Health Product Risk Communication: Is the Message Getting Through?

Executive Summary

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

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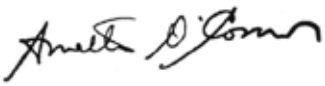
Message from the Chair

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.



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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:

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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.