

Decision-making Processes Regarding Cancer Technologies: A Review

Tania Stafinski, George P. Browman and Devidas Menon

The issue of timely access to high quality cancer care has heightened in Canada, fueled in part by incidence rates reaching levels where cancer now touches, in some way, the lives of most Canadians.¹ Thus, deliberations over how best to maximize the health of cancer patients are often emotionally and politically charged. Two major issues have been highlighted through the media and the political process: (1) timely access to required services (i.e., waiting times for radiation, surgery and specialist consultation), (2) limits placed on equitable access to services such as diagnostic interventions (e.g., MRI and PET) and (3) cancer drug treatments. As cancer agencies across the country look for ways to provide timely access to technologies that deliver high quality care, they do so facing unlimited demands, limited budgets, and intense scrutiny by both those affected and the media. There seems to be a growing lack of public confidence in decisions about which technologies to publicly fund, particularly in the case of promising, often high cost innovations championed by physicians, patients and manufacturers. As a result, policy-makers charged with the task of ensuring prudent and principled use of scarce resources have become demonized, since the essence of priority-setting means that access to some will be denied.

It has become increasingly clear that approaches to priority-setting require a blending of two decisional domains: effectiveness and efficiency (the evidence-based paradigm) and equity/fairness (the values/ethics based paradigm). What remains unclear are ways of marrying the two so that coverage decisions may be deemed legitimate and fair by all stakeholders.

Over the past three decades, an international body of work focusing on resource allocation and technology funding decision-making has emerged in response to the increasing pressures faced by governments to adopt new and innovative technologies into their health care systems.² It contains research which draws from many disciplines including: clinical medicine; epidemiology; political, social, behavioral and management sciences; economics; and ethics. This work examines how decisions are *actually* made (i.e., descriptive processes), how they *should* be made (i.e., normative processes), and tools for aiding or informing these processes.³ While the majority of this work has taken place outside of the cancer context, it addresses issues of a similar nature and complexity. This paper provides an overview of this work to inform both scholars (in ethics, law and health services research) and decision-makers in Canadian health care systems.

Descriptive Processes

Canadian research describing how funding recommendations or decisions for new cancer technologies are *actually* made is limited to a few case studies in Ontario.⁴ Factors shaping decisions were identified through a combination of document analysis, interviews of Cancer Care Ontario's Policy Advisory Committee, and observations of their meetings. These factors included: benefit to patients and its magnitude, quality of evidence (i.e., the degree of certainty of the benefit), existence of alternatives, treatment duration, total population of patients affected, total cost to the system, pressure from physician and patient groups, and historical precedent.



Cost-effectiveness was not used, but the committee discussed the concept of value-for-money. Although the committee had initially considered developing a list of funding recommendations, ranking them, comparing the costs against a known fixed budget, and then drawing a line at the end of the resources, it abandoned the idea when members failed to agree upon potential priority measures.⁵

Pressures from some health authorities to raise the threshold because of their individual financial constraints and from clinicians to lower the threshold to reflect their patients' expectations were reported.

A similar study was conducted in the United Kingdom, where a specialist cancer hospital and a consortium of six regional health authorities set priorities for funding new drugs.⁶ Decisions were based on evidence thresholds determined from evidence of clinical effectiveness. Of 16 proposed new drugs, only the seven that had so-called 'Category I' evidence (proven effectiveness over and above existing treatments) were funded. Key challenges reported in the study included: 1) a lack of comparative data on validated, relevant health and economic outcomes in new drug trials, which precluded their use in cost-effectiveness analyses, 2) disagreements over values placed on such outcomes, and 3) the absence of criteria used to determine what constituted satisfactory evidence of effectiveness. This, in turn, led to a call for the establishment of an agreed-to set of criteria before any future negotiations. Lastly, pressures from some health authorities to raise the threshold because of their individual financial constraints and from clinicians to lower the threshold to reflect their patients' expectations were reported.⁷

Most of the remaining literature on processes for making technology funding decisions have come from experiences of national systems in the U.K., Canada and the U.S., and have reported on decisions *across* diseases or conditions (as opposed to just cancer).⁸ The National Institute for Health and Clinical Excellence [NICE] in the

U.K. provides funding recommendations to the National Health Service [NHS] in England and Wales on the use of new and established health technologies.⁹ Guidance is based on an appraisal of the technology's health benefits (impact on quality of life and survival) and associated costs to the NHS. The appraisal, itself, comprises evidence from a technology assessment (typically a systematic review of clinical effectiveness data and an economic evaluation) and input from patient representatives, caregivers and health professionals, and manufacturers. Such information, along with other prescribed factors (including the government's priorities, clinical need, benefit-cost balances, potentially available resources and their effective use, and encouraging innovation that will benefit patients) are considered by an Appraisals Committee, who then determines whether the technology can be recommended as a "cost-effective use of NHS resources."¹⁰

It is mandatory for NHS organizations in England and Wales to provide technologies recommended by NICE. Recommendations are based on the incremental cost-effectiveness ratio [ICER] (i.e., the marginal increase in health likely to be gained from the marginal increase in expenditure) for a technology, expressed in terms of the cost/quality-adjusted-life-year [QALY].¹¹ The QALY is a metric intended to integrate length of life with the quality of that life, and thus it provides a common currency enabling comparisons in health gains to be made across different technologies and diseases. However, it has been criticized on a number of counts.¹² It assumes that 'all QALYs are equal,' a notion that has yet to receive widespread acceptance. Some have argued that "a short extension to a short life expectancy may be more valuable than the same extension to a longer life," questioning the fairness of counting five months as equal, whether they be added to five months or five years.¹³ Others have proposed more equally distributing quality adjusted life expectancy through the population, possibly by adopting a 'fair innings approach,' to better reflect the "equity dimension in health care rationing and elicit appropriate trade-offs between equity and efficiency."¹⁴ Under the fair innings approach everyone is entitled to a normal life span,¹⁵ therefore, resources are allocated with the goal of achieving equitable distributions of health, rather than maximizing health benefits, regardless of who benefits

Apart from the 'value of a QALY' debate, there are criticisms of the ICER threshold approach used by NICE



to decide whether a new technology offers a big enough ‘bang for the buck’ (i.e., if the ICER for the technology is less than the threshold, it is deemed cost-effective and, thus, appropriate for adoption). The criticisms of this approach have been two-fold. First, no empirical basis for the threshold ranges or evidence that such thresholds lead to the best use of healthcare resources have ever been provided.¹⁶ Second, ‘affordability’ is not considered during deliberations over the cost-effectiveness of a technology, yet it has been pointed out that “affordability is the only justification for having thresholds.”¹⁷ Moreover, studies assessing the ‘real world’ consequences of implementing ICERs in several health care systems around the world have found that they resulted in greater expenditures, with costs increasing by 10% to 15% per annum.¹⁸ Such findings have been attributed to, in part, the fact that a threshold implies increased expenditures on a program for every new technology introduced whenever the ICER value is positive (i.e., the drug has greater effects but costs more than the current treatment).¹⁹ Thus, evidence to suggest that such an approach has helped decision-makers achieve the goal of maximizing health gains from constrained resources appears lacking.

In Canada, the Common Drug Review [CDR] undertakes reviews of new drugs and makes funding recommendations to participating federal, provincial, and territorial drug benefit plans based on the “relative therapeutic merits of the drug and its cost-effectiveness.”²⁰ Manufacturers seeking coverage of a new product by a participating drug benefit plan must make a submission to the CDR. The Canadian Expert Drug Advisory Committee [CEDAC] reviews such information, including clinical, pharmacoeconomic, and budgetary impact data from the manufacturer, as well as internal analyses prepared by CDR staff. The CEDAC comprises physicians, pharmacists, two patient representatives, and other health professionals. After CEDAC generates a recommendation for use, each participating drug plan then makes its own listing decision. Although recommendations, accompanied by reasons for them, are made public, little information explicitly describing how CEDAC reaches its decisions (i.e., determines whether a new drug is cost-effective and, therefore, should be recommended for funding) seems to be available. This was highlighted in an independent evaluation of the CDR following its first year of operation which called for greater transparency in CDR processes.²¹ Further, patients and pharmaceutical industry representatives expressed

concern over the fairness of the process, with industry feeling that new drugs submitted to the CDR were expected to meet evidentiary standards never applied to existing, pre-CDR products. At the same time, CEDAC representatives noted the need for “manufacturers to conduct relevant ‘head-to-head’ comparator trials and to provide better quality data.”²² Such evidence expectations have fostered fear among patients and manufacturers that the CDR process may delay access to new and emerging drugs and stifle future innovation.

Coverage with Evidence Development [CED] is intended to provide access to, or more rapid adoption of promising, high value technologies that would not otherwise meet Medicare’s standards for ‘reasonable and necessary’ evidence.

In an effort to reconcile similar tensions between the “promise of technology and the perceived burden of strict evidence-based coverage standards,” the U.S. Centers for Medicare and Medicaid Services [CMS] have developed a new approach to reimbursement policy called Coverage with Evidence Development [CED].²³ CED is intended to provide access to, or more rapid adoption of promising, high value technologies that would not otherwise meet Medicare’s standards for ‘reasonable and necessary’ evidence. It links coverage to a requirement that patients participate in a registry or clinical trial. It provides a mechanism for gathering high quality evidence on the risks, benefits, and costs of technologies over time to support not only decision-makers during coverage deliberations, but also clinicians and patients in better understanding the relative values of alternative technologies.²⁴ The approach has already been applied to the coverage of several cancer technologies (e.g., off-label use of biologics for colorectal cancer). However, it has been acknowledged that key aspects, such as evidence standards, criteria for identifying the highest priority technologies, and strategies for the long term funding and management of CED projects remain to be defined.

There is growing use of CED-like ‘conditional approvals’ in other countries as well, as reported by the Organization



for Economic Co-Operation and Development [OECD], based on a survey of 12 countries.²⁵

Normative Processes

Research into how technology funding decisions *should* be made consists of hypothetical processes which are pilot-tested through demonstration projects, and conceptual processes which are presented in the form of decision-making frameworks or models. One of the most recent hypothetical processes is the 6-STEPPP tool, which is intended “for ranking new cancer drugs for priority-based funding decisions.” The process comprises decision clarification, criteria filtering (including aspects like strength of evidence, outcome benefit importance and regulatory status), clinical evaluation, cost modeling, data integration and values clarification, and process evaluation modules. This tool has undergone pilot-testing with several clinical groups in Alberta.²⁶

Demonstration projects in Sweden have produced ranked lists for cancer technology funding.²⁷ This has involved: pairing patient groups with interventions (e.g., surgery, chemotherapy, etc), identifying factors (and levels within factors) when determining the rank of each pair (i.e., total needs of different patient groups, expected benefit across a patient group, costs, and grade of evidence), assigning values to levels within factors, rating each pair on each factor, and summing the scores across factors to obtain an overall rank for each pair. Participating clinicians and decision-makers reported positively on the process. They indicated that it encouraged important dialogue among them, and provided clinicians with an enhanced awareness of the complexities of coverage decision-making.

Numerous conceptual frameworks for making coverage decisions have been proposed over the last 30 years. However, the majority offer only lists of priority-setting criteria, rather than processes through which coverage decisions may be made. One recent exception is the case-based model for evaluating new technologies.²⁸ Based upon the concept of ‘precedent’, case-based reasoning, and analogical methods of comparison, this model consists of an iterative, 3-step decision cycle. ‘Precedent’ technologies are first derived from knowledge of both reimbursed technologies and those for which coverage was expressly refused. An inventory of the types of commitments underlying such coverage decisions is also created. Next, the analogy of ‘precedent’ technologies

is applied to new or ‘candidate’ technologies to “determine their fit within the case and the coverage obligation that the fit implies.”²⁹ Like building a case in a court of law, this requires analyses of and deliberations over descriptive evidence (i.e., what the technology is and does), evaluative evidence (how much it does (e.g., clinical effectiveness or cost), and concrete policy commitments. The last step includes incorporating new decisions back into decision-makers’ understandings of basic commitments represented by already covered services. Over time, a ‘case history’ evolves, offering opportunities to reinterpret decisions and their rationales and reconsider the value system upon which they were based.

Tools for Aiding Technology Funding Decision-making Processes

A multitude of tools designed to aid/inform technology coverage decisions has emerged alongside work to develop improved decision-making processes over the past three decades. They have three potential purposes: 1) synthesizing and appraising evidence, 2) reallocating resources, and 3) ensuring fairness in the decision-making process. One of the most prominent tools for synthesizing and appraising evidence about a technology is health technology assessment [HTA], which is the systematic evaluation of existing information on the medical, social, legal, ethical, and economic implications of its use.³⁰ Many countries, including Canada, have invested significant resources in HTA, establishing national and regional HTA agencies (e.g., the Canadian Agency for Drugs and Technologies in Health [CADTH], WHO Collaborating Centre for Health Technology Assessment and its Equity Oriented HTA Toolkit,³¹ etc.). HTA relies upon tools, consisting of well-validated qualitative and quantitative methods for retrieving, synthesizing, and critically appraising clinical evidence (e.g., grades of evidence scales and checklists, drawn from clinical epidemiology) and methods for analyzing the benefits and costs of a technology (e.g., economic analyses). However, as decision-making time frames become shorter and evidence uncertainties around new and innovative technologies grow, HTA producers are challenged to find new HTA methods that are adequate for the purpose.³²

The second group of tools contains those for examining allocative efficiency, such as the ICER approach discussed above and Program Budget and Marginal



Analysis [PBMA]. PBMA uses the economic principle of opportunity cost, or the forgone benefits of the next best alternative use of a given set of resources, and marginal analysis, which examines the incremental costs and benefits of shifting resources from one area to another, to provide insight into whether such changes should be made. Although applied in several demonstration projects,³³ it faces many of the same criticisms as the ICER approach.³⁴

It is no longer acceptable to simply delay or obstruct the introduction of promising technologies because of evidence hurdles, nor make decisions based on arbitrarily-set QALY thresholds.

With calls for more public accountability in coverage decisions, a number of tools for ensuring their legitimacy and fairness have been developed. In general, they comprise sets of ethical principles, of which the most widely cited, albeit not well-validated, is referred to as ‘Accountability for Reasonableness’ [A4R].³⁵ A4R proposes that decision-making processes meet four conditions to be deemed fair and legitimate: publicity (public access to decisions and their rationales), relevance (evidence-based rationales, reasons, and principles that fair-minded parties would agree are relevant), appeals (a mechanism for challenging decisions and revising them), and enforcement (voluntary or public regulation to ensure the first three conditions are met). Over the past few years, A4R has become a popular tool for evaluating the fairness of coverage decision-making processes around the world.³⁶ The Ethical Force Program in the United States, a collaborative effort to create ‘self-assessment’ quality improvement tools for ethics in health care, has recently published its set of principles for improving fairness in coverage decision-making.³⁷ Under this set, processes must be: 1) transparent, 2) participatory, 3) equitable and consistent, 4) sensitive to value, and 5) compassionate. Each criterion is accompanied by explicit expectations and explanatory notes, which help to guide users in determining whether the criterion has been met. Notably, the ‘sensitive to value’ criterion contains a section for assessing the

appropriateness/ inappropriateness of cost-effectiveness analyses. Despite the availability and importance of such ethical tools, little attempt to compare them in a systematic manner, examining their perceived strengths and weaknesses (e.g., relevance, credibility, stakeholder acceptability, etc.), has been made.

In general, as efforts to measure the quality and short-term outcomes of coverage decisions become focused on better defining process-oriented parameters like ‘acceptability’ and ‘legitimacy,’ such tools for aiding decision-making, each with their own evaluative attributes (e.g., levels of evidence scales, cost-benefit trade-off exercises, and sets of ethical criteria), may serve to inspire important deliberations over what constitutes, for example, scientific/technical acceptability, structural/institutional acceptability, and ethical/political/social acceptability, and provide the foundation for an approach to evaluating technology funding decisions in Canada.³⁸

Conclusions

Important questions related to clinical (effectiveness) evidence development and the use of cost-effectiveness measures to support decision-making regarding new technologies still require substantial improvement from the methodological and academic perspectives. How much evidence is enough and what should that evidence look like? What constitutes “value for money”? It is no longer acceptable to simply delay or obstruct the introduction of promising technologies because of evidence hurdles, nor make decisions based on arbitrarily-set QALY thresholds. Perhaps what is needed is an entirely different approach to making funding decisions – one that incorporates broader stakeholder views and specific value propositions. In other words, a purely technical, criteria, or formula-based approach is unlikely to put us any further ahead.

From a practical perspective, decision-makers need to find ways to appropriately capture and articulate the values that they and their constituencies hold, and then develop funding processes accordingly. This will require that they take an active role in determining what information is required in order to make decisions for which they are ultimately prepared to be accountable.

Finally, knowledge translation challenges need to be met so that policy makers become more aware of the tools available, their uses and limitations, and the public



becomes more aware of the challenges facing policy makers who are contending with tough choices.

*Tania Stafinski is a PhD candidate in health policy at the School of Public Health, University of Alberta (tania@ualberta.ca); George Browman is Clinical Professor, Department of Health Care & Epidemiology, University of British Columbia and Medical Oncologist, B.C. Cancer Agency, Vancouver Island Centre (gbrowman@bccancer.bc.ca); and Devidas Menon is Professor of Health Policy and Management in the School of Public Health, University of Alberta (menon@ualberta.ca).

Endnotes

- 1 Devidas Menon, Tania Stafinski & Gavin Stuart, "Access to Drugs for Cancer: Does Where You Live Matter?" (2005) 96:6 Canadian Journal of Public Health 454.
- 2 The OECD Health Project, *Health Technology and Decision Making* (Paris: OECD, 2005); Nils Wilking & Bengt Jönsson, *A Pan-European Comparison Regarding Patient Access to Cancer Drugs* (Stockholm: Karolinska Institutet, 2006), online: Karolinska Institute <http://ki.se/content/1/c4/33/52/Cancer_Report.pdf>.
- 3 Devidas Menon *et al.*, *Incorporating Public Values and Technical Information into Health Care Resource Allocation Decision-making* (Edmonton, Alberta: Alberta Heritage Foundation for Medical Research, 2003), online: Alberta Heritage Foundation for Medical Research <http://www.ahfmr.ab.ca/grants/docs/state_of_science_reviews/Menon_Review.pdf>.
- 4 Douglas K. Martin, Mita Giacomini & Peter A. Singer, "Fairness, Accountability for Reasonableness, and the Views of Priority Setting Decision-makers" (2002) 61:3 Health Policy 279; Douglas K. Martin, Joseph L. Pater & Peter A. Singer, "Priority-setting Decisions for New Cancer Drugs: A Qualitative Case Study" (2001) 358:9294 Lancet 1676 [Martin, "Priority-setting Decisions"]; J.L. Pater *et al.*, "Funding New Cancer Drugs in Ontario: Closing the Loop in the Practice Guidelines Development Cycle" (2001) 19:14 Journal of Clinical Oncology 3392, online: ASCOpubs.org <<http://jco.ascopubs.org/cgi/reprint/19/14/3392>>; Peter A. Singer *et al.*, "Priority Setting for New Technologies in Medicine: Qualitative Case Study" (2000) 321:7272 BMJ 1316, online: BMJ.com <<http://bmj.bmjournals.com/cgi/reprint/321/7272/1316>>.
- 5 Martin, "Priority-setting Decisions", *ibid.*
- 6 Robbie Foy *et al.*, "Perspectives of Commissioners and Cancer Specialists in Prioritising New Cancer Drugs: Impact of the Evidence Threshold" (1999) 318:7181 BMJ 456, online: BMJ.com <<http://www.bmj.com/cgi/reprint/318/7181/456>>.
- 7 *Ibid.* at 458.
- 8 *Supra* note 3.
- 9 National Institute for Health and Clinical Excellence, *Guide to the Technology Appraisal Process* (London: National Institute for Health and Clinical Excellence, 2004), online: National Institute for Health and Clinical Excellence <<http://www.nice.org.uk/nicemedia/pdf/TAP.pdf>>.
- 10 *Ibid.* at 2.
- 11 Michael D. Rawlins & Anthony J. Culyer, "National Institute for Clinical Excellence and Its Value Judgments" (2004) 329:7459 BMJ 224, online: BMJ.com <<http://www.bmj.com/cgi/reprint/329/7459/224>>.
- 12 Alan Maynard, Karen Bloor & Nick Freemantle, "Challenges for the National Institute for Clinical Excellence" (2004) 329:7459 BMJ 227, online: BMJ.com <<http://www.bmj.com/cgi/reprint/329/7459/227>>.
- 13 Norman Waugh, "Health Technology Assessment in Cancer: A Personal View from Public Health" (2006) 42:17 European Journal of Cancer 2876 at 2877.
- 14 *Supra* note 12 at 228.
- 15 Alan Williams, "Inequalities in Health and Intergenerational Equity" (1999) 2:1 Ethical Theory and Moral Practice 47 at 50.
- 16 Amiram Gafni & Stephen Birch, "Incremental Cost-effectiveness Ratios (ICERs): The Silence of the Lambda" (2006) 62:9 Social Science & Medicine 2091.
- 17 *Ibid.* at 2095.
- 18 Andreas Laupacis *et al.*, "Gaps in the Evaluation and Monitoring of New Pharmaceuticals: Proposal for a Different Approach" (2003) 169:11 CMAJ 1167, online: CMAJ <<http://www.cmaj.ca/cgi/reprint/169/11/1167.pdf>>.
- 19 Stephen Birch & Amiram Gafni, "The Biggest Bang for the Buck or Bigger Bucks for the Bang: The Fallacy of the Cost-effectiveness Threshold" (2006)



- 11:1 *Journal of Health Services Research and Policy* 46.
- 20 Canadian Agency for Drugs and Technologies in Health, *Procedure for Common Drug Review* (Ottawa, Ont.: Canadian Agency for Drugs and Technologies in Health, 2008), online: Canadian Agency for Drugs and Technologies in Health <http://cadth.ca/media/cdr/process/CDR_Procedure_April%202008.pdf> at 1.
- 21 EKOS Research Associates Inc., *Evaluation of the First Year of Operation for the Common Drug Review: Final Report* (Ottawa, Ont.: Canadian Coordinating Office for Health Technology Assessment, 2005), online: Canadian Agency for Drugs and Technologies in Health <http://cadth.ca/media/cdr/cdr_evaluation_firstyear_oct2005.pdf>.
- 22 *Ibid.* at vii.
- 23 Sean R. Tunis & Steven D. Pearson, "Coverage Options for Promising Technologies: Medicare's 'Coverage with Evidence Development'" (2006) 25:5 *Health Affairs* 1218, online: HealthAffairs <<http://content.healthaffairs.org/cgi/reprint/25/5/1218?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&author1=tunis&andorexactfulltext=and&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT>>..
- 24 *Ibid.*
- 25 OECD Health Project, *supra* note 2.
- 26 George P. Browman *et al.*, "6-STEPPPs: A Modular Tool to Facilitate Clinician Participation in Fair Decisions for Funding New Cancer Drugs" (2008) 4:1 *Journal of Oncology Practice* 1 at 1; Shane Sinclair *et al.*, "Accounting for Reasonableness: Exploring the Personal Internal Framework Affecting Decisions About Cancer Drug Funding" (2008) 86:2-3 *Health Policy* 381.
- 27 Hans Starkhammar, "Aspects on Priority Settings in Cancer Treatment and Care" (2005) 44:7 *Acta Oncologica* 667.
- 28 Mita Giacomini, "One of These Things Is Not Like the Others: The Idea of Precedence in Health Technology Assessment and Coverage Decisions" (2005) 83:2 *Milbank Quarterly* 193.
- 29 *Ibid.* at 214.
- 30 OECD Health Project, *supra* note 2; Devidas Menon & Leigh-Ann Topfer, "Health Technology Assessment in Canada. A Decade in Review" (2000) 16:3 *International Journal of Technology Assessment in Healthcare* 896.
- 31 WHO Collaborating Center for Knowledge Translation and Health Technology Assessment in Health Equity, *Equity-Oriented Tool Kit for Health Technology Assessment* (Ottawa, Ont.: WHO Collaborating Center for Health Technology Assessment, 2004), online: University of Ottawa <http://www.intermed.med.uottawa.ca/research/globalhealth/WHOCC/projects/eo_toolkit/index.htm>.
- 32 OECD Health Project, *supra* note 2.
- 33 Craig Mitton & Cam Donaldson, "Health Care Priority Setting: Principles, Practice and Challenges" (2004) 2:1 *Cost Effectiveness and Resource Allocation* 3, online: *Cost Effectiveness and Resource Allocation* <<http://www.resource-allocation.com/content/2/1/3>>.
- 34 *Supra* note 15.
- 35 Norman Daniels & James Sabin, "The Ethics of Accountability in Managed Care Reform" (1998) 17:5 *Health Affairs* 50, online: HealthAffairs <<http://content.healthaffairs.org/cgi/reprint/17/5/50?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&author1=daniels&andorexactfulltext=and&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT>>; Norman Daniels, "Accountability for Reasonableness: Establishing a Fair Process for Priority-setting Is Easier Than Agreeing on Principles" (2000) 321:7272 *BMJ* 1300, online: *BMJ* <<http://www.bmj.com/cgi/reprint/321/7272/1300>>; Norman Daniels & James Sabin, "Limits to Health Care: Fair Procedures, Democratic Deliberation, and the Legitimacy Problem for Insurers" (1997) 26:4 *Philosophy & Public Affairs* 303.
- 36 Shannon Madden *et al.*, "Hospital Priority-setting with an Appeals Process: A Qualitative Case Study and Evaluation" (2005) 73:1 *Health Policy* 10.
- 37 Matthew K. Wynia *et al.*, "Improving Fairness in Coverage Decisions: Performance Expectations for Quality Improvement" (2004) 4:3 *American Journal of Bioethics* 87.
- 38 Iestyn Williams & Stirling Bryan, "Understanding the Limited Impact of Economic Evaluation in Health Care Resource Allocation: A Conceptual Framework" (2007) 80:1 *Health Policy* 135.

