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 regions[1]: 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.

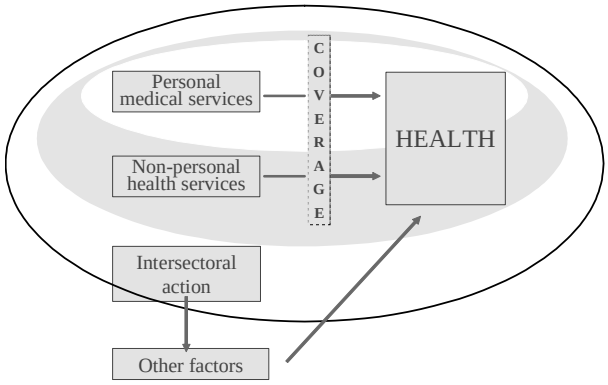

Figure 1: Relationship between Coverage and outcomes

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