

Recent Publications and Sources of Information

GMP training modules

Lack of good manufacturing practices (GMP) has been identified as a major obstacle to the production of locally manufactured medicines of assured quality. In 1998, with financial assistance from the Government of Japan, WHO initiated a project to promote implementation of GMP through development of a set of tools and methods defined to assist countries to improve GMP inspection.

Development of the Basic Training Modules covers Basic Principles of GMP (modules 1 to 14); GMP Inspection Process (modules 15 to 19) and Trainer's Notes (module 20). The modules were tested during a first pilot training workshop held in China in 1999 attended by inspectors from China, Indonesia, Lao People's Democratic Republic, Malaysia, Myanmar, Nepal, Philippines, and Thailand. A second pilot training workshop was held in South Africa in 2000 and was attended by inspectors from Ethiopia, Ghana, Malawi, Nigeria, South Africa, Tanzania, Uganda, Zambia and Zimbabwe. The resulting modules are now available as a CD-ROM.

WHO Basic Training Modules on GMP. A resource and study pack for trainers, is available from: Quality Assurance and Safety: Medicines, Essential Drugs and Medicines Policy, World Health Organization, 1211 Geneva 27, Switzerland. e-mail: GMP@who.int

Current challenges in pharmacovigilance

In spite of recent progress in the harmonization of terminology and processes affecting work on the clinical safety of medicines, consensus is needed on standards for many difficult aspects of day-to-day pharmacovigilance that continue to pose problems for both the pharmaceutical industry and drug regulators.

CIOMS Working Group V has generated proposals for pragmatic approaches to dealing with such issues as:

- Classification and handling of individual case reports from a variety of sources (spontaneous consumer reports, solicited reports, literature, the

Internet, observational studies and secondary data bases, disease and other registries, or regulatory ADR data bases).

- New approaches to case management and regulatory reporting practices — proper clinical evaluation of cases, incidental vs other events, patient and reporter identifiability, seriousness, expectedness, or case follow-up criteria, and the role and structure of case narratives.
- Improvements and efficiencies in the format, content and reporting of periodic safety update reports (PSUR) including results of an industry survey on PSUR workloads and practices, proposals for high case volume and long time-period reports, simplification of certain PSURs, summary bridging reports, addendum reports, license renewal reports for the EU and Japan, dealing with old products, and other technical details.
- Determination and use of population exposure (denominator) data, sources of data and a guide to analytical approaches for a variety of circumstances.

The Group has also taken stock of the current state of expedited and periodic clinical safety reporting requirements around the world, with summary data on regulations from more than 60 countries. Recommendations are made for enhancing the harmonization steps already taken as a result of previous CIOMS publications and the ICH process.

In addition to dealing with unfinished and unresolved issues from previous CIOMS initiatives, the report covers many emerging topics such as those involving new technologies. Its 20 Appendices provide a wealth of detailed explanations and reference information. It is the most comprehensive and recent treatment of difficult pharmacovigilance issues affecting the working practices and systems of drug safety and other pharmaceutical professionals.

Current Challenges in Pharmacovigilance: Pragmatic Approaches. Report of CIOMS Working Group V. Council for International Organizations of Medical Sciences (CIOMS), 2001. ISBN 92 9036 0747. Price Sw. fr. 30.- available from: World Health Organization, 1211 Geneva 27, Switzerland. <http://www.cioms.ch>

WHO Reproductive Health Library

The WHO Reproductive Health Library (RHL) project was initiated in April 1996. The project is a collaborative effort between WHO, the Cochrane Library and the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP) and collaborating institutions worldwide. RHL is updated annually and published in English and Spanish.

RHL contains systematic reviews of controlled trials on priority reproductive health topics, expert commentaries on the relevance of the findings for developing countries, and practical advice on the management of reproductive health problems. The systematic reviews come from the Cochrane Library (which is available on subscription from Update Software, Oxford, United Kingdom) and which contains systematic reviews on all areas of health care. Commentaries and practical advice are prepared by researchers from developing countries or by persons with extensive knowledge of the conditions and practice in such countries.

Currently, RHL No. 4 is available on CD-ROM from the Department of Reproductive Health and Research (RHR), and is free to scientists from developing countries.

The WHO Reproductive Health Library is available from: Department of Reproductive Health and Research, World Health Organization, 1211 Geneva 27, Switzerland. Fax: +41 22 791 41 71 and E-mail: rhl@who.int Price: US\$ 50.-

Management of sexually transmitted infections

Sexually transmitted infections remain a public health problem of major significance in most parts of the world, and failure to diagnose and treat STIs at an early stage may lead to serious complications involving unnecessary individual and national expenditure. Greater attention has been focused on STIs with the appearance of HIV and the strong correlation between prevalence of STIs and increased spread of HIV. Furthermore, antimicrobial resistance of several sexually transmitted pathogens is rendering some regimens ineffective.

In this environment, effective management of STIs and standardized treatment recommendations is a primary consideration. *Guidelines for the Management of Sexually Transmitted Infections* address such issues in a clearly arranged document which covers treatment of specific infections and STI-associated syndromes. It also provides invaluable information on choice of treatment, case management, evaluation in children and adolescents, education and counselling.

Guidelines for the Management of Sexually Transmitted Infections. Available from: Department of HIV/AIDS, World Health Organization, 1211 Geneva 27, Switzerland. Fax: +41 22 791 4834 and E-mail: hiv-aids@who.int

Safe Blood Starts With Me

The Blood Transfusion Safety Team at WHO is pleased to make available — free of charge — a CD-ROM containing facts, figures and photos on the importance of safe blood. This material, is an excellent educational tool for schools or health managers alike and includes:

- "Safe Blood Starts With Me". An easy-to-read brochure emphasizing the value of blood as an irreplaceable health asset, and why altruistic safe blood donation is so important. Available in English and French
- A colour poster with the safe blood logo in English, French, Spanish or Portuguese.

Available in Mac or PC versions from: The Blood Transfusion Safety Team, Blood Safety and Clinical Technology, World Health Organization, 1211 Geneva 19 Switzerland. E-mail: bloodsafety@who.int

Improved access to biomedical journals

The World Health Organization and the world's six biggest medical journal publishers have announced a new initiative which will enable close to one hundred developing countries gain access to vital scientific information that they otherwise could not afford. The arrangement would allow almost one thousand of the world's leading medical and scientific journals to become available through the Internet to selected medical schools and research institutions in developing countries based on tiered pricing.

Until now, biomedical journal subscriptions, both electronic and print, have been priced uniformly for medical schools, research centres and similar institutions irrespective of geographical location. Annual subscription prices cost on average several hundred dollars per title and many key titles cost more than \$1500 per year. This has made it all but impossible for the large majority of health and research institutions in the poorest countries to access critical scientific information.

Scheduled to start in January 2002, the initiative is expected to last for at least 3 years while being monitored for progress. It will benefit bona fide academic and research institutions, which depend on timely access to biomedical journals. Between now and the end of this year, these institutions will be identified individually and the process put in place. It is hoped that all parties, both the publishers and the participating institutions alike, will learn from this experience. Decisions about how to proceed will grow from the precedents the initiative sets and the working relationships developed among the partners.

The initiative is an important step in the establishment of the Health InterNetwork, a project introduced by the United Nations Secretary-General at the UN Millennium Summit last year. Led by WHO, the Health InterNetwork aims to strengthen public health services by providing public health workers, researchers and policy makers access to high-quality, relevant and timely health information through an Internet portal. It further aims to improve communication and networking. As key components, the project will provide training as well as information and communication technology applications for public health.

Working with the British Medical Journal and the Open Society Institute of the Soros Foundation network, WHO approached the six biggest medical journal publishers, Blackwell, Elsevier Science, the Harcourt Worldwide STM Group, Wolters Kluwer International Health & Science, Springer Verlag and John Wiley, with the aim of bringing them together with the countries concerned to seek a more affordable pricing structure for online access to their international biomedical journals.

Reference: <http://www.int/inf-pr-2001/en/pr2001-32.html>

Global information flow

According to the authors of an important article published in the *Lancet* last year, information flow could be one of the most important factors for improving health and development in resource-poor settings. However, it would seem that until now development organizations have not been responsive to this truism.

It is hoped that at the start of the information age, the importance of information will now be better understood. The millennium assembly of the UN emphasized this point in their statement on the right of access to information and communication. Information underpins the learning, research, and debate that drives a country forward. Access to information is essential for describing and understanding the deficiencies of the present, building visions of a better future, developing practical ways to achieve those visions, and educating and inspiring those who must make the future. Information empowers, and those who work with information flow in the rich world should find ways to enhance the flow, recognizing that the flow, like good communication, must be two way.

The information gap between the rich and the poor worlds is widening, both between and within countries. The digital divide is more striking than any other inequity in health or income. Those medical libraries in sub-Saharan Africa that have had no current journals for years still do not have them. Meanwhile, the electronic revolution is providing scientists and health workers in the developed world with unprecedented access to information. Whereas doctors in rural Africa may not have access to any information apart from outdated textbooks, doctors in the USA or the UK may be able to access hundreds of journals and other data bases from their homes and hospitals.

The information flow should not be one way. The appearance of PubMed Central, BioMed Central, and eprint servers at *The Lancet* and *British Medical Journal* makes it easier for scientists from the developing world to bring their research to the world's attention. BioMed Central also offers free technical support and can act as host to people wanting to start new electronic journals or to move existing journals to the web.

The electronic revolution should improve information flow in all directions, and many regions are establishing free networks for the exchange of health information. Good examples include the Scientific Electronic Library Online (www.scielo.org), Boline International (<http://bioline.bdt.org.br>), and African Journals Online (www.inasp.org.uk).

Those who would like to continue discussions might join the Health Information Forum-net at WHO, a dedicated e-mail discussion list run by the Health Information Forum (which includes INASP-Health and International Network for the Availability of Scientific Publications) and the WHO. To join, send an e-mail to INASP_Health@compuserve.com with your name, affiliation, and brief description of your professional interests.

Reference: Fiona Godlee, Richard Horton and Richard Smith. Global information flow. *Lancet*, 356: 1129-1130 (2000).

First Asian course in problem-based pharmacotherapy teaching

The first Asian training course on problem-based pharmacotherapy teaching will be held from 19-28 October 2001 (inclusive) in Manila, Philippine. It is being organized jointly by the Philippine Society of Experimental and Clinical Pharmacology and the WHO Collaborating Centre for Training in Pharmacotherapy & Rational Drug Use at the Faculty of Medicine and Health Sciences, University of Newcastle, Australia.

The course is designed primarily for teachers of pharmacotherapy working in undergraduate or post-graduate settings: medical schools, pharmacy schools, teaching hospitals etc. The course aims to provide practical instruction in, and experience of a problem-based approach to pharmacotherapy teaching. The course is based on the *WHO Guide to Good Prescribing*.

During the course participants will:

- study the problem-based approach to pharmacotherapy teaching;
- learn to act as facilitators for small-group, problem-based learning in practical pharmacotherapy;
- develop teaching/learning materials suitable for use in their own teaching environment;
- become familiar with modern educational strategies available for course development, student assessment, and course and tutor evaluation; and
- develop their own targets and objectives for introducing the problem-based approach to pharmacotherapy teaching in their local context.

Application forms can be obtained from Pharmacotherapy Course Secretariat, Discipline of Clinical Pharmacology, 5th Floor, Clinical Sciences Building Newcastle Mater Hospital, Waratah, NSW 2298 Australia. E-mail: mannix@mail.newcastle.edu.au fax: +612 4960 2088