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## Evidence-based health policy: context and utilisation

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### Abstract

Evidence-based decision-making is centred on the justification of decisions. In the shift from an individual-clinical to a population-policy level, the decision-making context becomes more uncertain, variable and complex. To address this we have developed a conceptual framework for evidence-based decision-making, focusing on how context impacts on what constitutes evidence and how that evidence is utilised. We present two distinct orientations towards what constitutes evidence, representing different relationships between evidence and context. We also categorise the decision-making context based on the ways in which context impacts on evidence-based decision-making. Furthermore, we invoke the concept of axes of evidence-based decision-making to describe the relationship between evidence and context as we move from evidence-based medicine to evidence-based health policy. From this, we suggest that it may be more important how evidence is utilised than how it is defined. Based on the research and knowledge utilisation literature, we present a process model of evidence utilisation, which forms the basis for the conceptual framework for *context-based* evidence-based decision-making. The conceptual framework attempts to capture the role that context plays in the introduction, interpretation and application of evidence. We illustrate this framework with examples from policy development for colorectal cancer screening.

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### Introduction

Over the last decade we have observed an explosion in both the availability and accessibility of information. With this, we have seen greater recognition of, and attention given to, the classic economic dilemma between the scarcity of resources and our potentially unlimited wants, raising difficult resource allocation, rationing and priority setting questions. Greater demand has been placed on decision-makers at all levels and in all fields to justify their decisions in response to this dilemma. Decisions are becoming more transparent, shifting from implicit to explicit methods of decision-making (Coast, Donovan, & Frankel, 1996). Evidence-based decision-making has been proffered as a means to

address this growing demand for explicitly justified decisions.

The field of medicine has embraced these movements with the development of evidence-based medicine (EBM) (Evidence-Based Medicine Working Group, 1992), defined as '...the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients' (Sackett, Rosenberg, Grover, Haynes, & Richardson, 1996). While focusing on the individual-clinical level, proponents of the EBM model have advanced a scientific conception of evidence—evidence developed through systematic and methodologically rigorous clinical research, emphasising the use of science while de-emphasising the use of intuition, unsystematic clinical experience, patient and professional values, and patho-physiologic rationale (Evidence-Based Medicine Working Group, 1992). Critics of EBM have suggested that a scientific conception of evidence is too narrow,

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neglecting a more expansive range of evidentiary sources relevant to clinical decision-making (Buetow & Kenealy, 2000; Miles et al., 2000). While proponents of EBM have recognised that scientific evidence, by itself, is not sufficient and needs to be integrated with other types of evidence (Haynes, Devereaux, & Guyatt, 2002; Rosenberg & Sackett, 1996), they still focus on the use of the 'best' sources of evidence (Sackett et al., 1996). This has led to the development of numerous hierarchies of evidence and classification criteria based largely on the sophistication of a study's design and its methodological rigour (Canadian Task Force on the Periodic Health Examination, 1994; Oxford Centre for Evidence-Based Medicine, 2001; US Preventive Services Task Force, 1996). Critics of EBM have countered that these evidence hierarchies lack their own evidence-base, imposing valuations and preferences that endeavour to constrain or limit the influence and impact of the full range of potential evidentiary sources on decision-making (Djulbegovic, Morris, & Lyman, 2000; Miles et al., 2000).

While these debates and discussions continue, EBM has grown more pervasive. Evidence-based decision-making is now garnering greater attention within the health policy environment, with peer-reviewed articles on evidence-based health policy increasingly common (Black, 2001; Harries, Elliot, & Higgins, 1999; Klein, 2000; Macintyre, Chalmers, Horton, & Smith, 2001; Niessen, Grijseels, & Rutten, 2000). But as Black (2001) stated, '[e]vidence-based policy is not simply an extension of EBM: it is qualitatively different'. As we move from EBM to evidence-based health policy, the decision-making context changes, shifting from the individual-clinical level to the population-policy level. Decisions are subject to greater public scrutiny and outcomes directly affect larger numbers of people, heightening the requirement for explicit justification. This shifting decision-making context highlights our current conceptual deficiencies and the limited attention given to understanding the role that context plays in influencing evidence-based decisions.

As the decision-making context shifts from the individual-clinical level to the population-policy level, should what constitutes evidence change? Should the value attributed to different types of evidence change? Should we change how we make evidence-based decisions? To address these issues, we have developed a conceptual framework for evidence-based decision-making, focusing on how context impacts on what constitutes evidence and how that evidence is utilised. We illustrate our framework through a case study of policy development for population-based colorectal cancer screening, which has been integrated throughout the major sections of the paper, to compare and contrast the similarities and differences between EBM and evidence-based health policy. Given the multidisciplinary

scope of this work, our hope is that the conceptual framework will stimulate further discussion regarding the role of evidence, context and utilisation in the development of health and social policy.

## Evidence and context

The two fundamental components of an evidence-based decision are evidence and context. Two distinct orientations towards determining what constitutes evidence are discussed, as is a basic categorisation of the ways in which the decision-making context can impact on evidence-based decision-making. Following this, the relationship between evidence and context in evidence-based decision-making is considered.

### *What constitutes evidence?*

This question is philosophical, rooted in epistemology and ontology theorising how we relate to the world in terms of the creation, interpretation and evaluation of information and knowledge. This question is also practical, embedded in the fundamental process of decision-making, explicating support and justification for the decisions we make. The philosophical and practical aspects of evidence support two distinct orientations to what constitutes evidence, reflecting fundamentally different relationships between evidence and context. The first is a philosophical-normative orientation, while the second is a practical-operational orientation.

The *philosophical-normative* orientation towards what constitutes evidence is unconstrained by context, addressing what sources of evidence would be most ideal for justifying a decision. This orientation suggests that evidence has inherent value with the potential to provide veridical justification for decisions (Achinstein, 2001). The philosophical-normative orientation directs focus towards the structural characteristics and properties of evidence (e.g. validity, reliability) in order to establish the appropriateness and credibility of specific types of evidentiary sources for supporting decisions (Schum, 1994). This normative evidence-based mindset (Upshur, VanDenKerkhof, & Goel, 2001) tends to see evidence and context as mutually exclusive, neglecting the role of context in evidence-based decision-making and focusing on what ought to be considered as evidence. Therefore, from a philosophical-normative orientation, what constitutes evidence is largely a function of the quality of the evidence, with the supposition being that higher quality evidence should lead, in turn, to higher quality decisions. Cochrane (1972) championed this focus on the quality of evidence, reflected in the development of numerous evidence hierarchies that employ quality of evidence criteria to classify decisions (e.g. Canadian Task Force

on the Periodic Health Examination, 1994). This focus on the quality of evidence has become further institutionalised with the creation of both the Cochrane and Campbell Collaborations, which facilitate the development of systematic reviews of high-quality scientific evidence for health and social policy, respectively.

In contrast, the *practical-operational* orientation to what constitutes evidence is context-based, with evidence defined with respect to a specific decision-making context. This orientation suggests that temporal and contextual variation heavily influence the determination of what constitutes evidence. Evidence is not static, but rather, is characterised by its emergent and provisional nature, being inevitably incomplete and inconclusive (Achinstein, 2001; Schum, 1994; Upshur et al., 2001). This orientation suggests that evidence is subjective (Achinstein, 2001), with different perspectives producing different explanations for the same decision outcome (Allison & Zelikow, 1999). Evidence may simply describe the state of knowledge at a particular time and place (Postman, 1999). This practical-operational orientation is more aligned with the decision-making sciences, focusing on how a multitude of factors contribute to a decision outcome. In contrast to the philosophical-normative orientation, the practical-operational orientation defines evidence less by its quality, and more by its relevance, applicability or generalisability to a specific context. This orientation suggests that evidence and context are mutually inclusive.

For example, in considering the development of screening policy for colorectal cancer, the philosophical-normative orientation would focus on randomised controlled trial (RCT) evidence, which exists only for the faecal occult blood test, one of a number of possible screening tests for colorectal cancer (Schoen, 2002). Non-experimental evidence for other potential screening tests, such as sigmoidoscopy and colonoscopy, would be subjected to strict evaluation and assessment regarding its intrinsic quality and susceptibility to bias, likely reducing its potential impact on the policy decision. From a practical-operational perspective, the RCT evidence would still provide the primary source of justification for the policy decision, but consideration would also be given to other forms of evidence to examine which screening test might be most appropriate in a particular setting. Furthermore, direct consideration of the local context would be made, incorporating information on ethnic and cultural differences regarding patient/provider acceptability of the various screening tests and assessing the local health system's capacity to provide different screening options on a population-wide basis.

While the philosophical-normative orientation allows important questions to be raised regarding the quality and appropriateness of evidentiary sources, this orientation also restricts thinking on evidence-based decision-

making to narrowly defined scientific evidence, neglecting the role context plays in impacting on what constitutes evidence. In contrast, the practical-operational orientation is based on the idea that context is integral to defining evidence. But what then constitutes context?

### *Two decision-making contexts*

While the philosophical-normative and practical-operational orientations present different relationships between evidence and context, they do not directly address what constitutes context. From a general perspective, we broadly define the decision-making context to include all factors within an environment where a decision is made. A decision-making context is characterised by its complexity, comprising both the known and the unknown and the certain and the uncertain (Plsek & Greenhalgh, 2001). However, we acknowledge that it is virtually impossible, and likely of limited utility, to fully account for all contextual factors that might have some potential influence or impact on a decision. Therefore, the objective in developing this conceptual framework was to focus on the *ways* in which context impacts on evidence-based decision-making. Two general contextual categories emerge: an internal decision-making context and an external one.

The internal decision-making context accounts for the environment in which a decision is *made* and includes factors such as the purpose for the decision-making activity, the role of participants in a decision-making process and the process employed to arrive at a decision outcome. Internal contextual factors can be manipulated and controlled, and explicitly reflect the contextual changes that occur as we move from EBM to evidence-based health policy.

The internal decision-making context is tied to purpose. More than just presenting objectives to address a problem, the purpose can identify contextual boundaries. However, some argue that the purpose is not always entirely clear (Langley, Mintzberg, Pitcher, Posada, & Saint-Macary, 1995; Miller, Hickson, & Wison, 1996). Langley et al. (1995), addressing organisational decision-making, asked the question, “[m]ust there always be a clear *point* as well as a clear *place* of decision” (italics in original)? They added that interpreting the nature of any commitment to decision-making is often difficult and that this is problematic as “...the measurement of associated decision characteristics...demand clear definitions of the temporal and substantive boundaries of the phenomenon” (Langley et al., 1995).

The role that participants in the policy-making process play in defining context is sometimes overlooked in the literature. Participants constitute a key factor that can impact both what constitutes evidence and how

evidence is interpreted and applied (Champagne, 1999; Langley et al., 1995; Lomas, 2000; Weiss, 1983). Participants can bring personal issues or relationships to the table that might not otherwise be addressed, altering the purpose and context for decision-making. Even proponents of EBM have acknowledged that “[e]vidence does not make decisions, people do” (Haynes et al., 2002).

Perhaps the most critical internal contextual factor is related to the process of decision-making. Process includes both purpose, the ‘why’, and participants, the ‘who’, but really addresses the structures and mechanisms for ‘how’ decisions are made. A number of models have been proposed to explain how decisions are made, including rational actor, organisational process, governmental political, incremental, mixed scanning and irrational (garbage can) models (Allison & Zelikow, 1999; Lindquist, 1988). However, these models often provide conflicting interpretations of how decisions are made (Allison & Zelikow, 1999). For example, rational actor models suggest that the evidence drives informed decision-making, whereas incremental models portray the decision-making process as a continual evolution without fixed temporal or contextual boundaries, dismissing the term ‘evidence’ as restrictive or artificial. More practically, the decision-making process can determine the nature and extent of background preparation, the inclusion/exclusion criteria and source of evidentiary inputs, the type of participant interaction, the requirements for consensus, and the support structure for the decision-making process (Lomas, 1991).

For example, when addressing the development of colorectal cancer screening policy, the purpose could differ between a focus on the efficacy (can it work?) and effectiveness (does it work?) of potential screening modalities (e.g. faecal occult blood test, sigmoidoscopy, double contrast barium enema, colonoscopy), to a focus on feasibility (should we do it?) and implementation (how do we do it?) of a population-wide cancer screening program in a specific context (e.g. capacity). With a focus on feasibility, one might see less support for a modality such as faecal occult blood testing, which has the highest quality RCT evidence, but which usually has lower acceptability and compliance. ‘Evidence’ on such contextual factors might enter decision-making based on surveys, interviews or focus groups, which would not traditionally be considered in evidence hierarchies. The participants involved could range from trained methodologists and clinicians (e.g. epidemiologists and oncologists) to broader stakeholder representatives (e.g. advocacy/survivor groups and professional organisations), obviously affecting the types and categories of evidence that would be considered in decision-making. Furthermore, the decision-making process itself could explicitly rely on the use of evidence hierarchies,

which would focus attention on scientifically defined evidence, or focus on achieving broad stakeholder consensus, which would bring in a wider array of types of information and knowledge for consideration.

The external decision-making context accounts for the environment in which a decision is *applied* and includes disease-specific, extra-jurisdictional and political factors. External contextual factors are fixed, uncontrollable and cannot be manipulated by decision-makers (at least in the short-term), but clearly play a role in decision-making.

Disease-specific factors include the geographic, demographic and epidemiologic characteristics of a disease, each of which can impact on what constitutes evidence and how that evidence is utilised. For example, the decision to screen for colorectal cancer can be differentially affected by the population’s geographic dispersion or disease-specific factors, such as the age distribution of cancer in the population and the capacity of the health system to provide follow-up services such as diagnostic imaging and colonoscopy in all geographic areas.

Extra-jurisdictional factors refer to the relevant experiences of other jurisdictions that, while operating in different environments, can impact on what constitutes evidence and how evidence is utilised for a specific decision-making context. For example, jurisdictions with experience running small or large-scale colorectal cancer screening programs can provide decision-makers in other jurisdictions with observational data to consider. While this extra-jurisdictional experience may provide limited data for addressing efficacy/effectiveness issues, it can provide important information on feasibility/implementation issues, ranging from compliance and acceptability to costs and consequences of their programs.

Political factors include a range of ideological, social, economic and legal issues. Features of a health care system, including the degree of public and/or private financing and service delivery, and the degree of centralisation or decentralisation, potentially constrain or limit policy alternatives. The political attractiveness of a policy issue influences the degree of formal and informal support, while financial implications can constrain decision-makers and dictate evidentiary requirements to support a decision. For example, in developing policy recommendations for colorectal screening many political interests can be considered, including those of patients with colorectal cancer and their families, different health providers and funders of health services. Health providers can have very different views on modalities for screening. Family physicians will speak to the difficulty of getting patients to comply with faecal occult blood testing. Not surprisingly, radiologists will usually favour screening with double contrast barium enemas, or now, virtual colonoscopy (a form of diagnostic imaging), while gastroenterologists and

surgeons will tend to favour sigmoidoscopy or colonoscopy as the modality for initial screening. Each of these stakeholders will put forward their own forms of evidence, as well as criteria for what should be considered to be good evidence, thus influencing the decision-making context.

Both the internal and external decision-making contexts affect what constitutes evidence and how that evidence is utilised. While few would support decisions based solely on purpose, process or participants, not many would argue against the significant role that these internal contextual factors play in any decision. The external decision-making context can play both a contextual and an evidentiary role, in some situations providing constraints or limits for a decision, and in other situations providing an evidentiary basis for supporting or justifying a decision.

#### *Axes of evidence-based decision-making*

While the two orientations for determining what constitutes evidence highlight different relationships between evidence and context, and the internal–external categorisation of contextual factors sets out a framework for the ways in which context can impact on evidence-based decision-making, we still need to understand how evidence-based decision-making differs as we move from EBM to evidence-based health policy.

To provide further elucidation, the concept of ‘axes of evidence-based decision-making’ has been invoked, comprising of an ‘evidence axis’ and a ‘context axis’ (Fig. 1). Advancing along the evidence axis, the importance of scientific evidentiary sources in decision-making increases, reflected in increasing demand for evidence from RCTs and meta-analyses. Advancing along the context axis, the importance and role of contextual factors in decision-making increases, related

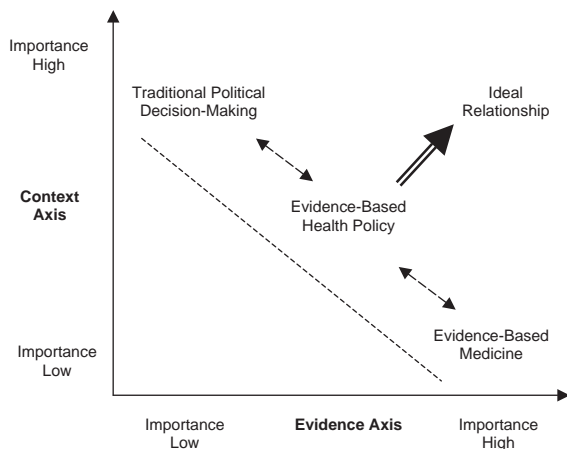


Fig. 1. Axes of evidence-based decision-making.

to both how the decision is made, and where the decision is applied.

EBM is positioned high on the evidence axis but low on the context axis. Consistent with a philosophical–normative orientation towards evidence, EBM focuses on the quality of evidence while attempting to neutralise the role or impact of the decision-making context. EBM has had a catalytic impact on the demands for high-quality evidence, reflected in increasing interest in meta-analyses and systematic reviews produced by the Cochrane Collaboration and others, and the extensive development of clinical practice guidelines, all of which strive to improve the quality of evidence. However with EBM, determination of the generalisability of evidence is implicitly left to the individual-clinical level, whereby clinicians assess the applicability of evidence and/or evidence-based guidelines with respect to each specific patient’s circumstances (Haynes et al., 2002). In the development of recommendations for population-wide colorectal cancer screening, the internal decision-making context would involve relatively fewer participants, a clearer purpose and a simpler process, while the external decision-making context with respect to an individual patient would be relatively less complex, variable or uncertain. EBM engages clinicians to remain up-to-date with the state of the science, through the maintenance of critical appraisal skills and the ongoing familiarity with the existence and use of clinical practice guidelines.

In contrast to EBM, traditional political decision-making is positioned high on the context axis and low on the evidence axis. Evidence is only one of a number of factors that affect decision-making, with internal and external contextual factors providing the basis for traditional political decision-making. Traditional political decision-making is defined by its context, and lacks a clear mechanism for defining or utilising evidence appropriately or effectively. Comments that policy decisions often lack an evidentiary base reflect this focus on context. For colorectal cancer screening, traditional political decision-making would typically address the relative need for a screening program, influenced largely by the interplay of key internal contextual factors (e.g. purpose, participants and process) and the impact of external contextual factors including political (e.g. what are the economic implications of a population-wide program, is it consistent with the ideological focus of the policy-makers, is it a politically attractive issue to pursue?), extra-jurisdictional (e.g. do similar population-wide programs exist in other jurisdictions?) and disease-specific characteristics (e.g. which population groups would be most affected by a population-wide program?). The quality of the scientific evidence available would be only one of several factors considered, if at all.

From an evidence-based health policy perspective, is there a middle ground? The axes of evidence-based



decision-making suggest that there is an inverse relationship between the importance of evidence and the importance of context as we move from EBM to traditional political decision-making. Evidence-based health policy-makers face conflicts when attempting to apply the highest quality evidence possible to population-wide health policy decisions, while at the same time recognising that evidentiary thresholds may have to be relaxed to incorporate a broader range of evidentiary sources. When is there enough evidence, of sufficient quality, and appropriately generalisable, to justify a population-wide evidence-based decision? Does the relationship between evidence and context necessitate a trade-off? Might it not be possible to attain a more ideal relationship where evidence-based decisions are based on the highest quality of evidence possible with a full consideration of context? These questions reflect a key distinction as we move from a philosophical-normative orientation to a practical-operational orientation, with the supposition that the better we understand the context, the better our position to utilise high-quality evidence of all types.

While both evidence and context are fundamental to evidence-based decision-making, there will always be grey zones blurring a clearly definable relationship between evidence and context (Naylor, 1995). Therefore it may be less critical how these fundamental components are *defined*, and rather more critical how the decision-making context impacts on how evidence is *utilised* in the development of evidence-based decisions.

### Evidence utilisation

The two fundamental components of evidence-based decision-making, evidence and context, have been addressed. However, it is the interaction between evidence and context in evidence-based decision-making that is most critical to the development of evidence-based health policy. Even when there is general agreement on what constitutes evidence, there is considerable observational work to suggest that the same evidence, utilised in different contexts, often leads to different decision outcomes (for an example, see Lipskie (1998)). What accounts for these apparent discrepancies? If the evidence is the same, do different contexts lead to different utilisation of the same evidence? To address these issues, several decades of research and development in the fields of research and knowledge utilisation have been reviewed, providing a theoretical base for thinking about 'evidence utilisation'. From this, a conceptual framework for evidence-based decision-making has been constructed.

### *From research and knowledge utilisation to evidence utilisation*

While the research and knowledge utilisation literatures are often used and cited interchangeably, they differ from one another in one important way. Whereas research utilisation has a more restricted focus on the use of scientifically produced research, knowledge utilisation is broader in scope, including a range of other sources of data and information. This distinction is important when considering 'evidence utilisation' as it marks a progression from a rather narrow focus on the utilisation of scientific research, to a broader focus on the utilisation of knowledge, to an unrestrained focus on the utilisation of scientifically and non-scientifically produced information and knowledge in support of a decision.

While several dimensions of utilisation have been addressed, including the purposes for utilisation (Weiss & Bucuvalas, 1980), the utility, degree or extent of utilisation (Beyer & Trice, 1982; Caplan, Morrison, & Stambaugh, 1975; Larsen & Werner, 1981; Rich, 1997), the ultimate impact of utilisation (Rich, 1997; Weiss, 1979), utilisation in relation to beliefs (Dunn, 1989; Zaltman & Deshpande, 1980) and non-utilisation (Rich, 1997), it is not entirely clear what 'utilisation' actually means. Weiss (1979) stated that "much of the ambiguity in the discussion of 'research utilisation'—the conflicting interpretations of its prevalence and the routes by which it occurs—derives from conceptual confusion". Almost two decades later, Rich (1997) added, with respect to knowledge utilisation, that "...it is essential that one be certain of what is meant by use, and that the concept can be operationalised in a fashion which realistically provides a basis for evaluation, accountability, and oversight".

However, recent developments in the fields of research and knowledge utilisation are attempting to address this conceptual confusion, characterised by a shift from the traditional *outcomes* (or input/output) model of utilisation to a *process* model of utilisation (Rich, 1997). The outcomes model was based on a framework whereby one could track the flow of research or knowledge from its introduction into a decision-making process until the time that an action was taken based on that research or knowledge; and that one could measure and assess the impact or influence of a single source of research or knowledge upon the decision-making process (Rich, 1997). These assumptions are deemed to be unrealistic for most decision-making processes as critics suggest that research or knowledge often produce multiple effects rather than a single effect, decision-making is affected by multiple variables other than simply research or knowledge, and that utilisation cannot always be tied to a particular action or choice (Landry, 1999; Lomas, 2000; Rich, 1997).

The process model, on the other hand, suggests that utilisation should be thought of as a series of events (Rich, 1997), incorporating ‘...the idea of stages that correspond to the different stages of the decision-making process’ (Landry, 1999). The process model considers the introduction of research or knowledge into the decision-making process and then opens up the black box, making a distinction between the *use* and the *impact* of research or knowledge (Lavis et al., 2000; Oh, 1996). Oh (1996) and Rich (1997) collaborated on the development of a conceptual framework for knowledge utilisation based on a three-stage process approach. Rich (1997) described these stages as (1) information pick-up, (2) information processing, and (3) information application. To further our understanding of how different contexts affect evidence utilisation, this framework can be applied to evidence-based decision-making, examining what constitutes evidence, how evidence is perceived, valued and interpreted, and how evidence is implicitly and explicitly linked to a decision outcome. Based on this process model of utilisation, the three main stages of evidence utilisation have been identified as the: (1) introduction of evidence, (2) interpretation of evidence and (3) application of evidence.

#### *Introduction of evidence*

The introduction of evidence stage refers to the means by which evidence is identified and the channels through which evidence is brought into the decision-making process. This stage addresses issues related to the availability and accessibility of evidence, including a range of evidence dissemination, transfer, diffusion and transmission activities. The introduction of evidence is based on both the perceived conception of evidence and the operationalisation of that conception of evidence, subject to both internal and external contextual factors.

The initial conception of evidence may be based on established evidence hierarchies, with an initial evidentiary threshold implicitly or explicitly outlined. For example, using the *Canadian Task Force on the Periodic Health Examination's* (1994) Quality of Evidence Criteria, the evidentiary threshold could be established at either Level I (e.g. RCTs) or Level II evidence (e.g. cohort or case-control studies). Evidentiary sources that meet these criteria could be directly introduced into the decision-making process through formal channels from conventional sources (e.g. published research papers). The introduction of other *potential* evidentiary sources (e.g. external contextual factors) may occur more informally, or at a subsequent stage of the evidence utilisation process.

The internal context can directly impact the introduction of evidence into a decision-making process. The purpose frames the problem, raising different questions.

For example, the purpose could be to make a treatment decision for an individual patient, develop practice guidelines for clinicians, or develop recommendations for a population-wide program. As we move from the individual-clinical level to the population-policy level, the purpose progresses from a focus on efficacy and effectiveness to a focus on feasibility and implementation issues. With these differing purposes, the conception of evidence could be broadened or narrowed, legitimising or de-legitimising the formal introduction of different evidentiary sources.

The process can affect the introduction of evidence through the decision to employ established evidence hierarchies and whether primary or secondary evidence reviews and searches will be conducted. The time and effort expended to access evidence and the extent of dissemination, transfer, diffusion and transmission activities can also affect what evidence is introduced. Increasingly more common is discussion of the linkages between the ‘two communities’, researchers and decision-makers (Lomas, 2000). The degree to which linkages exist could clearly have an effect at the introduction of evidence stage.

Decision-making participants can influence on the introduction of evidence by expressing personal values, interests, beliefs, or biases towards different evidentiary sources. As more decision-makers become involved in the decision-making process, participant variability increases. The role of interpersonal relationships, potential conflicts of interest, and individual responsibilities for identifying evidentiary sources, can also be critical.

External contextual factors can indirectly affect the introduction of evidence by altering the internal decision-making context. For example, variation in service capacity among urban and rural areas may influence the purpose for, and/or the participants involved in, a decision-making process, thereby potentially affecting the introduction of evidence. Furthermore, external contextual factors can directly affect the introduction of evidence if some of these factors are formally incorporated into the evidence base at the outset of a decision-making process.

For example, if the introduction of evidence for population-wide colorectal cancer screening is directed by evidence hierarchies, the focus may be restricted to RCT evidence on the efficacy/effectiveness of screening, which only exists for faecal occult blood testing. A broader conception of evidence might allow greater consideration of the role of other screening modalities and include proactive attempts to obtain or collect information on patient/provider preferences, or the system's capacity to provide population-wide services, thereby altering the evidence base for the decision.

### *Interpretation of evidence*

The second stage of the evidence utilisation process is the interpretation of evidence stage. This is where evidence that has been introduced into a decision-making process is synthesised, evaluated and assessed on its quality and generalisability. During this stage there is recognition, appreciation and determination of the relevance, appropriateness, applicability, acceptability and utility of individual sources of evidence for supporting and justifying a decision.

The internal decision-making context directly affects the interpretation of evidence stage. The purpose for the decision-making process can set out the extent to which internal validity will be evaluated and assessed, in some cases commanding decision-makers to rely on external reviews, and, in other cases, engaging decision-makers to directly assess the quality of the evidence themselves. The purpose can also establish limits for assessing the external validity of the evidence. Consider two purposes: one to develop clinical practice guidelines and another to develop a population-wide program. The development of clinical practice guidelines often focuses on the assessment of the internal validity of the evidence, with the assessment of external validity deferred to the clinician who would be responsible for interpreting whether or not an individual patient's specific context appropriately fits within the constraints of the evidence. However, the purpose of developing a population-wide program would place a much greater focus on the interpretation of external validity, requiring careful scrutiny of how applicable the evidence would be to the entire range of individuals making up the target population.

As in the introduction of evidence stage, the decision-making process can affect the interpretation of evidence based on the time and effort expended, the extent of dissemination, transfer, diffusion and transmission activities employed, and the intensity of the linkages between the research and decision-making communities. These process-related factors greatly affect the degree to which the internal and external validity of the evidence can be evaluated and assessed. The use of evidence hierarchies also affects the interpretation of evidence by explicitly prioritising different types of evidence, with limited consideration for the particular quality of individual sources of evidence (Djulgovic et al., 2000). For example, although most evidence hierarchies suggest RCTs produce the strongest evidence, not all RCTs are properly designed or conducted appropriately. However, decision-makers sometimes interpret RCT evidence as categorically strong without adequately evaluating characteristics of the specific design or its application. For example, compliance rates varied in the colorectal cancer screening trials and should be explicitly considered in the interpretation of evidence for population-wide policy decisions.

Participants can affect the interpretation of evidence stage for many of the same reasons as they affect what is introduced as evidence. This includes factors such as which particular participants ultimately take on the responsibility for interpreting the evidence, the inter-relationships among participants and personal conflicts of interest. Other critical factors include the participants' receptivity to the evidence, their cognitive and scientific skills, and the confirmation or challenges that the evidence presents to their existing beliefs, intuitions and assumptions (Oh, 1996).

External contextual factors can affect the assessment of internal validity to the extent that the evidence threshold is extended and more external contextual factors are directly considered as evidence. Given the different levels of methodological sophistication or scientific rigour associated with this 'evidence', the confidence in the interpretation of the quality of evidence can thereby be weakened. However external contextual factors, by their definition, are directly connected to the assessment of the external validity of evidence, and mark the most obvious and direct relationship between evidence and context. The more clearly the external decision-making context is understood, the more clearly the evidence is understood, resulting in improved interpretation of the generalisability of the evidence to a particular context in which a decision is to be applied. This reflects the growing recognition of the need to move beyond the usual focus on internal validity of evidentiary sources to improve methods for interpreting the external validity of evidence when making evidence-based decisions (Horton, 2000).

For colorectal cancer screening, evidence hierarchies play an important role in assessing the quality of the evidence on efficacy/effectiveness, favouring faecal occult blood testing which has RCT evidence, but providing an unclear framework for assessing the quality of evidence on other screening modalities within a population-wide context. As noted above, stakeholder representation can play an important role in assessing the quality and generalisability of evidence for feasibility and implementation, where RCT evidence is less likely.

### *Application of evidence*

The final stage of the evidence utilisation process is the application of evidence. This is where evidence, that has been introduced and interpreted, is applied to support or justify a decision. While in the interpretation of evidence stage, individual sources of evidence are evaluated and assessed, in the application of evidence stage, collective sources of evidence are weighted, prioritised and/or transformed.

This stage reflects the ultimate influence and impact that individual sources of evidence have on the decision outcome. Many previous frameworks on research or



knowledge utilisation, based on the outcomes model, more closely focused on this stage of the evidence utilisation process. However, again, what is important about the process model of utilisation is that the impact of evidence is distinguished from the use of evidence. Attention is given to subtle changes, partial usage and direct or indirect transformation between the evaluation and assessment of evidence and the weighting and prioritisation of evidence, with the key being the consistency of evidence utilisation between the interpretation and application stages. If there is inconsistency between these stages, what accounts for the transformation? As Upshur (1999) stated, “[i]t is necessary... to give an account that clarifies how the differing roles of evidence can be weighted at different contexts and levels of health care”.

Again, both internal and external contextual factors have an impact. The decision-making purpose (e.g. an individual-clinical treatment decision versus population-wide program development) can set out the level of demand and expectation for evidentiary support and justification of decision-making. The process can differ regarding the development of, or requirements for, consensus among decision-makers. As in the previous two stages, if a decision-making process employs an established evidence hierarchy, the application of evidence may reflect conformity to that evidence hierarchy, rather than incorporating less conventional evidentiary sources to support the decision. Decision-making participants can affect the application of evidence similar to their impact on the other stages, with personal factors, interpersonal relationships and individual and/or collective conflicts of interest, directly and indirectly affecting how evidence is applied to a decision.

The external decision-making context also plays an important role in influencing the application of evidence. This often relates to the ideological compatibility, political saleability or economic feasibility of a potential evidence-based decision. For example, the existing political governance or the ruling ideology can affect the application of evidence at a population-policy level by making certain decisions unacceptable, necessitating a transformation from an unpopular interpretation of evidence to an application of evidence that is more politically or ideologically acceptable. The external decision-making context can also affect the prioritisation of evidence if, for example, a population has a strong rural component, whereby accessibility and equity issues play an important role in determining how different evidentiary sources are weighted and prioritised to justify a decision.

For colorectal cancer screening, different means of weighting or prioritising evidence can alter how experimental and non-experimental evidence on different screening modalities are considered. For example, if

patient/provider preferences are assessed in the local context, and it is suggested that there would be poor compliance with faecal occult blood testing, other modalities might be considered more seriously. Another example is that despite the favourable characteristics of a uniphase colonoscopy screening program, the weighting of supportive evidence could be reduced by consideration of system capacity constraints which might suggest that a population-wide colonoscopy screening program would not be feasible. Therefore, the application of evidence plays a critical role in the ultimate support or justification for a decision.

### **A conceptual framework for context-based evidence-based decision-making**

Evidence utilisation includes not only the determination of what evidence is needed to make a decision, but also how the internal and external validity of individual sources of evidence are assessed and how individual sources of evidence are collectively weighted and prioritised. Both internal and external contextual factors fundamentally influence and affect what constitutes evidence and how we utilise that evidence to justify decisions. To better understand how evidence-based decisions are, and should be made, further understanding of how context affects the introduction, interpretation and application of evidence is needed. Thinking needs to shift from evidence-based decision-making to *context-based* evidence-based decision-making.

Fig. 2 provides a graphical representation of the conceptual framework for context-based evidence-based decision-making. Solid lines represent formal channels for evidence utilisation and the direct impact of internal and external contextual factors, while dashed lines represent informal channels for the indirect impact of internal and external contextual factors. The figure emphasises the conceptual difficulty in distinguishing between evidence and context by fusing the evidentiary sources box with the external contextual factors box. Greyed arrows represent the iterative nature of decision-making. The final arrow exiting the application of evidence box acknowledges the ‘post-evidence utilisation’ continuation of the evidence-based decision-making process (e.g. implementation, evaluation).

The colorectal cancer screening policy example reveals the utility of this conceptual framework for developing health policy. For example, it is clear that internal contextual factors play an important role in influencing evidence-based decisions by altering the range of purposes, participants and processes employed. The colorectal example emphasises the need to explicitly describe the internal decision-making context, minimising or balancing its impact on evidence utilisation. The

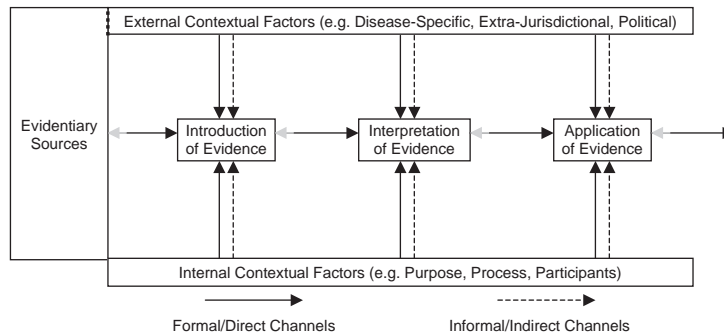


Fig. 2. Conceptual framework for context-based evidence-based decision-making.

external decision-making context, in addition to influencing and constraining evidence utilisation, has considerable potential to contribute to the evidence base. At a clinical level, the results of clinical research can be used to derive recommendations for clinical practice, and traditional evidence hierarchies can be used to assess the quality of the research evidence. However at the policy level, while the clinical research is an important consideration, the colorectal example highlights the need to explicitly acknowledge the role of other factors, such as system capacity constraints, patient/provider acceptability, and the strength of political support, encouraging active efforts to enhance the evidence base by reducing uncertainty in the decision-making context.

In summary, the evidence-based decision-making debate has largely focused on the 'evidence base' while neglecting the 'decision-making context'. With growing interest in evidence-based health policy it has become increasingly clear that existing models of evidence-based decision-making, focused solely on evidence, cannot adapt to the contextual features of broader policy environments. This conceptual framework attempts to shift that debate by suggesting that both evidence and context are integral components of an evidence-based decision. Understanding evidence utilisation within a population-policy context is truly a multidisciplinary challenge, not restricted to the field of health policy or medicine. It is hoped that this conceptual framework stimulates continued progress regarding both the conceptual and practical understanding of evidence-based decision-making with respect to health and social policy.

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