

Understanding the reasons for provincial discordance in cancer drug funding—a survey of policymakers

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ABSTRACT

Background Cancer drug-funding decisions between provinces shows discordance. The pan-Canadian Oncology Drug Review (pcodr) was implemented in 2011 partly to address uneven drug coverage and lack of transparency in the various provincial cancer drug review processes in Canada. We evaluated the underlying reasons for ongoing provincial discordance since the implementation of pcodr.

Methods Participation in an online survey was solicited from participating provincial ministries of health (монs) and cancer agencies (саs). The 4-question survey (with both multiple-choice and free-text responses) was administered between 4 March 2015 and 1 April 2015, inclusive. Anonymity was ensured. Descriptive statistics were used to evaluate responses.

Results Data were available from 9 provinces (all Canadian provinces except Quebec), with a response rate of 100%. The 12 responses received each came from a senior policymaker with more than 5 years' experience in cancer drug funding decision-making (5 from Mohs, 7 from Cas). Responses for 3 provinces came from both a Moh representative and a CA representative. The most common reason for funding a drug not recommended by pcodr was political pressure (64%). The most common reason not to fund a drug recommended by pcodr was budget constraints (91%). The most common reason for a province to fund a drug before completion of the pcodr review was also political pressure (57%).

Conclusions Political pressure and budgetary constraints continue to affect equity of access to cancer drugs for patients throughout Canada.

Key Words Cancer drugs, drug funding, discordance

Curr Oncol. 2018 Aug;25(4):257-261

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BACKGROUND

In Canada, variation in cancer-drug coverage between provinces and the appearance of discordance within the country have caused concern. For example, bevacizumab for metastatic colorectal cancer has been funded since January 2006 in British Columbia, but only since April 2009 in Alberta¹. Before 2007, Canadian provinces and territories had separate regional drug review processes to inform their local funding decisions^{2,3}. Provincial funding decisions were further affected by individual provincial budgets and priorities².

Because of similarities in the governance and accountability structures of provincial cancer systems such as cancer agencies (CAS), a collaborative interprovincial initiative known as the interim Joint Oncology Drug Review was undertaken in 2007². After an evaluation of that interim process, the Conference of Federal–Provincial–Territorial Deputy Ministers of Health in 2010 approved the creation of a permanent body, the pan-Canadian Oncology Drug Review (pcodr)². This formalized national body conducts reviews on behalf of all provinces and territories except Quebec². The pcodr began accepting drug submissions for review in July 2011⁴. On 1 April 2014, administration of

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the pcodr was assigned to the Canadian Agency for Drugs and Technologies in Health 4 .

Despite the implementation of pcodr, discordance in cancer-drug funding between provinces continues. As of 31 December 2015, 64 recommendations had been issued by the pcodr expert review committee (perc)⁵. Of those recommendations, 9 were positive without conditions, 41 were positive with conditions, and 14 were negative⁵. After negotiations with manufacturers to finalize pricing, the discordance rate with pcodr recommendations ranged from 0% to 5%, depending on the province⁵. Most of the discordance was associated with conditional recommendations⁵. The underlying causes of discordance are, however, unknown and have not been formally or clearly elucidated. In the present work, we sought to clarify the underlying reasons for provincial discordance with pcodr recommendations through direct feedback from policymakers.

METHODS

An online survey was developed and administered to participating provincial ministries of health (монs) and cas throughout Canada, except Quebec (Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Nova Scotia, Ontario, Prince Edward Island, and Saskatchewan). Key policymakers in either the provincial мон or са for each of the provinces were identified by the pcodr provincial advisory group (PAG). The PAG collated a list of eligible individuals who were participating in pcodr for each province and who were involved in provincial decisionmaking for cancer-drug funding. The list of individuals was reviewed by the pcodr PAG through two iterations to ensure that appropriate candidates were selected. The 12 candidates on the final list were chosen after consultation with the relevant mons and cas as candidates who, it was felt, would accurately convey the responses of their organization. The study team (through NP) contacted the candidates by e-mail. To minimize bias, policymakers with at least 5 years' experience in both the мон and са were identified. Experience of 5 years was chosen so that policymakers would have experience with 10 or more cancer-drug indication assessments, thereby ensuring that responses were not overly influenced by 1 or 2 decisions.

The 4-question survey (multiple-choice questions combined with the option to provide free-text answers) was administered between 4 March 2015 and 1 April 2015, inclusive. Table I lists survey questions and potential answers. Reasons for funding discordance were hypothesized and developed by perc members (of which there are 23), who have experience in cancer-drug funding decision-making, until saturation of responses was attained. The developed hypotheses with the highest frequencies were selected as potential answers to the multiple-choice questions. The small sample size of survey respondents was justified because saturation of ideas had been attained with the initial reasons for discordance hypothesized by the pcodr perc members. "Political pressure" was defined as any external pressure not related to high tumour group priority or financial pressure. Respondents were advised that responses to multiple-choice questions were independent; however,

respondents could select multiple options if applicable. In addition, questions were developed to assess challenges that limit health technology assessment processes and potential solutions that enhance alignment between perc recommendations and provincial drug funding decisions.

Anonymity of responses was maintained to ensure feedback. Results were analyzed using descriptive statistics. Percentages indicate total options selected and not unique respondents. Free-text responses were analyzed using thematic analysis⁶; responses were classified into distinct identifiable motifs and aggregated for frequency.

RESULTS

Baseline Characteristics

The response rate from the 9 provinces surveyed was 100%. Responses for 3 provinces came from both a мон representative and a са representative. The remaining 6 provinces provided 1 response each, from either the provincial мон or the са. The analysis included all 12 responses, 5 from a мон and 7 from a са. All respondents provided written comments in the free-text option.

Reasons for Discordance

The reasons most commonly given for provincial funding of drugs not recommended by pcodr were political pressure (63.6%), the comparator drug in the trial is not funded by the province (54.5%), the comparator drug in the trial is not relevant to practice (36.4%), and high tumour group priority (27.3%). With respect to comparator drugs, provinces that did not provide that option to patients felt that, despite the negative pcodr recommendation, funding the new drug was reasonable because it would provide a therapeutic option where no option was currently available.

Other reasons provided by respondents included the rarity of the tumour (low probability of future trials—2 respondents), exceptional access (patient subgroups had no other treatment options—2 respondents), risk-sharing agreement or pay-for-performance agreement in place (where if no patient benefit accrued, the province would not incur a cost—1 respondent), and the drug is listed as "under consideration" (which might mean that compassionate access is provided on a case-by-case basis, and the drug is not available to all patients—1 respondent).

The most common reasons for provinces not to fund a drug recommended by pcopr (with or without conditions) were budget constraints (90.9%), the drug is not a priority for the local tumour group (63.6%), the patient population or disease is not treated in the province (27.3%), disagreement with the clinical review (18.7%), or disagreement with the economic review (9.1%).

Other reasons provided by respondents included unsuccessful negotiation with the manufacturer (2 respondents), multiple choices or lines of therapy already exist (no therapeutic gap—1 respondent), and uncertainty about how funding the drug would affect the provincial budget (1 respondent).

Early Funding

In certain situations, a drug might be funded by a province before the pCODR review is completed. The most common TABLE I Survey questions

(Question Options (if applicable)			
1	(a)	If your province has made or is to make a funding decision to fund where the recommendation from the HTA review is to not fund, what are the reasons for funding? (Please check all that apply.)		
		 □ High tumour-group priority □ Political pressure □ High disease burden in the province □ Comparators in trial not funded by province □ Comparators in trial not funded by province 		
	(b)	Please provide further details on the above and other reasons not listed above.		
2	(a)	If your province has made or is to make a decision to not fund a drug where the recommendation from the HTA review is to fur (with or without conditions), what are the reasons for not funding? (Please check all that apply.)		
		 □ Budget constraint □ Patient population/disease not treated in province □ Disagreement with the clinical review □ Disagreement with the economic review □ Drug was not a priority for local tumour group 		
	(b)	Please provide further details on the above and other reasons not listed above.		
3	(a)	If your province makes a funding decision to fund a drug prior to completion of the HTA review, what would be the reason(s)? (Please check all that apply.)		
		 □ Local tumour group priority □ Political pressure □ Aligns with provincial budget cycle 		
	(b)	Please provide further details on the above and other reasons not listed above.		
4	(a)	In your opinion, what are the challenges and barriers that may limit the effectiveness of evidence-based recommendation?		
	(b)	In your opinion, what are the potential solutions to enhance alignment of funding decisions with HTA recommendations?		

HTA = health technology assessment.

reasons for a province to fund a drug before completion of the pCODR process were political pressure (57.1%), local tumour group priority (42.9%), and high disease burden in the province (28.6%).

Other reasons provided included overwhelming clinical need (4 respondents), evidence of survival advantage creates an ethical challenge not to fund (3 respondents), pressure for patient access to clinical trials (2 respondents), and expanded eligibilities not mentioned in the perc review (that is, indication creep—1 respondent).

Challenges to the Process and Potential Solutions

Challenges and barriers identified by respondents that limited the ability to fund drugs included trial populations that are not generalizable (too narrow or wide inclusion criteria—6 respondents), different standard of care in other jurisdictions (that is, the comparator is not available in Canada—4 respondents), re-interpretation of evidence not being studied in a clinical trial (4 respondents),

technology constraints (3 respondents), too much dependence on manufacturer for submissions (3 respondents), perc adherence to evidence-based eligibility (3 respondents), and the quality of the available clinical trials (1 respondent).

Potential solutions suggested by the respondents included leveraging the pan-Canadian Pricing Alliance, now the pan-Canadian Pharmaceutical Alliance, for pricing negotiations (5 respondents), increased tumour group input about priorities (4 respondents), increased alignment with provincial advisory groups to the perc process (wording of the same funding decision varies from province to province—4 respondents), quicker responses from pcode about recommendations (3 respondents), clearer prioritization from perc with each recommendation about which drugs should be funded first (3 respondents), strengthen or create a national consensus about treatment pathways (3 respondents), and create a national pharmacare program to improve accessibility (2 respondents).

DISCUSSION AND CONCLUSIONS

In Canada, surveys of key policymakers throughout the country have demonstrated that financial or political pressures faced by provinces are the leading reasons for funding decisions discordant with the national drug review process (that is, pcodr). Some degree of discordance is to be expected with health technology assessment recommendations and implementation. Through direct feedback from policymakers, the present study confirms for the first time the role that external pressures play in influencing policy decisions about cancer-drug therapy and how those pressures are partly responsible for the discordance. Although politics is understood to influence policy, our survey demonstrates, through direct confirmation from policymakers, the influence of political pressure and budgetary constraints. The study is significant in that, through that direct confirmation and acknowledgment, further discussions to improve transparency and concordance can be undertaken.

The findings in this study demonstrate the need for ongoing support to policymakers who are making funding decisions. Priority-setting for cancer therapies is recognized as a complex process in which external factors—including the involvement of media, patient advocates, politicians, and the pharmaceutical industry—can have significant influence^{7,8}. Studies have shown that greater media attention given to some drugs appears to be associated with more rapid review and approval processes^{7,9,10}.

Cancer, more than other diseases, seems to have a strong political component that must be recognized and accommodated^{2,8,11,12}. The difference is highlighted in the existence of two separate health technology assessment vehicles in Canada for the assessment of clinical efficacy and cost-effectiveness of drugs: one for cancer therapies, and another for all other therapeutic agents^{8,11,12}. Despite that "special status" for cancer therapies, an implicit expectation remains: within the assessment and funding of cancer drugs, the process will remain transparent.

The recognition that politics influences cancer-drug funding is evident in the numerous attempts in the medical literature to use various surrogates to quantify the political pressures—for example, the influence of the media^{7,9}, elections^{13,14}, pharmaceutical companies, and broader economic concerns¹⁵. That body of work attempts to identify the root causes that might lead to inequities in cancer-drug funding, with the aim of enabling policymakers and the public to work toward a better system. However, the research also highlights the challenge that faces researchers trying to transparently identify how politics influences cancer drug funding. Although all the foregoing factors coalesce to influence policymakers, the present study demonstrates that, across the country, policymakers acknowledge the discordance that politics can cause.

There are inherent trade-offs in funding drugs recommended or not recommended within an evidence-based framework; addressing local interests is one trade-off raised in the present study. Provinces are navigating the trade-offs by funding drugs in a manner that differs from the official eligibility criteria used or by undertaking caseby-case assessments. By expanding or limiting eligibility criteria, provinces steer through the challenging process

of increasing access for patients while addressing financial limitations.

A real concern is that the discordance driven by political pressure could lead to a lack of consistency in decision-making and a lack of transparency. Our qualitative study identifies an effect of the provincial political climate on policymakers.

Why is one particular drug for one condition approved on a case-by-case basis, while funding for another drug for a similar condition might be declined later on? There is no objective or standardized method of assessing how discordant decisions are made. "Institutional memory," in which provinces establish a precedent and continue to fund or not fund drugs in accordance with historical decisions, might play a role. To mitigate the uncertainty inherent in potentially ambiguous decisions, additional data, monitoring, oversight, and transparency are needed to reassure Canadians that fairness and accountability characterize the decision-making process. Ambiguous decision-making can potentially be exploited to the advantage of certain groups, or perhaps more worrisome, can be incorrectly perceived by the public as being exploited by those groups¹⁶.

Our study has limitations. First, it relies on the feedback of individual policymakers in the cancer-drug funding process. To minimize bias that might be attached to a particular individual, policymakers with at least 5 years' experience in both a MOH and a CA were identified. That minimum duration requirement was meant to ensure that several years of experience were informing the responses provided. It is reassuring that consistent and similar responses were provided by respondents throughout the country, supporting the likelihood that the findings are true and not influenced by the opinions of a single individual or a limited number of drug funding decisions.

Second, the overall study had a small sample size; additional respondents were not sought because the pool of policymakers with the required knowledge base was limited. To address the small sample size, the relevant institutions (that is, mohs and cas) and the poodr pag were consulted to ensure that candidates who could provide a breadth of responses were selected. Anonymity was required to ensure candid responses. Because of the challenges in accessing policymakers for study participation, a larger sample size was not feasible; however, given the similarity in the responses (as exemplified by the high percentages for the top responses), additional respondents were unlikely to change the main result. Additionally, the saturation of possible responses attained through the development of the survey by the perc lowered the likelihood that other influences were being missed.

In addition, we were unable to identify the factors that influenced specific decisions. For example, were cancer drugs for rare tumour sites more commonly funded because of limited treatment options? Or in contrast, were drugs for breast cancer funded because of political pressure? Although assumptions can be made, quantifying the influence of the cancer type on decision-making is impossible without objective data. Additionally, the pan-Canadian Pharmaceutical Alliance, an organization established in 2010, negotiates with drug manufacturers on

behalf of multiple provinces to leverage buying power into lower costs. The Alliance considers all drugs reviewed by pcode, although not all drugs undergo joint negotiations at a national level.

The willingness of policymakers to disclose the influence of external factors on decision-making is promising. Our study found that political pressures and budgetary constraints continue to affect the equity of patient access to cancer drugs throughout Canada. By recognizing those factors, strategies can be developed to ensure ongoing collaboration and transparency in future decision-making about drug funding.

ACKNOWLEDGMENTS

The authors thank all the members of the PCODR, PCODR'S Expert Review Committee, PCODR'S Provincial Advisory Group, and individuals at the provincial Mohs and Cas who supported this project. We also thank the Canadian Cancer Society Research Institute for their funding of the Canadian Centre for Applied Research in Cancer Control.

CONFLICT OF INTEREST DISCLOSURES

We have read and understood *Current Oncology*'s policy on disclosing conflicts of interest, and we declare that we have none. MS was the executive director of pcodr at the time of the study. AG and KKWC were members of pcodr's Expert Review Committee at the time of the study. NP was an employee of pcodr at the time of the study.

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