INTERNATIONAL PERSPECTIVES ON PATIENT SAFETY

Key information on selected notable patient safety programmes, initiatives and practices in place outside the United Kingdom

This report was compiled to inform a study of organisational learning for patient safety that was carried out by the National Audit Office, England, 2004-2005.

Any views expressed in this report are the author's own and do not necessarily reflect the views of the National Audit Office.

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> "According to a December 2002 survey by the Harvard School of Public Health and the Kaiser Family Foundation, 42 percent of the public says that they or a family member have experienced a medical error."
>
> *US Congressman John D Dingell*
> *In a statement to the US Senate on H.R. 663, "The Patient Safety and Quality Improvement Act"*
> *12 March 2003*

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> "Waiting for the perfect reporting and learning system guarantees nothing will happen. Accepting imperfection means you can forge ahead with learning, improving and making a difference."
>
> *Alison McMillan*
> *Head of Clinical Governance Unit*
> *Department of Human Services*
> *Victoria*

Preface

There has been an 'explosion' in all things 'patient safety' in recent years. To illustrate this, the table below gives results for Internet searches for "patient safety" using the Google™ search engine (www.google.com) carried out over a 21 month period. Between February 2004 and November 2005 there has been almost a twelve fold increase in the volume of catalogued web pages relating to patient safety.

Date of search	11 February 2004	1 March 2005	4 November 2005
No. of 'results'	500,000	2,680,000	5,800,000
Increase (ratio)	0	5.4	11.6

This report was principally written during 2004. At that time, the National Audit Office (NAO) was conducting a study of NHS Trusts in England focusing on the concept of 'organisational learning' for patient safety. The aim of the work associated with this report was to inform the NAO study by considering aspects of international activity relating to patient safety. This report does not comment on patient safety systems and developments in England as this is the subject of the NAO report on 'Learning to improve patient safety'

Given the 'explosion' in all things patient safety related, and the elapsed time between the work being carried out and the report being able to be published by the NAO, the information contained in this, or any report cannot hope to be exhaustive or, indeed, 'up to the minute'. Despite these caveats, this report does attempt to put a 'stick in the sand' that reflects the author's range of knowledge, experience and contacts cultivated during more than 10 years involvement in patient safety and related matters internationally. In this context, it is hoped that the information provides a useful summary of some of the significant programmes, initiatives and good practice in patient safety internationally.

About the author

Stuart Emslie is an independent healthcare consultant specialising in governance and risk, and Editor of 'Governance Matters', a regular newsletter for healthcare board members and senior managers. He is a Visiting Fellow at Loughborough University Business School and a Visiting Lecturer at Flinders University Medical School in South Australia. He is formerly Head of Controls Assurance for the NHS in England at the Department of Health. During his time at the Department, he assisted the Chief Medical Officer with the development of aspects of the patient safety agenda and wrote the blueprint for the new national system for learning from patient safety incidents contained in the Department of Health's publication 'Building a Safer NHS for Patients'.

Prior to joining the Department of Health, Stuart was Co-director of an academic research unit at Strathclyde University in Glasgow and from 1991-1997 he received significant funding from the four UK Health Departments and the NHS to develop the NHS's award-winning 'Safecode' suite of risk and quality management tools and methodologies. This included IRIS, the NHS's first national software-based 'Incident Recording and Information System', which, in 1994 contained the World's first healthcare root cause analysis methodology and was distributed free of charge to all UK hospitals by the UK health departments and the NHS. For his work in developing IRIS, Stuart was awarded the 1997 'Safety Trophy' from Zurich Municipal and the Institution of Occupational Safety and Health for "putting patients before paperwork."

In 1995-1996 Stuart helped the NAO develop a methodology for recording and costing adverse staff and patient incidents as part of their 1996 report on health and safety in acute NHS trusts in England. Subsequently, as Head of Controls Assurance at the Department of Health, he was an expert panel member for NAO reports on managing health and safety risks to NHS staff, protecting NHS Hospital and Ambulance Staff from Violence and Aggression, and achieving improvements through clinical governance. He has also assisted the NAO with studies on medical equipment management and on hospital acquired infection. Most recently, he worked with the NAO on an evaluation of international perspectives on patient safety for their report on learning to improve patient safety.

Acknowledgements

The following organisations and individuals provided helpful information and insights.

Australia

- Australian Council for Safety and Quality in Healthcare (Professor Bruce Barraclough)
- Clinical Governance Unit, John Hunter Hospital, Newcastle, New South Wales (Professor Allan Spigelman, Dr Maree Bellamy, Ms Sue Williams)
- NSW Institute for Clinical Excellence[1] (Dr Ian O'Rourke and Professor Bruce Barraclough)
- New South Wales Health Department
- Queensland Health Department (including Princess Alexandra Hospital)
- Victorian Health Department (Alison McMillan)
- Victorian Managed Insurance Authority (Dr Peter Kirker)
- Australian Patient Safety Foundation (Professor Bill Runciman)
- Patient Safety International, Australia (Marg Gherig)
- Dr Chris Farmer, Repatriation Hospital, Adelaide
- Dr Stephen Bolsin, Barwon Health, Victoria
- Professor Joseph Ibrahim, Peninsula Health, Victoria
- Dorothy Vicenzino, Queensland Health Department

Hong Kong

- Dr David Lau, Hong Kong Hospital Authority

USA

- Institute for Healthcare Improvement, Boston
- Cambridge Health Alliance, Boston
- Betsy Lehman Centre for Patient Safety, Boston
- Pennsylvania Patient Safety Authority (Dr Robert Muscalus)
- ECRI, Philadelphia (Dr Jeff Learner and Ms Ronni Solomon)
- Joint Commission on Accreditation of Healthcare Organisations, Chicago (JCAHO – Russ Massaro and Dr Rick Croteau)
- Veterans Affairs National Centre for Patient Safety (Dr James Bagian and Dr John Gosbee)
- Dr Sanjay Saint, University of Michigan
- Dr Paul Barach, Centre for Patient Safety, Jackson Memorial Hospital, Florida
- Jim Conway, Chief Operations Officer, Dana Faber Cancer Institute, Boston

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[1] Update Nov 2005: Now called The Clinical Excellence Commission

Introduction

The development of organisational learning from adverse patient safety incidents, and implementing effective strategies, or solutions, to reduce risk is currently a key objective of many health care systems and organisations around the World.

Organisational learning, in the context of patient safety, has been defined as "……a process of increasing the capacity for effective organisational action through knowledge and understanding[2]." In its wider context, Bob Garratt, an authority on creating 'corporate' learning organisations, argues that the board of directors is legally and practically responsible for ensuring a sufficient rate of learning within their organisation[3]. He states that "Executives and managers are then responsible for designing the systems (especially of learning) which create the positive emotional climate in which people go about their day-to-day work. How directors and managers ensure that this rate of learning is sufficient is the great challenge for creating and sustaining Learning Organizations – particularly as many do not even recognize that there is a challenge." Applying Bob Garratt's thinking to health care tells us that it is the boards of NHS organisations and their managers that present, perhaps, the greatest challenge to organisational learning for patient safety.

Fundamental to the NAO study was an understanding, in general terms, of where patient safety was 'at' internationally, outside the UK, with a particular emphasis on the recognised leading individuals and organisations in the field in Australia and the USA. To this end, the author arranged, for the NAO, two one week 'study tours' of selected key individuals and organisations in Australia in October 2003 and in the USA in January 2004. Visits were also made to Hong Kong Hospital Authority in October 2003 and March 2004 to discuss patient safety matters in the aftermath of SARS. A visit was made to Singapore Ministry of Health in March 2004.

Following these study tours it was decided to:

1. Utilise electronically recorded discussions and written notes of meetings with key individuals and organisations in Australia and the USA, together with relevant published information, including website materials, to 'provide a potentially useful source of knowledge and information to inform the patient safety study; and
2. provide useful information and identification of key published resources both for key organisations in Australia and the USA not included in the study tours, and for other selected key organisations involved in patient safety internationally.

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[2] *Leading organisational learning in health care*, J S Carroll, A C Edmondson. Journal of Quality and Safety in Healthcare 2002; 11:51-56.
[3] *The Learning Organization – Developing Democracy at Work*. Bob Garratt. ISBN 9 780006 530534

Summary of notable patient safety programmes, initiatives and practices in place internationally

Key:

Local	🟦
State/regional	🟩
National	🟨
Multi-national	🟧
International	🟥

COUNTRY	ORGANISATION	PROGRAMMES/INITIATIVES/PRACTICES	PAGE
Australia	Australian Council on Safety and Quality in Health Care	- Open Disclosure Standard - Patient safety system checklist - Glossary of safety and quality terms and definitions - Syllabus for education/training in patient safety - Ensuring correct patient, correct site, correct procedure protocol - Safe staffing 10 tips for safer health care: What everyone needs to know (available in 15 community languages)	21
	Australian Patient Safety Foundation (and Patient Safety International)	Advanced Incident Monitoring System (AIMS®)	21
	Geelong Hospital, Barwon Health, Victoria	Personal professional monitoring using personal digital assistants (PDAs)	22
	John Hunter Hospital Clinical Governance Unit, Newcastle, NSW	RCA-based patient safety improvement programme (based on Department of Veterans Affairs, USA)	23

COUNTRY	ORGANISATION	PROGRAMMES/INITIATIVES/PRACTICES	PAGE
	New South Wales Health Department (and Institute of Clinical Excellence – ICE[4])	• Sentinel Events reporting scheme and RCA process (based on Department of Veterans Affairs, USA) • Clinicians Toolkit • Safety Advocate – newsletter about Sentinel Events/Incidents • Pressure ulcer prevention clinical guidelines • Patient safety managers • Patient safety 'national' report	23
	Queensland Health Department	• Integrated risk management framework based for clinical and corporate services based on AS/NZS 4360:1999	25
	Victorian Department of Human Services (Clinical Risk Management)	• Sentinel Event reporting scheme • Annual Sentinel Events public report	25
	of Forensic Medicine	• Clinical Liaison Service – Connecting Clinicians with Coroners • Coronial Communiqué newsletter • Investigation Standard for Fall-Related Deaths in Hospitals	28
Canada	Canadian Council on Health Services Accreditation (CCHSA)	• Patient safety strategy • Adverse events in Canadian Health Care Study	31
	Canadian Patient Safety Institute (CPSI)	• Establishment of national patient safety body • Patient safety data dictionary	31
Hong Kong	Hospital Authority	• Integrated risk management standard incorporating patient safety programme • Intranet, web-based advanced incident reporting system (AIRS) • 'Just culture' and open disclosure • Root cause analysis training • Patient safety working groups	33

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[4] Update Nov 2005: Now called The Clinical Excellence Commission - www.cec.health.nsw.gov.au

COUNTRY	ORGANISATION	PROGRAMMES/INITIATIVES/PRACTICES	PAGE
International	World Health Organization	• Resolution setting out urgent activities to improve patient safety • Patient safety taxonomy • Estimating hazards • Reporting and learning systems	35
Ireland	Department Of Health	• Europe's first national patient safety incident reporting scheme	37
Japan	Japan Public Health Association	• Patient safety and medical malpractice	38
	Japan Medical Association	• Policies for the protection of patient safety	39
New Zealand	Ministry of Health	• Adverse Events in New Zealand Public Hospitals: Principal Findings from a National Survey • Toward Clinical Excellence: Learning from Experience. A Report to the Director-General of Health from the Sentinel Events Project Working Party • Sentinel Event reporting scheme and RCA process	40
	Standards New Zealand	• Sentinel Events Workbook – Standardized process for investigating Sentinel Events	42
USA	Agency for Healthcare Research and Quality (AHRQ)	• 'Reporting Systems and Learning: Best Practices' – major funded study commenced 2001 and due to report late 2005 • The Patient Safety Improvement Corps (PSIC) • Patient Safety E-newsletter • 'Morbidity and Mortality Rounds Online' - an online journal and forum on patient safety and health care quality • Patient safety indicators (PSIs) project	43
	Anaesthesia Patient Safety Foundation	• Data dictionary	44
	Betsy Lehman Centre for Patient Safety	• Establishment of a patient safety centre	44
	Cambridge Health Alliance, Boston	• Simplified RCA process for learning	45

COUNTRY	ORGANISATION	PROGRAMMES/INITIATIVES/PRACTICES	PAGE
	Columbia University	• [Medical event reporting system for transfusion medicine (MERS-TM)](#) • [Patient safety and the 'Just Culture' – A primer (publication)](#)	46
	Dana Faber Cancer Institute	• [Board involvement in patient safety](#)	47
	Department of Veterans Affairs, GAPS Centre	• [Patient safety stories](#) • [Creating patient safety with organizational learning](#)	47
	Department of Veterans Affairs, National Centre for Patient Safety	• [VA National Patient Safety Improvement handbook](#) • [RCA process, including triggering and triage questions, rules of causation and terms and definitions](#) • [Ensuring correct surgery (guidelines and training)](#) • [MRI hazards summary](#) • [Falls prevention toolkit](#) • [Healthcare Failure Modes and Effects Analysis (HFMEA)](#) • [Patient Safety Reporting System (PSRS)](#)	48
	ECRI	• [Patient Safety Center](#)	49
	Institute for Healthcare Improvement (IHI)	• [Several useful web-based patient safety tools, including safety climate survey tool and comprehensive change packages for surgical site infections and for improving medication systems](#)	51
	Institute for Safe Medication Practices (ISMP)	• [Medication errors reporting programme (MERP) – includes sharing information with other key stakeholders](#) • [Medication safety self assessment](#) • [Medication safety alerts](#)	51
	Institute of Medicine (IoM)	• [To Err is Human](#) • [Keeping Patients Safe: Transforming the Work Environment of Nurses](#) • [Patient safety: Achieving a new standard for care](#)	52
	Medical Centre	• [Case study on organizational learning for quality (safety) improvement](#)	53

COUNTRY	ORGANISATION	PROGRAMMES/INITIATIVES/PRACTICES	PAGE
	Joint Commission on Accreditation of Healthcare Organizations	• Patient safety-related standards • Sentinel Event Policy • Sentinel Event Alert • Sentinel Event Advisory Group • National Patient Safety Goals • The Universal Protocol • Office of Quality Monitoring • Patient safety resources • The Speak Up initiatives	54
	Leapfrog Group	• Computer Physician Order Entry best practice project • Evidence-based Hospital referral best practice project • ICU physician staffing best practice project • Leapfrog Quality Index	58
	Miami Centre for Patient Safety	• Establishment of a patient safety centre	59
	National Patient Safety Foundation	• Major web portal for resources and publications in the USA and internationally	60
	National Quality Forum	• Safe Practices for Better Healthcare: A Consensus Report (30 good practices outlined)	60
	New York State Health Department	• New York Patient Occurrence Reporting and Tracking System	62
	Oregon Patient Safety Commission	• Specification of an incident reporting system	62
	Pennsylvania Patient Safety Authority	• Development of web-based reporting and learning system (in association with ECRI)	65
	Senate	• The Patient Safety and Quality Improvement Act	66
	Michigan Health System	• Patient safety toolkit	66

General patterns, trends and learnings from international patient safety experience

This report merely touches upon the enormous amount of activity ongoing under the patient safety banner internationally outside the United Kingdom. Patient safety either is, or is becoming, the 'number one' issue in health care quality and risk management at local, regional and national levels around the World. Many countries, states/regions and local organisations are, of course, 'reinventing the wheel' – however, this is arguably necessary to promote 'local ownership' and hence improve prospects for achieving lasting patient safety improvements within individual countries, states/regions and local health care delivery organisations.

Through all the international activity, many lessons are being learned, and clear patterns and trends are emerging. For example, Neale et al[5] have collated information on international studies involving retrospective review of patient case records to determine the incidence of adverse events. This information is presented in Table 1.

From the nine studies presented, the average incidence of adverse events is 8.9% (range 3.8-16.6%) and the average incidence of potentially preventable adverse events is 3.4% (range 0.78-8.4%). The variation in data can, in part, be explained by differences in the underlying methodologies for screening records to determine adverse events.

Table 1 – Results of retrospective case record reviews

Study	Year	No. hospitals	No. case records	Incidence of Adverse Events %	Incidence of preventable Adverse Events %
California	1975	24	20864	4.6	0.78
NY State	1984	51	30121	3.8	0.95
Utah-Colorado	1992	28	14700	2.9	0.93
Australia (Victoria/S.Aust)	1993	31	14179	16.6	8.4
U.K. (London)	1999	2	1014	10.8	5.2
Denmark	2000	17	1097	9.0	3.6
N. Z. (Auckland)	2000	3	1326	10.7	4.3
Canada (Ottawa)	2002	20	3745	7.5	2.8
France (Aquitaine)	2002	7	778	14.5	4.0
AVERAGE		20	9758	8.9	3.4

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[5] Unpublished material. Adapted from Sisse Olsen, E Jane Chapman, Ara Darzi, Charles Vincent, Graham Neale. *A new structure for audit*. Presentation made by Graham Neale at *Making Health Care Safer 2004*, Royal College of Physicians, London, 21/22 October 2004. Used with permission.

The data presented in Table 1 come from time consuming and relatively resource intensive studies. The World Health Organisation (WHO) is developing "rapid assessment methods" to estimate harm caused by health systems.

From the work undertaken to produce this report, together with personal experiences over more than ten years, twelve issues in organisational learning for patient safety appear to be key. Figure 1 presents these issues under the simplified headings of 'mechanics' and 'mindsets'. 'Mechanics' represents the systematic needs for ensuring patient safety – 'mindsets' reflects the all important 'cultural' dimension, so crucial to the effective application of systematic approaches and, ultimately, to demonstrable patient safety improvement.

'MECHANICS'

Systems for:
- **Identifying and reporting incidents**
- **Intelligent data analysis**
- **Conducting RCA on selected individual incidents and aggregate data**
- **Prioritising, implementing and evaluating actions**
- **Demonstrating and sustaining improvement**
- **Disseminating learning**

'MINDSETS'

- **Leadership**
- **'Just' or 'fair' culture**
- **Open and honest reporting and disclosure**
- **Systems thinking**
- **Patient involvement**
- **Learning, changing and improving**

Figure 1 – 'Mechanics' and 'mindsets': Key requirements for organisational learning for patient safety

The 'mechanics' of organisational learning for patient safety

- **Identifying and reporting incidents**

There is a saying in quality management that 'if it's not being measured, it's not being improved.' It is essential, therefore, to measure the incidence of patient safety incidents to determine a baseline from which improvements can be demonstrated. Fundamentally, this implies that incidents involving patient safety considerations can be identified on a consistent basis, and appropriate information reported to those that need to know within local health care organisations and, increasingly, at state/region and national levels.

Incident reporting systems have been in place in many local health care organisations internationally for many years. With the exception of Australia's AIMS system, it is only in very recent years, and particularly since the publication of the USA Institute of Medicine report To Err is Human in November 1999, that concerted efforts have been made to devise state/regional and national reporting systems for patient safety. Whilst it is too early to make definitive statements about key learnings, we know that there are real challenges

in establishing large scale reporting systems. Australia's AIMS system, for example, a voluntary national reporting scheme, has been in place for several years but has yet to produce regular useful information for national learning and improvement[6], although it is being successfully used at state level across New South Wales Health Department. By contrast, the Pennsylvania Patient Safety Authority, only established in 2003, has been feeding back useful information based on State reporting since March 2004.

There are known challenges with incident reporting. The US Emergency Care Research Institute (ECRI) has outlined the following key barriers:

- o Time involved in reporting, lack of sufficient time to report
- o Extra work involved in reporting
- o Forgetting to complete an event report form
- o Not wanting to "tell" on another healthcare worker
- o Lack of anonymity
- o Reporting thought to be unnecessary due to lack of adverse outcome
- o Fear of punishment and fear of lawsuits
- o Reporting thought not to contribute to improvement, poor record of improvement
- o Unclear reporting protocols/lack of information on how to report events
- o Difficulty in accessing computer/unavailability of report forms

Incident reporting (and the learning that flows from reporting) is currently one of three key patient safety themes for the World Health Organisation (WHO), who had planned to publish guidelines in October 2005.

- **Intelligent data analysis**

Reported patient safety data needs 'intelligent' analysis to yield useful information for learning and improvement. A common expression, heard repeatedly around the World, is that health care organisations are "data rich, but information poor." The transition from data to useful information can be challenging.

Fundamental to 'intelligent data analysis' is a sound taxonomy for classifying patient safety incidents. However, the development and practical application of such taxonomies is a non-trivial task. There are essentially two types of taxonomy:

1. Relatively 'simple' classification schemes (e.g. see Victorian Department of Human Services) that can usually be easily applied with a minimum of training, but where many incidents end up being placed in the 'Other' category; or
2. Advance classification schemes (e.g. AIMS) which allow, essentially, 'infinite' categorisation of incidents, but which can only be consistently applied by experienced coders.

Many organisations around the World are developing taxonomies for patient safety generally, or specific areas of patient safety (e.g. medication error or anaesthesiology). The WHO recognises that "the lack of a standardized nomenclature and taxonomy for medical errors and system failures complicates the development of viable and sustainable solutions to the many problems related to patient safety." One of WHO's current three key patient safety priorities is development of a common taxonomy.

Of course, 'intelligent data analysis' is more than simply classification of incidents. IT systems are required to assist in converting data into meaningful information for analysis. There are wide variations in the sophistication of currently available IT systems for patient

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[6] This may be due to inadequate resourcing by State/Territory and National bodies.

safety, from those that produce simple reports and trend graphs, to more 'advance' systems that allow 'natural language' queries and 'pattern matching' in an attempt to elicit useful information from large data sets containing principally 'narrative' information.

- **Conducting RCA on selected individual incidents and aggregate data**

Root Cause Analysis (RCA) has been identified as "the key to unlocking the learning from patient safety incidents," and is being increasingly adopted around the World. RCA is variously defined as an approach to determining why things happen, and the actions necessary to prevent recurrence.

The first recorded use of an RCA methodology in health care was in 1994 in the UK when an approach used by a major international industrial organisation was adapted by the author for use in the 'IRIS' incident recording and information system – a software tool developed for the National Health Service and issued to all hospitals by the four UK health departments. In 1995, the Joint Commission on Accreditation of Health Care Organisations (JCAHO) in the USA produced a more detailed RCA methodology to underpin its 'Sentinel Event' reporting scheme. This was adapted by the US Department of Veterans Affairs (VA) for use in VA hospitals across America. Many organisations around the World (e.g. in Australia – see New South Wales Health Department or Victorian Department of Human Services) have adopted or adapted JCAHO and VA approaches to RCA for patient safety.

However, there is increasing recognition that, whilst RCA approaches based on JCAHO or the VA are thorough and produce useful learning, they are time consuming and resource intensive. The VA has recognised this and has decreed that certain types of incidents (falls, adverse drug events, missing patients, and parasuicidal behaviours) should be subject to quarterly aggregated review, rather than individual RCA. Other organisations (e.g. Clinical Governance Unit, John Hunter Hospital, Australia and Hong Kong Hospital Authority) are actively developing 'fast track' or 'mini' RCA approaches in an attempt to overcome some of the time and resource challenges of learning from patient safety incidents.

- **Prioritising, implementing and evaluating actions**

There is a need to ensure risk reduction strategies are implemented and the effectiveness of these strategies evaluated.

Having identified risk reduction strategies to be implemented from RCA, or by other means (e.g. such as proactive risk assessment, or 'failure modes and effects analysis'), individual actions need to be implemented in priority order and evaluated to determine their effectiveness in meeting patient safety objectives (see also 'Demonstrating and sustaining improvements', below). The evaluation of effectiveness forms part of the overall learning that should be disseminated appropriately (see 'Disseminating learning', below).

- **Demonstrating and sustaining improvement**

Patient safety improvements can be demonstrated with reference to determination of key performance indicators (e.g. see Agency for Healthcare Research and Quality patient safety indicators, and Institute for Healthcare Improvement tracker system).

Improvements can also be demonstrated with reference to compliance with dedicated patient safety and general risk and quality management standards (e.g. Joint Commission on Accreditation of Healthcare Organization).

Through sustained efforts to maintain standards and achieve improving performance (e.g. through clinical and/or internal audit processes), ongoing improvements can be demonstrated.

Some organisations internationally are integrating their risk management and quality improvement activity in an effort to rationalise their approach to safety and quality improvement, thereby improving efficiency and increasing the likelihood of achieving successful and sustained improvements.

- **Disseminating learning**

There is a need to share local, regional and national learnings, good or best practices, and initiatives underway to improve patient safety.

Typically, patient safety information and knowledge is disseminated via one or a combination of the following means:

1. conventional or electronic newsletters (e.g. Pennsylvania Patient Safety Authority or Agency for Healthcare Research and Quality e-newsletter);
2. books, journals and other publications, including electronic publications (e.g. Agency for Healthcare Research and Quality mortality and morbidity rounds on-line);
3. websites;
4. conferences, seminars and workshops; or
5. dedicated training and education (e.g. patient safety toolkit).

Of course, the rate at which information and knowledge is being generated is far exceeding the ability of most organisations, and certainly individual health care professionals, to keep abreast of developments (see 'Concluding comments', below). And anecdotal evidence suggests that the extent to which busy health care professionals, including managers, are able to access and absorb information in newsletters, journals, book, websites, attend training, etc. is severely limited by work time pressures.

The 'mindsets' required to achieve effective organisational learning for patient safety

- **Leadership**

There is a need for strong leadership at all levels to promote patient safety
Within local organisation, strong leadership and governance at CEO/Board level is crucial and is probably the main driver for patient safety (e.g. see Jefferson Regional Medical Centre or Dana-Faber Cancer Institute).

- **'Just' or' fair' culture**

Perhaps the most fundamental tenet of patient safety improvement is the need for a 'just' or 'fair' culture at all levels within health care systems, and particularly at local health care delivery level. When a patient safety incident occurs, staff need to be supported and treated in a fair manner. Further, there needs to be an organizational culture that supports the identification, disclosure, and investigation of adverse events and near misses, and that encourages the active seeking out of best practices in patient safety from elsewhere.

Many organisations around the World are working hard to improve their so-called 'safety culture' through implementation of 'non-punitive' policies for incident reporting. The challenge, however, is getting both staff and management 'buy-in' for such policies.

The Institute for Healthcare Improvement (IHI) has a freely available tool for assessing the safety culture of an organisation, which is particularly useful in demonstrating improvements made over time.

- **Open and honest reporting and disclosure**

With a 'just' or 'fair' culture comes open and honest reporting and disclosure of patient safety incidents.

The Australian Council for Safety and Quality in Health Care (ACSQHC) has developed an open disclosure standard, which is freely available and provides detailed guidance to health care organisations and their staff on disclosure of adverse events to patient and/or relatives as part of a wider risk management approach.

- **Systems thinking**

To prevent and understand the occurrence of patient safety incidents, there is a need to focus on system design, organization, and operations, rather than on individual performance. Systems can be so poor that they effectively (and unintentionally) set people up to fail. Thus part of the 'mindset' of modern health care is an approach to patient safety improvement that is fundamentally based on improving systems, particularly with reference to the results of detailed root cause analysis studies. All organisations referred to in this document subscribe either wholly, or in large part, to the need for a systems approach.

- **Patient involvement**

Involving patient in all aspects of their care has become a major imperative for many health care organisations. With specific reference to patient safety, patients need to be encourages to report incidents, and most national and state/regional reporting systems are including patient reporting as a key feature of their systems. Much work needs to be done, however, in actually getting patients involved.

The Australian Council for Safety and Quality in Health Care (ACSQHC) has developed specific tips for safer health care, which are aimed at patients and available in 15 community languages.

- **Learning, changing and improving**

Ultimately, it is through organisational and individual learning and change that real patient safety improvements will be made (e.g. see Jefferson Regional Medical Centre or Dana-Faber Cancer Institute or Department of Veterans Affairs GAPS Centre). Organisational learning is seen as ultimately being encapsulated within local policies/procedures and in education and training systems.

Increasingly, various web-based and other learning resources are becoming available for patient safety learning (e.g. see the patient safety toolkit, University of Michigan, or the Stories produced by the Department of Veterans Affairs GAPS Centre).

Similarly, tools for patient safety improvement are increasingly becoming available. The Institute for Healthcare Improvement (IHI) in Boston, USA has an excellent and expanding

range of tools for assisting with patient safety improvement, including demonstration of improvement over time. These tools can be freely accessed and used.

Concluding comments

The field of patient safety is expanding rapidly and new information and knowledge is becoming available on a daily basis. Whilst the key issues in patient safety, as identified in Figure 1, are relatively straightforward, keeping up with advances in the field internationally, and including the UK, is extremely challenging, but not impossible.

What is required is a concerted effort to keep abreast of international developments, to summarise these developments and make key information available to health care organisations and professionals on a 'need to know' basis. The time is ripe for development of a Web-based 'patient safety portal' that captures, stores and disseminates patient safety information to those who need it in a timely and efficacious way.

The remainder of this report summarises selected patient safety developments in comparative countries.

1.   Australia

Website: www.safetyandquality.org

The Australian Council for Safety and Quality in Health Care was established in January 2000 by Australian Health Ministers to lead national efforts to improve the safety and quality of health care provision in Australia. It reports annually to all Health Ministers and is supported by all State and Territory jurisdictions. The Council works closely with other national bodies to ensure that its work program complements the efforts of others.

The role of the Council is to:
- **Lead the way**, by developing a national strategy for improving safety and quality, defining national standards and influencing others to act to improve safety and quality in health care.
- **Define a framework for action**, by identifying national priorities and recommending specific actions that address the priorities.
- **Form partnerships**, by working with health care professionals, the Commonwealth, States and Territories, professional associations, private, non-government, and consumer organisations.
- **Coordinate existing activity** to better achieve action in priority areas.
- **Put consumers first**, by making sure that safety and quality measures are practical and will make a real difference.
- **Encourage public understanding** and increase the community's confidence in the steps being taken to improve the safety of health care.
- **Promote monitoring and research** to address the many things we still don't know about challenges with safety and quality and how to fix them.

Since its establishment in early 2000, the ACSQHC has undertaken an impressive range of development work resulting in the production of practical resources for health care organisations and consumers to use, including:

- Development of a comprehensive 'Open Disclosure' Standard based on AS/NZS 4360:1999, the Australian/New Zealand risk management standard (www.riskmanagement.com.au)
- Patient safety system checklist
- Glossary of safety and quality terms and definitions
- National Patient Safety Education Framework (www.patientsafety.org.au)
- Ensuring correct patient, correct site, correct procedure protocol
- Consultation document on safe staffing
- 10 tips for safer health care: What everyone needs to know (available in 15 community languages)

These and many other resources are freely available on or via the Council's website.

Websites: APSF www.apsf.net.au   PSI - www.patientsafetyint.com/

The Australian Patient Safety Foundation Inc. 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 subsidiary Patient Safety International (PSI), the APSF provides a software tool, the Advanced Incident Management System (AIMS®) to capture information from a wide variety of sources to enable "de-construction" and classification of incidents from "near misses" to "sentinel events" in a consistent way, so that subsequent, detailed analysis is possible. Professor Bill Runciman, principal inventor of the classification system contained within AIMS, believes that a classification scheme needs to have sufficient "granularity" to permit detailed, in depth analysis of incident data.

1.3   Geelong Hospital, Barwon Health, Victoria

Associate Professor Stephen Bolsin in the Department of Perioperative Medicine has developed, in conjunction with the Australian and New Zealand College of Anaesthetists (ANZCA), a personal professional monitoring project for anaesthetic registrars using personal digital assistants (PDAs - see Figure 1.3.1).

Dr Bolsin's achievements in helping improve the safety of care include his role in the Bristol paediatric heart surgery cases where he raised concerns about the safety and quality of care that eventually led to the Bristol Inquiry and a major drive to improve safety and quality in the NHS.

Figure 1.3.1 – Using a PALM PDA to record incidents and other performance information

Using the PDAs, registrars can log information on incidents etc. in under one minute. This information is then uploaded to a central server and can be used for professional monitoring and, ultimately, improving personal performance as well as reducing the incidence of incidents. Further, detailed information on the approach to improving patient safety and quality of care can be found in the Medical Journal of Australia at:

www.mja.com.au/public/issues/177_09_041102/ben10246_fm.html

1.3   John Hunter Hospital Clinical Governance Unit, Newcastle, NSW

Website: www.hunter.health.nsw.gov.au/clinicalgovernance

1.3.1   RCA-based patient safety improvement programme (based on Department of Veterans Affairs, USA)

Hunter Health[7] established its Clinical Governance Unit - the first of its kind in Australia - at the John Hunter Hospital in 1999. The aim of the Clinical Governance Unit is to ensure the provision of the highest standard of safe and appropriate patient care in Hunter Health facilities. The Unit assists with the management, monitoring, coordination, facilitation and evaluation of initiatives that protect the safety of patients through clinical quality activities and clinical risk management processes.

Central to the Unit's patient safety improvement activities is a root cause analysis programme based on the approach by the Department of Veterans Affairs in the USA, which has been rolled out across New South Wales under the auspices of the New South Wales Health Department and the Institute of Clinical Excellence (see section 1.4).

The RCA programme has been extremely beneficial in learning from serious adverse patient incidents and putting in place the risk reduction strategies necessary to effect improvement in patient safety. The Clinical Governance Unit appears to have been

> "Poor communication lies at the root of every preventable death we have had."
> *Professor Alan Spigelman, Director*
> *Clinical Governance Unit*
> *John Hunter Hospital, Newcastle*
> *New South Wales, Australia*

particularly effective in getting clinicians 'on board' with the process. Achievements include:

- Improved processes for reporting of abnormal results to responsible clinicians
- Review and re-distribution of policy re. management of cardiac arrest
- Improved CPR training and assessment, including mandatory education programmes and simulated exercises.
- Education of junior and senior medical staff re. need for contemporary documentation
- Development of appropriate discharge criteria for a recovery unit.
- Improved policy for transport and processing of bloods sent urgently after hours.
- Development of a policy and training programme for clinicians about the handover of unstable patients between treatment teams and shift
- Development of a process to ensure on-call individuals are aware that they are on-call.

1.4   New South Wales Health Department (and Institute of Clinical Excellence - ICE[8])

Website: www.health.nsw.gov.au/

The NSW Health Department has in place a major programme of safety and quality improvement. In December 2001, the Health Department the Institute for Clinical Excellence to "change health care across NSW, to make it safer and better for patients by: working collaboratively on high priority clinical projects across multiple sites with the focus on improved patient outcomes; driving implementation of clinical practice improvement and championing the lessons learned across the system; providing education and training

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[7] Update Nov 2005: Currently known as Hunter New England Health
[8] Update Nov 2005: Now called The Clinical Excellence Commission - www.cec.health.nsw.gov.au

to support the implementation of improvement projects; and supporting targeted health services research." One of the projects recently undertaken, which is already having a beneficial impact on patient safety (see 1.3) is the effective management of serious incidents (sentinel events) in the NSW health care system using root cause analysis (RCA). ICE and NSW Health produced a modified version of the Veterans Affairs (VA) National Centre for Patient Safety (NCPS) root cause analysis toolkit (see 9.8) and funded a major programme of training on RCA across New South Wales health providers.

Notable amongst NSW Health's publications is *The Clinician's Toolkit for Improving Patient Care* (www.health.nsw.gov.au/health-public-affairs/publications/quality/toolkit.html), which provides clinicians with information about the tools available to review and improve the safety and quality of their practice and how to report the findings of any review.

Also notable is *Safety Advocate*, a newsletter informs about incidents or sentinel events that have been reported to public and private health care organisations in NSW, Australia and overseas. It describes the common underlying causes of the events, suggests steps to prevent occurrences in the future and provides information sources to assist organisations in reviewing and updating their own systems. The following newsletters have been published:

- [Safety Advocate Issue 1, May 2002 - Sterilisation and disinfection](#)
- [Safety Advocate Issue 2, August 2002 - Medication safety](#)
- [Safety Advocate Issue 3, February 2003 - Fall injury prevention in acute care](#)
- [Safety Advocate Issue 4, April 2003- Bed Rail Hazards](#)
- [Safety Advocate Issue 5, September 2003 - Infusion pump safety](#)
- [Safety Advocate Issue 6 - Self-Inflating Bag/Mask Devices](#)
- [Safety Advocate Issue 7, July 2004 - Safe management of breast milk](#)

A common patient safety issue internationally is prevention of pressure ulcers. NSW Health Department has produced some notable risk-based guidelines Pressure Ulcer Prevention Clinical Guidelines for the following settings:

- [Acute Care Settings](#)
- [Community Care Settings](#)
- [Consumer Brochure](#)
- [Rehabilitation and Residential Settings](#)
- [Transport of the patient](#)

During 2004, NSW Health also had in place around 20 designated patient safety managers whose responsibility it is to disseminate patient safety information and guidance and generally assist their organisations with patient safety improvement processes.

In January 2005 NSW Health published a comprehensive report on [incident management](#) in the NSW public health system based on reported incidents during 2003-2004.

1.5   Queensland Health Department

Website: www.health.qld.gov.au

1.5.1 Integrated risk management framework for clinical and corporate services based on AS/NZS 4360:1999[9]

Queensland Health Department has long recognised the need to integrate its systems for clinical and non-clinical risk management. Their integrated risk management framework has been designed around AS/NZS 4360:1999 – the Australian/New Zealand risk management standard. The Health Department is developing e-learning tools in association with Standards Australia (www.standards.com.au) to facilitate risk management learning across its health care facilities and 54,000 staff.

> A telephone survey of Health Service Districts in May 2004 indicated that:
>
> * 56% of Districts deal with District Risk Registers as a formal part of the Executive meetings agenda
> * 59 % of the Districts have their Quality Co-ordinator being responsible for the local Integrated Risk Management roll-out and coordination
> * 65% of Districts have an up-to-date risk register.
>
> A number of Districts are still working towards risk management driven reporting structures and protocols and towards integration of the whole of the departmental Risk Management Framework in planning and decision making. We are currently rolling out an incident reporting system (built in-house) - so are working to integrated risk management from a top-down and bottom-up approach.
> *Dorothy Vicenzino*
> *Risk Management Coordinator*
> *Strategy Unit*
> *Queensland Health*

1.6   Victorian Department of Human Services (Clinical Risk Management)

Website: www.health.vic.gov.au/clinrisk

1.6.1   Sentinel Event reporting scheme

The Department of Human Services (DHS) operates a mandatory Sentinel Event reporting scheme based on the USA JCAHO model outlined in section 9.15.

Sentinel events to be reported to the Department of Human Services in 2004 -05 are:

> "Waiting for the perfect reporting and learning system guarantees nothing will happen. Accepting imperfection means you can forge ahead with learning, improving and making a difference."
> *Alison McMillan*
> *Head of Clinical Governance Unit*
> *Department of Human Services*
> *Victoria*

1. Procedures involving the wrong patient or body part;
2. Suicide in an inpatient unit;
3. Retained instruments or other material after surgery requiring re-operation or further surgical procedure;
4. Intravascular gas embolism resulting in death or neurological damage;
5. Haemolytic blood transfusion reaction resulting from ABO incompatibility;
6. Medication error leading to the death of patient reasonably believed to be due to incorrect administration of drugs;
7. Maternal death or serious morbidity associated with labour or delivery;

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[9] Update November 2005: The latest revision of the Australian/New Zealand risk management standard is 4360:2004

8. Infant discharged to wrong family; and
9. Other catastrophic event.

All hospitals are required to report Sentinel Events, by e-mail using a special form, within 15 days of occurring. In addition, a Root Cause Analysis and Risk Reduction Action Plan is required to be reported, by e-mail, on a special form. See www.health.vic.gov.au/clinrisk/sentin.htm
Risk Watch is a monthly newsletter providing information to individuals and health services on lessons learnt from the Sentinel Event Program. Copies of Risk Watch can be found at www.health.vic.gov.au/clinrisk/riskwatch.htm

1.6.2 Annual Sentinel Events public report

Following on from the Sentinel Events reporting scheme, an annual report is produced. The first report, for 2002-2003, is available for download at the following address:

www.health.vic.gov.au/clinrisk/sentin.htm#anrep0203

A total of 79 Sentinel Events were reported during 2002-2003. The first three tables from the report are reproduced below, showing:

1. Events reported by category
2. Classifications for 'Other catastrophic event' category
3. Contributing factors to sentinel events

The report also outlines the themes, issues and opportunities for learning identified by the sentinel event program, together with what was learned from the risk reduction strategies.

Table 1: Events reported from 1 July 2002 to 30 June 2003.

Event	Frequency
Procedures involving the wrong patient or body part	16
Suicide in an inpatient unit	5
Retained instruments or other material after surgery requiring re-operation or further surgical procedure	9
Intravascular gas embolism resulting in death or neurological damage	0
Haemolytic blood transfusion reaction resulting from ABO incompatibility	0
Medication error leading to the death of patient reasonably believed to be due to incorrect administration of drugs	3
Maternal death or serious morbidity associated with labour or delivery	4
Infant discharged to wrong family	0
Other catastrophic event	42
Total	79

Table 2: Classifications for 'other catastrophic events' category:

'Other catastrophic event category classifications	Number of events
Complication of emergency / resuscitation management	9
Complication of surgery	9
Foetal complication of delivery	3
Complication of inpatient fall	2
Patient absconding from inpatient unit with adverse outcome	2
Infection control breach	6
Hospital process issue	9
Other – unspecified	2
Total	**42**

Table 3: Contributing factors to sentinel events

Contributing factor	Frequency
Procedures/Guidelines	67
Behavioural assessment	5
Physical assessment	7
Patient observation process	1
Clinical Guidelines	10
Patient/site identification	11
Coordination of care	33
Human Resources	37
Staff allocation	15
Staff training	17
Staff supervision	3
Appraisals	1
Recruitment	1
Communication	34
Between staff	27
Between staff and patient/family	7
Health information	14
Equipment	15
Physical Environment	19
Environment (distraction etc)	11
Security/Design	8
External Factors	12
Other	12
Total	**210**

Sample risk reduction strategy report

Risk Reduction Strategies – Case 2

Description of event

Surgery was performed on the wrong knee.

Contributing factors to event

Policies and procedures

No final checking process immediately prior to incision

The lack of a final check immediately prior to incision in a side-specific surgery resulted in failure to recognise that the incorrect limb had been prepared for surgery by staff who had been influenced by visual clues in selecting which limb to prepare, this contributed to the wrong side surgery.

No policy for the surgeon actually performing the procedure to mark the site

The lack of a policy requiring the person actually doing the surgery to mark the side (or site), and place the tourniquet on to the appropriate limb, contributed to the marking of the wrong side. This process was undertaken by staff other than the surgeon.

Communication – between staff

No formalised system for triaging communication pagers. The lack of a formalised system for triaging doctor's pagers contributed to the doctor feeling obliged to answer all the pagers he/she received before he/she scrubbed for theatre. This contributed to the doctor and other staff involved in the actual surgery not realising that the wrong knee had been prepared for surgery and the wrong side was operated on.

Human Resources – allocation

No policy for dealing with task assignment when short-staffed – The lack of a policy to deal with task assignment in operating theatre when there was unexpected staff shortage, contributed to the nursing staff feeling obliged to take on additional tasks while the leg was being prepared for surgery. This contributed to the staff who were involved in the actual surgery not realising that the wrong knee had been prepared for surgery and the wrong side being operated on.

Risk reduction strategies

The following risk reduction strategies were implemented:

1. A system of 'time-out' be implemented in the Operating Theatres to ensure appropriate checks are done prior to incision. A time-out poster has been developed and is prominently displayed in Operating Theatres.

2. Unit based policy and procedure manual to be reviewed at regular intervals to ensure they are up to date and accurate.

3. That a policy be implemented that the person who is doing the surgery be responsible for marking the site and side in side-specific surgery.

4. That a system to allow triaging of pagers be implemented – Procedure developed in collaboration with Engineering department.

5. That a policy be formulated that specifies staff assignment in theatres and addresses issues of task assignment in times of staff shortage. A policy was developed in collaboration with the senior nurse managers.

1.7   Victorian Institute of Forensic Medicine

Website: www.vifm.org/n112.html

1.7.1   Clinical Liaison Service – Connecting Clinicians with Coroners

The Clinical Liaison Service (CLS) is a new and unique initiative of the State Coroners Office and the Victorian Institute of Forensic Medicine (VIFM) to improve patient safety. The need to establish this service is supported by an expanding body of research evidence indicating that addressing the contributing underlying system factors may prevent a significant proportion of adverse events.

The State Coroners Office and the Victorian Institute of Forensic Medicine recognises the increasing need for data relating to patient safety in health care institutions and the existing coronial information regarding deaths in health care settings is a unique and valuable resource that is under utilised. Furthermore, there is a need for a systematic process to ensure that the coronial recommendations and findings are applied towards

system improvements. This is currently staffed by two physicians, two registered nurses, a research assistant and an administrative officer.

Tasks

The tasks of the Clinical Liaison Services include:

- To assist the established coronial processes investigating adverse events.
- The formation of a validated method for classifying and recording information that may be related to adverse events within health care institutions. This information will have many uses, including the analysis of individual or clusters of such cases and the reporting of trends that may be useful in the early recognition of underlying systems issues in health care organisations.
- Explore how coronial data can be used effectively to inform changes to the health care system and whether there are possible reforms to the coronial process that will enhance the value of coronial data for patient safety initiatives.
- Identifying the reform priorities that reflect the interests of coroners, health departments and health care professionals throughout Australia for patient safety.
- Improving dialogue between coroners, health departments and health care professionals about adverse events.

1.7.2   Coronial Communiqué Newsletter

The Coronial Communiqué newsletter issued by the Clinical Liaison Service is an excellent example of good practice in communicating patient safety information resulting from coronial investigations and can be found at www.vifm.org/inclsnewsletter.html

The Coronial Communiqué highlights selected cases that have been reported to the State Coroner's Office and are of interest to healthcare professionals. The aims of the Communiqué are:

- To improve the awareness of clinicians and those in positions of governance about adverse events resulting from systems failures. Lessons from past cases can then be applied to their own institutions.
- To improve healthcare organisations' understanding of the coronial system and the work performed by the Clinical Liaison Service.

The Communiqué is produced quarterly and distributed electronically to subscribers who have registered their interest with the publication team. Subscription is free of charge.

> We presented a poster at the 2nd Australian Safety and Quality Conference in Canberra this year on the Coronial Communique, all the feed back we have had is very positive. It engages the clinical staff in serious adverse events in a language and style they are familiar with. It has created a stimulus for doctors and nurses to examine their practice and led to changes to improve patient care.
>
> *Professor Joseph E Ibrahim*
> *Director Aged Care Medicine*
> *Peninsula Health, Rehabilitation, Aged & Palliative Care Services,*
> *Victoria*
> *& Consulting Editor, Coronial Communique*

1.7.3   Investigation Standard for Fall-Related Deaths in Hospitals

In May 2003, the Clinical Liaison Service (CLS) convened and facilitated a forum to review the role of the Coronial process in the investigation of fall-related deaths in hospital. The Falls Forum and subsequently, the Falls Working Party involved a multidisciplinary team comprising:

Coroners (Victorian State Coroner's Office)
State Coroner's Assistants (Victorian State Coroner's Office)
Clinical Liaison Service (Victorian State Coroner's Office)
Researchers (National Ageing Research Institute)
Policymakers (Department of Human Services - Aged Care)
Quality Council (Victorian Quality Council)
Health service providers (Bayside Falls Prevention Project)
Consumers (Health Service Commissioner)

The aim of this collaboration was three-fold as described below:

First, the Falls Forum was convened to provide Coroner's Office staff with a general overview of the current research initiatives, practice changes and administrative systems that are used for the prevention and management of patient falls in hospital. Second, the multidisciplinary collaboration helped non-Coroner's staff to better understand the Coronial process in Victoria. The Coroner's jurisdictional duties with regard to the investigation of fall-related deaths were fully elucidated. Third, the Falls Working Party was established to devise a standardised process for investigating reported deaths following a fall in hospital.

As a result of this initiative, the three main aims were successfully achieved. Further, the relationships between the State Coroner's Office, the members of the Falls Working Party and other key stakeholders with an interest in falls prevention were strengthened.

The Falls Working Party developed the Coroner's "Investigation Standard" and distributed a copy to all rural and metropolitan public hospitals. The "Investigation Standard" was implemented in November 2003 and is now being used to investigate all fall-related deaths that are reported to the Coroner from hospital.

The Standard can be found at www.vifm.org/inclsfalls1.html

2.   Canada

Website: www.cchsa.ca

The mission of CCHSA is to promote excellence in health care and the effective use of resources in health services organizations nationally and internationally in order to improve the delivery of health services. To achieve its mission, CCHSA provides health services organizations with an accreditation program based on national standards and knowledge exchange.

CCHSA published a comprehensive patient safety strategy in May 2003. In it they describe the following common challenges/themes in patient safety that emerged from their review of the literature. These include the following:

• There is a need for strong leadership and an organizational culture that supports the identification, disclosure, and investigation of adverse events.
• To prevent and understand the occurrence of adverse events, there is a need to focus on system design, organization, and operations, rather than on individual performance.
• There is a need to develop effective strategies for risk management and to integrate risk management and quality improvement efforts.
• There is a lack of tools, systematic processes, and information to identify, learn from, and prevent adverse events.
• There is a need for education on the use of specific tools such as *Root Cause Analysis.*
• There is a need to share regional and national learnings, best practices, and initiatives underway to improve patient safety.

The CCHSA make reference to *The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada*, available at www.cmaj.ca/cgi/content/full/170/11/1678. The study, published in the Canadian Medical Association Journal on 25 May 2004, showed an overall incidence rate of adverse events of 7.5%. Thus, of the almost 2.5 million annual hospital admissions in Canada, about 185000 are associated with an adverse event and close to 70000 of these are potentially preventable.

2.2   Canadian Patient Safety Institute (CPSI)

Website: www.hc-sc.gc.ca/english/care/cpsi.html

In September, 2001, the Royal College of Physicians and Surgeons of Canada held a one-day forum on patient safety as part of its Annual Conference. Over 50 experts, health-care professionals, government officials and health-care association members (domestic and international) participated in the roundtable. Consensus was reached on the need to develop a coordinated strategy for improving patient safety within Canada.

> "Improving the safety of patients is about creating an environment that is open to disclosure and committed to change. There is a need to alter the culture of silence and promote a culture of sharing and learning such that safety can be improved."
> *Canadian Patient Safety Institute*
> *Website Home Page*

The National Steering Committee on Patient Safety (NSCPS) was created as a result of this one-day conference. The committee was supported by five working groups with responsibility to address the following aspects of patient safety:

- System Issues
- Legal/Regulatory Issues

- Measurement/Evaluation
- Education/Professional Development
- Information/Communication

In September 2002, the NSCPS released the report *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care* (http://rcpsc.medical.org/publicpolicy/index.php#cpsi). The report provided recommendations in the 5 theme areas listed above, along with 19 specific recommendations, including the establishment of a Canadian Patient Safety Institute (CPSI) to promote innovative ways of improving patient safety, such as professional development programs, and research and analysis of patient safety issues.

One notable output from the working group on system issues was the development of a comprehensive patient safety data dictionary that provides clear and concise definitions for key patient safety terms, together with a commentary (http://rcpsc.medical.org/publicpolicy/index.php#cpsi).

The mandate of the CPSI is to provide a leadership role with respect to patient safety issues in the context of improving health care quality, by providing advice to governments, stakeholders and the public on effective strategies. To that end, the CPSI will:

- foster the sharing of knowledge and information about optimal patient safety practices and models;
- influence change in culture and provide advice to support change in systems to improve patient safety; and
- collaborate with stakeholders in an ongoing dialogue to support patient safety improvements.

Patient safety issues cut across the continuum of care, care settings, and patient populations. The scope of the CPSI will be to examine issues of priority importance for patient safety, and bring forward what it considers to be the best practical information and strategies to support improvements in patient safety. The Institute will include an analysis of perspectives from a wide range of system stakeholders in its work.

Author's comments: As the establishment of the CPSI was only announced in December 2003, there is, at the time of writing this report, little information available on its progress in fulfilling its mandate.

3. Hong Kong

Website: www.ha.org.hk

The HKHA is a public health care system comprising 44 hospitals, including two University teaching hospitals, serving a population of around 7 million. In the aftermath of SARS, the HKHA has strengthened its patient safety programme through a number of key initiatives. One of the key attributes of the HKHA is its eagerness to learn from international experiences in an effort to minimise 'reinventing the wheel'.

3.1.1 Integrated risk management standard incorporating patient safety programme

The Authority has developed a comprehensive 'risk management standard' covering all risks, including patient safety risks, based on the NHS in England's Controls Assurance standard for risk management. The HKHA risk management standard requires that "Risks of all kinds are effectively managed through implementation of an integrated risk management system" and sets out a comprehensive framework of criteria for all Hong Kong hospitals to comply with. The criteria are reproduced in Table 5.1.1.

3.1.2 Intranet, web-based advanced incident reporting system (AIRS)

Hong Kong is fortunate in that all 44 hospitals share a common IT platform, serviced by the Hospital Authority Head Office. Development of AIRS has been informed by learnings from the development of the NHS's Safecode/IRIS incident recording and information system together with the National Patient Safety Agency's incident classification data set.

3.1.3 'Just culture' and open disclosure

HKHA is introducing a 'just culture' approach to promote the reporting of all adverse incidents, including 'near misses', by frontline staff. As part of this 'just culture' approach, a programme of Open Disclosure is being introduced based on the Australian Open Disclosure Standard (see 1.1).

3.1.4 Root cause analysis training and the 'mini-RCA'

The Authority has implemented a major programme of root cause analysis training so that lessons can be learned from adverse patient safety incidents, using an approach based partly on the Standards New Zealand Sentinel Events Workbook (see 7.2) together with USA and UK approaches. A key feature of the Hong Kong approach is the development of the 'mini-RCA', which significantly reduces the time required to be spent on root cause analysis[10].

3.1.5 Patient safety working groups

The Authority has established working groups for identified high priority patient care areas, including the following: Medication incidents; Missing patients; In-patient suicides; Re-use of single use medical devices; Point of care testing; Informed consent; Patient identification; and Patient transfer.

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[10] Contact Dr David Lau for further information on dhlau@ha.org.hk

Table 3.1.1 – Criteria contained in the HKHA risk management standard

Accountability criteria	
1	Cluster Chief Executive (CCE) responsibility for risk management is clearly defined and there are clear lines of accountability for risk management in each hospital leading up to the CCE.
2	There is a Cluster Risk Management Committee that has a representative who attends the HA Risk Management Committee and provides the HA with a bi-annual risk management performance report.
Process criteria	
3	An ongoing programme of patient safety improvement is in operation, which includes, appropriate communication and consultation with staff.
4	Incidents are systematically identified, recorded and reported to management.
5	There is an agreed policy of "just" culture for management of clinical incidents.
6	All reported incidents are managed in accordance with an agreed policy.
7	All reported incidents are graded according to severity and risk and, where appropriate, investigated to determine contributory factors and root causes.
8	Reported incidents are subjected to periodic aggregate reviews to identify trends and other performance information for management review.
9	All complaints and claims are systematically recorded and analysed to identify trends and other performance information for management review.
10	Risks of all kinds are systematically identified, assessed and managed in order of priority.
11	There is a Cluster-wide risk register that is populated by data representing all types of risk, both 'clinical' and 'non-clinical', and is maintained up-to-date.
12	Effective processes are in place for learning and for sharing information on good practice in risk management.
Capability criteria	
13	The Cluster provides realistic resources to implement and support risk management.
14	All staff are provided with adequate risk management information, instruction and training appropriate to their role.
Outcomes criteria	
15	Key performance indicators relating to risk have been defined and are used for the purposes of improvement.
16	There is demonstrable improvement in compliance with this risk management standard.
17	There is demonstrable improvement in reporting of numbers of incidents of all kinds, including near misses.
18	There is demonstrable reduction in severity of reported incidents.
19	There is demonstrable improvement in the reduction of complaints.
20	There is a demonstrable reduction in financial losses due to claims.
Monitoring and review criteria	
21	All aspects of the risk management system are monitored and reviewed by hospital management for the purposes of learning and improvement.
22	The Cluster Risk Management Committee monitors and reviews the risk management system in place across individual hospitals and shares information on learning and improvement at the Head Office Risk Management Committee.
23	The Hospital Governing Committee receives a bi-annual summary report on hospital compliance with this standard.
Independent assurance criteria	
24	Cluster Chief Executives periodically receive independent assurance(s) that a risk management system is in place that meets the requirements of this standard.

4.   International

4.1   World Health Organisation (WHO)[11]

Website: www.who.int/patientsafety/en/

4.1.1   Resolution setting out urgent activities to improve patient safety

In May 2002 the World Health Assembly passed resolution WHA55.18, which urged countries to pay the greatest possible attention to patient safety and requested the Director-General of WHO to carry out a series of actions to promote patient safety, including:

- development of global norms and standards;
- promotion of evidenced-based policies;
- promotion of mechanisms to recognize excellence in patient safety internationally;
- encouragement of research;
- provision of assistance to countries in several key areas.

The full resolution can be found at:

www.who.int/gb/ebwha/pdf_files/WHA55/ewha5518.pdf

According to WHO, the resolution has ensured that the drive for safer health care is now becoming a worldwide endeavour, bringing significant benefits to patients in countries rich and poor, developed and developing, in all corners of the globe.

Since that resolution was passed, WHO has brought together its technical experts in areas such as blood safety, injection safety, drugs and medicines, making pregnancy safer and medical devices, so that their individual expertise can be harnessed to tackle global patient safety issues.

WHO has also established a number of work programmes tackling systemic issues such as taxonomy, estimating hazards, and the development of reporting and learning systems. These are briefly outlined below.

4.1.2 Patient safety taxonomy

According to WHO, worldwide concerns about safety in patient care underscore the need to coordinate the monitoring, reporting and understanding of adverse events and "near misses". Better information on the number, types, severity, causes and consequences of adverse events is clearly needed within Member States in order to inform strategies towards reducing the risk of medical incidents and to mitigate the effects of medical errors. Studies and incident-monitoring systems reporting patient safety data often differ in the way they define, count and track adverse events. They use different terms, data and schemes to code and analyse adverse events. Thus, comparisons between schemes become complex.

The lack of standardized nomenclature and taxonomy for medical errors and system failures complicates the development of viable and sustainable solutions to the many problems related to patient safety. In order to make it easier to disseminate information

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[11] Update November 2005: Since the early work associated with this report, the WHO has established a 'World Alliance for Patient Safety'. See the main website for further information.

among systems that monitor and report incidents, a common terminology should be adopted so that information can be classified in a way that facilitates comparisons. The development of a common international system for classifying, measuring and reporting adverse events and "near misses" is a necessary first step in setting up a standardized approach. Initiatives are under way to tackle this problem in Australia, the United States of America and elsewhere. These initiatives could be greatly aided through WHO collaboration and support. WHO therefore plans to establish an international project on methods of intercountry comparisons, building on its own experience and that of institutions such as the WHO Collaborating Centre for International Drug Monitoring, in Uppsala, Sweden.

4.1.3 Estimating hazards

WHO is committed to making patient safety a priority on the policy agenda of Member States. This initially involves sensitizing Member States to the harm that can occur within health care systems, in order to provide a receptive context for studies and action on patient safety. The next task is to assess the nature and incidence of adverse outcomes. It then becomes necessary to understand the causes of these outcomes, which may vary according to country, health care system and treatment or procedure. Effective methods of prevention must then be tested, initially on a pilot basis. Where the nature and causes of a problem are well established, it may be possible to move directly to developing and applying preventive methods on a larger scale. Generally speaking, however, initial assessment of the nature and magnitude of the overall problem remains an important first step.

Of the 17 WHO epidemiological regions worldwide, only three include Member States that have carried out studies on adverse events: Region 3 (AMRO A: United States of America), Region 8 (EURO A: Denmark, United Kingdom) and Region 14 (WPRO A: Australia). WHO intends to estimate the extent to which health-care systems may create hazards to people in several Member States of the remaining 14 epidemiological regions . For this purpose, WHO convened an international meeting in December 2002 to consider the development of rapid assessment methods to estimate harm caused by the health system. Particular attention is being paid to the development of tools for use in data-poor environments, as well as to achieving a balance between robustness of scientific methods and the urgent need for assessment and action on vital safety issues. The report and recommendations of the meeting are intended for policy and decision-makers at national and international level, who are not necessarily experts in patient safety. The next step will be to launch the tools and initiate studies in 10 transitional and developing countries.

Report of the WHO working group meeting held in Geneva in December 2002 can be found at:

www.who.int/patientsafety/activities/system/en/rapid_assessment_methods.pdf

4.1.4 Reporting and learning systems

Several Member States have established reporting and learning systems for adverse events and "near misses". WHO is presently working with Professor Lucian Leape in the preparation of guidance to support and assist other countries that may wish to consider national reporting. The emphasis of the guidelines will be on learning by reporting, and the guidelines will focus on the desirable characteristics that should be considered when purchasing or developing a system.

The guidelines were originally due be published in October 2005.

5.   Ireland

5.1 Department of Health

Website – www.doh.ie/

5.1.1 Europe's first national patient safety incident reporting scheme

As part of a major overhaul and rationalisation in clinical and non-clinical indemnity arrangements, the Department of Health in Ireland decided, in 1999, to put in place a comprehensive national reporting system for all Irish hospitals. As part of this scheme, the Department was keen to eliminate barriers to comprehensive incident reporting and investigation introduced by 'traditional' indemnity schemes. The Department was also keen to maximise the opportunity to reduce the number of adverse events which ultimately lead to claims.

> "The collection of data on adverse incidents is not an end in itself. The data must be put to some use. This information is not being collected to identify doctors and nurses who make mistakes in order to punish them. It is being collected so that individual hospitals and the system as a whole can learn from the mistakes that are inevitably made in a system the size of the Irish health service. We know from claims that are taken against hospitals and doctors that to some extent the same mistakes keep being made. One explanation for this phenomenon is that there is no systematic analysis undertaken of what mistakes are made and why they are made. Good data on the incidents which do occur is the first step in gaining an understanding of the problem. This information is really required so that we can learn from it. That is why we want hospitals to have that information. Not for any other reason."
>
> *Micheál Martin T.D.*
> *Minister for Health and Children at the launch of the Clinical Indemnity Scheme incident reporting system (STARS)*
> *3 February 2004*

It was decided at an early stage to take the opportunity of putting this system in place to provide hospitals with a state of the art risk management system to allow them to investigate and analyse their own incidents and claims. It was also decided that, if at all possible, the system selected should allow hospitals to record their public liability incidents, employer's liability incidents and complaints in the one system. Following public advertisement and tendering, the STARS system developed by Marsh[12,13] was selected, adapted and tested in eight agencies[14]. The system went 'live' in April 2004.

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[12] www.starsinfo.com
[13] www.starsinfo.com/Download/sisecure/Marketing/STARSIrishNews.pdf
[14]

http://www.hebe.ie/NewsEvents/NewsArchive/Archive2004/February04/daterelease,1391,en.html

6.   Japan

Author's comments: Japan is not recognised internationally as a major player in the patient safety field. However, in March 1998 the Medical Safety Policy Committee of the Japan Medical Association (JMA) issued a report titled 'Risk Management in Medical Practice'. And in March 2000, the JMA took the initiative to issue an "Urgent Declaration on Patient Safety Policy", which called for immediate efforts for research and surveys on patient safety, and emphasised the need to train personnel capable of developing patient safety policies. And so in August 2001 the Medical Safety Policy Committee of the JMA issued its 'Policies for the Protection of Patient Safety' (see below). Interestingly, and in contrast with the majority of the rest of the patient safety community, the Committee believes that "the improvement of qualifications of medical practitioners as professionals is the most important element in patient safety." Additionally, the Japan Public Health Association (JPHA) in 2002 wrote about the increasing public concern with the "safety of medical care" and the fact that the Government took action to improve patient safety through the 2002 Medical Service Act. However, no mention was made in the Act of the need for a mandatory reporting system to learn from patient safety incidents. Given the very hierarchical nature of the medical professions in Japan, together with an apparent absence of multi-disciplinary team working, it is perhaps not surprising that the emphasis for patient safety improvement seems to be with individual doctors and not the systems they work within.

6.1   Japan Public Health Association (JPHA)

Website: www.jpha.or.jp/jpha/english/

The following is taken from chapter 4 (Patient safety and medical malpractice) of 'Public Health of Japan 2002' on the Japan Public Health Association website.

"Safety in medical care is increasingly drawing public attention almost in parallel with patients' awareness of their right. Japan has long been considered as non-litigious society but an alarming increase of the number of medical malpractice related litigations filed every year suggests a rapidly occurring transformation of both societal atmosphere and patients' attitude.

The Ministry of Health, Labor and Welfare (MHLW) has long taken a "hands-off" stance about medical malpractice and negligence on the basis that they are basically civil disputes, which should be settled among concerned parties. However a series of serious accidents disclosed

Malpractice litigations in Japan
[source: Supreme Court]

at major medical centers have prompted the government to intervene as a precautious measure.
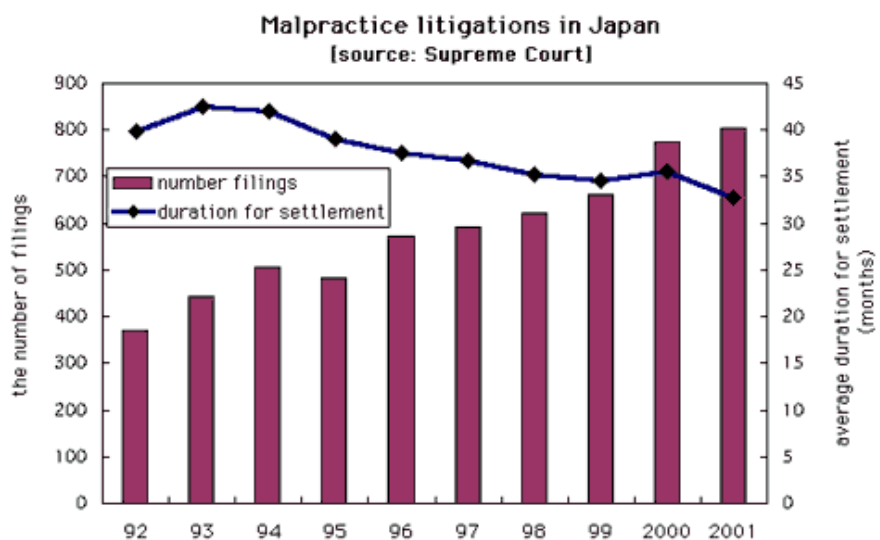
Effective in October 2002, the Medical Service Act will be revised to require that all hospitals as well as clinics with inpatient beds to take necessary precautious measures including a guideline to secure safety, reporting system from employees about any potentially dangerous pitfalls in daily operation and training and monitoring about safety. Particularly, academic medical centers will be required to appoint a full-time "risk manager" both for prevention of accidents and taking appropriate actions in case any claims are brought up patients. Still there is no officially mandated reporting system of any incidence and, therefore, the actual number of such incidence is open to guessing. The Physicians Act mandates that the doctor shall report to police when the patient dies of unexpected causes, but there is no mandatory reporting of incidence that fall short of death."

Website: www.med.or.jp/english/

On August 30 2000, the Medical Safety Policy Committee of the Japan Medical Association was tasked with reporting on "Policies for the Protection of Patient Safety."

The resulting policies, issued as a single document in August 2001, sets out a framework for patient safety that essentially places patient safety as the responsibility of "physicians". The policies recognise that "At this point, the establishment of the kind of public agency that can quickly develop proposals for public policies directly related to patient safety, and a

> As the [World Medical Association] Declaration of Helsinki states, "it is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfillment of this duty." It goes without saying that the improvement of qualifications of medical practitioners as professionals is the most important element in patient safety. Medical practitioners must study by themselves, work hard to learn from others, and train for qualifications, and this is the social and ethical duty of a professional organization.
> *Policies for the Protection of Patient Safety*
> *Japan Medical Association, August 2001*

reporting system (include exemption from legal liability) are a long way off."

However, the policies do make clear that proper causal analysis needs to be undertaken to establish why 'medical accidents' occur, and it is recognised that when responding to medical accidents, it is not sufficient to be satisfied with merely "assigning blame by finding out who was the last medical practitioner to treat the patient." Instead, "To prevent the repeated reoccurrence of medical accidents, it is essential to adopt a

> nurses (and obstetric nurses), supervising physicians and physicians-in-training, and among physicians and pharmacists and nurses, are the cause of more than a few medical accidents."
> *Policies for the Protection of Patient Safety*
> *Japan Medical Association, August 2001*

Cause Seeking Style approach and conduct a thorough investigation, to clarify the actual process of the accident and each element in its causation. In the process, the question of where the responsibility should have been for its prevention will also become obvious. If this kind of broader perspective is established, the Responsibility Seeking and Cause Seeking approaches need not be mutually exclusive. On the contrary, to find out where responsibility lies, it is necessary to have thorough analysis of what caused the accident."

7. New Zealand

Website: www.moh.govt.nz

7.1.1 Adverse Events in New Zealand Public Hospitals: Principal Findings from a National Survey

A detailed survey was carried out in 2001 to assess the occurrence, impact and preventability of adverse events recorded in New Zealand public hospitals.

A two-stage retrospective review was carried out on 6,579 medical records. These were selected by systematic list sample from admissions for 1998 occurring in 13 public hospitals throughout New Zealand providing acute care and with over 100 beds, excluding specialist institutions. Following initial screening, medical records were subject to structured implicit review (that is, the guided exercise of professional judgement) by a team of trained medical officers using a standardised protocol.

The information available in the sampled medical records was of a quality that permitted the adequate identification and analysis of adverse events. The processes and instruments used in comparator studies internationally were applied in the New Zealand setting with little difficulty. Reliability and validity measures displayed only moderate levels of agreement, however. Analysis of the 850 adverse events identified revealed a distribution, impact, and clinical context comparable with other studies. Adverse events (which may have occurred either within or outside public hospitals) were associated with 12.9 percent of admissions. Approximately 35 percent of adverse events were classified as highly preventable. Although less than 15 percent of adverse events resulted in permanent disability or death, an average of over nine days per event was added to hospital stay. Nearly a fifth of events originated from outside public hospitals, only a quarter of which arose in another institutional context. Patient age was an important risk factor for an adverse event. There were distinct patterns according to clinical and administrative context. Systems errors featured prominently in the analysis of areas for the prevention of recurrence.

The full report can be found at:

www.moh.govt.nz/moh.nsf/49ba80c00757b8804c256673001d47d0/d255c2525480c8a1cc256b120006cf25?OpenDocument

7.1.2 Toward Clinical Excellence: Learning from Experience. A Report to the Director-General of Health from the Sentinel Events Project Working Party

The Sentinel Events Project Working Party members were brought together from throughout the health sector to make recommendations to the Director-General of Health on the feasibility of implementing a mandatory event reporting system for health and disability services and related matters.

The Working Party reported in September 2001 and, among other things, concluded that health and disability services should be required to:

- complete investigations into Sentinel Events and report the results, along with any corrective action plans, to a central agency. The purpose of an investigation should be to identify the root causes or significant contributing factors that led to the event and that, if corrected, would prevent recurrence

- report progress on implementing the action plan through to completion
- provide an evaluation, after an appropriate period, of the intervention's effectiveness.

The Working Party stated that forthcoming information should be evaluated to determine if national learning can stem from a single event or from a series of events with similar causes. National learning might result in the development of clinical or management guidelines, changes to policy or legislation, changes to credentialing processes, and so on. To implement the national learning activities, priorities should be set and agreements sought with appropriate agencies.

From the consultation for this report, from the Working Party's experience and from the international literature, it became apparent that health and disability services in New Zealand will only provide the desirable level of information if:

- legal protection is provided to those involved in the reporting
- they have an assurance that the information will be used to improve safety nationally (and therefore producing some "reward" for the effort of reporting)
- the information is evaluated by an independent group of people with diverse skills and knowledge, e.g., in clinical experience, human factors theory, organisational learning and risk analysis.

Discussed within the report are key components to this environment: ensuring confidentiality and privacy, providing appropriate reward for participating in investigations, ensuring the central agency operates at arms length, resolving the question of whether to report only Sentinel Events or all close calls, and taking a broad, collective approach to national learning.

The full report can be found at:

www.moh.govt.nz/moh.nsf/238fd5fb4fd051844c256669006aed57/008deb2fa836ba68cc25 6ad000804456?OpenDocument

7.1.3   Reportable Events Guidelines
This document provides guidance on processes and systems for organisational reporting, managing and investigation of incidents, accidents and hazards in the health and disability sector.

The guidelines are intended to help the health and disability sector:
- encourage and support self learning from analysing reportable events
- promote the redesign of systems as the main methods for improving safety
- support a culture where every health care worker takes personal responsibility for consumer safety
- create an environment where discovering and reporting problems and mistakes is rewarded not punished.

The guidelines represent the culmination of two projects: the Sentinel Events Working Party Report to the Director, outlines in section 8.1.2, above, and the Sentinel Events Workbook developed with Standards New Zealand (see section 8.2).

The reportable events guidelines sets out comprehensive guidance and forms for reporting sentinel events and can be found at:

www.moh.govt.nz/moh.nsf/wpg_Index/Publications-Reportable+Events:+Guidelines,+September+2001

Website: www.standards.co.nz

In association with the Ministry of Health, Standards New Zealand has produced, in 2001, an excellent sentinel events workbook. The workbook "promotes a positive modern approach to addressing and investigating sentinel events. It assists in developing an understanding of the root causes of a sentinel event and improving safety through effective reporting. The processes in the workbook promote a culture of safety, where discovering and reporting mistakes, errors and close calls is rewarded and not punished."

The workbook is available for purchase at:

http://shop.standards.co.nz/productdetail.jsp?sku=8152%3A2001%28SNZ+HB%29

8.1   Agency for Healthcare Research & Quality (AHRQ)

Website: www.ahrq.gov/qual/errorsix.htm

The AHRQ Mission is "To improve the quality, safety, efficiency and effectiveness of health care for all Americans." AHRQ is a Federal body with a budget of around U$270 million (approx. £145 million). Its main function is to "sponsor and conduct research that provides evidence-based information on health care outcomes; quality; and cost, use, and access. The information helps health care decisionmakers—patients and clinicians, health system leaders, purchasers, and policymakers—make more informed decisions and improve the quality of health care services."

Part of AHRQ's portfolio is to "Promote patient safety and reduce medical errors." Notable programmes, initiatives and practices, for which further information is available from their Website address given above, include:

- A 4 year research project on 'Reporting Systems and Learning: Best Practices' (see Annex 1).
- The Patient Safety Improvement Corps (PSIC), which is a partnership program of the AHRQ and Veterans Administration (VA) with the primary goal of improving patient safety by providing the knowledge and skills necessary to:
    - Conduct effective investigations of reports of medical errors (e.g. close calls, errors with and without patient injury) by identifying their root causes with an emphasis on underlying system causes.
    - Prepare meaningful reports on the findings.
    - Develop and implement sustainable system interventions based on report findings.
    - Measure and evaluate the impact of the safety intervention (i.e., that will mitigate, reduce, or eliminate the opportunity for error and patient injury).
    - Ensure the sustainability of effective safety interventions by transforming them into standard clinical practice.
- AHRQ's Patient Safety E-newsletter – a free newsletter issued periodically to make available important patient safety news and information. The E-newsletter features concise descriptions of findings from AHRQ's published research, announcements about new products and tools, as well as updates on initiatives, meetings, and other key developments in the safety and quality field.
- 'Morbidity and Mortality Rounds Online' - an online journal and forum on patient safety and health care quality, which features expert analysis of medical errors reported anonymously by readers, interactive learning modules on patient safety ("Spotlight Cases"), and forums for online discussion. The figure opposite[15], for example, shows an example of a '*Did you know* …', which is a regular feature of the online journal.

- Patient Safety Indicators (PSI) project – see www.qualityindicators.ahrq.gov/psi_download.htm and also www.premierinc.com/all/advocacy/trustees/docs/ha-natl-profile-patient-safety-in-us-hospitals.pdf

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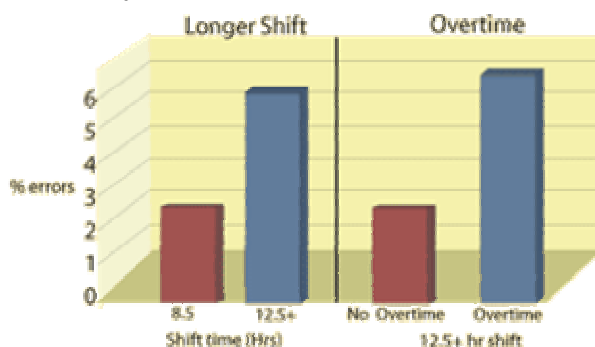
[15] From the following publication - Rogers AE, Hwang W, Scott LD, Aiken LH, Dinges DF. *The working hours of hospital staff nurses and patient safety.* Health Aff. 2004;23:202-212.

8.2   Anaesthesia Patient Safety Foundation (APSF)

Website: www.apsf.org

The mission of the Anaesthesia Patient Safety Foundation is to ensure that no patient shall be harmed by anaesthesia. The purposes of APSF are to: foster investigations that will provide a better understanding of preventable anaesthetic injuries; encourage programs that will reduce the number of anaesthetic injuries; and promote national and international communication of information and ideas about the causes and prevention of anaesthetic morbidity and mortality.

Of notable interest on the APSF site is the Data Dictionary Task Force (DDTF). The DDTF was formed to address two interrelated objectives:

1. Identification of the specific perioperative outcomes that should be investigated; i.e., what are the important questions in anaesthesia that should be asked and answered through data collection and analysis to achieve the greatest immediate patient benefit?
2. Creation of a data dictionary for the collection of the data elements required to answer these questions.

The DDTF is supported through a cooperative effort between industry and clinicians.

Further information on the DDTF can be found at www.asahq.org/Newsletters/2001/02_01/monk0201.htm

8.3   Betsy Lehman Centre for Patient Safety and Medical Error Reduction, Boston

Website: www.mass.gov/dph/betsylehman/ ; www.mass.gov/dph/media/2004/pr0112.htm

On 12 January 2004, Massachusetts Department of Public Health (DPH) announced the creation of the Betsy Lehman Center for Patient Safety and Medical Error Prevention. The Center is named for a Boston Globe health reporter, Betsy Lehman, who died in 1994 following a chemotherapy overdose.

According to the DPH, "The Lehman Center will serve the purposes of improving patient safety and reducing medical errors through coordinating state agency initiatives, promoting ongoing collaboration between the public and private sectors,

> important to all of us. Every breach of good medical practice in Massachusetts reinforces the necessity for implementing a specialized center for monitoring patient safety."
>
> *Christy Ferguson*
> *Commissioner*
> *Massachusetts Department of Public Health*

coordinating state and federal patient safety programs, and promoting patient safety through educating both health care providers and patients."

Patient safety initiatives to be undertaken by the Betsy Lehman Center include:

*   Establishment of a Patient Safety Ombudsman office within the Lehman Center, modelled on the highly successful managed care ombudsman (www.mass.gov/dph/opp/index.htm). The ombudsman will work with patients, families and consumers on patient safety related problems.
*   Establishment of a Patient Safety and Medical Errors Reduction Board to oversee the Center's Operations. Board members include the Secretary of Health and Human Services, the Director of Consumer Affairs and Business Regulation, and the Attorney General.

- Creation of an education and research program for the health care industry and the general public on issues related to the cause and consequence of medical errors.
- Establishment of a clearinghouse for best practices for reporting on improvements in the patient safety culture.
- Coordination of data collection and analysis to improve education and training programs which promote patient safety.
- Coordination of all state and federal patient safety programs.
- Participation in the Patient Safety Improvement Corps, a federal program with an emphasis on identification of root causes and underlying healthy system causes of medical errors.

8.4   Cambridge Health Alliance, Boston

Cambridge Health Alliance is a nationally recognized, award-winning healthcare system that serves the residents of Cambridge, Somerville and Boston's Metro-North region. It comprises three hospitals and more than 20 primary care practices. Cambridge Health Alliance operates an 'integrated system' that incorporates public health, clinical care, academics, and research.

A wide-ranging discussion was held with Dennis Keefe, CEO, and Priscilla Dasse, Senior Vice President, Performance Improvement, which principally focused on the practical experiences of Cambridge Health Alliance in implementing an organisation-wide patient safety

> This is forever. And it gets harder as you go on. Its the commitment to the learning and measurement and the focus that we want to bring."
>
> *Priscilla Dasse*
> *Senior Vice President, Performance Improvement*
> *Cambridge Health Alliance, MA*

improvement program. Dennis Keefe is particularly committed to patient safety, principally due to personal family experiences. He believes that, in spite of the hard work and commitment of health care professionals, the health care system is "broken" – yet he also believes it can be "fixed." He therefore chooses to spend time on patient safety and quality issues, thereby ensuring senior level commitment within the organisation to help ensure improvement.

The following key issues were identified and comments made.

Issue	Selected abridged comments made by Cambridge Health Alliance
Leadership	- The Board demonstrates 100% commitment to patient safety - Patient safety is a key strategic objective under the 'quality' umbrella – it has to be raised to strategic level to get the appropriate attention - CEO attends all key meetings to demonstrate support for patient safety
'Culture'	- Need to get the culture right – eradicate blame. "There are not many second chances in health care." - Need to have a resident medical officer on every RCA
Learning from best practice	- The organisation goes out and actively seeks out 'best in class'

Issue	Selected abridged comments made by Cambridge Health Alliance
Learning through root cause analysis (RCA)	• Originally applied the Veterans Health approach, which was good for learning, but was time consuming. • Have developed a less time consuming approach to RCA where the key to doing more RCAs is to do each RCA in less time, e.g. rather than have a whole group review the record, the risk manager can do it.
Communication	• The culture of medicine is such that it's hard to tell someone in authority over you that there is a patient safety problem
Measurement	• Good information systems are essential • Measuring the actions resulting from reporting incidents is important. People need to see that things are being done. • System-wide measures are needed • Specific measures include 'patient satisfaction' and 'patients suffering adverse medication events'. • Measuring the actions resulting from reporting incidents is important. People need to see that things are being done.

8.5 Columbia University

Website: www.mers-tm.net

Columbia University hosts MERS-TM - an event reporting system that facilitates continued improvement of blood product and transfusion safety through the systematic collection, analysis, and interpretation of information about events occurring at blood centers and transfusion medicine sites. The website contains comprehensive guidance and instruction, including online training, on application of the methodologies and procedure underpinning MERS-TM, including:

- completing all reporting forms
- recognizing active and latent errors
- identifying events by type
- performing root cause analyses
- assigning event and causal codes
- calculating a risk assessment index
- analyzing data using report and query functions

The website also hosts *Patient Safety and the "Just Culture"* – a primer for health care executive. This freely downloadable publication gives an excellent overview of the principles of implementing a 'just culture' in healthcare.

8.6 Dana-Farber Cancer Institute, Boston

Website: www.dfci.harvard.edu/

Following the tragic death of Betsy Lehman and significant medical interventions required involving another patient, the Dana-Farber Cancer Institute (DFCI) embraced risk management and quality improvement in a major way. They found that the role of executive management and, ultimately, the board in learning and improving patient safety is paramount. In Annex 2, Jim Conway, Chief Operations Officer at DFCI, provides a personal view of what it takes to improve patient safety. The Betsy Lehman story is included as a case study on the US Veterans Affairs Gaps Centre website (www.gapscenter.org/Stories.asp).

8.7 Department of Veterans Affairs, GAPS Centre

Website: www.gapscenter.org

The VA GAPS Center is a unique partnership of clinicians, administrators, and experts in human performance funded to improve patient safety in healthcare. The Center's focus is on how gaps in continuity of care are bridged by practitioners, and its goal is to create the components of a "safety culture". The GAPS Center aims to create, test, validate, and refine tools for healthcare workers and managers to use in coping with threats to safety, taking advantage of state of the art research results.

The GAPS Centre believes that "patient safety is not a commodity that can be ordered and checked off the organization's to do list. Rather, it is an iterative, evolving process requiring success in a variety of components, particularly technology, fault-free reporting systems, and leadership commitment in word and practice. In order to make genuine, sustainable progress toward a safety culture, organizational learning must be seeded and tended in a lifecycle of understanding. However, learning is often overlooked in the data-driven, outcomes-based assessment of safety progress. Without learning on both individual and organizational levels, the shift toward an organic safety culture is stymied. Learning includes the ability to see patterns in events and to interpret failure from a human factors viewpoint. In order to introduce key safety concepts, the VA GAPS Center has developed stories of accidents from a variety of sources, within and without health care. These concrete examples of failures intend to encourage curiosity, interpretation, and recognition of the underlying patterns of similarities that thread throughout the accidents. It is through the engagement of the viewer of events outside of his realm of experience that the understanding of the universal complexity of work and human factors challenges becomes tangible."

Thus, one example of notable practice is the GAPS Centre story approach. Stories from a variety of disciplines, both 'clinical' and 'non-clinical' with outcomes ranging from disastrous to heroic, are provided on the site "a concrete expression of fundamental patient safety concepts". Each story connects to a series of slides, a text Overview of the facts, the poster with links to the slides, a human factors explanation of the concept, provocative questions, and linked to relevant websites. The 'clinical', pr 'patient safety' stories include:

- Betsy Lehman Chemo overdose
- Willie King wrong leg amputation
- Failure of a blood storage refrigerator in an operating room (OR) resulting in 'near miss' patient death

An interesting paper available on the VA GAPS site is *Creating patient safety with organizational learning: A case-based learning intervention at a public and private hospital* which can be found at www.gapscenter.org/stories/HFES.pdf. Using an intervention called SafetyMinutes™, which is a six-month, case-based learning curriculum designed to shift the focus from the individual to systems when learning from incidents, the authors of the paper set out to attempt to create a 'safety culture' in both hospitals.

8.8 Department of Veterans Affairs, National Centre for Patient Safety (NCPS)

Website: www.patientsafety.gov

The Department of Veterans Affairs (VA) National Centre for Patient Safety (NCPS) has, under the direction of Dr James Bagian (an engineer, physician and NASA astronaut!), become internationally known for its achievements in implementing patient safety in VA hospitals across the USA. There is much on the NCPS website to learn from. Of particular note are the following:

> "We don't believe people come to work to do a bad job or make an error, but given the right set of circumstances any of us can make a mistake."
>
> *Dr James Bagian*
> *Director, National Center for Patient Safety*
> *Department of Veterans Affairs, USA*

- *VA Patient Safety Improvement Handbook*[16] – a very comprehensive 'how to do it' guide covering definitions of adverse events, sentinel events and close calls; how to address intentionally unsafe acts; reviewing and analysing reported events; informing patient about adverse events; and compensation for injured patients. The handbook also gives guidance on four types of events – falls, adverse drug events, missing patients, and parasuicidal behaviours - that should be subjected to root cause analysis (RCA) through quarterly Aggregated Reviews, rather than individual RCA. According to the NCPS, the use of Aggregated Reviews serves two important purposes. First, it provides greater utility of the analysis as trends or patterns not noticeable in individual case analysis are more likely to show up as the number of cases increases. Second, it makes wise use of the RCA team's time and expertise.
- *Root Cause Analysis methodology* – the VA approach to RCA builds on the JCAHO approach (see 8.14) and is, perhaps, the most widely known approach to RCA in health care in the World. In Australia, for example, there are many organisations using the VA approach, or some variant, and the New South Wales Health Department rolled out the VA model across all hospitals in New South Wales (e.g. see 1.3). The NCPS has developed good guidance in applying the VA RCA approach, including a set of 'Triggering and Triage Questions' and a publication defining the 'Rules of Causation'.
- *Safety topics of interest* – downloadable resources for four key safety topics of interest are available from the NCPS website. These are:
  - o *Ensuring correct surgery* – procedural documents and training materials are available. These have been utilised by the Australian Council on Safety and Quality in Health Care (see 1.1).
  - o *MRI hazard summary* – inspired by so many 'close calls' as well as events reported in the public press, and the fact that magnetic resonance (MR) hazards are complex and not obvious, the NCPS produced a detailed primer on MR hazards.
  - o *Healthcare Failure Mode and Effect Analysis (HFMEA^{TM})* – is the health care equivalent of the ubiquitous 'failure mode and effects analysis' used for many years in engineering. Essentially HFMEA is proactive risk assessment and

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[16] The VA Patient Safety Improvement Handbook significantly influenced the development of the draft guidance 'Doing Less Harm' issued by the Department of Health in August 2001 to underpin pilot work to establish the National Patient Safety Agency.

NCPS has provided a wider range of resources to help organisations with the approach.

- o *Falls prevention toolkit* - Many facilities are working to find ways to reduce the number of falls as well as the severity of the falls that do occur. In an effort to help facilities, NCPS created the Falls Toolkit, which provides information on: designing a falls prevention and management program; effective interventions for high-risk fall patients; implementing hip protectors for high-risk fall patients; and educating patients, families and staff on falls and fall-injury prevention.

In addition to the above, the Department of Veterans Affairs (VA) and the National Aeronautics and Space Administration (NASA) are jointly developing a Patient Safety Reporting System (PSRS) as a learning program. The PSRS invites all VA medical facility staff to voluntarily report any events or concerns that involve patient safety. The VA formed an agreement with NASA in May 2000 to develop a Patient Safety Reporting System for their healthcare facilities. This system's guiding principles are voluntary participation, confidentiality protection, and non-punitive reporting. It is designed to be a complementary external system to the current internal VA reporting system. NASA is using its experience from developing and running its highly successful Aviation Safety Reporting System (ASRS). NASA developed and has been running this system for the Federal Aviation Administration (FAA) since 1976. ASRS has been lauded for its strict confidentiality procedures, managed reports, database created for the easy retrieval of information, creation of safety products, and distribution of safety information. Their knowledge and experience in this area will be applied to PSRS.

8.9   ECRI

Website: www.ecri.org

Author's comments: ECRI was founded, over 30 years ago, as the non-profit 'Emergency Care Research Institute'. It has grown into perhaps the most formidable independent patient safety organisation in the World and is designated by the World Health Organisation as the WHO Collaborating Center for Patient Safety, Risk Management, and Healthcare Technology. ECRI's achievements are too numerous to list here, but mention will be made of some of their notable initiatives relating to incident reporting.

ECRI was the first organization to implement a medical product problem reporting and analysis system, over 30 years ago. The system assists health facilities, systems, and government agencies in creating new or improving existing reporting programs. Medical devices alerts are produced by ECRI based on this system. A complementary system, ECRI Alerts Tracker, is the first online hazard and recall management system that facilitates the distribution of information and recall alerts throughout a hospital, and automatically documents the actions of staff members take to resolve them.

ECRI is the principal contractor supporting the Pennsylvania Patient Safety Authority (See 8.21) in the design and implementation of a state-wide web-based incident reporting system.

ECRI has established a 'Patient Safety Centre' on its website, which provides public access to some of ECRI's extensive range of patient safety information (see www.ecri.org/Patient_Information/Patient_Safety/Default.aspx).

Three notable papers by ECRI available at their Patient Safety Center are:

- *Event reporting* (www.ecri.org/Patient_Information/Patient_Safety/IncRep1.pdf)

- *State-Based Initiatives for Medical Adverse-Event and Near-Miss Reporting: Lessons from the Private Sector* (www.ecri.org/Patient_Information/Patient_Safety/ECRI%20White%20Paper.pdf)
- *Nonpunitive Error-Reporting Programs: Overcoming the Problem of Fear* (www.ecri.org/Patient_Information/Patient_Safety/RMREP603.pdf)

With regard to 'event reporting' (i.e. 'incident' reporting), ECRI has derived the following list of common barriers to reporting incidents:

- Time involved in reporting, lack of sufficient time to report
- Extra work involved in reporting
- Forgetting to complete an event report form
- Not wanting to "tell" on another healthcare worker
- Lack of anonymity
- Reporting thought to be unnecessary due to lack of adverse outcome
- Fear of punishment and fear of lawsuits
- Reporting thought not to contribute to improvement, poor record of improvement
- Unclear reporting protocols/lack of information on how to report events
- Difficulty in accessing computer/unavailability of report forms

However, ECRI believes that for healthcare organizations to improve the effectiveness of activities aimed at improving patient safety and quality of care, there is a *critical* need to establish collective efforts to exchange information on the causes and prevention of adverse events and near misses. Thus it is imperative that the healthcare sector establish systems for identifying and learning from errors and near misses. In their *State-Based Initiatives for Medical Adverse-Event and Near-Miss Reporting: Lessons from the Private Sector* white paper, ECRI sets out the following as being elements of a successful incident reporting system:

- "No blame" culture
- Culture of trust and leadership support
- Cultural survey (how conducive is the current healthcare culture to reporting?)
- Standardized definitions (terminology, etc.)
- Standardized reporting formats
- Intelligent data analysis
- Provision of risk reduction guidance based on reporting
- Disclosure
- Consumer input

Nonpunitive Reporting

Figure 1. Increase in error reporting rates.
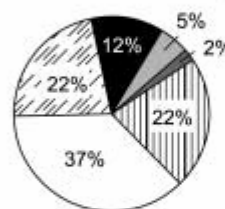
Figure 2. Increase in near miss reporting rates.

	No change in reporting rates
	Up to 25%
	26 to 50%
	51 to 100%
	More than 100%
	Not specified
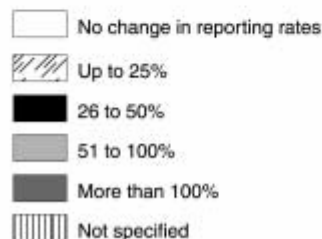
Source: HRC Reader Survey, 2003.

Getting at a 'no blame' culture is explored in ECRI's *Nonpunitive Error-Reporting Programs: Overcoming the Problem of Fear* paper, which forms part of the content of ECRI's 'The Risk Management Reporter' newsletter of June 2003. When the fear of punishment is removed as an impediment to reporting (and, hence, learning), reporting rates increase. The figure opposite shows the degree to which both 'error' and 'near miss' reporting rates have changed in a survey of newsletter readers as a consequence of introducing 'non punitive' policies for reporting. The two biggest obstacles to introducing non punitive policies described in the paper are 'getting staff buy in' and 'getting administration buy in'.

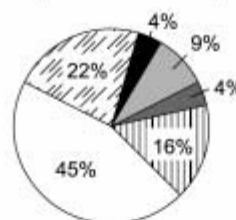## 8.10 Institute for Healthcare Improvement (IHI)

Website: www.ihi.org

The IHI, established by renowned US physician Don Berwick, has quickly become almost an international phenomenon. The IHI describes itself as "a reliable source of energy, knowledge, and support for a never-ending campaign to improve health care worldwide," and aims for "health care for all with no needless deaths; no needless pain or suffering; no helplessness in those served or serving; and no waste.

One of several 'topics' supported by the IHI, and sponsored by the National Patient Safety Agency, is 'patient safety' (www.ihi.org/IHI/Topics/PatientSafety/). The IHI has collected a number of tools and other resources for organisation to use in pursuit of patient safety improvement, including:

- A *safety climate survey* tool, developed by the Center of Excellence for Patient Safety Research & Practice, University of Texas. Using this survey tool, an organization can gain information about the perceptions of front-line clinical staff about safety in their clinical area and management's commitment to safety. The survey also provides information about how perceptions vary across different departments and disciplines. A typical improvement chart using this tool is shown opposite.

- A comprehensive change package for *reducing surgical site infections*.
- A comprehensive change package for *improving medication systems*.
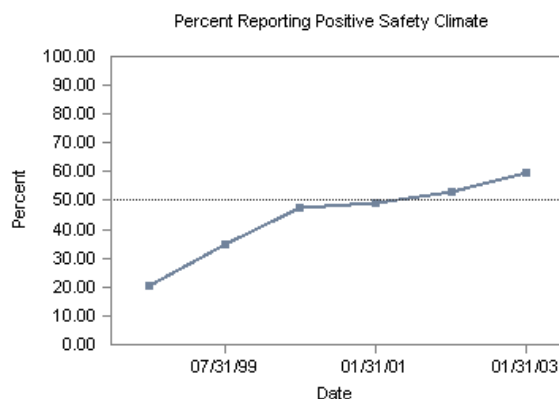
Many general improvement tools are available on the IHI website, including an *Improvement Tracker*, which is a simple but effective tool that allows you to track predefined standard measures (performance indicators) in several topic areas, with more being added periodically. Additionally, you can create your own custom measures to track any data you want. Many organisations around the World have already submitted patient safety measures, which can be found at www.ihi.org/ihi/workspace/tracker/#210

8.11 Institute for Safe Medication Practices (ISMP)

Website: www.ismp.org

The Institute for Safe Medication Practices (ISMP) is a non-profit organization that works closely with healthcare practitioners and institutions, regulatory agencies, professional organizations and the pharmaceutical industry to provide education about adverse drug events and their prevention. The Institute provides an independent review of medication errors that have been voluntarily submitted by practitioners to a national Medication Errors Reporting Program (MERP) operated by the United States Pharmacopoeia (USP) in the USA. Information from the reports may be used by USP to impact on drug standards. All information derived from the MERP is shared with the U.S. Food and Drug Administration (FDA) and pharmaceutical companies whose products are mentioned in reports.

The Institute is an FDA MEDWATCH partner and regularly communicates with the FDA to help to prevent medication errors. The Institute encourages the appropriate reporting of medication errors to the MEDWATCH Program.

Thus, ISMP is very much concerned with online reporting of medication errors. However, ISMP is also dedicated to the safe use of medications through improvements in drug distribution, naming, packaging, labelling, and delivery system design. The organization has established a national advisory board of practitioners to assist in problem solving.

Another notable initiative from ISMP is their *Medication Safety Self-Assessment for Hospitals 2004* (www.ismp.org/PDF/2004Hospsm.pdf), which is designed to "heighten awareness of distinguishing characteristics of a safe hospital medication system; create a new baseline of hospital efforts to enhance medication safety in 2004; and compare these findings with the results from the 2000 ISMP Medication Safety Self Assessment®." The results of these self-assessments are used for research and education purposes only.

Finally, the ISMP provides a comprehensive medication safety alert service (www.ismp.org/MSAarticles/msa.html) with different 'Editions' mainly sent by e-mail, covering:

- Acute care
- Community/Ambulatory care
- Consumers
- Nursing

8.12 Institute of Medicine (IoM)

Website: www.iom.edu

The IOM has published three seminal reports on patient safety, the first To Err is Human in November 1999, the second *Keeping Patients Safe: Transforming the Work Environment of Nurse*s in November 2003 and the third, *Patient Safety: Achieving a New Standard for Care*, also in November 2003.

To Err is Human lays out a comprehensive strategy by which government, health care providers, industry, and consumers can reduce preventable medical errors. Concluding that the know-how already exists to prevent many of these mistakes, the report sets as a minimum goal a 50 percent reduction in errors over the next five years.

*Keeping Patients Safe: Transforming the Work Environment of Nurse*s identifies solutions to problems in hospital, nursing home, and other health care organization work environments that threaten patient safety through their effect on nursing care. A companion to the Institute of Medicine's earlier patient safety report, *To Err is Human*, the report puts forth a blueprint of actions that all health care organizations which rely on nurses should take. The report's findings and recommendations address the related issues of management practices, workforce capability, work design, and organizational safety culture. Actions needed from the federal and state governments, as well as from coalitions of parties involved in shaping the work environments of nurses also are specified. The report presents evidence from health services, behavioral and organizational research, and human factors and engineering to address pressing public policy questions, including nurse staffing levels, nurse work hours, and mandatory overtime.
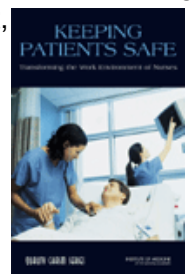
Patient Safety: Achieving a New Standard for Care provides a detailed plan to facilitate the development of data standards applicable to the collection, coding, and classification of patient safety information. This report addresses key areas related to the establishment of a national health information infrastructure, including: a process for the ongoing promulgation of data standards; the status of current standards-setting activities in health data interchange, terminologies, and medical knowledge representation; as well as the need for comprehensive patient safety programs in health care organizations.

8.13 Jefferson Regional Medical Center

Author's comments: The Commonwealth Fund website (www.cmwf.org) contains a number of case studies in improving the safety and quality of care, including a study of Jefferson Regional Medical Center, which outlines how they created a 'learning organisation' (www.cmwf.org/publications/publications_show.htm?doc_id=233893). The following is an extract from the full report. There are many similarities between Jefferson and the Cambridge Health Alliance (see 8.4).

High quality at Jefferson Regional Medical Center appears to be the result of a variety of institutional factors that collectively have created an internal environment constantly focused on delivering excellent medical care. It is largely not, however, the result of a push from external stakeholders, including employers, health plans, and regulators. Rather, because of strong leadership and a well-entrenched culture that emphasizes quality, along with productive cross-disciplinary relationships and a flexible, decentralized approach to problem-solving, Jefferson has created the type of learning environment that produces good outcomes and continuous improvement. This success has been facilitated by a set of nuts-and-bolts tools that leads to quality care on a daily basis. Key factors responsible for the creation of a learning environment within Jefferson include the following:

- A rich history and culture that supports quality.
- Leadership at all levels committed to quality, as evidenced by a consistent willingness to commit resources and absorb financial losses, if necessary, to ensure that quality is not compromised.
- Mutual respect and strong relations across disciplines, including between the administration and clinical care staff (both doctors and nurses) and between physicians and non-physician care staff.
- A highly skilled nursing and medical staff.
- Local (i.e., clinical department or unit-based) ownership and accountability for quality and quality improvement (QI).

With this learning environment in place, Jefferson has invested in a variety of nuts-and-bolts factors that keep quality at the forefront on a daily basis. Sophisticated information technology (IT), however, is not one of these tools, as IT has not played an important role in Jefferson's historical success. It is, however, a central component of future plans. Rather, this daily attention to quality and QI are the result of the following:
- Selected performance monitoring and reporting.
- A broad set of existing structures to identify and address quality and service issues, along with the ability to create ad hoc structures to tackle specific problems identified through data analysis.
- Aggressive case managers who ensure that patients receive appropriate and timely care and services, leading to the earliest possible rehabilitation and discharge.

Key challenges faced by Jefferson relate primarily to getting physicians to accept IT and standardized medicine (e.g., use of protocols). The hospital has achieved its strong performance without having made much progress to date in addressing these challenges.

Lessons learned from the Jefferson case study include the following:
- Leading-edge IT is not necessarily a prerequisite to quality nor is strong external pressure for quality or QI.
- There is no substitute for creating the type of organization where talented individuals want to work and for instilling a culture that values mutual respect and peer-type relations between administrators and clinicians and between physicians and non-physician caregivers.
- Physicians and other caregivers can and should be liberated to take local ownership and accountability for QI.
- An aggressive case management program can play a critical role in facilitating a team-based approach that gets patients appropriate care in a timely manner.

8.14 Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

Website: www.jcaho.org

The Joint Commission, or 'Jayco', is a major organization that accredits the majority of US health care facilities and is committed to improving safety for patients and residents in health care organizations. This commitment is inherent in its mission to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations. At its heart, accreditation is a risk-reduction activity; compliance with standards is intended to reduce the risk of adverse outcomes. The Joint Commission demonstrates its commitment to patient safety through numerous efforts that include:

- Setting state-of-the-art standards
- Enforcing its Sentinel Event Policy
- Issuing *Sentinel Event Alert*
- Establishing National Patient Safety Goals
- Sponsoring the Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Patient Surgery™
- Monitoring sentinel event responses
- Providing educational resources
- Disseminating Speak Up consumer information

8.14.1 Patient safety-related standards

Almost 50 percent of Joint Commission standards are *directly* related to safety, addressing such issues as medication use, infection control, surgery and anaesthesia, transfusions, restraint and seclusion, staffing and staff competence, fire safety, medical equipment, emergency management, and security. Additional patient safety standards went into effect for hospitals in 2001, and similar standards went into effect for behavioral health care and long term care organizations in 2003, and for ambulatory care and home care organizations in 2004. These standards address a number of significant patient safety issues, including the responsibility of organization leadership to create a culture of safety; the implementation of patient safety programs; the response to adverse events when they occur; the prevention of accidental harm through the prospective analysis and redesign of vulnerable patient systems (e.g. the ordering, preparation and dispensing of medications); and the organization's responsibility to tell a patient about the outcomes of the care provided to the patient—whether good or bad.

8.14.2 Sentinel Event Policy

The Joint Commission's Sentinel Event Policy, implemented in 1996, is designed to help health care organizations to identify sentinel events and take action to prevent their recurrence. A sentinel event is an unexpected occurrence involving death or serious physical—including loss of limb or function—or psychological injury, or the risk thereof. "Risk thereof" means that, although no harm occurred this time, any recurrence would carry a significant chance of a serious adverse outcome. Any time a sentinel event occurs, the health care organization is expected to complete a thorough and credible root cause analysis, implement improvements to reduce risk, and monitor the effectiveness of those improvements. The root cause analysis is expected to drill down to underlying organization systems and processes that can be altered to reduce the likelihood of a failure in the future and to protect patients from harm when a failure does occur. The Sentinel Event Policy also encourages organizations to report to the Joint Commission sentinel events that have resulted in death or serious injury, along with their root causes and related preventive actions, so that the Joint Commission can learn about the underlying causes of the sentinel events, share "lessons learned" with other health care organizations, and reduce the risk of future sentinel event occurrences.

8.14.3 Sentinel Event Alert

Sentinel Event Alert is a periodic newsletter that identifies specific sentinel events, describes their common underlying causes, and suggests steps to prevent occurrences in the future. Information for *Sentinel Event Alert* comes mainly from the Joint Commission's sentinel event database, as well as from experts and other organizations. The Joint Commission's database includes the sentinel events that have been reported to the Joint Commission, the root causes of these events, and strategies that health care organizations have used to reduce risk to patients. The Joint Commission began publishing *Sentinel Event Alert* in 1998 in order to share the most important "lessons learned" from its database and provide important information relating to the occurrence and management of sentinel events in health care organizations. *Sentinel Event Alert* has raised awareness in the health care community and the federal government about the occurrence of adverse events and ways that these events can be prevented in the future. Past issues are available on the Joint Commission's website, www.jcaho.org. Topics have included medication errors, wrong-site surgery, restraint-related deaths, blood transfusion errors, inpatient suicides, infant abductions, fatal falls and operative/post-operative complications.

8.14.4 Sentinel Event Advisory Group

In April 2002, the Joint Commission appointed a group of experienced physicians, nurses, pharmacists and other patient safety experts to advise the Joint Commission in the development of its first set of National Patient Safety Goals (NPSGs). Named for the Joint Commission's widely read patient safety advisory, the Sentinel Event Advisory Group conducts thorough reviews of all *Alert* recommendations and identifies those that are candidates for inclusion in the annual NPSGs. The NPSGs recommended by the Advisory Group are forwarded to the Joint Commission's Board of Commissioners for approval.

8.14.5 National Patient Safety Goals

In July 2002, the Joint Commission approved its first set of six National Patient Safety Goals (NPSGs) with 11 related specific requirements for improving the safety of patient care in health care organizations. All Joint Commission accredited health care organizations are surveyed for implementation of the goals and requirements—or acceptable alternatives—as appropriate to the services the organization provides. The goals and requirements are drawn from a "pool" of recommendations identified by the Sentinel Event Advisory Group as evidence- or consensus-based, cost-effective and

practical. Each year, new recommendations from *Sentinel Event Alert* newsletters published in the previous year are added to the pool. Future requirements will be drawn from the pool. In 2004, the Joint Commission began developing program-specific NPSGs for each of its accreditation and certification programs in order to make the goals and requirements more relevant to the non-hospital accreditation programs. In the development of these program-specific NPSGs, The Joint Commission took a two phase approach: Phase I involved "editing" the 2004 NPSGs to make them more applicable to each accreditation and certification program. Phase II involved identifying one or two new program-specific evidence- or experience-based goals and requirements to be implemented in 2005, along with the "core" NPSGs. The Sentinel Event Advisory Group also reviewed these proposed program-specific NPSGs.

The JCAHO has set patient safety goals for the following areas effective from 1 January 2005:

- Ambulatory Care and Office-Based Surgery
- Assisted Living
- Behavioral Health Care
- Critical Access Hospital
- Disease-Specific Care
- Home Care
- Hospital
- Laboratory
- Long Term Care
- Networks

The following are the seven Hospital Goals for 2005.

Goal: Improve the accuracy of patient identification.

- Use at least two patient identifiers (neither to be the patient's room number) whenever administering medications or blood products; taking blood samples and other specimens for clinical testing, or providing any other treatments or procedures.

Goal: Improve the effectiveness of communication among caregivers.

- For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person receiving the order or test result "read-back" the complete order or test result.
- Standardize a list of abbreviations, acronyms and symbols that are not to be used throughout the organization.
- Measure, assess and, if appropriate, take action to improve the timeliness of reporting, and the timeliness of receipt by the responsible licensed caregiver, of critical test results and values.

Goal: Improve the safety of using medications.

- Remove concentrated electrolytes (including, but not limited to, potassium chloride, potassium phosphate, sodium chloride >0.9%) from patient care units.
- Standardize and limit the number of drug concentrations available in the organization.
- Identify and, at a minimum, annually review a list of look-alike/sound-alike drugs used in the organization, and take action to prevent errors involving the interchange of these drugs.

Goal: Improve the safety of using infusion pumps.

- Ensure free-flow protection on all general-use and PCA (patient controlled analgesia) intravenous infusion pumps used in the organization.

Goal: Reduce the risk of health care-associated infections.

- Comply with current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines.
- Manage as sentinel events all identified cases of unanticipated death or major permanent loss of function associated with a health care-associated infection.

Goal: Accurately and completely reconcile medications across the continuum of care.

- During 2005, for full implementation by January 2006, develop a process for obtaining and documenting a complete list of the patient's current medications upon the patient's admission to the organization and with the involvement of the patient. This process includes a comparison of the medications the organization provides to those on the list.
- A complete list of the patient's medications is communicated to the next provider of service when it refers or transfers a patient to another setting, service, practitioner or level of care within or outside the organization.

Goal: Reduce the risk of patient harm resulting from falls.

- Assess and periodically reassess each patient's risk for falling, including the potential risk associated with the patient's medication regimen, and take action to address any identified risks.

8.14.6 The Universal Protocol

In July 2003, the Joint Commission's Board of Commissioners approved the Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery™. The Universal Protocol was created to address the continuing occurrence of these tragic medical errors in Joint Commission accredited organizations. Compliance with the Universal Protocol by all accredited hospitals, ambulatory care and office-based surgery facilities is currently being strongly encouraged and will be required beginning July 1, 2004. The Universal Protocol draws upon, and expands and integrates, a series of existing requirements under the Joint Commission's 2003 and 2004 National Patient Safety Goals. It will be applicable to all operative and other invasive procedures. The principal components of the Universal Protocol include: 1) the pre-operative verification process; 2) marking of the operative site; 3) taking a 'time out' immediately before starting the procedure; and 4) adaptation of the requirements to non-operating room settings, including bedside procedures. The protocol is endorsed by nearly 50 professional health care associations and organizations.

8.14.7 Office of Quality Monitoring

The Joint Commission's Office of Quality Monitoring receives, evaluates and tracks complaints and reports of concerns about health care organizations relating to quality of care issues. Information often comes from patients, their families or the public, as well as from an organization's own staff, government agencies and others. The Office has a toll free hot line and also receives written reports by mail or e-mail. When a report is submitted, the Joint Commission reviews any past reports and the organization's most

recent accreditation decision. Depending on the nature of the reported concern, the Joint Commission will take one of the following actions:

- Incorporate the reported concern into the quality monitoring database that is used to track health care organizations over time to identify trends or patterns in their performance.
- Ask the organization to provide a written response to the reported concern.
- Review the reported concern and compliance with related standards at the time of the organization's next accreditation survey, if it is scheduled in the near future.
- Conduct an unannounced on-site evaluation of the organization if the report raises serious concerns about a continuing threat to patient safety or continuing failure to comply with standards.

8.14.8 Patient safety resources

Joint Commission Resources (JCR) is a not-for-profit subsidiary of the Joint Commission that provides services independently and confidentially, disclosing no information about its clients to the Joint Commission or others. JCR offers a number of seminars, programs, publications, web-based training, good practices, custom education and consultation on patient safety, including: environment of care, restraint and seclusion, failure mode and effects analysis, prevention of medical errors, medication use, preventing sentinel events, risk reduction strategies, and how to conduct root cause analyses. JCR publishes *Joint Commission Perspectives on Patient Safety,* a monthly newsletter dedicated to providing information on the prevention of errors in health care settings. A bimonthly newsletter, *Environment of Care News*, focuses on patient and facility safety issues.

8.14.9 The Speak Up initiatives

In March 2002, the Joint Commission, together with the Centers for Medicare and Medicaid Services (CMS), launched a national program to urge patients to take a role in preventing health care errors by becoming active, involved and informed participants on the health care team. The program features brochures, posters and buttons on a variety of patient safety topics. In 2003, the Speak Up initiative was expanded to *Help Prevent Errors in Your Care: For Surgical Patients*. This program includes tips to help patients prepare for surgery and make sure that they have the correct procedure performed at the correct site on their body. In March 2004, *Preparing to be a Living Organ Donor* was launched. This campaign was created to help individuals prepare to become living organ donors and to make the process as safe as possible by becoming active, involved and informed. It includes basic facts about living organ donation and questions to ask the doctor. More patient safety topics will be addressed in the future, including infection control and stroke.

8.15 Leapfrog Group

Website: www.leapfroggroup.org/

The Leapfrog Group (Leapfrog) is an initiative driven by organizations that buy health care who are working to initiate breakthrough improvements in the safety, quality and affordability of healthcare for Americans. It is a voluntary program aimed at mobilizing employer purchasing power to alert America's health industry that big leaps in health care safety, quality and customer value will be recognized and rewarded. Leapfrog is a growing consortium of over 150 Fortune 500 companies and other large private and public healthcare purchasers founded by The Business Roundtable. In November 20002 Leapfrog launched a national effort in to reward hospitals for advances in patient safety and quality and to educate employees, retirees, and families about the importance of hospitals' efforts in this area. Leapfrog purchasers provide health benefits to more than 34

million Americans and spend billions on healthcare annually.

Leapfrog initially identified three patient safety practices (Leaps) as the focus for hospital recognition and reward. They are Computer Physician Order Entry, ICU Physician Staffing, and Evidence-Based Hospital Referral. Their research indicated that meeting these Leaps in non-rural hospitals could save more approximately 65,000 lives and prevent as many as 900,000 serious medication errors each year.

In May 2003, the National Quality Forum (NQF) released its Safe Practices Consensus Report identifying 30 practices that can have major impact on the safety of patients in healthcare settings. These 30 practices include the original three Leaps. In this 2004 version of the survey, the other 27 form a new fourth Leap which Leapfrog has endorsed.

In summary, the Leapfrog Group identified and has since refined four hospital quality and safety practices that are the focus of its health care provider performance comparisons and hospital recognition and reward. Based on independent scientific evidence, the quality practices are: computer physician order entry; evidence-based hospital referral; intensive care unit (ICU) staffing by physicians experienced in critical care medicine; and The Leapfrog Quality Index, based on the NQF-endorsed Safe Practices.

- **Computer Physician Order Entry (CPOE)**: With CPOE systems, hospital staff enter medication orders via computer linked to prescribing error prevention software. CPOE has been shown to reduce serious prescribing errors in hospitals by **more than 50%**.

- **Evidence-Based Hospital Referral (EHR)**: Consumers and health care purchasers should choose hospitals with extensive experience and the best results with certain high-risk surgeries and conditions. By referring patients needing certain complex medical procedures to hospitals offering the best survival odds based on scientifically valid criteria — such as the number of times a hospital performs these procedures each year or other process or outcomes data — research indicates that a patient's risk of dying could be reduced by **40%**.

- **ICU Physician Staffing (IPS)**: Staffing ICUs with doctors who have special training in critical care medicine, called 'intensivists', has been shown to reduce the risk of patients dying in the ICU by **40%**.

- **Leapfrog Quality Index - The National Quality Forum's 27 Safe Practices**: The National Quality Forum-endorsed 30 Safe Practices cover a range of practices that, if utilized, would reduce the risk of harm in certain processes, systems or environments of care. Included in the 30 practices are the original 3 Leapfrog leaps. For this new leap, added in April 2004, hospitals' progress on the remaining 27 safe practices will be assessed.

8.16 Miami Centre for Patient Safety

Website: http://umdas.med.miami.edu/MPSC/

The Mission of the University of Miami/Jackson Memorial Hospital Center for Patient Safety is "to improve the safety of patients and health care staff, by expanding, enriching and disseminating research-based knowledge relating to patient safety and systems redesign."

The Center for Patient Safety seeks to stimulate the growth of patient safety knowledge by conducting scientific and clinical investigations in collaboration with health care professionals and non - medical experts, and by designing innovative health care curricula

based on human factors, team training and simulation. It aims to raise public awareness to patient - centered care, and foster the exchange of information about patient safety throughout the medical community through recognition of the need for medical organizations to learn and their responsibility in creating positive safety cultures.

8.17 National Patient Safety Foundation (NPSF)

Website: www.npsf.org

The National Patient Safety Foundation (NPSF) is a major information 'portal' for patient safety. It's Mission is "To Improve the Safety of Patients through our efforts to: Identify and create a core body of knowledge; Identify pathways to apply the knowledge; Develop and enhance the culture of receptivity to patient safety; Raise public awareness and foster communications about patient safety; and Improve the status of the Foundation and its ability to meet its goals."

The NPSF Board has endorsed the following definitions:

- PATIENT SAFETY
  The prevention of healthcare errors, and the elimination or mitigation of patient injury caused by healthcare errors.
- HEALTHCARE ERROR
  An unintended healthcare outcome caused by a defect in the delivery of care to a patient. Healthcare errors may be errors of commission (doing the wrong thing), omission (not doing the right thing), or execution (doing the right thing incorrectly). Errors may be made by any member of the healthcare team in any healthcare setting.

The NPSF website is replete with information and other resources on patient safety. For example, the NPSF Bibliography/Library has over 5500 publication listed and can be searched in many different ways. There is also a moderated e-mail discussion forum that is "devoted to thoughtful conversation toward the development of a safer health care system."

8.18 National Quality Forum (NQF)

Website: www.qualityforum.org

The mission of the NQF is "to improve American healthcare through endorsement of consensus-based national standards for measurement and public reporting of healthcare performance data that provide meaningful information about whether care is safe, timely, beneficial, patient-centered, equitable and efficient."

8.18.1 Safe Practices for Better Healthcare

This report details 30 healthcare safe practices that should be universally utilized in applicable clinical care settings to reduce the risk of harm to patients and is used by the Leapfrog Group to determine a hospital's 'Leapfrog Quality Index' (see 8.15). In summary, the 30 healthcare safe practices are:

1. Create a healthcare culture of safety.
2. For designated high-risk, elective surgical procedures or other specified care, patients should be clearly informed of the likely reduced risk of an adverse outcome at treatment facilities that have demonstrated superior outcomes and should be referred to such facilities in accordance with the patient's stated preference.

3. Specify an explicit protocol to be used to ensure an adequate level of nursing based on the institution's usual patient mix and the experience and training of its nursing staff.

4. All patients in general intensive care units (both adult and pediatric) should be managed by physicians having specific training and certification in critical care medicine ("critical care certified").

5. Pharmacists should actively participate in the medication-use process, including, at a minimum, being available for consultation with prescribers on medication ordering, interpretation and review of medication orders, preparation of medications, dispensing of medications, and administration and monitoring of medications.

6. Verbal orders should be recorded whenever possible and immediately read back to the prescriber - i.e., a healthcare provider receiving a verbal order should read or repeat back the information that the prescriber conveys in order to verify the accuracy of what was heard.

7. Use only standardized abbreviations and dose designations.

8. Patient care summaries or other similar records should not be prepared from memory.

9. Ensure that care information, especially changes in orders and new diagnostic information, is transmitted in a timely and clearly understandable form to all of the patient's current healthcare providers who need that information to provide care.

10. Ask each patient or legal surrogate to recount what he or she has been told during the informed consent discussion.

11. Ensure that written documentation of the patient's preference for life-sustaining treatments is prominently displayed in his or her chart.

12. Implement a computerized prescriber order entry system.

13. Implement a standardized protocol to prevent the mislabelling of radiographs.

14. Implement standardized protocols to prevent the occurrence of wrong-site procedures or wrong-patient procedures.

15. Evaluate each patient undergoing elective surgery for risk of an acute ischemic cardiac event during surgery, and provide prophylactic treatment of high-risk patients with beta blockers.

16. Evaluate each patient upon admission, and regularly thereafter, for the risk of developing pressure ulcers. This evaluation should be repeated at regular intervals during care. Clinically appropriate preventive methods should be implemented consequent to the evaluation.

17. Evaluate each patient upon admission, and regularly thereafter, for the risk of developing deep vein thrombosis (DVT)/venous thromboembolism (VTE). Utilize clinically appropriate methods to prevent DVT/VTE.

18. Utilize dedicated anti-thrombotic (anti-coagulation) services that facilitate coordinated care management.

19. Upon admission, and regularly thereafter, evaluate each patient for the risk of aspiration.

20. Adhere to effective methods of preventing central venous catheter-associated blood stream infections.

21. Evaluate each pre-operative patient in light of his or her planned surgical procedure for the risk of surgical site infection, and implement appropriate antibiotic prophylaxis and other preventive measures based on that evaluation.

22. Utilize validated protocols to evaluate patients who are at risk for contrast media induced renal failure, and utilize a clinically appropriate method for reducing risk of renal injury based on the patient's kidney function evaluation.

23. Evaluate each patient upon admission, and regularly thereafter, for risk of malnutrition. Employ clinically appropriate strategies to prevent malnutrition.

24. Whenever a pneumatic tourniquet is used, evaluate the patient for the risk of an ischemic and/or thrombotic complication, and utilize appropriate prophylactic measures.

25. Decontaminate hands with either a hygienic hand rub or by washing with a disinfectant soap prior to and after direct contact with the patient or objects immediately around the patient.

26. Vaccinate healthcare workers against influenza to protect both them and patients from influenza.

27. Keep workspaces where medications are prepared clean, orderly, well lit, and free of clutter, distraction, and noise.

28. Standardize the methods for labelling, packaging, and storing medications.

29. Identify all "high alert" drugs (e.g., intravenous adrenergic agonists and antagonists, chemotherapy agents, anticoagulants and anti-thrombotics, concentrated parenteral electrolytes, general anesthetics, neuromuscular blockers, insulin and oral hypoglycemics, narcotics and opiates).

30. Dispense medications in unit-dose or, when appropriate, unit-of-use form, whenever possible.

A summary of the full report can be found at:
www.qualityforum.org/txsafeexecsumm+order6-8-03PUBLIC.pdf

8.19 New York State Health Department

Website: www.health.state.ny.us/nysdoh/healthinfo/patientsafety.htm

8.19.1 New York Patient Occurrence Reporting and Tracking System (NYPORTS)

NYPORTS is one of the first incident reporting systems in the USA to accumulate and disclose a wealth of corrective actions and risk reduction strategies stemming from the tracking, trending, and sharing of serious occurrences requiring Root Cause Analysis. The system is part of a major grant award from AHRQ (see 8.1 and Annex 1) to study best practices in reporting systems and learning.

The website contains only two NYPORTS annual reports, for 1999 and 2000/2001 (www.health.state.ny.us/nysdoh/hospital/nyports/index.htm). The 2000/2001 report contains extensive information on root causes and risk reduction strategies for various categories of adverse outcome.

8.20 Oregon Patient Safety Commission (OPSC)

Website: www.dhs.state.or.us/publichealth/hsp/patientsafety/commission.cfm

The Oregon Patient Safety Commission (OPSC) was created by the Oregon Legislature in July 2003. OPSC's mission is to improve patient safety by reducing the risk of serious adverse events occurring in Oregon's health care system and by encouraging a culture of patient safety. To accomplish its mission, the Commission is:
- establishing a confidential, voluntary serious adverse event reporting system in Oregon
- establishing quality improvement techniques to reduce systems' errors
- sharing evidence-based prevention practices to improve patient outcomes.

OPSC has identified and documented what its reporting system should look like – see www.dhs.state.or.us/publichealth/hsp/patientsafety/docs/wp05272004.pdf. Essentially, the OPSC should:

(1) develop "a serious adverse event reporting system" that shall include but is not limited to:
(a) Reporting by participants, in a timely manner and in the form determined by the Oregon Patient Safety Commission Board of Directors of the following:
    (A) Serious adverse events;
    (B) Root cause analyses of serious adverse events;
    (C) Action plans established to prevent similar serious adverse events; and
    (D) Patient safety plans establishing procedures and protocols.

(b) Analyzing reported serious adverse events, root cause analyses and action plans to develop and disseminate information to improve the quality of care with respect to patient safety. This information shall be made available to participants and shall include but is not limited to:

    (A) Statistical analyses;

    (B) Recommendations regarding quality improvement techniques;

    (C) Recommendations regarding standard protocols; and

    (D) Recommendations regarding best patient safety practices.

(c) Providing technical assistance to participants, including but not limited to recommendations and advice regarding methodology, communication, dissemination of information, data collection, security and confidentiality.

(d) Auditing participant reporting to assess the level of reporting of serious adverse events, root cause analyses and action plans.

 (e) Overseeing action plans to assess whether participants are taking sufficient steps to prevent the occurrence of serious adverse events.

 (f) Creating incentives to improve and reward participation, including but not limited to providing:

    (A) Feedback to participants; and

    (B) Rewards and recognition to participants.

(g) Distributing written reports using aggregate, de-identified data from the program to describe state-wide serious adverse event patterns and maintaining a website to facilitate public access to reports, as well as a list of names of participants. The reports shall include but are not limited to:

(A) The types and frequencies of serious adverse events;

(B) Yearly serious adverse event totals and trends;

(C) Clusters of serious adverse events;

(D) Demographics of patients involved in serious adverse events, including the frequency and types of serious adverse events associated with language barriers or ethnicity;

(E) Systems' factors associated with particular serious adverse events;

(F) Interventions to prevent frequent or high severity serious adverse events; and

(G) Appropriate consumer information regarding prevention of serious adverse events.

(2) Participation in the program is voluntary. The following entities are eligible to participate:

(a) Hospitals as defined in ORS 442.015;

(b) Long term care facilities as defined in ORS 442.015;

(c) Pharmacies licensed under ORS chapter 689;

(d) Ambulatory surgical centers as defined in ORS 442.015;

(e) Outpatient renal dialysis facilities as defined in ORS 442.015;

(f) Freestanding birthing centers as defined in ORS 442.015; and

(g) Independent professional health care societies or associations.

(3) Reports or other information developed and disseminated by the program may not contain or reveal the name of or other identifiable information with respect to a particular participant providing information to the commission for the purposes of sections 1 to 12 of this 2003 Act [442.820 to 442.835 and sections 1, 4 to 6, 8 to 10 and 12, chapter 686, Oregon Laws 2003], or to any individual identified in the report or information, and upon whose patient safety data, patient safety activities and reports the commission has relied in developing and disseminating information pursuant to this section.

(4) After a serious adverse event occurs, a participant must provide written notification in a timely manner to each patient served by the participant who is affected by the event. Notice provided under this subsection may not be construed as an admission of liability in a civil action. [2003 c.686 §4]

The OPSC has also defined key steps for creating a reporting system as:

1. Define "serious adverse events." The statutes say only that it "means an objective and definable negative consequence of patient care, or the risk thereof, that is unanticipated, usually preventable and results in, or presents a significant risk of, patient death or serious physical injury. [2003 c.686 §1]"

The Commission is required to "adopt rules necessary for the implementation of the Oregon Patient Safety Reporting Program, including but not limited to: (a) Developing a list of objective and definable serious adverse events to be reported by participants. In developing this list, the board shall consider similar lists developed in other states and nationally. The board may change the list from time to time. The first list developed by the board shall focus on serious adverse events that caused death or serious physical injury. Later lists may include, in the discretion of the board, serious adverse events that did not cause death or serious physical injury but posed a significant risk of death or a risk of significant physical injury." The original drafters of HB 2349 thought that the Commission might want to convene a panel of experts to discuss various approaches.

2. Define/clarify expectations about root cause analysis (RCA). There appears to be much variation among hospitals as to how RCAs are completed. RCAs are expense to perform, hospitals don't do many (an average of about 4 per year). Other reporting entities (long term care, pharmacies, etc.) might not do any currently.

3. Define/clarify expectations for action plans and patient safety plans. Same.

4. Define "timely." Reporting entities will be expected to report in a timely manner. What does that mean? When does the clock start? At first knowledge of event?

5. Imagine/create the technical reporting structure. 70% of Oregon hospitals use paper systems to collect information about adverse events. Should the Commission create a paper system, a web based system, something else? How will security be protected? How will information be shared? How will this system fit with other technologies rapidly being pursued by health providers?

6. Consider what will be required of the Commission to analyze serious adverse events, RCAs, action plans. How will the commission actually use information? What capacity does it need to create?

7. Consider what will be required to develop and disseminate information back to participants.

8. Define what written disclosure will look like. How providers talk to patients about medical errors and adverse events is an important and difficult topic. That the Commission requires written disclosure will likely cause some angst.

9. Determine which reporting entities will be asked to participate and when? Should the Commission start with hospitals only? When would other entities be asked to participate? The statutes state that the commission must have an implementation plan for pharmacy by September, 2006.

10. Establish auditing and oversight procedures. Statute says that the Commission's must have procedures that include: (A) Assessing completeness of reports from participants; (B) Assessing credibility and thoroughness of root cause analyses submitted to the program; (C) Assessing the acceptability of action plans and participant follow-up on the action plan; and (D) Obtaining certification by the Public Health Officer on the completeness, credibility, thoroughness and acceptability of participant reports, root cause analyses and action plans.

11. Establish criteria for terminating a participant from the program. Statute says that reasons for termination would include: incomplete reporting; failure to comply with the disclosure provision; failure to adequately implement an action plan.

8.21 Pennsylvania Patient Safety Authority (PPSA)

Website: www.psa.state.pa.us/psa/site/default.asp

Author's comments: The PPSA is a real 'gem' in the patient safety world. ECRI (see section 8.8) and partners (EDS and Institute of Safe Mediciation Practices) were appointed to implement a state-wide web-based patient safety reporting system in July 2003. By mid-November 2003 some 22 health care facilities, representing a cross-section of Philadelphia's healthcare institutions, were voluntarily participating in a test phase of the reporting system prior to state-wide rollout. From March 2004, ECRI, under contract to the PPSA, were producing a comprehensive quarterly newsletter containing wide-ranging feedback from the PPSA. State-wide rollout of the reporting system, involving over 400 healthcare facilities, commenced from June 2004 – a year following ECRI's appointment.

The Philadelphia Patient Safety Authority (PPSA) is an independent state agency established under Act 13 of 2002, the Medical Care Availability and Reduction of Error ("MCARE") Act. It is charged with taking steps to reduce and eliminate medical errors by identifying problems and recommending solutions that promote patient safety in hospitals, ambulatory surgical facilities and birthing centers. Under Act 13, all Pennsylvania-licensed hospitals, birthing centers and ambulatory surgical facilities are required to report what the Act defines as "serious events" and "incidents" to the Patient Safety Authority. In turn, the Authority will analyze the collected data to identify trends or systems failures that can be corrected to prevent future serious events and incidents.

The PPSA has implemented PA-PSRS, the mandatory state-wide Pennsylvania Patient Safety Reporting System. More than 400 healthcare facilities subject to Act 13 reporting requirements are submitting reports through PA-PSRS, making Pennsylvania the first state in the nation to require the reporting of both actual events and "near misses" Additional information about PA-PSRS is available online. Above all, the Authority is committed to assuring that PA-PSRS is a user-friendly, non-redundant system that provides valuable feedback to facilities for their internal patient safety and quality improvement activities. Health care facilities enrolled in mandatory reporting can log onto PA-PSRS to submit a report.

PA-PSRS is a secure, web-based system developed for the Authority under contract with ECRI, a Pennsylvania-based independent, non-profit health services research agency, in partnership with EDS, a leading international, information technology firm, and the Institute for Safe Medication Practices (ISMP), also a Pennsylvania-based, non-profit health research organization.

Useful information is already coming out of PA-PSRS and is being reported, principally, in the 'Patient Safety Advisory' newsletter, produced by ECRI and available for download on the PPSA website.

8.22 Senate

Website: http://jeffords.senate.gov/~jeffords/press/04/07/072304patient.html

On July 22, 2004, the US Senate passed 'The Patient Safety and Quality Improvement Act' - a bill that sets up a voluntary and confidential process for doctors and hospitals to report medical errors and "near misses" to newly created Patient Safety Organizations (PSOs).

> "We must encourage physicians and other health professionals to report and evaluate medical errors within a safe learning environment. We believe that this legislation will help us take an important step toward accomplishing this goal."
>
> *Thomas R. Russell, MD*
> *executive director of the American College of Surgeons*

The Act:

- Encourages a culture of safety and quality by providing for the legal protection of information reported voluntarily for the purposes of patient safety and quality improvement.
- Creates incentives for voluntary reporting systems that are non-punitive and promote learning to help ensure medical errors will not be repeated.
- Recognizes that to be effective, these systems must engender the trust and cooperation of the health care providers
- Provides for a mechanism to share and disseminate information learned about improving patient safety
- Complements many ongoing patient safety initiatives in the public and private sector in which operational expertise is currently being developed

> "Fear of unnecessary lawsuits has had a chilling effect on the sharing and analyzing of information that could reduce errors and save lives,"
>
> *Senator Bill Frist M.D.*

8.23 University of Michigan Health System

Website: www.med.umich.edu/patientsafetytoolkit/index.htm

8.21.1 Patient Safety Toolkit

The University of Michigan Health System recognizes the importance of promoting best practices that exemplify safe and high quality patient care. In an effort to achieve this objective, *"Improving Patient Safety in Hospitals: Turning Ideas into Action"* was developed as a 'toolkit' resource for clinicians and administrative leaders responsible for strategic initiatives aimed at creating and sustaining quality of care and patient safety in hospitals. This toolkit addresses issues considered to be critical to this mission and is intended to present ways of turning patient safety ideals into practical and achievable strategies.

The toolkit is divided into the following chapters: Overview; Safety Plan; Adverse Events; Infection Prevention and Control; Safety Culture; Safety Curriculum; Medication Safety; Disclosure

The UMHS Patient Safety Toolkit is part of a larger project to disseminate 'best practices' in patient safety undertaken by the University of Michigan Health System, and supported by an educational grant from the Blue Cross Blue Shield of Michigan Foundation.

Annex 1

Grant Number: U18 HS11905
PI Name: KAPLAN, HAROLD
Project Title: Reporting Systems and Learning: Best Practices

Abstract:

The need to improve reporting of non-routine events, errors, and preventable failures in the care of patients has emerged as one of the most important and challenging opportunities for the growing movement to advance patient safety. Reporting by itself, however, is only the first step in the critical process improvement sequence of detection, analysis, interpretation, solution implementation, and reevaluation. Ideally, event reporting serves many functions in complex socio-technical systems, among them an indispensable contribution to organizational learning and continuous system improvement as well as being a mutually reinforcing component of safety culture.

This demonstration project is a consortium effort of two large, geographically and ethnically diverse, integrated healthcare delivery systems: Columbia/Cornell/New York-Presbyterian Hospital and the University of Chicago Hospitals and Healthsystem. The core of our project is a voluntary near-miss Medical Event Reporting System (MERS) and a state-mandated incident reporting system, New York Patient Occurrence Reporting and Tracking System (NYPORTS). This integrated reporting system has been implemented in New York Presbyterian Hospital and is currently being rolled out to the constituent hospitals of the New York Presbyterian Network and the University of Chicago Network.

The specific aims of this proposal are to: (1) Expand our integrated event reporting system, MERS, to facilitate reporting of errors by patients and test this novel approach encouraging safety reporting in a largely unexplored venue, the outpatient setting. (2) Test novel. generalizable, informatics methods that allow MERS to manage and support learning from large numbers of reports in an effective and efficient manner. (3) Demonstrate the value of reporting by showing its effects on patient safety, organizational culture, and economic outcomes. Moreover, we will demonstrate the added value of near miss reporting by showing how efforts to address the causes of near miss events prevent sentinel events. (4) Improve healthcare delivery processes and training using failure mode analysis. systems redesign, safety curricula, and simulation based team training linked to MERS outputs. (5) Discover what kinds of safety information models of dissemination are valued by consumers, purchasers, policy makers, providers and regulatory agencies, and explore the practical pros and cons of alternative policy strategies to develop and disseminate such information.

Fiscal Year: 2001
Department: COLUMBIA UNIVERSITY HEALTH SCIENCES
Project Start: 09/30/2001
Project End: 08/31/2005
IRG: ZHS1
www.gold.ahrq.gov/PrintView.cfm?GrantNumber=U18%20HS11905

Annex 2

Patient Safety: The role of executive management and the board in learning and improving

Author's comments: The role of executive management and, ultimately, the board in learning and improving patient safety is paramount. In the following article, Mr James B. Conway, Executive Vice President and Chief Operations Officer, Dana-Farber Cancer Institute, Boston, USA[17], offers useful insights from his own experience of having to deal, at organisational level, with the consequences of high profile adverse patient incidents. The US Veterans Affairs Gaps Centre website contains a detailed summary, including root causes, of the Betsy Lehman incident (www.gapscenter.org/Stories.asp).

In February of 1995, the Dana-Farber Cancer Institute (DFCI) made a tragic discovery; our systems had failed two patients, their families, and our staff. Medical errors had caused the death of one patient, Betsy Lehman, and significant medical interventions to another, Maureen Bateman. Since that tragedy, DFCI's journey has been one of dramatic learning, continuous improvement, and ongoing organizational transformation. An essential element of this journey has been recognizing the awesome power and responsibility of leadership to create a culture of safety. Leadership is first and foremost the Board, with medical, nursing, and administrative executives operating in a partnership led by the Board and accountable for quality and patient safety.

Boston Globe health columnist Betsy Lehman, a 39 old mother of two, died from a massive overdose of a powerful chemotherapy drug at Boston's prestigious Dana Farber Cancer Institute. This deadly error was detected by a computer records employee not a doctor. The same hospital also gave an overdose of a chemotherapy drug to another woman who is now "seriously and chronically debilitated from irreversible heart damage."
(New York Times, 27/3/95).

What does successful leadership look like? Simply, Board members and executives are, and are seen as, committed to a culture of safety, vigilant to safe practice and the reduction of harm, aware of the practice issues in their organizations, and are personally at the table when issues around safety are discussed. When the failure of our systems led to the death of Betsy Lehman, this wasn't where we were.

Ten years ago our Board Quality Improvement (QI) and Risk Management Committee was not an "important" committee, it was dominated by administration, there was a predictable agenda and discussion, and the goals was always "no waves." Today this Committee is powerful, meets five times a year for three hours each time [moving to 6 times], utilizes templated Board guided agendas, and is driven by the active engagement and interaction of trustees, executive and senior leaders, staff, and patients/family members. This interaction helps identify items for careful consideration. Committee processes are stimulating, there is no dull repetition, and it is totally transparent. If we are "worried about it" we talk about it. Accountability and responsibility is clear. From this group, and its associated processes, issues of quality, safety, and risk are routinely brought to the full Board agenda and out across the organization.

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[17] Adapted from Conway JB. *Patient Safety: Trustee and Executive Responsibilities* in *Governance Matters* Issue 7, 2004 (www.witherbys.com). Originally adapted from Conway JB. *Patient safety: it starts at the top*. Trustee 2000; 53(5):24. Adapted for use by the National Audit Office with the kind permission of James B Conway.

In our conversations with trustees of other organizations, the spectrum of activity is broad. From some we are stealing shamelessly to enable our own journey, and for others their journey is either just beginning or it hasn't begun yet. As faculty at meetings, DFCI leaders have been humbled and challenged by comments that include:

- "No one in my hospital ever talks about these issues"

- "How can a Board member drive this when they don't understand medicine?"

- "As Board members, we really don't have any sense of the number or types of errors that occur in our hospital."

- "Our hospital doesn't have these errors!"

- "Could our hospital have these types of errors?"

- "Nobody ever asked the trustees for help"

- "You wouldn't believe what happened to my son in my own organization"

- "Does it take a death…?"

- "How do you create tension for change in the absence of a high profile event?"

Most executives and trustees are painfully concerned about safety but other pressures keep them from being or appearing actively engaging in these issues. Realities of practice often don't surface to leaders to "light the fire" or create the tension for change. Leaders and specifically Trustees must become more involved in and send stronger messages about patient safety to staff, patients, and families. Suggested approaches include:

- Have a place for quality, safety, and risk at every Board meeting. Stimulate honest discussion between the Board of Trustees and executive leadership. Board members should know the numbers, the cases, actions plans, and the significant opportunities that exist for improvement. While celebration is important, focus on the gaps is crucial. Board members in manufacturing, business, and engineering can make tremendous contributions through their experience in Six Sigma, Baldrige, quality auditing, ISO Certification, and zero defect quality management. Increasingly we must think of Boards in the context of the value they can bring as apposed to a structure for reporting.

- Organize one Board meeting to be an intense "state-of-the-union" on patient safety, medical error and risk in the hospital.

- Go looking for problems. Solicit the learning from Board members, family and friends around their often-sobering experiences with care in your own institution.

- Personally and organizationally approach accreditation as if it were truly voluntary; something you really wanted to do. We have found honest assessment of practice against the JCAHO standards powerful in engaging Governance and Leadership, as well as staff, in the quality improvement and patient safety.

- Become students in patient safety; there have never been more opportunities for Trustee and executive education.

- Establish a fair and just culture [non-punitive environment] that fosters internally reporting of errors and near misses. The principles, currently used at DFCI, drew enormously from the expertise of our trustees who have done similar work in other high-risk organizations.

- When critical incidents occur, ensure that interdisciplinary meetings are held immediately with executives participating to support staff and facilitate the process

[and not to place blame]. On doing this, one CEO said she never knew how complex errors were, or how fragile systems can be, until she completed a root-cause analysis. Another said he was struck at how important his support was at these meetings to staff who were all hurting and wanted to find out what went wrong and how to fix it.

- When sentinel (serious) events occur, the Chair of the Board and/or their designee should be notified.

- Utilize tools being made available through professional associations and Coalitions to conduct honest safety assessments and have the results discussed at key leadership and Trustee meetings. Again, the understanding of gaps that exist between where you are and where you need to be can be a powerful driver of "creative tension" for the whole leadership team.

- Front line staff should be invited to meet in forums with Trustees. At those moments and many others, learn to routinely ask all staff what they are loosing sleep over or what could fail or go wrong in a new system,

- Assure that the results of key safety indicators are communicated to staff

- Engage in safety discussions and educational programs with patients, family members, consumers, and (yes) the press.

- Include articles about patient safety broadly and in your own organization in publications that go to your Board members as well as to your staff and community.

Our journey, education, and interactions with others have made it clear that the Board, CEO, and Executive Leadership must shape the vision and establish a culture of safety, set priorities and allocate resources, and hold all accountable. It is time for all trustees and executives to declare that the current state of safety in healthcare is not where we want it to be. As institutional leaders and a healthcare industry, we must accept the burden for the errors that occur within our facilities and mobilize for dramatic improvement.

Ten years after the death of Betsy Lehman we are excellent……we are not perfect. DFCI carries the burden for all the patients, family members, and staff that have suffered as a result of the failure of our systems. We all must accept responsibility to learn from these errors and harm they cause and, in the process, use their power to take us to a very different and better place. Our patients, their family members, and our staff deserve no less.