

SETTING LIMITS IN HEALTHCARE

SETTING LIMITS IN HEALTHCARE:
THE ONTARIO DRUG BENEFIT PROGRAM AND ACCOUNTABILITY FOR REASONABLENESS

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A Thesis
Submitted to the School of Graduate Studies
in Partial Fulfillment of the Requirements
for the Degree
Master of Arts

McMaster University

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MASTER OF ARTS (2006)
(Philosophy)

McMaster University
Hamilton, Ontario

TITLE: Setting Limits in Healthcare:
The Ontario Drug Benefit Program and Accountability for Reasonableness

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NUMBER OF PAGES: vi, 85

ABSTRACT

Moderate scarcity is a basic social condition and resource constraints make limit setting in healthcare inevitable. Limits are already being set at many different levels in Canadian healthcare, but limit setting often proceeds in an uncoordinated and opaque manner, with little public knowledge or involvement. The need to set limits in healthcare raises important questions about distributive justice. Substantive approaches to distributive justice are subject to significant problems, and there is no theoretical consensus at the level of ethical theory. Procedural approaches are also subject to serious flaws, but in this thesis I argue that a procedural approach is currently the most appropriate way to deal with morally controversial aspects of limit setting. To illustrate principles of procedural justice and limit setting in healthcare I will use the Ontario Drug Benefit Program (ODB) as a case study. The ODB provides publicly funded prescription drug coverage for vulnerable groups in Ontario, but some drugs are not listed on the Provincial formulary. The ODB sets limits on what drugs are covered, but listing decisions can be morally controversial. “Accountability for Reasonableness” (A4R) is the leading ethical framework for limit setting in healthcare, and I provide a critical assessment of the ODB by applying this framework to the way in which these limits are set. The ODB meets some of the conditions of A4R, but there is significant room for improvement. I offer five recommendations to enhance the legitimacy and fairness of ODB limit setting.

ACKNOWLEDGMENTS

I would like to express my sincere thanks to Dr. Elisabeth Gedge for her guidance and support during the research and preparation of this thesis. I would also like to express my gratitude to Dr. Lisa Schwartz for the many helpful discussions and opportunities that she made available to me during my program of study. I am indebted to both of you for your unique contributions to my development as a researcher, teacher, and ethical thinker.

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INTRODUCTION

Canadians take pride in a healthcare system that is publicly funded and universally accessible but as costs continue to rise, timely access to necessary treatment has become an issue of great concern. Problems such as this should not surprise anyone: in 2002, two national commissions concluded that in its present form, the Canadian healthcare system is not sustainable.¹

The rising cost of healthcare is often associated with an aging population, expensive new technologies, and increased demand for services. In theory, the increased cost of healthcare could be addressed in four ways: 1) increase current funding; 2) reform healthcare delivery; 3) permit or increase private delivery; and 4) limit public services. Kirby and Romanow both recommend increased funding and delivery reform, both oppose increased privatization, but neither report directly addresses the need for limits in healthcare. Both reports assume that increased funding and appropriate reforms will be adequate to address our healthcare needs. This may be true in the short-term, but eventually the combined pressures already noted will overtake our ability to provide “everything for everybody.”

While funding increases are possible, healthcare spending cannot increase indefinitely. There is general support for modest reforms to delivery (e.g., increased primary and home care), but there is significant resistance to deep change (e.g., extending prescribing privileges to other providers; moving physicians from a fee-for-service to a

¹ Roy Romanow. *Building on Values: The Future of Health Care in Canada*. Commission on the future of health care in Canada, 2002; Michael J.L. Kirby and Marjory LeBreton. *The Health of Canadians – The Federal Role. Volume Six: Recommendations for Reform*. The Standing Senate Committee on Social Affairs, Science and Technology, 2002.

salary base). Canadian opinion about the need to maintain a strong public healthcare system remains strong, but a recent Quebec court challenge may signal the first wave of dissent.²

These issues are the source of much debate in Canada, but the need to set limits in healthcare is rarely discussed. This reluctance is understandable (no one *wants* to deny anyone the chance at improved health), but ultimately it is not in our best interest to avoid discussing the issue. Most would agree that moderate scarcity is a basic social condition, and because our resources are limited, the need to set limits is inevitable. The question is not *if* we should set limits in healthcare: we already *do* set limits in healthcare.³ The question we need to ask is this: what limits are fair, and how should they be set?⁴

Substantive approaches to distributive justice are subject to significant problems, and there is no theoretical consensus at the level of ethical theory. Procedural approaches are also subject to serious flaws, but in this thesis I argue that a procedural approach is currently the most appropriate way to deal with morally controversial aspects of limit setting. I will illustrate principles of fair and legitimate limit setting by applying the leading ethical framework (i.e., “Accountability for Reasonableness”) to the Ontario Drug Benefit Program.

In chapter one I outline some common substantive approaches to the problems of distributive justice. Here I include a general discussion of libertarian and egalitarian

² Chaoulli v. Quebec (AG) 2005 SCC 35. This case centers on issues of increased wait times for necessary surgeries and the prohibition of private insurance for health services that parallel publicly funded services.

³ Two examples: 1) some drugs/interventions are not publicly funded; and 2) the use of waiting lists implicitly limits access to treatment.

⁴ Norman Daniels. “Justice, Health, and Healthcare.” *American Journal of Bioethics*. 2001;1(2):2-16.

views of justice, a summary of the Rawlsian notion of “justice as fairness”, and the practical role of ethical principlism. I will show that these substantive approaches are all subject to significant problems. I then discuss the role of “reasonable disagreement” in the debate over matters of justice, and I conclude by showing why procedural approaches are currently the best way to deal with morally controversial issues of distributive justice.

In chapter two I deal with some general principles of resource allocation and I compare current healthcare costs in Ontario with levels of healthcare spending in Canada and other OECD countries. I also consider the question of sustainability and the call for reform in Canadian healthcare.

In chapter three I demonstrate that there is a need to set limits in healthcare, and I review the international experience of rationing and priority setting. Here I summarize various tools and techniques that decision makers currently use, and I discuss “Accountability for Reasonableness” (A4R), the leading ethical framework for legitimate and fair limit setting.

In chapter four I introduce a case study. The Ontario Drug Benefit Program (ODB) is a governmental program designed to provide drug coverage for vulnerable groups in Ontario. I review the processes used to determine which drugs are included on the provincial formulary, and how requests for drugs that do not appear on the formulary are managed.

Finally, in chapter five I critically assess the processes used by the ODB in light of the requirements of A4R. Many aspects of the current ODB system are consistent with the principles of A4R, but I will show that the ODB fails to meet the most important

requirements of “Accountability for Reasonableness.” I then offer a number of recommendations for change, which if implemented, would enhance the legitimacy and fairness of ODB limit setting decisions.

1. DISTRIBUTIVE JUSTICE

In this chapter I outline some common philosophical approaches to the problems of distributive justice. This will include a general discussion of libertarian and egalitarian views of justice, the Rawlsian notion of “justice as fairness”, and the practical role played by ethical principlism. I will discuss the role of “reasonable disagreement” in the debate over what constitutes justice, and I conclude by showing why procedural approaches are currently the best way to deal with morally controversial issues of distributive justice.

1.1 What is Justice?

Humans have strong intuitions about justice. Most of us agree that justice is a desirable end, but what that “end” should look like and how we might achieve it are matters of great debate. Philosophers have attempted to formalize our intuitions about justice, and the notions of equality, desert and fairness seem to be central to any account we might construct.

Traditionally, “justice” is defined by the Latin phrase: “*suum cunIQUE tribuere*” (i.e., allocate to each his own).⁵ In an early attempt at a systematic account of justice, Aristotle made a distinction between “general” and “particular” justice, and he included a discussion of just distribution, rectification and exchange.⁶ Most philosophers accept Aristotle’s principle of formal justice, that is, “equals should be treated equally.” Barry restates this ideal in a more contemporary account of justice when he writes: “in the

⁵ Brian Barry and Matt Matravers. “Justice.” *Routledge Encyclopedia of Philosophy*. London: Routledge, 1998: 141-147.

⁶ See *Nicomachean Ethics*, Book V. Terence Irwin (trans.). Indianapolis: Hackett Publishing, 1985.

absence of different desert claims, justice demands equality.”⁷ Equality and desert are clearly relevant to our understanding of justice, but it is important to mention the notion of need here as well. Need could be subsumed under equality or desert (e.g. equal needs, equal treatment; or, different needs deserve different treatment), or it could be identified as a separate principle (e.g. “to each according to their need”).

It is common to distinguish between two broad categories of justice: 1) “retributive” (or corrective) justice; and 2) “distributive” justice. Retributive justice deals with issues of punishment and correction (i.e., when does someone deserve to be punished? and, what constitutes an appropriate punishment?). Distributive justice addresses our concerns about how benefits and burdens are best shared in society. In this thesis I focus on issues of distributive justice.

Two additional distinctions are important in any discussion of justice: 1) “substantive” justice; and 2) “procedural” justice. Substantive justice refers to the notion that a particular outcome is objectively “just” or “fair”. A serious difficulty can be raised here: is there an unbiased and objective way to determine what actually constitutes justice? The second form of justice (procedural) focuses on the processes used in an attempt to reach a “just” decision or a “fair” outcome. Two concerns can be noted: 1) can we design a process that is in fact fair; and 2) do fair processes actually guarantee fair outcomes?

⁷ Brian Barry and Matt Matravers. “Justice.” *Routledge Encyclopedia of Philosophy*. London: Routledge, 1998: 141-147.

1.2 Three approaches to justice

Despite a vast literature, no consensus exists on what actually constitutes the final form of distributive justice, and different theorists propose different solutions. The first broad theory I will discuss is libertarianism.

1.2.1 Libertarian justice

Libertarians place a high priority on individual liberty, and they emphasize freedom of choice and personal responsibility. On this view, a minimal state is required but the role of the state is limited to those actions that are necessary to prevent harm, enforce contracts, and rectify injustices. Robert Nozick offers a libertarian account of distributive justice that he refers to as an “entitlement theory,” and he posits three necessary principles: 1) justice in acquisitions (how unheld property is acquired); 2) justice in transfers (voluntary exchanges); and 3) justice in rectification (correcting previous injustices). On this view any given distribution is “just” if and only if all individuals are entitled to their present holdings.⁸ Nozick’s view is theoretically tenable, but the most important problem with his theory is that he fails to give an adequate account of the rectification of injustice.⁹

The basic libertarian framework leads to the view that healthcare is a matter of personal responsibility. On this view, individuals should be free to choose the health services that they want to access, and they should be free to secure health insurance if they feel this is in their own interest. Libertarian principles of justice are most clearly

⁸ Robert Nozick. “Distributive Justice.” *Philosophy and Public Affairs*. 1972: 45-126.

⁹ For a discussion of Nozick’s theory see Allen Buchanan. “Justice: A Philosophical Review.” *Biomedical Ethics*, 5th ed., Thomas A. Mappes and David DeGrazia (eds.). New York: McGraw-Hill, 2001: 610-622.

reflected in healthcare systems that permit free market forces and private delivery (e.g. US).

The libertarian emphasis on personal responsibility with respect to healthcare has some intuitive appeal. If individuals are responsible for ensuring that their health needs are to be met, it seems reasonable to believe that they will make some effort to maintain their health (e.g., diet, exercise) and that they will make provision for future healthcare needs (e.g., savings, insurance). If they choose not to exercise these options, then it is just (from a libertarian perspective) that these individuals should be the ones to deal with the consequences of their previous decisions.¹⁰ This does not mean that people must be left to suffer: libertarian principles do allow for the free exercise of charitable forms of care. That said, libertarians are generally opposed to taxation for the purpose of publicly funded healthcare because this is seen to be a forced redistribution of wealth that violates individual freedom of choice. Canadian healthcare is compatible with some aspects of libertarianism (e.g. costs for prescription drugs are generally a private responsibility), but most of these principles of distributive justice are inconsistent with the values embodied in Canadian healthcare.¹¹

Libertarian accounts of distributive justice in relation to healthcare are subject to some serious philosophical criticisms. At the most general level, the libertarian concern about individual rights and responsibilities is justified, but libertarian approaches to distributive justice do not provide an adequate account of the collective nature of society.

¹⁰ This view does not take into account the fact that many health problems actually limit an individual's ability to choose (e.g. depression), and that many individuals are not able to purchase adequate insurance.

¹¹ Romanow identifies three core values (i.e., equity, fairness, and solidarity). See Roy Romanow. *Building on Values: The Future of Health Care in Canada*. Commission on the future of health care in Canada, 2002

Practical difficulties arise when we consider the role of social determinants of health. Is it just to make individuals pay for personal healthcare if their illnesses are caused or influenced by conditions in society (e.g., pollution and asthma)? Alternatively, what is the appropriate response to unhealthy activities that are permitted (or encouraged) by the state? (e.g. smoking and lung cancer). Problems such as these raise further problems of the rectification of injustice (e.g. who should be held liable for negative social conditions? who should be compensated? how should compensation be distributed?). Other difficulties could be added to this list, but the examples given should suffice to show that despite their strengths, libertarian approaches to distributive justice are still problematic.

1.2.2 Egalitarian justice

Equality is central to all egalitarian theories of justice, but it is important to ask: “equality of what?” Amartya Sen argues that egalitarians differ on what constitutes “base” equality (e.g. income, opportunity, well-being) and he adds that even if equality in a particular base can be achieved, this equality may not eliminate inequalities in other “spaces”.¹² It is possible to imagine a society that commits itself to the goal of ensuring equal opportunity for all by providing excellent healthcare and all necessary social supports, but given our physical and technical limitations, no combination of social programming can guarantee that every member of society will experience equal levels of well-being.

¹² Amartya Sen. “Equality of What?” *Inequality Reexamined*. Cambridge: Harvard University Press, 1992: 12-30.

Kai Nielsen opts for a focus on “moral equality” (i.e., the life of everyone matters, and it should matter equally).¹³ This suggestion is consistent with a wide variety of approaches, and it functions as an unstated premise in most egalitarian theories. We might be able to agree that “all persons are created equal” in the moral sense, but it is clear that all persons are not equal in terms of health. Individuals do not begin life with equal health potentials (e.g. differences in genetic endowment), and life circumstances lead to further differences in health and well-being (e.g. nutrition, parental competence, family income, access to medical care). There is currently no way to guarantee equal health, and as such, equal health outcomes are not a feasible base from which to assess distributive justice.

Health is basic to our ability to pursue our personal goals, and equal access to healthcare is central to most egalitarian theories. While it is possible to make room for some private sector involvement in healthcare, the costs associated with equal access to healthcare make public funding a practical necessity. Egalitarians generally support state efforts to make healthcare accessible to all apart from the ability to pay, and they do not oppose general taxation as a way to fund this basic social good. While we cannot guarantee equal health, we can attempt to provide equal access to healthcare, and this is a clearly stated goal of the Canada Health Act (CHA 1984).¹⁴

Equal access to healthcare is a commendable goal, but “equal access” does not guarantee equal health or equality of opportunity. In practical terms, even the more

¹³ Kai Nielsen. “Autonomy, Equality and a Just Health Care System.” *Biomedical Ethics*, 5th ed., Thomas A. Mappes and David DeGrazia (eds.). New York: McGraw-Hill, 2001: 622-627.

¹⁴ <http://laws.justice.gc.ca/en/C-6/233402.html> (Accessed 22 June 2006).

modest goal of “equal access” is difficult to achieve because of other social inequalities (e.g. geography, education, poverty). Equal access to healthcare does serve to mitigate health inequalities, and it is an important social attempt to improve individual well-being, but it does not achieve “equality” in the sense that many egalitarians hold to be the most important. Equality of opportunity is perhaps the broadest base on which equality can be measured, and as long as serious health inequalities exist, equality of opportunity can never be achieved. Egalitarian theories of distributive justice are intuitively attractive, but in a finite and limited world, physical and technological constraints make the basic goal of equality (in any “space”) a practical impossibility.

1.2.3 Justice as fairness

The most influential modern account of justice is John Rawls’ formulation of “Justice as Fairness”.¹⁵ Rawls offers a liberal egalitarian account of justice based on a social contract model. Rawls attempts to derive the basic principles of justice by proposing a hypothetical device (the “original position”) where autonomous rational agents consensually choose the principles of justice. Information about particulars is restricted (the agents are under a “veil of ignorance”) to ensure that personal bias does not influence the selection of the principles.

Rawls argues that a “maximin” strategy would be selected, that is, rational autonomous agents would choose to maximize the well-being of those minimally well-off because when the veil is lifted, they might in fact be part of that group. Three principles

¹⁵ John Rawls. *A Theory of Justice*. Cambridge: Harvard University Press, 1971. See also John Rawls. *Justice as Fairness: A Restatement*. Erin Kelly (ed.) Cambridge: Harvard University Press, 2001: 39-134.

of justice are then formulated: 1) the principle of equal liberty; 2) the principle of equal opportunity for positions and offices; and 3) the difference principle (differences are permitted only if they benefit the least advantaged in society). These principles are lexical (i.e., equal liberty must be ensured to all before opportunities for offices or differences enter considerations).

Rawls' view of society is one of social cooperation for mutual advantage. He argues that society should eliminate (or minimize) morally arbitrary features that arise as a result of "accidents of natural endowment and the contingencies of social circumstance." While Rawls does not explicitly address healthcare in his account, Norman Daniels has attempted to extend and apply the Rawlsian framework to the need for justice in healthcare. He does this by subsuming healthcare into the second principle (fair equality of opportunity).¹⁶ Daniels defines health and medical need by an appeal to species typical (normal) functioning and he argues that a just distribution of healthcare is one that attempts to ensure fair equality of opportunity (as far as this is possible).

"Justice as fairness" has been the source of both praise and criticism, and many others have commented on the strengths and weakness of Rawlsian theory.¹⁷ As it relates to healthcare, a few important problems can be noted: 1) because we cannot guarantee equal health, it is impossible to guarantee equality of opportunity (this is the second formal principle); 2) medical need and species typical function are notions that are very difficult to define (e.g., what services are truly "necessary"?); and 3) the social cost of healthcare

¹⁶ Norman Daniels. *Just Health Care*. Cambridge: Cambridge University Press, 1985.

¹⁷ For a discussion of Rawls see Serge-Christophe Kolm. "Distributive Justice." *A Companion to Contemporary Political Philosophy*. Robert E. Goodin and Philip Pettit (eds.) Cambridge: Basil Blackwell, 1993: 438-461.

is not sensitive to personal responsibility (i.e., individuals are free to neglect or abuse their personal health, but the cost of individual healthcare is borne by society). While there is no formal connection between this theory and the Canadian healthcare system, a liberal egalitarian view of justice such as this one seems to be consistent with the values inherent the Canadian system, and the theoretical problems identified above can be observed as practical problems in our current healthcare system: 1) current technologies do not allow us to equalize health or equality of opportunity; 2) there are ongoing debates over what constitutes medical need and what services should be listed; 3) many of the most common illnesses have strong links to personal behaviour (e.g. heart disease and obesity are closely linked to the lack of exercise and poor diet). “Justice as fairness” is a strong theoretical model and it continues to serve as a benchmark in discussions of distributive justice, but it is clear that it is not without problems.

1.3 Ethical Principlism

The previous discussion should suffice to show that on matters of distributive justice, we lack consensus at the level of ethical theory. Libertarian and egalitarian views on justice are widely divergent, and egalitarians differ amongst themselves on the specifics of equality. If we include some of the other theoretical alternatives such as Consequentialism, Deontology, Virtue ethics, and Feminist ethics, we may be tempted to conclude that no solution exists.

At the level of practice, we are required to make decisions, however tentative they might be. Major differences do exist at the theoretical level, but there is a surprising

amount of agreement on general principles of ethics. This has led some to appeal to principlism as a way through the fray. Consider the following examples:

Tom Beauchamp and James Childress are credited with the formulation of what is now a standard approach to healthcare ethics. Their framework involves the consideration of four primary principles: 1) autonomy; 2) beneficence; 3) nonmaleficence; and 4) justice.¹⁸ This approach is useful in that it provides a common vocabulary and frame of reference for ethical analysis, but two problems can be noted. While there is general agreement on the four principles, in particular situations the principles themselves may conflict. For example: for various reasons, some patients wish to refuse particular treatments. Respect for autonomy would suggest that healthcare professionals should honour a patient's expressed wishes, but if a patient is depressed, do beneficence, non-maleficence, and justice override concerns of autonomy? How should these principles be balanced? Beyond the problem of conflicting and balancing of principles, the principles themselves are non-specific. Questions about distributive justice are one clear example. The fourth principle, "justice" identifies a need to consider issues of justice in healthcare, but it does not provide any information or direction with respect to the demands of distributive justice.

"Equality" and "efficiency" are two other principles that appear frequently in the literature on resource allocation. Michael Stiglitz argues that equality and efficiency are basic social values, and that they are a necessary part of any discussion of the distribution

¹⁸ Tom L. Beauchamp and James F. Childress. *Principles of Biomedical Ethics*, 4th ed. New York: Oxford University Press, 1994.

of healthcare.¹⁹ In its simplest form, this assertion seems uncontroversial, but as we noted above, equality is a broad category and it does not provide specific direction in matters of distributive justice.

On first glance “efficiency” seems more promising. An appeal to the principle of efficiency addresses our concerns about the use of our limited resources. Most would agree that we want to minimize costs while maximizing health outcomes, and cost benefit analyses (CBA) would seem to be an appropriate step in the process. CBA is a useful tool in assessing the usefulness and the desirability of medical interventions, but this approach is subject to some significant limitations (e.g. what costs are included? how are benefits measured?)

Others appeal to “equity” as a fundamental principle of distributive justice, but this approach is subject to at least two problems: 1) In many contexts, the term “equity” serves as a synonym for fairness or justice, and at this level of analysis the introduction of “equity” as a principle of distributive justice is begging the question; 2) There is no consensus on what constitutes equity (or fairness, or justice), and the requirements of a given view must be specified before it can be assessed as a model of distributive justice.

Sen’s view of equity includes the notion of health equity, where health equity is viewed as a broad, multidimensional concept.²⁰ He points to the importance of the social determinants of health, and he suggests that social conditions as a whole should be directed toward the achievement of equal health. Sen is correct to note the importance of

¹⁹ Michael Stiglitz. “Equality and Efficiency as Basic Social Values.” *Readings in Health Care Ethics*. Elisabeth A. Boetzkes and Wilfrid J. Waluchow (eds.). Peterborough: Broadview Press, 2000: 511-520.

²⁰ Amartya Sen. “Why Health Equity?” *Health Economics*. 2002; 11: 659-666.

the social determinants of health, and there is clear evidence to establish a link between poverty and health. When individuals have inadequate incomes, health outcomes diminish for at least two reasons: 1) where there is poverty, there is an increased prevalence of disease (e.g. illnesses associated with inadequate nutrition); and 2) people living in poverty are less likely to access and receive appropriate healthcare. Many would agree with Sen that social conditions should be directed towards achieving equal health, but as noted above, equal health is not an achievable goal. Sen's notion of equity is actually a broader example of an egalitarian model that values a number of different bases of equality (e.g. equal access to healthcare, equal health). In the final analysis, equity is not actually a separate principle: equity is either a synonym for fairness, or it is a specific form of distributive justice.

As a final example, consider the work of Richard Cookson and Paul Dolan who identify three major principles of distributive justice in healthcare: 1) need; 2) maximization; and 3) egalitarian principles.²¹ Most would accept "need" as an appropriate criterion for receiving healthcare, but "medical necessity" is a very elastic term. There is no commonly accepted definition of medical need. Most would also agree that we should attempt to maximize health outcomes and maximize efficiencies, but there are circumstances that do not allow both goals to be realized (e.g. expensive cancer treatments that may prolong life but that are not curative). With the exception of emergencies, most would accept some form of "egalitarian" principles (e.g., first come,

²¹ Richard Cookson and Paul Dolan. "Principles of justice in health care rationing," *Journal of Medical Ethics* 2000; 26: 323-329.

first served). Need, maximization, and egalitarian principles are clearly relevant and widely accepted, but these principles alone do not solve the problems of distributive justice.

The examples above illustrate two important problems of principlism. The first is the need to identify and agree on the appropriate principle(s) in the case being considered. If this level of analysis is successful, a second problem may surface: if two or more principles apply, how are they to be balanced? To date we do not have a definitive way to answer these persistent ethical difficulties.

1.4 Reasonable disagreement

In *Law and Disagreement*, Jeremy Waldron addresses some of the problems associated with constitutionally entrenched rights and judicial review.²² Waldron begins by noting what he calls the “circumstances of politics”: 1) there is a need for citizens to cooperate; and 2) there is pervasive disagreement within society.²³ He points out that reasonable people often differ on their conceptions of “the good” and matters of “justice” (the previous discussion of philosophical approaches to distributive justice is clear evidence for this claim). Waldron is sympathetic to the goals of deliberative democracy (i.e., conversation and consensus), but he is correct to note that even in the context of healthy debate, good faith disagreements still persist.²⁴ Waldron also claims that there is a

²² Jeremy Waldron. *Law and Disagreement*. New York: Oxford University Press, 1999.

²³ *Law and Disagreement*. p.102.

²⁴ *Law and Disagreement*. p.91-93.

problem with the notion of moral objectivity: he argues that even if a morally objective view exists (he leaves this as an open question), we are not able to access it.

Waldron is critical of the practice of judicial review, noting that even Supreme Court decisions on matters of individual rights are decided by majority vote. This observation highlights the relationship between substantive and procedural justice. Courts are often considered to be a forum for substantive justice: we appeal to judges to make decisions about what is “right” and “just” but even at the level of the Supreme Court, many cases concerning individual rights are decided by a bare majority. It seems somewhat ironic that when the Supreme Court cannot agree on what is substantively just, the Court uses a procedural form of justice to make its final rulings! Ultimately Waldron supports a legislative solution to the problems associated with individual rights: he argues against the practice of judicial review, and he suggests that it is the right bearers themselves (through legislative representation) that should determine what their rights are and how these rights should be honoured.

Waldron’s arguments demonstrate some of the significant limitations of substantive approaches to justice, and he offers strong philosophical and political arguments for procedural forms of justice. While his focus is on justice and individual rights, Waldron’s basic arguments are also applicable to matters of distributive justice in healthcare.

1.5 Procedural Justice

We have seen that significant differences exist (and persist) at the level of ethical theory and principle. In the absence of consensus on matters of distributive justice, how do we move forward in policy and in practice? At the beginning of this chapter I noted the distinction between substantive and procedural justice. This distinction is often invoked when substantive differences have not or cannot be resolved, and procedural justice is generally defended as a reasonable way to resolve practical questions. Procedural justice is central to all democratic systems, and it is most obvious when it is expressed in decision making by majority vote. As Waldron points out, reasonable people do have good faith disagreements on important social questions, but social progress depends on social cooperation, and in the end decisions must be made. If deliberation and debate do not result in consensus, the best practical solution (to date) is to design a decision making process that is “fair” and “seen to be fair”. We are currently unable to agree on what is substantively “fair”, and this even includes our understanding of what constitutes a fair process. The design of a “fair” process is also subject to debate and disagreement, and in theory, this leads to an infinite regress. If this regress is to be blocked, some form of decision making must be accepted by everyone concerned. Democratic systems of government exhibit a wide variation in institutional design, but all democracies accept some form of majoritarianism as a basic decision making procedure. Majoritarianism is not without its own problems (e.g. the tyranny of the majority) but Constitutionalism and

Human Rights theory are two important responses to the difficulties inherent in democratic governance.²⁵

Procedural approaches to distributive justice are also subject to problems. The most obvious difficulties center around processes and outcomes: 1) what process is best? (e.g., who should be included in the process? is stakeholder representation necessary? can representatives actually represent individual stakeholders?); and 2) even if there is agreement at the level of process, substantively fair outcomes cannot be guaranteed. Procedural approaches are an imperfect solution to resolving matters of distributive justice, but where there is a pragmatic need to decide, most reasonable people accept the need for a formal decision making procedure. Procedural approaches acknowledge that there are limits to our ability to determine what is “fair” but they have at least two other benefits: 1) procedures that involve stakeholders recognize a principle that is very important to most reasonable people: those who are affected by a decision should have some say in that decision (this is one way to express respect for autonomy); and 2) processes can always be modified and iterated (this allows for improvements in decision making over time). Procedural approaches do not guarantee justice, but on the basis of the previous discussion, I contend that procedural approaches are the best available means to address morally controversial issues of distributive justice.

²⁵ Wil Waluchow, “Constitutionalism.” *Stanford Encyclopedia of Philosophy*. <http://www.seop.leeds.ac.uk/entries/constitutionalism/> (Accessed 21 July 2006).

1.6 Summary

At the level of ethical theory, there is no consensus on matters of distributive justice.

There is significant agreement at the level of ethical principle, but we currently have no definitive way to identify or balance all of the relevant principles. Reasonable people disagree on matters of justice: where there is no consensus on substantive justice, an appeal to procedural justice is theoretically and practically justified. Procedures do not guarantee justice, but procedural approaches are the best available means to address morally controversial issues of distributive justice.

2. THE COST OF HEALTHCARE

In this chapter I deal with some general principles of resource allocation and I compare current healthcare costs in Ontario with levels of healthcare spending in Canada and other OECD countries. I also consider the question of sustainability and the call for reform in Canadian healthcare.

2.1 Healthcare in Canada

In 1947 Saskatchewan became the first province in Canada to offer public hospital insurance to eligible residents, but full hospital and physician coverage was not extended to all Canadians until 1972. Today, health insurance in Canada consists of thirteen provincial and territorial health insurance plans, linked through adherence to national principles set at the federal level. This federal legislation appears as the *Canada Health Act*, 1984.²⁶

2.1.1 *Canada Health Act*

The constitution of Canada makes healthcare a Provincial responsibility,²⁷ but the Federal government plays a key role in the funding and delivery of healthcare through the Canada Health Act (CHA). The primary objective of the CHA 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.” The Act is intended to

²⁶ <http://laws.justice.gc.ca/en/c-6/17077.html> (Accessed 22 June 2006).

²⁷ <http://lois.justice.gc.ca/en/const/index.html> (Accessed 22 June 2006).

ensure that all Canadian residents have “reasonable access to medically necessary services on a prepaid basis.”²⁸

The CHA contains nine requirements that provinces and territories must satisfy to qualify for their full share of federal transfer payments made under the Canada Health and Social Transfer (CHST). The five central principles can be summarized as follows:

- 1) *Public Administration*: The administration of the health care insurance plan of a province or territory must be carried out on a non-profit basis by a public authority;
- 2) *Comprehensiveness*: All medically necessary services provided by hospitals and doctors must be insured;
- 3) *Universality*: All insured persons in the province or territory must be entitled to public health insurance coverage on uniform terms and conditions;
- 4) *Portability*: Coverage for insured services must be maintained (by the home province) when an insured person moves or travels within Canada or travels outside the country (for a prescribed period); and
- 5) *Accessibility*: Reasonable access by insured persons to medically necessary hospital and physician services must be unimpeded by charges (e.g. user charges or extra-billing) or other means (e.g. discrimination on the basis of age, health status or financial circumstances).

The CHA is egalitarian in principle and it attempts to ensure equal access to necessary health services, but three important problems must be noted: 1) the CHA fails to define “medical need,” and this makes it difficult to determine which health services

²⁸ http://www.hc-sc.gc.ca/hcs-sss/medi-assur/index_e.html (Accessed 22 June 2006).

should be covered; 2) practical constraints make “accessibility” an issue for some Canadians (e.g. some services may not be locally available); and 3) there are no explicit provisions governing the distribution of health services when demand for services exceeds supply (i.e., the CHA only guarantees “reasonable access” to insured services “where and as” available). This last problem is illustrated by the current concern over increased wait times for necessary services.

2.1.2 Resource Allocation

Resource allocation in Canadian healthcare is a complex process: it occurs at a number of levels and it proceeds in multiple stages. Three levels of allocation are commonly identified: 1) macro; 2) meso; and 3) micro.²⁹ Macro allocation usually refers to broad governmental policy and overall healthcare budgets: these decisions are generally made at the political level. Meso allocation is often used to describe institutional or administrative decision-making (e.g. hospital programming).³⁰ Micro allocation usually refers to the delivery of health services and patient care. Micro allocative decisions are generally made at the discretion of healthcare providers.

With this framework in mind, a brief outline of resource allocation in Canadian healthcare can be given. The Federal government sets an annual budget that includes an amount for the Canada Health and Social Transfer and these funds are allocated to individual Provinces. Each Province sets its own total healthcare budget, and it designates

²⁹ Eike-Henner W. Kluge. “Health Policy and the Allocation of Resources: The ethics of discrimination.” *Biomedical Ethics in a Canadian Context*. Scarborough: Prentice Hall, 1992: 205-236. See also, Michael Yeo and Anne Moorehouse (eds.). *Concepts and cases in nursing ethics* 2nd ed. Peterborough: Broadview Press, 1996.

³⁰ Martin F. McKneally, Bernard M. Dickens, Eric M. Meslin, Peter A. Singer. “Bioethics for clinicians: 13. Resource allocation.” *CMAJ* 1997; 157(2): 163-7.

specific amounts for various elements of the healthcare system (e.g. hospital funding, physician services). Hospitals are assigned a level of base funding and administrators are charged with the task of allocating these funds to cover hospital services and operating expenses. Physician services are generally reimbursed on a fee-for-service basis.

Resource allocation in Canadian healthcare is a matter of great debate. A full discussion of the criticisms of our system is beyond the scope of this paper, but I will note a few common concerns. At the most general level, there are concerns about political expedience (e.g. healthcare promises prior to elections) and blame shifting (e.g. Federal/ Provincial debates about inadequate funding). At the institutional level, concerns have been raised about the difficulties associated with annual budgeting and the need for long-term funding. At the level of healthcare providers, some suggest that fee-for-service billing results in unnecessary testing and increased expenditures. All levels of allocation are subject to problems of coordination (e.g. overlapping/ inadequate local services) and incrementalism (i.e., a bias toward annual increases of established services).

2.2 Healthcare Spending

In this section I provide an overview of healthcare spending in selected OECD (Organisation of Economic and Cooperative Development) countries.³¹ This is not intended to be a comprehensive or detailed comparison, and I do not attempt to link health outcomes with absolute spending levels. My main purpose here is to give the

³¹ <http://ocde.p4.siteinternet.com/publications/doi/files/012005061T002.xls> (Accessed 28 May 2006).

reader a sense of healthcare spending in Canada as it compares to spending in other developed countries.

2.2.1 International spending

In 2003, the United States ranked as the country with the highest healthcare spending of all OECD countries. This is true both as a function of Gross Domestic Product (GDP) and of per capita health expenditures (see Table 1). The OECD publishes figures for thirty countries and in 2003 Switzerland, Germany, Iceland, Norway and France round out the top six. Canada ranked seventh on GDP spending, and sixth on per capita spending.

Table 1: Health spending: Selected OECD Countries (2003)

| Ranking | Country | Health Expenditure as % of GDP | Health Expenditure Per Capita USD ppp |
|---------|-------------|--------------------------------|---------------------------------------|
| 1 | US | 15 | \$ 5 635 |
| 2 | Switzerland | 11.5 | 3 781 |
| 3 | Germany | 11.1 | 2 996 |
| 4 | Iceland | 10.5 | 3 115 |
| 5 | Norway | 10.3 | 3 807 |
| 6 | France | 10.1 | 2 903 |
| 7 | Canada | 9.9 | 3 003 |
| ... | | | |
| 20 | UK | 7.7 | 2 231 |
| ... | | | |
| 25 | Turkey | 6.6 | 452 |
| 30 | Korea | 5.6 | 1 074 |

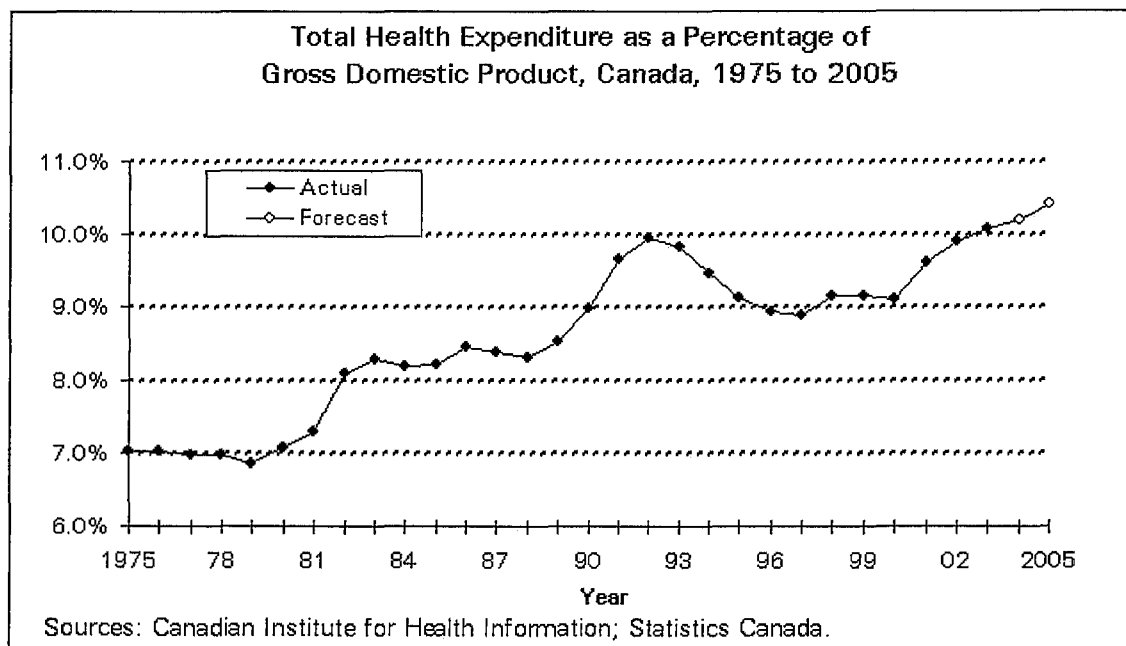
Source: *OECD Health Data 2005*, OECD, Paris, 2005.

A cursory comparison of the OECD figures shows the following: US healthcare spending was 15% GDP (\$5,635 pp); Canada spent 9.9% GDP (\$3,003 pp); UK spending was 7.7% GDP, (\$2,231 pp); and Turkey spent 6.6% (\$452 pp). These figures demonstrate a wide variation, but overall, Canadian healthcare spending is in line with most other developed liberal democracies (US excluded).

2.2.2 Canada

The Canadian Institute for Health Information (CIHI) collects and analyzes health information in Canada. According to their figures, in 1975 Canada's total health expenditure was approximately 7% of GDP (see Figure 1). Thirty years later, in 2005 health expenditures are projected to have risen to 10.5% GDP.³² The rate of growth of health spending as a percent of GDP has been subject to short-term fluctuations, but over the past three decades, the overall upward trend is clear.

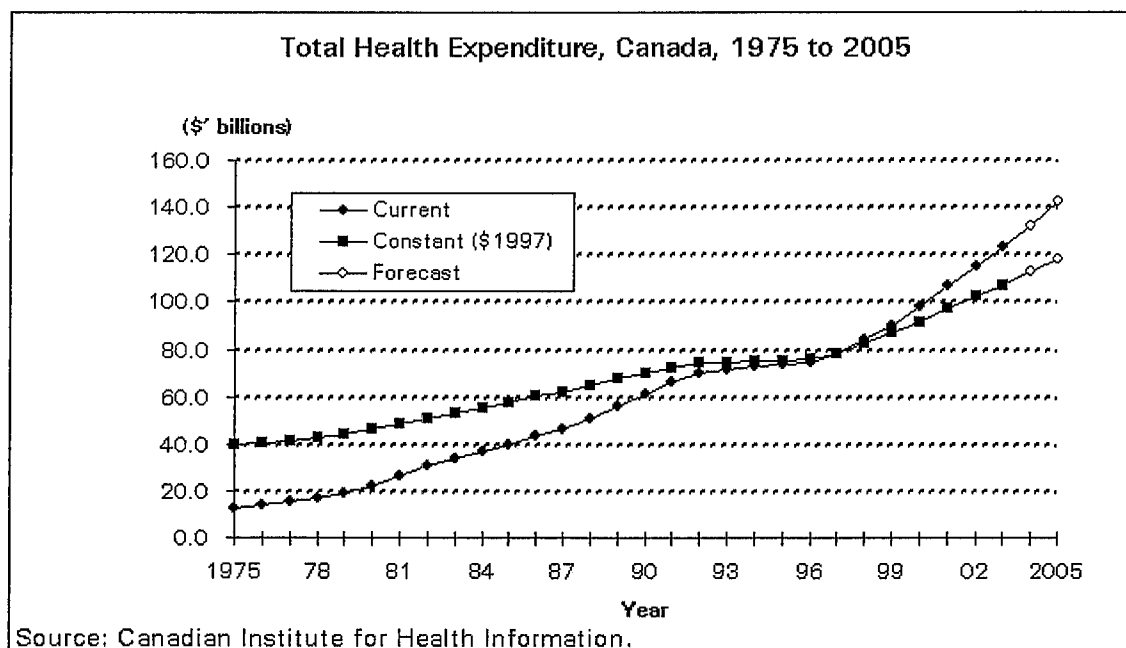
Figure 1: Total Health Expenditure as a Percentage of GDP (1975-2005)



³²http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=statistics_results_topic_macrospend_e&cw_topic=Health%20Spending&cw_subtopic=Macro%20Spending (Accessed 28 April 2006).

In terms of actual dollars spent, Canada's total health expenditure has risen from \$40 billion (1975) to an estimated \$142 billion (2005). Figure 2 demonstrates that from 1975 to 1991 Canada experienced a slow but steady increase in spending. Our spending was flat for the next four years (1992 to 1996), but from 1997 to 2005 our rate of spending jumped significantly. In the past ten years our spending (in dollars) has doubled! In spite of this major increase, healthcare spending has only risen to 10.5% GDP because Canada has experienced a concurrent period of economic growth.

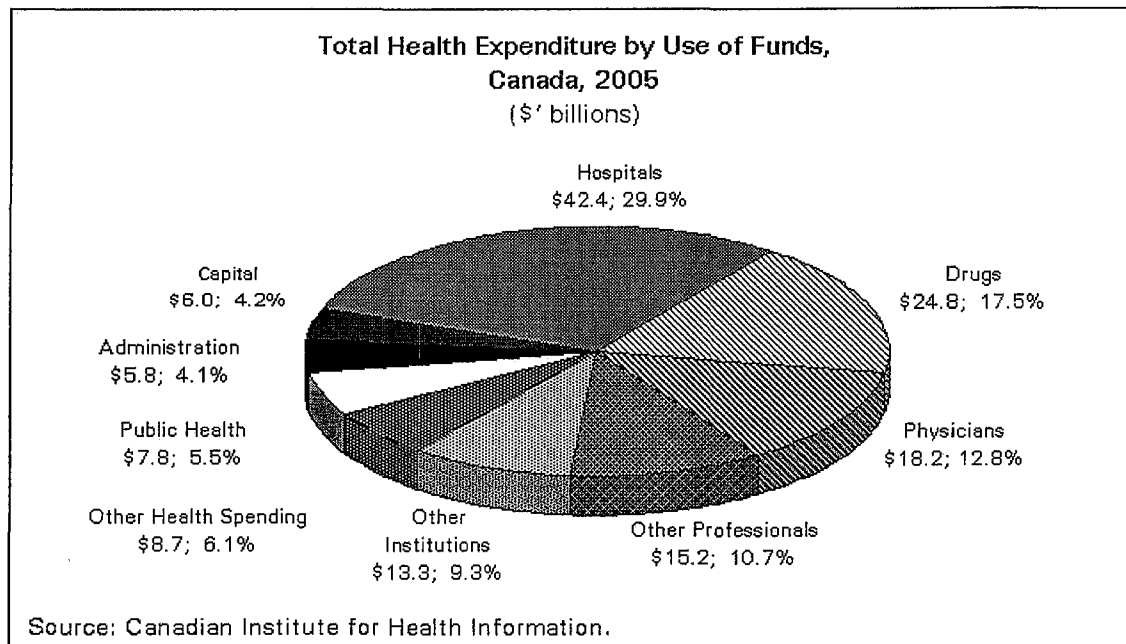
Figure 2: Total Health Expenditure (1975-2005)



Canada's 2005 healthcare budget was projected to be \$142 billion. Hospitals are the single most expensive cost in our system (29.9%). Physician services have traditionally taken second spot, but drug costs have recently overtaken doctor's services. Drugs now

account for 17.5% of our costs,³³ and physician services account for 12.8%. These three categories account for just over 60% of Canada's total health expenditures (see Figure 3).

Figure 3: Total Health Expenditure by Use of Funds (2005)



2.2.3 Ontario

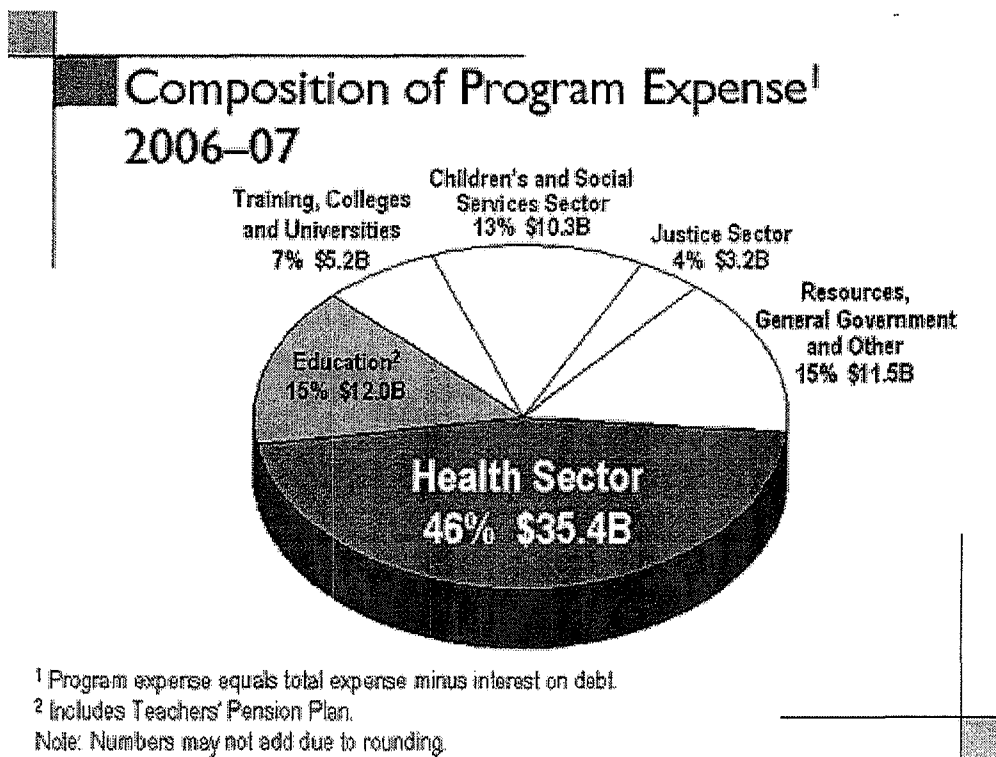
Healthcare is a provincial responsibility in Canada, and the amount of money that provinces allocate to healthcare is staggering. The Government of Ontario recently

³³ A dramatic example: annual expenditures of the new drug funding program at Cancer Care Ontario went from \$10 million/year in 1997 to over \$80 million in 2004/5. L. Schwartz, personal communication (11 August 2006).

released the 2006-2007 provincial budget.³⁴ In the next year Ontario will spend 46% (\$35.4B) of its entire budget on healthcare (approximately 10.6% of Provincial GDP).³⁵

To put this into perspective, consider what Ontario spends on other valued social programs: Education (15% GDP), Children and Social services (13%), Training, Colleges and Universities (7%), and Justice (4%) (See Figure 4). We spend more on healthcare than all of these other programs combined! Canadians value publicly funded, universally accessible healthcare, but do we understand how much we are spending, and do we appreciate the opportunity costs involved?

Figure 4: Composition of Program Expense: Ontario Budget (2006-2007)³⁶



³⁴ <http://www.ontariobudget.ca/english/aapp1.html> (Accessed 1 May 2006).

³⁵ http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=media_07dec2005_e (Accessed 2 May 2006).

³⁶ <http://www.ontariobudget.ca/english/aapp1.html> (Accessed 1 May 2006).

2.3 Sustainability: The Call for Reform in Canada

2.3.1 Kirby Report

In 2002 the Standing Senate Committee on Social Affairs, Science and Technology released its final report on the state of healthcare in Canada (informally known as “The Kirby Report”).³⁷ The Senate Committee took two years to study the issues and heard testimony from over four hundred experts and stakeholders. The Kirby report is both comprehensive and pragmatic: the central finding of the Committee was that Canadian healthcare, in its present form, is fiscally unsustainable. The Committee was also unanimous in its recommendations regarding necessary reforms to the delivery and funding of healthcare in Canada.

The Committee made many specific recommendations, but they fall into six broad categories: 1) restructure hospital and doctor systems to increase efficiency; 2) establish a “Health Care Guarantee” (i.e., set maximum wait times and guarantee treatment); 3) expand public coverage to include catastrophic drug costs, post-acute homecare, and palliative homecare; 4) strengthen the Federal role in healthcare infrastructure (e.g. health information, research); 5) recommendations on how new Federal revenue should be raised; and 6) a clear statement of the consequences of lack of reform (i.e., a Charter challenge based on the lack of access to care). Some of the more specific recommendations include the following: 1) shift hospitals from global to service-based

³⁷ Michael J.L. Kirby and Marjory LeBreton. *The Health of Canadians – The Federal Role. Volume Six: Recommendations for Reform*. The Standing Senate Committee on Social Affairs, Science and Technology, 2002. Available online at <http://www.parl.gc.ca/37/2/parlbus/commbus/senate/com-e/SOCI-E/rep-e/repoct02vol6-e.htm> (Accessed 3 May 2006).

funding; 2) give Regional Health Authorities more responsibility in planning and payment of health services; 3) primary care reform should focus on multidisciplinary teams, with a shift away from fee-for-service physician payments.

The Kirby Report concludes that governments must make an additional investment of at least \$5 billion dollars annually to make Canadian healthcare sustainable. The Committee also suggests that the Federal portion of this amount should be raised through earmarked funds, such as a National Healthcare Sales Tax (1.5% added to the GST) or a Variable National Healthcare Insurance Premium (administered through the current tax system, at progressive rates). The Committee included estimates for this second approach: according to their figures, Canadians would be required to pay an additional \$183 to \$1460 per person, per year (depending on income).

2.3.2 Romanow Report

In 2001 Roy Romanow was appointed to lead a national commission on the future of healthcare in Canada. The commission's mandate was to review Medicare, engage Canadians in dialogue about the future of healthcare in Canada, and to provide recommendations to enhance the quality and sustainability of our healthcare system. The commission heard testimony from experts and stakeholders, it commissioned various reviews and reports, and it held public consultations across the entire country. This process culminated in late 2002 with the release of the commission's final report,

*Building on Values: The future of health care in Canada.*³⁸

³⁸ Roy Romanow. *Building on Values: The Future of Health Care in Canada*. Commission on the future of health care in Canada, 2002.

Romanow identifies three core values (i.e., equity, fairness, and solidarity), and he maintains that “equality of access” is at the heart of Medicare in Canada. His overall conclusion is that our healthcare system is “as sustainable as we want it to be,” but he points to the need for reform and renewal. To this end Romanow offers forty-seven specific recommendations in ten general areas. The following is a list of some of his recommendations: 1) reform primary care and emphasize prevention (e.g. move toward multidisciplinary teams, with 24/7 access to care); 2) add homecare to the CHA as an essential service; 3) establish a National Health Council to facilitate cooperation, evaluate services, advise and coordinate reform; 4) enable the establishment of personal electronic health records; 5) increase and improve provider training; 6) create Aboriginal Health partnerships to organize and manage health services for Aboriginals; 7) establish a new dedicated cash-only Canada Health Transfer (CHT) and increase the federal share of funding; 8) provide new targeted funding (for 2 years) to address immediate issues (i.e., rural and remote access, diagnostic services, primary care reform, homecare, and catastrophic drug costs).

2.3.3 Chaoulli

The concerns expressed by Kirby in 2002 about the likelihood of a Charter challenge regarding access to health services have already been realized. In 2005 The Supreme Court of Canada heard its first case on this matter: *Chaoulli v. Quebec (AG)*. This Charter challenge was initiated by Dr. J. Chaoulli (a Quebec physician critical of the current system) and Mr. G. Zeliotis (a patient vocal about increasing wait times). Together they claimed that in the light of “unacceptable” wait times, Quebec’s

prohibition against private insurance for health services normally offered only in the public system violated their rights under the Quebec and Canadian Charters of Rights.³⁹ More specifically, they argued that the prohibition against private insurance violated the individual right to life, liberty and security of persons (s.9 QCR, s.7 CCRF).

Chaoulli lost in the lower courts but on the basis of a one day hearing, the Supreme Court (under McLachlin C.J.) returned a split decision, four to three in favour of Chaoulli. While all of the courts acknowledged that infringement of these individual rights sometimes occur, various judges disagreed about whether these infringements were contrary to the principles of fundamental justice, and if they could be demonstrably justified (s.1 CCRF). The dissenting judges held that the limits can be justified, and they argued that social policy is a matter for legislatures, not the courts. They also suggested that the courts are in a position to supervise the enforcement of the existing safety valve (i.e., the ability to obtain essential services outside of the province).

The actual legal decision in Chaoulli was quite limited: the court found that the Quebec prohibition against private insurance for health services that parallel public services violates s.1 of the Quebec Charter, and the government was given one year to find a remedy. In 2006 the Quebec government announced its plan to address the problem of excessive wait times by guaranteeing access to public services and increasing the role of the private sector. Premier Charest summarized the government position in this way:

³⁹ Chaoulli v. Quebec (AG) 2005 SCC 35.

“With regard to the Chaoulli decision, the government is responding to the Supreme Court ruling by progressively introducing guaranteed access to services in the public system, combined with an opening of the door to the private sector in respect of various common surgeries. In this way, while allowing citizens to take out private insurance for certain services, we are telling them that they will be treated in the private sector, at the expense of the public system, if the wait goes beyond an agreed period.

This response to the Chaoulli decision, then, is a reaffirmation of the relevance of our public system in today’s context. Our government has always asserted its unshakable attachment to a public health system within which the private sector could play a greater role. We are taking a cautious step in this direction. In this we are following the path proposed by many, particularly the Clair Commission, with the creation of private clinics affiliated with the public network.”⁴⁰

On 16 February 2006 Premier Charest and Health Minister Coulliard released a policy document that proposed guaranteed access wait times for several procedures including some radiation treatments and cardiac surgery, as well as knee and hip replacements and cataract surgery.⁴¹ This proposal would guarantee Quebecers access to knee and hip replacement and cataract surgeries within six months. If wait times are up to nine months in the public system, the government would pay for the procedure in an outpatient clinic, and if the wait time is more than nine months, the government would cover the cost of the procedure outside of the province or country. This plan is subject to public consultation, but if it is accepted, Quebecers will also be able to purchase private insurance for the designated procedures. The plan is estimated to cost \$20 million per year, and it would prohibit doctors from working in both public and private systems.

⁴⁰<http://recherched.gouv.qc.ca/internet/recherche.asp?query=chaoulli&curl=http%3A%2F%2Fwww.xml.gov.qc.ca%2Ffrecherche%2Fdelphes%2Fpgs%2F&int=PGS&sCatList=root&lx=780&hx=210&fy=100&mon=&n&rd=y&lang=en&adv=y&pagesize=10&cs=utf8> (Accessed 27 June 2006).

⁴¹ <http://www.cbc.ca/canada/montreal/story/2006/02/16/qc-healthque20060216.html> (Accessed 28 June 2006).

2.4 Summary

In an international comparison of OECD countries, Canada ranks sixth in overall healthcare spending. We currently spend 10.5 % (GDP) on healthcare (over \$3,500 pp). In Canada healthcare is a provincial responsibility, and Ontario currently spends 46% of its budget on healthcare. This is more than all other social programs combined. In 2002 two national commissions concluded that in its present form, healthcare in Canada is unsustainable. Both commissions recommended increased funding and delivery reform, both opposed increased privatization, but neither discussed the need to set limits in healthcare.

3. SETTING LIMITS IN HEALTHCARE

In this chapter I argue for the need to set limits in healthcare, and I review the international experience of rationing and priority setting. Here I summarize various tools and techniques that decision makers currently use, and I discuss “Accountability for Reasonableness” (A4R), the leading ethical framework for legitimate and fair limit setting.

3.1 The Need for Limits

In the previous chapter I established three important points: 1) Canada is among the top seven OECD countries in healthcare spending; 2) Ontario currently spends 46% of its entire budget on healthcare; 3) two national commissions have concluded that our present system is unsustainable, and both recommend increased funding and reform. These realities leave Canadians with some difficult choices. Are we willing to pay more (and more) for public healthcare? Are we willing to permit increased privatization of healthcare? Or, are Canadians willing to consider the need to set some limits in healthcare?

The idea of setting limits in healthcare raises many practical and ethical difficulties, but this alternative deserves serious consideration. A reluctance to debate this alternative is understandable, but many fail to realize that limits are already being set in healthcare. Limit setting is theoretically necessary because moderate scarcity is a basic social condition: our resources are limited and every decision we make about current resources affects all of our other options. Limit setting is also a practical necessity: social

cooperation requires that we allocate specific resources to specific needs (e.g. government budgets). We cannot choose *if* we will have limits: we have them by default. But this does not mean that we are without choice: we can choose to make our limits implicit or explicit, and we can exercise control over the limit setting process.

In Canada, most limit setting in healthcare is implicit (i.e., limits are set, but few of us are aware of the decisions or the processes involved). At the macro level governments set budgets for healthcare: decisions at this level place limits on what services will be available, but how governments set these spending limits is not a matter of public record (e.g. why does Ontario spend 46% of its budget on healthcare, and how did “we” arrive at this amount?). At the meso level, hospital boards must make decisions about what services they will be able to offer given certain budget constraints, and there is an upper limit to the number of patients who will be able to access these services.⁴² At the meso level, most priority setting is not characterized by transparency. Finally, at the micro level, Physicians function as “gate-keepers” in healthcare: doctors make time sensitive decisions about what interventions are appropriate for individual patients. When the choice of intervention is based on clinical judgment and service availability, many limits can be justified (e.g., minor injuries do not necessitate the use of MRI). “Bedside rationing” becomes problematic when decisions to limit treatment are based on considerations outside of the scope of medical expertise (e.g. moral or religious conviction).

⁴² Some institutions offer specialized services that are not available in all hospitals (e.g. The Children’s Hospital at McMaster University). Today most hospitals rely on private funding to maintain or increase the number and availability of the services that they want to offer.

Some healthcare systems operate with very explicit limits. For example: 1) healthcare in the US is explicitly limited by the “ability to pay.” Those who have money (or insurance) receive treatment, and only those who have a necessary minimum of income and assets are eligible for Medicare; 2) in the UK (National Health Service), dialysis services are explicitly limited by age (restricted after age 55); and 3) the Oregon Health Services Commission uses a public priority ranking system to determine the specific “basket of services” that are available to recipients of Medicare and Medicaid.⁴³

3.2 Limits, Priorities and Rationing

The terms ‘limits’, ‘priorities’, and ‘rationing’ all appear in the literature on resource allocation in healthcare and while there may be differences in connotation, most authors use them synonymously. What is clear is that all of these terms express a common idea: there is a need to make choices in light of our limited resources.

3.2.1 International experience

In *The Global Challenge of Health Care Rationing*, Coulter and Ham draw on the experiences of healthcare experts around the world and they conclude that: “there are no simple or technical solutions to the priority setting dilemma.” They go on to suggest that work carried out in various countries:

⁴³ Chris Ham. “Priority setting in health care: learning from international experience.” *Health Policy*. 1997;42: 49-66. See also Norman Daniels, “Is the Oregon Rationing Plan Fair?” *JAMA* 1991;265: 2232-2235.

“...can be likened to an exercise in policy learning in which policy makers have tried out a range of methods and approaches and have adjusted course several times in the process. What is apparent is that explicit priority setting is a continuous process which is not amenable to ‘once for all’ solutions.”⁴⁴

In their discussion, Coulter and Ham provide a number of examples of international attempts to set healthcare priorities. In the US, the Oregon Health Services Commission was established to priority rank a list of services that would allow Medicaid services to be extended to more citizens. The final ranking involved a combination of public consultations, research evidence, professional opinion, and committee judgment.

In New Zealand a Core Services Committee (later renamed the National Health Committee) was charged with the task of developing a basic benefit package. This group chose to consult doctors, experts, patient representatives, and members of the general public, and they used consensus conferences to establish evidence based guidelines and clinical criteria for health services.

In the Netherlands the Dunning Committee was appointed to advise the government on healthcare priorities. This committee established a framework of values to help guide decision-making, and they based many of their recommendations on health technology assessments, clinical guidelines and explicit clinical criteria.

As a final example, a Parliamentary Priorities Commission was formed in Sweden: this committee was comprised of members from all political parties and their emphasis was on developing an ethical platform to help guide all decision makers on how to think about the various questions associated with priority setting in healthcare.

⁴⁴ Angela Coulter and Chris Ham (eds.) *The Global Challenge of Health Care Rationing*. Buckingham: Open University Press, 2000.

Coulter and Ham draw eight lessons from their survey of the international experience of priority setting: 1) the responsibility for rationing occurs at different levels; 2) explicit rationing involves techniques and judgments; 3) in priority setting we must consider who's judgment is important; 4) attempts to be explicit reveal the difficulty of defining basic services; 5) priority setting often uses guidelines; 6) the emphasis has been placed on evidence-based guidelines⁴⁵; 7) the emphasis on judgment draws attention to values; and 8) importance has been placed on the process in decision making. Coulter and Ham summarize their findings in this way:

“In concluding this review of the experience reported here, we would echo the arguments of Martin and Singer who extend the analysis of Holm to suggest that what is needed in future is a third phase in the rationing debate which goes beyond the extremes of explicit/implicit, techniques and judgment and similar (artificial) dichotomies to seek a synthesis which reflects the complexities that exist in practice.”⁴⁶

3.2.2 Canada

According to Martin and Singer, priority setting in Canadian healthcare is difficult to describe because it occurs in various contexts, it proceeds by a wide variety of methods and there are few descriptions of the processes involved.⁴⁷ While there is no single procedural framework in Canadian priority setting, the current focus is on evidence based decision making and three particular approaches are common: 1) the use of health

⁴⁵ Evidence based funding preferences leave little if any funding for programs and interventions that do not have study support behind them because they are not researched. L. Schwartz, personal communication (11 Aug 2006).

⁴⁶ Angela Coulter and Chris Ham (eds.) *The Global Challenge of Health Care Rationing*. Buckingham: Open University Press, 2000. p. 250. See also Soren Holm. “Developments in the Nordic countries – goodbye to the simple solutions.” In *The Global Challenge of Health Care Rationing*. p. 29-37.

⁴⁷ Douglas Martin and Peter Singer. “Canada” in *Reasonable Rationing: International experience of priority setting in health care*. Chris Ham and Glenn Robert (eds.) 2003: 42-63.

technology assessment (HTA); 2) the use of cost-effectiveness analysis (CEA); and 3) the use of institutional advisory committees (e.g. Cardiac Care Network).

Martin and Singer conclude that priority setting in Canada is decentralized and that it occurs in an uncoordinated way. They argue that context specific priority setting does allow for flexibility and responsiveness, but they note that one significant problem with this approach is that policy learning is not systematically captured, analyzed and shared. Another important concern here is that there is no formal ethical accountability in Canada's decentralized approach to priority setting. Ethical considerations are often included in HTA and in Advisory group recommendations, but there are no national or provincial requirements for ethical review.

The Federal government has made an attempt to address this issue by establishing *The Canadian Coordinating Office for Health Technology Assessment* (CCOHTA). This is a national body established to conduct HTA, and its mandate is to encourage the appropriate use of health technology by providing relevant information, and by coordinating priority setting efforts and information exchange. According to CCOHTA, health technology assessment requires an interdisciplinary approach to analyze safety, cost, effectiveness, efficacy, ethics and quality of life measures associated with current and emerging health technologies. The CCOHTA has undergone a recent revision (2006) and has since emerged as The Canadian Agency for Drugs and Technologies in Health (CADTH).⁴⁸

⁴⁸ <http://www.cadth.ca/index.php/en/> (Accessed 26 June 2006).

3.3 Current Practices

3.3.1 Tools and Techniques

The literature pertaining to resource allocation in healthcare is extensive, but a review of the recent literature shows that current decision making relies on four general approaches in priority setting: 1) economic analyses; 2) ranking and rating schemes; 3) group processes; and 4) ethical frameworks.⁴⁹

Economic evaluations are used routinely to assess the merits of prospective healthcare initiatives. Cost-benefit analysis (CBA) and cost-effectiveness analysis (CEA) are well-established methods.⁵⁰ Program Budgeting and Marginal Analysis (PBMA) is relatively new form of analysis in the healthcare context, but it has been used in the UK, Australia, New Zealand and Canada.⁵¹

Many decision makers use ranking or rating schemes to help identify and set priorities. Ranking schemes challenge decision makers to make their preferences explicit by requiring definite choices between proposed options. Rating systems exhibit more variation: criteria must be selected (single or multiple), options must be rated (linear or ordinal scale), and aggregate scores must be measured (simple or weighted factors).⁵²

⁴⁹ Oliver Klimek. *Resource Allocation, priority setting and frameworks for decision making*. National Cancer Institute literature review, unpublished ms. 2003.

⁵⁰ R.H. Haveman and D.L. Weimer. "Cost-Benefit Analysis." *International Encyclopedia of the Social and Behavioural Sciences*. Oxford: Elsevier, 2001;4:2845-2851.; David W. Pearce (ed.) "Cost-benefit analysis; Cost-effectiveness analysis." *The MIT Dictionary of Modern Economics* (4th ed). Cambridge: The MIT Press, 1992: 83-84.

⁵¹ Craig R. Mitton and Cam Donaldson. "Setting priorities and allocating resources in health regions: lessons from a project evaluating program budgeting and marginal analysis (PBMA)." *Health Policy*. 2003;64(3):335-48.

⁵² Julie Astley and Wendy Wake-Dyster. "Evidence-based priority setting." *Australian Health Review*. 2001;24(2):32-39.; Ashley B. Coffield, M.V.Maciosek, M. McGinnis, J.R. Harris, M.B. Caldwell, S.M. Teutsch, D. Atkins, J. H. Richland and A. Haddix. "Priorities among recommended clinical preventive

Democratic decision-making relies heavily on group processes. Groups may be composed of experts (e.g. Delphi method) and/or stakeholders. To ensure legitimacy and broad based support for difficult decisions, many decision-making bodies seek public input on critical issues. Others choose to include stakeholders and community representatives as an integral part of their priority setting and decision making activities. There are a wide variety of approaches to engaging the public (e.g. surveys, focus groups, citizen juries).⁵³

The inclusion of ethical frameworks has become a central aspect of priority setting in healthcare. In 1997 Ham surveyed the international experience of priority setting in five countries that chose to include explicit values in their decision making: 1) in Oregon thirteen values were identified; 2) in the Netherlands four “sieves” were used (i.e., necessary, effective, efficient, individual responsibility); 3) in Sweden three ethical principles were established in rank order (i.e., human dignity, need and solidarity, cost effectiveness); 4) in New Zealand four “pragmatic” principles were identified (i.e., benefit, value for money, fairness, community values); and 5) in the UK three values were used (i.e., equity, efficiency, responsiveness).⁵⁴

services.” *American Journal of Preventive Medicine*. 2001;21(1):1-9.; Shelly Farrar, R. M. R. D. Ludbrook . “Using discrete choice modeling in priority setting: an application to clinical service developments.” *Social Science & Medicine*. 2000;50(1):63-75.

⁵³ Penelope M. Mullen. “Public involvement in health care priority setting: are the methods appropriate and valid?” Angela Coulter and Chris Ham (eds.) *The Global Challenge of Health Care Rationing* Buckingham: Open University Press, 2000:163-174.; Douglas K Martin, J.L Pater, P.A. Singer. “Priority-setting decisions for new cancer drugs: a qualitative case study.” *Lancet* 2001;358: 1676-1681.; P.M. Wortman. “Consensus Panels: Methodology.” *International Encyclopedia of the Social and Behavioural Sciences*. Oxford: Elsevier, 2001;4: 2609-2613.

⁵⁴ Chris Ham. “Priority setting in health care: learning from international experience.” *Health Policy*. 1997;42: 49-66.

These attempts to address ethical concerns and issues of fairness in limit setting are examples of ad hoc principlism, but Norman Daniels and James Sabin offer a philosophically based and empirically tested alternative. “Accountability for Reasonableness” is the leading ethical framework for fairness in limit setting, and this model outlines four conditions that promote legitimate and fair decision-making.⁵⁵

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These attempts to address ethical concerns and issues of fairness in limit setting are examples of ad hoc principlism, but Norman Daniels and James Sabin offer a philosophically based and empirically tested alternative. “Accountability for

⁵⁵ Norman Daniels and James E. Sabin. *Setting Limits Fairly: Can we learn to share medical resources*. Oxford: Oxford University Press, 2002.

⁵⁶ Chris Ham. “Priority setting in health care: learning from international experience.” *Health Policy*. 1997;42: 49-66.

Reasonableness” is the leading ethical framework for fairness in limit setting, and this model outlines four conditions that promote legitimate and fair decision-making.⁵⁷

3.3.2 Accountability for Reasonableness

In *Setting Limits Fairly*, Daniels and Sabin argue that in the context of limited resources, justice requires limits to care. They note the lack of consensus on formal principles of distributive justice and they conclude that: “we must develop an acceptable fair process for setting limits.”⁵⁸ The authors argue for a procedural approach to limit setting, and in “Accountability for Reasonableness” (A4R), they specify the following four conditions:⁵⁹

- 1) *Publicity*: decisions and rationales for limits must be publicly accessible;
- 2) *Relevance*: rationales should provide “reasonable” explanations (i.e., fair-minded people, appealing to mutually justifiable terms, regarding “value for money”);
- 3) *Revision and appeals*: mechanisms for dispute resolution and policy improvement must be in place; and
- 4) *Regulation and Enforcement*: voluntary or public regulation must ensure that the above conditions are met.

The four principles of A4R were developed on the basis of fieldwork conducted by the authors with organizations and decision groups in the US (e.g. Managed Care

⁵⁷ Norman Daniels and James E. Sabin. *Setting Limits Fairly: Can we learn to share medical resources*. Oxford: Oxford University Press, 2002.

⁵⁸ *Setting Limits Fairly* p. 10.

⁵⁹ The principles appear first in: Norman Daniels and James Sabin. “Limits to health care: Fair procedures, democratic deliberation, and the legitimacy problem for insurers.” *Philosophy and Public Affairs* 1997;264 (4): 303-350.

Organizations, Public Health Authorities, Insurance companies),⁶⁰ but a recent qualitative study by Gibson, Martin and Singer demonstrated that A4R is also applicable to the Canadian healthcare setting.⁶¹

A4R does not seek to define specific answers to specific questions: instead, it outlines conditions of procedural justice that can be applied in different contexts, and implemented in a variety of ways. This gives those who choose to use the model the freedom to determine the scope of its application. It could be applied at the micro level, but given that many healthcare decisions are time critical (e.g. emergency treatment), this is the least relevant area for its use. A4R can also be applied to macro level limit setting, and many elements of the model are already in use by democratic governments (e.g. public information and consultation, appeal processes).

A4R is perhaps best suited to meso level limit setting. Healthcare allocation at the meso level involves two primary concerns: 1) what services should we make available? and, 2) who should be eligible to receive these services? When practical limits are such that we cannot provide every intervention to every person, allocation decisions will involve limiting or denying some medical services to some individuals and groups in society and these decisions will be morally controversial. A4R does not provide a detailed procedural framework for this type of decision-making, but it does specify four necessary principles for legitimate and fair limit setting. This gives decision makers and

⁶⁰ Norman Daniels and James E. Sabin. "Last Chance Therapies and Managed Care: Pluralism, Fair procedures, and Legitimacy." *Hastings Center Report*. 1998;2: 27-41.

⁶¹ Martin, Douglas K., M. Giacomini and P.A. Singer. "Fairness, accountability for reasonableness, and the views of priority setting decision-makers." *Health Policy* 2002;61: 279-290.

Jennifer L. Gibson, D.K. Martin, P.A. Singer. "Priority setting for new technologies in medicine: A transdisciplinary study." *BMC Health Services Research*. 2002;2: 14.

stakeholders the freedom to establish procedures and timelines that are most suited to their particular contexts. Procedural details are not specified, but the four conditions of A4R are designed to make the limit setting an open, participatory and iterative process.

Adopting and applying the conditions specified by A4R requires a strong commitment to openness and transparency. The *publicity* condition requires decision makers to make their decisions *and* rationales known to the public. While there has already been a significant increase in the amount of information that is made available to the public (e.g. internet resources), the publicity condition goes beyond this. This condition asks decision makers to respect the public's need to know *why* certain decisions have been made. Making people aware of the rationales behind decisions can enhance the legitimacy of the decision making process and it is an important way to express respect for people as rational moral agents.

The *relevance* condition emphasizes the need for reasonable explanations and it addresses the role of values in decision-making. When a plurality of values exists, A4R suggests that decisions should be based on values that all parties agree on as being important and relevant to the decision. If differences remain, they will arise because these shared values are in conflict. There is no objective way to balance these conflicting values, and reasonable people may disagree. If this is the case, procedures must be in place to ensure a fair process is used to resolve the outstanding differences.

The third condition, *revision and appeals*, recognizes the need for review in decision-making. New information may come to light that may require changes in policy; or, if an error has been made, it can be corrected. The fourth condition, *enforcement*, aims

to ensure that the first three conditions are being met. Accountability is an important safeguard because it helps to ensure that decision makers maintain their commitment to fair and reasonable limits.

A4R relies on a procedural approach to issues of distributive justice, and it is open to some important criticisms. While flexibility and adaptability may be viewed as a positive feature of A4R, some may consider the lack of substantive guidance and a clearly defined process a limitation of this approach. Questions about representation are a valid concern (e.g. Who should be included in the decision making process? How can we ensure that all voices are heard?). And even if these (and other) concerns are adequately addressed, A4R is a democratic form of decision-making and it cannot guarantee a “just” outcome.

While majoritarian processes can result in outcomes that some consider substantively unjust (i.e., minority groups could be neglected or abused; majority preferences may not lead to “best” outcomes), this is a problem in all democratic systems, and it is not unique to A4R. The four conditions of A4R recognize this problem, and they are specifically formulated to avoid (and correct) these problems. In a democratic system, the healthcare needs of minority groups or people with “unpopular” illnesses are subject to majoritarian pressures. A4R offers individuals and minorities protection from majoritarian abuse in two ways: 1) rationales for limits must be made public and they must be based on grounds that all parties agree on (this offers protection from arbitrary discrimination); and 2) appeals allow for corrections to unjustifiable decisions (i.e., if

someone can show that a previous decision was unjustified, A4R requires decision makers to reverse the decision).

Decision makers who adopt this approach will need to apply the four principles to their specific contexts, and they may need to design new systems and institute new processes. Additional resources will be required to put A4R principles into practice, but the added cost of this type of review is justified by the purpose of the review itself (i.e., fairness in limit setting). A4R specifies conditions for an open and transparent decision-making process, and it allows for public involvement, revision and appeals. These conditions have been shown to enhance the legitimacy and fairness of limit setting in healthcare, and they are designed to protect individuals and groups from deliberate or unintentional harms that might result from limit setting decisions. These benefits are sufficient to justify the costs associated with the implementation of A4R and open review.

Clearly, A4R is not a simple solution. That said, the goal of A4R is fair and legitimate decision-making, not simplicity or ease of use. A4R is a philosophically based and empirically tested approach to limit setting, and it is an important contribution to our attempts to set fair limits in healthcare.

3.3.3 Four elements of limit setting

In light of the previous discussion, it seems that efforts to set fair limits in healthcare involve four key elements: 1) information; 2) values; 3) judgment; and 4) accountability.

Information is basic to the task of priority setting because it is central to rational discourse: it forms a natural foundation for deliberation. While information is commonly

considered to be the objective element in decision-making (not all critics would agree), information does serve as a common currency in priority setting discussions. In our cultural context, responsible decision-making requires the judicious use of information. Our need (and desire) for information is demonstrated by the pervasive use of CBA/CEA and our increasing reliance on evidence based medicine. Information about costs, benefits, and evidence of effectiveness are clearly relevant to the priority-setting task, but in practice complete and definitive information is not always available. This type of information gap contributes to uncertainty in decision-making and it limits the usefulness of priority assignments restricted to this level.

Values are basic to priority setting because they determine what information we accept, and they guide how we respond to the information that we have. People differ in their basic beliefs and moral intuitions and this can be a serious obstacle to building a meaningful consensus in society. If we look to the international experience of priority setting, some shared values seem to have emerged (i.e., efficiency, effectiveness, equity, evidence). These values may be shared, but in the practical context of allocating limited resources, even these widely accepted values are a potential source of conflict. The efficiency-equity debate is a prominent example. In the absence of a unifying ethical theory, our best attempt to deal with the reality of conflicting values is an appeal to procedural justice (i.e., institute fair processes).

Judgment is basic to priority setting because information and values do not in themselves yield decisions. Information can be gathered, and values can be made explicit, but ultimately a choice must be made. Decision makers must take the information that is

available (often limited), evaluate it (based on accepted standards), and make a judgment about what action to take. Unfortunately, no formula exists to guarantee that our reasoned judgments will be ‘right’, ‘just’ or ‘fair’. This leads to the fourth element of responsible decision making, that is, the need for *accountability*.

The conditions outlined by Daniels and Sabin (A4R) and confirmed in the Canadian context by Gibson, Martin and Singer provide a useful framework for accountability. Both of these models encourage decision makers to employ fair processes that include stakeholders and public representatives. Both argue for an openness and transparency (internal and external) that make decisions and rationales publicly accessible. And both point to the need for mechanisms of appeal and revision. If decision makers are concerned to make decisions that are fair (and seen to be so), public accountability will become an integral part of decision-making processes.

3.4 Summary

Moderate scarcity is a basic social condition and this makes limit setting in healthcare a theoretical and practical necessity. In Canada, most healthcare limits are implicit and limit setting often proceeds in an uncoordinated and opaque manner. No simple or technical solutions have emerged out of the international experience of priority setting, but appeals to evidence based guidelines and explicit values are common.

“Accountability for Reasonableness” is the leading ethical framework for limit setting in healthcare. The four conditions of A4R are publicity, relevance, revision and enforcement.

4. CASE STUDY: ONTARIO DRUG BENEFIT PROGRAM

The Ontario Drug Benefit Program (ODB) is a governmental program designed to provide drug coverage for vulnerable groups in Ontario. In this chapter I review the processes used to determine which drugs are included on the provincial formulary, and how requests for drugs that do not appear on the formulary are managed.

4.1 Background

In Ontario, the Ministry of Health and Long Term Care (MOHLTC) plans and administers a wide range of health programs (e.g. Healthcare professional regulation, Ontario Health Insurance Plan, Public Health). This Ministry also administers a number of drug programs for residents of Ontario, including the Ontario Drug Benefit Program (ODB).

The ODB is a provincial drug benefit program that covers most of the cost of prescription drugs for a number of groups in Ontario: 1) people over sixty five years of age; 2) residents of long-term care facilities; 3) residents of Homes for Special Care; 4) people receiving professional services under the Home Care Program; 5) Trillium Drug Program recipients; and 6) people receiving social assistance (Ontario Works, or Ontario Disability Support Program).⁶² In 2005, 2.2 million people were eligible for ODB. Depending on income, some residents who qualify for ODB are required to pay an initial deductible amount (\$100) and/or pay small co-payments towards dispensing fees (\$2 to \$6 dollars per prescription filled).

⁶² http://www.health.gov.on.ca/english/public/program/drugs/drugs_mn.html (Accessed 30 May 2006).

The ODB Formulary currently lists approximately three thousand drugs that are approved for coverage. If a drug is not approved for coverage, the patient must pay for the drug (unless they have some other form of private insurance). If they are unable to pay, they must forgo the prescribed treatment and accept an alternative treatment that is covered.

The government of Ontario makes final ODB formulary listing decisions, based in part on recommendations made by the Drug Quality and Therapeutics Committee (DQTC). This committee was established in 1968 to provide independent and specialized advice to the Ministry of Health on drug related matters.⁶³ The DQCT has twelve members (appointed) and it is made up of experts in various health-related fields including medicine, pharmacology, and health economics. The key functions of the DQTC are to assess the suitability of drug products for government funding by evaluating: 1) the therapeutic value of drugs; 2) the interchangeability of generic drugs; and 3) value for money of drug products. The DQTC also reviews a large number of physician requests for individual coverage of unlisted drugs (Section 8: Individual Clinical Review (ICR)).

Drugs must undergo a number of reviews before they can be listed on the ODB formulary.⁶⁴ In Canada, all new drugs must be reviewed and approved by the federal government's Health Products and Food Branch (HPFB). The HPFB evaluates a product's safety and efficacy and this process can take from one to two years. If

⁶³ <http://www.health.gov.on.ca/english/public/pub/drugs/dqtc.html> (Accessed 30 May 2006).

⁶⁴ <http://www.health.gov.on.ca/english/public/pub/drugs/approved.html> (Accessed 30 May 2006).

approved, a drug receives a Notice of Compliance (NOC) and a drug identification number (DIN), and manufacturers are then permitted to market the drug in Canada. Before a drug is considered for government funding, the manufacturer must file a submission to the national Common Drug Review (CDR) process. The CDR provides common listing recommendations to all governments based on rigorous clinical and pharmacoeconomic reviews. The CDR is part of CADTH, which receives expert advice from the Canadian Expert Drug Advisory Committee (CEDAC).

Drugs can be considered for listing on the ODB formulary once they have undergone the CDR process, but the manufacturer must make another formal submission to the DQTC. The committee can then recommend a drug to be listed as a general benefit or as a Limited Use (LU) benefit.⁶⁵ LU drugs are covered only under specified conditions of use, and physicians must confirm to the Ministry that patients meet these criteria. The DQTC may decide to recommend that a drug be considered for coverage under Section 8 (Individual Clinical Review)⁶⁶. This requires that a physician make a formal application on the patient's behalf to the DQTC, which then considers these requests on a case-by-case basis (a one page application outlining the patient's condition and reasons for the request). DQTC recommendations for listing and expenditure forecasts are then forwarded to the government's Management Board of Cabinet, Legislation and Regulations Committee and finally to Cabinet for approval.⁶⁷

⁶⁵ <http://www.health.gov.on.ca/english/public/pub/drugs/limited.html> (Accessed 30 May 2006).

⁶⁶ <http://www.health.gov.on.ca/english/public/pub/drugs/section8.html> (Accessed 30 May 2006).

⁶⁷ It is important to note that this recommendation/approval process is subject to internal and external pressures at every level of decision-making (e.g. conflicts of interest, special interest lobbies). The publicity condition of A4R is intended to function as a safeguard against these pressures.

4.2 ODB Report Card 2004-2005

The Ontario Ministry of Health publishes an annual Report Card for the ODB Program.⁶⁸

According to the most recent report, drugs accounted for 9% of total provincial health expenditures (\$7.4 billion) in 2004. The ODB paid for 45% of this amount (\$3.4B), while private insurers covered 35% and patients paid for 20% as out of pocket expenses.

In Ontario, 58% of residents have private insurance, 17% are uninsured, and 25% of the population is covered by the ODB. 70% of all ODB recipients are over 65 years of age. The prevalence of cardiovascular and heart disease in this age group is quite evident: 33% of ODB drug costs are for cardiovascular and antilipemic drugs alone. A small portion of beneficiaries (10%) accounted for a large portion of expenditures (40%), but no information is given about the groups or interventions that make up these figures.

In 2004 the DQTC made recommendations on fifty four drug submissions: twenty were declined, fifteen were recommended for ICR, six were listed as Limited Use drugs, and thirteen were approved under general benefits. The average time from submission to listing was 363 days. The DQTC received a staggering 143,370 requests for ICR in 2004: of these, 72% were approved, and 71% of all ICR responses were made within three weeks.⁶⁹

⁶⁸ http://www.health.gov.on.ca/english/public/pub/ministry_reports/odb_report04/drug_rep.html (Accessed 31 May 2006).

⁶⁹ The DQTC does not make detailed information about these requests public.

4.3 DQTC decision making

The DQTC advises the Ontario Minister of Health about public funding of pharmaceutical products after considering information on effectiveness, safety and cost. Manufacturers are required to submit information about cost-effectiveness and the DQTC publishes specific requirements and guidelines for the economic analysis of pharmaceutical products.⁷⁰ This information is requested to enable DQTC members to better judge the “value for money” associated with each product under review.⁷¹ The DQTC guidelines use the term “cost-effectiveness analysis” to refer to:

“...economic evaluations that consider both the comparative costs associated with the use of pharmaceutical products and the comparative clinical effects measured either in pure clinical units (effectiveness), or in health preferences (utilities), or comparative outcomes [e.g., quality adjusted life years (QALYs), or dollars (benefits)].⁷²

A full economic analysis includes seven components: 1) relevant costs and clinical outcomes; 2) incremental analysis (costs and outcomes associated with new products are compared with those of established therapies); 3) costs and outcomes are discounted over time; 4) the perspective of the decision maker is clearly identified (direct medical costs are disaggregated from societal costs); 5) all sources of data are identified; 6) sensitivity analyses are used to assess robustness of conclusions; and 7) incremental cost-effectiveness ratios are compared in similar units (a common approach is to present costs

⁷⁰ http://www.health.gov.on.ca/english/providers/pub/drugs/economic/economic_mn.html (Accessed 1 June 2006).

⁷¹ http://www.health.gov.on.ca/english/providers/pub/drugs/economic/econ_purpose.html (Accessed 1 June 2006).

⁷² http://www.health.gov.on.ca/english/providers/pub/drugs/economic/econ_analysis.html (Accessed 1 June 2006).

in dollars and clinical outcomes in QALYs gained; QALYs are derived from utilities plus mortality figures).

Incremental cost-effectiveness ratios, together with total aggregate expenditures required to benefit target populations can be used to set priorities for funding within a fixed budget. In principle, net benefits will be maximized but this assumes allocation of the total program budget at a single point in time. In practice, this is not how the ODB (or most public programs) allocate resources. A more common approach to resource allocation is to compare the incremental cost-effectiveness ratio of a particular intervention with that for other programs, to determine its relative economic attractiveness. This does not address the issue of what actually constitutes “high” or “low” economic attractiveness: “This is a qualitative and subjective judgment, that will vary according to the resources available...”⁷³ Some quantitative thresholds have been suggested in the literature (e.g. 1990 Canadian dollars per QALYs), but no explicit thresholds are currently used by the DQTC. According to the MOHLTC, future decision makers will have to determine how much they are willing to pay for the health effects achieved by a variety of interventions competing for resources.⁷⁴

4.4 DQTC in practice

The Ministry of Health recently completed a streamlining initiative in an effort to harmonize the ODB drug review process with Health Canada. Phase III streamlining

⁷³ http://www.health.gov.on.ca/english/providers/pub/drugs/economic/econ_ratios.html (Accessed 1 June 2006).

⁷⁴ http://www.health.gov.on.ca/english/providers/pub/drugs/economic/econ_ratios.html (Accessed 1 June 2006).

highlights include harmonization of generic product review, a reduction in the number of requirements for manufacturers, and more guidance for product submissions. The ODB also hopes to provide “more transparency to convey a clearer understanding of the DQTC reviews and recommendations.” In this context, improved “transparency” seems to be intended to benefit manufacturers (not physicians or ODB recipients).⁷⁵

The DQTC decision-making process was the subject of a recent qualitative study.⁷⁶ The authors sought to describe how ODB listing decisions were made, and in particular, the role of economic analyses in these decisions. At the time of their study, the DQTC committee consisted of twelve members (eight physicians, one pharmacist, one pharmacologist and two government employees). The committee met once a month for three-hour meetings. Prior to these meetings, two expert consultants (one clinical, one economic; these consultants may or may not be DQTC members) review manufacturers’ submissions, and each reviewer makes an independent recommendation on listing (general benefit, limited use, ICR). The DQTC reviews these recommendations and makes a final recommendation to the MOH and the manufacturer.

The names of the DQTC committee members are not a matter of public record, meetings are not open to the public, and all discussions are confidential. The study authors were permitted to attend nine meetings and interview committee members, but they were not given access to any written reports. The authors found that the clinical factor (effectiveness) was the driving force in listing recommendations, and that most of

⁷⁵ http://www.health.gov.on.ca/english/providers/pub/drugs/dsguide/dsguide_mn.html (Accessed 5 June 2006).

⁷⁶ Anne M. PausJenssen, P. Singer, A.S. Detsky. “Ontario’s Formulary Committee: How Recommendations are made.” *Pharmacoeconomics* 2003;21(4): 285-294.

the committee's time was spent on dissecting manufacturers' claims of clinical merit. They also looked at 'effect size' (comparison of clinical benefit, dose, and cost). The committee often reversed the recommendations of the clinical reviewer because they had considerable clinical expertise, but only one physician on the committee had any training in health economics, and this member was often asked to review products with high costs. The committee acknowledged that they relied heavily on the advice of an economic consultant (often external to the committee) to know if a product was "good value for the money." Complex economic analyses (i.e., analyses more involved than a simple cost-consequence analysis) played a limited role in listing recommendations, but the committee did discuss economic issues, and often performed informal economic analyses to guide decisions.

4.5 Summary

In 2005 the ODB provided prescription drug coverage for 2.2 million people in Ontario (25% of total population). 70% of ODB recipients are seniors. Total ODB spending was \$3.4 billion; 33% of this amount was for treatment of cardiovascular disease. The DQTC provides expert advice to the government on drug listings. Drugs can be listed on the provincial formulary as general benefit, limited use, or ICR. If a drug does not appear on the formulary, ODB recipients must pay for it themselves or accept an alternative treatment.

5. DISCUSSION

In this Chapter I evaluate the ODB in light of the requirements of A4R, and I focus on three areas of concern: 1) I will assess the limit setting practices of the ODB; 2) I will identify some of the implications of the system on the primary stakeholders; and 3) I will offer some recommendations on how ODB limit setting could be changed to better reflect the four conditions of A4R, thus enhancing the legitimacy and fairness of ODB decision making.

5.1 The ODB and Accountability for Reasonableness

5.1.1 Publicity

The first condition of A4R is publicity: legitimate and fair limit setting requires that information and rationales are made publicly accessible. The ODB meets the publicity condition in part, but in the most relevant sense, it falls far short of the intent of this condition.

The ODB makes a significant amount of information available to the public. Most of the information presented in Chapter four is sourced directly from the ODB web site. Some of this information outlines the general purpose and practice of the program, and this can be helpful to ODB recipients and the general public. There is also a significant amount of information available to physicians and manufacturers (e.g. ICR forms, submission guidelines and requirements, etc.). These public postings are helpful in at least three ways: 1) they simplify access to necessary information; 2) they standardize

and streamline submissions and requests; and 3) they facilitate the public review of the general conditions of review and approval of drugs.

The ODB can be commended for its effort to make important information available to the public, but some critical information is not made available. For example, the ODB does not publish any information on which drugs have been reviewed, or which drugs are currently under review. If a drug has been reviewed and approved, it will appear on the Formulary as a general benefit or a limited use drug and this does not pose a problem. But information about drugs that have not been recommended (or are currently under review) is not publicly available. This information would help to clarify to the primary users of the system (i.e., physicians, pharmacists and recipients) that certain drugs are not eligible for coverage, or that some particular drugs are being considered for future inclusion. It would also serve to reveal any disturbing patterns of refusals of coverage.

The most obvious way in which the ODB fails the publicity condition is that rationales for particular decisions are not made explicit. Recommendations are made on the basis of “safety, effectiveness and cost”, but this is a very general statement of the factors being considered, and it does not provide any concrete information on why a particular drug is being recommended or rejected. This information is especially relevant in cases where a drug is not included in the Formulary. Was this drug rejected because of inadequate clinical data? Was it rejected because it did not offer any additional clinical benefit? Or was this drug rejected because the cost was seen to be unacceptable? The reason for the decision to reject a drug is a key factor in assessing whether the decision is

“fair.” It is important to note that the mandate of the DQTC is to make recommendations to the MOH, and it is the government that makes the final decision on formulary inclusion. The final responsibility for making rationales publicly available rests with the government, but the publicity condition can (and should) be applied to both groups.

5.1.2 Relevance

The second condition specified by A4R is relevance: legitimate and fair limit setting requires that rationales should provide “reasonable” explanations (i.e., fair-minded people, appealing to mutually justifiable terms with respect to value for money). In other words, decisions to set specific limits on healthcare must be based on reasons or values that all stakeholders share. DQTC recommendations are currently made on three important shared values that meet the relevance condition: 1) safety; 2) efficacy; and 3) cost. It is not difficult to see that fair-minded people can agree that these three criteria are relevant to fair limit setting. For example: if evidence indicates that a particular drug is unsafe, a decision to withdraw the drug is warranted.⁷⁷ If a drug is beneficial, but associated with significant risk, limits on its use (e.g. clinical criteria) can be justified. The criterion of cost is perhaps the most difficult to address. Fair-minded people can agree that cost is relevant to limit setting, but there may be significant disagreement on what constitutes an acceptable cost-benefit or cost-effectiveness ratio. As noted earlier,

⁷⁷ The standards of evidence must also be “reasonable.”

the DQTC has not adopted a threshold ratio for recommendations; the committee currently uses its “judgment” on the basis of the available evidence.⁷⁸

Based on the DQTC recommendations, the MOHLTC and the government must then make its listing decisions. How these decisions are made is not a matter of public record. At this level additional factors may enter the debate (e.g. are some medical needs more important than others? are there social inequalities that need to be addressed? are there previous commitments or promises to be fulfilled?). Fair-minded people would probably agree that these are relevant considerations, but at the level of government decision making there is an ever present threat to fair decision making: political expedience. Political considerations do not meet the A4R relevance condition. If limit-setting decisions are made (or even influenced by) a government’s desire to retain power or garner electoral support, this is an instance of a criterion that is not mutually justified. Governments have an interest in their political standing, but as it relates to healthcare, the public has no interest in any particular party being in power. Governments are elected to make informed decisions in the public’s interest, not to enable them to enjoy the benefits of being in office.

The first two conditions of A4R work together to promote legitimacy and fairness in limit setting. Making decisions and the processes used to arrive at them a matter of public record is a good first step, but rationales must be included if transparency and accountability are to be ensured. When rationales are made explicit the public is invited

⁷⁸ The DQTC understanding of “benefit” is important here. If benefit is defined narrowly (e.g. extended life), fewer drugs will be recommended; if benefit is understood in a wider sense (e.g. improved well-being), more drugs will be recommended.

to understand the reasons behind these limits. This puts all stakeholders in a better position to accept the limits, and/or engage in further debate about the appropriateness of the limits.

5.1.3 Revision and appeals

The third condition of A4R is revision and appeals. The DQTC and the MOH both engage in regular revision of their decisions. When new products become available, or when new evidence comes to light, listing decisions can be revised. The MOH publishes regular Formulary updates to keep physicians informed of drugs that are covered by the ODB.

The ODB Section 8 mechanism (ICR) could be considered a form of revision or appeal. If a physician thinks that a particular drug is an appropriate intervention, an application for ICR can be made.⁷⁹ As noted earlier, this process is heavily used. The availability of this mechanism is consistent with A4R, but the pattern of use seems to indicate a need for change. The DQTC receives over 12,000 requests for ICR per month. How does a twelve-member committee, meeting twelve times per year, respond to this many applications? No information is given about who processes these claims, and how these decisions are made. And according to the ODB figures, 72 % of the requests are approved. If so many applications are meeting government criteria, perhaps it is time to consider reclassifying current listing decisions (from ICR to LU or General benefit).

⁷⁹<http://www.forms.ssb.gov.on.ca/mbs/ssb/forms/ssbforms.nsf/FormDetail?OpenForm&ACT=RDR&TAB=PROFILE&ENV=WWE&NO=014-4406-87> (Accessed 10 June 2006).

There are a number of other factors that could be considered. Given that ICR decisions are for the approval of medically necessary drugs, is the response to applications timely? The ODB figure cited is an average of three weeks: is this “reasonable?” Urgency of the medical need would clearly influence any response to this question, but a full assessment of this question is beyond the scope of this paper. Another important concern is the accessibility of the process itself. Physicians must submit the application for ICR and they are neither trained nor reimbursed for this additional work. If a physician does not raise an ICR application as possible alternative, patients may not know that this type of appeal is available. Even if a patient is aware of the ICR option, do they understand how the process works, and what they can expect? And finally, is there a process to appeal a refusal for coverage? The ODB posts a one-page form for a “Drug Benefit Claim/ Reversal.” Given the large amount of other information posted about other aspects of the program, it is curious that there are no explanations given about what this form is for, or who is entitled to use it.

The ODB program does meet the revision and appeals condition in part, but it cannot be described as an open and accessible process, and there is no clear way to appeal an actual refusal of coverage.

5.1.4 Regulation and enforcement

The final condition specified by A4R is regulation and enforcement. This fourth condition is intended to hold decision makers accountable for the decisions and methods used in the limit setting process. Voluntary or public regulation is one way to ensure that the first three conditions of A4R are being met.

DQTC membership and mandate is governed by legislation and this committee is directly accountable to the Minister of Health. As noted earlier, the government makes the final limit setting decisions: how does regulation and enforcement apply here? If individuals or groups believe that ODB decisions or procedures are “unfair,” they are free to contact the government and/or make their concerns more widely known through public channels. Freedom of expression and dissent are valuable rights in democratic societies, but this in itself does not ensure accountability.

Limit setting decisions in healthcare are controversial and they affect us in a unique way. In our present system, accountability is only ensured at the level of general elections, and this is a very imprecise way to express concern or dissent. The nature of limit setting in healthcare calls for the highest levels of transparency and accountability, and it would seem that regular independent review of government decision making is warranted. Governments already incorporate independent review to promote accountability (e.g. auditors, ombudsmen) and it would not be difficult to include this type of review in healthcare legislation.

The most important concern in the matter of accountability is that the public is given the means to assess government decision-making and action. Systems of regulation and accountability can be designed in many different ways, but if the general public is not aware of the actions of government, there is no way that they can come to hold informed opinions about the “reasonableness” of what is being done on their behalf. Informing and engaging the public in the difficult debates that surround limit setting in healthcare is the best way to ensure legitimacy and fairness in this type of decision making.

5.2 ODB stakeholders

The ODB affects five general groups of stakeholders: 1) the Government; 2) the general Public; 3) Pharmaceutical manufacturers; 4) Healthcare providers; and 5) ODB recipients.⁸⁰ Some interests are shared by all of these groups, and other interests are specific to particular groups and individuals. Governments and the general public share a basic interest in maximizing health benefits, responsible use of public funds, balancing competing social needs, and the provision of necessary drugs for vulnerable members of society. Ideally, pharmaceutical manufacturers will share these concerns, but corporate profits are clearly their primary interest. Healthcare providers and patients interact with the ODB more directly, and these two groups have a number of specific interests.

Physicians and pharmacists are healthcare providers that must deal with some unique concerns. Physicians act on the behalf of ODB recipients when they submit applications for limited use or ICR drug coverage (a time consuming service for which they are not trained or reimbursed). They must also deal with conflicts that arise between what constitutes the best available treatment and what drugs appear on the Formulary. Pharmacists fill prescriptions for ODB recipients who may or not understand the ODB system, and if a particular drug is not listed, they will often be the one to inform their clients that they are being denied drug coverage.

⁸⁰<http://www.forms.ssb.gov.on.ca/mbs/ssb/forms/ssbforms.nsf/FormDetail?openform&ENV=WWE&NO=014-2784-87> (Accessed 10 June 2006).

ODB recipients are the group most affected in this discussion. These individuals must navigate a complicated system with little or no information related to process or procedure. Individual health and well-being is at stake here, and if a prescribed drug is not publicly funded, most ODB recipients have few options open to them.⁸¹ If they are given a prescription for a drug that is not covered, they must find a way to pay for the drug or they must deal with the additional uncertainty associated with what might seem to be a less desirable treatment. To illustrate some of the issues that affect ODB recipients, I include here an account of some of the personal experiences of an individual who relies on the ODB for prescription drug coverage.

John is a forty-five year old man who has a distant history of leukemia, and a secondary blood disorder that is chronic but stable. There is no treatment available for this illness. The most prominent symptom he experiences is persistent fatigue. John also suffers from regular migraine headaches, an illness that is shared by other members of his family.

John is a University graduate, but his medical condition does not allow him to pursue full-time employment. At the age of 30 John applied for Ontario Disability Support and he was approved. When John first began receiving ODSP benefits, he was informed that he was also eligible for drug coverage under the ODB program. He began to receive a monthly form to document his coverage and he was told that if he needed prescription medications, he was to take the ODB “Card” to the pharmacy of his choice

⁸¹ There are a few exceptions: ODB recipients with families who are willing and able to pay for unlisted drugs, Seniors who have significant incomes/assets who are willing to pay, or those with some other form of private insurance.

and that the cost of these drugs would be covered by the program. Given that his ODSF income was very limited, John was grateful for this additional benefit. John did not require many prescription drugs, but for those that he did need, he did not experience any difficulties with the system.

John does not respond to standard medical interventions for migraine and he only experiences partial relief with analgesics. In recent years, a new class of drugs has been introduced for migraine management. "Triptans" (e.g. Imitrex, Zomig, Amerge etc.) act to constrict blood vessels in the brain that are thought to be the cause of migraine pain. John tried a number of these drugs (free pharmaceutical samples) and all were effective in stopping his migraines within one hour of taking the medication. John asked his physician for a prescription, but when he went to his pharmacy to pick up the medication, he was told that he would have to pay \$120. John reminded the pharmacy staff worker that he had ODB coverage, but he was told that this drug was not covered by the plan. The cost of the prescription was \$120 for six doses (a significant amount of money given John's limited income). John could not afford this amount, and he went back to his doctor to get a prescription for one of the other drugs. John's physician wrote a new prescription, but when John tried to have this prescription filled, it too was declined. He asked the pharmacy staff if any of the Triptans were covered, but no one seemed to know, and no one had any advice or suggestions on how John should proceed.

This is one man's story, and we cannot assume that it is representative of the experiences of others who rely on the ODB for drug coverage. The goals of the ODB are

commendable and the task of balancing needs and costs is difficult, but John's experience is real, and it illustrates some of the potential problems in this system.

In my own review of the ODB formulary I was able to confirm that none of the Triptan class of drugs is covered as a general or limited use drug. I then contacted the MOHLTC Drug Programs Branch (ODB) with two requests for information: 1) Has Imitrex been reviewed by the DQTC, and if so, what was their recommendation? And 2) Are any of the Triptan class of drugs currently under review? The Ministry response to these general questions was that this information was confidential, and that it was protected under the Privacy Act.⁸²

5.3 Recommendations for Change

The legitimacy and fairness of ODB limit setting could be enhanced if the following recommendations were implemented:

1) Canada: Introduce universal drug coverage

This recommendation extends to the entire Canadian healthcare system. The CHA entitles all eligible Canadians to publicly funded hospital and physician services and our public health insurance covers the cost of drugs received while in hospital, but it does not extend to outpatient prescription drugs. Given that drugs are central to most medical interventions, it seems that our current model suffers from a serious inconsistency. The justification for this difference is likely to be the additional cost, but universal public drug

⁸² Email correspondence (19, 25 May 2006).

coverage has a number of important advantages beyond consistency: 1) it would promote equality and solidarity in Canada; 2) it would improve health outcomes for individuals with low incomes; 3) it would simplify and coordinate drug review and listing decisions; 4) it would decrease overall drug costs.⁸³

2) Ontario: Apply "Accountability for Reasonableness" to ODB

The Ontario government meets the four conditions of A4R in part, but there is significant room for improvement. The ODB should make public the names of drugs that have been reviewed (or are under review), and they should post the DQTC recommendations forwarded to the government. The government should then make public their final listing decisions, and the rationales used to arrive at these decisions. A mechanism for independent review should be introduced, a clear and accessible process to appeal coverage decisions should be instituted, and the government should seek to include stakeholder perspectives at appropriate levels in listing decision-making.

3) Decrease onus on Physicians, increase usability of Formulary

The government should simplify and reduce the paperwork required of physicians (as far as this is possible) and physicians should be trained and reimbursed to make applications for ICR Formularies should be at hand and easily accessible (e.g. consultation room handbooks). Physicians should not have to do extensive "research" to determine if a

⁸³ Individual Provinces currently negotiate drug pricing with manufacturers. If all of the provinces cooperated (or if drugs were purchased by the Federal government), lower prices could be negotiated for bulk purchasing.

given drug is covered while they are seeing their patients, and no ODB recipient should be given a prescription for an unlisted drug, unless they understand that they will have to pay for it at the point of purchase.

4) Increase Role of Pharmacists

Pharmacists are in a unique position to counsel patients about their medications and they could help ODB recipients to understand and navigate the system. If a patient has questions about their coverage, or if they receive a prescription for an unlisted drug, Pharmacists should be able inform these individuals about the processes and options available to them. Pharmacies should also have basic ODB information sheets available for anyone who has questions about the program (i.e., a summary and overview of the ODB, with contact information; paper copies for seniors and others without computers).

5) Focus on Needs of Recipients

Government programs are bureaucratic by nature but it is important that programs are designed to retain their primary focus: in this case, the health and well-being of vulnerable individuals. All ODB stakeholders have their unique responsibilities, but the onus should never be on the patient to know the intricate details of the ODB. Recipients should learn about the system, to the extent that they can, with the understanding that individual recipients may be dealing with significant limitations (e.g., illness, language barriers, age etc.). Vulnerable people are the least able to advocate for themselves, and ODB processes should be designed with recipients in mind. If we are truly concerned

about the needs of these individuals, we should also find ways to involve ODB recipients in the development of the system, seeking their unique perspective and experiences.⁸⁴

5.4 Summary

The ODB meets the four conditions of A4R in part, but it fails in significant ways: some program information is not available; rationales for listing decisions are not available; a formal appeal process is not available. In practice, some physicians and pharmacists do not have sufficient knowledge of the system, and some recipients may be denied prescription drug coverage without adequate explanations. The legitimacy and fairness of ODB limit setting could be enhanced if the following recommendations were implemented: 1) introduce universal drug coverage; 2) apply A4R to ODB decision making; 3) decrease the onus on physicians and increase formulary usability; 4) increase the role of pharmacists; and 5) focus on needs of ODB recipients. Additional resources will be required to put these recommendations into practice, but these changes could be funded within current healthcare spending if we chose to limit some of our current services. It has not been my purpose to suggest which services might be limited. Instead I have argued that limits must be set, and that A4R is the leading ethical framework for limit setting in healthcare. The costs associated with an open, accountable limit setting process are justified by the underlying goals of the process (i.e., fairness and legitimacy in morally controversial decision making).

⁸⁴ Douglas Martin, J. Abelson, P. Singer. "Participation in health care priority-setting through the eyes of the participants." *Journal of Health Service Research Policy*. 2002;7(4): 222-229.

CONCLUSION

At the level of ethical theory, there is no consensus on matters of distributive justice. There is significant agreement at the level of ethical principle, but there is currently no simple way to identify and balance the relevant principles. Reasonable people disagree on what is substantively just. In the absence of a theoretical consensus, procedural forms of justice are theoretically and practically justified, and they are currently the best means available to address morally controversial issues of distributive justice.

In an international comparison of OECD countries, Canada ranks sixth in overall healthcare spending. We currently spend 10.5 % (GDP) on healthcare (over \$3,500 pp). In Canada healthcare is a provincial responsibility, and Ontario currently spends 46% of its budget on healthcare. This is more than all other social programs combined. In 2002 two national commissions concluded that in its present form, healthcare in Canada is unsustainable. Both commissions recommended increased funding and reforms in delivery; both opposed increased privatization, but neither discussed the need to set limits in healthcare.

Moderate scarcity is a basic social condition and this makes limit setting in healthcare a theoretical and practical necessity. In Canada, most healthcare limits are implicit, and limit setting often proceeds in an uncoordinated and opaque manner. No simple or technical solutions have emerged out of the international experience of priority setting, but appeals to evidence based guidelines and explicit values are common. “Accountability for Reasonableness” is the leading ethical framework for limit setting in

healthcare. The four conditions of A4R are publicity, relevance, revision and enforcement.

In 2005 the ODB provided prescription drug coverage for 2.2 million people in Ontario (25% of population), and 70% of all ODB recipients are seniors. Total ODB spending was \$3.4 billion; 33% of this amount was for treatment of cardiovascular disease. The DQTC provides expert advice to the government on drug listings. Drugs can be listed on the provincial formulary as general benefit, limited use, or ICR. If a drug does not appear on the formulary, ODB recipients must pay for it themselves or accept an alternative treatment.

The ODB meets the four conditions of A4R in part, but it fails in significant ways: some program information is not available; rationales for listing decisions are not available; a formal appeal process is not available. In practice, some physicians and pharmacists do not have sufficient knowledge of the system, and some recipients may be denied prescription drug coverage without adequate explanations.

In Canada, the need to set limits in healthcare is rarely discussed. While this reluctance is understandable, it is not in our best interest to avoid discussing the issue. Limit setting in healthcare is not easy, but it is necessary. If we want to set limits fairly, we need to increase our commitment to transparency and accountability, and we need to make limit setting a matter of public debate. We cannot just close our eyes and hope for the best; we must accept that our resources are limited, and we must make some choices about what we value and how much we are willing to pay for it. Healthcare is not an unqualified individual right: it is an ongoing social choice.

EPILOGUE

Bill 102: Transparent Drug Systems for Patients Act, 2006

During the preparation of this manuscript the Ontario government introduced Bill 102, *The Transparent Drug System for Patients Act* (TDSPA).⁸⁵ On June 19, 2006 the Bill passed third reading and it becomes law on October 1, 2006.⁸⁶ The TDSPA is intended to provide Ontario residents with “better access to drugs while ensuring significant new savings.” The government expects to save \$277 million per year, and they plan to reinvest these savings to improve patient access to drugs.⁸⁷

According to the government, this plan to reform the drug system includes:⁸⁸

- 1) achieving savings through volume discounts on the purchase of ODB drugs;
- 2) improving patient access to drugs through new conditional listings, Exceptional Access and rapid reviews of innovative drugs;
- 3) listening to the views of Ontarians through a new Citizen’s Council that will advise the Ministry and the Executive Officer of Drug Programs;
- 4) instituting an automatic second review of decisions by the Committee to Evaluate Drugs or the Executive Officer not to list drugs;

⁸⁵ http://www.health.gov.on.ca/english/public/legislation/drugs/hu_drugsact.html (Accessed 27 June 2006).

⁸⁶ http://www.ontla.on.ca/documents/Bills/38_Parliament/session2/index.htm#P831_51626 (Accessed 27 June 2006).

⁸⁷ http://www.health.gov.on.ca/english/media/news_releases/archives/nr_06/jun/nr_061906.html (Accessed 27 June 2006).

⁸⁸ http://www.health.gov.on.ca/english/media/news_releases/archives/nr_06/jun/nr_061906.html (Accessed 27 June 2006).
http://www.health.gov.on.ca/english/media/news_releases/archives/nr_06/jun/nr_060606.html (Accessed 27 June 2006).

- 5) strengthening transparency by giving patients a role in drug listing decisions, and by requiring the Executive Officer to prepare an annual report;
- 6) recognizing the role of pharmacists in patient care by paying them for enhanced patient counselling;
- 7) utilizing the expertise of pharmacists through a new Pharmacy Council;
- 8) freeing doctors of the burden of Section 8 paperwork.

The changes associated with this new legislation address many of the criticisms I noted in my review of the ODB. Savings through volume purchasing, streamlining listing decisions, and reducing paper work for physicians are good efficiency measures. Increasing the role of pharmacists and reimbursing them for patient counselling recognizes their importance as front-line healthcare providers. The automatic review of a decisions *not* to list a drug is an excellent way to safeguard patient interests.

All of the planned reforms are consistent with the four conditions of A4R, but the changes that give citizens and patients a voice in the system are of particular relevance. The new Citizen's Council is one way to include input from the general public in priority setting decision-making. Giving patients a role in listing decisions is one way to express respect for the experience and opinion of those who are most affected by listing decisions. In principle, both of these changes enhance legitimacy and fairness because they improve transparency and accountability, and they recognize that on matters that are morally controversial, those affected by the final decisions should have a say in the decision making process.

The administrative details of the new bill have not yet been drafted, so a detailed analysis of the new system is not possible here. A number of important questions will need to be addressed. For example: 1) how will the Citizen and Pharmacy councils be selected and what are their respective mandates? 2) how will the Council's input affect government decision making (i.e., are these bodies simply advisory or will their recommendations be implemented); 3) at what level will patients be included in decision making? (studies have demonstrated that members of the public find it difficult to express their views in groups of experts).⁸⁹

In addition to these concerns, the legislation does not provide details on what information will be publicly available under the new system (e.g. will the government post the names of drugs reviewed or under review; will they publish Council recommendations?)

The TDSPA introduces many positive changes to Ontario's drug programs, but one important element is missing: the legislation does not address the need to focus on the reasoning behind particular decisions. One of the most basic insights of "Accountability for Reasonableness," is the centrality of "rationales." Rationales are important to the individuals who must accept the impact of morally controversial decisions (e.g. patients who are denied coverage for a particular drug), and they are important because they serve to include the wider public in the debate that surrounds limits in healthcare.

⁸⁹ Douglas Martin, Abelson J, Singer P. "Participation in health care priority-setting through the eyes of the participants." *Journal of Health Services Research Policy* 7(4):222-229, 2002.

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