



## ORIGINAL ARTICLE

# Decision-making frameworks and considerations for informing coverage decisions for healthcare interventions: a critical interpretive synthesis

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**Abstract**

**Objective:** To guide decision-making about whether or not to pay for a new healthcare intervention, a number of existing frameworks systematically weigh scientific evidence, cost, and social and ethical values. Each framework has strengths and limitations. This study aims to review and summarize available frameworks and generate an integrated framework, if and where applicable, highlighting particular issues faced with expensive but effective and desirable healthcare interventions.

**Study Design and Setting:** We conducted a critical interpretive synthesis to inform decision-making about healthcare interventions. We updated prior systematic reviews on decision-making frameworks through 2015. Purposive sampling identified relevant constructs and considerations to facilitate decision-making.

**Results:** Of 2,980 references, we purposively sampled 19 frameworks. The new framework, which built on the GRADE Evidence to Decision framework, included burden of disease, benefits and harms, values and preferences, resource use, equity, acceptability, and feasibility. Modifications to the Evidence to Decision framework included adding limitations of alternative technologies considerations in use (expanding benefits and harms) and broadening acceptability and feasibility constructs to include political and health system factors. No modifications appeared necessary to address the situation of effective but expensive and desirable interventions.

**Conclusion:** Guideline developers, health technology assessment producers, and decision-makers can use our integrated framework to inform decision-making about healthcare interventions. © 2017 Elsevier Inc. All rights reserved.

*Keywords:* Decision-making; Health policy; Health resources; Framework; GRADE; Critical interpretive synthesis

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## 1. Introduction

To guide decision-making about whether or not to pay for a new healthcare intervention (e.g., test, treatment, or procedure), decision-makers have access to various frameworks that systematically weigh evidence, cost, and social and ethical values [1,2]. However, additional guidance may be needed when addressing the uncertainty in decision-making for coverage decisions of healthcare interventions that are of high effectiveness and valued by

patients but that are particularly costly to the health system. Highly effective and desirable interventions are defined as ones where, for the individual or patient, all or most of the benefit(s) would clearly outweigh the harms [3]. Examples of such interventions that also come with very high cost include some treatments for cancer and rare diseases, as well as the recently released therapeutic regimens to treat persons with chronic hepatitis C virus infection [4].

A systematic review completed in February 2007 identified 10 distinct methods and models to develop, evaluate, and synthesize health technology and related recommendations [2]. This review informed the development of a framework to guide health technology assessment (HTA) decision-making in Ontario. The search conducted to inform this framework revealed that frameworks facilitating decision-making about a healthcare intervention need

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**What is new?****Key findings**

- While no modifications to the seven-construct GRADE Evidence to Decision (EtD) framework (i.e., burden of disease, benefits and harms, values and preferences, resource use, equity, acceptability, and feasibility) appeared necessary to address effective but expensive and desirable interventions, suggested modifications to the EtD framework include adding consideration of limitations of the alternative technologies in use (as an elaboration of benefits and harms) and, more importantly, broadening acceptability and feasibility constructs to include political and health system factors.

**What this adds to what was known?**

- Modifications to the GRADE EtD framework that consider limitations of alternative technologies and broadening of acceptability and feasibility to include political and health system factors would increase its applicability in a range of political and health systems.

**What is the implication and what should change now?**

- Guideline developers, health technology assessment producers, and health care decision-makers should adopt the suggested framework as a comprehensive and conceptually rigorous now available that also takes into consideration particular issues faced with expensive but effective and desirable healthcare interventions.

not be restricted to HTAs, but encompass frameworks intended to inform recommendations for treatment or procedural topics. Since that review, additional frameworks to guide decision-making have been developed. The review by Johnson et al. was updated through May 2013 and identified 20 new frameworks published in the peer-reviewed literature and nine frameworks from a web-based search of decision-making organizations [1]. From the frameworks identified, similar terms were grouped by construct, with several addressing issues of efficacy (e.g., clinical efficacy), desirability (e.g., patient autonomy or patient preference), and cost (e.g., cost per patient or cost savings from the intervention) or overlapping of those issues (e.g., disease burden/cost, clinical need, and opportunity cost); however, no integrated framework was proposed based on these findings. Moreover, no effort was made to identify the most salient constructs when considering effective and desirable interventions that are particularly costly or to align

constructs with those addressing the political and health systems where decisions will ultimately be made [5,6].

By identifying and synthesizing published decision-making frameworks developed to guide healthcare decision-making, this critical interpretive synthesis will present key constructs with a structured decision-making framework that could be used to inform decision-making about healthcare interventions, including consideration of expensive yet effective and desirable healthcare interventions and across a range of political and health systems.

**2. Materials and methods**

This critical interpretive synthesis featured a three-stage design. Initially, we conducted a systematic survey to identify decision-making frameworks. Second, we identified constructs and dimensions of constructs that were compared across frameworks and then organized into a structured decision-making framework. Finally, we added considerations specific to expensive but effective and desirable tests, treatments, or procedures and to key political and health system factors.

*2.1. Study design*

We determined critical interpretive synthesis to be the most appropriate knowledge synthesis approach for this study as it facilitates iterative and dynamic analyses of complex bodies of evidence to inform the development of new concepts and theories [7,8]. Guided by the compass question “What are the dimensions of a decision-making framework to inform policymakers when considering expensive yet effective and desirable healthcare interventions?”, researchers integrated methodologically diverse literature, including nonempirical literature to delineate constructs and the relationship between them. Researchers iteratively and reflexively assessed the credibility of those findings considering relevance to the compass question, whether or not the study builds from a theoretical basis and the consistency of the results with the theory, how current the research is in the literature, and inconsistency between the studies. Use of critical interpretive synthesis allows data sources, in addition to the databases searched for the review, to be purposively sampled to fill gaps identified during the abstraction process and contribute to the framework throughout the analytic process. The result of a critical interpretive synthesis is a framework which, in this case, was informed by iterative purposive sampling throughout the analysis of literature that was likely or known to be relevant to our topic.

*2.2. Search methods*

A systematic survey was performed of peer-reviewed and gray literature published in the English language, with a focus on January 2013 through December 2015, to update

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