E^3 Decision Making Framework Nova Scotia CSTPC

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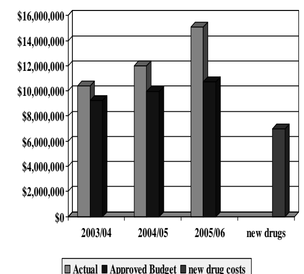
Presentation Agenda

- Background
- Decision Making Framework
- Lessons Learned
- What's Next
- Questions

Background

Background

- Issues identified by District CEOs:
  - Budget overruns
  - Problems forecasting



Background

Nova Scotia Cancer Systemic Therapy Policy Committee (CSTPC)

- first meeting held in June 2005

Background

CSTPC Mandate

- To monitor and support the operations of the CCNS Systemic Therapy Program, including the surveillance of systemic therapy volumes and costs, relative to a provincial cancer formulary
- To make recommendations regarding the introduction of new therapies and new indications for, additions to, and modifications of, the cancer formulary
- To recommend adjustments to DOH and DHA budgets for the addition of new therapies and/or indications, as well as to identify significant workload implications in the delivery of cancer systemic therapies that need to be addressed through the business planning process
- To consider the implications of oral and home-based systemic therapies and direct these issues to the appropriate DOH committee

Background

- **CSTPC – first recommendations January 2006**
- **Identified gaps/deficiencies:**
  - Committee membership
    - Health economist
    - Heath care ethicist
    - Relevant stakeholders, i.e., persons with cancer, participants from other health sectors
  - Comprehensive decision making process

Background

- Health economist and health care ethicist added to the Committee in April 2006
- Collaborative development of an evidence-, economics- and ethics-informed decision making framework

Decision Making Framework

Decision Making Framework

- Initial framework draft completed June 2006
- Used for the review of four therapies to date:
  2 approved; 1 rejected; and 1 pending
- Evolutionary, reiterative development process

E³ Decision Making Framework©

Oncology Therapies Version

Purpose

- To promote and facilitate evidence-, economics- and ethics-informed decision making by the 'right' stakeholders in the making of recommendations to the Deputy Minister of Health regarding the public funding of cancer therapies
- To respect collaboratively-established <u>process values</u>* that have been actively incorporated into the decision making framework, i.e., inclusiveness, collaboration, accountability, transparency, consistency and procedural fairness

  *Chosen by NS CSTPC: promote regional contextualization

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 therapy, e.g.,
  - Financial - shareholding in pharmaceutical company that holds patent for and/or produces therapy

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 do not vote; the Chair votes in the event of a tie

Step 3. Substantive Values and Principles

- Reflect on collaboratively-established substantive values and principles* that are to inform, and act as foundational ethics criteria for, decision making:
  - Beneficence/nonmaleficence
  - Health equity
  - Efficiency
  - Sustainability
  - Justice

  *Chosen by NS CSTPC: promote regional contextualization
- Pay attention to how these values and principles may conflict and lead to competing obligations

Substantive Vs & Ps

- Beneficence/nonmaleficence
  - Benefit, and reduce burdens to, persons living-with-cancer and their families/ intimate others
  - Benefit, and reduce harms to, the 'health' (WHO: "state of …physical, mental and social well-being") of all citizens

Substantive Vs & Ps

- Health Equity
  - WHO: "*a fair chance for all*"
  - Obligation to reduce disparities among individuals and groups of persons in:
    - Opportunities for (good) 'health'
    - Access to health care

Substantive Vs & Ps

- Efficiency
  - Carefully consider in decision making:
    - The efficacy and clinical relevance of the therapy
    - The cost-effectiveness of the considered therapy
  - Promote efficiency in the delivery of limited health resources

Substantive Vs & Ps

- Sustainability
  - Take into meaningful account:
    - The sustainability of resources for the therapy if funded (including drug-only costs and costs of human/infrastructure resources for therapy administration and management of toxicities/side effects, etc.)
    - The sustainability of global resources intended to meet the legitimate health care needs of all citizens
  - Anticipate future health care needs and challenges

Substantive Vs & Ps

- Justice – three relevant types of:
  - Distributive justice: distribute benefits and burdens fairly on the basis of health needs and available resources; in modern times, this entails allocation of limited health resources
  - Formal justice: treat individuals and groups of persons the same unless there is a demonstrable *relevant* difference between/among them that *should* be taken into account

Substantive Vs & Ps

- Social justice: identify, and reflect on, the particular disadvantages and vulnerabilities of individuals and groups of persons who will be directly affected by the recommendation; determine ways to attend to, and reduce, social injustice in the decision making process and its outcomes

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 research studies and the related degree of knowledge certainty
  - The "Guidelines for Role of Therapy" established by the cancer site team and approved by the Oncology Subcommittee

Step 5. Critical PE Appraisal

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

Step 6. Other Information

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

Step 7. Constraints

- Identify and acknowledge 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

- Identify and discuss possible recommendation options, e.g.,
  - Approval of funding for use of therapy as per ‘Guidelines for Role of Therapy’ established by the 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(s) of income and/or other indices of disadvantage/vulnerability
  - Denial of coverage
    - A. Take no further action
    - B. Attempt to negotiate down cost with pharmaceutical company provide

Step 9. Analysis of Options

- A. Identify and consider projected <u>benefits</u> of each possible option
  - See benefits section of evidence column of Therapy Analysis Worksheet
    - E.g. for approval options: review of positive clinical outcome measures and quality-of-life benefits; consideration of anticipated savings from discontinuation of supplanted therapies

Analysis of Options

- B. Identify and consider projected <u>burdens</u> of each possible option
  - See burdens section of evidence column of Therapy Analysis Worksheet
    - E.g., for approval options: review of anticipated, common toxicities/side effects of the therapy

Analysis of Options

- C. Review of relevant <u>pharmacoeconomic indicators</u>, 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 appropriate <u>comparators</u>
  - 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
  - See Comparator Analysis Worksheet

Analysis of Options

- E. Ethicist-facilitated 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 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 Recommendation (first of post-mtg. steps)

- 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 balancing of evidence, economics and ethics in the analysis
  - As appropriate, a Dissenting Opinion Appendix
  - A suggested communication strategy and briefing notes (should the recommendation be accepted by the Deputy Minister)

Step 12. Appeal Mechanism

- An appeal of the Deputy Minister's decision may be made by relevant stakeholders and/or members of the public (excluding CSTPC members)
- An independent Appeals Panel evaluates appeals on the basis of one or more of the following, specific criteria:
  1. The presence of new evidence (analysis provided by the relevant cancer site team)
  2. The demonstration of a significant error(s) in the use of the framework
  3. A significant, sustained reduction in cost of the therapy (which is guaranteed by the pharmaceutical company provider)
- 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

Lessons Learned

Lessons Learned

An evolutionary, reiterative development process…

1. Committee structure/size
2. Committee administrative support
3. PE analysis
4. Comparator analysis
5. Clinician and administrator involvement
6. Transparency
7. Public involvement

What's Next?

What's Next?

- Resize the committee
- Increase transparency
- Refine and pilot the appeals process
- Refine comparative analysis
- Share the framework nationally

Information Sharing

Hot off the presses…

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

Canadian Journal of Clinical Pharmacology