a general introduction to patient safety for all NHS staff. There is a communications tool - freely downloadable from the NPSA website - that communications leads in healthcare organisations can use to help them manage the communications aspects of a serious adverse incident. This tool, which has been much welcomed, is to help the management of the communications maze that erupts when there is a serious adverse incident. We have organised national, regional and specialist events. Examples of the latter include the steering groups for system evaluation, primary care and mental health. There was a successful series of one-day course on root cause analysis events that we hope the National Patient Safety Agency will repeat next month. And finally, we have provided grants of £5,000 to all pilot sites for them to spend on anything that will help them help us to deliver the new national system.

How the pilot sites are helping us

The invaluable help that the pilot sites have been giving in return has enabled the OWAM team to achieve Departmental objectives within very tight timescales. They helped develop and test the *Doing Less Harm* guidance by evaluating the risk grading matrix, which is based on a similar matrix previously developed and tested by Maria Dineen, the efficacy of the minimum data sets, and the effectiveness of the proposed overall national system. They have helped optimise means of feedback that will be crucial to the success of the National Patient Safety Agency. For example, we plan to introduce, very shortly, a text-messaging service to keep risk managers apprised of serious incidents, relevant to their organisations, that happen elsewhere. And we are running, in conjunction with Clinical Risk (part of the APSF Consortium) introductory root cause analysis training events as a precursor to the development of detailed root cause analysis guidance, which is planned to be issued by December 2001. Feedback

⁹ Available on the NPSA website – www.npsa.org.uk

from the pilot sites will be essential to the development of relevant root cause guidance, and for the development of a national training strategy for building capability across the NHS in root cause analysis techniques.

Some examples of feedback from pilot sites

I am very proud of what we in the OWAM implementation team have achieved. In the face of extremely tight timescales we have delivered, and we have done so in a way that should make a difference. However, for me – someone who has never been at the frontline in healthcare – what has been illuminating has been to see the work of those who are first hand. Here are some of their comments:

- ❑ *From Sarah Dugan, Risk Manager for South Birmingham Mental Health Trust: “A significant challenge of being involved has been the rapid timescales of the project falling across the summer months. One of the real positives of being involved is that the pilot site representatives have been consulted and involved at every stage and as such the project has evolved. We have felt that we can make a difference to this process and influence its future. Comments from the pilot sites on draft documents have led to real changes in practice for the future implementation of the system.”*
- ❑ *From Jean Carter, Assistant Director of Nursing Practices (Legal/Risk) for South Tees Acute Hospital NHS Trust: “The pilot has hosted a great networking opportunity for members. Resources and experience are being shared. The pilot organisations are discussing opportunities for both benchmarking and sharing good practice. The potential of a District/Regional Risk Forum has been suggested by a number of members to facilitate joint working. Overall no problems from any of our pilot sites. Members have been impressed by the true consultation that has taken place with the OWAM team members. The focus groups for Primary Care and Mental Health will be of great benefit.”*

Some key concerns

Feedback has also revealed concerns that the National Patient Safety Agency will need to act on rapidly to ensure its credibility with the NHS. Here are some examples:

- ❑ “There is a definite blame culture in the NHS, which needs to be eradicated.”
- ❑ “How will confidentiality and protection from disclosure be assured?”
- ❑ “We need to see real benefits for patients, quickly.”
- ❑ “How do we deal with the perceptions of the media and the public?”
- ❑ “We are looking for solutions not more problems.”
- ❑ “What is most needed from the NPSA is vision and leadership, not additional bureaucracy.”

Emerging lessons

The emerging lessons from the pilots and evaluations have both local and national implications. It is clear that successful policy making at the highest levels requires the policy maker to also be the policy implementer. Furthermore, the participation of frontline NHS staff is essential. Even the first few incidents in the acute, primary care /community and mental health sectors have been very instructive. Root cause analysis is not rocket science and often may be conducted very effectively by getting the right people round the table to consider why something went wrong in a no-blame environment. The underlying causes are system and not personal failures that often may be remedied by simple managerial actions, and can quickly highlight the need for changes in national policy. In short, I think we have learnt how to make policy that is both relevant and useful.

And finally two advance notices. The first is to expect lessons from current research into the barriers to reporting and good practice – co-ordinated on behalf of the Department of Health by Professor Richard Lilford at Birmingham University - to be available from the Department later this year. The second is that we shall be learning from clinical negligence litigation information held by the NHS Litigation Authority and others. Significant work has been undertaken by the NHS Litigation Authority, Medical Defence Union, Medical Protection Society and by legal firms such as Capsticks. These organisations have said that they already know the root causes of adverse patient incidents resulting in litigation. All have agreed to supply their findings to the National Patient Safety Agency for distribution for the benefit of healthcare organisations and patients. And as part of the Department's patient safety research, work has been commissioned to analyse, in some detail, claims information held by the NHS Litigation Authority as part of its Clinical Negligence Scheme for Trusts (CNST).

Concluding remarks

Just six months have passed between the publication of *Building a Safer NHS for Patients* and the birth of the National Patient Safety Agency. In that time we have made significant progress on implementing the Government's patient safety agenda through the pilots and other evaluations. I want to give my personal thanks to the OWAM team and to the pilot sites for their enthusiasm and exemplary work. We look forward to seeing the National Patient Safety Agency use and build on the work already carried out by the Department of Health. I wish the NPSA every success in making a real contribution to improving patient safety in the NHS. Thank you.

Acknowledgments

The OWAM Implementation Team comprises, in addition to myself, Marcia Fry, Stuart Emslie, Louis Rieunier, Kevin Hall, Mike Paskavitz, Julian Furbank, Maria Dineen, Lesley Stuart, Jenny Deedman, Allison Bailey, and the APSF Consortium, in particular Ray Blight and Bob Lowe.

4

Introducing the National Patient Safety Agency

Professor Rory Shaw

Chairman

National Patient Safety Agency

Introduction

My interest in patient safety began 25 years ago with a salutary lesson when I was a houseman on a medical ward. The ward had the classic Florence Nightingale layout with a small treatment area - by the doors - where a very competent staff nurse was preparing medications at the end of the evening visiting hour. The following figure shows a modern but very similar treatment room.



Figure 4.1 A modern treatment room

It was about 8.45 pm and many of the relatives popped into the treatment area to ask the nurse questions as they were leaving. These she answered courteously whilst preparing vials and filling syringes of medications such as antibiotics and cytotoxics that I was later to administer by intravenous bolus injection. Despite my tiredness - we had in those days to work a 120-hour week - I decided to check the medications in the kidney dish. I then noticed that one of the cytotoxics had been made up in 100%

potassium chloride: the patient would have died at the end of the needle. The nurse was shocked and stunned when I later told her of this near miss which I then realised was happening all over the country. No one was at fault but good, competent people were working in a system that predisposed to adverse events and near misses. “Here but for the grace of God go I - and my patient” has been whispered at some time by most clinicians. I am therefore very pleased that the Government has established the National Patient Safety Agency to help get to grips with this problem.

The Agency is a Special Health Authority, has a Chairman - myself - and joint Chief Executives - Sue Osborn and Susan Williams - who started work on October 1. Many of the Board members are present today and we have our first board meeting next week. Our goal is straightforward: to improve patient safety by reducing medical error.

How large a problem is medical error?

How large a problem is medical error? If we go beyond our personal experience and anecdotal evidence then there are many useful studies among which that by Charles Vincent¹ is exemplary. He reviewed more than 1,000 records and found that:

- 10.8% of patients had experienced an adverse event
- half of these events were preventable; and
- a third of adverse events led to either serious complications or death.

Figure 4.2 summarises key data about adverse events in the NHS in terms of patient numbers, wasted money and wasted lives.



Figure 4.2 Key data on adverse events in the NHS

¹ Vincent, C. et al – *Adverse events in British Hospitals – preliminary retrospective record review*. BMJ 2001;322:517-519

Improving patient safety – the systems approach

We have already heard this morning, and shall hear again later today, of accumulating evidence that poor patient safety is a systemic problem in healthcare throughout the world. The management of risks in the NHS has only been recognised as an important management and clinical function within the last few years. However risk management expertise has existed for much longer outside healthcare. There appear to be two approaches to risk management. We can use the *People Approach* whereby staff are first trained and then threatened - with the General Medical Council for example - in an attempt to make them act safely and those that fail are punished.

Alternatively we can use the *Systems Approach*, which rather than blame the individuals, asks three questions. Why do we need to do this? How can we make the process less error prone? What are the barriers to error? James Reason is a British academic psychologist who is pre-eminent in research on the systems approach and has proposed the 'Swiss Cheese Model' shown below². The idea is that any organisation has several defensive barriers that are designed to and usually do prevent accidents. The inevitable imperfections in all barriers are represented by holes and an accident happens when through force of circumstances all holes are aligned.

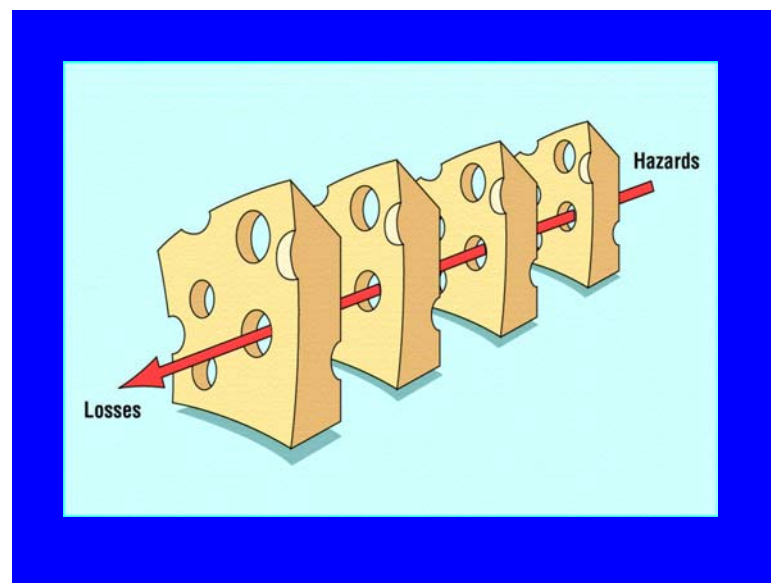


Figure 4.3 The Swiss Cheese Model of accident causation

² E.g. see Vincent, C. and Reason, J. *Human factors approaches in medicine in Medical Mishaps – Pieces of the Puzzle*, edited by Rosenthal, M., Mulcahy, L. & Lloyd-Bostock, S. Open University Press. 1999. ISBN 0-335-20258-6.

Active failures and latent conditions

Reason has proposed that system barriers fail in two ways. There are *Active Failures* - slips, lapses, fumbles, mistakes and procedural violations. There also *Latent Conditions* that converts into error-provoking conditions. For instance accidents are likely if staff work under intense time pressure with poor equipment or perhaps using unworkable procedures. Too many inexperienced and/or inadequately trained staff is another latent condition for failure. System failures are also found in the home. All of us have burnt toast usually by misadjusting the controls - an active failure - but an electrical fault in the toaster is a latent condition that can also burn the toast and much else besides. Figure 4.4 helpfully shows that the combination of corporate culture and managerial decisions sustain conditions that routinely produce both errors and violations of protocols. Whether an incident happens or not is merely a matter of chance when all defensive barriers are simultaneously/successively breached.

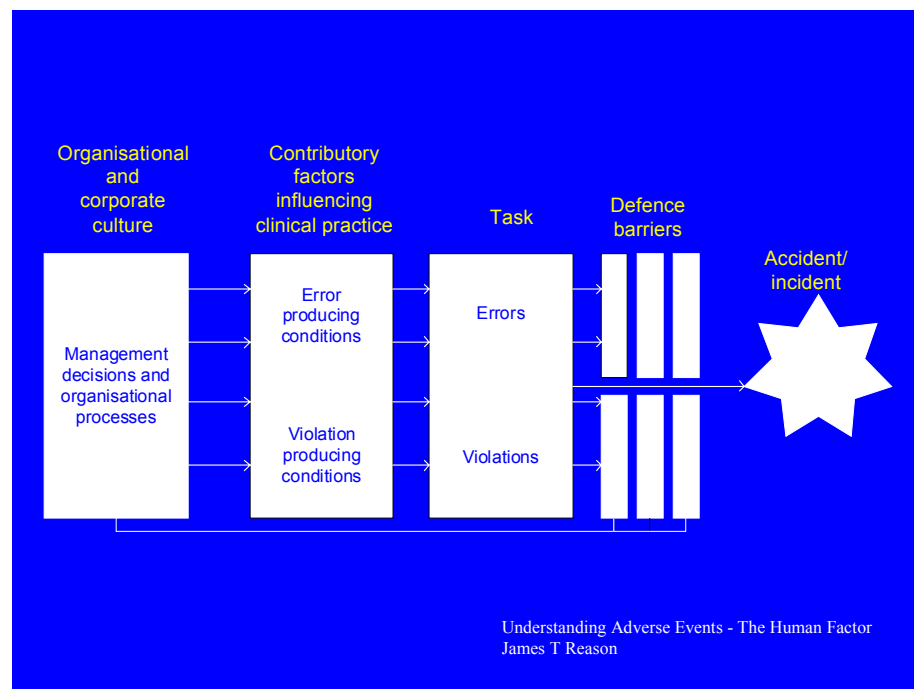


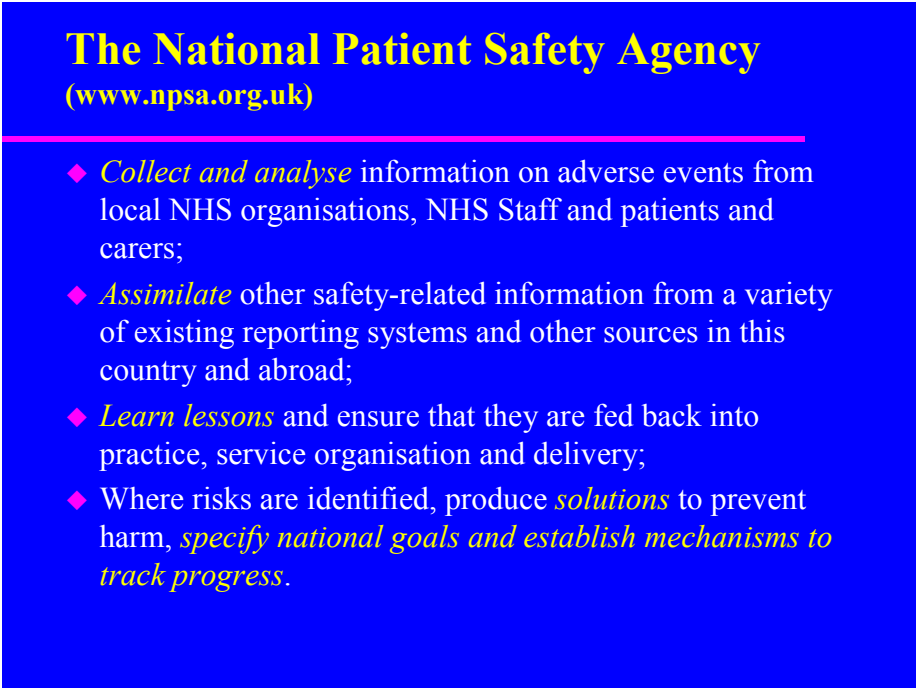
Figure 4.4 The relationship between culture, decisions and incidents

Using figure 4.4 we can ask three questions that will assist the root cause analysis of incidents.

1. What happened?
2. What were the predisposing conditions?
3. What were the failures in the defence mechanisms?

The National Patient Safety Agency: role, aims and objectives

The National Patient Safety Agency will build on Reason's academic analysis once we have begun to collect national data about incidents in the NHS. I have talked to many people over the last three months in many NHS Trusts across the country and have found that much is happening in risk management, incident reporting and incident investigation. We must build upon this and not distort or disturb valuable local databases. We need to learn national lessons that can then be applied locally. Thus the best safe-practice in Truro, for example, can then be transferred to Barnstaple without the latter having to re-invent the wheel. I envisage that the National Patient Safety Agency will be very much a learning and not a policing agency. Our mission is to practice safer and therefore better healthcare for the benefit of patients. Here is a summary of the overall agency objectives.



The National Patient Safety Agency
(www.npsa.org.uk)

- ◆ *Collect and analyse* information on adverse events from local NHS organisations, NHS Staff and 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 that they are fed back into practice, service organisation and delivery;
- ◆ Where risks are identified, produce *solutions* to prevent harm, *specify national goals and establish mechanisms to track progress*.

Figure 4.5 The overall objectives of the National Patient Safety Agency

Working with others

So many people have either good ideas or locally implemented solutions for improving patient safety, which we must find, evaluate and arrange to be used throughout the service. I have summarised in figure 4.6 the huge communications network that we must establish to achieve incident analysis, solution finding and solution implementation.

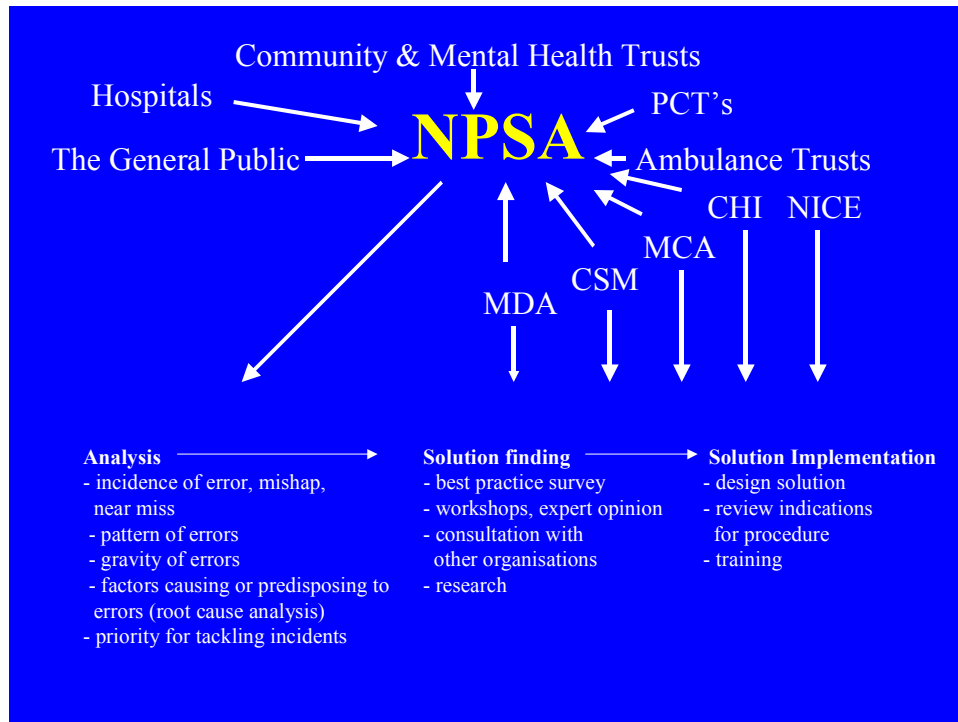


Figure 4.6 The NPSA communications network

The National Patient Safety Agency will work very closely with, for example, the Medical Devices and Medicines Control Agencies who have similar but specific responsibilities. However improved patient safety needs the collaboration of other agencies and organisations both within and outside Government. For example, there is a huge amount of creative thinking in the Royal Colleges; collaboration and creativity are the key to obtaining solutions.

The new national systems for learning from adverse incidents

The precursor to better patient safety is a national database of incidents, which will also be discussed by some of the later speakers. Two of its building blocks that we now have in place are national definitions of incidents and a universal generic method of grading the severity of incidents in relation to actual harm and potential future risk.

An adverse patient incident is *any event or circumstance that could have or did lead to unintended or unexpected harm, loss or damage*. If the incident caused harm, loss or damage then it is an *adverse event*. If it did not then it is a *near miss*. We have already heard of the importance of assessing the gravity of the incident and figure 7 shows a five-by-five matrix to grade severity against the likelihood of recurrence.

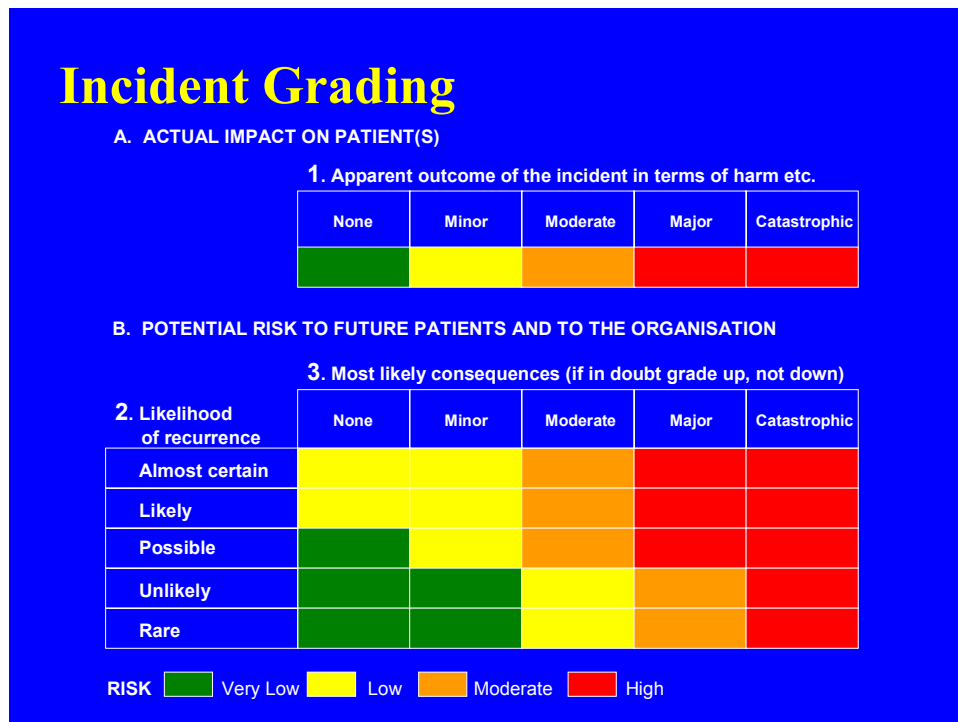


Figure 4.7 A risk-based incident-grading matrix

Although the matrix appears simple on the surface, much work must be done to ensure that it is useful both locally and nationally. The Government wants information about the scale and gravity of a problem across the NHS but the matrix must also be a practical tool for Trusts of all kinds. The needs and environment of a rural Primary Care Trust are very different from those of a large multi-site London teaching hospital. We at the National Patient Safety Agency need a continuing dialogue with colleagues throughout the service to make this matrix universally useful for incident grading. We must also recognise that incident investigations must be matched with and prioritised against local management resources.

The third building block of the national incident database is the minimum data set, which has yet to be completed. What are we going to ask from you? Figure 4.8 outlines the underpinning questions in the minimum data set from *Building a safer NHS for Patients*³ and note that none of the questions begin with 'Who?' because the systems approach does not assign individual blame. The questions begin with 'What?', 'Where?', 'When?' 'How?' and 'Why?' and the answers will address such factors as: orientation/training, patient assessment processes, staffing levels and equipment condition.

³ www.doh.gov.uk/buildsafenhhs

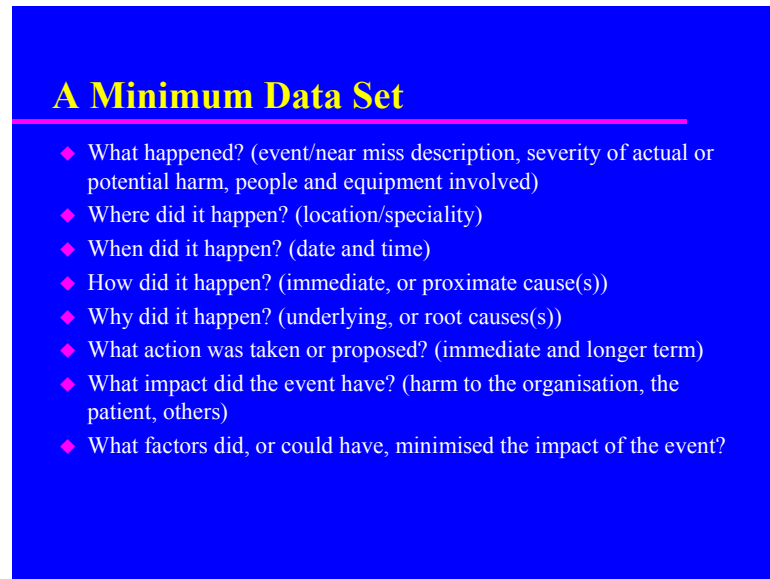


Figure 4.8 Minimum data set for adverse patient incident reporting

Reason's model of system failures suggests that the root causes of incidents are analogous to the plot of a story and the obvious conclusion is that changed outcomes require changed plots rather than new staff. This has to be a core principal of our work. What can be done to remove the problem once the causes have been identified? There are four possible generic courses of action. We could design out the problem; misleading drug labels are good candidates for redesign to prevent drug errors. We could completely change the way a particular service would be undertaken. We could train people; this might range from general training for all staff to intensive targeted training for very specific occupations. For instance only a limited number of surgeons in the NHS have been trained and are thus allowed to undertake cardiothoracic surgery. Such a group might receive additional targeted training. We could rehearse for specific emergencies. The advanced life-support courses have greatly improved the efficacy and safety of resuscitation. Finally we could change healthcare culture so that all staff become more aware of system failures with ensuing continual changes in organisational practices to minimise patient risk.

Communication, communication, communication

I have described how errors are caused by *Active Failures* and *Latent Conditions* and every step in a healthcare service is prone to errors. Research has shown that there are more than a hundred steps from a patient visiting the GP to the completion of an ENT operation. What then is the likelihood that this patient may receive a service that is entirely free from errors? The answer is surprisingly low even if for every 100 steps of the same kind that the staff perform, ninety-nine are perfect. What the patient expects is that all steps are performed perfectly but the more steps in the sequence the lower is the likelihood of an error-free service. If we could treat this problem as similar to that

of calculating the chance of winning the Lottery then the patient only has a 60% chance of a perfect sequence of the first 22 steps. Not every error will cause an adverse incident but all will degrade quality and if noticed by the patient - and relatives - will diminish the reputation of that part of the NHS. Some errors have the potential for catastrophe. We need to find mechanisms to check that previous steps in a process have been completed correctly. How can we check for the misidentification of the patient when blood is sampled prior to a transfusion? We must think creatively about methods to check complex procedures and not be complacent about the small proportion of errors that may have been achieved in individual steps. Communication is going to be critical. The National Patient Safety Agency faces the task of communicating with huge numbers of people to improve safety but good work is already being done by other agencies in this field from which we should learn. Overleaf you will find an excellent example - one of the 'One Liners' from the Medical Devices Agency.

Education and training

Training is one of the solutions and the NHS already does much but the National Patient Safety Agency needs to promote training that improves safety and risk awareness. Some simple but very effective safety actions are known but insufficiently used. For example too few doctors and nurses wash their hands between patients even though this is known to reduce the incidence of nosocomial infections. A change of NHS culture is needed and there is now leadership at the top embodied in the statement below from the NHS Plan and reinforced by the Minister's presence and speech today.

"All those providing care will work to make it even safer, and support a culture where we can learn from and effectively reduce mistakes."

The NHS Plan, July 2000⁴

Concluding remarks

In conclusion we must accept that to err is human and so the objectives of the National Patient Safety Agency are to reduce the frequency and the severity of errors. The Agency will provide data, develop risk-reducing solutions and will promote a risk-conscious culture. Thank you.

⁴ www.doh.gov.uk/nhsplan



MEDICAL DEVICES ONE LINERS

ALL medical devices can fail but an increasing number of incidents which result in significant mortality arise out of user/device interface problems or because of poor practices.

The aim of this news-sheet is to detail briefly some of the problems in an attempt to make users more aware of what can go wrong.....it is all too easy to take equipment for granted.....

Stripped To The Bone

MDA has received an unusual report of an incident where the patella button component of a total knee replacement was inadvertently dislodged by a vein stripper.

All surgeons involved in vascular work should take care when stripping veins in the presence of a total knee replacement implant.

Silent Witness

MDA has learnt of a hospital where it was routine to place adhesive tape over the loudspeaker of an alarm on a critical care monitor. The hospital has now taken steps to ensure that staff discontinue this practice.

Alarms are there to alert clinical staff of a change in the patient's condition and must never be muted in this way.

Steamed up!

MDA has received a number of reports of patients who have had to be recalled for vaginal examination because vaginal speculae had not been adequately sterilised following cleaning.

MDA recommends the use of steam sterilisation at 134°-137° C for 3 minutes rather than dry heat sterilisation (hot air ovens) because it is quicker, more effective and more controllable. See SAB(94)23: Dry heat sterilisers: Purchase, Maintenance and Use; DB9605: The Purchase, Operation and Maintenance of Bench-top Sterilisers.

Food For Thought

There is a risk of microbial contamination of enteral feeding sets. For vulnerable patients (e.g. immuno-suppressed and cancer patients), the risk minimised by the use of sterile feed and single-use components. In other circumstances, where reusable products are used, particular care is necessary in following the cleaning, decontamination and change intervals recommended by the manufacture.

Please let us know if you have experienced any problems or confusion over the choice or use of enteral feeding sets

Under Pressure!

MDA has received a number of reports of pressure or necrosis or blistering resulting from the use of tape to hold the pulse oximeter probes in place for prolonged application.

Do not use tape to hold the probe in place unless specified by the manufacture. Check and resite the probe in accordance with the manufactures' instructions or more often if indicated by circulatory status and/or skin integrity.

Invisible Ink

CTG and ECG charts printed on thermal paper only remain legible for five years.

For longer storage (which is required by HSC 1999/053), alternative means of storage should be considered, e.g. photocopy, microfilming, electronic or optical storage.



Published by the Medical Devices Agency - an executive agency of the Department of Health. We investigate problems arising from the use or misuse of medical devices when health or safety have been put at risk. If you would like to discuss or report an incident or request any of the publications referred to above, contact us on 0207 972 8123 (medical), 8128 (nursing) or e-mail address: clin@medical-devices.gov.uk

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Figure 4.9 Medical devices 'one liners'

Part II – Case studies and examples from America and Australia

5

Lessons from the USA

Paul Barach, M.D.
Center for Patient Safety
University of Chicago

The paradox of American healthcare

The paradox of American healthcare is that there is a scarcity of safety amidst an abundance of highly trained practitioners, modern technology, biomedical research and dollars. If American healthcare is likened to a manufacturing company then it would have gone bust long ago because for many years it has not been delivering the highest quality and safe care that patients deserve and need.

Some time ago I made a mistake similar to that which Professor Rory Shaw described this morning - except that I injected the contents of the wrongly-labelled syringe of Epinephrine. The patient had a cardiac arrest and ever since I check both the drug and dose in the syringe several times myself before administration.

Question What is the lesson?

Answer Do not trust anyone including yourself because risks arise through making and acting upon assumptions about your senses, skills, and knowledge.

It is very humbling to realize that you can be fooled by your own eyes and ears. However the starting point of safer healthcare delivery is a no-blame work culture where one can freely admit mistakes so that everyone can learn from them. Figure 5.1 suggests just how far we are from creating this culture.

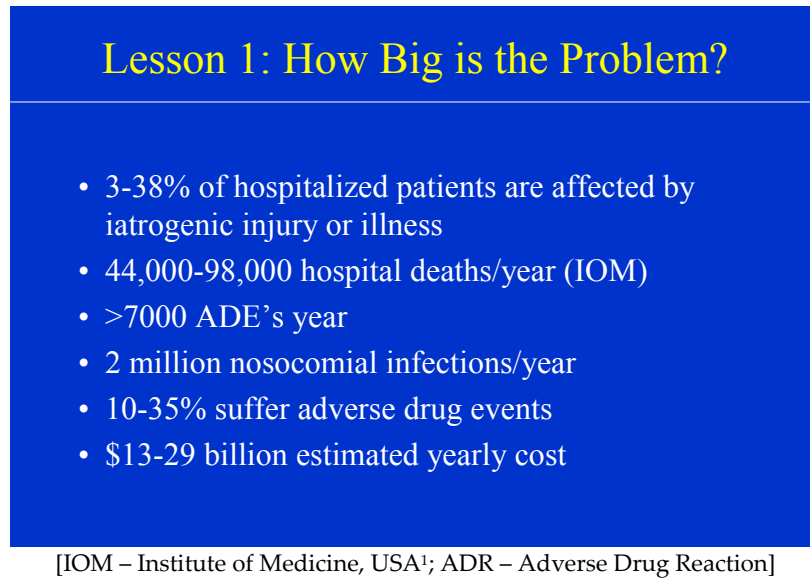


Figure 5.1 How safe is American healthcare?

Teamwork, patients and safety

My military experience in special-forces units taught me about real teamwork in which the team's goals are put above individual needs and the individual's ego has no place.

Questions

1. *Does your hospital have Operating Room (OR) teams or are they just groups of individuals that occupy the same real estate?*
2. *Are your OR teams like highly performing SAS teams in Afghanistan?*

My view is that people in healthcare have no idea about high performance teamwork and one reason is that learning to be a team is not part of the education of healthcare professionals - physicians, nurses, pharmacists etc. Change at work is directed at the individual who is either rebuked, or retrained or removed and the team as a complete unit is ignored. This is one major reason why healthcare cannot deliver safe patient care. Allow me to echo the words of one of my patients who defined patient safety as "the ability and interest of the patient to leave and return home in one piece²."

¹ *To Err is Human* – www.nap.edu/readingroom and www.iom.edu

² There is an interesting book by two US authors, Sheldon P. Blau M.D., and Elaine Fantle Shimberg titled '*How to get out of the hospital alive – A guide to patient power.*' 1998. ISBN 0-02-862363-0

What is Patient Safety?



In its simplest form, patient safety is freedom from accidental injury while receiving healthcare services.

The safest healthcare environment is one where clinical care is measured and managed and desired clinical outcomes are achieved

*The objective –
to splice safety into the genome of
processes of care and into the healthcare
system at all levels.*

Figure 5.2 Patient safety: definitions and objective

Question How can we splice safety into the healthcare genome?

Answer Replace the fragmented approach by teamwork and invite the patient into the system.

Quality and safety

The Institute of Medicine in the USA has recently identified six dimensions of quality in which patient-centred safe and effective healthcare is prominent³.

6 Dimensions of Quality

- Safe
- Patient Centered-customer value and expectations
- Effective-Evidence based practices and outcomes
- Timely
- Efficient
- Equitable

IOM. Crossing the Quality Chasm. National Academy Press, 2001.

Figure 5.3 Dimensions of quality

³ IOM – Crossing the Quality Chasm – www.nap.edu/readingroom and www.iom.edu

Questions

1. Have all your clinical and administrative procedures been devised with patient benefit uppermost in mind?
2. Are you willing to discuss the uncertain results of clinical procedures with patients?
3. Are you worried that such a discussion might disturb the patient or might show you up to be a weak practitioner?

Highly performing manufacturers achieve the six sigma quality standard ⁴; six sigma means that 99.99966% of products are perfect. Anaesthesia lies between three and four sigma because safety and quality have been targeted for about twenty years. However the rest of healthcare only achieves at best between one and two sigma. This is on a par with baggage handling at airports, the Inland Revenue Service and food preparation in poor restaurants.

Could gender, race and background differences affect the culture of safety in your organization? I wonder if quality and safety would be more readily embraced if there were more women leaders in healthcare? Maybe we need more sensitive, listening and consensus working in healthcare, traits more traditionally associated with women.

One measure of the lack of healthcare safety both here and in the US is the comparison of accidental deaths in the healthcare with those in activities that are thought to be high risk or at least have a high media prominence - driving, the workplace and aviation. Figure 5.4 makes it clear that adverse medical event fatalities far exceeds other high-risk activities such as car crash fatalities.

⁴ For a detailed consideration of the application of 'six-sigma' in healthcare, see *The Past, Present and Future of Health Care Quality* – www.tuvm.com/services/fitness/articles/merry.pdf

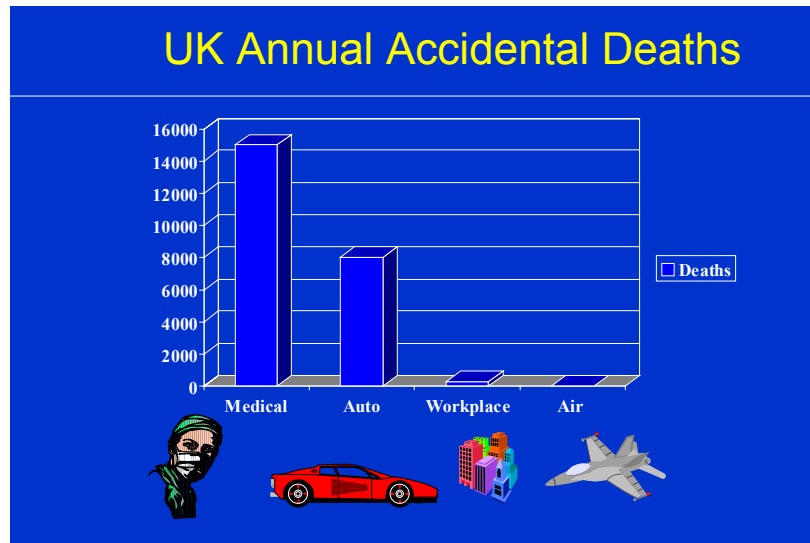


Figure 5.4 UK accidental death by activity

The importance of the six dimensions of quality is that they remove the underlying financial motive of quality typified by the view that the cheapest drug of its type in the formulary should always be used. Safety delivers the financial punch and the potential savings are huge. Stuart Emslie has already said this morning that an estimated 7% of the NHS budget (at least) is diverted to deal with the effects of adverse patient incidents.

Defining medical error and the value of near misses

Heinrich, a pioneer in research on industrial accidents, found that for each type of accident that caused a major injury there were 29 similar accidents that caused minor injuries and 300 where no injury resulted. I find the 'iceberg' model of accidents and errors very useful as it helps to illustrate how systems of definitions have made comparisons between different research studies so difficult. Why do the American and Australian healthcare services appear to have very different frequencies of accidents and errors? Is this due to national characteristics or different organisational cultures? No. The reason is that accidents and errors were defined differently in the respective research studies. The Australian and American error/adverse event rates are similar to one another when common definitions are used. There is now an international project to agree on the categories of accidents that range from those that cause deaths to those in which no injuries are caused. The iceberg model in figure 5.5 is adapted with permission from Hal Kaplan.

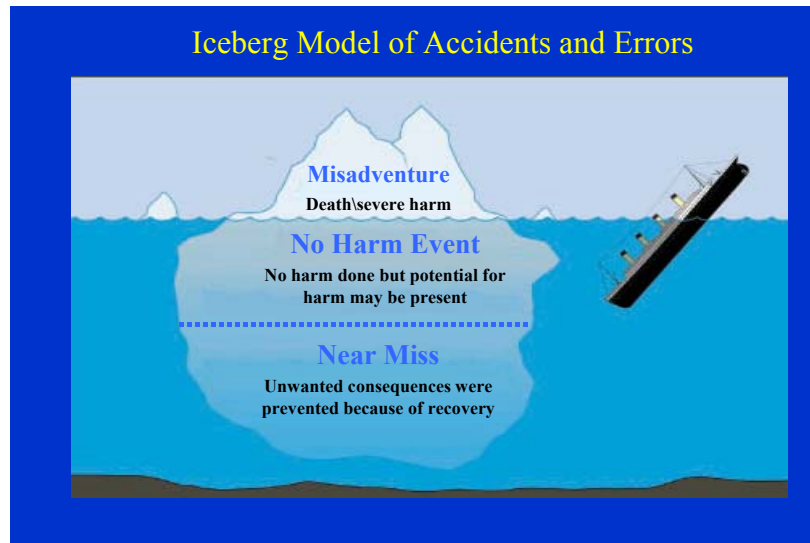


Figure 5.5 The Iceberg Model of accidents and errors

We can focus on rare events, but why not learn from near misses, which are several fold more common. Look upon these as a free resource of information from which no harm and no guilt results. Because near misses are so much more common than serious adverse events your analysis of trends will be both easier to undertake and will encounter fewer statistical problems.

Case study

The indications to give concentrated potassium chloride are very rare except in cardiac surgery. Yet two years ago there were 50 reported deaths in the state of Massachusetts alone, caused by the administration of this drug. The removal of concentrated potassium chloride from formularies would have been speedier had there been an examination of relationship between the rarity of indications to use this drug and the (obvious) large of number of near misses.

The prerequisites of an adverse event

Reason's model of accident mechanisms in organisations, which I have modified in figure 5.6, shows that the prerequisites of an adverse event are always present. Unless safety and reliability are re-accomplished over and over the chance will rise continually that the defences in the organisation will be breached. Safety and reliability are not bankable; each extra day in hospital increases the chance that the patient may come to harm.

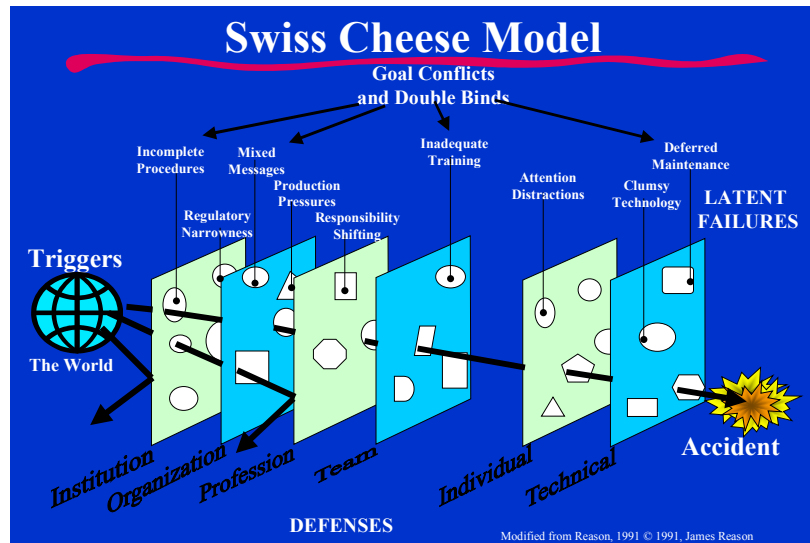


Figure 5.6 The Swiss Cheese Model (modified) of accident causation

The prerequisites of safe healthcare

Only a change in culture will create and sustain safety. Reason has emphasised that organisational cultures are shaped by both shared practices and collective learning. The culture of safety needs to be: knowledgeable, just, flexible, capable of learning and able to encourage reporting.

Case study

An obstetrician at Beth Israel Hospital in New York had carved his initials on the belly of a woman patient⁵. No action was at first taken by the hospital management until the case was publicised by two newspapers and after a further delay the obstetrician was fired but then was employed by another hospital.

⁵ See http://www.ahcpub.com/ahc_root_html/hot/archive/hrm0300.html

Questions

1. How do you think the New York public viewed the way in which this criminal act was treated by the authorities?
2. How accountable are your physicians to their colleagues (nurses, pharmacists and technicians)?
3. What kind of an organisational culture exists in your workplace?
4. When there is a reported incident (whether serious or not) does the organisation:
 - a) Shoot the messenger?
 - b) Write a new rule?
 - c) Understand the broader implications and strive to learn from the event?

In response to the fourth question, the first culture is pathologic, the second bureaucratic whilst the third is a learning generative culture. Healthcare organisations are a messy mixture of all three cultures.

Reporting is a delicate balancing act between required accountability to one's employer (which may result in disciplinary action) and open communication, which needs voluntary, confidential reporting without ensuing recrimination.

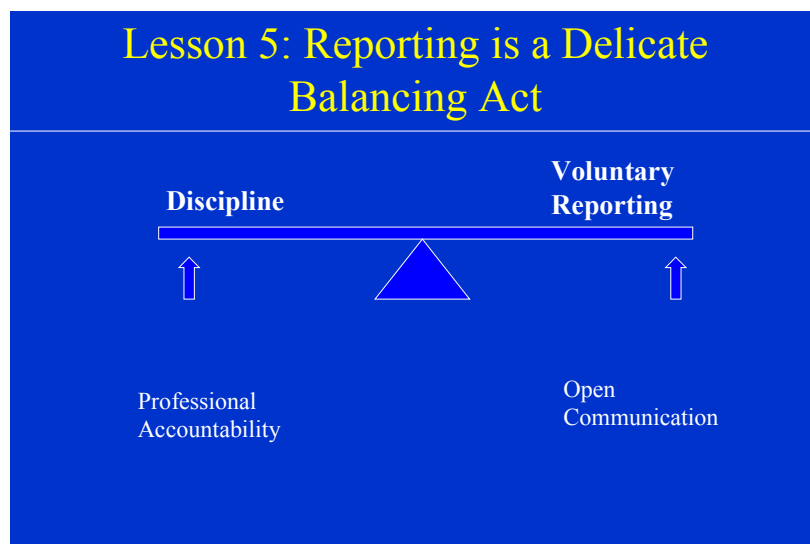


Figure 5.7 Reporting incidents: accountability versus voluntarism

This balance recognises that people hide rather than disclose if they believe that their jobs and reputations will suffer. The myth of perfectionism often marches hand-in-hand with a punitive culture that focuses on fault, assigns blame and then administers punishment. Sometimes the workplace culture is more complicated than this. My own hospital proclaims that 'We have a wonderful reporting system and a learning culture', but the nurses will say 'Three strikes and you are out'. The adverse consequences of a punitive culture are well known but often ignored. The culture encourages people to hide their mistakes, obscures the opportunity to identify latent factors in accidents and focuses on blaming individuals who are then either retrained or retired.

Case study

Perhaps the biggest stimulus to better adverse event reporting arose through the death of a well-known healthcare reporter for the *Boston Globe* who died in 1995 from a overdose of a cytotoxic drug. The cause of death was only detected months later through audit. Then a second patient nearly died from the same overdose. Ultimately, eighteen nurses were censured and the senior physicians were fired. A major underlying reason for these deaths was the non-standardized hospital drug policies for treating cancer patients. Every patient had a unique protocol, none were standardised and there were no computer aids for decision-making by physicians.

Questions

1. Should healthcare aim for perfection?
2. Could you live up to these standards?

James Reason has summarised the factors that determine the quantity and quality of incident reports and are summarised in figure 5.8. The key staff needs are *trust* and *motivation*. A variety of reporting methods should be tried and perhaps used alongside one another.

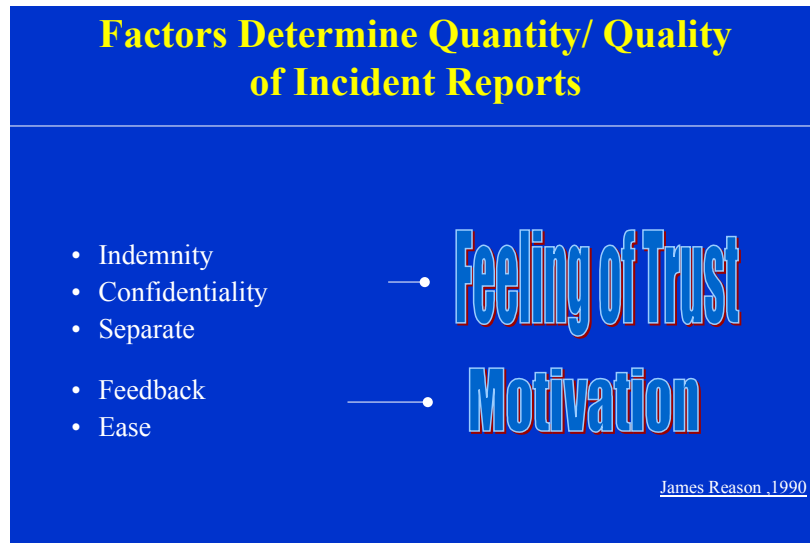


Figure 5.8 Factors determining the quantity and quality of incident reports

Learning lessons from aviation and the military

Healthcare needs to learn from the success of high reliability organisations like aviation and special forces military units. Five key factors create and sustain high safety standards despite considerable danger.

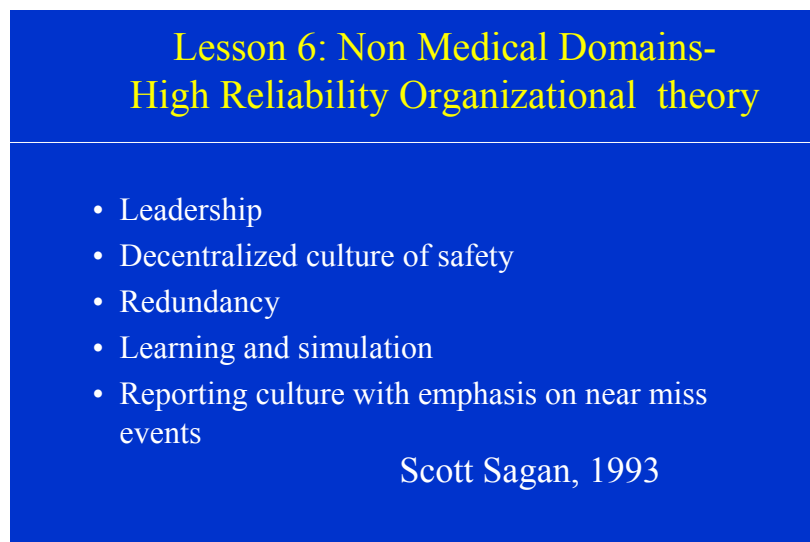


Figure 5.9 How high safety and high danger can co-exist

Consider the high safety record of aircraft carriers that fly missions in almost all weather and sea conditions without loss of pilots and aircraft. Decisions about take-off and landing (for instance) are taken by the person who is most capable, irrespective of rank. Everyone is responsible for safety and all are encouraged to report events with the emphasis on near misses. The concept of redundancy means independent checks of all steps of the procedure. Why do two nurses independently check the same drug calculation rather than each check different steps in the complete drug administration procedure ?

Safety Curriculum

Safety is the cornerstone of training in all non-medical high-risk industries/activities, which use simulation intensively and train teams rather than individuals. What a contrast to medical education, which lacks any formal safety or simulation training.

Question If pilots are re-tested twice a year in a simulator and must pass to keep flying, should healthcare staff have a permanent, un-tested right to practice once qualified?

High-risk teams in aviation, the military, chemical processing, and space-travel train continually with an emphasis on learning to deal with dangerous situations by simulation training. Many studies have documented improved performance, reduced training times for peak performance and overall subjective satisfaction.

Technology interventions

Questions

1. How can we reduce prescribing errors by 50% and prescribing costs by 33%?
2. How can we ensure that the right nurse administers the right drug dose to the right patient with a success rate of 99.99966%?

The range of technological interventions listed below can transform the safety of drug prescription and administration. Some are very expensive, some are not. For instance a bar-code reader costs 1,000 dollars and enables the nurse to check that he/she, the patient and the drug are the right combination.

Lesson 7: Technology Interventions

- Physician order entry (POE)/electronic prescribing
- Pharmacy information systems
- Robotics for dispensing
- Bar code technologies for medication management: dispensing → administration
- Non-POE rules-based surveillance of orders
- Computer-assisted surveillance for errors
- Robust fail safe patient identification systems

Figure 5.10 Medication safety and technology interventions

Question If most of us cannot programme our video recorder timer then why would you expect to be able to programme a sophisticated modern infusion pump?

Here is a list of the key requirements for the safety curriculum throughout healthcare.

Lesson 8: Safety Curriculum

- Presently mostly absent from medical education
- Cornerstone of all non-medical high risk industries
- Must start from the first day of medical training
- Incorporate into all healthcare professional training
- Includes but not limited to:
 - Human Factors
 - Communication
 - Safety culture
 - Team Training :Key unit of analysis
 - Simulation

Figure 5.11 Education for safety

Strategies for safety in healthcare

The holy grail for healthcare in the twenty first century is increased safety, quality and patient satisfaction. Patient care and patient satisfaction should be at the centre of the healthcare universe; hospitals (for example) are only one means to these ends. Patient safety must be a leadership and executive priority; managers and chief executives should be incentivised to achieve safety gains with at least 20-25% of their pay tied to safety improvements.

Question What is the message of the story contained in figure 5.12?

Safety Consultants

A man is flying in a hot air balloon and realizes he is lost. He reduces height and spots a man down below. He lowers the balloon further and shouts: "Excuse me, can you tell me where I am?"

The man below says: "Yes, you're in a hot air balloon, hovering 30 feet above this field."

"You must work in Information Technology," says the balloonist.

"I do," replies the man. "How did you know?"

"Well," says the balloonist, "everything you have told me is technically correct, but it's of no use to anyone."

The man below says "You must be an executive."

"I am" replies the balloonist, "but how did you know?"

"Well," says the man, "you don't know where you are, or where you're going, but you expect me to be able to help. You're in the same position you were before we met, but now it's my fault."




Figure 5.12 Passing the blame

Safety is about each and every one of you going back to your institutions and infecting your colleagues with the safety bug. Inviting safety consultants is the first step, but will not change the system. Healthcare professionals have mostly avoided the tough question of how safety can become central to their work. Employing an expert will not reduce harm. A general call to embrace the safety ethic may influence a few but will not produce system changes. Care will only be safer when we learn to work together as genuine teams. For most of the system failures we do not know what will work; that has to be discovered. For some simple problems such as accidental injection of potassium chloride we need to stop unnecessary access to its concentrated form; to prevent accidental intrathecal neurotoxic drug injections - e.g. Vincristine - we need to

create unique connectors that prevent confusion and do not allow an inadvertent intrathecal injection.

We need a national strategy and I was pleased to hear, this morning, Stuart Emslie and Kirstine Knox describe their excellent work to-date at the Department of Health. Their visionary pioneering efforts, along with those of your Chief Medical Officer, Professor Liam Donaldson, have set the stage for the creation and success of the National Patient Safety Agency.

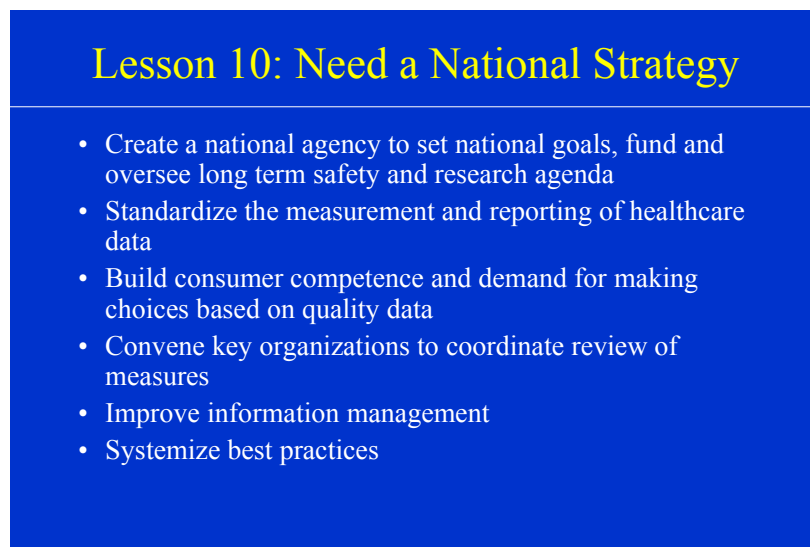
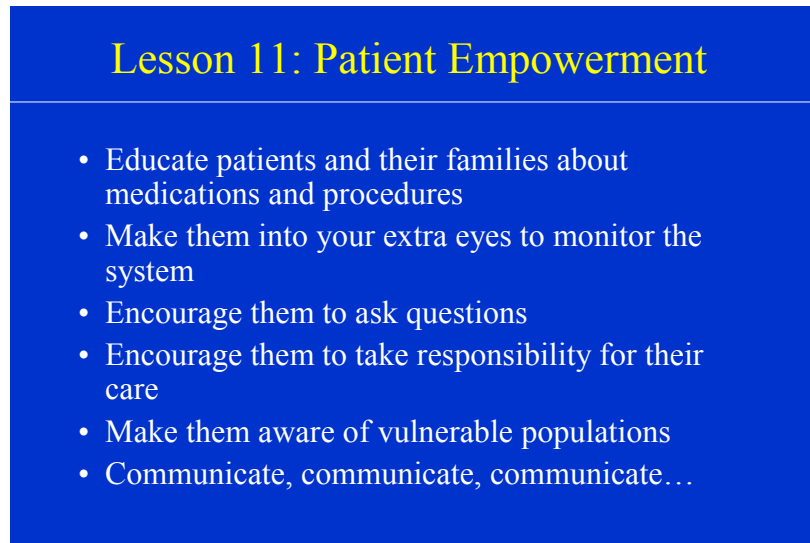


Figure 5.13 A national healthcare safety strategy

Safety and patient empowerment

There are six simple rules that should inform the work of both the NHS and the National Patient Safety Agency. The patient should be the source of control; the professional should not control care. Decision-making should be evidence-based because professional autonomy drives service variability. The system should anticipate needs rather than react to needs. Knowledge and information are like fertilizer - best when spread around rather than kept in a closed sack. Transparency and openness should replace secrecy. Safety is a system property that should replace the individual responsibility behind *First, do no harm*.

We should all learn what accountability to patients really means. We must always acknowledge error and injury and learn to apologise and then provide restorative and remedial care. Because care really begins after an adverse event.



Lesson 11: Patient Empowerment

- Educate patients and their families about medications and procedures
- Make them into your extra eyes to monitor the system
- Encourage them to ask questions
- Encourage them to take responsibility for their care
- Make them aware of vulnerable populations
- Communicate, communicate, communicate...

Figure 5.14 Take the patient seriously

Conclusions

Quality and safety will be the holy grail of twenty first century healthcare. This pipedream for rapid change is possible and we can simultaneously improve services, safety, and reduce costs. One key starting point is to establish clear lines of accountability and proper coordination. Improving patient safety should be one of the highest priorities of healthcare leaders. Perhaps things are about to change. The National Patient Safety Agency has just been set up in the UK, and the US Agency for Healthcare Research and Quality has been tasked by the President, with an initial budget increase of \$250 million over five years, to aggressively promote and support patient safety research.

Thank you and I wish the National Patient Safety Agency well.

6

What makes reporting systems successful?

James P. Bagian, M.D., P.E.

Director, National Center for Patient Safety

Veterans Health Administration¹

Birth of a Patient Safety System

The Veterans Health Administration (VHA) of the US Department of Veterans Affairs' (VA) has been developing a patient safety system for several years and has answers to some of the questions that Paul Barach raised earlier. For instance, we have a bar-coding system that safely links the patient, the drug, the patient's computerized medical record and the nurse. But this bar-coding system is just a small part of the far-reaching systems approach the VHA has taken with regard to patient safety. Here is a brief history of the system, and I must emphasise that we did not succeed first time. We began our patient safety initiative in 1997. This was 18 months before the Institute of Medicine published its much-publicized report *To Err is Human*². The VHA has 163 hospitals, over 800 outpatient clinics, 135 nursing homes, and 43 residential care facilities and is probably equivalent in size to one of the NHS English regions.

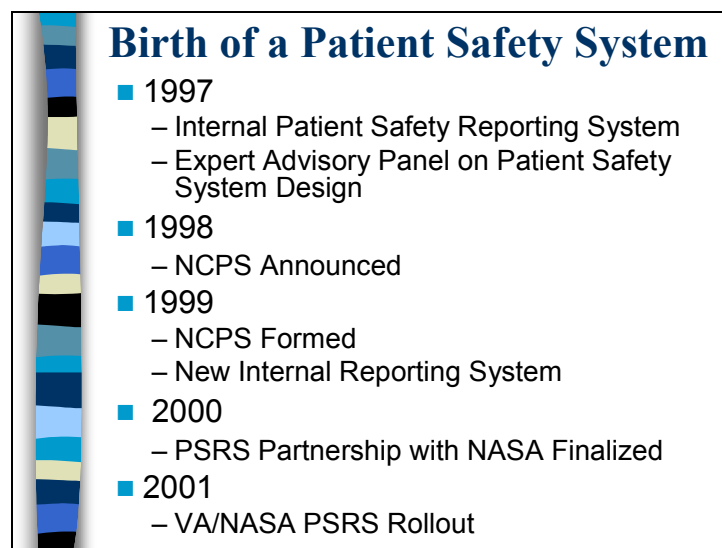


Figure 6.1 The birth of the VHA patient safety system

¹ www.va.gov

² *To Err is Human* – www.nap.edu/readingroom and www.iom.edu

What was wrong? The chief executive of VHA recognised the patient safety system was tackling problems superficially and needed to be changed. Here are some examples of what was wrong:

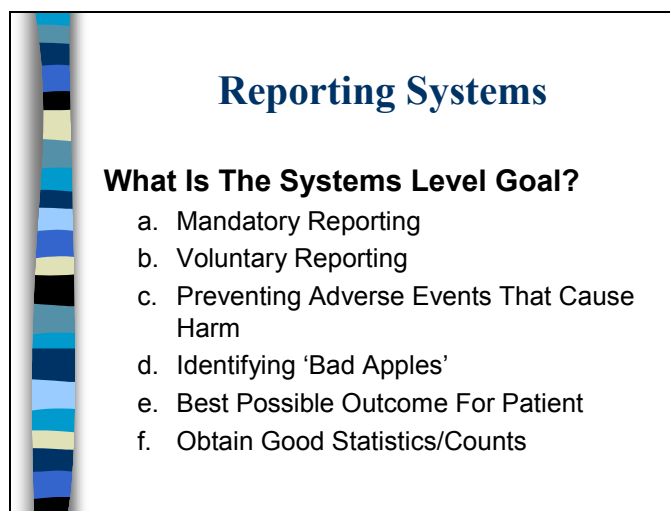
1. Nurses would be told to 'be more careful' instead of implementing more effective systems-level solutions.
2. There was inadequate follow-up to incident reports to be sure they achieved the desired outcome and did not create new problems.
3. There was no recognition that incident reports are only one 'fuel source' for the improvement engine of patient safety.

Directives by e-mail are not an effective way to institute meaningful change. Yes, bureaucrats may well be pleased by the list of e-mails, but that isn't necessarily linked to system-wide improvement. A multi-page directive by e-mail is likely only to be used as a doorstop rather than result in any lasting meaningful change.

What are the System Goals?

Actions that effectively deal with the vulnerabilities described in reports, rather than the reports themselves, are what matters. Inaction creates both cynicism and distrust at the front line, which then stops positive change. The emphasis should be on prevention rather than punishment. A critical underlying problem in the initial system was that the real goal for the system was not clearly understood by personnel at the frontline.

Task Decide at the end of this talk what you think the systems goal should be of those that are listed below.



Reporting Systems

What Is The Systems Level Goal?

- a. Mandatory Reporting
- b. Voluntary Reporting
- c. Preventing Adverse Events That Cause Harm
- d. Identifying 'Bad Apples'
- e. Best Possible Outcome For Patient
- f. Obtain Good Statistics/Counts

Figure 6.2 Different systems-level goals

What kind of culture do we need?

The culture of the organisation is the key to improved patient safety and you cannot create the culture by rules and regulations. Let us look at high reliability organisations like aerospace and nuclear power. Here you find clear and unfettered communication between the front line and decision makers. A guiding principle is “If you’re not sure it’s safe, then it is *not* safe” and irrespective of your position you tell your superiors you’re not sure it is safe by whatever means are available. In healthcare the methods of communication should be those that foster timely and accurate exchange of critical information. You communicate by phone, e-mail or visit your superior directly. This is a significant change in culture and attitudes from what now exists - take the OR team as an example:

Question Would the scrub nurse tell the eminent consultant surgeon that he might be able to operate more safely if he were to use an alternative surgical instrument? This does not happen in the US (and probably not in the UK), but this kind of change must come.

Aviation safety and reporting cultures

Case study 1

A catastrophe is often needed to cause organisations to change. The wake-up-call for US civil aviation came in 1974 when TWA Flight 514 flew into a hill outside of Washington, D.C., killing all 92 people on board. The flight misinterpreted instructions to descend by air traffic control and proceeded to descend at an altitude that was below the approaching hill. The investigation revealed that cloud cover was below the hill, so the crew didn’t see the hill approaching. An almost identical incident had occurred six weeks before, but fortunately there was no cloud cover and the pilots missed the hill by between fifteen to thirty feet. The aircrew that narrowly averted disaster *were reluctant to report this close call (near miss) because they could have had their licenses to fly suspended*. So they only communicated it in a limited manner and thus deprived the air traffic control system of information that may have averted the tragedy that befell TWA Flight 514.

Question How would/do you encourage reporting and remove the fear of retribution?



Figure 6.3 The wake-up call for US civil aviation

Case study 2

NASA has received over 500,000 incident reports over the last twenty-five years and has never revealed the names of reporters. The civil aviation authorities in New Zealand had a similar system, but over ten years ago violated their promise of confidentiality and revealed the name of one captain who filed a report. The system immediately lost the trust of the aviation community and was disbanded. Since then there have been two attempts to relaunch the system with no success. Why? *Because once you have broken your solemn word you are unlikely to be trusted in the future.*

Case study 3

Pilots have always accepted the dangers of flying (still reflected in extra pay), but approximately fifty years ago the military aviation community decided to examine and try to reduce the number of serious mishaps. Figure 6.4 shows the experience of the US Navy that a sustained program of safety actions over 50 years has lowered the rate of Class A (catastrophic) mishaps from 54 to less than 2 per 100,000 flying hours currently. This is a reduction of twenty-seven fold, despite the fact that today the US Navy flies faster, lower and in worse conditions than previously.

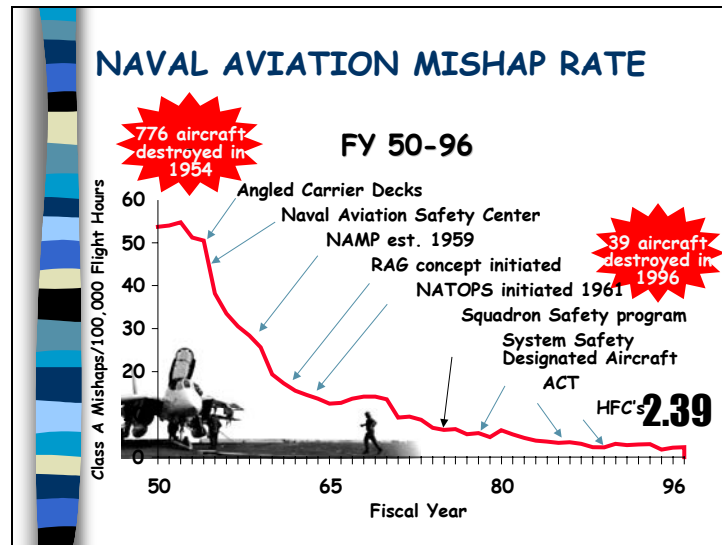


Figure 6.4 US Naval aviation: improving safety

Case study 4

The Johnson Space Center (JSC) has a reporting system for industrial safety that focuses on 'close calls'³ and instituting appropriate preventive action. They have an incident reporting form that has a tick-box at the bottom right-hand edge of the form. The originator (reporter) has the option of not revealing his/her name. However, reporters do not ask to remain confidential because the Johnson Space Centre has a culture where reporters are valued and recognised as top-class employees. The Centre realised that the risk to employees should be managed as a first priority, not the risk to the corporation. In this way the problems are prevented at their source, rather than being handled after the fact as a damage control activity.

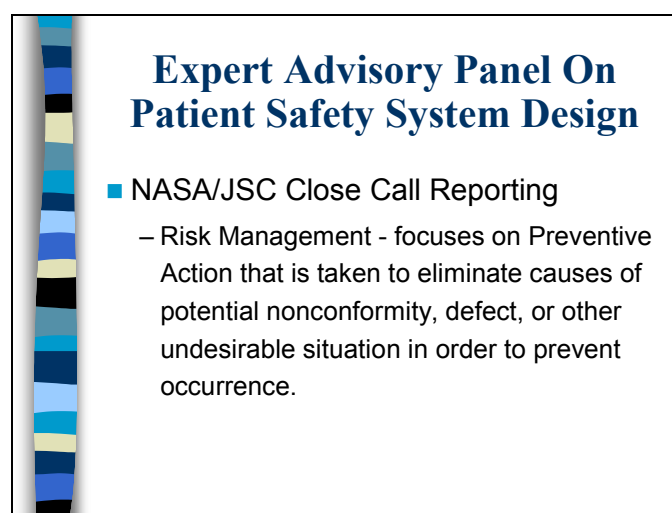


Figure 6.5 Close calls and risk management

³ Referred to as 'near misses' in the NHS

The result? In 1994 there was one close call per 233 employees, but in 1997, three years after greater emphasis on the program, there was one close call per 54 employees. This represented a five-fold increase in reports. What was the outcome though? Between 1994 and 1997 the number of lost work days through injury per 100 employees had been reduced by approximately 70 percent. The key is not the number of reports of close calls, but the action taken to prevent accidents to staff and their effectiveness. Actions do encourage further reporting and improve trust in the organisation. The utility of reporting close calls, which far outnumber adverse events, is sometimes questioned. The concern being that very few of the close calls will be worth pursuing and acting on. The Johnson Space Centre found that less than one close call in twelve did not directly result in action being taken. So their reporting is definitely not a waste of time.

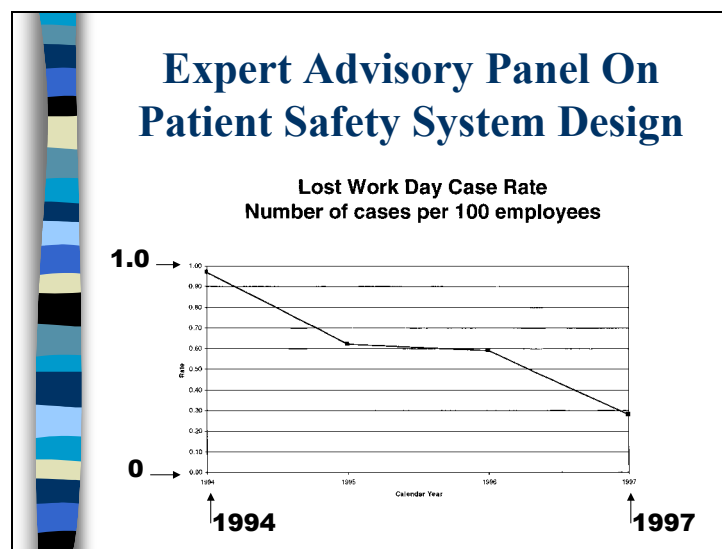


Figure 6.6 Lost workday case rate since the program started

Questions

Whose risk should be managed in healthcare? The patient's or the organisation's?

Whose risk do you think your employer is really most concerned about?

When there is an incident are you asked to reveal nothing to the patient?

Healthcare organisations must make reducing the risk to the patient their first priority and this will in the long term minimise the risk to the organisation. Since the early 1980's, the VHA's policy has mandated disclosure to the patient or to the patient's

relatives of events that cause harm to the patient. We then offer compensation and tell the person how they can file a legal case against us if they so choose.

Question What does your organisation do?

Guiding principles for a patient safety system

What are the guiding principles for a patient safety system? The key is to build a learning system, not an accountability system. Most systems have no shortage of accountability systems and yet another is unlikely to make healthcare appreciably safer. The reports should contain narratives and not just tick-boxes. The narratives provide much more thorough understanding than tick boxes alone ever can. Use interdisciplinary teams to review reports and change membership of these teams often to prevent them from becoming closed shops. Their job of the reporting system is to identify system vulnerabilities that then lead to action, not to generate statistics.

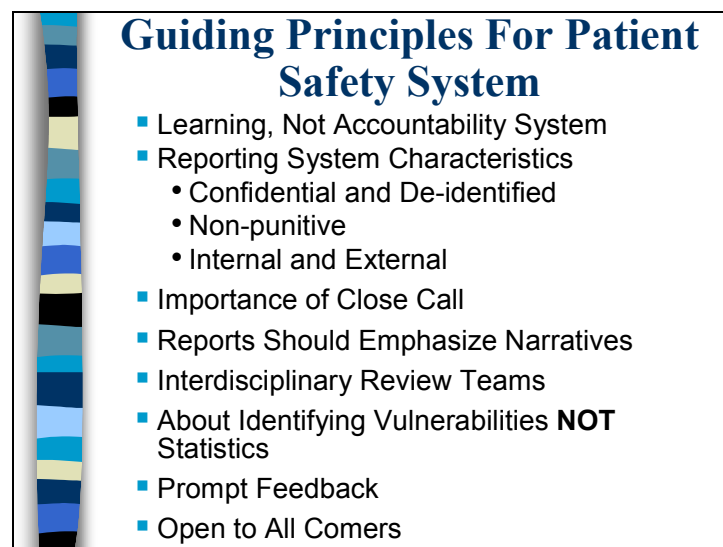


Figure 6.7 The underlying principles of a patient safety system

Patient safety and the failings of healthcare

Try to build a fair system - fair from the point of view of your staff - do this and people will flock to join the effort. However, recognise the barriers that you will face. Medicine traditionally views errors as the failure of individuals who must first be blamed and then retrained. The attitude of 'no blood, no foul' is at the heart of the problems that

were described in your report *Organisation with a Memory*. You will not typically hear the phrase “whose fault is this” in an aircraft incident investigation. Instead, three questions are asked:

1. What happened?
2. Why did it happen?
3. What can we do to prevent it from happening in the future?

Blind adherence to the rules does not make healthcare safer. At the VHA we urge staff to remember that while rules and policies are important, no rule is right for all occasions. We encourage questioning and say “If you think that the rule is unsuitable for a given set of circumstances and there is no time for discussion then do what you think is right and we will discuss the matter later.”

Case study in system risks

Consider this common occurrence. An ICU nurse phones in at the start of her shift because of illness. Almost certainly the supervisor will then ask another nurse whose shift is about to end if she will work the next one. This action achieves a replacement warm body, but not an alert and rested member of the team, and the supervisor has increased the risk of mistakes being made versus the situation where a rested nurse would be on the job. So why not share work that is most impacted by fatigue with another nurse who is rested? This kind of thoughtful action is seldom done in the US and probably not in the UK.

Barriers to cultural change

Your biggest hurdles are likely to be a lack of awareness of the problem at all levels in the organisation and the sense of shame that adverse events engender. The latter is a product of an inappropriate workplace culture. Consider the findings of both the VHA and other private healthcare organisations. When all ranks were questioned, from drivers to chief executives, the results were:

1. Only 27% agreed that errors were a serious problem.
2. That 49% stated they felt ‘ashamed’ about their errors.

You cannot expect to change the way business is conducted if only one-quarter of your people believe a problem exists.

Strategies for change

Strategy 1

Bin the inaccurate phrase 'blame-free', recognising that by using the term you will be ridiculed by the press, the media and Parliament. Besides, there are circumstances where blame is appropriate. Instead adopt the term 'blame-worthy.' We at the VHA use the term 'intentionally unsafe acts' to describe three types of acts we view as blame-worthy that should be dealt with by the administrative system by means that may include punitive action. Intentionally unsafe acts are criminal acts, acts performed while being under the influence of alcohol or illicit substances, and purposely-unsafe acts. All else is placed in the confidential reporting system. This makes people feel safe about reporting since they can readily satisfy themselves if they are associated with an intentionally unsafe act.

Strategy 2

Invite people to play by removing barriers such as replacing punishment by prevention, replacing accountability by learning and giving prompt feedback and instituting preventive actions.

Strategy 3

Encourage middle and top management to act promptly and provide timely feedback on information provided by your front line people so as to gain frontline support for patient safety efforts.

Strategy 4

Introduce tools that make the job both easier to do and increase patient safety. These tools help to shape behaviour and change both culture and attitudes.

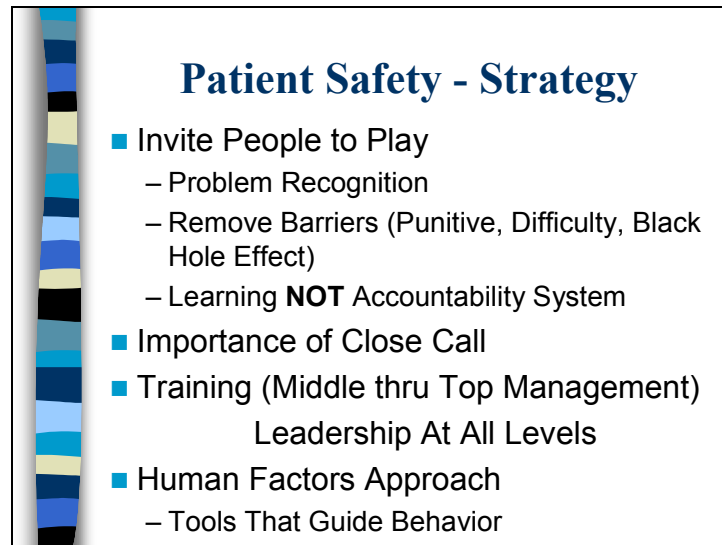


Figure 6.8 The strategy for patient safety

VHA Patient Safety Accomplishments

Since instituting our new system⁴, the VHA has seen, on an annualized basis, a thirty-fold increase in reporting events and a nine-hundred fold increase in the number of close calls. Close calls make up ninety-four percent of all reported events, rather than a negligible fraction, as was previously the case. The chief executives now have a much better dialogue with their front line teams because they have to explicitly respond to all recommended safety actions. Their acceptance or non-acceptance of actions and accompanying rationale is kept as part of the investigation's record.

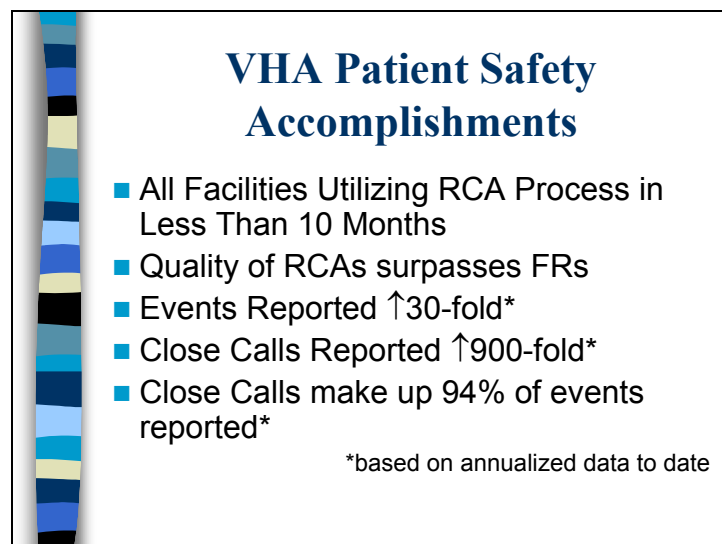


Figure 6.9 Patient safety at the VHA: key accomplishments

⁴ See patient safety handbook at <http://www.va.gov/publ/direc/health/handbook/1051-1hk1-30-02.pdf>

The business case for the patient safety system

The business case is so self-evident (a 'no-brainer') that I have only included this section because so much NHS activity is dependent on making the 'business case.' Each root cause analysis takes between sixty and sixty-five staff hours to complete, spread between three people over six weeks. That is less than four hours per person per week with a relatively small work impact. Here are two examples of the benefits:

1. The VHA estimates that in emergency airway management requiring intubation outside of the operating room, 8% result in oesophageal intubations. We have proposed using carbon dioxide detectors and other adjuncts to verify appropriate tracheal intubations. For a small price (approximately \$12 per unit), these disposable and easy-to-use devices have been found to be extremely effective. We expect this improvement to avoid some of the settlement costs for improper intubations, not to mention the most important benefit, which is better patient care through the avoidance of harm to patients.
2. Replacing the unsafe ventilator humidification system by a less expensive and safer device can save a typical hospital \$114,000 annually. This saving alone more than pays for the hospital patient safety officer. This saving doesn't even take credit for the reduction in morbidity and mortality of the patients.

What is the Systems Level Goal?

Now that I have finished, perhaps you have had time to decide what is the right systems level goal.

Is it mandatory reporting? No.

Is it voluntary reporting? No.

Is it to prevent harmful adverse events? Yes.

Is it to identify 'bad apples'? No.

Is it to obtain the best possible outcome for the patient? Yes, this is the overarching goal.

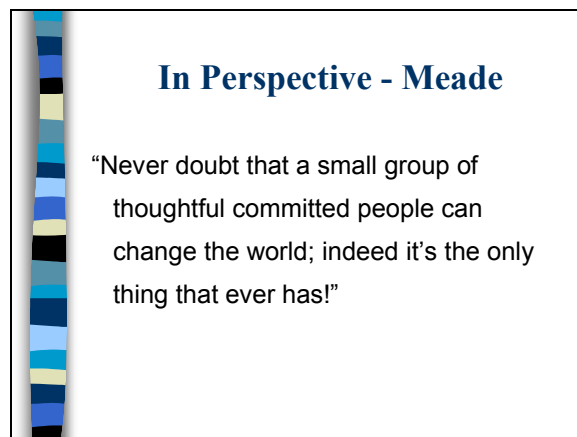
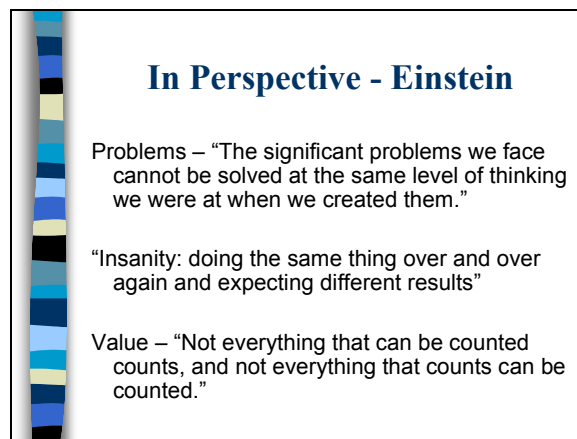
Is it to obtain good statistics? No.

What have we learned?

You must win support for culture change, this cannot be done by force or fiat⁵. Leadership at the top must maintain the drumbeat and personal - *not electronic* - communication is the key. Your frontline people are the priority and systems must suit their - not your own - needs. Safety-related duties can never be an afterthought. Safety is the foundation upon which quality is built; the two are not independent factors.

Final perspectives

I leave you with the thoughts of Einstein and Meade to guide your futures into safer healthcare.



Figures 6.10 & 6.11 Guiding and profound advice

⁵ Decree or order.

7

Medical device safety reporting systems – 30 years of ECRI experience

Joel J. Nobel, M.D.
Founding President
ECRI

Introduction

It is a pleasure and a privilege to participate in a truly remarkable program and a welcome introduction to the UK's new National Patient Safety Agency. This new Agency will undoubtedly impact positively on the lives of thousands of patients over the next few years. Its vision is clearly enunciated, its functions are well defined, and its commitment to collaborate with like-minded organisations is thoughtfully stated. Congratulations on seizing the challenge.

I will first briefly introduce ECRI and then take you back to the 1960s when spurious research, falsified data, charlatans, gullible biomedical engineers, and imaginative media types ushered in our country's first widespread patient safety campaign, flawed reporting systems, and poorly considered medical device regulations.

ECRI's remit and work

ECRI is a 33-year-old non-profit, health services research organization and is a Collaborating Centre of the World Health Organization. Apart from our headquarters in the US, we have branch offices here, in Dubai, and in Kuala Lumpur. Our medical device reporting and resolution systems are a much smaller part of our activities than are healthcare technology, healthcare risk management, and healthcare environmental management. And over the past five years, we have substantially expanded into healthcare standards, clinical guidelines, and medical error. Our technology-related activities can be categorized as assessment, planning, procurement, and management.

Medical device reporting systems are but one part of technology management. ECRI's obligation to the World Health Organisation under our terms of reference requires the worldwide collection, analysis, and dissemination of medical device failures, problems, and adverse events. There are now about one million entries in our 'Health Alerts' database. We have 220 staff: physicians, engineers, medical scientists, information system types, lawyers, editors, and other life forms. Independence requires that we have tough rules about conflicts of interests that, for example, prohibit sponsorship by our staff consulting for medical device or pharmaceutical companies or owning stock

shares in such companies. ECRI produces some 35 databases and publications and probably provides more information about medical technology than any other source.

Historical context

My own modest endeavours in this field began in the 1960s when I was a house officer and noticed two faults in the ICU that was to be opened shortly. The electrical earthing was inadequate and the wall supports for patient monitors were not strong enough. My observations were reported to the Chief Executive and duly ignored, since a house officer is the hospital's lowest evolved life form. Two days after opening the unit, a nurse, patient, and physician received simultaneously an electric shock at full mains voltage from an ultrasonic nebuliser resting against a bed rail. The next day a monitor - which weighed 85 pounds - mounted on a wall fell onto a patient's head. The Chief Executive was furious with me, unable to distinguish between predicting and causing an adverse event. I suspect that even today the prediction of harm is viewed with suspicion. If the event occurs, witchcraft is suspected; if it does not then the messenger is branded an alarmist.

In 1968, a well-known surgeon stated at a prestigious conference that 1,200 patients were electrocuted annually in US hospitals; the media loved it. Then in 1970, a self-styled professor of biomedical engineering announced at another conference that he had personally investigated 2,500 electrical accidents over the past 10 years, 60% of which were fatal. This would have required investigating an accident every working day over an immense geographical area for a decade and the investigation of a fatality every 1.7 working days. An impossibility: The man was lying. However, Ralph Nader picked up the story and so a Detroit newspaper announced, "US medics electrocute 4,000 patients annually." Apparently we physicians regarded this as a form of recreation. Then that prestigious medical publication, *The Lady's Home Journal*, declared that 15,000 patients were accidentally electrocuted annually in hospitals. We were puzzled. We simply did not have that many unexplained bodies.

Bioengineering departments were established, regulations were passed, consultants benefited, and the industry sold expensive safety systems. The pinnacle of this sorry episode was the almost successful attempt by the surgeon owning shares in manufacturers of safety systems to change the national electrical code to mandate the use of these safety systems. The cost would have been about \$5,000 per bed. Our investigation of the 'professor' of bioengineering showed that he was nothing of the sort, but a former part-time student in theology from a Munich university. We spent much time and energy refuting these people.

Data is not the plural of anecdote

No real data was ever produced by anyone about patient deaths by electrocution. As Don Berwick has noted, "Data is not the plural of anecdote." A subsequent detailed investigation over a decade showed that, at worst, there may have been four deaths by micro shock. Hundreds of millions of dollars were spent by hospitals defending patients and themselves from a risk that had been immensely exaggerated. To this day, disproportionate efforts are expended by biomedical and electrical engineers focused on the electrical safety of medical devices. Yet the real risks are mechanical problems. Plumbing, gas-line mix-ups, and the failure to connect ventilators properly to patients are examples. Patients have died because oxygen and nitrous oxide lines have been interchanged during construction or renovation. Furthermore, about 50% of adverse incidents have been caused by operator error, which needs to be remedied through training, and human factors design-areas that get inadequate attention.

We often hold data in high regard, but good reliable data are very hard to produce. Those of us with experience in technology assessment know that most peer-reviewed papers published in hallowed medical journals do not withstand stringent re-examination of both study design and statistical analysis. Oncological studies are particularly fragile. Study design is often compromised by such factors as shortage of time, emotional adhesion to pet theories, sponsorship, an inability to distinguish between the interest of patient and clinical researchers, and the intellectual limitations of the researcher. All these problems pollute data and so make research into patient safety more difficult. When common sense, experience, and even intuition contradict the data, be very sceptical. Examine all the assumptions and methods that underpin the data before discarding these other ways to get at the truth. In short, raw sewage and data have one thing in common: both need appropriate treatment before they are useful or at least harmless.

The four pre-eminent reporting systems

Let us now turn to the four pre-eminent reporting systems: the systems run in the UK by the Medical Devices Agency (MDA), that in Australia by the Therapeutic Goods Administration, and those in the US by ECRI and by the Federal Drug Administration (FDA). All were established in different environments to serve different societies with their own unique healthcare services, information cultures, and legal climates. Yet all have common objectives and share some methods. The ECRI, Australian, and MDA systems all rely upon voluntary reporting by the user and stress quality of information, follow-up, and resolution. In contrast, the FDA, until recently, has striven for comprehensive mandatory reporting as demanded by our obsessive-compulsives in Congress.

Is more data better? Intuitively you would probably think so, but generally it has not proven to be the case. We at ECRI believe that comprehensive reporting is both

unnecessary and sometimes counterproductive. The reason is the signal-to-noise ratio. In our experience, one incident report is often sufficient to trigger investigation and establish cause, especially for design defects. More than two or three are usually unnecessary. If you collect 500 reports, your resources are diverted to a gigantic data processing and communications exercise with little institutional energy left for analysis, resolution, and corrective action. In short, too much data is often a problem, not a solution. And so the FDA has more recently developed a key hospital sampling approach - not unlike our more focused approach with our member hospitals, except that the FDA approach will probably have better statistical strengths.

None of the four systems are perfect

None of the four systems are perfect in all respects, but they are beginning to converge as we learn from one another. The ECRI system was designed at the outset in 1971 to be international, drawing material from many countries. One of ECRI's contributions to the global harmonization of incident reporting has been to devise and promulgate a standard nomenclature for medical devices and a taxonomy for the causes of device failures and mechanisms of injury. This nomenclature and taxonomy is now used in 60 countries by 5,000 institutions. Our paper-based and online international reporting systems are used by 3,000 member hospitals around the world. We stress quality, not quantity, of reports, often receive drawings and photos with text from reporters, and continue to train our community of users in selective reporting of high quality.

The MDA states that it operates what was the first national reporting system and that 9% of reported incidents last year were caused by user error. ECRI's experience and that of others suggests that operator-error-related adverse effects actually account for between 50% and 60% of adverse effects. Perhaps this disparity is due to different criteria or methods of data collection or what each organisation gives priority. Our Health Devices Alerts database contains close to a million entries. You are welcome to examine the Medical Device Safety Reports and our recommendations derived from over three decades of experience on the free side of our web site at www.ecri.org.

Both the MDA and ECRI also operate device-evaluation programs. ECRI's has led to thousands of product improvements. The FDA system does not yet have this public record of achievement, which it more than deserves. Its actual achievements are understated, much being accomplished behind the scenes, and certain data about its accomplishments are not collected or publicized as well as they might be.

ECRI's medical device reporting system

In April 1971 we began publication of our monthly journal *Health Devices*, with its comparative evaluation of medical equipment and hazard reports of equipment that we found dangerous. In July 1971, we published a protocol to help assure effective equipment management in hospital, device safety, and investigation of adverse effects. Those protocols improved over the ensuing three decades and remain the doctrinal basis for hospital bioengineering departments today. The protocols included reporting forms and instructions that in several months evolved into ECRI's international medical device problem reporting system. That system became a much-emulated model.

In 1973, under contract to the FDA, we undertook an extensive study of health professionals at all levels to ascertain attitudes toward reporting. Meanwhile, data from our reporting system was helping us set product evaluation priorities.

In early 1973, the most common adverse effects we investigated were radio-frequency burns to patients from surgical diathermy units. We responded to approximately 120 communications monthly from hospitals related to electro-surgical units (ESUs). Later that year, we published an extensive study on ESUs, really the first major article since Bovie published in 1928. Within three months, ESU-related questions dropped to about 30 per month. Within the year, manufacturers had redesigned safer units in response to our technical criticism. By 1976, with newer safer units replacing older ones, we began to notice a decline in injuries. By 1985, we estimated that 60% of the nation's ESUs had been replaced, and by 1995, almost all were. Today ESU burns are relatively rare—perhaps about 15th or 18th in the accident types we investigate.

In short, our problem reporting system helped identify design and safety defects associated with all brands and models of a very commonly used type of equipment. We identified the causes, manufacturers responded, hospitals replaced equipment and trained staff based on our safety recommendations information, and the injury rate dropped radically. Everything operated on a voluntary basis. We have no regulatory power - only the power to advise our member hospitals not to buy certain brands and models of equipment and the power of an educated marketplace.

Anyone can report a medical device problem to us by letter, fax, e-mail, or online. Most reports come from member hospitals and regulatory agencies worldwide - about 300 per year. Around 18% of those reported are published and disseminated to member hospitals and regulatory agencies. Some are translated into other languages. Five to ten reports we publish each year are generic types of risks, rather than brand and model specific, typically with human factor engineering implications. These are of broad and repetitive significance and are posted on the public (freely accessible) part of our web site as Medical Device Safety Reports.

Now, 300 reports a year may seem paltry compared to the tens of thousands of reports received by our FDA. Most reports to the FDA are from manufacturers and hospitals in accordance with regulatory requirements. But last year we published 48 hazard reports, which is close to the MDA's total of 51 for that year, but is based on a much smaller number of reports than the MDA received. Less than one in five reports to us lead to a justifiable hazard report.

We've shown repeatedly that one or two reports of a significant problem will trigger effective investigation. On occasion, when we are not sure if we are dealing with a marginal problem or a single sample defect, we ask the user community to collect and report data selectively for that device. This has worked quite well. In short, we regard our system as a source of markers or pointers rather than as a statistically valid framework. We've now received and investigated over 9,000 reports and induced thousands of product changes.

Are things better, the same, worse, or merely different after some 30 years? My sense of it is that new types of devices with new types of risks have increased the incidence of device-related adverse effects, especially considering technology intensity, more patients, less time, and, at least in the US, some dumbing down of our nursing workforce. For example, 30 years ago we lacked lasers, so we had no laser-related fires in the operating theatre. We have now investigated more than 160 such fires, typically occurring during head and neck surgery.

While problem reports are generally examined in our laboratories, many of our accident and forensic studies are carried out in the field in hospitals that have asked for assistance - over 2,000 cases. While most are in North America, we've undertaken field investigations for hospitals, law enforcement authorities, insurance companies, and others in Malaysia, Germany, and the UK. Cases range from the death of an infant in a defective incubator to homicides in which devices were used as weapons.

What other lessons have we learned?

1. It is unnecessary to exaggerate risks to get attention and produce constructive change. It destroys credibility and distorts safety priorities - regardless of how media and politicians love it. Too-many-scaries drive health professionals into a refractory state and they can't respond to further stimuli.
2. When alarming new studies are inconsistent with general experience and common sense, don't jump on the safety bandwagon. Be sceptical. Somebody is probably trying to sell something. There are enough real problems to solve to keep us all gainfully employed for a while.
3. Voluntary systems, of which the MDA, Australian, and ECRI systems are the best, have generally proven to work well for reporting and resolution. The few

mandatory systems produce lots of data, much of it quite useful, but have tended to be a bit weaker in achieving resolutions. This is probably less related to the issue of 'mandatory versus voluntary' and more related to resource limitations.

4. Large-scale systems tend to lack feedback to the reporters, which, in turn, demotivates them. You should acknowledge receipt of reports and tell reporters what you have learned.
5. In accident investigation we find that experience is probably the most critical factor. Borrowing analytic methodologies from other fields is less useful than focused experience.

For a superb example of balanced perspectives in examining adverse efforts, we should look to the extraordinary accomplishments of the Australian Patient Safety Foundation. Its practical accomplishments in the field of patient safety deserve both praise and emulation.

It is interesting that all three US speakers this afternoon have military backgrounds. We have the Air Force and Special Operations, and mine is submarines. Submariners, incidentally, have a simple view of life: there two kinds of ships - submarines and targets - and the targets of healthcare are also pretty basic:

1. to reduce pain and suffering;
2. to ameliorate and attenuate disease and disability; and
3. to postpone death when it is meaningful to do so. Above all, do no harm; when it occurs, despite our best intentions, we must report, investigate, resolve, and prevent!

Thank you.

8 Lessons from Australia

Professor Bill Runciman
President
Australian Patient Safety Foundation

Introduction

As much of what I was going to say has already been covered by other speakers, I am going to give a relatively narrow talk that is based mainly on examples from our incident reporting system. However the starting point must be the Australian/New Zealand risk management process (AS/NZS 4360:1999¹) that has been adopted by the NHS². Here is a simplified picture of the process.

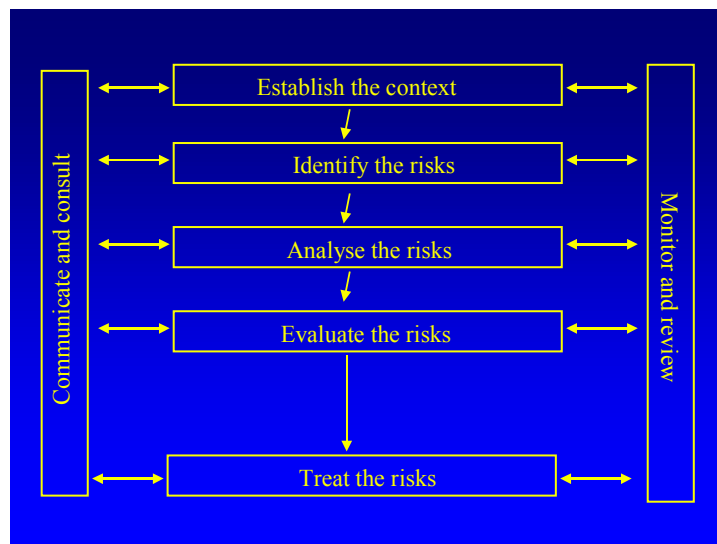


Figure 8.1 Simplified Australian/New Zealand risk management process

This is a five step sequence: establish the context, identify then analyse then evaluate and finally treat the risks. Simultaneously one must monitor, review, communicate and consult.

Identify the risks

You get a quite different version of reality about patient safety from each method of risk assessment. However we must not become wedded to only one version by our

¹ www.riskmanagement.com.au

² www.controlsassurance.info

choice of method. Figure 8.2. demonstrates the point by comparing incident data from our AIMS database with data from the *Quality in Australian Healthcare Study* (QAHCS). AIMS stands for the *Australian Incident Management System*³; the QAHCS was a review of a sample of 15,000 medical records, looking for adverse events.

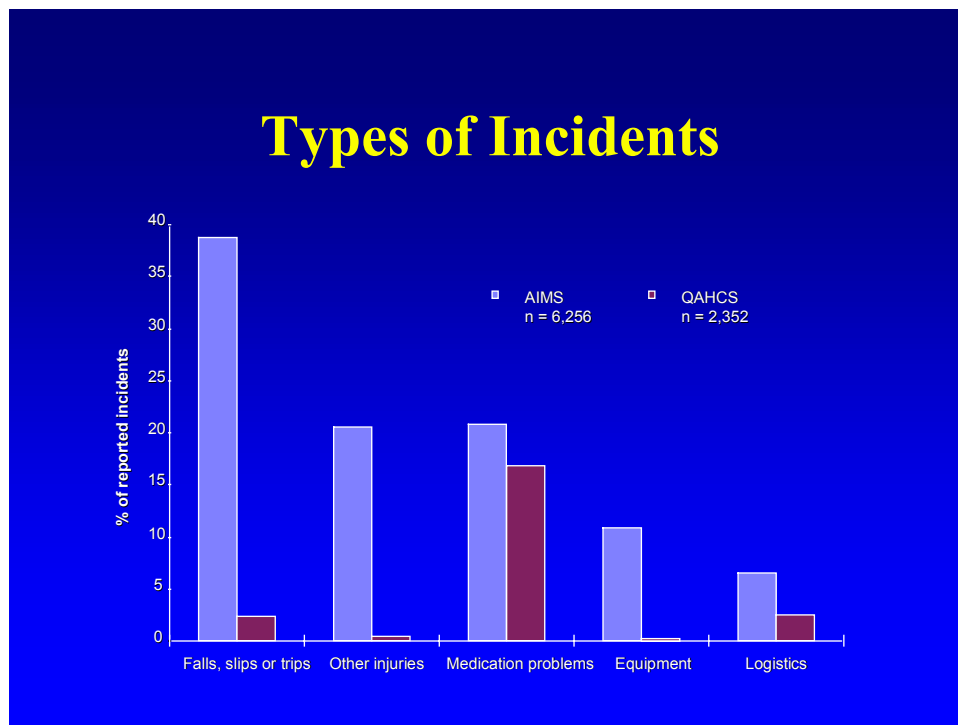


Figure 8.2 Frequencies of incident types using different measurement methods

The patterns are entirely different because, for example, medical records do not include equipment problems, or much about falls, slips and trips. Furthermore morbidity and mortality codes from the International Classification of Disease (ICD-10) at discharge and death pick up less than half of the information in medical records. However our database combines information from many measurement techniques to give a more complete version of reality. So we collect information about things that have gone wrong from: incident reports, incident monitoring, complaints files, medico-legal files, death certificates and coroners' recommendations, case reports and 'letters to the editor'. All these should go into a big *national* database and *size* matters for a fundamental reason. Most types of adverse events and near misses occur infrequently. So to discover both their primary and secondary causes enough information must be collected from many hospitals and from many sources. For instance AIMS records the safety/restraint devices associated with falls.

³ See the Australian Patient Safety Foundation at www.apsf.net.au

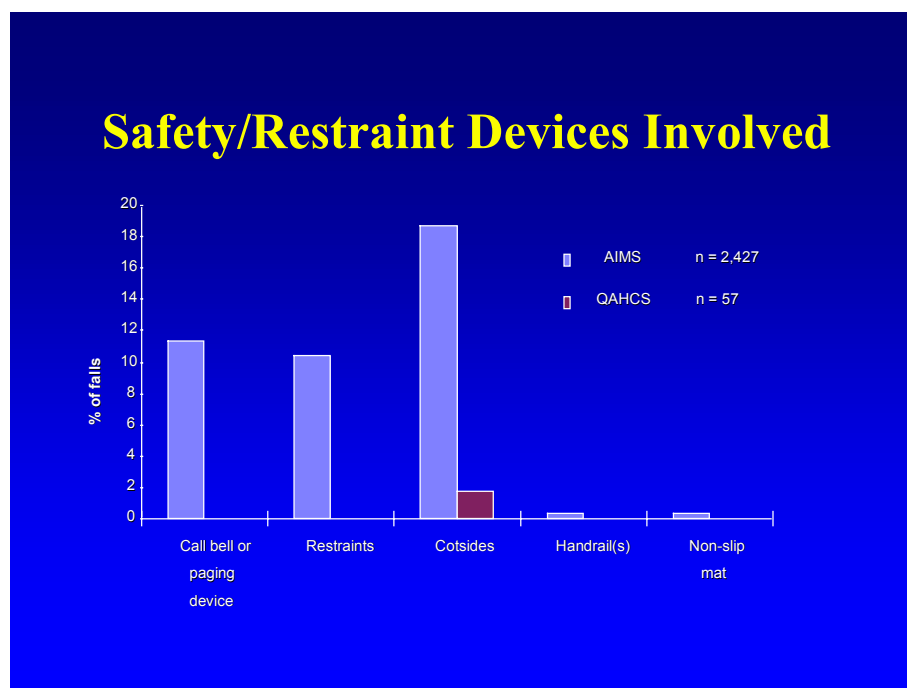


Figure 8.3 The frequencies of falls associated with safety/restraint devices

We can probe further and discover the factors that contributed to falls from cotsides. Figure 8.4 shows the total number of falls (455) and below that the breakdown of contributory factors to cotside falls.

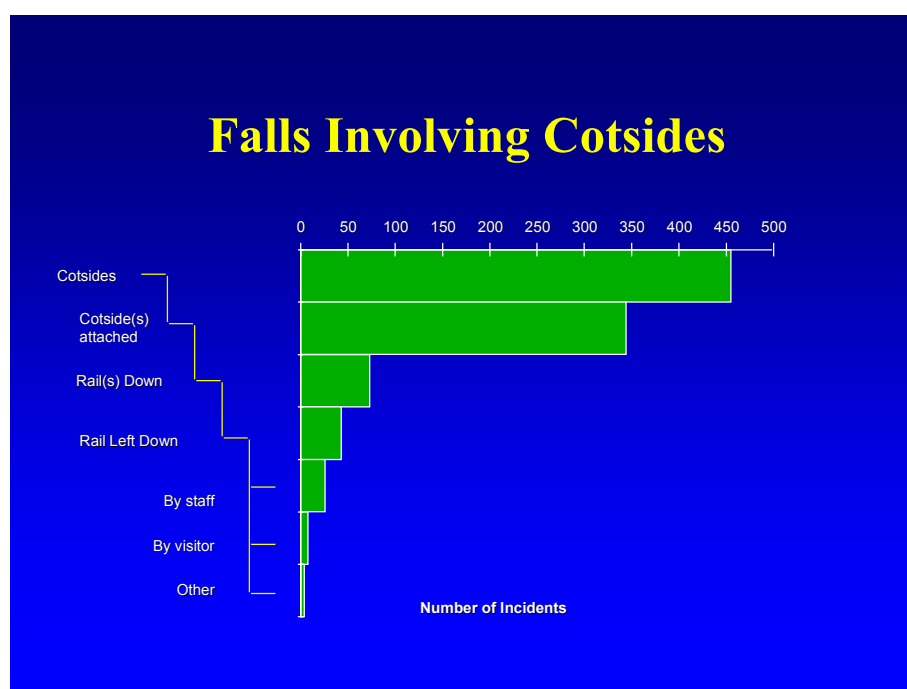


Figure 8.4 Analysis of falls associated with cotsides

Anonymity and confidentiality

I believe that the reporter must have the right to anonymity. This right is rarely exercised and as Jim Bagian has already pointed out a successful *blame-free* culture destroys the fear of reporting. Some reporters will want to have their identifiers on the reports because they want to ensure that changes are effected. Of course anonymous and confidential data must be widely publicised in aggregated form.

However anonymity should not be confused with confidentiality and great care must be taken to sustain absolute confidentiality when identifiers *are* provided. We always advise that the frontline troops should choose or vote for their co-ordinators who have permission to view reports. The wrong people in these positions have often killed reporting stone dead in their hospital areas. No line manager or anyone who can control the careers of reporters should be allowed access.

We also believe that all the information should be legally privileged so that it cannot be used in court cases. The NHS may well encounter external interest in reports and if opinions from them are obtained for purposes other than quality and improvement (such as defending medico-legal claims) then the reporting system may be imperilled. Anonymity does solve this potential problem. In short I do not believe that the reports should be in the public domain and I agree absolutely with what other speakers have said on this subject.

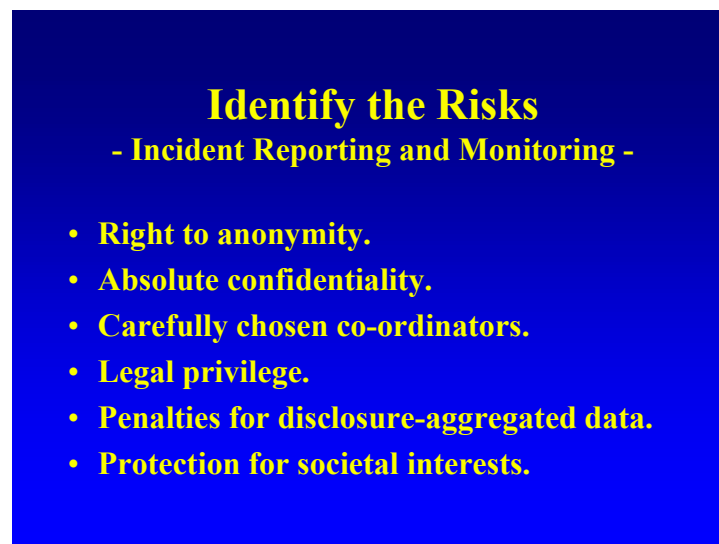


Figure 8.5 Anonymity and confidentiality: underpinning principles

There should be a *firewall* between the systems for learning and those for accountability. A *just culture* must define what is acceptable. There is a line beyond which behaviour and actions are unacceptable and demand censure. However, the people that ensure accountability and discipline cannot be responsible for the learning

system. There must be penalties for disclosure. Jim Bagian takes a very strong line with Chief Executive Officers (CEOs) to stop disclosure of confidential information by anyone in their hospitals. The mess that we are in about patient safety is in the face of quite elaborate and comprehensive mechanisms to protect the interests of individuals. We must begin to redress the balance for the protection of societal interests.

This is our incident report form. The light yellow areas are filled in - all free text and no tick boxes. The blue areas are prompts and the dark yellow areas say 'Do not fill these in if you wish to remain anonymous'.

Incident Form		<small>AUSTRALIAN PATIENT apsf SAFETY FOUNDATION</small>		<small>OFFICE USE ONLY INBURY AIMS - SOFTWARE NUMBER HERE</small>	
APSF, GPO BOX 2050 ADELAIDE SA 5001					
<p><i>Ensure that any person involved is safe and that all necessary steps have been taken to support and treat this person and to prevent injury to others. Ensure medical records are factual and up to date.</i></p>					
<p>If you want to submit an anonymous report, leave the dark yellow sections blank.</p>					
<p>Please print clearly and use a blue or black pen</p>					
INSTITUTION NAME (where relevant)			AUSTRALIAN INCIDENT MONITORING SYSTEM (AIMS)		
Details of the subject of the incident * See important information on the bottom of this and the back page			<ul style="list-style-type: none"> AIMS provides a mechanism for identifying problems and their causes across the entire health care system. Any provider or recipient of health care can report an incident. An incident is any event or circumstance that could have or did cause unplanned harm, suffering, loss or damage. This information will be used to develop corrective strategies to try to prevent similar problems in the future. * See important information on the bottom of this and the back page. 		
Last Name: _____		First Name: _____			
Record / Patient number: _____					
(or patient label)					
Date of birth / age: _____		Ward/Unit: _____			
Mental Health Clients					
<input type="checkbox"/> Detained <input type="checkbox"/> Voluntary <input type="checkbox"/> Unknown					
Reporter's details (optional when remaining anonymous)					
Name: _____			Contact number: _____		
<input type="checkbox"/> Nurse (Specify level _____)		<input type="checkbox"/> Patient		<input type="checkbox"/> Allied Health Worker (Specify _____)	
<input type="checkbox"/> Doctor (Specify level _____)		<input type="checkbox"/> Visitor		<input type="checkbox"/> Other (Specify _____)	
1st Witness name: _____			Contact number: _____		
2nd Witness name: _____			Contact number: _____		
Place of incident					
Where did the incident occur e.g. (the toilet in ward 7A, the stairwell in medical administration, the road outside the police station): _____					
Date of incident: / / Time of incident: _____					
Current and relevant diagnoses / problems _____					
Was the next of kin / guardian notified? <input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No					
Was a Medical Practitioner notified? <input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No					
Medical practitioner's examination of subject * See important information on the bottom of this and the back page					
Name of practitioner: _____		Signature: _____		Time: _____	
If relevant, please describe the assessment of the patient's condition and list treatments / investigations ordered. Ensure the patient's medical record is complete.					
_____ _____ _____ _____ _____					
(DO NOT USE THIS FORM FOR REPORTING INCIDENTS TO OTHER BODIES)					
If you think there is any risk of litigation, complete this form and also report the incident separately to the relevant person (e.g. risk manager).					
If the incident involved a reaction to a correctly used drug, report the details to your pharmacy or direct to the Adverse Drug Reactions Advisory Committee (ADRAC).					
If the incident involved equipment failure, also report the details separately to your biomedical engineer or direct to the Therapeutic Goods Administration (TGA).					

Figure 8.6 Incident report form of the Australian Patient Safety Foundation

The reporting base

We continue our efforts to widen the reporting base from the traditional nurse-based systems to medical specialists and other medical and paramedical staff; we are setting up studies to try a variety of techniques to achieve this aim and have developed an aide-memoire - a memory jogger - to be used at discharge and during audits. We propose 'burst' reporting - for limited periods of time, such as a month - and setting units in competition with one another by bribing them with prizes for the best or most reports. Feedback and documented action is vital and other speakers have spoken about this already. The National Patient Safety Agency has the exciting opportunity to conduct randomised interventions among NHS organisations to decide the most effective types of incentives for reporting. Like us, the Agency will face the challenge of widening the reporting base.

Analysis of the risks

Having collected the information you need to analyse the risks, which is stage three in the simplified Australian/New Zealand risk management process outlined in figure 8.1.

We now have 60,000 incident reports including 8,000 from critical care units. How do we capture learning from our collective experiences? Part of the answer is the way reports are coded. We started with key words but found them hit-and-miss and time-consuming. Consider the analogous problem of using key words to search a library database. We then looked at routine data collection from discharge and death certificates, coded using ICD-10, and routine surveys of general practice, coded in the same way, and found the information about adverse events to be very incomplete. Eventually we developed our own 'Generic Occurrence Classification' (GOC), which was based on a few thousand incidents and adverse events. Later we collected everything we could not code from 60,000 adverse events and came up with GOC+ that has been combined with new software called AIMS2. It is this combination that will be customised for the National Patient Safety Agency using UK needs, terminology and data.

In conclusion I believe that the reporting system of the National Patient Safety Agency must have the characteristics outlined in figure 8.7.

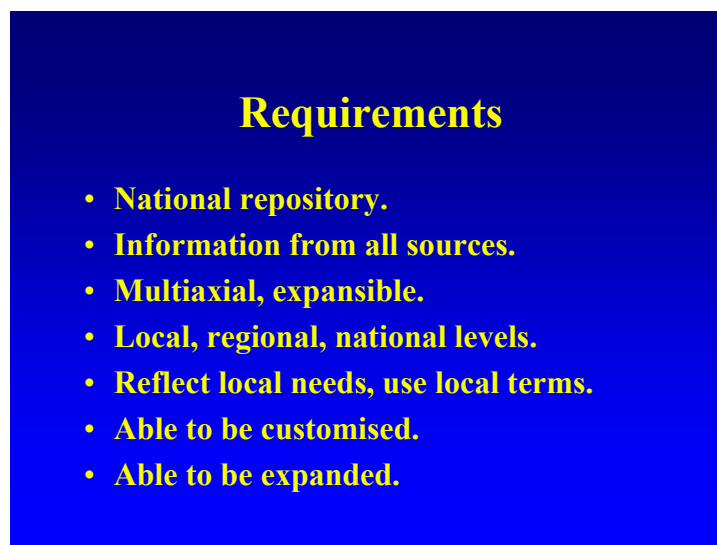


Figure 8.7 Proposed characteristics of the UK incident reporting system

It should be a national repository of information from all available sources. The database will have a multi-axial classification system with expandable categories incorporating UK needs and UK terms. There will be rapid and sophisticated feedback at local, regional and national levels. The system will be customised to accommodate specialists, craft groups and specialist areas such as dialysis and critical care services.

Figure 8.8 is extremely important. It shows a bar chart of the number of adverse events in each category of event - the vertical axis - against the different types of clinical categories - the horizontal axis.

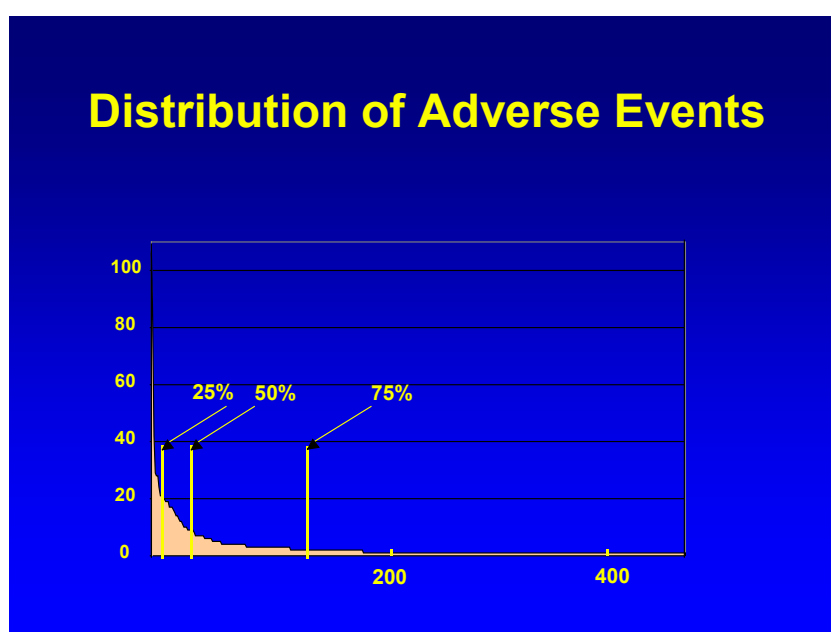


Figure 8.8 The distribution of frequencies for different types of adverse event

Note that the bars have been placed in succession starting with the largest number of events and ending with lowest number. This is representative of data collected over a year from a typical 250-bedded hospital. Figure 8.8 is important because it shows that there are only a handful of types of frequent events, such as adverse drug reactions or nosocomial infections, and that all the other types are rare. Note that although the *top* 25% of events fall into only 20 categories, the *bottom* 25% occur only once or twice a year. So a national database is needed to learn about these rare events.

Figure 8.9 magnifies the first part of this graph and superimposed on these more common categories are the red bars showing those event types for which medico-legal files were opened.

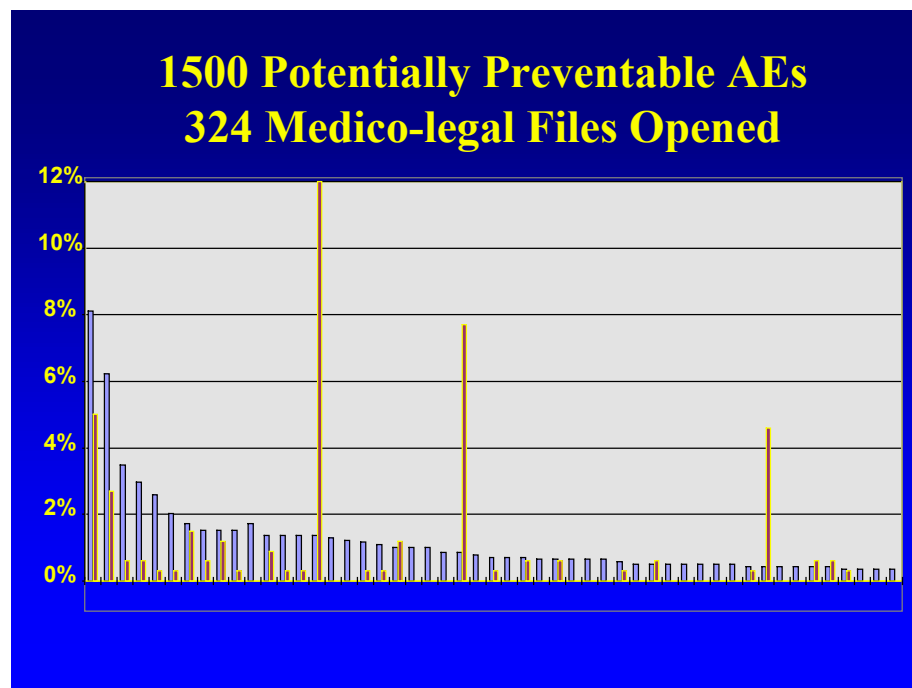


Figure 8.9 Frequencies of commonly occurring events and opened medico-legal files

As you can see there is no relation between the frequency of the preventable adverse events and subsequent legal action. This is partly because frequency does not necessarily tally with severity of harm or with how obvious it is that the harm was preventable and in Australian healthcare people are only clobbered for inflicting certain kinds of patient injuries. The tallest red bar corresponds to endoscopic examinations that caused perforated organs. It is important to note that only *four* in every *thousand* of all potentially preventable events result in compensation for the patient.

Figures 8.10 and 8.11 show how consistently our healthcare system fails to address patient safety. Both figures are twin pie charts that compare how our hospital - hospital 21 - compares with all hospitals in our State of South Australia. The charts for our hospital mirror those of all hospitals whether looking at contributory factors to the outcomes of the events or the outcomes themselves. The conclusion is obvious. The patterns are very consistent. Without re-design, the system will continue with relentless inefficiency to kill 10,000 patients and generate 500,000 adverse events annually in Australia.

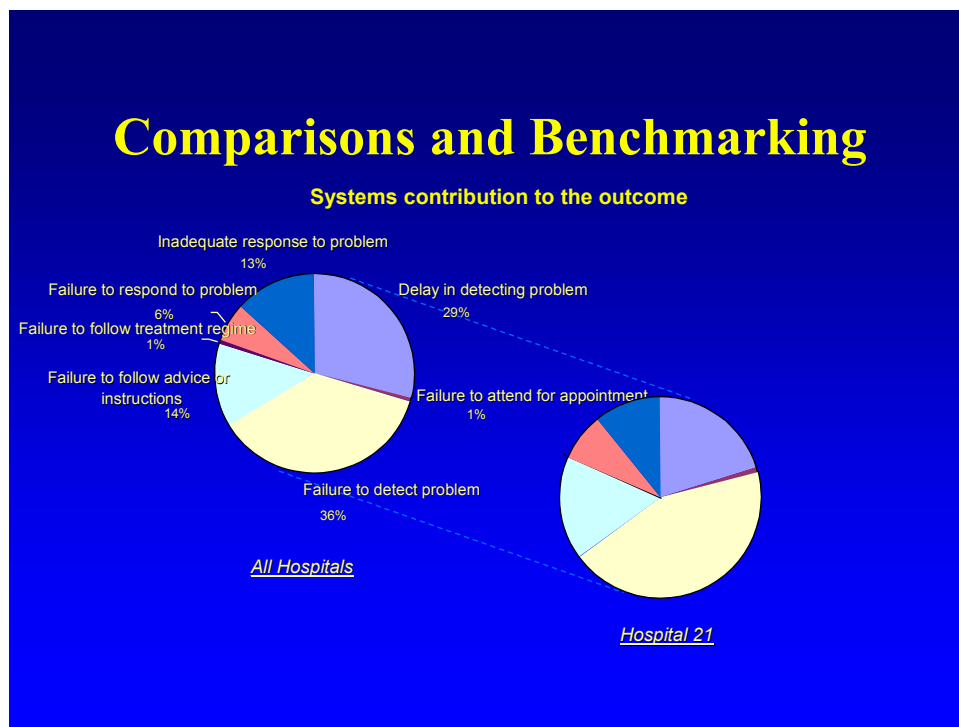


Figure 8.10 Systems contribution to the outcome: Royal Adelaide hospital compared with all South Australian hospitals

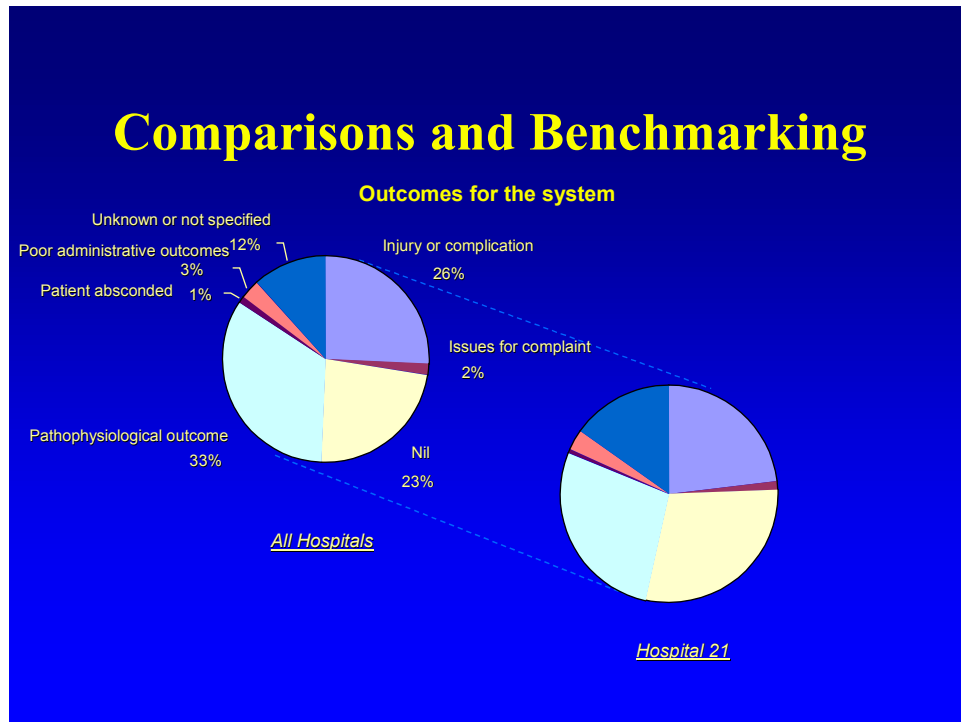


Figure 8.11 Outcomes for the system: Royal Adelaide hospital compared with all South Australian hospitals

Case studies

How have we used the AIMS database to improve patient safety at a national level? In the second half of my talk I shall give some examples of successes and failures and will show that the system is a mine of undiscovered and valuable information. However getting the Australian healthcare service to change is another matter. In contrast, Jim Bagian's work for the Veterans Health Administration has achieved change at the frontline and we can learn much from the role and structure of his organisation.

1. *Saving lives with pulse oximeters*

We used data in AIMS to show that pulse oximeters saved lives by the reliable detection of hypoxia. The findings were statistically significant for death, which was not the case in a randomised prospective trial of pulse oximetry that used 20,000 patients. How long did we take to interrogate the database to obtain the key information? Four hours! This information had an important influence on setting international safety standards for the conduct of anaesthesia.

2. *Vaporisers and the case of the man in Tasmania*

In 1994 a man in Tasmania was having a total hip replacement. During the operation the anaesthetist changed the vaporiser but the replacement did not seat properly. The

ventilator - a falling-bellows type - then began to entrain air and reduced the level of anaesthesia to the point where the patient, who fortunately was receiving an epidural, could hear everything the orthopaedic surgeon was saying. Later the patient talked on the television and radio about being completely awake but paralysed during the operation. The College of Anaesthetists blamed the manufacturer of the equipment and demanded withdrawal of the equipment. The company in turn pointed out that none of the staff had attended the relevant company training courses and so the cause was user error. At that time our database had more than three thousand five hundred reports - these were early days - of which 134 were serious incidents or near misses involving vaporisers. There were deaths, people did not know what the ventilators had been filled with, ventilators had been dropped or tipped over and had then produced fatal concentrations. Two had been filled with detergent solution and left on a shelf. The detergent had then corroded the bypass channel and so the first two children on the paediatric list died because they had received the solution by the non-bypass route. One ventilator did not send patients to sleep because it had been filled with urine.

We found that 60% of the problems were caused by users. For example some ventilators were switched on when they were supposed to be switched off (and the reverse), others were producing high halothane concentrations when low concentrations should have been used (and the reverse). We showed that the manifestation of the underlying problems was context-dependent because of complex interactions between the type of ventilator and the way it had been linked with the anaesthetic machine. For instance the falling-bellows design of ventilator caused leaks but the rising-bellows counterpart under-ventilated the patient. The opinions of experts and the literature were both useless - for example research on the performance of ventilators at high altitudes would only serve those who wished to build a hospital on a mountain top.

The solution to this problem was simple and was introduced as a requirement for every anaesthetic in Australia - in-line monitoring of volatile agents during anaesthesia. The solution is now practised through Australian anaesthetic practice and is done for a dollar-a-patient.

3. Anticoagulants

Anticoagulants cost the NHS an estimated one million dollars (£400,000) *daily* and are a major problem in healthcare everywhere. Here are some examples: patients who should be on Warfarin and are not and have an embolic stroke, those who are on Warfarin but bleed and patients who wrongly receive the drug. Failure to use Heparin peri-operatively is also known to be associated with an increased rate of thromboembolism. Below are the key facts that should alert all of us. In Australia anticoagulants:

- cause one third of preventable adverse drug events;
- cause one third of deaths associated with adverse drug events (451 deaths); and

- are number three on the list of drug-related admissions.

The first two points came from the *Quality in Australian Healthcare Study* and the third by examining 14 studies of drug-related admissions. Our monitoring of medication incidents always puts Heparin and Warfarin at numbers two and seven, respectively, on the list in terms of frequency of reports.

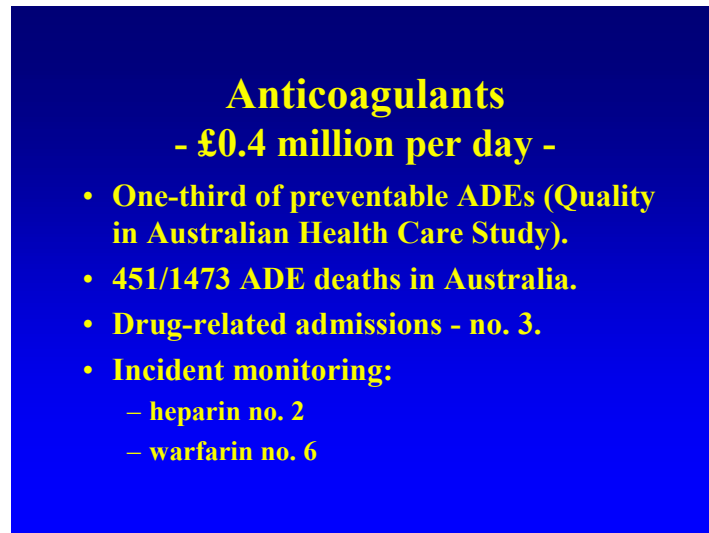


Figure 8.12 Anticoagulants: their problems for healthcare

Heparin is consistently the second most common drug implicated in an incident. We examined the staff factors in Heparin-related reports from our own hospital. These are summarised below:

Table 8.1 Staff factors in Heparin-related reports at the Royal Adelaide Hospital

Staff factor	Number of Heparin-related reports
Lack of orientation*	11
Lack of knowledge	10
Inadequate knowledge /training qualifications	10
Insufficient staff rostered on shift	2

* orientation: new staff being 'shown the ropes'

The striking conclusion was that the lack of knowledge, training, experience and orientation of nurses were far more important factors than were staff numbers. In short neither the many agency nurses nor their full-time colleagues on shift knew what they were doing with respect to aspects of Heparin administration. We then used the

database to compare the effects of lack of knowledge, training, experience and orientation on the kinds of Heparin-related incidents in our hospital with those state-wide. The results are shown in figure 8.13. All hospitals are on the left and our hospital is on the right.

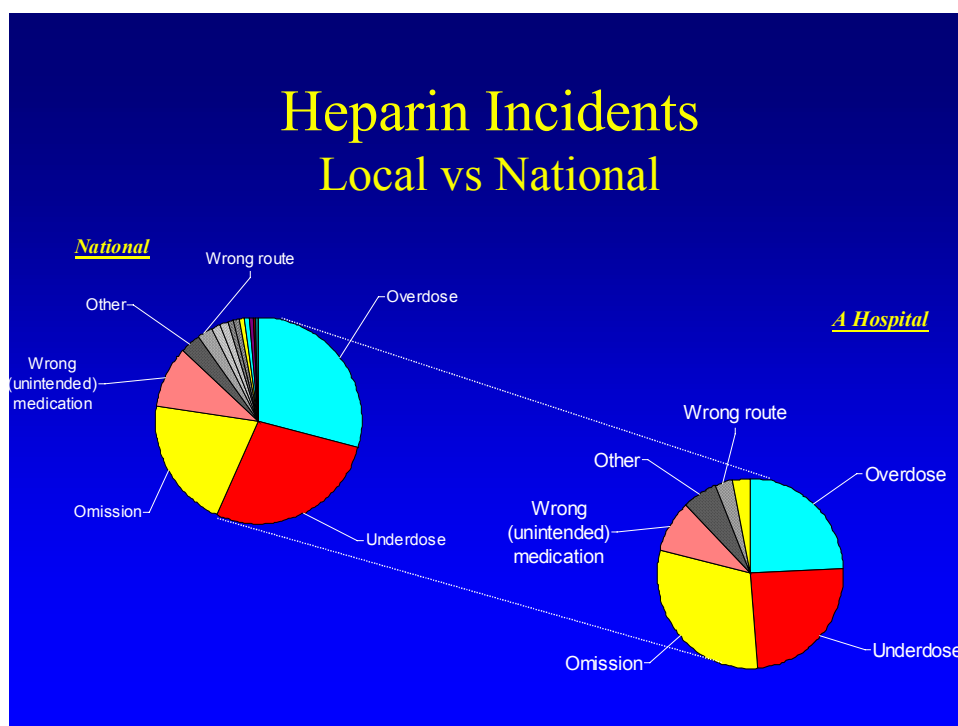


Figure 8.13 The kinds of Heparin-related incidents: local versus national

The pie charts are strikingly similar to one another, which suggests that the causes of overdoses, underdoses, the wrong patient receiving Heparin etc are the same throughout Australian healthcare. The culprits are the miscalculation of doses for infusion, and the misuse of infusion pumps. People made mistakes because many rather than one method of calculating doses were in use (particularly in orthopaedic wards). Some did not know that the pharmacy prepared premixed syringes. We found that 60% of the problems were ultimately caused by the lack of standardisation of the makes and models of infusion pumps. In our hospital there were 14 different makes and models of infusion pumps and syringe drivers. 'Hide and hoard' (where equipment is locked away in cupboards) is widespread in Australian healthcare which also prevents the regular servicing of equipment. I can tell from the smiles of the audience that the NHS has the same problem. In short we allow a shambles to exist in healthcare that would not be tolerated in aviation. Would the aircraft's compass be hidden in a cupboard or the lavatory paper be selfishly snaffled for use by the select few? We now have an Equipment Committee, which is as powerful as the Drugs and Therapeutics Committee in our hospital, but such mechanisms for producing change have not yet been effected throughout the healthcare system.

4. Nosocomial infections

Nosocomial infections are top of the list in the *Quality in Australian Healthcare Study* and bloodstream infections that are caused by central venous catheters are also in the top twenty. The 3,000 cases of bloodstream infections a year almost certainly kill 300 patients and are implicated in a further 700 deaths. Forty studies were re-analysed. It was demonstrated that the choice of catheter could prevent infections and so a decision-support model was built (figure 8.14). This predicted and proved that the switch to Minocycline-Rifampin coated catheters would reduce the infection rate from 8% to 1%, reduce annual deaths, if used nationally, from 300 to about 30 and save our hospital alone one million dollars a year.

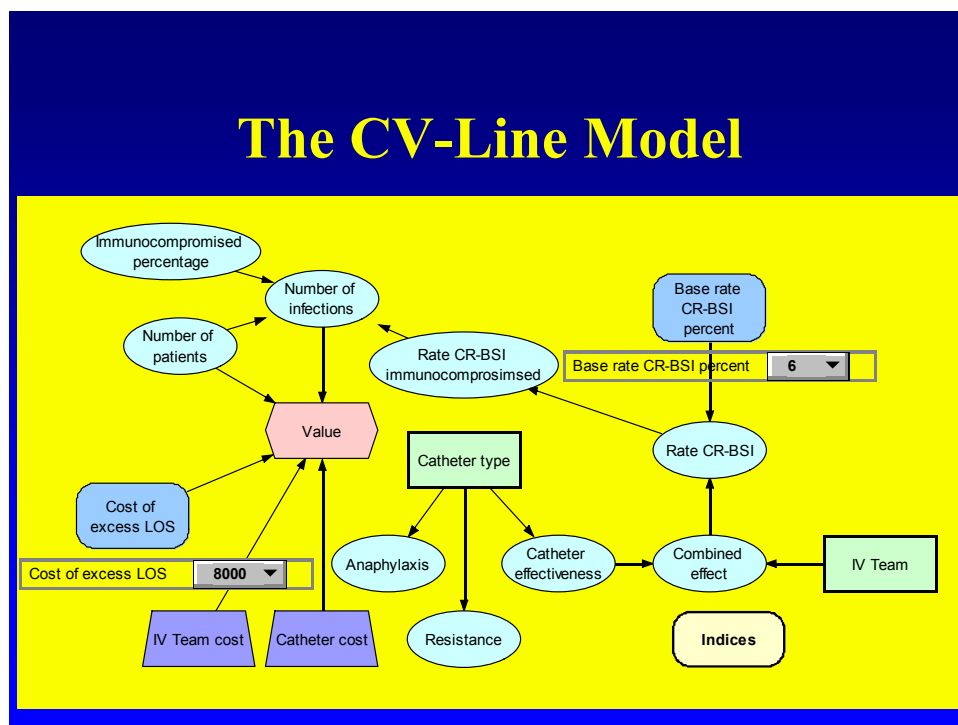


Figure 8.14 The decision-support model to reduce catheter-induced nosocomial infections (after Pradhan and Wilkinson)

Do you think that our actions attracted interest elsewhere? I emphasise that we only asked people to change catheters, not culture. There was less interest in achieving an eight-fold increase in patient safety than in the precise measurement of the present infection rate. Again I emphasise the contrast between care about patient safety by the health system overall and the reaction of car manufacturers to safety. A hundred thousand cars can be withdrawn for a fault that has yet to kill anyone. However, a simple-to-implement cost-effective measure to reduce death in healthcare may not attract widespread interest.

5. Elderly patients and NSAID use

Sometimes we do achieve success on a large scale. GPs in South Australia were asked, using 'academic detailing' to reduce prescribing non-steroidal drugs to elderly patients and there was a gratifying reduction of both such prescriptions and admissions to hospitals of patients with suspected peptic ulcers.

What is the final score?

AIMS is a powerful tool but we have had mixed results when trying to change national healthcare practices. The score sheet for these case studies is below.

Table 8.2 Case study 'score sheet' – change at national or local level

<i>Case study</i>	<i>Change at national or local level</i>
Saving lives with pulse oximeters	Powerful, national and international
Vaporisers and the case of the man in Tasmania	National change
Anticoagulants	Some local change
Nosocomial infections	Some local change
Elderly patients and NSAID use	State-wide change

Current work

Finally I shall summarise our current work. We are building a decision-support model to be used at the pre-operative assessment and planning stage using computerised histories. The model has the potential to save one in eight of all adverse events by providing optimal *state-of-the-art* treatment for the prophylaxis of nausea, vomiting, pain, infections and thromboembolism in the peri-operative period.

What lessons have we learnt?

1. Protect the reporter.
2. Have a national database that is customised for UK use that can accommodate results from all sources of things that go wrong in healthcare.
3. Use a common terminology, allowing reporting by any means – e.g. the web, fax etc. - publish updated definitions, and disseminate change strategies that have been derived from analysis of reports and the literature.
4. Re-engineer aspects of the healthcare system - e.g. universal computerised prescribing with decision-support - by providing the necessary commitment and investment.

Bill Runciman

I wish the NPSA well and urge the Agency and the NHS to collaborate with us and others in developing systemic solutions and common tools for systemic problems in worldwide healthcare. Thank you.

Part III – Case studies and examples from the NHS

9

Medication errors and organisational culture in the Pharmacy

Professor Nick Barber
Professor of Pharmacy
School of Pharmacy, London

Introduction

When I was a basic grade pharmacist I once dispensed Promazine for an elderly woman patient to help her sleep (the drug was not available on the ward). The next day the sister asked, "Could I have a word?" and showed me a bottle of Promazine with a label stating it contained five milligramme tablets. I said "I did not know that you could get five milligramme tablets" and then realised that I had mis-labelled the bottle, and so the patient had been given five times the correct dose. The doctors and nurses covered for me, saying to relatives that the patient was sleeping deeply because this was part of the healing process. Eventually she awoke, but not before I had spent a sleepless night (as many healthcare professionals have done) wondering if I ought to do a different job that had no contact with patients. I tell this story because pharmacists, who specialise in the detection and prevention of errors, make mistakes too – but I am not here to preach.

So what is special and different about pharmacy? Other healthcare specialties such as surgery, dentistry and ophthalmology, focus on the body. Pharmacy is about materials for healing - chemicals, plant extracts and their methods of production. The ancient Greek origin of pharmacy is 'pharmacon' which means both a medicine and a poison. Pharmacists are specialists in the careful use of poisons to heal patients, and so we have always tried to minimise the risks associated with medicines. For example the school of pharmacy where I qualified was established in 1842 and the lectures at that time were about the correct identification of plants. Later, chemical analysis was added to the curriculum as concern grew about the presence of harmful heavy metals. So the risks that pharmacists try to reduce change with time; for example, economic risks are the most recent addition.

Risks in pharmacy

There are three broad categories of risk that we try to detect and prevent.

1. Risk in the medicine itself.
2. Risk in manufacture, storage and distribution (perhaps you are not aware that hospital pharmacies manufacture medicines).
3. Risk in use. For example, patients may not take their medication and nurses may miscompound medicines.

Although I am a Professor of Pharmacy I am actually registered as a pharmaceutical chemist, which illustrates that we specialise in the manufacture and the safe use of effective materials for healing.

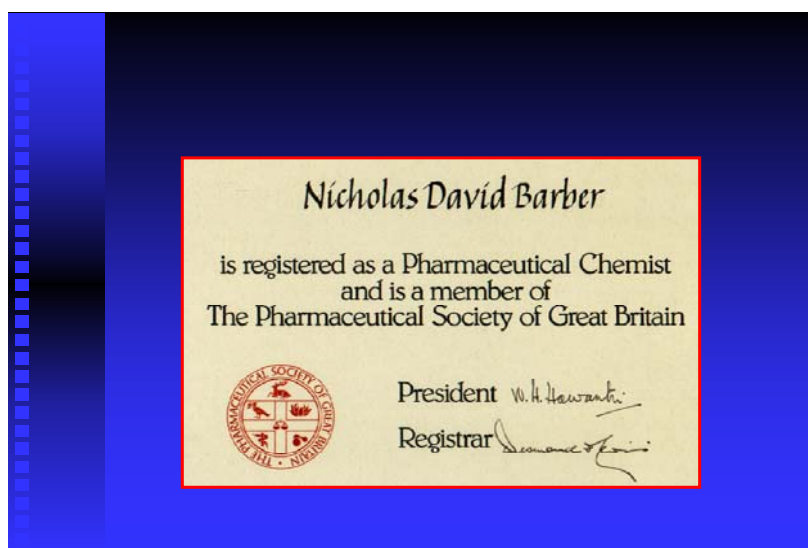


Figure 9.1 Registered as a pharmaceutical chemist not a pharmacist

The kind of culture that we have now has been very heavily influenced by the functions of pharmacy. We measure precisely minute amounts of drugs. We are in-hospital manufacturers of medicines and many hospital pharmacies - hopefully all in the future - are licensed to produce medicines to the same standards as any major industrial company. Until five years ago the undergraduates where I work could design such industrial production plants as part of course work and some received prizes from the Chemical Engineers Association. We test each stage in production, storage and distribution of medicines and check on every step of their use from the prescription to the reliability with which patients take their medication at home. Pharmacists expect things to go wrong and always ask three questions:

1. What happened?
2. Why did it happen?
3. What can we do to stop recurrence?

In short, pharmacy is similar to high quality manufacturing industry. We expect errors to occur and design systems to reduce them; there is no room for a punitive culture whereby the individual is blamed.

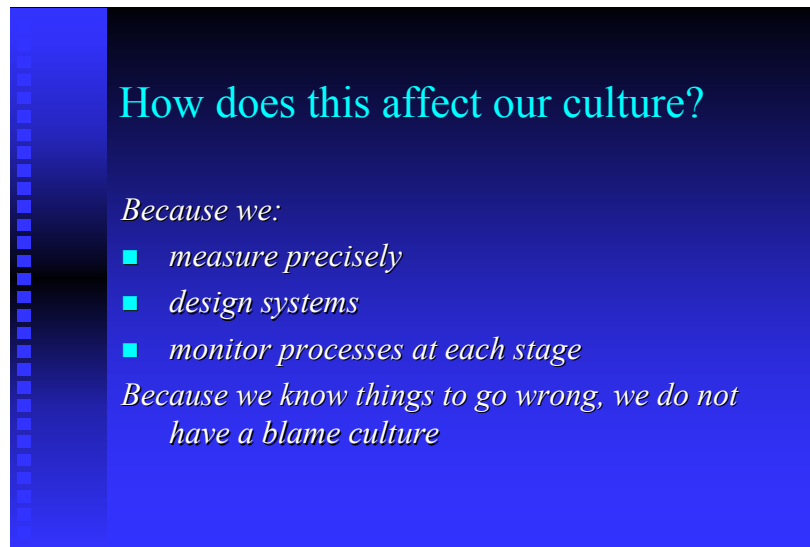


Figure 9.2 Activities and culture in Pharmacy

There are several pharmacy services to reduce risks in hospitals.

1. The ward drug chart - surely one of the design icons of the last half-century.
2. Checking the prescription and supplying the drug.
3. Reconstituting cytotoxic drugs.
4. The uses of pharmacokinetic calculations to assess toxic and sub-therapeutic doses.
5. The licensed production of medicines under the Manufacture Controls Assurance scheme.
6. Quality control and assurance.

Ward pharmacy services, which were first proposed as a health policy in 1970, detect and prevent prescribing errors. When I was regional director of clinical pharmacy for North West Thames region we analysed prescribing error data from the region's 32 acute hospitals and found that there was an average of thirty interventions per 100 beds per week (figure 9.3) However, the rate ranged from four to 80 interventions. We wanted to know if this range was caused by variations in the quality of pharmacy

services and found that there were three important drivers of variable intervention rate.

1. The type of ward, with the Intensive Therapy Unit (ITU) at the top of the list as it had the most problems, errors and interventions.
2. The grade of pharmacist - the higher the grade the greater the number of errors detected and interventions made.
3. The length of stay of the pharmacist on the ward. This is important given the current shortage of pharmacists and the consequent pressure to reduce time spent on wards.

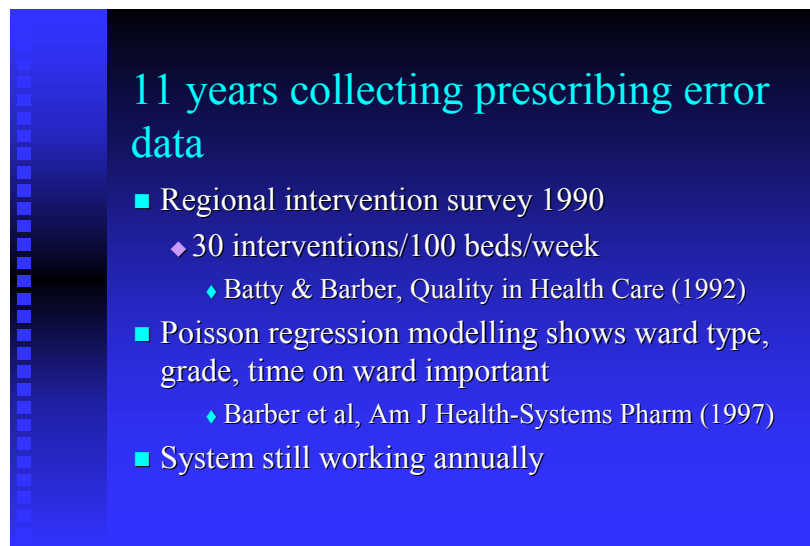


Figure 9.3 Analysis of prescribing error data: key results

This analysis is still carried out yearly by the London Regional Pharmaceutical Service. Could better internal use be made of the data that pharmacists collect on ward rounds? I give the example of the approach at the Hammersmith Hospital with which we have a joint academic unit. Here the original reporting route for errors detected by pharmacists was to the drugs and therapeutics committee. Then reports were made to clinical directors and finally error reporting is now multidisciplinary and a specialist group examines the data.

Whilst we know the numbers and types of errors, we have not known until very recently what proportion of hospital prescriptions are incorrect. My colleagues and I measured the prescribing error rate in one teaching hospital. We adapted the routine ward checks that pharmacists undertake by first defining 'prescribing error' to everyone's satisfaction, using this definition to record inpatient errors for one month

and also finding out the total number of prescriptions written. The results are summarised below. One and a half percent of all 36,200 prescriptions that were written over four weeks were faulty; one error in four was serious (five per day). Most faulty prescriptions were written in hospital. Mistakes in admissions history and discharge prescriptions were rare. Fifty nine percent of mistakes were the wrong dose.

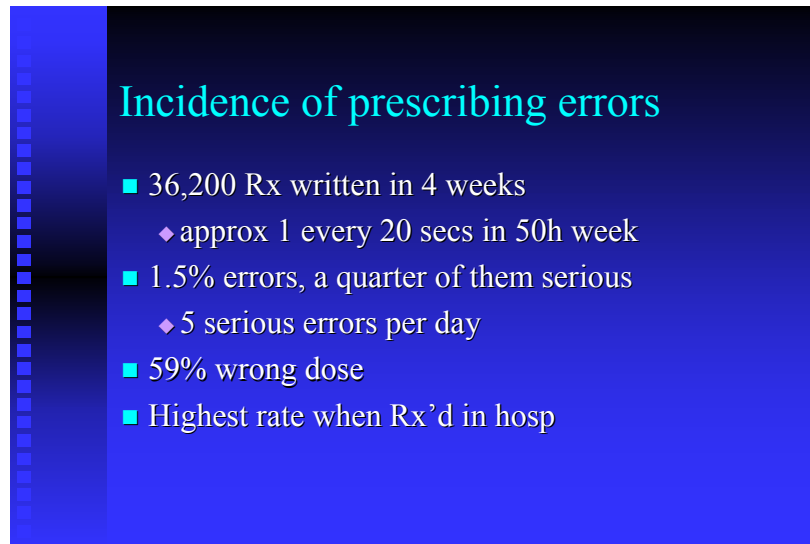


Figure 9.4 Incidence of prescribing errors: key data

However, we still do not know how many patients are harmed as a result of prescribing errors and research is needed to complete the picture. We need to remember that the pharmacist is a key defence against drug errors for the patient and is a backstop if all the other defences are breached. This work, which is to be published shortly, was done in collaboration with Charles Vincent (Professor of Psychology at University College London), Mike Schachter (Consultant Clinical Pharmacologist at Imperial College London) and Bryony Dean (Head of the Academic Practice Unit, Hammersmith Hospital). The methods summarised above could be adapted to help achieve the target of a forty percent reduction in serious prescribing errors by 2005. However the key question is how do we prevent them in the first place? There are many contributing factors that we have uncovered in very recent research on interviews with doctors who had made serious errors using Human Error Theory (similar to root cause analysis).

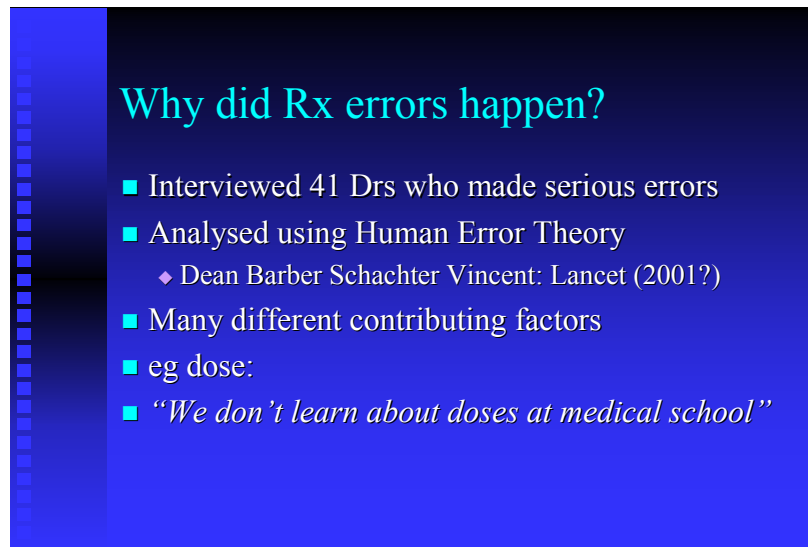


Figure 9.5 Research on causes of serious errors

Here are two reasons for mistakes: 'We don't learn about doses at medical school' and 'I've heard of Thyroxine of course but I've no idea what dose to give' (a Senior House Officer). The interviews revealed that such ignorance is not helped by the way senior consultants sometimes fail to teach junior doctors to look at the detail in the drug chart and do not explain the drug dose when describing the therapy. Prevention may well start with better induction of junior registrars and consultants could provide simulation training to teach young doctors about drugs and doses.

Hospital pharmacy has taken many initiatives to reduce medication errors and I have highlighted some in figure 9.6. Prescribing errors are reported and should be acted upon - as the Commission for Health Improvement has recently recommended to one hospital¹. Pharmacists, such as David Cousins, alert colleagues about errors via journals². Dispensary errors are monitored and Mike Spence at Cardiff has done good work here. Colleagues at Nottingham have examined errors dispensing the patients' own drugs. Ann Jacklin at the Hammersmith and Martin Pickstone who is to talk next have developed a simple system to relate the risk of IV therapy to the precision of the infusion pump. Pharmacists now prescribe, e.g. Warfarin, and check or do admission and discharge medication.

¹ www.chi.nhs.uk

² http://www.ismp.org/Pages/mederr_intl.html



Figure 9.6 Reducing medication errors: initiatives by hospital pharmacists

Evaluating new services

We can use research to evaluate new services prospectively before making the investment and changing the organisation. For instance, Bryony Dean used mathematical modelling techniques to simulate how different service changes may alter the rate of wrong prescriptions. She 'introduced' computerised prescribing, vacuum tubes for rapid drug transport and changed portering. Mathematical modelling allows us to explore and sift options before investing in costly technology. I have often heard arguments that more technology is needed in pharmacy to reduce errors. So here are four cautionary case studies.

Case study 1

Colleagues at Manchester University and I investigated the use of the Meditrol automated drug dispensing system at a district general hospital. The Meditrol system works in the US. We found that there was no difference in the administration error rate compared to that previously, however the computer-controlled system needed seven and a half extra staff of whom six were pharmacists.

Case study 2

Does computerised prescribing reduce the administration error rate? The argument is that the patient is safer if the pharmacy receives the prescription as soon as it is written. A comparison between two hospitals, one of which had the technology and the other one had not, showed no difference in rates.

Case study 3

We have recently investigated the effectiveness of computerised discharge prescriptions by studying medication errors in surgical elective admissions following patients from admission to discharge at a hospital. Nearly half of the errors occurred during the use of the computerised discharge system. Selection errors and omissions were the main culprits.

Case study 4

We know that between one-third and two-thirds of patients do not receive the right prescription within a month of discharge. To remove the communication problems the suggestion was tried of inserting an extra carbonised sheet in the TTA ('To take away'), which the patient gives to the community pharmacist. Five hundred patients were followed up at home. The scheme worked and research showed that only nineteen patients had to receive one of these sheets for an adverse event to be avoided. The cost was fifteen pence per patient. I believe that more research should be done into simple and cost-effective ways of changing systems that do not require the extensive use of new technology.

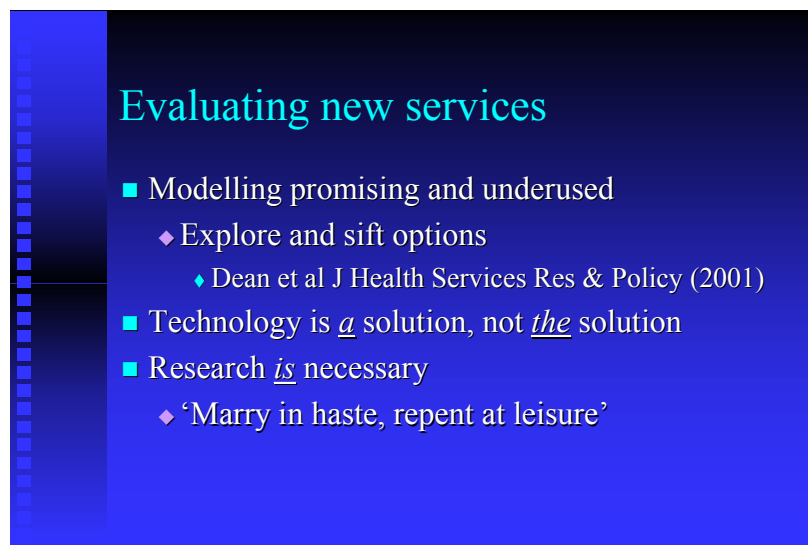


Figure 9.7 Evaluating new services

Conclusions

Technology is one solution - but not the only solution. Sometimes very simple ideas can be effective and the computer-controlled technology that has been developed for US healthcare has not been designed to tackle our problems in the NHS. For instance American pharmacists have their own complex unit-based method of prescribing.

Closing thoughts

1. Community pharmacies do not appear to fit well into the remit of the National Patient Safety Agency. Those that are shareholder companies have special concerns. A central, standardised dispensing error reporting system that is just for pharmacies may be the best way forward, if it can be linked to the NPSA in some way.
2. The drug industry can and must play an important part in reducing errors by writing understandable 'instructions for use' for nurses. Some of their written material is not adequate.
3. Pharmacists are changing from checking the prescribing of others, to doing some of it themselves; this will grow under current NHS plans. So who, once they are prescribing, watches over the pharmacists?

Summary

1. Pharmacy's culture of error detection is not easily transferable, so we should use pharmacists in multidisciplinary teams.
2. Better use could be made of the data that pharmacists collect.
3. We must not let the need for action lead us into the naive adoption of technology.

10 Making IV therapy safer – competence training, safety culture and technology

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Mr Chris Quinn
Medical Devices Officer
Newcastle upon Tyne
Hospitals NHS Trust

Part I – Talk by Martin Pickstone

Introduction

I shall talk about unsafe practices and competence training and my colleague Chris Quinn will present the other topics in our joint presentation. Let me pose and answer two questions. Why today are we discussing IV therapy & why training?

1. Intravenous therapy is used in most clinical specialities, is administered by very many nurses and is associated with some of the most serious types of medication errors.
2. After a serious infusion incident has been reported and analysed then in-service training & education is needed to change behaviour & practice.

Complexities of IV therapy hazards

The hazards of IV therapy are complex. There are three main types - dose effects, vascular damage and the entry of foreign bodies into the cardiovascular system - and at least at least nine hazard subtypes.

Both medication errors and uncontrolled flow of the drug solution during the therapy can overdose the patient. Infusion pumps deliver variable and sometimes delayed doses that may be harmful. Vascular damage is common: phlebitis (aseptic inflammation), venous occlusion and extravasation (penetration of the solution into the perivascular tissues). Finally the solution may contain air, particles and bacteria all of which may be harmful. Present advice from the Department of Health is to use five categories of patient injury¹. So there are at least 45 combinations of hazard type and injury level. The frequency of each depends on the patient, the drug, the type of infusion system, the point of entry - peripheral or central venous - and whether the

¹ See figure 4.7 in Professor Rory Shaw's chapter.

therapy is at hospital or home. Thus each type of therapy has an associated pattern of risks. The idea that there is one type of IV therapy-related hazard is wrong and a potential threat to patient safety.

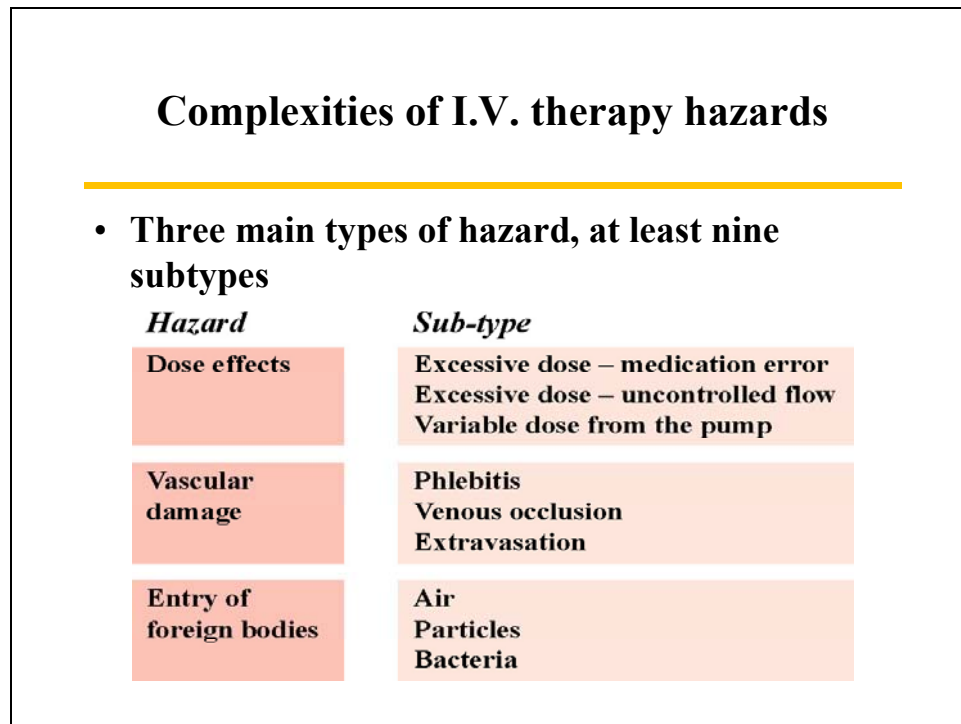


Figure 10.1 Complexities of IV therapy hazards

Strategy for reducing industrial accidents

I began my research into competence training to use infusion systems by looking at four major studies of industrial accidents (covering 2.75 million accidents). The triangular diagram in figure 10.2 summarises their findings. I used the conclusion of some industrial safety managers that training should be used to reduce the base of the triangle i.e. the frequency of unsafe practices & working conditions, so that the frequency of accidents of all kinds of seriousness would also decrease.

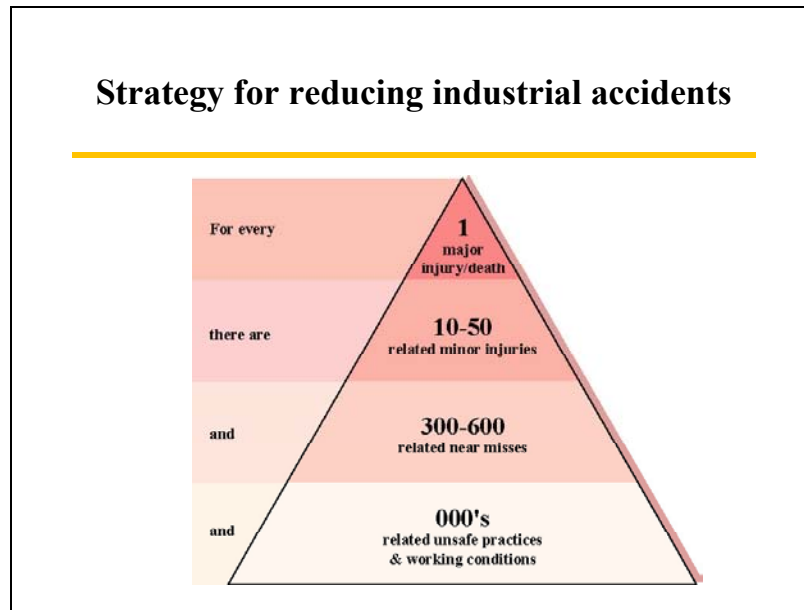


Figure 10.2 Research into industrial accidents: key findings for accident reduction

The next stage was to ask a large number of people about what sort of training nurses should be given so that they would use infusion systems safely. Guess what? People mostly told stories about unsafe practices/working conditions and near misses. The training method has reversed these into training objectives - 102 objectives that divide almost 2:1 in favour of background knowledge and understanding over practical skills (see figure 10.3). A similar investigation into the use of cardiocograph monitors in labour wards yielded nearly 60 training objectives.

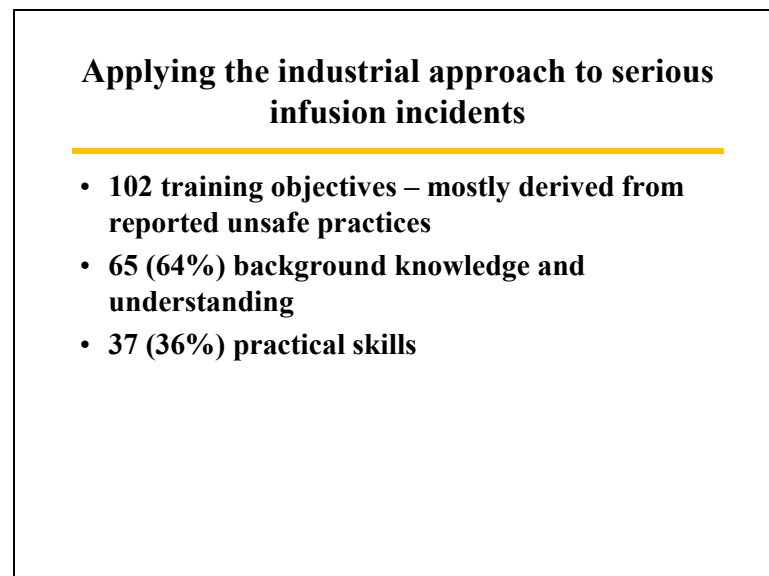


Figure 10.3 Applying the industrial approach to infusion therapy training

Competence training to use infusion systems

Competence training is not a state secret. It is the marriage of practical skills with knowledge and understanding so that the trainee can deal with the unexpected. The trainee acquires tested transferable skills. Figure 10.4 shows a flow diagram for the infusion systems training method and that of the old-fashioned driving test.

Competence – the structure of training and testing

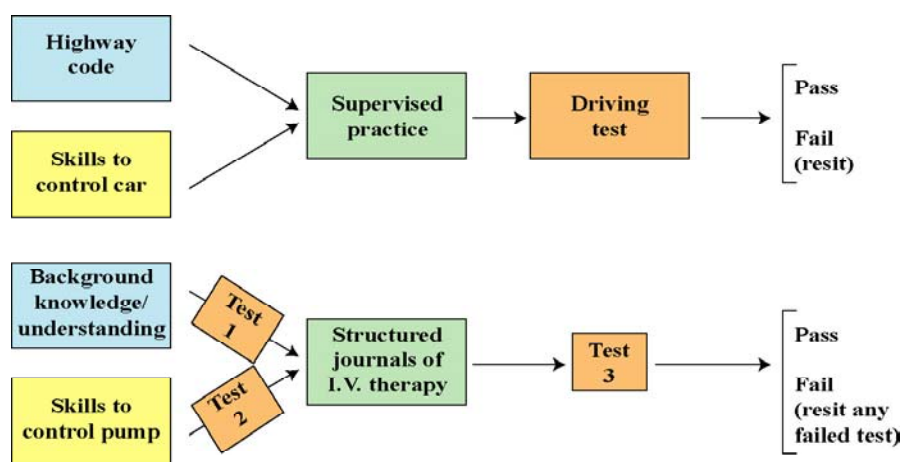


Figure 10.4 Competence: how definition determines training and testing

Believe it or not, the driving test is a crude measure of driving competence. The driver learns to combine the skills to control the car with background knowledge; the Highway Code is the rules-of-the-road for safe driving. The flow diagrams show that the same definition of competence is used but infusion systems training has three staged-tests and structured (reflective) journals of IV therapy. The complete infusion process listed below is contained within the three large blocks in the diagram:

1. Drug calculations
2. Making up drug solutions
3. Presenting the infusion - low concentrations/high volumes, or the reverse
4. Choosing the equipment to minimise risk
5. Using the equipment from start-up to close-down

The training objectives span this process to achieve a comprehensive approach to patient safety. Training objectives can be grouped into elements of competence whose pass marks and relative importance are then used to define assessment criteria and

competence standards. However the basis is unsafe practices, working conditions and hazards.

Two conclusions

1. Why is this form of training needed? One example says it all for me. A few months ago I was asked to comment on a fatal infusion incident in which a woman patient was administered Dobutamine at fifty times the rate that should have been prescribed. What shone through the paperwork was that neither the nurses nor doctors understood that if the infusion rate is increased fiftyfold then to a first approximation so is the equilibrium dose in the patient. The staff had the practical skills but lacked critical understanding. By definition this is incompetence and a patient died. Knowledge and understanding is neither an optional luxury nor an a-la-carte/pick-and-mix menu.
2. Finally, you might care to consider how the British army successfully reduced trench foot in the First World War. The soldiers used the 'buddy' system. You looked after your mate's feet, he looked after yours. If he got trench foot, you got five years penal servitude - beginning after the war had ended. Thank you.

Part II – Talk by Chris Quinn

SECTION A

The Technology Triangle, learning & safety

What I want to do is follow on from Martin Pickstone and talk about the reality of learning from unsafe practices, near misses and adverse events. The story started seven years ago when a multi-disciplinary team at the Royal Victoria Infirmary (now part of the Newcastle upon Tyne Hospitals NHS Trust) began to be concerned about the increasing number of serious infusion incidents in which the therapy had been delivered by pump. Later the Trust collaborated with the Imperial College School of Medicine in the development of competence training so that nurses would safely use infusion systems - pumps, administration sets and syringes/bags. I was in that team and soon realised that competence training alone would only partly improve the safety of pump-delivered IV therapy.

Martin Pickstone and I then invented the Technology Triangle (see figure 10.5) which is a simple visual tool that illustrates the relationships between the objectives of technology management in clinical procedures, the practical actions necessary for their achievement and the end result - better patient care. The triangle's apices represent the objectives (safe choice & applications of technology, right size of stock of well-maintained technology and proper use and care of technology). The sides represent the

practical actions (assessing clinical needs, competence training and maintenance/calibration) whilst the intended result (better patient care) is at the centre of the triangle.

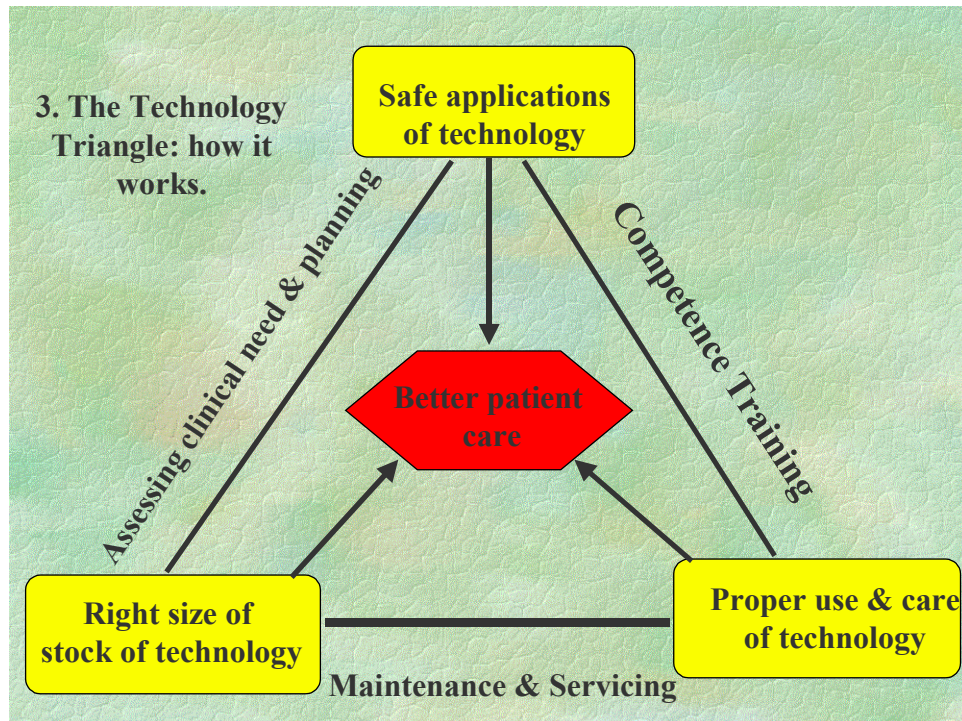


Figure 10.5 The technology triangle

Two observations underpin the triangle. First, six broad objectives of technology management in clinical procedures can be devised that can be grouped into three related pairs. Secondly, three general kinds of practical actions are necessary and each simultaneously achieves two different objectives. Thus the assessment of clinical needs ensures both the proper choice of technologies and determines the correct size of stocks to satisfy patient needs. Competence training for specific technologies ensures that *all* relevant staff safely apply, skilfully operate and care for equipment to defined performance standards. Finally, the maintenance and calibration service in a hospital not only provides technical care of equipment but also maximises the stocks of safe technology. In short the Technology Triangle illustrates the integration of six objectives and three practical actions to maximise patient care.

We use the Technology Triangle first to diagnose how unsafe practices and adverse events can affect the safety of technology-assisted clinical procedures and then to predict the effects of countervailing practical safety actions. I shall present two case studies, one about infusion systems the other about the use of Resuscitaires, which provide newborns with heat and supplemental oxygen in delivery suites.

Case study 1 - infusion systems

A review of IV therapy practice in 1995/6 revealed the following.

1. A 246% increase in the number of serious infusion incidents delivered by infusion pump from 1993 to the end of 1996. This increase was equivalent to an annual compound growth rate of more than 35% over four years.
2. The stocks of infusion pumps contained more than 40 different models, 25 of which were obsolete. The practice of 'Hide and Hoard' already described by Professor Bill Runciman was rife.
3. No nurse had received formal competency-based training to use infusion systems safely. Informal training - 'Nellie see, Nellie do' – was used sporadically by colleagues and company representatives.
4. There were extremely low standards of housekeeping of infusion pumps, monitors and other commonly used devices. Such poor care can be inferred from figure 10.6, which shows a typical ward equipment store at the time of the survey. Note that in the top right hand section of the cupboard there is a jumble of five syringe pumps that together cost about £8,000 (US\$12,000, or A\$20,000), which is as much as the price of a decent second-hand family car. Clearly there was no ownership of the ward equipment by the doctors and nurses.
5. Only 40% of the infusion pump stock was being used in one wing of the hospital that I surveyed. This was the average of a fluctuating usage and excluded critical care areas. Although 60% of the stock was idle the nurses were convinced that there was a shortage and often spent time on the telephone trying to find more pumps.



Figure 10.6 A typical ward equipment store at the time of the survey

Risk assessment and application of the Technology Triangle

The large number of pump models added an unnecessary training burden on both nurses and the Trust - and increased the likelihood that an adverse event might result due to unfamiliarity with the equipment. The obsolete equipment was, by definition, not fit for purpose (inadequate safety features and performances) and in consequence decreased the size of stock of safe infusion models. 'Hide and Hoard' had three pernicious effects: the pumps may have become unsafe because they were neither serviced nor repaired, nurses were less likely to be familiar with the use of hidden equipment and the size of *available* stock that was properly maintained and safe was permanently decreased. Informal training is *not* competence training and so did not ensure that *all* relevant staff safely apply, skilfully operate and care for infusion systems to defined performance standards. Dirty and roughly handled equipment (poor housekeeping) may have had inferior performance and sometimes may have been electrically unsafe. When nurses spent time on the telephone trying to find pumps the ensuing delayed IV therapy degraded both patient safety and patient care because poor organisation had diminished the stock that was believed to be available. The 60% idle stock in one hospital wing was a huge waste of money and helped to justify the post of Medical Devices Officer - my job.

IV therapy practice at that time was riddled with unsafe practices that Professor Reason calls 'Latent Conditions' for system failure and which competence training

alone would not eradicate. I have used the Technology Triangle to summarise the problem in Table 10.1, which shows that the combination of unsafe practices prevented the achievement of all the objectives that are needed to manage the stocks of infusion systems. Infusion systems were neither being chosen safely nor knowingly for the IV therapy, stocks were neither matched to the need nor were maintained properly and the proper care and use of equipment was minimal.

Table 10.1 Unsafe practices & the achievement of technology objectives

<i>Unsafe practice</i>	Safe choice/applications?	Right stock size?	Proper use /care?
40 models	No	n/a	No
Obsolete models	No	No	n/a
'Hide and Hoard'	No	No	No
Informal training	No	n/a	No
Poor housekeeping	n/a	No	No
Looking for pumps	n/a	No	n/a

I ascribe the rapid growth in serious infusion incidents to the *Training Gap* - my hypothesis that has been supported in part at this conference by Dr Joel Nobel, Founding President of ECRI. Below is an illustration of this idea, which has a simple explanation. Training to use medical technology has fallen further and further behind the growth in the types, number and complexity of medical devices. As this gap grows so do the chances of serious device-related incidents. Before the development of infusion pumps, nurses administered IV therapy by drip; they checked progress using their eyes and perhaps that spatula which showed drop rates and corresponding flows rates. Pumps have largely replaced this painstaking procedure, but we are one of the few Trusts to have recognised that nurses should be trained and must pass a kind of 'driving test' for infusion pumps before they can use modern, complex infusion systems to defined standards of competence.

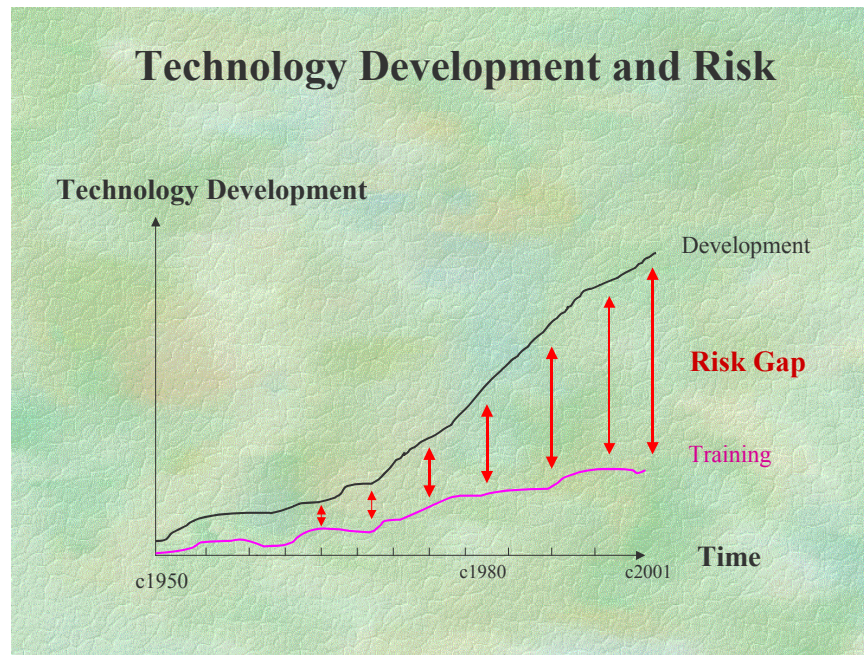


Figure 10.7 The training gap

What have we learnt from these unsafe practices to make IV therapy safer for our patients? Equipment standardisation, equipment libraries and competence training have transformed the safety of IV therapy in the last four years and continue to do so. The growing culture of safety has also been a powerful stimulus that I shall discuss in the second part of this paper. Now the Trust has only one supplier of each type of infusion pump: volumetric, syringe, ambulatory, patient-controlled analgesic and pump. Standardisation is progressively reducing the training burden on both the organisation and nurses as stock is renewed. It fosters the safe choice and application of pumps. The Trust has an equipment library (with two more in the pipeline) to match the size of stock to clinical demand in non-critical-care wards. The library also ensures a supply of clean and properly maintained equipment. For the past four years nurses have received competence training to safely apply, skilfully operate and care for infusion systems to defined performance standards. Martin Pickstone has already explained the principles of this training, which are based on a thorough study of 102 unsafe practices in NHS intravenous therapy services. So I shall only emphasise that IV therapy is treated as a five-stage process (see below) by which the right drug dose is delivered by an infusion system that is correctly chosen for the therapy, properly cared for and skilfully operated - all to defined performance standards.

1. Drug calculations
2. Making up drug solutions
3. Presenting the infusion - low concentrations/high volumes or the reverse
4. Choosing the equipment to minimise risk
5. Using the equipment from start-up to close-down

So far, approximately 2,000 nurses have been through the programme and passed their infusion pump ‘driving test’. This throughput suited the Royal Victoria Infirmary, which has 3,000 nurses. There are, however, 10,000 nurses in the whole Newcastle upon Tyne Hospitals NHS Trust. The existing training methods that require a day’s release from the ward and the present organisation of training cannot cope with a tripling of the programme. E-learning and e-training would be a more productive method in such a large Trust and we are trying to develop a regional consortium to justify the cost of developing the software. E-learning and e-training would be delivered via local PC’s and includes skills training to operate pumps with on-line assessment. Table 10.2 shows how the combination of practical safety actions has achieved all the objectives of technology management of IV therapy.

Table 10.2 Practical safety actions & the achievement of technology objectives

<i>Practical safety action</i>	Safe choice/applications?	Right stock size?	Proper use /care?
Standardisation	Yes	n/a	n/a
Equipment library	n/a	Yes	Yes
Competence training	Yes	n/a	Yes
E-learning/training	Yes	n/a	Yes

Case study 2 - oxygen explosion in a Resuscitaire

Resuscitaires provide newborns with heat and supplemental oxygen in delivery suites. During a routine check by a midwife of the device’s two oxygen cylinders, there was first an explosion and then a fire. Had the Resuscitaire been in use the baby may well have been killed. The midwife received second-degree burns (her uniform caught fire) and others suffered from smoke inhalation. The Delivery Suite was evacuated and the fire was rapidly extinguished.

The oxygen cylinders were attached to a three millimetre thick steel plate. The explosion had the focussed power of a thermal lance, punched a hole in the plate and then ignited both the bedding and the midwife’s uniform. This was an adverse event that injured staff, could have injured patients, disrupted maternity services and had the potential for a very adverse reaction from both the media and the public. No similar explosions have been reported. The NHS in England and Wales uses around ten million oxygen cylinders annually so this was an extremely rare incident but one with very serious consequences. The Trust and the Health and Safety Executive both investigated the incident and, in total, some nine groups of Trust staff and five external organisations were involved in the entire investigation process.

The exact cause of the explosion could never be established but grease inside the cylinder valve (also called the regulator) was the most likely fuel. Grease should never

contaminate the valve. However the investigations revealed two groups of unsafe practices that acted as latent conditions for the explosion.

1. Knowledge deficits. No-one understood the mechanism of fires in which pure oxygen plays a pivotal role. Nurses neither knew how to find out the capacity of oxygen cylinders nor how to calculate their duration for a given rate of oxygen administration to a patient. They did not know the clinical criteria governing the use of portable oxygen in hospitals and in primary care.
2. Inadequate safety checks by front line staff. There was no clarity over who was responsible for changing cylinders, checking regulators, and checking that cylinders were stored safely. Maintenance procedures for storage, transport and checking the safety of both cylinders and oxygen-using equipment varied in the Trust.

The knowledge deficits have been removed by specific training during both staff induction and Health and Safety training days. A new policy for oxygen management (particularly for piped supply) has been introduced. There are now standard and uniform maintenance procedures for oxygen-using equipment and improved signage for the storage and safety of all gases. The stocks of cylinders, their cradles, regulators and equipment have been upgraded and increased. The Technology Triangle has also been applied to this case study and Table 10.3 shows how the combination of practical safety actions has achieved all the objectives of technology management of oxygen.

Table 10.3 Practical safety actions & the achievement of technology objectives

<i>Practical safety action</i>	Safe choice/applications?	Right stock size?	Proper use /care?
Training	Yes	n/a	Yes
O ₂ * management policy	Yes	Yes	Yes
Maintenance procedures	n/a	Yes	Yes
Improved signage	n/a	Yes	Yes
Enhanced stocks	n/a	Yes	Yes

* Oxygen

SECTION B

Safety culture & change at the Newcastle-upon-Tyne Hospitals NHS Trust

I shall be brief about this topic but Martin Pickstone and I hope that our more detailed analysis will be published in 2002. Figure 10.8 shows the annual numbers of serious infusion incidents (pump-delivered) between 1993 and the end of 1998. Comparable

data for successive years does not exist because the Infirmary was merged with other hospitals to create the current Trust and, in the process, the incident recording system was changed.

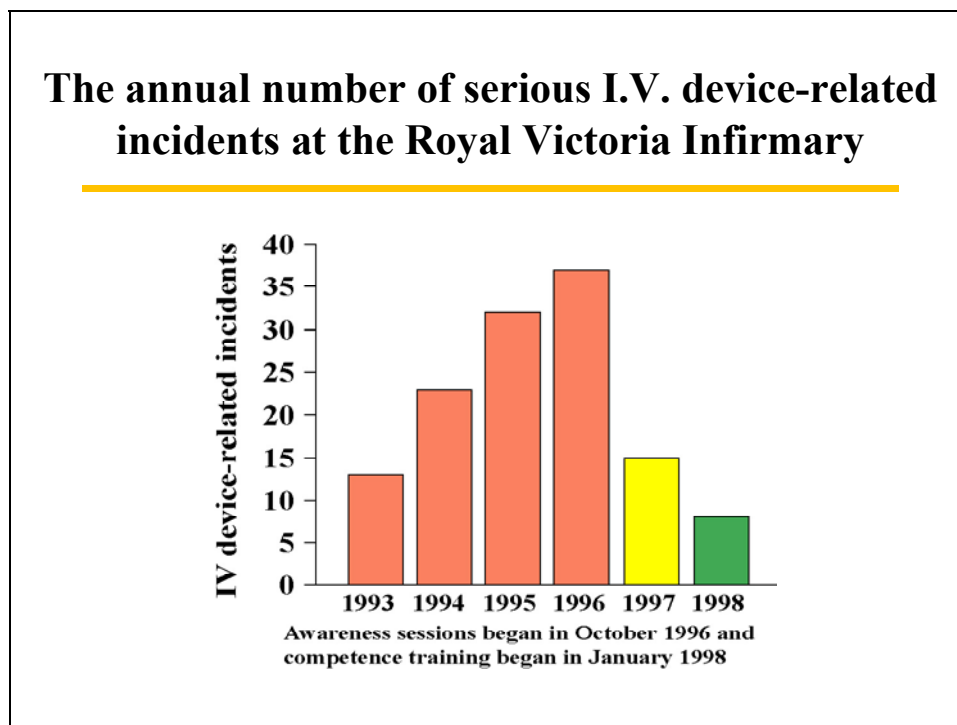


Figure 10.8 The annual number of serious infusion incidents (pump-delivered) at the Royal Victoria Infirmary, Newcastle upon Tyne

There was first a continuous increase for four years that was equivalent to an annual compound growth rate of more than 35%. Then there was a decrease of 60% by the end of 1997 and another decrease during the next year. Why? I started awareness training in October 1996 and by the end of the next year 400 of the 3,000 nurses had attended the two-sessions in which I would explain the complications of IV therapy, go through some of the issues of the day and the latest reports from the Medical Devices Agency about infusion devices. However the reduction of serious incidents that occurred over two years was out of all proportion to both the possible effectiveness of awareness sessions and the small proportion (13%) of participating nurses. Furthermore, these sessions were not full competence training, which only started in March 1998. I believe that the start and growth of a culture of safety is the cause of this substantial and sustained reduction in serious pump-related infusion incidents. Staff are encouraged and are unafraid to report incidents and problems. I get many phone calls along the lines of 'Chris I've got a problem. Could you give me some advice?'

There has been extensive and real consultation with staff to revise the drug policy and to decide the sub-cutaneous infusion safety policy. A single incident form and simple

centralised reporting have replaced the previous muddle. The culture of safety has had another effect - people work more pro-actively and more often in multi-disciplinary teams making the patient their first priority. The case-study of the Resuscitaire is an example. Figure 10.9 shows that once the five basic practical safety actions had been achieved (see Table 3) people then *of their own accord* focussed on practice in related areas. So an information booklet for families was written, a community loan policy for oxygen bottles was developed, families were trained to administer oxygen at home, oxygen calculation tables were devised and decontamination for oxygen-using equipment prepared. Thank you.

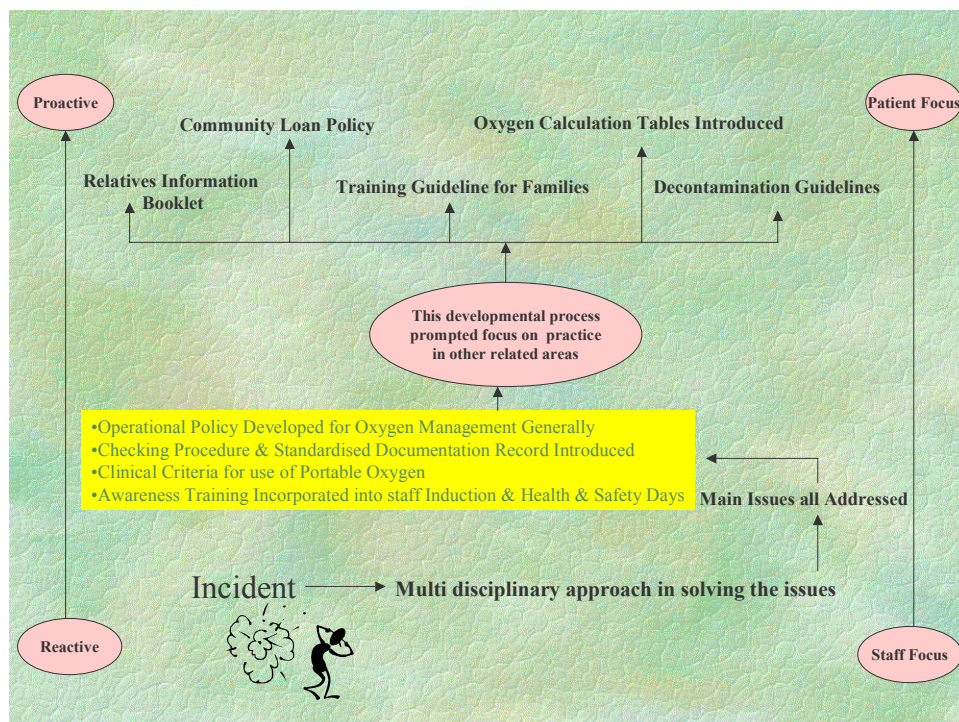


Figure 10.9 Proactive team working for enhanced safety

Further reading

Pickstone M, ed. *A Pocketbook for Safer IV Therapy (Drugs, Giving Sets & Infusion Pumps)*. Margate: Scitech Educational, Reprinted 1999. ISBN 0 948672 32 3.

Quinn C, *Infusion Devices: a bleeding vein of clinical negligence?* J Nursing Management, 1988, 6, 209 - 214.

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11 The Medicines Control Agency – Adverse Drug Reaction reporting

Dr June M. Raine
Director, Post Licensing Division
Medicines Control Agency¹

Introduction

Today's conference celebrates the birth of the National Patient Safety Agency as a major step forward in improving patient safety. At the Medicines Control Agency we have a system of reporting adverse drug reactions which is well past its infancy and into maturity – but it is still growing, developing and contributing to the protection of public health. This presentation will focus on some of the key lessons learnt during 37 years of adverse drug reaction reporting and how MCA can support the work of the National Patient Safety Agency. I will also highlight some recent work by MCA which will contribute to meeting the target for reduction of serious medication errors identified in *Building a safer NHS for patients*².

Background

It is no secret that medicines can harm as well as benefit patients. Open any newspaper and the chances are you will be reading something about the safety of medicines. The public are rightly concerned about adverse drug reactions (ADRs) - responses to medicines, which are unintended harmful reactions occurring at normal doses for treatment or prophylaxis. The problems associated with adverse drug reactions are well recognised. They complicate existing disease and affect quality of life. ADRs can cause a patient to lose confidence in their carers and their medicines, resulting in poor compliance and treatment failure. At worst they threaten or limit life. Public awareness of drug safety has never been greater.

Why monitor drug safety?

The MCA adverse drug reaction monitoring system is based on important principles. First, while the quality and efficacy of a medicine are fairly well defined at the time of licensing, the clinical trials in support of a licence application can only provide limited data on a medicine's safety profile. On average only around 1,500-2,000 patients have

¹ www.mca.gov.uk

² www.doh.gov.uk/buildsafenhhs

been studied in clinical trials before licensing. Secondly, pharmaceutical science is rapidly evolving, particularly in biotechnology and new developments such as gene therapy, so that we are beginning to see new patterns of adverse drug reactions emerging. Thirdly, there is an emphasis on a continuous process of monitoring throughout the lifetime on the market of a medicine. That market is sizeable - there are around 17,000 authorised medicines in the UK. Usage of medicines continues to be a mainstay of NHS treatment, with about 1.5 million GP prescriptions written daily and a further 0.5 million in hospital. The increasing move to over-the-counter availability of medicines reflects the growing wish for patients to manage their own conditions.

Impact of Adverse Drug Reactions

A US study in 1994 suggested that ADRs are between the fourth and sixth leading cause of death in the USA. A review of studies of ADR-related hospital admissions in the UK showed that, on average, 5.5% of all hospital admissions are due to ADRs, with an incidence varying from 0.2% to 21.7% depending on the population being studied. For example, elderly populations have a higher rate than surgical patients. A recent meta-analysis suggested that 6.7% of hospital patients suffer serious ADRs and 0.32% fatal ADRs. Most importantly, studies have shown that many ADR related admissions are preventable. An Australian study, found that 38.5% of ADRs thought to have caused hospital admissions were either definitely or possibly avoidable. In a small study in the UK in Liverpool published last year, two-thirds of ADRs identified were potentially avoidable.

The Yellow Card Scheme

It is salutary at this point to remember how adverse drug reaction reporting began. It was in the early 1960s when the thalidomide disaster tragically demonstrated the need for systematic collection of reports of adverse drug reactions. There was complete failure to recognise the limb deformity phocomelia (see figure 11.1) associated with thalidomide in pregnancy until around 10,000 fetuses had been affected. With a system of notification it should have been possible to recognise the association of a specific drug with a very rare disorder, at least three orders of magnitude more effectively, that is - with perhaps 10 or fewer cases. In 1964 Sir Derrick Dunlop, Chairman of the Committee on Safety of Drugs, wrote to every member of the medical profession in the UK asking them to voluntarily report details of any untoward condition in a patient which might be the result of drug treatment. Confidentiality was guaranteed and reports were sought promptly, to be submitted on the basis of suspicion rather than waiting for firm proof. These three principles have stood the test of time and remain the foundation of today's system!

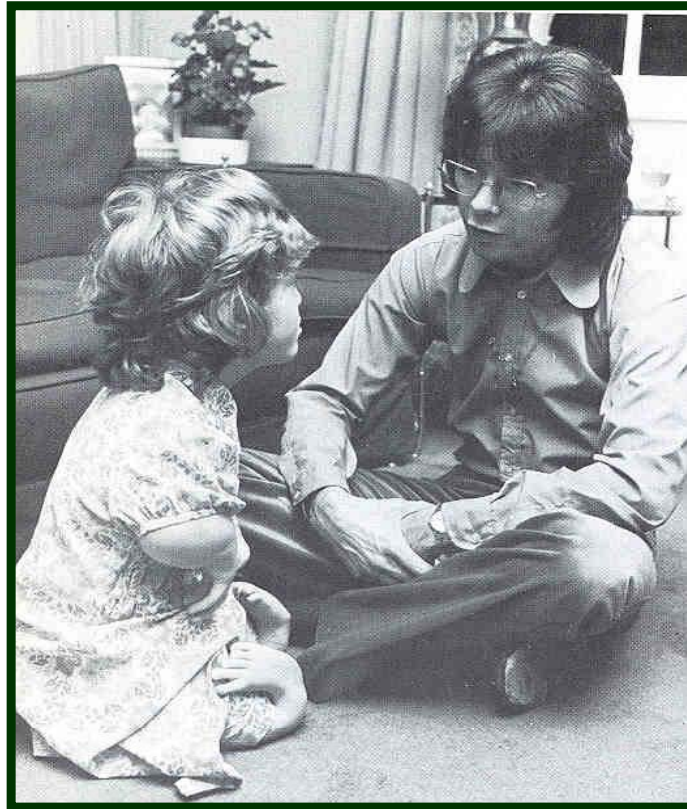


Figure 11.1 Phocomelia and Thalidomide

Reports were to be made on specially provided yellow reporting forms that were provided with Sir Derrick's letter. The significance of the yellow colour is no more than that there was by coincidence a large supply of yellow paper unutilised in the Department at that time.

So the Yellow Card Scheme began. Adverse drug reaction reports are also received via the pharmaceutical industry, which has a statutory obligation to report suspected ADRs. The Committee on Safety of Medicines continues to be responsible for the scheme, which is now run on the Committee's behalf by the Medicines Control Agency using the Adverse Drug Reactions On-Line Information Tracking (ADROIT) database to facilitate rapid processing and analysis of reports and detection of signals of drug safety hazards.

There has been an increase in yellow card reporting since 1964 – a step up in the late 70s when yellow cards were included in GPs' prescription pads, and a slight decline in the 1990s, possibly related to increasing pressures on health professionals' time and the burden of paperwork (Figure 11.2).

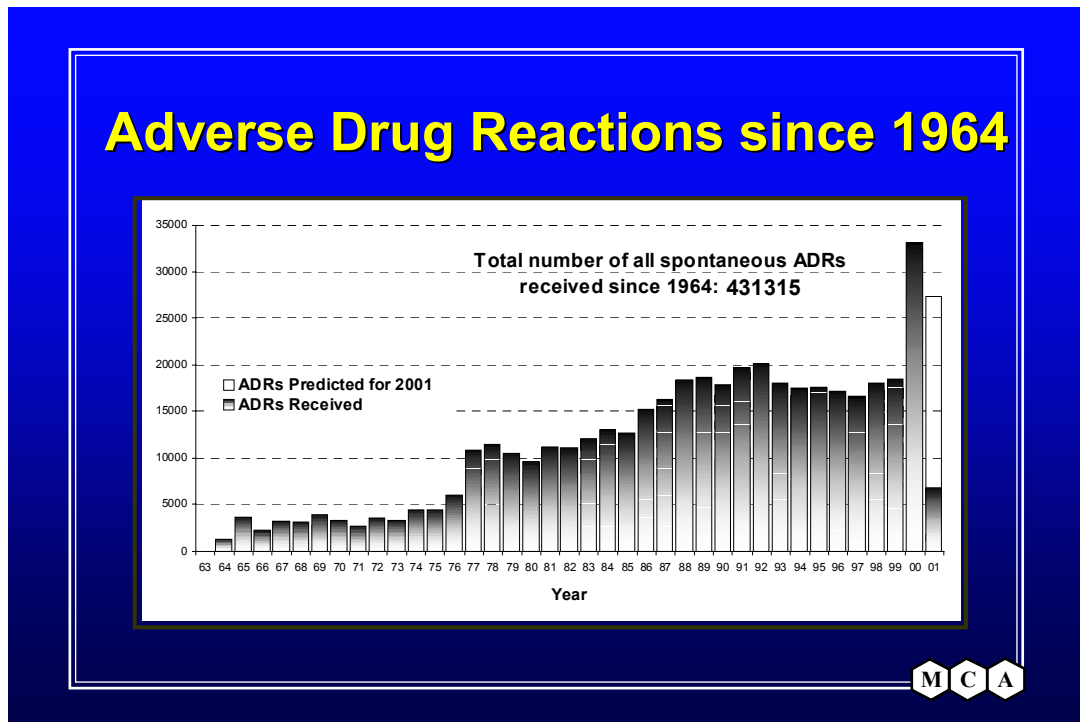


Figure 11.2 The pattern of ADR reporting since 1964

The massive increase in 2000 related to the Meningitis C vaccine campaign (over 12,000 reports). There has been an increase even after meningitis C vaccine reports are excluded, which is very encouraging. GPs are not the only reporters – hospital doctors and hospital and community pharmacists also report (Figure 11.3) and, more recently, for Meningitis C vaccine, nurses report. The backbone of the scheme is in primary care, with general practitioners submitting over half of the reports, while hospital doctors contribute a quarter of reports and hospital pharmacists an increasing number. We wish to strengthen hospital reporting and our collaboration with the National Patient Safety Agency will assist with this.

Early Warnings from Yellow Cards

Since 1964 over 430,000 Yellow Card reports have been received, and a wide range of important early warning signals have been detected as a result. Figure 11.4 shows some examples to illustrate the significance and diversity of the signals. Remoxipride, a newly introduced anti-psychotic agent, was implicated in spontaneous reports of aplastic anaemia, leading to its withdrawal after 10,000 patients had used the drug. The non-steroidal anti-inflammatory drug Tiaprofenic acid was associated with severe cystitis. Delay in identifying the association meant that some patients underwent total cystectomy. High lipase pancreatins for cystic fibrosis was associated with reports of colonic strictures in children. After the Committee on Safety of Medicines (CSM) advised against using high strength enzymes in 1995 there have been no further cases.

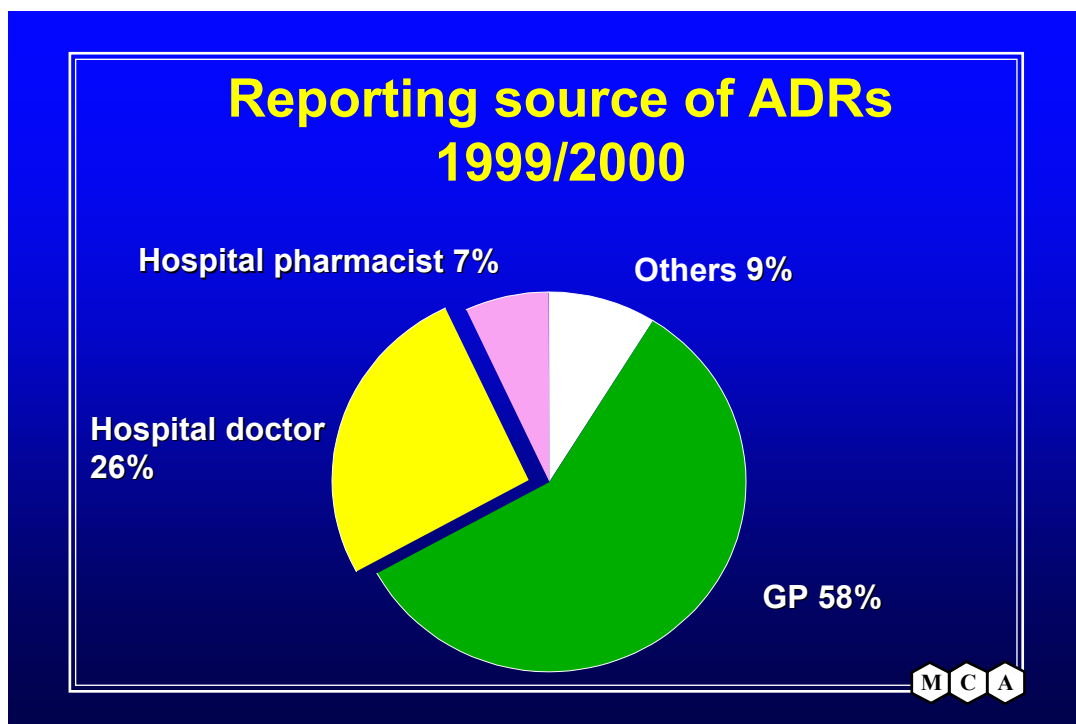


Figure 11.3 Sources of ADR reports (1999/2000)

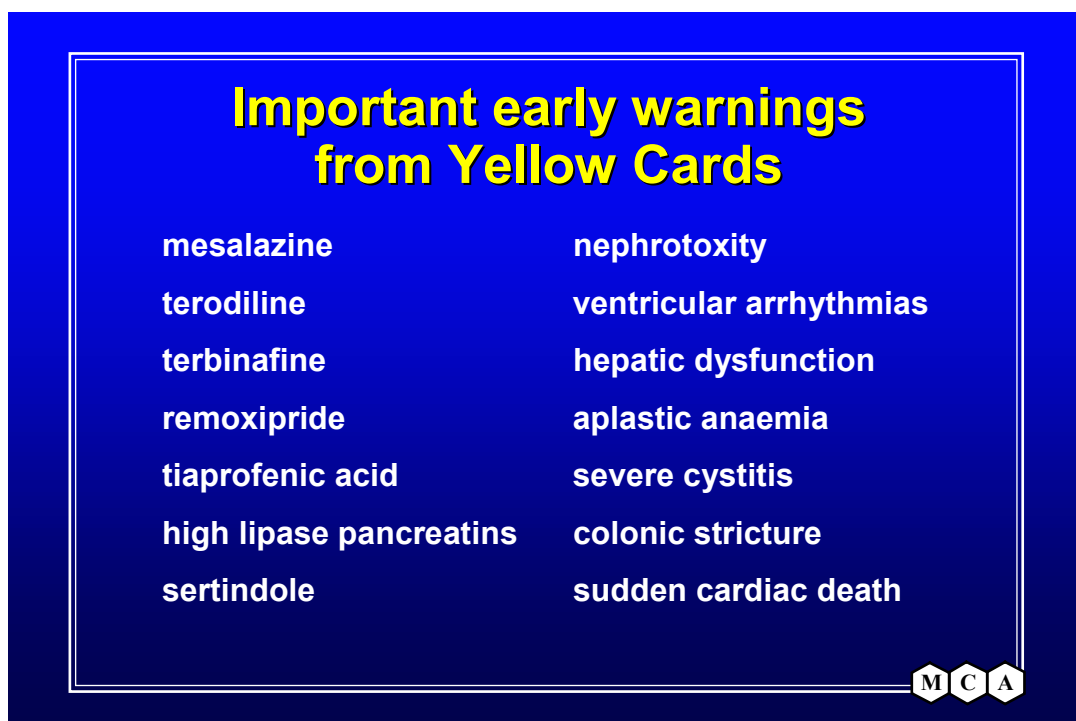


Figure 11.4 Important early warnings from Yellow Cards

Strengthening ADR Reporting

We continually seek to strengthen ADR reporting based on three strategies. We have set up four Regional Monitoring Centres - Merseyside, Northern, Wales, and West Midlands - which are responsible for about a fifth of all reports. Launch of a Scottish Regional Monitoring Centre in Edinburgh is planned for 2002. Secondly, we have widened the reporting base from the original doctors, dentists, and coroners, to include pharmacists. Following successful reporting during the Meningitis C vaccine campaign, we plan to include nurses as reporters. We hope shortly to initiate a pilot of patient reporting. Thirdly, use of electronic systems to facilitate reporting is clearly the way of the future. Electronic reporting is now routine for a number of pharmaceutical companies, and we are also piloting the use of electronic reporting for health professionals. Although most of the 8,000 electronic reports received have come from the industry, an increasing number of GPs are reporting electronically.

Taking action to improve safe use of medicines

There are a number of strategies to address risk in relation to adverse drug reactions. The same principles apply as for NPSA - the identification of trends and patterns, and conducting causality assessment, to allow targeted action to avoid or minimise risk. Action may include withdrawal or restriction of availability of a medicine and there are communication mechanisms to health professionals and to patients via patient information leaflets. The *Current Problems in Pharmacovigilance* bulletin has been an important vehicle for disseminating safety messages, including advice about the types of problems such as Methotrexate prescribing-errors, iron overdose in children and use of alcohol-based prepping agents during electro surgery, which will concern NPSA.

Building a Safer NHS for patients

How is MCA contributing to building a safer NHS for patients? Some of the most serious adverse incidents in the NHS occur as a result of mistaken administration of drugs. Since publication of *Building a safer NHS for patients*³ we have reviewed how labelling of medicines can be improved within the regulatory framework with the aim of contributing to the national target to reduce by 40% the number of serious errors in the use of prescribed drugs by 2005. We are currently consulting on a new proposal to improve the identification of medicines by use of a number plate approach to ensure all the information to be checked to avoid administration errors is accessible in one place. Of course, this does not preclude specific solutions for medicines implicated in particular medication errors, such as vinca alkaloids, methotrexate, and potassium chloride.

³ www.doh.gov.uk/buildsafenhhs

Conclusion

The MCA will support the work of NPSA towards successful outcomes in a number of ways. First, by ensuring that information collection systems make provision for rapid exchange and sharing of data. Secondly, to work towards more effective communications to ensure that action is taken and lessons learnt. And thirdly, to monitor outcomes of action, using for example the General Practice Research Database. Last but not least, we will actively pursue our strategy for improved medicines labelling in support of the goal of reducing serious medication errors. In conclusion, the MCA welcomes the launch of NPSA and will play its part in ensuring its success.

12 The Medical Devices Agency - Medical device adverse incident reporting

Dr David Jefferys
Chief Executive
Medical Devices Agency

Introduction

First of all may I say what a pleasure it is to be here at this introductory conference for the National Patient Safety Agency. We at the Medical Devices Agency have been delighted to offer practical support both as secondments to those who have created the agency and expertise in IT systems. I think it self-evident that we have a significant public health issue whose solution will require creative thinking. Two weeks ago Lord Hunt said “we were going to need a grand coalition to solve this problem” at the MDA stakeholder conference. He envisages a grand coalition of several agencies working together and with you in the service.

Today I want to present how one of the older regulatory agencies has encouraged best practice in the safe use of medical devices. My starting point is to define the size of the medical technologies sector which plays a vital role in both health and community care. We can describe this sector in several useful ways:

- ❑ Twenty thousand different devices are currently available in the UK health/community care market.
- ❑ Every day more than thirty six million people use a medical devices ranging from sticking plasters and incontinence pads to sophisticated interventional instruments.
- ❑ Devices are becoming more complex and controlled by software. There is also a very significant transfer of technology from hospitals to primary care and community care, for instance monitors that would only have been found in critical care units five or six years ago are now being used by patients at home. This trend both creates patient opportunities and benefits but also increases the risk of harm. We have to recognise this trend and plan accordingly.
- ❑ There is a very great increase in the sale of medical devices to and direct use by customers who do not regard themselves as patients but whose safety we must ensure.

Finally we need to understand that the manufacture and sale of medical technologies is a global industry that is regulated globally. The Secretary of State's responsibilities and powers derive from both European directives and international agreements. The latter are shortly to be discussed by senior representatives from the UK, US, Australia, Canada, Japan, the World Health Organisation and the European Commission.

The role and remit of the MDA

The Medical Devices Agency operates two incident reporting systems. The first is for mandatory reporting by manufacturers and is required by European directives throughout the Community. The second is our adverse incident user reporting system which began in the early 1960's and was the first such system in the world. It is the largest and most comprehensive user system worldwide, relies on voluntary reporting and has been first on many occasions to detect specific problems. We have greatly improved our information technology both to better track adverse incidents and to receive direct electronic reporting from both hospitals and now from patients - another international first. Because our reporters enter their information directly via the Internet we save the time and possible errors associated with the previous manual entry. In short we have improved both efficiency and quality.

We also co-operate in the International Vigilance Scheme both to learn the lessons from Europe and elsewhere and to transfer UK experience for the benefit of our partners. There is no point in any healthcare organisation reinventing the wheel. The MDA system is the source of more than sixty percent of Vigilance Reports - reports about deaths and serious incidents - exchanged among the twenty-nine countries in the Wider European Area. These have been required by European legislation since 1995. We receive more than eight thousand reports annually from users.

Figure 12.1 shows the number of annual reports from 1995 to 2000 shows a gratifying increase, mainly due to hard work by our medical device liaison officers throughout the NHS. The numbers of reports about CE-marked devices, which are highlighted by the darker colour, increased particularly rapidly from 1998. This has happened because European legislation allowed a transitional period from 1995 to July 1998 before reporting about such devices became compulsory - the transitional period for in-vitro diagnostic devices ends in 2003. We expect the numbers of reports about CE-marked devices to increase continually for many years as the NHS replaces older equipment that pre-dates the regulations about the use of CE-marked devices.

Most reports are provided by the NHS and community care but an increasing proportion come from the manufacturers of devices. Let us not forget that manufacturers of medical technology are important stakeholders in modern healthcare and I am pleased that the National Patient Safety Agency has already met our four trade associations.

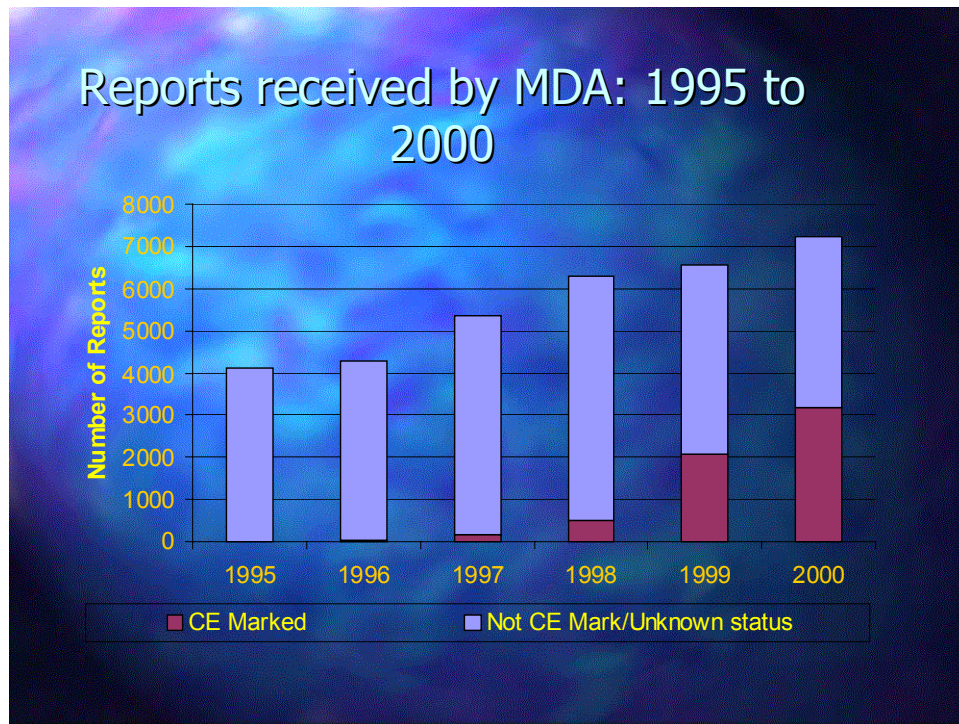


Figure 12.1 The pattern of incident reporting 1995-2000

Figure 12.2 reveals that reporting rates have varied considerably among the NHS English regions between 1997 and 2000. Furthermore reporting rates have also decreased in recent years in three of the eight regions whereas the opposite has occurred in the others. We know that neither population nor the amount of equipment can explain this anomaly. The reason is underreporting. We have a many-pronged strategy to encourage reporting throughout health and community care.

This begins with educational programmes at postgraduate level for targeted healthcare professions. All Trusts, Health Authorities and Social Service Departments have liaison officers for medical devices and we want similar appointments in primary care trusts. The public can now directly communicate user problems via the Internet. We benchmark the quality of our adverse incident reporting system against the standards of the Medicines Control Agency and the Food & Drugs Administration of America and are very much looking forward to working with the National Patient Safety Agency.

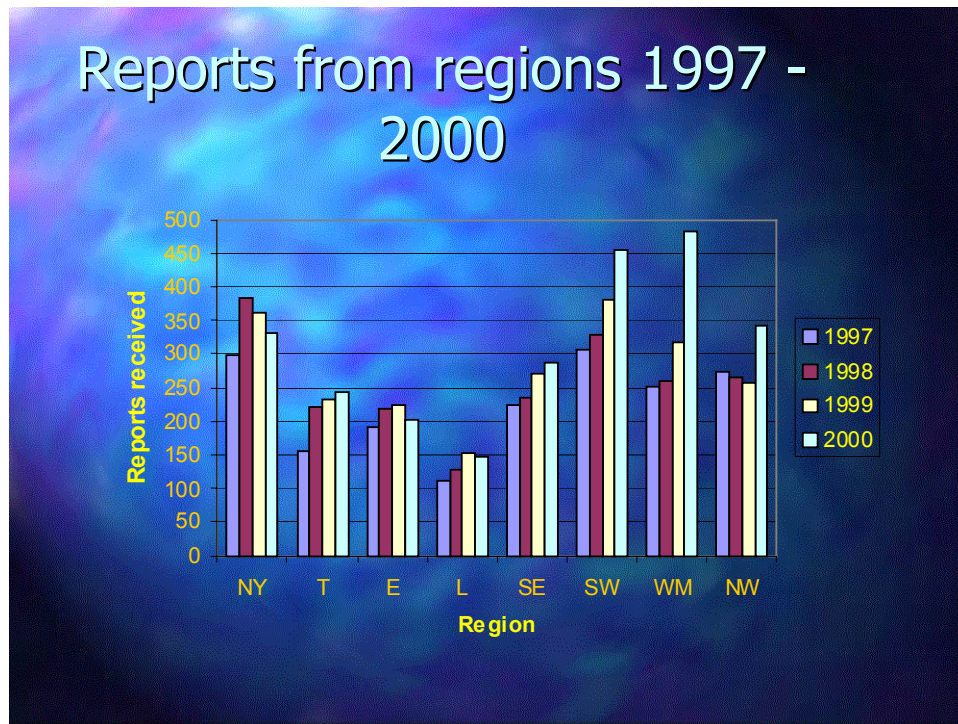


Figure 12.2 Regional variations in annual reporting rates

What do we get each year and what do we do with it? Here are the figures for last year.

We received reports of 87 deaths and 558 serious injuries in which medical devices were implicated.

- ❑ We undertook more than 1,600 extensive (and expensive) root cause investigations by our 96 device specialists (more are needed) supported by staff in MDA Evaluation Centres and by external panels of experts.
- ❑ Manufacturers investigated almost 2,900 incidents under our supervision, as required by European directive.
- ❑ Other organisations such as the Police, Health and Safety Executive and the Radiological Protection Board, investigated over four hundred incidents and then told us of their findings.
- ❑ Almost 1,400 incidents did not need immediate action but help the understanding of trends.

Figure 10.3 shows the top 12 devices that harmed patients. Top of the list is wheeled mobility equipment in community care and sixty percent of those injured do not regard themselves as patients within the health service.

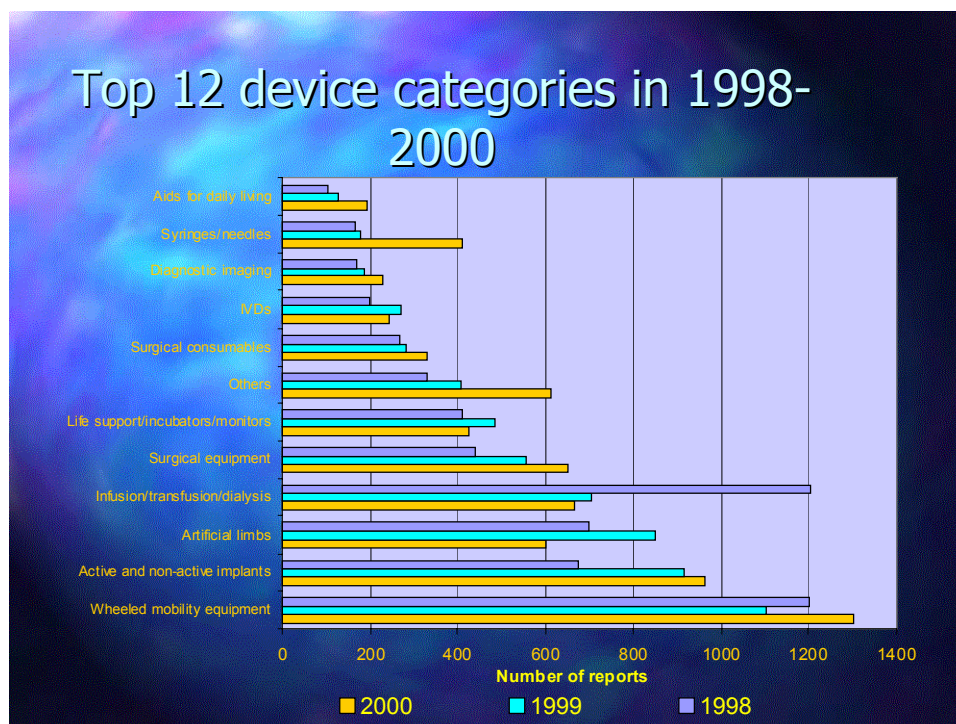


Figure 12.3 The top 12 devices that harmed patients 1998-2000

Note also that adverse incidents involving infusion pumps have decreased sharply and I will explain later the work that the MDA has been doing to increase the safety of intravenous therapy, which I believe has caused this improvement. What actions did we take last year following these investigations?

- ❑ We published 51 Safety Warnings, Hazard Notices and Device Alerts for immediate action by trust chief executives.
- ❑ We supervised or participated in 99 product recalls/field corrections and monitored more than 120 further cases in which the manufacturers took corrective action.
- ❑ We gave advice on the safer use of devices or improved staff training in 173 cases. This is an example of action with the user after root cause analysis.
- ❑ In over a thousand instances manufacturers improved either their product designs or manufacturing systems. These actions are a reminder that health and community care is served by a responsible industry.

I have summarised the causes of adverse incidents in the year 2000 with a pi chart. Forty percent arise before delivery of the device - design faults, production problems and damage during transport. Twenty three percent happen after delivery. Poor maintenance and record keeping are examples of reasons. We know that user error causes 9% of incidents but may be the cause of some of the 28% for which no explanation could be found.

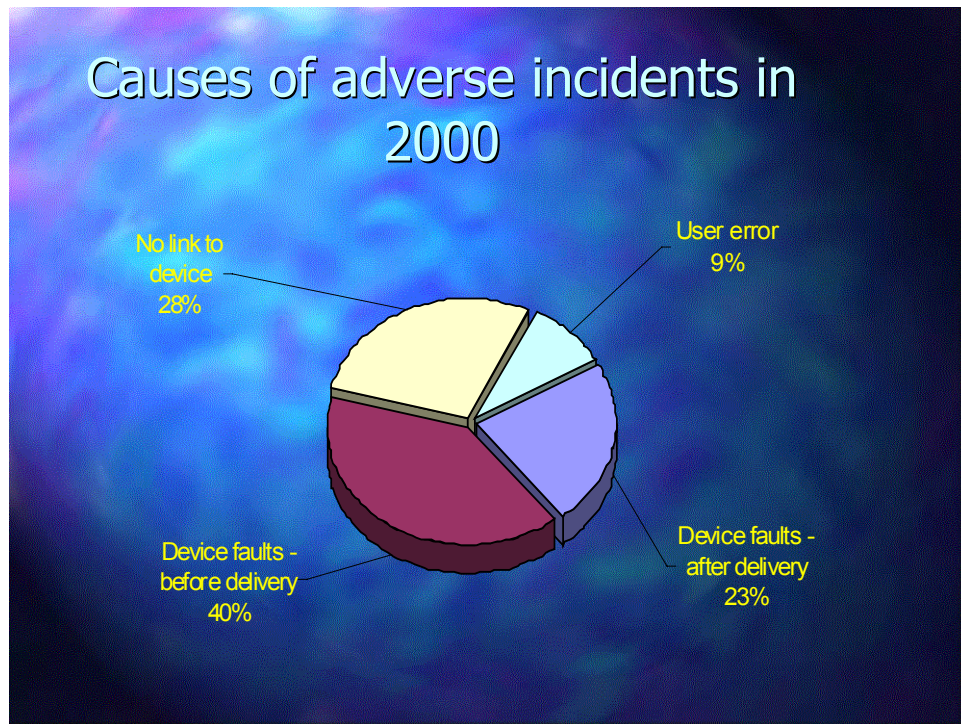


Figure 12.4 The general causes of adverse incidents in year 2000

Concluding remarks

We at the MDA know that just issuing more paper is not going to change cultures and have discussed new tactics with Professor Rory Shaw. One example is better education about the safer use infusion pumps and there have been four national study days; more are planned. In these study days we work through the reasons for accidents with pumps. We also collaborate with manufacturers to improve the layout of pump control panels. We intend to make the Controls Assurance document DB 9801, with which many of you are familiar, easier to use and available in interactive electronic form. More practical advice is needed about decontamination and sterilisation. However primary care, where very many more complex devices are now in use than before, is a new and important focus for the MDA. We have issued the highly acclaimed publication 'Equipped to Care'. This important publication asks staff in primary care 'Are you trained to use this piece of equipment on the patient?' 'Can you explain to the patient how he/she should use this device at home?' On November 27 the MDA is holding a conference in primary care to tackle these problems. We now have a new 'Committee on the Safety of Devices' that is giving valuable advice and ideas on, for example, diathermy and in-vitro diagnostics. So Chairman, what I have tried to do today is to show how the Medical Devices Agency works with health and community care services to make the patient the centre of our organisation.

Resources

Website addresses

MDA website <http://www.medical-devices.gov.uk>

GHTF Website <http://www.ghtf.org>
(Global Harmonization Task Force for medical devices)

Useful reading

1. Jefferys DB, *Comparison of the regulatory controls for medical devices and medicinal products* International Journal of Pharmaceutical Medicine 2001
2. Jefferys DB, *The regulation of medical devices and the role of the Medical Devices Agency* Br Clin Pharmacol, 2001 52. 229-235
3. Medical Devices Agency Adverse Incident Reports 2000 MDA DB 2001(01), 2001

Part IV - Annexes

1 Key messages – the editors’ judgment

In this section, the editors have extracted what they believe to be the key messages from the contributions to this publication contained in the preceding twelve main chapters. It is hoped that these key messages may prove useful. Responsibility for any errors or omissions rests entirely with the editors.

1. Lord Hunt of Kings Heath OBE

- Improving quality is the lynchpin of the Government’s plan for modernising the NHS - Patient safety is an integral part of the drive to improve quality.
- Research suggests that 1 in 20 patients admitted to UK hospitals suffers an adverse resulting in over 34,000 deaths and associated financial losses in excess of £2.5 billion per year.
- When something goes wrong we should learn from the experience and strive to reduce risks to future patients locally, nationally and globally.
- Root cause analysis is the key to learning. It is a structured investigation that aims to identify the true cause of a problem and the actions necessary to eliminate it.
- Improvement strategies that focus on blaming individual frontline clinicians for poor performance are misguided and do not work. Instead, we need to concentrate on fixing dysfunctional systems. To this end, we need to move the balance from one of blaming frontline staff to one of organisational accountability, openness and, as far as is possible, prevention.

2. Mr Stuart Emslie

- The practice of scapegoating frontline doctors and nurses - much abetted by the media - is wrong and does not help patients. Evidence from the USA indicates that 1) the causes of serious adverse patient incidents cannot be blamed on frontline clinicians; and 2) because there is often more than one cause associated with an incident, most serious incidents cannot be blamed on one person. The root causes identified in the USA are systemic causes, which are a *management* responsibility.
- Root cause analysis - “the key to learning” - is not rocket science. It is a straightforward, systematic process that aims to arrive at *why* an incident occurred and the actions necessary to prevent recurrence. In many instances it need not take significant time and effort to conduct a suitable root cause analysis. At its simplest level, it is about getting the right people together to constructively

and openly look at the sequence of events leading up to an incident in order to determine underlying systemic causes.

- The goal of improving patient safety can only be achieved through a fundamental change in NHS organisational culture and in the culture of the media and the public.
- The key ingredient that makes or breaks a healthcare organisation is how well it is *managed*. *Managing* healthcare needs, therefore, to be given greater investment priority.
- In line with best governance/management practice in the private sector, all NHS organisations should maintain a *sound system of internal control* and provide assurances as to its effectiveness. The system of internal control exists to minimise the risk of failing to meet organisational objectives and should, therefore, include an effective risk management process, embedded at all levels throughout the organisation.
- The National Patient Safety Agency is key piece of the NHS Governance and Controls Assurance jigsaw and should assist greatly in determining how effective an organisation's system of internal control is in meeting patient safety objectives.

3. Dr Kirstine Knox

- Policy makers should work closely with frontline healthcare staff and become policy implementers. This makes for policy that is relevant and capable of being implemented locally.
- Early feedback on adverse incidents from the pilot sites supports the widely-held view that systems failures, and not frontline staff, are the cause of adverse patient incidents.
- The root causes of many types of adverse patient incident are already known by various clinical litigation defence organisations, e.g. the NHS Litigation Authority. This information could be quickly utilised to help improve patient safety.
- The new National Patient Safety Agency will need to act quickly on the following key issues to ensure its credibility with the NHS:
 1. Eradication of the NHS culture of blame.
 2. Assuring confidentiality and protection from disclosure of adverse events.
 3. Demonstrating real benefits for patients.
 4. The perceptions of the media and the public.
 5. Providing solutions, not more problems.
 6. Providing vision and leadership in patient safety - not additional bureaucracy.

4. Professor Rory Shaw

- The management of risk in the NHS is now recognised as an important management and clinical function.
- Reason's model of system failures suggests that the root causes of incidents are analogous to the plot of a story and the obvious conclusion is that changed outcomes require changed plots rather than new staff.
- Healthcare must use the *Systems Approach*, which rather than blame the individuals, asks three questions. Why do we need to do this? How can we make the process less error prone? What are the barriers to error?
- System barriers fail in two ways. There are *Active Failures* - slips, lapses, fumbles, mistakes and procedural violations. There also *Latent Conditions* that converts into error-provoking conditions. For instance accidents are likely if staff work under intense time pressure with poor equipment or perhaps using unworkable procedures.
- The combination of corporate culture and managerial decisions sustain conditions that routinely produce both errors and violations of protocols.
- The precursor of better patient safety is a national database of incidents built on national definitions of incidents, a universal generic method of grading the severity of incidents in relation to actual harm and potential future risk and a minimum data set for reporting incidents.
- Improved patient safety needs, in addition to the National Patient Safety Agency, the collaboration of other agencies and organisations both within and outside Government. For example, there is a huge amount of creative thinking in the Royal Colleges; collaboration and creativity are the key to obtaining solutions.
- To err is human. We need to find mechanisms to check that previous steps in a process have been completed correctly; we need to communicate effectively; and we need to provide training that promotes safety and risk awareness for frontline staff.

5. Dr Paul Barach

- The starting point of safer healthcare delivery is a no-blame work culture where one can freely admit mistakes so that everyone can learn from them
- Do not trust anyone including yourself because risks arise through making and acting upon assumptions about one senses, skills, and knowledge.
- People in healthcare have no idea about high performance teamwork. This is one major reason why healthcare cannot deliver safe patient care. We need to replace fragmented approaches to healthcare delivery by teamwork and by accepting patients into the system of safer healthcare.
- We need to learn from near misses. Look upon these as a free resource of information from which no harm and no guilt results. Because near misses are so much more common than serious adverse events your analysis of trends will be both easier to undertake and will encounter fewer statistical problems.

- Safety is the cornerstone of training in all non-medical high risk industries/activities, which use simulation intensively and train teams rather than individuals. What a contrast to medical education, which lacks any formal safety or simulation training.
- Patient safety must be a leadership and executive priority; managers and chief executives should be incentivised to achieve safety gains with at least 20 - 25% of their pay tied to safety improvements.

6. Dr Jim Bagian

- Healthcare organisations must make reducing the risk to the patient their first priority and this will, in the long term, minimise the risk to the organisation.
- Directives by e-mail are not an effective way to institute meaningful change. Yes, bureaucrats may well be pleased by the list of e-mails, but that isn't necessarily linked to system-wide improvement
- Actions that effectively deal with the vulnerabilities described in reports, rather than the reports themselves, are what matters. Inaction creates both cynicism and distrust at the front line, which then stops positive change.
- The culture of the organisation is the key to improved patient safety and you cannot create the culture by rules and regulations.
- The key to incident reporting is to build a learning system, not an accountability system. Their job of the reporting system is to identify system vulnerabilities that then lead to action, not to generate statistics. The reports should contain narratives and not just tick-boxes. Use interdisciplinary teams to review reports and change membership of these teams often to prevent them from becoming closed shops.
- Try to build a fair patient safety system - fair from the point of view of your staff – do this and people will flock to join the effort. However, recognise the barriers that you will face. The biggest hurdles are likely to be a lack of awareness of the problem at all levels in the organisation and the sense of shame that adverse events engender.
- The overall goal of the patient safety system is to prevent adverse events and obtain the best possible outcome for the patient.

7. Dr Joel Nobel

- With regard to incident reporting, is more data better? Intuitively you would probably think so, but generally it has not proven to be the case. Comprehensive reporting is both unnecessary and sometimes counterproductive. The reason is the signal-to-noise ratio. One incident report is often sufficient to trigger investigation and establish cause, especially for design defects. More than two or three are usually unnecessary. If you collect 500 reports, your resources are diverted to a gigantic data processing and communications exercise with little institutional

energy left for analysis, resolution, and corrective action. In short, too much data is often a problem, not a solution.

- Voluntary reporting systems have generally proven to work well for reporting and resolution. The few mandatory systems produce lots of data, much of it quite useful, but have tended to be a bit weaker in achieving resolutions. This is probably less related to the issue of 'mandatory versus voluntary' and more related to resource limitations.
- Large-scale systems tend to lack feedback to the reporters, which, in turn, demotivates them. You should acknowledge receipt of reports and tell reporters what you have learned.
- It is unnecessary to exaggerate risks to get attention and produce constructive change. It destroys credibility and distorts safety priorities - regardless of how media and politicians love it. Too many scares drive health professionals into a refractory state and they can't respond to further stimuli.
- When alarming new studies are inconsistent with general experience and common sense, don't jump on the safety bandwagon. Be sceptical. Somebody is probably trying to sell something. There are enough real problems to solve to keep us all gainfully employed for a while.
- In accident investigation we find that experience is probably the most critical factor. Borrowing analytic methodologies from other fields is less useful than focused experience.

8. Professor Bill Runciman

- Without re-design, the Australian healthcare system will continue with relentless inefficiency to kill 10,000 patients and generate 500,000 adverse events annually.
- When it comes to learning from incident databases, *size matters* for a fundamental reason. Most types of adverse events and near misses occur infrequently. So to discover both their primary and secondary causes enough information must be collected from many hospitals/healthcare facilities nationally, and from many sources.
- The reporter must be protected through ensuring confidentiality and, where necessary, anonymity. All information should be legally privileged so that it does not end up in court cases.
- Use common incident reporting and analysis terminology and allow reporting by any means – e.g. the web, fax etc. Publish updated definitions, and disseminate change strategies that have been derived from analysis of reports and the literature
- 'Burst' reporting - for limited periods of time, such as a month - and setting units in competition with one another by bribing them with prizes for the best or most reports can provide significant useful information on adverse incidents for learning.
- There should be a *firewall* between the systems for learning and those for accountability. A *just culture* must define what is acceptable. There is a line

beyond which behaviour and actions are unacceptable and demand censure. However, the people that ensure accountability and discipline cannot be responsible for the learning system. There must be penalties for disclosure.

9. Professor Nick Barber

- We do not know how many patients are harmed as a result of prescribing errors and research is needed to complete the picture.
- The pharmacist is a key defence against drug errors for the patient and is a backstop if all the other defences are breached.
- Prevention of drug errors may well start with better induction of junior registrars, and consultants could provide simulation training to teach young doctors about drugs and doses.
- It is often argued that more technology is needed in pharmacy to reduce errors. We must not, however, let the need for action lead us into the naive adoption of technology. Technology is one solution - but not the only solution.
- Community pharmacies do not appear to fit well into the remit of the National Patient Safety Agency. Those that are shareholder companies have special concerns. A central, standardised dispensing error reporting system just for pharmacies may be the best way forward, if it can be linked to the NPSA in some way.
- The drug industry can and must play an important part in reducing errors by writing understandable 'instructions for use' for nurses. Some of their written material is not adequate.
- Pharmacists are changing from checking the prescribing of others, to doing some of it themselves; this will grow under current NHS plans. So who, once they are prescribing, watches over the pharmacists?

10. Dr Martin Pickstone & Mr Chris Quinn

- Training to use medical technology has fallen further and further behind the growth in the types, number and complexity of medical devices. As this gap grows so do the chances of serious device-related incidents.
- In order to use medical technology effectively, staff need competence training. Competence training is the marriage of practical skills with knowledge & understanding so that the trainee can deal with the unexpected. In this process, the trainee acquires tested transferable skills.
- We have learned from unsafe practices that equipment standardisation, equipment libraries, competence training have transformed the safety of IV therapy.
- The technology triangle is a simple visual tool that illustrates the relationships between the objectives of technology management in clinical procedures, the practical actions necessary for their achievement and the end result - better patient care.

11. Dr June Raine

- It is salutary to remember how adverse drug reaction reporting began. It was in the early 1960s when the Thalidomide disaster tragically demonstrated the need for systematic collection of reports of adverse drug reactions.
- In 1964 Sir Derrick Dunlop, Chairman of the Committee on Safety of Drugs, wrote to every member of the medical profession in the UK asking them to voluntarily report details of any untoward condition in a patient which might be the result of drug treatment. Confidentiality was guaranteed and reports were sought promptly, to be submitted on the basis of suspicion rather than waiting for firm proof. These three principles have stood the test of time and remain the foundation of today's system!
- Since 1964 over 430,000 Yellow Card reports have been received, and a wide range of important early warning signals have been detected as a result.
- The Medicines Control Agency is currently consulting on a new proposal to improve the identification of medicines by use of a number plate approach, to ensure all the information to be checked to avoid administration errors is accessible in one place.

12. Dr David Jefferys

- The medical technologies sector plays a vital role in healthcare. Some 20,000 different devices are currently available in the UK market and every day more than thirty six million people use a medical device, ranging from sticking plasters and incontinence pads to sophisticated interventional instruments.
- The Medical Devices Agency (MDA) operates two incident reporting systems. The first is for mandatory reporting by manufacturers and is required by European directives throughout the Community. The second is our adverse incident user reporting system which began in the early 1960's and was the first such system in the world.
- The MDA also co-operates in the International Vigilance Scheme both to learn the lessons from Europe and elsewhere and to transfer UK experience for the benefit of our partners.
- In 2000, the MDA received reports of 87 deaths and 558 serious injuries in which medical devices were implicated.
- The causes of adverse incidents involving medical devices in 2000 were - 40% arise before delivery of the device - design faults, production problems and damage during transport; 23% happen after delivery - poor maintenance and record keeping are examples of reasons; and user error causes 9% of incidents but may be the cause of some of the 28% for which no explanation could be found.

2

Summary of websites and further reading

Foreword – Dr Fiona Moss

1. *Medical Mishaps – Pieces of the Puzzle* edited by Marilyn Rosenthal, Linda Mulcahy, Sally Lloyd-Bostock. Open University Press. ISBN 0-335-20258-6
2. *The Management and Control of Hospital Acquired Infection in Acute NHS Trusts in England*. HC 230 Session 1999-00, Feb 2000, London. The Stationary Office
3. *An Organisation with a Memory* www.doh.gov.uk/orgmemreport
4. *The Journal of Quality and Safety in Health Care* www.qualityhealthcare.com

Chapter 1 – Lord Hunt of Kings Heath OBE

1. *An Organisation with a Memory* www.doh.gov.uk/orgmemreport
2. *The NHS Plan* www.doh.gov.uk/nhsplan
3. National Service Frameworks www.doh.gov.uk/nsf
4. National Institute for Clinical Excellence www.nice.org.uk
5. NHS Controls Assurance project www.controlsassurance.info
6. NHS Clinical Governance Support Team www.cgsupport.org
7. Commission for Health Improvement www.chi.nhs.uk
8. Department of Health NHS performance indicators website www.doh.gov.uk/nhsperformanceindicators
9. *Health Act 1999* www.hmso.gov/acts/acts1999/19990008.htm
10. www.npsa.org.uk

Chapter 2 – Mr Stuart Emslie

1. Patient safety at Kaiser Permanente, USA www.kaiserpermanente.org/medicine/permjournal/sum01/PatientSafety.html
2. Joint Commission on Accreditation of Healthcare Organizations www.jcaho.org
3. *Health Service Journal* www.hsj.co.uk
4. Controls Assurance core standard on Governance, available at www.controlsassurance.info.
5. Department of Health NHS performance indicators website www.doh.gov.uk/nhsperformanceindicators
6. Controls Assurance Support Unit www.casu.org.uk
7. *HSC 1999/123* and associated guidance available from www.controlsassurance.info
8. *Governance in the NHS: Statement on Internal Control for 2002/2002 and beyond* available from www.controlsassurance.info

9. AS/NZS 4360: 1999 – Risk management. www.standards.com.au and www.riskmanagement.com.au
10. HB 228:2001 - Guidelines for managing risk in the healthcare sector. www.standards.com.au
11. Building a safer NHS for Patients www.doh.gov.uk/buildsafenhs
12. The National Patient Safety Agency www.npsa.org.uk
13. An excellent primer on Patient Safety and the “Just culture” written for healthcare executives can be freely downloaded from www.mers-tm.net
14. University College London & Association of Litigation and Risk management (ALARM). A protocol for the investigation of clinical incidents. Royal Society of Medicine Press, 1999. Telephone (44) 0207 290 2968.
15. How to investigate and analyse clinical incidents: Clinical Risk Unit and Association of Litigation and Risk Management Protocol. Charles Vincent *et al.* BMJ Volume 320 – 18 March 2000. www.bmj.com
16. BMJ Journal of Quality and Safety in Health Care www.qualityhealthcare.com
17. ECRI www.ecri.org

Chapter 3 – Dr Kirstine Knox

1. An Organisation with a Memory www.doh.gov.uk/orgmemreport
2. NHS Controls Assurance project www.controlsassurance.info
3. NHS Litigation Authority www.nhsla.com
4. Australian Patient Safety Foundation www.apsf.net.au
5. Safecode Ltd. www.safecode.co.uk
6. BUPA Healthcare www.bupa.co.uk
7. National Patient Safety Agency www.npsa.org.uk

Chapter 4 – Professor Rory Shaw

1. Vincent, C. *et al* – Adverse events in British Hospitals – preliminary retrospective record review. BMJ 2001;322:517-519
2. Vincent, C. and Reason, J. Human factors approaches in medicine in Medical Mishaps – Pieces of the Puzzle, edited by Rosenthal, M., Mulcahy, L. & Lloyd-Bostock, S. Open University Press. 1999. ISBN 0-335-20258-6.
3. Building a safer NHS for patients www.doh.gov.uk/buildsafenhs
4. The NHS Plan www.doh.gov.uk/nhsplan

Chapter 5 – Dr Paul Barach

1. *To Err is Human* – www.nap.edu/readingroom and www.iom.edu
2. Sheldon P. Blau M.D., and Elaine Fantle Shimberg titled '*How to get out of the hospital alive – A guide to patient power.*' 1998. ISBN 0-02-862363-0
3. IOM – *Crossing the Quality Chasm* – www.nap.edu/readingroom and www.iom.edu
4. For a detailed consideration of the application of 'six-sigma' in healthcare, see *The Past, Present and Future of Health Care Quality* – www.tuvam.com/services/fitness/articles/merry.pdf
5. An obstetrician at Beth Israel Hospital in New York carved his initials on the belly of a woman patient. For further information, see:
http://www.ahcpub.com/ahc_root_html/hot/archive/hrm0300.html

Chapter 6 – Dr Jim Bagian

1. Veterans Health Administration www.va.gov
2. *To Err is Human* – www.nap.edu/readingroom and www.iom.edu
3. See VHA patient safety handbook at
<http://www.va.gov/publ/direc/health/handbook/1051-1hk1-30-02.pdf>

Chapter 8 – Professor Bill Runciman

1. Standards Australia risk management website www.riskmanagement.com.au
2. NHS Controls Assurance project www.controlsassurance.info
3. Australian Patient Safety Foundation www.apsf.net.au

Chapter 9 – Professor Nick Barber

1. Commission for Health Improvement www.chi.nhs.uk
2. International medication error reporting programs
http://www.ismp.org/Pages/mederr_intl.html

Chapter 10 – Dr Martin Pickstone & Mr Chris Quinn

1. Pickstone M, ed. A Pocketbook for Safer IV Therapy (*Drugs, Giving Sets & Infusion Pumps*). Margate: Scitech Educational, Reprinted 1999. ISBN 0 948672 32 3.
2. Quinn C, Infusion Devices: a bleeding vein of clinical negligence? J Nursing Management, 1988, 6, 209 - 214.
3. Infusion systems. MDA DB 9503. Medical Devices Agency May 1995:1 - 54.
4. Pickstone M, Quinn C. Using the technology triangle to assess the safety of technology-controlled clinical procedures in critical care. *Int J Intensive Care* 2000; 7: 90 - 96.

Chapter 11 - Dr June Raine

1. Medicines Control Agency www.mca.gov.uk
2. Building a safer NHS for patients www.doh.gov.uk/buildsafenhhs

Chapter 12 – Dr David Jefferys

1. Medical Devices Agency www.medical-devices.gov.uk
2. Global Harmonization Task Force for medical devices www.ghtf.org
3. Jefferys DB, *Comparison of the regulatory controls for medical devices and medicinal products* International Journal of Pharmaceutical Medicine 2001
4. Jefferys DB, *The regulation of medical devices and the role of the Medical Devices Agency* Br Clin Pharmacol, 2001 52. 229-235
5. Medical Devices Agency Adverse Incident Reports 2000 MDA DB 2001(01), 2001

3

Conference questions and answers

Question and Answer Session 1 (morning)

Questioner – Mr Dave Thomas, National , National Orthopaedic Centre NHS Trust, Oxford

I have three questions. The Standardised Minimum Data Set for incidents will be recorded on many different IT systems across the NHS. So is there going to be central coordination to ensure that all systems can record and then transmit the Standardised Minimum Data Set to the NPSA? The second question is about the Risk Rating Matrix. The Australian/New Zealand standard uses a 6 by 6 matrix but the Department is introducing a 5 by 5 matrix. However many Trusts will use the Australian-New Zealand standard following advice from Controls Assurance. So is there to be a Standard Risk Rating Matrix? My final question is about a completely different aspect of incident recording. Is the NHS to name individuals in reports to the NPSA? Professor Rory Shaw did not state explicitly that staff identifiers would be removed from reports.

Answer by Mr Stuart Emslie to questions 1 and 2

There will be central coordination of key software providers and of those Trusts that have developed their own software. Dr Kirstine Knox will talk after coffee about the solution to the problem of extracting standardised data sets from different IT systems. The Australian/New Zealand standard positively encourages the Risk Rating Matrix to be adapted to suit local needs and I want to stress that the present 5 by 5 matrix is being piloted but is not set in tablets of stone. The NPSA will only finalise the design of the matrix after consultation and completion of the pilot programme.

Answer by Professor Rory Shaw to question 3

I shall start by emphasising that the pilot programme (which incorporates IT for incident-recording) is a shared endeavour that must benefit without burdening NHS staff. The end-result will be the means to obtain anonymised data in a standard format from which we can start to learn generic lessons. There is no intention to identify individuals - even if patients directly report incidents to the agency. Trusts already have plenty of mechanisms to ensure personal accountability.

Question

I am a hospital pharmacist dealing daily with patient safety matters. We have learnt from the Yellow Card Reporting System that fear of blame inhibits incident reporting. How will you stop the lawyers accessing the data?

Answer by Professor Rory Shaw

This is a key issue for the National Patient Safety Agency. We shall collect and aggregate data centrally without patient identifiers and so the data will be of no use in medical negligence claims. Claims about alleged negligence in hospitals are made against the Trust and not the staff.

Answer by Mr Stuart Emslie

This is also a key issue for the Department and we shall evaluate the progress of the pilot programme and the growing experience of the agency. We have not ruled out the need for primary legislation to protect confidentiality.

Questioner - Mr Paul Rowbotham, Northampton General Hospital

I have two questions about the resources that hospitals will need to work with the National Patient Safety Agency. We have calculated that the average district general hospital with 50,000 annual in-patients will need nine full-time staff to record and analyse incidents. This estimate uses the epidemiological data for UK medical errors and the time needed for the root cause analysis of a code red event of between two and 20 days. However we already know from past research the likely conclusions of future root cause analyses - inadequate staffing levels and poor equipment are examples. Whether or not these conclusions are predictable improving safety will cost money. So my questions are.

1. Where do we find the money first to feed data to the NPSA and then to implement lessons that will improve patient safety?
2. How is the Department of Health going to raise resources for management from the present level of three percent of turnover to that required for a large and complex organisation (15-20%)?

Answer by Mr Stuart Emslie

I am personally very keen to find answers to these questions and will be pursuing and exploring various avenues within the Department of Health. As some of you may be aware, setting robust investment priorities for patient safety, and all other areas of risk control, based on risk ranking and cost-benefit analysis is a key requirement set out under the NHS Controls Assurance project. What I can say now is that one of the main

purposes of the pilot programme is to start the investigation of the resources necessary for safer healthcare. One point of detail is that the range quoted of between two and twenty days is the estimated *elapsed* time needed for a root cause analysis. In other words this is the likely time to arrange, and undertake interviews of all key people about a category red incident and is not the *cumulative* time required for the analysis. Comments and feedback from the pilot sites are crucial if the NPSA is to issue high quality guidance on these resource issues - which we hope will be early in 2002.

Answer by Professor Rory Shaw

Most Trusts do have some form of incident reporting system and the agency intends to support rather than supplant existing arrangements. The National Patient Safety Agency knows that recommendations will create cost pressures, which will be discussed and agreed with the Department of Health, before their release.

Questioner – Dr Fiona Moss for the BMJ Journal of Quality & Safety in Healthcare

What clout will the NPSA have to influence training and education in healthcare? Speaking in my role as a clinician we teach young doctors to look after their patients really well but we fail completely to teach them to care for healthcare systems and so place these young people at a disadvantage.

Answer by Professor Rory Shaw

Influencing the education of all healthcare staff is on my agenda. We want to act with the agreement and help of other agencies/organisations to make staff more risk-aware through (longer-term) changes in educational curricula. However we want other actions, such as encouraging hand-washing, to improve patient safety as soon as possible.

Questioner – Mr Nigel Offen, Eastern Regional Office, Department of Health

Does the agency intend to study how hierarchical behaviour both prevents reporting and causes accidents? Evidence from aviation shows that the large differences between the number of deaths per passenger mile in Western airlines and those in Eastern Europe and the Far East can be attributed to hierarchical behaviour in the cockpit rather than to poor servicing. The NHS is full of such behaviour.

Answer by Professor Rory Shaw

The responsiveness of senior consultants to worried junior staff is a measure of the penetration of a risk-conscious culture in a Trust. The NPSA intends to promote both the culture and this responsiveness.

Questioner – Mr Ted Willmot, Chairman Hereford Primary Care Trust

I approve of all that has been said about the need for a risk-aware culture. However what about the risk-aware culture of the Minister? A shiver went down my spine when the Minister talked of speeding up the process (reduced waiting times) whilst improving safety. These words could have been said by the chief executive of a train operating company or of an airline who wanted to increase volume at the expense of safety.

Answer by Professor Rory Shaw

All organisations have to balance the triangle of volume, quality and cost. Our mission is to concentrate on safety whilst remaining aware of resource constraints and implications of our actions.

Question and answer session 2 (afternoon)

Questioner

Suppose a safety culture has been created with ensuing growth in the reporting of near misses but then the reporting frequency starts to decrease. How can you decide whether this decrease is the result of safer healthcare or due to the re-emergence of the old culture of fear and secrecy?

Answer by Professor Bill Runciman

Safer healthcare is shown both by a continuous increase in overall number of reports and by the changed proportions of the types of reported incidents. For instance the training to use infusion pumps competently that was described by the last two speakers will drive down the number of errors (and related reports) due to staff ignorance and will, for example, improve the safety of intravenous Heparin administration.

Answer by Dr Jim Bagian

This is a question that we worry about all the time because voluntary reporting never reveals the actual frequency of events. Dr Nobel has pointed out that countermeasures can be taken against errors that are revealed in a very small number of reports. We prove the efficacy of countermeasures by before-and-after observations at numerous sites. However, observational studies are lengthy, expensive and are only performed on the most far reaching, high impact and expensive countermeasures. Otherwise we rely upon the changing rates of voluntary reporting.

Additional comment by Professor Bill Runciman

60% of events reported are too infrequent for before-and-after observations to be cost-effective and then you analyse the changed pattern of types of reports.

Questioner

How can senior managers be made to understand that they are on probation because voluntary reporting in their organisations can stop when only one reporter is hanged by his/her action?

Answer by Professor Rory Shaw

We have to foster an organisational environment in which reporting is both valued and is expected of staff at all levels. The National Patient Safety Agency needs to find ways of creating the incentive to report.

Answer by Dr Jim Bagian

I agree, but a safety culture has two sides to it just like a coin - reporting and the follow-up actions that improve patient safety. Evidence from other industries shows that people use incentives for their own benefit. So if you reward high reporting, then you get high reporting. But this kind of incentive alone will not improve the safety of patients. We at the VHA focus on actions that have been implemented as a result of these reports. We say to chief executives 'Show us your results, show us what organisational vulnerabilities you have identified and the changes you have made to eliminate them.' We show our people the changes that result from their reports and tell them how we value their actions. This in turn increases their support and their incentive to report.

Questioner

There is an obvious global mutual interest in an international database whose only objective is patient welfare. How can we stop ownership from clouding this objective?

Answer by Dr Jim Bagian

While an international database is important, I estimate that 90% of an improvement is because of what is discovered at the frontline, what is analysed at the frontline and what is corrected at the frontline. The local organisation owns the improvements and the VA National Center of Patient Safety (NCPS) is a facilitator of local cultural change. We have several roles: looking for patterns in the information communicated by our healthcare organisations, disseminating good practices and undertaking before-and-after observations on which mandatory standards of care may depend. We also detect the rogue administrator who suppresses reporting and who is either retrained or removed. However if NCPS ceased to exist, then 90% of the value of past improvements would be retained because frontline staff have a systems understanding and have incorporated what they have learned into their daily work. We think that communication and the database are important, but the action takes place at the frontline. That is where problems are detected and where most change should be implemented.

4 *Post-conference questions, suggestions and comments*

A total of 52 conference delegates submitted written questions, suggestions and comments. These are summarised overleaf.

Position/Function	Topics that could have been either expanded upon or included in the conference	Specific questions	Other patient safety matters considered important
Policy Maker	<ul style="list-style-type: none"> Medicines adverse events as distinct from adverse drug reactions (ADRs). An ethical framework for sharing adverse events and near misses Discussion of the IT systems available 	<ul style="list-style-type: none"> Can some clarity be given around patient incidents related to medicines – prescribing errors, administration problems, dispensing, etc.? 	<ul style="list-style-type: none"> Provision/non-provision of patient information
Health Authority Manager	<ul style="list-style-type: none"> Patient safety in primary care and care provided by independent contractors 	<ul style="list-style-type: none"> How will clinicians and managers become receptive to the lessons from the NPSA? How can NPSA use mediation and dispute resolution techniques to identify root causes and improve receptiveness of healthcare providers? 	<ul style="list-style-type: none"> More attention to feedback from NPSA to practitioners. We need to consider how to make often painful lessons of errors and disputes safe and accessible to learners
Board Chairman	<ul style="list-style-type: none"> Lessons from pilots in primary care 	<ul style="list-style-type: none"> What is NPSA doing to change culture NOW in politicians, media and legal professions to appreciate that safety must be <i>primus inter pares</i> with waiting list/time targets? (public perception must be rooted in realistic expectations) 	
Board Member	<ul style="list-style-type: none"> Reporting systems – international contrasts and purpose/context ('fitness for purpose') 	<ul style="list-style-type: none"> What is NPSA going to do to encourage the public to understand that risk is possible/real? 	
Director of Corporate Services	<ul style="list-style-type: none"> Experience from pilot sites Priorities and programme from NPSA over next 12-24 months 	<ul style="list-style-type: none"> What can be done to ensure support from Government when open/no-blame reporting receives the usual negative media response? 	
Director of Operations - Community	<ul style="list-style-type: none"> Practical examples of root cause analysis More examples appropriate to primary care Speaker from a pilot site 	<ul style="list-style-type: none"> How do we get GPs on-board? (some don't think this incident reporting system applies to them as independent contractors) 	<ul style="list-style-type: none"> There is an issue regarding patients being looked after by the independent sector, i.e. nursing homes, domiciliary carers. Training and culture issues apply in all setting, not just acute hospitals.
Director of Facilities	<ul style="list-style-type: none"> Systems and implementation Co-ordination of central reporting requirements 	<ul style="list-style-type: none"> Can we get real about blame? The Government and organisations do look for blame. It can be that people must be supported and accountable people held to account. Can there be clear definitions? 	

Position/Function	Topics that could have been either expanded upon or included in the conference	Specific questions	Other patient safety matters considered important
Clinical Director	<ul style="list-style-type: none"> Evidence from outside healthcare (aviation etc.) 		
Director of Public Health	<ul style="list-style-type: none"> Real examples – maybe from a surgeon or paediatrician of how this can be made to work Pilot sites speaking about how it really felt and what they did when resources were required to put systems in place 	<ul style="list-style-type: none"> How will resources follow the process so clinicians can have confidence that not only will they be heard, but also something will be done? 	
Director of Public Health	<ul style="list-style-type: none"> Reporting systems 		
Primary Care Advisor/Consultant in Public Health	<ul style="list-style-type: none"> How workforce planning, locum recruitment and HR processes can be managed to reduce risk How to take this agenda forward in non-managed independent contractor professions in primary care 	<ul style="list-style-type: none"> What changes in national policy and DH performance requirements from NHS are required to create a supportive blame-free culture resourced to establish sustainable changes in systems? 	<ul style="list-style-type: none"> Curriculum safety
Director of Clinical Quality & Learning/Nurse Lead			<ul style="list-style-type: none"> I agree with Dr Kirstine Knox that the centre cannot and should not develop policy on its own, if that policy is to be successfully implemented
Director of Nursing	<ul style="list-style-type: none"> Risk registers Toolkits and frameworks 		
Consultant Anaesthetist	<ul style="list-style-type: none"> The problems of meeting the needs of health and safety reporting (HSE/RIDDOR) with the needs of clinical incident reporting 	<ul style="list-style-type: none"> Are there any plans for direct confidential reporting (as in the airline industry)? 	<ul style="list-style-type: none"> For the culture to change there is a need for the leaders (politicians, DoH, etc.) to demand change – CHI has so far failed to do that
Consultant Anaesthetist & Lead Clinician for Risk	<ul style="list-style-type: none"> Medical Devices Agency presentation could have been expanded upon 	<ul style="list-style-type: none"> What degree of pragmatism is involved in MDA recommendations e.g. re. Use of anaesthetic circuitry, which is presented unsterile? 	
Deputy Director – Clinical Governance	<ul style="list-style-type: none"> Additional examples of incidents in primary care Speaker from a pilot site to describe progress and impact of grading matrix in an organisation 	<ul style="list-style-type: none"> When will we be advised of the definitive implementation date from NPSA? 	<ul style="list-style-type: none"> Guidance on use of most appropriate IT system e.g. Safecode or Datix – which would give most benefits?
Assistant Director of Clinical Governance	<ul style="list-style-type: none"> Reporting systems – success Lessons from other countries Primary care – examples of good practice 		

Position/Function	Topics that could have been either expanded upon or included in the conference	Specific questions	Other patient safety matters considered important
PCT Clinical Governance Lead			<ul style="list-style-type: none"> In a similar vein to involvement of community pharmacists in NPSA scheme, there could be problems involving some GPs (self-employed)
Clinical Services Manager	<ul style="list-style-type: none"> Case studies What makes reporting systems successful 		
Clinical Risk Manager	<ul style="list-style-type: none"> Operational detail re. NPSA Detail of national groups looking at specific targets for 40% reduction in drug error and 25% reduction in preventable harm in obstetrics 	<ul style="list-style-type: none"> Will root cause analysis training be available for all as per pilot or will we just get the promised guidance? How much preparation/development can we realistically aim for prior to Start 2002, bearing in mind big disclaimer on 'Doing Less Harm'? 	<ul style="list-style-type: none"> More availability of training on root cause analysis – 'quick and simple' as promoted by Dr Kirstine Knox – NOT massively time consuming like Reason's model and UCL/ALARM tool
Clinical Risk Manager	<ul style="list-style-type: none"> Something on security/violence/aggression as patient safety is often compromised because of these factors 	<ul style="list-style-type: none"> When are national benchmark codes going to be issued? How often will NPSA be expecting locally reported incidents to be sent to them? Where does the reporting of 'serious untoward incidents' fit into the NPSA system? 	
Clinical Risk Advisor (Nursing)		<ul style="list-style-type: none"> Will there be a national incident reporting form? Will there be a specific list of reportable incidents? How can medical staff be encouraged to report? 	
Associate Director - NHS Acute Trust		<ul style="list-style-type: none"> MDA/manufacture interface – How is identification and packaging of single-use-medical devices negotiated'? (there is a cynical view at local level concerning manufacturers taking advantage of prion disease situation and making a quick buck) 	
Risk Manager	<ul style="list-style-type: none"> Learning from international lessons – systems, implementation and motivation 		
Risk Manager	<ul style="list-style-type: none"> Root cause analysis techniques Strategic view for risk management in Trusts/Unified Boards 	<ul style="list-style-type: none"> Literature suggests avoid 'anonymous' reporting but support 'confidential' reporting. What is the view of the morning panel as opposed to the US and Australian views expressed in the afternoon? 	

Position/Function	Topics that could have been either expanded upon or included in the conference	Specific questions	Other patient safety matters considered important
Risk Management Co-ordinator	<ul style="list-style-type: none"> Lessons from Australia 		
Risk Management Co-ordinator	<ul style="list-style-type: none"> Definitions – agreement of and explanation, and relevance to HSE, etc. 	<ul style="list-style-type: none"> National data collection – will this affect Scotland? Patient/Public involvement – where will it fit in with NPSA? 	
Non-clinical Risk Manager	<ul style="list-style-type: none"> More feedback from pilots Resourcing Training opportunities for RCA 	<ul style="list-style-type: none"> Most presentations seemed to be biased towards patient safety being all about managing so-called clinical risks. What will the NPSA be doing to promote a seamless risk management approach to incident management? Will the NPSA be doing anything to promote ‘single point’ reporting to avoid multi-agency reports (e.g. MDA, HSE, Regional Offices, etc.) and reduce duplication of effort? 	
Project Manager		<ul style="list-style-type: none"> How does research and research governance fit in with the development of the NPSA? 	
Director of Pharmacy	<ul style="list-style-type: none"> Actual details of NPSA report systems for Trusts 		
Chief Pharmacist		<ul style="list-style-type: none"> What about looking at information on serious errors that we know currently exist and implement solutions or look at solutions that may have worked (we don’t need to collect data about some currently serious errors)? 	
Chief Pharmacist	<ul style="list-style-type: none"> Other healthcare experiences – feedback from existing pilots giving ‘hands-on’ experience 		
Chief Pharmacist	<ul style="list-style-type: none"> Lessons from and experience of international systems – e.g. Australian database showed what could come out of a national reporting system Pilot sites talking about their experiences 		
Chief Pharmacist		<ul style="list-style-type: none"> When the NPSA begins to advise on how we analyse incident (root cause) and change practice, how will we get resource support? 	<ul style="list-style-type: none"> Priority is to include patient safety in core education of all healthcare professionals Patient safety should be mandatory part of induction training
Pharmacy Manager			<ul style="list-style-type: none"> Adopt 100% IV drug preparation in pharmacy

Position/Function	Topics that could have been either expanded upon or included in the conference	Specific questions	Other patient safety matters considered important
Principal Pharmacist	<ul style="list-style-type: none"> Lessons from international systems – especially what makes reporting systems successful 	<ul style="list-style-type: none"> A pharmacists job is to error detect. Do we report all of these and, if not, how do you select which errors to report? 	
Hospital Clinical Pharmacist	<ul style="list-style-type: none"> How to change medical culture (its embedded in pharmacy practice – why not learn from it?) Pharmacist intervention data – a learning opportunity Examples of process re-engineering risks 	<ul style="list-style-type: none"> Having learnt from ADR reporting (yellow card scheme) that fear of blame inhibits reporting, how do you stop lawyers accessing the data (one event will kill off reporting by doctors)? 	<ul style="list-style-type: none"> No-blame culture must be implemented to enable learning Department of Health must resist temptation to blame individuals at all costs!
Pharmacist	<ul style="list-style-type: none"> Lessons from the USA (Dr James Bagian) 	<ul style="list-style-type: none"> How will primary care get involved? (this could come across as 'hospital only') 	
Drug Administration Co-ordinator			<ul style="list-style-type: none"> New Junior House Officers start their hospital experience 1 August (in Scotland). British National Formularies are not available until mid-September. Room for error?
-	<ul style="list-style-type: none"> How Trusts will get resources and implement NPSA requirements What will be done with the data supplied to NPSA Using a common language for risk across clinical and non-clinical areas Accountability for clinicians (how accepting responsibility does not mean clinicians are opening themselves up to litigation) 		
-	<ul style="list-style-type: none"> UK perspectives on patient safety 		
-	<ul style="list-style-type: none"> More on learning from international experiences 	<ul style="list-style-type: none"> 	
-	<ul style="list-style-type: none"> The role of human factors training 	<ul style="list-style-type: none"> What is being done to inform management of their responsibility NOT to punish/discipline people who too the trouble/risk to report incidents? 	
-	<ul style="list-style-type: none"> Implementation Changing culture How to get Trust Boards on-board! Suggested structures for reporting to NPSA – i.e. within Trusts 	<ul style="list-style-type: none"> Any chance of video/CD/speakers coming from NPSA to show and demonstrate to Trust Board/Senior Teams – would ensure consistency and understanding 	

Position/Function	Topics that could have been either expanded upon or included in the conference	Specific questions	Other patient safety matters considered important
-	<ul style="list-style-type: none"> Root cause analysis 	<ul style="list-style-type: none"> Will NPSA be looking at wider patient safety issues surrounding lack of or delay in delivery of important patient interventions (Many patients, one assumes, suffer from such deficiencies)? 	
-	<ul style="list-style-type: none"> Practical lessons from American experiences Australian risk management standard (AS/NZS 4360:1999) 		<ul style="list-style-type: none"> Interference from Government ministers – their agenda is often self-insurance rather than what's best for the patient or the hospital
-		<ul style="list-style-type: none"> Do Trusts still report Adverse Incidents to the MDA now that NPSA had been established? 	
-	<ul style="list-style-type: none"> More about the issues for primary care where lines of management and authority are less clear i.e. PCTs do not employ GPs and practice nurses 		
-		<ul style="list-style-type: none"> Prof. Shaw mentioned potassium chloride strong IV bolus as a House Officer. Why wait for reporting systems to be in place before it's removed from the market? 	<ul style="list-style-type: none"> There is an urgent need to have barcodes on all drug packaging that is uniform. Barcodes should be available on individual ampoules!
-	<ul style="list-style-type: none"> Primary care – systems and outcomes Feedback from pilot sites – specifically primary/community care 		
-		<ul style="list-style-type: none"> What enforcement powers will NPSA have? What links will NPSA have with enforcement bodies (e.g. HSE) Will there be a national syllabus and standard training on root cause analysis? 	
-	<ul style="list-style-type: none"> More on international lessons 		