Transparency in Canadian Public Drug Advisory Committees

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Objectives

- Decisions regarding public drug formulary listings can be controversial
- In Canada, these decisions are typically made by provincial or territorial Ministries of Health based on recommendations from drug advisory committees
- Because these decisions can be contentious, the recommendation process should be legitimate and fair
- Transparency is an important component for judging fairness
- Transparency in health resource allocation decision making requires that information regarding the recommendation process and the recommendation rationale are publicly available
- We created 7 criteria of transparency and used them to evaluate the degree of transparency across 11 Canadian drug advisory committees

Approach

Data collection

- Key informant interviews
  - Inclusion criteria:
    - Conversant in English
    - Current or former member of a provincial or federal drug advisory committee, government employee, patient advocacy group representative, or pharmaceutical industry employee
- Literature review:
  - Examined frameworks of public and patient involvement in decision making found in the areas of health and environmental studies
- Document review:
  - Collected documents from ten committee websites
  - Documents from the Drugs and Therapeutics Advisory Committee for the Non-insured Health Benefits were not available online and therefore were not included
- Committees represented Yukon Territory, British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Quebec, Atlantic provinces, Nunavut and North West Territories

Data analysis

- Coding and concept formation were conducted using a qualitative thematic approach
  - Line-by-line coding established categories and themes
  - Constant comparison determined relationships within and across codes
- Interviewing continued until no new themes emerged (often referred to as reaching saturation)

Transparency Criteria

- We selected seven criteria based on a literature review and our conceptual understanding of transparency
  1. Mechanisms for appeal;
  2. Stakeholder input during the review process (permitting stakeholders to submit input through submissions, web forms etc.);
  3. Public disclosure of committee members' names;
  4. Publicly available criteria for selection of committee members;
  5. Public posting of negative decisions;
  6. Public posting of decision rationales (including the evidence upon which decisions were made); and
  7. Public posting of members' conflict of interest disclosures
- When rationales were posted on the internet, we assessed:
  1. Their accessibility through direct links on committee websites; and
  2. The readability of the five most recently documents on each website using the Flesch-Kincaid or the Kandel-Moles instrument for English and French rationales, respectively

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Results

Interviews

- We interviewed 27 participants from 11 committees (5 clinical experts and 6 public/patient expert members), 6 patient group representatives, 4 industry representatives and 6 employees of provincial Ministries of Health
- The median age was 55 (range 39 to 68)
- 18 (67%) of participants were women
- 20 (74%) had a professional or graduate degree
- Three major themes emerged from the interview data:
  - Accessibility
  - Communication
  - Confidentiality

Documents

- We obtained data from eight provincial and two national Canadian public drug expert advisory committees

Transparency Criteria

- Of our seven transparency criteria, the median number addressed by committees was 2 (range 0 to 6)
- Both national committees, British Columbia, Quebec and Ontario each met six criteria; the Yukon Territory and Manitoba did not meet any criteria
- Of the five committees that posted rationales, each posted a direct link on the website to rationales that were at a grade 12 reading level or less
- No committee had mechanisms for appeal but most had processes for reconsideration
- The criterion that was least likely to be consistently addressed was making member selection criteria available (addressed by four committees)
- The criterion that was most likely to be addressed was posting of members' names online (met by eight committees)

Table 1. Comparison of Canadian Drug Advisory Committees

	YT	BC	AB	SK	MB	ON	QC	ATL	NIHB	CDEC	pERC
Members											
Clinical experts (N)	3	9	8	12	6	15	11	10	12	12	14
Patient or public expert members (N)	0	3	0	2	0	2	2	0	0	2	2
Transparency Criteria											
Are member names available online?	N	Y	Y	Y	N	Y	Y	Y	N	Y	Y
Are member selection criteria available online?	N	Y	N	N	N	Y	N	N	N	Y	Y
Are "no" decision available online?	N	Y	N	Y	N	Y	N	Y	N	Y	Y
Is there stakeholder input prior to recommendation?	N	Y	Y	N	N	Y	Y	N	N	Y	Y
• Registered Patient Group	N/A	Y	Not Specified	N/A	N/A	Y	Y	N/A	N/A	Y	Y
• Individuals	N/A	Y	Not Specified	N/A	N/A	N	N	N/A	N/A	N	N
Is there an appeals process?	N	N	N	N	N	N	N	N	N	N	N
Are rationales available online?	N	Y	N	N	N	Y	Y	N	N	Y	Y
Are members' conflict of interest disclosures available online?	N	N	N	N	N	N	N	N	N	Y	Y

N denotes No, Y denotes Yes, N/A denoted not applicable, YT denotes Yukon Territory, BC denotes British Columbia, AB denotes Alberta, SK denotes Saskatchewan, MB denotes Manitoba, ON denotes Ontario, QC denotes Quebec, NIHB denotes Drugs and therapeutics advisory committee for the non-insured health benefits; CDEC denotes Canadian Drug Expert Committee; pERC denotes p-CODR Expert Review Committee

Table 2. Characteristics of Revisions Mechanisms

Jurisdiction	Circumstance	Stakeholder who can appeal	Type of mechanism	Adjudication
YT	Any decision of the Yukon Formulary Working Group	Not specified	Reconsideration	Director
BC	Recommendation is not supported by the evidence Process of the submission reviewed was not properly followed New information	Manufacturers	Reconsideration	Ministry DBC Secretariat in consultation with committee Chair
AB	Request a change in the current special authorization or restricted benefit status Request a change in current criteria for coverage	Manufacturer	Reconsideration	Committee
SK*	Recommendation is not supported by the evidence New information	Physicians or manufacturer	Reconsideration	Committee
MB	New information Change in pricing	Manufacturer	Reconsideration	Committee
ON	Process of the submission reviewed was not properly followed Recommendation is not supported by the evidence	Manufacturers	Reconsideration	Committee
QC	The Minister asks committee to revise position	Minister	Reconsideration	Minister of Health
ATL	New information	Manufacturers	Resubmission	Committee
NIHB*	New information Change in pricing	Manufacturers, patient groups	Reconsideration	Committee
CDEC	Process of the submission reviewed was not properly followed Recommendation is not supported by the evidence	Manufacturers	Reconsideration	Committee
pERC	Feedback was received on the initial recommendation Consensus was not reached by stakeholders The recommendation was negative	Stakeholders (including but not limited to manufacturers or their representative organizations, tumour groups, and patient advocacy groups)	Reconsideration	Committee

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*These are informal processes

Conclusions

- Most committees have some mechanisms to address transparency but none had a fully transparent process
- The most important ways to improve transparency are to create formal appeal mechanisms, improve communication, and establish consistent rules about the use of, and public access, to proprietary evidence

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