



patient safety

281733
e

WHO/EIP/OSD/2003.5

- > REPORTING AND LEARNING SYSTEMS
- > TAXONOMY
- > ESTIMATING HAZARDS
- > CLINICAL PROCEDURES
- > DRUG MONITORING AND USE
- > INJECTIONS
- > MEDICAL DEVICES AND EQUIPMENT
- > POISON CENTRES
- > MAKING PREGNANCY SAFER
- > IMMUNIZATIONS
- > NURSING
- > BLOOD TRANSFUSION
- > WORKING WITH MEMBER STATES, INSTITUTIONS, AGENCIES, EXPERTS...

The increasing incidence of documented cases of adverse events in health care has led to growing concern about patient safety in many Member States. Patient safety remains a fundamental principle of patient care and a critical component of quality management.

THE WORLD HEALTH ORGANIZATION AND PATIENT SAFETY: WHAT IS HAPPENING?

The World Health Organization (WHO) sees this as a challenge for quality improvement and the enhancement of provider performance. WHO has identified the need for con-

certed international effort with a broad system perspective in which it should play a proactive leadership role. Resolution WHA55.18 of the World Health Assembly in May 2000 calls on WHO and its Member States to carry out activities aimed at improving patient safety and quality of care.

As part of 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 Member States. The WHO secretariat is currently initiating and pursuing work programmes to support implementation of the resolution. This paper briefly describes these as well as outlining some of the WHO activities concerned with patient safety.

REPORTING AND LEARNING SYSTEMS

Several Member States have established reporting and learning systems for adverse events and "near misses". To support and assist countries that may wish to consider national reporting, WHO is preparing guidance. The emphasis will be on learning by reporting, and the guidelines will focus on the desirable characteristics that should be considered when purchasing or developing a system.

For further information, please contact:
philipp@who.int

TAXONOMY

Worldwide concerns about safety in patient care underscore the need to coordinate the monitoring, reporting and understanding of adverse events and "near misses." Better information on the number, types, severity, causes and consequences of adverse events is clearly needed within Member States in order to inform strategies towards reducing the risk of medical incidents and to mitigate the effects of medical errors. Studies and incident monitoring systems reporting patient safety data often differ in the way they define, count and track adverse events, using different terms, data and schemes to code and analyse adverse events, thus comparisons

between schemes become complex. The lack of standardized nomenclature and taxonomy for medical errors and system failures can therefore complicate the development of viable and sustainable solutions to the many problems related to patient safety. In order to facilitate the dissemination of information among incident monitoring and reporting systems, one must adopt a common terminology and classify information in a way that facilitates comparisons.

The development of a common international system for classifying, measuring and reporting adverse events and "near misses" is a necessary first step in setting up a standardized approach. Initiatives are under way to tackle this problem in Australia, the USA and elsewhere, and could be greatly aided through WHO collaboration and support. WHO therefore plans to establish an international project building on its own experience in methods of intercountry comparisons, including that of institutions such as the WHO Collaborating Centre for International Drug Monitoring, in Uppsala, Sweden.

For further information, please contact:
philipp@who.int

ESTIMATING HAZARDS

WHO is committed to making patient safety a priority on the policy agenda of Member States. This initially involves sensitizing Member States to the harm that can occur within health care systems, in order to provide a receptive context for studies and action on patient safety. The next task is to assess the nature and incidence of adverse outcomes. It then becomes necessary to understand further the causes of these outcomes, which may vary according to country, health care system and treatment or procedure. Effective methods of prevention must then be tested, initially on a pilot basis. Where the nature and causes of a problem are well established, it may be possible to move directly to developing and applying methods on a larger scale. Generally speaking, however, initial assessment of the nature and magnitude of the overall problem remains an important first step.

Of the 17 WHO epidemiological regions worldwide, only three include Member States that have carried out adverse event studies: Region 3 (AMRO A: USA), Region 8 (EURO A: Denmark, United Kingdom) and Region 14 (WPRO A: Australia). WHO intends to estimate the extent to which health care systems may create hazards to people in several Member States of the remaining 14 epidemiological regions. To this purpose, WHO convened an international meeting in December 2002 to consider the development of rapid assessment methods to estimate harm caused by the health system, with particular attention to the development of tools for use in data-poor environments and to achieving a balance between robustness of scientific methods and the need for urgent assessment and action on vital safety issues. The report and recommendations of the meeting are intended for policy and decision makers at national and international level, who are not necessarily experts in patient safety. The next step will be to initiate studies in four of the 14 epidemiological regions using the methods identified by the meeting.

For further information, please contact: philipp@who.int

CLINICAL PROCEDURES

The following is an outline of current/planned work on patient safety in essential clinical care services, such as inappropriate use of essential procedures and equipment.

NORMATIVE ACTIVITIES IN PATIENT SAFETY

These include setting up a checklist of hospital procedures, developing education and training tools, and implementing country support. The HQ Expert Panel for Clinical Surgical Services assists in this; examples of intercluster cooperation are given hereunder.

HEADQUARTERS

1. Checklist of essential surgical procedures at the district hospital, with an aide-mémoire of procedures commonly undertaken, of the risks these entail and of the measures that can be taken to mitigate those risks.
2. Development of educational and training tools:
 - > Handouts on surgical care at the district hospital for essential surgery, anaesthesia, obstetrics and trauma
 - > E-learning tools (CD ROM, training videos)
3. Expert Panel for Clinical Surgical Services; intercluster collaborations:
 - > Guidelines on essential trauma care
 - > Guidelines on clinical use of oxygen
 - > Safe use of essential equipment and devices
 - > List of approved oxygen concentrators
 - > Use of simple devices (e.g. the Haemoglobin Colour Scale to assess and treat anaemia)
 - > Anaesthetic equipment, diathermy

COUNTRY SUPPORT

1. Collaboration with other organizations:
 - > International surgical and orthopaedic societies for training programmes for essential surgical services in developing Member States
 - > World Federation of Societies of Anaesthesiologists.
2. Training of trainers in essential emergency surgical procedures (trauma, gery, obstetrics and anaesthesia) and equipment towards safe clinical practice.

For further information, please contact:
cherianm@who.int

DRUG MONITORING AND USE

The Quality Assurance and Safety of Medicines (QSM) team in WHO handles issues pertaining to drug safety and drug use. QSM ensures reliable exchange of information on medicines, promotes pharmacovigilance activities in Member States, encourages participation in the WHO Programme for International Drug Monitoring and assists Member States in developing an adequate system for obtaining drug utilization statistics.

EXCHANGE OF INFORMATION

The team maintains active and rapid communication with a network of designated national information officers in Member States on the safety and efficacy of pharmaceutical products and on new information regarding adverse effects and related regulatory measures. This is ensured through periodic publication of regulatory information in the *WHO Pharmaceuticals Newsletter* and the dissemination of one-page Alerts on an ad hoc basis. Relevant regulatory decisions are compiled in the *United Nations Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved by Governments*.

PHARMACOVIGILANCE

The objectives are:

- > To promote patient care and patient safety in relation to the use of medicines, especially with regard to the prevention of unintended harm from the use of drugs
- > To contribute to the assessment of the risk-benefit profile of medicines
- > To improve public health and safety in relation to the use of medicines through the provision of reliable and balanced information
- > To encourage safer and more effective use of medicines.

WHO (QSM) organizes periodic training courses aimed at capacity building and providing guidance on how to set up and run a pharmacovigilance centre. WHO has also published guidelines to promote operational aspects of pharmacovigilance and recently established an Advisory Committee on the Safety of Medicinal Products (ACSoMP).

INTERNATIONAL DRUG MONITORING PROGRAMME

Adverse reactions to drugs are monitored and stored in a database using information derived from Member States participating in the programme. The WHO Collaborating Centre for International Drug Monitoring, in Uppsala, Sweden, holds the operational responsibility for the programme, including maintenance of the database that currently contains more than 3 million reports of suspected adverse drug reactions (ADRs). As of 2003, 71 Member States participate in the programme. ADR reports stored in the database are periodically subjected to causality assessment by a panel of international experts. The results of the analysis are compiled as "signal" documents and sent to Member States for their information and action, as appropriate.

STATISTICS ON THE USE OF DRUGS

Through the WHO Collaborating Centre for Drug Statistics Methodology, in Oslo, Norway, QSM maintains the Anatomical, Therapeutic and Chemical WHO Classification System and Defined Daily Dose (ATC/DDD) for classified drugs. The remit of the centre is to:

- > Classify drugs according to the ATC system
- > Establish DDDs for drugs with an assigned ATC code
- > Review and revise as necessary the ATC classification system and DDDs
- > Stimulate and influence use of the ATC system by cooperating with researchers in the drug utilization field.

For further information, please contact: couperm@who.int
Web site: www.who-umc.org

INJECTIONS

WHO estimates that in developing and transitional Member States, 16 billion health care injections are administered each year (an average of 3.4 injections per person per year). This figure, along with reports indicating inappropriate use of injections, suggests that injections are overused as a means of administering medications. In addition to being overused, injections may also be administered through unsafe procedures and cause infections. A safe injection should not harm the patient, the health care worker or the community. Injections may harm the patient when injection devices are reused in the absence of sterilization. Injections may harm health care workers when dirty needles are not collected in safety boxes, and the community at large when health care facilities are surrounded by sharp health care waste – mostly dirty syringes and needles. Reuse of injection devices in the absence of sterilization is of greatest concern, since it leads to the heaviest burden of disease. A mathematical model developed by WHO suggests that in 2000, in developing and transitional Member States, reuse of injector devices accounted for an estimated 22 million new infections with Hepatitis B virus (one-third of all such infections), 2 million new infections with Hepatitis C virus (40%) and 260 000 new HIV infections (5%). The infections acquired in 2000 alone are expected to lead to an estimated 9 million years of life lost (adjusted for disability) between 2000 and 2030.

MEDICAL DEVICES AND EQUIPMENT

Activities to ensure the safety of patients, health care workers and the community with regard to medical devices and equipment are carried out within four strategic areas:

- > Development of **national policy**: tools to assess and strengthen national regulatory authorities, including the recent Medical Device Regulations: Global Overview and Guiding Principles, in order to ensure national responsibility and management of equipment
- > **Quality and safety**: elements such as the elaboration of new ISO standards and WHO performance specifications, the pre-qualification of suppliers, the development of standardized procedures for alerts and recalls and of tools to assess safety and performance of products, all undertaken in collaboration with the Global Harmonization Task Force, in order to reduce risks linked to substandard products and procedures

Evidence shows that death and disability associated with unsafe injections are highly preventable. First, interventions that aim at improving communication between patients and doctors and at improving prescriptions through monitoring of providers have effectively decreased injection overuse. Second, interventions to make single-use syringes regularly available in each health care facility effectively prevent reuse of injection devices.

In addition to being highly effective, policies and plans for the safe and appropriate use of injections are a sound investment in health. WHO estimates that interventions implemented in 2000 for the safe and appropriate use of injections would have cost US\$102 per year of life saved (adjusted for disability). This cost is less than the threshold value of 1 year of average per capita income in developing Member States used by the WHO Commission on Macroeconomics and Health as a criterion for an intervention to be considered very cost-effective.

WHO assists Member States in benchmarking, assessing, planning, implementing and evaluating national policies for the safe and appropriate use of injections along four key interventions:

- > Increasing population awareness regarding the risk of HIV and other infections associated with unsafe injections
- > Making sure there are sufficient quantities of single-use injection devices and safety boxes in every health care facility where injections are administered
- > Ensuring that donors and lenders supporting the supply of injectable substances in developing and transitional Member States also support the provision of injection devices with reuse-prevention features and safety boxes
- > Managing the waste associated with dirty syringes and needles in a safe and appropriate way.

Web site: www.injectionsafety.org

> **Access**: safer equipment in order to improve patient safety, i.a. through the development of a model list of essential equipment, including the WHO Essential Healthcare Technology Package, through guidelines for good donation practices and through increased collaboration with industry

> Appropriate **use of equipment** in order to reduce risks: elaboration and diffusion of materials on information, education and communication (IEC) and of training manuals for managers and users of equipment, particularly as regards preventive maintenance.

A WHO Subgroup on Product Safety established in 2002 focuses on issues specifically related to vaccines, biologicals, medicines and equipment.

Web site: www.who.int/bct



WORKING WITH MEMBER STATES, INSTITUTIONS, AGENCIES, EXPERTS...

WHO has developed an extensive network of relationships and collaborations to support its work on patient safety.

Early in 2004, WHO will launch a patient safety web site to assist international communication and collaboration in all matters relating to patient safety, at www.who.int/patientsafety.

For further information, please contact philipp@who.int at the Department of Health Service Provision, World Health Organization, Geneva.

POISON CENTRES

The WHO International Programme on Chemical Safety works with Member States to develop poison centres. At present, the data reported to these centres vary considerably according to the environment within which the centres operate, and information coverage is therefore variable. WHO is working with the centres in order to achieve a degree of international agreement on data reporting.

Seventy to 80 of the recorded centres currently take part in an electronic network that now focuses mainly on emergency solutions (e.g. antidotes). The centres also collect some useful data concerning patient safety issues. WHO is keen to foster their development and their relationship with the WHO Collaborating Centre for International Drug Monitoring, in Uppsala, Sweden.

For further information, please contact:
www.who.int/pcs/

MAKING PREGNANCY SAFER

The initiative Making Pregnancy Safer represents WHO's continued contribution towards the goals and objectives of the international Safe Motherhood campaign. Its strategy is designed to strengthen the capacity of health systems to improve the health of mothers and neonates by increasing equitable access, use, quality and safety of health services for mothers and neonates through concerted action at the policy, service and community level, with special attention to reaching the poor and most vulnerable.

The strategy, based on accumulated scientific evidence and experience, identifies cost-effective interventions that have been shown to improve quality and ensure safety during pregnancy, childbirth and postpartum. The WHO Making

Pregnancy Safer initiative, which works with its partners and builds on the latter's experience, operates at global, regional and country levels. It focuses on the following key areas of work in which WHO has a United Nations mandate and can assist through its corporate and technical advantages:

- > Providing technical and policy support in order to strengthen government capacity in the planning, design and implementation of effective strategies to achieve improved maternal and newborn health
- > Developing a package of evidence-based standards and tools for the integrated management of pregnancy and childbirth, including essential care and a safe approach to complications during pregnancy and childbirth
- > Supporting Member States and partners in adapting and disseminating appropriate tools for local use
- > Generating evidence crucial to the improvement of quality and safety in maternal and newborn health and disseminating research findings
- > Monitoring relevant goals listed in the United Nations Millennium Declaration at global and regional level in order to provide information for better decision making
- > Undertaking advocacy at the global level in order to elicit the long-term financial and technical support to Member States needed to implement strategies to reduce maternal and newborn mortality, and to keep Safe Motherhood high on the global agenda
- > At global, regional and country levels, building efficient partnerships for Safe Motherhood committed to achieving the goals listed in the Millennium Declaration.

For further information, please contact:

fogstadh@who.int or kabrar@who.int

Web site: www.who.int/reproductive-health/MNBH

IMMUNIZATIONS

The Department of Vaccines and Biologicals at WHO/HQ set up the WHO Immunization Safety Priority Project in 1999 in order to establish a comprehensive system for the safety of all immunizations given in national programmes.

The four major areas of focus of the project are:

- > To promote and coordinate research and development for safer and simpler delivery systems
- > To ensure vaccine safety, from vaccine development through clinical trials and vaccine distribution to the point of use
- > To broaden access to safer and more efficient systems for vaccine delivery and management of sharps waste
- > To establish efficient mechanisms for the detection of serious or potentially serious adverse events following immunization, with a prompt and effective response.

Close cooperation with partners is essential to the progress of the project, and advisory bodies have been set up to facilitate this. The Steering Committee on Immunization Safety provides strategic direction to the project. The Global Advisory Committee on Vaccine Safety was established to respond promptly, efficiently and with scientific rigour to vaccine safety issues of potential global importance. The project emphasizes the importance of advocating safety and building capacity at national level.

Web sites:

www.who.int/vaccines-surveillance/ISPP/Index.shtml

www.who.int/vaccine_safety/en/

NURSING

As regards the quality and safety of nursing care, the Nursing and Midwifery Group within WHO currently focuses on the impact of staffing conditions on the quality and safety of patient care. The Report of the Secretariat submitted to the 56th World Health Assembly identified the negative impact of changing staffing conditions as a primary and growing concern among Member States. Since the human resources crisis – and particularly the shortage of nursing and midwifery personnel – is expected to deepen in the coming years, guidance on how to ensure quality and safety of care in resource-limited settings becomes vital. The Nursing and Midwifery Group has therefore recently engaged in preparing a briefing document based on studies that have established a link between inadequate staffing conditions and patient status or outcome and intended to show how the organization of care, the various approaches to using the skill mix of staff and the organizational climate all contribute to patient and provider outcomes.

Regional offices are equally active in moving the patient safety agenda forward. The Eastern Mediterranean Region has recently developed guidelines for the regulation of nursing and midwifery practice, the essential components of which refer to ensuring that outcomes of nursing and midwifery care are of high quality and that practices are safe. The region has also launched a comprehensive and standardized assessment of the quality of nursing services across its Member States.

In order to ensure the safety of care procedures, both the South-East Asian and European regions have recently published infection control training manuals and guidelines. These efforts are part of a worldwide initiative to strengthen nursing and midwifery services and will be complemented by further activities.

For further information, please contact:
algasseern@who.int

BLOOD TRANSFUSION

The mission of the Blood Transfusion Safety team within WHO is to promote the formation of national blood programmes ensuring the safety, quality and adequacy of blood and blood products to meet the needs of all patients (transfused only when necessary). They are provided as part of a sustainable blood programme within the health care system.

WHO has developed the following integrated strategy for blood safety:

- > Establishment of a nationally coordinated blood transfusion service that can ensure adequate and timely availability of safe blood for all patients in need
- > Collection of blood from voluntary, nonremunerated blood donors from low-risk populations
- > Testing of all donated blood for transfusion-transmissible infections, blood grouping and compatibility testing
- > Appropriate clinical use of blood and blood products.

The strategy addresses all the steps in collecting, testing, processing, storage and use of blood and blood products that could directly or indirectly influence the safety of patients. It can be effective only if quality systems cover all aspects of transfusion, from recruitment and selection of blood donors to transfusion of blood and blood products.

Supporting the elaboration of national policy and guidelines and monitoring and evaluation to assess the patterns of blood usage and their impact on transfusion practice are all part of approaches towards ensuring appropriate clinical use of blood and blood products. One of the tools that should be in place is a system for collecting and collating data on the hazards linked to the transfusion of blood and blood components, a process broadly termed haemovigilance. Activities carried out in this regard include the collection of information such as the prevalence of infection in blood donors and the occurrence among recipients of adverse events (including errors) associated with the transfusion of labile blood components. These data will help improve patient safety in issues related to blood transfusion.

For further information, please contact:
bloodsafety@who.int