Ethical Decision-Making in Cancer Treatment

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ABSTRACT
There are many ethical issues and challenges that arise when governments allocate limited resources in a publicly funded health care system. The increasing cost of healthcare has resulted in the need to ration services and set priorities. Healthcare spending in Canada was expected to reach $183 billion in 2009 and much of this growth can be attributed to an increase in intensity of treatment and services including technological advances in treatment modalities and new drugs. This paper explores the ethical challenges inherent in decisions to fund life-prolonging cancer drugs for a relatively small group of patients versus investing in treatments with wider applications that would benefit many. There is a need for transparency and accountability regarding the decision-making process for drug approval in Canada. Three ethical decision-making frameworks are critiqued in the context of their applicability and usefulness.

Canada’s healthcare system is based on the values of equity and justice. Canadian citizens in need of care will not be denied because of personal characteristics, cultural ethnicity or economic status. These underlying values imply that providers of care remain impartial in decisions regarding the treatment of patients and that all people should expect to be treated equally. In order to facilitate equal treatment across Canada, healthcare services deemed to be medically necessary are governed under the Canada Health Act, Canada’s federal legislation for publicly funded health care insurance. The legislation was created as a means to define national
standards and to provide a mechanism for their enforcement in the delivery of health care across the country. The primary objective of Canadian health care policy and the Act is to “protect, promote and restore the physical and mental well-being of residents of Canada and to facilitate reasonable access to health services without financial or other barriers.”

There are criteria set out in the Canada Health Act that allow limits to be placed on a patient’s ability to access certain treatments and drugs. These limits are dependent upon what the medical community within the province defines as “medically necessary”. The lack of national consistency in defining what treatments are considered medically necessary creates confusion for patients and care providers. Provincial variations pose challenges not only for healthcare administrators and providers but for the public service as a whole as political leaders struggle to maintain trust in public institutions. The premise of universal healthcare is that the well-being of society and its citizens is dependent upon financial resources and support made available through government policies and programs. Ethical dilemmas arise when resources are limited and there is a need to balance efficiency and equity.

The purpose of the Canada Health Act is to “establish criteria and conditions in respect of insured health services and extended health care services provided under provincial law that must be met before a full cash contribution may be made.” The Act stipulates that five program criteria be met before a province is eligible to receive the full federal funding allotment: public administration, comprehensiveness, universality, portability, and accessibility. Insured services are to be administered by a public, not-for-profit authority to all eligible Canadians on “uniform terms and conditions”. With respect to accessibility, there are to be no out of pocket charges and medically necessary services are to be made available to everyone equally regardless of age, health status or financial means. “Reasonable access in terms of physical availability of medically necessary services has been interpreted under the Act using the ‘where and as available’ rule.”

With respect to cancer treatment, the Canada Health Act does not provide adequate clarity to resolve ethical dilemmas regarding the just distribution of resources. There is enough grey area to prevent uniform application of the principles underlying universal healthcare. The delivery of healthcare through public hospitals falls under provincial jurisdiction, including drugs administered within a hospital setting. “Each province develops its own formulary, the list of drugs it pays for during hospital stays and for those covered by provincial outpatient drug plans.” In essence, each province decides whether a particular drug is too expensive.
to use within the context of competing claims for healthcare resources within that province. Cancer drugs are very expensive and the cost of newer formulations is ever-increasing. “Hospital spending for cancer drugs quintupled nationally between 1998 and 2008, from $145 million to $725 million. During the same period, spending by jurisdictions for cancer drugs also grew. For example, British Columbia’s total spending on oral and intravenous oncology drugs, which includes both hospital and community spending, rose from $17 million to $114 million.” The Canada Health Act criteria require that medically necessary services be universally accessible to all citizens without financial barriers, “where and as” they are available. The definition of “medically necessary” with respect to cancer treatment is debated and the types of drugs made available vary widely across the country. “The debates focus not only on the costs of these treatments, but also on their relatively modest benefits, which are often on the order of a few weeks or months of increased life expectancy.” A drug may not meet the standards set out in provincial approval bodies for various reasons. “There may not be enough evidence or enough high-quality evidence of its effectiveness to support funding the drug; the drug’s medical benefit might be limited; the drug may not offer enough of a benefit over treatments that are already available; and the potential dangers or side effects of the drug may outweigh its benefits.” The drug may also be targeted to meet the needs of only a very small group of patients, therefore decreasing cost effectiveness.

The approval process for drugs for use in Canada is very fragmented. Drugs that have been approved by Health Canada may not be listed uniformly on provincial formularies and may not be covered by private insurance in certain provinces. Until 2006, when the Joint Oncology Drug Review was developed, each province was developing its own list. Managed through Cancer Care Ontario, the group makes recommendations regarding which oncology drugs should be approved for national use by Health Canada. Provinces use this information to make decisions about which drugs to include in their formularies but each province is free to make its own choices. This process is not clearly understood by the public and most cancer patients have no idea how decisions regarding drug funding are made or by whom they are made. Reporting in the Globe and Mail, Linda Priest noted that a woman with breast cancer had to “battle the Medicare bureaucracy in her final months”. CITE Ontario finally decided to pay for a drug combination that was already available to other patients around the country. At the time the case was initially publicized, Ontario’s drug approval body had not signed off on funding even though the drug was approved by Health Canada.
Many similar stories reported in the media point to the need for transparency around decisions and a greater understanding of how they are made. Are funding decisions purely economical? Are they guided by formal, documented processes based on standards or principles? Patients, drug manufacturers and healthcare providers need an understanding of what factors are weighed in funding decisions. A common and clear understanding is needed of “how different outcomes – improved quality of life, disease-free survival, and overall survival – are weighted in economic analysis.”

It is also important for stakeholders to know whether there are different standards applied to specific drugs that benefit a small number of patients versus those with a wider application. Decisions with far-reaching ethical impacts require the use of frameworks to help set priorities. A common theme in priority setting is the value of justice and the requirement that the rationales for decisions use fair and legitimate processes. In the case of setting priorities for new cancer drugs, there are many value laden rationales that can be employed which result in hypothetical tradeoffs which are not easily justified or unanimously agreed upon. How does one reconcile trade-offs between “life-saving technologies versus community services, withholding of life prolonging medical care from critically ill elderly people, equity versus cost-effectiveness or good outcomes, do-no-harm principle versus maximizing outcomes, helping the worst off versus maximizing outcomes, and personal treatment preferences versus abstract measures of utility.”

Competing claims for healthcare pose practical and ethical dilemmas for both government and clinicians. The decision to withhold treatment on the basis of a perceived level of need or the probability of a positive outcome can be viewed by patients as purely subjective. In order to ensure public trust, it is critical that decisions are seen to be impartial, using clinically relevant factors that balance the needs of the individual patient with those of society as a whole. It is difficult to create clear and fair policies for treatment in the context of a shortage of funds, and the current lack of transparency results in ethical challenges. The Canadian Medical Association bases policy decisions on three broad categories: quality, economics and ethics. Quality of care factors are based on clinical practice guidelines, mortality rates and various historical outcomes supported by data. Economic factors include the cost of treatment and related costs including provision of direct care and ancillary services. Both categories are fairly easy to comprehend and are based on facts and data. The third category, ethics, is where the water gets muddy.
People come into every situation with their own principles and values. Personal values guide day to day decision-making and often decisions based on ethics come down to individual beliefs about morality, justice, and right and wrong. When we talk about publicly delivered healthcare where values are not focused on profit or financial gain, it is more difficult to balance the three categories. “Because there is no overarching theory of justice to balance the competing claims between morally relevant criteria such as need and benefit, fair, open and publicly defensible resource allocation procedures are critical.”

Tools are needed to guide open processes and legitimize decisions. Lewis and Gilman explore several models to assist the public service manager in ethical decision-making, including tools such as “Role Diagnosis”. This model is relevant to this topic in that the role of the physician and the physician’s fiduciary duty toward the patient must be balanced against the priorities and obligations of sustainability and humanity at large. The model states that all roles should be examined when making a decision along with the seriousness of ethical claims being considered. The idea is that decisions may differ based on a person’s role in a certain circumstance and one role does not hold more weight than another. For example, the extent of the physicians’ ethical duty to promote the patients’ best interest in the face of resource allocation decisions is dependent upon the role in which they see themselves at the time. “[A] patient’s interests must be weighed against the legitimate competing claims of other patients, of payers, of society as a whole, and sometimes even the physician himself.” This model can be used with more success at the macro level for provincial funding decisions from a broader public service perspective. Difficulties arise at the micro level when a physician’s personal and professional obligations to a patient conflict with obligations in his/her role as a public service provider.

C. W. Lewis’ “Pursue the Public Interest” is another ethical decision-making model with relevant implications to the topic of fair and equitable resource allocation. The tool suggests exploring grouped values such as responsiveness and receptiveness, inclusion and impartiality, empathy and benevolence in successive order while reflecting on four guiding principles. The principles are: the trustee principle which seeks to protect future generations’ interests; the sustainability principle which is based on securing future generations’ opportunity for comparable quality of life; the obligation principle which seeks to provide for the needs of current and coming generations giving priority to concrete risks over longer term hypothetical risks; and finally the precautionary principle which in the absence of compelling needs calls for the avoidance of
imposing risk of irreversible harm.\textsuperscript{16} This model places greater emphasis on the needs of society and the obligation to consider the impact of decisions on future generations.

In the case of funding expensive cancer drugs, decisions need to consider the relationship between the cost and outcome both on individual and social terms. If fiscal restraint is not practiced, Canada’s universal healthcare system may not be able to offer future generations a comparable quality of life. The total cost of a new drug treatment has to be defined in terms of the net cost to society of offering or not offering the treatment and this is extremely difficult to quantify. The \textit{obligation} and \textit{precautionary} principles can sometimes be at odds with one another. In the example of a patient with cancer that has been offered a chance at prolonged life there is a “compelling need” to risk resources for future generations to provide for the needs of current generations. While these models offer some means to frame decisions, they fall short when there are complex, competing claims such as those relating to the provision of healthcare services. Healthcare is seen as an important social good and citizens tend to be more critical with regard to the responsiveness and transparency of the system and decisions governing the provision of care. There is an underlying requirement for the decision-making process to be seen as democratic and at the very least accountable to the public.

Recognizing the struggle of decision-makers to set priorities with respect to cancer drugs, a group of researchers were commissioned by a provincial cancer agency to create a ranking tool that would be considered fair and could be used to track decisions regarding cancer drug funding, thus contributing to transparency. The tool, 6-STEPPPs (Systematic Tool for Evaluating Pharmaceutical Products for Public Funding Decisions) was based on the ethical framework Accountability for Reasonableness (A4R) which uses \textit{publicity}: transparency of process, \textit{reasons}: content validity, \textit{appeals}: opportunity for challenge and \textit{enforcement}: mechanism to ensure conditions are met. The A4R elements define fair priority setting for decisions requiring resource allocation.\textsuperscript{17} The 6-STEPPPs tool is very comprehensive and includes several modules that guide decisions through clinical evaluation, administrative evaluation, and policy decision phases.

Data is synthesized and integrated with cost modeling. Drugs are ranked within a matrix of key data, scoring patterns, and indexed across various modules. Those using the tool are encouraged to examine and comment on the different criteria and costing data so that deliberations can be recorded to reveal how differences in opinion were handled.\textsuperscript{18} The thoroughness of the tool at the different phases in the decision-making process allows decision-makers the opportunity to examine their own
internal, subjective framework for arriving at opinions. A qualitative study was conducted which examined the internal frameworks that supported and challenged participants as they worked through the 6-STEPPPs tool. The study used a simulated multi-stakeholder drug decision-making exercise based on role playing. Participant observations, focus group discussions, and videotaped transcripts were examined to arrive at conclusions.¹⁹

A recurring theme in the review of the use of the tool was that it could not overcome inevitable challenges and tensions involved in coming to a consensus. “While the tool provides opportunity for weighting overall scores, it did not alleviate the difficulty in making decisions among different and apparently competing individual belief systems, reflected in the perspectives of the needs of patients, clinicians, administrators and more broadly, the needs of society.”²⁰ Many participants advocated for individual patients regardless of their assigned role. A tendency to focus on the prolongation of life led to discussions regarding drugs that could cure versus those that may provide some measure of quality of life. “Societal stewardship” was mentioned throughout discussions regardless of the participant’s role with respect to what is worth funding. An example of $14 million dollars being used to treat 400 patients that are destined to die within two to seven months was brought forward as a case where the average citizen would likely consider the use of funds a waste.²¹

The bottom line conclusion of the study was that despite the availability of a decision making tool that attempts to focus on science and impartiality, “frameworks for new drug therapies need to consider the subjective internal frameworks that affect decisions. Understanding the very human, internal turmoil experienced by individuals involved in healthcare resource allocation, sheds insight into ... how to better support difficult decisions through transparent, value-based resource allocation policy, procedures and processes.”²² The 6-STEPPPs tool is too complex to inform public debate on the issue of resource allocation. Most Canadians would not comprehend all the factors that form part of the decision to fund a cancer drug and in many cases would not agree with the outcome because of personal beliefs or values. Public debate often centers on fairness and those who are denied access to treatment will likely view what is fair in a different way.

A recent article in the Toronto Star talks about the need for an “adult conversation” with respect to the claim that the cost of Canada’s Medicare system is unsustainable. As Robert G. Evans noted in June 1, 2010, “an aging population will remain secondary to the increases in intensity and costliness of care. This is the real issue. Where is the money
going…and are we getting value?” CITE Many patients are opting to pay for drugs out of pocket in a private setting and many stakeholders advocate for the expansion of markets for private providers and insurers.

The Canadian government’s mandate is to protect the interests of Canadians by ensuring that the public system is not eroded for those who are not able to pay. Policy-makers need a better understanding of how funding decisions are made at the micro level, and decision-makers need to be held accountable through transparent processes as the debate about the allocation of scarce public resources continues. What is missing thus far is a societal perspective on what kinds of trade-offs are implicit in funding decisions and what principles and values are generally agreed upon. The media consistently reports widespread support for publicly funded healthcare. However, there is consensus building around the need for change in order to sustain it. It is time for open dialogue around the ethical issues facing Canadians and the sustainability of our universal healthcare system. Cancer patients should take a lead role in public debate as they are acutely feeling the impact of a constrained public system.
NOTES

2 Department of Justice. “Canada Health Act [C-6], R.S., 1985, c. C-6, s. 4; 1995, c. 17, s. 35.” http://laws-lois.justice.gc.ca/eng/C-6/index.html
9 Andrews and Usher, 9.
10 Ibid, 10.
13 Ibid.
15 McKneally et. al., 164.
16 Lewis and Gilman, 312-321.
19 Ibid, 2-7.
20 Sinclair et al., 384.
21 Ibid, 381-390.
22 Ibid, 381.
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Department of Justice, “Canada Health Act [C-6], R.S., 1985.” c. C-6, s. 4; 1995, c. 17, s. 35. http://laws-lois.justice.gc.ca/eng/C-6/index.html


