

***“Healing with Dollars and Sense:
The Ethics of Cost-Effectiveness Analysis
in Health Care Decision Making”***

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REPORT FROM THE WORKSHOP

Hosted by: **The Defining the Medicare Basket Research Project
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Project Overview

The Defining the Medicare Basket Project is led by three Co-Principal Investigators from the University of Toronto who are well known and respected for their work in the health care policy academy. They are: Professor Colleen M. Flood, a Canada Research Chair at the Faculty of Law; Professor Carolyn Tuohy, Vice-President (Government and Institutional Relations) for the University, whose background brings a political science perspective to the research; and Professor Mark Stabile, a widely-regarded and sought after health economist from the University's Department of Economics. While the Project is hosted by the Faculty of Law at University of Toronto, the research team comprises leading academics from across many disciplines and organisations. A full listing of the team can be found on the Project's website: <http://www.law.utoronto.ca/healthlaw/basket/index.html>

Introduction

Professor Carolyn Tuohy, Vice President (Government and Institutional Relations),
University of Toronto

The Defining the Medicare Basket Project is a collaboration of many organisations. The major sponsor institutions are the Canadian Health Services Research Foundation and the Ontario Ministry of Health and Long-Term Care. Along with these two sponsors, the Project enjoys support from the following groups:

- Health Canada
- Canadian Medical Association
- Ontario Medical Association
- Merck Frosst Canada Limited
- Centre for Innovation Law and Policy
- Institute for Research on Public Policy

The major aim of the Project is to assess the “Canadian Model” for the allocation of health care resources. Canada's way of drawing the boundary between public and private finance for health care is unique among advanced industrial nations. Canada has, in essence, three realms of finance:

- Exclusive, universal, first-dollar public coverage
- Public coverage with limited eligibility conditions, co-payments or both
- Fully private finance, either out-of-pocket or privately insured

In previous work, Professor Tuohy has illustrated these financing divisions as “Concentric Circles” which can be filled according to different health care sectors (see Figure 1). Thus, we find:

- Hospital and physician services in the core
- Home care, long-term care, pharmaceuticals, etc. in the intermediate ring
- All other services in the outer ring

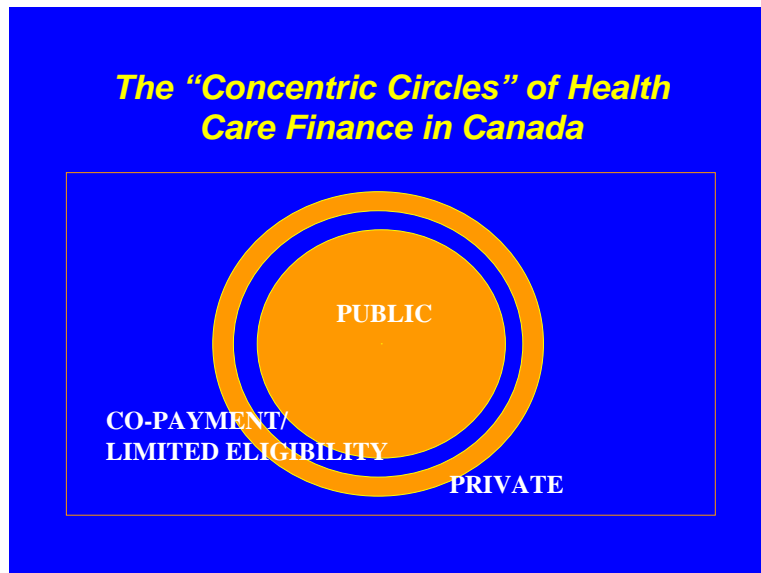


Figure 1: Concentric circles of health care finance in Canada

In assessing the Canadian Model, the research team must ask about the advantages and disadvantages of this model. Should the model itself be changed and, if so, how? If the model is acceptable, are there any modifications needed within it? To elaborate on these issues, we need to consider whether decisions on the extent of public coverage should be based on patient need and/or the cost-effectiveness of a service (in contrast to the current basis of provider type or the site of health service provision). This point is well illustrated by the example of annual physical examinations by doctors (currently covered because it is a service provided by a physician) compared with the provision of insulin (only partially covered by public funding). There is little evidence to show that annual physicals are beneficial to the population, whereas it is clear that all diabetics require insulin to avoid serious illness or even death. Can we address such anomalies by having some services span two concentric circles (i.e. attracting full, partial or no public coverage depending on patient need)?

Five general points should guide the discussion:

1. What should be the basis for the divisions - Need, Cost-Effectiveness, or Site?
2. What services should be publicly covered?
3. Should there be overlap between sectors?
 - a. if so, could private providers be encouraged to do individual assessments?
 - b. should enhanced services be bundled with others?
 - c. should public funding be based on a guarantee, e.g., waiting times?
4. What procedures/process should be used to make allocation decisions?
5. What values/factors should be considered?
 - a. principles of equity & justice?
 - b. incentive effects on providers and users?
 - c. political effects of decisions?

We can also ask: what processes should be used to make these decisions? Processes involving public consultation have given political legitimacy to the overall framework of coverage in other countries – e.g. Netherlands, Oregon. But ultimately scientific knowledge and professional judgment are essential. And the question is: how do we bring the two together? In all of these discussions the Values sub-project is key in providing guidance.

In closing, Professor Tuohy also highlighted other research themes currently being pursued by the Project Team:

- Analysis of current mechanisms for defining extent of coverage – e.g. Physician Bargaining; Provincial/Territorial Medical Directors; Health Services Appeal and Review Board, Provincial Drug Formulary Committees, etc.
- Effects of “de-listing”
- Alternative Physician Compensation Arrangements

Developing a Principled Framework for Decision Making

Professor Gopal Sreenivasan, Department of Philosophy, University of Toronto

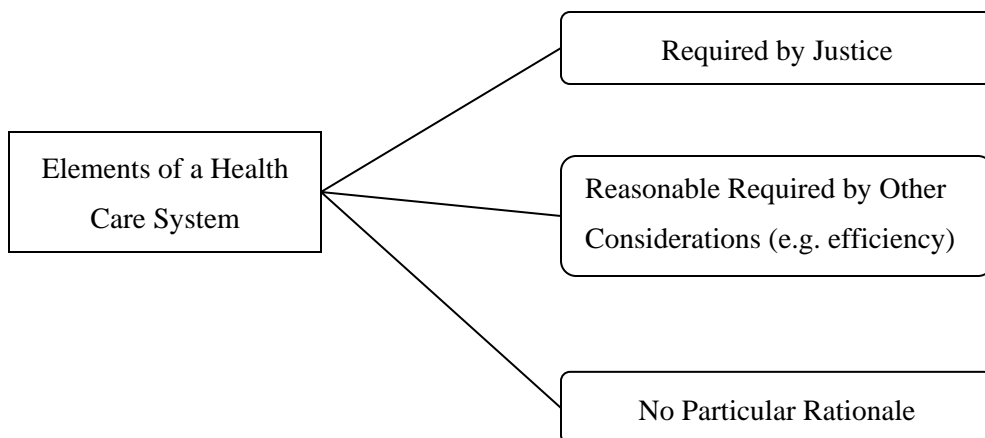
Professor Sreenivasan began by highlighting two assumptions that motivate and structure his thinking on these matters. The two assumptions are:

1. The scope of the Medicare Basket question — what should be included in the basket of insured medical services — rests on cost-effectiveness analysis (in some sense or degree);
and
2. There is a need for public participation in the allocation discussion, and this need is a process-driven consideration.

Beginning with the first assumption, it is a mistake to view an appeal to cost-effectiveness as a compromise in justice. For once we allow that there are other competing values at play then limiting services is in fact a requirement of justice rather than an exception to it. It is therefore a mistake to view an appeal to cost-effectiveness as being inimical to a values-based understanding of the nature of allocative decisions in the health care context.

With respect to the second assumption, even if we grant a distinction between substantive and procedural justice (or fairness), the procedure to be followed in making room for public participation must still be constrained in some manner. That is to say, there must be some limits on what counts as a fair or just procedure for gathering information about the public's views on health care decision making. In other words, 'punting' is not an option: not any procedure will do. But we can go on to say something else, namely that some reasonable procedure is going to be needed independently of any substantive questions about the nature of fairness; which is to say that we need a way of addressing disagreement among participants to the public discussion.

At the moment, there are many elements to the health system, some of which are required for some reasons; some of which are required for other reasons; and some of which are in place for no obvious reasons at all. In short, we can think of the elements of a decision matrix hierarchically, as follows:



Ultimately, the question has to do with the nature of the health care system as it is currently structured. With this in mind, it may not be worthwhile, given the institutional framework, history, and constraints, to change elements at the bottom level, even if there is no particular rationale for why those elements are in place (perhaps politically it is not worth the effort). But the broader point is that it doesn't follow that because an element to the framework lacks a rationale, that element should be rejected.

Thus we can see that the problem with health care reform, and the role that justice plays in it, is much more nuanced than it might initially appear. Appeals to cost-effectiveness are compatible with justice, and so cannot be dispensed with on the grounds that they violate principles of just or fair distribution of medical resources. And rejection of elements of the current health care system might not be justified even if the reason they are in place has nothing to do with justice.

Priority Setting: Beyond Evidence-based Medicine and Cost-effectiveness Analysis

Professor Douglas Martin, Department of Health Policy, Management and Evaluation,
and the Joint Centre for Bioethics, University of Toronto

Professor Martin's talk had three broad components:

- I. Where we have been – the 1980s & 1990s*
- II. Where we are going – 2000 to 2010*
- III. Improving priority setting*

I. WHERE WE HAVE BEEN

Priority Setting (PS) has to do with the distribution of goods and services between competing needs. Thus, it needs to be kept in mind that PS occurs at all levels of the health care system: government, RHAs¹, disease management organizations, research agencies, PBM², hospitals, and clinical programs. This indicates that it is a mistake to talk about '*the*' Medicare basket; for there are really *many* Medicare baskets about which PS decisions must be made. It also needs to be kept in mind that PS terminology has evolved from talk of rationing to talk of resource allocation to priority setting to sustainability.

Evidence-based Medicine (EBM) & Cost-effectiveness Analysis (CEA) have been dominant views in the PS field, yet there are a number of problems with this. Some of the problems with CEA are technical:

- what levels of evidence are sufficient?
- what types of benefits are at issue?
- what sort of economic analysis is warranted?

Some of the problems are more practical. For example, as noted by PaussJensen, Singer, & Detsky,³ "complex economic analyses played a limited role" in PS decision-making. This means that PS decisions are subject to significant gaps in knowledge. Thus:

¹ Regional Health Authorities.

² Pharmacy Benefit Manager.

³ PaussJensen A. M., Singer P. S., & Detsky A. S., "Ontario's Formulary Committee: How Recommendations are Made" Pharmacoeconomics Vol. 21(4): 285-294 (2003).

- We should say goodbye to simple solutions (Holm, BMJ 2000)
- We should be sceptical of purely normative approaches (e.g. philosophy, health economics)
- The values identified by the above methods tend to conflict preventing consensus
- Empirical approaches can tell us what is done or what can be done, but they fail to tell us what should be done

We can all agree on the how: the PS process *ought* to be fair. But what is fair? One proposal is ‘Accountability for Reasonableness’, which comprises the following:⁴

- Relevance: based on reasons upon which stakeholders can agree in the circumstances
- Publicity: reasons publicly accessible
- Revision/Appeals: mechanism for challenging/revising reasons
- Enforcement: to ensure the 3 conditions are met

II. WHERE WE ARE GOING

So-called “simple solutions” on the one hand, and “muddling through” on the other – also referred to as substantive versus procedural criteria – represent dialectically opposite extremes. A synthesized conceptual model or framework, grounded in real experience and taking account of various discipline-specific perspectives, represents the next phase of PS.

The criteria and process for this model must include a measure by which success can be evaluated. One problem with PS decisions as they are currently made is that they involve competing goals and multiple stakeholder relationships (patient, physician, hospital). Efficiency considerations or technical solutions are of limited practical influence and importance in such settings, and so are not sufficient to enable stakeholders to make PS decisions. Moreover, an evaluation of the normative ‘rightness’ of PS criteria in any given decision-making setting depends on the specific institutional circumstances, the stakeholders who are affected, and the strategic goals that are being pursued. This last observation is important, as it underscores the importance of procedural fairness to secure socially acceptable priority setting decisions and to ensure public accountability.

The key idea in this new model is that of what Professor Martin calls ‘Informal Networks of Deliberation’. These informal networks would operate beyond formal, institutional structures,

⁴ See also the section by Norman Daniels later in this report.

although they would be composed of members of institutions, as well as members of the public, patients, physicians, and other health care providers. They would emphasize ‘public good’ over ‘private interests’ and would provide more information about others’ preferences than do current models. In addition, the informal networks model promises to engage inherent human ability to assess different reasons for decisions⁵ and will, ideally, render decisions legitimate in the eyes of participants. This is because groups can pool their experience and creativity and because the model promises to enhance ‘buy-in’.

Improving Priority Setting involves: 1) Describing; 2) Evaluating; and 3) Improving. We must **describe** case study methods and what groups actually do. Then we can **evaluate** according to ‘Accountability for reasonableness’; what groups should do; correspondence on good practices; and the gaps, or opportunities for improvement. Finally, we can **improve** by:

- a. Implementing strategies to close gaps
- b. Utilising the benefits of describe/evaluate/improve
- c. Providing Institutions: with quality improvement, political involvement, learning organization, and leadership.

To illustrate this claim, let us consider PS decisions and Hospital Strategic Planning. We can divide the informal network process into a number of different stages:

1. Relevance
 - a. ensure information captures the impact on academic programs and the hospital’s community
 - b. optimize inclusivity / exclusivity
 - c. revise agreement mechanism
2. Publicity
 - a. develop a comprehensive communication plan
 - b. clarify strategic plan
3. Appeals
 - a. develop an appeals process (determine the necessary grounds for appeal)
4. Enforcement
 - a. start data consultation and data collection earlier
 - b. describe, evaluate, and improve again!

⁵ See Manin, Bernard; “On Legitimacy and Political Deliberation” *Political Theory* 15: 338-68 (1987).

The goal, in all of this, is to develop what might be called a “Database of Learning”. This database would be shared, and would enable individuals and institutions to make ‘private decisions public’. It would also serve an important educative function, since it would allow people to learn how PS decisions are, in fact, made. It would also create a body of “case law” or precedents of PS decisions, which would enable the attainment of an ‘institutional reflective equilibrium’ whereby individuals and institutions, with an eye to the future, could look at past decisions and reach a reflective equilibrium about how PS decisions ought to be made.⁶

III. Beyond and Forward

In conclusion, some synthesis of economic and normative models is required if PS decisions are to be fair and consistent both geographically (across institutions) and temporally (i.e., across decisions). PS decisions are, in part, value-based decisions about which there is much conflict and cost-effectiveness analysis, while arguably necessary, is insufficient to generate PS decisions that can be accepted by all stakeholders. What’s needed in addition is a process that enhances the legitimacy and accountability of PS decisions. This is precisely what informal networks of deliberation promise to do. Such networks create a climate of ‘public good’, and allow for a fair and in-depth assessment of the reasons for such decisions. They also serve to enhance problem-solving in the PS context, and promise to increase ‘buy-in’ on the part of those for whom decisions are being made, as well as by those who are making the decisions. It should not be forgotten, however, that all PS involves an ongoing process of social policy learning. The hope evinced by Professor Martin was that the informal networks of deliberation model will contribute to this learning process in a way that is fair to all participants to PS decisions.

⁶ Other examples of settings in which Professor Martin argued that the informal networks model has shown signs of success are:

- Martin DK & Singer PA., *Priority setting for health technologies in Canada*, in Ham C, Roberts G (eds.) Reasonable Rationing: International Experiences of Priority Setting in Health Care (Maidenhead, UK: Open University Press) 2003;42-63.
- PausJensen AM, Singer PA, & Detsky AS, “Ontario’s Formulary Committee: How Recommendations Are Made”, *Pharmacoeconomics* 2003;21(4):285-94
- Martin DK, Hollenberg D, MacRae S, Madden S, & Singer P, “Priority setting in a hospital drug formulary: a qualitative case study and evaluation” *Health Policy* 2003 Dec;66(3):295-303
- Martin DK, Pater JL, Singer PA, “Priority-setting Decisions For New Cancer Drugs: A Qualitative Case Study” *Lancet* 2001; 358: 1676-1681
- Mielke J, Martin DK, Singer PA, “Priority setting in a hospital critical care unit: qualitative case study” *Critical Care Medicine* 2003;31:2764–8; Martin DK, Singer PA, & Bernstein M., “Access to intensive care unit beds for neurosurgery patients: a qualitative case study” *Journal of Neurology, Neurosurgery and Psychiatry* 2003;74:1299–1303.

Some Practical Ethics in Cost-Effectiveness in Health Care

Decision Making: Reflections from the Experience of NICE

Dr. Anthony Culyer, Chief Scientist, Institute for Work & Health, Toronto

In the UK, the legitimacy and resulting authority of coverage decisions depends on a perception that they are ethical i.e. made in accordance with core values of the system: publicity of decisions, equal and affordable access to services, and more recently, cost-effectiveness – performance based funding is an example in this area. Health care that does not increase health is wasteful; hence, on a utilitarian approach unethical.

Dr Culyer set the context for ethical decision making in health care. There should be publicly funded provision of services (regardless of the ownership of the actual providers); citizens should have equal access to services at reasonable costs (“cheap”); and public funding to providers should be conditional on performance.

There are, however, certain ‘ethical points of departure’ within this context. The authority to deliver health care must be ‘efficient’ and ‘equitable’, yet these two concepts can conflict. Decision making will, at some point, require the consideration of preferences and yet must somehow also be distributionally neutral or silent.

The NHS for England and Wales is a system that provides public funding for a wide range of services. There is mixed public and private provision of these services to meet the somewhat broad and vague goal of maximising national “health”.

NICE was created in 1999 with a mandate to improve cost effectiveness by reviewing new technologies and updating and centralizing the best clinical practices. On the technology front, the NICE has more decision making powers, whereas with reviewing practices it is advisory only. However, the NHS is required to fund and plan in a way that takes account of the NICE report. NICE identifies cost-effective technologies and makes recommendations for their use in the NHS. It also creates authoritative clinical guidelines to support cost-effective clinical practice in all health settings. The mandate of what constitutes ‘technology’ is broad. Its recommendations with respect to clinical practice guidelines are not binding *per se* on the NHS, but the NHS is under a

statutory obligation to fund clinical decisions based on NICE guidance. The NICE process is transparent and includes public participation.

Transparency comes through open Board meetings held around England and Wales and through the publication of the minutes from those meetings. NICE also hears from Partners Councils and Citizens Councils, which transmit local values to the NICE Board. Transparency is categorically and instrumentally good, but it can create expectations and make decision makers hostages to fortune.

NICE has developed a “reference case” to aid with consistent decision making. As the NICE Annual Report 2004 states:

The Institute has to make decisions across different technologies and disease areas. It is, therefore, important that analyses of clinical and cost effectiveness undertaken to inform the appraisal adopt a consistent approach. To facilitate this, the Institute has defined a ‘reference case’ that specifies the methods considered by the Institute to be the most appropriate for the Appraisal Committee’s purpose and consistent with an NHS objective of maximising health gain from limited resources. ... This does not preclude additional analyses being presented where one or more aspects of methods differ from the reference case. However, these must be justified and clearly distinguished from the reference case.

(NICE 2004, p.19)

This reference case has three implications: 1) the scope is constrained by the maximum health gain that might possibly be ethically justified; 2) it is constrained by a need for consistency in analytic methods; and 3) it is pragmatic in that exceptions to the reference case are permitted. Readers are directed to the “Defining the Medicare Basket Project” website to read Dr Culyer’s presentation and learn more specifics about the Reference Case, including actions taken in the scoping phase of a decision. The pragmatic nature of the NICE reference case materialises in two ways. Firstly, the method locates the task as one of optimising services within a frame defined by a budget and a mission statement. Secondly, it has a caveat that enables other elements to be considered when judgment (usually that of the NICE Board) suggests that it may be desirable.

The outcome of a NICE evaluation is expressed in the EQ-5D version on the QALY. Each additional QALY has the same weight regardless of the other characteristics of the patient. Why does NICE use the QALY?

There was general agreement amongst the founders of NICE that it needed an outcome measure that related as closely as possible to the Secretaries of State's charge to NICE regarding "health" (effectively recognising his "authority"). It was sufficiently close to common outcome measures used by clinicians in research (e.g. life-years or 5-year survival rates) to be a familiar starting point and was an index rather than a profile. The QALY is also generic, applicable to a wide range of technologies and thus facilitating comparison of relative cost-effectiveness. Its theoretical properties and their consequences were (or were becoming) well-understood (properties such as constant proportional trade-off, risk neutrality over life-years, additive independence in health states) and the trade-offs embodied in it were derived from a representative sample of the UK population.

The ethical arguments adduced against it did not seem persuasive – particularly when it was compared with practical alternatives. It had the attractive attribute of identifying, in a classically reductionist way, a set of value-judgmental issues for resolution (once one had, of course, accepted the essentially pragmatically crude utilitarian nature of the construct). And, finally, it was simple and low-cost.

It should be noted that decisions of NICE can be appealed against. The appeal is heard by a panel comprising members of the NICE board. The grounds for appeal are:

- procedure was not followed
- the decision is manifestly perverse in light of the evidence
- NICE has exceeded its statutory powers in making the decision

Dr Culyer concluded by noting the usefulness of adopting an extra-welfarist perspective on the ethical issues involved in appraising health care technologies (whether by cost-effectiveness analysis or anything else). It provides a systematic mode of thinking through the myriad issues that need to be resolved. Also, the flexibility of the extra-welfarist approach enables many considerations to be adduced (or excluded) according to the "rulings" of the ethical "authority". Key features of the NICE approach are the explicitness with which the key issues are brought into the light for debate and decision, and the empiricist approach to finding out what values are held in the community as a basis for embodying consensus (if it exists) in the analysis.

Some Key Ethical Problems in Using Cost Effectiveness Analysis for Health Care Coverage Decisions⁷

Professor Dan W. Brock, Brown University

Introduction

Professor Brock began with a familiar problem: given limited resources for health care, how should such resources be allocated? This could be called the ‘allocation problem’ and can be analysed as follows:

- Macro level 1: how much to health care vs. other goods?
- Macro level 2: how much to different health care needs?
 - Includes different diseases.
 - Includes different classes of patients, e.g. young vs. old.
- Micro level: selecting among different patients with similar health care needs when not all can be treated.
 - E.g. selecting patients for organ transplantation.

Cost-effectiveness analysis (CEA) has principally been used for Macro level 2 choices, since this is where coverage decisions are made. There are two kinds of issues at each of these levels:

- What are the substantive principles by which the allocation decisions should be made?
- Given that there will be disagreement about the principles, what procedures should be used to make the choices?

Although both principles and procedures are important, Professor Brock chose to focus on principles and the substantive issues.

There are two broad goals for resource allocation — 1) maximize the benefits from limited resources, and 2) distribute the benefits equitably. These goals can and do conflict. CEA is the

⁷ This presentation is based on a paper that draws heavily on Brock’s “Considerations of Equity in Relation to Prioritization and Allocation of Health Care Resources,” in *Ethics, Equity and Health For All*, eds Z. Bankowski, J.H. Bryant and J. Gallagher (Geneva: CIOMS, 1997) and “Ethical Issues in the Development of Summary Measures of Population Health States” in *Summarizing Population Health: Directions for the Development and Application of Population Metrics* (Washington DC: National Academy Press, 1998). The paper can be found at: <http://www.nyu.edu/gsas/dept/philo/courses/bioethics/Papers/EthicalIssues.PDF>

analytic method to determine what will maximize benefits, but it ignores issues of equity or fairness. So the problem is, what are the equity issues? As there was not enough time in this workshop to cover all the issues completely, this discussion will focus on a few central issues. One can begin by distinguishing ethical issues that arise for how to do a CEA from issues that arise about when to use the results of the CEA for prioritization decisions. CEA requires a measure of the costs, which is typically in dollars, and it also requires a measurement of the benefits of alternative health interventions or programs. Health benefits are gains in quality and length of life, typically measured in quality-adjusted life years (QALYs).

Ethical Issues in Doing a CEA

An obvious first question is how should states of health and disability be evaluated? They are typically evaluated on a zero to one scale, with zero being death and one being full health. Values of different health states are determined using people's preferences for the different states. But whose preferences should be used for evaluation of health and disability states? Normal functioning persons evaluate disability states as worse than those who suffer those states, in part due to false beliefs, prejudices and stereotypes about disability states, and in part due to accommodation, coping, and adjustment. However, using 'disabled' preferences undervalues prevention and rehabilitation, while using 'normal' preferences undervalues life saving for the disabled. This is really a perspectives problem: neither evaluative perspective is mistaken.

Should QALYs be Age-Weighted?

CEAs generally reject the age weighting of QALYs. Age weighting has an ethically problematic rationale as it depends on the social, economic and psychological dependence of the very young and the old on persons in their productive years. This values the health of persons according to their instrumental value to others. Still, there is a fairness or 'fair innings' rationale for a different age weighting, at least for life years.⁸ For one thing, a year of life extension has greater moral importance the younger its recipient. This suggests a principle according to which we should give to those who, if not helped, will have had less of the good our resource can provide. This accords a higher moral priority to reaching the normal lifespan than to living beyond it.

⁸ For an example of the "fair innings" concept, see Alan Williams, "Intergenerational Equity: An Exploration of the 'Fair Innings' Argument", *Health Econ.* 6: 117-132 (1997).

Should discount rates be applied to health benefits?

This is an ethical, not just an economic, issue. There is no disagreement that monetary costs and benefits should be discounted—the issue is health benefits. In particular, why should the same health gain for an individual have less value merely because it occurs in the future? There is the same size health gain for the same or for different future individuals. And while rationality requires equal concern for all periods of one's life, equity requires equal concern for all persons, independent of the generation to which they belong. This observation is of importance for preventive and public health programs.

What Costs and Benefits Should Count in the CEA?

There are two issues here: first, should benefits be restricted to health benefits or include as well non-health (e.g. economic) benefits; and second, whether only direct, or also indirect, benefits and costs be considered? There is some practical importance of the issue — indirect, non-health benefits can swamp the direct health benefits of health programs, and advocates for particular health needs often appeal to indirect, non-health benefits of meeting them (e.g. substance abuse).

The two issues should be distinguished. Take the surgeon case:⁹ you can save either A or B. However, B is a surgeon who will then save five additional lives. The additional lives are an indirect health benefit. Compare this with the Wisdom case: you can treat either A or B and cure their disease. If you treat B you will also impart great wisdom to her, wisdom that A would not get if you were to treat her. The wisdom seems a direct, but non-health related, benefit. Practically, most non-health benefits will be indirect, and vice versa.

Restrict CEA to Health Benefits: The Separate Spheres' View

According to this view, the sphere of an activity is determined by its purpose. Some examples might be criminal punishment, democratic elections, social gatherings, and health care. The purpose determines the basis for distributing the “goods” and the “bads”. The purpose is determined by actual purposes of participants and the social meanings of the activity, but the purpose is plausibly constrained by the causal consequences of the activity. That is to say, the

⁹ Professor Brock references the work of Frances M Kamm in her book: Morality, Mortality. Volume I: Death and Whom to Save From It? (Oxford: Oxford University Press, 1993).

purpose of health care could not plausibly be to produce great literature and the purposes of social activities cannot be changed at will by individual participants.

Brock sees the purpose of health care as being health and economic benefits. The German health system in the 19th Century sought both health and a productive workforce. In endorsing this view, one would not be making a conceptual mistake and so one would need a moral justification for limiting the purpose to health. We could give the activity a new name reflecting these dual purposes. In fact, the purpose is now accepted as not health, but rather points towards overall well-being. On this view, health can be sacrificed for overall well-being.

Moral Significance of the Distinctions

Let's return to the distinction between direct and indirect benefits. There is a moral argument for considering all costs and benefits in which indirect, non-health benefits and costs are real benefits and costs. Ignoring them has opportunity costs and will result in failing to identify the most cost-effective alternative resource allocations. This failure might result in decreased health care opportunities for others. Thus, again, we need a moral reason for ignoring such benefits and costs. We often legitimately use indirect means to our ends and have multiple aims in our activities. Why not also in the health care system?

It is important to note that this is not just a problem for Consequentialists. For example, Prioritarians give special weight to benefiting the worse off. Are the worse off the sickest, or those with worse overall well-being? One objection to this is the Fairness Objection, according to which it is unfair to favour some patients or health care needs over others merely because doing so produces indirect, non-health benefits for others. If health care needs are equal, then people have equal moral claims to have them met. Treating working age substance abusers (group A) also benefits their employers and the economy, while treating retired substance abusers (group B) does not. But both groups have equal claims to have their health needs met. It would be unfair to give preference to the working age patients on this ground. We could try to distinguish moral claims ("a duty owed to the candidate herself for a commodity that she should have it") from other moral reasons why she should get it. Fairness is about mediating claims of individuals. For example, A has no claim to a resource merely because his getting it would benefit C. Likewise, the surgeon (mentioned above) has no greater claim to needed care because she would save others if treated. There would be no unfairness to A if she did not get preference for the resource for this reason.

Pragmatic Arguments for Ignoring Non-health Benefits

Health planners and physicians are trained to evaluate health benefits and costs, not indirect non-health benefits or costs. These other benefits and costs generally are difficult, uncertain, and costly to calculate. This increases the potential for bias, prejudices, stereotypes, and self- or group interest to affect the assessment of benefits or costs. For example, work in the home, traditionally done by women, will be undervalued. If we are confident of the indirect, non-health effects only in some cases, it would be inconsistent and in turn unfair to selectively use them only in those cases. These non-health assessments will also be controversial and could undermine confidence in the fairness of the allocation process. In many cases the added effort, time, and expense of gaining data on indirect, non-health effects may not justify doing so. Why is social context and role important? It matters for three reasons.

1. It will affect the alternatives from which choices must be made.
 - Legislators allocate between health and other aims.
 - Health Ministers or administrators allocate between different health needs.
 - Physicians must choose between different patients.
2. It will affect the nature of what is to be allocated.
 - Legislators and Health Ministers or administrators allocate money to health care and particular health care programs.
 - Physicians allocate treatments to individual patients.
3. It will affect the professional roles and responsibilities of the allocators.
 - Legislators are responsible to the electorate.
 - Health plan administrators are responsible to plan members.
 - Physicians are responsible to their individual patients.

As a pragmatic matter, governments divide up their responsibilities to different agencies. The Health Minister's responsibility is to promote health. Spill-over effects, positive or negative, are viewed as not being part of the Minister's responsibility. This leads to a rough generalization about social context and role, namely, that the higher the level the macro prioritization decision, the more defensible it is to give weight to indirect non-health benefits and costs. The closer the decision is to micro level choices between individual patients, the stronger the case is for ignoring

them on grounds of fairness. An alternative position is to give them some, but lesser, weight than direct health benefits.

Ethical Issues in Using CEA for Resource Prioritization

Ethical issues remain in trying to use CEA for the prioritization of resources. One problem is what might be called the “aggregation problem”. CEA puts no limits on the aggregation of different size benefits to different persons — only the aggregate benefits of different alternatives matter. Oregon experienced this problem when it was forced to decide between capping teeth and providing appendectomies. Ordinary people’s priorities are typically based on one-to-one comparisons, but this ignores cost differences. But the aggregation of benefits is not always rejected — see, for example, the case of Coby Howard.¹⁰ The ethical problem is when, and for what reason, is the aggregation of benefits ethically acceptable? This question gives rise to a question about commitment to equality of opportunity. There are, broadly speaking, two views on this subject: the maximizing and the prioritarian interpretation.

According to the priority view, “benefiting people matters more the worse off people are”.¹¹ On this view, the worse off one is, the greater relative improvement a given size health benefit will produce. The strength of claims for health improvements are greater, the greater the undeserved health deprivation. But who are the “worse off” for the purposes of health care resource prioritization? Is it the *sickest* or those with *worse overall well-being*? The global view contends that the units for distribution are whole human lives¹² and focuses on the poor whose overall well-being tends to be worse. But this has counterintuitive implications since it counsels us to treat the less sick poor before the sicker rich.

¹⁰ Coby Howard was a 7-year-old boy diagnosed with leukemia. Howard required a bone marrow transplant. The Oregon legislature, however, had decided earlier that year not to fund transplant operations, which were an optional service at the discretion of states under the Medicaid program that provides insurance to low-income Americans. The state consequently refused to pay for the operation. The case drew substantial media attention, and private efforts to raise money for the operation were undertaken, but Coby Howard died later that year before sufficient funds were raised. For more information on this case, see Oberlander J, Marmor T, and Jacobs L, “Rationing medical care: rhetoric and reality in the Oregon Health Plan” *CMAJ* • May 29, 2001; 164 (11).

¹¹ Parfit D, “Equality or Priority?” in: Clayton, Williams, eds. *The Ideal of Equality*. (Basingstoke: Palgrave, Macmillan), 2000.

¹² Thomas Nagel, Equality and Partiality (New York: Oxford University Press, 1991), p. 69.

On the other hand, there is the “Separate Spheres” view, according to which priority for health care should depend only on health needs. This view admits of a Kantian moral justification insofar as it gives equal weight to equal health needs. But it also admits of a pragmatic policy justification, according to which physicians and health policy analysts can reliably judge health needs, but not people’s overall well-being.

Conclusion

Professor Brock concluded by briefly recapitulating the ethical problems involved in doing or using CEA for resource prioritization. As he noted, fair procedures may be necessary for legitimate political resolutions, but fair procedures are not enough. Those procedures should be informed by our best analyses of ethical issues.

Preference Measurement in CEA:

Are we capturing values or creating them?

Professor Peter Ubel, Director, Program for Improving Health Care Decisions,
Ann Arbor VAMC and Univ. of Michigan

Cost-effectiveness analysis (CEA) is designed to maximize the average health of populations. Professor Ubel presented evidence demonstrating that CEA does not capture people's allocation preferences. However, this is not the end of things. One can also argue that people's allocation preferences, while at odds with CEA, are often at odds with themselves, in the sense that they are internally inconsistent, susceptible to irrelevant information, and occasionally downright confused.

What values should guide allocation decisions? The answer to this question, based on statistical surveys, has various elements.

1. Priority for treating severely ill patients

Imagine an illness – “A” – that causes severe health problems, the treatment of which will help patients a little. Imagine, also, an illness – “B” – that causes moderate problems but the treatment of which will help patients considerably. Suppose, moreover, that the cost of treatment is the same in both cases. Which would you fund and to what extent? In surveys, 40% said that most funding should be allocated to illness A, involving severe health problems that improve a little, while 60% said that most funding should be allocated to illness B, involving moderate health problems that improve considerably.

2. Avoiding Discrimination Against People With Disabilities

Another survey asked: How many lives of people with paraplegia would need to be saved to be equally beneficial as saving 100 lives of people who could be returned to perfect health? The results showed that 65% of people said the number should be 100.

3. Age discrimination is Permissible

When asked how they would allocate 100 transplantable livers among 1) one hundred 35-year olds, and 2) one hundred 65-year olds, an even distribution was favoured by 40% of respondents, while priority to younger patients was favoured by 57%.

This suggests that some tweaking is required in order to make CEA plausible, but how might we go about fine-tuning CEA? As Ubel says, “It’s time to shatter some assumptions.” The problems confronting advocates of CEA are:

a. People Get Confused

In survey experiments where participants had already made choices regarding the allocation of livers, they were then asked what distribution of organs would maximize survival. In all cases, the ‘correct’ answer according to CEA was that all 100 organs should go to the group with better prognosis. However, the majority of respondents did not give this answer. Even when people aren’t confused, they can still make mistakes. Thus, suppose 200 transplant candidates can be ranked from 1 – 200 by prognosis based on a blood test. In response to the question, “Would you give organs to the top 100 patients?”, the majority of participants say “Yes”.

b. People hate saying “no” to a whole group of patients

Again, suppose a blood test ranks people 1 – 200. The blood test divides patients into two groups, of which only one group can be treated. Of course, no one wants to abandon second group. What if you could ignore blood test? Surprisingly, 41% of experiment participants would choose to do so.

c. People like “easy outs”

When faced with two illnesses – A, which involves severe health problems that improve a little with treatment; and B, which involves moderate health problems that improve considerably with treatment – a majority of respondents (75%) chose to fund both treatments equally.

d. People often refuse to make tradeoffs

The Person Tradeoff (PTO) preference measure provides us with two types of refusals to making tradeoffs.

- i) Equality Refusals – this is where the choices facing a decision maker are equally good – i.e., curing 100 people of quadriplegia is seen as the same as curing 100 people of foot numbness.
- ii) High Refusals – this is where there are extremely high indifference points – i.e., curing 100 people of quadriplegia compared to curing 300,000,000 people of foot numbness.

What is the frequency of PTO Refusal? Is the problem the Decision-maker Perspective?

Imagine that you are the executive director of a regional health system and that you have only enough money to fund one treatment program. And suppose that the **final** decision is **up to you**. Does perspective matter? In other words, will a non-decision-making perspective encourage more people to make tradeoffs? On the one hand, there is

- Less negative emotion
- Less pressure
- Easier

Now imagine that the situation has changed in the following way: Because of an unusually weak economy, the number of people poor enough to qualify for Medicaid is doubled. That means twice as many people will be enrolled in Medicaid as had been predicted. However, there's no change in the budget for colon cancer screening. Would this change things? If so, how and why?

Arbitrary Results: Another problem is that CEA results are arbitrary and often depend on the manner in which at risk populations are defined. For one thing, preferences for equity vs. efficiency are fragile and depend on whether more effective tests can be offered to 100% of a population. People are only moderately sensitive to the “arbitrariness” with which populations are defined.

Revisiting age-based rationing: As you will recall from the beginning of this discussion, people favour distributing life saving resources to 35 year olds over 65 year olds. Some CEA experts say this should lead to age-weighted QALYs but we should be aware of what happens when we explore these values more thoroughly. For example, when deciding on how to allocate “life-

saving” treatments, there is often a preference for young over old patients. However, when considering “palliative care”, the preference is to allocate resources to older patients.

Is there any value in measuring public values? To answer this, let’s consider the alternative: before QALYs, the standard measure was dollars per life year. That meant we had no ability to capture the value of interventions that improve Quality of Life, or to compare life-saving treatments to life-*improving* ones. The upshot is that CEA is not perfect. This is because there is no single \$/QALY figure for any intervention, nor is there an exact \$/QALY threshold for society. At best, CEA is a tool to guide decisions. Different people will place a different value on saving the lives of non-disabled people, people with pre-existing paraplegia, and people with onset of paraplegia. Those various values are messy and complicated. For example, why do people think paraplegia is so bad? Perhaps they do so because they fail to consider emotional adaptation; because they consistently mis-estimate the Quality of Life for people suffering from a chronic illness or disability — while patients report high levels of well-being, the public imagines misery. But the public can be prodded to think about adaptation – think about a bad event that might have happened more than 6 months ago. Does that event seem as bad to you now as it seemed to you then?

Final, ‘inconclusive’ thoughts –

Professor Ubel concluded with a Future Agenda. This agenda contained the following advice and admonitions: develop methods for measuring public values that are more stable and more consistent; recognize that those values are not fully formed before measurement; and remember that even though ‘value’ measurement is flawed, measuring cost-effectiveness without QALYs is not an option.

The ‘QALY Trap’: Can Rationally Maximizing Health Benefit be Reconciled with Principles of Non-Discrimination

Professor Paul Menzel, Professor of Philosophy, Pacific Lutheran University

Professor Menzel began with what he sees as the problem of the ‘QALY Trap’ and Discrimination. The problem of discrimination is at the heart of the conceptual structure of the QALY. We should be concerned with ensuring non-discrimination in the application of CEA and QALYs. It would appear that using QALYs allows us to make a trade-off between the value of life-saving and the improvement of quality of life. If we lose this element, then the QALY is less use to us.

One plausible escape from this trap is the ‘Societal Value Measurement’, which can be demonstrated in examples describing health interventions that simultaneously save lives and cure disability. We should look at what is going on in this trade-off – what do people think of the value of lives saved (when asked about the difference between achieving full health and having a disability, either pre-existing or onset)? Generally, people would choose to provide life-saving treatments even if the treatment would maintain or result in a disabled quality of life. The question that remains is: Could the equal value of lifesaving still be a judgment of individual utility?

Another escape from the trap is simply to accept discrimination in lifesaving.

To describe this situation, we must create values with which to work. Let’s say that we have three people: A, who is at full health (value = 1.0); B and C are paraplegics at a health value of 0.8 (this value is arbitrary). Subjectively, the value of the *life* of a person at 0.8 health (B & C) is seen as the same for someone at 1.0 health (A). We can ask the question of whether B or C value their current life (at 0.8) less than someone in full health? Further, will they gamble their current health state to cure their ‘illness’.

What, then, is the “societal value” of a life? Let’s say that A, B, and C suffer an accident – the treatment available to them can save their lives. A is in full health, and society values saving A’s life and preventing paraplegia as 1.0 – being the value between death (0) and full health (1). B is

paraplegic and has a life health value of 0.8 – to save B’s life but leave him as a paraplegic, is thus less of a value than for A (going only from 0 to 0.8). Lastly, C is paraplegic (i.e. 0.8) but through this treatment can be saved *and* actually cured of his paraplegia thus raising his life health value from 0.8 to 1.0 – however, is C’s life-saving really only worth 0.2?

The *societal value* of a life is always equal – i.e. a life is a life is a life, regardless of any pre-existing conditions of the people involved. The “QALY Trap” is one where people are discriminated against depending on the number of QALYs they receive from their treatment (ie compare A, B and C).

There are two ‘gamble’ scenarios to consider:

- TTO – time trade-off – where one may be treated for illness but will lose 20% of full health;
- SG – standard gamble – where one faces a 20% chance of dying in being treated.

Another question to be considered is: what have the disabled said about the value of their own life? The disabled are saying that a cure for their paraplegia has a certain proportion of the value of saving their very life. But have they thereby said that their very life itself (with paraplegia, e.g.) has less value than the life of another person in full health? This is extremely unlikely. Isn’t it likely that they have said that their life with paraplegia, compared to death, is just as valuable to them as anyone else’s “better” life is to him or her?

Professor Menzel concluded by arguing that a moment’s thought is sufficient to convince most people that their very life itself, even if they were disabled, would be just as valuable to them as another person’s very life in full health was to that other person. Societal Value is the solution to that QALY Trap described above – our doubts about whether there is a difference between saving A and B come back to our views on individual utility (and thus, a form of discrimination).

CEA and Fair Process: Specifying the MEDICARE Benefit Package

Professor Norman Daniels, Harvard School of Public Health

Professor Daniels began with an overview of allocation decision-making in health care contexts. In his view, Justice requires meeting needs fairly under resource constraints — it involves limit setting decisions at various levels despite moral disagreements. Cost-effectiveness analysis (CEA) is a maximizing strategy (net aggregate benefits) open to well-rehearsed ethical objections. This leaves two strategies: a) ethically weighted CEA vs b) CEA as one input to fair deliberative process. His goal is to argue for (b) plus other inputs to produce a process that is Accountable For Reasonableness.

There are three questions of justice relevant here:

1. Why is health especially important?
2. When are health inequalities unjust?
3. How can we meet health needs fairly when we cannot meet them all?

This discussion concentrates mainly on the third question, but let's set the stage by talking briefly about the first two. According to the Fair Equality of Opportunity (FEO) account of the moral importance of health care:

- Disease and disability are departures from normal functioning
- Departures from normal functioning impair opportunity
- Meeting health needs promotes/protects normal functioning
- The principle governing the meeting of health needs is the FEO principle

This account employs a version of Rawls' "Justice as Fairness",¹³ which involves a hypothetical contract. We can make a further simplifying assumption, namely that normal functioning is measured over lifespan. We also require an index of Primary Social Goods that is based on three principles:

1. Equal basic liberties; fair value of political liberties
2. Fair equality of opportunity

¹³ Rawls, J. A Theory of Justice (1971), in which Rawls lays out his own moral theory, called "Justice as Fairness", and his two famous principles of justice, *the liberty principle* and *the difference principle*.

3. The “Difference Principle”

Extending Justice as Fairness (JAF) to Health Care

For the purposes of this discussion, the JAF principle is simplified to the case where there is no disease, disability or premature death. This view is open to criticism¹⁴ that the theory cannot accommodate important variations among people that create inequalities whereas the FEO account permits the theory to handle departures from normal functioning.

Extending FEO to Social Determinants

Health Care needs are those things that we need to promote, maintain, or restore normal functioning. They include adequate nutrition, shelter, safe living and working environments, exercise, and rest — as well as medical services (traditional public health). What distribution of social determinants is needed to promote normal functioning? This theory proposes that the use of Justice in this distribution is good for our health: conformance to Rawls’s principles of justice as fairness flattens health gradient to extent that justice requires.

How can we use the FEO principle to define a ‘just’ Medicare benefit package? We must begin by assuming reasonable resource constraints (health care not only important good). Thus, ‘Just Health’ proposes that all people are entitled to make contingent claims on a reasonable array of medical and ancillary services that meet health care needs regardless of ability to pay (a ‘right’ to health care). Some medical services do not meet health care needs but meet other social obligations (e.g., non-therapeutic abortion). Reasonable people may disagree about the contents of a benefits package on empirical and, especially, ethical grounds. For example, they might disagree over how much priority to accord to the sickest patients (see also the reports from the Swedish and Dutch commissions on health priorities).¹⁵ Or they might disagree about when aggregated benefits to more patients outweigh larger benefits to fewer patients, or when to give people some “fair” chance at benefit rather than favour those who will have best outcomes.

¹⁴ See, for example, Arrow K.J., A.K. Sen, K. Suzumura (eds.) 1997, *Social Choice Re-examined*, 2 vol., International Economic Association, New York: St Martin's Press and London: Macmillan; and K.J. Arrow (1967)*, "Values and Collective Decision-Making", in P. Laslett and W.G. Runcimann (eds), *Philosophy, Politics and Society*, 3rd Series, New York: Barnes and Noble, 215-32.

¹⁵ Swedish Parliamentary Priorities Commission, Priorities in health care, Stockholm: Ministry of Health and Social Affairs, 1995; and Government Committee on Choices in Health Care Report, Rijswijk, Netherlands: Ministry of Welfare, Health and Cultural Affairs, 1992.

When do we yield to public opinion about priorities even when that may not produce most health or fairly distributed health?

Limit-setting decisions (including defining a benefits package) are morally controversial because they have ‘winners’ and ‘losers’, and fundamentally affect well-being. There is no prior agreement on principles that are capable of resolving disputes about benefit packages. So we must ask: under what conditions (who and how) are these decisions accepted as fair and legitimate? If no prior agreement on principles of distribution, need fair process to yield decisions people can regard as fair. The promise of CEA is that it is an “Objective” Tool that reflects public valuation of health states, and takes account of each person. We owe to each other what works; in this it aims to be a measure of effectiveness of health interventions. In addition, however, it requires us to weigh opportunity cost of alternatives, and considers both life extension and quality.

Ethical Problems with CEA

The foundational problem with CEA is that it confuses social values with preferences or utilities¹⁶ and that it employs a maximizing methodology rather than a methodology of fairness.¹⁷ Another general problem is that there is not even a fiction about potential *pareto* improvement, as in Cost-Benefit Analysis, to offset the concern about fairness. There is also the priorities problem and the aggregation problem (the Oregon experience demonstrates this).

The challenge, then, is to construct an ethically sensitive CEA. One proposal (made by Nord and others) is to use surveys (person-trade-offs) to better capture social values involved in alternative uses of health care interventions. The hope is that the resulting transformations will compress weights given to utility based health states. Such a corrected CEA (CVA not CUA) better captures societal values and gives better input into decision-making. The result is a better democratic proxy than CEA (“public policy should reflect the public’s values”).

¹⁶ See: Nord E, Richardson J, Street A, Kuhse H and Singer P 1995, ‘Who cares about cost: Does economic analysis impose or reflect ethical values’, *Health Policy*, vol 34, pp 79-94; and Hausman D 2000, ‘Why not just ask? Preferences, “Empirical Ethics” and the role of ethical reflection’, Paper presented to WHO Initiative on Ethical Issues in Health Resource allocation, WHO, URL: www.who.int/whosis/fairness.

¹⁷ See: Ubel PA, Nord E, Gold MR, Menzel P, Pinto-Prades JL, Richardson J., “Improving value measurement in cost-effectiveness analysis” (2000) *Med. Care* 38(9):892–901; Menzel P, Gold MR, Nord E, Pinto-Prades JL, Richardson J, Ubel P. “Toward a broader view of values in cost-effectiveness analysis of health” (1999) *HastingsCent. Rep.* 29(3):7–15

Problems with weighted CEA

Yet there remain problems even with a weighted CEA. For one thing, there is a lack of transparency: stakeholders won't understand the weights and how they were derived. There are also methodological problems: there is considerable variance (framing, anchoring) and there is no way to explain whether this is random or systematic (matters of taste vs. constellations of values). The result of this is scepticism about the legitimacy of a weighted CEA: the first two problems make this no substitute for fair deliberation; what is wanted is a process that mirrors moral deliberation, and such a process is not given by a weighted function.

Accountability for Reasonableness (A4R)

This proposal included four principles:

- Publicity (transparency including reasons)
- Relevant reasons (as judged by appropriate stakeholders)
- Revisability (in light of new evidence, arguments, appeals)
- Enforceability (assurance that other conditions are met)

Background to A4R

A4R grew out of a study of managed care decision-making (aimed at coming up with a feasible model in the hardest setting). It was applied to technology assessment, pharmacy benefit design, physician incentives, and scaling up ARTs in developing countries. It is part of the research agenda in Canada, Norway, New Zealand, and various other developed and developing countries and was included in WHO/UNAIDS guidelines on equity.

The case law on A4R counters distrust. In A4R there is a presumption of similar treatment for similar cases. There is a commitment to coherent use of reasons. "Similarity" is defined by reference to reasons and principles. Still, there are also losers in A4R. For instance, although there might be agreement on the nature of relevant reasons, there is still room for disagreement about the weight given to such reasons. There are also losers in procedural democracy: any reasons held by the majority tend to outweigh reasons advanced by the minority. Finally, there are losers in democratic deliberation since only relevant reasons play a role in deliberation, which means that losers may feel that "might makes right".

What is needed, then, is a middle path or union between explicit and implicit principles and reasons. Explicit principles yield transparency about reasons, while implicit principles allow for

the possibility that not all reasons will be agreed upon prior to fair process; rather, decisions will be made at various levels with expert input. This promises the best of both worlds: justifiability and flexibility.

More particularly, with respect to the four principles guiding A4R, Professor Daniels argued that we would have the following check-list:

1. Publicity

Does decision-maker (at whatever level):

- Provide public access to full rationales
- Hold public hearings, wide consultations
- Make rationales comprehensible
- Use stakeholder involvement in generating rationales to promote transparency
- Make public objections from other levels

2. Relevant Reasons

Does Decision-maker:

- Gather relevant evidence,
- Distinguish ethical issues
- Welcome relevant stakeholders to deliberation
- Support, empower stakeholders with info, respect
- Respect disagreements, seek agreement
- Deliberate about process for resolving disputes
- Develop rationales inclusive of points of disagreement
- Give adequate room for local discretion and authority
- Insist on fair process at other levels

3. Revisability

Does decision-maker:

- Invite disagreements from other levels
- Respect need for iterative decision-making
- Assure decision-makers at other levels they have responsibility to raise objections, provide opportunity to do so
- Assure appropriate stakeholders involved in revising decisions

- Provide mechanism for appeals
- Use appeals to improve quality of decision-making?

4. Enforcement

Does decision-maker:

- Make itself accountable to lower levels for carrying out fair process?
- Challenge decisions when fair process missing?
- Seek international agreements and national regulations on elements of fair process
- Seek agreements across levels of decision-making on components of fair process

Deciding about the Universal Benefits Package

Dr. Ezekiel Emanuel, National Institutes of Health

Dr. Emanuel observed that all health care systems in developed countries face the same set of problems: they are inequitable, inefficient, and increasingly unaffordable. Despite the growing cost problem, decision makers at all levels are wary of dealing with costs. Commissions in Europe dedicated to priority setting have downplayed the importance of dealing with cost as a principle. Politicians are understandably loath to tell their constituencies that they cannot get every medical treatment they want.

The System of the Future

Through many different paths and after trying many alternatives, all developed countries will converge on a similar health care system. This will be a social insurance system with market elements where delivery of health care services will be organized into larger integrated groups that are held accountable for outcomes and performance. The systems will have the following characteristics:

1. A universal benefit package (UBP) for all citizens (extensive but not comprehensive).
2. The UBP will be tax financed.
3. A close link between tax level and benefit level (i.e. along with point [4] below, the rich and those willing to devote more of their own personal resources will get more health care services than others).
4. Individuals will be able to purchase additional services and/or amenities with their own funds.
5. Delivery will be through larger integrated groups that can collect and process information on patient outcomes and quality of care.
6. It will include technology assessment to develop and analyze objective data on outcomes, performance, and impact of medical interventions.

The fundamental policy, economic, and ethical question that must be answered by all health care systems will be: What services will be in the Universal Benefit Package? The short answer is that the UBP will contain all effective medical services – the definition of “effective services” are those services that improve quality of life or longevity.

Unfortunately, a comprehensive UBP will be impossible in the near future, primarily because it will be too costly. The concern with building a UBP under this definition is that expensive treatments can also improve quality or quantity of life. The challenge, then, is to get value for money – not to pay for every improvement in quality or quantity of life no matter how much.

Ethics and the Universal Benefits Package

Problems of justice arise because we have limited resources. Society cannot provide for all the needs and desires people have and thus society must choose between health care and education or the environment or social security (amongst other priorities). Moreover, within health care we must choose which services to guarantee and which to leave to individuals. Providing less than a comprehensive UBP is not only necessary in the sense that developed societies cannot afford to provide everything, it is just and ethical. This means that we should **not** apologize or feel bad about not being able to provide all services. Rather, we should feel that we are acting ethically within the constraints imposed on us.

Substantive Principles

Dr. Emanuel asked what principles might guide us in making allocation decisions about health care resources. He traced the development of such principles, beginning with the utilitarian principle of cost-effectiveness analysis (CEA). He felt that it was attacked for the “usual” anti-utilitarian reasons:

- It did not take account of the distribution of benefits and burdens.
- It emphasized saving lives—longevity—and greater numbers of people.

However, what is sometimes overlooked are its advantages. For example, a CEA cut-off of say \$60,000 per QALY is useful because it sends a signal to developers of new medical technologies about what to pursue and how to allocate investment dollars. This forces a change in investment strategy away from expensive interventions in favour of effective ones.

Other substantive principles for defining a UBP failed because they faced a dilemma – either they were insufficiently specific to actually guide policymakers in allocating resources; or they were too specific, in which case they were not neutral but highly controversial. In response to this dilemma, Norman Daniels proposed the Principle of Fair Equality of Opportunity:

Citizens should be guaranteed medical services needed to maintain, restore, or compensate for the loss of normal species-typical functioning and thereby guarantee people have a fair opportunity to pursue their personal life plans.

This principle was attractive because it provided for comprehensive benefits. However, it failed to be sufficiently specific to guide policymakers on key questions, such as how to choose between the few with serious health problems or the many with less serious health problems, or between those with high probability of improvement or those with lower but not zero probability of improvement. There is no consensus on substantive principles to guide the allocation of health care benefits. No substantive principles have proven to be sufficiently comprehensive to address all benefits and specific to guide decisions about which benefits to include.

Procedural Principles

Due to the failure of any substantive principles, theorists have replaced them with procedural principles for the just allocation of health care resources. To this end, Daniels and Sabin proposed the principle of Accountability for Reasonableness based on four principles:

Publicity; Relevance; Appeals; Oversight

There are problems, though, with these principles as well. For one thing, they are controversial: they embody one conception of deliberative democracy and the very conception itself is controversial. In addition, they are incomplete—they fail to include empowerment of citizens, although Daniels and Sabin have begun to discuss public “engagement.” Furthermore, there is a second sense in which the principles are incomplete, and that is that procedural principles themselves will always require substantive principles for the actual decisions. Thus, if policymakers are to justify decisions based on relevant criteria, then they will need to invoke substantive principles or values of some kind for the justification. These will be controversial. For example, publicly disclosing relevant reasons inherently means citing values to justify decisions. This requires weighing or emphasizing certain values over others, and this is not consistent with neutrality.

To use an example, faced with these problems, how should a hospital board decide on whether to include or exclude Avastin—a new agent for the treatment of metastatic colon cancer for patients who were not previously treated? The relevant facts are as follows:

- It prolongs median survival by about 5 months from 15 to 20 months.

- It costs about \$11,000 for 8 weeks of treatment.

Or how should a board decide on including or excluding ICSI—intracytoplasmic sperm injection?

- It produces fertilized eggs for couples where the man produces few fertile sperm.
- It costs about \$12,500 per treatment.

Policymakers deciding on the UBP will have to justify publicly whether such prolongations of life or fertility treatments are “worth it”. Policymakers will have to invoke some substantive principles. These principles will weigh some values over other values, such as the value of reproduction or the value of longevity.

Preliminary Conclusions

Dr. Emanuel’s first conclusion is that policy makers ought to embrace controversy. There is — and always will be — disagreement about what to include in the UBP. Disagreement is inherent because of pluralism, which is to say, people value many diverse things and weigh these values differently. Thus, rather than fighting the fact that allocation decisions will be controversial we should acknowledge it as inherent and embrace it. As a result, we need a procedure to permit diverse UBPs within one society.

His second conclusion is that the shift between procedural and substantive principles is illusory. Any mechanism to decide the UBP will incorporate both procedural and substantive principles. This is not an “either/or” situation; rather, it must be a “both/and” situation.

His third conclusion is that we ought to embrace pragmatism. All methods to decide UBPs have deficiencies — that is, have failed thus far — and this leads one to be sceptical that any one method will work. As a result, the best approach is to be practical — make the decisions in an active, iterative process.

How, then, to proceed? Dr. Emanuel suggests that we begin with the fairly generous benefit package people now get and closely link it to taxes ear-marked for health care. As tax receipts lag behind escalating medical costs, limits on services will be required. But cuts will not be all at once. In his view, the basic procedural principles are clear: they are Daniels and Sabin’s four principles of publicity, relevance, appeals, and oversight with the addition of an important fifth principle: empowerment. Empowerment requires two things:

1. Ability to select a UBP that fits (not necessarily perfectly but closely) with one's values;
2. Ability to influence and shape the deliberations about what is in the UBP.

Selection of a UBP that fits with one's values can be achieved relatively easily through market mechanisms. As delivery will be through larger integrated groups, it is possible to have diverse UBPs — different packages for each group. Dr. Emanuel accepts that this proposal has deficiencies in that it makes it harder for consumers to compare different groups and makes a loophole for adverse selection. One partial solution to these problems is to change from annual enrollment to a 3 year enrollment. This makes people and insurance companies stay with one group over time and live with actual decisions.

In contrast, Dr. Emanuel notes that providing mechanisms to shape deliberations about a UBP is more difficult. Doing so requires procedures for input, such as: surveys, advisory councils, CHAT activities, and fora to discuss trade-offs. Participation in these events will only work if people see them as actually linked to concrete decisions about the UBP. In addition, the procedures must be iterative and decisions will have to be actively revised regularly and periodically.

Substantive Principles

Different UBPs will emphasize different values and be publicly justified by invoking the importance or lower importance of certain values. There will be no clear comprehensive set of substantive principles; rather, according to Dr. Emanuel, the principles will be emergent. For example, Martha Nussbaum identifies 10 central functionings, among which are:

- Life – not to die prematurely
- Bodily health – to be free from disease and injury
- Bodily integrity - freedom of mobility and reproduction
- Cognitive functioning
- Emotions – not depressed or anxious
- Practical reasoning – cognitive reasoning
- Affiliations – engage in social interaction and do productive work
- Other species – connected to animals and nature
- Play – control over one's environment

These are what Dr. Emanuel called “*threshold functionings*”. We want to get people to a minimal level of functioning. Each of the above items is a separate functioning, but ideally we want to

realize all of the 10 functionings. We are not satisfied by having more of one while being below the threshold for others. Nevertheless, not all the functionings need to be weighed the same. In particular, Nussbaum emphasizes affiliation and practical reason as “first among equals” but others might emphasize life and bodily health. More generally, some UBPs may emphasize reproduction, others mobility, others longevity, others cognitive faculties, others more risk taking, etc., while others may emphasize health care over other goods, requiring higher outlays by members. Over time we will become clearer about the threshold and how important these different functionings are relative to each other.

The attraction of this method is that it allows people to choose between different services based on whether the services achieve the threshold of the functionings that are important to them.

Final Conclusions

It is a mistake to feel guilty or apologetic for not being able to provide a comprehensive benefits package to everyone. Rather, what is important to recognize is that rationing is the just and ethical thing. Restraining health care costs is a good, not a bad, thing. To be sure, what should be included in a UBP is inherently controversial. But this simply shows that we need multiple UBPs.

In short, we need a set of both procedural and substantive principles, where **empowerment** is the key procedural principle and where linking functionings to services is the key to delineating the substantive principles.

Workshop Concluding Remarks –

Professor Arthur Ripstein, University of Toronto

The workshop closed with remarks from Professor Arthur Ripstein from the Faculty of Law. Professor Ripstein voiced the opinion of all who attended in praising the presentations of all the speakers over the two day workshop. He noted the generous support of Health Canada and the Department of Philosophy in holding this event and thanked Greig Hinds, the Project’s Research Manager, for his efforts in organising the workshop. Professor Ripstein thanked all the attendees for their participation and wished everyone a safe journey as they departed the venue.