COMMENTARY

A Canadian Framework for Applying the Precautionary Principle to Public Health Issues

Erica Weir, MD, MSc,[1] Richard Schabas, MD,[2] Kumanan Wilson, MD, MSc,[3] Chris Mackie, MD, MHSc[4]

ABSTRACT

The precautionary principle has influenced environmental and public health policy. It essentially states that complete evidence of a potential risk is not required before action is taken to mitigate the effects of the potential risk. The application of precaution to public health issues is not straightforward and could paradoxically cause harm to the public's health when applied inappropriately. To avoid this, we propose a framework for applying the precautionary principle to potential public health risks. The framework consists of ten guiding questions to help establish whether a proposed application of the precautionary principle on a public health matter is based on adequacy of the evidence of causation, severity of harm and acceptability of the precautionary measures.

Key words: Public health policy; precautionary principle; risk assessment; causation; evidence-based decision making

La traduction du résumé se trouve à la fin de l'article.

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The precautionary principle is one of the central concepts of modern environmental policy. While having many definitions, the principle essentially states that complete evidence of a potential risk is not required before action is taken to mitigate the effects of the potential risk. Incorporated in the Rio Declaration on Environment and Development[1] and a founding concept of the Maastricht Treaty[2] creating the European Union, the principle has substantially influenced policy concerning risks to the environment. The precautionary principle is also used increasingly in the formulation of public health policy.[3] The American Public Health Association has adopted the principle as guidance for formulating policy concerning children's health.[4] In Canada, the Krever Commission of Inquiry on the Blood System in Canada[5] and the Campbell Commission[6] recommend that the precautionary principle guide future responses to impending infectious diseases and other public health threats.

However, the application of precaution to public health is not straightforward. Several issues have emerged in the application of the precautionary principle in the environmental sector. Criticisms include that the unclear definition creates contradictions and loop holes,[7] and that the principle blocks technological progress,[7] reduces the role of the scientific process in policy-making, and is misused for purposes aside from the protection of health or the environment, such as trade protectionism.

More unique to the field of public health is the risk that the application of precaution to protect the public's health could paradoxically cause harm to the public's health. This could occur through the removal of a potentially beneficial product, for example vaccines or blood products, because of theoretical concerns about harm.[8] Indeed one example that resulted in serious public health consequences was the decision not to chlorinate drinking water in Peru because of concerns about the harm of disinfection by-products. This decision contributed to an epidemic of cholera that afflicted more than 500,000 cases and resulted in 4,700 deaths.[9] A second example was Zambia's rejection of genetically modified corn during the 2002-2003 famine.[10]

Despite the problems with applying the principle in public health, the importance of the precautionary principle cannot be ignored. Two Canadian judicial inquiries have called for its use in public health. The lesson from these inquiries is that if the precautionary principle is not defined by Canadian public health officials, others will define it for them.

The purpose of this paper is to provide guidance based on established public health principles and practical experience on how the precautionary principle should be applied. A primary objective is to encourage transparency and accountability in the principle's application.

What is the precautionary principle?

There are multiple interpretations of the precautionary principle ranging from stronger interpretations, which essentially state that persuasive evidence of harm does not have to exist before measures are taken to protect individuals and society from the harm, to

Author Affiliations

1. Adjunct Professor, Division of Epidemiology, Dalla Lana School of Public Health, University of Toronto, Toronto, ON
2. Associate Professor, Department of Community Health and Epidemiology, Queen's University, Kingston, ON
3. Associate Professor, Department of Medicine and Canada Research Chair in public health policy, University of Ottawa, Ottawa, ON
4. Assistant Professor, Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, ON

Correspondence: Dr. Erica Weir, Associate Medical Officer of Health, Community and Health Services, Regional Municipality of York, 17250 Yonge Street, Newmarket, ON L3Y 6Z1, Tel: 905-830-4444, ext. 4042, Fax: 905-895-3166, E-mail: Erica.weir@york.ca

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weaker interpretations which argue that actions taken to protect against a harm could be taken, but are not required, and the costs of the precautionary measures should be considered. Nevertheless core concepts within all interpretations of the principle include advocating anticipatory action to protect against a potential harm before definitive evidence of the harm materializes and shifting some of the burden of proof to proponents of a potential harm to prove its safety.

One influential interpretation of the precautionary principle, the Wingspread Consensus Statement, coined in 1998 by a group of scholars, activists and environmentalists, states "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."[11] The Rio Declaration,[1] a more nuanced interpretation, states "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

The various criticisms of the precautionary principle highlight the importance of clear criteria for its application. For example, Beloin and Gagnon suggest that three major issues must be addressed when determining how to use the principle: certainty of a cause and effect relationship, severity of the potential health impact and characteristics of the precautionary measures.[12] They argue that the precautionary principle must only be applied when the alleged risk is sufficiently severe, the relationship between cause and effect is somewhat likely, and precautionary measures are acceptable. If these conditions are not met, then the precautionary principle is likely to be overused. Our approach will be guided by these criteria.

Guiding framework

We believe it is incumbent upon Canadian public health practitioners to develop a framework for applying the principle to matters of public health risk. We believe this is a three-part enterprise. The first part is to establish the level of certainty of the cause and effect relationship between the exposure and the supposed harm. This calls for an analysis of the existing science/epidemiology relating to the purported risk. The Bradford-Hill[13] criteria for assessing causation can assist in this quantification of certainty (Question 1, Appendix 1). The second part is to assess the nature of the risk and the level of certainty of harm (Questions 2-5, Appendix 1) that is required before arguing for precautionary action to be taken. Factors such as the potential scope of the exposure, the severity of potential harm and the societal consequences of action and inaction are considered. In general, the greater the magnitude of these factors, the lower the level of certainty that is required for public health action to be taken. The third part (Questions 6-10, Appendix 1) is to conduct a careful assessment of the precautionary measures that could be applied to reduce or eliminate the exposure of concern to ensure they are proportional to the level of certainty about and magnitude of risk averted.

We believe that the appropriateness of applying the precautionary principle increases:[14]

- when the exposure or harm is widespread;
- when the incidence of the harm (i.e., observed health effect) is increasing and is otherwise unexplained;
- when the suspected harm associated with the exposure is serious;
- when the suspected harm associated with the exposure is not easily treatable or reversible;
- when the economic and social costs of removing the exposure are small relative to the suspected harm;
- when the health costs of removing the exposure are minimal;
- when, in addition to the uncertain harms, there are known health, economic or social harms caused by the exposure.

Appendix 1. Ten guiding questions

1. Is there sufficient evidence to support a reasonable suspicion that the exposure of interest causes the proposed harm? (Apply the Bradford-Hill criteria)
   a) Do studies consistently show an effect?
   b) Has a strong association been demonstrated?
   c) Is this a specific outcome associated with a specific exposure?
   d) Has a dose-response (biological gradient) been observed?
   e) Has a temporal relationship been observed?
   f) Is the relationship biologically plausible?
   g) Is the proposed relationship coherent with existing theory and knowledge?
   h) Is there an analogy with a proven cause and effect relationship?
   i) Does experimental evidence support the relationship?
2. Is the harm associated with the suspected exposure serious?
3. Is the suspected exposure widespread?
4. Is there an observed increase in the incidence of the suspected harm that is temporally associated with increased exposure?
5. Is the harm associated with the suspected exposure difficult to treat or reverse?
6. What are the economic and non-economic costs and benefits of action and non-action?
7. Are the proposed control measures proportional to the level of risk? Are the economic costs of removing the exposure minimal? Are the health and societal costs of removing the exposure minimal?
8. Are comparable situations being treated similarly according to a standard of practice?
9. Is the level of the protective measures consistent with equivalent areas in which scientific data are available?
10. If precautionary measures are adopted, is there any new evidence to reduce the level of uncertainty about harm and benefit?

Once the decision is made to apply the precautionary principle to a public health risk, consideration needs to be given as to how the principle should be applied. We believe the European Union[15] guidance on applying the precautionary principle is useful in this respect and can be adopted for public health decision-making in Canada. According to the EU guidance, the level of precautionary measures taken should be guided by the following key concepts:

Proportionality means tailoring measures to the chosen level of protection. Risk can rarely be reduced to zero, but incomplete risk assessments may greatly reduce the range of options open to risk managers. A total ban may not be a proportional response to a potential risk in all cases. However, in certain cases, it is the sole possible response to a given risk.

Non-discrimination means that comparable situations should not be treated differently and that different situations should not be treated in the same way unless there are objective grounds for doing so.

Consistency means that measures should be of comparable scope and nature to those already taken in equivalent areas in which scientific data are available.

Examining costs and benefits entails comparing the overall cost of action and lack of action in both the short and long term. This is not simply an economic cost-benefit analysis: its scope is much broader, and includes non-economic considerations, such as the efficacy of possible options and their acceptability to the public.

Subject to review in the light of new scientific data means that when the precautionary principle and measures are applied, the chosen level of protection should be maintained so long as scientific information is incomplete or inconclusive and the risk to public health

resulting from the removal of the precautionary measures continues to be considered too high to impose on society.

CONCLUSION

We propose ten guiding questions (Appendix 1) to help establish whether a proposed application of the precautionary principle on a public health matter is based on adequacy of the evidence of causation, severity of the harm(s), and acceptability of the precautionary measures. We encourage public health practitioners to use these questions when deliberating on the appropriateness of applying the precautionary principle to matters of public health policy.

REFERENCES

1. United Nations. Report of the United Nations Conference on Environment and Development, Rio Declaration on Environment and Development. 1992.
2. Treaty Establishing the European Community, February 7, 1992, reprinted in 31 ILM 247 art 130r(2) (1992).
3. Kriebel D, Tickner J. The precautionary principle and public health. Reenergizing public health through precaution. *Am J Public Health* 2001;91:1351-55.
4. American Public Health Association Policy Statement #200011: The Precautionary Principle and Children's Health. Available at: www.apha.org/advocacy/policy/policysearch/default.htm?id=216 (Accessed July 29, 2010).
5. Final Report. Commission of Inquiry on the Blood System in Canada. Public Works and Government Services Canada, 1997. Available at: http://www.hc-sc.gc.ca/ahc-asc/activit/com/krever-eng.php (Accessed July 29, 2010).
6. The Honourable Mr. Justice Archie Campbell. The SARS Commission, Final Report. Commission to Investigate the Introduction and Spread of SARS in Ontario. Available at: http://www.health.gov.on.ca/english/public/pub/ministry_reports/campbell06/online_rep/index.html (Accessed July 29, 2010).
7. Sandin P, Peterson M, Hansson SO, Ruden C, Juthe A. Five charges against the precautionary principle. *J Risk Research* 2002;5(4):287-99.
8. Wilson K, Wilson M, Graham I, Hebert P. The application of the precautionary principle to the health sector: Lessons learned from decisions concerning variant Creutzfeldt-Jakob disease and the blood supply. *Transfusion Med Rev* 2002;17:89-94.
9. Swerdlow D, Mintz E, Rodriguez M, Tejada E, Ocampo C, Espejo L, et al. Waterborne transmission of epidemic cholera in Trujillo, Peru: Lessons for a continent at risk. *Lancet* 1992;340:20-21.
10. Bohannon J. Food aid: Zambia rejects GM corn on scientists' advice. *Science* 2002;298:1153-54.
11. Wingspread Conference Participants. Wingspread statement on the Precautionary Principle. Wingspread Conference. Racine, Wisconsin, 1998.
12. Beloin V, Gagnon F. Public Policies Guided by the Precautionary Principle. National Collaborating Center for Healthy Public Policy, 2008. Available at: www.ncchpp.ca/docs/VBeloinAnC_MEP.pdf (Accessed July 29, 2010).
13. Hill AB. The environment and disease: Association or causation? *Proceedings of the Royal Society of Medicine* 1965;58:295-300.
14. Wilson K. Risk, causation and precaution: Understanding policy-making regarding public health risks. In: Bailey T, Caulfield T, Ries N (Eds.), *Public Health Law and Policy in Canada*. Markham, ON: Butterworth Press, 2005.
15. EU communication on precautionary principle. Brussels, February 2, 2000. Available at: http://www.gdrc.org/u-gov/precaution-4.html (Accessed July 29, 2010).

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RÉSUMÉ

Le principe de précaution, qui influence les politiques environnementales et sanitaires, dit essentiellement qu'un risque potentiel n'a pas besoin d'être entièrement prouvé pour que l'on prenne des mesures afin d'en atténuer les effets. L'application de ce principe aux problèmes de santé publique n'est pas simple et pourrait paradoxalement porter préjudice à la santé du public si elle est faite de façon inappropriée. Pour éviter ceci, nous proposons un cadre d'application du principe de précaution à des risques possibles pour la santé publique. Ce cadre comporte 10 questions indicatives en vue d'établir si une application proposée du principe de précaution à une question de santé publique repose sur des preuves suffisantes de causalité, de gravité des préjudices et d'acceptabilité des mesures de précaution.

Mots clés : politique sanitaire; principe de précaution; évaluation du risque; causalité; prise de décision scientifiquement fondée