WORLD HEALTH ORGANIZATION

FIFTY-FIFTH WORLD HEALTH ASSEMBLY A55/13
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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 1960s[1] 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.

[1] A full bibliography, including the studies mentioned in this document, is available on request.

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