COMMENTARY

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The Erice Declaration

The Critical Role of Communication in Drug Safety

Bruce Hugman

The Uppsala Monitoring Centre, Uppsala, Sweden

Abstract

The Erice Declaration on Communicating Drug Safety Information, first published in September 1997, provides a vision of vigorous, open, ethical, patient-centred communications in drug safety that the world has yet to achieve. The Declaration is reprinted here as a further stimulus to all parties to renew their commitment and to add new momentum to the improvements which have undoubtedly taken place in the past few years. The content of the Declaration is briefly reviewed, and some of the continuing communications challenges and problems are outlined.

The publication of *The Erice Declaration on Communicating Drug Safety Information* in September 1997 coincided with, and was probably significantly instrumental in achieving, a worldwide movement to include communications high on the core agenda of pharmacovigilance. The topic has remained firmly on that agenda and has shown increasing prominence in the literature, at workshops and conferences, and in almost all drug safety debates.[1-8] The Declaration itself is often cited.

The international group, which met in Erice (see Appendix) and drafted the Declaration, represented most stake holders in the drug safety arena: patients, clinicians, lawyers, regulators, industry, researchers and campaigners, journalists and communications experts, academics and international health organisations. It was this unique assembly of interests and skills that led to the radical and comprehensive sweep of the document's content – concluding above all that the primary goals of patient safety and public health could be achieved only through open, transparent, ethical and effective communication of drug safety issues involving all players and tailored to their needs.

The fundamental shift implied was from the processing and distribution of information to the active engagement of all parties and to the understanding and meeting of their wishes and needs: from an essentially bureaucratic, distributive model to an interactive, patient-centred model.

The Declaration asserts the *right* of patients and the public to good information about the safety of drugs "ethically and effectively communicated". It deals particularly with that problematic area, lack of certainty: "Facts, hypotheses and conclusions should be distinguished, uncertainty acknowledged…". It insists that *all* the information relating to benefit and harm, effectiveness and risk about medicines should be openly available and debated.

The Declaration is a very short document (one A4 page), but the challenges it raises are profound and they are still far from being met. We know that much regulatory communication is ineffective;[9,10] we know that large numbers of patients experience serious or fatal damage from their medicines;[11] we know that flawed behaviour by doctors and patients is widespread;[12] we know that drug crises and scares damage the credibility of regulation, industry, medicine and the welfare of patients.[13-15] At the heart of many of these problems is a failure to grasp the rigorous demands of good communications practice, including openness and transparency.

The Declaration (see figure 1) promotes a visionary agenda for everyone involved in drug safety and,

The Erice Declaration – On Communicating Drug Safety Information

The following declaration was drawn up at the International Conference on Developing Effective Communications in Pharmacovigilance, Erice, Sicily, 24-27 September 1997. It was attended by health professionals, researchers, academics, media writers, representatives of the pharmaceutical industry, drug regulators, patients, lawyers, consumers and international health organisations.

Preamble

Monitoring, evaluating and communicating drug safety is a public-health activity with profound implications that depend on the integrity and collective responsibility of all parties – consumers, health professionals, researchers, academia, media, pharmaceutical industry, drug regulators, governments and international organisations – working together. High scientific, ethical and professional standards and a moral code should govern this activity. The inherent uncertainty of the risks and benefits of drugs needs to be acknowledged and explained. Decisions and actions that are based on this uncertainty should be informed by scientific and clinical considerations and should take into account social realities and circumstances.

Flaws in drug safety communication at all levels of society can lead to mistrust, misinformation and misguided actions resulting in harm and the creation of a climate where drug safety data may be hidden, withheld, or ignored.

Fact should be distinguished from speculation and hypothesis, and actions taken should reflect the needs of those affected and the care they require. These actions call for systems and legislation, nationally and internationally, that ensure full and open exchange of information, and effective standards of evaluation. These standards will ensure that risks and benefits can be assessed, explained and acted upon openly and in a spirit that promotes general confidence and trust.

The following statements set forth the basic requirements for this to happen, and were agreed upon by all participants from 34 countries at Erice:

1. Drug safety information must serve the health of the public. Such information should be ethically and effectively communicated in terms of both content and method. Facts, hypotheses and conclusions should be distinguished, uncertainty acknowledged, and information provided in ways that meet both general and individual needs.
2. Education in the appropriate use of drugs, including interpretation of safety information, is essential for the public at large, as well as for patients and health-care providers. Such education requires special commitment and resources. Drug information directed to the public in whatever form should be balanced with respect to risks and benefits.
3. All the evidence needed to assess and understand risks and benefits must be openly available. Constraints on communication parties, which hinder their ability to meet this goal must be recognised and overcome.
4. Every country needs a system with independent expertise to ensure that safety information on all available drugs is adequately collected, impartially evaluated, and made accessible to all. Adequate non-partisan financing must be available to support the system. Exchange of data and evaluations among countries must be encouraged and supported.
5. A strong basis for drug safety monitoring has been laid over a long period, although sometimes in response to disasters. Innovation in this field now needs to ensure that emergent problems are promptly recognised and efficiently dealt with, and that information and solutions are effectively communicated.

These ideals are achievable and the participants at the conference commit themselves accordingly. Details of what might be done to give effect to this declaration have been considered at the conference and form the substance of the conference report.

Erice, 27 September 1997

Fig. 1. The Erice Declaration

8 years on, still sets standards that we are far from reaching, though some progress is being made.

A detailed report[16] was published, and a handbook on the principles and skills of effective communication in pharmacovigilance arising from the meeting is also available.[17] Both publications can be obtained from the Uppsala Monitoring Centre (www.who-umc.org).

Acknowledgements

Bruce Hugman is a consultant in communications to the Uppsala Monitoring Centre, and was one of the organising team for the 1997 Erice meeting. Professor I. Ralph Edwards and Professor Giampaolo Velo share the views expressed by Bruce Hugman in this article.

Appendix

Erice

Erice is a pre-medieval town with a history going back to ancient times, perched on a lofty mountain at the western tip of Sicily in the province of Trapani. Its most outstanding institution is the Ettore Majorana Centre for Scientific Culture, which has 113 Schools that cover all branches of science. All activities are housed in meticulously renovated ancient buildings. From time to time, this unusual academy brings together groups of distinguished scientists and thinkers from all over the world to think, talk, share their knowledge and research, and to debate future agendas and strategies in their specialty.

It was here, under the auspices of the International School of Pharmacology, that *The Erice Declaration on Communicating Drug Safety Information* was debated and written. In May 2002, there was a second meeting addressing the problematic issue of direct-to-consumer (DTC) advertising of drugs. This second workshop, Drug Advertising and Consumers, was organised by the Verona Reference Centre for Education and Communication within the WHO Programme for International Drug Monitoring. This reached an impasse as a result of the irreconcilable, well argued and passionately felt positions of those who wanted cautious, regulated liberalistion, and of those who were implacably opposed to any kind of DTC. The Erice Statement on Drug Advertising to the Consumer will be available soon (www.sfm.univr.it).

Information about the Erice process

Professor Giampaolo Velo, Clinical Pharmacology Unit and Reference Centre for Education and Communication within the WHO Programme for International Drug Monitoring, University of Verona, Verona, Italy (gpvelo@sfm.univr.it). Professor I. Ralph Edwards, the Uppsala Monitoring Centre, Uppsala, Sweden (ralph.edwards@who-umc.org).

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Correspondence and offprints: *Bruce Hugman*, PO Box 246, Amphur Muang, Chiang Rai 5700, Thailand.
E-mail: mail@brucehugman.net