



Communicating About Risks and Safe Use of Medicines

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Wise men speak because they have something to say;
fools because they have to say something.

Plato

The single biggest problem in communication is the
illusion that it has taken place.

George Bernard Shaw

In this century, we have seen an explosion in communication in all walks of life. Much of it lacks the insight recommended by Plato, and worse, we have had a recent increase in ‘fake news’, all of which is brought to our attention by multiple forms of media.

At the same time, there are new ideas, social developments, research news, entertainment possibilities, sudden disasters of many kinds, the creeping harms from global warming, and so much more. We might like to pay attention to all these matters, and it is via communications that we try to succeed in this. Can we really?

Priya Bahri has brought together a group of authors whose aim is to tell us how to communicate in an area that is complex and important to all of us. The subheading to the title of the book is “Real Life and Applied Research”. In this respect, Plato would be happy with this book and its content: there is an enormous amount of important content.

George Bernard Shaw would be similarly pleased that not only is the aim of the book to ensure that useful communication does take place, the book also gives a lot of useful information on how we can assess whether communication has taken place.

In her preface, Dr. Bahri considers the question of how to read this book; I wondered why. Her opening chapter gives an answer as well as an introduction to the book’s content as a whole. The chapter is amazing in its summary coverage

of the complexities of risk recognition, evaluation, and management internationally and also introduces us to the ensuing complexity of the multiple communications/messages that need to be passed to a hugely variable audience. Dr. Bahri suggests one way through the complexities of the book is to use the index to find areas of interest to the reader and go to relevant areas. But she does more by giving (on pp. 58–59) a content guide dealing with ways in which different disciplines may have valuable insights into various aspects of the science of communication.

For her own chapter, the first, I was much aided by four tables of what she describes as typologies, the types being: 1.1 risk communication events (which also indicates the multiplicity of players involved and their interests in medication safety); 1.2 the types of risk communication outcomes; 1.3 reviews of risk communication interventions and their outcomes; 1.4 the intents of risk communication research. The tables were a great aid in making sense of the multilayered research framework, as well as the potential for confusion in communication, and that safety in medical care is a moving target: there is no single prescription for a communication method, any more than there is a way for us to predict the risks and harms that we will face in any other area of life. (Similar tables appeared in some of the other chapters in the book, and I always found them of value.)

Bahri’s chapter is about the multilayered research framework, and I have respect for its apparently entangled coverage of all aspects of the topic, and it does emphasise to us that we are about to enter a book that is about research. I think, however, that the reader will find more questions and doubts than clear answers to any particular topic. I, therefore, wonder about its value to anyone who has only a casual interest in the area; one certainly needs to be keen to attempt a straight-through reading of the book as I did.

This view is reinforced by the way Part 1 of the book deals with the concerns around real life examples with retrospective analyses of the methodology and results of research

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in medicines risk, safety, and effectiveness. The problems of science described in those examples have an all-important impact on communication: How can communication be useful when the underlying information is debatable, dubious, or missing? What can one say about uncertainty?

The chapters on the “pill scare” (Chapter 2) and on the cyclooxygenase-2 (COX-2) medicines (Chapter 3) both show that a major problem with communication lies in the uncertainties in the underlying science around a new post-marketing risk finding and in the public debate in the media that accompanies them.

The isotretinoin example (Chapter 4) is different in that the risk was known prior to marketing and product warnings and recommendations for avoiding birth defects were in place. This is a clearer situation that allows us to focus on the many communication-associated challenges, particularly considering societal differences relating to sex, abortion, and contraception. There is an example of an ongoing scientific debate over the risk of suicide that complicates communication of this other serious possible risk.

The last case example is the use of pandemic influenza vaccination (Chapter 5). The challenge with this is associated with convincing the public, globally, that prevention of a disease is desirable for society as a whole and not just for an individual. As communication aspects are very much to the fore with considerations of expected benefits and harm, I was surprised that the protracted debate about the safety of measles, mumps, and rubella (MMR) vaccination as well as the association of narcolepsy with the H1N1 vaccines were not mentioned. There is much useful information in this chapter about the basic considerations of public awareness and risk versus effectiveness attitudes.

Together, the chapters in Part 1 support the contention that communication is a tangled web starting with uncertainty and scientific evidence that is variable in its quality, aim, context, and, above all, interpretation.

Since I was deeply involved in the pharmacovigilance in all of these cases, I am surprised that no mention is made of the collections of case data that provide early signals of most harms possibly caused by medicines. The COX-2 risk of myocardial infarction in older people exceeding the recommended dose and duration was seen within 6 months of the drugs being marketed. This was recognised in the product information in some countries, but not others. When should actions be taken on pharmacovigilance case data to evaluate reported signals further or even to warn the public of possible risks? This important question is not directly considered in the retrospective reviews, though the authors of the pill scare review refer the issue to Chapter 7 in Part 11.

I also shall move to Part 11 now.

The first chapter (Chapter 6) is on ethics, and it carefully and plainly discusses matters relevant to ethical principles regarding issues such as patient information confidentiality,

and also gives an up-to-date view on the application of ethics in general, including the issue mentioned above. A simple version of ethics related to communication is given in the Erice Declaration:

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.

Hugman, B. “The Erice Declaration.” *Drug Safety* 29, 91–93 (2006) (<https://doi.org/10.2165/00002018-200629010-00007>)

Now, a more considered view of the consequences suggests a much more nuanced approach to uncertainty, but the practical outcomes of a broader view are open to debate!

The next chapters (Chapters 7 and 8) on the relevance of cognitive, behavioural, and social sciences are clear and extremely useful—a must read. The first comment in the “Conclusions” section of Chapter 7 says that, “People’s risk perceptions are more important than the actual risks in determining behaviour...”, and the first concluding comment of Chapter 8 says that qualitative methods “Commonly used in social sciences have much to contribute to the creation of generalizable knowledge to inform the development of risk communication approaches and to evaluate established risk communication interventions.” I believe these are most important issues in the evaluation and presentation of evidence that increasingly contains mainly metrics and their interpretations.

The next chapter (Chapter 9) is concerned with how rhetorical analysis (“how humans use language and other symbols to influence each other and reach agreement in order to coordinate social action”) can be useful. There are two examples given on public hearings on problems with medicines and the impact they had on the health scares regarding Eltroxin in New Zealand and Avastin in the United States. As the authors claim, “Rhetoric enables textual analysis of how issues are framed and how contrastive rhetoric may exacerbate gaps between public and scientific counterparts.”

The next chapter (Chapter 10) is about media science and practice. It was this chapter particularly that made the strengths and important limitations of this book clear. Much of this chapter includes approaches mentioned in the previous two but emphasises another useful tool, that of focus groups, to investigate the formative (preparatory) work needed before communication and to test impacts. There is, however, little or nothing about the special motivations, needs, and aims of the media.

The chapter on social media research that follows (Chapter 11) covers this growing area of interest, pointing out that it is a real-time dialogue between an often large, self-selecting group of variously motivated people and researchers. The value of such research is debated fairly in the chapter, but my take is that much more evidence about the value of social media is needed apart from producing hints, ideas, and signals about medicines' effectiveness and adverse outcomes.

There is little doubt that design of particularly written information is important. The topic is well presented in the next chapter (Chapter 12), which, like Chapters 1 and 7, makes extensive and good use of tabulated information. Amongst the many important points made, a design science-based approach is user orientated and tested.

Naturally, how communications are implemented is important and often overlooked. Moreover, the implementation must be evaluated for its success. Chapter 13 includes many issues mentioned in the previous chapters. It is easy to skip this topic, but this and the next two chapters [one on pharmacoepidemiology (Chapter 14) and the other on legal frameworks (Chapter 15)] contain more material from disciplines not involved directly with communication. I appreciated the clear introductions to the dimensions of sometimes important knowledge behind any communication that is intended for public use in the area of medicine safety.

Chapters 8, 14, and particularly 15 include comments on causality, though I think more emphasis should be given to the importance of this topic, since misunderstandings in interpretation around causal claims are an important matter in communicating on medicine-related risks.

The last two chapters take us to the patients' perspective (Chapter 16) and a short afterword, a perspective from India, that could be taken as usefully representing some non-European and non-United States interests. In the foreword, we were warned that the book presented Western thinking, but it did also argue that a broader audience, including interested patients, might find it worth a read. I must disagree. This book is superb for anyone with an active interest in the scientific underpinnings of a particularly challenging research area of communication in medical care, but only one chapter, at the end of the book, deals with the patient and their

concerns, and then a short, but important afterword tells us that there are certainly some additional considerations regarding dealing with communication in other territories.

One issue that could have been more fully considered is when, where, how, and to whom do patients communicate their concerns about medicines. This issue is mentioned in Chapters 7, 11, and 16, which argue that more research is needed, but surely a chapter and critique of the current practices of pharmacovigilance systems would have been appropriate in a patient-centred book.

As mentioned earlier, one major value of this book is that it states and explains the complexities of communication in the risk and safety of medicines. It also pursues the ways in which different disciplines and players can critically contribute their particular expertise to better communication. But it is important to bear in mind that each different approach is giving a different insight to the same matters that are unique in some ways and context dependent.

There is no one size that fits all; you will need to use this treasure trove of knowledge proactively and wisely before putting the proverbial pen to paper.

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