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Transparency in Canadian public drug advisory committees

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ABSTRACT

Background: Transparency in health care resource allocation decisions is a criterion of a fair process. We used qualitative methods to explore transparency across 11 Canadian drug advisory committees.
Methods: We developed seven criteria to assess transparency (disclosure of members' names, disclosure of membership selection criteria, disclosure of conflict of interest guidelines and members' conflicts, public posting of decisions not to fund drugs, public posting of rationales for decisions, stakeholder input, and presence of an appeals mechanism) and two sub-criteria for when rationales were posted (direct website link and readability). We interviewed a purposeful sample of key informants who were conversant in English and a current or past member of either a committee or a stakeholder group. We analyzed data using a thematic approach. Interviewing continued until saturation was reached.
Results: We examined documents from 10 committees and conducted 27 interviews. The median number of criteria addressed by committees was 2 (range 0–6). Major interview themes included addressing: (1) accessibility issues, including stakeholders' degree of access to the decision making process and appeal mechanisms; (2) communication issues, including improving internal and external communication and public access to information; and (3) confidentiality issues, including the use of proprietary evidence.
Conclusion: Most committees have some mechanisms to address transparency but none had a fully transparent process. The most important ways to improve transparency include creating formal appeal mechanisms, improving communication, and establishing consistent rules about the use of, and public access to, proprietary evidence.

1. Introduction

Decisions regarding public drug formulary listings can be controversial [1]. In Canada, such decisions are generally 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 [2,3]. The American College of Physicians defines transparency within the health care context as "making available to the public, in a reliable and understandable manner, information on the health care system's quality, efficiency and consumer experience with care" [4]. Accountability for Reasonableness, a popular framework for judging fairness in health care, asserts that transparency in health resource allocation decision making requires

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that both the recommendation process and the rationale for making recommendations are publicly available [3]. Transparency is valued because it may result in better informed recommendations, decrease appeals, increase public acceptance of recommendations, and enhance trust in the overall process [1,5].

In Canada, public drug plans are administered at a subnational (provincial or territorial) level; a few national plans also exist for specialized populations, including First Nations and Inuit Canadians, inmates in federal penitentiaries, refugee claimants, military personnel, members of the Royal Canadian Mounted Police, and veterans [6]. Drug plans vary in their coverage but all insure people who are receiving social assistance [7,8]. Some drug plans insure the elderly or have established catastrophic coverage [9]. Coverage decisions are typically made at the ministerial or senior bureaucratic level, based on the recommendation of a sub-national drug advisory committee. These committees, in turn, receive recommendations from two national committees—one assessing cancer drugs and another assessing all other drugs. These review processes are known as the pan-Canadian Oncology Drug Review and the Common Drug Review, respectively, and their expert committees. The province of Quebec has opted not to participate in the national review committee and has its own processes and committees which operate separately [10]. The number of people served by each public plan varies widely, reflecting large variations in the populations of each region and coverage policies.

The review process typically starts with a submission from a manufacturer for consideration of listing on a public drug formulary. The review includes assessments by staff members of the drug's effectiveness, safety, and cost-effectiveness compared to current treatments. At the national level, review staff solicit input from patient groups as well as from the manufacturer. All of these materials are provided to the expert committees as inputs into their decision making process.

In summary, drug coverage in Canada integrates provincial and federal payors, multiple advisory committees, and a federal system in which accountability for most funding decisions is at the sub-national level. Because this system is complex and regionalized, there is the potential for considerable heterogeneity in processes [1,2,11–13]. Furthermore, small committees might not have the same resources or pressures as their larger counterparts. Transparency, as a component of fairness, has not been formally assessed within this context. We used qualitative methods to evaluate transparency across 11 Canadian drug advisory committees.

2. Methods

We used a literature review, key informant interviews, and document reviews to assess transparency.

2.1. Definition of transparency

We based our definition of transparency on Daniels and Sabin's "Accountability for Reasonableness" priority setting framework, which considers decisions to be legitimate and fair if they satisfy four conditions: publicity, relevance, revision and appeals, and regulation (also referred to as enforcement or leadership) [3]. Gibson and colleagues have proposed adding a fifth "empowerment" condition, which focuses on addressing power differences between groups within the decision-making context and to optimising opportunities for participation [14]. We focused on the conditions that we considered most relevant to issues of transparency (publicity, relevance, revisions appeal, and empowerment). Accordingly, transparency requires that reports, appraisals and decision processes are readily available and that the decision process includes definitions of the roles and responsibilities of each stakeholder.

We defined four criteria related to the condition of publicity: public disclosure of committee members' names; publicly available criteria by which committee members are selected; public disclosure of conflict of interest guidelines and committee members' conflicts; and public posting of decisions not to fund drugs. We included a criterion related to relevance, public posting of rationales for decisions (including the evidence upon which decisions were made) and a criterion related to empowerment, assessing whether there were adequate opportunities for stakeholder input during the review process. Finally, we included a seventh criterion to assess the presence or absence of a mechanism for appeal.

When rationales were posted on the internet, we also assessed: (1) whether they were accessible through direct links on committee websites; and (2) the readability of the five most recent documents posted on the websites, using the Flesch–Kincaid or the Kandel–Moles instrument for English and French rationales, respectively [15,16]. We scored rationales as readable if they scored at a grade 12 level or lower which should make them accessible to 87% of Canadians who have at least a high school education [17]. The rationales reviewed for readability are listed in the Supplementary Appendix.

2.2. Interviews and documents

We identified potentially eligible key informants from websites listing drug advisory committee members, suggestions by staff in Ministries of Health, and other informants [18,19]. Our respondents represented a purposeful sample with a range of views, selected to develop a rich understanding of the topic. We used a combination of maximum variation sampling, in which we selected respondents that were representative of different stakeholder groups, and snowball sampling, in which we asked respondents to identify other participants. Our inclusion criteria were as follows: individuals who were conversant in English, who were either current or former members of provincial or federal drug advisory committees (including clinical and public or patient experts), employees of a Ministry of Health, members of a patient advocacy group, or employees of a pharmaceutical manufacturer. Interviews were semi-structured and based on a pre-established interview guide (Box 1, Interview Guide). All interviews were digitally recorded and professionally transcribed.