Health Product Risk Communication: Is the Message Getting Through?

The Expert Panel on the Effectiveness of Health Product Risk Communication

Council of Canadian Academies
Conseil des académies canadiennes

Science Advice in the Public Interest

HEALTH PRODUCT RISK COMMUNICATION: IS THE MESSAGE GETTING THROUGH?

The Expert Panel on the Effectiveness of Health Product Risk Communication

THE COUNCIL OF CANADIAN ACADEMIES
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Expert Panel on the Effectiveness of Health Product Risk Communication

Annette M. Cormier O'Connor, FRSC, FCAHS (Chair), Distinguished Professor, Professor Emerita, School of Nursing, Faculty of Health Sciences, University of Ottawa (Ottawa, ON)

Wändi Bruine de Bruin, University Leadership Chair of Behavioural Decision Making and Co-Director of the Centre for Decision Research, University of Leeds (Leeds, United Kingdom) and Collaborating Professor, Engineering and Public Policy, Carnegie Mellon University (Pittsburgh, PA)

Alan Cassels, Affiliated Researcher, University of Victoria (Victoria, BC)

S. Michelle Driedger, Professor, Tier II Canada Research Chair in Environment and Health Risk Communication, Community Health Services, University of Manitoba (Winnipeg, MB)

Josh Greenberg, Associate Professor of Communication, Director, School of Journalism and Communication, Carleton University (Ottawa, ON)

Paul R. Gully, Public Health Consultant; Adjunct Professor, School of Population and Public Health, University of British Columbia (Vancouver, BC)

Gary Kreps, University Distinguished Professor, Director, Center for Health and Risk Communication, George Mason University (Fairfax, VA)

Louise Lemyre, FRSC, Professor and the McLaughlin Chair on Psychosocial Risk, School of Psychology, Faculty of Social Sciences, Institute of Population Health, University of Ottawa (Ottawa, ON)

Ragnar E. Löfstedt, Professor of Risk Management, King's College London (London, United Kingdom)

D. Warner North, Principal Scientist, NorthWorks (San Francisco, CA)

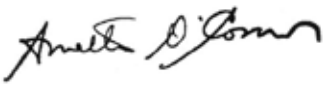
Barbara Riley, Executive Director, Propel Centre for Population Health Impact, University of Waterloo (Waterloo, ON)

Message from the Chair

Regulators have a responsibility to warn individuals about the potential harms of drugs and other health products. Although they use several tools to communicate risks, we know little about whether their messages are reaching and influencing the views and behaviours of various populations. Without evaluative information on who is paying attention, what they are learning, and what impacts are occurring, mistakes may be repeated and opportunities to demonstrate success may be lost. The evidence is clear regarding the positive value in undertaking evaluation of risk communication. With dedicated commitment and resources, there is an opportunity for Canada to take international leadership in this field. This assessment is intended to inform the continuing dialogue across Canada and internationally on the evaluation of the effectiveness of health risk communication.

The Expert Panel on the Effectiveness of Health Product Risk Communication is deeply appreciative of the opportunity to explore this important question and of the input and assistance it received throughout the course of its work. Several individuals provided helpful advice and assistance early in the process. In particular, Matthew LeBrun, Scientific Evaluator, and Lisa Lange, Director, at the Health Products and Food Branch at Health Canada provided background on the work of the Therapeutic Effectiveness and Policy Bureau as well as guidance on the impetus for the report and scope of the assessment questions. The Panel also wishes to thank the report reviewers for making valuable suggestions for improving the quality and comprehensiveness of its work. The final report would not have been the same without their sage advice.

Finally, the Panel is most grateful for the outstanding support that it received from staff members of the Council of Canadian Academies.



Annette M. Cormier O'Connor, FRSC, FCAHS
Chair, Expert Panel on the Effectiveness of Health Product Risk Communication

Project Staff of the Council of Canadian Academies

Assessment Team:	Andrew Taylor, Program Director Rebecca Chapman, Research Associate Joe Rowsell, Research Associate Andrea Hopkins, Program Coordinator
With assistance from:	Carolyn Brown, Editor Clare Walker, Editor Accurate Design & Communication, Report Design

Report Review

This report was reviewed in draft form by the individuals listed below — a group of reviewers selected by the Council of Canadian Academies for their diverse perspectives, areas of expertise, and broad representation of academic, industrial, policy, and non-governmental organizations.

The reviewers assessed the objectivity and quality of the report. Their submissions — which will remain confidential — were considered in full by the Panel, and many of their suggestions were incorporated into the report. They were not asked to endorse the conclusions, nor did they see the final draft of the report before its release. Responsibility for the final content of this report rests entirely with the authoring Panel and the Council.

The Council wishes to thank the following individuals for their review of this report:

Priya Bahri, Lead, Pharmacovigilance Guidelines and Communication Research, European Medicines Agency (London, United Kingdom)

Carmen Bozic, Senior Vice President, Biogen Idec (Cambridge, MA)

Baruch Fischhoff, Howard Heinz University Professor, Department of Engineering and Public Policy, Department of Social and Decision Sciences, Carnegie Mellon University (Pittsburgh, PA)

John Mayne, Advisor on Public Sector Performance (Ottawa, ON)

Steve Montague, Partner, Performance Management Network; Adjunct Professor, Carleton University (Ottawa, ON)

Jennifer O'Loughlin, FCAHS, Canada Research Chair in the Early Determinants of Adult Chronic Disease; Professor, Department of Social and Preventative Medicine, School of Public Health, University of Montréal; Epidemiologist, Centre de recherche du Centre hospitalier de l'Université de Montréal (Montréal, QC)

Ellen Peters, Professor of Psychology and Director of the Decision Sciences Collaborative, The Ohio State University (Columbus, OH)

Scott Ratzan, Adjunct Professor, Mailman School of Public Health, Columbia University (New York, NY)

Ortwin Renn, Professor and Director, Stuttgart University (Stuttgart, Germany)

David Ropeik, Instructor, Program on Environmental Management, Harvard University Extension School (Concord, MA)

Sanjeev Sridharan, Director, The Evaluation Centre for Complex Health Intervention, St. Michael's Hospital (Toronto, ON)

The report review procedure was monitored on behalf of the Council's Board of Governors and Scientific Advisory Committee by **Jean Gray, C.M., FCAHS,** Professor of Medicine (Emeritus), Dalhousie University (Halifax, NS). The role of the report review monitor is to ensure that the Panel gives full and fair consideration to the submissions of the report reviewers. The Board of the Council authorizes public release of an expert panel report only after the report review monitor confirms that the Council's report review requirements have been satisfied. The Council thanks Dr. Gray for her diligent contribution as report review monitor.

Janet W. Bax, Interim President
Council of Canadian Academies

Executive Summary

Risk communication is an important component of improving the health and safety of Canadians. For numerous departments and agencies at all levels of government, as well as public and private organizations, effective risk communication can protect Canadians from preventable hazards. The Minister of Health, on behalf of Health Canada (the Sponsor), asked the Council of Canadian Academies (the Council) to provide an evidence-based and authoritative assessment of the state of knowledge on measurement and evaluation of health risk communication. This assessment focuses on identifying tools, evaluation methods, gaps in the literature, and barriers and facilitators to carrying out successful communication and evaluation activities. Specifically, this assessment examines the following questions:

How can the effectiveness of health risk communications be measured and evaluated?

- *What types of instruments/tools are currently available for health risk communication?*
- *What methodological best practices can be used to evaluate the reach, use and benefit of health risk communication?*
- *What research could be done to inform the measurement of the effectiveness of risk communications?*
- *What are the existing barriers to effective risk communications and what best practices exist to address these challenges?*

To address the charge, the Council assembled a multi-disciplinary panel of 11 experts (the Panel) from Canada and abroad. The Panel's composition reflected a balance of expertise, experience, and demonstrated leadership in academic, clinical, and regulatory fields. Each member served as an informed individual, rather than as a representative of a particular discipline, patron, organization, or region.

The focus, as specified by the Sponsor, is risk communication for health products, which includes pharmaceuticals, biologics and vaccines, medical devices, and natural health products. Consumer products, other products, and general health promotion communications were considered out of scope. Health product risks generally involve known side effects, medication and medical device errors, product defects, and uncertainty in information. From its discussions and review of the current state of the evidence, the Panel identified four key findings that serve to answer the charge put forward by Health Canada. The following executive summary presents those findings; a more detailed discussion continues in the Panel's full report. The Panel also created a report roadmap to guide the reader through each chapter of the full report (Figure 1). It summarizes the discussion of the context of health product risk communication, related tools, and the role evaluation plays throughout the entire communication process.

Recognition of the importance of dialogue and ongoing relationships is prompting a paradigm shift for risk communication.

Risk can be defined in a number ways, but ultimately refers to probabilities of different possible outcomes and the severity of those outcomes. Risk cannot always be quantified and often involves a range of uncertainties. It evolves with changing awareness and views of hazard and safety and is influenced by social and cultural factors. Communicating about health risk can therefore not be reduced to a simple formula. The process includes analysis of a potential threat, understanding what is important to the populations meant to receive a risk communication, and disseminating the message in an understandable and appropriate way. Risk communication is also fundamentally a socially and politically interactive process in which individuals are informed of real or potential risks and are expected to use this information to undertake personal strategies to manage that risk. Although often approached as a simple one-way transfer of information from an organization (e.g., government body, pharmaceutical company) to an individual, risk communication is a complex process of ongoing relations that involve multiple stakeholders and interactions at many different levels and points in time (i.e., multi-way and multi-level transfer of information).

Figure 1

Evaluation of Health Product Risk Communication – A Report Roadmap

Chapter 2 (represented in blue) describes the context of risk communication. A paradigm shift shapes contemporary risk communication by building on the learning from the past to address new communication challenges related to building strong and meaningful relationships. This new paradigm also reframes the goals of risk communication to broaden potential outcomes related to development, reach, use, and impact. In this context specific health product risk communication tools are created and implemented to fulfill regulatory responsibilities. Chapter 3 (represented in grey) examines both established and emerging tools used to communicate ongoing, incident(s)-based, and error-related health product risk information. Chapter 4 (represented in red) explores how such communication tools can be evaluated to ensure they are achieving their goals. However, evaluation is an integral component to the entire risk communication process and not simply an end-stage task carried out after the communication is completed. There is no universal evaluation approach; rather selecting the most appropriate approach is a function of the evidence required and resources available to answer specific evaluation questions. These questions stem from identifying and integrating information needs and motivations as well as the attributes of a risk communication including type of risk communication tool, stage (needs assessment, pre-testing, process/implementation, and outcome), and communication goals. Chapter 4 also explores how to ensure the foundation for evaluation — institutional commitment and sufficient resources — is secured.

The understanding of, and approach to, risk communication has evolved. Contemporary risk communication typically comprises the following:

- **Characterizing and managing risk:** using accurate science and data analysis to establish risk assessment and management strategies, including identifying what scientific information and uncertainty need to be communicated and understanding the larger context and population needs inherent to a given risk communication.
- **Creating messaging:** applying multidisciplinary knowledge of how individuals interpret, process, and respond to risk-related information, and how socio-cultural factors shape those activities, to create messages that are understood and meaningful. A large body of research specific to health risk and the science of science communication can inform this process.
- **Ongoing partnership and exchange:** recognizing the influence and importance of broader societal factors to focus on communicating messages in a way that respects dialogue, exchange, and relationship-building. This can be fostered by understanding and appreciating the senders and receivers of information and other stakeholders, and ensuring meaningful dialogue in which all parties learn from the experience.

These activities will ultimately lead to the development of specific communication products that should be assessed for their reach, how they are being used, and whether they are having an impact. However, evaluation is more than an end-stage task carried out after the risk communication is completed. To ensure that communications are meeting their goals, getting through to people, and avoiding any adverse or unintentional effects, evaluation is needed throughout the entire risk communication process, starting with planning and development.

Recognition of the importance of multi-way dialogue and the need to build, foster, and maintain strong relationships over time is prompting a paradigm shift for risk communication. This emerging paradigm builds on the learning from the past to address new challenges relevant for evaluation of health product risk communication:

- **Governance:** addressing the challenges that stem from shared responsibility within the risk management and communication environment by establishing who is responsible for what and ensuring coordination, exchange, and flow of data and information across organizations and jurisdictional boundaries.

- **Complexity:** navigating the inherent complexities of the risk and the communication environment that comprises multiple stakeholders through recognition of shared responsibility, potentially competing priorities, and the need for coordination and collaboration.
- **Uncertainty:** communicating uncertainty and multiple interpretations of the evidence in a manner that is clear, understandable, proactive, and central to the risk communication at hand as well as communicating what is being done to minimize or reduce uncertainty over time.
- **Empowerment:** moving from providing prescriptive statements to enabling solutions and empowerment by creating messaging that is appropriate for understanding, comprehension, and action; involving the receivers of information and other stakeholders in the decision-making process; and focusing on long-term relationships.
- **Timeliness:** ensuring timely and proactive responses that build trust over time through having communication guidelines, using new enabling communication sources, and establishing relationships.
- **Transparency:** ensuring reasoned transparency that increases the public's access to and ability to understand health information, through striking a balance between openness, urgency, and confidentiality.

These dimensions are variable depending on the nature and context of the risk and may evolve. They do not exist in isolation, and elements of one can affect another. A common theme that cuts across dimensions is the role of trust in building relationships over time.

Regulators around the world use similar health product risk communication tools that are not systematically evaluated.

The Canadian regulatory context for health product risk communication is similar to that in other jurisdictions, including the United States, the United Kingdom, Australia, and Europe. Although regulatory authority to require further studies, issue recalls or label changes, or withdraw a drug from the market is variable, most regulators have such authority. Passive systems for monitoring health product risks are also common, affecting the post-marketing identification of health product risks. In addition, all regulators have or are developing frameworks that guide the communication of health product risks. The frameworks generally emphasize two-way communication, engagement with affected populations, and meaningful and accessible messaging for a range of groups. However, while recognizing the importance of evaluating risk communication, most frameworks do not provide any detail or guidance on how it should be defined, how it is to be carried out, or if it is actually being done.

Regulators from the jurisdictions examined use similar tools to communicate health product risk information. The Panel classified them as ongoing communication, incident(s)-based communication, and defect and error communication. A lack of readily available information on the use of some tools made them difficult to characterize. Despite this challenge, the Panel found important similarities across established tools, many of which do not align with evidence-informed communication practices. Many tools, for example, were primarily text-based with few visuals and sparse colour. Images used were generally illustrations or pictures rather than graphic risk presentations. Posting online was the most common method of dissemination (with the notable exception of leaflets), although some of the tools aimed at healthcare professionals were also disseminated by other methods such as mail. Most of the tools that targeted the public often did not quantify risk, instead using vague terms such as "increased risk," "rare," or "chance of." Detailed information about risk was available in some comprehensive ongoing communication documents, which were also longer and written in more technical language.

The Panel identified several emerging communication tools that use new technologies, platforms, and multi-media approaches to expand the reach of communications, change the conditions that shape behaviour to support informed decision-making, or change how messages are framed and presented to improve use and impact. For example, drug fact boxes present the risk and benefit information for prescription drugs in a manner similar to nutrition labels. Although more research is needed on their real-world applicability for varying populations, the Panel identified drug fact boxes as the most promising innovation in health product risk communication.

There are few publicly available and publicly conducted evaluations of established health product risk communication tools in any jurisdiction. Regulators have either not evaluated their effectiveness or used the results of external evaluations, and in any case not made results public or easily accessible. This gap could have implications for the quality of risk communication. The majority of the evaluations identified for ongoing communication focused primarily on indicators of understandability (e.g., readability) and user surveys, expert analysis, and public consultations. Those identified for incident(s)-based communication examined effectiveness in terms of use and impact after implementation and completion of the communication. These studies most often used medical or pharmacy claims (e.g., prescribing rates) as indicators.

Given the similarities in regulatory contexts and communication tools, it is not surprising that Health Canada's challenges in evaluating and enhancing health product risk communication are common. Health Canada can benefit from the lessons learned by other regulators and from innovations that they have adopted. Canada also has the opportunity to lead globally in aligning its communication tools with evidence-informed communication practices and implementing effective evaluations.

Evaluation is an integral part of risk communication and can be supported with institutional commitment and sufficient resources.

Proper evaluation is integral to risk communication activities and can aid in fulfilling regulatory and fiduciary obligations, demonstrating a commitment to transparency and accountability, and attaining an understanding of the strengths and weaknesses of risk communication efforts. Evaluation activities can improve decision-making and real-world applications of a communication and ultimately help to ensure the health and safety of the population. Evaluation can also improve content and processes, build trust and relationships, assess whether communications have achieved their objectives, and identify who is paying attention, what they are learning, and what impacts are occurring across a range of different groups. Without adequate evaluation, not only is there potential for mistakes, but there is also the risk of missing opportunities to continue or build on proven successes.

Ensuring that evaluation evidence is meaningful and useful demands institutional commitment and sufficient resources — the biggest challenge to evaluation overall. This challenge can be addressed by:

- fostering a learning culture that encourages and facilitates continuous learning and values evaluation;
- demonstrating the value of evaluation relative to other spending priorities to establish its sufficient and stable funding as an integral part of risk communication;
- standardizing communication appraisal tools and checklists, which include evidence-informed communication practices, so that risk communications meet certain minimum standards and reduce constraints on time, money, and human resources; and
- encouraging peer learning and sharing of experiences from other jurisdictions by bringing together evaluation experts, risk communication researchers, regulators, and affected populations to identify examples of strong evaluations and leading evaluation practices.

Careful planning determines relevant evaluation questions, which guide evaluation methods.

Evaluation methods are sometimes selected without properly understanding the context of a risk communication and the information needs and motivations of regulators and government institutions communicating risk, receivers of risk information, and other stakeholders. Since different evaluation methods produce different knowledge and have varying strengths and weaknesses, they may be more or less applicable. There is also no universal way to evaluate a communication; different methods may be applied in different ways to address various situations, needs, and goals. It follows that careful planning efforts are needed to first determine the most relevant evaluation questions before choosing evaluation methods. The best questions result from identifying and integrating information needs and the attributes of a risk communication tool, including the communication goals. Selecting an evaluation method then becomes a function of the evidence required to answer an evaluation question and the level of available resources. Evaluation conducted on this premise and involving relevant stakeholders will reveal the most relevant and meaningful information.

Information Needs and Motivations

Regulators and other government institutions communicating health product risks (the senders of information) may be interested in accountability, program improvement, or transparency. Receivers of information, however, may need to determine credibility and who to trust, feel engaged in the communication process, and feel empowered to use the information. Each of these needs and motivations will shape evaluation questions and subsequent choices around appropriate methods.

Communication Attributes

Evaluation questions should also take into account the three main attributes of a risk communication tool: its type, stage, and goal.

Evaluations are influenced by the *type* of tool involved. For ongoing communication there is potential to conduct more systematic and comprehensive evaluation and engage affected populations before, during, and after the evaluation. The time sensitivity of incident(s)-based communication implies that evaluation is often undertaken with less planning, uses less comprehensive methods, and faces additional challenges in engaging different groups. Since it is delivered at a fixed point in time, there is a clear baseline from which to measure various goals and to use before and after comparison groups. Evaluation is more likely to be demanded for high-profile incident(s)-based communication. In these

cases, regulators and other government institutions may be more interested in demonstrating that proper processes were followed than in measuring long-term impacts.

Four types of evaluation highlight certain *stages* of risk communication and link to information needs and communication goals:

- **Needs assessment:** undertaken to identify the information needs of the senders and receivers of information and other stakeholders. Its findings can increase the likelihood that a risk communication will be effective.
- **Pre-testing:** undertaken before the full implementation of a risk communication to preliminarily test the feasibility, appropriateness, and effectiveness of the identified communication tool in sub-groups. Its findings can lead to changes to the communication, which will further increase the likelihood that it will be effective.
- **Process/Implementation:** typically undertaken during the implementation of a risk communication to provide evidence that it is progressing as planned. Its findings provide insight into potential revisions to implementation strategies, the need for reassessing goals and potential outcomes, and the potential value in conducting outcome evaluations in the future.
- **Outcome:** conducted after a risk communication has been disseminated and completed to link meaningful short-, medium-, and long-term outcomes to the tool in question. Although considered end-stage efforts, more rigorous evaluations usually establish a baseline prior to the implementation of the communication followed by ongoing measurement.

Different types of evaluation should be undertaken for different risk communication *goals*. These goals will ultimately align with information needs and motivations as well as other communication attributes to shape evaluation questions and determine appropriate methods. Goals are defined here and dimensions for each are described in Table 1:

- **Development –** incorporating evaluation methods and learning into the steps involved in designing risk communications, including when characterizing and managing risk, creating messaging, and ensuring ongoing partnership and exchange;
- **Reach –** how and when the communication is sent and received and by whom;
- **Use –** how the information is considered, its timeliness, and the reactions and actions taken as a result of the communication, thus exploring understandability, timeliness, informed decision-making, and behaviour; and
- **Impact –** achieving a desired result with respect to various outcomes related to the senders and receivers of information and the relationship between them.

Choosing Evaluation Methods

Once evaluation questions have been established, methods can be chosen that best provide the required evidence to answer the questions. This increases the likelihood that an evaluation will produce meaningful results. The Panel organized the numerous available methods into five broad approaches that are feasible for regulators and other government institutions and relevant for health product risk communication:

- **Synthesis:** Methods include literature reviews, systematic reviews, and meta-analyses.
- **Records-based:** Methods include textual, archival, and administrative data analysis.
- **Self-reported data:** Methods include interviews, focus groups, and population-based surveys.
- **Experimental:** Methods include quasi-experimental methods, natural experiments, and randomized controlled trials.
- **Mixed methods:** This involves combining quantitative and qualitative methods from different approaches in the same evaluation.

These approaches vary in complexity and in how data is collected and used (i.e., employing qualitative and quantitative methods). They also vary in the extent to which receivers of information and other stakeholders participate in data collection (e.g., self-reporting the effects of risk communication or acting as participants in a controlled RCT). Table 1 summarizes the relevant evaluation questions and methods across the four goals of risk communication. Methods are ordered from simple to more complex. Taken together, they can help design and re-design communications that are aligned with the needs of various affected populations, to account for and learn from past mistakes, and to continue or build on identified successes.

Table 1

Key Points for Matching Evaluation Questions and Methods

Goal	Dimensions	Evaluation Questions	Methods
Development: incorporating evaluation methods and learning into the steps involved in designing risk communications	Characterizing and Managing Risk	• Who needs to receive the risk communication? • Who wants to receive the risk communication? • What needs to be communicated? • Who is the source of the risk information? • What is the accuracy and credibility of the evidence base?	• Literature review/ Systematic review/ Meta-analysis • Textual analysis • Interviews and focus groups • Randomized controlled trials • Mixed methods
	Creating Messaging	• What are the communication wants and needs of the receivers of information? • How do the receivers of information make sense of risk? • Will they understand the content? • What will the content look like (e.g., text, images, colour)? • Does the content address wants and needs? • How will the risk communication be disseminated? • Are the communication channels appropriate for all groups receiving the information?	
	Ongoing Partnership and Exchange	• What is the relationship between the sender and receiver of information? • How could that relationship change, stay the same, or be strengthened? • What is the best way to engage the receivers of information in the evaluation process? • How can the senders and receivers of information and other stakeholders be involved in the implementation of evaluation?	
Reach: how and when the communication is sent and received and by whom	Delivery	• Was the risk communication sent and to whom specifically?	• Administrative data analysis • Interviews and focus groups • Population-based surveys
	Receipt	• Did those groups receive the risk communication? • Are those groups aware of the risk communication?	

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Goal	Dimensions	Evaluation Questions	Methods
Use: how the information is considered, its timeliness, and the reactions and actions taken as a result of the communication	Understandability	• What are the barriers (facilitators) that might prevent (support) understanding the message? • Was information sent in a way that overcomes barriers and leverages facilitators to understanding? • How does the information align with evidence-informed practices in communication and health literacy? • Is the information understood by those receiving the information? • Was awareness of the risk increased in the receivers of information?	• Textual analysis • Interviews and focus groups • Population-based surveys • Quasi-experiments
	Timeliness	• How much time has elapsed between identification and dissemination? • What is the justification for this amount of time and is it based on reasonable grounds? • Did the senders and receivers of information and other stakeholder groups consider the risk communication timely to inform their decision-making and behaviour? How do expectations compare across these groups?	
	Informed Decision-Making	• Did the receivers of information, both among the public and among healthcare professionals, seek the risk communication out? • Did the receivers of information feel that the communication provided meaningful information? • Did the risk communication contain messages that the receivers of information believe they can successfully carry out and were those messages believed to be successful for averting any harm? • Did the risk communication influence shared decision-making between healthcare professionals and the receivers of information?	

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Goal	Dimensions	Evaluation Questions	Methods
	Behaviour	• Did the risk communication change the risk perceptions of the receivers of information? • Were there any changes in the preferences of the receivers of information (e.g., patients, healthcare professionals)? • Was information used by healthcare professionals and the groups that they work with? • Did the receivers of information change their behaviour or continue recommended desirable behaviour? • Was the risk minimized by actions based on specific recommendations from the risk communication?	
Impact: achieving a desired result with respect to various outcomes related to the senders and receivers of information and the relationship between them	Outcomes for Receivers of Information	• What individual and population health outcomes have improved as a result of the risk communication in the groups receiving the information and other stakeholders? • What individual and population health outcomes have worsened (i.e., unintended impacts) as a result of the risk communication in those same groups? • Have knowledge, attitudes, and perceptions advanced or changed as a result of the risk communication?	• Archival and administrative data analysis • Population-based surveys • Interviews and focus groups • Quasi-experiments • Natural experiments • Mixed methods

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Goal	Dimensions	Evaluation Questions	Methods
	Outcomes for Senders of Information	• What organizational constraints hindered the risk communication? Did the risk communication make efficient use of financial and human resources? How did the organization overcome these constraints? • Did the receivers of information and other stakeholders trust the risk communication and how has it affected general perceptions of trust? • What was the effect of the risk communication on the credibility of the organization? • Did the receivers of information and other stakeholders view the risk communication as transparent and how has it affected general perceptions of transparency?	
	Outcomes Related to Relationships Between Senders and Receivers	• Were there opportunities for those receiving information and other stakeholders to provide feedback? How were affected populations and other stakeholders engaged? • Did the sender of information receive that feedback and make use of it to improve the risk communication? • Did receivers of information feel empowered by the risk communication? • How has the risk communication contributed to future communications and opportunities for cooperation?	

Final Reflections

The Panel found no clear best methodological practices to evaluate health product risk communication. There are, however, many promising evaluation methods, which if tailored to the type, stage, and goal of a risk communication, can provide strong evidence of effectiveness. While this assessment has outlined a range of methods, some of which require significant time and resources, the Panel firmly believes that even a minimal evaluation can provide benefits. With commitment and sufficient resources, however, there are opportunities for regulators and other government institutions around the world to become leaders in this area, conducting relevant, well-planned, comprehensive, systematic, and rigorous evaluations.

Overall, the Panel believes there is significant room for improvement in the volume and quality of evaluations on health product risk communication, conducted both in Canada and elsewhere. While there are numerous challenges, even when taken together, they are far from insurmountable. Since evaluation can fundamentally improve the health of Canadians, now and in the future, the Panel concluded that engaging in the challenges is therefore worth the effort.

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1 Introduction

1.1 BACKGROUND AND PURPOSE

Risk communication is an important component of improving the health and safety of Canadians. For numerous departments and agencies at all levels of government, as well as public and private organizations, effective risk communication can protect Canadians from preventable hazards associated with medicine, food, and various consumer products. These communication efforts exist in a complex environment involving many stakeholders with varying levels of expertise and multiple sources of information. In Canada, communication must also span large and complex geographic, social, and cultural settings, in which varied communicators and audiences play dual roles of both senders and receivers of information.

Pressures on government for greater openness and transparency have also increased. A 2011 Auditor General's report recommends that Health Canada assess its communication efforts about medical device risks to ensure that they are effectively reaching affected populations in a timely manner (Office of the Auditor General of Canada, 2011). A similar report from the Auditor General in 2013 on Canada's Food Recall System finds that, although public warnings were issued in a timely manner, few follow-up activities were completed to confirm that products were removed from shelves (Office of the Auditor General of Canada, 2013). There have also been a number of reviews of public health incidents — including the H1N1 pandemic, the listeriosis outbreak, and numerous drug recalls and related inquests — all of which recommend improving timeliness, outreach, and plain language approaches, particularly for vulnerable populations. For example, the five-member coroner's jury looking into the suicide of 18-year-old Sara Carlin (who was taking an antidepressant) recommended that Health Canada seek to "maximize the effect" of health product advisories by considering that they "be succinct; clearly set out the warning; clearly set out the body of evidence giving rise to the warning; be specific; [and] be profiled in a way to attract physician's attention" (Chief Coroner Province of Ontario, 2010).

These pressures have been met with several government commitments. In its *Regulatory Transparency and Openness Framework*, Health Canada commits to addressing criticisms by "making information easier to understand…making more information available…[and] making the decision-making process more open" (Health Canada, 2014a). This framework is an extension of a broader

federal government effort committing to *Canada's Action Plan on Open Government,* which sets out similar principles involving availability of information and citizen participation (GOC, 2014). These larger policy directions have created new realities for all government departments and agencies in terms of openness and transparency. It follows that better evaluation and quality improvement efforts, and the communication of the results of those activities, will become that much more important. However, in this environment, although there is general guidance for evaluating the effectiveness of programs and interventions, there is no clear consensus on appropriate practices and strategies for risk communication efforts specifically. While this lack of guidance and consensus does not diminish the need for evaluations using available principles and knowledge, it does contribute to gaps in understanding whether the risk communication activities of regulators are achieving the goals of improving and protecting the health of Canadians.

Evaluating health risk communication can aid in fulfilling regulatory and fiduciary obligations, demonstrating commitment to transparency and accountability, and attaining an understanding of the strengths and weaknesses of risk communication efforts. Evaluation also helps to improve their content, processes, and outcomes. Without formal evaluation, it is difficult to assess whether a communication has reached its objectives or made the situation worse, to identify its impacts on different audiences, or to determine who is paying attention and what they are learning from the communication (Kreps, 2014). Without this feedback, not only is there potential for mistakes, but there is also the risk of missing opportunities to continue or build on success.

In this context, this assessment comprehensively examines the state of knowledge on the evaluation of health product risk communication, including methods and barriers to evaluation, as well as lessons learned from international experiences. The report fills a distinctive niche in the effort to advance the evaluation of health product risk communication in Canada and abroad.

1.2 CHARGE TO THE PANEL

Recognizing the importance of successfully evaluating health risk communication, the Minister of Health, on behalf of Health Canada (the Sponsor), asked the Council of Canadian Academies (the Council) to provide an evidence-based and authoritative assessment of the state of knowledge on measurement and evaluation of health risk communication. This assessment focuses on identifying

risk communication tools, evaluation methods, gaps in the literature, and barriers and facilitators to carrying out successful communication and evaluation activities. Specifically, this assessment examines the following questions:

- *How can the effectiveness of health risk communications be measured and evaluated?*
  - *What types of instruments/tools are currently available for health risk communication?*
  - *What methodological best practices can be used to evaluate the reach, use and benefit of health risk communication?*
  - *What research could be done to inform the measurement of the effectiveness of risk communications?*
  - *What are the existing barriers to effective risk communications and what best practices exist to address these challenges?*

To address the charge, the Council assembled a multi-disciplinary panel of 11 experts (the Panel) from Canada and abroad. The Panel's composition reflects a balance of expertise, experience, and demonstrated leadership in academic, clinical, and regulatory fields. Panel members brought knowledge from the disciplines of healthcare, behaviour and decision-making science, environmental and health risk communication and management, population health, and research and evaluation. Each member served on the Panel as an informed individual, rather than as a representative of a particular discipline, patron, organization, or region.

Over 12 months, the Panel met in person four times to refine its assessment of the issue at hand. At the beginning of the assessment process, the Panel met with the Sponsor to acquire a full understanding of the charge and receive additional direction:

- The report was to focus specifically on risk communication for health products, which may include pharmaceuticals, biologics and vaccines, medical devices, and natural health products. Consumer products, other products, and general health promotion communications were considered out of scope.
- The Panel agreed to focus broadly on a range of tools/instruments (e.g., public warnings, recall notices, product monographs) used in health product risk communication (i.e., all aspects of specific actions taken to deal with a particular hazard).
- The Sponsor confirmed they were open to the Panel's assessment of appropriate approaches to effectiveness as well as to alternative dimensions of effectiveness that can realistically be measured. Although reach, use, and impact were the primary focus, the Panel also set out to explore timeliness, informed refusal/choice, multi-way dialogue, trust, and credibility.

- Based on Sponsor interest and clarification, the report was to focus more heavily on barriers to evaluating risk communication activities. As a result, the Panel placed less emphasis on practices for addressing challenges that constrain health risk communication more generally.

1.2.1 Scope

The report examines:

- the role of health product risk communication, and its evaluation, in decision-making;
- activities for health product risk communication, especially the varying types of tools used to communicate risk to a range of different populations;
- approaches to evaluation from a variety of disciplines, sectors, jurisdictions, and organizations in Canada and internationally, which could be used to assess the effectiveness of health product risk communication;
- knowledge gaps in the state of evidence; and
- barriers and facilitators to evaluating the effectiveness of health product risk communication, and potential strategies to address these factors.

The report does not:

- evaluate actual risk communication initiatives or make judgments on their effectiveness;
- address cost-effectiveness of risk communication initiatives;
- specifically explore issues related to consumer products, other products, and general health promotion communication, although lessons from health product risk communication may apply to these areas; or
- provide formal recommendations.

1.3 PANEL'S APPROACH AND METHODOLOGY

The Panel's assessment of the state of the literature is based on various sources of evidence. Primary evidence-gathering activities included a review of:

- academic literature from peer-reviewed publications exploring risk communication, risk perception and decision-making, and risk management, as well as approaches for evaluating health risk communication and population-based intervention;
- publicly available government information that describes regulatory context and specific policy and communication initiatives; and
- other grey literature[1] relating to risk communication and evaluation planning and implementation.

1 *Grey literature* refers to various types of documents produced by government, academics, industry, and other organizations that are not published commercially/formally.

In seeking the most relevant evidence, the Panel conducted keyword-based searches of published literature and explored websites of various regulatory agencies in Canada and internationally. The search strategies varied across different topics in the report, and evolved as the Panel assessed the availability of the most recent information. The report underwent a formal peer review process to assure quality and objectivity; all comments from the reviewers were considered by the Panel, although not all comments resulted in revisions to the report. This process also contributed to the identification of new evidence for the Panel's deliberations. The report is the result of the Panel's deliberations on the charge and the available evidence. The Panel's discussions generated original interpretations of the evidence and provided insight into the state of the evidence and how it could be strengthened or improved.

1.3.1 Key Terms

The Panel has defined terms central to the charge, based on its interpretation of the Sponsor's interest. These definitions, defined below, differ in some cases from traditional understandings of the concepts. The Panel's choices reflect a careful reading of the questions and, in some instances, a blend of definitions put forward in other sources.

The Panel adopted the U.S. National Research Council (NRC) definition of *risk communication*: "an interactive process of exchange of information and opinion among individuals, groups and institutions. It involves multiple messages about the nature of risk and other messages, not strictly about risk, that express concerns, opinions or reactions to risk messages or to legal and institutional arrangements for risk management" (NRC, 1989). Risk communication, it follows, is an ongoing process meant to improve individual and population health over time.

Health products are defined broadly in the context of this report and include over-the-counter and prescription pharmaceuticals (small-molecule drugs, mainly consisting of chemical compounds); biologics (drugs derived from biotechnology or living sources, including vaccines, blood, and blood products); medical devices and combination products (devices used for diagnosis, treatment, mitigation, or prevention of a disorder or its symptoms or those used to restore, correct, or modify body structure or function); and natural health products (vitamins, minerals, herbal remedies, homeopathic or traditional medicines, or probiotics).

Effectiveness is defined as producing a desired result and depends largely on the goals of the communication in question. Within the context of this report, effectiveness is explored across the following goals:

- **Development** includes incorporating evaluation methods and learning into the design of risk communication.
- **Reach** includes aspects of how and when the information is sent and received and by whom.
- **Use** involves how the information is considered, its timeliness, and the reactions and actions taken as a result of the communication.
- **Impact** refers to achieving a desired result with respect to various outcomes related to the senders and receivers of information and the relationship between them.

Best practice is interpreted broadly in this report to include practices that may exist across a continuum of established quality. This continuum may range from emerging (e.g., based on prior sound evidence and incorporating a process for evaluation and continual improvement), to promising (e.g., beginning to show evidence of positive outcomes), to best (e.g., shown to improve outcomes based on a range of rigorous evaluation methods and is generalizable to a range of contexts). The Panel did not formally assess or distinguish practices along this continuum, but rather broadly captured all practices to provide a picture of the state of the evidence.

Evaluation is defined as an integral component to all stages of the risk communication process (i.e., planning, implementation, and assessment) and not simply as an end-stage task carried out after the risk communication is completed. This assessment therefore looks at evaluation across the full range of risk communication and includes needs assessment, pre-testing, process/implementation, and outcome evaluation. Evaluation is also understood as an applied research process that focuses on improving decision-making and real-world applications of a communication.

Traditionally, the terms *sender, communicator, audience*, and *target* are used in risk communication to capture the distinction between the communicator and the target audience of a communication. These terms reflect a simple one-way interpretation of risk communication. However, current theory suggests that effective communication is two-way, enabling dialogue and back and forth exchange between traditional communicators and audiences. The terms

audience or *target* do not capture this deliberative approach. Furthermore, many other groups (e.g., media, health professionals, interpersonal networks) may influence perceptions and appropriate management of risk. Along with audiences, these groups are often called stakeholders. For the sake of clarity, this report uses *senders of information* to denote the authorities who are responsible for ongoing risk communication efforts and who originate particular messages, *receivers of information* to denote audiences who become active participants in the communication process, and *stakeholders* to mean the people and groups who shape those relationships and the communication process. Receivers of information and stakeholders should be seen as active participants in the risk communication process.

1.4 ORGANIZATION OF THE REPORT

The final report is an in-depth assessment of the state of scientific knowledge on evaluating the effectiveness of health product risk communication. As such, it is intended primarily as a tool to inform evaluation and decision-making within government departments and agencies responsible for risk communication and looking to improve their efforts. It may also be relevant to stakeholders concerned with public health and safety, including regulatory bodies and health authorities that communicate risk to the public, industries and manufacturers that evaluate the effectiveness of their communication products, non-governmental organizations and associations that advocate on behalf of populations, and community-based organizations and research institutes that work with populations to mitigate risk. The Panel intends this report to inform the continuing dialogue across Canada and internationally, and across many sectors, on the broader evaluation of health risk communication and population-based intervention.

Chapter 2 provides an overview of risk and risk communication, particularly for health and health products. It defines characteristics of effective risk communication, outlines the evolving state of the literature, and notes the dimensions of a paradigm shift that is influencing the traditional goals of health risk communication.

Chapter 3 discusses health product risk communication in Canada and other similar jurisdictions, beginning with an overview of the regulatory regimes, including their responsibility and authority for health product risk communication. It also provides an overview of the communication tools commonly used now, and those that are emerging, in Canada and other jurisdictions.

Chapter 4 explores the evaluation of health product risk communication. It considers how specific information needs and motivations and communication attributes of health product risk communications, including communication goals, can shape evaluation questions and subsequent evaluation methods. It demonstrates that there is no one-size-fits-all approach to evaluation. The selected examples illustrate the practice and challenge of health product risk evaluation across different goals.

Chapter 5 synthesizes gaps in the current evidence on the evaluation of health product risk communication, summarizes the Panel's main findings, and provides final reflections.

Ultimately, the Panel summarized these chapters in a report roadmap that guides the reader through the report (Figure 1.1). It summarizes the discussion of the context of health product risk communication, related tools, and the role evaluation plays throughout the entire communication process.

Figure 1.1

Evaluation of Health Product Risk Communication – A Report Roadmap

Chapter 2 (represented in blue) describes the context of risk communication. A paradigm shift shapes contemporary risk communication by building on the learning from the past to address new communication challenges related to building strong and meaningful relationships. This new paradigm also reframes the goals of risk communication to broaden potential outcomes related to development, reach, use, and impact. In this context specific health product risk communication tools are created and implemented to fulfill regulatory responsibilities. Chapter 3 (represented in grey) examines both established and emerging tools used to communicate ongoing, incident(s)-based, and error-related health product risk information. Chapter 4 (represented in red) explores how such communication tools can be evaluated to ensure they are achieving their goals. However, evaluation is an integral component to the entire risk communication process and not simply an end-stage task carried out after the communication is completed. There is no universal evaluation approach; rather selecting the most appropriate approach is a function of the evidence required and resources available to answer specific evaluation questions. These questions stem from identifying and integrating information needs and motivations as well as the attributes of a risk communication including type of risk communication tool, stage (needs assessment, pre-testing, process/implementation, and outcome), and communication goals. Chapter 4 also explores how to ensure the foundation for evaluation — institutional commitment and sufficient resources — is secured.

2

Context and Overview of Health Product Risk Communication

- Defining and Understanding Risk
- Defining and Understanding Risk Communication
- The New Paradigm of Risk Communication
- Reframing the Goals of Risk Communication
- Conclusion

2 Context and Overview of Health Product Risk Communication

Communicating about risk cannot be reduced to a simple formula. There are a range of potential hazards that can pose risks to health, and these risks can vary in severity, certainty, probability, and complexity. The communication of these issues takes place in a complex environment with many stakeholders and sources of information, which vary in their reliability and importance. Risk communication therefore involves a combination of complex processes, including scientific appraisal and characterization of risk, application of knowledge concerning people's values, perception and management of risk, and ongoing partnership and information exchange. In this chapter, the Panel examines established and evolving approaches to risk communication. It also looks at how this evolution creates specific challenges for health product risk communication and helps shape communication goals.

2.1 DEFINING AND UNDERSTANDING RISK

Key Findings

- Risk can be defined in a number ways but ultimately refers to probabilities of different possible outcomes and the severity of those outcomes. Risk cannot always be quantified and often involves a range of uncertainties.
- Risk evolves with changing awareness and views of hazard and safety, and is influenced by social and cultural factors.
- Health product risks generally involve known side effects, medication/medical device errors, product defects, and uncertainty in information.

Risk is defined in a number of ways, from colloquial usage to expert understandings, and can have many different meanings. A broad definition of *risk* considers "the possibility of physical and/or social and/or financial harm/detriment/loss due to a hazard within a particular time frame" (Rohrmann, 2008). Although in most contexts risk refers to negative outcomes, in some fields it is used to describe probabilistic outcomes that can be positive or negative (Rohrmann, 1998; Slovic, 2000; Kahneman, 2011). The International Risk Governance Council (IRGC) definition of *risk* refers to "an uncertain (generally adverse) consequence of an event or activity with respect to something that humans value," but also explains that risk can have positive or negative consequences depending on the values that individuals or groups associate with them (IRGC, 2008).

Quantifying a risk can be challenging because many effects cannot easily be measured or described in quantitative terms. For instance, certain outcomes, such as effects on mental health or disrupted family ties, may be observable but hard to put a number on (Rohrmann, 2008). In some cases (e.g., the monetary value of the environment), quantification may even be controversial and equivocal (Fischhoff & Kadvany, 2011). Quantification can also be complicated by uncertainties, including those related to lack of information, differences in interpretation, or inherent unknowns (see Table 2.3 and Section 2.2.3).

Because of varying interpretations and values, as well as the challenges associated with quantification, risks must be understood as dynamic, rather than static. As more information becomes known about a hazard, a situation previously viewed as safe may be perceived as risky (e.g., hormone replacement therapy for menopausal women (Watkins, 2007)) or the understanding of what is safe may swing back and forth over time (e.g., sleeping position for an infant (Gilbert *et al.*, 2005)). In some cases, this evolution may give rise to awareness of new risks that must be addressed (e.g., the dangers of second-hand smoke (U.S. Department of Health and Human Services, 2006)) or new ways of thinking about risk (e.g., viewing health as something dependent not solely on individual genetics and behaviour but also on socio-economic, demographic, and cultural considerations (Kasperson *et al.*, 1988; Mikkonen & Raphael, 2010)). The perception of risk is dependent on context, socially and culturally mediated, and influenced by emotional responses such as trust in institutions and sources of information.

2.1.1 Health and Health Product Risk

Risks to health and risks from health products are a subset of risks. Health Canada (2000) formally defines *health risk* as "a measure of both the harm to human health that results from being exposed to a hazardous agent, together with the likelihood that the harm will occur."

Since characterizing, managing, and communicating potential risks varies greatly depending on the agent, it is important to clearly define the nature of the hazard involved (IRGC, 2005). This report focuses on risks associated with health products: over-the-counter and prescription drugs; biologics (including blood, blood products, and vaccines); medical devices and combination products; and natural health products (recall Section 1.3.1). While noting that risks and benefits are often communicated together, the Panel concentrates on potential negative outcomes associated with the use of these products, rather than their potential therapeutic benefits. For example, although the effectiveness of vaccines and the potential risks due to lack of vaccination are considered beyond the scope of this assessment, the risks associated with receiving particular vaccines

(e.g., risks arising from a manufacturing error) are in scope. Although this report does not explicitly focus on hazards associated with consumer products or food, it may provide insight into risk communication concerning those comparable hazards.

The risks associated with health products are variable, but can be broadly classified into four categories:

- **Known side effects:** risks associated with health products that were detected before they were approved for sale (identified in the approval process) or after they have been on the market for some time through post-marketing monitoring and surveillance (identified through pharmacovigilance).
- **Medication/medical device errors:** risks associated with inadvertent misuse of a health product (e.g., accidental overdose) or from interactions between different health products (e.g., between two drugs).
- **Product defects:** risks resulting from an error in the production process or from incorrect or incomplete labelling of health products (e.g., a natural health product that contains allergens not included in the ingredient list). This category does not refer to labelling that is incomplete because of new knowledge that has only emerged recently.
- **Remaining uncertainties:** risks associated with uncertainty (e.g., the effect of a new drug on a population that has not been studied in clinical trials, such as infants).

(Task Force on Risk Management, 1999)

All of the above risk categories could lead to negative consequences that are known or mild (e.g., headache or nausea) or more severe or unknown (e.g., adverse drug reactions (ADRs)[2] such as increased risk of heart attack that may result from the use of certain non-steroidal anti-inflammatory drugs (Health Canada, 2014b)). In cases of highly likely risks or serious ADRs, a medicine may be taken off the market. There may also be risks stemming from intentional misuse of a health product (e.g., self-medication, overdose, self-harm); however, this topic is beyond the scope of the Panel's assessment.

2 An *ADR* is defined by Health Canada (2012a) as a "noxious and unintended response to a drug which occurs at doses normally used or tested for the diagnosis, treatment or prevention of a disease or the modification of an organic function."

2.2 DEFINING AND UNDERSTANDING RISK COMMUNICATION

Key Findings

- Risk characterization involves quantifying and understanding the probability and potential damage of a hazard as well as the larger context and needs of affected populations.
- Understanding how individuals make decisions under risk, as well as socio-economic and cultural factors that shape those decisions, are central to effective messaging.
- Ongoing partnership and exchange among all relevant stakeholders allow communication to evolve to meet changing needs and perceptions.

2.2.1 Definition and Traditional Goals of Health Risk Communication

Health risk communication is part of the responsibilities of several regulatory agencies around the world. Each of these agencies defines health risk communication in a different way, but each definition includes the concept of exchange of information to improve or maintain health (Health Canada, 2006; FDA, 2009; EMA, 2010; MHRA, 2010; enHealth, 2012). Taking into account these definitions, the Panel adopted the U.S. NRC definition, one of the more progressive because it captures the importance of ongoing and evolving dialogue involving all stakeholders:

> Risk communication is an interactive process of exchange of information and opinion among individuals, groups and institutions. It involves multiple messages about the nature of risk and other messages, not strictly about risk, that express concerns, opinions or reactions to risk messages or to legal and institutional arrangements for risk management.
>
> (NRC, 1989)

Meeting all dimensions of this definition is challenging and is seldom achieved in practice. Many organizations adopt a more general definition of risk communication and develop a set of discrete goals to guide their efforts. In the charge to the Council, the Sponsor discusses its risk communication goals in terms of reach, use, and impact (as introduced in Chapter 1). Table 2.1 defines these goals along with examples of desired outcomes, as they were presented by the Sponsor to the Panel (this table will be re-examined and broadened in Section 2.4).

Table 2.1

Goals of Risk Communication as Provided by Sponsor

Goal	Definition	Potential Desired Outcome
Reach	How the information is sent and received and by whom.	• sent/directed at the appropriate target receivers • received by the target receivers • considered timely
Use	How the information is considered by the target receivers and what action is taken.	• sought out by the target populations • the target receivers can make informed choices based on the risk information provided • action taken based on the opinions, perceptions, and/or beliefs of the recipient • risk minimized by actions based on specific instructions/recommendations
Impact	What effects the information has immediately and over time.	• appropriate change in behaviour observed • risk of serious harm reduced (minimized) • awareness of the risk increased in target receivers

2.2.2 Process of Risk Communication

Communicating health risks entails several stages, including analysis of a potential threat, understanding the perceptions of relevant populations, and disseminating the message in an appropriate manner (Fischhoff *et al.*, 2011). This process allows a risk to be communicated based on evidence and in a manner that ensures that those most likely to be affected by it will receive the message. However, risk communication is also fundamentally a socially and politically interactive process in which individuals are informed of real or potential risks and are expected to use this information to undertake personal strategies to manage that risk. Risk communication requires the identification of the most important facts and information related to a risk, often from large amounts of technical information, by experts in health-related fields (Fischhoff & Kadvany, 2011). It also involves communication specialists conveying information in a manner that is comprehensible to various populations with a wide variety of life experiences and values. Therefore, although risk communication may be seen as a simple one-way transfer of information from an organization (e.g., government body, pharmaceutical manufacturer) to an individual, it is a more complex process of ongoing relations that involve multiple stakeholders and interactions at many levels (i.e., multi-way and multi-level transfer of information). The ongoing and dynamic nature of risk communication and the importance of life experiences and values are incorporated in the IRGC risk governance framework, which, in identifying several stages in risk governance, notes risk communication as central to all (IRGC, 2008).

While this broadened view of risk communication is now widely accepted, this was not always the case. How regulators view and approach risk communication has changed dramatically over time. Table 2.2 synthesizes the learning from three key phases of this evolution.

Table 2.2

Phases in Risk Communication and Management

Synthesis	Fischhoff's (1995) Developmental Stages in Risk Management	Leiss's (1996) Risk Communication Phases (as summarized by Bouder (2011))	Krimsky's (2007) Stages in the Evolution of Risk Communication
Phase 1: Establish accurate science and data analysis to educate. **Key Learning:** Need to properly identify the science that needs to be communicated.	"All we have to do is get the numbers right All we have to do is tell them the numbers All we have to do is explain what we mean by the numbers."	"The first phase focused on the necessity of conveying probabilistic thinking to the general public and to educated lay audiences."	Communications are delivered from the top down in a linear process to address "the public's potentially irrational or unrealistic response to a risk."
Phase 2: Focus on persuasion and paternalistic messaging. **Key Learning:** Need to be clear and address the needs and perceived reality of stakeholders involved.	"All we have to do is show them that they've accepted similar risk in the past All we have to do is show them that it's a good deal for them All we have to do is treat them nice."	"The second phase focused on the persuasion of audiences and the management of public relations to convince people that some of their behaviour is inappropriate."	Communicating about risk emphasized scientific uncertainty, and the cultural and subjective aspects of risk.
Phase 3: Move from persuasion to partnership. **Key Learning:** Risk is socially constructed, and therefore ongoing partnership and interactive exchange are needed.	"All we have to do is make them partners All of the above."	"In the third phase, the aim has been to develop a two-way communication process in which scientists, risk managers, and various laypersons engage in a social learning process."	Risk estimates and perceptions in the post-modernist social constructionist view include scientific bias and hazards that are socially constructed.

Contemporary risk communication is influenced by the legacy of these three phases and typically consists of:

- **Characterizing and managing risk:** using accurate science and data analysis to establish risk assessment and management strategies, including identifying what scientific information and uncertainty need to be communicated and understanding the larger context and population needs inherent to a given risk communication.
- **Creating messaging:** applying multidisciplinary knowledge of how individuals interpret, process, and respond to risk-related information, and how socio-cultural factors shape those activities, to create messages that are understood and meaningful.
- **Ongoing partnership and exchange:** recognizing the influence and importance of broader societal factors to focus on communicating messages in ways that respect dialogue, exchange, and relationship-building.

These activities will ultimately lead to the development of specific communication products that should be assessed for their reach, how they are being used, and whether they are having an impact. However, evaluation is more than an end-stage task carried out after the risk communication is completed. To ensure that communications are meeting their goals, getting through to people, and avoiding any adverse or unintentional effects, evaluation is needed throughout the entire risk communication process, starting with planning and development. Evaluation of health product risk communication is explored in more depth in Chapters 3 and 4.

2.2.3 Characterizing and Managing Risk

Establishing what is known and not known about a given risk is the first step in risk management and communication. Risk characterization synthesizes knowledge in two areas: (i) quantifying and understanding the probability of a hazard and potential for (and extent of) damage; and (ii) understanding the larger context and stakeholder needs at multiple levels.

Establishing the probability of a hazard and outcomes may seem straightforward, but the multi-faceted nature of risk and uncertainty in the data can make it challenging. The U.S. NRC states that quantifying and understanding potential adverse health effects consists of four major steps:

- **Hazard identification:** assessing the nature and strength of the evidence for causal association between a hazard and negative health outcome(s).
- **Dose-response assessment:** assessing the incidence of an adverse effect, the intensity of exposure, and the various factors that may affect response.
- **Exposure assessment:** assessing the intensity, frequency, and duration of exposures and any uncertainties that may be involved.

- **Risk characterization:** estimating the incidence of adverse events in a given population, combining the dose-response and exposure assessments described above.

(NRC, 1983)

Similarly, considering health product risks, Bouder (2011) proposes five key dimensions to assess when characterizing risks and benefits for a particular situation:

- **Seriousness:** level of threat to human health, regardless of exposure factors (e.g., intake quantity). Key question: will this lead to negative outcomes (e.g., fatalities)?
- **Uncertainty:** how much is known and not known. Key question: what is the state and quality of the evidence and what can it really tell us?
- **Complexity:** challenges associated with dealing with multiple causes and a range of possible consequences. Key question: will a coordinated response be required and what factors need to be addressed beyond the hazard itself?
- **Ambiguity:** variability of the explanations stemming from a fixed data set. Key question: what does that evidence actually show (e.g., does a rise in reported outcomes stem from better monitoring and awareness or actual increases in incidence)?
- **Confidence:** the degree of uncertainty surrounding efficacy. Key question: does the health product really do what it claims and is it worth the risk?

(Bouder, 2011)

Ideally, the magnitude and likelihood of a risk and any associated uncertainty can be identified from dimensions such as these; however, this depends on the quantity and quality of the evidence available (Paté-Cornell & Cox, 2014). There is therefore no single approach to quantifying risk. The approach that is most relevant depends on the information available and the level and type of uncertainty in the data.

In general, uncertainty arises in the four situations listed in Table 2.3.

Table 2.3

Descriptions of the Types of Risk Uncertainty

Name and Definition	Effect of New Information	Method for Analysis	Example
Variability (aleatoric uncertainty) involves risks that are inherently complex that can "behave in different ways or… [be] valued differently."	Not modified by new or additional information.	Traditional methods for analyzing medical data (frequentist statistics) are most relevant, providing objective measures of the strength of evidence and the probability of obtaining a given result.*	A drug is effective at relieving symptoms in 50% of patients (regardless of age, gender, etc.).
Limited knowledge (epistemic uncertainty) involves situations when there is little or no information (i.e., there is scientific uncertainty) about a particular risk.	Decreases as new information and data are collected.	Bayesian techniques** are often most relevant, enabling the integration of all known information, even from different experiments, as it becomes available.	If a certain population is not included in the clinical trials for a particular drug, ongoing surveillance activities following wider distribution of the drug may reveal new information for that population.
Interpretative ambiguity involves situations where knowledge about a risk allows different interpretations of its seriousness or likelihood.	New information can reduce ambiguity by lending support to one (or more) particular interpretation.	Will depend on the amount of knowledge and variability.	Two experts come to different conclusions about the likelihood of a risk (e.g., a particular adverse effect) despite having the same evidence base to draw from.
Socio-cultural or normative ambiguity involves situations where there are variable beliefs about what is tolerable or acceptable as a risk.			Acceptability of pre-natal genetic screening or amniocentesis varies across parents and medical professionals.

Source: (Paté-Cornell, 1996; Goodman, 1999; Van Asselt & Rotmans, 2002; Walker, 2003; IRGC, 2008; Klinke & Renn, 2012; Markon *et al.*, 2013; Gregory & Dieckmann, 2014)

* Probability is based on independent and identically distributed observations, and background information is combined with significance tests to interpret any results.

** Bayesian methods define probability as a degree of belief that can be supported by data, models, and expert opinions, allowing different types of information to be combined to produce a new probability distribution.

Getting the numbers right can therefore be a complicated process. When the evidence is less clear, it becomes more important to understand the larger context and varying stakeholder needs, interpretations, and perspectives (Krewski *et al.*, 2007). In these situations it is also important that risk characterization be an iterative process that involves participation of the interested and affected parties and incorporates their feedback as appropriate. Further, while risk characterization requires considering a wide variety of outcomes and consequences, in practice the appropriate level of effort for a risk characterization is specific to each situation (NRC, 1996).

Once a risk is characterized, this information can be used to determine activities to manage the risk. There are several definitions of *risk management*, and the Panel decided to adapt the definition developed by NRC (1983) by expanding it beyond regulatory decision-making:

> The process of individuals, families, and/or other groups weighing alternatives and selecting the most appropriate action, integrating the results of risk assessment with multiple forms of evidence and social, economic, and political concerns to reach a decision.

Inherent in this definition is that risk management policy includes judgments (specific to each case) concerning the public perception of risk and the benefits and costs of control strategies. Risk management can relate to the hazard itself or to the consequences it produces; depending on the risk involved (including any associated uncertainty), the management process will differ (Rohrmann, 2008; Klinke & Renn, 2012). To be effective, risk management needs to be tailored based on the nature of the risk in question. One approach to tailoring management is outlined in the IRGC (2005) risk governance framework, which uses different classifications of risks to guide management (Table 2.4).

Table 2.4

Linking Risk Management Strategies and Knowledge Characteristics

Knowledge Characteristics	Management Strategy	Example
Simple (or linear) risk problems.	Routine-based strategies (e.g., introducing a law or regulation).	Known health risks (e.g., known side effects of a given prescription drug).
Complexity-induced risk problems.	Robust strategies developed by accessing and acting on the best available scientific evidence.	Risks of critical loads (e.g., of fertilizer contaminants) to ecosystems.
Uncertainty-induced risk problems.	Strategies that are focused on resilience and are precaution-based, with the capacity to cope with surprises and reverse critical decisions.	Health effects of pollutants below the threshold of statistical significance (e.g., below the limit of detection).
Ambiguity-induced risk problems.	Dialogue-based strategies to enable a mutual understanding of conflicting views with the aim to eventually reconcile them.	Interpretive ambiguity: low-dose radiation. Normative ambiguity: pre-natal genetic screening.

Summarized and adapted from: (IRGC, 2005, 2007)

2.2.4 Creating Messaging

Understanding how individuals interpret, process, and respond to risk and risk information is important for creating appropriate messaging that will be understood and accepted. Research on individual risk perception explores how psychological and other processes filter and modify technical risk information, amplifying or attenuating public responses to risk (Slovic, 1987, 2000). A set of key risk characteristics have been found to affect public perception of risk acceptability: voluntariness, controllability, equity, time period/delay effect, and dread (described in Table 2.5). Because these factors are correlated with each other in varying ways, Slovic (1987) simplifies these perceptions into two general factors: *dread risk*, involving "a perceived lack of control, dread, catastrophic potential, fatal consequences, and the inequitable distribution of risks and benefits;" and *unknown risk*, involving "hazards judging to be unobservable, unknown, new, and delayed in their manifestations of harm."[3] Linked to these ideas are cognitive biases, such as loss aversion, which affect how people view probability of risk (Table 2.5) information (Tversky & Kahneman, 1979, 1992; Fox & Poldrack, 2008; Kahneman, 2011). Research also suggests that individuals use heuristics — quick decision factors or

3 These terms may be understood differently in the case of health products (e.g., an adverse reaction that has a known delayed onset will be a known risk for medicine safety assessors — not an unknown one).

rules of thumb — to process, filter, and modify risk information (Tversky & Kahneman, 1979, 1981; Kahneman & Tversky, 2000; Kahneman, 2011). They thus simplify risk information and often make very rapid decisions in situations involving risk (Kahneman & Tversky, 2000; Kahneman, 2011). Four important heuristics are introduced in Table 2.5: representativeness, availability, anchoring, and affect.

Many demographic and social characteristics may influence an individual's risk perception, including age, gender, ethnicity, income, and education (Slovic, 2000; Morgan *et al.*, 2002; Bennett *et al.*, 2011). Socio-economic and cultural factors therefore also play an important role in shaping risk perception. *Vulnerable populations*, those groups that cannot be reached with timely risk information because of cultural or socio-economic reasons, face "increased potential for loss in a hazardous situation" (Vaughan & Tinker, 2009). As Fothergill and Peek (2004) argue, in addition to actually facing greater risks, low-income populations experience heightened perceptions of risk because they typically have less control over their lives and tend to normalize everyday exposure to hazards. Many groups cannot be reached effectively with general risk messages because of linguistic or socio-economic factors, or cultural experiences that may lead them to mistrust health officials and government authorities. For this reason, risk communicators must be able to determine for which segments of the population specialized communication may be required and to evaluate whether the risk information that they are providing is being understood by vulnerable groups.

As Kasperson *et al.* (1988) argue, "the investigation of risk is at once a scientific activity and an expression of culture." Indeed, the role of culture in shaping risk perceptions has been an active area of research for several decades (Kahan, 2012). Successful risk communication depends on understanding differences in cultural practices and beliefs. In some contexts, a pervasive media environment plays a strong role in shaping public responses to risk events, including their assessment of the performance of health regulators or other government agencies in managing risk exposure. In other contexts, the role of community elders, peer groups, or religious and spiritual beliefs may play a more powerful role in shaping risk perceptions. As Abraham (2009) argues, "[d]ifferent cultures ascribe different meanings to illness, sickness and disease and biomedical explanations of disease are not universally accepted." Yet, within a given culture, there may also be variability that risk communicators need to understand. In Canada this includes addressing the multicultural dynamics of diverse urban populations and the differences in risk perception and health behaviour between Aboriginal and non-Aboriginal populations (NAHO, 2007; Vukic *et al.*, 2011). Research has led to the identification of

several processes (described in Table 2.5) whereby cultural world views and risk perception interact such as identity-protective thinking (Finucane *et al.*, 2000; Slovic, 2000; Kahan *et al.*, 2010a), culturally biased assimilation (Kahan, 2012), and the social amplification of risk (Kasperson *et al.*, 1988).

Table 2.5

Risk Characteristics, Mental Heuristics, and Socio-Cultural Factors that Affect Risk Perception

Risk Characteristic	Description	Example
Voluntariness	Imposed risks are less acceptable than voluntary risks (i.e., risk is amplified if the risk is imposed and attenuated if it is voluntary). Individuals will accept voluntary risks that are much more risky than involuntary risks.	Taking natural health products is seen as voluntary while being prescribed a medication is seen as imposed. This leads people to believe that natural health products may carry less risk.
Controllability	Risks that individuals cannot control are less acceptable than risks perceived to be under individual control. Perceived control is not necessarily the same as actual control. Individuals often overestimate their ability to control a situation/risk (i.e., over-confidence).	Chronic diseases such as type II diabetes or heart disease are viewed as less risky or fear-inducing because they often relate to lifestyle choices within an individual's control compared with being exposed to outbreaks of a severe virus, which is seen as less controllable.
Equity	Distribution of risk impacts is perceived as more important than the overall impact of risk. Risks that are perceived to be unfairly distributed are less acceptable than risks perceived to be fairly distributed.	Flu outbreaks in the community are perceived to be fairly distributed across the population while hospital infections are seen to be unfairly distributed in particular cases, and are therefore less acceptable.
Time Period/Delay Effect	The time period between an initial risk event or risk behaviour and the eventual impact influences the perceived level of risk. Generally, risks with delayed impacts are perceived as lower risk no matter how severe their consequences.	There is a long delay between poor eating habits and the onset of heart disease and a short delay between exposure to a virus and the onset of symptoms.
Dread	Risks that evoke fear/great apprehension are perceived to be less acceptable than those that do not.	The risk of Ebola evokes dread while the risk of heart disease does not.
Cognitive Bias	**Description**	**Example**
Loss Aversion	Individuals have a tendency to strongly prefer avoiding losses to acquiring gains.	An individual may fear the negative outcomes associated with taking a drug over the potential benefits of that product even if the benefits are greater.

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Individual Heuristic	Description	Example
Representativeness	Leads individuals to evaluate the probability of a risk event by how similar it is to a stereotype or other pre-existing knowledge structure. Can lead to biases because the fact that something is more representative does not make it more likely.	Individuals using a stereotype of the "typical woman who gets breast cancer" when considering their risk of getting the disease.
Availability	Leads individuals to evaluate the probability of a risk event by whether similar occurrences can be brought to mind.	Someone underestimating the risks of genetic testing for cancer because they cannot recall risks associated with the testing.
Anchoring	Leads individuals to estimate probabilities by starting from an initial piece of information that may be unrelated to the risk.	Women who overestimate their risk of breast cancer pre-genetic counselling may continue to significantly overestimate their risk post-counselling.
Affect	Leads individuals to estimate risk based on their subjective impression of the goodness/badness of the situation.	Someone overestimating their risk of cancer because he/she has personal experience with the disease through friends or family.
Socio-Cultural Factor	**Description**	**Example**
Cultural Identity-Protective Cognition	People tend to align their views with others with whom they share some important cultural characteristic.	Tendency for white men to view environmental risks as less serious than they are viewed by women and minorities.
Culturally Biased Assimilation	Leads individuals to reinforce those arguments that reinforce their cultural viewpoint while dismissing those that do not, leading to polarization of groups even when they are exposed to the same information.	Tendency for those with egalitarian and communitarianism world views to be less fearful of the risks associated with the HPV vaccine compared with those with hierarchical and individualistic world views.
Social Amplification of Risk	An original real-world event creates a signal whose magnitude (i.e., the perceived threat) is changed as it moves through a given society. Every person who receives the risk signal also engages in amplification or attenuation processes and therefore has an effect on the risk signal. Initially, social amplification of risk encompasses only those who are directly impacted by a risk (or the first group made aware of it). But over time the impacts extend to other groups.	The magnitude of fear associated with the Ebola virus has been amplified by discussions in media, social media, and personal networks of peers. Other groups that impact the Ebola risk signal include domestic and international governance groups.

Source: (Tversky & Kahneman, 1979, 1981; Kasperson *et al.*, 1988; Cull *et al.*, 1999; Finucane *et al.*, 2000; Kahneman & Tversky, 2000; Slovic, 2000; Gerend *et al.*, 2004; Peters *et al.*, 2006; Kahan *et al.*, 2010a, 2010b; Kahneman, 2011; Kahan, 2012; Roeser *et al.*, 2012)

While there is strong evidence for the described risk perception factors, they may not be true in all cases. Furthermore, the research on individual decision-making is not specific to health product risks. Therefore, targeted research on these relationships for health product risks is needed to better understand how they affect communication. For a more thorough and in-depth discussion of these research areas, the reader is directed to more comprehensive sources such as Kahneman & Tversky (2000), Slovic (2000), Kahneman (2011), Kahan (2012), Roeser *et al.* (2012).

Risk Communication Practices Supported by Scientific Research

Research into how people interpret and respond to health risk communication specifically could be used to guide communication development and to ensure that people understand and use information. For example, when communicating health-related probabilities and uncertainties, research has shown that numbers are more effective than words in conveying probabilistic information to patients (Marteau *et al.*, 2000; Man-Son-Hing *et al.*, 2002; Trevena *et al.*, 2004; West *et al.*, 2013). Furthermore, numeric information (over words) about adverse events increases risk comprehension across numeracy levels (i.e., those who are less numerate benefit along with those with high numeracy) (Peters *et al.*, 2013). Research also indicates that illustrations should be used to complement the presentation of probabilities when possible, and that there are advantages and disadvantages of the many different types of illustrations available (Lipkus, 2007; Fagerlin & Peters, 2011; Mt-Isa *et al.*, 2013a, 2013b).

The emotional response to a communication is also an important dimension in understanding how an individual reacts to recommendations. Emotions (or affect) can be induced either integrally or incidentally. *Integral* affect describes feelings that result from an explicit part of the communication, whereas *incidental* affect refers to feelings that are only indirectly induced by the communication or independent of the communication (Lerner & Keltner, 2000; Visschers *et al.*, 2012). The emotions induced incidentally depend on the unique context of that individual and may result from social amplification (e.g., media) or past experiences (e.g., a previous hospitalization) (Lerner & Keltner, 2000). While the sender has greater control over integral affect, negative incidental affect requires careful consideration and planning to mitigate, when possible (Visschers *et al.*, 2012).

Linked to this idea is the use of fear in communication efforts. Although not appropriate for risk communication in general, a meta-analysis demonstrates that it can be effective to invoke fear in public health campaigns when messaging depicts a "significant and relevant threat," when recipients feel the advice will be

successful in averting the threat, and when recipients believe they can successfully implement the advice. Fear appeals, however, need to be used cautiously as they can backfire when these conditions are not met (Witte & Allen, 2000).

These examples are only a small sample of the relevant research studies that have yielded useful information on how individuals interpret/respond to risk information. For example, a comprehensive review of evidence supporting patient decision-aids (a type of risk communication tool) in clinical care have been summarized and a set of communication appraisal standards have been developed (Volk *et al.*, 2013). For government agencies and health regulators there are several publications that provide guidance based on research into health risk communication (Fischhoff *et al.*, 2011; Mt-Isa *et al.*, 2013a, 2013b). The Panel has identified *Communicating Risks and Benefits: An Evidence-Based User's Guide*, a publication prepared for the U.S. Food and Drug Administration (FDA), as providing the most thorough discussion of evidence-informed communication practices for health regulators (summarized in Table 2.6).

Table 2.6

Risk Communication Practices Supported by Scientific Evidence

Category	Evidence-Informed Communication Practices
Definitions of Outcomes	Use standard definitions for risks with multiple outcomes.
	Use standard definitions for risks with multiple features.
	Use standard definitions for outcomes that occur over time.
Quantitative Information	Provide numeric likelihoods of risks and benefits.
	Provide absolute risks, not just relative risks.
	Keep denominators constant for comparisons.
	Keep timeframes constant.
	Use pictographs and other visual aids when possible.
	Make the differences between baseline and treatment risks and benefits clear.
	Reduce the amount of information shown as much as possible.
	Provide both positive and negative frames.
	Use interpretive labels or symbols with care to convey the meaning of important information.
	Test communications prior to use.

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Category	Evidence-Informed Communication Practices
Qualitative Information	Identify the main factors determining the risks and benefits of a choice, along with the relationships among them.
	Characterize existing beliefs in terms comparable to the formal model.
	Draft, test, and redraft communications, addressing the critical differences between what people know and what they need to know.
Health Literacy (e.g., Treatment Labelling)	Organize components to reflect how people process instructions.
	Emphasize critical information.
	Simplify language.
	Give explicit time periods.
	Include purpose for use.
	Limit auxiliary information.
	Address language proficiency.
	Select appropriate font.
	Improve readability.
Affect and Emotion	Provide risk and benefit information about taking an action.
	Consider presenting risks and benefits of not taking an action.
	Make the affective meaning of important information easy to access.
	When emotions are expected to be high (and potentially harm decisions), provide methods to "stop and think" to reduce affective input.
	Fight fire with fire (when persuasive communication is needed).
	Consider the effects of advertising, brand names, and other promotional efforts on perceptions of the risks and benefits of products.

Source: (Downs & Fischhoff, 2011; Fagerlin & Peters, 2011; Fischhoff, 2011; Peters, 2011; Wolf, 2011)

2.2.5 Ongoing Partnership and Exchange

Given the importance of contextual factors and the needs of various populations and stakeholders, risk communication has moved from a model of one-way (expert-to-public) dissemination of information to multi-level and multi-way exchange among all relevant populations and stakeholder groups (Leiss, 1996). This new communication practice involves more than simply monitoring what particular groups are saying with the goal of changing their behaviour. Rather, it focuses on understanding and appreciating the concerns of those involved to establish a meaningful dialogue in which all parties learn from the experience and remain open to adjusting their positions accordingly.

Importantly, the nature of each risk situation will dictate the level of dialogue appropriate for different receivers of information and stakeholders. For example, while in many cases communications are improved through coordination with industry stakeholders, there may be situations for health products where it is most appropriate for the regulator to issue communications independently and without consulting those groups. While stakeholder engagement and multi-way exchange are important, there may be instances where command and control communications that focus on one-way exchange could still be useful. For instance, in emergency situations where the risk of harm is great or imminent, there may not be time for detailed and lengthy consultation with all relevant groups. These situations are often predictable, however, and communications can be tailored to the specific situation at hand through pre-testing with experts knowledgeable about affected populations but not involved in content development (Fischhoff, 2005).

The necessity of command and control communications in some situations illustrates the importance of ensuring continuous dialogue between the senders and receivers of information, and other stakeholders, so that there is a foundation on which communications can rely. Ongoing dialogue is needed to find out what different groups already know about a risk and where there are gaps and information needs. Communicators also need to understand the concerns of particular affected groups. Because people actively seek out (or avoid) risk information and evaluate a given risk based on their own set of criteria (Alaszewski, 2005), communicators need to recognize and understand a group's broader social context, needs, and cultural factors (Frewer, 2004). Multi-way communication involves understandable, decision-relevant information and the incorporation of meaningful feedback to policy and planning. The exchange requires the receivers of information to be respected and viewed as legitimate partners whose input is valued and heard (Covello, 2010). A commitment to active listening with the intention of dealing openly with concerns is crucial for meaningful, ongoing dialogue.

There are several benefits to ensuring that dialogue starts early, is ongoing, and does not end once a particular risk communication is released. Any communication may cause a risk to evolve as needs change or perceptions are modified. Continued dialogue is needed to monitor, and adequately respond, to the changing context (Veil *et al.*, 2008). Ongoing communication can help ensure that all stakeholders feel listened to, provided communication is done

in good faith. This includes responding to specific concerns or comments and clarifying what action will follow as a result. This type of engagement at multiple levels may help establish and build trust, foster credibility, and develop common understanding over time, which provides the foundation for future risk communications and events. Having established positive relationships with a variety of groups will be especially important in those cases where only one-way communications are possible due to time or other constraints.

2.2.6 Moving Forward

While the literature recognizes the importance of many different communication practices, they may not always be incorporated in practice. In fact, some research suggests that risk communication by government agencies has, in many ways, changed little in the past several decades (Kasperson, 2014). Notably, while the importance of ongoing exchange and relationships with all stakeholders is recognized in theory, the broader steps needed to develop these relationships are rarely considered. Recognition that relationships with stakeholders need to be fostered and managed will bring risk communication into a new paradigm with broader goals and new ways of communicating (discussed in the next section). At the same time, the lessons and practices of the past should not be forgotten: sound risk characterization, clear and appropriate messaging, and ongoing partnerships and exchange will continue to be very important for effective health product risk communication in the future.

2.3 THE NEW PARADIGM OF RISK COMMUNICATION

Key Findings

- The complex environment for health product risk communication demands shared responsibility, coordination, and collaboration among several different groups.
- Communicators better meet the needs of various populations when communicating uncertainty clearly and proactively and making it a central component of any risk communication message.
- Communicators can increase the public's access to and ability to understand health information as well as empower and build trust by involving the public in decision-making and by valuing transparency efforts. These efforts can lay the groundwork for meaningful risk communication dialogue over the long term.
- Established relationships with various affected populations and stakeholders can enable timeliness and acting proactively in the face of new risks.

Recognition of multi-way dialogue, and the need to build strong relationships over time, is prompting a paradigm shift for risk communication. This emerging paradigm builds on the learning from the past to address new challenges relevant for evaluation of health product risk communication:

- **Governance:** addressing the challenges that stem from shared responsibility within the risk management and communication environment.
- **Complexity:** navigating the inherent complexities of the risk and the communication environment that comprises multiple stakeholders and priorities.
- **Uncertainty:** communicating uncertainty and multiple interpretations of the evidence.
- **Empowerment:** moving from providing prescriptive statements to enabling solutions and empowerment.
- **Timeliness:** ensuring timely and proactive responses that build trust over time.
- **Transparency:** ensuring reasoned transparency that increases the public's access to and ability to understand health information.

These challenges vary depending on the nature and context of the risk. They also do not exist in isolation, and elements of one affect another. For example, uncertainty can be influenced by the complexity of the communication environment, and both of these challenges may affect the timeliness of a communication and empowerment. There are also common themes that cut across challenges, most notably the role of trust in building relationships over time.

2.3.1 Governance

The complicated governance structures for health in Canada create challenges for the communication of health product risks. At the federal level, Health Canada is responsible for the regulation of health products, approving drugs and medical devices for sale, and carrying out post-marketing evaluation to ensure these products are safe (regulatory responsibilities are described further in Chapter 3). However, industry (or market authorization holders, MAHs) plays a critical role in health product risk communication and is responsible for the identification of risks. For example, some risks (e.g., known side effects) are detected during clinical trials and included in the materials submitted by industry to seek market approval. In many cases, the MAHs actually produce and distribute the health product risk communication tools also distributed by Health Canada (e.g., public advisories). For communications such as drug labels, dear doctor letters, and public advisories, Health Canada provides detailed guidance documents and templates outlining the format and content to be included in risk communications, and approves the final product. Health Canada does, however, distribute its own communication tools when an MAH refuses

or is unable to do so (Health Canada, 2008). It is clear that regulators and health product manufacturers and distributors have a shared responsibility that must be coordinated in any communication effort on health product risk. This can be challenging to navigate given that regulators and industry groups may have competing goals.

Adding to this governance structure is the segmentation of different health communication activities across different orders of government. As Driedger *et al.* (2013) explains, "the nature of the Canadian confederation, with its federal-provincial-territorial division of powers and responsibilities makes it ripe for risk communication quagmires." In the case of health products, Health Canada acts as the regulator; provincial health ministries are responsible for the administration and delivery of health services (except for First Nations and Inuit, military personnel, veterans, and members of the Royal Canadian Mounted Police, who are under federal jurisdiction); and local authorities provide public health services in their jurisdiction such as influenza immunization clinics, sexual health clinics, outbreak investigation, and food establishment inspection. This shared responsibility can lead to a lack of clarity on the responsibilities of each level of government for communication and evaluation, particularly when different communication programs in different jurisdictions are designed to influence similar health outcomes.

During the H1N1 pandemic of 2009, for example, several government agencies had a role to play in managing the outbreak (PHAC, 2010). These included two federal players, Health Canada (e.g., ensure vaccine safety) and the Public Health Agency of Canada (e.g., analyze and interpret surveillance information); provincial health departments (e.g., cover the costs and provide vaccines); Aboriginal leaders (e.g., arrange for the delivery of vaccinations); and city/regional public health departments (e.g., deliver vaccinations through clinics, monitor local health events). Furthermore, given the global nature of the outbreak, international organizations like the World Health Organization (WHO) coordinated international responses and made recommendations on when to start vaccine production. Cooperation and coordination during the crisis was identified as one of the factors that worked well and helped manage the pandemic in Canada (PHAC, 2010).

Depending on the nature of a health risk, the affected populations receiving information, and other stakeholders, responsibilities for risk management may also involve non-health government departments and agencies. For example, in Canada, for certain risks, communication may need to involve the Canadian Food Inspection Agency, Environment Canada, or Aboriginal Affairs and Northern Development Canada at the federal level. Similarly,

there may need to be coordination with non-health departments at provincial or municipal levels. In some cases, risk governance may also include groups outside formal government structures, such as interest and advocacy groups or individuals on social media. A Canadian event in the 1980s demonstrated the severe consequences of poor coordination and collaboration among these groups. Contaminated blood resulted in infection of at least 30,000 and 2,000 individuals with hepatitis C and HIV, respectively. In response to the crisis, a commission of inquiry was established, which found the contamination of the blood supply was inevitable, but that failures by all organizations responsible for regulating blood made the problem worse (Krever, 1997). These failures included an absence of communication of risk among different agencies and organizations, and among doctors and patients, as well as unclear mandates of key organizations such as the Canadian Red Cross Society (Norris, 2008; GOC, 2013b).

Moving Forward

Establishing who is responsible for what and exchanging data and information can be difficult when multiple authorities or jurisdictions are involved in risk communication and its evaluation. Ensuring coordination and flow of information in these cases is essential for success (WHO, 2001). Strong relationships and cooperation among the different governance bodies, along with good planning that considers complicated governance structures, can support the development and dissemination of effective risk communications and their evaluation.

2.3.2 Complexity

The communication of health product risk does not take place in a vacuum: beyond the levels of government and industry there are multiple stakeholders involved who add their own interpretive dimension to any communication. Further, complexity may arise from the nature of the risk, the knowledge about that risk, or any resulting discourse. Complexity stems from the hazards causing a risk, the knowledge and uncertainty in the effects, the interactions between effects, and other political, ethical, economic, and social dimensions.

Multiple Players

Although the regulator often develops or approves strategies for communicating health product risk, several other groups influence how that information will reach, or be interpreted by, various populations. Many of these groups are responsible for disseminating risk information to consumers directly. They may change the original message entirely or influence what information people see as relevant, important, or credible, thus supporting or hindering the dissemination of accurate information. For example, a study of vaccination seeking behaviours during the H1N1 outbreak found that media coverage

as well as messages from authority groups competed to shape and frame people's view of the pandemic (Boerner *et al.*, 2013). Study participants were also far more likely to mention the media stories (rather than government communications) during focus groups (Boerner *et al.*, 2013). Non-governmental health organizations (e.g., counselling services for pregnant women) and health professionals were also trusted sources of information that shaped how people viewed the pandemic and vaccinations (Lynch *et al.*, 2011; Sakaguchi *et al.*, 2011). How these different sources of information may agree with or challenge the recommendations communicated by regulators can increase the complexity of the overall communication environment.

Health Professionals

In communicating about health products, health professionals (e.g., paramedics, nurses, pharmacists, physicians) often interact most directly with the public and are among one of the most trusted groups in Canada (Ipsos, 2012). Health professionals are expected to be up to date on the nature of the risks associated with health products and provide the information needed to work with the public. The public assumes that health professionals will disclose all of the safety information available. It is therefore essential to engage and involve these professionals in any communication effort.

Organizations

In Canada a wide variety of health-based organizations have a role in creating or disseminating health product risk communications, and each organization has access to its own unique group of people. Disease-based support or fundraising organizations (e.g., the Canadian Cancer Society) communicate with patients and interested members of the general public. Organizations that accredit, regulate, license, or advocate for health professionals may provide guidance to their members on how to use health product risk information and on the treatment of patients, in general or in cases of identified risks. For example, the Canadian Association of Gastroenterology issued a position statement with recommendations on prescriptions of proton pump inhibitor drugs in response to emerging concerns about their effect on risk of bacterial infections (The Canadian Association of Gastroenterology, 2005).

Media

Often much of the information that the general public receives about a health product risk comes through the media (e.g., newspaper, radio, television). According to the WHO, "the media may merely transmit a message, or they may create or interpret a message. They are not limited to official sources of information and their messages often reflect the concerns of the public and other sectors of society" (WHO, 1998). Journalists may act as partners (particularly

during periods of crisis or emergency) and as key players who can contribute or enhance outrage and/or the social amplification of risk. News media therefore not only reflect what risks mean to different groups and actors, but actively shape the discursive environment through which risks emerge as problematic and in need of action (Greenberg, 2012). In some cases, the success or failure of a risk communication may be influenced by media coverage. For example, a communication on the risks associated with co-dispensing cisapride with other medications issued in the United States in 1998 was found to have an impact on co-prescriptions when earlier warnings did not, partly because it was more widely publicized in the media (Weatherby *et al.*, 2002). In contrast, in 2009 the U.S. Preventive Services Task Force recommended that routine mammograms should start at age 50, while women in their forties should decide whether to undergo the test only after discussing their risk factors with their doctor (Schwitzer, 2011). Many news stories discussing these recommendations focused on anecdotes and overstated the benefits of mammography, while downplaying potential harms, thus contradicting the recommendations (Schwitzer, 2011). Examples such as these seem to be a widespread problem; in an analysis of 1,400 news articles related to health, about 70% failed to adequately mention the harms and benefits of interventions being discussed (Brainard, 2011; Schwitzer, 2011).

Individuals, Communities, and the Influence of Social Media

The critical role of the public must also be considered. Individuals are generally responsible for decision-making on their own health, and in many cases have significant influence on decisions about the health of their friends and family. Health decision-making is informed by the risk information an individual or group accesses, and how they interpret it. Social media provide new platforms that can be exploited to spread messages quickly, effectively, and in different ways (e.g., Instagram for photos, Facebook for personal connections and engagement) as part of an overall risk communication strategy. Participatory media like Twitter and Facebook can potentially amplify the demands for greater accountability and transparency and can challenge the nature of the relationship between communicator and receiver by facilitating discussions and building trust among these groups. They can also provide potential sources of intelligence for issue surveillance. These changes move the internet beyond a new medium to disseminate risk information to a social movement that can accelerate behaviours and challenge authority. By contrast, the wide availability of counter-information online can be spread quickly through social media and influence how people interpret and react to risk. Social media are therefore not a panacea and should be used as part of an overall risk communication strategy that recognizes that different platforms are appropriate for different communication goals.

Complex Risks and Hazards

Risk decision-making must account for a myriad of demographic, socio-economic, environmental, political, and organizational factors, which may interact in largely unpredictable ways to produce the outcomes associated with a risk communication. These relationships are themselves complex, non-linear, and dynamic. Even in cases where there is a clear hazard leading to a risk (e.g., smoking and lung cancer), the factors comprising the risk context influence risk management activities among various groups, making the situation and behaviour difficult to understand. Situational complexity consists of multiple factors: the impact of the risk (actual, perceived, and potential); the vulnerability or resilience of those affected by the risk; and the uncertainties associated with the evidence surrounding the risk (Lemyre *et al.*, 2011).

Furthermore, the many, and often competing, interests, values, expectations, and needs of the interdisciplinary players involved with any particular risk situation go well beyond their role in communicating about risk. Each player exists in its own context and sees risk through a unique lens (Stame, 2004). These contexts are not independent of one another, however, given the social and power dynamics that exist across all risk communication players (Stame, 2004). Health product risks also have material, economic, political, social, and other dimensions that add to their complexity. This wide range of competing interests and needs make it challenging to link any one input to another because so many factors can interact with and affect one another, sometimes producing largely unexpected outcomes (Pawson & Tilley, 1997; Weiss, 1998).

Moving Forward

The complex environment for health product risk communication can be addressed through consideration of a range of relevant interests and coordination of key players. Coordination and collaboration with all relevant stakeholders, including health professionals, organizations, media, and the public, can help regulators in the integration and communication of available information on a given risk. These relationships can foster a greater understanding of the range of complexities associated with a risky situation. This is especially important when there are competing interests, perspectives, and interpretations. An absence of coordination can increase uncertainty among the receivers of information and, in some cases, increase risk.

2.3.3 Uncertainty

While uncertainty is inherent in all types of risk (see Section 2.2.3), it is very relevant in the context of health product risk. Risks of recently approved health products are based on limited evidence from controlled trials, and information from long-term real-world use is lacking. If drugs were approved through

accelerated processes and/or processes with surrogate outcomes, this adds to uncertainty (IOM, 2014). Uncertainty may diminish as real-world experience accumulates; however, socio-cultural ambiguity may increase if there are differing interpretations of whether benefits outweigh known side effects and other risks. Communicating uncertainty in the context of health products is also complicated for both the senders and receivers of information (Kasperson, 2014). Experts may be reluctant to communicate uncertainty because of perception that uncertainty is "misplaced imprecision" that provides unnecessary complication or doubt; poor opinion of "lay audiences" or decision-makers and the expectation that information will be misunderstood; fear of being punished for being candid about the presence of uncertainty; or their own inability to properly express uncertainty in a clear and succinct way (Fischhoff, 2012; IOM, 2014). Experts may also have concerns that the public cannot conceptualize the uncertainties associated with risk estimates (Frewer, 2004), leading to misunderstanding of risk information, or that they will view scientific uncertainty as incompetence (Frewer *et al.*, 2003; Wynne, 2008; Markon *et al.*, 2013).

Reluctance to explain uncertainty can stem from a view of risk communication as a tool for persuasion rather than empowerment, as it does not take into account the views and desires of those receiving risk information. Open discussion with the public about the multiple sources of uncertainty is believed to improve risk communication and encourage trust in the senders of information (Palenchar & Heath, 2007; Wynne, 2008), although there has been limited research in this area to provide empirical support (Johnson, 2003; Markon *et al.*, 2013). There is evidence, however, that the ability of non-experts to understand uncertainty has been underestimated, and that the public can recognize and distinguish between different types of uncertainty (Markon & Lemyre, 2013). In addition, research has found that individuals often want information about the uncertainties associated with risk information (Frewer, 2004).

As an example, during the H1N1 outbreak, health agencies around the world strongly recommended that pregnant women get vaccinated as they were at higher risk from the illness (PHAC, 2010). Pregnant women, however, had concerns about the uncertainty associated with effects of the vaccine on themselves and their babies (Lynch *et al.*, 2011; Sakaguchi *et al.*, 2011). They are taught to be selective about medicines and are therefore generally hesitant to take any medication during pregnancy because of fears of harming their babies and affecting breast feeding after birth (Bonari *et al.*, 2005; Lynch *et al.*, 2011). However, research suggested that pregnant women were willing to reassess their previous views "after exposure to engaged discussion" (Lynch *et al.*, 2011).

Poor communication around uncertainty has been shown to have negative outcomes. These include needless hesitation or, conversely, unwarranted confidence, inappropriate choices, personal regret, or interpersonal resentment (IOM, 2014). For example, conflicting messaging about which vaccine pregnant women should take caused further confusion during the H1N1 outbreak (Babbage, 2009; Smith, 2009). Failure to communicate known ambiguity may also have negative implications: conflict among different sources has been found to lead to more alarmist perceptions than conflicting data presented from the same source (Viscusi, 1997).

The context and nature of the risk information may affect how much uncertainty information is needed in communication efforts. Research has found that people value an uncertainty discussion, using that conversation to inform their choices about a given health risk, but do not need to know all of the known uncertainties (Fischhoff, 2013; Kasperson, 2014). Furthermore, they generally do not want uncertainty information about risks outside of their personal control (Frewer *et al.*, 2002). People may be more comfortable with uncertainty stemming from divergent data than with uncertainty stemming from divergent interpretations by experts (Markon *et al.*, 2013). For example, in the case of vaccines, people in focus groups in Edmonton, Winnipeg, and Toronto felt that the messaging from alternative communicators was more credible than provincial/federal health agencies because these alternative sources presented both pro- and anti-sides of the vaccine debate for their consideration while health agencies presented a one-sided campaign (Boerner *et al.*, 2013).

As with transparency about past failures, openness about uncertainty can decrease public confidence in an organization (Kasperson, 2008). In fact, research has demonstrated that uncertainty information may lead people to view the institution responsible for the communication as more honest but less competent (Johnson & Slovic, 1995). In contrast, while communication of uncertainty is often associated with greater perceived risk (Slovic, 1987; Löfstedt, 2003), this is not always the case. For example, Frewer (2004) found that, while disclosing uncertainty does increase perceived risk for those people who were previously indifferent to the issue, it can actually reduce the perceived level of risk of those people who were previously very concerned. Despite the potentially negative trade-offs, building trust through communicating uncertainty in an appropriate manner can result in a strong relationship between the senders and receivers of information.

Moving Forward

There is potential benefit to accounting for uncertainty in risk communications, but how to present that information depends on the type of uncertainty, the objectives of the communication, and evidence-based communication practices (Table 2.6). Although there is sometimes debate about the best way to present uncertainty, appropriate communication practices will help. Such practices aid not only in getting the message through but also in building the trust and relationships needed for ongoing exchange. Further research is needed on promising ways to communicate uncertainty, when it matters, and when it can be harmful.

2.3.4 Empowerment

Empowerment of individuals to make informed decisions (i.e., to change behaviour or make an informed refusal) is one of the shifts in the evolving risk communication paradigm and is an important way to mitigate or avoid negative responses among populations receiving information. Aiming for empowerment recognizes that regardless of how effective risk communication is, reasonable people may disagree about the best path forward (Fischhoff, 2013). Empowerment thus requires that communication considers and respects the values, desires, and knowledge gaps of various populations.

Risk communication must make sense to those affected, and empowerment strategies can help in this regard. For example, when developing a sexual health intervention aimed at empowering young women, one study focused on a suite of factors that might affect decisions on sex (including pleasure and personal relations) (Bruine de Bruin *et al.*, 2007). An interactive DVD was then developed to fill the knowledge gaps identified and to present both positive and negative outcomes. This format allowed for the presentation of information "more easily seen than explained" (e.g., how to put on a condom), helped teens to select the material most relevant to them, and avoided the awkwardness associated with discussions on sex between teens and educators (Bruine de Bruin *et al.*, 2007). By considering the knowledge needs of young women, the tool avoided the pitfalls of many sexual health education programs (e.g., not emphasizing the risk of ongoing unprotected sex) (Downs *et al.*, 2004a, 2004b; Bruine de Bruin *et al.*, 2007). Overall, the DVD was found to reduce condom failures *and* increase abstinence while also decreasing incidence of sexually transmitted infections when compared with other interventions (Bruine de Bruin *et al.*, 2007).

The importance of empowerment through shared decision-making has been recognized in the health risk communication literature, most notably in patient-physician joint decision-making to choose treatment plans for very serious health issues (Charles *et al.*, 1999; O'Connor *et al.*, 2003; Jardine & Driedger, 2014). This approach recognizes patients as part of the decision-making team, rather than simply as a target for risk information, and considers their values and preferences in the decision-making process, aspects of which could be extrapolated to broader health product communication efforts by regulators (Jardine & Driedger, 2014). Interventions like this have been linked to positive health outcomes. For example, Greene and Hibbard (2011) demonstrates the strong links between patient activation ("having the knowledge, skills, and confidence to manage one's health") and a range of positive health outcomes, including systolic blood pressure in the normal range, lower rates of obesity, and fewer hospitalizations. Engaging affected populations in the decision-making process includes sharing in a way that is both available and appropriate (Jardine & Driedger, 2014). This means using effective presentation methods to ensure risk information can be understood (see Table 2.6) and including an appropriate amount of information. Providing too little can leave people feeling ill informed while too much can make it difficult to identify what information is important and make the process feel overwhelming. Similarly, messaging is more effective if it provides accessible solutions that are considered realistic by those receiving the information (O'Carroll *et al.*, 2013).

Trust and empowerment efforts are greatly linked. People who do not have core values on a given issue look towards credible communications to make decisions in the face of uncertainty (Bostrom, 1997; Downs *et al.*, 2008). Much of this group's responsiveness to what is communicated is related to their trust in the agency doing the communication, and how complete they believe that information to be. Empowerment helps build trust, while communications that do not address population needs risk losing it. For example, sexual health programs often fail to consider that teens and adults may view the same decisions about sexual intercourse differently and educators may attribute the risky behaviour of teens to their acting irrationally or underestimating the risks (Bruine de Bruin *et al.*, 2007). Communications based on these misconceptions may lead to teens "draw[ing] erroneous inferences" and "resent[ing] adults who seem to be wasting their time with simplistic, incomplete, and repetitious messages." Teens may start to mistrust the source if their real-life experiences contradict the sexual health messages that they are being told (Bruine de Bruin *et al.*, 2007). Likewise, health product regulators may lose public trust as a result of specific crises (e.g., Vioxx®) where communications are reactive. This exacerbates the loss of trust, whereas proactive communication can

rebuild public trust (Morgan *et al.*, 2002; Löfstedt, 2010). The importance of the participation of health product users in the entire risk management process (including communication), and its role in building trust, has been recognized (Bahri, 2010). A lack of trust makes empowerment of those who are exposed to a given risk all the more important.

Moving Forward

Messaging that does not meet the needs of groups receiving the information is typically not effective in changing behaviours and can cause people to avoid risk information or ignore messaging. Empowerment efforts can be effective in creating meaningful dialogue that better meets people's needs. These efforts include creating appropriate messaging for understanding, comprehension, and action; engaging populations receiving information as members of the decision-making process; and focusing on long-term relationships and informed change. In an empowerment context, communicators must respect informed individual decisions that may go against risk communication messaging. In practice, ensuring that populations receiving information are empowered is a long-term process that is achieved incrementally (Jardine & Driedger, 2014).

2.3.5 Timeliness

Balancing Trade-Offs and Expectations

An organization should communicate relevant information within a suitable timeframe after it becomes aware of a risk. This is particularly true for regulators that become aware of health product risks because the regulator has a responsibility to ensure that people have the necessary information to make informed decisions about their health. The definition of *timely* will vary for each risk situation and depend on the severity, probability, and uncertainty associated with a given risk. There are also important trade-offs to be considered, including balancing the time needed for proper risk assessment with getting information out to the public quickly. If inaccurate information is released too early, it can cause unnecessary anxiety or, conversely, a false reassurance concerning a product. It can also lead to a need to correct information that has already been disseminated. On the other hand, waiting too long to release important information may put patients at risk. If risk information is not communicated in a timely manner, public opinion may have already started to take shape on the nature of the risk and blame for the problem (Greenberg, 2012; RSI, 2013). Even in cases where there is limited information, communicating early may not be harmful if done honestly, humbly, and cautiously. Ensuring risk communication is done early can have long-term benefits, setting the stage for the next hazard by building trust over time.

Many stakeholders can impact the public's perception of timeliness, particularly the media. For example, during the 2011 Ottawa endoscopy scare,[4] the news media received limited information before Ottawa Public Health (OPH) was ready to make a formal public announcement about the breach in infection control measures at a local, non-hospital medical clinic. The public health unit was therefore forced to accelerate the timeline for public disclosure under pressure from the media. Initially, OPH released only general information about the event (e.g., the specific source not released) for a variety of reasons, including concerns over patient privacy, doctor-patient confidentiality, and the ability of the public health department to deal with increased demand for testing and information expected to result from a full announcement (Greenberg, 2012). Detailed information about the nature of the risk was released two days later. The media were highly critical of the health unit's risk communication strategy, and journalists reported that the decision initially to release only partial details led to increased public anxiety and a loss of confidence in the public health system (Greenberg, 2012).

Social media and the internet have changed expectations around timeliness. Information available online can spread quickly through social networks, making the challenges of establishing message control once risk information becomes known even more difficult (Greenberg, 2012). The strengths and challenges associated with social media only confirm what has been recognized for decades: that "audiences are not passive recipients of information, that calculations of risk that ignore social components are worthless and that controversies over risk are often surrogates for concern over process, values, and identity" (Neeley, 2014). The above example illustrates these issues further. After the partial release of information by OPH on the Ottawa endoscopy scare, social media discussion about the incident initially involved "unsubstantiated claims [that] attributed the infection lapse to tattoo parlours, dentist offices, and flu clinics, among other locations" (Greenberg, 2012). OPH could not correct this misinformation, as it was not active on social media during the 36 to 48 hours following the initial media release (Greenberg, 2012).

Moving Forward

While what is considered timely will be different for each risk communication situation, communicators can lay the groundwork to ensure that they are able to respond to risks quickly. Having clear risk communication guidelines and established relationships with various populations and stakeholders can enable organizations to act proactively in the face of new risks. In addition, using

4 A non-hospital medical clinic did not carry out the proper safety and sterilization procedures on endoscopes over a 10-year period, potentially exposing thousands of patients to HIV and hepatitis (Ottawa Public Health, 2011).

new communication sources such as social media to strengthen relationships and engage with affected populations and stakeholders can help set a strong foundation to deal with future risk situations.

2.3.6 Transparency

Transparency can build empowerment, trust, and quality relationships between the senders and receivers of information. It lays the groundwork for proactive and timely communication efforts over the long term. "[T]ransparency is crucial to effective risk communication because it is the bedrock on which public trust is based" (Greenberg, 2012), and it is the foundation for turning the populations that receive information into partners in risk communication (Markon *et al.*, 2013). Calls for transparency have increased in recent years, generally following a scandal or signal of lack of trust in governments, regulators, or communicators (Löfstedt & Bouder, 2014). For example, Health Canada has been criticized for the perceived lack of openness in releasing confidential business information submitted to it for licensure, which some observers say is needed to identify where there are weaknesses in the evidence, maintain public trust, and protect the health of the general public (Turner *et al.*, 2008; Hébert *et al.*, 2011; Herder, 2012).

In response to these concerns, transparency has become a focus for many governments. *Canada's Action Plan on Open Government* sets out four principles for the federal government: availability of information, citizen participation, professional integrity, and new technologies for openness and accountability (GOC, 2014). As part of this action plan, the government promises to issue a policy directive that will provide guidance to all federal departments on "what they must do to maximize the availability of online information and data, identify the nature of information to be published, as well as the timing, formats, and standards that departments will be required to adopt" (GOC, 2014). Health Canada's *Regulatory Transparency and Openness Framework*, released in 2014 (Health Canada, 2014a), recognizes the importance of *openness*, defined as "inviting, hearing, considering and sharing information with the public as Health Canada makes its regulatory decisions." The framework refers to three goals for risk communications: "Making information easier to understand," "Making more information available," and "Making the decision-making process more open" (Health Canada, 2014a). The Framework website highlights the availability of existing documents (e.g., summary basis of decision documents and recent plain language efforts that seek to make drug labels more comprehensible) (see Chapter 3 for more detail).

Internationally, calls for transparency have been prominent for health products (Löfstedt & Bouder, 2014). In response to drug scares (e.g., withdrawal of Vioxx® from the market), there have been demands that regulators improve the transparency of their decision-making processes. The European Medicines Agency (EMA) has recently announced its intention to release all clinical trial information accompanying market authorization applications for new medicines (EMA, 2014d), later broadening to trial information accompanying applications for extension of indication and line extension for existing medicines (EMA, 2014e). The policy change came after consultations with a variety of stakeholders, including patients, healthcare providers, and academics. The information provided will not be without limits, however. MAHs will be able to redact information that is considered commercially confidential, and none of the information released can be used for commercial purposes (EMA, 2014d). Eventually, the EMA also plans to make individual patient data available but acknowledges the need to first address the privacy, legal, and technical issues that would accompany such a release (EMA, 2014d). Global policy shifts such as this will have far-reaching effects for other jurisdictions, including Canada, and point to a need for proactive response.

Transparency is often poorly defined, and establishing transparency is not a cut-and-dry process. Measures to increase transparency are not a panacea in terms of establishing trust, and in some cases initiatives can have no effect or the opposite effect (Löfstedt & Bouder, 2014). Ensuring transparency is challenging, as it requires trade-offs with urgency and confidentiality, and measures intended to enhance transparency may have counterintuitive impacts (Löfstedt & Bouder, 2014). In some cases, notably the health field, there will be limitations to the degree to which some information can legally be released (e.g., in cases of individual health data). Making promises in terms of transparency that cannot be met because of these privacy and/or legal limitations can be destructive overall. Research has demonstrated that measures to increase transparency need to be well planned, and consider the information needs of all relevant groups and all potential impacts. A *data dump*, in which large amounts of data are released online without explanatory or contextual information, does not increase the public's access to, or ability to understand, health information (Chakraborty & Löfstedt, 2012). It may even result in confusion. An approach that recognizes the impacts of disclosure of information on the audience and takes the science of risk communication into account is termed *reasoned transparency* (Löfstedt & Bouder, 2014).

Moving Forward

Transparency can build empowerment, trust, and relationships between the senders and receivers of information. Reasoned transparency can lay the groundwork for timely communication efforts by striking a balance between openness, urgency, and confidentiality. This type of approach can also support the application of good risk communication science and the provision of appropriate information that is meaningful for dialogue.

2.4 REFRAMING THE GOALS OF RISK COMMUNICATION

As discussed earlier in the chapter, the goals of health risk communication are often classified as reach, use, and impact. While these goals are useful, they need to capture the evolving knowledge of risk communication. Focus should also include the less tangible, but no less important, goals of comprehensibility, trust, empowerment, engagement, and transparency. Table 2.7 reintroduces the definitions of reach, use, and impact first introduced in Table 2.1, along with modified examples of desired outcomes for each.

Setting risk communication goals implies careful and thorough evaluation to determine whether these goals have been met. As Fischhoff (2009) explains, "one should no more release untested communications than untested pharmaceuticals." While reach, use, and impact are key, evaluation can also be helpful during the important steps that occur before a communication is issued. For this reason, the Panel expands reach, use, and impact to include a fourth goal, development (see Table 2.7). This additional goal captures how evaluation can support the formal and informal processes that lead to the development of specific risk communications. The processes of assessing specific needs and developing specific communications can best be described by the risk communication dimensions discussed in Section 2.2: characterizing and managing risk, creating messaging, and ongoing partnership and exchange. Further discussion of how evaluation can be carried out and inform the communication goals of development, reach, use, and impact across varying health product risk communications is explored in depth in Chapter 4.

This expanded view of communication goals recognizes that risk communication has moved beyond the paternalistic view of the past that the public chose not to follow public health advice because of ignorance (see references from Löfstedt & 6 (2008)). In the emerging risk communication paradigm, this view is challenged by many experts who "argue that the public are not generally stupid, but distrusting for explicable reasons" (Löfstedt & 6, 2008). Clear evidence demonstrates that, in general, people are not acting groundlessly when they respond to risk in ways that are inconsistent with the expectations of health agencies (Alaszewski, 2005). Instead, they are evaluating risks in the

context of their personal criteria and values. Risk communication that seeks to empower people and that uses evaluation approaches to help incorporate their values, beliefs, and views throughout planning, implementation, and assessment therefore has greater potential to have widespread benefits.

Table 2.7

Reframed Goals of Risk Communication

Goals	Broadened Definitions	Potential Desired Outcomes
Development	Incorporating evaluation methods and learning into the steps involved in designing risk communications, including when characterizing and managing risk, creating messaging, and ensuring ongoing partnership and exchange.	• needs and wants of affected populations and stakeholders have been identified during risk characterization efforts • preliminary messages use evidence-informed communication practices (Table 2.6) and have been tested with identified populations to ensure meaningful communication content, design, and channel • efforts have been made to understand the best way to engage various populations • affected populations have been engaged in risk communication and evaluation planning and implementation
Reach	How and when the communication is sent and received and by whom.	• information sent/directed to the appropriate populations • information received by those populations • affected populations aware of the communication
Use	How the information is considered, its timeliness, and the reactions and actions taken as a result of the communication.	• information understood by affected populations • information sent in a way that overcomes barriers to understanding • affected populations aware of the specific risk information from the communication • information considered timely (based on urgency, severity, probability, and uncertainty associated with risk) • information sought out by populations • these populations are able to make informed choices based on the risk information provided including informed refusal of risk taking advice • action taken based on the opinions, perceptions, and/or beliefs of the recipient • risk minimized by actions based on specific instructions/recommendations • when relevant, information in communication used by health professionals and the groups with whom they work • continuing of desired behaviour or changing behaviour • changing preferences in affected groups (e.g., patients, healthcare practitioners)

continued on next page

Goals	Broadened Definitions	Potential Desired Outcomes
Impact	Achieving a desired result with respect to various outcomes related to the senders and receivers of information and the relationship between them.	• individual and population health outcomes improved (e.g., reduce incidence of disease) and mechanisms in place to monitor unintended effects • knowledge, attitudes, and perceptions advanced or changed • organization characteristics (e.g., efficiency, responsiveness) improved • trust and credibility built over time • communication seen as transparent by those receiving the information and other stakeholders • feedback on the communication provided by the recipients • feedback used by the sender to modify the process • affected groups trust message and feel empowered to act • communication facilitates cooperation, exchange, and empowerment

2.5 CONCLUSION

Risk can be defined as the probabilities of different possible outcomes and the severity of those outcomes. It is dependent on context, evolves, and is socially and culturally mediated. Risks often cannot be fully quantified and may involve a range of uncertainty. In the case of health products, risks generally fall into one of four categories: known side effects, medication/medical device errors, product defects, and remaining uncertainties. All of these categories could lead to negative consequences that are known or mild or to more severe or unknown adverse events that result in hospitalization or death.

Communicating risks has evolved, moving from a sole emphasis on accurate risk characterization, to a focus on understanding how individuals respond to risk and risk information, and finally to recognition of the broader social and collective context. Each offers important lessons: (i) risk communication is a process, during which the risk must be characterized and managed; (ii) messaging needs to be created for particular receivers of information and with evidence-informed communication practices in mind; and (iii) relationships need to be built and managed with multiple stakeholder groups, including organizations, media, health professionals, and the public.

Risk communication has undergone a paradigm shift over the last 20 years, from one-way messaging between the senders and receivers of information, towards multi-way dialogue in which all parties learn and grow from the communication experience. The current context includes five key challenges that will continue to shape and reshape future communication efforts: cooperation and coordination in multi-level governance structures; navigating the complexities and shared responsibilities of the risk communication environment; addressing the presence of uncertainty and multiple interpretations of the evidence; focusing on communications that help empower populations receiving information; and ensuring timeliness, transparency, and proactive responses that build trust in the long term. These challenges are unique for every risk situation and may also continue to evolve.

Setting out clear goals at the beginning of the risk communication process helps to guide design, dissemination, and evaluation activities. To ensure effective communication in the future, the goals of risk communication need to be broad and include development, reach, use, and impact, but also less tangible goals like understandability, trust, empowerment, engagement, and transparency as well as relationship-building more generally.

3

Health Product Risk Communication in Practice

- Regulatory Context
- Established Health Product Risk Communication Tools
- Emerging Tools for Health Product Risk Communications
- Conclusion

3 Health Product Risk Communication in Practice

To help set additional context for evaluation and to address the charge to the Panel, this chapter explores how health risk communication is carried out in Canada and other similar jurisdictions around the world and the extent to which it is evaluated. It first reviews the responsibilities and approaches of regulators that focus on health products. The chapter then goes on to identify established health product risk communication tools and some examples of emerging tools that could be considered when communicating risks in the future. For each of these areas, the Panel also considers the current state of evaluation.

3.1 REGULATORY CONTEXT

Key Findings

- Passive systems for monitoring health product risks are common across jurisdictions, affecting post-marketing identification of risks.
- Authority to require further studies, issue recalls or label changes, or withdraw a drug from the market is variable across jurisdictions although most regulators have such authority.
- All jurisdictions examined have communication frameworks (or are developing them), and subsequently emphasize two-way communication, population engagement, and meaningful and accessible messages. While evaluation is mentioned, most frameworks do not state how it is defined, how it is to be carried out, or if it is actually being done.

In Canada, regulation of health products is the responsibility of Canada's federal department of health, Health Canada, as part of its larger task of protecting and promoting the health of Canadians. A part of this task includes health product risk communication. Examining the various principles and frameworks that guide risk communication activities can help explain how and why communication tools are created, disseminated, and evaluated. Canada is not alone in facing challenges associated with health product regulation and risk communication, and international agencies around the world have also developed principles and frameworks. Exploring the similarities and differences between these activities and the resulting communication strategies provides further insight into tools for health product risk communication and their subsequent evaluation.

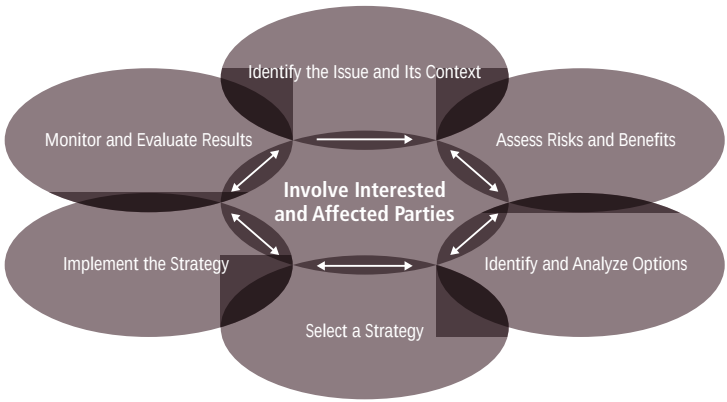
3.1.1 Health Canada

One of the core objectives of Health Canada is "provid[ing] health information to help Canadians make informed decisions" (Health Canada, 2011b). In addition to regulating health products, Health Canada also regulates natural health products (e.g., vitamins, homeopathic medicines) under the *Natural Health Products Regulations* (Health Canada, 2012b). Health Canada's pre- and post-marketing powers are laid out in the *Food and Drugs Act* (GOC, 2013a). Before a drug is authorized for sale in Canada, it must undergo a drug review process, during which an application is reviewed to assess its efficacy and safety (Health Canada, 2001). This assessment is carried out by Health Canada scientists and, sometimes, outside experts (Health Canada, 2001). In some cases, important health risks will not be detected during the approval process. About 20% of drugs approved in Canada from 1995 to 2010 were later found to have serious safety issues with a higher probability for those drugs that underwent a priority review (i.e., fast-tracked) (Lexchin, 2012). Because of cases such as these, post-marketing surveillance is important. Health Canada's authority in post-marketing safety issues is limited but evolving. In the past, it could not require companies to carry out post-marketing studies, require a label change, require a recall, or monitor industry patient registries (Wiktorowicz *et al.,* 2010; GOC, 2013a). These limited powers and the extent and nature of its post-approval drug safety monitoring (pharmacovigilance) have been criticized as inadequate and ineffective (Lexchin, 2009; Wiktorowicz *et al.,* 2010). As post-marketing testing of drugs was not legally required in Canada (and often does not occur), pharmacovigilance activities depended on the reporting of ADRs (Wiktorowicz *et al.,* 2010). There are many different mechanisms for collecting information about ADRs in Canada. However, overall the system is passive, making it likely that only a minority of ADRs are actually reported (Environics Research Group, 2007; Wiktorowicz *et al.,* 2010). This lack of information about risks subsequently affects the ability to communicate risks to the public.

Recently, the federal government received royal assent for new patient safety legislation in 2014 (the *Protecting Canadians from Unsafe Drugs Act*). This led to an immediate change in post-marketing authority including giving Health Canada the ability to order a recall or a change to the label of a health product, to require the provision of information, and to disclose confidential business information in certain circumstances. Although the full details on how further proposed changes will be incorporated in regulation and amendments to the *Food and Drugs Act* are yet to be determined, it is clear that the new law will also enable the government to compel MAHs to carry out further testing on a product, apply tougher measures for non-compliance, and make reporting of ADRs and medical device incidents by healthcare institutions mandatory

(Health Canada, 2013). The Act applies to prescription and over-the-counter drugs, vaccines, gene therapies, and medical devices, but does not extend to natural health products. Although these changes have implications for identification of health product risks and the amount of data that will be available for consumption, it is not clear how (or if) the tools used for health product risk communication will change nor how an increase in new pharmacovigilance data will be communicated. As these changes are leading to a restructuring of the pharmacovigilance system, it is an ideal time for Health Canada to examine and improve how they communicate safety information.

Health Canada's most recent risk management decision-making framework[5] includes several principles that provide a basis for the decisions and actions taken by the department (Health Canada, 2000) (Figure 3.1). The primary principle is to maintain and improve health. Other principles include, but are not limited to, the following: communicate effectively, use a broad perspective and collaborate, incorporate sound science in the process, take a precautionary



Source: (Health Canada, 2000)

Figure 3.1

Health Canada's Risk Management Decision-Making Framework

The framework illustrates the three phases proposed by Health Canada for risk management decision-making. As described by Health Canada (2000), these phases are: "issue identification (identify the issue and put it into context); risk assessment (assess risks and benefits); and risk management (identify and analyze options; select a strategy; implement the strategy; and monitor and evaluate the results)." Engagement of various populations is seen as central to each phase.

5 Health Canada's framework builds on the one developed by the U.S. Presidential/Congressional Commission on Risk Assessment and Risk Management (The Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997a, 1997b).

approach, and ensure that the process is as transparent as possible. The framework is intended to be flexible and dynamic. Fundamental to each decision-making phase is the involvement of interested and affected parties, including the public, partners, and other stakeholders. Health Canada (2000) chose a circular design for the framework as it "reflects an emphasis on an integrated decision process, its component steps, and their interrelationships."

Risk Communication Framework

Health Canada's core objectives all encompass some element of risk communication. To guide these activities, Health Canada, with the Public Health Agency of Canada, established a *Strategic Risk Communications Framework* in 2006 (Health Canada, 2006), which presents an integrated approach to risk management and risk communication. Based on Health Canada's definition of risk communication, this framework lays out five guidelines that are informed by risk perception, risk communications, and social interaction. Under these guidelines, Health Canada stresses that the preparation and implementation of risk communications should follow a cyclical process based on this framework:

- **Focus current understanding:** review and synthesize scientific knowledge and technical information related to all factors surrounding the risks of concern.
- **Develop communications strategies sensitive to current understanding, goals, and options of affected populations:** develop an in-depth understanding of affected populations using accepted qualitative research methods and subsequently develop strategies, plans, and messages that fit the expectations of those receiving information. Begin an iterative drafting process of the communication with a team of individuals with backgrounds in risk, communication, and organizational issues to ensure all aspects are covered.
- **Pre-test strategies, plans, and messages:** evaluate approaches to risk communication empirically to ensure optimal performance of messages.
- **Implement according to risk communication plan:** act on the plan to facilitate proper processes both internally and externally and to enable the evaluation of the risk communication process and outcomes.
- **Evaluate the risk communication process and outcomes:** measure the effectiveness of the risk communication process (including the team) and the outcomes to signal how to better address future risk-related challenges. Share evaluation results with team and share measurement results with stakeholders.

(Health Canada, 2006)

It is difficult, however, to assess if the principles of the framework are used and what they mean, in practice. The framework does not include a clear definition of effective risk communication or its evaluation. It mentions the need to evaluate the effectiveness of a given approach to communicating risk,

but does not offer guidance on risk communication or suggested practices from previous experiences. Because evidence of evaluation is difficult to track down in the literature (see Section 3.2), this lack of guidance in publicly available strategic documents further makes it difficult to assess the effectiveness of actual communication practices. Guidance on what is required for a good evaluation is provided elsewhere, however, including by the Treasury Board Secretariat of Canada (see Box 3.1).

Box 3.1
Evaluation Standards

Evaluation standards provide clear guidance for carrying out effective evaluation. For example, the Treasury Board Secretariat of Canada has developed best practices for all government departments carrying out evaluations (TBS, 2004), and these align well with similar standards established or adopted by other key stakeholders (CDC, 2006; CES, 2014). Combining the insights of these three sources reveals some common characteristics that underlie successful evaluation:

- Evaluations should be **credible, objective, and reliable**. This requires them to be transparent, fair, and open about any conflicts of interests (real or perceived).
- Evaluations should **understand the information needs** of stakeholders to ensure they provide **relevant and timely information**.
- Evaluations should support the **collection of meaningful and valid data** to ensure that they meet stakeholder needs and that any conclusions reached are justified.
- Evaluation **results should be reported in a timely manner** to ensure that the information needs of affected groups are met and the results can be used in decision-making.
- Evaluations should **engage all stakeholders** affected by the program being evaluated, especially those most directly affected by the risk communication, making sure to protect their rights and welfare.
- Evaluation activities should be **feasible**, given time, human, and financial resources.

Health Canada is also undertaking a range of activities related to risk communication as a part of the *Regulatory Transparency and Openness Framework* released in 2014 (Health Canada, 2014a). For instance, it has undertaken a plain language labelling project to improve the clarity and understandability of health product labels for both prescription and non-prescription drugs (Health Canada, 2014f). To date, the project is proposing changes to the

way information on labels is organized to make it clearer, improvements to documents used by healthcare providers, and more rapid online posting of product information. The changes were informed by consultations with relevant stakeholders, and further consultations and recommendations are expected (Health Canada, 2014f). Health Canada has also committed to a user-friendly web portal that will list Health Canada-approved product information and data sets linking information from product monographs (see Section 3.2.1) and pharmacovigilance systems (Health Canada, 2014a).

Although Health Canada's risk communication activities are constantly evolving, the Panel did note that there was limited evidence in the guidance documents that these activities were being evaluated or that the risk communication process was engaging populations, despite the importance of these steps in Health Canada's risk communication framework. However, there was evidence of a small number of limited surveys involving the public and health professionals carried out between 2003 and 2007 to assess stakeholder awareness and understanding (Evaluation Directorate, 2014c).

3.1.2 International Approaches

Looking at similar communication frameworks from outside Canada can reveal some of the common challenges associated with health product risk communication, provide lessons learned, and help identify areas in which Canada could improve and be a leader. The Panel examined four jurisdictions: the United States, the United Kingdom, Australia, and the European Union.

United States: Food and Drug Administration

In the United States, the FDA shares many of the same responsibilities as Health Canada. It is responsible for "protecting the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices" (FDA, 2014a). Similar to Health Canada's past authority, while the FDA can cancel the market authorization of a product, it cannot require MAHs to issue a recall, but can request one. The FDA's largely passive post-marketing evaluation of health products is also similar to that of Health Canada. In 2007, however, the FDA was granted greater powers in post-marketing risk identification (FDA, 2007b; Wiktorowicz *et al.,* 2010). It now has the authority to order MAHs to carry out post-marketing studies (under certain conditions) or make safety label changes (FDA, 2007b). Unlike Health Canada, however, the FDA does not impose regulations on natural health products, and manufacturers of these products are only required to register with the agency (FDA, 2014c).

The FDA's equivalent to Health Canada's communication framework is the *Strategic Plan for Risk Communication* (FDA, 2009), which incorporates a multidimensional understanding of risk. *Effective risk communication* is defined as the ability to influence individuals by informing them of both the positive and negative consequences of health-related decisions. Unlike Health Canada, the FDA explicitly outlines "intermediate outcomes" for assessing the effectiveness of risk communications:

- better understanding of both the risks and benefits of regulated products;
- increased public awareness of crisis events;
- increased public view of the FDA as an expert; and
- increased confidence that affected populations are getting information that is useful and timely.

(FDA, 2009)

The FDA has also set several goals related to risk communication:

- increasing the use of plain language so that target audiences can understand the message;
- increasing the quality and timeliness of messages;
- increasing feedback on communications from the public and healthcare professionals; and
- increasing the number of highly credible websites linking to FDA communications.

(FDA, 2009)

It is difficult, however, to assess whether the principles of the FDA's strategic plan are used in practice. It is also unclear whether its tools have been evaluated against these outcomes and goals because evidence of evaluation is difficult to track down or lacking in publicly available strategic and guidance documents.

United Kingdom: Medicines and Healthcare Products Regulatory Agency

Each EU member state has an agency that issues market authorizations and regulates health products. In the United Kingdom, this responsibility lies with the Medicines and Healthcare Products Regulatory Agency (MHRA), an executive agency of the Department of Health. The MHRA has many of the same responsibilities as Health Canada, regulating medicines (including advanced therapies such as somatic cells), medical devices, and blood products. Market authorization for most innovative drug products is done through the European Union, with the MHRA (along with national authorities for EU member states) contributing to the process under the coordination of the EMA (EMA, 2015b). Only medicines require market authorization. Industry-led organizations approve medical devices, and natural health products are simply registered with the MHRA. Unlike its counterparts in the United States (and until recently Canada), the MHRA has the authority to require a

product recall. This power is rarely used, however, and the MAH generally issues recalls in the United Kingdom (Wiktorowicz *et al.,* 2010). As is the case for Health Canada, the MHRA has a largely passive system for post-marketing health product monitoring.

The MHRA's (2010) *Communication Strategy 2010–2015* outlines its current approach to communicating health risks, setting out a series of overarching priorities and success measures rather than a strict set of policy-oriented goals. The Strategy advocates focusing less on reach (e.g., the number of people who receive or view communications) and more on use (e.g., the number of people who change their behaviour in response to communications), impact (e.g., how communications affect public health), and stakeholder engagement. Most important is the need for two-way communication with affected groups and the ability to adapt communication practices as online media become more accessible and effective in reaching a variety of populations. In its strategy, the MHRA recognizes the need to rely on its priority groups — health professionals, industry, and MHRA staff — to communicate with the public (MHRA, 2010).

The MHRA also recognizes the importance of evaluating risk communication. In its communication strategy, the MHRA states that "to measure the effectiveness and success [of our risk communication] strategy, evaluation needs to be an integral part of the planning process, [and] take place at regular intervals throughout implementation." Furthermore, it recognizes that evaluation has not been done consistently in the past, yet is necessary "to ensure maximum return on our investment in communication" (MHRA, 2010). To measure the effectiveness of its approach to risk communication, the MHRA alludes to measureable objectives. It does not, however, provide a clear definition of effective communication, and it appears that either little evaluation of its risk communication tools has been done or that any such evaluation is not publicly available in the guidance documents provided.

Australia: Therapeutics Goods Administration

In Australia, regulation of therapeutic goods (medicines, medical devices, biologics, and complementary medicines, the latter of which are called natural health products in Canada) is the responsibility of the Therapeutics Goods Administration (TGA), part of the Australian Government Department of Health. As in Canada and the United States, regulation includes pre-market assessment of products, post-marketing monitoring, licensing of domestic manufacturers, and verification that overseas manufacturers comply with local regulations. As in the United Kingdom, although recalls are generally MAH-led, the TGA has the authority to issue mandatory recalls (TGA, 2014c). Similar to the other jurisdictions discussed, Australia has a largely passive post-marketing monitoring system to detect health product risks.

In 2011, the TGA carried out a review of how it communicates its regulatory methods and decisions related to drug approvals, with the aim of improving their transparency (TGA, 2011). The government stated that the review was called because "a perception has arisen in the community that the TGA does not provide the public with sufficient information about its activities and about the therapeutic goods that it regulates" (TGA, 2011). The review led to several recommendations, grouped into three areas:

- **Raise stakeholder involvement in the TGA:** for example, by establishing a Australian Therapeutic Goods Advisory Council.
- **Improve market authorization process:** for example, working with stakeholders to improve the requirements for labels and packaging.
- **Improve post-marketing activities (monitoring and compliance):** for example, conducting a feasibility study into an early post-marketing risk communication scheme (i.e., similar to the black triangle system in the European Union, described in Section 3.2.1).

(TGA, 2011)

The review also recommended that "the TGA develop and implement a comprehensive communication strategy to inform and educate," as the agency does not currently have such a strategy (TGA, 2011). As of publication, no such strategy could be found on the TGA website, although the government had agreed with the recommendation to develop one (TGA, 2014b). The TGA's review did not include an evaluation of its current health product risk communication tools, beyond stating that more effective communication was needed. In addition, the review did not mention evaluation of the effectiveness of future communication efforts. The agency has carried out, however, some qualitative and quantitative market research with consumers, health professionals, and industry, to help identify communication gaps and inform the development of effective communication strategies (TGA, 2014e, 2014a).

Europe: European Medicines Agency

For health products in the European Union, the EMA has some of the same regulatory roles as Health Canada. It is responsible for evaluating centralized procedure applications for medicines, the safety monitoring of these medicines, and referrals (scientific assessments of a drug on behalf of the European Union). The EMA does not, however, issue market authorizations (providing only advice to either the European Commission or the relevant authorities in member states), develop laws or policies related to medicines, or evaluate all medicines in the European Union (only those that have centralized procedure applications). The EMA, the European Commission, and regulatory authorities in member states are all involved in pharmacovigilance in the European Union. Some pharmacovigilance activities are complicated by jurisdictional issues,

as EU and national legislation are not always the same. Patient registries, for example, are under national legislation, which can make post-marketing studies at the EU level more challenging (Wiktorowicz *et al.,* 2010).

The EMA adopted the *European Risk Management Strategy* to help mitigate health-related risks from medicines (EMA, 2008) and included information on risk communication in the guidelines for pharmacovigilance in the *Rules Governing Medicinal Products in the European Union* (European Commission, 2008). The EMA updated its risk management initiative in 2010 to increase openness and transparency in communicating safety-related issues associated with medicines (EMA, 2010).

The EMA has since released more specific guidance related to health product risk communication through its guideline on good pharmacovigilance practices. Module XV of the guideline, released in 2013, provides guidance to MAHs, the EMA, and authorities in member states on safety communications for medicines (EMA, 2013). This includes broad principles on communication and general information on several different classes of communication tools (e.g., websites, press communications), with detailed material on direct healthcare professional communications. The module defines a communication as effective "when the message transmitted is received and understood by the target audience in the way it was intended, and appropriate action is taken by the target audience" and states that effectiveness should be evaluated (EMA, 2013).

Furthermore, Module XVI on risk minimization efforts (released in 2014) provides general guidance on educational tools for risk minimization and highlights the importance of both process and outcome evaluation (EMA, 2014a). Evaluation and communication will also be a specific focus of Module XII, which will provide guidance on continuous pharmacovigilance (including communication planning and ongoing evaluation) and is expected to be released for public consultation in 2015 (EMA, 2015a).

3.1.3 Comparison of Regulators

While regulatory systems in all of the jurisdictions examined are similar, with comparable authority over prescription medicines and approval processes for new medicines, there are also important differences. Regulators in the United Kingdom and Australia have the authority to order the recall of a medicine, although most recalls continue to be made by the manufacturer. Health Canada was recently given similar authority in 2014 but it is unclear how this will take place in the future and how that may shape risk communication efforts. Health Canada's authority over natural health products is more extensive than that of its counterparts, requiring evidence for any claims made for these products.

All of the jurisdictions examined have some sort of communication framework or guidelines, with the exception of Australia (which has a strategy in development). While these frameworks vary greatly in level of detail and guidance, they include elements relating to development, reach, use, and impact. In addition, all of the strategies call for two-way communication, engagement of groups receiving information and other stakeholders, and meaningful and accessible messages. Some have gone so far as to establish advisory councils and ongoing consultation mechanisms. Finally, all frameworks explicitly or implicitly discuss the importance of establishing trust with the public. However, there are some differences in emphasis on the goals of risk communication. Canada and the United States focus on ensuring that communications meet goals for development and reach, through developing communications based on the understandings of affected groups or using plain language. The U.K. MHRA emphasizes how many people regularly use (and seek out) risk information and how these communications influence public health, thus focusing more on use and impact.

The importance of evaluation is clearly recognized in the communication frameworks used by Health Canada, the FDA, and the MHRA, but it is not always clear how evaluation is defined. The EMA defines effectiveness and provides general guidance on evaluation in its guidelines on good pharmacovigilance practices, and is currently in the process of expanding these guidelines further. In most cases, frameworks or guidelines explicitly or implicitly refer to outcome or impact evaluation (see Chapter 4). While needs assessment or pre-testing prior to implementing a communication (see Chapter 4) is not formally included in the frameworks or guidelines, some of the activities that would make up such an evaluation often are. Despite the guidance available, there are limited examples of evaluation in regulatory frameworks and guidance documents. Overall, it appears that either real-world evaluation of health product risk communication tools is not taking place or, if evaluations have been undertaken, the results are not being made public or easily accessible. These ideas will be explored more fully in the following section.

3.2 ESTABLISHED HEALTH PRODUCT RISK COMMUNICATION TOOLS

Key Findings

- Regulators around the world have adopted similar tools for communicating health product risks. Many of these tools have similar formats and make use of online dissemination, but it appears that they are subject to few evaluations.
- Established communication tools often describe risk qualitatively, use text exclusively, lack colour or graphics, and/or do not adhere to other aspects of evidence-informed risk communication practices.

As part of its charge, the Panel was asked to identify "types of instruments/tools [that] are currently available for health risk communication," with a focus on health products (see Chapter 1). The Panel carried out a scan of publicly available materials to create a catalogue of tools currently used by health product regulators in the jurisdictions discussed above. Various characteristics of the identified tools are described, including organization, goals, information communicated, target population, dissemination methods used, and evaluation. If certain characteristics were not explicit, the Panel identified them by looking at several direct examples. This section describes established tools, while the following section notes less traditional tools that are not in widespread use.

Tools can generally be divided into three categories:

- **Ongoing communications:** presents what is known about the risks (and sometimes benefits) associated with a marketed health product.
- **Incident(s)-based communications:** presents new information about health product risks, which may be updated information about a known risk or information about a newly discovered risk.
- **Defect and error communications:** presents information about the risks associated with an error or deficiency in manufacturing practices in the production or packaging of a health product.

3.2.1 Ongoing Communications

Ongoing communications generally relate to health product risks associated with known side effects, medication errors, and, in some cases, uncertainty in the evidence. These risks are generally communicated to patients in inserts included with a new medication and in online documents. The information comes from pre-marketing studies, such as side effects detected in randomized controlled trials (RCTs), or as a precaution associated with uncertainties in the evidence (e.g., no pregnant women included in RCTs). Over time, post-marketing monitoring may lead to updates or changes to ongoing communication tools (e.g., the addition of a FDA black box warning, as described below, as a result of a serious ADR detected through pharmacovigilance). Table 3.1 summarizes select examples of these tools.

Table 3.1

Select Ongoing Communication Tools for Health Product Risks

Drug Approval Documents	
Product Monograph – Health Canada	
Description	Report-style document with three parts: (i) health professional information, (ii) scientific information, and (iii) medication information. May include graphs and tables to present risk information and illustrations in selected cases (e.g., images to illustrate where to inject a drug). Quantitative risk information presented in natural frequencies and percentages (in parts 1 and 2). Qualitative risk information provided in part 3. Varies in length significantly but is generally about 50 pages.
Purpose	To inform on the "properties, claims, indications, and conditions of use for the drug, [and] any other information that may be required for optimal, safe, and effective use of the drug."
Target	Patients, healthcare professionals
Dissemination	Posted on the Health Canada Drug Product Database website (drugs from after January 2004). It is recommended that the health professional information is included with promotion of the drug, and in any reference manuals distributed.
Examples of Evaluation	None identified.

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Summary Basis of Decision (SBD) – Health Canada	
Description	Report-style document that includes five sections: (i) product and submission information, (ii) notice of decision, (iii) scientific and regulatory basis for decision (largest section), (iv) benefit/risk assessment, and (v) recommendation, submission milestones. May include graphs and tables to present risk information and illustrations in selected cases (e.g., images to illustrate where to inject a drug). Quantitative risk information presented as frequencies. Varies in length but is generally about 15–30 pages.
Purpose	Scientific and regulatory basis for decision section includes information on the clinical and non-clinical basis for the approval or rejection of a drug.
Target	Healthcare professionals, general public
Dissemination	Posted on the Health Canada website.
Examples of Evaluation	Analysis of SBDs found that "significant omissions in the level of clinical trial information in SBDs provide little to aid clinicians in their decision-making" (Habibi & Lexchin, 2014). Health Canada evaluation found a little over half of respondents (online workbook) found SBDs "useful in helping them make informed treatment choices (for themselves or their patients)" (Health Canada, 2010).
Summary of Product Characteristics – EMA (European Union)	
Description	Report-style document. May include tables and illustrations in selected cases (e.g., images to illustrate where to inject a drug). For side effects qualitative risk information often given using terms such as *rare, very rare, common*, etc. (ranges given for qualitative terms). Quantitative information also sometimes given. Varies in length, but is generally very long (around 100 pages).
Purpose	Summarizes all of the information needed to approve a drug (e.g., information for doctors, information for patients). The basis for all information given to healthcare professionals and for the package leaflet.
Target	Healthcare professionals, general public
Dissemination	Documents posted on the EMA website.
Examples of Evaluation	Small study concluded that doctors found it challenging to identify the important points within a summary. Comments included that summaries are muddled and contain considerable repetition (Raynor, 2011; Edwards & Chakraborty, 2012).

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European Public Assessment Reports (EPAR) Summary for the Public – EMA (European Union)	
Description	Text-based document written in a question-and-answer format. Qualitative risk information given for most common side effects. Text provided gives general ranges for qualitative terms (e.g., < 1000). Generally around 2 to 3 pages.
Purpose	To inform the general public what the drug is, how it works, why it was approved (i.e., benefits observed in clinical trials), and any associated risks
Target	General public
Dissemination	Published on the EMA website.
Examples of Evaluation	EPARs have been criticized for having irregular and unreliable styles of reporting (Barbui *et al*., 2011).
Consumer/Patient Leaflets	
Package Insert – Health Canada	
Description	Leaflet that presents information on a medicine (e.g., dosage, benefits, side effects). Generally the same as part (i) (health professional information) of the product monograph, but may also include part (iii) (medication information). May include graphs and tables to present risk information and illustrations in selected cases (e.g., images to illustrate where to inject a drug). Quantitative risk information presented in natural frequencies and percentages. Qualitative risk information also may be included.
Purpose	To describe the properties and conditions for use of the drug, including any information that may be required for safe and effective use of the drug, and potential side effects.
Target	Healthcare professionals, patients
Dissemination	Included in the package of name-brand prescription drugs. Not required, but if not included the label must state: "Product monograph, package insert or prescribing information available on request."
Examples of Evaluation	None identified.

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Prescribing Information (patient package insert) – FDA (United States)	
Description	Leaflet that includes information on effectiveness, contraindications, and information of the risks (including side effects) and benefits. Only needs to be approved for oral contraceptives and estrogen. MHAs often submit patient package inserts to FDA for approval voluntarily. Quantitative risk information presented in a variety of formats. Qualitative descriptions of risk also used. May include graphs and tables to present risk information and illustrations in selected cases (e.g., to illustrate the order in which to take birth control pills).
Purpose	To enable the safe and effective use of a drug by fully informing patients of the benefits and risks associated with the use of drug.
Target	Patients
Dissemination	Only required for oral contraceptives and estrogen (considered voluntary for all other drugs). Included in the package of a drug.
Examples of Evaluation	None identified.
Medication Guide – FDA (United States)	
Description	Paper document that includes information on the side effects and/or drug interactions associated with a medicine. Considered part of the labelling process. Qualitative risk information provided (e.g., using terms such as common, rare). Tables and illustrations included in selected cases (e.g., images to illustrate where to apply a gel). Varies in length but is generally under 10 pages.
Purpose	To inform about issues that are specific to that particular drug (or drug class) to help prevent adverse events.
Target	Patients
Dissemination	Provided with certain prescription medicines (required).
Examples of Evaluation	None identified.

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Consumer Medication Information – FDA (United States)	
Description	Does not need to be approved and can take any form. Examples examined include only text. Risks listed provide no qualitative or quantitative information (e.g., "these side effects may occur").
Purpose	To provide information for the safe and effective use of a prescription drug or specific over-the-counter medicine.
Target	Patients
Dissemination	Provided voluntarily by pharmacies with prescription drugs. Usually included inside or stapled to the outside of the bag containing the medication. Written by the pharmacy or an outside company.
Examples of Evaluation	Evaluation (by experts) of CMIs for two drugs found that these documents had "very low levels of quality" in terms of meeting communication standards/criteria in 14% (drug 1) and 16% (drug 2) of cases (Kimberlin & Winterstein, 2008).
Product Information – TGA (Australia)	
Description	Report-style document that contains information on a prescription medication, including pharmacology, indications, precautions, clinical trials, contraindications, adverse effects, dosage, and storage. Quantitative risk information presented in natural frequencies and percentages. May include graphs and tables to present risk information. Generally 10 to 30 pages.
Purpose	To "[provide] a summary of the scientific information for the safe and effective use of a prescription medicine."
Target	Healthcare professionals
Dissemination	Published on the TGA website. Published in the *MIMS Annual* and the *Prescription Products Guide*. Included in full or abridged form in journal advertisements.
Examples of Evaluation	None identified.

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Consumer Medicines Information – TGA (Australia)	
Description	Brochure-style document that contains information on a prescription medication, including dosage, precautions, interactions, how to use the medicine, side effects, and how to store the medicine. Risks listed but no qualitative or quantitative information given (e.g., tell your doctor if you experience these side effects and they worry you). Generally 5 to 10 pages.
Purpose	To "[provide] information on the safe and effective use of a prescription medicine."
Target	Patients
Dissemination	Required to be "made available to consumers either in the pack or in another manner that will enable the information to be given to the person to whom the medicines are administered or otherwise dispensed." Published on the TGA website.
Examples of Evaluation	None identified.
Patient Information Leaflet – EMA (European Union)	
Description	Leaflet that presents written information on the drug (e.g., dosage, benefits, side effects). May contain illustrations (e.g., images to illustrate where to inject a drug). Qualitative risk information provided (e.g., using terms such as *common, rare*).
Purpose	To describe the properties and conditions for use of the drug, including any information that may be required for safe and effective use of the drug, and potential side effects.
Target	Patients
Dissemination	Package leaflet must be included with all medicines. Posted on the EMA website.
Examples of Evaluation	Although no specific evaluation was identified in the EU, patient information leaflets must be tested to ensure they are effective at conveying information (generally use the Australian method) (Edwards & Chakraborty, 2012).

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Warnings	
Boxed Warnings ("black box warnings") – FDA (United States)	
Description	A black box at the top of documents that provides a summary of serious risk. The box includes the word WARNING (in upper case). Appears on the risk communication documents for a given drug (e.g., package inserts).
Purpose	To inform about "certain contraindications or serious warnings [of a drug], particularly those that may lead to death or serious injury."
Target	Healthcare professionals, patients
Dissemination	Warning appears in a box at the top of medication insert, entry in the Physicians' Desk Reference, FDA website, website of drug marketing companies, and other information on the drug.
Examples of Evaluation	Study in Boston found that 0.7% of 324,548 prescriptions issued in 51 outpatient practices violated the boxed warning (highest violations for patients over 75) (Lasser *et al.*, 2006). Review of evaluations on regulator-issued warnings (black box, dear doctor, and public advisories) found that the intended effects were reported in 29 of 52 cases (56%). Mixed impacts were found in 13 of 52 cases (21%). When unintended effects were assessed, they were almost always present (demonstrating the need to consider unintended effects) (Piening *et al.*, 2012).
Black Triangle Scheme – EMA (European Union)	
Description	A small black triangle that appears at the top of communication documents for a given drug along with the words: "this medicinal product is subject to additional monitoring."* Appears on the risk communication documents for a given drug (e.g., package leaflet).
Purpose	To encourage the reporting of adverse reactions by indicating that a product is being monitored more intensively than other health products (e.g., because of uncertainty associated with a new-to-market drug).
Target	Healthcare professionals, general public
Dissemination	Appears on the package leaflet and summary of product characteristics. Appears on the EMA website for the drug.
Examples of Evaluation	None identified.

* Text as it appears in the United Kingdom.

Sources: (Wooler, 1995; EMA, 2006, 2009, 2014b, 2014c; FDA, 2006, 2007a, 2013; Health Canada, 2010, 2014d, 2014e; TGA, 2014d, 2014f)

The most common document for presenting risk information is the package insert, some form of which exists in all jurisdictions. In Canada, all prescription drugs must either include a package insert or a statement on the packaging that the product information is available on request (Health Canada, 2014d). The EMA requires inserts for all medicines; the FDA requires them for certain medicines; and the TGA requires that they be "made available to consumers either in the pack or in another manner." In the European Union, inserts (i.e., patient information leaflets) must be tested by MAHs (i.e., pre-testing evaluation) to ensure that they are effective at conveying information. EU regulations state that "the package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use" (European Parliament, 2001). Generally, an MAH undertakes face-to-face interviews with members of the general public to meet these requirements. Package inserts generally give risk information in qualitative terms, although in some cases quantitative ranges are given (e.g., a side effect is expected in 10 out of every 1,000 people who take a drug). Canada and the United States have no testing requirements (Edwards & Chakraborty, 2012).

While inserts generally present information in a similar way in all jurisdictions, there are a few notable exceptions. In EU member states, a small black triangle appears at the top of the package leaflet and summary of product characteristics to indicate that a product is being monitored more intensively than other health products because of the presence of uncertainty in the evidence (usually related to long-term effects of a drug that is new to the market) (EMA, 2014c). While the purpose of the triangle is to encourage the reporting of adverse reactions, it also serves as a simple visual cue to quickly convey a particular type of risk information (i.e., uncertainty). In "exceptional cases," the EMA also has the option to propose the inclusion of a boxed warning (in bold) in the summary of product characteristics (in the section on special warnings and precautions for use) (European Commission, 2009). Black box warnings in the United States are also a simple visual cue to indicate a particular type of risk, in this case a serious warning. These warnings appear at the top of any document used to provide information on the drug (e.g., insert, promotional material) (FDA, 2013).

All jurisdictions post online a wide range of ongoing communication documents, which vary in length and in intended targets. Those intended for the general public (e.g., part 3 of Health Canada's product monograph and the EMA's EPAR for the public) are generally much shorter than those for other audiences and often do not include quantitative information. More detailed documents aimed at healthcare professionals, which are longer and contain more medical terminology, are also available online.

In general, the Panel found few publicly available evaluations of ongoing communication tools (see Table 3.1 for examples). For all tools except black box warnings, evaluations primarily related to measuring either the quality of a tool's content or whether users could understand content. These evaluations relied on either individual interviews or expert analysis and were mainly conducted at the end-stage, with the exception of evaluation of the package inserts in the European Union, which is conducted at the pre-testing stage by law. In the case of black box warnings, Piening *et al.* (2012) identified 15 evaluation studies, all of which were outcome measures of use and impact. Common indicators for measuring effectiveness were prescription rates, new users, or overall drug use volume.

3.2.2 Incident(s)-Based Communications

Incident(s)-based communications alert healthcare professionals and the public to newly discovered side effects, adverse drug reactions, or medication or device errors. This information often leads to an update to the risk information included in ongoing communication tools. The most common incident(s)-based communication tools are advisories for the public and dear doctor letters for healthcare professionals. The risk information contained in them is largely from post-marketing pharmacovigilance. Table 3.2 summarizes select examples of these tools.

Table 3.2

Select Incident(s)-Based Communication Tools for Health Product Risks

Public Documents	
Public Advisory – Health Canada	
Description	Memo-style document that contains information on a risk. Most salient points are listed at the top of the document as bolded bullets. Quantitative risk information provided in some cases. Includes a link to the safety review summary when one is available. Often includes references. Generally less than two pages.
Purpose	To "inform about a situation in which the use of, or exposure to, a product may cause adverse health consequences or where the probability of serious adverse health consequences is remote."
Target	General public
Dissemination	Posting on the Health Canada and MedEffect™ Canada websites. Distribution through Health Canada's media listserv and the MedEffect™ mailing list. Distribution to various relevant parties (e.g., healthcare professional associations). *Health Product InfoWatch*.
Examples of Evaluation*	Canada: Standardized readability and Suitability Assessment of Materials (SAM) tests found that advisories required a post-secondary level of reading to understand and that new templates improved SAM scores but not readability (LeBrun *et al*., 2013). U.S: Study of FDA safety advisories found that notices had variable effects, with some having significant impact, others having delayed effects, and some having no effect at all. In some cases, the effects were not consistent with the recommendations contained in the warnings (Dusetzina *et al*., 2012; Edwards & Chakraborty, 2012). Review of evaluations on regulator-issued warnings (black box, dear doctor, and public advisories) found that the intended effects were reported in 29 of 52 cases (56%). Mixed impacts were found in 13 of 52 cases (21%). When unintended effects were assessed, they were almost always present (demonstrating the need to consider unintended effects) (Piening *et al*., 2012).

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Drug Safety Communication – FDA (United States)	
Description	Memo-style document that contains information on a safety announcement. Most salient points may be bolded. May include a section on additional information for patients, and for healthcare professionals. Quantitative risk information (in frequencies) sometimes provided. Includes reference list. May summarize the results of a safety review. May include images and graphs.
Purpose	To "provide information and advice regarding an emerging drug safety issue or other important public health information."
Target	General public, healthcare professionals, patients
Dissemination	Posted on the drug safety communication website. Promotion of the FDA_Drug_Info Twitter feed.
Examples of Evaluation	*same as Public Advisory – Health Canada
Safety Review Summary – Health Canada	
Description	Text-based report that summarizes the results of a Health Canada safety review. Qualitative risk information provided (e.g., increased risk). Includes a reference list. Generally about three pages.
Purpose	To inform on the results of a safety review (i.e., is there evidence that there is a safety risk?).
Target	General public, healthcare professionals
Dissemination	Summaries of reviews posted on the Health Canada website. Full safety reviews can be obtained by emailing the directorate, although "these reports are subject to redactions of personal and confidential information."
Examples of Evaluation	None identified.
Question and Answer – FDA (United States)	
Description	Document with common questions and answers related to a drug safety communication. Quantitative risk information often provided.
Purpose	To provide a plain language overview of a potential safety issue associated with a medicine.
Target	General public
Dissemination	Posted on the FDA website. A link is included at the bottom of the corresponding drug safety communication.
Examples of Evaluation	None identified.

continued on next page

Physician Warnings	
Dear Health Care Professional Letter – Health Canada	
Description	Letter with information on a new health product warning(s). Most salient points are listed in the letter as bolded bullets. Quantitative risk information provided in some cases. Generally two pages or less.
Purpose	To "inform about time-sensitive issues regarding the safety or effectiveness (or both) of a marketed health product."
Target	Healthcare professionals
Dissemination	Distribution by mail-out of printed copies (fax-out under exceptional circumstances). Posting on MedEffect™ Canada, MAH, and association websites. Distribution through the MedEffect™ email list. *Health Product InfoWatch*.
Examples of Evaluation	None identified.
Dear Health Care Provider Letter – FDA (United States)	
Description	Letter with information on a new health product warning(s). Generally includes quantitative risk information. Generally includes reference list. Generally two pages or less.
Purpose	Inform about emerging data on a risk associated with a post-market medicine.
Target	Healthcare professionals
Dissemination	Mailed to physicians.
Examples of Evaluation	A highly publicized dear doctor letter sent in June 1998 led to a 58% decline in the concomitant dispensing rate with the contradicted drugs. An earlier letter with less publicity led to no measurable effect (Weatherby *et al.*, 2002). A study of dear doctor letters sent to inform of a change in the warning section of the drug label found that they varied in where key information was placed, length, and formatting. Doctor ratings found that 25% were deficient in clarity, 28% in readability, and 28% in overall effectiveness (Mazor *et al.*, 2005).

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Direct Healthcare Professional Communication – EMA (European Union)	
Description	Letter with information on a new health product warning(s). Quantitative risk information provided. Summary appears at top of letter in bold.
Purpose	Inform about emerging data on a risk associated with a post-market medicine.
Target	Healthcare professionals
Dissemination	Distributed to the national health service through the Central Alerting System (in the case of MHRA). Posted on the national regulator website. Commonly accompanied by an EMA press release or EMA public health communication.
Examples of Evaluation	Direct healthcare professional communications in the Netherlands were found to have greater impact when a template was used (emphasizing the main risk) and for high risks (e.g., death) (Reber *et al.*, 2013).
Other Healthcare Professional Warnings	
Health Product InfoWatch – Health Canada	
Description	Replaced the *Canadian Adverse Reaction Newsletter*. Colour newsletter that includes a summary of all advisories (including notices to hospitals, summary safety reviews, etc.) and review articles on selected advisories. Articles often provide quantitative risk information. Published monthly.
Purpose	To raise awareness of new health product safety information and provide a recap of health product advisories and summary safety reviews. Includes information from other tools.
Target	Healthcare professionals
Dissemination	Posting on the MedEffect™ Canada website. Emailed to a list of relevant stakeholders.
Examples of Evaluation	None identified.

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Drug Safety Update – MHRA (United Kingdom)	
Description	Monthly electronic colour newsletter that contains articles on recently identified risks (or new information on known risks). End of each article has a box with advice for healthcare professionals. Quantitative risk information provided.
Purpose	To provide the "very latest information and advice to support the safer use of medicines."
Target	Healthcare professionals
Dissemination	Posted on the MHRA website. Sent out by email (to those who register).
Examples of Evaluation	None identified.
Australian Prescriber – TGA (Australia)	
Description	Bi-monthly colour journal that includes letters, articles, medicine safety update, and information on new drugs and diagnostic tests. Some articles include figures and graphs. Some articles have detailed quantitative risk information; others include only qualitative risk information. Articles include references.
Purpose	To "provide expert, balanced, impartial, reliable and up-to-date information for its readers by reviewing recent evidence where therapy is evolving and updating readers on therapeutics in their own and other fields."
Target	Healthcare professionals
Dissemination	Published in print and online. Physical copies sent to prescribing healthcare professionals in Australia, as well as medical schools and teaching hospitals.
Examples of Evaluation	None identified.

continued on next page

Medicines Safety Update – TGA (Australia)	
Description	Newsletter that contains articles on recently identified risks (or new information on known risks) related to health products. Sometimes includes references. Quantitative information sometimes provided.
Purpose	To "[provide] practical information and advice on drug safety and information about emerging safety issues."
Target	Healthcare professionals
Dissemination	Posted on the TGA website. Appears in each edition of the *Australian Prescriber*.
Examples of Evaluation	None identified.

Source: (FDA, 2007a, 2011; Health Canada, 2008, 2014c, 2015; Australian Prescriber, 2014; MHRA, 2014a, 2014b; TGA, 2014g)

When the safety of a drug on the market comes into question, a regulator may undertake a safety review to determine whether there is a new risk that needs to be communicated. Recently, Health Canada announced that it will release summaries of its safety reviews. These summaries are generally about three pages long and include quantitative risk information and a reference list (Health Canada, 2014c). These documents are not linked to the Health Canada drug database, but can be found through the safety review website or a link given on the corresponding advisory. The EMA and FDA also publish summarized results of selected drug safety reviews using their public advisory platforms.

The dear doctor letters used in Canada, the United States, and the European Union (including the United Kingdom) have similar layouts, generally containing a reference list and some quantitative risk information. As discussed in Chapter 2, Health Canada provides detailed guidance documents and templates to guide MHAs in the development of both dear doctor letters and public communications. The dissemination methods vary slightly, with letters mailed to physicians in Canada[6] and the United States, but sent electronically in the United Kingdom (see discussion of the Central Alerting System in Section 3.3.2). In all cases, the letters are also posted online. Most jurisdictions publish a newsletter or journal for physicians that summarizes new risks. While Canada requires a corresponding public document to be released at the same time as a dear doctor letter (Health Canada, 2008), this is not the case in all jurisdictions. In the United Kingdom the majority of dear doctor letters do not appear to have a corresponding document intended for the general public, whereas in the

6 In some cases letters in Canada are disseminated by fax.

United States and Australia drug safety communication documents are aimed at the general public and healthcare professionals. In Canada, the documents intended for the general public are posted online (and linked through apps, social media, and other online tools).

Similar to ongoing communication, the Panel identified only a few publicly available evaluations of incident(s)-based communications (see Table 3.2 for examples). Two evaluations examined readability using either standardized tests or a survey. Health Canada carried out one of these studies, which demonstrated that its public advisories were rated as "requiring a college/university education comprehension level." Recent changes to the template used by MAHs to create public advisories have improved their Suitability Assessment of Materials (SAM) scores, but not their readability (LeBrun *et al.*, 2013). This evaluation demonstrates the utility in evaluating the templates used to develop a class of risk communication tools, as these evaluations can provide useful information on development (e.g., are templates based on evidence-informed communication practices) without examining each individual tool produced. The Panel identified several evaluations related to use and impact, which used similar indicators to evaluate ongoing communications, notably prescription and drug dispensing rates. Piening *et al.* (2012) conducted a systematic review of evaluations of health warnings (public health advisories, dear healthcare provider letters, and black box warnings) and found 52 studies in a period of 14 years. All of the studies involved warnings on antidepressants, third generation birth control, or cisapride and came to a range of conclusions on their effectiveness. In 9 of the 14 articles looking at warnings related to antidepressants and 9 of 17 articles evaluating warnings about cisapride, the intended effects of the warnings were observed (i.e., decreased use in children or reduced drug use volume or contraindicated drug use respectively). About half of the studies also assessed and found unintended effects (e.g., increased drug use volume) in almost all cases (Piening *et al.*, 2012). Similarly, Dusetzina *et al.* (2012), who authored a review of evaluations of FDA warnings (label changes, public health advisories, and dear healthcare provider letters), found that while some warnings did have strong effects, others had delayed or no effects. In some cases the effects observed were not consistent with the recommendations contained in the warnings; for example, while, in general, warnings recommending increased clinical or laboratory monitoring resulted in decreased usage, they led to only small short-term increases in monitoring (Dusetzina *et al.*, 2012). The results of these reviews demonstrate the importance of considering both intended and unintended effects when developing and evaluating communication tools (Dusetzina *et al.*, 2012; Piening *et al.*, 2012).

3.2.3 Defect and Error Communications

Defect and error communications present information about risks associated with product defects and labelling errors. These risks are communicated to the public and healthcare professionals using recalls or some other alert (e.g., foreign product alert or natural health product advisory) and are usually identified by pharmacovigilance post-market monitoring or regular monitoring efforts carried out by manufacturers. Table 3.3 summarizes select examples of these tools.

Table 3.3

Select Defect and Error Communication Tools for Health Product Risks

Health Product Recall – Health Canada	
Description	Memo-style document that includes information on the recall, how to identify the affected lots, who is affected, and what should be done with the product.
Purpose	To inform about a recall and change behaviour (i.e., stop using a recalled product).
Target	Can include healthcare professionals, general public, distributors, and hospitals
Dissemination	Posting on the Health Product and Foods Branch Inspectorate website. Posting on the MedEffect™ website (when deemed necessary). Includes a public advisory if Health Canada deems one necessary.
Examples of Evaluation	An external review of the Alysena™ 28 recall concluded that Health Canada could have issued a public communication sooner and the appropriate experts were not informed until too late in the process (RSI, 2013).
Foreign Product Alert – Health Canada	
Description	Memo-style document that includes information on the product, hazard, place of origin, and what should be done.
Purpose	To communicate warnings about risks from the use of products that are not authorized for sale in Canada.
Target	General public
Dissemination	Posting on the Health Canada and MedEffect™ Canada websites. Distribution of the message through Health Canada's media listserv and the MedEffect™ e-Notice mailing list. *Health Product InfoWatch*.
Examples of Evaluation	None identified.

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Public Notice About Drug or Medical Device Recalls – FDA (United States)	
Description	Press release-style document that includes information on the recall, how to identify the affected lots, who is affected, and what should be done with the product.
Purpose	To inform about a recall and change behaviour (i.e., stop using a recalled product).
Target	Can include healthcare professionals, general public, distributors, and hospitals
Dissemination	Posted on the FDA website. Released on the FDA recall RSS feed. Press release may be issued.
Examples of Evaluation	None identified.
Drug Alert Letter – MHRA (United Kingdom)	
Description	Letter that includes information on the recall, how to identify the affected lots, who is affected, and what should be done with the product.
Purpose	To inform about a recall and change behaviour (i.e., stop using a recalled product).
Target	Healthcare professionals, (in some cases) patients
Dissemination	Posted on the MHRA website. Distributed through the Central Alerting System.
Examples of Evaluation	None identified.
Health Product Recall – TGA (Australia)	
Description	Letters, ads, or summaries that include written information on the recall, how to identify the affected lots, contact information, and what should be done with the product.
Purpose	To inform about a recall and change behaviour (i.e., stop using a recalled product).
Target	Can include healthcare professionals, general public, distributors, and hospitals
Dissemination	Summaries posted on the TGA website. In some cases letters mailed to affected groups (e.g., hospitals). Paid advertisements in daily print media when the recall is at a consumer level and the affected consumers cannot be identified.
Examples of Evaluation	None identified.

Source: (Health Canada, 2008; RSI, 2013; FDA, 2014b; TGA, 2014c; MHRA, n.d.)

The most common defect and error communication documents are those that accompany recalls. In all jurisdictions, recall documents are almost always developed by industry (even where the regulator has the authority to order a recall) and contain similar information (e.g., affected lots, what should be done). Their layout, however, varies. In Canada, recall documents are written in a memo format (Health Canada has developed guidance for MAHs developing content), including headers and bulleted lists; in the United States they are written in a press release style; in the United Kingdom they are written as letters to healthcare professionals (it appears that there is no corresponding public document);[7] and in Australia they present information in a table format. There does not appear to be any evaluation of which format is best at conveying information. For the most part, it is the prerogative of the media themselves to decide whether to report on a recall (as with other types of communications). However, the TGA requires that paid advertisements be placed in daily print media as part of a recall at the consumer level when the affected consumers cannot be identified. In Canada, the United States, the United Kingdom, and Australia, recall documents (or notices about recalls) are posted on the same website as advisories and have similar look and tone to them.

The Panel identified only one publicly available evaluation specifically related to health product error communication. The evaluation, which concerned the recall of the Alysena™ 28 (an oral contraceptive) in Canada, was a process/implementation evaluation (see Chapter 4) based on expert analysis of the timelines associated with the recall and the associated media and public perception. It found that, while Health Canada's process was followed, the regulator could have issued a public communication sooner than it did (RSI, 2013).

3.2.4 Summary and Comments on Evaluation

Overall, the Panel found it challenging to characterize many health product risk communication tools because of a lack of readily available information summarizing and describing tools in use. In many cases, the information presented in Tables 3.1, 3.2, and 3.3 was deduced through reading several examples of the tool in question.[8] Furthermore, in some cases, regulator documents reference an internal evaluation, but the Panel could not find any

7 The recall information released publicly by the MHRA (or any national regulator in Europe) is often supplied by the EMA.

8 Given that this exercise was not meant to be exhaustive, there are health product risk communication tools that exist in the different jurisdictions examined, which the Panel chose not to include due to space constraints or because information was difficult to locate. It is also possible that the information described under tool characteristics may need updating or revision as new information becomes available.

concrete information on the nature of the study, timeframe, methods, or results. As this report is based on publicly available information, these evaluations could not be included in the summary tables.

Although the Panel identified a range of established risk communication tools, several shared similar features. Many tools, for example, were primarily text-based with few visuals and sparse colour. While some tools used images, these were generally illustrations or pictures rather than graphic risk presentations. The most common method of dissemination was through posting online (with the notable exception of leaflets), although some of the tools aimed at healthcare professionals were also disseminated by other methods such as mail. Occasionally, tools consisted of an addition or change to another established tool, such as a black box on a leaflet. Most of the tools that targeted the public often did not quantify risk, instead using terms such as "increased risk," "rare," or "chance of." Detailed information about risk was generally available in some of the comprehensive ongoing communication documents (e.g., summary basis of decision documents), but these documents were also longer and written in more technical language. Many of these observations, however, do not align with the evidence-informed communication practices outlined in Chapter 2 and Table 2.6.

For evaluation to be undertaken successfully, the goals of a risk communication need to be defined. Although the desired populations that a communication is intended to reach might vary, the goal of sending the communication in a timely and appropriate manner was constant in the identified evaluations. Generally, evaluations used individual interviews, surveys, standardized tests, or expert analysis to mostly measure the readability or clarity of a given tool. Importantly, these evaluations only provided evidence on the content of a communication tool and did not evaluate if it achieved broader goals such as whether it was understood and incorporated into the behaviours and decision-making of the targeted receivers of information.

In most cases of the evaluations reviewed by the Panel, the desired goals of the communication tools could be characterized simply as either informing select groups, changing their behaviour (and possibly seeking out more information), or both. For instance, a public recall has the goal of changing behaviour (i.e., stop using a product) while a product insert has the goal of informing patients about the risks and benefits associated with a medication. Some evaluations also explored broader goals such as enhancing the health of Canadians. The outcome evaluations that examined use and impact most often used medical or pharmacy data (e.g., prescribing rates, new users) as

indicators. There was no apparent evaluation of larger overarching goals related to relationship-building such as establishing trust with the public, empowerment, or becoming the go-to source for health information.

Overall, the Panel found little publicly available and publicly conducted evaluation results on the effectiveness of health product risk communication tools or template documents. Of the evaluations identified, the majority related to tools used by the FDA. For example, Dusetzina *et al.* (2012) identified 49 outcome evaluations of FDA dear doctor letters, public advisories, or black box warnings over a period of 20 years. However, most of these evaluations were done by independent researchers rather than the FDA and it is not clear how the regulator is applying the evaluation results. It seems that regulators have either not evaluated the effectiveness of their health product risk communication tools or used the results of external evaluations, and in any case have not made these results public or easily accessible. This gap could have implications for the quality of risk communication.

Apart from the evaluation of specific health product risk communication tools, Health Canada has released some broader evaluations of programs with a range of communication activities, which demonstrate some learning (see Box 3.2). It has also discussed plans for specific evaluation and public engagement activities related to risk communication, but the results of these activities are either not yet completed or have not been released. For example, public consultations and public surveys have been identified as methods to engage receivers of information and other stakeholders and to "collect important data to inform the Department of the effectiveness of current methods used to communicate drug safety information and to identify areas where the Department needs to make improvements" (Health Canada, 2011a). The specific results of these activities, however, do not appear to be public and the Panel could only find limited evidence of similar surveys conducted between 2003 and 2007 that indicated a number of opportunities for improved awareness among the public and health professionals (Evaluation Directorate, 2014c).

Box 3.2.
Broader Health Canada Program Evaluations

Although there are few targeted evaluations of specific Health Canada communication tools, the regulator has included communication elements in the evaluations of broader health product programs including those relating to biologics, medical devices, and human drugs. These recent evaluations include assessment of all program activities (i.e., all ongoing, incident(s), and defect related tools were included in addition to all other Health Canada activities) and a range of outcome variables related to "relevance and performance (effectiveness, efficiency, and economy)." The studies were carried out by an external evaluation firm using literature, document (government) and administrative data reviews, case studies, surveys of industry and other stakeholders (patients, healthcare professionals), focus groups with manufacturers, and key informant interviews. These studies illustrate a comprehensive approach to reviewing regulatory activities.

With respect to communication-related findings, the program evaluations note that in the past decade Health Canada has implemented a number of new initiatives to improve communication, openness, and engagement. These initiatives include the publication of summary basis of decision documents, public consultations on proposed policies, and improvements to the MedEffect™ website (e.g., adding an advanced search option). While the evaluation states that Health Canada's activities are expected to "lead stakeholders…to adopt safe behaviours" and "produce increased awareness and understanding…of risks and benefits," it did not determine whether communication tools were actually achieving these outcomes or other communication goals related to development, reach, use, or impact. The evaluation also found no evidence of other evaluations that draw these types of conclusions, apart from a small number of limited public opinion surveys.

In all of these more comprehensive program evaluation activities, it was noted that the "vast scope and complexity of the subject matter" was a challenge for document review as was locating all relevant internal documents, and that there were problems with very low survey response rates and difficulties in organizing interviews. These limitations highlight the opportunity for Health Canada to carry out more targeted evaluations of specific health product tools, which would better scope the subject matter, better explore communication specific goals, and better engage more specialized evaluation participants.

(Evaluation Directorate, 2014a, 2014b, 2014c)

Health Canada has also stated that it is working with experts in knowledge translation to help evaluate the effectiveness of its public advisory template in terms of "reducing the health literacy burden on Canadians," carrying out readability tests on its public advisories template (see Section 3.2.2), and collecting data to establish whether prescribing patterns are influenced by dear healthcare professional letters (Health Canada, 2011a). The results of the evaluation on doctor letters have not yet been released. Finally, the Panel is aware that Health Canada is currently planning an evaluation of the effectiveness of risk communications. However, no results of this evaluation have been made public and no description of the types of activities that are/would be included were available at the time of report publication (Evaluation Directorate, 2014a, 2014b, 2014c).

Ultimately, a health agency has a responsibility to the citizens it protects. The Panel identified clear instances where Health Canada has demonstrated its recognition of the importance of openness and evaluation (e.g., plain language initiative, public communication documents to coincide with communication documents for healthcare professionals, release of safety reviews, readability evaluations). These exemplars signify that Health Canada could position itself as a leader in the evaluation of health product risk communication. However, these evaluations must be publicly available if any agency wants to establish a long-term commitment to building and establishing trust with the people it intends to reach. The benefits, process, and challenges associated with evaluation are discussed further in Chapter 4.

3.3 EMERGING TOOLS FOR HEALTH PRODUCT RISK COMMUNICATIONS

Key Findings

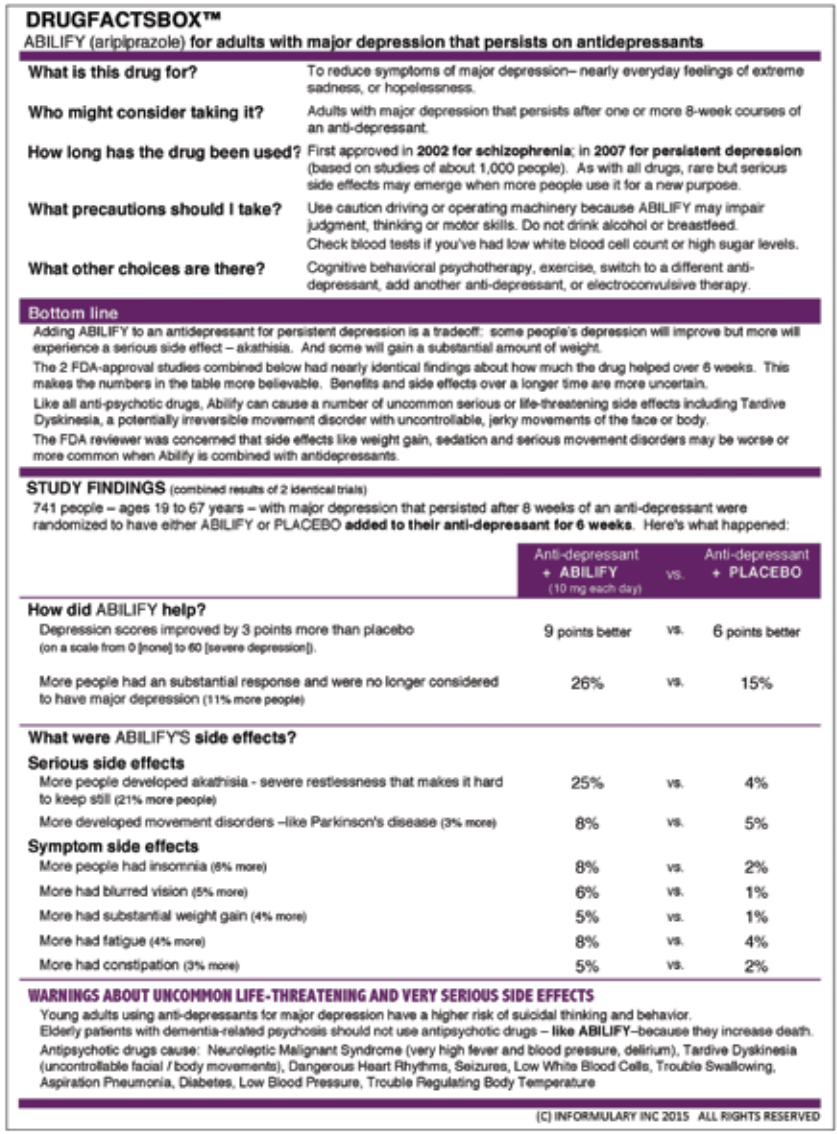
- Promising developments that could shape the future of health product risk communication include refining how the message is presented, changing the conditions that shape behaviour, using multi-media approaches, taking advantage of new mediums, and improving dissemination.
- Emerging tools provide new opportunities for communication and evaluation.

In addition to established tools, the Panel identified several classes of emerging tools that are being used, or have been proposed, for communication of risks associated with health products. These new approaches tackle the challenges associated with risk communication, for example, through ongoing communication tools that refine how the message is framed or incident(s)-based tools that use new mediums to improve reach. Some of them have been adopted by regulators while others have been developed by researchers.

3.3.1 Ongoing Communications

Refining How the Message is Presented: Drug Fact Boxes

One of the criticisms of medication guides and drug labels is that they neither discuss the benefits of taking the drug nor prioritize or quantify side effects (Schwartz & Woloshin, 2013). This may make it challenging for physicians and consumers to determine the best treatment. This information is part of the documentation submitted during the review process for new drugs but is currently available only in relatively inaccessible formats (e.g., in Health Canada's summary basis of decision documents). Drug fact boxes have been proposed as an alternative method to present the risk and benefit information associated with prescription drugs in a manner similar to nutrition labels. These boxes are one page and standardized across all prescription medications, with one version for physicians and one for consumers. As Schwartz and Woloshin (2013) describes, "the central feature of the box is a data table with the absolute risks of various outcomes with and without the drug." To address the challenges associated with determining which data to present in the boxes, Schwartz and Woloshin have developed (and tested) a handbook (Schwartz & Woloshin, 2013). Figure 3.2 shows an example box for prescription drug aripiprazole (brand name Abilify®), designed for adults suffering from major depression that persists despite taking antidepressants.



DRUGFACTSBOX™

ABILIFY (aripiprazole) **for adults with major depression that persists on antidepressants**

What is this drug for?	To reduce symptoms of major depression– nearly everyday feelings of extreme sadness, or hopelessness.
Who might consider taking it?	Adults with major depression that persists after one or more 8-week courses of an anti-depressant.
How long has the drug been used?	First approved in **2002 for schizophrenia**; in **2007 for persistent depression** (based on studies of about 1,000 people). As with all drugs, rare but serious side effects may emerge when more people use it for a new purpose.
What precautions should I take?	Use caution driving or operating machinery because ABILIFY may impair judgment, thinking or motor skills. Do not drink alcohol or breastfeed. Check blood tests if you've had low white blood cell count or high sugar levels.
What other choices are there?	Cognitive behavioral psychotherapy, exercise, switch to a different anti-depressant, add another anti-depressant, or electroconvulsive therapy.

Bottom line

Adding ABILIFY to an antidepressant for persistent depression is a tradeoff: some people's depression will improve but more will experience a serious side effect – akathisia. And some will gain a substantial amount of weight.

The 2 FDA-approval studies combined below had nearly identical findings about how much the drug helped over 6 weeks. This makes the numbers in the table more believable. Benefits and side effects over a longer time are more uncertain.

Like all anti-psychotic drugs, Abilify can cause a number of uncommon serious or life-threatening side effects including Tardive Dyskinesia, a potentially irreversible movement disorder with uncontrollable, jerky movements of the face or body.

The FDA reviewer was concerned that side effects like weight gain, sedation and serious movement disorders may be worse or more common when Abilify is combined with antidepressants.

STUDY FINDINGS (combined results of 2 identical trials)

741 people – ages 19 to 67 years – with major depression that persisted after 8 weeks of an anti-depressant were randomized to have either ABILIFY or PLACEBO **added to their anti-depressant for 6 weeks**. Here's what happened:

	Anti-depressant + ABILIFY (10 mg each day)	vs.	Anti-depressant + PLACEBO
How did ABILIFY help?			
Depression scores improved by 3 points more than placebo (on a scale from 0 [none] to 60 [severe depression]).	9 points better	vs.	6 points better
More people had an substantial response and were no longer considered to have major depression (11% more people)	26%	vs.	15%
What were ABILIFY'S side effects?			
Serious side effects			
More people developed akathisia - severe restlessness that makes it hard to keep still (21% more people)	25%	vs.	4%
More developed movement disorders –like Parkinson's disease (3% more)	8%	vs.	5%
Symptom side effects			
More people had insomnia (6% more)	8%	vs.	2%
More had blurred vision (5% more)	6%	vs.	1%
More had substantial weight gain (4% more)	5%	vs.	1%
More had fatigue (4% more)	8%	vs.	4%
More had constipation (3% more)	5%	vs.	2%

WARNINGS ABOUT UNCOMMON LIFE-THREATENING AND VERY SERIOUS SIDE EFFECTS

Young adults using anti-depressants for major depression have a higher risk of suicidal thinking and behavior.
Elderly patients with dementia-related psychosis should not use antipsychotic drugs – **like ABILIFY**–because they increase death.
Antipsychotic drugs cause: Neuroleptic Malignant Syndrome (very high fever and blood pressure, delirium), Tardive Dyskinesia (uncontrollable facial / body movements), Dangerous Heart Rhythms, Seizures, Low White Blood Cells, Trouble Swallowing, Aspiration Pneumonia, Diabetes, Low Blood Pressure, Trouble Regulating Body Temperature

Source: (Schwartz & Woloshin, 2013)

Figure 3.2

Drug Fact Box for Aripiprazole, an Antipsychotic

This drug fact box is designed to present the risks and benefits of aripiprazole to adults suffering from major depression who have symptoms that persist despite antidepressant therapy. Another version of the box would be used to present this information to healthcare professionals or patients taking the drug for another condition.

Research has shown that most consumers can understand the risk-benefit data presented in drug fact boxes (Schwartz *et al.*, 2009; Schwartz & Woloshin, 2011). Studies have also further improved their clarity (Schwartz & Woloshin, 2011; Woloshin & Schwartz, 2011). One surprising result of these studies was that presenting the prevalence of side effects using percentages alone was as good, if not better, than using percentages and frequencies (Woloshin & Schwartz, 2011). However, natural frequencies (which have been identified as the most understandable way to present probabilistic information (Akl Elie *et al.*, 2011)) were not tested (Gigerenzer, 2011). These results demonstrate the importance of using all available data when developing a communication, as opposed to simply adopting a one-size-fits-all approach.

As drug fact boxes are not radically different from currently used ongoing communication tools (e.g., based on the same information, text-based), they could be implemented more easily than some other innovations, and provide immediate benefit in terms of clarity and understandability. Currently, the FDA is considering implementing the boxes, but has stated that it needs three to five years to study the evidence (Schwartz & Woloshin, 2013). In the Panel's opinion, although more research is needed on the real-world applicability of the tool for varying populations, drug fact boxes are the most promising innovation in the field of health product risk communication.

Changing the Conditions that Shape Behaviour

Nudge approaches to changing behaviour (as popularized in Thaler & Sunstein (2008) and Sunstein (2014)) have potential for health product risk communication. They are based on the notion that indirect suggestions or imposed structures can encourage changes in people's behaviours while preserving freedom of choice (e.g., encouraging healthy eating in cafeterias by placing the salad bar before other food options). These types of interventions have been used in the past, but have only recently been given a common name (nudge).

An example of such an approach applied to the health product field is illustrated through a recent RCT on the treatment of patients with acute respiratory infections (ARIs) at five outpatient primary care clinics in Los Angeles. The study found that simply displaying poster-sized commitments in exam rooms led to a decrease in antibiotic prescribing rates for ARIs where antibiotics were inappropriate (Meeker *et al.*, 2014). This decrease was relative both to a control group and the intervention group's previous prescribing rates. The commitment letters stated the physician's pledge to avoid prescribing antibiotics for ARIs when they were not appropriate and also contained the physician's

photo and signature. Nudge approaches could also be used to encourage physician-patient risk communication through reimbursement policies that incentivize these activities.

Using Multi-Media Approaches

With the internet and social media available for disseminating risk information, regulators can use coordinated multi-media approaches to reach various populations. Different mediums are appropriate in different cases, and the selection of which, and how many, mediums to use depends on several factors, including time constraints, severity of the risk, and characteristics of the key receivers of information (such as age).

Two examples of coordinated initiatives that used different types of communication tools are Get Smart, a U.S. Centers for Disease Control and Prevention (CDC) campaign (CDC, 2006) and the Do Bugs Need Drugs? (DBND) program funded by the British Columbia ministry of health[9] (Do Bugs Need Drugs?, 2014). Both initiatives aimed to educate the public and healthcare professionals on the risks associated with misuse of antibiotics, and included several tools that took advantage of different dissemination methods, including pamphlets, internet, print media, and television. DBND also collaborated with community partners and the education system to enable the teaching of specially developed public teaching programs to different age groups. The multi-media approaches enabled the communicators to target different segments of the public using different (and tailored) tools. For example, Get Smart used Spanish-language tools to target the Hispanic population (CDC, 2006), and DBND developed television advertisements that targeted children aged 2 to 11 and their mothers (Do Bugs Need Drugs?, 2014).

There has been some evaluation of both programs. Evaluation activities of Get Smart focused on two dimensions: patient and provider educational materials (including community-based education) and a media campaign in selected communities (including posters and radio public service announcements) (CDC, 2006). Using program logs, sign-in sheets, and registration forms, the evaluations could assess reach, although the results were not published. In addition, a post-communication questionnaire was given to both providers and patients. Providers had a high level of satisfaction with the educational materials, but patients reported much lower levels. Interviews with patients revealed that their dissatisfaction stemmed from finding the materials overly complicated and lacking clear explanations of what to do when antibiotics were not necessary. In the case of the media campaign, program logs and media

9 There is a similar program in Alberta, but the discussion here is limited to the British Columbia program.

tracking demonstrated that "all media materials were developed as planned but that ad placement varied dramatically between communities", with greater public exposure to ads in one of the communities as a result of outside partnerships (CDC, 2006). Despite this, however, demand for antibiotics (self-reported) did not change significantly.

Evaluation of DBND focused on the program's reach and select outcomes (Do Bugs Need Drugs?, 2014). For example, the evaluation determined that in 2013 public transit advertisements were seen an estimated 30 million times and television advertisements reached at least 70% of the target audience (women aged 25 to 54) in all markets. An online survey to assess public knowledge found that 71% of respondents had seen DBND materials and that there was a high level of awareness around appropriate antibiotic use in the province (Do Bugs Need Drugs?, 2014). In addition, since the program has been implemented, the rate of antibiotic consumption for all age groups has decreased (with the greatest decrease observed in children[10]) (Do Bugs Need Drugs?, 2013). Although the evaluation did not attempt to assign causation, and acknowledged that there are many factors that affect antibiotic prescribing, it did state that DBND "likely contributed to some of the decrease" in antibiotic use (Do Bugs Need Drugs?, 2013).

3.3.2 Incident(s)-Based and Error Communications

Taking Advantage of New Mediums

Social media provide new opportunities to improve risk communication, and the Panel identified several examples of tools that take advantage of social media to disseminate risk information. These include Twitter feeds, Facebook pages, smartphone apps, podcasts, and YouTube videos. Social media have several benefits for dissemination, including speed and accessibility (Rutsaert *et al.*, 2014). Although these tools take advantage of different media, they often present the health product risk information in the same manner as established tools. For instance, Health Canada's recall app, Recalls and Safety Alerts, takes advantage of smartphone technology, but simply has links to public advisories and recalls already available on the Health Canada website. Similarly, the FDA's Consumer Update YouTube videos describe a risk in a similar manner to the text of the corresponding consumer update document, either through a voiceover or an expert discussing the issue on-screen.

10 In children, antibiotic prescriptions, rather than consumption, are used as a proxy for antibiotic usage (Do Bugs Need Drugs?, 2014).

Social media, however, are more than simply a new way to disseminate information. Used properly, social media can enable meaningful dialogue, free of any filter, between the senders and receivers of information (Veil *et al.*, 2011). As Veil *et al.* (2011) explains, "the greatest reason for communication practitioners to use social media [...] is that stakeholders are already using social media to communicate." Direct discussions with different groups receiving information allow communicators to monitor how these groups are feeling about and reacting to a particular risk and to respond quickly to rumours or misinformation (Waters *et al.*, 2009). This type of dialogue can build trust and increase satisfaction in communicators. For example, the CDC encouraged a dialogue with the public during the H1N1 pandemic, even among people with beliefs counter to the CDC recommendations. This was associated with an increase in the CDC American Customer Satisfaction Index, with those who used social media giving CDC higher ratings than those that did not (Reynolds, 2010; Veil *et al.*, 2011).

Improving Dissemination

Some regulators are using different approaches to ensure that risk communications *reach* desired groups. In the United Kingdom, for example, communications meant for healthcare professionals are delivered via the Central Alerting System (CAS). The CAS is defined as, "a web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical information and guidance" (U.K. Department of Health, 2015). Messages are delivered electronically to hospitals and other healthcare facilities, which can then distribute them further. The CAS, however, is only a delivery system, and the documents delivered are of the same type as those described above (e.g., recalls, dear doctor letters). In a survey of 1,800 respondents, 42% found CAS alerts "always relevant," while receiving too many irrelevant alerts and the time of day when alerts were received were identified as problems (MHRA, 2013).

Alert (or message) fatigue occurs when people start tuning out risk messages because of the large amount of information to which they are exposed (much of which may be minor or irrelevant to their lives) (FDA, 2012; CBC News, 2014). Baseman *et al.* (2013) found, for example, that for each additional public health message to which healthcare providers are exposed (per week) there is a decrease in the odds that they will be able to recall the content of that message. This can lead to important warnings being missed. Emerging practices could help overcome the challenges of alert fatigue by directing communications at the point of care and decision-making. Requiring that all prescribing be done electronically, for example, would ensure that physicians see warnings when they make the initial prescription (CBC News, 2014). Other healthcare partners could also be used to amplify the dissemination of information beyond the

direct healthcare prescriber. For example, at the pharmacy level, software that cannot be disabled and requires a user to give a reason for overriding warnings could ensure that pharmacists consider all relevant advisories (CBC News, 2014). Furthermore, software could ensure that more serious warnings are given first and could distinguish them from minor risks in some way.

3.3.3 Summary and Comments on Evaluation

Although the emerging tools described above are not in widespread use, they have often been subjected to important evaluation efforts including using pre-testing data to improve reach and understandability and measuring the initial impact of tools to assess changes in health outcomes. Such new tools may be perceived as unproven and therefore in need of more evaluation than established tools. The developers may also wish to publish articles about them in peer-reviewed journals, which often require some type of evaluative evidence. Needs evaluation and pre-testing are especially important for emerging tools, as there is an opportunity, and even an expectation, that the tools can be improved. Similarly, process evaluation can be used to audit and improve the development and release plan. As many of these emerging tools are not yet being used on a wide scale, outcome evaluations will be limited but, as demonstrated by the evaluation results discussed above, important observations for a range of communication goals can be obtained with concerted efforts.

Emerging tools provide new opportunities for communication, and for evaluation. For example, online access opens the door to online surveys before and after a communication is released. Social media, in particular, allow collection of feedback from a wide range of populations and stakeholders quickly and directly (Rutsaert *et al.*, 2013). This enables regulators to monitor public opinion on a risk before and after a communication is released. Online resources also provide new metrics that could be useful in evaluation, such as website hits, downloads, search terms, or retweets. The FDA has recognized the usefulness of social media for evaluation, and has recently requested proposals from companies to carry out social media monitoring (Anonymous, 2014). This monitoring will be used to evaluate the effectiveness of the FDA's risk and benefit communications through social media listening (Anonymous, 2014).

3.4 CONCLUSION

The Canadian regulatory context for health product risk communication is similar to that in other jurisdictions, including the United States, United Kingdom, Australia, and Europe. Given these similar contexts, it is not surprising that Health Canada's challenges in evaluating and enhancing health product risk communication are common. Health Canada can benefit from the lessons learned by other regulators and from innovations adopted in health product risk management. However, given the general lack of evaluation across jurisdictions, Canada has the opportunity to lead in implementing effective health risk communication evaluation efforts.

Regulators around the world use similar tools to communicate health product risk information. The tools identified by the Panel can be classified into three categories: ongoing communications, incident(s)-based communications, and defect and error communications. While many different individual tools were identified, in many cases information about their structure, target, dissemination methods, and purpose could not be found. However, the Panel found some important similarities across all tools. For example, most tools identified are almost exclusively text-based, and the most common dissemination method is posting online. Emerging tools or approaches include those that refine how the message is presented, change the conditions that shape behaviour, use multi-media approaches, take advantage of new mediums, and improve dissemination.

Evaluation of health product risk communication is essential for determining whether a tool is achieving, or is likely to achieve, the desired outcomes, and for improving future communications. Although extremely limited, the evaluation literature on established tools has shed some light on useful approaches. Emerging tools seem to be subject to greater evaluation scrutiny and point to new evaluation opportunities. The range of tools identified by the Panel highlights that evaluation cannot be done in a one-size-fits-all fashion, or simply tacked on at the end of the risk communication process. Instead, it should be considered throughout all stages of a communication. Just as risk communication tools are tailored to varying goals and populations, so too must the corresponding evaluation activities be tailored. Furthermore, communication tools will evolve, and evaluation plans will need to be updated accordingly. The Panel expands on these points in Chapter 4.

4

Evaluating the Effectiveness of Health Product Risk Communication

4 Evaluating the Effectiveness of Health Product Risk Communication

Evaluation of health product risk communication is lacking in many jurisdictions, despite its integral role in risk communication and its demonstrated value in supporting communication goals and improvements to content, processes, outcomes, and resource use. Evaluation not only provides feedback on the effectiveness of risk communications, but also helps to design and re-design communications aligned with the needs of various populations, to account for and learn from past mistakes, and to continue or build on identified successes. This chapter explores the general principles of evaluation by examining how careful planning and the determination of evaluation questions can shape the choice and application of evaluation methods. It examines the unique information needs and communication attributes, including the four goals specific to health product risk communication, and how these can determine the most appropriate methods. Where possible, the Panel uses illustrative examples of actual evaluations. The chapter concludes with discussion of strategies for securing commitment and resources for evaluation efforts.

4.1 ALIGNING HEALTH PRODUCT RISK COMMUNICATION AND EVALUATION

Key Findings

- Evaluation has tremendous value for effective risk communication since it can address a range of decision-making needs.
- Careful planning efforts determine relevant evaluation questions by identifying and integrating information needs and motivations, and the attributes of the risk communication tool, including the goals of risk communication.
- Different evaluation methods produce different kinds of evidence and require different levels of resources. They reveal the most meaningful information when they are an extension of well-developed evaluation questions.

Evaluation is central to developing effective risk communication tools, allowing communicators to learn from and improve upon new and existing communication efforts. It can therefore help maximize resources and opportunities to inform the behaviour of the receivers of information as well as avoid negative outcomes associated with certain health product risks. Evaluation can also help fulfil regulatory and fiduciary obligations and demonstrate commitment to transparency

and accountability, which can have positive implications for gaining trust and credibility. In general, evaluation is essential to understand the extent to which a communication is achieving its goals and to improve future communication and related decision-making. This focus on improving decision-making and real-world applications distinguishes it as an applied form of research (CDC, 2006; DFID, 2012; Kreps, 2014). Evaluations therefore often focus on understanding the broader context and the relationships involved in communications among a range of other factors (Kasperson & Palmlund, 1989; Pawson & Tilley, 1997; Weiss, 1998; Mayne, 2011b; Berriet-Solliec *et al.*, 2014). For example, beyond finding evidence of impact, an evaluation may also aim to understand why a communication had impact, determine if it will have similar impacts in other settings, make the results of an evaluation transparent and accessible, or build trust with the receivers of information and other stakeholders. As such, the range of evaluation goals and related questions is extensive.

Often those conducting the evaluation may quickly jump to the identification of methods without properly assessing the specific context and decision-making needs for a given situation. However, since different evaluation methods produce a range of knowledge and have varying strengths and weaknesses, they may be more or less applicable to the evaluation of a particular communication (Rothman & Greenland, 2005; Cartwright & Munro, 2010; Fischhoff *et al.*, 2011; DFID, 2012; Mayne, 2012). Moreover, there is also no universal way to evaluate a communication tool. Different evaluation methods may be applied in different ways to address various situations, needs, motivations, and goals. A truly successful evaluation therefore depends on taking the necessary time to develop appropriate and feasible evaluation questions and a better understanding of why the evaluation is taking place, who is conducting the evaluation, and for whom it is being conducted (Kasperson & Palmlund, 1989).

Given the varied attributes of most risk communication tools, evaluation planning can help identify the most salient factors to explore and situate the goals of a tool within the complex environment in which it exists. Detailed and thoughtful planning must start as soon as possible and can determine relevant evaluation questions by identifying and integrating information needs and motivations, and accounting for the attributes of the tool, including the goals of risk communication. Planning allows an evaluation to take stock of the situation, ensuring that methods become an extension and build on evaluation questions. This increases the likelihood that appropriate evidence is collected and that the evaluation will produce meaningful knowledge for the senders and receivers of information and other stakeholders. The following subsections explore some

of the key factors in determining meaningful evaluation questions and identify some of the more feasible evaluation methods for regulators responsible for health product risk communication.

4.1.1 Determining Evaluation Questions

Ultimately, there is no one-size-fits-all way to conduct an evaluation. Successful evaluations are structured around clear evaluation questions determined by (i) information needs and motivations of the senders and receivers of risk information, and (ii) the communication attributes of the tool used.

Information Needs and Motivations

Senders of Information

As discussed in Chapter 3, regulators around the world use a range of similar tools for communicating the risks associated with health products. These tools are important for demonstrating action in the public interest and proof of their commitment and competence as leaders in protecting and promoting the health and safety of the population (Kasperson & Palmlund, 1989). Evaluation can "serve the central purpose of solidifying, justifying, or extending" these tools by demonstrating that they work and that the regulator is committed to ensuring they continue to meet government goals and work in the public interest (Kasperson & Palmlund, 1989).

Most regulators are interested in demonstrating accountability: that is, the compliance of their risk communication tools with regulatory responsibilities or requirements established by external oversight mechanisms (Kasperson & Palmlund, 1989). For this purpose, they may want to prove that a risk communication followed internal protocols and contributed to the short-, medium-, and long-term goals established during program planning. Evaluations may focus solely on attributing a communication to a set of pre-determined goals, seeking to establish a relationship between a risk communication tool and desired outcomes, and proving that the tool worked at a given time in a given context (Shadish *et al.*, 2002; Cartwright, 2007; DFID, 2012).

Evaluations may also be motivated by the need to improve future risk communication, answer questions about performance, address failures or criticisms, or make decisions about the allocation of scarce resources (Kasperson & Palmlund, 1989). In these situations, evaluations become broader in nature and should seek to explain "how" and "why" a risk communication tool led to desired outcomes. It is therefore about understanding the nature of the relationship between tools and outcomes and what factors may influence that relationship (Cartwright & Hardie, 2012; DFID, 2012). Evaluations may therefore be concerned with whether the risk communication tool is necessary

and/or sufficient for producing an outcome and with identifying the range of factors that also contribute to various outcomes (DFID, 2012). The complexity of risk communication (see Chapter 2) renders the relationship between a tool and an outcome non-linear — that is, very difficult to attribute a given tool to a particular outcome. As such, the evaluation literature points to the notion of contribution, recognizing that a given outcome is the product of many factors (Rothman & Greenland, 2005; Pawson, 2006; Cartwright, 2007; Mayne, 2011a; DFID, 2012).

Finally, evaluation can demonstrate a clear commitment to transparency. In these cases, "evaluation has not only a factual but also a symbolic role — in demonstrating interest in what went wrong, in seeking solutions, in making concessions to outside critics, and in allocating blame and responsibility" (Kasperson & Palmlund, 1989). Therefore, an evaluation must be seen as relevant and trustworthy. High-level, rigorous evaluations may be of limited use to regulators if the results are not relevant or are seen as biased and subject to conflict of interests. In these cases, the composition of the evaluation team and the evaluation process are most important (Kasperson & Palmlund, 1989). Lack of relevance may be due to inaccessible findings (e.g., too technical, narrowly communicated) or to lack of stakeholder engagement and involvement. The Panel considers it is critical for those conducting an evaluation to understand the receivers of information and other stakeholders, involving them in a transparent manner to build trust and ensure relevance. As discussed in Chapter 2, institutions can help build trust by providing accurate risk communications that take into account the information needs, capabilities, and feelings of affected populations; evaluation efforts are no different.

Receivers of Information

The identification of individual and group information needs is an outstanding challenge in risk communication and for the social sciences more generally (Fischhoff & Manski, 1999; Glimcher & Fehr, 2013). In the Panel's view, however, the central motivation specific to the receivers of information and other stakeholders is determining credibility and who to trust when making decisions about health product risk information. As discussed in Chapter 2, these needs can be supported by ensuring that affected groups feel engaged in the communication process and empowered to use the information provided (NRC, 1996; Lundgren & McMakin, 2013). Similarly, they need to feel that their involvement in evaluation will be taken seriously, with their needs and concerns fully acknowledged. In some cases, there may be a degree of mistrust of risk communicators or those conducting the evaluation among different groups, owing to a lack of transparency (Garcia-Retamero & Cokely, 2014; Löfstedt & Bouder, 2014), concerns over previous evaluations, or a general

mistrust of particular institutions (Löfstedt & 6, 2008; Victory *et al.*, 2014). Ensuring that the receivers of information and other stakeholders are consulted in ways that are meaningful and sensitive to outside concerns requires those conducting the evaluation to be knowledgeable about appropriate evaluation methods; participatory techniques and strategies that are feasible given resource and time constraints; and particular population beliefs, values, and needs that are specific to receiving risk information, participating in evaluation projects, and being engaged in dialogue.

Communication Attributes

The increasingly complex world in which communication tools are implemented creates many different attributes that need to be accounted for in establishing evaluation questions. To develop evaluation questions, the Panel concluded that differentiating health product risk communication tools across three main attributes was most salient for regulators and other government institutions: (i) type, (ii) stage, and (iii) goal.

Type of Health Product Risk Communication Tool

Chapter 3 highlights three main types of risk communication tools, which can be further grouped as ongoing communication and incident(s)-based communication.[11] Ongoing communication involves those tools that present known information about health product risks, and they are neither immediately pressing nor time sensitive. Incident(s)-based communication, on the other hand, involves newly discovered information and is often related to crises or emergencies. This means that these tools are time sensitive and subject to the pressures of immediately getting information into the public realm, while taking the time necessary to establish the full extent of the risk and risk management strategy. In both situations, multiple sources of information are simultaneously competing for the attention of affected populations, and these sources can differ in how, and by how much, they influence reception of information and decision-making.

How an evaluation is carried out will be different depending on the type of tool. With ongoing communication tools, there will be more time to gain sufficient resources, conduct systematic assessments, use comprehensive methods, and fully engage the receivers of information prior to, during, and after the evaluation. It may be difficult, however, to justify an evaluation of a tool that has been in use for a number of years. Conversely, with the limited time for evaluation planning and implementation that results from incident(s)-based

11 Recall that incident(s)-based communication tools share many similarities to errors and defects communication tools and are therefore grouped for the purposes of discussion in this chapter.

communication, evaluations will likely be working with fewer resources, less comprehensive evaluation methods, and limited engagement opportunities. Alternatively, the ability to assess various goals using clear before and after comparison groups becomes more viable for incident(s)-based communication. Because incident(s)-based communications are delivered at a fixed point in time, there is a clear baseline from which to measure the distribution of a communication. In this sense, it is relatively straightforward to measure the effectiveness of specific distribution channels. In contrast, since ongoing communications are delivered in a continuous manner, it is difficult to identify a baseline start date and end date for analysis.

Finally, the public is more likely to demand certain types of evaluation for high-profile incident(s)-based communications that need to be done quickly and in full view of the public. In these situations transparency is critical. Regulators and other government institutions may be more interested in evaluations that demonstrate appropriate and proper processes were followed over demonstrating long-term impacts. To conduct a successful evaluation, those conducting the evaluation also need to be aware of other types of information on a given risk and how they may play out differently in ongoing versus incident(s)-based situations.

Health Product Risk Communication Stage

The different stages in the risk communication process (i.e., planning, implementation, and assessment) translate into different types of evaluation (Rohrmann, 1992; Jardine, 2008; Downs, 2011). Ultimately, evaluation is integral to all stages and is not simply an end-stage task carried out after the risk communication is completed. The Panel selected the following categories to distinguish types of evaluation because they most clearly highlight the stages of health product risk communication and link to the information needs and goals of risk communication:

- **Needs assessment:** undertaken to identify the information needs of the senders and receivers of information and other stakeholders — why the communication is taking place, what needs to be communicated and the quality of that evidence, for whom the communication is intended, and the most appropriate communication tool. Its findings can increase the likelihood that a risk communication will be effective.
- **Pre-testing:** undertaken before the full implementation of a risk communication to preliminarily test the feasibility, appropriateness, and effectiveness of the identified communication tool in sub-groups of the population intended to receive the final communication. Its findings can lead to changes to the communication, which will further increase the likelihood that it will be effective.

- **Process/Implementation:** typically undertaken during the implementation of a risk communication to provide evidence that it is progressing as planned and that an organization is following its internal protocols and plans. It may also be done retrospectively to identify lessons learned. Its findings provide insight into potential revisions to implementation strategies and the need for reassessing goals and potential outcomes. It can also help identify the potential value of conducting outcome evaluations in the future.
- **Outcome:** conducted after a risk communication has been disseminated and completed to link meaningful short-, medium-, and long-term outcomes to the tool in question. It is capable of producing various kinds of evidence, from largely descriptive findings to more rigorous explorations of the relationships between tools and outcomes, and the nature and factors that may influence those relationships. Although considered end-stage efforts, more rigorous evaluations will usually establish a baseline prior to the implementation of the communication followed by ongoing measurement.

Health Product Risk Communication Goals

Defining risk communication goals implies that evaluation will be done to establish whether these goals have been met. Many of the evaluations identified by the Panel that were specific to certain tools had a limited focus and often only looked at singular components (e.g., readability) or singular goals (e.g., use) (see Chapter 3). However, it is important to establish a broad range of goals for proper testing. In Chapter 2, four goals for health product risk communication were introduced to capture the range of short-, medium-, and long-term outcomes to be assessed through evaluation:

- **Development:** incorporating evaluation methods and learning into the steps involved in designing risk communications, including when characterizing and managing risk, creating messaging, and ensuring ongoing partnership and exchange.
- **Reach:** how and when the communication is sent and received and by whom.
- **Use:** how the information is considered, its timeliness, and the reactions and actions taken as a result of the communication, thus exploring understandability, timeliness, informed decision-making, and behaviour.
- **Impact:** achieving a desired result with respect to various outcomes related to the senders and receivers of information and the relationship between them.

These goals will ultimately align with information needs and motivations of decision-makers, as well as with other communication attributes, to shape evaluation questions and subsequent methods. For example, development aligns with needs assessment and pre-testing evaluations, reach and use align with process/implementation evaluation, and impact aligns with outcome evaluation. In addition, development and reach align with information needs

and motivations related to accountability, whereas use aligns better with program improvement motivations, and impact is an important goal to demonstrate in meeting transparency-oriented motivations.

Research demonstrates that even with concrete goals and a clear idea of relevant and meaningful outcomes, it may be difficult to collect indicators that are sufficient proxies for these outcomes. Indicators must be reliable to the extent that they consistently represent the same outcome when repeatedly used across different situations and over time. Indicators must also be able to represent what they are intended to represent, and be precise, accurate, and comprehensive in scope. Based on the Panel's review of available evaluations, it appears that for many outcomes related to behavioural change, and to development, reach, use, and impact more generally, there is little consensus on which indicators are truly valid, reliable, and comprehensive over time. Therefore, better knowledge involving measurement is needed in the field of risk communication; however, this is no excuse for limited evaluation. Rather, a range of methods can be used to more fully capture the range of communication goals. The dimensions and associated evaluation methods for each of the four communication goals are described in Sections 4.2 to 4.5.

4.1.2 Selecting Evaluation Methods

Evaluation methods can become an extension and build on the evaluation questions selected, thereby increasing the likelihood that the evaluation will produce meaningful results. A wide array of methods can be used, ranging from simple to complicated and from quantitative to qualitative. Each method can be applied in different ways for different situations, and provide different types of knowledge and carry different strengths and weaknesses. There are a number of ways to classify these methods in the evaluation literature (Fischhoff *et al.*, 2011; DFID, 2012; McDavid *et al.*, 2013; Kreps, 2014). The Panel organized available methods into five broad approaches that it determined to be the most relevant for health product risk communication and the most feasible for regulators and other government institutions to implement:

- **Synthesis:** Methods include literature reviews, systematic reviews, and meta-analyses.
- **Records-based:** Methods include textual, archival, and administrative data analysis.
- **Self-reported data:** Methods include interviews, focus groups, and population-based surveys.
- **Experimental:** Methods include quasi-experimental methods, natural experiments, and RCTs.
- **Mixed methods:** This involves combining quantitative and qualitative methods from different approaches in the same evaluation.

The list is not meant to be exhaustive and readers are encouraged to look to other sources for more detailed guidance (HM Treasury, 2011; Owen, 2011; DFID, 2012; McDavid *et al.*, 2013; Lance *et al.*, 2014; Web Center for Social Research Methods, n.d.). Appendix A provides a basic overview of the types of knowledge gained, advantages, and challenges associated with key approaches and constituent methods; this information is also summarized in Table 4.1. Sections 4.2 to 4.5 explore how various methods can be adapted across different communication goals and related evaluation questions.

Table 4.1

Overview of Approaches and Methods for Evaluation

Synthesis Approach			
Methods	**Type of Knowledge Gained**	**Advantages**	**Challenges**
• Literature and Systematic Reviews, and Meta-Analyses	• Expert/scientific model of risk understanding • Understanding of health risk and associated factors • Suggests hypotheses, methodological challenges, and other evaluation issues	• Efficient • Low cost	• Difficult to determine accuracy/quality • Not always comparable/ relevant
Records-Based Approach			
Methods	**Type of Knowledge Gained**	**Advantages**	**Challenges**
• Textual Analysis	• Patterns in recorded presentation and language used in risk communication tools	• Efficient • Low cost	• Not generalizable • Often limited quantitative data
• Archival and Administrative Data Analysis	• Background information • Data on program outcomes/impacts • Quantitative measures of health, economic, and social conditions	• Efficient • Low cost	• Sometimes incomplete/ inaccurate

continued on next page

Self-Reported Approach			
Methods	**Type of Knowledge Gained**	**Advantages**	**Challenges**
• Interviews and Focus Groups	• In-depth knowledge of population needs, beliefs, and behaviours • Gain understanding of social meaning of risk and why people make the decisions they do • Preferred wording and context of communication tools	• Reliable • Versatile • Focus on breadth and depth • Produces shared understanding as part of social context	• Accuracy of responses • No control group • Human resource requirements • Variable costs, ranging from low to high depending on design
• Population-Based Surveys	• Superficial knowledge of population needs, beliefs, and behaviours • Various types of quantitative and qualitative data and information, depending on evaluation needs	• Allows comparisons across larger groups of individuals and is representative of more people • Varying sampling strategies	• Variable costs, ranging from low to high depending on design
Experimental Approach			
Methods	**Type of Knowledge Gained**	**Advantages**	**Challenges**
• RCTs • Quasi-Experimental Methods • Natural Experiments	• Comparison of effects between those who receive communications and those who do not • Strength of attribution depends on strength of the research design	• Allows comparisons across individuals and populations • Reliable comparison population can account for influencing factors • Varying sampling strategies • Generalizable and can be compared to other similar studies	• Can be difficult to implement • Costly • Provides less information on context and larger social process • Ethical and acceptability issues involved in randomization • Normally limited participation from affected groups
Mixed Methods Approach			
Methods	**Type of Knowledge Gained**	**Advantages**	**Challenges**
• Variable	• Range of evidence from information needs and beliefs/behaviours to valid causal inferences and in-depth understanding of communication results	• Diverse • Versatile • Combines the best aspects of different methods	• Can be costly • Human resource requirements • Time intensive

4.2 DEVELOPMENT: MATCHING EVALUATION METHODS TO RELEVANT QUESTIONS

Key Findings – Development

- *Development* refers to incorporating evaluation methods and learning into the steps involved in designing risk communications.
- The relevant evaluation questions and methods for dimensions of development are listed below.

Dimensions	Evaluation Questions	Methods
Characterizing and Managing Risk	• Who needs to receive the risk communication? • Who wants to receive the risk communication? • What needs to be communicated? • Who is the source of the risk information? • What is the accuracy and credibility of the evidence base?	• Literature review/ Systematic review/ Meta-analysis • Textual analysis • Interviews and focus groups • RCTs • Mixed methods
Creating Messaging	• What are the communication wants and needs of the receivers of information? • How do the receivers of information make sense of risk? • Will they understand the content? • What will the content look like (e.g., text, images, colour)? • Does the content address wants and needs? • How will the risk communication be disseminated? • Are the communication channels appropriate for all groups receiving the information?	
Ongoing Partnership and Exchange	• What is the relationship between the sender and receiver of information? • How could that relationship change, stay the same, or be strengthened? • What is the best way to engage the receivers of information in the evaluation process? • How can the senders and receivers of information and other stakeholders be involved in the implementation of evaluation?	

Before launching a risk communication, evaluation methods can be used to inform its development, using evidence to increase the likelihood that it will lead to desired and meaningful outcomes (Jardine, 2008; Downs, 2011; Bruine de Bruin & Bostrom, 2013). This process can best be described by exploring needs assessment and pre-testing activities (see Section 4.1.1) and the risk communication dimensions discussed in Chapter 2: (i) characterizing and managing risk; (ii) creating messaging; and (iii) ongoing partnership and exchange.

Evaluation can help establish what needs to be communicated; to whom it needs to be communicated; and the appropriate content, design, and delivery channels for those populations. Moreover, relationships between the senders and receivers of information, those conducting the evaluation, and other stakeholders can be fostered through engagement in evaluation planning and pre-testing as well as through participatory evaluation approaches. Sometimes communicators fail to conduct this type of evaluation because they are overconfident about understanding the needs of varying groups, they are unaware of leading methods, or they face resource constraints (Rohrmann, 1992; Bruine de Bruin & Bostrom, 2013; Fischhoff, 2013). However, even though assessing needs and pre-testing preliminary messages does not guarantee that a risk communication will be successful, it does reduce the chance of failure due to developmental flaws (Jardine, 2008).

4.2.1 Dimensions and Evaluation Questions

Characterizing and Managing Risk

As discussed in Chapter 2, risk characterization involves considering a given hazard and its potential outcomes as well as identifying affected populations and their needs. Understanding the risks for a given health product is rarely straightforward (NRC, 1996). It requires assessing the state of knowledge possessed by experts and the public. Broadly speaking, *expert understanding* refers to the current scientific and technical knowledge about the nature and magnitude of a health product risk and approaches to its management (Morgan *et al.*, 2002; Bruine de Bruin & Bostrom, 2013). Expert opinion can be drawn from risk and decision analysts, behavioural scientists, subject matter experts, and communication practitioners (Fischhoff, 2009). In contrast, the state of the *public's understanding* refers to the general level of knowledge across individuals and groups, which is shaped by social and cultural values and individual risk perceptions (Kasperson *et al.*, 1988; Slovic, 2000; Kahan, 2012). This process consists of identifying the receivers of information, the risk issues most in need of communication, and the quality of available evidence (source). As such, evaluations must explore the following questions:

- Who needs to receive the risk communication?
- Who wants to receive the risk communication?

- What needs to be communicated?
- Who is the source of the risk information?
- What is the accuracy and credibility of the evidence base?

Creating Messaging

Creating messaging requires further understanding the traits of the receivers of information, their approaches to decision-making, and their information wants and needs. Understanding the information needs and expected reach, use, and impact of communications is facilitated by evaluation specific to the risk, to the communication, and to the demographic, socio-economic, and health characteristics of the populations involved. This approach helps ascertain how a communication responds to the "concerns, needs, perspectives, and communication styles" of different groups and whether the information will be personally relevant, comprehended, considered, and accepted (Kreps, 2014). It can identify the "relevant performance gaps between ideal and actual health outcomes that might necessitate development of targeted health risk communication[s]" and, ultimately, if there is enough demand for new communications that promote health (Kreps, 2014). This information is complemented by collecting data on health behaviours; how people communicate and their preferences (e.g., use of social media, preferences for communication channels, literacy, and language preferences); knowledge, attitudes, values, and emotions related to the communication topics across groups; "cultural habits and preferences; effective motivational factors; and potential barriers to accepting information and changing health behaviours" (Kreps, 2014). This information is then used to establish the most appropriate communication content, design, and channel, which can then be pre-tested in sub-groups of the population intended to receive the final communication. As such, evaluations must explore the following questions:

- What are the communication wants and needs of the receivers of information?
- How do the receivers of information make sense of risk?
- Will they understand the content?
- What will the content look like (e.g., text, images, colour)?
- Does the content address wants and needs?
- How will the risk communication be disseminated?
- Are the communication channels appropriate for all groups receiving the information?

Ongoing Partnership and Exchange

The benefits of engaging the receivers of information and other potential stakeholders in evaluation planning are explained simply: "stakeholders are much more likely to buy into and support the evaluation if they are involved in the evaluation process in the beginning" (CDC, 2011). How engagement

takes place can vary based on a number of factors and there are many types of engagement (IRGC, 2014). Co-determination models, which engage stakeholders and members of the affected public to co-design policies and assist in making joint decisions (IRGC, 2014), hold promise for meaningful engagement strategies. The Panel notes that further research is needed on how best to engage, when to engage, and who to engage in the context of health product risk, specifically.

Undertaking engagement activities early in the planning process, enables those conducting an evaluation to dispel any misconceptions about the process (e.g., explain its limitations and quell any anxieties over the goals of an evaluation). In addition, ongoing engagement models can help prepare various populations for negative evaluation results (Bowen, 2012) and ensure that results are actually used in future decision-making. Receivers of information and other stakeholders that have a sense of ownership over an evaluation are more likely to consult and use its results in the future (Cargo & Mercer, 2008; Bowen, 2012). Establishing relationships between those conducting an evaluation and those sending and receiving information throughout planning can also benefit future communications. As with risk communication in general, an ongoing relationship builds trust over time, which can have long-term benefits for future evaluations. As such, evaluations must explore the following questions:

- What is the relationship between the sender and receiver of information?
- How could that relationship change, stay the same, or be strengthened?
- What is the best way to engage the receivers of information in the evaluation process?
- How can the senders and receivers of information and other stakeholders be involved in the implementation of evaluation?

4.2.2 Relevant Methods

A range of methods can be used to evaluate the potential effectiveness of a risk communication before implementation, depending on the resources available. Conducting a *literature review, systematic review,* or *meta-analysis* (i.e., a synthesis approach) of the existing literature can accomplish several goals. It can highlight the risk information that needs to be communicated and the sources of risk communication to which the receivers of information may have access. Moreover, it can provide guidance on the most effective means of presenting and designing a risk communication. This is often the first step in the design of an effective risk communication. A slightly more labour-intensive method is to conduct a *textual analysis* of current and previously issued risk communications to understand common types of content, designs, and delivery channels. Taken together, the synthesis approach and textual analysis can provide an accurate risk characterization, understanding of risk decision-making, and overview of the

most essential features of an effective risk communication. With these benefits in mind, the generality of these methods provides limited guidance about a specific risk communication in a specific context.

Interviews and *focus groups* examine the information needs, beliefs, and behaviours of the receivers of information in the context of a specific health product risk communication. This provides an initial characterization of the information needed, including preferred wording and style of presentation (Jardine, 2008; Bruine de Bruin & Bostrom, 2013). Moreover, focus groups provide a relatively straightforward way to engage the receivers of information and other stakeholders. Once a risk communication has been designed, but before it is implemented, an evaluation using these methods can also test whether it will be effective by directly asking participants about the relevance of the communication content and how it may influence their decision-making and behaviour (Fischhoff, 2009). There are, however, a number of challenges associated with this type of testing. Participants may be unaware and/or unable to predict how information will inform their decision-making. It may also be difficult to determine the accuracy of responses and how they compare across individuals. Finally, these methods do not provide a means to compare the decision-making of individuals who receive a risk communication with those who do not.

At this stage, *RCT*s can be used by randomly assigning individuals to receive different types of information by altering the content, design, or delivery of risk communications. For example, as described in Chapter 3, Schwartz *et al.* (2009) conducted two RCTs to test the effectiveness of drug fact boxes relative to direct-to-consumer drug ads. One trial involved information related to a drugs ability to alleviate allergy or heartburn symptoms (symptom drug boxes), while the other focused on a drugs ability to prevent cardiovascular events (prevention drug boxes). In both trials, the control groups received two actual drug ads that consisted of a front page and a summary while the treatment group received the same ads with the summary replaced by a drug fact box. In the trial using symptom drug boxes, 68% of the treatment group chose the superior drug (compared to 31% in the control group) while in the trial using prevention drug boxes, 72% of the treatment correctly identified the drug benefit (compared to 9% in the control group) (Schwartz *et al.*, 2009). This study provides clear evidence that a drug fact box is an effective risk communication tool. RCTs are an effective method for conducting controlled tests of various content, design, and delivery channels across the receivers of information; however, these results are specific to a given setting and cannot be easily generalized to other situations (Cartwright & Munro, 2010; DFID, 2012). Of the methods described in this section, RCTs are the most resource intensive and difficult to conduct.

With sufficient resources and commitment, mixed methods provide the most comprehensive way to identify the appropriate populations, sources, content, design, and delivery channels for a risk communication, ultimately informing its development. Box 4.1 provides a case study of one such evaluation.

Box 4.1

Developing Risk Communication Tools with Mixed Methods Evaluation

A study of the beliefs of adolescent girls related to sexual behaviour provides an example of how mixed methods evaluation can inform risk communication development. Bruine de Bruin *et al.* (2007) note, based on a literature review, that adults and teens view sexual health risks differently, and that the former group may make erroneous assumptions about why teens engage in risky sexual behaviour. To develop a more effective risk communication tool about sexual health and use of related health products (e.g., condoms), needs assessment and pre-testing were carried out using mental models (Morgan *et al.*, 2002). This process involved examining the available scientific model and the model of a sample of adolescent girls. To develop the adolescent girl model, engagement with this group was needed. This was achieved through in-depth individual interviews using non-directive questions and increasingly specific prompts (to explore understanding, including intuitive theories), followed by written surveys to "[measure] the prevalence and correlates of potentially critical beliefs, as identified by the interviews" (Bruine de Bruin *et al.*, 2007).

Based on the gap between the scientific and adolescent models, an interactive video format on DVD (*What Could You Do?*) was developed to empower young women in making sexual health decisions (Bruine de Bruin *et al.*, 2007). As the authors describe, "empowering [young women]…means helping them to understand their world and work it to their best advantage. Given the complexity of sexual decisions, young women need a broad perspective to create and evaluate options, adapt to unanticipated obstacles and opportunities, and consider the broader context that gives meaning to their lives and relationships." Further evaluation methods that used think-aloud protocols helped to make the content realistic, compelling, and understandable (Bruine de Bruin *et al.*, 2007).

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An evaluation to measure the effectiveness of the DVD was then undertaken. In an RCT, the researchers evaluated the communication's effects on 300 female urban adolescents' knowledge about sexually transmitted infections, self-reported sexual risk behaviour, and acquisition of sexually transmitted infections (Downs *et al.*, 2004b; Bruine de Bruin *et al.*, 2007). The interactive DVD was compared with two control groups: one that received the same content in book form, the other in commercially available brochures. After three months, self-reports revealed that those in the DVD group were significantly more likely to be abstinent than those in either control group. After six months, those in the DVD group were significantly less likely to report having had a condom break, leak or fall off, or to have been diagnosed with a sexually transmitted infection (Downs *et al.*, 2004b; Bruine de Bruin *et al.*, 2007). This highlights the power of evaluation for developing effective risk communication tools that engage with the receivers of information.

4.3 REACH: MATCHING EVALUATION METHODS TO RELEVANT QUESTIONS

Key Findings – Reach

- *Reach* refers to how and when the communication is sent and received and by whom.
- The relevant evaluation questions and methods for dimensions of reach are listed below.

Dimensions	Evaluation Questions	Methods
Delivery	• Was the risk communication sent and to whom specifically?	• Administrative data analysis • Interviews and focus groups • Population-based surveys
Receipt	• Did those groups receive the risk communication? • Are those groups aware of the risk communication?	

Evaluating the reach of a risk communication requires gathering evidence on how the risk communication was distributed and whether the affected populations received it (Chen, 2005; Montague & Porteous, 2013). This information allows the senders of information to modify processes and procedures during implementation to ensure that the messages are reaching affected groups through the selected channels (Jardine, 2008; Downs, 2011). While this approach

to evaluation is closely linked to process/implementation evaluation, delivery and receipt can be evaluated retrospectively as part of an outcome evaluation. Although this type of evaluation cannot ensure that a communication is achieving use and impact, it can provide evidence that a risk communication is implemented as intended, on track, and on time, and whether the budget is sufficient (Jardine, 2008; Downs, 2011). The findings of such an evaluation also provide insight into potential revisions to communication goals and strategies.

4.3.1 Dimensions and Evaluation Questions

Evaluating reach is relatively straightforward and involves two main dimensions: delivery and receipt. This can include describing the program, documenting the steps for implementing it, and identifying who will deliver (e.g., the regulator) and who will receive the communication (e.g., particular patient groups, professionals, other stakeholders) (Downs, 2011). A data collection plan is then developed to observe the outcome of interest (Downs, 2011), such as the volume of communications sent and received. Although they can be done retrospectively, these evaluations are particularly valuable for assessing how well procedures follow the communication plan conceived during development, and how they may need to be adapted during implementation. Reach evaluations should be tailored to the internal needs of the organization(s) implementing the risk communication. As such, they must explore the following questions:

- Was the risk communication sent and to whom specifically?
- Did those groups receive the risk communication?
- Are those groups aware of the risk communication?

4.3.2 Relevant Methods

While there are numerous ways to evaluate reach, the Panel notes three methods that align with these evaluation questions. *Administrative data analysis* consist of collecting basic descriptive statistics from program records that provide indicators such as: posting on the organization's website or social media, number of website hits or read tweets, press releases, number of pamphlets or posters, number of package inserts, and letters sent to physicians. It explores the channels of risk communication distribution and can effectively answer the question: was the risk communication sent and to whom specifically? In general, this provides an overall picture of the degree to which a risk communication was distributed and requires relatively few resources. However, it does not capture if affected populations received it. For example, in the evaluation of the Do Bugs Need Drugs? (DBND) program discussed in Chapter 3, administrative data in the form of distribution numbers and estimated transit ridership were used to demonstrate that 75,000 print materials were distributed across

British Columbia, 14,700 books were distributed to healthcare professionals, and public transit advertisements were viewed an estimated 30 million times (Do Bugs Need Drugs?, 2014).

Interviews and *focus groups*, while requiring more resources and time than administrative data analysis, allow evaluation teams to more accurately, and with a higher degree of confidence, evaluate whether affected populations actually received and are aware of the distributed risk communication, and which channels of distribution were the most effective. Interviews can be carried out at one point in time or used to further refine and enhance the evaluation process. For example, Chakraborty and Löfstedt (2012) conducted 70 interviews across two major U.S. metropolitan areas considered to be representative for assessing public perceptions, to assess the FDA Adverse Event Reporting System (AERS). The interviews were modified based on analysis from preliminary findings, and revealed that awareness of AERS was low and it was viewed as inaccessible or confusing. Interviews do not have to strictly involve the public; they may also explore perceptions of risk communicators, regulators, industry, and others involved in risk communication dissemination.

Population-based surveys randomly sample the receivers of information or other relevant stakeholders to explore both delivery and receipt. Overall, the large sample inherent in these surveys can provide confidence in results; however, this method is resource and time intensive. Many surveys are conducted by third party market research companies to provide regulators and other government institutions with an independent assessment of reach. For example, the DBND program contracted an independent market research firm to assess program activities with an emphasis on awareness of the DBND media campaign related to antibiotic use. Based on an online survey of 1,002 B.C. residents, 71% of respondents were aware of promotional material, and 54% had seen a television advertisement about the program (Do Bugs Need Drugs?, 2014). Similarly, in 2003 and 2006, Health Canada commissioned surveys of healthcare professionals and the general public to assess the reach of certain health product risk communication tools, such as those related to drugs (Evaluation Directorate, 2014c). Among the healthcare professionals who responded, 54% were very or somewhat familiar with manufacturer-issued Dear Health Professional Letters (DHPLs, includes Dear Health Care Professional Letters and Notice to Hospitals) compared with 42% with Health Canada-issued DHPLs and 38% with Health Canada's online drug safety advisories. Across respondents from the public, only 36% were aware of Health Canada's website as a source of new safety information about drugs while 62% were aware of public advisories issued through the media (Evaluation Directorate, 2014c).

4.4 USE: MATCHING EVALUATION METHODS TO RELEVANT QUESTIONS

Key Findings – Use

- *Use* refers to how the information is considered, its timeliness, and the reactions and actions taken as a result of the communication.
- The relevant evaluation questions and methods for dimensions of use are listed below.

Dimensions	Evaluation Questions	Methods
Understand-ability	• What are the barriers (facilitators) that might prevent (support) understanding the message? • Was information sent in a way that overcomes barriers and leverages facilitators to understanding? • How does the information align with evidence-informed practices in communication and health literacy? • Is the information understood by those receiving the information? • Was awareness of the risk increased in the receivers of information?	• Textual analysis • Interviews and focus groups • Population-based surveys • Quasi-experiments
Timeliness	• How much time has elapsed between identification and dissemination? • What is the justification for this amount of time and is it based on reasonable grounds? • Did the senders and receivers of information and other stakeholder groups consider the risk communication timely to inform their decision-making and behaviour? How do expectations compare across these groups?	
Informed Decision-Making	• Did the receivers of information, both among the public and among healthcare professionals, seek the risk communication out? • Did the receivers of information feel that the communication provided meaningful information? • Did the risk communication contain messages that the receivers of information believe they can successfully carry out and were those messages believed to be successful for averting any harm? • Did the risk communication influence shared decision-making between healthcare professionals and the receivers of information?	
Behaviour	• Did the risk communication change the risk perceptions of the receivers of information? • Were there any changes in the preferences of the receivers of information (e.g., patients, healthcare professionals)? • Was information used by healthcare professionals and the groups that they work with? • Did the receivers of information change their behaviour or continue recommended desirable behaviour? • Was the risk minimized by actions based on specific recommendations from the risk communication?	

Evaluating the use of a risk communication requires gathering evidence on whether it influences the decision-making and behaviour of populations receiving the message (DFID, 2012; Mayne, 2012; McDavid *et al.*, 2013). It involves exploring many dimensions related to how the communication is understood or considered, its timeliness, and the reactions to and actions taken as a result of it. This kind of evaluation most closely matches process/implementation and outcome evaluation. Therefore, although it may be valuable to explore use retrospectively, it is most meaningful when undertaken during the implementation of a risk communication to provide insight into program fidelity and potential revisions to communication activities and goals. It is difficult to assess decision-making and behaviour, particularly informed refusal, and the subjective nature of dimensions such as timeliness. It follows that evaluating use mostly involves qualitative methods that explore the beliefs, values, and behaviours of the receivers of information (although quantitative approaches can be useful when there are clear indicators of behaviour change such as prescribing rates or drug use).

4.4.1 Dimensions and Evaluation Questions

Understandability

It is important to determine whether the messaging of the communication is understood by the receivers of information and other stakeholders. In the evaluations of health product risk communication tools identified in Chapter 3, understandability was one of the most common goals. Generally, these kinds of evaluations use interviews, surveys, and expert analysis to mostly measure indicators such as readability, clarity, and literacy. They assess both the tools themselves and the levels of comprehension of different groups receiving the information. As such, evaluations must explore the following questions:

- What are the barriers (facilitators) that might prevent (support) understanding the message?
- Was information sent in a way that overcomes barriers and leverages facilitators to understanding?
- How does the information align with evidence-informed practices in communication and health literacy?
- Is the information understood by those receiving the information?
- Was awareness of the risk increased in the receivers of information?

Timeliness

Timeliness refers to the degree to which an organization communicated relevant information within a suitable timeframe after a risk incident. It depends on the urgency, severity, probability, and uncertainty associated with a risk and the need to balance the speed of dissemination with establishing quality information. While timeliness can be measured as the elapsed time between a risk event

(identification) and a communication release (dissemination), timeliness can largely be a subjective notion for the senders and receivers of information and other stakeholders. As such, evaluations must explore the following questions:

- How much time has elapsed between identification and dissemination?
- What is the justification for this amount of time and is it based on reasonable grounds?
- Did the senders and receivers of information and other stakeholders consider the risk communication timely to inform their decision-making and behaviour? How do expectations compare across these groups?

Informed Decision-Making

An effective risk communication enables the receivers of information to make informed choices, including informed refusal, based, in part, on the information in a risk communication. This requires that the receivers of information seek out the risk communication and are able and willing to use that information in their personal risk management decision-making and self-care strategies. Informed decision-making can be assessed by exploring the beliefs and behaviours of the public and sub-populations that are affected by the messaging in question; however, it may also involve assessing other stakeholders who influence the shared decision-making process related to healthcare. As such, evaluations must explore the following questions:

- Did the receivers of information, both among the public and among healthcare professionals, seek the risk communication out?
- Did the receivers of information feel that the risk communication provided meaningful information?
- Did the risk communication contain messages that receivers of information believe they can successfully carry out and were those messages believed to be successful for averting any harm?
- Did the risk communication influence shared decision-making between healthcare professionals and the receivers of information?

Behaviour

As described in Chapter 2, risk behaviour depends on a range of factors. Fundamentally, a risk communication can induce behaviour change (or reinforce existing behaviour) if it influences the risk perceptions or knowledge of those receiving the information since both factors can change the way an individual understands the risk (relative to the benefit) of health product use. This can be observed directly by looking at rates of health product use or prescription rates for example, or by asking the receivers of information how a communication influenced their risk perceptions and subsequent behaviour. As with informed

decision-making, various populations (e.g., patients, healthcare professionals) that are affected by the risk communication are important to include when evaluating use. As such, evaluations must explore the following questions:

- Did the risk communication change the risk perceptions of the receivers of information?
- Were there any changes in the preferences of receivers of information (e.g., patients, healthcare professionals)?
- Was information used by healthcare professionals and the groups that they work with?
- Did the receivers of information change their behaviour or continue recommended desirable behaviour?
- Was the risk minimized by actions based on specific recommendations from the communication?

4.4.2 Relevant Methods

Of the numerous ways to evaluate use, the Panel noted four methods that vary in the evaluation questions answered and the resources required. *Textual analysis* evaluates understandability, by exploring the degree to which the content and design of a risk communication is accurate, clear, and well-presented in alignment with evidence-informed risk communication practices (recall Table 2.6). It typically involves experienced individuals using standardized tests or tools to compare various components related to understandability. For example, LeBrun *et al.* (2013) undertook Suitability Assessment of Materials (SAM) and readability tests on 46 Health Canada public advisories to determine the school grade reading equivalent needed to understand the advisories. In the end, it was determined that all of the assessed public advisories required "college/university education comprehensive" (LeBrun *et al.*, 2013). Similar methods can track improvements in the content and presentation of information over time in response to feedback. Although this method requires relatively few resources, they are also limited to expert analysis with little engagement opportunities with the people actually receiving the information.

Interviews and *focus groups* are the primary method to explore how a risk communication influenced decision-making. This is accomplished by asking the receivers of information about their understanding of a risk communication, its effect on their risk perceptions and knowledge, and its role in shaping their subsequent behaviour. Although this method typically involves fewer participants, a major advantage of well-conducted focus groups is that they generate rich in-depth data by providing a context in which the claims that people make about various issues, topics, or events (risk related or otherwise) are challenged and shaped collectively. This better represents the social and interactional ways through which people come to make sense of risks in their lives. These findings can then be combined with information from individual

interviews to provide a comprehensive assessment of how differing groups receive, make sense of, and use risk information. For example, Driedger *et al.* (2013) examined how First Nations and Métis perceived and responded to the public health management of pandemic H1N1. Focus groups were used to explore First Nation and Métis views around the identification of groups most at risk for H1N1, the safety and effectiveness of the H1N1 vaccine, and identification of priority groups to receive the vaccine. Different health decision-makers (e.g., public health officials, communicators, representatives from First Nations and Métis self-governing organizations) were also interviewed to understand and align their intentions with focus group findings. The evaluation demonstrated that risk communication practices have improved, but that one-size-fits-all communications are not effective, particularly when communicating to the groups most at risk. This underscores the need for communicators to account for "specific socio-economic, historical, and cultural contexts" of affected populations when planning, implementing, and managing communications (Driedger *et al.*, 2013).

Population-based surveys can explore self-reported use of risk information in decision-making and behaviour as well as perceptions around understandability and timeliness. The large sample allows evaluation teams to explore existing risk perceptions and knowledge and how they may change as a result of the communication. For example, Garbutt (2010), mailed a survey to 105 pediatricians and had 1265 parents complete a self-administered survey during a medical visit to evaluate the use of a 2008 FDA public advisory noting the dangers of using over-the-counter cough and cold products for children under 2 years old. Using both descriptive statistics and logistic regression, they found that among surveyed physicians, 100% were aware of the advisory, 75% agreed with the content, and post advisory, 35% were less likely to prescribe cough and cold products. In addition, across parents, 73% were aware of the advisory, 68% did not believe the products were dangerous, and post advisory, 21% of parents were more likely to request antibiotics in place of cough and cold products (Garbutt, 2010). Similarly, Bhatia *et al.* (2008) conducted a survey of 1521 prescribing clinicians to evaluate the effectiveness of 2004 FDA black box warning on SSRIs. They found that 97% were aware of the warning and that 16% and 37% decreased their prescribing frequency for children and adolescents, respectively (Bhatia *et al.*, 2008).

Quasi-experimental methods, using techniques, such as matching estimation and time-series analysis, to create statistical control groups enables the comparison of the receivers of information without needing to randomize the delivery of the communication (Gertler *et al.*, 2011). These methods can be used to assess behavioural changes in various populations (e.g., healthcare professionals, the public), using

metrics such as prescribing rates and actual drug use; however, their usefulness as an engagement tool is limited. Box 4.2 describes the use of quasi-experimental methods to assess use of risk communications involving SSRIs over time.

Box 4.2
Using Quasi-Experimental Methods to Assess Behaviour Changes

The link between use of SSRIs and the increased risk of suicide in young people has been debated for more than a decade (Breggin, 2004; Lu *et al.*, 2014). There has been conflicting evidence about the magnitude of such a link, but in the early 2000s regulators around the world deemed the risk great enough to warrant warnings. The MHRA in the United Kingdom first advised that children should not take the SSRI paroxetine (Cheung *et al.*, 2004) and later extended this advisory to all SSRIs, with the exception of fluoxetine. Health Canada (and the MAHs for these drugs) and the FDA released their own warnings that extra vigilance should be taken for children taking antidepressants (Breggin, 2004; Health Canada, 2004). A year later, the FDA issued another advisory and made it mandatory to include a black box warning outlining the risk in all communication materials for SSRIs (Breggin, 2004; Cheung *et al.*, 2004).

Research has been done in both Canada and the United States on the effectiveness of these risk communications on prescribing of SSRIs to children. In Ontario, a population-based, time series analysis of new prescriptions dispensed by the Ontario Drug Benefits plan (only available to low-income Ontarians) over a seven-year period found that the number of new prescriptions for all SSRIs did not change after the release of the warnings (Kurdyak *et al.*, 2007). This was true for all age groups (under 20 years old, 20 to 65 year-olds, and older than 65). The rate of prescriptions for paroxetine (the specific antidepressant named in the initial U.K. warning) did decrease by 54% for people under the age of 20 (Kurdyak *et al.*, 2007). A study of Manitoba youth found that following the advisories, the rate of prescriptions of antidepressants decreased for children and adolescents (aged 17 and under) and for young adults (aged 19 to 24) (Katz *et al.*, 2008). In the United States, there have been several studies on the impact of the FDA advisories and black box warnings on SSRI prescriptions. One quasi-experimental study found that after the FDA warning, relative changes in antidepressant use were negative in all groups (although the percentage of young adults and adults taking antidepressants remained relatively constant and there was only a slight initial decrease in the percentage of adolescents taking the drugs) (Lu *et al.*, 2014). An earlier study had also found that the percentage of children diagnosed with depression being prescribed antidepressants decreased after the advisories (Libby *et al.*, 2007). The number of pediatric diagnoses of depression also decreased following the warnings.

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It is difficult to link any changes observed to one regulator's specific advisory, given the media attention garnered by these warnings, which crossed borders. Even in cases where relationships can be observed (e.g., prescription rates going down after the warning), the nature of those relationships is very difficult to determine. While it may be the result of the warning, it may also be the result of reduced incidence of a disease, a change in consumer preferences, or economic factors. Greater understanding and learning comes from comparing and considering the study results together. The different studies, based on different outcome variables, were often confirmatory, and enriched the picture of what happened after the warning.

With sufficient resources and commitment, evaluation of the use of a health product risk communication and/or the process involved in its implementation can improve the future timeliness of the communication, its potential effect on decision-making and behaviour, and understanding of public expectations and confidence. The most successful evaluations of use typically involve combining the knowledge gained through the range of methods identified above, as demonstrated by Box 4.3.

Box 4.3
Evaluating Use to Improve Risk Communication

In 2013, Apotex sent notices of a recall of a single lot of Alysena™ 28, an oral contraceptive, to its wholesalers and distributors (RSI, 2013). The recall was in response to the identification of a problem in the packaging of the drug (i.e., more placebos pills than usual). Health Canada posted notice of the recall on its website five days later. The delays were due to Apotex initiating the recall before notifying the regulator, Health Canada's internal review process being interrupted by a weekend, and other factors. There was significant public concern about multiple dimensions of the recall, including the number of women at risk of becoming pregnant, the efficacy of the drug in general, and Health Canada's handling of the situation. These concerns were driven by media coverage of the recall, some of which contained only partial information (RSI, 2013).

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The criticisms and concerns spurred an investigation into Health Canada's handling of the recall and subsequent risk communication activities. Health Canada contracted a third party to carry out an evaluation of the events that occurred during the recall (RSI, 2013). The evaluation used a combination of methods: an archival analysis provided an understanding of the responsibilities and processes of industry and regulator groups during a recall and demonstrated what information was available from both industry and regulator groups, how it was presented, and when it was released; a textual analysis enabled an understanding of public reaction, confusion, and how information of the recall spread; and the individual interviews (anonymous) provided a timeline of when recall events occurred and regulator perceptions of the causes of public and media concerns (RSI, 2013). The use of different methods established a more complete picture of the events surrounding the recall and the challenges encountered, including the views and perceptions of Health Canada employees who were part of the process. Coordination of information from all risk communication players (e.g., Health Canada, industry, and the media) also enabled a more thorough evaluation of the situation.

The evaluation identified multiple areas where Health Canada could improve risk communication processes. For example, given that public expectations of performance and accountability exceeded the powers of Health Canada to regulate industry behaviour, better communication of the roles and responsibilities of different players and limitations facing Health Canada surrounding recalls could be useful. Other lessons involved clarifying/modifying the timing of recall notification requirements, and properly considering the social concerns surrounding a particular recall.

4.5 IMPACT: MATCHING EVALUATION METHODS TO RELEVANT QUESTIONS

Key Findings – Impact

- *Impact* refers to achieving a desired result with respect to various outcomes related to the senders and receivers of information and the relationship between them.
- The relevant evaluation questions and methods for dimensions of impact are listed below.

Dimensions	Evaluation Questions	Methods
Outcomes for Receivers of Information	• What individual and population health outcomes have improved as a result of the risk communication in the groups receiving the information and other stakeholders? • What individual and population health outcomes have worsened (i.e., unintended impacts) as a result of the risk communication in those same groups? • Have knowledge, attitudes, and perceptions advanced or changed as a result of the risk communication?	• Archival and administrative data analysis • Population-based surveys • Interviews and focus groups • Quasi-experiments • Natural experiments • Mixed methods
Outcomes for Senders of Information	• What organizational constraints hindered the risk communication? Did the risk communication make efficient use of financial and human resources? How did the organization overcome these constraints? • Did the receivers of information and other stakeholders trust the risk communication and how has it affected general perceptions of trust? • What was the effect of the risk communication on the credibility of the organization? • Did the receivers of information and other stakeholders view the risk communication as transparent and how has it affected general perceptions of transparency?	
Outcomes Related to Relationships Between Senders and Receivers	• Were there opportunities for those receiving information and other stakeholders to provide feedback? How were the receivers of information and other stakeholders engaged? • Did the sender of information receive that feedback and make use of it to improve the risk communication? • Did the receivers of information feel empowered by the risk communication? • How has the risk communication contributed to future communications and opportunities for cooperation?	

Impact or outcome evaluation is fundamentally intended to link the risk communication to particular short-, medium-, and long-term impacts and to explain how and/or why these impacts were achieved (DFID, 2012; Mayne, 2012; McDavid *et al.*, 2013). Evaluations thus generally explore questions such as "How much of the impact can be attributed to the intervention? [...] Did the intervention make a difference? [...] How has the intervention made a difference? [...] [And] will the intervention work elsewhere?" (DFID, 2012). The information needs and motivations of decision-makers most clearly shape the selection of a particular method for assessing impact (Kasperson & Palmlund, 1989). For example, an evaluation motivated by accountability may be more focused on demonstrating program fidelity and finding simple indicators that a risk communication worked. In such instances, archival or administrative data analysis or quasi-experimental methods are most applicable. However, evaluations motivated by transparency or program improvement would likely focus more on methods to build trust with the receivers of information and other stakeholders as well as gain more detailed and nuanced understanding of context and influencing factors. As such, drawing more heavily on interviews, focus groups, and population-based surveys may be more appropriate in these cases. Given the paradigm shift of modern risk communication (recall Chapter 2), which focuses on multi-way communication and the relationship between senders and receivers of information, the Panel concluded that dimensions for impact evaluation should also include relationships between these groups.

4.5.1 Dimensions and Evaluation Questions

Outcomes for the Receivers of Information

Outcomes related to the receivers of information comprise a range of individual- and population-level indicators of health status, exploring both quantitative and qualitative aspects, such as reported adverse events related to health products, hospitalizations, perceived wellness, and mortality and morbidity rates (CDC, 2006; Fischhoff *et al.*, 2011; Dusetzina *et al.*, 2012; Kreps, 2014). These outcomes are determined by a wide number of factors, many of which are outside both the sphere of control and the sphere of direct influence of a risk communication (Montague & Porteous, 2013). Factors such as lifestyle, demographics, socio-economic characteristics, and pre-existing risk perceptions will influence health outcomes in ways that are complex and difficult to predict. This makes the relationship between an outcome and a risk communication, and the nature of that relationship, difficult to fully establish and understand. In some cases, some methods can control for these factors (e.g., quasi-experimental methods); however, often evaluations need to articulate spheres of influence

and identify the contribution of a risk communication to outcomes in relation to other factors (Mayne, 2012; Montague & Porteous, 2013). As such, evaluations must explore the following questions:

- What individual and population health outcomes have improved as a result of the risk communication in the groups receiving the information and other stakeholders?
- What individual and population health outcomes have worsened (i.e., unintended impacts) as a result of the risk communication in those same groups?
- Have knowledge, attitudes, and perceptions advanced or changed as a result of the communication?

Outcomes for the Senders of Information

Outcomes related to the senders of information build on the information needs and motivations of the regulators and other government institutions: accountability, program improvement, and transparency. These institutions have a responsibility to the citizens they protect and want to be seen as a credible and respected information source. Beyond questions of internal efficiencies and improvement, assessing various organizational and corporate outcomes, such as trust, transparency, and credibility, over time and across a range of communication activities and events, can provide a clearer picture of success, failure, and opportunities for future improvement. This kind of self-reflection also contributes to a learning culture (Section 4.6.2) and can further position regulators and other government institutions as global leaders in the evaluation of health product risk communication. As such, evaluations must explore the following questions:

- What organizational constraints hindered the communication? Did the risk communication make efficient use of financial and human resources? How did the organization overcome these constraints?
- Did the receivers of information and other stakeholders trust the risk communication and how has it affected general perceptions of trust?
- What was the effect of the risk communication on the credibility of the organization?
- Did the receivers of information and other stakeholders view the risk communication as transparent and how has it affected general perceptions of transparency?

Outcomes Related to Relationships Between Senders and Receivers

The most effective risk communications often include multi-way and multi-level dialogue whereby the receivers of information and other stakeholders provide feedback, which is used by communicators to improve future risk communication. Communication is approached as a learning experience

where all parties involved interact and come away with new understandings and better connections to support future communication needs. Indicators of good relationships and functioning include: outcomes that relate to evidence of active listening and opportunities for feedback; empowerment of affected groups and stakeholders; and engagement, exchange, and cooperation. As such, evaluations must explore the following questions:

- Were there opportunities for those receiving information and other stakeholders to provide feedback? How were the receivers of information and other stakeholders engaged?
- Did the sender of information receive that feedback and make use of it to improve the risk communication?
- Did the receivers of information feel empowered by the risk communication?
- How has the risk communication contributed to future communications and opportunities for cooperation?

4.5.2 Relevant Methods

As the International Initiative for Impact Evaluation (2008) notes, "[r]igorous impact evaluation studies are analyses that measure the net change in outcomes for a particular group of people that can be attributed to a specific program using the best methodology available, feasible and appropriate to the evaluation question that is being investigated, and to the specific context." As argued throughout this chapter, evaluation should be tailored to evaluation questions and employ a range of methods, building on the relative strengths of each. Although a method on its own may not be sufficient to establish a relationship between the risk communication and a given outcome, combining the findings of several methods can lead to more comprehensive knowledge. It also helps better understand why an evaluation has impact, how meaningful it is to various groups, and the importance of contextual factors.

Archival and *administrative data analysis* can be used to evaluate outcomes for various senders and receivers of information. They can provide relevant information for accountability, improvement, and transparency; however, engagement is limited. The cost and human resources vary depending on the methods used to analyze data. Statistical methods range from simple descriptive statistics to more complex interrupted time series analysis, to link these outcomes to risk communications (Dusetzina *et al.*, 2012). This type of analysis can answer evaluation questions about whether a communication has led to improvements or identify unintended consequences when it results in negative outcomes over time (Piening *et al.*, 2012).

Population-based surveys can be used to evaluate all three dimensions of impact. They can be administered to the receivers of information, other stakeholders, and experts to collect information on health status and opinions on aspects related to credibility, transparency, empowerment, engagement, and trust (Evaluation Directorate, 2014c). The potentially large sample can lead to greater confidence in results; however, increasing sample sizes requires greater financial and human resources.

Interviews and *focus groups* can also evaluate all three dimensions of impact. Interviews or focus groups with the receivers of information, other stakeholders, and experts can explore how and why a risk communication led to health status outcomes, enhance credibility and transparency, and foster relationships. They can also provide information about why a communication was not successful. For example, Richardson *et al.* (2007) conducted focus groups with 35 health care professionals to evaluate the effectiveness of a 2004 FDA black box warning on depression treatment. They found that since treatment was constrained by "lack of availability of mental health resources in the community, feeling responsible for helping based on long-standing relationships with patients and families, and patient and family beliefs and preferences regarding treatment" most health care professionals were unable to change treatment options in line with the black box warning (Richardson *et al.*, 2007). Essential for improving future risk communications, these methods can be a key engagement strategy and the cost and human resources vary depending on the number of interviews and the size of focus groups.

Quasi-experimental methods can be useful because of their ability to enable the comparison of different groups without needing to randomize the delivery of the communication (Gertler *et al.*, 2011). These methods are most applicable for evaluating outcomes in the populations receiving information and provide evidence of impact that is relevant for accountability, improvement, and transparency purposes. For example, research has been done on the impact of SSRIs warnings (see Box 4.2) on several health-related indicators such as attempted and completed suicides and healthcare utilization in children and youth. A study of Manitoba youth found that following SSRI advisories, there was a decrease in the rate of ambulatory visits and an increase in the rate of completed suicides for children and adolescents (Katz *et al.*, 2008). Another quasi-experimental study found that after a similar FDA warning, there were relative increases in the psychotropic (i.e., mood altering) drug poisonings among adolescents and young adults, but no change in the number of completed suicides per 100,000 people for any age group (Lu *et al.*, 2014). These studies

also highlight the importance of acknowledging the limitations of empirical estimates, including data challenges and the reliability and validity of indicators chosen to measure real-world outcomes. For example, there was significant controversy around the results of Lu *et al.* (2014) because psychotropic drug poisoning was used as a proxy for attempted suicide (BMJ, 2014). While the author stated that this proxy was validated, several researchers questioned that conclusion and therefore the legitimacy of the study's findings (BMJ, 2014). The debate on this issue demonstrates the importance of being clear on the limitations of proxies used and, when relevant, the debate about their validity.

Natural experiments have gained popularity as method to evaluate public health interventions in general (Gertler *et al.*, 2011; Craig *et al.*, 2012; DFID, 2012). In the context of health product risk communication, natural experiments require situations where either aspects of the risk communication (e.g., content, design, and delivery) or the risk itself vary naturally across sub-populations, allowing for the creation of treatment and control groups. For instance, if different risk communications about the same risk were disseminated to affected populations in different provinces, an evaluation could compare outcomes for receivers of information in a naturally controlled manner. This provides strong evidence of impact and helps to account for factors that may influence the relationship between a communication and certain outcomes. This method is useful for accountability and to improve future risk communications. Box 4.4 provides examples of natural experiments based on variation in a risk and in risk communications.

Box 4.4
Using Natural Experiments to Evaluate the Impact of Risk Communications

Body mass index (BMI) screening with parental notification of weight status is a potential means of reducing pediatric obesity; however, there is disagreement on the merits of such communication (Institute of Medicine, 2005; U.S. Preventative Services Task Force, 2005). Madsen (2011) explored the effectiveness of these risk communications with a natural experiment. In California, while annual BMI screening is conducted in the fifth, seventh, and ninth grades by the majority of public schools, parental notification of the results is optional. This creates the treatment and control groups, screened/notified and screened/not notified, respectively. Administrative data from the California Department of Education (e.g., enrollment, BMI status, sex, ethnicity) was supplemented by structured telephone interviews with school districts, which provided data on notification rates and delivery channel: mailing a notification letter or sending it home with children. Using these data, Madsen (2011) tested whether notification in a given year impacts BMI z-scores two years later using a mixed-effects linear regression.* The researchers found that prior parental BMI notification in fifth and/or seventh grade did not lead to a change in the BMI of those children when they reached seventh or ninth grade and that there was no difference between the two delivery channels or across ethnicities. While these results may not be generalizable with other jurisdictions, this study provides evidence that parental notification of BMI screening results is a largely ineffective form of risk communication in California (Madsen, 2011).

Another example of the use of a natural experiment to evaluate the effectiveness of a risk communication is provided in Johnson and Luke (1987), who examined the impact of the Maine Medical Center (MMC) radon information pamphlet on both perceived risks and household mitigating behaviour. In this case, the differentiation between the treatment and control groups — both of whom received the pamphlet — was made on the basis of radon exposure level (i.e., objective risk). The treatment group consisted of households with high radon exposure while the control consisted of households with various radon exposure levels. Based on data collected through telephone interviews on pamphlet understandability, risk perceptions, risk mitigation, health and socioeconomic status, the study found: a statistically insignificant correlation between objective and perceived risk, with respondents understating the former by orders of magnitude; and no relationship between objective risk and the decision to mitigate/mitigation expenditure level. Together, these findings underscore that communicating "fairly technical information on health risk" will neither induce "accurate perceptions . . . [n]or protective measures" in the general public (Johnson & Luke, 1987).

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* Body mass index z-scores are measures of relative weight adjusted for sex and age. The mixed-effect includes a random effect for district "to account for repeated measures within districts over time and clustering of students within districts" (Madsen, 2011).

4.6 ENSURING EVALUATION HAPPENS

Key Findings

- Ensuring that evaluation evidence is meaningful, useful, and transparent demands institutional commitment, and sufficient financial and human resources — the biggest challenge to evaluation overall.
- Securing institutional commitment is a function of fostering and supporting a learning culture, demonstrating the value of evaluation relative to other spending priorities, standardizing communication appraisal tools, and encouraging learning and sharing of experiences from other jurisdictions.

While evaluation can help organizations achieve a wide range of objectives, the value of an evaluation is often the knowledge that it provides on how to improve future risk communication and build on proven success. Employing a range of methods helps ensure that the evidence collected is meaningful, useful, and transparent. Evaluation of this variety, however, demands institutional commitment, and sufficient financial and human resources.

4.6.1 Securing Institutional Commitment and Resources

There are at least two challenges to gaining commitment and resources: institutional resistance and organizational mandate. An evaluation may provide evidence that risk communications are ineffective, raising a quandary: should an organization be willing to show that it is committed to evaluation by revealing that it is falling short in its risk communication activities? Indeed, institutional resistance, apathy, and other characteristics have been identified as among the most common reasons for failing to evaluate (Jardine, 2008). Apathy towards evaluation often stems from concerns that a specific evaluation will assign blame if a communication did not meet its objectives (Interagency Task Force on Environmental Cancer and Heart and Lung Disease, 1991). This view of evaluations as tools for blame, rather than for learning, may contribute to them only being done when the results are likely to be positive or in cases of significant public outcry.

The extent to which evaluation is identified in an organization's mandate may either encourage or hinder its practice. For example, gaining commitment and resources is more challenging if a regulator has a mandate to communicate about health product risks, but no clear mandate to gather evidence about its effectiveness. As discussed in Chapter 3, this is partially the case in Canada.

Evaluation is explicitly recognized in Health Canada's communication framework, but there is no clear set of objectives, standards, or best practices for evaluation. Similarly, Health Canada provides guidance to industry about when and how to issue various risk communications (Health Canada, 2014d, 2014e), but not on how to collect data or evaluate these efforts. Regardless of whether the regulator or industry is responsible for initiating a health product risk communication, it may not be entirely clear whether it has an obligation to perform an evaluation of its effectiveness. The segmentation of health responsibilities between different government agencies and levels of government in Canada can also lead to confusion over who has responsibility for evaluation of health product risk communication.

4.6.2 Supporting and Fostering Evaluation

Fostering a Learning Culture

Developing a learning culture within organizations can help secure institutional commitment and resources (Barrette, 2012). In a learning culture, continuous learning is encouraged and facilitated to help the organization improve. To support a learning culture, a number of factors must be considered when evaluating, including the type of knowledge to be gained, the relevance of the evaluation, and the meaningfulness and credibility of evaluation results. Research on what leads to institutional resistance to evaluation, the consequences of this resistance on communication planning and implementation, and the value of establishing a learning culture can help to identify factors that will facilitate or hinder organizational commitment to evaluation in the future.

Demonstrating the Value of Evaluation

Governments face many competing demands and should show good value for money when using public dollars. With several spending priorities, some of which lead to short-term, visible, and politically advantageous effects, it is critical to demonstrate a return on public investments of any kind. In the case of evaluation, as noted, institutional resistance and organizational mandate can serve to undermine its perceived value (Interagency Task Force on Environmental Cancer and Heart and Lung Disease, 1991; Jardine, 2008). Even when value and responsibility are evident, undertaking evaluation is often perceived as too costly. Furthermore, finding appropriate evaluation experts for a given communication, whether internal or external, may be difficult (Interagency Task Force on Environmental Cancer and Heart and Lung Disease, 1991). Even if the necessary human resources are available, ensuring sufficient time for evaluation is important. For instance, undertaking an outcome evaluation after the completion of a risk communication may be seen as prohibitive, especially when an organization's focus has shifted to the

next risk to be communicated. Fischhoff *et al.* (2011) have classified a range of evaluation options according to their cost, showing that some evaluations are feasible even under constrained resources.

Improved knowledge and sharing experiences that demonstrate the value of evaluation can provide the foundation for sufficient and stable funding of evaluation as an integral part of risk communication. Specifically, evidence of the cost-benefit of various types of evidence and evaluation methods will enable decision-makers to determine the most appropriate and cost-effective evaluation to meet their needs.

Standardizing Risk Communication Appraisal Tools and Checklists

Recognizing that each evaluation will be different, standardizing appraisal tools or checklists can ensure that all risk communication tools meet certain minimum standards, but can also be more efficient and less resource intensive, thereby encouraging evaluation. While regulators have developed guidelines for the development of many of the established communication tools discussed in Chapter 3 (e.g., product monographs (Health Canada, 2014e)), there does not appear to be any widespread standardization of communication appraisal tools or checklists.

Standardized appraisal tools that promote minimum-quality criteria are in development in other health fields and may offer important lessons for communication of health product risk. For instance, research into a checklist of potential certification criteria for patient decision aids has been ongoing for some time (Elwyn *et al.*, 2006; Joseph-Williams *et al.*, 2013; Volk *et al.*, 2013). Patient decision aids are evidence-informed communication tools (e.g., pamphlets, videos, web-based information) that help individuals engage in decision-making about healthcare options. They are used when more than one medically reasonable option is apparent and the best choice depends on a patient's personal preferences (Stacey *et al.*, 2014). Generally, a decision aid helps people to: recognize that a decision needs to be considered and that the best choice depends on what matters most to them; understand their health condition, the available options, associated benefits, harms, probabilities, and scientific uncertainties; and implicitly or explicitly clarify the value placed on specific harms, benefits, and uncertainties.

Joseph-Williams *et al.* (2013) have identified criteria for preparing a checklist to evaluate decision aids by building on quality criteria previously established (Elwyn *et al.*, 2006, 2009) and refining these by consulting expert groups. The criteria are grouped into three categories: qualifying criteria that demonstrate that an intervention can be considered a decision aid; certification criteria that

demonstrate that a decision aid can be classified as less likely to be biased; and quality criteria that demonstrate that a decision aid can be considered strong (Joseph-Williams *et al.*, 2013). This type of checklist does not rate the science being communicated, but rather the communication effort itself. As Joseph-Williams *et al.* (2013) explains, "the proposed standards are designed to rate the quality of the development process and shared decision-making design elements, not the quality of the [patient decision aid's] clinical content."

The checklist approach could be modified for evaluation of the health product risk communication tools of regulators or other government institutions by drawing on the considerable scientific research on health risk communication practices (see Table 2.6 for examples). Checklists centred around effective communication practices (Fischhoff, 2011; Volk *et al.*, 2013) could help regulators to ensure that their communication tools are less likely to be biased and clearly present risk information using the practices supported by scientific research (e.g., using numbers instead of words). These checklists could be incorporated into the guidance documents and templates provided by Health Canada, and used to facilitate the approval of specific tools (e.g., a tool could be automatically rejected if it does not conform to the checklist). As the checklist would be standardized and relevant for all communication efforts, it could be implemented easily, with less time and fewer human and financial resources. The use of checklists also provides a way to compare different risk communications and tools and, when applied consistently, to support a learning culture.

Encouraging Peer Learning

As highlighted in Chapter 3, most jurisdictions share a similar set of risk communication tools. Given these similarities, there is potential for learning when evaluations use different methods to evaluate similar tools. A jurisdiction can take advantage of the diversity of knowledge and consistency of results without necessarily having to undertake mixed methods or multiple evaluations themselves. Moreover, comparing cases where the health product risk is similar, but the context or the communication is different, roughly creates natural experiments that provide the variation needed to draw more fulsome information on the relationships between a communication and certain outcomes. In general, since all jurisdictions face similar evaluation challenges, bringing together evaluation experts, risk communication researchers, regulators, and affected populations can help identify examples of strong evaluations and leading evaluation practices. Indeed, strong relationships and cooperation between different governance bodies and other groups, along with good planning that considers complicated governance structures, can more effectively support the development and dissemination of effective risk communications and their evaluation.

4.7 CONCLUSION

Effective risk communication requires understanding the nature of a risk, including how perception of the risk differs across various populations. This is complicated by the fact that the risk decision-making and information needs of varying groups are governed by a range of cognitive, demographic, and socio-economic factors that are difficult to understand, let alone control. A given risk communication exists within a surplus of additional information sources and disparate stakeholder concerns, and involves various institutions both inside and outside of government. Evaluating the effectiveness of a risk communication requires navigating through this complexity to determine if a single communication leads to change. There are many benefits of performing evaluation activities throughout the risk communication process and evaluation overall contributes to effectiveness of communication efforts.

The Panel found a limited number of publicly available evaluations of health product risk communication from which to glean best practices. Of the evaluations identified, all attempted to provide evidence that a risk communication was achieving certain goals (e.g., reach, use), but there was limited consistency in the measures of these goals and the application of methods to assess them. Effectiveness was sometimes measured using simple indicators like downloaded communication materials or changes in prescription rates, and other times measured using more complex qualitative explorations of timeliness or trust. In general, measurements were therefore specific to a given evaluation and varied greatly across evaluations. The story was similar for the application of different evaluation methods. There was no universal approach, and evaluations employed methods ranging from basic descriptive statistics to quasi-experimental methods and from a small number of interviews to extensive focus groups and population-based surveys. Ultimately, there is therefore no single approach to evaluation; different approaches and methods produce different kinds of evidence and require different levels of resources.

Given this relative dearth of evidence and the need for a tailored approach, the Panel suggests an overarching strategy for the evaluation of health product risk communications whereby evaluation methods are an extension of evaluation questions that take into account information needs, attributes, and goals. In general, the most valuable evaluations consider more than just the relationship between risk communications and their eventual outcomes. Rather, they also account for the information needs and motivations of regulators and government institutions communicating risk, receivers of risk information, and other stakeholder groups. Moreover, the right evaluation questions consider the attributes of the risk communication, including the type of communication tool, its stage of development, and most importantly, the goals of risk communication:

development, reach, use, and impact. Instead of jumping straight to a method, evaluations should ensure methods are an extension of evaluation questions that account for these information needs and risk communication attributes. Selecting an evaluation method then becomes a function of the evidence required to answer an evaluation question and the level of available resources. Evaluation conducted according to this premise will reveal the most meaningful information. Overall, a strong and dedicated focus on evaluation is needed throughout all stages of the risk communication process. Evaluation is most effective with sufficient resources and when embedded into the organizational culture of those communicating health product risk and when it engages relevant populations in appropriate aspects of the design, implementation, and use of the evaluation.

5

Conclusions

- What Types of Instruments/Tools Are Currently Available for Health Risk Communication?
- What Methodological Best Practices Can Be Used to Evaluate the Reach, Use, and Benefit of Health Risk Communication?
- What Research Could Be Done to Inform the Measurement of the Effectiveness of Risk Communications?
- What are the Existing Barriers to Effective Risk Communications and What Best Practices Exist to Address These Challenges?
- Final Reflections

5 Conclusions

Despite the barriers that can make the evaluation of health product risk communication challenging, the evidence is clear that there is tremendous value in undertaking such efforts. Proper evaluation is integral to risk communication activities and can aid in fulfilling regulatory and fiduciary obligations, demonstrating a commitment to transparency and accountability, and attaining an understanding of the strengths and weaknesses of risk communication efforts. Evaluation activities can improve decision-making and real-world applications of a communication and ultimately help to ensure the health and safety of the population. They can also help to improve content and processes, build trust and relationships, assess whether communications have achieved their objectives, and identify who is paying attention, what they are learning, and what impacts are occurring across a range of different groups. Without adequate study, not only is there potential for mistakes, but there is also the risk of missing opportunities to continue or build on proven successes. With dedicated resources, careful planning, and well executed evaluations, even the most complex communications can be evaluated in a meaningful way.

This chapter summarizes the evidence reviewed in Chapters 2 to 4, to answer the main charge to the Panel: *How can the effectiveness of health risk communications be measured and evaluated?* It is organized across the four sub-questions that make up the charge (Section 1.2), and provides the Panel's conclusions and final reflections. Although the report's focus is health products, the Panel intends lessons on evaluation and risk communication to apply to other types of risks.

5.1 WHAT TYPES OF INSTRUMENTS/TOOLS ARE CURRENTLY AVAILABLE FOR HEALTH RISK COMMUNICATION?

Health Canada's regulatory responsibilities and monitoring activities for health products are similar to that of the FDA (United States), MHRA (United Kingdom), TGA (Australia), and EMA (European Union). However, the authority granted to these regulators varies. For example, Health Canada has greater authority over regulation of natural health products than other regulators, but only recently gained the authority to issue a recall or demand a label change, like the TGA and MHRA. All five regulators have or are developing communication frameworks relevant for the communication of health product risks. The frameworks generally emphasize two-way communication, engagement with affected populations, and meaningful and accessible messaging for a range of groups. Some have even gone so far as to establish advisory councils and ongoing consultation mechanisms. Most frameworks also explicitly or implicitly discuss the importance of establishing quality relationships with the various populations receiving health

risk communications and other affected stakeholders as well as related objectives such as trust. While the frameworks recognize the importance of evaluating risk communication, the level of detail or guidance provided varies greatly. Based on the Panel's review of the evidence, it is unclear how evaluation and related outcomes are actually defined and how (if) evaluation is being carried out in practice across jurisdictions.

Given the similar communication frameworks and regulatory authority, it is not surprising that regulators have adopted similar tools for communicating health product risks. In general, health product risks involve known side effects, medication/medical device errors, product defects, and uncertainty in information. Tools used to communicate these risks can be classified as (i) ongoing communication, which disseminates information on known risks about a product; (ii) incident(s)-based communication, which disseminates information on newly discovered risks (or new information on known risks); and (iii) defect and error communication. Established risk communication tools aimed primarily at the public tend to describe risk in qualitative or general quantitative terms, use text exclusively, and lack colour and graphics showing risk, thereby ignoring important aspects of evidence-informed risk communication practices. The most common dissemination method is posting online, with the exception of inserts, which are included in the packages of many patent-protected medications (although not required in Canada). Tools aimed at healthcare professionals often contain more quantitative information than those aimed at the public and messages are disseminated in a greater variety of ways (e.g., mail, online, inclusion in journals or newsletters).

There are few publicly available and publicly conducted evaluations of established health product risk communication tools in any jurisdiction. Of the evaluations identified, most relate to the tools used by the FDA but, for the most part, they were done by academic researchers. The majority of the evaluations identified for ongoing communication focused primarily on indicators of understandability (e.g., readability) and user surveys, expert analysis, and public consultations. There does not appear to be any systematic needs assessment or pre-testing evaluations for any of the established tools. Most of the evaluations identified for incident(s)-based communication examined effectiveness in terms of use and impact after implementation and completion of the communication (outcome evaluations). These studies most often used medical or pharmacy claims (e.g., prescribing rates, new users) as indicators.

There are promising developments in risk communication that could shape the future of health product risk communication. These include work that is refining how the message is framed, changing the context in which risk communication is done, taking advantage of multi-media approaches and new mediums, and improving dissemination and access to data and evidence. Of these emerging tools, the Panel identified drug fact boxes, which refine the framing of the message, as the most promising. More research is needed, however, on their real-world applicability for varying populations.

Evaluation is important in the process of communicating health product risks, but done differently for different tools and purposes. For example, pre-testing data and measuring the initial impacts are important for emerging tools to optimize their design and delivery, and for established tools to see if they are ready for more outcome-oriented evaluation. Outcome evaluation is most suitable for established tools that are likely to be successful based on these initial evaluation efforts.

5.2 WHAT METHODOLOGICAL BEST PRACTICES CAN BE USED TO EVALUATE THE REACH, USE, AND BENEFIT OF HEALTH RISK COMMUNICATION?

Evaluation is essential to understand the extent to which a risk communication is achieving its goals, to improve future risk communication and related decision-making, to foster transparency, and to improve engagement with affected populations and other stakeholders. Sometimes evaluation methods are selected without properly understanding the context of a risk communication and the information needs and motivations of regulators and government institutions communicating risk, receivers of risk information, and other stakeholders. However, different evaluation methods produce a range of knowledge and have varying strengths and weaknesses, and therefore may be more or less applicable. There is also no universal way to evaluate a communication; different methods may be applied in different ways to address various situations, needs, and goals. It follows that careful planning efforts are therefore necessary to first determine the most relevant evaluation questions before choosing an evaluation method. The best questions result from identifying and integrating information needs and motivations and the attributes of the risk communication tool, including the communication goals. Selecting evaluation methods then becomes a function of the evidence required to answer an evaluation question and the level of available resources. Evaluation conducted on this premise and involving appropriate stakeholders will reveal the most relevant and meaningful information.

Evaluations should be shaped by the information needs and motivations of the senders and receivers of information. Regulators and other government institutions communicating health product risks may be interested in accountability, program improvement, or transparency. Alternatively, receivers of information may need to determine credibility and who to trust, feel engaged in the communication process, and feel empowered to use the information provided. Evaluation questions should also consider three main attributes of risk communication tools: type, stage, and goal.

Evaluations are influenced by the *type* of tool. For ongoing communication there is potential to conduct more systematic and comprehensive evaluation and engage affected populations and other stakeholders before, during, and after the evaluation. The time sensitivity of incident(s)-based communication implies that evaluation is often undertaken with less planning, is less comprehensive, and faces additional challenges in engaging different groups. Since it is delivered at a fixed point in time, there is a clear baseline from which to measure various goals and to use before and after comparison groups. This is not generally the case for ongoing communication tools since they are delivered in a more continuous manner. Finally, evaluation is more likely to be demanded for high-profile incident(s)-based communication. In these cases, transparency is critical, with regulators and other government institutions more interested in demonstrating that proper processes were followed than with measuring long-term impacts.

Evaluation varies across the *stages* of risk communication and is integral to the entire process. It is not simply an end-stage task following the completion of a communication. Four types of evaluation highlight the stages of risk communication and link to information needs and goals of risk communication:

- **Needs assessment:** undertaken to identify the information needs of the senders and receivers of information and other stakeholders. Its findings can increase the likelihood that a risk communication will be effective.
- **Pre-testing:** undertaken before the full implementation of a risk communication to preliminarily test the feasibility, appropriateness, and effectiveness of the identified communication tool in sub-groups. Its findings can lead to changes to the communication, which will further increase the likelihood that it will be effective.

- **Process/implementation:** typically undertaken during the implementation of a risk communication to provide evidence that it is progressing as planned. Its findings provide insight into potential revisions to implementation strategies, the need for reassessing goals and potential outcomes, and the potential value in conducting outcome evaluations in the future.
- **Outcome:** conducted after a risk communication has been disseminated and completed to link meaningful short-, medium-, and long-term outcomes to the tool in question. Although these are considered end-stage efforts, more rigorous evaluations usually establish a baseline prior to the implementation of the communication followed by ongoing measurement throughout implementation.

Different types of evaluation should be undertaken for different risk communication goals. These goals will ultimately align with information needs and motivations as well as other communication attributes to shape evaluation questions and determine appropriate methods. Goals are defined here and various dimensions for each goal are described in Table 5.1:

- **Development:** incorporating evaluation methods and learning into the steps involved in designing risk communications, including when characterizing and managing risk, creating messaging, and ensuring ongoing partnership and exchange.
- **Reach:** how and when the communication is sent and received and by whom.
- **Use:** how the information is considered, its timeliness, and the reactions and actions taken as a result of the communication, thus exploring understandability, timeliness, informed decision-making, and behaviour.
- **Impact:** achieving a desired result with respect to various outcomes related to the senders and receivers of information and the relationship between them.

Once evaluation questions have been established, approaches, and then specific methods, can be chosen that best provide the required evidence to answer those questions. This increases the likelihood that the evaluation will produce meaningful results. Numerous approaches can be employed in evaluation, ranging from simple to complicated and from quantitative to qualitative. The Panel identified the following approaches, and related methods, as feasible for regulators and other government institutions and highly relevant for health product risk communication:

- **Synthesis:** Methods include literature reviews, systematic reviews, and meta-analyses.
- **Records-Based:** Methods include textual, archival, and administrative data analysis.

- **Self-reported data:** Methods include interviews, focus groups, and population-based surveys.
- **Experimental:** Methods include quasi-experimental methods, natural experiments, and RCTs.
- **Mixed Methods:** This involves combining quantitative and qualitative methods from different approaches in the same evaluation.

Table 5.1 summarizes the relevant evaluation questions and methods (ordered from simpler to more complex) across the four goals of risk communication. The Panel found no clear best methodological practices to evaluate health product risk communication. There are, however, many promising methods, which if tailored to the type, stage, and goal of a risk communication, can provide strong evidence of effectiveness. Taken together, they can help design and re-design communications that are aligned with the needs of various affected populations, to account for and learn from past mistakes, and to continue or build on identified successes. Employing a range of methods to ensure that evaluation evidence is meaningful, useful, and transparent, however, demands institutional commitment and sufficient financial and human resources — the biggest challenge to evaluation overall.

Table 5.1

Key Points for Matching Evaluation Questions and Methods

Goal	Dimensions	Evaluation Questions	Methods
Development: incorporating evaluation methods and learning into the steps involved in designing risk communications	Characterizing and Managing Risk	• Who needs to receive the risk communication? • Who wants to receive the risk communication? • What needs to be communicated? • Who is the source of the risk information? • What is the accuracy and credibility of the evidence base?	• Literature review/ Systematic review/ Meta-analysis • Textual analysis • Interviews and focus groups • Randomized controlled trials • Mixed methods
	Creating Messaging	• What are the communication wants and needs of the receivers of information? • How do the receivers of information make sense of risk? • Will they understand the content? • What will the content look like (e.g., text, images, colour)? • Does the content address wants and needs? • How will the risk communication be disseminated? • Are the communication channels appropriate for all groups receiving the information?	
	Ongoing Partnership and Exchange	• What is the relationship between the sender and receiver of information? • How could that relationship change, stay the same, or be strengthened? • What is the best way to engage the receivers of information in the evaluation process? • How can the senders and receivers of information and other stakeholders be involved in the implementation of evaluation?	
Reach: how and when the communication is sent and received and by whom	Delivery	• Was the risk communication sent and to whom specifically?	• Administrative data analysis • Interviews and focus groups • Population-based surveys
	Receipt	• Did those groups receive the risk communication? • Are those groups aware of the risk communication?	

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Goal	Dimensions	Evaluation Questions	Methods
Use: how the information is considered, its timeliness, and the reactions and actions taken as a result of the communication	Understandability	• What are the barriers (facilitators) that might prevent (support) understanding the message? • Was information sent in a way that overcomes barriers and leverages facilitators to understanding? • How does the information align with evidence-informed practices in communication and health literacy? • Is the information understood by those receiving the information? • Was awareness of the risk increased in the receivers of information?	• Textual analysis • Interviews and focus groups • Population-based surveys • Quasi-experiments
	Timeliness	• How much time has elapsed between identification and dissemination? • What is the justification for this amount of time and is it based on reasonable grounds? • Did the senders and receivers of information and other stakeholder groups consider the risk communication timely to inform their decision-making and behaviour? How do expectations compare across these groups?	
	Informed Decision-Making	• Did the receivers of information, both among the public and among healthcare professionals, seek the risk communication out? • Did the receivers of information feel that the communication provided meaningful information? • Did the risk communication contain messages that the receivers of information believe they can successfully carry out and were those messages believed to be successful for averting any harm? • Did the risk communication influence shared decision-making between healthcare professionals and the receivers of information?	

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Goal	Dimensions	Evaluation Questions	Methods
	Behaviour	• Did the risk communication change the risk perceptions of the receivers of information? • Were there any changes in the preferences of the receivers of information (e.g., patients, healthcare professionals)? • Was information used by healthcare professionals and the groups that they work with? • Did the receivers of information change their behaviour or continue recommended desirable behaviour? • Was the risk minimized by actions based on specific recommendations from the risk communication?	
Impact: achieving a desired result with respect to various outcomes related to the senders and receivers of information and the relationship between them	Outcomes for Receivers of Information	• What individual and population health outcomes have improved as a result of the risk communication in the groups receiving the information and other stakeholders? • What individual and population health outcomes have worsened (i.e., unintended impacts) as a result of the risk communication in those same groups? • Have knowledge, attitudes, and perceptions advanced or changed as a result of the risk communication?	• Archival and administrative data analysis • Population-based surveys • Interviews and focus groups • Quasi-experiments • Natural experiments • Mixed methods

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Goal	Dimensions	Evaluation Questions	Methods
	Outcomes for Senders of Information	• What organizational constraints hindered the risk communication? Did the risk communication make efficient use of financial and human resources? How did the organization overcome these constraints? • Did the receivers of information and other stakeholders trust the risk communication and how has it affected general perceptions of trust? • What was the effect of the risk communication on the credibility of the organization? • Did the receivers of information and other stakeholders view the risk communication as transparent and how has it affected general perceptions of transparency?	
	Outcomes Related to Relationships Between Senders and Receivers	• Were there opportunities for those receiving information and other stakeholders to provide feedback? How were affected populations and other stakeholders engaged? • Did the sender of information receive that feedback and make use of it to improve the risk communication? • Did receivers of information feel empowered by the risk communication? • How has the risk communication contributed to future communications and opportunities for cooperation?	

5.3 WHAT RESEARCH COULD BE DONE TO INFORM THE MEASUREMENT OF THE EFFECTIVENESS OF RISK COMMUNICATIONS?

It is clear that evaluations need to explore a range of outcomes to inform risk communication, across development, reach, use, and impact goals. While this is sometimes done for risk communication in general, there is a big gap in health product specific studies. Health product risk communication has unique challenges (e.g., multi-jurisdictional responsibility, the need for ongoing and incident(s)-based communication) that could provide valuable knowledge to the larger field of risk communication. Conducting health product specific studies more regularly in the future would build the evidence base and confirm whether the general learning from other relevant fields (e.g., decision science, public health evaluation) is indeed transferable.

Evaluation is not simply about establishing metrics; often a detailed understanding of context and qualitative elements is needed. With this in mind, there are several gaps in the measurement of effectiveness, related to outcomes and indicator development, which could benefit from future research and guidance:

- **Standardization and application:** The evidence indicates that many complex ideas could be a part of a risk communication evaluation including shared decision-making, informed decision-making, empowerment, quality relationships, cooperation, trust, and credibility. However, the literature is unclear on the best ways for regulators to effectively measure these complex ideas in the case of health products and health product communication. There is also a need for further prioritization and standardization of these key concepts. Even in cases where standardization may be clearer, how to best operationalize and apply those concepts in the evaluation process is still a major challenge.
- **Reliability and validity of indicators:** Research demonstrates that even with concrete goals and a clear idea of relevant and meaningful outcomes, it may be difficult to collect indicators that are sufficient proxies for these outcomes. Indicators must be reliable to the extent that they consistently represent the same outcome when repeatedly used across different situations and over time. They must also be able to represent what they are intended to represent, and be precise, accurate, and comprehensive in scope. It appears that for many outcomes related to behavioural change, and to development, reach, use, and impact more generally, there is little consensus on which indicators are truly valid, reliable, and comprehensive over time, particularly in the context of health product risk communication.

- **Integration across disciplines:** Multiple theories exist in the literature around how people make decisions in risky situations. Some literature attempts to combine the learning from these fields into evidence-informed communication practices; however, better measurement and integration of key concepts from across disciplines would ensure interdisciplinary learning and better communication and evaluation practices.

Across different evaluations, when measuring health product specific outcomes, those conducting the evaluation must work with a range of administrative data, and often with very personal health information. While new forms of media including Facebook, Twitter, and other forms of social media present new opportunities for communication and evaluation, they also create a wealth of new privacy concerns. Ethical standards relating to the use of big data, sharing of personal health information, and privacy can also vary across jurisdictions (e.g., in Canada across provinces and territories and among federal bodies). In the future clear ethical standards are needed to enable evaluations to use such information while maintaining individual privacy. This guidance must be dynamic and responsive to changes over time.

Similarly, further research is needed on practices for engaging the various populations that receive health product information and other relevant stakeholders, and in fostering transparency in both communication and evaluation. Future evaluation attempting to engage different groups would benefit from definitive research that explores how best to engage, when to engage, and who to engage in the context of health products specifically. Answers to these questions would enable those doing risk communication and evaluation to better empower the receivers of information and develop meaningful, long-lasting relationships. In addition, examining ways to share results to foster transparency and trust would improve the use of evaluation findings in decision-making. This is closely linked to the communication of uncertainty. Further research is needed on promising ways to communicate uncertainty, when it matters, and when it can be harmful.

5.4 WHAT ARE THE EXISTING BARRIERS TO EFFECTIVE RISK COMMUNICATIONS AND WHAT BEST PRACTICES EXIST TO ADDRESS THESE CHALLENGES?

Risk communication has evolved, from initial formulation as educating the public with accurate scientific information, to paternalistic persuasion, to a paradigm shift that recognizes ongoing partnership and exchange. All three views inform contemporary risk communication and demonstrate that

there is no one-size-fits-all approach to communication or its evaluation. Recognizing this diversity, evidence-informed practices related to effective risk communication typically involve:

- characterizing risk with larger context and population needs in mind;
- focusing on the importance of presentation and employing strategies for making information accessible and clear, accounting for literacy and numeracy, and addressing influence of framing effects, emotional responses, core values, and the ways that individuals process information;
- ensuring ongoing partnership and multi-level/multi-way communication that takes into account multiple concerns, factors, and needs at varying socio-economic levels;
- committing to sustained communication and relationships that evolve and change when new information is available;
- developing communications to be open, transparent, and honest about the level of (un)certainty and the evidence that is guiding decisions; and
- embedding evaluation in the planning and implementation of risk communication and not leaving it as an end-stage task.

Recognition of the importance of an ongoing and strong relationship between the senders and receivers of risk communication and other stakeholders has led to an emerging paradigm that builds on the learning from the past to address new challenges relevant for evaluation of health product risk communication:

- **Governance:** addressing the challenges that stem from shared responsibility within the risk management and communication environment.
- **Complexity:** navigating the inherent complexities of the risk and the communication environment that comprises multiple players and priorities.
- **Uncertainty:** communicating uncertainty and multiple interpretations of the evidence.
- **Empowerment:** moving from providing prescriptive statements to enabling solutions and empowerment.
- **Timeliness:** ensuring timely and proactive responses that build trust over time.
- **Transparency:** ensuring reasoned transparency that increases the public's access to and ability to understand health information.

The complicated governance around health products in Canada includes all three levels of government, industry, and many other groups. This shared responsibility for risk communication and evaluation demands establishing roles and responsibilities for the exchange of information, planning and coordination of communications, and strong relationships and cooperation between different senders and receivers of information and other stakeholders. It also means navigating the sometimes competing motivations of regulators and other groups. Depending on the nature of the situation, regulators

must facilitate cooperation and coordination between groups while at other times compel and act independently of those groups. Within such shared governance structures it can be challenging to gain institutional commitment and resources for evaluation. Factors that could address this key challenge include: (i) fostering a learning culture; (ii) demonstrating the value of evaluation relative to other spending priorities; (iii) standardizing communication appraisal tools and checklists to limit resources needed, improve comparability, and make evaluation more routine; and (iv) encouraging peer learning and sharing of experiences across jurisdictions.

Risk communication is an inherently complex exercise. Beyond the involvement of multiple players and mediums for communication that may play dual roles of sender and receiver of information at any given point, there are also inherent complexities associated with risk itself. This complexity stems from the hazards, the probabilities and uncertainties in the effects, the interactions between effects, and other political, ethical, economic, and social dimensions. The complicated environment for health product risk communication therefore requires coordination, collaboration, and ongoing dialogue between many different groups. Furthermore, the complexity associated with risks themselves needs to be considered and acknowledged when developing and disseminating risk communications.

Although there is sometimes debate about the best way to present uncertainty, it is an important consideration for any risk communication. It depends on the type of uncertainty and the objectives of the communication. Communicators must therefore distinguish the type of uncertainty associated with a given risk and present uncertainties in a manner that supports decision-making. Although further research is needed on best practices (i.e., when it matters and when it can be harmful), evidence suggests that communicating uncertainty can often help get the message through and build the trust and relationships needed for ongoing exchange. Improved evaluation can help reduce the challenges associated with uncertainty by creating a strong evidence base. Evaluations that integrate and use different data sets and methods would improve reliability and reduce uncertainty of the evidence.

Empowerment of individuals to make informed decisions (i.e., to support existing behaviours in line with recommendations, to change behaviour, or to make an informed refusal) involves messaging appropriate for understanding and comprehension as well as for effective and meaningful dialogue. It is an important way to mitigate or avoid negative responses from populations receiving information. Within the context of communication this means collaborating with and empowering individuals, communities, and various affected groups

to act as platforms for further coordinated communication efforts. Within the context of evaluation, this involves engaging affected populations and other relevant stakeholders as members of the decision-making process at all stages of a continuous and ongoing evaluation process, thereby focusing on long-term relationships. Those sending and evaluating a risk communication must also respect informed individual decisions that may go against messaging. Empowerment during evaluation can help build strong relationships over time, which can support the proactive and timely delivery of future communications in the face of new risks.

While what is considered timely will be different for each risk communication situation, communicators can lay the groundwork to ensure that they are able to respond to risks quickly. Having clear guidelines and established relationships can enable organizations to act proactively in the face of new risks. In addition, using new communication sources such as social media to strengthen relationships and engage with affected populations can help set a strong foundation to deal with future risk situations. Similarly, the public and policy-makers around the world are increasingly recognizing the importance of transparency for governments, industry, and other communicators of risk. Reasoned transparency moves beyond simply releasing large amounts of data and increases the public's ability to access and understand health information. It can build empowerment, trust, and relationships between the senders and receivers of information. When done effectively, it can also lay the groundwork for timely communication efforts by striking a balance between openness, on the one hand, and urgency and confidentiality, on the other.

5.5 FINAL REFLECTIONS

The evaluation of health product risk communication is rare. The complexities associated with health products, and the scarcity of dedicated resources, make this type of evaluation challenging. It is, however, no more difficult than the evaluation of other health interventions, which also have a unique set of challenges. That the Panel found a dearth of publicly available evaluations should not be taken as evidence that these evaluations lack real-world importance. In fact, failing to evaluate can be a dangerous oversight since ineffective communication may lead to negative health outcomes and erosion in the credibility and trust of those who communicate. Moreover, the lack of guidance and consensus does not diminish the need for evaluative efforts using available principles and knowledge.

Like other regulators and government institutions around the world, Health Canada has the opportunity to conduct and publicly release more evaluations on health product risk communication and to engage relevant stakeholders in the process. While this assessment has outlined a range of methods, some of which require significant time and resources, the Panel firmly believes that even a minimal evaluation can provide benefits. With commitment and sufficient resources, however, Health Canada could become a world leader in the area, conducting relevant, well-planned, comprehensive, systematic, and rigorous evaluations that apply appropriate and best available methods. A commitment to publicly accessible and publicly conducted evaluations would put Health Canada ahead of the curve on open government policy, which is an apparent global trend. Overall, the Panel believes that there is significant room for improvement in the volume and quality of evaluations on health product risk communication, conducted both in Canada and elsewhere. While there are numerous challenges, even when taken together, they are far from insurmountable. Evaluation can fundamentally improve the health of Canadians, now and in the future. Engaging in the challenges associated with evaluation is therefore worth the effort.

Appendix A
Relevant Evaluation Approaches for Health Product Risk Communication

Appendix A Relevant Evaluation Approaches for Health Product Risk Communication

This appendix provides a basic overview of the types of knowledge gained, advantages, and challenges associated with key evaluation approaches, and their constituent methods. As Chapter 4 notes, the Panel categorized evaluation methods in five broad approaches:

- **Synthesis:** Methods include literature reviews, systematic reviews, and meta-analyses.
- **Records-based:** Methods include textual, archival, and administrative data analysis.
- **Self-reported data:** Methods include interviews, focus groups, and population-based surveys.
- **Experimental:** Methods include quasi-experimental methods, natural experiments, and RCTs.
- **Mixed methods:** This involves combining quantitative and qualitative methods from different approaches in the same evaluation.

These approaches vary in complexity and in how data is collected and used (i.e., employing qualitative and quantitative methods). They also vary in the extent to which receivers of information and other stakeholders participate in data collection (e.g., self-reporting the effects of risk communication or acting as participants in a controlled RCT). The Panel organized the numerous available methods based on what they felt was feasible for regulators and other government institutions and relevant for health product risk communication. The list is therefore not meant to be exhaustive and there are numerous classification schemes in the literature that interested readers are encouraged to consultant (Fischhoff *et al.*, 2011; HM Treasury, 2011; Owen, 2011; DFID, 2012; McDavid *et al.*, 2013; Kreps, 2014; Lance *et al.*, 2014; Web Center for Social Research Methods, n.d.).

Synthesis Approaches

A synthesis of the relevant literature enables the evaluation team to use previous research to provide valuable insight into the communication being evaluated (DFID, 2012; Dusetzina *et al.*, 2012; Piening *et al.*, 2012; Stacey *et al.*, 2014). In general, a literature review consists of reviewing academic and grey literature for past research associated with a risk communication. This may suggest testable hypotheses, methodological challenges, and pertinent evaluation issues. Overall, a literature review is an economical and efficient way of collecting the initial evidence that can inform the development and implementation of an effective risk communication. Other more detailed methods include systematic reviews

and meta-analyses. While synthesis related methods can help provide the evidence about a given risk communication or its evaluation, it may not be relevant for a particular context given they are inherently retrospective.

Records-Based Approaches

Records-based approaches consist of: textual, archival, and administrative data analysis. Textual analysis examines language, numbers, symbols and non-verbal cues through observational research methods (e.g., content analysis, rhetorical criticism, interaction analysis, discourse analysis) in order to describe and interpret the features of visual or auditory messages (Frey, 2000; Kreps, 2011). Evaluation using textual analysis is usually conducted with existing texts, such as archival records, books, newspapers, videos, and websites that are not produced, or influenced by the evaluation team (Hoff & Witt, 2000; Kreps, 2011). This implies that the data generated from textual analysis is unlikely to suffer from response bias (Kreps, 2011). Nonetheless, evaluations should carefully gather representative texts, and establish coding strategies that are valid and reliable (Frey, 2000; Kreps, 2011).

Archival and administrative data analysis consists of using statistical tools to present and interpret data that are collected for and about a communication. An evaluation can review program files that provide information on scope and cost of the communication, characteristics of participants, outcomes of participants, and project management. A review of program files can provide valuable background data on the program design, context, and results, and offer a useful starting point for further data gathering. In some cases, the data needed to accurately evaluate may not be available or practical to collect. In emergency risk communication situations, for example, the communication and its success depend on the rapidity of disseminating the message, precluding the ability to collect baseline data from participants, and limiting the choice of indicators to assess its effectiveness (Interagency Task Force on Environmental Cancer and Heart and Lung Disease, 1991). Policies that limit an organization's ability to gather information from the public may also be a barrier to collecting data (Interagency Task Force on Environmental Cancer and Heart and Lung Disease, 1991). This is an issue of particular relevance in the health field, as sensitive patient health data are confidential and may be made available only in certain circumstances, constraining the data available for evaluations (CCA, 2015). Finally, there may also be uncertainty in the data or incomplete datasets as a result of constraints in the data collection mechanism.

Self-Reported Data Approaches

Self-reported data approaches consist of population-based surveys (which can be qualitative or quantitative), focus groups, and interviews. Surveys are a systematic way of collecting data on the attitudes, beliefs, and activities of varying populations at various time points in a risk communication. There are several types of surveys described in the literature, including face-to-face and telephone-based interviews, and paper-and-pencil and computer-delivered questionnaires. The use of computer-assisted telephone interviewing equipment (CATI) provides access to populations over a large geographical area, and helps to automate entry and analysis of data (Kreps, 2011). However, diminishing response rates to telephone surveys threaten the representativeness of data gathered (U.S. Cancer Statistics Working Group, 2004 as cited in Kreps, 2011).

Focus groups (and qualitative methods generally) do not strive for reliability in the manner of quantitative research, but rather are more concerned with questions of validity (King *et al.*, 2004; Ulin *et al.*, 2004). Although this typically involves fewer participants, a major advantage of well-conducted focus groups is that they generate rich in-depth data by providing a context in which the claims people make about various issues, topics, or events (risk related or otherwise) are challenged and shaped collectively. This better represents the social and interactional ways through which people come to make sense of risks in their lives. Individual interviews provide the best mechanisms for eliciting a rich, deep understanding because there are better opportunities for exploring nuances in a more fulsome way, but the trade-off is that even fewer people can be engaged and it loses the socially contingent nature of how people make sense of risk issues. Surveys, by comparison do not necessarily probe the social dimensions of risk decision-making nor provide the deep contextual understanding of focus groups and individual interviews. The advantage of surveys however is that they often reach a greater number of participants and can be representative of a larger group of perspectives; although, these data tend to be fairly superficial and often do not explain why people respond the way they do. Surveys require samples to be more carefully constructed than focus groups and individual interviews, particularly if it is aiming for a random representative sample as opposed to a purposive sample. All of these different data collection methods involve significant human resources and complex data analysis, although the resource intensity and analysis complexity can vary depending on the needs of those conducting the evaluation.

Experimental Approaches

Experimental approaches assign participants to a treatment or control group. In principle, the only difference between these two groups should be the communication (TBS, 1998; Gertler *et al.*, 2011). These approaches typically

measure both the baseline and the final outcomes, ultimately seeking to show a causal link between the communication and its outcomes. One such method, RCTs, are very popular in impact measurement studies in international public health interventions (Gertler *et al.*, 2011; DFID, 2012) and elsewhere (CCA, 2013). In practice, it is difficult to create perfect equivalence between the treatment and control group given there are always some differences because of natural variation among participants (Cartwright & Munro, 2010). Three types of randomized control group designs are discussed in the literature. Classical randomized comparison groups consist of randomly assigning participants to treatment and control groups and taking measurements before and after the intervention (TBS, 1998; Shadish *et al.*, 2002). Post-program randomized comparison groups also consist of randomly assigning participants to treatment and control groups; however, measurements are taken only after the intervention. While this minimizes testing bias, there may be differences between treatment and control groups before the intervention. Lastly, randomized block and Latin square entails dividing the population into treatment and control groups by at least one control variable that is expected to influence the impact of the intervention (e.g., gender, urban-rural) (TBS, 1998). This approach can be used for small samples, but there is the possibility of selection bias (Shadish *et al.*, 2002).

Quasi-experimental methods use comparison groups to make causal inferences; however, unlike RCTs, they do not use randomization to create treatment and control groups (Grimshaw *et al.*, 2000; Shadish *et al.*, 2002; Gertler *et al.*, 2011; DFID, 2012; CCA, 2013; Penfold & Zhang, 2013). Instead they use statistical approaches to create a control group that matches the treatment group as much as possible. Two quasi-experimental methods are discussed here: matching estimation and regression discontinuity design (RDD). Matching estimation finds non-participants that are statistically similar enough to participations to create a reliable control group using information on individual characteristics (e.g., demographic, socio-economic, cultural) (Gertler *et al.*, 2011). This technique can be used to evaluate almost many different kinds of interventions including risk communications (Dehejia & Sadek, 1999); however data requirements are significant (Todd, 2008). RDD ranks individuals according to criteria, usually individual characteristics, and uses a threshold to create a control group (Gertler *et al.*, 2011; CCA, 2013). It is assumed that around this threshold, individuals have enough similarity that it mimics randomization.

Natural experiments require capturing the experience of implementing a risk communication that affects some individuals but not others (Gertler *et al.*, 2011; Craig *et al.*, 2012; DFID, 2012). For instance, it could involve monitoring the experience of implementing a similar risk communication in two communities that differ from one another or it could involve capturing how two different communications compare if implemented in similar communities. Natural experiments therefore do not control what groups get what communications, or in other words, there is no random assignment. In many cases, the communication affects only a sub-group of individuals (Gertler *et al.*, 2011; CCA, 2013).

Mixed Methods Approaches

No single approach or method can answer all evaluation questions and each will have their own particular strengths, weakness, and knowledge gained (DFID, 2012). *Mixed methods* refers to combining several of the methodological tools described in this section (that are both quantitative and qualitative) in the same evaluation (King *et al.*, 2004; Ulin *et al.*, 2004; Lieberman, 2005; Creswell & Clark, 2010). Mixed methods is an extremely relevant approach when evaluating complex health interventions and risk communications because it combines two or more of the other methods (e.g., RCT and survey, textual analysis and focus groups) therefore providing the greatest range and diversity of evidence. When the evidence collected from different approaches is consistent, confidence in the findings increases. When the evidence is inconsistent across the different approaches, this helps identify gaps and sources of error in the evaluation. Mixed methods evaluation can create a more comprehensive picture of the influence of a communication on subsequent outcomes over time.

References

References

Abraham, T. (2009). Risk and outbreak communication: Lessons from alternative paradigms. *Bulletin of the World Health Organization, 87*(8), 604-607.

Akl Elie, A., Oxman Andrew, D., Herrin, J., Vist Gunn, E., Terrenato, I., Sperati, F.,... Schünemann, H. (2011). Using alternative statistical formats for presenting risks and risk reductions. *Cochrane Database of Systematic Reviews, 16*(3), CD006776.

Alaszewski, A. (2005). Risk communication: Identifying the importance of social context. *Health, Risk & Society, 7*(2), 101-105.

Anonymous. (2014). Use of social media to meet FDA's risk communication requirement. *Reactions, 1493*(1), 3.

Australian Prescriber. (2014). What We Do. Retrieved July 2014, from http://www.australianprescriber.com/about-us/what-we-do.

Babbage, M. (2009, October 16). Conflicting Advice Offered to Pregnant Women on H1N1 Vaccine, *Winnipeg Free Press*.

Bahri, P. (2010). Public pharmacovigilance communication. A process calling for evidence-based, objective-driven strategies. *Drug Safety, 33*(12), 1065-1079.

Barbui, C., Baschirotto, C., & Cipriani, A. (2011). EMA must improve the quality of its clinical trial reports. *BMJ, 342*, 1-5.

Barrette, J., Lemyre, L., Corneil, W., Beauregard, N. (2012). Organizational learning facilitators in the Canadian public sector. *International Journal of Public Administration, 35*(2), 137-149.

Baseman, J. G., Revere, D., Painter, I., Toyoji, M., Thiede, H., & Duchin, J. (2013). Public health communications and alert fatigue. *BMC Health Services Research, 13*, 295.

Bennett, P., Calman, K., Curtis, S., & Fischbacher-Smith, D. (Eds.). (2011). *Risk Communication and Public Health, 2nd Edition*. Oxford, United Kingdom: Oxford University Press.

Berriet-Solliec, M., Labarthe, P., & Laurent, C. (2014). Goals of evaluation and types of evidence. *Evaluation, 20*(2), 195-213.

Bhatia, S. K., Rezac, A. J., & Vitiello, B. (2008). Antidepressant prescribing practices for the treatment of children and adolescents. *Journal of Child and Adolescent Psychopharmacology, 18*, 70-80.

BMJ. (2014). Changes in Antidepressant Use by Young People and Suicidal Behavior After FDA Warnings and Media Coverage: Quasi-Experimental Study. All Rapid Responses. Retrieved November 2014, from http://www.bmj.com/content/348/bmj.g3596/rapid-responses.

Boerner, F., Keelan, J., Winton, L., Jardine, C., & Driedger, S. M. (2013). Understanding the interplay of factors informing vaccination behavior in three Canadian provinces. *Human Vaccines and Immunotherapeutics, 9*(7), 1477-1484.

Bonari, L., Koren, G., Einarson, T. G., Jasper, J. D., Taddio, A., & Einarson, A. (2005). Use of antidepressants by pregnant women: Evaluation of perception of risk, efficacy of evidence based counseling and determinants of decision making. *Archives of Women's Mental Health, 8*(5), 214-220.

Bostrom, A. (1997). Vaccine risk communication: Lessons from risk perception, decision making and environmental risk communication research. *Risk: Health, Safety & Environment, 8*, 173-200.

Bouder, F. (2011). *Benefit/Risk Communication by the European Medicines Agency: A Study of Influential Stakeholders' Expectations and Attitudes*. London, United Kingdom: European Medicines Agency.

Bowen, S. (2012). *A Guide to Evaluation in Health Research*. Ottawa (ON): Canadian Institutes of Health Research.

Brainard, C. (2011). Mixed Grades for Medical Coverage. Retrieved June 2014, from http://www.cjr.org/the_observatory/mixed_grades_for_med_coverage.php.

Breggin, P. R. (2004). Recent U.S., Canadian and British regulatory agency actions concerning antidepressant-induced harm to self and others: A review and analysis. *International Journal of Risk Assessment and Management, 16*, 247-259.

Bruine de Bruin, W., Downs, J. S., & Fischhoff, B. (2007). Adolescents' Thinking about the Risks of Sexual Behaviors. In M. C. Lovett & P. Shah (Eds.), *Thinking with Data*. Mahwah (NJ): Erlbaum.

Bruine de Bruin, W. & Bostrom, A. (2013). Assessing what to address in science communication. *Proceedings of the National Academy of Sciences, 110*, 14062-14068.

Cargo, M. & Mercer, S. L. (2008). The value and challenges of participatory research: Strengthening its practice. *Annual Review of Public Health, 29*, 325-350.

Cartwright, N. (2007). *Hunting Causes and Using Them: Applications in Philosophy and Economics*. Cambridge, United Kingdom: Cambridge University Press.

Cartwright, N. & Munro, E. (2010). The limitations of randomized controlled trials in predicting effectiveness. *Journal of Evaluation in Clinical Practice, 16*, 260-266.

Cartwright, N. & Hardie, J. (2012). *Evidence-based Policy: Doing it Better. A Practical Guide to Predicting If a Policy Will Work For You*. Oxford, United Kingdom: Oxford University Press.

CBC News. (2014). Pharmacists Still the 'Best Placed Health Professionals' to Check Drug Risks. Retrieved October 2014, from http://www.cbc.ca/news/canada/pharmacists-still-the-best-placed-health-professionals-to-check-drug-risks-1.2789218.

CCA (Council of Canadian Academies). (2013). *Innovation Impacts: Measurement and Assessment*. Ottawa (ON): Expert Panel on the Socio-economic Impacts of Innovation Investments.

CCA (Council of Canadian Academies). (2015). *Accessing Health and Health-Related Data in Canada*. Ottawa (ON): The Expert Panel on Timely Access to Health and Social Data for Health Research and Health System Innovation.

CDC (Centers for Disease Control and Prevention). (2006). *Evaluating Appropriate Antibiotic Use Programs*. Atlanta (GA): CDC.

CDC (Centers for Disease Control and Prevention). (2011). *Developing an Effective Evalaution Plan*. Atlanta (GA): CDC.

CES (Canadian Evaluation Society). (2014). Program Evaluation Standards. Retrieved August 2014, from http://www.evaluationcanada.ca/site.cgi?s=6&ss=10&_lang=EN.

Chakraborty, S. & Löfstedt, R. (2012). Transparency initiative by the FDA's Center for Drug Evaluation and Research (CDER): Two qualitative studies of public perceptions. *European Journal of Risk Regulation, 3*(1), 57-71.

Charles, C., Whelan, T., & Gafni, A. (1999). What do we mean by partnership in making decisions about treatment? *BMJ, 319*, 780-782.

Chen, H. T. (2005). *Practical Program Evaluation*. San Francisco (CA): Jossey-Bass.

Cheung, A., Emslie, G. J., & Mayner, T. L. (2004). Commentary: Efficacy and safety of antidepressants in youth depression. *The Canadian Child and Adolescent Psychiatry Review, 13*(4), 98-104.

Chief Coroner Province of Ontario. (2010). *Inquest. Touching the Death of Sara Carlin. Jury Verdict and Recommendations*. Toronto (ON): Chief Coroner Province of Ontario.

Covello, V. (2010). Best practices in public health risk and crisis communication. *Journal of Health Communication, 8*(1), 5-8.

Craig, P., Cooper, C., Gunnell, D., Haw, S., Lawson, K., Macintyre, S.,... Sutton, M. (2012). Using natural experiments to evaluate population health interventions: New Medical Research Council guidance. *Journal of Epidemiology and Community Health, 66*, 1182-1186.

Creswell, J. & Clark, V. (2010). *Designing and Conducting Mixed Methods Research, Second Edition*. Los Angeles (CA): Sage Publications.

Cull, A., Anderson, E. D. C., Campbell, S., Mackay, J., Smyth, E., & Steel, M. (1999). The impact of genetic counseling about breast cancer risk on women's risk perceptions and levels of distress. *British Journal of Cancer, 79*(34), 501-508.

Dehejia, R. & Sadek, W. (1999). Causal effects in nonexperimental studies: Reevaluating the evaluation of training programs. *Journal of the American Statistical Association, 94*(448), 1053-1062.

DFID (Department for International Development). (2012). *Broadening the Range of Designs and Methods for Impact Evaluation: Report of a Study Commissioned by the Department for International Development.* London, United Kingdom: Department for International Development.

Do Bugs Need Drugs? (2013). *Antibiotic Utilization in the Province of British Columbia.* Vancouver (BC): B.C. Centre for Disease Control.

Do Bugs Need Drugs? (2014). *Do Bugs Need Drugs? Annual Evaluation Report.* Vancouver (BC): B.C. Centre for Disease Control.

Downs, J. S., Bruine de Bruin, W., Murray, P. J., & Fischhoff, B. (2004a). When "it only takes once" fails: Perceived infertility after unsafe sex predicts condom use and STI acquisition. *Journal of Pediatric and Adolescent Gynecology, 17*, 224.

Downs, J. S., Murray, P. J., Bruine de Bruin, W., Penrose, J., Palmgren, C., & Fischhoff, B. (2004b). Interactive video behavioral intervention to reduce adolescent females' STD risk: A randomized controlled trial. *Social Science & Medicine, 59*, 1561-1572.

Downs, J. S., Bruine de Bruin, W., & Fischhoff, B. (2008). Parents' vaccination comprehension and decisions. *Vaccine, 26*(12), 1595-1607.

Downs, J. S. (2011). Evaluation. In B. Fischhoff, N. T. Brewer & J. S. Downs (Eds.), *Communciating Risks and Benefits: An Evidence-Based User's Guide.* Silver Spring (MD): FDA.

Downs, J. S. & Fischhoff, B. (2011). Qualitative Information. In B. Fischhoff, N. T. Brewer & J. S. Downs (Eds.), *Communciating Risks and Benefits: An Evidence-Based User's Guide.* Silver Spring (MD): FDA.

Driedger, S. M., Cooper, E. J., Jardine, C. G., Furgal, C., & Bartlett, J. (2013). Communicating risk to Aboriginal Peoples: First Nations and Métis responses to H1N1 risk messages. *PLOS One, 8*(8), e71106.

Dusetzina, S. B., Higashi, A. S., Dorsey, E. R., Conti, R., Huskamp, H. A., Zhu, S.,... Alexander, G. C. (2012). Impact of FDA drug risk communications on health care utilization and health behaviors. *Medical Care, 50*(6), 466-478.

Edwards, B. & Chakraborty, S. (2012). Risk communication and the pharmaceutical industry. What is the reality? *Drug Safety, 35*(11), 1027-1040.

Elwyn, G., O'Connor, A., Stacey, D., Volk, R., Edwards, A., Coulter, A.,... Whelan, T. (2006). Developing a quality criteria framework for patient decision aids: Online international Delphi consensus process. *BMJ, 333*(7465), 417.

Elwyn, G., O'Connor, A. M., Bennett, C., Newcombe, R. G., Politi, M., Durand, M.-A.,... Edwards, A. (2009). Assessing the quality of decision support technologies using the International Patient Decision Aid Standards instrument (IPDASi). *PLOS One, 4*(3), e4705.

EMA (European Medicines Agency). (2006). *EPAR Summary for the Public.* London, United Kingdom: EMA.

EMA (European Medicines Agency). (2008). *Implementation of the Action Plan to Further Progress the European Risk Management Strategy: Rolling Two-Year Work Programme (2008–2009).* London, United Kingdom: EMA.

EMA (European Medicines Agency). (2009). *Guideline on the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use.* Brussels, Belgium: EMA.

EMA (European Medicines Agency). (2010). *The European Medicines Agency Road Map to 2015: The Agency's Contribution to Science, Medicines, Health.* London, United Kingdom: EMA.

EMA (European Medicines Agency). (2013). *Guideline on Good Pharmacovigilance Practices (GVP). Module XV – Safety Communication.* London, United Kingdom: EMA.

EMA (European Medicines Agency). (2014a). *Guideline on Good Pharmacovigilance Practices (GVP). Module XVI– Risk Minimisation Measures: Selection of Tools and Effectiveness Indicators (Rev 1).* London, United Kingdom: EMA.

EMA (European Medicines Agency). (2014b). How to Prepare and Review a Summary of Product Characteristics. Retrieved July 2014, from http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000357.jsp&mid=WC0b01ac05806361e1.

EMA (European Medicines Agency). (2014c). Medicines Under Additional Monitoring. Retrieved June 2014, from http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/document_listing/document_listing_000365.jsp.

EMA (European Medicines Agency). (2014d). *Publication of Clinical Reports.* London, United Kingdom: EMA.

EMA (European Medicines Agency). (2014e). *Questions and Answers on the European Medicines Agency Policy on Publication of Clinical Data for Medicinal Products for Human Use.* London, United Kingdom: EMA.

EMA (European Medicines Agency). (2015a). Good Pharmacovigilance Practices. Retrieved February 2015, from http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp#section2.

EMA (European Medicines Agency). (2015b). Central Authorisation of Medicines. Retrieved February 2015, from http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000109.jsp.

enHealth (Environmental Health Standing Committee). (2012). *Environmental Health Risk Assessment: Guidelines for Assessing Human Health Risks from Environmental Hazards*. Canberra, Australia: Australian Government Department of Health.

Environics Research Group. (2007). *Adverse Reaction Reporting - Survey with Health Professionals*. Ottawa (ON): Health Canada.

European Commission. (2008). *Volume 9A of The Rules Governing Medicinal Products in the European Union. Guidelines on Pharmacovigilance for Medicinal Products for Human Use*. Brussels, Belgium: European Commission.

European Commission. (2009). *A Guideline on Summary of Product Characteristics*. Brussels, Belgium: European Commission.

European Parliament. (2001). *Directive 2001/83/EC of the European Parliament and of the Council*. Brussels, Belgium: European Parliament.

Evaluation Directorate. (2014a). *Evaluation of the Medical Devices Program 1999–2000 to 2011-2012*. Ottawa (ON): Health Canada and the Public Health Agency of Canada.

Evaluation Directorate. (2014b). *Evaluation of the Biologics Program 1999-2000 to 2012–2013*. Ottawa (ON): Health Canada and the Public Health Agency of Canada.

Evaluation Directorate. (2014c). *Evaluation of the Human Drugs Program 1999–2000 to 2011–2012*. Ottawa (ON): Health Canada and the Public Health Agency of Canada.

Fagerlin, A. & Peters, E. (2011). Quantitative Information. In B. Fischhoff, N. T. Brewer & J. S. Downs (Eds.), *Communciating Risks and Benefits: An Evidence-Based User's Guide*. Silver Spring (MD): FDA.

FDA (Food and Drug Administration). (2006). *Guidance. Useful Written Consumer Medication Information (CMI)*. Rockville (MD): FDA.

FDA (Food and Drug Administration). (2007a). *Guidance. Drug Safety Information – FDA's Communication to the Public*. Washington (DC): FDA.

FDA (Food and Drug Administration). (2007b). *Food and Drug Administration Amendments Act of 2007*. Washington (DC): FDA.

FDA (Food and Drug Administration). (2009). *FDA's Strategic Plan for Risk Communication*. Washington (DC): FDA.

FDA (Food and Drug Administration). (2011). Questions and Answers – Ongoing Safety Review of Birth Control Pills Containing Drospirenone and a Possible Increased Risk of Blood Clots. Retrieved July 2014, from http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm257175.htm.

FDA (Food and Drug Administration). (2012). *Discussion Topics and Background for FDA's Risk Communication Advisory Committee (November 2, 2012)*. Silver Spring (MD): FDA.

FDA (Food and Drug Administration). (2013). *Title 21 - Food and Drugs. Subchapter C - Drugs: General*. Washington (DC): FDA.

FDA (Food and Drug Administration). (2014a). FDA Fundamentals. Retrieved May 2014, from http://www.fda.gov/aboutfda/transparency/basics/ucm192695.htm.

FDA (Food and Drug Administration). (2014b). Recalls, Market Withdrawals & Safety Alerts. Retrieved July 2014, from http://www.fda.gov/safety/recalls/.

FDA (Food and Drug Administration). (2014c). Q&A on Dietary Supplements. Retrieved June 2014, from http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/default.htm.

Finucane, M., Slovic, P., Mertz, C. K., Flynn, J., & Satterfield, T. A. (2000). Gender, race, and percieved risk: The "white male" effect. *Health Risk and Society, 3*(2), 159-172.

Fischhoff, B., Slovic, P., Lichtenstein, S., Read, S., & Combs, B. (1978). How safe is safe enough? A psychometric study of attitudes towards technological risks and benefits. *Policy Sciences, 9*(2), 127-152.

Fischhoff, B. (1995). Risk perception and communication unplugged: Twenty years of process. *Risk Analysis, 15*(2), 137-145.

Fischhoff, B. & Manski, C. F. (1999). Elicitation of preferences. *Journal of Risk and Uncertainty, 19*(1-3), 5-6.

Fischhoff, B. (2005). Scientifically sound pandemic risk communication (House Science Committee Briefing, Gaps in the National Flu Preparedness Plan: Social Science Planning and Response, December). In D. Kamien (Ed.), *McGraw Hill Handbook of Terrorism and Counter-terrorism*. New York (NY): McGraw Hill.

Fischhoff, B. (2009). Risk Perception and Communication. In R. Detels, R. Beaglehole, M. Lansang & M. Guillford (Eds.), *Oxford Textbook of Public Health*. Oxford, United Kingdom: Oxford University Press.

Fischhoff, B. (2011). Definitions. In B. Fischhoff, N. T. Brewer & J. S. Downs (Eds.), *Communciating Risks and Benefits: An Evidence-Based User's Guide*. Silver Spring (MD): FDA.

Fischhoff, B. & Kadvany, J. D. (2011). *Risk: A Very Short Introduction*. London, United Kingdom: Oxford University Press.

Fischhoff, B. (2012). Communication uncertainty. Fulfilling the duty to inform. *Issues in Science and Technology, 28*(4), 63-70.

Fischhoff, B. (2013). The sciences of science communication. *Proceedings of the National Academy of Sciences, 110*, 14033-14039.

Fischhoff, B., Brewer, N. T., & Downs, J. S. (Eds.). (2011). *Communciating Risks and Benefits: An Evidence-Based User's Guide*. Silver Spring (MD): FDA.

Fothergill, A. & Peek, L. A. (2004). Poverty and disasters in the United States: A review of recent sociological findings. *Natural Hazards, 32*(1), 89-110.

Fox, C. R. & Poldrack, R. A. (2008). Prospect Theory and the Brain. In P. Glimcher, E. Fehr, C. Camerer & R. Poldrack (Eds.), *Handbook of Neuroeconomics*. San Diego (CA): Academic Press.

Frewer, L. J., Miles, S., Brennan, M., Kuznesof, S., Ness, M., & Ritson, C. (2002). Public preferences for informed choices under conditions of risk uncertainty. *Public Understanding of Science, 11*(4), 363-372.

Frewer, L. J., Hunt, S., Brennan, M., Kuznesof, S., Ness, M., & Ritson, C. (2003). The views of scientific experts on how the public conceptualize uncertainty. *Journal of Risk Research, 6*(1), 75-85.

Frewer, L. J. (2004). The public and effective risk communication. *Toxicology Letters, 149*(1-3), 391-397.

Frey, L. R., Botan, C.H., Kreps, G.L. (2000). *Investigating Communication: An Introduction to Research Methods (2nd edition)*. Boston (MA): Allyn & Bacon.

Garbutt, J. M., Sterkel, R., Banister, C. (2010). Physician and parent response to the FDA advisory about use of over-the-counter cough and cold medications. *Academic Pediatrics 10*, 64-69.

Garcia-Retamero, R. & Cokely, E. T. (2014). *Risk Literacy and Transparent Risk Communication in Health: A Review*. Paper presented at Risk, Perception, and Response, Cambridge (MA).

Gerend, M. A., Aiken, L. S., West, S. G., & Erchull, M. J. (2004). Beyond medical risk: Investigating the psychological factors underlying women's perceptions of susceptibility to breast cancer, heart disease, and osteoporosis. *Health Psychology, 23*, 247-258.

Gertler, P. J., Martinez, S., Premand, P., Rawlings, L. B., & Vermeersch, C. M. J. (2011). *Impact Evaluation in Practice*. Washington (DC): World Bank.

Gigerenzer, G. (2011). What are natural frequencies? *BMJ, 343*, d6386.

Gilbert, R., Salanti, G., Harden, M., & See, S. (2005). Infant sleeping position and the sudden infant death syndrome: Systematic review of observational studies and historical review of recommendations from 1940 to 2002. *International Journal of Epidemiology, 34*(4), 874-887.

Glimcher, P. W. & Fehr, E. (Eds.). (2013). *Neuroeconomics: Decision Making and the Brain*. London, United Kingdom: Elsevier Inc.

GOC (Government of Canada). (2013a). *Food and Drugs Act (R.S.C., 1985 c. F-27)*. Ottawa (ON): GOC.

GOC (Government of Canada). (2013b). *Canada Gazette Part II. Vol. 147, No. 22*. Ottawa (ON): GOC.

GOC (Government of Canada). (2014). Canada's Action Plan on Open Government. Retrieved October 2014, from http://data.gc.ca/eng/canadas-action-plan-open-government.

Goodman, S. N. (1999). Toward evidence-based medical statistics: 1: The *P* value fallacy. *Annals of Internal Medicine, 130*(12), 995-1004.

Greenberg, J. (2012). Risk communication and the disclosure dilemma: The case of Ottawa's endoscopy infection 'scare'. *Journal of Professional Communication, 2*(1), 53-75.

Greene, J. & Hibbard, J. H. (2011). Why does patient activation matter? An examination of the relationships between patient activation and health-related outcomes. *Journal of General Internal Medicine, 27*(5), 520-526.

Gregory, R. & Dieckmann, N. (2014). Communicating About Uncertainty in Multistakeholder Groups. In J. Arvai & L. Rivers III (Eds.), *Effective Risk Communication*. New York (NY): Earthscan from Routledge.

Grimshaw, J., Campbell, M., & Eccles, M. (2000). Experimental and quasi-experimental designs for evaluating guideline implementation strategies. *Family Practice, 17*, S11-S16.

Habibi, R. & Lexchin, J. (2014). Quality and quantity of information in summary basis of decision documents issued by Health Canada. *PLOS One, 9*(3), e92038.

Health Canada. (2000). *Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks*. Ottawa (ON): Health Canada.

Health Canada. (2001). *How Drugs are Reviewed in Canada*. Ottawa (ON): Health Canada.

Health Canada. (2004). Archived - Correction: Health Canada Advises Canadians Under the Age of 18 to Consult Physicians if they are Being Treated With Newer Anti-Depressants. Retrieved July 2014, from http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2004/13053a-eng.php.

Health Canada. (2006). *Strategic Risk Communications Framework for Health Canada and the Public Health Agency of Canada*. Ottawa (ON): Health Canada and the Public Health Agency of Canada.

Health Canada. (2008). *Description of Current Risk Communication Documents for Marketed Health Products for Human Use*. Ottawa (ON): Health Canada.

Health Canada. (2010). *Evaluation of Phase I of the Summary Basis of Decision Project*. Ottawa (ON): Health Canada.

Health Canada. (2011a). Health Canada's Response to the Carlin Jury Recommendations Aimed at the Department or Directly Relevant to its Mandate. Retrieved June 2014, from http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/inquest-enquete_carlin-eng.php.

Health Canada. (2011b). About Health Canada: Mission, Values, Activities. Retrieved August 2013, from www.hc-sc.gc.ca/ahc-asc/activit/about-apropos/index-eng.php.

Health Canada. (2012a). Adverse Reaction Information. Retrieved July 2014, from http://www.hc-sc.gc.ca/dhp-mps/medeff/advers-react-neg/index-eng.php.

Health Canada. (2012b). About Natural Health Product Regulation in Canada. Retrieved June 2013, from http://www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/index-eng.php.

Health Canada. (2013). Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) Amendments to the Food and Drugs Act (Bill C-17). Retrieved June 2014, from http://www.hc-sc.gc.ca/dhp-mps/legislation/unsafedrugs-droguesdangereuses-eng.php.

Health Canada. (2014a). Regulatory Transparency and Openness. Retrieved May 2014, from http://www.hc-sc.gc.ca/home-accueil/rto-tor/index-eng.php.

Health Canada. (2014b). Diclofenac - Update to Heart and Stroke Related Safety Information and Decrease in the Maximum Recommended Daily Dose for Tablets and Suppositories - For Health Professionals. Retrieved November 2014, from http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/41701a-eng.php.

Health Canada. (2014c). Safety Reviews. Retrieved July 2014, from http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/review-examen/index-eng.php.

Health Canada. (2014d). *Guidance Document: Labelling of Pharmaceutical Drugs for Human Use*. Ottawa (ON): Health Canada.

Health Canada. (2014e). *Guidance Document. Product Monograph*. Ottawa (ON): Health Canada.

Health Canada. (2014f). Information for Canadians about the Plain Language Labelling Initiative. Retrieved October 2014, from www.hc-sc.gc.ca/dhp-mps/consultation/drug-medic/pll_info_cdns_elc-eng.php.

Health Canada. (2015). *Health Product Infowatch - January 2015*. Ottawa (ON): Health Canada.

Hébert, P. C., Stanbrook, M. B., MacDonald, N., Flegel, K., Coutts, J., & MacLeod, S. (2011). Can Health Canada do better in protecting Canadians from unsafe drugs? *Canadian Medical Association Journal, 183*(10), 1125-1126.

Herder, M. (2012). Unlocking Health Canada's cache of trade secrets: Mandatory disclosure of clinical trial results. *Canadian Medical Association Journal, 184*(2), 194-199.

HM Treasury (Her Majesty's Treasury). (2011). *Magenta Book: Guidance for Evaluation*. London, United Kingdom: HM Treasury.

Hoff, T. J. & Witt, L. C. (2000). Exploring the use of qualitative methods in published health services and management research. *Medical Care Research and Review, 57*(2), 139-160.

Institute of Medicine. (2005). *Preventing Childhood Obesity: Health in the Balance*. Washington (DC): National Academies Press.

Interagency Task Force on Environmental Cancer and Heart and Lung Disease. (1991). *Evaluation and Effective Risk Communication Workshop Proceedings.* Paper presented at The Evaluation and Effective Risk Communication Workshop, Washington (DC).

International Initiative for Impact Evaluation (3ie). (2008). *Founding Document for Establishing the International Initiative for Impact Evaluation.* New Delhi, India: 3ie.

IOM (Institute of Medicine). (2014). *Characterizing and Communicating Uncertainty in the Assessment of Benefits and Risks of Pharmaceutical Products: Workshop Summary.* Washington (DC): National Academy of Sciences.

Ipsos. (2012). Life-Savers, Medical Professionals Top the List of Most Trusted Professionals. Retrieved June 2014, from http://www.ipsos-na.com/news-polls/pressrelease.aspx?id=5663.

IRGC (International Risk Governance Council). (2005). *White Paper on Risk Governance: Towards on Integrative Approach.* Geneva, Switzerland: IRGC.

IRGC (International Risk Governance Council). (2007). *Risk Governance: Trends and Challenges.* Geneva, Switzerland: IRGC.

IRGC (International Risk Governance Council). (2008). *An Introduction to the IRGC Risk Governance Framework.* Geneva, Switzerland: IRGC.

IRGC (International Risk Governance Council). (2014). Stakeholder Engagement Resource Guide. Retrieved May 2014, from http://stakeholder.irgc.org/resource-guide/.

Jardine, C. G. (2008). Evaluation of Risk Communication Efforts. In E. Melnick & B. Everitt (Eds.), *Encyclopedia Quantitative Risk Analysis and Assessment.* Toronto (ON): John Wiley & Sons, Ltd.

Jardine, C. G. & Driedger, S. M. (2014). Risk Communication for Empowerment. In J. Arvai & L. Rivers III (Eds.), *Effective Risk Communication.* New York (NY): Earthscan from Routledge.

Johnson, B. B. & Slovic, P. (1995). Presenting uncertainty in health risk assessment: Initial studies of its effects on risk perception and trust. *Risk Analysis, 15*(4), 485-495.

Johnson, B. B. (2003). Further notes on public response to uncertainty in risks and science. *Risk Analysis, 23*(4), 781-789.

Johnson, F. R. & Luke, R. A. (1987). Radon risk information and voluntary protection: Evidence from a natural experiment. *Risk Analysis, 7*(1), 97-107.

Joseph-Williams, N., Newcombe, R., Politi, M., Durand, M.-A., Sivell, S., Stacey, D.,... Elwyn, G. (2013). Toward minimum standards for certifying patient decision aids: A modified Delphi consensus process. *Medical Decision Making, 34*(6), 699-710.

Kahan, D. (2012). Cultural Cognition as a Conception of the Cultural Theory of Risk. In S. Roeser, R. Hillerbrand, P. Sandin & M. Peterson (Eds.), *Handbook of Risk Theory*. New York (NY): Springer.

Kahan, D. M., Braman, D., Cohen, G., Gastil, J., & Slovic, P. (2010a). Who fears the HPV vaccine, who doesn't, and why? An experimental study of the mechanisms of cultural cognition. *Law and Human Behavior, 34*(6), 501-516.

Kahan, D. M., Braman, D., Gastil, J., Slovic, P., & Mertz, C. K. (2010b). Culture and identity-protective cognition: Explaining the white-male effect in risk perception. *Journal of Empirical Legal Studies, 4*(3), 465-505.

Kahneman, D. & Tversky, A. (1979). Prospect theory: An analysis of decisions under risk. *Econometrica, 47*(2), 313-327.

Kahneman, D. (2011). *Thinking, Fast and Slow*. New York (NY): Farrar, Straus and Giroux.

Kahneman, D. & Tversky, A. (Eds.). (2000). *Choices, Values, and Frames*. New York (NY): Cambridge University Press.

Kasperson, R. & Palmlund, I. (1989). Evaluating Risk Communication. In V. T. Covello, D. B. McCallum & M. T. Pavlova (Eds.), *Effective Risk Communication: The Role and Responsibility of Government and Nongovernment Organizations*. New York (NY): Plenum Press.

Kasperson, R. (2014). Four questions for risk communication. *Journal of Risk Research, 17*(10), 1233-1239.

Kasperson, R. E., Renn, O., Slovic, P., Brown, H., Emel, J., Goble, R.,... Ratick, S. (1988). The social amplification of risk: A conceptual framework. *Risk Analysis, 8*(2), 177-187.

Kasperson, R. E. (2008). Coping With Deep Uncertainty: Challenges for Environmental Assessment and Decision Making. In G. Bammer & M. Smithson (Eds.), *Uncertainty and Risk: Multidisciplinary Perspectives*. London, United Kindgom: Earthscan.

Katz, L. Y., Kozyrskyj, A. L., Prior, H. J., Enns, M. W., Cox, B. J., & Sareen, J. (2008). Effect of regulatory warnings on antidepressant prescription rates, use of health services and outcomes among children, adolescents and young adults. *Canadian Medical Association Journal, 178*(8), 1005-1011.

Kimberlin, C. L. & Winterstein, A. G. (2008). *Expert and Consumer Evaluation of Consumer Medication Information - 2008*. Gainesville (FL): Food and Drug Administration.

King, G., Keohane, R. O., & Verba, S. (2004). *Designing Social Inquiry: Scientific Inference in Qualitative Research*. Princeton (NJ): Princeton University Press.

Klinke, A. & Renn, O. (2012). Adaptive and integrative governance on risk and uncertainty. *Journal of Risk Research, 15*(3), 237-292.

Kreps, G. L. (2011). Methodological diversity and integration in health communication inquiry. *Patient Education and Counseling, 82*(3), 285-291.

Kreps, G. L. (2014). Evaluating health communication programs to enhance health care and health promotion. *Journal of Health Communication, 19*(12), 1449-1459.

Krever, H. (1997). *Final Report: Commission of Inquiry on the Blood System in Canada.* Ottawa (ON): Government of Canada.

Krewski, D., Hogan, V., Turner, M. C., Zeman, P. L., McDowell, I., Edwards, N., & Losos, J. (2007). An integrated framework for risk management and population health. *Human and Ecological Risk Assessment: An International Journal, 13*(6), 1288-1312.

Krimsky, S. (2007). Risk communication in the internet age: The rise of disorganized skepticism. *Environmental Hazards, 7*, 157-164.

Kurdyak, P. A., Juurlink, D. N., & Mamdani, M. M. (2007). The effect of antidepressant warnings on prescribing trends in Ontario, Canada. *American Journal of Public Health, 97*(4), 750-754.

Lance, P., Guilkey, D., Hattori, A., & Angeles, G. (2014). *How Do We Know if a Program Made a Difference? A Guide to Statistical Methods for Program Impact Evaluation.* Chapel Hill (NC): MEASURE Evaluation.

Lasser, K. E., Seger, D. L., Yu, D. T., Karson, A. S., Fiskio, J. M., Seger, A. C.,... Bates, D. W. (2006). Adherence to black box warnings for prescription medications for outpatients. *Archives of Internal Medicine, 166*(3), 338-344.

LeBrun, M., DiMuzio, J., Beauchamp, B., Reid, S., & Hogan, V. (2013). Evaluating the health literacy burden of Canada's public advisories: A comparative effectiveness study on clarity and readability. *Drug Safety, 36*(12), 1179-1187.

Leiss, W. (1996). Three phases in the evolution of risk communication practice. *Annals of the American Academy of Political and Social Science, 545*, 85-94.

Lemyre, L., Pinsent, C., Johnson, C., Boutette, P., Corneil, W., Riding, J.,... Riding, D. (2011). *Developing Collaboration in Complex Events: A Model for Civil-Military Inter-Organizational Problem-Solving and Decision-Making.* Paper presented at 16th ICCRTS "Collective C2 in Multinational Civil-Military Operations", Québec (QC).

Lerner, J. S. & Keltner, D. (2000). Beyond valence: Toward a model of emotion-specific influences on judgement and choice. *Cognition and Emotion, 14*(4), 473-493.

Lexchin, J. (2009). *Drug Safety and Health Canada: Going, Going.....Gone?* Ottawa (ON): Canadian Centre for Policy Alternatives.

Lexchin, J. (2012). New drugs and safety: What happened to new active substances approved in Canada between 1995 and 2010? *Archives of Internal Medicine, 172*(21), 1680-1681.

Libby, A. M., Brent, D. A., Morrato, E. H., Orton, H. D., Allen, R., & Valuck, R. J. (2007). Decline in treatment of pediatric depression after FDA advisory on risk of suicidality with SSRIs. *American Journal of Psychiatry, 164*(6), 884-891.

Lieberman, E. (2005). Nested analysis as a mixed-method strategy for comparative research. *American Political Science Review, 99*(2), 435-452.

Lipkus, I. (2007). Numeric, verbal, and visual formats of conveying health risks: Suggested best practices and future recommendations. *Medical Decision Making, 27*(5), 696-713.

Löfstedt, R. (2003). Science communication and the Swedish acrylamide "alarm". *Journal of Health Communication, 8*(5), 407-432.

Löfstedt, R. & 6, P. (2008). What environmental and technological risk communication research and health risk research can learn from each other. *Journal of Risk Research, 11*(1), 141-167.

Löfstedt, R. (2010). Risk communication: The Avandia case, a pilot study. *Expert Review of Clinical Pharmacology, 3*(1), 31-41.

Löfstedt, R. & Bouder, F. (2014). New Transparency Policies: Risk Communication's Doom? In J. Arvai & L. Rivers III (Eds.), *Effective Risk Communication*. New York (NY): Earthscan from Routledge.

Lu, C. Y., Zhang, F., Lakoma, M. D., Madden, J. M., Rusinak, D., Penfold, R. B.,... Soumerai, S. B. (2014). Changes in antidepressant use by young people and suicidal behavior after FDA warnings and media coverage: Quasi-experimental study. *BMJ, 348*, g3596.

Lundgren, R. E. & McMakin, A. H. (2013). *Risk Communication: A Handbook for Communicating Environmental, Safety, and Health Risks* (5th ed.). Hoboken (NJ): John Wiley & Sons, Inc.

Lynch, M. M., Mitchell, E. W., Williams, J. L., Brumbaugh, K., Jones-Bell, M., Pinkney, D. E.,... Smith, L. R. (2011). Pregnant and recently pregnant women's perceptions about influenza A pandemic (H1N1) 2009: Implications for public health and provider communication. *Maternal and Child Health Journal, 16*, 1657-1664.

Madsen, K. (2011). School-based body mass index screening and parent notification: A statewide natural experiment. *Archives of Pediatrics & Adolescent Medicine, 165*(11), 987-992.

Man-Son-Hing, M., O'Connor, A. M., Drake, E., Biggs, J., Hum, V., & Laupacis, A. (2002). The effect of qualitative vs. quantitative presentation of probability estimates on patient decision-making: A randomized trial. *Health Expectations, 5*(3), 246-255.

Markon, M.-P. L., Crowe, J., & Lemyre, L. (2013). Examining uncertainties in government risk communication: Citizens' expectations. *Health, Risk & Society, 15*(4), 313-332.

Markon, M.-P. L. & Lemyre, L. (2013). Public reactions to risk messages communicating different sources of uncertainty: An experimental test. *Human and Ecological Risk Assessment: An International Journal, 19*(4), 1102-1126.

Marteau, T. M., Saidi, G., Goodburn, S., Lawton, J., Michie, S., & Bobrow, M. (2000). Numbers or words? A randomized controlled trial of presenting screen negative results to pregnant women. *Prenatal Diagnosis, 20*(9), 714-718.

Mayne, J. (2011a). Contribution Analysis: Addressing Cause and Effect. In R. Schwartz, K. Forss & M. Marra (Eds.), *Evaluating the Complex*. Piscataway (NJ): Transaction Publishers.

Mayne, J. (2011b). Addressing Cause and Effect in Simple and Complex Settings through Contribution Analysis. In R. Schwartz, K. Forss & M. Marra (Eds.), *Evaluating the Complex*. Piscataway (NJ): Transaction Publishers.

Mayne, J. (2012). *ILAC Brief 26. Making Causal Claims*. Rome, Italy: Institutional Learning & Change (ILAC) Initiative.

Mazor, K. M., Andrade, S. E., Auger, J., Fish, L., & Gurwitz, J. H. (2005). Communicating safety information to physicians: An examination of dear doctor letters. *Pharmacoepidemiology and Drug Safety, 14*, 869-875.

McDavid, J., Huse, I., & Hawthorn, L. (2013). *Program Evaluation and Performance Measurement, 2nd Edition*. Victoria (BC): University of Victoria.

Meeker, D., Knight, T. K., Friedberg, M. W., Linder, J. A., Goldstein, N. J., Fox, C. R.,... Doctor, J. N. (2014). Nudging guideline-concordant antibiotic prescribing: A randomized clinical trial. *JAMA Internal Medicine, 174*(3), 425-431.

MHRA (Medicines and Healthcare Products Regulatory Agency). (2010). *Communication Strategy 2010-2015*. London, United Kingdom: MHRA.

MHRA (Medicines and Healthcare Products Regulatory Agency). (2013). *Central Alerting System*. London, United Kingdom: MHRA.

MHRA (Medicines and Healthcare Products Regulatory Agency). (2014a). Guidance on Letter Drafting for Market Authorisation Holders. Retrieved July 2014, from http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/Monthlylistsofinformationforhealthcareprofessionalsonthesafetyofmedicines/Guidanceondraftingformarketauthorisationholders/.

MHRA (Medicines and Healthcare Products Regulatory Agency). (2014b). Drug Safety Update. Retrieved July 2014, from http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/index.htm.

MHRA (Medicines and Healthcare Products Regulatory Agency). (n.d.). *A Guide to Defective Medicinal Products*. London, United Kingdom: MHRA.

Mikkonen, J. & Raphael, D. (2010). *Social Determinants of Health: The Canadian Facts*. Toronto (ON): York University School of Health Policy and Management.

Montague, S. & Porteous, N. (2013). The case for including reach as key element of program theory. *Evaluation and Program Planning*, 177-183.

Morgan, M., Fischhoff, B., Bostrom, A., & Atman, C. (2002). *Risk Communication: A Mental Models Approach*. New York (NY): Cambridge University Press.

Mt-Isa, S., Hallgreen, C. E., Asiimwe, A., Downey, G., Genov, G., Hermann, R.,... Tzoulaki, I. (2013a). *Review of Visualisation Methods for the Representation of Benefit-Risk Assessment of Medication: Stage 2 of 2*. London, United Kingdom: PROTECT Consortium.

Mt-Isa, S., Peters, R., Phillips, L. D., Chan, K., Hockley, K. S., Wang, N.,... Tzoulaki, I. (2013b). *Review of Visualisation Methods for the Representation of Benefit-Risk Assessment of Medication: Stage 1 of 2*. London, United Kingdom: PROTECT Consortium.

NAHO (National Aboriginal Health Organization). (2007). *Broader Determinants of Health in an Aboriginal Context*. Ottawa (ON): NAHO.

Neeley, L. (2014). Risk Communication in Social Media. In J. Arvai & L. Rivers III (Eds.), *Effective Risk Communication*. New York (NY): Earthscan from Routledge.

Norris, S. (2008). *Canada's Blood Supply Ten Years After the Krever Commission*. Ottawa (ON): Library of Parliament.

NRC (National Research Council). (1983). *Risk Assessment in the Federal Government: Managing the Process*. Washington (DC): National Academy of Sciences.

NRC (National Research Council). (1989). *Improving Risk Communication*. Washington (DC): National Academy of Sciences.

NRC (National Research Council). (1996). *Understanding Risk: Informing Decisions in a Democratic Society*. Washington (DC): National Academy of Sciences.

O'Carroll, R. E., Chambers, J. A., Dennis, M., Sudlow, C., & Johnston, M. (2013). Improving adherence to medication in stroke survivors: A pilot randomised controlled trial. *Annals of Behavioral Medicine, 46*(3), 358-368.

O'Connor, A. M., Legare, F., & Stacey, D. (2003). Risk communication in practice: The contribution of decision aids. *BMJ, 327*(7417), 736-740.

Office of the Auditor General of Canada. (2011). *Status Report of the Auditor General of Canada to the House of Commons*. Ottawa (ON): Office of the Auditor General of Canada.

Office of the Auditor General of Canada. (2013). *2013 Fall Report of the Auditor General of Canada*. Ottawa (ON): Office of the Auditor General of Canada.

Ottawa Public Health. (2011). *Ottawa Public Health Annual Report 2011*. Ottawa (ON): Ottawa Public Health.

Owen, J. M. (2011). *Program Evaluation, Third Edition: Forms and Approaches*. New York (NY): The Guilford Press.

Palenchar, M. J. & Heath, R. L. (2007). Strategic risk communication: Adding value to society. *Pubic Relations Review, 33*(2), 120-129.

Paté-Cornell, E. (1996). Uncertainties in risk analysis: Six levels of treatment. *Reliability Engineering and System Safety, 54*, 95-111.

Paté-Cornell, E. & Cox, L. A. (2014). Improving risk management: From lame excuses to principled practice. *Risk Analysis, 34*(7), 1228-1239.

Pawson, R. D. & Tilley, N. (1997). *Realistic Evaluation*. London, United Kingdom: Sage Publications.

Pawson, R. D. (2006). *Evidence-based Policy: A Realist Perspective*. London, United Kingdom: Sage Publications.

Penfold, R. B. & Zhang, F. (2013). Use of interrupted time series analysis in evaluating health care quality improvements. *Academic Pediatrics, 13*(6S), S38-S44.

Peters, E., McCaul, K. D., Stefanek, M., & Nelson, W. (2006). A heuristics approach to understanding cancer risk perception: Contributions from judgment and decision-making research. *Annals of Behavioral Medicine, 31*(1), 45-52.

Peters, E. (2011). Affect and Emotion. In B. Fischhoff, N. T. Brewer & J. S. Downs (Eds.), *Communciating Risks and Benefits: An Evidence-Based User's Guide*. Silver Spring (MD): FDA.

Peters, E. P., Hart, S., Tusler, M., & Fraenkel, L. (2013). Numbers matter to informed patient choices: A randomized design across age and numeracy levels. *Medical Decision Making, 34*(4), 430-442.

PHAC (Public Health Agency of Canada). (2010). *Lessons Learned Review: Public Health Agency of Canada and Health Canada Response to the 2009 H1N1 Pandemic*. Ottawa (ON): PHAC.

Piening, S., Haaijer-Ruskamp, F. M., de Vries, J. T. N., van der Elst, M. E., de Graeff, P. A., Straus, S. M. J. M., & Mol, P. G. M. (2012). Impact of safety-related regulatory action on clinical practice: A systematic review. *Drug Safety, 35*(5), 373-385.

Raynor, D. K. T. (2011). *What is Wrong with Current SmPCs?* Paper presented at DIA Product Information Forum, London, United Kingdom.

Reber, K. C., Piening, S., Wieringa, J. E., Straus, S. M. J. M., Raine, J. M., de Graeff, P. A.,... Mol, P. G. M. (2013). When direct health-care professional communications have an impact on inappropriate and unsafe use of medicines. *Clinical Pharmacology and Therapeutics, 93*(4), 360.

Reynolds, B. J. (2010). Building trust through social media. *Marketing Health Services, 30*(2), 18-21.

Richardson, L. P., Lewis, C. W., & Casey-Goldstein, M. (2007). Pediatric primary care providers and adolescent depression: A qualitative study of barriers to treatment and the effect of the black box warning. *Journal of Adolescent Health, 40*, 433-439.

Roeser, S., Hillerbrand, R., Sandin, P., & Peterson, M. (Eds.). (2012). *Handbook of Risk Theory*. London, United Kingdom: Springer Dordrecht Heidelberg.

Rohrmann, B. (1992). The evaluation of risk communication effectiveness. *Acata Psychologica, 81*(2), 169-192.

Rohrmann, B. (1998). The Risk Notion: Epistemological and Empirical Considerations. In M. G. Stewart & R. E. Melchers (Eds.), *Integrated Risk Assessment*. Rotterdamn, The Netherlands: Balkema.

Rohrmann, B. (2008). *Risk Perception, Risk Attitude, Risk Communication, Risk Management: A Conceptual Appraisal*. Paper presented at The International Emergency Management Society TIEMS-2008, Prague, Czech Republic.

Rothman, K. J. & Greenland, S. (2005). Causation and causal inference in epidemiology. *American Journal of Public Health, 95*(S1), 144-150.

RSI (Risk Sciences International). (2013). *Review of Health Canada's Actions in the Recall of Alysena™ 28*. Ottawa (ON): Health Canada.

Rutsaert, P., Regan, A., Pieniak, Z., McConnon, A., Moss, A., Wall, P., & Verbeke, W. (2013). The use of social media in food risk and benefit communication. *Trends in Food Science & Technology, 30*, 84-91.

Rutsaert, P., Pieniak, Z., Regan, A., McConnon, A., Kuttschreuter, M., Lores, M.,... Verbeke, W. (2014). Social media as a useful tool in food risk and benefit communication? A strategic orientation approach. *Food Policy, 46*, 84-93.

Sakaguchi, S., Weitzner, B., Carey, N., Bozzo, P., Mirdamadi, K., Samuel, N.,... Einarson, A. (2011). Pregnant women's perception of risk with use of the H1N1 vaccine. *Journal of Obstetrics and Gynaecology Canada, 33*(5), 460-467.

Schwartz, L., Woloshin, S., & Welch, H. G. (2009). Using a drug facts box to communicate drug benefits and harms: Two randomized controlled trials. *Annals of Internal Medicine, 150*(9), 516-527.

Schwartz, L. M. & Woloshin, S. (2011). Communicating uncertainties about prescription drugs to the public: A national randomized trial. *Archives of Internal Medicine, 171*(16), 1463-1468.

Schwartz, L. M. & Woloshin, S. (2013). The drug facts box: Improving the communication of prescription drug information. *Proceedings of the National Academy of Sciences, 110*(3), 14069-14074.

Schwitzer, G. (2011). News Coverage. In B. Fischhoff, N. T. Brewer & J. S. Downs (Eds.), *Communciating Risks and Benefits: An Evidence-Based User's Guide*. Silver Spring (MD): FDA.

Shadish, W. R., Cook, T. D., & Campbell, D. T. (2002). *Experimental and Quasi-Experimental Designs for Generalized Causal Inference*. Boston (MA): Houghton Mifflin Company.

Slovic, P. (1987). Perceptions of risk. *Science, 236*(4799), 280-285.

Slovic, P. (2000). *The Perception of Risk*. London, United Kingdom: Earthscan Publications Ltd.

Smith, J. (2009, November 9). Special H1N1 Vaccine for Pregnant Women Now Here, *Toronto Star*.

Stacey, D., Légaré, F., Col, N. F., Bennett, C. L., Barry, M. J., Eden, K. B.,... Wu, J. H. (2014). Decision aids for people facing health treatment or screening decisions. *Cochrane Database of Systematic Reviews, 1*, CD001431.

Stame, N. (2004). Theory-based evaluation and types of complexity. *Evaluation, 10*(1), 58-76.

Sunstein, C. R. (2014). *Why Nudge? The Politics of Libertarian Paternalism*. New Haven (CT): Yale University Press.

Task Force on Risk Management. (1999). *Report to the FDA Commissioner: Manging the Risks from Medical Product Use: Creating a Risk Management Framework*. Rockville (MD): Food and Drug Administration.

TBS (Treasury Board of Canada Secretariat). (1998). *Program Evaluation Methods: Measurement and Attribution of Program Results*. Ottawa (ON): TBS.

TBS (Treasury Board of Canada Secretariat). (2004). *Report on Effective Evaluation Practices*. Ottawa (ON): TBS.

TGA (Therapeutic Goods Administration). (2011). *Review to Improve the Transparency of the Therapeutic Goods Administration. Final Report*. Woden, Australia: TGA.

TGA (Therapeutic Goods Administration). (2014a). *Informing TGA Education and Communication Activities. Market Research: Stage Two – Quantitative Research Report*. Woden, Australia: TGA.

TGA (Therapeutic Goods Administration). (2014b). TGA Reforms: A Blueprint for TGA's Future. Retrieved May 2015, from http://www.tga.gov.au/about/tga-reforms-blueprint-09-appendix1.htm#.VBhRyhbdImR.

TGA (Therapeutic Goods Administration). (2014c). *Uniform Recall Procedure for Therapeutic Goods*. Wodon, Australia: TGA.

TGA (Therapeutic Goods Administration). (2014d). Consumer Medicines Information (CMI). Retrieved August 2014, from http://www.tga.gov.au/consumers/information-medicines-cmi.htm#.U-0eR2PdImQ.

TGA (Therapeutic Goods Administration). (2014e). *Informing TGA Education and Communication Activities. Market Research: Stage One – Qualitative Research Report*. Woden, Australia: TGA.

TGA (Therapeutic Goods Administration). (2014f). Product Information (PI). Retrieved August 2014, from http://www.tga.gov.au/hp/information-medicines-pi.htm#.U-0eAmPdImQ.

TGA (Therapeutic Goods Administration). (2014g). Medicines Safety Update. Retrieved July 2014, from http://www.tga.gov.au/hp/msu.htm#.U8_TJbHdImQ.

Thaler, R. H. & Sunstein, C. R. (2008). *Nudge: Improving Decisions about Health, Wealth, and Happiness*. New Haven (CT): Yale University Press.

The Canadian Association of Gastroenterology. (2005). Clostridium difficile-associated diarrhea (CDAD) and proton pump inhibitor therapy: CAG Position Statement. *Canadian Journal of Gastroenterology, 19*(9), 1-3.

The Presidential/Congressional Commission on Risk Assessment and Risk Management. (1997a). *Framework for Environmental Health Risk Management. Final Report Vol. 1*. Washington (DC): The Presidential/Congressional Commission on Risk Assessment and Risk Management.

The Presidential/Congressional Commission on Risk Assessment and Risk Management. (1997b). *Framework for Environmental Health Risk Management. Final Report Vol. 2*. Washington (DC): The Presidential/Congressional Commission on Risk Assessment and Risk Management.

Todd, P. (2008). Matching Estimators. In S. Durlauf & L. Blume (Eds.), *The New Palgrave Dictionary of Economics, 2nd Edition*. New York (NY): Macmillan.

Trevena, L. J., Davey, H. M., Barratt, A., Butow, P., & Caldwell, P. (2004). A systematic review on communicating with patients about evidence. *Journal of Evaluation in Clinical Practice, 12*(1), 13-23.

Turner, E. H., Matthews, A. M., Linardatos, E., Tell, R. A., & Rosenthal, R. (2008). Selective publication of antidepressant trials and its influence on apparent efficacy. *The New England Journal of Medicine, 358*(3), 252-260.

Tversky, A. & Kahneman, D. (1979). Judgment under uncertainty: Heuristics and biases. *Science, 185*(4157), 1124-1131.

Tversky, A. & Kahneman, D. (1981). The framing of decisions and the psychology of choice. *Science, 211*(4481), 453-458.

Tversky, A. & Kahneman, D. (1992). Advances in prospect theory: Cumulative representation of uncertainty. *Journal of Risk Uncertainty, 5*(4), 297-323.

U.K. Department of Health. (2015). Central Alerting System. Retrieved February, 2015, from https://www.cas.dh.gov.uk/Home.aspx.

U.S. Cancer Statistics Working Group. (2004). United States Cancer Statistics: 1999–2001. Incidence and Mortality Web-Based Report Version. Retrieved February 2015, from www.cdc.gov/cancer/npcr/uscs.

U.S. Department of Health and Human Services. (2006). *The Health Consequences of Involuntary Exposure to Tobacco Smoke*. Atlanta (GA): CDC (Centers for Disease Control and Prevention).

U.S. Preventative Services Task Force. (2005). Screening and interventions for overweight in children and adolescents: Recommendation statement. *Pediatrics, 116*(1), 205-209.

Ulin, P., Robinson, E., & Tolley, E. (2004). *Qualitative Methods in Public Health: A Field Guide for Applied Research.* San Francisco (CA): Jossey-Bass.

Van Asselt, M. B. A. & Rotmans, J. (2002). Uncertainty in integrated assessment modelling: From positivism to pluralism. *Climatic Change, 54*(1-2), 75-105.

Vaughan, E. & Tinker, T. (2009). Effective health risk communication about pandemic influenza for vulnerable populations. *American Journal of Public Health, 99*(S2), S324-332.

Veil, S., Reynolds, B., Sellnow, T. L., & Seeger, M. W. (2008). CERC as a Theoretical Framework for Research and Practice. *Health Promotion Practice, 9*(4 suppl), 26S-34S.

Veil, S. R., Buehner, T., & Palenchar, M. J. (2011). A work-in-process literature review: Incorporating social media in risk and crisis communication. *Journal of Contingencies and Crisis Management, 19*(2), 110-122.

Victory, K., Cabrera, N., Larson, D., Reynolds, K., Latura, J., & Beamer, P. (2014). *Risks and Risk Perception Related to Drinking Bottled Water.* Paper presented at Risk, Perception, and Response, Cambridge (MA).

Viscusi, W. K. (1997). Alarmist decisions with divergent risk information. *The Economic Journal, 107* (445), 1657-1670.

Visschers, V. H. M., Wiedmann, P. M., Gutscher, H., Kurzenhäuser, S., Seidl, R., Jardine, C. G., & Timmermans, D. R. M. (2012). Affect-inducing risk communication: Current knowledge and future directions. *Journal of Risk Research, 15*(3), 257-271.

Volk, R. J., Llewellyn-Thomas, H., Stacey, D., & Elwyn, G. (2013). Ten years of the International Patient Decision Aid Standards Collaboration: Evolution of the core dimensions for assessing the quality of patient decision aids. *BMC Medical Informatics and Decision Making, 13*(2), S1.

Vukic, A., Gregory, D., Martin-Misener, R., & Etowa, J. (2011). Aboriginal and Western conceptions of mental health and illness. *Pimatisiwin: A Journal of Aboriginal and Indigenous Community Health, 9*(1), 65-86.

Walker, W. E. (2003). Defining uncertainty: A conceptual basis for uncertainty management in model-based decision support. *Integrated Assessment 4*(1), 5-17.

Waters, R. D., Burnett, E., Lamm, A., & Lucas, J. (2009). Engaging stakeholders through social networking: How nonprofit organizations are using Facebook. *Pubic Relations Review, 35*, 102-106.

Watkins, E. S. (2007). *The Estrogen Elixir: A History of Hormone Replacement Therapy in America.* Baltimore (MD): Johns Hopkins University Press.

Weatherby, L. B., Nordstrom, B. L., Fife, D., & Walker, A. M. (2002). The impact of wording in "Dear doctor" letters and in black box labels. *Clinical Pharmacology and Therapeutics, 72*, 735-742.

Web Center for Social Research Methods. (n.d.). Research Methods Knowledge Base. Retrieved January 2015, from http://www.socialresearchmethods.net/kb/.

Weiss, C. (1998). *Evaluation: Methods for Studying Programs and Policies*. Englewood Cliffs (NJ): Prentice Hall.

West, S. L., Squiers, L. B., McCormack, L., Southwell, B. G., Brouwer, E. S., Ashok, M.,... Sullivan, H. W. (2013). Communicating quantitative risks and benefits in promotional prescription drug labeling or print advertising. *Pharmacoepidemiology and Drug Safety, 22*(5), 447-458.

WHO (World Health Organization). (1998). *The Application of Risk Communication to Food Standards and Safety Matters*. Rome, Italy: WHO.

WHO (World Health Organization). (2001). *Evaluation in Health Promotion: Principles and Perspectives*. Copenhagen, Denmark: Regional Office for Europe of the World Health Organization.

Wiktorowicz, M. E., Lexchin, J., Moscou, K., Silversides, A., & Eggertson, L. (2010). *Keeping an Eye on Prescription Drugs, Keeping Canadians Safe*. Toronto (ON): Health Council of Canada.

Witte, K. & Allen, M. (2000). A meta-analysis of fear appeals: Implications for effective public health campaigns. *Health Education & Behavior, 27*(5), 591-615.

Wolf, M. (2011). Health Literacy. In B. Fischhoff, N. T. Brewer & J. S. Downs (Eds.), *Communciating Risks and Benefits: An Evidence-Based User's Guide*. Silver Spring (MD): FDA.

Woloshin, S. & Schwartz, L. M. (2011). Communicating data about the benefits and harms of treatment: A randomized trial. *Annals of Internal Medicine, 155*(2), 87-96.

Wooller, H. O. (1995). Product Information: A pharmaceutical industry perspective. *Australian Prescriber, 18*, 19-21.

Wynne, B. (2008). Elephants in the rooms where publics encounter "science"?: A response to Darrin Durant, "Accounting for expertise: Wynne and the autonomy of the lay public." *Public Understanding of Science, 17*, 21-33.

Assessments of the Council of Canadian Academies

The assessment reports listed below are accessible through the Council's website (www.scienceadvice.ca):

- Health Product Risk Communication: Is the Message Getting Through? (2015)
- Technological Prospects for Reducing the Environmental Footprint of Canadian Oil Sands (2015)
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- Vision for the Canadian Arctic Research Initiative: Assessing the Opportunities (2008)
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The assessments listed below are in the process of expert panel deliberation:

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Council of Canadian Academies
180 Elgin Street, Suite 1401
Ottawa, ON K2P 2K3
Tel: 613-567-5000
www.scienceadvice.ca