



WORLD HEALTH ORGANIZATION

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Quality of care: patient safety

Report by the Secretariat¹

1. Resolution WHA55.18 urges Member States to pay the closest possible attention to patient safety and requests the Director-General, *inter alia*, to develop global norms and standards; promote framing of evidence-based policies and mechanisms to recognize excellence in patient safety internationally; encourage research; and support the efforts of Member States in several key, clearly delineated areas.
2. An intercluster working group on patient safety was set up in 2002 and has been instrumental in bringing together all the relevant activities in WHO for consolidated action in response to the resolution. A web site for this area of work is in preparation. This report reviews progress in the main areas of WHO's work on patient safety, namely, systemic factors, product safety and safety of services.

SYSTEMIC FACTORS

3. This aspect of the work aims at a common understanding of concepts and terms relating to patient safety, including preparation of a taxonomy of health-care errors and system failures; development of methods and tools for estimating hazards in different country situations; and promoting systems for reporting and learning as proven mechanisms for improving patient safety.
4. **Taxonomy.** Concepts relating to patient safety differ from one country to another. A common international understanding of these concepts and their definitions is therefore a necessary first step to facilitating international collaboration and exchange of information. WHO is preparing a standardized nomenclature and taxonomy of medical errors and health-care system failures, building on its experience of country comparisons, existing programmes for product and service safety, and the work of institutions such as the WHO Collaborating Centre for International Drug Monitoring in Uppsala, Sweden. Experts at a meeting held in October 2003 in Geneva discussed an international collaborative effort to work out a taxonomy and to produce a dictionary of terms.
5. **Estimating hazards.** In order to raise the priority of policies on patient safety, WHO is sensitizing countries to the harmful consequences of adverse events within health-care systems. Initial assessment of the nature and magnitude of the problem is an important precursor to devising and applying methods to prevent health-care errors and system failures, and to mitigate their effects.

¹ See also document EB113/10.

To support countries in this task, WHO has determined the applicability of available methods to such aspects as policy formulation, improvement of clinical practice and patient awareness. WHO is also designing rapid-assessment methods and tools for use in data-poor environments, where other methods may not be appropriate.

6. **Reporting and learning systems.** Reporting and learning systems are important in the area of safety improvement, by enabling lessons to be learned from adverse events and “near misses”. Several Member States have established such systems nationally and in specific organizations. WHO is preparing guidelines for such systems, identifying best practices and promoting their adoption in countries.

PRODUCT SAFETY

7. A subgroup on product safety of the WHO working group on patient safety, also established in 2002, focuses on issues specifically related to vaccines, other biologicals, medicines and equipment.

8. **Drug monitoring and use.** The Programme for International Drug Monitoring ensures reliable exchange of information on medicines, promotes pharmacovigilance activities in Member States, encourages participation and supports Member States in developing an adequate system for obtaining statistics on drug use. It also maintains a network of national information officers for safety and efficacy of pharmaceutical products and disseminating new information on adverse effects and related regulatory measures. Regulatory information is periodically published in the *WHO Pharmaceuticals Newsletter* and alerts are disseminated as needed. Relevant regulatory decisions are compiled in a United Nations consolidated list.¹

9. WHO has published guidelines for and provides training courses in countries on the setting up and running of pharmacovigilance centres, and recently established an Advisory Committee for the Safety of Medicinal Products.

10. As of November 2003 the Programme for International Drug Monitoring had 72 official members and included more than three million records, from which “signals” of adverse events are analysed and notified to Member States. Through the WHO Collaborating Centre for Drug Statistics Methodology in Oslo, WHO maintains the Anatomical Therapeutic Chemical classification system and the defined daily dose as unit of measurement for classified drugs.

11. **Medical devices and equipment.** To ensure safety of patients, health workers and the community with regard to medical devices and equipment, WHO carries out activities in several areas: policy and planning; quality and safety; norms and standards; technology management; and capacity building. Equipment safety is comprehensively dealt with in a set of guidelines for improved management of physical resources in health care, including a software-based resource-planning methodology and management tool, the Essential Healthcare Technology Package.

12. In August 2003 WHO added to its work on medical devices a set of regulations on such devices² aimed at promoting preparation of national regulations. To reduce risks linked to substandard

¹ *United Nations Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or not Approved by Governments*, New York, United Nations, 7th ed., 2003.

² *Medical device regulations: global overview and guiding principles*. Geneva, World Health Organization, 2003.

products and procedures, WHO is working on new ISO standards and WHO performance specifications, “pre-qualification” of suppliers, and development of standardized procedures for alerts and recalls and of tools to assess device safety and performance. The Organization has promoted the concept of a WHO model list of essential medical devices to increase access to high-quality medical products, and focused on training in the appropriate use of equipment, especially care and maintenance of equipment. WHO works closely in this area with the Global Harmonization Task Force.

SAFETY OF SERVICES

13. WHO’s work in this area covers safety in laboratory practice; diagnostic and treatment procedures and/or clinical practice; medical decision-making; medication errors; safe use of equipment; immunization and injection safety; hospital infections; patient management; and staff technical performance and/or competence.

14. **Essential clinical care procedures.** WHO has prepared an aide-mémoire on essential surgical care; needs-assessment tools on procedures and equipment safety; and guidelines on essential trauma care and the clinical use of oxygen. These materials will be deployed in collaboration with partners such as the international surgical and orthopaedic societies for training programmes in developing countries, and the World Federation of Societies of Anaesthesiologists.

15. **Injection safety.** WHO estimates that in 2000, in developing and transitional Member States, reuse of injection devices accounted for 24.3 million new infections: 22 million with hepatitis B virus, (some 33% of all such infections), 2 million with hepatitis C virus (40%) and 260 000 with HIV (5%). These infections alone are expected to lead to an estimated 9 million years of life lost (adjusted for disability) between 2000 and 2030.

16. Death and disability associated with unsafe injections can be prevented by reducing excessive use of injections (currently averaging each year 3.4 injections per person) through better communication between patients and doctors, improving prescriptions through monitoring of providers and making single-use syringes more readily available in health-care facilities. Interventions for the safe and appropriate use of injections are cost-effective, as defined in the criteria of the WHO Commission on Macroeconomics and Health.

17. To support Member States in assessing, planning, implementing and evaluating national policies for the safe and appropriate use of injections, WHO continues four main activities: increasing awareness; broadening the availability of single-use injection devices and safety boxes in health-care facilities; ensuring provision of injection devices with reuse-prevention features and safety boxes by donors and lenders that support the supply of injectable substances; and proper management of waste associated with dirty syringes and needles.

18. **Making pregnancy safer.** WHO continues to contribute to the goals of the international Safe Motherhood Initiative through its Making Pregnancy Safer initiative. Its strategy is to strengthen the capacity of health systems to improve the health of mothers and neonates by increasing equitable access, use, quality and safety of appropriate health services through concerted action at the policy, service and community levels, with special attention to reaching the poor and most vulnerable groups. WHO’s initiative pursues activities to support Member States, extend advocacy at the global level, build partnerships at global, regional and country levels and monitor progress towards relevant Millennium Development Goals.

19. Evidence generated by the initiative has shown that the preventive use of magnesium sulfate could more than halve the risk of eclampsia, a major cause of maternal deaths. Several interventions on the integrated management of pregnancy and childbirth are being used in countries after compilation of evidence and worldwide distribution of a manual on Managing complications in pregnancy and childbirth.¹ A package of evidence-based standards and tools for the integrated management of mother and newborn is in development.

20. **Nursing.** Recent reports have shown the impact of staffing conditions on the quality and safety of patient care. As the worldwide shortage of nursing and midwifery personnel is expected to increase in the coming years, it is vitally important to provide guidance to countries in ensuring quality and safety of care in these conditions. Briefing documents are being prepared to show how the organization of care, the various approaches to using the skill mix of staff and the organizational culture can contribute to improved patient and provider outcomes.

21. **Blood transfusion.** Only 40% of the estimated 80 million units of blood collected annually worldwide are collected in the developing world, where 80% of the world's population live. The shortfall has a particular impact on women with pregnancy complications, trauma victims and children with severe life-threatening anaemia. Thousands of pregnancy-related deaths could be avoided each year through access to safe blood. In addition, millions are exposed to avoidable, life-threatening risks through the transfusion of unsafe blood. The risk of acquiring HIV through transfusion with HIV-infected blood is about 100%. Blood is also one of the most effective means of transmitting hepatitis B and hepatitis C viruses and the infectious agents for syphilis, malaria and Chagas disease.

22. These infections can also be transmitted by transfusion as a result of the collection of blood from unsafe donors, irregular or inadequate supplies of materials required to test blood for infections, poor laboratory procedures, inadequately trained staff, absence of quality systems and unnecessary transfusions. In addition, emerging diseases such as new variant Creutzfeldt-Jakob disease, West Nile virus disease and severe acute respiratory syndrome (SARS) pose a potential threat to the stability of national blood supplies because of demands for additional testing.

23. WHO's blood safety programme actively promotes the formation of national blood programmes that ensure the provision and use of safe, high-quality and adequate blood and blood products to meet the needs of all patients. WHO has formulated an integrated strategy for blood safety setting out all the steps in the collection, testing, processing, storage and use of blood and blood products. The programme supports Member States in strengthening their national blood programmes through advocacy, technical cooperation, capacity building, the preparation of guidelines, recommendations and training materials and through collaborative partnerships in blood safety. Although there has been a significant reduction in HIV infections transmitted through transfusion due to implementation of safe blood strategies in many countries, further support and investment are required to prevent all transfusion-transmitted infections.

24. **Poison centres.** The WHO International Programme on Chemical Safety works with Member States to create or strengthen poison centres. More than 70 of these centres are linked in an electronic network that focuses on emergency solutions, such as antidotes. The information coverage of these centres is variable, and WHO is working towards international harmonization of data reporting. Efforts are under way to link the centres to the WHO Collaborating Centre for International Drug Monitoring.

¹ *Managing complications in pregnancy and childbirth: A guide for midwives and doctors.* Geneva, World Health Organization, 2000.

25. **Immunization safety.** WHO's Immunization Safety Priority Project assists national immunization programmes to prevent or detect as early as possible and quickly respond to adverse events following immunization, so as to minimize their negative impact on health and on immunization programmes. The project has achieved major successes in some key areas.

26. The applications of 52 of 75 countries eligible for injection safety support from the Vaccine Fund of the Global Alliance for Vaccines and Immunization have been approved, totalling in excess of US\$ 77 million. By the end of 2002 more than 40% of all non-industrialized countries had introduced auto-disable syringes, thus closing in on the target for all countries set by a WHO/UNICEF/UNFPA joint statement.¹ Efforts are ongoing to reduce the cost of auto-disable syringes still further through technology transfer, and these devices are now being produced in some developing countries.

27. The WHO Expert Committee for Biological Standardization adopted guidelines and recommendations in 2003 relating to: the production and control of smallpox vaccine; the safe production and quality control of inactivated poliomyelitis vaccine; regulatory expectations related to the elimination, reduction or replacement of thiomersal in vaccines; and the production and control of group C meningococcal conjugate vaccine.

28. Significant progress has been made on early detection and management of adverse events following immunization. As of June 2003, 49 assessments of national surveillance systems for such adverse events were completed and 44% of the population in all Member States were being monitored by a documented surveillance system. The Global Training Network on monitoring for and management of adverse events after immunization now includes two new regional training centres, one in Tunisia and the other in Sri Lanka. Technical and financial support have been provided to the Brighton Collaboration, an international voluntary collaboration developing globally accepted and implemented standardized case definitions of adverse events following immunization in order to improve analysis and comparability of clinical trials and surveillance data. The Global Advisory Committee on Vaccine Safety carried out work on a possible link between autism and measles, mumps and rubella vaccine as well as on the safety of thiomersal in vaccines.

29. New training modules for mid-level managers and a set of manuals for health-care workers entitled "Immunization in practice" are being prepared, and a web site providing information for the public on vaccine safety issues was developed in 2003.

REGIONAL ACTIVITIES

30. Regional offices are equally active in moving the patient safety agenda forward.

31. After presenting resolution WHA55.18 at the 52nd session of the Regional Committee for Africa in October 2002 as an item of particular interest to the Region, and seeking guidance on its implementation, the **Regional Office for Africa** has identified priority activities in the area of patient safety. These have been included in the plan of action for 2004-2005, as no funds were earmarked for patient safety during 2003.

32. The **Regional Offices for South-East Asia and for Europe** have recently published training manuals and guidelines on infection control, in an effort to ensure safety of care procedures.

¹ *Safety of injections: WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services.* Geneva, World Health Organization, 2nd rev., 1999.

33. The **Regional Office for the Eastern Mediterranean** has recently developed guidelines for the regulation of nursing and midwifery practice, to ensure high-quality outcomes of care and safe practices. It has also launched a comprehensive and standardized assessment of the quality of nursing services throughout the Region.

34. Activities to improve quality of care and patient safety in the **Western Pacific Region** include: work on guidelines for effective regulation of health professionals, and analysis and advice on improving legislation on the provision of services and professional practice; advice on improving national systems of auditing and accreditation of providers; support to countries in developing and implementing national drug policies, including the rational use of drugs, and activities in injection safety; and an evidence-based approach to the use of traditional medicines. The Regional Office continues to support a regional external quality-assurance scheme for laboratories that covers 22 of the countries in the Region. Materials on hospital infection control have been developed and provided to many countries. Training activities for health workers have been organized in such areas as integrated management of childhood illnesses, blood safety and various aspects of clinical practice. The Regional Office has also developed guidelines for, and promoted quality assurance in, basic medical education and has developed clinical practice guidelines for countries.

INTERNATIONAL COLLABORATION

35. In view of the broad international interest in the subject, an International Alliance for Patient Safety was created in November 2003, bringing together countries, interested bodies and experts for the promotion of patient safety in Member States. The Alliance will accelerate improvements in patient safety in countries through its core functions: supporting the development of patient safety policy and practice; enabling countries to assess their progress towards patient safety; global reporting; solution development; and research and development. These functions will be supplemented by short-term initiatives.

36. The Alliance is an important way forward and will encourage concerted action from a range of sectors with a key initial target of adequate representation from all WHO regions and, eventually, the participation of all Member States.

ACTION BY THE EXECUTIVE BOARD

37. The Executive Board is invited to note the report.

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