

“First, do no harm..”
Attributed to Hippocrates circa 470-360 B.C.



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WORLD ALLIANCE FOR PATIENT SAFETY

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Introduction

Today's health-care context is highly complex. Care is often delivered in a pressurized and fast-moving environment, involving a vast array of technology and, daily, many individual decisions and judgements by health-care professional staff. In such circumstances things can and do go wrong. Sometimes unintentional harm comes to a patient during a clinical procedure or as a result of a clinical decision. Errors in the process of care can result in injury. Sometimes the harm that patients experience is serious and sometimes people die.

The problem of adverse events in health care is not new. Studies as early as the 1950s and 1960s reported on adverse events, but the subject remained largely neglected. A body of evidence started to emerge in the early 1990s with the publication of the results of the Harvard Medical Practice Study in 1991 (1,2). Subsequent research in Australia (3), the United Kingdom of Great Britain and Northern Ireland (UK) (4) and the United States of America (USA) and in particular the 1999 publication *To err is human: building a safer health system* by the Institute of Medicine (5), provided further data and brought the subject to the top of the policy agenda and the forefront of public debate worldwide. Today more countries, including Canada, Denmark, the Netherlands, Sweden and other member countries of OECD, are taking a serious look at the problem. New Zealand (6,7) and Canada (8) have recently published research into adverse events in public hospitals.

Various studies have investigated the extent of adverse events (see Table 1). The Harvard study found that 4% of patients suffer some kind of harm in hospital; 70% of the adverse events result in short-lived disability, but 14% of the incidents lead to death (1,2). The Institute of Medicine (IOM) report estimated that “medical errors” cause between 44 000 and 98 000 deaths annually in hospitals in the USA — more than car accidents, breast cancer or AIDS (5). The UK Department of Health, in its 2000 report, *An organisation with a memory*, estimated that adverse events occur in around 10% of hospital admissions or about 850 000 adverse events a year (13). The Quality in Australian Health Care Study (QAHCS), released in 1995, found an adverse-event rate of 16.6% among hospital patients (3). The Hospitals for Europe's Working Party on Quality Care in Hospitals estimated, in 2000, that every tenth patient in hospitals in Europe suffers from preventable harm and adverse effects related to his or her care (14). The New Zealand and Canadian studies have also suggested relatively high rates of adverse events: around 10% (6,7,8).

Table 1. Data on adverse events in health care from several countries

Study	Study focus (date of admissions)	Number of hospital admissions	Number of adverse events	Adverse event rate (%)
USA (New York State) (Harvard Medical Practice Study) (1,2)	Acute care hospitals (1984)	30 195	1 133	3.8
USA (Utah-Colorado Study (UTCOS)) (10)	Acute care hospitals (1992)	14 565	475	3.2
USA (UTCOS) ¹ (10)	Acute care hospitals (1992)	14 565	787	5.4
Australia (Quality in Australian Health Care Study (QAHCS)) (3)	Acute care hospitals (1992)	14 179	2 353	16.6
Australia (QAHCS) ² (10)	Acute care hospitals (1992)	14 179	1 499	10.6
UK (4)	Acute care hospitals (1999-2000)	1 014	119	11.7
Denmark (12)	Acute care hospitals (1998)	1 097	176	9.0
New Zealand (6,7)	Acute care (1998)	6 579	849	12.9
Canada (8)	Acute and community hospitals (2001)	3 720	279	7.5

1. UTCOS revised using the same methodology as the Quality in Australian Health Care Study (harmonizing the four methodological discrepancies between the two studies).

2. QAHCS revised using the same methodology as UTCOS (harmonizing the four methodological discrepancies between the two studies).

Adverse events exact a high toll in financial loss as well. In the UK consequent additional hospital stays alone cost about £ 2000 million a year (13), and paid litigation claims cost the National Health Service around £ 400 million annually, in addition to an estimated potential liability of £ 2400 million for existing and expected claims (13). The total national cost of preventable adverse medical events in the USA, including lost income, disability and medical expenses, is estimated at between US\$ 17 000 million and US\$ 29 000 million annually (5). Added to these costs is the erosion of trust, confidence and satisfaction among the public and health-care providers.

The situation in developing countries and countries in economic transition merits particular attention. The poor state of infrastructure and equipment, unreliable supply and quality of drugs, shortcomings in waste management and infection control, poor performance of personnel because of low motivation or insufficient technical skills, and severe under financing



of essential operating costs of health services make the probability of adverse events much higher than in industrialized nations. World Health Organization (WHO) figures suggest that developing countries account for around 77% of all reported cases of counterfeit and substandard drugs (15). It is also reported that at least half of all medical equipment in most of these countries is unusable or only partly usable, at any given time, resulting in neglect of patients or increased risk of harm to them and to health workers (16). In the European countries that have achieved independence in recent years, about 40% of hospital beds are reported to be located in structures originally built for other purposes (17). This makes facilities for radiation protection and infection control extremely difficult to incorporate, with the result that such facilities are often either substandard or absent.

Most of the current evidence on adverse events comes from hospitals, because the risks associated with hospital care are high, strategies for improvement are better documented, and the importance of patient trust is paramount. But many adverse events occur in other health-care settings, such as physicians' offices, nursing homes, pharmacies and patients' homes. Recent literature highlights concerns about outpatients as well, but there are few data on the extent of the problem outside hospitals.

Every point in the process of care giving contains a certain inherent lack of safety: side-effects of drugs or drug combinations, hazards posed by a medical device, substandard or faulty products entering the health service, human shortcomings, or system (latent) failures. Adverse events may therefore result from problems in practice, products, procedures or systems. Immunization, which is given to healthy individuals, poses a particular challenge. With the decline in prevalence of vaccine-preventable diseases, concern about potential adverse events following immunization may have a negative impact on national immunization programmes and preventive health care in general.

Current conceptual thinking on the safety of patients places the prime responsibility for adverse events on deficiencies in system design, organization and operation rather than on individual providers or individual products. Adverse drug events in the Utah-Colorado Study in the USA (see Table 1) provide a dramatic example, 75% of them being attributable to system failures (9,10). Similarly, most adverse events are not the result of negligence or lack of training, but rather occur because of latent causes within systems.

For those who work on systems, adverse events are shaped and provoked by "upstream" systemic factors, which include the particular organization's strategy, its culture, its approach towards quality management and



risk prevention, and its capacity for learning from failures. Countermeasures based on changes in the system are therefore more productive than those that target individual practices or products.

Safety is a fundamental principle of patient care and a critical component of quality management. Its improvement demands a complex system-wide effort, involving a broad range of actions in performance improvement, environmental safety and risk management, including infection control, safe use of medicines, equipment safety, safe clinical practice and safe environment of care. It embraces nearly all health-care disciplines and actors, and thus requires a comprehensive, multifaceted approach to identifying and managing actual and potential risks to patient safety in individual services and finding broad long-term solutions for the system as a whole.

Thinking in terms of “systems” offers the greatest promise of definitive risk-reduction solutions, which place the appropriate emphasis on every component of patient safety, as opposed to solutions driven by narrower and more specific aspects of the problem, which tend to underestimate the importance of other perspectives.

Enhancing the safety of patients includes three complementary actions: preventing adverse events; making them visible; and mitigating their effects when they occur. This requires: (a) increased ability to learn from mistakes, through better reporting systems, skilful investigation of incidents and responsible sharing of data; (b) greater capacity to anticipate mistakes and probe systemic weaknesses that might lead to an adverse event; (c) identifying existing knowledge resources, within and outside the health sector; and (d) improvements in the health-care delivery system itself, so that structures are reconfigured, incentives are realigned, and quality is placed at the core of the system. In general, national programmes are built around these principles.

Despite growing interest in the safety of patients, there is still widespread lack of awareness of the problem of adverse events. Capacity for reporting, analysing and learning from experience is still seriously hampered by lack of methodological uniformity in identification and measurement, inadequate adverse event reporting schemes, undue concerns over breaches in confidentiality of data, the fear of professional liability, and weak information systems. Understanding and knowledge of the epidemiology of adverse events — frequency, causes, determinants and impact on patient outcomes, and of effective methods for preventing them — are still limited. Although there are examples of successful initiatives for reducing the incidence of adverse events, none has been expanded to the level of an entire health system.

Practices relating to quality management in health care differ from one country and culture to another. There is a need for international standardization of terminology in definition, common methods for measurement, and compatible reporting of adverse events. These could be achieved by building on WHO's experience in the methodology of international comparisons.

Answers to the following crucial questions should be sought internationally, so that best practices can be established to provide decision-makers with options when shaping their strategies:

- > What can policies and regulations governing the health-care system do to improve health-care safety?
- > How can we best create leadership, undertake research and develop tools to enhance the knowledge base about safety?
- > How can we best identify and learn from adverse events through mandatory and voluntary reporting systems?
- > What are the best mechanisms for raising standards and expectations for improvements in safety through the actions of oversight bodies, group purchasers and professional associations?
- > How do we best deal with issues related to the cost of safety measures, and possible variations in acceptable levels of risk, especially in resource-poor settings?





WHO and Patient Safety

In January 2002, the Executive Board of WHO extensively discussed the subject of patient safety and recommended a resolution to the Fifty-fifth World Health Assembly. Resolution WHA55.18, adopted by the Health Assembly in May 2002, urged Member States to pay the closest possible attention to the problem of patient safety and to establish and strengthen science-based systems necessary for improving patients' safety and the quality of health care, including the monitoring of drugs, medical equipment and technology (18). Further, it requested the Director-General to develop global norms and standards; to promote the framing of evidence-based policies and to develop mechanisms in order to recognize excellence in patient safety internationally; to encourage research on the subject; and to support Member States in several key areas.

Since then, many Member States have taken initiatives on patient safety within their own health-care systems. Many more have contacted the Organization seeking information or support in elaborating the theme of patient safety. Indeed, since the World Health Assembly resolution was adopted, more than half WHO's 192 Member States have made contact with the Organization about patient safety.

In May 2004, the Fifty-seventh World Health Assembly noted the progress in implementing Resolution WHA55.18, and the high level of participation by Member States in a technical briefing. The World Health Assembly considered a proposal to form an international alliance for improving patient safety as a global initiative.

World Alliance for Patient Safety

The creation of a world alliance for patient safety is a significant step in the quest to improve the safety of health care in all Member States. At present, no single player has the expertise, funding or research and delivery capabilities to tackle the full range of patient safety issues on a worldwide scale.

The programme set out below, which builds on the deliberations of a high-level seminar held in London in November of 2003, the discussion at the World Health Assembly in May 2004 and a meeting of expert advisers held in Dublin and chaired by Sir Liam Donaldson earlier this year, comprises six areas of action.

1

Global Patient Safety Challenge: 2005–2006



A core element of the new Alliance will be the formulation of a *Global Patient Safety Challenge*. A topic that covers a major and significant aspect of risk to patients receiving health care and which is relevant to every WHO Member State will

be identified for action over an initial two-year cycle.

The topic chosen for the first *Global Patient Safety Challenge* covering 2005 and 2006 is health-care-associated infection. Infection complicates the treatment and care of millions of patients worldwide every year. As a result, some patients become more seriously ill than they would have been otherwise, some have prolonged stays in hospital, some experience long-term disability and some die. Because of health-care-associated infection, as well as

the human costs, health-care systems carry a massive additional financial burden. The following table (Table 2) lists a number of studies that were carried out in recent years to estimate costs due to nosocomial infections.

Table 2. Studies estimating the costs of nosocomial infection

Reference	Country	Study period	Type of facility	Estimated costs
19	Netherlands	1991–2000	Ten-year survey of screening, surveillance and outbreaks at a University Medical Centre	Cost estimated at 2 800 000 Euros for eradication of methicillin-resistant staphylococcus aureus (MRSA)
20	Thailand	1988	Nationwide cross-sectional survey of all hospitals	Estimated annual costs 1000 million bahts for hospital-acquired infections in Thailand. In some hospitals the expenditure on the management of hospital-acquired infections accounted for almost 10% of the total hospital budget.
21	Trinidad and Tobago	1992–1998	Rural government hospital providing primary and tertiary care	Cost estimated at US\$ 697 000 annually for nosocomial infections
22	UK	April 1994 to May 1995	District general hospital	Infected patients on average incurred hospital costs 2.9 times higher than uninfected patients, equivalent to an additional £ 3154. At National Health Service hospitals in England it is estimated that 320 994 patients per annum acquire one or more hospital infections which present during the inpatient period, and these infections cost the hospital sector an estimated £ 930 620 million per annum.
23	USA	Review	Hospitals	Cost estimated at US\$ 558 for urinary tract infection, US\$ 2734 for surgical site infection, US\$ 3061–40 000 for bloodstream infection, US\$ 4947 for pneumonia. Hospitals lose from US\$ 583 to US\$ 4886 for each nosocomial infection.



As can be seen from Table 2 the average cost of nosocomial infections varies from country to country, depending on the type of infections prevalent in the hospitals, the infection rate and the cost of health care.

Health-care associated infection presents the main characteristics of a major patient safety problem; it affects large numbers of patients worldwide; it has multiple causes, with many factors relating to the systems and processes of care provision and others to human behaviour; it cannot be eliminated but some health-care institutions have controlled the problem and the risks to patients much better than others (there is thus a patient safety improvement gap); good data can be assembled to assess the size and nature of the problem and to create a basis for monitoring the effectiveness of action programmes.

The problem of health-care-associated infection is more serious in some countries than others and there is considerable variation in its frequency between hospitals and other health-care organizations within countries. There are also sources of risk of infection that have particular importance or significance in some parts of the world. WHO programmes already address some of these, for example:

- > unsafe injection practice;
- > transmission of HIV through unsafe health-care procedures;
- > transmission of infection by blood transfusion.

The *Global Patient Safety Challenge* will therefore be open to countries in all WHO regions even though the nature of the problem of health-care-associated infection differs between them. The challenge will also embrace existing WHO programmes on infection in so far as they have a direct bearing on patient safety.

The title of the *Global Patient Safety Challenge* for 2005 to 2006 is *Clean Care is Safer Care*. Countries will be invited to adopt this challenge for their own health-care systems with the following main principles:

- > formally assessing the scale and nature of health-care-associated infection within the health-care system;
- > adopting an internationally recognized approach to surveillance of the problems so that current baseline incidence of infection can be established and change can be monitored;
- > conducting an analysis of the root causes of the problem with particular emphasis on “systems thinking”;



- > developing solutions to improve safety and reduce risk by focusing on five action areas in particular:
 - clean hands
 - clean practices
 - clean products
 - clean environment
 - clean equipment
- > relying on evidence-based best practice in all aspects of addressing the challenge;
- > fully engaging patients and service users as well as health care professionals in improvement and action plans;
- > ensuring the sustainability of all action beyond the initial two-year *Challenge* period.

The World Alliance for Patient Safety will not be able to be directly involved with all the initiatives that countries joining the *Challenge* might want to take but will work closely with one health-care area in each WHO region. Information and experience gained from these six *Challenge* sites will be made available to all Member States who enrol for the *Clean Care is Safer Care* commitment.

2. Patient and consumer involvement



By definition, patients and consumers of health care are at the very centre of the quest to improve patient safety. When things go wrong they are the victims of the harm induced. Their plight and that of their families and carers is often compounded by the way that a serious adverse event is handled — an unwillingness to be open and honest about what happened, the absence of an apology, the lack of any ongoing counselling and support and the failure to provide an explanation of what went wrong or any reassurance that it could not happen again to somebody else.



In this respect, viewing the true needs of patients who are harmed generates an impetus for much fundamental work with patients and their representatives in order to transform the present situation.

Equally, patients and patient organizations could play a vital role in helping to identify risks and to devise solutions. Worldwide there are organizations and movements that have focused on meeting this current need, for example, “Consumers Advancing Patient Safety” in the USA and “Action against Medical Accidents” in the UK.

Moreover, there are examples of within-country patient safety programmes where the consumers’ involvement has been developed as an important strand within the overall programme, a good example of which is the “Speak Up for Patient Safety” campaign launched in the USA in 2001 by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

The World Alliance for Patient Safety represents a major opportunity to put the patient and the consumer at the centre of the international movement to improve patient safety. For all these reasons, the Alliance’s second action area will seek to mobilize and empower patients and their representatives worldwide under the theme *Patients for Patient Safety*.

This action area, which will be led by the patient safety consumer movement, will include initiatives such as the Leapfrog partnership and the Speak Up campaign. Leapfrog is a coalition of healthcare purchasers and JCAHO and is supported by Medicare and Medicaid.



The Speak Up campaign comprises the following actions by patients:

SPEAK UP

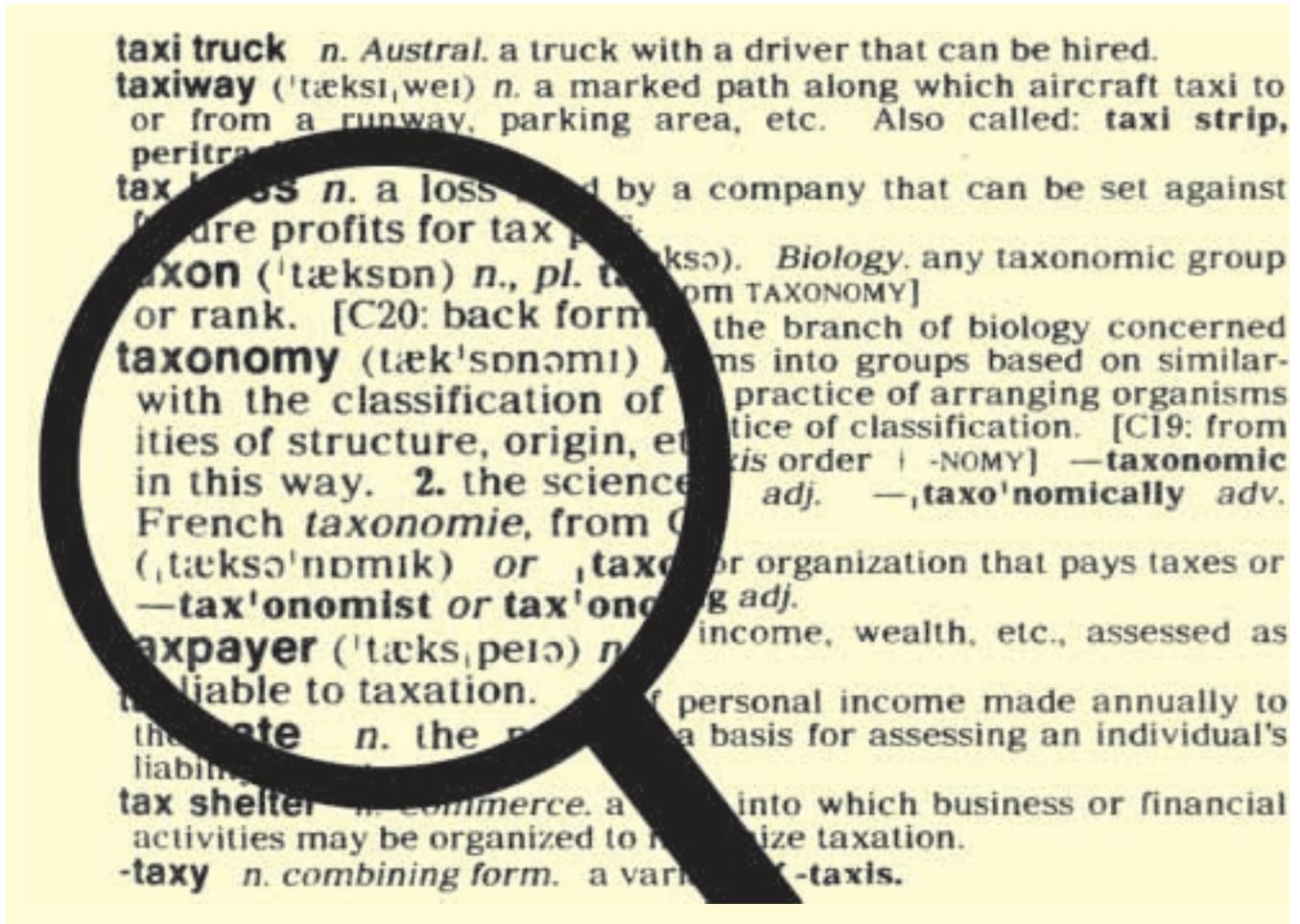
- S**peak up if you have questions or concerns: it's your right to know
- P**ay attention to the care you are receiving
- E**ducate yourself about your diagnosis, test and treatment
- A**sk a trusted family member or friend to be your advocate
- K**now what medications you take and why you take them
- U**se a health-care provider that rigorously evaluates itself against safety standards
- P**articipate in all decisions about your care.

Patients for Patient Safety will:

- > establish an inventory of patient safety and consumer advocacy initiatives currently being implemented (or at an advanced stage of planning) by governmental, educational and private organizations;
- > create routes of access for participation and information for consumers worldwide who want to contribute to the Alliance or to the patient safety movement more generally;
- > facilitate a baseline survey of consumers and providers on patient safety matters and associated cultural issues;
- > support demonstration initiatives to design and evaluate programmes for active consumer participation in programmes based in hospitals or national health systems to reduce medical errors;
- > develop model policies and guidance for engaging consumers, patients and organizations representing them in efforts to build safer health-care systems;
- > create a network of advisers from the health-care consumer movement to be available to countries that want to apply the *Patients for Patient Safety* philosophy within their national or local patient safety initiatives.

3

Developing a patient safety taxonomy



Although patient safety is now recognized as a priority for any health-care system seeking to assure and improve the quality of its care of patients, this is a relatively recent position. Safety movements in other fields, such as aviation, are longer established. As a consequence, the concepts, principles, norms, and terminology are much more advanced in some other fields of safety than in health care.

Seeking to introduce clarity, consistency, and some degree of standardization, within these fields may seem an uninteresting and bureaucratic endeavour. Yet, it is vitally important that it is prioritized for action globally. An international patient safety taxonomy has not only the potential to facilitate global monitoring and reporting of errors, adverse events and near misses but

can also contribute to the understanding of these incidents through better information on their prevalence, types, causes, severity and consequences. A taxonomy is the science, laws and principles of classification.

Without it, international or within-country comparisons of patient safety problems will have limited meaning, potential research opportunities will not be taken and the insights and analysis necessary to produce solutions will be lost.

The third Alliance action area will be a *Taxonomy for Patient Safety*. The Alliance will launch an 18-month project to develop a taxonomy for internationally acceptable patient safety data standards applicable to the collection, coding and classification of adverse events and near misses in health-care settings worldwide. This taxonomy, to be named International Patient Safety Event Taxonomy (IPSET), will serve to provide a uniform approach for linking the panoply of patient safety reporting activities undertaken in WHO Member States and to build a common information infrastructure for WHO to support initiatives to reduce medical errors and improve delivery of high-quality, safe care. The standards are being developed in order to ensure that those data most important to detecting, analysing, understanding and learning from patient safety related events are comparable across existing reporting systems.

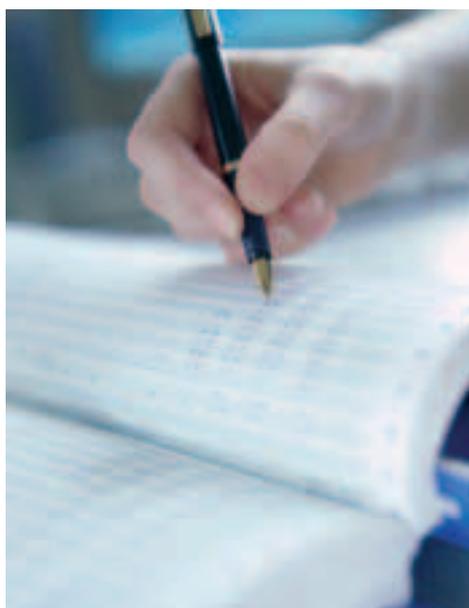


4. Research in the field of patient safety



Much of the original impetus for coordinated action on patient safety came from the publication of studies (using similar methodologies) on the level of error during the care of hospital patients.

Studies of adverse outcomes and harm to patients have been carried out for many years. As far back as 1850, Hungarian physician Ignaz Semmelweiss linked transmission of infection to poor hand hygiene, but failed to persuade his colleagues to alter their behaviour (24). In the USA at the beginning of the 20th century, Ernest Codman, a Boston surgeon, argued for the routine assessment of outcomes (25). The *Confidential Enquiry into Maternal Deaths in the UK* dates from 1952. Many other examples could be given of isolated studies into errors and iatrogenic



effects of drugs and other effects. But it was not until the 1970s that any attempt was made to provide an overview of the scale of harm and adverse outcomes. In 1977, the California medical insurance feasibility study suggested that almost 4% of patients admitted to hospital suffered some kind of adverse event (26). Ivan Illich's critique *Limits to medicine: medical nemesis, the expropriation of health* went so far as to argue that health care was in fact a major threat to health (27).

The rising rate of litigation in the 1970s and 1980s was another important stimulus to raising awareness of the problem of patient safety. In the USA and later elsewhere, this led to the development of risk-management programmes. Initially, these had an almost exclusively legal and financial focus, aimed at protecting the institutions concerned; they gradually evolved to tackle clinical issues and act as a gateway to the underlying problem of patient safety revealed by retrospective record reviews such as the Harvard Medical Practice Study (1,2). The Harvard study was initially commissioned to assess the potential for no-fault compensation in New York State, but its major legacy has been to reveal the scale of harm to patients from health care and to stimulate a number of similar studies.

The most powerful evidence of harm to patients from health-care systems comes from several retrospective reviews of case records in which clinicians assessed the presence or absence of adverse events instances of harm to patients from health-care management rather than disease. The Harvard study found that patients were unintentionally harmed by treatment in almost 4% of hospital admissions in New York State (1,2). For 70% of these patients the resulting disability was slight or temporary, but in 7% it was permanent and 14% of these patients died, partly as a result of their treatment. Serious harm, therefore, came to about 1% of patients admitted to hospital. Similar findings were reported from Colorado and Utah (9). A parallel Australian study found a 16.6% adverse events rate, where about half the cases were judged preventable, but with a similar number of serious incidents to that in the USA studies (3,11). In the UK a review of patient records indicated a 10.8% adverse events rate, again about half being preventable (4). Findings in Denmark (12), New Zealand (6,7) and Canada (8) also suggest a relatively high rate of adverse events around 10%.

The financial cost of adverse events, in terms of additional treatment and extra days in hospital, is vastly greater than the costs of litigation. In the UK the cost of preventable adverse events is estimated to be £ 1000 million per annum in lost bed days alone (4). The wider costs of lost working time, disability benefits and the wider economic consequences are greater still. There is also an enormous human cost. Many patients suffer increased pain,

disability and psychological trauma and may experience failures in their treatment as a terrible betrayal of trust. Staff may experience shame, guilt and depression after making a mistake, with litigation and complaints imposing an additional burden. Doctors or nurses whose confidence has been impaired will work less effectively and efficiently; at worst they may abandon medicine as a career. The consequences of adverse events in advanced health-care systems are therefore huge. In less-developed health-care systems they may be greater still in relation to the benefits derived from the system.

Several important new initiatives in the past five years underline the increasing attention being paid to patient safety. In the USA, organizations such as the National Patient Safety Foundation are pioneering a much more sophisticated approach to patient safety, drawing on research and practice from a number of different industries. The report of the Institute of Medicine, *To err is human: Building a safer health system*, which starkly sets out the scale of harm to patients and has an ambitious and radical agenda for change, attracted presidential backing in the USA (5). In Australia, the results of the *Quality in Australian Health Care Study* were initially marked by political interest, which influenced the implementation programme that was to follow (3). High-profile cases in several countries, such as the Bristol inquiry into paediatric cardiac surgery in the UK and the similar *Winnipeg inquiry* in Canada, also played a part in raising public awareness and driving policy change (28). In the UK, the Department of Health commissioned a major report for the National Health Service that covered similar ground to the Institute of Medicine report, which in turn has led to the creation of the National Patient Safety Agency (13). The *British Medical Journal* devoted an entire issue to the subject of medical error in a determined effort to move the subject to the mainstream of academic and clinical enquiry, and other leading journals are now running series on patient safety.

Further examples could be given of initiatives in Canada, in several European countries, and in Asia of an increasing interest in research on patient safety and practical approaches to the management of risk. As awareness of the international nature of the problem has grown, other countries have moved more quickly towards action. Japan's patient safety programme was triggered by a single major incident, although this was thought to be symptomatic of more widespread problems.

Research has not been limited to establishing the prevalence of adverse events or medical errors within health-care systems. A comprehensive research strategy (later calling for research proposals) was published by



the Agency for Health Care Research and Quality (AHRQ) highlighting a number of priorities for research into patient safety.

The AHRQ agenda now states that we need more information in topics such as:

- > the epidemiology of errors, for instance the types and rates of errors in different health-care settings;
- > the infrastructure to improve patient safety, for example the analytic capacity and organizational culture required;
- > information systems, for instance development of common definitions of a reporting system and how to evaluate its success;
- > knowledge about which interventions should be adopted and how to encourage adoption of patient safety practices.

The importance of research in understanding the problem of patient safety as well as developing solutions cannot be underestimated. The fourth action area for the Alliance therefore will be *Research for Patient Safety*.

A research-needs strategy will be produced by the Alliance, drawing on existing strategies with the aim of identifying the major gaps in evidence and knowledge in relation to patient safety. This will serve as a guide to researchers, research funding bodies and generally will stimulate the growth of research interest and research studies in this important field.

Recent baseline studies of the prevalence of medical errors or adverse events have been referred to. It could be argued that there is no further need for such studies given that several authoritative publications have now identified the size of the problem within a range of prevalence estimates. There are two important reasons for continuing with such studies. Firstly, they have been shown to provide the mandate and commitment for action on patient safety within a country and a health-care system. Although policy-makers or practitioners can stay within a “comfort zone” if studies have been undertaken elsewhere, they cannot do so if a valid study shows that their system shares in the problem. Secondly, there has been much less work to establish the scale and the nature of patient safety problems in developing countries.

For these reasons, the Alliance will coordinate and commission prevalence studies of medical errors and adverse events in 13 developing and transitional countries as well as producing a methodological tool kit for countries or providers who want to conduct their own baseline surveys, confident that they will be doing so using internationally-developed and high-quality research methodologies.

5

Solutions to reduce the risks of health care and improve its safety



MEDICATION ALERT!

Oral potassium chloride salt for oral use given inappropriately

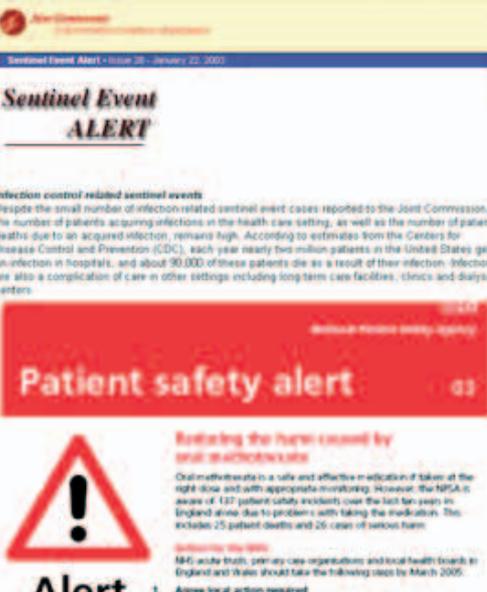
Sentinel Event ALERT

Alert

25 January 2004

Alert

25 January 2004



Patient safety alert

Alert

23 September 2003

Patient safety alert

Alert

25 July 2004



Patient safety alert

Alert

23 September 2003

Patient safety alert

Alert

25 July 2004

Safer practice notice

Notice

20 May 2004

Issue 1

The most important knowledge in the field of patient safety is how to prevent harm to patients.

The belief that one day it may be possible for the bad experience of a patient in one place to be the source of transmitted learning that benefits future patients in many countries of the world is a powerful element of the Alliance's vision. A first step to turning such a vision into reality is to ensure that interventions and actions that have solved patient safety problems in one area are made widely available in a form that is accessible and understandable and where the basis for replicating the success is made clear.

6 Reporting and learning to improve patient safety



A major element of programmes to improve patient safety is having the capacity and capability to capture comprehensive information on adverse events, errors and near-misses so that it can be used as a source of learning and as the basis for preventive action in the future.

If an event and the results of any analysis are not acted on locally where they occurred, then the lessons cannot be learned more widely, the opportunity to generalize the problem is lost and the capability to produce powerful and more widely applicable solutions will not be realised.

Several reporting systems have been developed around the world. They vary in their nature, scope and complexity. Some are open-ended and

Countries that have developed or are considering implementing reporting systems:

Australia, Azerbaijan, Canada, Cook Islands, Czech Republic, Denmark, Fiji, France, Gambia, Germany, Japan, Lebanon, Iran, Ireland, Myanmar, Mongolia, Namibia, the Netherlands, Niue, Malawi, Oman, the Philippines, Poland, Samoa, Saudi Arabia, Seychelles, Slovenia, South Africa, Sri Lanka, Sweden, Switzerland, Thailand, Tonga, Uganda, United Kingdom, United States of America, Viet Nam, Zimbabwe.



attempt to capture adverse events and near-misses along the entire spectrum of care delivery. Others focus on particular types of adverse events or on technologies or process of care where errors and adverse events can occur (e.g. medical devices, blood transfusion, medication use).

The primary purpose of reporting systems is to learn from experience. It is important to note that reporting in itself does not improve safety. It is the response to reports that leads to change. Within a health-care institution, the reporting of a serious event or serious near-miss should trigger an in-depth investigation to identify underlying systems failures and lead to efforts to redesign the systems to prevent recurrence.

In a state or national system, expert analyses of reports and dissemination of lessons learned are required if reports are to influence safety. Merely collecting data contributes little to the advancement of patient safety. Even monitoring for trends requires considerable expert analysis and oversight of the reported data.

The important point is that a reporting system must produce a visible, useful response by the recipient to justify the resources expended in reporting, or, for that matter, to stimulate individuals or institutions to report. The response system is more important than the reporting system.

Reporting can lead in several ways to learning and improved safety. Firstly, it can generate alerts regarding significant new hazards (e.g. complications of a new drug). Secondly, lessons learned by hospitals from investigating a serious event can be disseminated. Thirdly, analysis of many reports by the receiving agency can reveal unrecognized trends and hazards requiring attention. Finally, analysis of multiple reports can lead to insights into underlying systems failures and generate recommendations for “best practices” for all to follow.

The sixth Alliance theme will be *Reporting and Learning*. The Alliance will develop best-practice guidelines that can be used to facilitate the development of new reporting systems to improve patient safety and to improve existing reporting systems. The core principles underlying the guideline development will be:

- > the fundamental role of reporting systems is to enhance safety by learning from failures, i.e. errors and injuries caused by medical treatment;
- > reporting must be safe, individuals who report incidents must not be punished or suffer other consequences;
- > reporting is only of value if it leads to a constructive response. At a minimum, this entails feedback of findings from data analysis. Ideally, it also includes recommendations for changes in processes and systems of health care;

- > meaningful analysis of, learning from, and dissemination of lessons learnt from reports require expertise and other human and financial resources. The agency that receives reports must be able to influence solutions, disseminate information and make recommendations for changes.

The Alliance will also work with governments and agencies that have established reporting systems to facilitate finding and interpreting international data for early detection of potential problems and sharing of results to ensure that solutions can be developed.



Governance and programme support



The World Alliance for Patient Safety will be a “WHO Alliance” and its secretariat, to be based in WHO headquarters, will be managed by the WHO Patient Safety Programme.

The Alliance will have several advisory committees which will assist in designing, planning and monitoring the implementation of its action areas/work programmes. The committees will take advice from stakeholders and will have appropriate membership to ensure expertise from all parts of the world.

Each Alliance programme will have a detailed project plan with specific objectives to be achieved within a specified timescale. It is likely that all the programmes will have a “lead” body that will be supported by the secretariat. The secretariat will closely monitor the delivery of each programme and will ensure that progress is communicated to the wider stakeholder group using the WHO web site.

The Alliance funding will be allocated through WHO, either from WHO regular budget or extrabudgetary sources.

The Alliance will hold an annual Alliance Day — an opportunity to review progress made and to discuss proposals for new programmes. The meeting, which will be held in a different WHO region each year, will also highlight patient safety challenges and advances in countries in the host region.

The Alliance will use the new site on patient safety within the main WHO web site — **www.who.int/patientsafety** — as its main vehicle to support international communication.



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