

Public Involvement in Centralized Drug Reimbursement Processes

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Common Drug Review

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What is the Common Drug Review?

- A single process for:
 - conducting objective, rigorous reviews of the clinical and economic evidence for new drugs, and
 - providing formulary listing recommendations to 18 publicly funded drug plans in Canada (excludes Quebec)
 - currently reviews only new drugs
- Formulary decisions are made by the drug plans
 - based on CDR recommendation, and plan mandates, priorities, resources

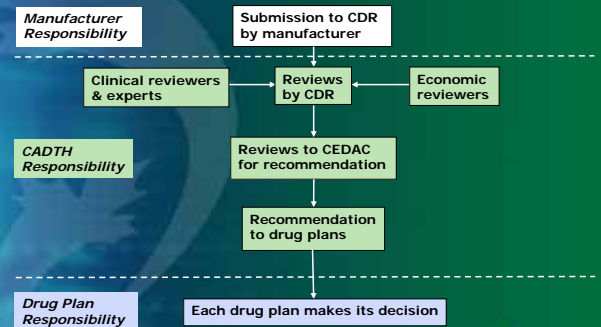
Who Does What – CDR's Role

FEDERAL GOVERNMENT
Approval of new drugs for sale in Canada

CDR Program at CADTH
Evidence-based review
Common listing recommendation (CEDAC)

F/P/T DRUG PLANS
Listing and coverage decision

CDR Process



CDR Fairness and Transparency

- Information available on web site: www.cadth.ca
 - submission guidelines, procedures documents
 - CEDAC bios and conflict of interest disclosures
 - submission status reports
 - 1-2 page recommendations and reasons for recommendation
- In 2007-08:
 - Increased transparency – e.g. published reviews, CEDAC minutes, lay versions of recommendations

Public Involvement at CADTH

- Little call for public involvement when CADTH was doing only evidence-based reviews
- Increased need when CEDAC started making recommendations in 2004
- 2005: CADTH Board asked for options to involve public
- 2006: 2 public members added to CEDAC
- 2007: 2 public members appointed to CERC

Benefits of Public Involvement

- Add a public interest perspective to CADTH's work, increase the relevance of recommendations
- Improve public awareness and understanding of processes and recommendations
- Enhanced opportunities for public support and buy-in

What is Public Involvement?

- Transparency
- Membership
- Expert committees
- Citizen councils
- Integrated committees

Potential for Public Input into Reviews

- Submit drugs/topics
- Contribute to evidence
- Comment on reviews
- Participate in expert committees
- Participate in decision making

Public Involvement - Definitions

- *"Health professional" includes, but is not limited to: physicians, nurses, pharmacists, dentists, hospital administrators, natural health practitioners and alternative medicine practitioners.*
- *"Patients" are persons who require or who are under medical care. A patient may also be a consumer, but not all consumers are patients.*
- *"Public Member" is a person selected to be a member of an expert advisory committee in the capacity of a member of the general public and not as a representative of any specific interest, group or organization.*

Adding Public Members to CEDAC

- Objectives
- Revise Terms of Reference
- Recruitment
- Selection
- Training and orientation
- Integration into committee
- Support participation
- Evaluation
- Continuous improvement

Objectives of Public Involvement

- To assist in identifying the public interest perspective on matters under deliberation, including matters subject to advice and recommendations
- To add credence and improve the public legitimacy and acceptance of recommendations/decisions
- To support greater public awareness and understanding
- To involve informed and interested members of the public and stakeholder groups on relevant matters

CEDAC Terms of Reference

- Public Member – a person selected to be a member of CEDAC in the capacity of a member of the general public and not as a representative of any specific interest, group, or organization
- Should mandate of committee be changed?



Recruitment

- Advertisement in Globe and Mail
- E-mail to CDR stakeholders
- Posting on CADTH website
- Engaged consultant in public and stakeholder engagement



Profile of a CEDAC Public Member

- Knowledge of, or interest in, issues related to the health care system
- Knowledge of, or interest in, issues relevant to CADTH's mandate and the mandate of the committee
- Experience in committee and/or community work
- Demonstrated awareness of, and interest in, the perspectives of members of the general public on issues related to health care services and medicines
- Ability to act with integrity and independence of specific interests



Profile of a CEDAC Public Member (Cont'd)

- Ability to relate to and respect a diverse range of values and beliefs
- Ability to gain respect and credibility within a diverse range of stakeholders and the wider public
- Ability to work constructively as a member of a team
- Ability to form constructive working relationships
- Ability to communicate effectively
- Ability to review and synthesize considerable amounts of information



Selection

- Screened by consultant
- Screened for conflicts
- Reviewed by Nominating Committee
- Shortlist
- Reference check
- Selected by CEDAC Nominating Committee based on ideal member profile
- Demographics considered but not a requirement



CEDAC Public Members

Nancy McColl

- Bachelor of Arts and Education degrees, currently an English/Drama teacher with the Ottawa-Carleton District School Board
- Served on a public advisory committee for Health Canada, Health Products and Food Branch; consulted on a wide range of national health issues, including best practices in the reporting of adverse drug reactions and drug labeling for health product safety
- Invited to attend Expert Advisory Panel on the safety and effectiveness of silicone gel-filled breast implants, provided advice to Health Canada as an independent public member



CEDAC Public Members

Brad Neubauer

- A rancher and businessman in Irvine, Alberta; Bachelor of Arts degree in Political Science and Philosophy
- Actively involved as a member of the public in health care, has served as a member of local and provincial bioethics and research ethics committees
- Has also volunteered in support of the local theatre community in Medicine Hat



Orientation

- CADTH overview, drug approval and use in Canada
- Primer on evidence-based medicine
- Use of cost-effectiveness in decision-making
- Observer at CEDAC meeting
- De-brief after CEDAC meeting
- Primer on health economics and cost-effectiveness
- Common Drug Review overview
- Practical issues for CEDAC members



Integration and Participation

- Orientation of professional members to role of public members
- Social interaction between all members
- Observer status at first meeting
- Points of contact at CDR for support



Evaluation and Improvements

- Underway



Other Considerations

- Remuneration
- When does a public member become an "expert"?
- Lobbying of public members



Other Options for Public Involvement

- Patient representation
 - Ontario Committee to Evaluate Drugs
- Citizen councils
 - National Institute for Health and Clinical Excellence (NICE)
 - Planned for Ontario drug program
 - Citizens Assembly for Electoral Reform



NICE Citizens Council

- 30 member committee
- Reflects the age, range, gender, socio-economic status, disability, geographic location and ethnicity of England and Wales
- Meets twice per year
- Asked for views on issues where NICE needs advice
- Meetings facilitated by an independent organization
- Report and conclusions presented to Board – consensus not necessary



Examples of Referred Issues

- Should the National Health Service (NHS) be prepared to pay a premium price for drugs to treat patients with very rare diseases?
- Should NICE issue guidance that concentrates resources on trying to improve the health of the whole population even if there is a risk of widening the gap between socioeconomic groups?
- Is there a preference to save the life of people in imminent danger of dying, instead of improving the life of other people whose lives are not in immediate danger? Or saving the lives of many people in the future through disease prevention programs?



Conclusions on Ultra-orphan Drugs

- Just over half (16 of 27) of NICE Citizens Council members thought that, with certain conditions, the NHS should consider paying premium prices for drugs to treat patients with very rare diseases
- Four people thought the NHS should pay whatever premium price is required for drugs to treat patients with very rare diseases
- Seven concluded the NHS should not consider paying premium prices for drugs to treat patients with very rare diseases, but should decide whether or not to provide ultra orphan drugs using the same clinical and cost effectiveness appraisals as any other treatment



Summary

- Public involvement in healthcare decision making is a growing trend
- Several options, not mutually exclusive, are available to engage the public
- Important to clearly understand the objectives of public involvement e.g. who, why, how
- Must be support throughout organization
- Public involvement must be
 - Real
 - Relevant
 - Realistic

