



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Focussing on Risk Communication: Why now? What next?

Global lessons learnt from the *Drug Safety* theme edition

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Why?

- Pharmacovigilance objective: Risk minimisation and patient safety/"Prevention of drug-related problems"
- Communication as a pharmacovigilance tool recognised for more than 15 years
- Delay in implementation of best practices
- Increasing focus in the pharmacovigilance community over the last years



Why now?

- Needs for and demands from patients for informed therapeutic choice and clear risk minimisation advice
- Changing communication environment
- Ongoing implementation of the risk management approach
- Delayed translation of evidence into healthcare
- Negative patient outcomes even with established medicines



Why now urgently?

- Adverse reactions
- Medication errors

= Leading cause for morbidity and mortality

= Source of mistrust



What now?

Bringing communication science into
pharmacovigilance!



Drug Safety theme edition on risk communication 1/2

Cox AR, Butt TF: When the risk becomes a reality for patients

Fischhoff B: Good decision-making requires good communication

Hugman B: Protecting the people?: risk communication and the chequered history and performance of bureaucracy

Edwards B, Chakraborty S: Risk communication and the pharmaceutical industry: what is the reality?

Hartigan-Go K: Challenges of drug risk communications in the Philippines



Drug Safety theme edition on risk communication 2/2

Dodoo A, Hugman B: Risk perception and communication in Sub-Saharan Africa

Larson H, Brocard Paterson P, Erondur N: The globalization of risk and risk perception: why we need a new model of risk communication for vaccines

Piening S, Haaijer-Ruskamp FM, de Graef PM, Straus SMJM. Mol PGM: Healthcare professionals' self-reported experiences and preferences related to direct healthcare professional communications: a survey conducted in the Netherlands

Bahri P, Harrison-Woolrych M: Focusing on risk communication about medicines; why now? (editorial)



Global lessons learnt: Evidence

- Communication barriers
- Rigid mind sets and procedures
- Eroding trust
- Need for transparent benefit-risk assessment frameworks
- Social and political dimensions
- Need for situation-/audience-specific tailoring
- Research gaps



Global lessons learnt: Proposals

What next?

- Research
- Listen to and deal with patients' and public concerns
- Analysis of the social and political contexts
- Integration of benefit-risk assessment and communication
- Culture shifts



What next at EMA?

- Good pharmacovigilance practices (GVP)
- Methods development
- Research advocacy
- Outreach across stakeholders in the EU



We are together here

- Regulators
- Patients: Clear needs as a population and multiple individual needs, demands and contributions
- Healthcare professionals: Multiple contributions, roles, pressures and options/opportunities, needs of their own



What next – we together?

- User testing
- Analysis of contexts, concerns and information needs?
- Rebuilding of trust...



What next – we together?



DISCUSSION

