International Journal of Risk & Safety in Medicine, 1 (1990) 153–156
Elsevier

RSM 00029

Meeting Report

Improving drug safety: a joint responsibility

W.P. von Wartburg
Ciba-Geigy, Basel, Switzerland

Report of the Second Wolfsberg Conference on the Perception and Management of Drug Safety; Wolfsburg, April 17th–20th 1990.

Over the past decades, health care delivery has become more complex, and the traditional roles and relationships that structure this process have altered to allow new decision makers to enter the arena. Responsibility for drug safety, previously perceived by the public as belonging to regulatory bodies and physicians, has, in their eyes, now extended to the manufacturer. Increasingly, benefits from health-care goods must now be balanced against society's demand for safety, and to this end data must be amassed and analyzed.

The developing science of pharmacoepidemiology uses new technology, including data base linkages, to expand scientific knowledge on how drugs affect patients. More specifically, it monitors the effect of adverse drug reactions (ADR) in large populations, as well as determining the benefits that specific drugs yield in fighting specific ailments.

The RAD-AR (Risk/Benefit Assessment of Drugs – Analysis and Response) initiative was launched in 1988 by Ciba-Geigy to address the issue of drug safety, with the aim of studying and assessing drug risks and benefits, and communicating their findings to the public. In April 1988, representatives from 30 research-based pharmaceutical companies in North America, Europe and Japan, consumer organisations and the media gathered in Switzerland to participate in the first Wolfsberg Conference on the perception and management of drug safety.

Since then, there has been a full agenda of meetings, workshops and seminars held all over the world. Co-operative efforts between members have resulted in the design and implementation of new projects to promote drug safety in different countries. These have included the production of data resource handbooks – now available for North America, the United Kingdom, Europe and Japan; these volumes list population and sample descriptions with demographic data, coding information for diagnosis, data linkage capabilities, the availability of data bases to

Correspondence to: Prof. W.P. von Wartburg, Ciba-Geigy AG, Basel, Switzerland.

outside research groups, reference material, and the name and address of a current contact person.

The second Wolfsberg conference, which took place between 17th and 20th April this year, was attended by more than 100 experts from industry, government, the medical professions, the academic world, the media, and international health and consumer organisations. The conference was organized by the Council for International Organizations of Medical Sciences (CIOMS) and by the International Federation of Pharmaceutical Manufacturers Association (IFPMA) as well as by RAD-AR interested companies. The participants came from Europe, including the German Democratic Republic, North America, and Japan, as well as China and Australia.

The emphasis of the conference was on dialogue between the different constituencies represented. Mr Peter Simon, head of the pharmaceuticals division at Hoffmann-La Roche Ltd., said: "It is the first time that all groups involved in drug safety issues have the possibility to listen to each other, and to understand each other's position". Dr Jean Pfanner, director of the Swiss regulatory agency IKS, expressed his hope that: "This unique opportunity for a dialogue between several groups with a different scope of interest will help to open doors for better communication between them". In his opening speech, Professor Zbigniew Bankowski, Secretary-General of the Council for International Organizations of Medical Sciences (CIOMS) remarked that "The objective of RAD-AR is to improve drug safety in a collaborative effort, and to approach this problem from an ethical point of view." It is the ethical view that provided the context in which the conference took place.

The conference was spread over four days, starting with a session that laid out the ethical guidelines that should be implicit in discussions on drug safety. In the two days that followed, the mornings were given over to a series of presentations, dealing first with ways and means of generating reliable knowledge about drug risks and benefits, and assessing the balance between them.

On the following day, the second session treated drug safety communication – what information should be passed on, to whom and how. During the afternoon sessions of the second and third days, the participants formed three working groups to discuss issues in the context of the morning's proceedings, and formulate proposals for action. To ensure as wide-ranging a discussion as possible, the working groups included representatives from each of the constituency groups present. The final session was taken up with reports from the working parties and feedback from the ethical experts on what they had observed.

The first session set the scene by starting with an overview of ethical theory, in order to help participants understand how and why they should try to overcome the inherent biases of their backgrounds and perspectives. It went on to focus on the principles of biomedical and corporate ethics, underlining the reality that commercial success could no longer be determined simply by annual profits. Social responsibility, the wise management of energy and other resources, and the environment's protection are among the factors increasingly required by the consumer.

The Hippocratic dictum "above all, do no harm" was used as the point of reference for the working group discussions, and it was felt that this was no longer

as easily applicable to the risk/benefit equation, but rather that the probability of benefit should outweigh the likelihood of harm. To this end, the illusion that drugs do no harm should be swept away in favour of the reality that risk and benefit must be weighed up and balanced.

One working group suggested that government, industry and academia should be jointly responsible for setting up an international, funded system for drug surveillance. The issue of confidentiality of information in relation to data bases and ADR reporting gave rise to much discussion, with representatives of industry arguing that confidentiality was necessary in order to avoid misuse of information. Participants felt that existing data bases should be made more accessible before considering setting up new ones.

ADR monitoring was judged to be a shared responsibility, with important roles played by the manufacturer and regulatory bodies, but it was agreed that the legitimate role of the public and the media should be recognised, and that industry should provide full information on all drug effects. The constituencies agreed on the importance of monitoring patterns of use and effect, and felt that manufacturers should not aim to penetrate the market with a drug faster than its effects could be measured and assessed. Factors such as quality of survival, quality of life and health status, it was felt, were significant and should be used in the evaluation of drugs, despite difficulties in their quantification.

Participants considered that it was the duty of the pharmaceutical industry to provide physicians and patients with comprehensive information as well as to accept feedback. On the subject of patient package inserts (PPIs) it was felt that drugs unaccompanied by written patient information amounted to bad medicine. In discussing the concept of an "optimal degree of information", many participants felt that it was unrealistic in global terms, but that drug safety information should be target specific. This puts the onus on those supplying information to explore the needs of the target group, not forgetting that the language in which the information is expressed must be understood, even by lay people.

Concern was expressed that the stereotype of the passive patient should not simply be replaced by a different stereotype: that of the active consumer. Instead, it was agreed that consumers should be enabled to exercise their right to define the level of involvement desired in decision making, and those providing health care should aim at understanding individual needs.

Physicians, it was felt, carried a major responsibility in assessing drug effects that should be effected by encouraging and entering into dialogue with the patient. Patients need to be taught to express not only their needs but also their concerns to health providers. It was concluded that the patient's right to choose is one that must be protected at all costs even if at times that choice does not fit in with the expert's assessment of the best course of action. The responsibility for ensuring that decisions are based on reliable and valid information that has been clearly communicated should be shared.

Participants felt that risk/benefit information should be passed on to the public through the available intermediaries of physician and media, and that the latter, preferably with some background in science, should behave responsibly when

conveying information, taking care to be honest, impartial and comprehensive.

Principal among the many proposals for action suggested by the participants at the 1990 Wolfsberg conference was that a task force should be set up to establish the criteria by which the RAD-AR initiative could be translated into a formal body with the power to initiate and carry out proposals, and decide on a business plan for action. Professor Bankowski of CIOMS and industry members from the RAD-AR consortium agreed to meet this challenge.

The 1990 Wolfsberg Conference provided a forum for dialogue between the different constituencies in health care, and it is hoped that this dialogue will continue on a national and international level, within and between companies, and between the different constituencies themselves.

Forthcoming Meetings

First International Symposium on Advances in Legal Medicine. Kanazawa, Japan, October 12–15, 1990. Information: Dr T.T.Noguchi, 1200 N State St., Room 2519. Los Angeles, CA, U.S.A. 90033–1084. Tel. (213) 226 7126.

World Medical Association. Stouffler Esmeralda. Rancho Mirage. California. October 22–28, 1990. Information: Dr A. Wynen, 28. Avenue des Alpes, 0210 Ferney-Voltaire, France.Tel. 50 40 7575.

American Academy of Psychiatry and Law. Hotel del Coronado, San Diego, California. October 25–28, 1990. Information: Dr J.R.Rappeport, 1211 Cathedral Street, Baltimore, MD 21201, U.S.A. Tel. (301) 539 0379.

International Conference on Qualitative Health Research. Edmonton, Canada, February 22–23, 1991. Information: Dr J. Morse, Faculty of Nursing, CSB 3–120, University of Alberta, Edmonton, Alberta, Canada T6G 2G3.

First Workshop on Strategies for the European Pharmaceutical Industry and Patient Interests. Brussels, Belgium. January 31–February 1, 1991. Information: European Institute for Advanced Studies in Management, Conference Department, Rue d'Egmont 13, B-1050, Brussels, Belgium.