Less Than Ideal: How Oncologists Practice With Limited Drug Access

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Abstract

Purpose: To evaluate Canadian medical oncologists' perspectives on how barriers to accessing new expensive cancer drugs have affected their practice and their opinions on the drug approval and funding processes.

Methods: Canadian medical oncologists treating colorectal cancer (CRC) were surveyed by means of a self-administered, cross-sectional survey.

Results: Of the 164 eligible oncologists, there were 68 respondents (41.4% response rate). Only 29.4% of physicians felt they had been using the ideal first-line chemotherapy regimen for patients with metastatic CRC. Although all considered bevacizumab to be a component of the ideal first-line regimen, only 18% could use bevacizumab routinely, and less than half (44.8%)

always discussed its role with their patients. In terms of accessing unfunded drugs, most physicians agreed that private payment should be allowed for drugs to be delivered at their own centers (76.1%) or private infusion clinics (52.2%). Ninety-seven percent of physicians reported major concerns about the drug approval and funding processes, and 85% of physicians supported the establishment of a national drug formulary.

Conclusions: Canadian medical oncologists are struggling to provide optimal cancer care for their patients with metastatic CRC as a result of nonuniform access to preferred therapeutic drugs. In face of these challenges, physicians have had to use clinical trials and private infusion clinics and, at times, may avoid discussing drugs with limited access. Many oncologists are dissatisfied with the existing funding mechanism and approval processes and support private payment for unfunded drugs.

Introduction

Recent advances in cancer systemic therapy have resulted in a decrease in cancer-related mortality.¹⁻¹¹ For example, the addition of antiangiogenic therapy with bevacizumab combined with fluorouracil-based chemotherapy has been shown to provide a higher response rate, longer median time to disease progression, and longer median survival (from 15.6 to 20.3 months) for patients with metastatic colorectal cancer (CRC).⁸ The FOLFOX regimen of oxaliplatin and infused fluorouracil plus leucovorin has correspondingly also been found to extend the median time to progression to 8.7 months and to provide a median survival time of 19.5 months.⁹ Similarly, cetuximab has not only improved overall survival, but has also been shown to preserve quality-of-life measures, particularly physical function and global health status scores in this population.¹¹ Existing literature suggests that maximizing exposure to these new drugs, whether in combination or in sequence, improves the survival of patients with advanced CRC.¹²

Although the advent of these new and effective drugs has ignited new hope for patients and their health providers, the cost of these expensive drugs has also posed challenges for payers of health care systems globally. Despite their inherent differences, both American and Canadian systems have struggled with the rising costs of chemotherapeutic drugs in a climate of limited fiscal resources. In contrast to the multipayer American system, the Canadian system is publicly funded under the Can-

ada Health Act and is guided by its core tenets of universality, accessibility, portability, comprehensiveness, and public administration.

Yet this system has not always led to uniform drug funding and access: although drug approval is determined on a national (federal) level by Health Canada, public drug funding is independently established by each of the provinces through governments, cancer agencies, and individual hospitals.¹³ Under this framework, the decision to reimburse costs for a particular drug, the speed at which a decision is made, the level of coverage, and the eligibility requirements vary significantly by province and by drug.^{14,15} In the case of metastatic CRC, bevacizumab and cetuximab were approved in Canada in 2005, approximately 1.5 years after US Food and Drug Administration (FDA) approval.¹⁶⁻¹⁸ Despite federal drug approval, access to these drugs remained limited: at the time this study was conducted in 2007, two provinces (British Columbia and Newfoundland) funded bevacizumab and none funded cetuximab. Before its Health Canada approval in June 2007, which was 3.5 years after FDA approval, oxaliplatin was available through a special access program that provided partial income-based coverage. The lack of prompt and uniform access to these drugs may have been related to their cost effectiveness, as well as other regulatory issues associated with pricing and patent protection.¹⁹

Drugs funded by provincial health plans are administered in public institutions without private payment. For unfunded

drugs, most institutions do not allow for private payment, although private payment by patients or third-party insurers is now occurring in some public institutions and private clinics for unfunded drugs²⁰ without explicit government sanction or regulation.²¹ Despite a report by an Ontario provincial working group from Cancer Care Ontario that made recommendations about the delivery of oncology medications for private payment in public hospitals,²² neither the provincial nor federal governments have taken a clear position on this issue.

There is a need to understand how medical oncologists cope with the challenges of limited drug access in an increasingly cost-conscious environment. These issues have been examined qualitatively in an earlier study.²³ To build on this research, our study was designed to examine the magnitude of these barriers to drug access and their effect on the practice of Canadian medical oncologists. Furthermore, this study assessed the opinions of the medical oncology community on the drug approval and funding processes in the context of treating patients with metastatic CRC.

Methods

Using the modified Delphi method, an English-language survey instrument was developed by three medical oncologists (K.K.C., L.L.S., and S.R.B.) and a clinical epidemiologist (S.E.S.). MEDLINE was searched for potentially relevant English-language articles relating to oncology, with no limitation on year, using the following key search terms: “drug funding,” “drug access,” and “survey.” These articles were then reviewed to identify important issues regarding perception and satisfaction with access and funding of oncology drugs. To enhance reliability and face validity, the initial survey was pretested among a panel of three medical oncologists, which resulted in only minor revisions. The final version of the survey is shown as a Data Supplement.

The cross-sectional, anonymous survey was sent by mail with an invitation letter to medical oncologists treating patients with CRC identified by the directories of the Royal College of Physicians and Surgeons of Canada (physicians with a subspecialty certification in medical oncology [FRCPC]), provincial licensing colleges, and local experts. The province of Quebec was not included in this survey because limited resources did not allow for the translation and pilot testing of the survey instruments into French (and translation of these responses back to English). Participants were able to respond by completing the survey by mail or electronically. The surveys were first sent out in May 2007, followed by two reminder e-mails at 4 weeks and 8 weeks after the initial invitation. The last response was obtained in December 2007.

Analyses were conducted using SPSS statistical software (SPSS for Windows, v15.0; SPSS Inc., Chicago, IL).²⁰ Descriptive statistics were performed on all variables, including summary statistics of proportion or mean, as appropriate.

The study was approved by the University Health Network Research Ethics Board at the University of Toronto

Results

Of the 164 eligible medical oncologists, there were 68 respondents (41.4% response rate). Demographic characteristics of respondents are provided in Table 1.

Ideal Regimens

Use of ideal chemotherapeutic regimens varied across the provinces, especially with first-line treatment ($P < .001$ by Fisher's exact test). As seen in Figure 1, British Columbia had the highest proportion of respondents who felt they were providing ideal first-line treatment, with respondents from the Prairies having the lowest proportion. With respect to first-line chemotherapy for patients with metastatic CRC and good performance status, 70.6% of respondents felt they had not been using the ideal regimen given available drugs when treating patients outside of clinical trials. Although all respondents considered bevacizumab to be a component of the ideal first-line regimen, only 18% used bevacizumab routinely in first-line chemotherapy regimens. The leading first-line chemotherapy used routinely in practice was FOLFIRI (irinotecan, infusional fluorouracil, and leucovorin) at 72.1%, followed by FOLFOX (oxaliplatin, infusional fluorouracil, and leucovorin) at 8.8% (Appendix Figure A1, online only).

For second-line chemotherapy regimens, almost half of respondents (47.1%) felt they had not been using the ideal second-line regimen as a result of lack of access. Most respondents (86.8%) routinely use FOLFOX alone, although the majority would have ideally preferred to include bevacizumab (62.5%) as a component of treatment (Appendix Figure A2, online only).

Similarly, the majority (66.2%) of respondents felt that they had not been using their ideal regimen during third-line treatment. Although the majority (90%) considered cetuximab to be part of an ideal third-line regimen, only 26% were able to use cetuximab routinely as a third-line treatment (Appendix Figure A3, online only).

Accessing Unfunded Drugs

To aid their patients in accessing bevacizumab, more than half (58.2%) of the respondents facilitated patient enrollment onto clinical trials in which bevacizumab was available to all trial participants. One-third (32.8%) of the respondents had bevacizumab treatments paid for by the patients or third-party insurers at their centers if this method of payment was allowed in their centers. A proportion (41.8%) of respondents sent patients to private infusion clinics to obtain the drug by private payment: 26.9% within their own city, 11.9% in another Canadian city, and 3.0% at American centers. An additional 1.5% of respondents reported that their patients received bevacizumab treatments at American centers, paid for by their respective province. Similarly, in addition to obtaining cetuximab through clinical trials (42%) and private payment (46.3%), almost one-third of respondents (29.9%) also reported referring patients to American centers to receive cetuximab paid for by the province.

Figure 1. Ideal regimen by region and line of treatment.

Discussion About Expensive Cancer Drugs

Bevacizumab, an agent agreed on by all respondents to be part of their ideal first-line regimen, was always discussed by less than half (44.8%) of respondents, and 9% rarely discussed its role with their patients. Similarly, although one-third (31.3%) of respondents always discussed the role of cetuximab, it was rarely discussed by an almost equal proportion (26.9%) of respondents. In contrast, more than 80% of respondents always discussed the role of oxaliplatin with their patients.

Table 1. Demographic Characteristics of the Respondents (N = 68)

Characteristic	No.	%
Respondent by province/region		
British Columbia	11	16
Alberta	7	10
Prairies (excluding Alberta)	8	12
Ontario	29	43
Maritimes	13	19
Type of practice*		
University-affiliated center	34	50
Regional cancer center	28	41
Community practice	14	21
No. of patients treated in the past 12 months		
1-10	13	19
11-20	13	19
21-50	27	40
51-100	14	21
101-200	1	1
Years of practice		
0-5	22	32
6-10	18	27
11-20	14	21
21-30	12	18
> 30	2	3

* Some respondents practiced in more than one type of setting.

Figure 2. Perceptions and opinions of medical oncologists on allowing private payment (PP).

Oncologists' Views on Payers and Location of Administration of Unfunded Oncology Drugs

Most respondents (76.1%) agreed that private payment should be allowed for unfunded drugs to be delivered in their own centers, as well as private infusion clinics (52.2%) (Figure 2). A minority of respondents (20.9% and 16.0%, respectively) disagreed with these proposals.

Oncologists' Views on the Drug Approval and Public Funding Processes

Ninety-seven percent of respondents expressed major concerns regarding the design of drug approval and reimbursement processes in Canada, including the time taken to make decisions (76.1%), the lack of transparency (56.7%), increasing reliance on cost-effectiveness analysis in decision making (49.3%), and the lack of an appeal process (40.3%). Although respondents appeared to be evenly divided on the degree to which economic evaluation should be used in decisions regarding drug reimbursement, a majority (85.1%) of respondents supported the establishment of a national drug formulary to approve and fund new cancer drugs to achieve equity of access nationwide.

Impact of Impaired Access to New Drugs on Medical Oncologists

Almost two thirds (64.1%) of respondents agreed that the time spent discussing access issues with patients, completing paperwork, or making phone calls to help patients access these new chemotherapy drugs have decreased their morale. Nearly one quarter (23.9%) of respondents reported spending an additional 1 to 2 hours per week performing the above tasks, with another 7.5% of respondents spending an additional 2 to 5 hours per week. Furthermore, almost half (44.7%) of the respondents agreed that the additional time they spend has negatively affected their ability to see new patients.

Discussion

To the best of our knowledge, our study is the first to provide a quantitative report that a majority of Canadian medical oncologist respondents felt that they could not provide what they

considered to be the ideal treatments within the design of drug approval and funding processes. Furthermore, our study revealed that there were significant variations in the usage of ideal treatments across the country. In order to help their patients access ideal treatments, many physicians used clinical trials, private infusion clinics, and clinics in the United States, which were sometimes paid for by the provincial health plan. Some avoided this issue by not routinely discussing these drugs with patients. Most felt that private payments for unfunded drugs should be allowed in public hospitals. They were also concerned about the timeliness and lack of transparency of the drug approval and funding processes.

The Canadian single-payer, publicly funded health care system was founded on the principles of universality, comprehensiveness, and accessibility. Despite these principles, medical oncologists have found themselves unable to offer what they believed to be ideal treatments to their patients, and they struggle with the fact that the ability of patients to access ideal treatments varies across the country. Therefore, it would appear that the design of the drug funding process and resulting funding decisions might not be congruent with the principles valued by the general public. Further work is needed to realign the founding principles of the system with the values of the public.

As a result of limited access to ideal treatments, physicians and patients had to go through unconventional means to gain access to unfunded drugs, and this confirms the results of a previous qualitative analysis suggesting that physicians spend considerable time and effort finding an alternative funding source for such drugs.²³ Our findings showed that some patients might even receive funding from the public system to receive unfunded drugs far away from home where their primary oncologists would not be able to provide direct supervision. In addition to the inconvenience for patients and the questionable cost effectiveness of this arrangement, there are also significant safety and legal liability concerns as the medical oncologists remain the physicians most responsible for this external drug administration.

A previous Australian study²⁴ suggested, on the basis of hypothetical scenarios, that 28% to 41% of oncologists would not discuss high-cost drugs with their patients. Our study confirms that lack of discussion about expensive unfunded drugs does occur in real-world practice. The ethical principles underlying informed patient decision making require full disclosure of all potential treatments, and most patients express a strong desire to be fully informed, active participants in treatment decision making.²⁵⁻²⁸ Therefore, it is concerning that when ideal treatments were not funded, a substantial proportion of Canadian medical oncologists in our study did not always discuss these treatments with their patients. Although their reasons were not explored in our study, previous studies have documented oncologists' reluctance to discuss high-cost drugs,^{24,29,30} often related to concerns regarding the potential emotional impact and distress for patients. Other possible contributing factors include the time-consuming nature of these discussions and that oncologists feel ill equipped to use cost-effectiveness information and explain it to their patients, as found

in a previous study.³⁰ These communication challenges were addressed in the recent ASCO guidance statement, which outlined the need to improve physician-patient communication about costs.³¹

The issue of accessing unfunded drugs is not unique to Canada's public health care system. For example, England recognized the need for guidelines on how patients should access unfunded cancer drugs, and the National Cancer Director published a report recommending how patients might access drugs that are not funded by the National Health Service.³² It recommended patients receive such drugs through a private provider, either in an independent treatment center or in a private facility within a National Health Service hospital, but separately from publicly funded care. This recommendation has been accepted by the United Kingdom Secretary of State for Health. Similarly, an Ontario Working Group commissioned by Cancer Care Ontario made recommendations in 2006 to allow private payments for unfunded drugs in public hospitals.²² This proposed model would create a system more similar to the current US system. The strong consensus among our study respondents regarding the allowance of private payment in their own centers suggested that the recommendations by this Working Group have gained acceptance in the oncology community. It would be important for the governments to establish a clear position on access to unfunded drugs as more new expensive and effective drugs are developed in oncology.

Our study also revealed that many Canadian medical oncologists expressed an overall dissatisfaction with the existing funding and approval processes, particularly with decision-making time, which is consistent with previous studies.²³ At the time this survey was conducted, each province had a separate oncology drug review with an independent decision-making process. Since then, the interim Joint Oncology Drug Review was established to provide a joint recommendation of oncology drug funding based on clinical and pharmacoeconomic evidence. In the latter part of 2011, this process was gradually transitioned to become the pan-Canadian Oncology Drug Review to ensure nationwide representation and provide consistent funding recommendations for oncology drugs that each province could use for their own funding decisions. The first drug submission was made, and the review process begun, in November 2011. This may improve the timeliness and increase the transparency of the decision making process. This transparency could aid physicians in understanding the reasons for nonfunding which may then increase their comfort level when discussing such unfunded drugs with their patients. Further research in this area will be crucial to assess the outcome of this new drug review processes and its impact on accessibility and clinical practice.

Limitations of our study include the possibility of response bias with the use of self-reported outcomes and the lower response rates from some provinces. Response rate (41%) was low but comparable to those of similar surveys on oncologists' viewpoints.^{26,33} Another limitation is that our study was conducted in 2007, and there have been changes to access since then. However, limits to accessing ideal treatments and variations among the provinces remain, with only seven out of 10 provinces funding bevacizumab and four provinces funding cetux-

imab. Clearly, ongoing assessment of oncologists' perceptions is needed as design of the drug funding process continues to evolve. Although this study is limited by focusing on CRC, the observed phenomena will likely be applicable to other expensive new drugs for the treatment of other malignancies.

In conclusion, our study showed that limited and nonuniform drug funding and access had a significant negative impact on oncologists' practice and their views of the design of the health care system. This contributes to a relationship between payer and provider that is less than ideal.

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