

# Focusing on Risk Communication About Medicines

## Why Now?

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Communication about the risks of medicines is not a new issue. Patients have long since sought advice about remedies, whether from family, healthcare workers or the wider community in traditional ways, or via websites and social media in today's world. As pharmacovigilance professionals, interacting with patients, healthcare professionals, health policy makers, journalists and the general public has become part of our daily activity, in order to manage risks with medicines appropriately and reduce patient harm.

So why is this theme edition of *Drug Safety* focusing on risk communication now? A decade ago, risk management was introduced into pharmacovigilance,<sup>[1]</sup> and the implementation and evaluation of this approach are still subject to improvement in the light of experience gained so far. But it has become clear that at the core of successful risk management lies effective risk communication. This applies to formal risk management plans as well as to risk minimization action otherwise taken for a medicine and interactions between healthcare professionals and patients. *Drug Safety* has increasingly been a forum for discussing risk communication,<sup>[2-11]</sup> and given that applying communication science to pharmacovigilance is relatively new, we thank the journal editors for now dedicating a whole edition to this topic.

Articles were invited from authors with different kinds of relevant expertise and with a view

to covering perspectives from various stakeholders and world regions. The resulting contributions include original research, reviews and opinion papers. It is perhaps not surprising – due to the still limited research – that often opinions are underpinned by experiences rather than systematic evidence, and this illustrates the need for further research. There is now an urgent need to look at old and new ideas for risk communication under a magnifying glass, in order to explore how to put established principles into practice and to experiment with new approaches.

Why is this urgent? Avoidable adverse reactions and medication errors are still a leading cause for morbidity and mortality,<sup>[12-21]</sup> and there are ongoing patient needs for information to facilitate treatment choices.<sup>[22]</sup>

In their article on patients' expectations, Cox and Butt<sup>[23]</sup> remind us of the need for information about benefits as well as risks and that prescribers may prefer to highlight benefits rather than risks of medicines. Referring to their own research, they stress that patients often lack understandable risk information and want their negative experiences to be taken seriously. This is described as fundamental for the trust of patients in their healthcare professionals and treatments. Furthermore, the authors discuss that differences in risk perceptions between patients and healthcare professionals may be a barrier to one-to-one communication.

This barrier also exists when communicating with broader audiences, and Doodoo and Hugman<sup>[24]</sup> give us important advice in this respect: public concerns have to be addressed, whether or not, as pharmacovigilance professionals, we share these concerns. The authors take us on a journey through sub-Saharan Africa, with examples illustrating how risk communication may be linked with social problems and citizens' trust – or often mistrust – in governments. We should hence understand that we cannot look at a safety concern in isolation, but that the social and political context should be considered for every communication intervention about a medicine with public health relevance. Every time communication fails, public trust in medicines is eroded and this trust is difficult to re-build. This may result in using medicines inappropriately or avoiding them altogether, which could threaten patient and public health. The need to establish trust in pharmacovigilance systems at both individual and population level adds to the urgency of this theme edition.

Similar lessons can be learnt from the Philippines, and Hartigan-Go<sup>[25]</sup> advises us to keep ourselves on a constant learning curve, as past experiences should inform future communication strategies. He advocates that risk management and communication should become an accepted culture within governments, healthcare and pharmaceutical industry, and recommends applying the social marketing approach for promoting safe use of medicines. Among the many challenges he describes as prevalent in the developing world is also the difficulty for healthcare professionals to keep aware of all latest evidence.

This is not easy elsewhere either, as reported from the Netherlands by Piening et al.<sup>[26]</sup> By means of a survey, they further found that the majority of Dutch healthcare professionals considered receiving risk communication important and that almost one-third reported taking action following a direct healthcare professional communication (DHPC). This might be considered a disappointing figure, but in some other areas achieving a behavioural impact by a single act of communication in one-third of the targeted audience would be a success. The authors suggest a mix of tools for disseminating information to

impact on more healthcare professionals, as necessary for patient safety. This kind of research into healthcare professional and other audiences is much needed and we hope to see more in other countries too. We will also need objective measurements of behaviour, rather than relying on self-reported impact. The impact crucially depends on the trust in the information source, and Piening et al.<sup>[26]</sup> found that healthcare professionals prefer to be informed by governmental or their own professional bodies, and not by pharmaceutical industry.

Edwards and Chakraborty<sup>[27]</sup> discuss communication from manufacturers, including public mistrust. They highlight that improvements through proper effectiveness evaluation of communication remains to be achieved and suggest learning from patient information leaflets, which have been improved much through testing. For manufacturers' communication strategies, the authors recommend coherent strategies across the organization and agreeing the strategy's objectives with the regulatory authority. But they also conclude that common understanding between manufacturers and regulators is often lacking, as to whether risk communication intends to inform, to help understanding or to change behaviour of medicine users. So working together towards a common understanding is fundamental for future progress.

How regulators can gain clarity on their communication objectives can be learnt from the article by Fischhoff.<sup>[28]</sup> He proposes a framework for decision making on the benefit-risk balance of medicines, which both requires and facilitates communication. The framework integrates calculations and statistics with judgement on the quality and strength of the evidence, based on transparently agreed values and criteria. Methodological clarity should facilitate communication between experts, decision makers and other stakeholders, with a view to explaining to the public why a certain decision was taken. This honesty about value-based judgements upon the evidence may enable us, as pharmacovigilance experts, to communicate effectively in the given social and political contexts.

These contexts have been studied for vaccines more than for most other medicines, and Larson et al.<sup>[29]</sup> give us proof of many points discussed in

other articles in this theme edition, with major examples for vaccines. Again, there is advocacy for an integrated approach of risk assessment, minimization and communication, also integrating the monitoring of public concerns. The authors make other very important points: listening must be part of communication, and rather than sticking to standard messages that have not worked in certain circumstances, messages should be tailored to respect each community, address their specific concerns and gain their trust. This approach could increase vaccine acceptance, and given the examples of (re)occurrence of vaccine-preventable disease outbreaks, this is another urgent call.

While we may realize that we need to urgently improve risk communication, we should also understand that to make that happen a fundamental shift is needed in the way we work as pharmacovigilance professionals, in whichever setting.

To help us in making that shift, Hugman<sup>[30]</sup> whirls us across countries, backwards and forwards in time and through fiction and non-fiction. While appreciating the principles of democratic public administrations to provide services to the public based on equality and fairness, he warns us of obstacles administrations can create with negative impact on communication. He applies his criticism of bureaucracies not only to public administrations, but also to those in healthcare and pharmaceutical industry. In order to overcome rigid mindsets, he draws our eyes to compassionate problem solving through 'creative bureaucracies' which are honest, ethical, efficient, motivating, non-hierarchical, networking, interdisciplinary, multicultural and, of course, patient-centred! Ultimately, Hugman<sup>[30]</sup> gives us the lens for our focus in pharmacovigilance in general and communication in particular: how can we ensure that everything we do contributes to patient safety and welfare?

Applying this lens to the integration of risk assessment, minimization and communication and decision making upon the benefit-risk balance of a medicine, shows us that an integrating framework should not add procedural obstacles, but facilitate problem solving.

We also agree that this should result in communication interventions tailored for specific

audiences and that 'not one size fits all', as discussed in articles in this theme edition. However, we face a dilemma when we have to communicate with broad audiences as regards how far we can tailor messages without appearing to issue inconsistent messages. Also, since communication needs and preferences differ by many factors, we should reflect upon the need for, but also the feasibility of, audience segment-specific data versus the generalizability of less segmented data.

Furthermore, we must consider that patients and healthcare professionals may already be confused by different information sources, as some authors highlight. Team effort, in particular with listening to patients and working with patient organizations, is therefore required from as many stakeholders as possible to get agreement on messages. Embracing our world of plurality, we need to strengthen our communication practices in order to make our voice heard in the interest of patients.

Where should we focus now in order to progress? Not all ideas presented in this theme edition are new – most importantly we should remember the Erice Report<sup>[31]</sup> and its recent update enforcing patients' interests<sup>[32]</sup> – but implementation is not so easy. While progress has been achieved in some areas, other established principles of good communication practices are not yet systematically followed. Also, the communication environment has seen rapid changes recently in terms of social and political contexts, such as increased public demands for information, as well as significant developments in information technology and related communication behaviour. This theme edition reflects upon the challenges these changes present, and we are grateful to the authors for inspiring us with new ideas on how to tackle these.

Ultimately, the usefulness of all our efforts in pharmacovigilance will manifest itself in our ability to communicate practical advice for the safe use of medicines. This advice should achieve improved patient health outcomes. This is a high goal, but we cannot settle for less. Inadequate communication is a risk in itself, and hence communication expertise and functions within pharmacovigilance should be installed alongside all other crucial functions. Let's focus on this now – the safety of patients will depend on it.

## Acknowledgements

The views expressed in this editorial are the personal views of the guest editors and may not be understood or quoted as being made on behalf of or reflecting the position of any of the organizations the guest editors are affiliated to. No sources of funding were used to prepare this article and the guest editors have no conflicts of interest to declare.

This editorial is part of a theme issue co-edited by Priya Bahri, European Medicines Agency, UK, and Mira Harrison-Woolrych, New Zealand Pharmacovigilance Centre, New Zealand. No external funding was used to support the publication of this theme issue.

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