



Addressing Challenges to Public Drug Plan Decision Making *A Provincial Case Study*

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Background

- 25- 30% annual increase in cancer drug costs
- **Cancer Systemic Therapy Policy Committee (CSTPC)** formed: initial funding decisions based on NS Department of Health's review processes for publicly funded drugs (evidence plus economics)



CSTPC

- Small treatment benefits
- Lack of robust clinical data
- Lack of economic data

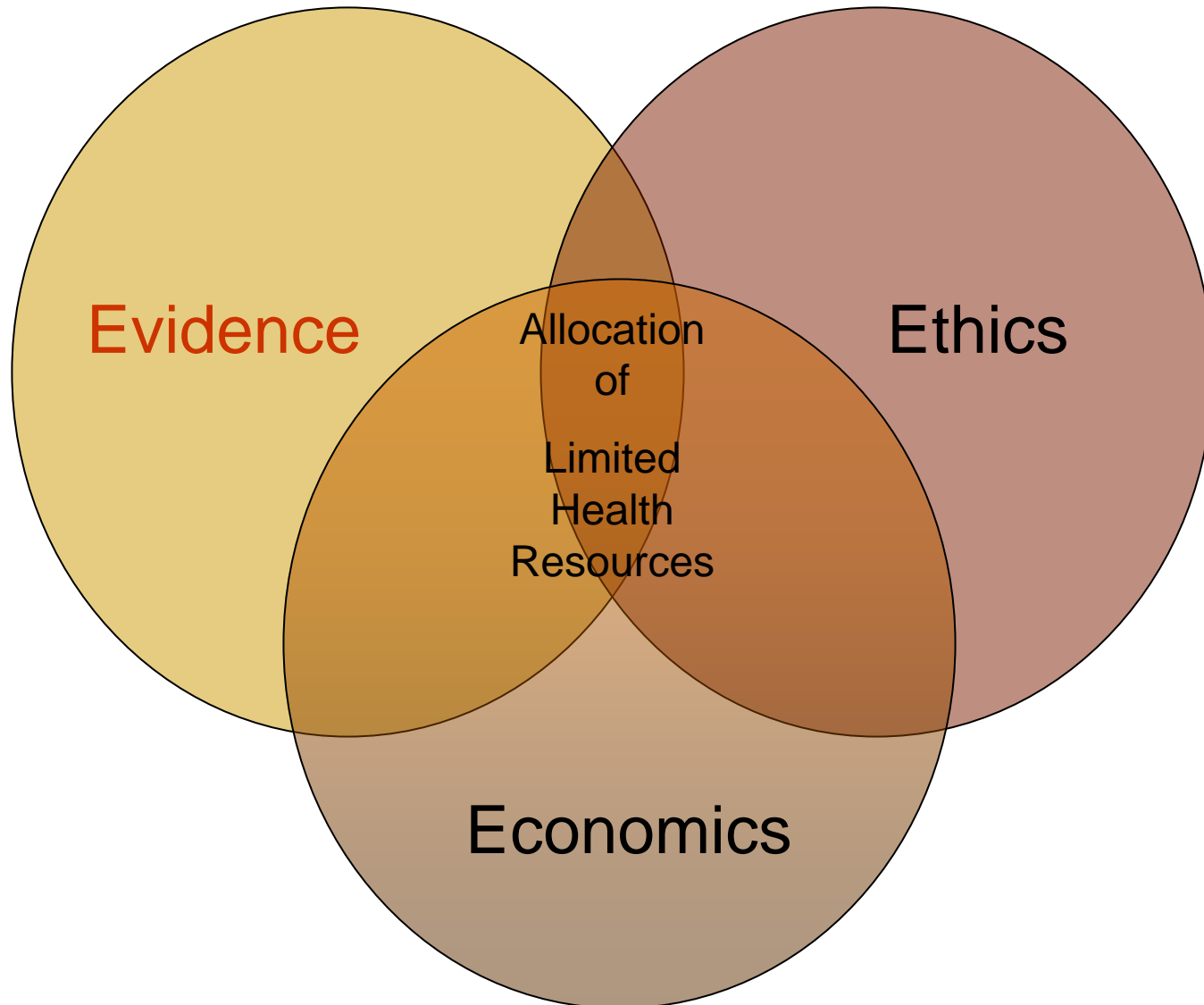
Intense public pressure to fund regardless of cost with little or no concern for sustainability



The goal...

- To develop an inclusive, fair and defensible decision making process for the making of recommendations to the Deputy Minister of Health regarding the public funding of (expensive) cancer therapies that could effectively integrate and synthesize three key elements: **evidence**, economics and ethics = '3E' Decision Making Framework

Public Drug Plan Decision Making





The 'right' decision makers

- Broad, multi-stakeholder group (CSTPC):
 - Persons living-with-cancer
 - Public/community members
 - Health care providers/**researchers**: oncologists, oncology nurses/social workers, etc.
 - Participants from:
 - Cancer Care Nova Scotia
 - Nova Scotia Department of Health
 - Other provincial health care sectors, e.g., Public Health
 - Health economist
 - health care ethicist



Instantiated process values

- Reflection on collaboratively-established process values that are actively incorporated into the '3E' decision making framework:
 - Inclusiveness
 - Collaboration
 - Accountability
 - Procedural fairness
 - Transparency
 - Consistency
 - Responsiveness



Step 1: conflicts of interest

- Acknowledgement and active management by the Chair of any conflicts of interest of individual Committee members with regard to the considered cancer therapy
 - E.g., Financial: shareholding in pharmaceutical company that holds patent for and/or produces the therapy



Step 3: substantive values and principles

- Reflection on collaboratively-established substantive values and principles that are to inform, and act as ethics criteria for, decision making:
 - **Beneficence/nonmaleficence**
 - **Health equity**
 - **Efficiency** (inclusive of drug safety and effectiveness)
 - **Sustainability**
 - **Justice** (determination of a fair distribution of benefits and burdens requires good evidence)



Step 4: clinical presentation

- An invited clinical expert from the relevant cancer site team provides brief, ‘understandable’ descriptions of:
 - The relevant health condition (cancer) and its corresponding incidence/prevalence
 - The therapy and its known or theoretical mechanism(s) of action
 - The results of pivotal (pre and post market) research studies and the related degree of knowledge certainty
 - The clinical guidelines established by the cancer site team and approved by the NS Oncology Subcommittee



Step 2: review of voting process

- A Committee quorum is required for use of the framework
- Decisions re. funding recommendations are made by majority vote as determined by secret, electronic ballot conducted by the Chair one week after use of the framework; Committee members who actively participate in use of the framework are required to vote within one week of receiving their ballots; members who do not participate in use of the framework do not vote; the Chair votes in the event of a tie (mechanisms to mitigate non-constructive power differentials)



Step 5: critical PE appraisal

- The Committee's health economist provides an 'understandable' summary of his/her conclusions/opinions arising from a critical appraisal of the best available pharmacoeconomic analysis(es) of the cancer therapy



Step 6: other information

- Identification and discussion of other relevant information, e.g.,
 - Particular social groups with high risk of the cancer and/or increased vulnerability to non-funding of the therapy
 - Current status of funding in other jurisdictions, e.g., other provinces, UK, Australia
 - The present provincial and Canadian ‘social consensus’ re. public funding of this and similar cancer therapies, if known or determinable



Step 7: constraints

- Identification and acknowledgement of existing constraints on decision making, e.g.,
 - Limited provincial health resources – ‘a given’
 - Government mandates:
 - Provision of particular health services at prescribed volumes
 - Existing inter-provincial agreements
 - Established health care and funding priorities
 - Delays in release of operational funds due to budget implementation challenges, etc.
 - ‘The Law’ and Human Rights Legislation



Step 8: recommendation options

- Identification and discussion of possible recommendation options, e.g.,
 - Approval of funding for use of therapy as per clinical guidelines established by the relevant cancer site team
 - Approval of funding for use of therapy with further restrictions
 - Approval of ‘in-between’ options, e.g., partial coverage with amount determined by sliding scale of income and/or other indices of disadvantage/vulnerability
 - Denial of coverage
 - A. Take no further action
 - B. Attempt to negotiate down drug cost with pharmaceutical company provider



Step 9: analysis of options

- A. Identification and consideration of projected benefits of each possible option
 - E.g. for approval options: review of positive **clinical outcome measures and quality-of-life benefits**; consideration of anticipated savings from discontinuation of supplanted cancer therapies



Analysis of options

- B. Identification and consideration of projected burdens of each possible option
 - E.g., for approval options: review of the therapy's **anticipated, common toxicities/side effects** and related 'systems costs' of their management; anticipation of potential 'opportunity costs'



Analysis of options

o C. Review of relevant pharmacoeconomic indicators, e.g.,

- Drug-only cost per patient per median therapy duration
- Anticipated human and infrastructure resource costs
- Cost per gained QALY
- Budget impact analysis



Analysis of options

- D. Review of appropriate comparators
 - Member of Comparator Analysis Working Group provides a brief summary of actual (or projected) costs of selected, comparable (funded and non-funded) cancer and non-cancer therapies, and, as appropriate, early intervention initiatives, e.g., non-funded screening programs for the cancer



Analysis of options

- E. Ethicist-facilitated Committee discussion of the ethics dimensions, e.g.,
 - The degree of alignment of the possible recommendation options with the five substantive values and principles
 - Competing obligations arising from application of the substantive values and principles
 - Competing legitimate interests: persons living-with-cancer, health care providers/administrators, provincial citizens, etc.
 - Ethics concepts and issues of particular relevance



Analysis of options

- F. Chair-facilitated dialogue with the goal of synthesis and optimal balancing of the evidence, economics and ethics elements in the analysis and comparison of the possible recommendation options



Step 10. determination of the recommendation

- As per step 2., the recommendation to the Deputy Minister is determined by majority vote through secret, electronic ballot
 - After the voting outcome is communicated to Committee members, minority dissenters have the option of submitting their opinions (and rationales for same) to the Chair; these are included in the Dissenting Opinion Appendix to the formal Report & Recommendation



Step 11: report & recommendation

- The Chair prepares a Report & Recommendation to the Deputy Minister, which includes:
 - The CSTPC's majority recommendation
 - The voting outcome in numbers, e.g., 9 to 4
 - A summary record of the key deliberations and the efforts to balance evidence, economics and ethics in the analysis
 - As appropriate, a Dissenting Opinion Appendix
 - A suggested communication strategy and relevant briefing notes



Step 12: appeal mechanism

- An appeal of the Deputy Minister's decision may be made by any member of the public
- An independent Appeals Panel evaluates appeals on the basis of one or more of the following, specific criteria:
 1. The presence of new, relevant **evidence (e.g., from post market studies)**
 2. The demonstration of a significant error(s) in the process (use of the framework)
 3. A significant, sustained reduction in cost of the therapy



Appeal mechanism

- The Appeals Panel recommends to the Deputy Minister one of the following:
 1. Denial of the appeal, i.e., maintenance of the original decision
 2. Re-review of the therapy by the CSTPC through use of the framework



Step 13: follow through

- The framework is reviewed and evaluated on a regular basis by the Committee with regard to:
 - Experiences with its use and the recognition of potential enhancements on the basis of new knowledge/insights and identified gaps/deficiencies
 - Consideration of serial recommendations to assess decision making consistency and the ‘big picture’ outcomes of the framework’s application



Unanswered questions and identified gaps

- How do we fill the gaps in evidence for oncology drugs?
- Should different levels of evidence be used for different classes of drugs?
- Should different review processes be used for different classes of drugs?

- What is the most pragmatic way to enable the public to provide meaningful input into decision making?
- How do we educate the public and politicians so that they are informed and may choose to support these policy decisions once they have been made?



Options under consideration for public engagement

- Citizens juries/panels

A group of randomly selected citizens gather once (in the case of a jury) or regularly (in the case of a panel) to discuss/dialogue and answer policy questions or to address broader issues related to the allocation of limited health resources



Options for public engagement

- Consensus conferences

A group of citizens meet to discuss issues of a scientific or technical nature at: a) a meeting with experts where the goal of the deliberative dialogue is to reach a consensus on management of the issue 'that all can live with', or b) a conference during which key observations and recommendations are presented to the general public (and media)



Options for public engagement

- Deliberative polling

An opinion poll that incorporates an element of deliberation (citizens polled are informed and engaged by the pollster regarding a particular issue) to determine what the public believes/thinks about the issue



Academic paper

The Public Funding of Expensive Cancer Therapies: Synthesizing the ‘3Es’ – Evidence, Economics and Ethics

Citation:

Kirby J, Somers E, Simpson C, McPhee J. The Public Funding of Expensive Cancer Therapies: Synthesizing the ‘3Es’ – Evidence, Economics and Ethics. *Organizational Ethics: Healthcare, Business, and Policy* 2008. 4,2: in press.