Working title

How is uncertainty characterised in policy analysis and which approaches are relevant to health technology assessment (HTA)? A scoping review protocol.

Introduction

Uncertainty is inherent in any policy analysis, arising from natural randomness or variability, imperfect knowledge, and stakeholder interpretation of a system [1–3]. This is no different for health technology assessment (HTA), which is often applied as a tool to optimise the efficiency, equitability, and quality of universal health coverage schemes with constrained resources [4]. In HTA, for instance, uncertainty may arise through variation in outcomes between individuals, poor quality data and imperfect model structure, as well as through interpretation of the evidence by policy bodies and application of decision rules [5–9]. The way in which such uncertainty is analysed, communicated, and managed during the policy process can affect the decisions that are made [10]. Varying tolerance to uncertainty across HTA committees, for example, is thought to partly explain divergent medicine reimbursement decisions between European countries [11,12].

In HTA, discussion of uncertainty has traditionally been restricted to quantitative analysis of parameter uncertainty, often evaluated through deterministic and probabilistic sensitivity analysis [6,13,14]. Over the last 20 years, there have been significant advances in the literature regarding methods to characterise uncertainty in HTA. These include value of information analysis to determine whether further research is warranted [15], methods to quantify structural uncertainty (relating to assumptions in model structure, functions, and clinical progression) [7,16], and methods to qualitatively or quantitatively consider indirect uncertainty (concerned with data quality and relevance) [17,18]. Yet, to date, there has been limited systematic implementation of these methods in HTA [19–21] or consideration of how to use the outputs of uncertainty analysis to guide recommendations [10]. HTA researchers and policymakers have highlighted that further guidance is required on when quantification of uncertainty is merited [22], the situations in which parameterisation approaches are appropriate [7,18], and what constitutes a comprehensive uncertainty assessment [23]. Furthermore, the outlined methods tend to focus on decision-analytic models, with less attention to combination of decision criteria during policy discussions, uncertainty around the use of decision criteria and thresholds, and uncertainty related to policy implementation [8].

Many frameworks exist to delineate different types of uncertainty in policy analysis [1,6,16,24,25], or to set out best practice for how uncertainty should be assessed [6,7,26,27], communicated [28–30], or managed [2,3,5]. However, the scope, definitions and terminology used across these frameworks are inconsistent. The purpose of this review is to identify commonalities and differences in the types of uncertainty characterised in the literature, as well as the methods proposed to assess, communicate, or manage uncertainty in the policy process. Scoping review methodology will be used as a means by which to identify the nature and diversity of available knowledge [31]. The scope of this review will cover the full policy analysis process, from definition of the problem to analysis, appraisal, decision and implementation.

The specific research questions for this scoping review are as follows:

1. Which types of uncertainty are described in the policy analysis literature?
2. Which classification systems are described in the policy analysis literature?

3. Which methods exist to analyse, communicate and manage different types of uncertainty?
4. To what extent do questions 1-3 differ between health policy literature and other disciplines?

Methods

This scoping review will be conducted in accordance with the JBI Institute methodology for scoping reviews [31].

Eligibility criteria

This review will include papers related to uncertainty in policy analysis. For inclusion, the primary aim of the paper must either be to classify different types of uncertainty or to describe approaches to analyse, communicate, or appraise different types of uncertainty. Primary articles, editorials, and reviews published in peer-reviewed journals will be included as well as book chapters. Papers will be excluded if they fail to provide a definition of uncertainty, or if they do not describe one or more distinct types of uncertainty with a clear description of each. The search dates will be set from 1990 to date of search, to cover literature published since a key publication on uncertainty in policy analysis [3].

Search strategy

The search strategy was developed using the comprehensive pearl growing approach [32]. An initial list of eight studies already known to study authors was used as a benchmark [1,2,5,6,24,28,29,33]. To identify appropriate databases, Web of Science, ProQuest, Scopus, PubMed, EBSCOhost and Embase were searched for these benchmark papers and seven additional papers with a narrower scope [16,18,19,34–37]. Web of Science indexed 14 of the 15 reference papers (93%) followed by ProQuest (13 papers, 87%) and Scopus (12 papers, 80%) (Supplement 1). None of the databases contained one of the reference papers (Walker et al, 2003 [24]), so Google Scholar was also searched and found to contain all 15 reference papers. Google Scholar and Web of Science were therefore selected as appropriate databases for the scoping review.

Key words were extracted from the title, abstract, and Web of Science Keywords Plus for each of the benchmark papers to develop an initial search strategy (Supplement 1). The draft search strategy was run in Web of Science and resulting articles were screened for additional key words until no new key words were identified. Since the updated search yielded 44,486 results in Web of Science, papers resulting from key words with a high number of hits were screened to refine the key words (Supplement 1).

Study selection and data extraction

Removal of duplicates and study screening will be managed in Rayyan [38]. Title/abstract screening and full screening will be conducted by a single reviewer, with 10% of articles checked by a second reviewer. Forward and backward snowballing will be conducted to identify citing references and cited references by browsing the reference list and citation index.

A standardised data extraction template will be used, comprising the following elements:

- citation details (author, year, type of paper, discipline);
- purpose of the paper;
- definition of uncertainty and any other relevant terms (e.g. risk, quality);
- explanation of each type of uncertainty identified (definition, examples, approaches for analysis/evaluation, communication methods, interpretation techniques for decision-making);
- mechanisms for validation of the framework or techniques used in the paper; and
- other notes (for example, if the paper explicitly mentions excluding a commonly accepted type of uncertainty).

The data extraction form will be piloted with five papers and revised before use. Data extraction will not be conducted in duplicate, but a second reviewer will extract data for 20% of studies independently to assess the level of agreement.

Data synthesis

Grounded theory will be used for data analysis. This approach has been chosen to allow concepts from the various frameworks and guidance to surface [39] since a framework developed a priori by authors may miss key concepts. Following the methods put forward by Wolfswinkel et al. for using grounded theory in systematic reviews, open coding will be used to develop concepts before identifying categories and relationships through axial coding, and using selective coding to refine and validate codes [39].

Since this scoping review is primarily a mapping exercise, included papers will not be assessed for quality. However, influential papers will be identified by mapping citation patterns between included papers over time. Borrowing from the network model of technological change (CD_t index) to measure the impact of publications, a paper will be considered disruptive if subsequent work is more likely to cite the paper in question than its predecessors, and a paper will be considered consolidating if subsequent work is more likely to cite both papers [40,41]. For the purposes of this scoping review, citation patterns will be restricted to included papers and presented graphically.

To improve validity of the findings, the results from the preliminary analysis will be reviewed by a panel of experts in HTA.

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