

Patient Safety: Rapid Assessment Methods for Estimating Hazards

Report of the WHO Working Group meeting

Geneva, 17-19 December 2002



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Introduction

The increasing incidence of documented cases of adverse events in health care has led to growing concern in a number of countries about patient safety, which remains a fundamental principle of patient care and a critical component of quality management. The World Health Organization (WHO) has identified the need for a concerted international effort with a broad system perspective in which it plays a proactive leadership role. WHO sees patient safety as a major challenge for quality improvement and enhancing provider performance. (See Annex 1 for a background document on the subject). Resolution WHA55.18 of the World Health Assembly held in May 2000 confirms this, and calls on the Organization to carry out activities aimed at improving patient safety and quality of care. (See Annex 3 for the full text of the resolution). As part of its response to the mandate given by the World Health Assembly in resolution WHA55.18, WHO is committed to making patient safety a high priority on the policy agenda of countries. As an important step in this process, the Department of Health Service Provision convened an international Working Group meeting on this subject in Geneva, on 17–19 December 2002.

Objectives of the Working Group

The purpose of the meeting was to provide guidance and input towards the development of rapid assessment methodologies for estimating harm caused by the health care system. Particular attention was to be given to the development of tools for use in data-poor environments. A balance was to be sought between robustness of scientific method and the need for urgent assessment and action on vital patient safety issues. This report and the recommendations of the Working Group meeting were to be targeted at policy and decision-makers, at national and international level, who are not necessarily experts in the field of patient safety. It was also expected that the Working Group meeting would contribute to the preparation of a memorandum on strategic and programmatic orientations for international action on estimating harm to patients, as well as providing inputs for updating the WHO work programme on patient safety.

The primary objectives of the Working Group meeting, as initially set out, were as follows:

- To discuss opportunities and challenges for health care systems that arise from the World Health Assembly resolution on quality of care and patient safety, with particular focus on implications for countries at various stages of development.
- To identify, for further development, rapid assessment methodologies and tools for estimating the extent of hazards caused by the health care system, that can be used in data poor environments.
- To identify sources of data for use with the methodologies and tools.

- To propose pilot countries for studies, using the methodologies, in the following WHO epidemiologic regions¹: 1-2, 4-7 and 9-17.
- To identify gaps in the evidence base and in national and international capacity that urgently need to be filled in order to address priority problems comprehensively and coherently to enable health systems in countries to better plan and implement hazards analyses.
- To exchange various related experiences from different perspectives represented at the Working Group meeting.

While the members of the Working Group accepted these objectives as important, there was a strong view that it was vital, even at this early stage, to set out a vision of safe health care and to link assessment of hazards clearly to action on patient safety. The section on “Enhancing patient safety” provides this broader context.

Approach taken by the Working Group

The meeting brought together 14 experts from nine countries, as well as WHO staff working on various aspects of patient safety: product safety, safety of services and systemic aspects. The following served as officials of the meeting:

Chairman: Dr James Bagian, Director, National Center for Patient Safety, US Department of Veterans Affairs, Ann Arbor, USA

Rapporteurs: Professor Charles Vincent, Smith and Nephew Foundation Professor of Clinical Safety Research, Department of Surgical Oncology and Technology, Imperial College, London, United Kingdom

Dr Peter Mack, Department of Surgery, Singapore General Hospital, Singapore

Secretary: Professor Yunkap Kwankam, Scientist, Department of Health Service Provision, World Health Organization, Geneva, Switzerland

Presentations were made by Dr Christopher Murray, Executive Director, Cluster on Evidence and Information for Policy, WHO, on “The WHO initiative on patient safety”, which provided the broader context for patient safety within the overall programme of WHO. Professor Charles Vincent introduced the background paper for the meeting, which covered the development of patient safety and presented a preliminary list of methods for assessing harm to patients, with comments on the strengths and limitations of specific methodologies. The Working Group reviewed the objectives of the meeting and the progress of patient safety worldwide. A consensus position was established—described below—on the necessary foundations for action on patient safety, the stages of work required and the broad aims of any such endeavour.

¹ *The Global Burden of Disease 2000 project: aims, methods and data sources. Global Programme on Evidence for Health Policy Discussion Paper No. 36.* Geneva, World Health Organization, 2001 [http://www3.who.int/whosis/burden/papers/discussion_papers.cfm?path=evidence,burden,burden_papers&language=english].

Sessions on the second day were devoted to an examination of specific methodologies. The Working Group discussed a range of methodologies for studying adverse events, but focused on those for raising awareness and assessing the nature and scale of harm. Those primarily aimed at assessing the causes of harm and establishing and implementing methods of prevention are at least equally important, but lay outside the immediate objectives of this meeting. To facilitate discussion, and to provide a useful framework to countries proposing to assess the nature and scale of harm, each methodology was assessed on a number of indices. In the final sessions, a draft outline of this publication and draft conclusions of the meeting were agreed upon.

Background: the Development of Patient Safety

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. In the United States at the beginning of the 20th century, Ernest Codman, a Boston surgeon, argued for the routine assessment of outcomes. The Confidential Enquiry into Maternal Deaths in the United Kingdom dates from 1952. Many other examples could be given of isolated studies into errors and iatrogenic effects of drugs and other effects. But not until the 1970s was any attempt made to provide an overview of the scale of harm and adverse outcomes. In 1974 the California medical insurance feasibility study (1) suggested that almost 4% of patients admitted to hospital suffered some kind of adverse event. Ivan Illich's critique *Limits to medicine: medical nemesis, the expropriation of health* (2) went so far as to argue that health care was in fact a major threat to health.

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 United States, 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 address clinical issues and act as a gateway to the underlying problem of patient safety ultimately revealed by retrospective record reviews such as the Harvard Medical Practice Study (3). 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 admissions in New York State. 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 (4). A parallel Australian study (5) found a 16.6% adverse events rate, where about half the cases were judged preventable, but with a number of serious incidents similar to the United States studies. In the United Kingdom, a review of patient records indicated a 10.8% adverse events rate, again about half being preventable (6). Emerging findings in Denmark and New Zealand also suggest a relatively high rate of adverse events—around 10%. Similar studies are under way in Canada and Singapore.

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 Britain the cost of preventable adverse events is one thousand million pounds sterling per annum in lost bed days alone (6). The wider costs of lost working time, disability benefits and the wider economic consequences are greater still. There is also an enormous human cost (7). 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 last five years underline the increasing attention paid to patient safety. In the United States, 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 recent report of the Institute of Medicine, *To err is human: Building a safer health system*, (8) which starkly sets out the scale of harm to patients and an ambitious and radical agenda for change, attracted presidential backing in the United States. In Australia the results of the *Quality in Australian Health Care Study* (5) were initially marred by political interference, setting back the implementation programme that was to follow. High-profile cases in several countries, such as the Bristol inquiry into paediatric cardiac surgery in the United Kingdom and the similar Winnipeg inquiry in Canada, also played a part in raising public awareness and driving policy change (9). But major initiatives are now under way at both a federal and national level. In England the Department of Health commissioned a major report on the National Health Service (10) that covered similar ground to the Institute of Medicine report, which in turn has led to the creation of the National Patient Safety Agency. The *British Medical Journal* devoted an entire issue to the subject of medical error (11) 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.

The context of patient safety

Patient safety, as the preceding section shows, has distinctive intellectual roots and has been driven by somewhat different imperatives than the wider movement to improve the overall quality of health care. In practice, risk management and patient safety initiatives in health care organizations have seldom been integrated with broader quality programmes, leading to a confused and diffuse strategy for improvement of service provision. In the WHO framework, however, patient safety is properly seen as a critical component of quality, which is in turn set in the still broader context of provision of health services.

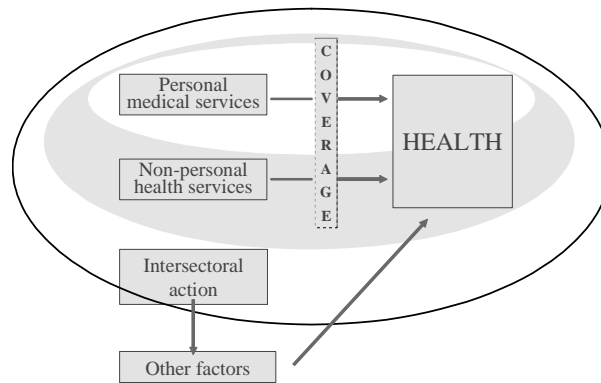


Figure 1: Relationship between Coverage and outcomes

In the WHO framework, effective health coverage is the probability of an individual’s receiving health gain if needed, which is influenced by a range of clinical, economic, political and other factors (Fig. 1). In this framework, quality of care is defined as the proportion of potential health gain actually delivered by a health care organization to its set of patients. Potential health gain may not be realized for a variety of quality problems, such as inequity of provision, lack of access to care, inefficiency and unsafe, perhaps harmful, health care. The extent to which poor quality is due to safety-related problems is currently unknown and remains to be quantified.

The construct of patient safety

Critical component of quality as defined by WHO

System design: systemic factors that contribute to safety

Product safety: drugs, devices, vaccines, and other biologicals

Safety of services: inpatient and outpatient medical practices, non-personal services

Safe environment of care: facilities, waste management, environmental considerations

Box 1: The construct of patient safety

Enhancing patient safety

A completely safe health care system is an ideal that may never be realized but it nevertheless provides a vision and expands our view of what might be achieved. In practice, progress is likely to come from a sustained attack on major sources of harm to patients and a gradual reduction in the level of hazards and instances of actual harm. This process can be helpfully divided into a number of stages which describe the actions required, and may also be used to assess the stage of development of a country or institution in the area of patient safety. These stages are all necessary

and may proceed concurrently. For instance, a programme to reduce an immediately identified problem of nosocomial infection may proceed in parallel with a project to assess the overall scale of harm to patients within a country.

Raising awareness

Drawing attention to the harm caused by health care systems, or to the potential for harm, provides a receptive context for further studies and action on patient safety. Unless both policy-makers and clinicians are convinced that patient safety is a problem, progress in patient safety will not be sustained or effective. A fundamental question applicable to any environment and any health care system is: “What risks does this system pose to the people it is intended to help?” Collecting data on these issues should serve to make all stakeholders realize that reported hazardous situations are not isolated, but are probably more general and widespread.

Assessing the nature and scale of harm to patients

Planning and prioritizing effective safety interventions requires, as does any public health problem, a thorough understanding of the nature of the problem. Countries must assess both the overall burden on the population and the health care system of harm to patients in order to guide policy. At the clinical level, understanding the specific problems particular to each speciality is necessary for effective intervention. In all cases, data collection is not an end in itself but a necessary prelude to effective action and need not delay action on immediate and obvious local problems. An example given in the meeting was of high mortality arising from the inappropriate use of bolus doses of insulin in the treatment of diabetes and the urgent need for education and training to correct a widespread misunderstanding among health care workers about the delivery of insulin.

Understanding the causes of harm

The causes of adverse outcomes, therefore, must be understood. These may vary widely according to the country, the health care system, and the treatment or procedure in question. In some instances, causes may be immediately apparent, while in others sophisticated methodologies may need to be employed.

Developing and testing methods of prevention

Methods of prevention will depend on the nature of the problem identified and the health care system in which the problem occurs. Developed health care systems, with highly trained staff, have looked to high-risk safety-critical industries for models of safety enhancement, with a consequent emphasis on technological solutions and standardization of complex processes. In contrast, the WHO injection safety programme has achieved profound changes through a focus on education, attitude change and public information, combined with relatively simple adjustments to syringe design to render them unusable after a single injection. While some methods with clear-cut benefits can be introduced immediately, others will require piloting and evaluation.

Developing and running ongoing safety programmes

Few health care systems have yet developed effective, ongoing safety programmes that aim both to monitor and to react to safety issues and proactively assess potential risks and hazards. Incident monitoring systems are now relatively common in a number of OECD countries, but seldom

systematically linked to action at the clinical level. For many countries such a system may now seem an impossible ideal, but it is nevertheless important to maintain this vision. Local champions may establish exemplar systems that can guide to, and stimulate wider initiatives.

Methodologies for studying adverse events in health care

Many different methodologies are available for studying adverse events, and they all have their respective strengths and limitations. Discussions of appropriate methodology in this area are frequently marred by a simplistic attempt to identify the “best” method, as if only one type of study were needed. This is most frequently seen in arguments about the value of the major retrospective reviews, sometimes criticized for not providing data on human factors and other key issues not identified in medical records. In fact, such studies are not intended to provide such information. Their primary purpose is to assess the nature and scale of harm, although recent review techniques also suggest that valuable information on cause and prevention can be extracted. The key point is that the appropriate methodology will depend, as it usually does, on the questions being addressed, the resources available and the context of the study.

The Working Group discussed a range of methodologies for studying adverse events, but focused on those for raising awareness and assessing the nature and scale of harm. Those primarily aimed at assessing the causes of harm and establishing and implementing methods of prevention are at least as important, but lay outside the immediate objectives of this meeting. The list of methods is presented in Table 1, together with an indication of whether they are primarily useful for raising awareness or for scoping the nature and scale of harm. Some of the methods—media attention, for instance—obviously do not constitute formal studies but have nevertheless been important in driving patient safety. Patient safety initiatives in Japan, for example, were triggered by public and media reaction to an incident at Yokohama hospital in which surgery was carried out on the wrong patient. High-profile cases in many countries have been similarly influential.

To facilitate discussion and to provide a useful framework to countries proposing to assess the nature and scale of harm, each methodology was assessed on a number of indices:

- Effectiveness in capturing the extent of harm (in different environments)
- Suitability for large-scale or small repeated studies
- Availability of reliable data
- Costs (financial, human resources, time and burden on system)
- Effectiveness in influencing policy
- Effectiveness in influencing hospital and local safety procedures and outcome
- Synergy with other domains of quality of care.

The major methodologies were all ranked (high, medium or low) on each of the criteria to produce a summary of the key strengths and limitations of each approach. Each approach was considered in relation to information-rich environments and those in which data may be scarce or unreliable, and in relation to urban, rural and home environments. The methods reviewed have widely differing purposes, strengths and limitations and we do not pretend that a simple ranking on each criterion

gives an adequate picture of each approach. Nevertheless, the list of methodologies and the illustrative ranking on the criteria provided a starting point for assessing the nature and scale of harm and for action on patient safety, in that they facilitated identification of appropriate methodologies from among available alternatives. The resultant matrix is not shown in the report as it was primarily a working document, but the principal conclusions are encapsulated in the discussion of specific methods.

Table I: Studies and data sources for raising awareness and assessing the nature and scale of harm to patients

<p>Raising awareness</p> <p><i>General awareness</i></p> <ul style="list-style-type: none"> Major government reports Patient safety literature Adverse events review studies WHO programmes <p><i>Local awareness at country level</i></p> <ul style="list-style-type: none"> Awareness of international attention to patient safety High-profile cases/media attention Litigation and complaints Existing research and data sources relevant to adverse events <p>Assessing the nature and scale of harm</p> <p><i>Studies with record or document review as a central component</i></p> <ul style="list-style-type: none"> Retrospective record review Confidential enquiries Studies of error rates Litigation and complaints data <p><i>Studies with data gathered actively from health care professionals as a central component</i></p> <ul style="list-style-type: none"> Prospective record review combined with interviews Cross-sectional surveys <p><i>Observational studies</i></p> <p><i>Analysis of routinely collected and existing data</i></p> <ul style="list-style-type: none"> Mortality and morbidity meetings Autopsies and coroners' reports Variation registers Clinical and technology audit, quality assurance programmes International Classification of Diseases (ICD) codes Insurance data <p><i>Reporting systems</i></p> <ul style="list-style-type: none"> External to organization Internal to organization Professional (e.g. speciality-led) <p><i>Key informants methods</i></p> <ul style="list-style-type: none"> Interview (individual and focus groups) Self-administered questionnaire to professionals

An important proviso should be made about the list of methods considered here. A number of important methodologies for studying adverse events, such as human factors analyses and case studies, are not discussed in this document. This is simply because the objectives of our working group were to consider methods of raising awareness and scoping the scale of harm. For this reason methods that are primarily applicable to the understanding of causes or the development and evaluation of methods of prevention are not considered here. It is equally important to note that the methods discussed may provide information on causes and potential methods of prevention in addition to their use in scoping the nature and scale of harm.

The importance of context and infrastructure

A key objective for the Working Group was to provide guidance on methodologies appropriate for assessing the nature and scale of harm in developing countries and data-poor environments. In most countries there is a particular need to estimate adverse events outside of acute-care hospitals because of the volume of health care provided in other types of services. So far only two studies have examined adverse events in primary care and it is possible that these events may be even more prevalent than in the acute setting (12-14). For the majority of populations, hospitals are the least frequently used component of formal health systems (15). The home may also merit attention, as 70%-90% of all interventions occur in there (16).

The need to assess the scale of harm outside the hospital and in data-poor environments suggests that record review can be only one component of a broader strategy. The choice of methods will depend, as always, on the questions addressed and methodological criteria. But it is also necessary to consider the context in which data collection takes place, as this will place limitations on the methods employed and on the feasibility of patient safety interventions. For instance, in South Africa urban communities and some rural communities have a well-organized health care infrastructure that makes effective use of outreach clinics, but other rural areas have only basic organization and infrastructure. Without some basic infrastructure the delivery of health care, and in consequence the assessment of its safety, is much more difficult and the use of complex or costly methods of data collection may not be feasible. But this does not imply that safety is any less important in an impoverished health care system; indeed, it may assume an even greater importance.

The choice of method of data collection must, therefore, take a number of contextual factors into account. These include: the degree of basic organization and infrastructure; where the majority of care is provided (hospital, clinic or in the home); the level of training of health care workers and their familiarity and attitude to the collection of data and assessment of quality; and the range of clinical activities undertaken.

Even in the poorest environments and the least-developed health care systems some assessment of harm from the system can be made. Interviews with patients and health care workers, and observation and self-assessment by health care workers are all feasible in the most basic systems. But any system of data collection will have some basic requirements, such as a clearly designed method and definitions, training of observers or assessors, methodological supervision during data collection and some approach to validation of the data collected. Many WHO programmes could provide models for data collection in these circumstances.

Comparing methodologies to assess the incidence of harm

In this section we provide more detailed commentary on some of the principal methods for assessing the incidence of harm. These comments are not intended to be an exhaustive list of possibilities or to provide a complete overview of the respective methodologies. They do, however, point to the range of methods available and give some indication of their respective strengths, limitations, and adaptability to different contexts.

Retrospective and prospective case record reviews

Retrospective record reviews provide a good indication of the nature, incidence and economic impact of adverse events; are carried out by external, independent assessors; and use a relatively standardized method of recording. Their primary purpose is epidemiological in that case record review can never provide the same level of detail as interviews or observation. Detailed observational studies may also reveal higher levels of adverse events (17). Nevertheless, recent case review methods can potentially provide richer information on causes and methods of prevention than has hitherto been the case.

A recent French study (18) has found that a prospective method, based on data actively gathered from doctors and nurses by external investigators periodically visiting the unit, is more effective at identifying preventable adverse events, has greater reliability for identifying adverse events and has higher face validity. The cost of this method was approximately 20% higher than standard record review, but potentially brings richer and more valid data. This method could be useful for a better understanding of the causes of harm, as well as its nature and incidence.

The main drawback of such studies, at least on a national level, is that they are time-consuming and expensive. Given that a number of national studies have now been completed (for example, in Australia, Denmark, New Zealand, the United Kingdom and the USA) or are under way (in Canada and France, for instance), the justification for further studies should be carefully considered. They would be warranted if they provided details on the particular types of adverse events, their causes and economic impact, over and above national incidence rates.

In addition, medical record review is unlikely to be useful in its present form in data-poor environments. Record review requires accurate and complete hospital records, as such studies are predicated on the availability of data of good quality. In most developing countries, however, the likelihood of obtaining complete and accurate records is low. This is particularly true outside acute-care facilities. Also, the volume of care provided through acute-care facilities is significantly less than is provided through primary care services, especially in developing countries where large sections of the populations may live their entire lives without ever visiting an acute care facility.

Cross sectional surveys

Where formal record review is not practical, cross-sectional surveys may be of value. In this approach, data are actively gathered from health care professionals by external investigators on a given day. This epidemiological method is commonly used for specific risks such as nosocomial infections or drug-related adverse events. In relation to the detection of adverse events it shares some of the advantages of retrospective and prospective reviews, in that data collection is systematic

and well defined. The approach is less costly, but experience in France suggests that it has lower validity than the review methods (18). If human resources are available, cross-sectional studies may offer additional advantages since local assessors would be trained during the survey—competence transfer—and therefore would have some experience in implementing effective follow-up actions. Finally, this method contributes to raising the awareness of the professionals and the health care organizations participating in the survey about patient safety issues.

Observational studies

Observational methods potentially offer a more rigorous and robust approach without many of the biases associated with retrospective review. However, such studies are very expensive—even more so than retrospective reviews—in terms of both the resources and the expertise required. To make an overall, aggregate assessment of adverse events with an observational methodology would mean tracking thousands of patients through a health care system, which would be massively resource-intensive. It is therefore unlikely that aggregate epidemiological data will be obtained by this means. But observational studies do offer great promise in the analysis of specific types of procedure (e.g. surgery) that are relatively well-specified and of reasonably brief duration.

Use of routinely collected or existing data

Many WHO programmes collect information of relevance to patient safety. For example, the injection safety initiative, now coordinated by the Department of Essential Health Technologies, addresses a fundamental patient safety issue and could provide both incidence data and experience with intervention programmes. Many of the quality indicators used in quality-improvement programmes, as well as those proposed for provider performance assessment by WHO's Department of Human Resources for Health (HRH), deal with safety issues.

At both national and local level, countries also collect data that, while they may not be true incidence or prevalence data, at least indicate problem areas and the likely scale of harm to patients. Such data include reports of claims and complaints, rates of hospital-acquired infection, and complication rates in surgery. Many other potential sources could provide a starting point for reviews of patient safety data and activities.

The utility of this approach depends very much on whether the data collected truly reflect the underlying level of harm. The Working Group rated this approach as low in identifying harm, both because much of these data are collected for other purposes and because of the low reliability of much routinely collected information. Such systems are also resource-intensive, although this may not be important if a patient safety programme is simply making use of an existing system.

Reporting systems

Although reporting systems are not formal studies, and so are not reviewed in the matrix, they are central to many patient-safety initiatives and are potentially important sources of information. Their strengths and limitations need to be understood, however.

Many countries already operate reporting systems for one or more of the following: adverse effects of drugs, problems with medical devices, the safety of blood products, and other matters. In response to concerns about patient safety, new reporting systems have been initiated that are

intended to cover a much wider range of adverse outcomes, errors and near-misses. These may operate at national level (e.g. the Australian Incidence Monitoring System, National Patient Safety Agency in the United Kingdom, the Joint Commission on Accreditation of Healthcare Organizations) or at local level (risk-management systems in hospitals). Sophisticated systems have also been established to investigate and understand a variety of specific issues, such as transfusion problems or safety in intensive care. Some of the more sophisticated systems now involve an examination of human factors and detailed information on the causes of adverse events.

Reporting systems can provide warnings, point to important problems and provide some understanding of causes. They serve an important function in raising awareness and enhancing safety. The results of reporting are often misunderstood, however, in that the results are held to be a true reflection of the underlying rate of errors and adverse events. The reality is that underreporting is the norm in all areas. This does not necessarily affect the usefulness of the systems as long as it is clearly understood, although it does limit the usefulness of these data for assessing incidence. Further problems are that some classes of incidents (e.g. unusual ones, or ones with a severe outcome) may be more frequently reported than common, yet important, minor issues.

Key informants methods

If few resources are available, however, and records are poor, it may well be valuable to begin with a less rigorous, opportunistic survey specifically aimed at drawing up a list of potential and actual hazards. A key objective of such a preliminary scoping exercise would, of course, be to identify potential methods and data sources for estimating the scale of hazards from the health care system in question. Surveys may use structured interviews with individual patients or health care workers, either individually or in groups, or questionnaires to clinicians or managers of health care organizations. Surveys of this kind may not achieve the rigour of a full-scale formal study, but may nevertheless identify the major sources of harm in a variety of environments at moderate cost in both time and resources.

Recommendations of the Working Group

The Working Group proposed a broad strategy for action on patient safety activities by WHO and by countries. While the aim of WHO is to stimulate action on patient safety worldwide, the Group considered that experience with other WHO programmes suggested this was best achieved in the first instance by selecting a number of pilot countries for assessment of the extent of hazards. Preference would be given to those that have so far undertaken little work on patient safety but have sufficient local organization and leadership to make data collection and subsequent action feasible.

The strategy for assessment of incidence, nature and impact of adverse outcomes will, of course, vary from region to region. Strategies will also vary in their range and depth of enquiry, their cost and the precise nature of the questions posed. However, the Working Group proposed some broad steps that should be applicable to any country.

Initial action by WHO

- Review of data on incidence of harm, available from existing WHO programmes and other WHO sources. This information may come from a number of different programmes previously thought of as largely separate. Patient safety will be the unifying theme and umbrella concept for all sources of harm from health care. (See Annex 4 for an initial description of potential sources of information.)
- Identification of quality improvement methodologies that could be applied to resolve issues of patient safety.
- Identification of selected countries outside the three WHO epidemiologic regions where some countries have already initiated national patient safety programmes (Region 3 (AMRO A), Region 8 (EURO A) and Region 14 (WPRO A)). The countries selected would:
 - be representative of the regions;
 - have good data availability or potential for collection of reliable data;
 - have sufficient infrastructure to initiate activities;
 - have potential for policy level action and change in safety practices.
- Identification of local champions to lead and pioneer patient safety initiatives
- Identification of existing patient safety initiatives in the selected countries. An important first step is to commission a review of what information is already available in each of these countries, in terms of studies, data and information on the subject of patient safety.
- Identification of ways in which countries might build on existing activities, such as injection and product safety, and identifying ways of creating synergies with these activities. This would ensure that WHO initiatives built on existing activities and were complementary to them.
- Preparation of a resource pack of literature and specific tools and techniques to enable countries to initiate patient safety activities.
- Collection of patient-safety “success stories” from a range of different countries and contexts to stimulate further action and provide direction to countries with less-developed patient safety programmes.

Action by selected countries

Review of data already available in the country that pertain to patient-safety issues. Possible sources include:

- Reporting systems for drugs, medical devices and other safety issues.
- Complaints, claims and media coverage of adverse health care outcomes.
- Government or agency reports.
- Studies of specific kinds of error and adverse outcome.
- Review the extent and quality of routine health care information and potential for extracting information relevant to the detection and assessment of adverse outcomes

- Identification of areas of actual or potential harm to patients where solutions are known and programmes of prevention can be piloted with a view to being widely implemented.
- Identification of areas in which further information is needed on the nature and scale of harm. Carrying out scoping studies, employing methods recommended by WHO, and selecting those appropriate to the local context.
- Consideration of the value and potential for formal studies to assess the overall nature and incidence of adverse events (e.g. record review), the causes of such events and the development of effective methods of prevention.

Longer-term action by WHO

- Expanding the pilot activities to stimulate action on patient safety in all WHO Member States. WHO should, where possible, empower countries to carry out patient-safety studies and programmes themselves. This would create local ownership and good prospects for subsequent development of programmes to enhance safety.
- Develop a standardized methodology for estimating the extent to which the health care system causes hazards to the clients it serves.
- Development of an international common understanding and terminology for patient safety work. There is clearly potential for confusion and a need for clear definition of terms to enable international communication. Some initiatives are already under way to tackle this problem—in Australia and elsewhere—but these could be greatly aided by WHO collaboration and support.
- Development of specific safety tools and techniques, and a model for implementation of patient safety programmes. Such models might draw on the experience of existing WHO programmes, such as those dealing with drug safety, vaccines and immunization safety, safety of blood products and injection safety.
- Consider the collection of worldwide data on adverse events and clinical incidents in the manner of the WHO Collaborating Centre for International Drug Monitoring (the Uppsala Monitoring Centre, UMC) for adverse drug reactions.

Next steps

The progress made at this Working Group meeting towards developing methods for estimating hazards in health care systems is a small step on the long road to full implementation of the World Health Assembly resolution on patient safety. This progress must be consolidated through effective follow-up action. This publication is one important expected output; it is envisaged that it will be translated into other WHO official languages.

In addition, it was suggested that continued exchange of ideas and experiences in a coordinated manner among the participants would be beneficial to the work, particularly in view of the long-term actions envisioned above. This coordinated exchange of ideas could be accomplished through the creation of a network. WHO will examine the prospects for the creation of an e-mail discussion list as an initial mechanism to achieve this purpose.

Looking to the future: a vision of safe, high-quality health care

The problem of patient safety is potentially immense and the nature and scale of harm from health care systems worldwide is largely uncharted. Unsafe care may have tragic consequences for patients and their families, be a source of great distress to staff and be a massive economic burden for both the health care system and the wider society. Achieving safe health care, therefore, has the potential to bring very great benefits to patients, families and all involved in the delivery of care. Patient safety is currently a priority in only a few affluent countries. However, about 40 countries took the floor to share experiences and comment on the background paper during the discussion leading up to the World Health Assembly resolution on patient safety in May 2002. WHO's work on patient safety should aim to bring the benefits of these initiatives to all Member States. In the long term, making health care safe may confer greater health gain than almost any other public health programme.

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Annex 1

**WORLD HEALTH ORGANIZATION****FIFTY-FIFTH WORLD HEALTH ASSEMBLY**
Provisional agenda item 13.9**A55/13**
23 March 2002

Quality of care: patient safety

Report by the Secretariat

1. Health care interventions are intended to benefit patients, but they can also cause harm. The complex combination of processes, technologies and human interactions that constitutes the modern health care delivery system can bring significant benefits. However, it also involves an inevitable risk of adverse events that can – and too often do – happen.
2. The problem of adverse events in health care is not new. Studies as early as the 1950s and 1960s¹ 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. Subsequent research in Australia, the United Kingdom of Great Britain and Northern Ireland and the United States of America in particular, the 1999 publication *To err is human: building a safer health system* by the Institute of Medicine in the United States of America provided further data and brought the subject to the top of the policy agenda and the forefront of the 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 has carried out a feasibility study on research into adverse events in public hospitals.

EXTENT OF ADVERSE EVENTS

3. Various studies have investigated the extent of adverse events (see Table). 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. The Institute of Medicine report estimated that “medical errors” cause between 44 000 and 98 000 deaths annually in hospitals in the United States of America – more than car accidents, breast cancer or AIDS. The United Kingdom Department of Health, in its 2000 report, *An organization with a memory*, estimated that adverse events occur in around 10% of hospital admissions, or about 850 000 adverse events a year. The Quality in Australian Health Care Study (QAHCS) released in 1995 found an adverse-event rate of 16.6% among hospital patients. 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.

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 (%)
United States of America (New York State) (Harvard Medical Practice Study)	Acute care hospitals (1984)	30 195	1 133	3.8
United States of America (Utah-Colorado Study (UTCOS))	Acute care hospitals (1992)	14 565	475	3.2
United States of America (UTCOS) ¹	Acute care hospitals (1992)	14 565	787	5.4
Australia (Quality in Australian Health Care Study (QAHCS))	Acute care hospitals (1992)	14 179	2 353	16.6
Australia (QAHCS) ²	Acute care hospitals (1992)	14 179	1 499	10.6
United Kingdom of Great Britain and Northern Ireland	Acute care hospitals (1999-2000)	1 014	119	11.7
Denmark	Acute care hospitals (1998)	1 097	176	9.0

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).

4. Adverse events exact a high toll in financial loss as well. In the United Kingdom of Great Britain and Northern Ireland consequent additional hospital stays alone cost about £2000 million a year, 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, whereas hospital-acquired infections – 15% of which may be avoidable – are estimated to cost nearly £1000 million every year. The total national cost of preventable adverse medical events in the United States of America, including lost income, disability and medical expenses, is estimated at between US\$ 17 000 million and US\$ 29 000 million annually. Added to these costs is the erosion of trust, confidence and satisfaction among the public and health care providers.

5. 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 underfinancing of essential operating costs of health services make the probability of adverse events much higher than in industrialized nations. WHO figures suggest that developing countries account for around 77% of all reported cases of counterfeit and substandard drugs.

It is also reported that at least 50% 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. In the Newly Independent States, about 40% of hospital beds are located in structures originally built for other purposes. 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.

WHERE AND WHY ADVERSE EVENTS OCCUR

6. 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 very few data on the extent of the problem outside hospitals.

7. Every point in the process of care-giving contains a certain degree of inherent unsafety: 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.

8. 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 United States of America (see Table) provide a dramatic example, 75% of them being attributable to system failures. Similarly, most adverse events are not the result of negligence or lack of training, but rather occur because of latent causes within systems.

9. 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. Counter measures based on changes in the system are therefore more productive than those that target individual practices or products.

STRATEGIES TO ENHANCE THE SAFETY OF PATIENTS

10. 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 wide 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.

11. 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.

12. 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; (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.

INSUFFICIENCY OF CURRENT EFFORTS

13. 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 of occurrence, 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 scaled up to embrace an entire health system.

14. 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 intercountry comparisons.

15. Critical questions to which answers should be sought internationally, so that best practices can be established to provide decision-makers with options when shaping their strategies, are as follows:

- 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?
- What are the best paradigms for implementing safe practices at the health care delivery level?

WHAT NEEDS TO BE DONE

16. Effective reduction of adverse outcomes for patients calls for a concerted international effort in which WHO would play a proactive leadership role, particularly as part of its important focus on enhancing health systems performance. The experience of countries that are heavily engaged in national efforts clearly demonstrates that, although health care systems differ from country to country, many threats to patient

safety have similar causes and often similar solutions. There is great scope for collaboration in designing and implementing systems for patient safety.

17. WHO has taken the lead in tackling some specific aspects of the problem. Its Programme for international drug monitoring with its collaborating centre in Sweden have instituted a coherent programme of action including pharmacovigilance, harmonization of drug regulations, monitoring of drug safety, bridging the gap between industry and regulatory authorities, and other important actions. Its Immunization Safety Priority Project aims to establish a comprehensive system to ensure safety of all immunizations. In addition, the Global Advisory Committee on Vaccine Safety has been established to provide independent scientific assessment of vaccine safety issues. Another major effort centres on injection safety, where WHO coordinates the Safe Injection Global Network. These current activities will be further elaborated, in conjunction with actions promoting environmental safety, safety of blood products, safe laboratory practices, and safe use of medical devices and clinical procedures.

18. Action is also needed at another level, from a broader system perspective viewing the safety of patients as a major element in improving the quality of care and enhancing the performance of health care providers. Other urgent activities include the following:

- to develop common definitions of patient safety, adverse events and related terms;
- to emphasize the safety of patients as a prime concern in health system performance and quality management;
- to investigate how countries and organizations classify, measure, report and attempt to prevent adverse events, and establish a comprehensive evidence base on these practices;
- to draw up a framework for WHO support to countries for activities including: (a) classifying, measuring, reporting and preventing adverse events; establishing a comprehensive evidence base on the epidemiology of adverse events; devising a common set of measures; and identifying best practices; (b) promoting expectations for safety and developing health service performance standards; (c) identifying and implementing strategies and mechanisms for safety systems in health care organizations; (d) developing and implementing regulatory frameworks for preventing, monitoring and reporting adverse events; and (e) facilitating information exchange and data sharing;
- to establish a network of collaborating institutions as centres of excellence in Member States to support research and the implementation of research findings;
- to promote partnerships between the public and private sectors in developing appropriate responses to the problem of adverse events in health care.

19. These matters were debated by the Executive Board at its 109th session,¹ which adopted a draft resolution for consideration by the Health Assembly.

ACTION BY THE HEALTH ASSEMBLY

20. The Health Assembly is invited to consider adoption of the resolution contained in resolution EB109.R16.

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¹See document EB109/2002/REC/2, Summary records of the sixth and ninth meetings.

Annex 2

Methodologies for studies shown in Table 1 of Quality of care: patient safety. Report by the Secretariat Fifty-fifth World Health Assembly, A55/13.

Large variations in reported adverse event rates from the Australian (QAHCS) and USA (UTCOS) studies (see Table 1) underscore the need for a common understanding of the concepts and methods. The two studies use similar methodologies but the results show a surprising five-fold difference in adverse event rate (16.6% against 2.9%). Even after harmonization of the four points of divergence in methodological details there is still a two-fold difference. Some researchers question the validity of retrospective studies in the study of adverse events and propose prospective observational methods using ethnographers trained in qualitative research (1).

Common feature

All studies in Table 1 use a retrospective analysis of randomly selected hospital case records in acute care non psychiatric hospitals, with 18 predefined criteria and a two- or three-level assessment. Adverse event is defined as “an unintended injury that was caused by medical management and that resulted in measurable disability”. First level assessment is by nurses, and positive records are reviewed by clinicians, with all but UTCOS resolving clinician disagreement through a consensus conference.

Differences

Table 2: Specific features of major studies

Study	Date of admissions	Specific features
USA <i>New York State)</i>	1984	51 hospitals, randomly selected
Australia (QAHCS)	1992	28 hospitals in New South Wales and South Australia
USA (Utah-Colorado Study – UTCOS)	1992	Voluntary participation of 28 hospitals
Denmark	1998	17 hospitals, Records sampled proportionally with 20 to 204 admissions in each
United Kingdom	1999 - 2000	2 hospitals in London area

Four major points of divergence between UTCOS and QAHCS (2;3)

Context of studies

UTCOS, aimed at examining the feasibility of a “no fault insurance scheme”, therefore judged negligence, and estimated costs. QAHCS was commissioned by the Australian Government to assess prevalence of iatrogenic injury, and thus the burden to Australian society. Reviewers judged the preventability of adverse events and estimated the number of index admissions with which an adverse event would be associated.

Selection of hospitals

In UTCOS, all selected hospitals accepted and participated voluntarily. QAHCS used a stratified sampling of hospitals, with the likelihood of selection proportional to the number of inpatient separations in 1992

Nurse review

Interpretation of: “readmission linked to previous admission”. In QAHCS, all records for which there was a readmission were forwarded for medical review, regardless of when the resulting adverse event took place; in UTCOS, records were forwarded only if readmission occurred within six months for patients 65 years and older, or within 12 months for all other patients. The resulting referral rate was 43.7% for QAHCS and 19.5 for UTCOS.

Medical review

- The threshold for defining an adverse event (on a scale from 1-6; 2 for QAHCS and 4 for UTCOS)
- One medical review with final decision powers for UTCOS, and two reviewers—with third reviewer in the case of disagreement
- The same “index admission” was used by both. However, UTCOS included only those adverse events that caused the index, or occurred and were discovered during the admission. QAHCS included all index admission associated with adverse events which occurred and were discovered before or during—also those discovered later but which occurred during admission.

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Annex 3

WHA55.18 Quality of care: patient safety

The Fifty-fifth World Health Assembly,

Having considered the report on quality of care: patient safety;¹

Concerned that the incidence of adverse events is a challenge to quality of care, a significant avoidable cause of human suffering, and a high toll in financial loss and opportunity cost to health services;

Noting that significant enhancement of health systems' performance can be achieved in Member States by preventing adverse events in particular, and improving patient safety and health care quality in general;

Recognizing the need to promote patient safety as a fundamental principle of all health systems,

1. URGES Member States:

(1) to pay the closest possible attention to the problem of patient safety;

(2) 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;

2. REQUESTS the Director-General, in the context of a quality programme:

(1) to develop global norms, standards and guidelines for quality of care and patient safety, and the definition, measurement and reporting of adverse events and near misses in health care, by reviewing experiences from existing programmes and seeking inputs from Member States, in order to provide support in developing reporting systems, taking preventive action, and implementing measures to reduce risks;

(2) to promote framing of evidence-based policies, including global standards that will improve patient care, with particular emphasis on product safety, safe clinical practice in compliance with appropriate guidelines, and safe use of medicinal products and medical devices, taking into consideration the views of policy-makers, administrators, health-care providers and consumers;

(3) to support the efforts of Member States to promote a culture of safety within health care organizations and to develop mechanisms, for example through accreditation or other means, in accordance with national conditions and requirements, to recognize the characteristics of health care providers that offer a benchmark for excellence in patient safety internationally;

¹Document A55/13.

(4) to encourage research into patient safety, including epidemiological studies of risk factors, effective protective interventions, and assessment of associated costs of damage and protection;

(5) to report on progress to the Executive Board at its 113th session and to the Fifty-seventh World Health Assembly.

(Ninth plenary meeting, 18 May 2002 –
Committee A, third report)

Annex 4

Data on incidence of harm potentially available from existing WHO Programmes and other WHO sources

This annex provides a brief outline of some of the data on incidence of harm that are potentially available from existing WHO programmes and other WHO sources. The compilation is by no means exhaustive, but will be extended and updated through the work of the inter-cluster working group on patient safety within WHO. The annex also makes no reference, at this stage, to the significant amount of data that are also available from national and agency reporting systems.

Drug Safety Monitoring Programme

The work of WHO in the area of safety monitoring of medicines products is carried out both in headquarters and in the WHO Collaborating Centre for International Drug Monitoring in Uppsala, Sweden. The centre now receives data from 70 national centres and four associate members. The main aims of the Programme are to:

- Provide an efficient means of exchange of information on matters of safety of medicines
- Maintain the global database and to use it to determine “signals”
- Provide support to countries in developing and maintaining pharmacovigilance systems
- Develop policies, guidelines and normative documents
- Collaborate with other partners in the field of pharmacovigilance

For further information on the Programme see:

<http://www.who.int/medicines/organization/qsm/activities/drugsafety/orgdrugsafety.shtml> and <http://www.who-umc.org/>

Vaccine and Immunisation Safety

The Global Advisory Committee in Vaccine Safety (GACVS) was established in 1999 by WHO to respond promptly, efficiently, independently (of WHO), and with scientific rigour to vaccine safety issues of potential global importance.

In 1999 the WHO Department of Vaccines and Biologicals also launched the Immunisation Safety Priority Project with the aim of establishing a comprehensive system to ensure the safety of all immunisations given in national immunisation programmes.

WHO has developed a set of resource documents and guidelines on the reporting and investigation of adverse events following immunisation. The guidelines state that adverse events should be reported, investigated, and that corrective action should be taken. Countries are also advised that annual reporting should take place at a national level.

WHO receives data annually from national health authorities. These data encompass criteria concerned with immunisation safety monitoring, reported adverse events, and a number of other indicators important to injection safety. The quality of the data is variable.

Injection Safety

The Safe Infection Global Network (SIGN) was launched in October 1999. It is a voluntary association made up of interested individuals, representatives of public and private organisations, and national public health officials; it aims to achieve safe and appropriate use of injections throughout the world.

WHO and SIGN have developed a range of aide-memoirs and other documents on injection safety and waste disposal. They include a tool for the assessment of injection safety (2001) and a rapid assessment and response guide for injection practices (2002). The “Injection Practices: Rapid Assessment and Response Guide” is being piloted in countries.

WHO carried out a study of injection practices worldwide in 2002. The work focused on 10 of the 14 WHO epidemiologic regions, and found that injection overuse and unsafe practices are still common in developing and transitional countries.

A number of studies have now been conducted using the standard WHO tool. Data are also being collected on injection safety through a number of surveys and national reporting systems, e.g. The Demographic and Health Surveys, the Expanded Programme on Immunisation, etc.

Chemical Safety

The WHO chemical safety programme works with countries to develop poison centres. At present the coverage of these centres is variable and the data reported to them depend very often on the local environment within which they operate. WHO is working with the centres in order to achieve a degree of international agreement on data reporting.

At present 70-80 of the centres take part in an electronic network which tends to focus on emergency solutions (i.e. antidotes.) The centres do, however, collect some very useful data concerning patient safety issues. WHO is keen to foster their development and their relationship with the Uppsala Monitoring Centre.

Blood Safety

Following the launch of the Global Collaboration for Blood Safety by WHO, it became apparent that baseline information was required about blood transfusion services in Member States to identify the exact nature of problems and develop appropriate strategies. The WHO Global Database in Blood Safety (GDBS) was, therefore, established with the following objectives:

- To assess the global situation in blood safety.
- To obtain the best information available in blood transfusion services in each Member State.

- To identify problems and needs in order to provide support.
- To identify countries for priority assistance.
- To monitor progress and trends in blood safety.

A questionnaire, based on the aide-memoir, was developed in 1997 as a tool for the standardisation of data collection from Member States and was sent to national health authorities for completion. Field visits were also conducted in selected countries to assist in the analysis of data.

Data were obtained from 175 of the 191 Member States, and were analysed on a regional and global basis. This exercise has recently been repeated using a modified questionnaire and the response rate from countries was higher. It is anticipated that analysis of the data will be completed in the spring of 2003.

The global database is a dynamic on-going project.

Medical Devices

WHO is engaged in developing international guidelines for medical device regulation. It is anticipated that the guidelines will be produced during 2003 and they are expected to lead to better collaboration between Member States in the monitoring of safety in relation to medical devices.

At present the monitoring of adverse events tends to occur at national or sub-national level. Countries such as the United Kingdom have had adverse incident user reporting since the 1960s. European Union countries are required, under European law, to have mandatory reporting systems in place. A number of countries cooperate in the international vigilance scheme both to learn lessons and to transfer experience for international benefit.

ECRI, a WHO collaborating centre, collects, analyses and disseminates information on medical device failures, problems and adverse events. The reporting system is now used by 3000 member hospitals around the world.

Other WHO sources

Data are available from other WHO sources such as: The World Health Report 2002, and a number of programmes and activities—for example, prevention of hospital-acquired infection, communicable disease surveillance, antimicrobial resistance, HIV, TB, etc.—which may also be very important when considering patient safety issues.

Annex 5

List of participants

WHO Working Group meeting on Patient Safety: Rapid Assessment Methods for Estimating Hazards Geneva, 17 to 19 December 2002

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Annex 6

Programme for the Working Group meeting *on* Patient Safety: Rapid Assessment Methods for Estimating Hazards

Tuesday 17 December 2002

09:30 -10:30	Opening session
10:30 -11:00	Coffee break
11:00 -12:30	Session 2
<i>12:30 – 14:00</i>	<i>Lunch break</i>
14:00 – 15:30	Session 3
15:30 – 16:00	Coffee break
16:00 – 17:30	Session 4
18:00 – 19:30	Cocktail

Wednesday 18 December 2002

09:00 - 10:30	Session 5
10:30 - 11:00	Coffee break
11:00 - 12:30	Session 6
<i>12:30 – 14:00</i>	<i>Lunch break</i>
14:00 – 15:30	Session 7
15:30 – 16:00	Coffee break
16:00 – 17:30	Session 8

Thursday 19 December 2002

09:00 - 10:30	Session 9
10:30 - 11:00	Coffee break
11:00 - 12:00	Closing session

Session contents

Opening session

Welcome – Mr Orvill Adams, Director OSD

Introduction of participants

Opening address – Dr Christopher Murray, Executive Director, EIP cluster

Designation of Chairman and Rapporteurs

Session 2

Presentation of background paper – Dr Yunkap Kwankam and Professor Charles Vincent.
Working methods.

Session 3

Open discussion on methods

Session 4

Open discussion on methods

Session 5

Formal analysis of strengths and weaknesses of various methods

Session 6

Formal analysis of strengths and weaknesses of various methods

Session 7

Data sources for various types of studies, continued

Session 8

Comparison of various types of studies using framework

Session 9

Proposal of methodology adapted to the needs of data-poor environments
-strengths and weaknesses of the methodology
-availability and sources of data for the methodology

Closing session

Conclusions and next steps

