

WEIGHING UP THE EVIDENCE

**Making evidence-informed guidance accurate,
achievable, and acceptable**

A summary of the workshop held on September 29, 2005

JANUARY 2006



Canadian Health Services Research **Foundation**
Fondation canadienne de la recherche sur les services de santé

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...pour que la recherche porte ses fruits*

OUR PURPOSE

Vision

A strong Canadian healthcare system driven by solid, research-informed management and policy decisions

Mission

To support evidence-informed decision-making in the organization, management, and delivery of health services through funding research, building capacity, and transferring knowledge

Strategy

To bring researchers and decision makers together regularly to understand each other's goals and professional culture, influence each other's work, and forge new partnerships

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Weighing Up the Evidence

Making evidence-informed guidance accurate, achievable, and acceptable

I. Introduction

By the end of 2005, Canadian first ministers had agreed on evidence-informed benchmarks for medically acceptable waiting times. This laudable objective demands reflection on what types of information should count as evidence and how they can be appropriately combined to create guidance. To assist in this reflection, in May 2005 the foundation released *Conceptualizing and Combining Evidence for Health System Guidance*, a systematic review on the meaning of evidence in healthcare (see www.chsrf.ca/other_documents/evidence_e.php). Within this report, an additional review was conducted to examine deliberative processes that aim to combine different forms of evidence to produce health system guidance.

The report identifies two kinds of scientific evidence: *context-free* and *context-sensitive*. It also identifies a third kind of evidence, *colloquial evidence*, which represents the non-scientific sources of information that decision makers often call evidence. The review of deliberative processes did not reveal anything conclusive on best practices, but it laid the groundwork for future experimentation.

Based on the report's findings, on September 29, 2005 the foundation hosted a one-day international workshop of leaders of organizations mandated to provide guidance to health systems. The objectives for this event were:

- to discuss the roles of different kinds of research in evidence-informed decision-making;
- to discuss the role of colloquial forms of evidence as complements to research-based evidence; and
- to share experiences and explore potential best practices related to using deliberative processes to combine multiple forms of evidence.

The following report provides the essence of discussions at the workshop.

II. Key Messages

- Participants found the distinction between context-free and context-sensitive evidence useful and appropriate. However, rather than absolute categories, they should be treated as the two poles of a continuum of scientific evidence.
- Context is as challenging a concept as evidence. Some participants pointed out that effectiveness research is about testing how contextual factors moderate an effect. Therefore, it is accurate to call efficacy studies context-free but not effectiveness studies. It was agreed that context in the case of context-sensitive guidance meant something different — it is about the factors influencing how implementable an intervention will be, not an effect.
- Guidance is another term that needs more definition. Guidance is not equivalent to summarizing research or combining different forms of evidence. Guidance includes detailed recommendations for action that respond to a health system priority.
- Although the literature shows that decision makers work with a colloquial understanding of evidence (often alongside a scientific understanding), some participants felt strongly that the information classified as colloquial evidence should not be called evidence. They acknowledged the importance of this information but suggested finding a substitute term, such as “colloquial knowledge” or “colloquial factors.”
- Debate over colloquial evidence led to the suggestion that we should consider the quality of different sources of colloquial evidence. Unverified assertion, for example, is not of the same nature as direct observation, though both could be classified as colloquial evidence.
- Colloquial evidence should not be, and probably cannot be, combined with scientific evidence. The role of colloquial evidence is more to *inform* the scientific evidence — guiding the selection and interpretation of science and filling in gaps when they appear.
- A key function of the deliberative process is to ensure the scientific forms of evidence take priority over colloquial evidence. The biggest challenge in designing a deliberative process is figuring out how to incorporate the colloquial while keeping it subsidiary to the scientific.
- A deliberative process can be a step towards the implementation of the guidance it produces, as well as a tool for combining different forms of evidence. It could add scientific and social credibility to the decision-making process because it brings together stakeholders who will be directly affected by whatever decision is eventually made on the basis of the guidance.
- The core features of a deliberative process include the presence of a strong chairperson; consideration of different types of evidence; engagement between the scientific and decision-maker communities; an explicit process of exclusion and inclusion; face-to-face discussions; an appropriate timeline for questions; and a mechanism to elicit the values of the participants. There should also be a venue for expressing minority views at the end of the process.

III. Workshop Summary

a. Scientific Evidence

The term “evidence” can conjure up different meanings for different people. In evidence-informed healthcare, evidence is usually equated with the results of scientific research. However, *Conceptualizing and Combining Evidence* showed that science tends to be considered rather restrictively, privileging research in the efficacy and effectiveness mode. The report describes this as context-free evidence and points out that there are other kinds of research, such as those found in the social sciences, that can count as scientific evidence. This research tends to focus on contextual factors related to the environment within which interventions are introduced, so it is called context-sensitive evidence. The first session of the day tested the assertion that fully evidence-informed guidance should combine evidence of what works in general — context-free evidence — with evidence about the conditions of implementation — context-sensitive evidence.

The right context?

No one disputed the suggestion that there are multiple scientific approaches, each qualifying as evidence in evidence-informed guidance. However, there was some disagreement around the use of the term context. Like evidence, context can mean different things in different settings.

Some felt compelled to make the point that, in reality, no evidence can be entirely free of context. Even in efficacy studies, they argued, we must take into account some form of context for the evidence to be valid. Moreover, research is always conducted within a context. Context-free evidence is not free of human influence, nor free of interpretation. Some participants also found the term “context-free” pejorative because it suggests there is something wrong with the goals of efficacy research.

One starts to ask questions about context when one moves from “can it work?” to “does it work?”

A few participants were critical of the report’s classification of effectiveness research as context-free evidence. They pointed out that effectiveness research is about testing how contextual factors moderate an effect. It is perhaps fair to call efficacy studies, with their meticulously controlled conditions, context-free, but effectiveness studies are, at least to a degree, context-sensitive. One starts to ask questions about context when one moves from “can it work?” to “does it work?”

This point made, the group agreed that effectiveness research does not fully represent what was intended by the label “context-sensitive evidence.” Whatever contextual knowledge is provided by effectiveness studies can be augmented by other forms of research. Once research is compiled on what interventions can work and in what settings they are proven to work, one can further investigate research on the organizations, practitioners, and patients in the region for which guidance is being produced. Scientific evidence is potentially available on a host of factors that could mitigate the applicability of something that is proven effective. This evidence on context can help with leftover questions; for instance, about the external validity of context-free evidence, changing how a policy or decision is implemented when other factors, such as location, politics, and morals, are taken into account. Thus, context-sensitive evidence can identify factors which may influence the applicability of context-free evidence.

Generally, participants of the “Weighing Up the Evidence” workshop found the distinction between context-free and context-sensitive evidence a useful categorization of the scientific evidence that should inform guidance and decision-making. Their reservations were about the possibility of treating these as absolute categories. One suggestion was to consider the most appropriate evidence for the question under consideration, rather than considering it essential to always combine two categories of science to produce guidance. The best mix of context-free and context-sensitive evidence will be different for different questions. In order to find the right evidence, the nature and objective of the question must be identified. In addition, both types of scientific evidence have different roles in the construction of guidance, and both should be considered to make realistic and implementable decisions. Therefore, rather than absolute categories, they should be treated as the two poles of a continuum of scientific evidence.

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b. Colloquial Evidence

In its efforts to bridge the researcher and decision-maker communities, the foundation has long observed that each works with a different understanding of evidence. This observation was confirmed by the systematic review, which coined the term colloquial evidence to cover the many non-scientific forms of information decision makers call evidence. It was hoped the report helped clarify the potential role of this form of evidence instead of having the concept of evidence be a pivot point for misunderstandings between researchers and decision makers.

The role of colloquial evidence

Colloquial evidence plays an important role when one moves from summarizing research to providing guidance. It surrounds the research to provide another form of contextual information such as resources, expert and professional opinion, political judgment, values, habits and traditions, output from lobbyists and pressure groups, and the particular pragmatics and contingencies of the situation (see Figure 1). Although the literature shows decision makers work with a colloquial understanding of evidence (often alongside a scientific understanding), many participants, particularly the researchers, felt strongly that the information classified as colloquial evidence should not be called evidence. They acknowledged the importance of this information but suggested finding a substitute term such as “colloquial knowledge” or “colloquial factors.”

Some of the researcher participants held strong opinions about the notion of colloquial evidence. According to one, “managers may call this (colloquial evidence) evidence, but they are wrong.” This discomfort is likely due to the fact that colloquial evidence is not typically gathered in a rigorous or systematic way. There is no scientific way to account for, or validate, this type of evidence. As discussed in *Conceptualizing and Combining Evidence*, knowledge is

considered scientific evidence when it is generated through explicit, systematic, and replicable methods. Evidence on people's values, habits, traditions, and professional experience can be considered scientific evidence when it is gathered using social science or other replicable methods. Relevant, non-scientific information is also available in each of these areas. Some find it desirable to marginalize this information, but all agree that it is always present and influences guidance and decision-making. The group did not agree on whether it should be granted an explicit role or kept at the sidelines.

Because of the fluid and informal nature of colloquial evidence, many participants felt it gives special interest groups two “kicks at the can.”

Decision-making is not just one event. It takes place over time, and often there can be multiple opportunities for input. Because of the fluid and informal nature of colloquial evidence, many participants felt it gives special interest groups two “kicks at the can.” “Colloquial evidence provides too many weapons. It not only stacks the deck but also determines the rules of the game.” Colloquial evidence is brought in at the beginning of the decision-

making process and then again throughout the process, giving groups such as lobbyists and pressure groups an opportunity to “trump” scientific evidence with the last word. “Scientists get one kick at the can,” said one participant. “After that, it’s out of their hands. They’re stuck with what they said two years ago.” There was an expressed preference to have scientific evidence heard throughout the decision-making process and not just at the beginning. Under this scenario, the result would be a more level or appropriate playing field for all the evidence presented. The Chaoulli case* was held up as a classic example of how colloquial evidence can overshadow scientific evidence, leading to a decision few, if any, would call evidence-informed.

Participants generally agreed that context-free and context-sensitive evidence could be combined because their foundations are both scientific. Colloquial evidence is entirely different in nature, so it should be considered and weighed differently. The role of colloquial evidence, incorporated into some form of deliberative process, is to *inform* the scientific evidence — guiding the selection and interpretation of science, filling in gaps when they appear, but always subsidiary to the scientific evidence.

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* The Chaoulli case refers to a Supreme Court of Canada decision which considered both forms of evidence for a judgment on waiting times and the right to access private insurance for healthcare services in Quebec. On June 9, 2005, the Supreme Court of Canada struck down Quebec's laws prohibiting private health insurance for medically necessary doctor and hospital services provided under the public health plan. George Zeliotis, a hip surgery patient, and Dr. Jacques Chaoulli, a Quebec physician who favours private healthcare, argued public-system waiting lists cause delays in getting treatment that violate Quebecers' rights to life and security of the person under the *Canadian Charter of Rights and Freedoms* and the *Quebec Charter of Human Rights and Freedoms*.

For more information about the key issues, please see the summary of the conference “Access to Care, Access to Justice: The Legal Debate Over Private Health Insurance in Canada,” at www.chsrf.ca/knowledge_transfer/pdf/access_to_care_access_to_justice_e.pdf.

Figure 1: Colloquial Evidence



Considering the source

According to the report, evidence received from lobbyists and pressure groups is considered colloquial evidence (see Figure 1). However, many participants felt it is inappropriate to consider this type of information as evidence because of its admittedly biased nature. The lobbyist’s job, after all, is to push and promote a specific agenda. Though the views of the public may not be complete or informed, does it make the colloquial evidence less valid? Quality issues aside, some participants felt that decision makers have a responsibility to take into account, in some way, the citizen’s knowledge of the issue, whether it is correct or not.

Debate over colloquial evidence led to the suggestion that the quality and nature of different sources of colloquial evidence should be considered. Unverified opinions or statements should not be weighed equally with direct observation, though both would be classified as colloquial. This is why scientific evidence should be explicitly privileged over colloquial evidence in the production of guidance. It was felt by some that in the end, the political agenda of the day will ultimately determine the implementability of a decision. Whether this is true or not, it was agreed that decision makers should consider the sources of colloquial evidence and give appropriate weights. There can be such a thing as bad evidence.

Defining Terms

Participants found many of the key terms of our discussion unclear and proposed that the foundation work on defining them. Since the workshop, we drafted the following definitions:

Context

With respect to evidence-informed guidance, context refers to the conditions of implementation. A proven intervention will be more or less effective depending on the context in which it is deployed.

Guidance

Guidance is the set of options presented to decision makers by neutral parties on what to do in response to a particular issue and how to do it. Evidence-informed guidance goes beyond summaries or syntheses of research; it makes recommendations for concrete action that consider scientifically proven practices and the contextual factors moderating implementability.

Deliberative process

A deliberative process is a tool for producing guidance based on heterogeneous evidence. It is a participatory process that includes representation from experts and stakeholders, face-to-face interaction, criteria for the sources of scientific evidence and their weight, and a mechanism for eliciting colloquial evidence while making it subsidiary to the science.

c. Deliberative Processes

Different forms of evidence do not combine of themselves into guidance. Decisions need to be made about what sources of information will be gathered and how they will be weighed. In *Conceptualizing and Combining Evidence* we proposed that this decision-making would be best addressed through a deliberative process. Unfortunately, the review found little on the use of deliberative processes to produce health system guidance.

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Though we have little empirical knowledge about how well they work, there is much to be said in favour of deliberative processes on grounds of principle. In the original report, the deliberative process is considered to be needed when there is uncertainty and the issues at stake are seen as debatable. A deliberative process is participative and often follows a period of consultation with relevant stakeholders. It entails both the eliciting and the combining of various types of evidence to reach an evidence-informed judgment. One of the main reasons for convening this workshop was to learn how, or whether,

guidance-producing organizations had tried to use techniques similar to what is called a deliberative process to combine heterogeneous forms of evidence. It was hoped these experts in the production of guidance would outline what a good deliberative process might look like in the healthcare setting. The emphasis, however, was on guidance and judgment; this is an input to, but is not coincident with, the final decision, which is always the prerogative of the manager or policy maker who will be held accountable.

“Fixing the dice”

A key function of the deliberative process would be to ensure scientific forms of evidence take priority over colloquial evidence. The biggest challenge in designing a deliberative process is figuring out how to incorporate the colloquial while keeping it subsidiary to the scientific.

As well as a tool for combining different forms of evidence, a deliberative process can contribute to the implementation of the guidance it produces. A deliberative process could add scientific and social credibility to the decision-making process because it brings together stakeholders who will be directly affected by the decision eventually made on the basis of the guidance.

Participants voiced the concern that making the process participatory mixes science and values. This is exactly the concern voiced earlier about including colloquial sources of information as evidence. The deliberative process, it was argued, is never value-free. Hence, if the process is to be democratic, the values need to be explicit rather than implicit.

It was agreed that the functions of a deliberative process are to combine the context-free and context-sensitive scientific evidence, to elicit colloquial evidence, and to supplement the scientific with the colloquial evidence. Although there can be exceptions, the colloquial evidence should play a secondary, supporting role. Where science is lacking colloquial evidence can directly inform guidance, but it is usually invoked as a tool for filling in contextual details or assisting with the interpretation when, for example, the implications of the science are ambiguous. The deliberative process, therefore, can provide a venue for the colloquial evidence to inform the scientific evidence. The challenge, as one participant put it, is “fixing the dice” to privilege the science while at the same time eliciting relevant colloquial evidence.

The deliberative process, therefore, can provide a venue for the colloquial evidence to inform the scientific evidence.

Participants noted that there are advantages and disadvantages to having the process open to the public. Some felt an open process would consider the values of the public, rather than having their interests declared for them. As a result, the decision will be more readily endorsed by politicians. However, some felt that by having an open forum, there is a risk of being misinterpreted, and strong views may affect the outcome. With a public forum, it was felt that there is also a chance that participants would not feel as open to express or change their positions throughout the process. Some decisions, it was felt, need to be made behind closed doors. On the other hand, transparency enhances credibility. Public confidence is strengthened if they get a view into or participate in the process. Many stakeholders will need some assurance

that recommendations are not based on colloquial evidence and then cloaked in a scientific rationale. Most felt that a certain amount of openness would be beneficial, but the final outcome should be decided privately.

The time required to undertake a deliberative process was also a concern. Some participants felt that it can be a challenge to get the information needed from a deliberative process in a timely way. There must be enough time to properly define the right question, conduct the research, and then ensure the evidence is presented and debated. This means that the use of a deliberative process would not be appropriate for all the questions on which guidance is sought. Deliberation takes time.

The group was asked to consider how it would revise the Petts definition of a deliberative process, quoted in *Conceptualizing and Combining Evidence*: “[a] participatory process that has clear objectives; is inclusive and transparent; challenges science; promotes dialogue between all parties; promotes a consensus about the potential decision, and directly impacts [sic] on the decision itself.” Participants were unsatisfied with this definition and requested that the foundation work on one of its own. One commenter said it could be used to describe many things that are not considered a deliberative process. Though a new definition was not proposed at the meeting, suggestions for core features emerged.

The core features of a deliberative process should include:

- the presence of a strong chairperson;
- consideration of different types of evidence;
- engagement between the scientific and decision-maker communities;
- an explicit inclusion process;
- face-to-face discussions;
- an appropriate timeline for questions;
- a mechanism to elicit the values of the participants; and
- a venue or process for minority views to be expressed and considered.

Characteristics of a deliberative process

Participants discussed the characteristics of a deliberative process that give the right balance, debated the current definition of a deliberative process, and explored each other’s individual experiences through panel presentations and anecdotes.

Select thoughts on evidence and deliberation

A select panel presented its approaches to producing evidence-informed guidance, including establishing a network, formal consultations, task forces, and systematic reviews:

Tony Culyer

National Institute for Health and Clinical Excellence (U.K.)

The National Institute for Health and Clinical Excellence (NICE) conducts both consultations and deliberative processes for health system guidance. The consultations with partnering organizations lead up to deliberative processes, and selected commentators can engage in the process as well. As part of the deliberative process, NICE engages the views of patients and of the public on the values associated with the issue, but the “big test” is professional implementation at the grassroots level.

Shubhada Watson

World Health Organization

The World Health Organization’s Evidence for Health Needs Interventions program provides guidance or policy options to decision makers, not recommendations.

WHO implemented a health evidence network, built evidence-based case studies on issues of interest, and established a policy dialogue series. They also recently established “Health Intelligence,” a tool for 24-hour turnaround for health information evidence.

“We’re talking about managing change. Anytime there’s change, there are leaders and champions. Otherwise, nothing will happen after the discussions. You are the change agents and leaders.”

Although there may be no perfect, cookie-cutter way to design a deliberative process appropriate for all healthcare guidance, it was felt that the “perfect should not be the enemy of the merely good.” The purpose of the deliberative process may be simply to provide an explicit process for something that is often implicit for health system guidance. As one participant summed, “We’re talking about managing change. Anytime there’s change, there are leaders and champions. Otherwise, nothing will happen after the discussions. You are the change agents and leaders.”

Although there may be no perfect, cookie-cutter way to design a deliberative process appropriate for all healthcare guidance, it was felt that the “perfect should not be the enemy of the merely good.” The

Kathleen Lohr
Agency for Healthcare Research and Quality’s Evidence-Based Practice Center
University of North Carolina

At the Agency for Healthcare Research and Quality (AHRQ), the first step of the guidance process is to amass and synthesize research evidence. The implications of the findings are then presented for discussion. Through a task force and then a peer review, the process allows opponents of the possible decision to have an opportunity to add to or object to the report. This step is an explicit process that engages stakeholders and ensures all perspectives are heard.

Ms. Lohr, drawing on her experience at the Institute of Medicine, also added that the keys to a strong deliberative process are allowing the production and release of minority reports; ensuring staff are empowered to complete tasks that inform the guidance; and establishing clear rules of engagement.

Reiner Banken
L’Agence d’évaluation des technologies et des modes d’intervention en santé

As a health technology assessment organization, L’Agence d’évaluation des technologies et des modes d’intervention en santé (AETMIS) recognizes that deliberation and knowledge about context is essential for the evidence-based decision-making process. As opposed to a formal, one-time deliberative process, AETMIS uses deliberation constantly and throughout decision-making. Using councils, peer reviews, critical analyses, and liaisons with stakeholders, their process involves constant interaction with stakeholders to ensure the process is on track.

APPENDIX 1

WEIGHING UP THE EVIDENCE

Making evidence-informed guidance accurate, achievable, and acceptable

PARTICIPANTS

Meena Ballantyne Director General Health Care Policy Directorate Health Canada Ottawa, Ontario	Reiner Banken Deputy CEO, Development and Partnerships Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) Montreal, Quebec
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<p>John Wade Chair Canadian Patient Safety Institute Edmonton, Alberta</p>	<p>Shubhada Watson Regional Advisor, Evidence for Health Needs and Interventions World Health Organization Copenhagen, Denmark</p>

APPENDIX 2

WEIGHING UP THE EVIDENCE

Making evidence-informed guidance accurate, achievable, and acceptable

The Sheraton Hotel Ottawa
O'Connor Room
150 Albert Street
Ottawa, Ontario

September 29, 2005
9 a.m. – 5 p.m.

Objectives:

1. Discuss the roles of different kinds of research in evidence-informed decision-making
2. Discuss the role of colloquial forms of evidence as complements to research-based evidence
3. Share experiences and explore potential best practices related to using deliberative processes to combine multiple forms of evidence

AGENDA

BREAKFAST	8:30 a.m. – 9 a.m.
Welcome <i>Lillian Bayne</i>	9 a.m. – 9:15 a.m.
I. FORMS OF EVIDENCE	
Context-free vs. context-sensitive <i>Introduction by Jonathan Lomas followed by discussion</i>	9:15 a.m. – 10:30 a.m.
BREAK	10:30 a.m. – 11 a.m.
Complementing research: colloquial evidence <i>Introduction by Jonathan Lomas followed by discussion</i>	11 a.m. – 12:15 p.m.
II. FROM EVIDENCE TO GUIDANCE	
Appropriately combining evidence through a deliberative process <i>Introduction by Tony Culyer</i>	12:15 p.m. – 12:45 p.m.
LUNCH	12:45 p.m. – 1:45 p.m.
Appropriately combining evidence through a deliberative process (Continued) <i>Panel Reactions: Shubhada Watson, Reiner Banken, Kathy Lohr</i>	1:45 p.m. – 2:30 p.m.
Implications for health system guidance <i>Discussion</i>	2:30 p.m. – 3:30 p.m.
BREAK	3:30 p.m. – 4 p.m.
<i>Discussion</i>	4 p.m. – 4:45 p.m.
<i>Wrap-up</i>	4:45 p.m. – 5 p.m.