BJCP British Journal of Clinical Pharmacology

DOI:10.1111/j.1365-2125.2009.03562.x

Letter to the Editors

Erice Statement 2009: communication, medicines and patient safety

Twelve years after the original Erice Declaration, this current statement was also prepared in Erice, by an international group of volunteer professionals, representing themselves, and drawn from a broad range of stakeholder interests.

The original Erice Declaration of 1997 was a visionary statement of the achievable ideals for drug safety communication at the time, much of which remains potent and relevant today. Since then, however, the landscape has changed:

- ❖ Pharmacovigilance now extends to broader concerns relating to the safety of patients taking medicines, including medication error, off-label use, counterfeit products, erosion of trust and the potential risks to humans from drug residuals in the environment
- ❖ Dramatic information technology and electronic media developments worldwide have changed the nature of communications of all kinds
- ❖ The expansion and complexity of stakeholder involvement, and particularly societal and patient expectations, have radically altered the demands on healthcare providers and drug safety professionals.

New priorities and challenges have emerged as a result of the changes in these and other areas. Continued progress towards the ideals expressed in the original Erice Declaration is influenced—and sometimes hindered—by scientific and technical, but also political, financial, social and psychological factors.

- ■ The authentic needs and wishes of the multiplicity of stakeholders, often with diverse and sometimes conflicting interests, are not well known.
  - ○ Active research must be undertaken to understand stakeholders' perceptions, requirements, roles and interactions
  - ○ Reciprocal partnerships must be built and managed based on mutual respect, sound knowledge, and with clear and agreed roles and responsibilities
  - ○ Targeted messages must be developed at a level of complexity matched to the abilities and needs of audiences, and using the richness of modern resources.
- ■ There is extensive existing safety knowledge and experience outside the drug safety domain, and within it, that is not exploited and shared between individuals, disciplines and systems concerned with patient safety.
  - ○ Medicines safety communications with patients and the general public must be focused on achieving a culture of dialogue and joint-responsibility for safe and rational therapy
  - ○ Recognized health authorities must provide guidance for all audiences on finding, interpreting and assessing the reliability of safety information from existing sources, including unregulated information on the internet
  - ○ Existing knowledge and experience in drug safety communication must be given a much higher priority in all areas of professional education and training.
- ■ Decisions in relation to drug regulation and therapy involve probabilistic assessments of risks and benefits, often based on limited information. Fear of litigation hampers open debate and transparency over judgements behind decisions, and clarity of information can be compromised by legal and legalistic concerns.
  - ○ A positive safety culture must be established, based on team-working processes and thinking that acknowledge responsibility, are free from blame and allocate accountability.
- ■ The presence of widely dispersed drugs and drug metabolites in the environment poses a potential direct, and indirect, risk to humans.
  - ○ The nature and extent of the potential risks must be further investigated and assessed
  - ○ Safe disposal of medicines must be promoted, and appropriate facilities set up and used
  - ○ Further measures may have to be taken to reduce drug discharge into the environment, including education
  - ○ The promotion of rational drug use should reduce the volume of medicines finding their way into the environment.
- ■ Progress in the area of gathering and storing health information brings with it challenges in ethics, and in assessing and managing quality, of both the data and the systems.
  - ○ Active efforts must be made to promote and seek public approval of the use of anonymized patient information as essential for research and safe and effective therapy

- Those responsible for IT systems must ensure the highest level of security and quality to achieve public trust and willingness to contribute anonymized personal information.

■ The media and professional communicators have an important role, not only as safety partners, but also in scrutinising the performance of drug safety systems.

- New ways to cooperate with the media as professional equals must be explored to help in the provision of balanced, comprehensible, trustworthy and interesting safety information to the public on a regular basis, apart from specific announcements or reports of problems or crises.

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The interests of all participants were openly declared.

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The meeting was organized by the International School of Pharmacology at the Ettore Majorana Foundation and Centre for Scientific Culture in Erice, Sicily, Italy, in collaboration with the International Society of Pharmacovigilance (ISoP), SK Foundation and the Uppsala Monitoring Centre (UMC).

RECEIVED
12 October 2009

ACCEPTED
14 October 2009

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