



Evidence and Value: Impact on DecisionMaking – the EVIDEM framework and potential applications

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Background

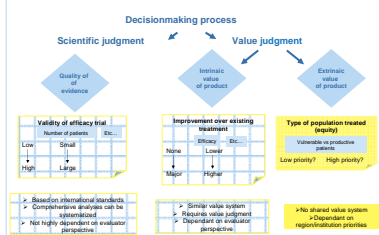
- Healthcare decisionmaking is a complex process that requires simultaneous integration of numerous disparate types of information.¹
- Population based and individual decisionmaking can be divided into two steps: scientific judgment to evaluate the quality of evidence and value judgment about the healthcare intervention.^{2,3}
- There is a need, nationally and internationally, for transparent access to evidence and values on which healthcare decisions are made.⁴⁻¹¹
- Multi-Criteria Decision Analysis (MCDA) is an established method widely used in numerous disciplines. It structures the decisionmaking process by breaking down the problem into a set of criteria which are expected to impact the value of an option.^{1,12} It has been applied to several aspects of healthcare decisionmaking¹³⁻¹⁶ and presents a promising approach to reimbursement decisionmaking.
- We hypothesized that healthcare decisionmaking could be facilitated by structuring evidence and value judgment on which it is based into a practical and transparent architecture and that transparency would enhance understanding of healthcare decisions.

Objectives

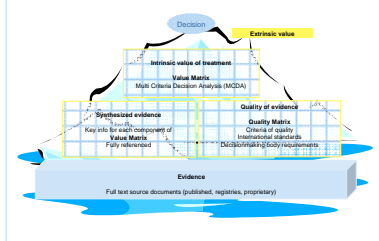
- Breakdown components of healthcare decisionmaking into practical tools structuring and quantifying assessment of healthcare interventions to facilitate decisionmaking
- Build an iceberg architecture to provide multiple layers of transparent access to components of decisionmaking
- Ultimately, optimize health by best use of healthcare interventions

Conceptual framework and architecture

- A conceptual framework was developed that segregated components of decisionmaking into quality of evidence and two types of value judgment: intrinsic value of the healthcare intervention and extrinsic or system related value.
- It was hypothesized that segregating these concepts would make reasoning more explicit, increase transparency and facilitate complex healthcare decisionmaking.
- Quantifiable components that shared commonly agreed direction of scoring were organized into matrices.



- A practical iceberg architecture was designed to support decisionmaking using a MCDA approach to structure intrinsic value components (Value Matrix + VM) while providing transparent access to evidence (synthesized and full text) and quality of evidence (Quality Matrix - QM).
- The architecture was built to facilitate communication, connecting data producers with data users.
- Integrated procedures was developed to ensure efficient use of resources as we develop & apply this architecture to healthcare intervention assessment.



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MCDA Value Matrix

- Assesses the intrinsic value of a healthcare intervention from a specific perspective; it is applicable by decisionmakers at micro (patients, clinicians), meso (payers, institutions), and macro (healthcare policymakers) levels.
- Components defining intrinsic value were identified through literature review, review of explicit criteria used by decisionmaking bodies, and also criteria used to prioritize technology assessment in numerous jurisdictions globally.^{17,18}
- 15 components were selected to fulfill MCDA methodological criteria on completeness, redundancy, operationality & mutual independence.^{1,12} and grouped in 4 clusters.

Cluster	Component of value assessment (alphabetical by cluster)	Weight 1-5 ¹	Systemized Information ²	Score 0-3	Value
Quality of evidence	C1: Adherence to methods of decisionmaking body (dossier)				
	C2: Completeness and accuracy of evidence presented (dossier)		Quality Matrix		
	C3: Reliability and validity of evidence (dossier and dossier)				
Clinical impact	C4: Disease severity (rate of death & disability, incidence)				
	C5: Size of population affected by disease				
	C6: Size of population affected by disease				
Current practice	T1: Current clinical guidelines on treatment or products of same class				
	T2: Current treatment (dossier)				
	T3: Improvement of medical services - efficacy	Independent of product	Structured summary of evidence for treatment	Score: intrinsic and extrinsic	Value score (inner matrix)
Healthcare system	T4: Improvement of medical services - safety & identify				
	T5: Improvement of medical services - patient reported outcomes, satisfaction & adherence				
	T6: Public health related (prevention & risk reduction)				
Economic	T7: Total of medical costs (human value, drug, etc.)				
	T8: Budget impact of healthcare treatment on drug class				
	T9: Cost-effectiveness of treatment				
Social	T10: Access to treatment (based on healthcare spending including financial equity)				
	T11: Social equity				
Total		Aggregated value scores (%) of maximum scoring			

- Available information from public domain and manufacturer
- 2-step assessment:
 - Weighting of VM components from the societal perspective, independent of scoring healthcare intervention; and
 - Scoring of healthcare intervention using scale anchors & scoring guidelines combined with access to synthesized data (prepared using standardized methodology), quality of evidence scores & rationales (QM) and full text sources.

MCDA Quality Matrix

- Assess the quality of all types of evidence for a healthcare intervention;
- 12 QM components (rows) identified from literature review and requirements from more than 20 decisionmaking bodies worldwide¹⁷ organized by field of research;
- 3 QM criteria of quality (columns) relating to: 1) scientific quality (relevance and validity of evidence available); 2) quality of reporting (completeness and accuracy of evidence in dossier, and 3) adherence to decisionmaking body requirements;
- Questions and checklists for 36 QM cells derived from international scientific standards (e.g., CONSORT, CHEC, STROBE, Siegel et al, Mauskopf et al).¹⁹⁻²³

Matrix component	Definition	Adherence to requirements (binary)	Completeness (binary)	Reliability & validity (binary & degree)
1. Disease information	Disease description, disease epidemiology, pathophysiology, clinical presentation, severity of disease etc.			
2. Treatment products	Interventions, active ingredients, formulation, indications, contraindications, side effects, etc.			
3. Impact of treatment	Expected rate of treatment, impact on healthcare system, etc.			
4. Epidemiology	Prevalence, incidence, risk factors, sub-population etc. as applicable and risk factors, trends, sub-population etc. as applicable and risk factors.			
5. Treatment characteristics	Indication, pharmacology, pharmacokinetics, resistance, contraindications, adverse effects, drug-drug interactions, etc.			
6. Clinical data	Randomized clinical trials from clinical trials published, observational studies, etc. from clinical trials published, published in regulatory bodies, etc. from clinical trials published.	Quality score	Quality score	Quality score
7. Patient reported	Patient reported outcomes for treatment including quality of life, satisfaction, compliance etc.	Quality score	Quality score	Quality score
8. Comparative treatment data	Comparative treatment data, head-to-head, etc. from clinical trials published, characteristics for comparative treatment, etc. as applicable.	Quality score	Quality score	Quality score
9. Field of treatment and comparison, drug classification	Field of treatment and comparison, drug classification, etc. as applicable.	Quality score	Quality score	Quality score
10. Economic evaluation	Economic evaluation, impact of treatment on healthcare system, budget impact, etc. as applicable.	Quality score	Quality score	Quality score
11. Social equity	Access to treatment, financial equity, etc. as applicable.	Quality score	Quality score	Quality score
Total		Aggregated quality score (%) of maximum scoring		

- 4-step assessment:
 - Literature review for all types of evidence for the healthcare intervention;
 - Analysis of available evidence (public and manufacturer);
 - Analysis of requirements of decisionmaking body to which manufacturer dossier is submitted; and
 - Scoring and providing rationale for each QM cell.

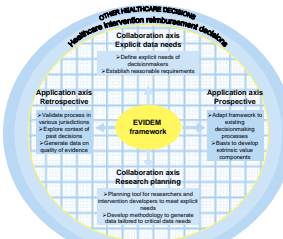
Proof of concept: Pilot study in Canadian context

- The feasibility and value of EVIDEM was assessed by applying it to Canadian historical cases: 10 medicines were assessed (in therapeutic areas of cardiovascular disease, endocrinology, infectious disease, neurology, oncology, ophthalmology) using data from literature review and manufacturer dossiers submitted to the Canadian Common Drug Review (CDR) and Québec Conseil du Médicament (QM). QM scoring was performed by EVIDEM investigators. VM weights and scores, and feedback on process was provided by the Canadian Value Panel, composed of representative stakeholders from across Canada (decisionmakers, specialists, generalists, nurses, pharmacists, health economists/epidemiologists).

- Was the approach feasible? An algorithm was developed to operationalize each cell of the matrices and this was applicable to all therapeutic areas and jurisdictions covered
- Was it practical? It took 30 min on average to apply VM by stakeholders and about 250 hrs to build the structured package of fully traceable information (quality, synthesized format and full text access) and value scores (e.g., 72±25% of max score for T3 for medicine J)
- Feedback from panelists: value of EVIDEM was in structuring evidence, assessing strengths and weaknesses systematically sharing values and value scores
- Limitations of pilot included limited access for panelists to the underlying source data (electronic interface to be developed) and extrinsic components not covered (to be explored)

Potential applications & developments

- EVIDEM supports decisionmaking by structuring, segregating and providing transparent access to data, and by allowing communication of value judgments among stakeholders.
- It can be applied retrospectively to generate data on quality of evidence or on past decisions and prospectively to integrate tools into existing decisionmaking processes and explore extrinsic components (Application axis).
- On the collaboration axis, EVIDEM provides a practical framework to facilitate communication between those who generate data and those who need to make decisions, facilitating future healthcare decisionmaking.
- It can be used for any type of healthcare intervention, and by policy or clinical decisionmakers.



- Future developments include collaborative studies and iterative processes to explore the value of EVIDEM in context as well as development of an interactive electronic architecture integrating evidence and value for various healthcare interventions.
- The expected outcome of a systematized and shareable approach for data access and value assessment is to optimize resources, decisions and health.

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