The Role of Economic Evidence in Canadian Oncology
Reimbursement Decision-Making: To Lambda and Beyond

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Introduction

The reimbursement decision-making process has become an important step for Canadians to access new pharmaceuticals. There is a worry among patients (and often, clinicians) that the reimbursement review process can delay or impede access to effective new medications. In an area like cancer, this is seen to be particularly problematic.

Reimbursement review agencies require cost-effectiveness data to assess the value of new pharmaceuticals. However, it is not clear how this information is used. There are suggestions that decision-making bodies have implicitly or explicitly thresholds (lambda, λ) for cost-effectiveness above which interventions will not be reimbursed. This was investigated, with a focus on oncology drugs.

Objective

The objective of this research was to examine both the use of economic evidence and the role of cost-effectiveness thresholds in reimbursement decision-making for oncology drugs in Canada.

Methods

Three research methods were employed to collect data on the role of economic evidence and the existence of a threshold. Parts (1) and (2) included non-econometric and oncology drugs, to broaden the base of evidence and to provide a comparison:

(1) a literature review
(2) a review of recommendations generated by the Common Drug Review (CDR)
(3) a key informant round table, to gain information outside of the public domain.

Round table participants included:

- three oncologists (two of whom sit on provincial cancer boards)
- three pharmacists (all cancer board members)
- two provincial drug plan advisory board members
- two health economic/health policy academics
- an ethicist
- two patients
- two provincial drug plan managers and two CEDAC members invited but were not able to attend.

The panel was asked to address questions covering the following topics:

- Evidence requirements
  - clinical evidence
  - health economic evidence
  - budget impact evidence
  - Non-evidentiary considerations
    - equity
    - historical precedents
    - role of rescue
    - ethics and law that should guide decision-making
    - role of stakeholders
    - composition of decision-making committees
    - impact of a separate process for oncology drugs

Results

CDR Recommendations:

- Economic evidence went beyond price in only 40% of 62 CDR recommendations.
- For the remaining 60%, price alone categorized most decisions.
- For the 40% which mentioned cost-effectiveness, the reasons for recommendation indicated inconsistent valuation of clinical and economic evidence.
- Recommended oncology drugs reported the highest “acceptable” cost-effectiveness ratios (at $80K/QALY or $71K/LYG), while for non-oncology drugs, $50K/QALY seemed to be considered an approximate upper limit of acceptability.
- Inconsistency and struggles with non-evidentiary factors were also noted in several decisions (equity, affordability and historical precedence).

Roundtable Findings:

Use of economic evidence and existence of thresholds

- There were strong disagreements about the role of economic evidence:
  - Majority thought that health economics had a role, as additional supportive evidence (with the primary evidence being clinical)
  - Minority thought that economic evidence was misused, abused and useless to the decision-making
  - Majority agreed that QALYs and other aggregate measures were unavoidable.
  - Minority argued that QALYs and other aggregate measures should not be used.
- All agreed that the focus on a single metric (QALYs) and a single measure (ICERs) was detrimental; panelists rejected the idea of a simplistic threshold for value.
- It was noted that any positive ICER represents additional spending, which might not be affordable or sustainable.

Beyond evidence

- The ethical conflicts in decision-making were repeatedly raised. When the good of the community and that of particular individuals are in conflict, ethics requires that we can justify not honouring the claims that are not fulfilled. Currently there is a failure to acknowledge ethical conflict.
- Equity is an issue in cancer and non-cancer drug decision-making: not all health gains are valued equally (e.g. children as a patient group are often preferred) but there are no clear guidelines outlining these societal preferences.
- Evidence is not uniformly valued either, and is context-sensitive. Moreover, reimbursement informational demands are different from regulatory informational needs, and this often results in an evidence gap. This difficulty is exaggerated in oncology, where there can be a rapid uptake based on limited data.
- In the absence of an explicit weighting system for evidence and values, decisions can appear inconsistent and not easily defensible.

Discussion

Thresholds of economic value offer a tempting simplicity to reimbursement decision-making. Canadians involved in these processes claim to be rejecting their use, although CDR recommendations indicate an implicit threshold (higher for oncology).

There is a broad desire to go beyond thresholds to enhance the quality and consistency of decision-making.

Suggestions for improvements include:

- Improved transparency of decisions and processes
- Dynamic formulae, including conditional listings
- Expanding the membership of review panels to provide different types of expertise
- Recognition of the inherent conflict in values, depending on the level of decision-making (patient, provider, institution, government)
- Development of explicit Canadian weighting systems for (1) evidence and (2) values

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