University of Alberta

SOCIAL VALUES AND THEIR ROLE IN ALLOCATING RESOURCES FOR NEW HEALTH TECHNOLOGIES

by

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ABSTRACT

Every healthcare system faces unlimited demands and limited resources, creating a need to make decisions that may limit access to some new, potentially effective technologies. It has become increasingly clearer that such decisions are more than technical ones. They require social value judgements - statements of the public's distributive preferences for healthcare across the population. However, these value judgements largely remain ill-defined. The purpose of this thesis was to explicate distributive preferences of the public to inform funding/coverage decisions on new health technologies. It contains six papers. The first comprises a systematic review of current coverage processes around the world, including value assumptions embedded within them. The second paper presents findings from an expert workshop and key-informant interviews with senior-level healthcare decision-makers in Canada. A technology funding decision-making framework, informed by the results of the first paper and the experiences of these decision-makers, was developed. Their input also highlighted the lack of and need for information on values that reflect those of the Canadian public. The third paper provides a systematic review of empirical studies attempting to explicate distributive preferences of the public. It also includes an analysis of social value arguments found in appeals to negative coverage decisions. From the results of both components, possible approaches to eliciting social values from the public and a list of factors around which distributive preferences may be sought were compiled. Such factors represented characteristics of unique, competing patient populations. Building on findings from the third paper, the fourth paper describes a citizens' jury held to explicate distributive preferences for new health technologies in Alberta, Canada.

The jury involved a broadly representative sample of the public, who participated in decision simulation exercises involving trade-offs between patient populations characterized by different combinations of factors. A list of preference statements, demonstrating interactions among such factors, emerged. The fifth and sixth papers address methodological issues related to citizens' juries, including the comparability of findings from those carried out in the same way but with different samples of the public, and the extent to which they changed the views of individuals who participate in them.

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INTRODUCTION

In Canada and other countries around the world, healthcare systems face competing demands and resource constraints. As a result, there is a need to set priorities, which inevitably limits access to some potentially beneficial health services.[1,2] Within the last five years, issues around access to "high quality cancer care", in particular, have heightened in Canada, fuelled in part by growing availability and public awareness of new technologies that offer improved diagnostic and therapeutic options.[3,4] Such issues, highlighted through the media and political processes, have primarily pertained to timeliness of access, equity in access, or access to promising, new, high cost technologies championed by physicians, patients, and manufacturers.[5] [6-9] Reports of a general lack of public confidence in resource allocation decisions for healthcare have also emerged, further increasing pressure on policy-makers to establish funding/coverage processes that may be deemed legitimate and fair by stakeholders.[10-12]

Over the past decade, efforts to improve decisions around which health services to provide, and for whom, have largely focussed on determining requirements for clinical and economic evidence.[13-18] However, it has become widely recognized that underlying all such decisions are social value judgements – statements of the public's preferences for the distribution of health resources across competing patient populations.[19-21] Often, these judgements remain ill-defined, and evidence of what they comprise is limited.[22,23]

The purpose of this thesis is to explicate social values to inform resource allocation decision-making around new health technologies in Alberta. It contains a series of six sequential papers, each building upon the previous ones. Collectively, the papers examine

the place of social values within current coverage processes and what they might comprise.

The first paper addresses the question, "How are funding decisions on new health technologies currently made in Canada and abroad?" Awareness of existing processes, criticisms faced, and approaches used to manage them was seen as an important first step in identifying any value assumptions already implicit in decisions.

Building on the first paper, the second paper presents a technology funding decision-making framework informed by the experiences of multiple healthcare systems and the views of senior-level decision-makers in Canada. It identifies the points at which value judgements come into play. It also highlights concerns of decision-makers over the lack of and need for information on distributive preferences of the Canadian public.

The third paper addresses two questions: "On what factors/patient characteristics have distributive preferences of the public been sought?", and "What methods have been used to elicit social values or deliberative preferences of the public for resource allocation decision-making in healthcare?". It provides a comprehensive review and critical appraisal of relevant published empirical studies, identifying important gaps in the evidence accumulated to date. It also examines social value claims made in appeals to actual decisions as a means of ensuring that the review captured those already affecting the allocation of resources.

Drawing on findings from the third paper, the fourth paper describes attempts to answer the question, "What are the preferences of the public for the distribution of health

services across the population?", using a citizens' jury. Citizens' juries offer an approach to seeking informed public views on complex issues, such as the allocation of resources for healthcare. Through a series of decision simulation exercises involving trade-off questions, the interactions among factors that shape distributive preferences were identified and a set of social value statements was generated.

The fifth and sixth papers focus on methodological questions related to citizens' juries. The fifth paper explores the comparability of findings from two citizens' juries carried out in the same way but with different samples of the public. A mixed methods approach was used, combining statistical measurements of agreement and qualitative constant comparison techniques. The scarcity of information comparing findings from different juries designed to address a common question has been cited as one of the main reasons for its limited use in healthcare policy environments.[24] The sixth and final paper explores the impact of deliberative processes on the views of participants. It has been argued that such processes offer an opportunity to elicit informed, rather than uninformed, opinions. However, the extent to which jurors' views change following participation in a citizens' jury and are sustained over time is not known. This information is needed in order to assess the broader value of this approach over less resource intensive alternatives. Findings from quantitative analyses and follow-up interviews with jury participants are presented.

Thus, collectively, these papers 1) define the current state of the science regarding social values in resource allocation decision-making for new health technologies and 2) provide new insights into the complexity of distributive preferences of the public and the

methodological issues precluding more widespread use of deliberative processes for eliciting such preferences.

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CHAPTER 1:
HEALTH TECHNOLOGY FUNDING DECISION-MAKING PROCESSES AROUND THE WORLD: THE SAME, YET DIFFERENT

ABSTRACT

Introduction:

All health care systems routinely make resource allocation decisions which trade off potential health gains to different patient populations. However, when such trade-offs relate to the introduction of new, promising health technologies, perceived 'winners' and 'losers' are more apparent. In recent years, public scrutiny over such decisions has intensified, raising the need to better understand how they are currently made and how they might be improved.

Objectives:

To critically review and compare current processes for making health technology funding decisions at the regional, state/provincial, and national level in 20 countries around the world.

Methods:

A comprehensive search for published, peer-reviewed and grey literature describing *actual* national, state/provincial, and regional/institutional technology decision-making processes was conducted. Information was extracted by two independent reviewers and tabulated to facilitate qualitative comparative analyses. To identify strengths and weaknesses of the processes identified, websites of corresponding organizations were searched for commissioned reviews or evaluations, which were subsequently analysed using standard qualitative methods.

Results:

Twenty-one national, four provincial/state, and six regional/institutional level processes were found. Although the information on each one varied, it could be grouped into four sequential categories: 1) Identification of the decision problem; 2) Information inputs; 3) Elements of the decision-making process; and 4) Public accountability and decision implementation. While the information requirements of all processes appeared to be substantial and decision-making factors comprehensive, the way in which they were utilized was often unclear, as were the approaches used to incorporate social values or equity arguments into decisions.

Conclusions:

A comprehensive inventory of approaches to implementing the four main components of all technology funding decision-making processes was compiled, from which areas for future work or research aimed at improving the acceptability of decisions were identified. They include the explication of decision criteria and social values underpinning processes.

INTRODUCTION

All publicly-funded healthcare systems face competing demands and resource constraints. Thus, they routinely make limit-setting decisions, the consequences of which are trade-offs in potential health gains to different groups of individuals.[1-3] However, when such decisions relate to the introduction of new health technologies (e.g., pharmaceuticals, devices, diagnostic tests, procedures), the perceived 'winners' and 'losers' are more apparent.[4] In recent years, media reports of failed attempts by patients to gain access to promising new technologies from which they may benefit have become commonplace in Canada, and public scrutiny over how funding decisions are made has heightened.[1-3,5-8] As a result, decision-makers, charged with ensuring prudent and principled use of scarce resources, find themselves under increasing pressure to improve the acceptability of such processes.

The challenge of determining which new health technologies to include in the basket of publicly insured services is a shared one. Therefore, insights into *actual* decision-making processes in various jurisdictions around the world, the criticisms they have faced, and approaches used to manage them may serve as an important guide for healthcare systems considering options for revising their processes to improve the acceptability of decisions.

OBJECTIVES

1. To compile an inventory of actual processes for making funding/coverage decisions on new health technologies at the institutional/regional, provincial/state and national level in different publicly funded health care systems;
2. To examine similarities and differences across processes on key elements; and
3. To critically review criticisms faced and mechanisms used to remedy them.

METHODS

Creation of an inventory of current resource allocation decision-making processes for new technologies

1. Search for relevant literature

A comprehensive, systematic search was conducted for relevant information available in the public domain. To locate peer-reviewed, English language literature published as of January 2010, a structured search strategy that combined controlled vocabulary terms (MeSH and EMTREE) (e.g., "decision making"; "policy making"; "resource allocation"; and "health care rationing"; "decision-making, organizational", etc.) with free text terms related to the introduction or coverage of new technologies (e.g., funding, coverage, reimbursement, etc.) was first developed.[9,10] Search terms were identified through an analysis of words used to index known key references (i.e., citation pearl growing),[11] and a workshop involving members of the multidisciplinary investigative team for the research program through which the project was funded. The search strategy was applied to the following biomedical, health research, social sciences, and economics

databases: PubMed, MEDLINE, EMBASE, HealthSTAR, CINAHL, EconLit, PASCAL, SCOPUS, International Pharmaceutical Abstracts, Web of Science, and the UK Centre for Reviews and Dissemination (CRD) databases (DARE, NHS EED, and HTA). To increase the likelihood of identifying information that accurately reflected *current* processes, a publication limit of 2005 or later was applied. Lastly, updated scans of the same databases using the same search strategy were performed monthly in order to capture any papers published between January 2010 and June 2010.

For comprehensiveness, the electronic search was supplemented by a manual search of reference lists of retrieved papers and the most recent issues of health policy journals.

A search for unpublished or "grey literature" (i.e., that not published in peer-reviewed journals, for example, working papers, reports, conference abstracts, presentations, meeting proceedings, etc.) was also conducted. This involved a series of Internet searches in which free text terms from the main search strategy (see Appendix 1-1) were used with the Google search engine. In addition, several databases containing grey literature were searched, including the Grey Literature database (New York Academy of Medicine), KU-UC database, Systematic Reviews for Management and Policy Making (PPD/CCNC database), and NHS Evidence: Evidence in Health and Social Care. Separate searches for information on technology decision-making processes established in health care systems of the

top 20 countries ranked according to Gross Domestic Product per capita by the World Bank and with populations over 1 million were also performed.[12] Specifically, websites of corresponding ministries of health (translated into English using Babylon® translation software, where necessary) were scanned for documents outlining policies and/or processes for making coverage/funding decisions on new health technologies, such as pharmaceuticals, devices, diagnostic tests, and procedures.

Citations from the various searches were imported into a bibliographic database using Reference Manager® (version 11.0) software.

2. Selection of papers for inclusion in the inventory

Adhering to widely cited, published guidelines for conducting systematic reviews, the titles and abstracts of all citations were first screened independently by two researchers (experienced in applying such guidelines) using pre-determined inclusion criteria.[13] Those unrelated to the introduction of individual health technologies (e.g., macro-level priority-setting processes for allocating resources across programs) were excluded, along with abstracts presenting tools used to support decision-making or discussing one component of decision-making (e.g., collection of clinical evidence). Papers corresponding to citations deemed potentially relevant were retrieved for full review. Any disagreements between reviewers were resolved through discussion, and if necessary, third party

adjudication. The degree of agreement between researchers was assessed using the Kappa statistic, with K=1.0 indicating perfect agreement.

3. Extraction of information from included papers

Information from selected documents/papers was independently extracted by the same two reviewers using a standardized, pre-tested data abstraction form. The form comprised process-related elements thought to influence coverage or reimbursement decisions: 1) type of technology (e.g., pharmaceuticals, devices, diagnostic tests, interventional procedures, etc.); 2) available decision options (e.g., fund, do not fund, or fund with conditions, etc.); 3) evidence requirements (e.g., controlled clinical trials, economic evaluations, etc.); 4) ethical considerations and equity and efficiency assumptions; 5) any pre-defined decision criteria or rules; 6) role of different stakeholders; 7), decision-making committee structure and governance, and 8) public accountability mechanisms (e.g., public access to decisions and rationale, appeals processes, etc.).[14-18] To verify the accuracy of data collected on each resource allocation decision-making process identified through the literature search, a series of 'member checks' (in which individuals who contributed information are asked to review results to ensure they correctly reflect such information) were performed with corresponding authors, 'contact persons' noted on organizations' websites, and policy experts known to members of the research team.[19]

4. Synthesis of information collected

Information extracted was summarized in tabular form to identify any patterns or trends across decision-making processes, and analysed qualitatively using content analysis and constant comparison techniques.[20]

Identification of issues related to existing processes

1. Search for relevant literature

Papers/documents located through the main literature search (above) were also scanned independently by two reviewers to identify reported strengths and weaknesses of processes comprising the inventory. In addition, individual searches of websites of corresponding organizations were conducted to identify commissioned or official reviews/evaluations of each process.

2. Synthesis of information collected

Papers/documents on each process were analysed separately using content analysis. Emerging themes relating to strengths, achievements, or successes, and weaknesses or challenges were noted. For each process, information collected was sorted chronologically (by publication date) to identify possible mechanisms used to manage any criticisms.[19]

RESULTS

Review of existing resource allocation decision-making processes for new technologies

The initial literature search yielded more than 3,500 discrete references, of which approximately 200 met the study's inclusion criteria. The majority represented "grey literature", comprising government commissioned evaluations or reviews, manufacturer submission or application procedures, organization-specific guidance for the assessment of technologies, policy documents, and presentations. Papers located within the peer-reviewed literature were typically commentaries on existing processes or elements of them (e.g., the use of cost-effectiveness thresholds).

Thirty examples of funding/coverage decision-making processes for new technologies were identified: 24 at the national level, four at the provincial/state/county level, and two at the institutional level.[21-229] Information found broadly related to 1) the decision problem itself (Table 1-1); 2) evidence inputs (i.e., topics to be addressed by materials feeding into the decision-making process) (Table 1-2); 3) the actual decision-making process (i.e., steps involved and criteria applied) (Table 1-3); and 4) implementation of the decision (i.e., public accountability mechanisms) (Table 1-4).

Specifications of the decision problem

1. Technology type

Just over half (17/30) of the processes pertained exclusively to new pharmaceuticals (primarily prescription). Of the remaining 13 processes, seven were used to make funding decisions on non-pharmaceuticals only (e.g., devices, diagnostic tests, procedures, etc.) while six spanned both pharmaceutical and non-pharmaceutical technologies.

2. Selection of technologies for review

In one third of the processes, technologies considered were those submitted by manufacturers seeking reimbursement/coverage as an insured "service". In two cases, technologies (pharmaceuticals) automatically entered the funding decision-making process upon receipt of market approval (Norway and Scotland). Four processes accepted technology referrals from anyone (e.g., patients and carers, health care providers, administrators, manufacturers, the public, etc.), and had established prioritization or selection criteria for determining those that would undergo review (United Kingdom (UK), United States (US), Alberta, and Washington State). Such criteria typically included: 1) potential health impact (i.e., whether the technology represents a significant clinical advance that will likely yield substantial health benefits); 2) potential impact on resources (i.e., whether the technology could result in significant cost-savings or expenditures); 3) policy importance (extent to which implementation of the technology aligns with government priorities); and 4) degree of uncertainty around appropriateness

of use (e.g., patient selection, training and facility requirements, etc.). The remaining processes reviewed technologies identified by payers (government or insurers) or health care providers.

3. Decision options

Almost all of the processes considered the following three funding decision options: 1) provide the technology; 2) do not provide the technology, or 3) provide the technology with conditions (i.e., restrict use to certain providers or patients). In addition, one third of the processes had introduced a fourth option, 'provide with data collection'. Commonly called "Access with Evidence Development (AED)", this option takes the form of a provisional coverage arrangement where interim funding is granted to facilitate the generation of evidence needed to support a definitive coverage decision.[230] There are primarily two types: 1) those in which payers provide interim funding for a technology within a clinical study that is designed to collect the information needed to reduce decision uncertainties (coverage as part of a clinical study); and 2) those based on an outcomes guarantee implemented through contractual arrangements between payers and manufacturers (coverage tied to outcomes guarantee). Because the latter aim to distribute accountability and risk involved in decisions across both parties (i.e., supplier and purchaser), they have collectively been referred to as "risk sharing schemes". With one exception (US), processes that featured the first AED option (coverage as part of a clinical study) managed the introduction

of non-pharmaceutical technologies. In contrast, those employing risk-sharing schemes made funding decisions on pharmaceuticals only.

4. Role of stakeholders

Potential opportunities for engagement of stakeholders (i.e., patients, carers, health care providers, payers, administrators, manufacturers, and the public) in activities related to specification of the decision problem include referral and prioritization/selection of technologies for review. While one third of processes accepted topics from multiple stakeholders (and in some cases, from anyone), only one (UK) involved them in determining which technologies to review.

Information inputs into the decision-making process

1. Information inputs

Regardless of technology type and jurisdictional level of the process (national, state/provincial, or institutional), the following information was required: 1) indications for the technology and "therapeutic claim"; 2) summary of relevant patient populations (including burden and severity of disease, as well as incidence and prevalence); 3) description of current standard management (including proposed place of the technology in existing care pathways); 4) studies demonstrating safety, clinical efficacy and effectiveness (across subgroups); and 5) an analysis of resource implications (costs, at minimum). With respect to clinical evidence, most processes considered all randomized controlled trials (RCTs), non-RCTs, and observational studies comparing the technology to

standard care, but stated a strong preference for high quality, head-to-head RCTs. Regarding economic evidence, two thirds required some form of budget impact analysis. Although economic evaluations complying with published guidelines were mandatory in 24 of the 28 national and provincial/state level processes, the type was not stipulated (except in the cases of the UK and The Netherlands). In general, the comparator required was the most commonly used alternative technology. However, the perspective for the evaluation varied across processes, with half using that of the payer and half specifying a societal one.

Information inputs unique to pharmaceutical coverage decision-making processes, but not required by all those examined, were market share, reimbursement status, and price comparisons.

2. Sources of information

Responsibility for compiling evidence to comprise the information inputs rested with either the requestor of the technology (i.e., the applicant) or the decision-making organization. In cases where decision-making organizations undertook such syntheses, the scope often included multiple indications for one technology or multiple technologies for one indication, taking a disease management approach (i.e., multiple technology appraisal). Topics, which spanned all technology types, were identified by stakeholders other than the manufacturer(s) of the technology. The reviews/assessments, themselves, were typically commissioned to independent, academic groups with methodological expertise in

performing systematic reviews and economic analyses. Where manufacturers prepared evidence syntheses (e.g., single technology appraisals), an evaluation or critical appraisal of material submitted was conducted by either internal staff of the decision-making organization or an external academic group.

One third of the processes reported involving stakeholders in the collection and synthesis of information. Among them, over half (six) invited patients, carers, and healthcare providers (either individually or through organizations/associations) to provide written "testaments" of their experiences with the condition and/or technology, while four accepted submissions from anyone (facilitated through the respective decision-making organization's website). In addition, four of the processes sought advice from health care providers (clinical experts) and three consulted patients (nominated by relevant patient or consumer organizations) during the preparation of assessment or evaluation reports. With two exceptions (multiple technology appraisals processes in the UK and France), manufacturer involvement appeared limited to commenting upon draft reports and responding to questions from those conducting the assessment or evaluation.

Elements of the decision-making process

1. Advisory or decision-making committee membership

In all processes, an appointed, multi-disciplinary committee was tasked with making technology funding recommendations or decisions. Where reported, committees consisted of seven to 25 members, representing, at a minimum, payers

(e.g., government, health regions, insurance funds, etc.) and health care providers (primarily physicians). In addition, the majority contained academics with methodological expertise in relevant areas, such as health economics. Nearly half involved patient or public representatives, but not always as voting members. Similarly, only two of the four committees that included industry/manufacturer representatives did so as voting members (Scotland and the UK). Based on findings from qualitative subgroup analyses, neither committee size nor breadth of membership appeared to vary with technology type or jurisdictional level. In almost all of the processes, committees served as advisory bodies, making recommendations to a higher authority rather than decisions.

2. Steps in decision-making process

In general, processes shared the following basic steps: 1) identification of a technology for review (as described above); 2) coordination of review materials (information inputs) by the Secretariat to the advisory/decision making committee; 3) internal or external evaluation of applicant's submission or preparation of full assessment; 4) distribution of emerging report(s) to manufacturers and, in some cases, other stakeholder groups for comment; 5) committee meeting to deliberate over information inputs (which may include in-person presentations from invited clinical and/or patient experts, in addition to reports, feedback collected, and any other information submitted) and formulate recommendation(s); 6) communication of provisional recommendations to the manufacturer (at a minimum); 7) finalization of recommendations, taking into

account responses received; and 8) if applicable, submission of recommendations to the decision-maker for approval. The main differences related to the inclusiveness of processes (i.e., the extent to which attempts were made to capture comprehensive information on both the value and relative value of the technology). Several created technology specific, multi-disciplinary expert advisory panels for each review (e.g., Alberta, Australia, and the UK). Others consulted working groups and/or standing clinical or methodological sub-committees (e.g., France and Australia), and one held committee meetings in public to solicit the views of all "interested parties" (Oregon). Importantly, the degree of inclusiveness did not vary according to technology type or jurisdictional level.

3. Decision-making criteria/factors

Criteria common to all advisory/decision-making committees included: 1) clinical need (informed by severity of the condition, burden of illness, and availability of already funded, alternative interventions/therapies); 2) health impact (i.e., benefits versus harms (ratios) derived from evidence of safety, efficacy, and effectiveness compared to current care); and 3) affordability (budget impact, taking into account the number of patients expected to receive the technology and per-patient costs over the duration of its use, as well as other resource implications). While most committees also considered 'value for money' (efficiency), they differed in their approach to assessing or defining it. Close to one third referred to an incremental cost-effectiveness ratio (ICER)

threshold in determining whether a technology represented an efficient use of health resources. Briefly, an ICER is the ratio between the difference in costs and the difference in benefits of two technologies, where costs and benefits are measured in monetary units and quality-adjusted life years (QALYs), respectively. An ICER threshold comprises a point below which an ICER corresponding to a technology should fall in order for that technology to be deemed cost-effective or good 'value for money'. In such processes, committees were guided by, but not restricted to, the threshold when formulating recommendations or decisions. The acceptability of ICERs above the threshold depended upon uncertainties in estimates of outcomes, the severity of the condition, nature of the technology, and wider social benefits (e.g., The Netherlands, Scotland, Wales, etc.).

Information on assessment of 'value for money' by the remaining committees (i.e., those which had not implemented ICER thresholds) was limited to single statements, such as "reasonableness of price relative to therapeutic value", "cost-effectiveness", "efficiency", " ICERs of already funded programs", and "rationalization of public pharmaceutical expenditures". Similarly, 'social and equity' considerations formed a decision criterion in six of the processes, but no information describing how it was applied or operationalized by committees could be located. Less common criteria (reported in four or fewer processes) included: 1) alignment with government health-related priorities; 2) feasibility (ease of

implementation); 3) possibility of "off label" use; and 4) innovativeness (potential to encourage innovation).

4. Equity and efficiency assumptions/ethical considerations

Information on the ethical considerations used to guide committee deliberations was limited. One process stated that all decisions were to reflect the following two principles: 1) the "need and solidarity principle" (i.e., patients in greatest need or "worse off" must be given priority); and 2) the "human value principle" (i.e., characteristics of patients, such as age, gender, social position and income, must not influence decisions) (Sweden). A second process also reported adopting a 'solidarity' principle (Norway). A third referred to efforts to develop a "social benefit measure" (France); however, no further details were found. Ethical considerations among remaining processes with information available pertained to equity assumptions underpinning the use of ICERs, in which each QALY gained carries the same weight, regardless of the characteristics of patients receiving it (e.g., age, gender, social status, income, health condition, etc.). To capture societal values around solidarity, such processes had established 'exception' conditions under which the normal efficiency assumptions would not need to be met. They related to 'last chance' technologies (i.e., those used to treat severe conditions for which there are no alternatives beyond best supportive care (e.g., many of the "ultra-orphan" conditions), and "life-extending, end-of-life treatments"(UK)). In such circumstances, not all QALYs are viewed as equal.

Rather, a form of 'solidarity' premium is applied so that, for example, QALYs gained in the later stages of disease are given greater weight.

5. Role of stakeholders

Reported approaches for gathering stakeholders' views during decision-making, beyond the use of multidisciplinary committee structures, included opportunities to: 1) present to the committee; 2) attend and participate in public committee meetings; and 3) provide comments on provisional recommendations. Across all of the processes, only two accepted unsolicited presentations by anyone (US), although two others invited presentations from patients and health care providers (The Netherlands and the UK). Only one of the processes held full committee meetings in public and welcomed input from attendees (Washington State). In contrast, almost one third sought feedback on preliminary recommendations from stakeholders other than the manufacturer.

Public accountability and decision implementation considerations

1. Transparency

In general, decisions and rationales were publicly accessible through the organizations' websites. However, the level of detail provided varied. Two thirds of the processes also made the assessment or evaluation reports available. Those that did not were exclusively pharmaceutical-based.

2. Appeals mechanisms

Formal mechanisms for appealing recommendations or decisions had been established in two thirds of the processes. Of these, one third permitted appeals related to process ("failed to act in accordance with processes" and recommendations/decisions considered "perverse" in light of the evidence) and scientific disputes (disagreements over interpretation of the evidence), and one third accepted only those related to process. In the remaining one third, grounds for launching appeals were not specified. Where reported, appeals were typically heard by an expert panel appointed by the respective health care organization. In only one process could individuals other than the applicant file an appeal (UK).

3. Reassessment or review of decisions

In the majority of processes, positive funding decisions were reviewed "regularly", with time periods ranging from one and a half to five years after the initial decision. Other processes reassessed decisions when new evidence became available (e.g., Scotland, Sweden, and Wales), or in follow-up to a 'provide with data collection' decision (e.g., Australia and Italy).

4. Conditions of implementation

With the exception of national level processes in the United Kingdom, Ireland, and the United States, no information on time frames for implementation of a decision were found. In these processes, funding for technologies was to be made available within 90 days, 40 days, and 180 days, respectively.

Identification of issues related to existing processes

Criticisms, which mainly emerged from government-commissioned evaluations of processes and published commentaries, included: 1) timeliness; 2) methodological considerations; 3) explication of social values; 4) stakeholder engagement; 5) transparency; 6) contestability; 7) accountability; and 8) consistency.

1. Timeliness

The overall length of time required by a process (i.e., from submission to decision) was often viewed as excessive and a barrier to access.[79,84,231-233] Delays were generally attributed to the time needed to conduct comprehensive, independent assessments of the technology. Approaches used to address this issue included: 1) implementation of "expedited" review procedures for "highly innovative" technologies or those for treating life-threatening illnesses (e.g., Canada, France and The Netherlands); 2) increased reliance on information submitted by the applicant (i.e., less externally conducted full assessments, e.g., the UK and France); and 3) application of interim funding arrangements linked to access with evidence development (AED) mechanisms (e.g., France, Italy, Ontario, Sweden, and the US).

2. Methodological considerations

Criteria for assessing economic implications have generated significant debate.[232] For the most part, such debate has focussed on 'affordability' versus 'cost-

effectiveness'. It has been argued that it "makes little sense" to adopt an efficiency goal without considering budget impact, since a technology can be cost-effective but unaffordable when the number of individuals expected to receive that technology is taken into account.[231,234-236]

The absence of an 'affordability' criterion in some processes has frustrated payers who must implement decisions made by a committee with no budgetary accountability.[231] In response, such processes have either included budget impact analyses in their evidence requirements (Table 1-2), or incorporated health resource implications into their decision-making criteria. As mentioned above, the use of cost-effectiveness thresholds as measures of value for money has been widely contested by many stakeholder groups over the years. However, the introduction of 'exception' rules in most processes, whereby the threshold is 'waived' in light of important characteristics of the patient population, appears to have alleviated some of the concern.[237]

3. Explication of social values

It has been widely recognized that decisions on which technologies to fund and for whom are value-laden, heightening concerns over the lack of information explicating those values and how they are operationalized. Social value judgements comprise statements of society's distributive preferences for the allocation of health care resources across populations. Therefore, they can offer important insights into the relative value of technologies. To date, efforts by

processes to elucidate social value judgements appear sparse. The review identified two examples, both of which focussed on the creation of citizens' panels (Ontario and the UK). Such panels comprise members of the public who convene to deliberate over a specific issue (e.g., the importance of rarity of a condition versus severity, or whether society is willing to place a premium on technologies to extend life at the end of a terminal disease).[238,239]

4. Stakeholder engagement

Over the past five years, several commissioned reviews have identified the need for more inclusive, repeated consultation, and dialogue with all relevant stakeholder groups to ensure that a full range of perspectives on the value of a technology is captured.[231,232,240] Although many of the processes now, in some way, consult patients/carers and providers, only one has established mechanisms that allow anyone to provide feedback at multiple points in the decision-making process.[224]

5. Transparency

Various stakeholder groups have voiced criticisms over the lack of transparency around criteria, procedures, decisions, and rationales.[169,232,240] One reason cited by processes which do not make public the assessment or evaluation reports is their inclusion of confidential commercial data. While almost all of the processes post decisions and rationale on their websites, the level of detail provided has frequently been viewed as insufficient.[79,232,240,241] Holding committee meetings

fully in public has been suggested, but at present, only one process appears to have implemented such an approach.[224]

6. Contestability

Concerns related to mechanisms for appealing recommendations or decisions have been two-fold. In some processes, no formal mechanisms exist, requiring disputes to be resolved through courts. In those with such mechanisms, panels hearing appeals have not been viewed as truly independent, since their appointment is made by the same organization which oversees the decision-making process.[79] One attempt to address this issue has been retention of a "commissioner" unaffiliated with the same organization to manage appeals.[21,31,42]

7. Accountability

Questions around to whom such processes are accountable and to whom they should be accountable have been raised. But, no clear attempts to resolve them were identified.[231,233,242]

8. Consistency

Some stakeholders have argued that the "rules of the game" are often "unpredictable", and stressed the importance of precedence in achieving procedural fairness.[169,231,232,242] With the exception of policies introduced to improve transparency, no information on specific approaches aimed at alleviating such concerns was found.

DISCUSSION

To our knowledge, this paper, while limited to information available in the public domain, offers the first structured, international, comparative review of pharmaceutical and non-pharmaceutical technology coverage decision-making processes across different jurisdictional levels. It highlights key similarities and differences, few of which were found to be related to technology type (i.e., pharmaceuticals versus non-pharmaceuticals). In general, all processes comprise four, sequential components, which begin with specification of the decision problem and end with implementation of the decision. They involve multi-disciplinary advisory or decision-making committees who review a minimum common set of information inputs. Requirements for input beyond this set appeared to be related to the 'place' of the process within the regulatory and pricing systems. For example, those linked to pricing typically requested market share forecasts, and those financially accountable for fixed budgets required budget impact analyses.

With few exceptions, decision-making criteria comprised lists of factors to be taken into account, rather than precise decision rules. Despite the lack of information on the relative weight of such factors during decision-making, the willingness of committees to make trade-offs between equity and efficiency positions (i.e., sacrifice health gain to reduce perceived inequalities in health) was clear. However, little information on how they accomplish this could be found.

Since it is widely recognized that health technology resource allocation decisions are value-laden, criticisms around the lack of transparent, explicit approaches to incorporating social values or equity arguments into such decisions seem legitimate.

The review demonstrated that stakeholders (primarily patients and physicians) have a role in almost all processes, but the nature of their role (i.e., whether they are engaged or merely consulted and at which points) varies. This may be a reflection of the extent to which different health systems have embraced the notion of stakeholder involvement in decision-making. It could also be associated with time constraints on decisions. Processes incorporating multiple opportunities for stakeholder involvement at multiple points tended to take longer to arrive at decisions. Notably, timeliness of the decision-making process was one of stakeholders' most commonly expressed concerns.

CONCLUSION

By examining technology coverage decision-making processes in many countries, this review presents a comprehensive inventory of approaches to implementing the four main components of all processes. It also highlights areas for future work or research aimed at improving the acceptability of decisions (i.e., the explication of decision criteria and social values underpinning these processes).

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Table 1-1. Specifications of the decision problem

Country	Advisor and/or decision-maker	Type of technology	Selection of technologies	Decision options	Role of stakeholders
National level					
Australia [21-44]	Department of Health and Ageing (decisions) Pharmaceutical Benefits Advisory Committee (PBAC) (recommendations)	• Pharmaceuticals	Technologies may be referred by anyone, but typically manufacturers, health care professional associations/organizations, patient and carer organizations, Department of Health and Ageing, or Health Policy Advisory Committee on Emerging Technologies	• Provide technology • Do not provide technology • Provide technology with conditions (restricted to certain providers or patients) • Provide technology with data collection	Submit technology for consideration: • Patient and/or carer organizations • Health care professional associations • Manufacturers • Government
Australia [23,45-56]	Department of Health and Ageing (decisions) Medical Services Advisory Committee (MSAC) (recommendations)	• Devices • Procedures • Diagnostic tests	Technologies may be referred by anyone, but typically manufacturer, health care professional associations/organization, patient and carer organizations, Department of Health and Ageing, or Health Policy Advisory Committee on emerging technologies Prioritization criteria: • Clinical need • Severity and burden of illness • Disease/condition incidence and prevalence • Current standard treatment • Expected utilization • Likelihood that the technology offers a significant advance in the management of the condition • Costs • Likely benefit of conducting an assessment • Other factors determined by MSAC (e.g., access and equity)	• Provide technology • Do not provide technology • Provide technology with conditions (restricted to certain providers or patients) • Provide technology with data collection	Submit technology for consideration: • Patients and/or carer organizations • Health care professional associations • Manufacturers • Government

Table 1-1. Specifications of the decision problem

Country	Advisor and/or decision-maker	Type of technology	Selection of technologies	Decision options	Role of stakeholders
Austria [57-61]	Association of Austrian Social Security Institutions (HVB) (decisions) Austrian Medicines Evaluation Commission (HEK) (recommendations)	• Pharmaceuticals	New, licensed pharmaceuticals submitted by manufacturer	• Provide technology • Do not provide technology • Provide technology with conditions (restricted to certain providers or patients)	None specified
Belgium [60,62-66]	Ministry of Health and Social Affairs (decisions) Drug Reimbursement Committee (DRC) (recommendations)	• Pharmaceuticals	New, licensed pharmaceuticals submitted by manufacturer	• Provide technology • Do not provide technology • Provide technology with conditions (restricted to certain providers or patients) • Provide technology with data collection	None specified
Canada [26,45,56,67-70]	Canadian Agency for Drugs and Technologies in Health: Common Drug Review (CDR) (recommendation) Participating provincial/territorial pharmaceutical benefit plans (decisions)	• Pharmaceuticals (excluding cancer drugs)	Pharmaceuticals (may be newly licensed pharmaceuticals, new combination products, pharmaceuticals with new indications, those pending licensing, or "old" pharmaceuticals not currently funded through provincial benefit plan) May be referred by: • Manufacturer • Advisory Committee on Pharmaceuticals (ACP) within the Canadian Agency for Drugs and Technologies in Health (CADTH) • Participating provincial/territorial government pharmaceutical benefits plan	• Provide technology • Do not provide technology • Provide technology with conditions (restricted to certain providers or patients)	Submit technology topics for consideration: • Manufacturer • Advisory Committee on Pharmaceuticals (ACP) within the Canadian Agency for Drugs and Technologies in Health (CADTH) • Participating provincial/territorial government pharmaceutical benefits plan

Table 1-1. Specifications of the decision problem

Country	Advisor and/or decision-maker	Type of technology	Selection of technologies	Decision options	Role of stakeholders
			Prioritization criteria: • Typically reviewed in order received unless granted priority status (effective treatment for immediately life threatening condition, pharmaceutical for which there is no comparable product marketed in Canada, or pharmaceutical that could significantly reduce expenditures)		
Denmark [60,71-77]	Danish Medicines Agency (decisions)	• Pharmaceuticals	New, licensed pharmaceuticals submitted by manufacturer for "general" reimbursement	• Provide technology • Do not provide technology • Provide technology with conditions (restricted to certain providers or patients)	None specified
Finland [78-83]	Pharmaceuticals Pricing Board	• Pharmaceuticals	• All new, licensed pharmaceuticals (excludes generics and non-prescription pharmaceuticals)	• Provide technology • Do not provide technology • Provide technology with conditions (restricted to certain providers or patients)	None specified
France [43,60,77,79,84-96]	Ministry for Health and Social Security (decisions) French National Authority for Health (HAS) (recommendations)	• Pharmaceuticals • Devices • Procedures • Diagnostic tests	*Single Technology Appraisals* • Pharmaceuticals and devices: submitted by manufacturer • Procedures: submitted by health care professional associations (typically medical) *Multiple Technology Appraisals* Technologies (typically therapeutic classes of drugs or categories of devices)	• Provide technology • Do not provide technology • Provide technology with conditions (restricted to certain providers or patients) • Provide technology with data collection	*Multiple technology appraisals:* Submit technology topics for consideration: • Patient and/or carer organizations • Health care professional associations • Government • National Union of Health

Table 1-1. Specifications of the decision problem

Country	Advisor and/or decision-maker	Type of technology	Selection of technologies	Decision options	Role of stakeholders
			may be referred by: • Patient and/or carer organizations • Health care professional associations • Government (through Ministry of Health) (annual consultation) • National Union of Health Insurance Funds (through annual consultation)		Insurance Funds
Germany[43,56,60,77,79,88,97-107]	Federal Joint Committee (G-BA) (decisions)	• Pharmaceuticals • Devices • Procedures • Diagnostic tests	Technologies referred by G-BA, Ministry of Health, or Institute for Quality and Efficiency in Health Care (IQWiG)	• Provide technology • Do not provide technology • Provide technology with conditions (restricted to certain providers or patients) • Provide technology with data collection	None specified
Greece [108-110]	Transparency Committee in the Reimbursement and Medicinal Products (EDAF) in the National Drug Organization (NDO) (decisions)	• Pharmaceuticals	All new, licensed pharmaceuticals (excludes non-prescription pharmaceuticals)	• Pharmaceutical automatically reimbursed once classified by the EDAP into a therapeutic category for which a reference price has already been assigned	None specified
Ireland[60,111-117]	Health Services Executive Corporate Pharmaceutical Unit (HSE-CPU) (decisions)	• Pharmaceuticals • Devices • Diagnostic tests	All new pharmaceuticals, as well as new and existing devices and diagnostic tests that "may incur a high cost or have a significant budget impact" identified by the Department of Health and Children of the Health Services Executive	• Provide technology • Do not provide technology • Provide technology with conditions (restricted to certain providers or patients)	None specified
Italy [29,60,88,118-121]	Italian Medicines Agency (AIFA) (decisions)	• Pharmaceuticals	New, licensed pharmaceuticals submitted by manufacturer	• Provide technology • Do not provide technology	None specified

Table 1-1. Specifications of the decision problem

Country	Advisor and/or decision-maker	Type of technology	Selection of technologies	Decision options	Role of stakeholders
				• Provide technology with conditions (restricted to certain providers or patients) • Provide technology with data collection	
Japan [122-125]	Drug Pricing Organization (DPO) (recommendations) Central Social Insurance Medical Council (Chuikyo) (decisions)	• Pharmaceuticals	New, licensed pharmaceuticals submitted by manufacturer	• Provide technology • Do not provide technology	Submit technology for consideration: • Manufacturer
New Zealand[26,44,45,98, 126-140]	Pharmaceutical Management Agency of New Zealand (PHARMAC) (decisions)	• Pharmaceuticals	New, licensed pharmaceuticals, with the exception of high cost pharmaceuticals (handled directly by Ministry of Health) May be referred by anyone	• Provide technology • Do not provide technology • Provide technology with conditions (restricted to certain providers or patients	Submit technology for consideration: • Anyone
Norway[141-144]	Norwegian Medicines Agency	• Pharmaceuticals	All new, licensed pharmaceuticals (excludes generics and non-prescription pharmaceuticals)	• Provide technology • Do not provide technology • Provide technology with conditions (restricted to certain providers or patients)	None specified
Singapore[118,122,145, 146]	Singapore Ministry of Health (decisions) Drug Advisory Committee (recommendations)	• Pharmaceuticals	Pharmaceuticals submitted by medical boards of public hospitals	• Provide technology • Do not provide technology	Submit technology for consideration: • Hospitals
Scotland [147-152]	Scottish Medicines Consortium (recommendations)	• Pharmaceuticals	All new, licensed pharmaceuticals (excludes vaccines, generics, non-prescription pharmaceuticals, blood products, and diagnostic pharmaceuticals)	• Provide technology • Do not provide technology	None specified

Table 1-1. Specifications of the decision problem

Country	Advisor and/or decision-maker	Type of technology	Selection of technologies	Decision options	Role of stakeholders
				• Provide technology with conditions (restricted to certain providers or patients)	
Spain [60,153-155]	Ministry of Health (Directorate General of Pharmacy and Health Products) (decisions)	• Pharmaceuticals	New, licensed pharmaceuticals identified by Ministry of Health	• Provide technology • Do not provide technology • Provide technology with conditions (restricted to certain providers or patients)	None specified
Spain [60,154]	National Health System Interterritorial Council (decisions)	• Devices • Procedures • Diagnostic tests	New technologies typically referred by regional governments	• Provide technology • Do not provide technology	Submit technology for consideration: • Regional governments
Sweden [60,77,156-166]	Dental and Pharmaceutical Benefits Board (TLV) (decisions)	• Pharmaceuticals • Devices used to deliver pharmaceuticals	New, licensed pharmaceuticals and devices submitted by manufacturer	• Provide technology • Do not provide technology • Provide technology with conditions (restricted to certain providers or patients) • Provide technology with data collection	Submit technology for consideration: • Manufacturer
The Netherlands [60,77,79,167-180]	Ministry of Health, Welfare, and Sport (decisions) Dutch Health Care Insurance Board (CVZ) (recommendations)	• Pharmaceuticals • Procedures	Technologies may be referred by: • Manufacturers (typically for pharmaceuticals) • CVZ • Ministry of Health, Welfare, and Sport • Health Council • Insurance funds Occasionally: • Patients and carers • Health care providers	• Provide technology • Do not provide technology • Provide technology with conditions (restricted to certain providers or patients) • Provide technology with data collection	Submit technology topics for consideration: • Manufacturers • Payers (insurers and government) • Patients and carers • Health care providers
United Kingdom,	National Institute for Health	• Pharmaceuticals	Technologies may be referred by anyone	• Provide technology	Submit technology topics

Table 1-1. Specifications of the decision problem

Country	Advisor and/or decision-maker	Type of technology	Selection of technologies	Decision options	Role of stakeholders
Wales, and United Ireland[26,43,44,56,77,88,181-200]	and Clinical Excellence (NICE) (decisions) Note: Decisions may be overridden by the Secretary of State for Health	• Devices • Procedures • Diagnostic tests	Selection criteria: • Burden of disease • Resource impact (impact on costs and resources of the National Health Service) • Policy importance (impact on government priority areas) • Variations in practice • Whether national guidance is likely to add value Final decision made by the Department of Health	• Provide technology with conditions (restricted to certain providers or patients) • Do not provide technology • Provide technology with data collection	for consideration: • Patients, patient representatives, and carers • General public • Health care providers • Health care professional associations • Manufacturers Members of topic selection panel: • Patients, patient representatives, and carers • Health care providers (typically clinical specialists)
United States[43,201-212]	Centers for Medicare and Medicaid Services (CMS) (decisions)	New or existing but substantially modified: • Pharmaceuticals • Devices • Procedures • Diagnostic tests	Technologies may be referred by: • Patients and/or carers • Health care providers • Health care professional associations • Health insurance plans • Suppliers • Manufacturers • Internal CMS staff Selection criteria for internal requests: • Technology represents substantial clinical advance that will likely result in significant health benefits • More rapid diffusion of technology will likely have a significant programmatic impact • Significant uncertainty exists around concerning health benefits, patient	• Provide technology • Do not provide technology • Provide technology with conditions (restricted to certain providers or patients) • Provide technology with data collection	Submit technology for consideration: • Patients and/or carers • Health care providers • Health care professional associations • Health insurance plans • Suppliers • Manufacturers • CMS staff Comment or provide additional information on potential technology topics identified by CMS staff through organization's website: • Anyone

Table 1-1. Specifications of the decision problem

Country	Advisor and/or decision-maker	Type of technology	Selection of technologies	Decision options	Role of stakeholders
			selection, or appropriate facility and staffing requirements Prioritization criteria: • Magnitude of impact on Medicare program and beneficiaries (e.g., life saving cancer treatment)		
Wales [195,213-216]	All Wales Medicines Strategy Group (AWMSG) (decisions)	• High cost pharmaceuticals (> £2,000/patient/year)	All new high cost pharmaceuticals submitted by manufacturer	• Provide technology • Provide technology with conditions (restricted to certain providers or patients) • Do not provide technology	Submit technology for consideration: • Manufacturer of technology
Provincial/state/county level					
Alberta, Canada[217,218]	Alberta Health and Wellness (decisions)	• Devices • Diagnostic tests • Procedures	Technologies may be referred by: Anyone, but primarily: • From within Alberta Health and Wellness • Health care providers • Alberta Health Technology Advisory Committee • Other health advisory groups Also through: • Periodic canvassing of key stakeholders • Environmental scanning Selection criteria: • Impact on individual and population health • Estimated incremental cost • Feasibility review	• Provide technology • Do not provide technology • Provide technology with conditions (restricted to certain providers or patients) • Provide technology with data collection	Submit technology for consideration: • Anyone
Ontario,	Ontario Ministry of Health and	• Devices	Technologies may be referred by:	• Provide technology	Submit technology for

Table 1-1. Specifications of the decision problem

Country	Advisor and/or decision-maker	Type of technology	Selection of technologies	Decision options	Role of stakeholders
Canada[219-221]	Long Term Care (decisions) Ontario Health Technologies Advisory Committee (OHTAC) (recommendations)	• Diagnostic tests • Procedures	• Hospitals • Ministry of Health and Long Term Care	• Do not provide technology • Provide technology with conditions (restricted to certain providers or patients) • Provide technology with data collection	consideration: • Health care providers (through hospitals) • Government (through Ministry of Health and Long Term Care)
Oregon, United States [222,223]	State of Oregon Health Resources Commission (recommendations)	• Devices • Diagnostic tests • Procedures	Technologies may be referred by anyone	• Provide technology • Provide technology with conditions (restricted to certain providers or patients) • Do not provide technology	Submit technology for consideration: • Anyone
Washington, United States [204,224-227]	Washington State Healthcare Authority (decisions)	• Devices • Diagnostic tests • Procedures	Technologies referred by Agency Medical Director Offices Workgroup or the public Final selection made by Health Care Authority Administrator Selection criteria (in order or importance – highest to lowest): • Potential patient harms/safety concerns • Therapeutic efficacy or accuracy and appropriateness of outcomes concerns • Estimated total direct cost per year • Number of patients affected per year • Severity/burden of illness • Urgency/diffusion concern • Variations in access • Special populations/ethical concerns	• Provide technology • Provide technology with conditions (restricted to certain providers or patients) • Do not provide technology	No information found

Table 1-1. Specifications of the decision problem

Country	Advisor and/or decision-maker	Type of technology	Selection of technologies	Decision options	Role of stakeholders
Institutional/regional level					
Sydney public hospital, Sydney Australia [228]	High Cost Drug Sub-Committee (HCD-SC) (advisory)	• High cost pharmaceuticals (>AU$5,000/patient/year)	Technologies may be referred by: • Physicians	• Provide technology • Provide technology with conditions (restricted to certain providers or patients) • Do not provide technology	Submit technology for consideration: • Physicians
Calgary Health Region, Calgary, Canada [229]	Regional Department of Surgery Executive Committee (decisions)	• Surgical devices • Surgical procedures	Technologies may be referred by: • Surgeons within the department	• Provide technology • Do not provide technology	Submit technology for consideration: • Surgeons within the department

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
National level							
Australia [21-44]	Department of Health and Ageing (decisions) Pharmaceutical Benefits Advisory Committee (PBAC) (recommendations)	• Pharmaceuticals	• Indications for technology and therapeutic claim • Burden and severity of illness • Disease incidence and prevalence • Clinical need • Current standard management/treatment • Safety • Clinical effectiveness • Cost-effectiveness • Budget impact • Issues relating to access or equity	• Submission prepared by applicant using standard format • Evaluation report reviewing evidence submission prepared by secretariat in collaboration with sub-committee secretariats and commissioned independent academic group Submissions/ assessments consider: • Published studies • Unpublished studies • Expert opinion (clinicians or patients and carers)	• Evidence from all available Randomized Controlled Trials (RCTs) and non-RCTS (experimental and observational) • Strong preference for meta-analyses of head-to-head RCTs • Systematic review and/or meta-analysis should comply with PBAC submission guidelines	• Economic evaluation required: any type (cost-minimization, cost-consequence, cost-effectiveness, cost-utility, cost-benefit) but rationale for selection must be presented • Methods must comply with PBAC economic guidelines • Comparator: most commonly used alternative • Perspective for economic model: payer • Budget impact analysis	Provide advice during preparation of evaluation report through membership on sub-committee: • Health care professionals • Patients and/or carers • Pharmaceutical industry
Australia [23,45-56]	Department of Health and Ageing (decisions) Medical Services Advisory	• Devices • Procedures • Diagnostic tests	• Indications for technology and therapeutic claim • Burden and severity of illness • Disease incidence and	• Submission prepared by applicant using standard format • Systematic review prepared by	• Evidence from all available RCTs and non-RCTS (experimental and observational)	• Review and critical appraisal of published cost- effectiveness analyses • Economic evaluation	Participate in defining scope of the appraisal: • Applicant • Patient or carer representative

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
	Committee (MSAC) (recommendations)		prevalence • Clinical need • Current standard management/treatment • Safety • Clinical effectiveness • Economic evaluation • Estimated number of patients receiving technology • Service setting (where service is to be performed and by whom) • Proposed fee • Budget impact • Issues relating to access or equity	commissioned independent academic group Submissions/ assessments consider: • Published studies • Unpublished studies • Expert opinion (clinicians, patients and carers through Advisory Panel) • Comments from relevant medical bodies	• Strong preference for RCTs • Summary of adverse events • Systematic review and/or meta-analysis should comply with MSAC submission guidelines	required: any type (cost-minimization, cost-consequence, cost-effectiveness, cost-utility, cost-benefit) but rationale for selection must be presented • Methods must comply with MSAC economic guidelines • Comparator: most commonly used alternative • Perspective for economic model: societal and payer • Budget impact analysis	(through advisory panel) • Health care professionals (typically clinical specialists) (through advisory panel) Nominate clinical expert to offer advice to group conducting assessment: • Applicant Nominate individual to serve on advisory panel: • Patient or carer representative (through Consumer Health Forum of Australia) • Health care professionals (typically clinical specialists)
Austria [57-61]	Association of Austrian Social Security	• Pharmaceuticals	• Indications for technology and therapeutic claim	• Submission prepared by applicant using standard format	• Evidence from meta-analyses of RCTs preferred	• Review of published cost-effectiveness analyses	None specified

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
	Institutions (HVB) (decisions) Austrian Medicines Evaluation Commission (HEK) (recommendations)		• Clinical effectiveness (across population subgroups) • Target population • Budget impact • Economic evaluation (if required) • Price comparisons with same or similar products in Austria • Market forecast (3 years) • Current sales	• Evaluation report reviewing evidence submission prepared by HEK	• Systematic review and/or meta-analysis should comply with internationally recognized guidelines • No formal evidence requirements	• Economic analysis required for "innovative products providing a substantial therapeutic benefit" or where "no comparable medical preparation exists" any type (cost-minimization, cost-consequence, cost-effectiveness, cost-utility, cost-benefit) but rationale for selection must be presented • Comparator: most commonly used treatment • Methods should comply with internationally recognized economic guidelines • Perspective for economic model: must be specified	
Belgium [60,62-66]	Drug Reimbursement Committee (DRC)	• Pharmaceuticals	• Indications for technology and therapeutic claim	• Submission prepared by manufacturer using	• Evidence from all available RCTs and non-RCTS	• Economic evaluation only required for "Class I pharmaceuticals "(i.e.,	None specified

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
	(decisions)		• Target population • Safety • Clinical efficacy and effectiveness • Economic evaluation • Budget impact • Price • Reimbursement status and prices in other European Union countries	standard format • Evaluation report reviewing submission prepared by internal staff with support from external clinical and methodological experts Submissions/ assessments consider: • Published studies • Unpublished studies	(experimental and observational) comparing pharmaceutical to relevant comparator • Systematic review and/or meta-analysis should comply with internationally recognized guidelines	demonstrated added therapeutic value relative to alternatives) • Comparator: most commonly used alternative or, if different, treatment most likely to be replaced by new treatment • Perspective for economic model: payer • Budget impact analysis	
Canada[26,45,56,67-70]	Canadian Agency for Drugs and Technologies in Health: Common Drug Review (CDR) (recommendations)	• Pharmaceuticals	• Indications for technology and therapeutic claim • Burden and severity of illness • Disease incidence and prevalence • Safety • Clinical efficacy and effectiveness • Economic evaluation • Budget impact (if granted priority review based on cost savings) • Price	• Submission prepared by manufacturer using form/template • Evaluation report reviewing submission prepared by internal staff with support from external clinical and methodological experts Submissions/ assessments consider:	• Systematic review and/or meta-analysis must comply with CDR guidelines • Evidence from all available RCTs and non-RCTS (experimental and observational) must be included	• Cost-effectiveness analysis or cost-utility analysis required for analyses based on final clinical outcomes; cost-consequence analysis required for analyses based on intermediate outcomes (rationale for selection must be presented) • Methods must comply with CDR economic guidelines	Submit information to group preparing evaluation report: • Patient and/or carer organizations

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
			• Equity considerations	• Published studies • Unpublished studies • Editorials relating to published studies • "Patient Group Input" submission		• Comparator: most commonly used alternative • Perspective for model: payer (wider costs to be presented separately)	
Denmark [60,71-77]	Danish Medicines Agency (decisions)	• Pharmaceuticals	• Indications for technology and therapeutic claim • Target population • Safety • Clinical effectiveness (across population subgroups) • Cost-effectiveness • Estimated number of patients receiving technology • Expected utilization • Budget impact • Reimbursement status and prices in other EU countries	• Submission prepared by manufacturer using form/template • Evaluation report reviewing submission prepared by internal staff with support from external clinical and methodological experts	• Evidence from available RCTs and non-RCTS (experimental and observational) comparing pharmaceutical to standard treatment	• Formal economic analysis voluntary (often included in order to justify high price) • Methods should comply with Danish Guidelines for the Socio-economic analysis of medicines • Perspective for economic model: societal • Budget impact	None specified
Finland [78-83]	Pharmaceuticals Pricing Board (PPB) (decisions)	• Pharmaceuticals	• Indications for technology and therapeutic claim • Severity and burden of illness • Target population • Clinical effectiveness	• Submission prepared by applicant using standard format • Evaluation report reviewing submission prepared by internal	• Evidence from head to head RCTs preferred • Evidence from other available RCTs and non-RCTS	• Systematic review of published economic studies • Economic analysis required: any type (cost- minimization,	None specified

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
			• Economic evaluation • Expected utilization • Budgetary impact • Reimbursement status and prices in other EU countries • Market forecasts	staff with support from external clinical and methodological experts	(experimental and observational), as well as meta-analyses, should also be included	cost-effectiveness, cost-utility, cost-benefit) but rationale for selection must be presented • Methods must comply with guidelines of the Ministry of Social Affairs and Health • Comparator: most commonly used treatment, most effective treatment, or minimum routine treatment – rationale for selection must be presented • Perspective for economic model: societal	
France[43,60,77,79,84-96]	Ministry for Health and Social Security (decisions) French National Authority for Health (HAS) (recommendations)	• Pharmaceuticals • Devices • Procedures • Diagnostic tests	• Severity and burden of illness • Target population • Current standard management/treatment • Clinical effectiveness (across population subgroups) • Place of technology in care pathway	*Single Technology Appraisals* • Submission prepared by applicant using standard format • Evaluation report reviewing submission prepared by internal staff with support	• Evidence from all available RCTs, non-RCTS (experimental and observational), and post marketing studies • Preference for head-to-head	*Multiple Technology Appraisals* • Type of economic evaluation (if required): any type (cost-minimization, cost-effectiveness, cost-utility, cost-benefit) but rationale for selection must be presented	*Multiple Technology Appraisals* Participate in defining scope of the appraisal: • Patient representatives • Health care professionals

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
			• Economic evaluation (multiple technology appraisals only - if requested) • Budget impact • Costs • Legal implications (multiple technology appraisals only - if requested) • Ethical implications (multiple technology appraisals only - if requested)	from external clinical and methodological experts *Multiple Technology Appraisals* • Assessment (clinical review and economic evaluation (if required)) prepared by internal staff and/or commissioned independent academic/expert groups Submissions/ assessments consider: • Published studies • Expert opinion (clinicians or patients and carers) • Surveys of practice • Analyses of original and commercial data	RCTs • Critical appraisal (level and quality of evidence) required • Systematic review and/or meta-analysis should comply with published systematic review guidelines	• For pharmaceuticals: 3 comparators required: 1) Most commonly used alternative 2) Cheapest treatment costs 3) Alternative treatment most recently added to list of publicly funded services • Methods must comply with economic guidelines • Perspective for economic model: payer • Budget impact analysis	• Payers (decision-makers from government and National Union of Health Insurance Funds) • Manufacturers Participate in consultations during assessment: • Patient representatives • Health care professionals • Payers (decision-makers from government and National Union of Health Insurance Funds) • Manufacturers
Germany [43,56,60,77,79,88,97-107]	Federal Joint Committee (G-BA) (decisions)	• Pharmaceuticals • Devices • Procedures • Diagnostic tests	• Severity and burden of illness • Cost-benefit assessment (includes magnitude of therapeutic effect and	• Assessment (clinical review and cost-benefit analysis prepared by internal staff and/or	• RCTs preferred, but must include quality of life data (minimum of 1 RCT required)	• Systematic review of published economic studies • Cost-benefit analysis	Participate in defining scope and protocol: • Patient and/or carer organizations

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
			safety profile) • Efficiency frontier analysis (relative value of different technologies within a therapeutic area) • Budget impact	commissioned independent academic/expert groups Submissions/ assessments can consider: • Published studies • Unpublished studies • Expert opinion (clinician, patient, and carer)	• Systematic review and/or meta-analysis must comply with internationally recognized guidelines	required • Efficiency frontier analysis • Comparator: most commonly used treatment, most effective treatment, or minimum routine treatment • Methods must comply with internationally recognized economic guidelines • Budget impact analysis	• Health care professionals Provide comments on draft protocol: • Anyone Submit information to group preparing assessment report: • Anyone
Greece [108-110]	Transparency Committee in the Reimbursement and Medicinal Products (EDAF) in the National Drug Organization (NDO) (decisions)	• Pharmaceuticals	• Safety • Clinical effectiveness • Economic evaluation • Cost of daily treatment • Budget impact	• Submission prepared by manufacturer	No information found	No information found	None specified
Ireland [60,111-117]	Health Services Executive Corporate Pharmaceutical	• Pharmaceuticals • Devices • Diagnostic tests	• Clinical effectiveness • Economic evaluation • Budget impact	• Submission prepared by manufacturer using standard format to be	• Evidence from head to head RCTs preferred • Evidence from	• Cost-effectiveness analysis or cost- utility analysis preferred, but other types (e.g., cost-	Submit information to group preparing assessment report:

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
	Unit (HSE-CPU)			completed within 90 days of application • Evaluation report reviewing submission prepared by staff of independent agency, who may seek support from external clinical experts	other available RCTs and non-RCTS (experimental and observational), as well as meta-analyses, should also be included Methods must comply with Irish Health Technology Assessment Guidelines	minimization or cost-benefit) accepted - rationale for selection must be presented Methods must comply with Irish Healthcare Technology Assessment Guidelines • Comparator: not specified but rationale for choice must be provided • Perspective for model: societal	• Manufacturer
Italy[29,60,88,118-121]	Italian Medicines Agency (AIFA)	• Pharmaceuticals	• Indications for technology and therapeutic claim • Severity and burden of illness • Current standard treatment/management • Safety • Clinical effectiveness (across population subgroups) • Cost-effectiveness • Estimated number of patients receiving technology	• Submission prepared by manufacturer of technology using standard format • Evaluation report prepared internally • Information on expenditures and consumption of comparator pharmaceuticals provided by National	• Evidence from all available RCTs and non-RCTS (experimental and observational) comparing pharmaceutical to standard treatment • Systematic review and/or meta-analysis should comply with Italian submission	• Cost -effectiveness analysis or cost- utility analysis (preferred) • Methods must comply with Italian pharmaco-economic guidelines • Comparator: most commonly used alternative • Perspective for economic model: societal	Submit information to group preparing evaluation report: • Manufacturer of technology

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
			• Cost of treatment compared to those in same therapeutic class • Reimbursement status, prices, and consumption in other European Union countries	Observatory on the Use of Medicines	guidelines	• Budget impact analysis	
Japan [122-125]	Drug Pricing Organization (DPO) (recommendations) Central Social Insurance Medical Council (Chuikyo) (decisions)	• Pharmaceuticals	• Current standard treatment/management • Safety • Clinical efficacy • Cost	• Submission prepared by manufacturer of technology using standard format • Evaluation report prepared internally by Medical Economics Division	No information found	• Formal economic evaluation not required	None specified
New Zealand [26,44,45,98,126-140]	PHARMAC (decisions)	• Pharmaceuticals	• Indications for technology and therapeutic claim • Severity and burden of illness • Clinical effectiveness (across population subgroups) • Economic evaluation • Cost • Budget impact • Reimbursement status and prices in other countries	• Submission prepared by manufacturer of technology using standard format • Evaluation report reviewing submission prepared by internal PHARMAC staff Submissions/ assessments can consider:	• Evidence from "well conducted" RCTs and meta-analyses preferred • If no RCTs, evidence from highest level of study available should be included	• Cost -effectiveness analysis or cost-utility analysis preferred, but other types (e.g., cost-minimization or cost-benefit) accepted (rationale for selection must be presented) Methods must comply with PHARMAC Pharmacoeconomic Guidelines • Comparator: 1)	Submit information to group preparing evaluation report: • Anyone who PHARMAC believes might be affected by the decision

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
				• Published studies • Unpublished studies • Expert opinion (clinician, patient, and carer)		Technology that most prescribers would replace and 2) Treatment prescribed to greatest number of patients • Perspective for model: payer • Budget impact analysis	
Norway[141-144]	Norwegian Medicines Agency (NoMA) (decisions)	• Pharmaceuticals	• Indications for technology and therapeutic claim • Severity and burden of illness • Target population • Current standard treatment/management • Position of technology in • Safety profile • Clinical effectiveness (across population subgroups) care pathway • Economic evaluation • Expected utilization • Reimbursement status and prices in other countries	• Submission prepared by manufacturer of technology using standard format • Evaluation report reviewing submission prepared by internal NoMA staff Submissions/ assessments can consider: • Published studies • Unpublished studies	• Evidence from head to head RCTs preferred • Evidence from other available RCTs and non-RCTS (experimental and observational), as well as meta-analyses, should also be included • Systematic review and/or meta-analysis should comply with internationally	• Economic evaluation required: any type (cost-minimization, cost-consequence, cost-effectiveness, cost-utility, cost-benefit, or cost-value) but rationale for selection must be presented • Cost-utility analysis should be supplemented by cost-value analysis • Comparator: Most commonly used alternative (preferred) • Perspective for model:	None specified

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
			• Budget impact • Market forecasts • Social considerations		recognized submission guidelines	societal	
Scotland [147-152]	Scottish Medicines Consortium (recommendations)	• Pharmaceuticals	• Indications for technology and therapeutic claim • Severity and burden of illness • Current standard management/treatment • Position of technology in care pathway • "Comparative" safety • Clinical effectiveness (across population subgroups) • Cost effectiveness • NHS resource implications	• Submission prepared by manufacturer of technology using standard format • Evaluation report reviewing evidence submission prepared by internal "Assessment Team" • Invited written statements from patient organizations and clinical experts Submissions/ assessments can consider: • Published studies • Unpublished studies • Expert opinion (clinician, patient, and carer)	• Evidence from all available RCTs and non-RCTS (experimental and observational) must be included • Systematic review and/or meta-analysis should comply with SMC submission guidelines	• Economic evaluation required: any type (cost-minimization, cost-consequence, cost-effectiveness, cost-utility, cost-benefit) but rationale for selection must be presented • Methods must comply with SMC economic guidelines • Comparator: most commonly used alternative • Perspective for economic model: payer • Resource implications	Submit information to group preparing evaluation report: • Manufacturer of technology • Clinical experts selected by SMC Provide advice to group conducting/reviewing assessment: • Clinical experts selected by SMC
Singapore [118,122,145,146]	Singapore Ministry of Health (decisions) Drug Advisory	• Pharmaceuticals	• Clinical efficacy and effectiveness • Economic analysis (although not mandatory)	• Assessment submitted by requesting Medical Board	No information found	• Economic evaluation not mandatory	None specified

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
	Committee (recommendations)			• Evaluation report prepared with support from Pharmacoeconomics and Drug Utilization Unit			
Spain [60,153-155]	Ministry of Health (Directorate General of Pharmacy and Health Products) (decisions)	• Pharmaceuticals	• Indications for technology and therapeutic claim • Severity and burden of illness • Safety • Clinical efficacy and effectiveness • Cost • Budget impact compared to "corresponding products" • "Health care utility"	• Assessment report prepared by Ministry of Health	• Systematic review of evidence from all available RCTs and non-RCTs	• Economic evaluation not mandatory • Cost effectiveness analysis or cost-utility analysis preferred	Submit information to group preparing assessment report: • Manufacturer of technology
Spain [60,154]	National Health System Interterritorial Council (decisions)	• Devices • Procedures • Diagnostic tests	• Safety • Clinical efficacy and effectiveness • Cost • "Efficiency" • "Health care utility"	• Assessment report prepared by Ministry of Health (with support from national or regional HTA agencies)	No information found	No information found	None specified
Sweden [60,77,156-166]	Dental and Pharmaceutical Benefits Board (TLV) (decisions)	• Pharmaceuticals • Devices used to deliver pharmaceuticals	• Indications for technology and therapeutic claim • Severity and burden of illness • Current standard	• Submission prepared by manufacturer of technology using standard format • Evaluation report	• Evidence from all available RCTs and non-RCTS (experimental and observational) must be included	• "Cost benefit value analysis" required: could take several forms (cost-minimization analysis, cost-effectiveness	Submit information to group preparing evaluation report: • Manufacturer of technology

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
			management/treatment • Clinical effectiveness (across population subgroups) • Economic evaluation ("cost benefit value analysis") • Estimated number of patients receiving technology • Costs	("case") reviewing evidence submission and proposing a decision prepared by allocated executive officer, health economist, legal expert, and Pharmaceutical Benefits Group for County Councils Submissions consider: • Published studies • Unpublished studies	• Preference for direct comparative studies	analysis or cost-utility analysis); rationale for choice must be presented • Exceptions to requirements for economic information may be made for orphan technologies • Methods should comply with TLV economic guidelines • Comparator: most commonly used alternative, non-medical intervention, and "do nothing" • Perspective for model: societal	Respond to questions from TLV during review of submission: • Manufacturer of technology
The Netherlands [60,77,79,167-180]	Ministry of Health, Welfare, and Sport (decisions) Dutch Health Care Insurance Board (CVZ) (recommendations)	• Pharmaceuticals • Procedures	• Severity and burden of illness • Disease incidence and prevalence • Target population • Safety • Clinical efficacy and effectiveness • Substitution effects	• Submission prepared by applicant using standard format • Evaluation report reviewing submission prepared by internal staff with support from external clinical	• Evidence from RCTs preferred • Systematic review and/or meta-analysis must comply with internationally recognized	• Cost-effectiveness analysis or cost-utility analysis required for "unique" pharmaceuticals • Methods must comply with CVZ economic guidelines	None specified

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
			• Expected utilization (including length of treatment and delivery mode) • Price • Potential for off-label use • Cost-effectiveness • Budget impact	and methodological experts Submissions/ assessments can consider • Published studies • Unpublished studies • Expert opinion (clinician, patient, and carer)	guidelines	• Comparator: most commonly used alternative, relevant already reimbursed pharmaceutical • Perspective for model: societal	
United Kingdom, Wales, and United Ireland [26,43,44,56,77,88,181-200]	National Institute for Health and Clinical Excellence (NICE) (decisions) Note: Decisions may be overridden by the Secretary of State for Health	• Pharmaceuticals • Devices • Procedures • Diagnostic tests	• Severity and burden of illness • Indications for technology and therapeutic claim • Current standard management/treatment • Clinical effectiveness (across population subgroups) • Position of technology in care pathway • Cost-effectiveness • NHS resource implications • "Special considerations related to equity or equality"	*Single technology appraisals (STAs)* • Submission prepared by manufacturer of technology using standard format • Evaluation report reviewing evidence submission prepared by commissioned independent academic group *Multiple technology appraisals (MTAs)* • Clinical review and cost-effectiveness analysis ("assessment")	• Systematic review and/or meta-analysis must comply with NICE methods guidelines • Evidence from all available RCTs and non-RCTS (experimental and observational) must be included • Strong preference for head to head RCTs • Preference for studies of clinical effectiveness over studies of clinical	• Cost-effectiveness analysis or cost-utility analysis required • Methods must comply with NICE economic guidelines • Comparator: most commonly used alternative • Perspective for model: payer (NHS/PPS)	Participate in defining scope of the appraisal: • Patient and/or carer organizations • Health care professional associations •Administrators (representing primary care trusts) • Government • Manufacturer(s) • Manufacturer(s) of comparator technologies • NHS Quality Improvement Scotland • Relevant national

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
				prepared by commissioned independent academic group using standard format *STAs and MTAs:* Submissions/ assessments can consider • Published studies • Unpublished studies • Patient surveys • Expert opinion (through invited written statements from "consultees" and oral statements from patient experts and clinical specialists during committee meeting)	efficacy		collaborating centres and academic research groups Submit information to group conducting assessment (MTA) or preparing evaluation report (STA): • Patient and carer organizations • Health care professional associations •Administrators (representing primary care trusts) • Government • Manufacturer(s)
United States [43,201-212]	Centers for Medicare and Medicaid Services (decisions)	New or existing but substantially modified: • Pharmaceuticals • Devices • Procedures • Diagnostic tests	• Indications for technology and therapeutic claim • Target population • Safety • Clinical effectiveness	• Submission prepared by requestor of technology using standard format • Evaluation report reviewing evidence submission prepared by internal staff	• Evidence from all available RCTs and non-RCTS (experimental and observational) should be included • Rationale for how evidence	Economic implications not considered	Submit information to group preparing evaluation report: • Anyone

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
				• If necessary, assessment report prepared by commissioned independent academic group Submissions/ assessments consider • Published studies • Unpublished studies • Recommendations from expert panels • Clinical experience	demonstrates medical benefit for target Medicare population		
Wales [195,213-216]	All Wales Medicines Strategy Group (AWMSG) (decisions)	• High cost pharmaceuticals (> £2,000/patient/ year) • Excludes pharmaceuticals for which NICE guidance is expected within 18 months	• Indications for technology and therapeutic claim • Severity and burden of illness • Position of technology in care pathway • "Comparative" safety • Clinical effectiveness (across population subgroups) • Economic evaluation • Impact on NHS Wales resources • Budget impact	• Submission prepared by manufacturer of technology using standard template • Evaluation report reviewing evidence submission prepared by commissioned independent academic group • Invited written statements from patient organizations and clinical experts	• Evidence from all available RCTs and non-RCTS (experimental and observational) must be included • Systematic review and/or meta-analysis should comply with submission guidelines • Qualitative studies of patient and carer experiences with	• Cost-minimization, cost-effectiveness analysis or cost-utility analysis required (rationale for choice must be presented) • Methods must comply with economic guidelines • Comparator: most commonly used alternative • Perspective for economic model:	Submit information to group preparing evaluation report: • Patients, patient representatives, and carers • Health care professionals (clinical experts)

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
				Submissions/ assessments may consider • Published studies • Unpublished studies • Expert opinion (clinician, patient, and/or carer)	the technology	societal • Budget impact	
Provincial/state/county level							
Alberta, Canada [217,218]	Alberta Health and Wellness (decisions)	• Devices • Procedures • Diagnostic tests	• Severity and burden of illness • Disease prevalence and incidence • Target population • Current standard management/treatment • Current practice patterns and utilization • Status of technology in other jurisdictions • Safety • Clinical efficacy and effectiveness • Resource requirements for implementation • Budget impact • Economic evaluation • Potential inequities in health status or care across population groups	• Assessment prepared by commissioned external, independent academic group Submissions/ assessments may consider • Published studies • Unpublished studies • Expert opinion (from advisory groups) • Analyses of provincial administrative databases	• Systematic review and/or meta-analysis should comply with internationally recognized systematic review guidelines	• Economic analysis required: any type (cost-minimization, cost-consequence, cost-effectiveness, cost-utility, cost-benefit) but rationale for selection must be presented • Budget impact	None specified
Ontario, Canada [219-221]	Ontario Ministry of Health and	• Devices • Procedures	• Severity and burden of illness	• Assessment prepared by internal	• Evidence from all available RCTs	• Cost-effectiveness analysis (no further	None specified

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
	Long Term Care (decisions) Ontario Health Technologies Advisory Committee (OHTAC) (recommendations)	• Diagnostic tests	• Disease prevalence and incidence • Target population • Current standard management/treatment • Current practice patterns and utilization • Status of technology in other jurisdictions • Clinical efficacy and effectiveness • Cost-effectiveness • Budget impact • Societal, ethical, and regulatory implications	staff or commissioned independent academic group Submissions/ assessments may consider • Published studies • Expert opinion (from advisory groups) • Analyses of provincial administrative databases	and non-RCTS (experimental and observational) should be included • Systematic review and/or meta-analysis should comply with internationally recognized systematic review guidelines	information found) • Perspective for economic model: payer • Budget impact analysis	
Oregon, United States [222,223]	Oregon Health Services Commission (recommendations) State Legislature (decisions)	• Devices • Procedures • Diagnostic tests	• "Comparative" safety • Clinical efficacy and effectiveness (across population subgroups) • Compliance • Cost-effectiveness • Cost • Budget impact	• Assessment prepared by commissioned independent academic/expert groups Submissions/ assessments may consider • Published studies • Unpublished studies • Expert opinion (clinician, patient, and carer)	• Systematic review and/or meta-analysis should comply with internationally recognized systematic review guidelines	• Cost-effectiveness analysis (no further information found)	Submit information to group preparing assessment report: • Anyone
Washington,	Washington State	• Devices	• Safety	• Assessment	• Evidence from all	No information found	Submit

Table 1-2. Information inputs into the decision-making process

Country	Advisors and/or Decision-makers	Type of technology	Information inputs	Information sources	Evidence requirements		Role of stakeholders
					Clinical	Economic	
United States [204,224-227]	Healthcare Authority Health Technology Clinical Committee (HTCC) (recommendations) Participating state agencies (decisions)	• Procedures • Diagnostic tests	• Clinical effectiveness • Cost comparisons	prepared by commissioned independent academic/research groups Submissions/ assessments can consider • Published studies • Unpublished studies • Expert opinion	available RCTs and non-RCTS (experimental and observational), as well as existing systematic reviews		information to group preparing evaluation report: • Anyone
Institutional/regional level							
Sydney public hospital, Sydney Australia [228]	High Cost Drug Sub-Committee (HCD-SC) (advisory)	• High cost pharmaceuticals	• Clinical effectiveness • Expected utilization (including length of treatment and delivery mode) • Estimated number of patients receiving technology • Budget impact	No information found	No information found	• Budget impact analysis	No information found
Calgary Health Region (Calgary, Canada) [229]	Regional Department of Surgery Executive Committee	• Surgical devices • Surgical procedures	No information found	No information found	No information found	No information found	No information found

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
National level						
Australia [21-44]	Pharmaceutical Benefits Advisory Committee (PBAC): • Pharmacists • General practitioners • Clinical specialists • Clinical pharmacologists • Health economists • Patient representative PBAC Drug Utilization Sub-Committee (DUSC): Members with expertise in "evaluation of drug utilization" PBAC Economics Sub-Committee (ESC): • Health care providers (clinicians and clinical pharmacologists) • Clinical epidemiologists • Health economists • Biostatisticians	PBAC: Advisory Final decisions made by Minister of Health and Ageing	1. Submission from applicant received by PBAC secretariat 2. Submission reviewed by secretariat and subcommittee secretariats (if necessary) 3. Overview and evaluation report prepared by secretariat 4. Provisional 'tier' status to submission allocated by Pharmaceutical Pricing Section 5. Applicant notified of tier status and inclusion of submission on the PBAC agenda 6. Evaluation report sent to applicant for comment 7. Submission, overview, evaluation report and applicant response, considered jointly by ESC and DUSC 8. Formal advice for PBAC meeting prepared by sub-committees 9. Advice sent to applicant for comment 10. Submission, overview, evaluation report, DUSC and ESC advice, applicants' responses to these documents, and	• Severity and burden of illness • Clinical need • Availability of alternative treatments • Quality of and uncertainty in evidence (including appropriateness of comparator) • Clinical effectiveness • Benefits and harms compared to current standard treatment; differential benefits of technology across population subgroups • Value for money: uses cost-effectiveness (CE) threshold of AU $42,000/QALY - acceptability of incremental cost-effectiveness ratios (ICERs) above this depends on uncertainty in estimates, nature of technology, condition, and wider societal costs and benefits • Affordability (budget impact)	*Equity* • ICER calculation assumes each QALY gained has the same weight regardless of the characteristics of patients receiving it (e.g., age, health condition) • "Access and equity" stated as decision criteria • Pharmaceuticals with ICERs above the accepted CE threshold may be provided through "life saving drugs program" if they are used to treat very rare, life-threatening conditions and have been deemed necessary and effective *Efficiency* Technologies with ICERs in or below CE threshold range considered 'value for money'	Provide comments on evaluation report and advice: • Applicant Present views during committee/ board meeting: • Applicant

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
			presentations from applicant and two PBAC members with relevant expertise, considered by PBAC to formulate advice 11. Public Summary Document (PSD) containing recommendations/advice prepared 12. Decision made by minister following formal pricing discussions	• Financial implications for Pharmaceutical Benefits Scheme and government (if potential costs exceed AU$10 million, submission must undergo "whole of government consideration") • Access and equity		
Australia [23,45-56]	Medical Services Advisory Committee (MSAC): 20 members including: • 3 executive members • Health care providers (clinical specialists) • Health economists • Epidemiologist • Patient representative	MSAC: Advisory Final decisions made by Minister of Health and Ageing	1. Submission from applicant received by DoHA: eligibility for assessment determined 2. Independent academic group commissioned to conduct assessment (systematic review and economic evaluation) 3. Advisory panel appointed to assist in assessment 4. Protocol for assessment drafted in collaboration with advisory panel and MSAC's committee and sent to applicant for comment 5. Assessment report, along with responses from applicant, compiled and sent to MSAC 6. Advice formulated in MSAC meeting: critique of report, first presented by independent member of advisory panel, followed by	• Severity and burden of illness • Clinical need • Quality of and uncertainty in evidence • Safety • Clinical effectiveness • Benefits and harms compared to current standard treatment; differential benefits of technology across population subgroups • Value for money • Costs relative to current treatment • Affordability (budget impact) • Access and equity	• Access and equity stated as decision criteria (no further information found)	Nominate clinical experts to be contacted for advice during assessment: • Applicant Provide comments on report and draft recommendations: • Applicant • Department of Health

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
			advisory panel chair, and member of economics sub-committee 7. Public Summary Document (PSD) containing recommendations/advice prepared 8. Where advice supports funding technology, DoHA is asked by the Minister to conduct further consultations on policy-related issues 9. Decision made by Minister - based on recommendations from MSAC and policy advice from DoHA			
Austria [57-61]	Austrian Medicines Evaluation Commission (HEK): 20 members including: • Representatives from social insurance institutions • Health care providers (clinicians, clinical pharmacologists, and pharmacists) • Government	HEK: Advisory Final decisions made by Association of Austrian Social Security Institutions (HVB)	1. Submission from manufacturer received by Association of Austrian Social Security Institutions 2. Submission reviewed by internal staff and evaluation report prepared 3. Evaluation report sent to HEK 4. Report reviewed by HEK: recommendation made 5. Report and recommendations sent to HVB 6. Recommendation considered by HVB: decision made	• Severity and burden of illness • Clinical need • Availability of alternative treatments • "Medical and therapeutic value" • Innovativeness of the technology • Affordability (budget impact) • "Pharmaco-economic evidence"	No information found	None specified
Belgium [60,62-66]	Drug Reimbursement Committee (DRC): Including 22 voting	DRC: Advisory Final decisions	1. Submission from manufacturer received by DRC 2. Submission sent to Bureau of	• "Therapeutic value" • Safety • Clinical efficacy and	*Equity* Cost-effectiveness analysis as means of assessing "value	None specified

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
	members: • 7 clinical and methodological experts (from universities) • 8 representatives from the sick funds • 4 representatives from physicians' association • 3 representatives from pharmacists' association 6 non-voting members: • 3 Ministry representatives • 1 representative from National Institute for Health and Disability Insurance • 2 representatives from pharmaceutical industry association	made by Minister of Health and Social Affairs	DRC 3. Submission reviewed by internal staff with support from external experts and scientific report prepared 3. Report sent to Committee for review 4. Evaluation report prepared based on Committee's deliberations 5. Evaluation report sent to manufacturer for comment 6. Recommendations formulated by DRC, taking into account manufacturer's comments 7. DRC recommendations sent to manufacturer 8. Final DRC recommendations made 9. Final recommendations sent to Minister of Health and Social Affairs for decision	effectiveness • Benefits and harms compared to current standard treatment; differential benefits of technology across population subgroups • Convenience of the technology • Feasibility of implementation • Likely impact, taking into account therapeutic and social needs • Value for money from National Health Insurance perspective • Affordability (budget impact)	for money" waived for pharmaceuticals used to treat rare diseases or indications	
Canada [26,45,56,67-70]	CDR - Canadian Expert Drug Advisory Committee (CEDAC): • Health care providers (physicians and clinical pharmacologists) • Public representatives (2) • Health economist	CEDAC: Advisory Final decisions rest with individual participating provincial pharmaceutical benefit plans	1. Submission received by CDR secretariat 2. Internal or external review team allocated to submission 3. Review protocol developed with input from provincial plans, CEDAC members, "other experts" and Patient Group Input 4. Independent literature review to	• Safety • Clinical efficacy and effectiveness • Benefits and harms compared to current standard treatment; differential benefits of technology across population subgroups • Value for money (relative	No information found	Present views during committee/board meeting: • Invited "external experts"

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
			supplement manufacturer's submission conducted by review team: clinical evaluation report (Clinical Review Report) prepared 5. Economic analyses submitted by manufacturer assessed by review team: pharmacoeconomic evaluation report (Pharmacoeconomic Review Report) prepared 6. Both evaluation reports sent to manufacturer for comment and to CEDAC members 8. Final evaluation report (CEDAC Brief), containing both reports, manufacturer's comments, review team's responses to comments, and patient group input, sent to CEDAC members 9. Documents reviewed and invited external experts consulted during CEDAC meeting: recommendations formulated 10. Recommendations sent to participating plans for final decision	to accepted therapy) • Patient perspective		
Denmark [60,71-77]	Danish Medicines Agency Reimbursement Committee:	Reimbursement Committee: Advisory	1. Submission from manufacturer received by Danish Medicines Agency	• Therapeutic value on well defined indication • Safety	No information found	Provide comments on report and draft recommendations:

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
	7 members including: • 2 physicians • 1 representative from the regions	Final decisions made by the Danish Medicines Agency	2. Submission reviewed by internal staff with support from external experts, if necessary, and evaluation report (focussing on clinical effect compared to reimbursed treatments for similar indications) prepared 3. Simultaneously: price survey prepared by Danish Medicines Agency 4. Economic analyses (if submitted) reviewed by expert in health economics 5. Clinical evaluation report, price survey, and review of economic analysis sent to Reimbursement Committee 6. Report reviewed and recommendations formulated during committee meeting 7. If negative recommendation, manufacturer is consulted by Danish Medicines Agency before decision is made 8. Decision finalized during Board meeting	• Clinical efficacy and effectiveness • Benefits and harms compared to current standard treatment; differential benefits of technology across population subgroups • Reasonableness of price relative to therapeutic value Criteria for denial of reimbursement: • Considerable risk of off-label use • Use requires special medical exam or diagnostic procedure • Unreasonable to expect National Health Service to reimburse treatment for particular purpose • Effect not clinically documented • Risk of use as first line therapy, regardless of Danish Medicines Agency opinion • Possibility of abuse		• Manufacturer of technology
Finland [78-83]	Pharmaceuticals Pricing Board (PPB):	PPB Expert Group: Advisory	1. Submission from manufacturer received by PPB Secretariat	• Severity and burden of illness	*Efficiency* • No cost-effectiveness	Provide comments on report and draft

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
	7 members: • 2 Ministry of Social Affairs and Health • 2 Social Insurance Institution (Kela) • 1 Ministry of Finance • 1 from National Agency for Medicines • 1 National Research and Development Centre for Welfare and Health PPB Expert Group: 7 members with medical, pharmacological, health economics and social insurance expertise	Final decisions made by PPB	2. Submission reviewed by Secretariat staff with expertise in pharmacology, pharmacoepidemiology, and pharmacoeconomics: evaluation report prepared; additional support provided by members of Expert Group 3. Report sent to Expert Group 4. Report and opinions of Expert Group sent to PPB 5. Presentation to PPB made by Secretariat; written statement regarding potential impact on its budget provided by Kela 6. PPB formulates recommendations 7. If negative recommendation, manufacturer consulted by PPB before decision is made (manufacturer may lower price) 8. Decision finalized during PPB meeting	• Clinical need • Clinical efficacy and effectiveness • Benefits and harms compared to current standard treatment; differential benefits of technology across population subgroups • Quality and strength of evidence • Value for money • Affordability (budget impact) • Cost of treatment per day relative to treatments with the same efficacy • Market share • Prices and consumption in other European countries	threshold	recommendations: • Manufacturer of technology
France [43,60,77,79,84-96]	HAS Board: 8 members appointed by different government bodies 7 HAS specialist sub-committees: comprised of clinical experts	HAS: Advisory Final decisions made by Ministry for Health and Social Security	*Single Technology Appraisal* 1. Submission received by HAS secretariat 2. Evaluation report (focussing on clinical effectiveness, target population, and conditions of use for already reimbursed technologies) prepared by internal	• Severity and burden of illness • Clinical need • "Clinical efficacy/safety ratio" • Costs relative to current treatment • Public health impact	• In the process of developing "social benefit measure" to capture ethical and social considerations (no further information found)	Provide comments on report and draft recommendations: • Patient representatives • Health care providers • Payers (decision-

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
	HAS Interdisciplinary Economic Evaluation and Public Health Committee (CEESP): 25 members including: • Patient representatives • Health care providers • Experts from economics, public health, management, administration, epidemiology, sociology, and philosophy		assessment team 3. Evaluation report sent to external clinical and methodological experts, and CEESP (if necessary) for validation 4. Evaluation report and experts' comments sent to appropriate specialist sub-committee 5. "Intrinsic value of the technology" and "therapeutic improvement" (clinical improvement offered relative to existing treatments) assessed by specialist sub-committee: score based on 5 point scale (I – major improvement to V – no improvement) provided 7. Committee advice sent to Ministry for Health and Social Security for final decision *Multiple Technologies Appraisal* 1. Consultations with relevant stakeholders (including CEESP) held to define scope and protocol 2. Assessment report (clinical review and economic evaluation (if necessary) prepared by internal staff and/or commissioned independent academic/expert			makers from government and National Union of Health Insurance Funds) • Manufacturer of technology Participate in working groups/committees • Patient representatives • Health care providers

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
			groups 3. Assessment report validated by external clinical experts and CEESP (if necessary) 4. Assessment report sent to relevant stakeholders for comment 5. Stakeholders consulted through working group meetings 6. Assessment report peer-reviewed 7. Assessment report and stakeholder comments sent to specialist subcommittee 8. Appraisal report containing assessment and final recommendations prepared 9. Appraisal report sent to HAS Board for approval			
Germany [43,56,60,77,79,88,97-107]	Federal Joint Committee (G-BA): 13 members including: • Representatives from sickness funds (insurers) • Health care providers (physicians, dentists, psychologists, and hospital representatives) • 5 Patient representatives sit on	Decisions made by G-BA	1. Technology sent to Institute for Quality and Efficiency in Health Care (IQWiG) 2. Internal team appointed to manage and/or conduct assessment 3. Consultations with external clinical experts and patient/carer organizations held to define scope and protocol 4. Draft protocol prepared and posted on organization's website	In order of importance: • Clinical effectiveness • Clinical need • Availability of alternative treatments • "Medical and therapeutic value" • Innovativeness of the technology (defined as different mechanism of action or less side effects) • "Efficiency"	*Efficiency* Assumes value for money should be determined by considering costs and benefits of alternative treatments within a therapeutic area (as opposed to across therapeutic areas using cost/QALY ratios)	Provide comments on draft assessment report and preliminary recommendations: • Anyone

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
	committee as advisors		for public comment 5. Protocol finalized and posted along with comments received on website 6. Draft assessment report prepared (clinical benefit assessment performed first; if technology demonstrates benefit over existing treatments, cost-benefit analysis performed) 7. Draft assessment report including preliminary recommendations prepared with support from external experts 8. Draft reviewed by IQWiG Steering Committee for quality assurance 9. Draft assessment report and recommendations posted on organization's website for public comment (4 weeks) 10. Final report, which takes into account comments received and includes final recommendations, prepared and sent to IQWiG Steering Committee for quality assurance and then to Board for final approval 11. Final report reviewed during G-BA meeting: final decision made			

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
Greece [108-110]	Transparency Committee in the Reimbursement and Medicinal Products (EDAF): 7 members including representatives from: • Ministry of Health • Ministry of Finance • Ministry of Employment and Social Protection • Merchant Marine	Decisions on classification of pharmaceuticals into therapeutic category made by EDAF	1. New, licensed pharmaceutical submitted to EDAF 2. Recommendation on therapeutic classification made by EDAF 3. Recommendation sent to Ministry of Health for approval 4. Price assigned using the average of the 3 lowest European prices	Classification of pharmaceutical into therapeutic category based on "therapeutic and pharmacoeconomic effectiveness"	No information found	No information found
Ireland [60,111-117]	Health Services Executive Corporate Pharmaceutical Unit (HSE-CPU): Members not specified	Decisions made by HSE-CPU	1. Technology for assessment referred by Department of Health and Children (DoHC) or HSE 2. Technology referred by DoHA (in collaboration with HSE-CPU) to National Centre for Pharmaceoeconomics and/or Health Information Quality Authority (NCPE) 3. Manufacturer met with: information requirements determined BY NCPE 4. For pharmaceuticals, pharmacoeconomic submission prepared by manufacturer; alternatively, economic assessment prepared by NCPE 5. Manufacturer's submission	• Decisions guided by cost-effectiveness (CE) threshold of €45,000/QALY	*Equity* • In general, each QALY gained has the same weight regardless of the characteristics of patients receiving it (e.g., age, health condition) • For pharmaceuticals above CE threshold, HSE-CPU considers other factors: • Magnitude of health benefit • Severity of illness • Innovativeness of technology • Wider societal costs and benefits	None specified

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
			evaluated by NCPE review group: draft evaluation report (appraisal) prepared 6. Draft evaluation report sent to manufacturer for comment 7. Final evaluation report sent to HSE-CPU for decision		*Efficiency* Technologies with ICERs in or below CE threshold range considered 'value for money'	
Italy [29,60,88,118-121]	Italian Pharmaceuticals Agency (AIFA) Technical Scientific Committee (CTS): 17 members including: • Health care providers • Pharmacists • Pharmacologists AIFA Pricing and Reimbursement Committee (CPR): • Health care providers • Administrators with responsibility for management of pharmaceutical services • Academics (economics, pharmacoeconomics, and business administration)	CPR: Advisory Final decisions made by CTS	1. Submission from manufacturer received by AIFA 2. Submission reviewed by CTS, who provides advice on clinical value based on ranking system: pharmaceutical first assigned to 1 of 3 classes (I – treatments for serious diseases, II – treatments to reduce or eliminate risk of serious disease, and III – treatments for non-serious diseases); degree of innovation assessed by considering availability of existing treatments and extent of therapeutic benefit (each scored on a scale); scores combined to determine if pharmaceutical represents "important, moderate, or modest therapeutic innovation" 3. Submission and CTS evaluation sent to CPR 4. Submission and CTS advice are reviewed by CPR 5.Manufacturer contacted by CPR	• Severity and burden of illness • Clinical need • Availability of alternative treatments • Benefits and harms compared to current standard treatment; differential benefits of technology across population subgroups • Value for money • Impact on health resources • Cost of treatment per day relative to treatments with the same efficacy • Market share • Prices and consumption in other European countries	No information found	None specified

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
			to negotiate preliminary reimbursement status and price 6. Report containing negotiation outcomes submitted to CTS for final decision			
Japan [122-125]	Drug Pricing Organization (DPO) (recommendations): 11 members including: • 6 physicians • 2 dentists • 2 pharmacists • 1 health economist Central Social Insurance Medical Council (Chuikyo) (decisions): 20 members including: • 7 representatives from health insurance • 7 health care providers • 7 members of the public	DPO: Advisory to Chuikyo Final decisions made by Chuikyo	1. Submission from manufacturer received by Ministry 2. Hearing held with Economic Affairs Division 3. Data submitted at hearing reviewed by Medical Economics Division: pricing draft prepared 4. Draft reviewed at DPO meeting: manufacturer and other "experts" consulted 5. DPO recommendation on pricing draft made 6. Recommendation sent to manufacturer for comment 7. Recommendation sent to Chuikyo for approval	• Availability of similar pharmaceuticals • Suitability of similar pharmaceuticals • "Necessity of applying premiums" • Cost	No information found	None specified
New Zealand [26,44,45,98,126-140]	PHARMAC Pharmacology and Therapeutics Advisory Committee (PTAC): Includes: • Physicians nominated by professional	PTAC: Advisory Final decisions made by PHARMAC	1. Submission received by PHARMAC 2. Submission reviewed, additional information sought out (if necessary) and evaluation report (summary proposal) prepared, by PHARMAC staff	• "Health needs of all eligible people within New Zealand" • Availability of alternative treatments • Clinical effectiveness • Benefits and harms	*Equity* Decisions must take into account "health needs of all eligible people within New Zealand" and the particular needs of Maori and Pacific peoples	Provide comments on evaluation report: • "Interested parties" identified by committee

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
	organizations and appointed by the Director General of Health Numerous sub-committees with different clinical expertise		3. Evaluation report sent to PTAC or relevant sub-committee for review 4. Whether to seek comments from "other interested parties" decided by Committee 5. Committee recommendations formulated 4. Consultation report ("cover letter") - containing summary of proposal, minutes of committee/sub-committee meetings, and decision criteria applied when formulating recommendations – prepared by PHARMAC staff 5. Consultation report sent to "sectors" affected by decision for comment 6. Consultation report along with responses analysed and sent to PHARMAC Board 7. Recommendations considered by PHARMAC Board in light of cost effectiveness criteria: final decision made	compared to current standard treatment; differential benefits of technology across population subgroups • Value for money • Affordability (impact on pharmaceutical budget and overall health budget) • Direct cost to patients • Government's priorities for health funding	• "Exceptional circumstances schemes" available: provides funding for pharmaceuticals used to manage rare conditions (<10 patients nationally), where reactions to alternative funded treatments are unusual, or where an unusual set of circumstances exists *Efficiency* No cost-effectiveness threshold	
Norway[141-144]	Norwegian Medicines Agency (NoMA) National Advisory Committee for Drug Reimbursement:	NoMA National Advisory Committee for Drug Reimbursement:	If anticipated budget impact < NOK 5 million/year: 1. Submission from manufacturer received by NoMA 2. Submission reviewed by	• Severity and burden of illness • Clinical need • Therapeutic value on well defined indication	*Equity* • Health care decisions must reflect "principles concerning medical needs and solidarity"	None specified

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
	No information found National Council for Health Care Priorities (NCHCP)	Advisory NCHCP: Advisory If expected budget impact <NOK 5 million NoMA makes decision If expected budget impact >NOK 5 million Parliament makes decision	NoMA Department of Pharmacoeconomics: evaluation report prepared 3. Evaluation report reviewed by NoMA: decision made If anticipated budget impact > NOK 5 million/year: 1. Submission from manufacturer received by NoMA 2. Submission reviewed by NoMA Department of Pharmacoeconomics: evaluation report prepared 3. Evaluation report reviewed by NoMA; National Advisory Committee for Drug Reimbursement consulted for advice 4. Evaluation report sent to Ministry of Health and Care Services 5. NCHCP consulted on whether "money would be well spent" by Ministry of Health and Care Services 6. Positive recommendations from Ministry sent to Parliament for approval	• Clinical efficacy and effectiveness • Benefits and harms compared to current standard treatment; differential benefits of technology across population subgroups • Value for money (reimbursement decision "depends strongly on the result of the pharmacoeconomic evaluation") • Affordability (budget impact)	*Efficiency* • No cost-effectiveness threshold used • Health care decisions must reflect principles of rationality (encourage clinically rational and cost-effective use of pharmaceuticals)	
Scotland [147-152]	Scottish Medicines Consortium (SMC)	NDC: Advisory	1. Submission from manufacturer, using standard template (ideally	• Clinical effectiveness • Benefits and harms	For technologies not falling within accepted CE	Provide comments on report and draft

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
	Includes: • Health care providers (from NHS Boards) with expertise in assessing pharmaceuticals • Administrators/ managers • Representatives from patient and carer organizations • Representatives from pharmaceutical industry New Drugs Committee (NDC): 20 members including: • Health care providers with clinical and/or pharmacy backgrounds • Representatives from pharmaceutical industry	Final decisions made by SMC (implementation not mandatory)	prior to licensing), received from SMC 2. Submission allocated to internal "Assessment Team", comprising clinical and economic assessors 3. Submission reviewed by Assessment Team and report prepared 4. Report reviewed by NDC, who makes preliminary recommendations 5. Report and preliminary recommendations sent to manufacturer for comment 6. Report, preliminary recommendations, manufacturer response, and written views from clinical experts and patient organizations submitted to SMC 7. Information received during SMC meeting considered by SMC 8. Final decision made by SMC	compared to current standard treatment; differential benefits of technology across population subgroups, taking into account patients' perspectives • Value for money: uses cost-effectiveness (CE) threshold range of £20,000 - £30,000/QALY - acceptability of incremental cost-effectiveness ratios (ICERs) above range depends on uncertainty in estimates, nature of technology, condition, and wider societal costs and benefits	threshold range, SMC considers: • Whether technology is for ultra orphan condition *Equity* • In general, each QALY gained has the same weight regardless of the characteristics of patients receiving it (e.g., age, health condition) • Whether technology represents life-extending, end of life treatment taken into consideration (greater weight given to QALYs achieved in the later stages of a terminal disease) *Efficiency* Technologies with ICERs in or below CE threshold range considered 'value for money'	recommendations: • Manufacturer(s) of technology Submit written testaments to SMC: • Patient and/or carer organizations through SMC Patient and Public Involvement Group (includes 3 members of general public)
Singapore [118,122,145,146]	Drug Advisory Committee (DAC): No information found	DAC: Advisory Final decisions made by Singapore Ministry of Health	1. Ranked applications from hospitals to DAC sent by Medical Board 2. Applications - with input from clinicians and technical support	• Whether condition/disease is common and an important cause of morbidity and mortality in Singapore • Whether pharmaceutical is	No information found	None specified

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
			from Pharmacoeconomics and Drug Utilization Unit – evaluated by DAC 3. Recommendation made by DAC and sent to Ministry of Health 4. Final decision made by ministry of health	essential for the treatment of the conditions • Whether pharmaceutical offers a "major improvement in terms of efficacy and effectiveness, as compared to existing standard drugs" • Whether sufficient long term safety data are available • Whether "sufficient evidence of cost-benefits" exists • Whether pharmaceutical appears on international formularies such as the WHO Essential Drug List, the Australia Pharmaceutical Benefit Scheme, and the US Kaiser Permanente Drug List		
Spain [60,153-155]	National Health System Interterritorial Council: Includes representatives of national and autonomous regional governments	Final decisions made by National Health System Interterritorial Council Note: Technologies that could significantly increase health expenditures also require approval	1. Technology referred for consideration 2. National HTA agency contacted by Ministry of Health to plan assessment 3. Assessment report prepared by Ministry of Health in collaboration with HTA agency 4. Report submitted to National Health System Interterritorial Council for consideration 5. Final decision made by council	• Severity and burden of illness • Clinical need • Clinical effectiveness • Benefits and harms compared to current standard treatment; differential benefits of technology across population subgroups • "Therapeutic and social utility" • Impact on health resources	No information found	None specified

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
		by Fiscal and Financial Policy Council				
Spain [60,154]	Ministry of Health (Directorate General of Pharmacy and Health Products) Inter-Ministerial Pricing Commission: Includes representatives from several government ministries: Health, Economy, and Industry	Inter-Ministerial Pricing Commission decisions: Binding	1. Reimbursement decision-making process initiated by Ministry of Health when notice of market approval for new pharmaceutical is received 2. Manufacturer invited to provide information to Inter-Ministerial Pricing Commission (CIPM) 3. Assessment report prepared by Ministry of Health 4. Report reviewed by CIPM: decision made	• Severity and burden of illness • Clinical need • Clinical effectiveness • Benefits and harms compared to current standard treatment; differential benefits of technology across population subgroups • "Therapeutic and social utility" • "Rationalization of public pharmaceutical expenditures" • Availability of alternative treatments • Innovativeness of the technology	No information found *Efficiency* • None specified, but rationalization of pharmaceutical expenditures comprises a decision criterion	No information found
Sweden [60,77,156-166]	Dental and Pharmaceutical Benefits Board (TLV): 11 members, and a Chair, including: • 4 health care providers (clinical expertise) • 4 health economists • 2 representatives from patient organizations	TLV decisions: Binding	1. Submission from manufacturer received by TLV 2. Submission reviewed by assigned executive officer, health economist and "legal expert" 3. Submission also sent to Pharmaceutical Benefits Group for County Councils for review 4. Manufacturer contacted to clarify questions and obtain	• Severity and burden of illness • Clinical need • Clinical effectiveness • Benefits and harms compared to current standard treatment; differential benefits of technology across population subgroups • Marginal benefit (no other	*Equity* • Decisions must adhere to human value principle – all individuals have equal value (characteristics of patients (e.g., age, social position, income, etc.) must not influence decisions) • Decisions must adhere to	Provide comments on report and draft recommendations: • Manufacturer(s) of technology Present views during committee/board meeting:

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
			further information, if necessary 5. Report ("memorandum") containing findings from review and proposed decision prepared 6. Report sent to manufacturer for comment 7. Report and comments from manufacturer sent to Board 8. Manufacturer given opportunity to present views to Board during its meeting 9. Final decision made by Board	more appropriate technologies available) • Value for money: guided by (but not restricted to) cost-effectiveness (CE) threshold of €45,000/QALY	need and solidarity principle – patients in greatest medical need or "worst off" must be given priority • CE threshold may be adjusted based on severity of the condition *Efficiency* • Decisions must adhere to cost-effectiveness principle – (cost must be considered reasonable from "medical, humanitarian, and economic point of view") • Considered cost-effectiveness (CE) threshold of €45,000/QALY	• Manufacturer(s) of technology
The Netherlands [60,77,79,167-180]	Dutch Health Care Insurance Board (CVZ) Committee for Pharmaceutical Aid (CFH): • Pharmacists • Physicians • Economists • Psychologists • Epidemiologists	CVZ: Advisory Final decisions made by Ministry of Health, Sport, and Welfare decisions	1. Submission received by Ministry of Health, Welfare, and Sport 2. Submission sent to CVZ 3. Submission reviewed by CVZ staff, who may consult with external experts; full assessment may be commissioned to external independent academic group/agency	• Severity and burden of illness • Clinical need • Quality and strength of evidence • "Therapeutic value" • Clinical efficacy and effectiveness • Benefits and harms (side effects) compared to current	*Equity* • Economic evaluation not required for pharmaceuticals used to treat: 1) Rare conditions 2) Life threatening conditions 3) Conditions for which there are no other alternatives	Present views at the request of CVZ: • Patients and carers • Health care providers

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
	• Ministry representatives		4. Evaluation report prepared and sent to appropriate committee (CFH for pharmaceuticals) 5. Report reviewed by CFH/CVZ: recommendations formulated 6. Recommendations sent to Ministry for final decision	standard treatment; differential benefits of technology across population subgroups • Experience with the technology • Applicability (ease of implementation) • Value for money: guided by (but not restricted to) cost-effectiveness (CE) threshold of €20,000/QALY • Individual versus collective responsibility • Potential for off-label use • Affordability (budget impact) • "Other social, ethical, and legal considerations"	• CE threshold may be adjusted based on need (severity of the condition and availability of alternative treatments) or equity considerations *Efficiency* In general, technologies with ICERs in or below CE threshold range considered 'value for money'	
United Kingdom, Wales, and United Ireland [26,43,44,56,77,88,181-200]	NICE Technology Appraisals Committee (TAC): • Health care providers within the National Health Service • Representatives from patient and carer organizations • Academics (e.g., health economists) • Representatives from	TAC: Advisory Final decisions made by NICE Executive	*Single Technology Appraisal* 1. Technology selected for appraisal (based on criteria of potential to have a significant impact on health benefits and/or cost and unexplained variations in current practice) 2. Stakeholders (i.e., consultees and commentators) identified and invited to participate 3. Evidence submitted by manufacturer	• Severity and burden of illness • Clinical need • Clinical effectiveness • Benefits and harms compared to current standard treatment; differential benefits of technology across population subgroups, taking into account patients' perspectives • Quality of and uncertainty	For technologies not falling within accepted CE threshold range, TAC considers: • Advice provided by NICE *Equity* In general, each QALY gained has the same weight regardless of the characteristics of patients receiving it (e.g., age, health	Nominate clinical and/or patient experts to present oral testaments to TAC: • Patient and/or carer organizations • Health care professional associations •Administrators (representing

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
	pharmaceutical and medical devices industries		4. Submission reviewed by independent academic group and report prepared 5. Evaluation report prepared (contains review group report, written statements from invited stakeholders, clinical and patient expert statements, and comments received on review group report) 6. Evaluation report reviewed by TAC, who also hears from nominated clinical and patient experts 7. Provisional recommendations made and appraisal consultation document prepared 8. Stakeholders given 4 weeks to comment on document 9. Comments considered by TAC: final recommendations (final appraisal determination (FAD)) made 10. Final recommendations submitted to Guidance Executive for approval *Multiple technologies appraisal* Similar process except: 1) Scoping process (to develop appraisal protocol) required 2) Evidence submission prepared	in evidence (including appropriateness of comparator) • Value for money: uses cost-effectiveness (CE) threshold range of £20,000 - £30,000/QALY - acceptability of incremental cost effectiveness ratios (ICERs) above range depends on uncertainty in estimates, nature of technology, condition, and wider societal costs and benefits • Impact on health programmes • ICERs of funded programmes • Any guidance issued by Secretary of State • Long term objective of encouraging innovation	condition) Citizens Council in "Social value judgements" document • Whether technology is for ultra orphan condition • Whether technology represents life-extending, end of life treatment (greater weight given to QALYs achieved in the later stages of a terminal disease) *Efficiency* Technologies with ICERs in or below CE threshold range considered 'value for money'	primary care trusts) • Government • Manufacturer(s) of technology (can only nominate clinical experts) • Manufacturer(s) of comparator technologies • NHS Quality Improvement Scotland • Relevant national collaborating centres and academic research groups Provide comments on report and draft recommendations • Public • Patient and/or carer organizations • Health care providers • Health care professional associations •Administrators

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
			by an independent academic group, not the manufacturer, (i.e., no evaluation report)			(representing primary care trusts) • Government • Manufacturer(s) of technology • Manufacturer(s) of comparator technologies • NHS Quality Improvement Scotland • Relevant national collaborating centres and academic research groups
United States [43,201-212]	Centers for Medicare and Medicaid Services (CMS) Medicare Evidence Development and Coverage Advisory Committee (MEDCAC): 15 members with expertise in "clinical and administrative medicine, biologic and physical sciences,	MEDCAC: Advisory Final decisions made by CMS	1. Formal request (submission) for National Coverage Determination (NCD) received by CMS 2. Submission reviewed by staff for completeness: applicant notified of acceptance 3. Technology posted on website under "pending coverage issues" 4. Evaluation report prepared by staff 5. Submissions involving complex issues referred to	• Quality of and uncertainty in evidence • Safety • Clinical effectiveness • Benefits and harms compared to current standard treatment; differential benefits of technology across population subgroups • Relevance of findings to demographics of Medicare beneficiaries • Appropriateness	No information found	Submit additional evidence to CMS via website: • Anyone Make presentation to committee: • Anyone who registers in advance

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
	public health administration, patient advocacy, health care data and information management and analysis, health care economics, and medical ethics" Patient and industry representatives serve as non-voting members		MEDCAC; may also commission full health technology assessment 6. Submission reviewed, presentations and comments from interested parties heard, during a public MEDCAC meeting: recommendation made 7. Recommendation posted on CMS website 8. Within 60 days of receiving recommendation, CMS issues formal decision memorandum (explains MEDCAC recommendation and how it was considered in finalizing decision			
Wales [195,213-216]	AWMSG: • Health care providers in the NHS • Pharmacists • Representatives from patient and carer organizations • Academics (including health economists) • Representatives from pharmaceutical industry	AWMSG: Advisory Final decisions made by Minister for Health and Social Services of the Welsh Assembly	1. "Intent to submit" from manufacturer received by AWMSG 2. Need for full appraisal determined 3. If yes, evidence submitted by manufacturer 4. Clinical experts and patient organizations identified and invited to submit written views 5. Submission reviewed by Secretariat (Welsh Members Partnership) and report prepared 6. Report sent to manufacturer for response 7. Report, manufacturer	• Severity and burden of illness • Clinical need • Clinical effectiveness • Benefits and harms compared to current standard treatment; differential benefits of technology across population subgroups, taking into account patients' perspectives • Quality of and uncertainty in evidence (including appropriateness of comparator) • Value for money: uses	*Equity* • In general, each QALY gained has the same weight regardless of the characteristics of patients receiving it (e.g., age, health condition) • For technologies not falling within accepted CE threshold range, AWMSG considers: 1) Whether technology is for ultra orphan condition 2) Whether technology represents life-extending,	Provide comments on report and draft recommendations: • Manufacturer(s) of technology Attend AWMSG meeting: • Manufacturer(s) of technology • Public • Patient and/or carer organizations • Health care providers

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
			response, and written views from clinical experts and patient organizations submitted to New Medicines Group (NMG) (includes clinicians, pharmacists, pharmacologists, a health economist, nurse, patient/consumer representative, and a representative from pharmaceutical industry association) 8. Provisional recommendations made and preliminary appraisal report prepared 9. Report sent to manufacturer and posted on website 10. Report and company response during public meeting are considered by AWMSG 11. Recommendation made by AWMSG: final appraisal report prepared 12. Recommendation sent to Minister for approval upon receiving confirmation from manufacturer	cost-effectiveness (CE) threshold £20,000/QALY - acceptability of ICERs above this depends on uncertainty in estimates, nature of technology, condition, and wider societal costs and benefits • Impact on health programmes • Affordability (budget impact) • ICERs of funded programmes widely regarded as cost-effective • Any guidance issued by Welsh Assembly Government • Long term objective of encouraging innovation	end of life treatment (greater weight given to QALYs achieved in the later stages of a terminal disease) *Efficiency* Technologies with ICERs in or below CE threshold range considered 'value for money'	
Provincial/state/county level						
Alberta, Canada [217,218]	Executive Committee of Alberta Health and Wellness (AHW)	Executive Committee of Alberta Health and Wellness:	1. Technology selected 2. Expert Advisory Group (EAG) appointed by Ministry 3. Assessment commissioned to	No information found	No information found	Provide comments on report and policy options: • Provincial health

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
	Executive committee (recommendations) Project-specific Expert Advisory Group: Members include clinicians and administrators familiar with specific technologies and their uses)	Advisory Final decisions made by Minister of Health and Wellness	independent, external academic group 4. Scope and protocol defined during meeting between EAG, Ministry and academic group 5. Draft assessment report prepared and sent to EAG for comment 6. Final assessment report prepared - EAG comments taken into account 7. Policy component, containing policy options, prepared by internal staff or external consultant 8. "Synthesis report", containing assessment and policy component, prepared and sent to the provincial health authority, medical association, bodies regulating medical practice, and relevant programs for comment 9. Draft recommendations (received comments taken into account) formulated by Ministry staff 10. Recommendations sent to Executive Committee for approval 11. Recommendations sent to Minister for final decision			authority • Medical association • Bodies regulating medical practice •Relevant health care programs across the province

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
Ontario, Canada [219-221]	Ontario Health Technology Advisory Committee (OHTAC): Minimum of 12 members including representatives from: • Ontario Medical Association • Ontario Hospital Association • Community and long-term care sectors • Nursing • Medical professions • Health economist • Ethicist	OHTAC: Advisory Final decisions made by Minister of Health and Long Term Care	1. Technology application received by OHTAC Secretariat 2. Applications prioritized by OHTAC and sent to Medical Advisory Secretariat (MAS) 3. Assessment (health technology policy analysis) prepared by internal MAS staff 4. Assessment sent to OHTAC 5. Review of assessment and draft of recommendations made during OHTAC meeting 6. Draft recommendations posted on OHTAC website for 21 days for public comment 7. Final recommendations (with received comments taken into account) prepared and forwarded to the Ministry for approval 8. Final decision made by Ministry	• Severity and burden of illness • Clinical need • Clinical effectiveness • Benefits and harms compared to current standard treatment; differential benefits of technology across population subgroups • Quality and strength of evidence • Consistency with expected social and ethical values • Value for money • Organizational feasibility	• Consistency with expected social and ethical values mentioned as a decision criterion (no further information found)	Provide comments on report and draft recommendations: • Anyone
Oregon, United States [222,223]	State of Oregon Health Resources Commission Health Services Commission: 12 members including: • 4 Physicians • 2 Pharmacists • 1 Hospital representative • 1 Insurance	HTCC: Advisory to Health Resources Commission Health Resources Commission: Advisory to Legislature	1. Technology identified and notice of review posted on organization's website 2. Technical assessment commissioned and initiated within 30 days of posting 3. Information submitted by interested parties to Commission 4. Evidence assessing technical merits of technology within	• Benefits and harms compared to current standard treatment; differential benefits of technology across population subgroups • Quality of and uncertainty in evidence • Value for money compared to established technologies • Costs relative to current	*Equity* • Impact on special patient populations comprises a decision-making criterion (sex, age, ethnicity, race, and disability)	Provide comments on report and draft recommendations: • Anyone Attend public meeting: • Anyone

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
	representative • 1 "Business" representative • 1 Patient/consumer representative • 1 Representative from "organized labor"	Final decision made by Governor	clinical context reviewed by relevant subcommittee (may seek input from additional "experts") 5. Report prepared by subcommittee 6. Public meeting held to present report and solicit public input 8. Revised report prepared by subcommittee and presented to Commission at public meeting, with further opportunity for public comment 9. Policy component conducted by Commission 10. One or more epidemiologists, biostatisticians, health economists, health services researchers, or others appointed to provide advice and consider recommendations from patient advocates, payers, and manufacturers 11. Draft report containing technical assessment, policy component, and recommendations prepared 12. Report sent to interested parties for comment 13. Final report (received comments taken into account) prepared and sent to Governor	treatment • Affordability (budget impact) • "Special patient populations that would be affected" • Other social, ethical, legal issues		

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
Washington, United States [204,224-227]	Washington State Healthcare Authority Health Technology Clinical Committee (HTCC): 11 members including: • 6 Practicing physicians • 5 Other practicing licensed health professionals	Washington State Healthcare Authority Health Technology Clinical Committee (HTCC): Advisory	1. Technology selected for review 2. External assessment report commissioned by Administrator of Technology Assessment Program 3. Input from any interested parties coordinated by program staff 4. HTCC appointed by administrator 5. Assessment report reviewed and public "testimonies" witnessed during HTCC meeting 6. If necessary, ad hoc group convened by HTCC for guidance 7. Draft report containing recommendations prepared by HTCC 8. Draft report posted on website for comment 9. Received comments taken into account: final HTCC recommendations (determination) formulated 10. Recommendations sent to participating state agencies for a decision	• Severity and burden of illness • Disease incidence and prevalence • Target population • Safety • Clinical efficacy and/or effectiveness (including appropriateness of outcomes) • Affordability (budget impact) • Technology diffusion • Special populations/ethical considerations	*Equity* • Impact on special patient populations comprises a decision-making criterion	Provide comments on report and draft recommendations: • Anyone Attend Committee meeting: • Anyone Make presentation to Committee: • Anyone
Institutional/regional level						
Sydney public hospital, Sydney	High Cost Drug Sub-Committee (HCD-SC): Includes:	High Cost Drug Sub-Committee (HCD-SC):	1. Request submitted to HCD-SC by physician 2. Physician invited to make	• Safety • Clinical effectiveness • Number of patients	No information found	Participate in committee meeting:

Table 1-3. Elements of the decision-making process

Country	Advisory/ Decision-making committee membership	Committee authority	Steps in decision-making process	Pre-defined decision-making criteria/factors	Equity and efficiency assumptions/Ethical considerations	Role of stakeholders
Australia [228]	• Executive Director • Director of Pharmacy • Chair of Drug and Therapeutics Committee • Senior physician • Ethicist	Advisory Final decisions made by hospital's Drug and Therapeutics Committee	presentation to HCD-SC and take part in deliberations 3. HCD-SC recommendation made 4. Recommendation sent to Drug and Therapeutics Committee for final decision	expected to benefit (improved quality of life and/or prolonged survival) • Affordability (budget impact)		• Requesting physician
Calgary Health Region (Calgary, Alberta, Canada) [229]	Regional Department of Surgery Executive Committee: No further information found	Executive Committee decisions: Binding	• Application presented by surgeon to the Calgary Health Region Department of Surgery Executive Committee (no further information found)	Priority given to technologies that: • "Will be used in a multidisciplinary fashion • "Will reduce length of stay" • "Will improve patient well being"	No information found	No information found

Table 1-4. Public accountability and decision implementation considerations

Country	Transparency	Appeals mechanisms	Reassessment or review of decisions	Conditions of implementation	Role of stakeholders
National level					
Australia [21-44]	• Evaluation reports not made public • PBAC recommendations, along with rationale, and minutes of meetings publicly available on organization's website (6 weeks after meeting) • "Public summary document" containing final decisions and rationale publicly available on organization's website	• May formally request independent review of decision • Independent reviewer (not affiliated with PBAC or involved in initial review) appointed by a convenor (convenor does not contribute to the content or findings of a review)	• Decisions reviewed regularly (no further information found)	• Pharmaceuticals receiving positive recommendations from PBAC must be approved by the Minister • Pharmaceuticals receiving negative recommendations from PBAC cannot be funded	Appeal recommendations: • Applicant Provide comments on public summary document before posted on website: • Applicant
Australia [23,45-56]	• MSAC recommendations, along with rationale and minutes of meetings, publicly available on organization's website	• No separate appeals mechanism	• Applies to technologies receiving reimbursement conditional upon collection of further data	• MSAC recommendations approved by the Minister must be implemented (no further information found)	No information found
Austria [57-61]	No information found	• Appeals may be launched to Independent Pharmaceuticals Commission	No information found	No information found	No information found
Belgium [60,62-66]	• Final decisions, along with rationale, publicly available on organization's website	No information found	• Decisions reviewed every 1.5 to 3 years	No information found	No information found
Canada [26,45,56,67-70]	• Evaluation reports not made public • CEDAC recommendations, along with rationale, publicly available on organization's website	• Appeals may be launched within 10 working days of receipt of recommendations • Only process-related appeals are accepted (e.g., failed to act in accordance with processes, recommendations considered	None information found	• CEDAC recommendations not binding - individual participating provincial/territorial benefit plans make final reimbursement decisions	Appeal recommendations: • Manufacturer

Table 1-4. Public accountability and decision implementation considerations

Country	Transparency	Appeals mechanisms	Reassessment or review of decisions	Conditions of implementation	Role of stakeholders
		"perverse" in light of the evidence, etc.)			
Denmark [60,71-77]	• Evaluation reports not made public • Final decisions, along with rationale and minutes of meetings, publicly available on organization's website	• Only process-related appeals accepted • Appeals must be filed with Ministry of Health and Prevention	• Decisions must be reviewed within 5 years of reimbursement	No information found	No information found
Finland [78-83]	• Final decisions, along with rationale, publicly available on organization's website	• No separate appeals mechanism • Appeals must be filed with court	• Decisions reviewed every 3 to 5 years	No information found	No information found
France [43,60,77,79,84-96]	• Assessment and evaluation reports, final recommendations, and guidance (decisions), publicly available on organization's website	• Appeals may be launched within 8 working days of receipt of final recommendations •After a decision has been made, applicant (typically manufacturer) may file appeal with public administrative court	• Pharmaceutical decisions reviewed every 5 years • Device and procedure decisions reviewed within 5 years of reimbursement • For technologies receiving reimbursement conditional upon collection of further data: date set when decision is made	*Single Technology Appraisals* Pricing negotiations must take place before final decision on reimbursement can be made *Multiple Technologies Appraisals* HAS guidance not binding	Appeal recommendations: • Applicant
Germany [43,56,60,77,79,88,97-107]	• Assessment and evaluation reports, final recommendations, and decisions, publicly available on organization's website	• No separate appeals mechanism • Appeals may be filed with court	No information found	• Pharmaceuticals receiving positive decision must be reimbursed by sickness funds	No information found
Greece [108-110]	No information found	No information found	No information found	• Pharmaceuticals automatically reimbursed once price established	No information found
Ireland [60,111-117]	• Assessment and evaluation reports publicly available on organization's website	• Appeals related to process and scientific disputes accepted • Appeals may be launched within	No information found	• Pharmaceuticals receiving positive decision must become reimbursable within	Appeal recommendations: • Applicant

Table 1-4. Public accountability and decision implementation considerations

Country	Transparency	Appeals mechanisms	Reassessment or review of decisions	Conditions of implementation	Role of stakeholders
		90 days of decision • Involves expert panel with membership agreed-to by the Irish Pharmaceutical Healthcare Association and the Health Service Executive • Decisions made by expert panel are binding		40 days of the decision	
Italy [29,60,88,118-121]	• Final decisions, along with rationale, and minutes of meetings, publicly available on organization's website	No information found	• Applies to technologies receiving reimbursement conditional upon collection of further data	• Pharmaceuticals receiving positive decisions placed on national formulary (no further information found)	No information found
Japan [122-125]	No information found	• Appeals may be made to Drug Pricing Organization (DPO) • Second meeting of DPO held, during which manufacturer is invited to present case • If necessary, recommendations are revised and manufacturer is notified	• Pharmaceuticals reviewed every 2 years through pricing surveys	• Pharmaceuticals receiving positive decisions placed on National Health Insurance Drug Price List (list of drugs for which providers can be reimbursed)	Appeal recommendations: • Manufacturer(s) of technology
New Zealand [26,44,45,98,126-140]	• Assessment and evaluation reports not made public • Minutes of meetings publicly available on organization's website, but parts can be withheld at applicant's request	• No separate appeals mechanism	No information found	• Pharmaceuticals receiving a positive decision placed on national formulary (no further information found)	No information found
Norway [141-144]	• Final decisions, along with rationale, publicly available on organization's website	• Appeals may be made to the Ministry of Health and Care Services within 3 months of the decision	• Pharmaceuticals may be reviewed as part of ongoing therapeutic class/group reviews	No information found	Appeal recommendations: • Applicant
Scotland [147-152]	• Assessment and evaluation reports,	• Appeals related to process and	• Review date varies with	• National Health Service	Appeal

Table 1-4. Public accountability and decision implementation considerations

Country	Transparency	Appeals mechanisms	Reassessment or review of decisions	Conditions of implementation	Role of stakeholders
	final recommendations, decisions, and minutes of meetings, publicly available on organization's website	scientific disputes accepted • Process related: manufacturer expresses concerns to Secretariat and/or Chairs of Scottish Medicines Consortium (SMC) or New Drugs Committee (NDC): may be resolved through discussion; if they remain unresolved, company can seek judicial review • Scientific disputes: 2 options: 1) resubmission or 2) convene appeals panel (independent review panel) • Appeals panel appointed by SMC (includes 7 members: 3 appointed from SMC and 4 from either Scottish Area Drug and Therapeutics Advisory Committees and/or other respected experts in relevant field)	available evidence for technology (usually determined when decision is made)	encouraged to make funding available to provide technology (no further information found)	recommendations: • Manufacturer(s) of technology Ensure patient/carer perspective is prominent in all SMC assessments: • SMC Patient and Public Involvement Group (includes 3 members of general public)
Singapore [118,122,145,146]	No information found	No information found	• Pharmaceuticals on national formulary (Standard Drug List) reviewed and revised "regularly"	No information found	No information found
Spain [60,153-155]	No information found	No information found	No information found	No information found	No information found
Spain [60,154]	No information found	No information found	No information found	• National Health Service must make funding available to provide pharmaceuticals approved by CIPM (no	No information found

Table 1-4. Public accountability and decision implementation considerations

Country	Transparency	Appeals mechanisms	Reassessment or review of decisions	Conditions of implementation	Role of stakeholders
				further information found)	
Sweden [60,77,156-166]	• Final decisions, along with rationale and minutes of meetings, publicly available on organization's website	• No separate appeals mechanism • Appeals must be filed with court	• Decisions time limited • Review date varies with available evidence for technology • Pharmaceutical may also be reassessed as part of ongoing review of therapeutic classes of pharmaceuticals	• County councils must make funding available to provide technologies approved by TLV (no further information found)	Appeal decisions: • Manufacturer(s) of technology
The Netherlands [60,77,79,167-180]	• Evaluation reports and/or assessments, recommendations, and minutes of meetings, publicly available on organization's website	• No separate appeals mechanism	• Decisions time limited: automatic post reimbursement review undertaken to assess "value for money" in practice	No information found	No information found
United Kingdom, Wales, and United Ireland [26,43,44,56,77,88,181-200]	• Assessment and evaluation reports, final recommendations, decisions, and minutes of meetings, publicly available on organization's website • Committee meetings partly held in public	• Appeals may be launched within 10 working days of circulating final recommendations • Only process-related appeals accepted (i.e., failed to act in accordance with processes, "perverse" guidance prepared in light of evidence, or "exceeded powers") • Appeals panel appointed by NICE board (includes at least 1 non executive director of NICE, 1 member working in NHS, 1 member with experience in the clinical field or industry and 1	• Date for review of "guidance" set when first guidance is published • Date varies with available evidence for technology • May be reviewed before date if evidence likely to change recommendations becomes available	• NHS must make funding available to provide technologies approved by NICE within 3 months of the decision unless this period is extended by the Department of Health (DoH)	Appeal recommendations: • Patient and carer groups • Health care professional associations • Government (e.g., DoH) • Manufacturer(s) of technology

Table 1-4. Public accountability and decision implementation considerations

Country	Transparency	Appeals mechanisms	Reassessment or review of decisions	Conditions of implementation	Role of stakeholders
		member from a patient organization) • Appeals can only be made by "consultees", identified at the beginning of the technology review process, who are not representing NHS trusts or local boards			
United States [43,201-212]	• Summary of assessment and evaluation reports, responses to public comments, advisory committee recommendations and rationale for decisions, publicly available on organization's website • Meetings of Medicare Evidence Development and Coverage Advisory Committee held in public	• Appeals may be made to the Appeals Board	• Review of new evidence related to "national coverage determinations": ongoing	• "National coverage determinations" must be implemented within 180 days of the decision	Appeal recommendations: • Anyone
Wales [195,213-216]	• Assessment and evaluation reports, final recommendations, guidance (decisions), and minutes of meetings, publicly available on organization's website • AWMSG Committee meetings held in public	• Appeals may be launched within 10 working days of circulating final recommendations • Appeals related to process and scientific disputes accepted • Appeals panel (independent review panel) appointed by Welsh Medicines Partnership secretariat (includes 7 members: 3 appointed from AWMSG and 4 from either Wales Medicines and Therapeutics Advisory Committees and/or other	• Reassessment date varies with available evidence for technology	• Local health boards must make funding available to provide technologies approved by Minister within 3 months of the decision	Appeal recommendations: • Manufacturer(s) of technology

Table 1-4. Public accountability and decision implementation considerations

Country	Transparency	Appeals mechanisms	Reassessment or review of decisions	Conditions of implementation	Role of stakeholders
		respected experts in relevant field			
Provincial/state/county level					
Alberta, Canada[217,218]	• "Synthesis report" publicly available on organization's website	• None	• None	No information found	No information found
Ontario, Canada [219-221]	• Assessment and evaluation reports, and final recommendations, publicly available on organization's website	• Appeals may be launched within 60 days of circulating final recommendations • Disputes on the grounds that relevant evidence has been overlooked or misinterpreted accepted • Appellant invited to make 20 minute presentation to OHTAC	No information found	Recommendations must be approved by the Ministry of Health and Long Term Care (no further information found)	Appeal recommendations: • Anyone
Oregon, United States [222,223]	• Summary of assessment and evaluation reports, responses to public comments, advisory committee recommendations and rationale for recommendations, publicly available on organization's website • Meetings held in public	No information found	• Review date varies with available evidence for technology – may extend expiration date or reassess recommendations after 18 months	Recommendations must be approved by the State Legislature	No information found
Washington, United States [204,224-227]	• Summary of assessment and evaluation reports, responses to public comments, advisory committee recommendations and rationale for recommendations, publicly available on organization's website • Meetings held in public	No information found	No information found	• Committee recommendations not binding - individual participating agencies make final reimbursement decisions	No information found
Institutional/regional level					

Table 1-4. Public accountability and decision implementation considerations

Country	Transparency	Appeals mechanisms	Reassessment or review of decisions	Conditions of implementation	Role of stakeholders
Sydney public hospital, Sydney Australia [228]	• Rationale for decision available to physician requesting the technology	• Appeals accepted if new information becomes available	No information found	No information found	Appeal decisions: • Requesting physician
Calgary Health Region (Calgary, Alberta, Canada) [229]	No information found	No information found	No information found	No information found	No information found

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APPENDIX 1-1. DETAILED SUMMARY OF LITERATURE SEARCH

Run January 10 – 25, 2010

1. PubMed

#130	Search ("2005"[Publication Date] : "3000"[Publication Date]) AND (#127 AND #128)	3379
#129	Search #127 AND #128	17649
#128	Search #113 OR #114 OR #115 OR #116 OR #117 OR #118 OR #119 OR #120 OR #121 OR #122 OR #123 OR #124 OR #125 OR #126	76723
#127	Search #96 OR #97 OR #98 OR #99 OR #100 OR #101 OR #102 OR #103 OR #104 OR #105 OR #106 OR #107 OR #108 OR #109 OR #110 OR #111 OR #112	188439
#126	Search technology assessment, biomedical[mh]	8002
#125	Search technology, medical[mh]	9152
#124	Search biomedical technology[mh]	4018
#123	Search "medical technologies"[ti]	153
#122	Search "health technologies"[ti]	102
#121	Search funding[ti]	3934
#120	Search coverage[ti]	7585
#119	Search "setting priorities"[ti]	172
#118	Search "priority setting"[ti]	329
#117	Search health priorities[mh]	7154
#116	Search allocating[ti]	245
#115	Search resource allocation[mh]	12998
#114	Search reimbursement[ti]	3491
#113	Search reimbursement mechanisms[mh]	25683
#112	Search "health policies"[ti]	355
#111	Search "health policy"[ti]	2860
#110	Search health policy[mh]	60769
#109	Search "policy makers"[ti]	190
#108	Search policymaking[ti]	110
#107	Search "policy making"[ti]	292
#106	Search policy making[mh]	14245
#105	Search "healthcare rationing"[ti]	25
#104	Search "health care rationing"[ti]	113
#103	Search health care rationing[mh]	9137
#102	Search government agencies[mh]	11302
#101	Search decision making, organizational[mh]	9500
#100	Search "decision makers"[ti]	264
#99	Search "decisions"[ti]	8089
#98	Search "decisionmaking"[ti]	176
#97	Search "decision making"[ti]	9936
#96	Search decision making[mh]	86603

2. HealthSTAR (Ovid) 1966-December 2009

1	exp decision making/	88114
2	decision making.ti.	9605
3	decisionmaking.ti.	183
4	decisions.ti.	7366
5	decision makers.ti.	269
6	exp decision making, organizational/	9651
7	exp government agencies/	83928
8	exp health care rationing/	9739
9	health care rationing.ti.	115
10	healthcare rationing.ti.	22
11	exp policy making/	15212
12	policy making.ti.	297
13	policymaking.ti.	93
14	policy makers.ti.	184
15	exp health policy/	64294
16	health policy.ti.	2902
17	health policies.ti.	358
18	exp reimbursement mechanisms/	26535
19	reimbursement.ti.	3516
20	exp resource allocation/	13839
21	allocating.ti.	234
22	exp health priorities/	7784
23	priority setting.ti.	302
24	setting priorities.ti.	177
25	coverage.ti.	6584
26	funding.ti.	3781
27	health technologies.ti.	91
28	medical technologies.ti.	153
29	exp biomedical technology/	4095
30	exp technology, medical/	8891
31	exp technology assessment, biomedical/	8479
32	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17	260597
33	18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31	77888
34	32 and 33	23007
35	limit 34 to yr="2005 -Current"	4242

3. EMBASE (Ovid)

1	exp decision making/	45877
2	decision making.ti.	6388
3	decisionmaking.ti.	70
4	decisions.ti.	4421
5	decision makers.ti.	193
6	exp government/	36860
7	health care rationing.ti.	54
8	healthcare rationing.ti.	14
9	policy making.ti.	183
10	policymaking.ti.	45
11	policy makers.ti.	126
12	exp health care policy/	62970
13	health policy.ti.	1577
14	health policies.ti.	133
15	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14	141249
16	exp reimbursement/	12261
17	reimbursement.ti.	1570
18	exp resource allocation/	8172
19	allocating.ti.	144
20	priority setting.ti.	235
21	setting priorities.ti.	102
22	coverage.ti.	4129
23	funding.ti.	2149
24	health technologies.ti.	74
25	medical technologies.ti.	88
26	exp medical technology/	12991
27	exp biomedical technology assessment/	5880
28	16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27	44572
29	15 and 28	7826
30	limit 29 to yr="2005 -Current"	3238

4. Web of Science

Title=(decision* OR "health care rationing" OR "healthcare rationing" OR "health polic*") AND Title=(reimbursement OR "resource allocation" OR allocating OR priorit* OR funding OR coverage) AND Title=(health OR technolog* OR medical OR healthcare OR drugs OR pharmaceuticals OR devices)
Timespan=2005-2010. Databases=SCI-EXPANDED, SSCI, A&HCI.
= 51 references

5. SCOPUS * excluded physical sciences

Your query: (TITLE(decision* OR "health care rationing" OR "healthcare rationing" OR "health polic*") AND TITLE(reimbursement OR "resource allocation" OR allocating OR priorit* OR funding OR coverage)) AND SUBJAREA(mult OR agri OR bioc OR immu OR neur OR phar OR mult OR medi OR nurs OR vete OR dent OR heal OR mult OR arts OR busi OR deci OR econ OR psyc OR soci) AND PUBYEAR AFT 2004
= 233 references

6. Centre for Reviews & Dissemination (HTA, DARE, NHS EED) databases

(decision*:ti OR rationing:ti OR polic*:ti OR reimbursement:ti OR allocat*:ti OR fund*:ti OR coverage:ti) AND (technolog* OR medical OR healthcare OR priority OR priorities OR drugs OR pharmaceuticals OR devices) RESTRICT YR 2005 2010: 243 documents found

7. Locatorplus http://locatorplus.gov

Decision making (MeSH), English language and 2005 to date = 216 references
Technology assessment, Biomedical (MeSH), English language and 2005 to date = 136 references

8. NLM Gateway http://gateway.nlm.nih.gov/

decision making AND technology assessment, biomedical, English language and 2005 to date = 406 references ** only meeting abstracts (=90) scanned

9. EconLit

S3	TX (decision making OR government policy) and TX health technologies Limiters - Published Date from: 20050101-20101231 Search modes - Boolean/Phrase	(118)
S2	TX (decision making OR government policy) and TX health technologies	(253)
S1	TX decision making and TX health technologies	(200)

10. Health Policy Reference Center (EBSCOHost)

S5	SU decision making and SU medical technology	Limiters - Publication Date: 20050101-20101231; Language: English Search modes - Boolean/Phrase	(36)
S4	SU decision making and SU medical technology	Search modes - Boolean/Phrase	(56)
S3	TI decision making and TI (health OR healthcare OR medical) and TI (drugs OR pharmaceuticals OR technologies OR rationing OR priority OR priorities)	Search modes - Boolean/Phrase	(15)
S2	TX decision making and TX (health OR healthcare OR medical) and TX (drugs OR pharmaceuticals OR technologies OR rationing OR priority OR priorities)	Search modes - Boolean/Phrase	(12887)
S1	TX decision making and TX health	Search modes - Boolean/Phrase	(19245)

Grey literature

1. KU-UC database

http://kuuc.chair.ulaval.ca/english/index.php

a. Scanned publications under Technology assessment category (140 hits)

b. Scanned publications under Evidence-based decision making (200 hits)

2. Grey Literature database

http://www.nyam.org/library/pages/grey_literature_report

search terms: decision making (2005-) (63 hits) / decisionmakers (16 hits) / health technology assessment (131 hits)

3. Google

www.google.ca

21,000,000 for (decision* OR rationing OR policy OR policies OR reimbursement OR allocating OR allocation OR funding OR coverage) AND ("health technologies" OR "medical technology" OR "new drugs" OR "new pharmaceutical*" OR "medical devices") AND (government OR provincial OR state OR "regional health" OR "primary care trust" OR lhin) ** scanned first 500 hits only

4. Systematic Reviews for Management and Policy-Making (PPD/CCNC database) http://www.researchtopolicy.ca/Search/Reviews.aspx

scanned all under categories: Governance arrangements / Financial arrangements

5. NHS Evidence: Evidence in Health and Social Care

http://www.evidence.nhs.uk/default.aspx

Decision making = 12,961 ****scanned first 500 hits only**

Country specific search **stopped after first unsuccessful attempts

CHAPTER 2:
TO FUND OR NOT TO FUND: DEVELOPMENT OF A DECISION-MAKING FRAMEWORK FOR THE ALLOCATION OF RESOURCES TO NEW HEALTH TECHNOLOGIES

ABSTRACT

Introduction:

Attempts to improve the acceptability of resource allocation decisions around new health technologies have spanned many years and disciplines. Various theories of decision-making have been tested and methods piloted. But, despite their availability, evidence of sustained uptake is limited. Since the challenge of determining which of many technologies to fund is one that healthcare systems have faced since their inception, a critical analysis of *actual* processes, criticisms confronted, and approaches used to manage them may serve to guide the development of an 'evidence-informed' decision-making framework to improve the acceptability of decisions.

Objective:

To develop a technology funding decision-making framework, informed by the experiences of multiple healthcare systems and the views of senior-level decision-makers in Canada.

Methods:

A one-day, facilitated workshop was held with 16 Canadian, senior-level healthcare decision-makers. International examples of actual technology funding decision-making processes were presented. Participants discussed key elements of these processes, debated strengths and weaknesses, and highlighted unresolved challenges. The findings were used to construct a technology decision-making framework on which participant feedback was then sought. Its relevance, content,

structure, and feasibility were further assessed through key informant interviews with 10 additional senior-level decision-makers.

Results:

Six main issues surrounding current processes were raised: 1) timeliness; 2) methodological considerations; 3) interpretations of 'value for money'; 4) explication of social values; 5) stakeholder engagement; and 6) 'accountability for reasonableness'. While no attempt was made to force consensus on what should constitute each of these, there was widespread agreement on questions that must be addressed through a 'robust' process. These questions, grouped and ordered into three phases, became the final framework.

Conclusions:

A decision-making framework informed by processes in other jurisdictions and the views of local decision-makers was developed. Pilot-testing underway in one Canadian jurisdiction will identify any further refinements needed to optimize its usefulness.

INTRODUCTION

How should resource allocation decisions around new health technologies be made? Efforts to address this question have spanned many years and fields, including business, management, economics, political science, sociology, law, and ethics.[1-3] Various theories of decision-making have been proposed and tested.[4-6] Several methods originating from health economics have been piloted in systems around the world.[7-10] However, despite the availability of these approaches and decision-makers' awareness of them, evidence of their use beyond the 'demonstration project' phase is sparse.

While the challenge of determining which new health technologies to include in the basket of publicly insured services may have heightened in recent years, it is not a new one. Therefore, insights into *actual* processes implemented in healthcare systems, criticisms faced, and approaches used to manage them may serve to guide the development of an 'evidence-informed' decision-making framework designed to improve the acceptability of resource allocation decisions for which there will inevitably be "winners" and "losers".

Building upon findings from a recently completed critical review of health technology coverage decision-making processes in 20 countries,[11] this project engaged senior-level decision-makers in discussions around the necessary

components of a framework for selecting new health technologies to fund through the public healthcare system.

OBJECTIVE

Specifically, the objective was to develop a technology funding decision-making framework informed by the experiences of multiple healthcare systems and the views of senior-level decision-makers in Canada.

BACKGROUND

Attempts to apply existing decision-making theories or models originating from the non-healthcare sector and championed by some scholarly communities to decisions in the healthcare sector (i.e., the funding of health technologies) have proved challenging. For example, the *rational model* of decision-making assumes that a clear decision objective exists and that decision-making can be carried out in an orderly fashion with full knowledge of all of the "facts".[12] In this model, all possible alternatives and consequences are identified and the alternative that best meets the objective is selected. In healthcare, resource allocation decision-making, particularly around promising, new health technologies, takes place under conditions of uncertainty, as available evidence of clinical benefit, need, utilization, and economic implications are typically limited and of poor quality. Moreover, in publicly funded healthcare systems, the objective of the decision (i.e., desired outcome) is not always clear or shared by all members of a decision-making committee. Committees often comprise representatives from different

stakeholder groups with competing interests, claims, and objectives, such as protecting patient choice, maximizing health outcomes, and containing costs.[13]

Recognizing the limitations of strict rationality, the *bounded-rationality model* (BRM) has been proposed. Under BRM, the range of possible options is narrowed down first, thus reducing the type and amount of information needed.[14] However, it still assumes consensus on a decision outcome, thereby conceding to the same limitation as the rational model.

A third model, the *incremental decision-making model* or *muddling through*, assumes that decision-makers have little time and resources and, thus, are only capable of undertaking non-comprehensive analyses of small changes, which ultimately lead to decisions that do not deviate considerably from the status quo.[6] While this model may help to explain existing resource allocation decision-making processes in some organizations, it offers little insight into how it should be done.

Mixed scanning is viewed as a compromise between rational decision-making and incremental decision-making.[15] Also referred to as a "focussed trial and error approach", it proposes that decision-making is guided by a clear objective, and only alternatives consistent with that objective are pursued. It combines a wide, but not deep, examination of facts with a more detailed analysis of selected

options. Although more realistic than rational or incremental decision-making models, it still requires consensus on a decision objective.

In contrast, the *garbage can model* suggests that decisions take place when three "streams" (problems, solutions and political opportunity) meet (i.e., when an implementable solution to the problem identified already exists).[5] Thus, decisions are driven by the 'timing' of potential solutions. However, most health care organizations engage in some form of programmatic decision-making, in which committees meet at pre-determined intervals to consider new technologies or services for funding. Consequently, the relevance of this model may be limited.

A considerable amount of academically driven research in the area of healthcare resource allocation has been conducted over the last 25 years. While a comprehensive review of such work is beyond the scope of this paper, there appears to be a lack of evidence of sustained uptake of these approaches into real-world decision-making. Reasons for this have included: 1) the evidence requirements are too large; 2) the proposed steps are too resource intensive; 3) the approach assumes flexibility that is not feasible in practice; 4) the outcomes upon which the process is based do not capture the important effects of a technology or service; and 5) a consensus on ethical assumptions that should guide the process could not be reached.[16-26]

METHODS

Development of the decision-making framework involved three main steps: 1) identification of key components; 2) construction of a draft framework; and 3) verification of the framework.

Identification of key components of the framework

1. Recruitment of senior-level decision-makers

Purposive sampling techniques were used to identify 16 senior-level decision-makers, whose mandates included the introduction of new health technologies within their organizations, to take part in a one-day workshop.[27] Technologies were defined as pharmaceuticals, devices, diagnostic tests, and interventional procedures. A sample size of 16 was considered large enough to capture a range of decision-making contexts and small enough to facilitate active engagement of all participants. Since in recent years, much of the criticisms around access to new health technologies in Canada have pertained to cancer,[28-31] one senior executive from each of the 10 provincial cancer agencies was invited to the workshop. Invitations were also extended to the chair of Canada's centralized pharmaceutical review process (which makes recommendations on the coverage of new, non-cancer drugs to participating provincial pharmaceutical benefit plans), as well as a convenience sample of five provincial decision-makers representing either branches responsible for the coverage of pharmaceuticals, or non-pharmaceutical technologies, or the whole of the ministry of health (at the deputy minister level) (three from Alberta, one from Ontario, and one from

Saskatchewan). Formal letters explaining the study were mailed and sent electronically to all 16 decision-makers. To optimize response rates, follow-up telephone calls were completed by members of the investigative team already known to potential participants.

2. Organization of the expert workshop

The one-day, expert workshop was held to gather input from participants on important components of a technology decision-making framework. To encourage discussions that considered a sufficiently broad range of options, the workshop began with an overview presentation comparing current national, provincial/state/county and regional/institutional technology decision-making processes in countries economically similar to Canada.[11] This was followed by facilitated deliberations over the relevance, content, and feasibility of such processes within the participants' own organizations. Strengths and weaknesses were highlighted, along with 'missing elements'. Participants then broke into small groups to discuss the most significant challenges they faced and suggest basic requirements for an 'acceptable' technology decision-making framework. They then reconvened for a final, large group session, during which findings from small groups were shared and used to identify elements for inclusion in the framework.

To encourage candid discussions among participants throughout the workshop, sessions were not audio-taped. Instead, four researchers independently took notes

of participants' comments and actions. These notes were compiled and then validated through 'member-checking' with participants.

Construction of a draft framework

1. Analysis of workshop proceedings

Thematic analyses of workshop notes were performed to identify not only themes corresponding to necessary elements of a decision-making framework, but also the potential 'place' of those elements, relative to one another.

2. Assembly of the framework

Based on findings from qualitative analyses, elements were ordered and grouped into distinct, coherent, sequential phases, forming the structure for the framework. They were then converted into questions to be addressed by decision-makers as they 'work through' a technology funding decision problem.

Verification of the framework

The relevance, structure, content, and feasibility of the framework were assessed in two ways.

1. Review by workshop participants

The framework was sent to all workshop participants, who were asked to comment on whether it accurately reflected their views.

2. Key informant interviews with other senior-level decision-makers

Key informant interviews (in-person or by telephone) were conducted with senior-level decision-makers from the same or similar organizations (e.g., cancer agencies, provincial governments, regional health authorities, etc.), who did not to participate in the workshop. To reduce observer bias, an interview guide was prepared and sessions were conducted by the same two members of the investigative team. Participants were presented with copies of the framework and asked about the extent to which they felt it captured the realities of resource allocation decision-making, was comprehensive, followed a logical sequence, and appeared actionable (in their organizations). A total of 10 interviews were conducted, at which point saturation had been reached (i.e., no new points were being raised).[27]

Lastly, a modified Delphi process was used to incorporate all feedback into the framework.[27,32] Specifically, decision-makers who participated in the workshop or key informant interviews were sent revised versions in several rounds until no additional comments were received.

RESULTS

All 16 decision-makers attended the workshop.

Issues identified by workshop participants

Participants raised six main issues surrounding current processes: 1) timeliness; 2) methodological considerations; 3) interpretations of 'value for money'; 4) explication of social values; 5) stakeholder engagement; and 6) 'accountability for reasonableness'. Discussions around timeliness focussed on the tension between rigour and efficiency in processes, and the risk of making a 'wrong' decision, which could lead to poorer health outcomes and wasted resources. One participant stated, "We need to better understand what the opportunity costs of expedited reviews really are". Regarding methodological considerations, the small groups had compiled lists of what they felt were critical information inputs into decision-making processes. The lists included: 1) severity and burden of the condition (including availability of alternatives); 2) clinical effectiveness; 3) cost-effectiveness; 4) budget impact; 5) patient preferences, and 6) "broader impacts of the technology". Groups also considered proposing minimum evidence expectations, particularly for clinical and economic inputs (e.g., requirement for cost-utility analysis). In the end, they abandoned the idea, taking the view that "the decision problem and possible decision options should guide information requirements". In addition, participants noted the absence of well-established, validated methods of assessing the "broader impacts of a technology" (e.g., "psychosocial, operational, societal", etc.), and indicated "the need to develop and measure metrics around [such] impacts in order to better understand the value of a technology".

A discussion around efficiency assumptions (i.e., what constitutes value for money) followed. While views about how this should be defined differed, participants agreed on the need to "be clear about whether there is an explicit or implicit threshold embedded in the process". The value-laden nature of decisions was also raised. "Decisions are made to facilitate technology access, distribution, redistribution, etc., all of which are predicated on a value decision".

Participants described specific challenges involved in allocating resources for cancer technologies, where "denial of a new treatment can be perceived as equivalent to a death sentence". Such challenges related to 1) defining values and resolving value conflicts among different perspectives ("The extent to which our committee's values actually represent those of the public is not clear"; "Our decisions should reflect societal values, but we don't know what they are"; and "There is a values dissonance where the values we have as individuals and the values of the organization may be in conflict – do we leave our values at the door?"); and 2) establishing clear and transparent mechanisms for incorporating them into decisions ("we don't have the language to capture competing values, yet we need to be able to articulate how our decisions rest on them"). This discussion evolved into one around stakeholder engagement. It was acknowledged that "a good decision is one made with the broadest possible input", but input, by itself, was not enough. "We need to find a way to manage expectations from the public". Participants felt this could be achieved through "better stakeholder engagement

and communication during the decision-making process", the first steps of which would be to "define who might be impacted and who needs to be consulted".

Groups then discussed challenges to meaningful engagement of different stakeholder groups, including the public, patients/carers health care providers, and industry/manufacturers. Two challenges were identified: 1) finding appropriate methods ("How do we involve the public?"; "Should we have citizens' councils like [Province Y], which recently created one as part of its formulary decision-making process?"); and 2) establishing trust among stakeholders and decision-makers ("Companies must buy into the process and be willing to share information…trust goes both ways"). After considerable debate over the various roles that different stakeholders might play at different steps in the decision-making process, participants agreed that "who and how should depend on the type of decision problem" (whether to add, replace, or delist (i.e., no longer provide) a technology).

Issues related to transparency, accountability, contestability, and consistency surfaced during discussions about 'accountability for reasonableness (A4R)'. The A4R principles were raised by several participants.[2,33,34] A4R is an ethical framework proposing key elements of fair processes for setting priorities in healthcare. They involve 1) transparency around grounds for decisions; 2) rationales that can be accepted as relevant to meeting healthcare needs fairly; 3)

procedures for revising decisions in light of new evidence or considerations; and 4) mechanisms to ensure the above three principles are met.

Participants were unanimous on the need for increased transparency in processes, indicating that their "constituents feel funding decisions are made secretively and are totally non-transparent". However, one participant expressed caution as well, explaining the risks of transparency. "But if we become more transparent, does that leave us open to gaming by industry?" Several argued that "everybody, including decision-makers, game…we can't let that stop us from trying to achieve procedural justice". "Without transparency and openness, the process cannot be accountable".

There was consensus on the importance of establishing appeals mechanisms. "The public should have the right to appeal" and "mechanisms must be available to challenge both the decision and the process". Participants identified two necessary appeals points: 1) following release of recommendations; and 2) when a decision is made. While they agreed on the need for independence in such mechanisms, they were uncertain whether this could ever be feasible.

Finally, participants highlighted the lack of consistency in decision-making process. "In an ideal executive, decisions should arise out of processes and values that are set ahead of time – and what comes to you is simply just confirmation". "Currently, there is an assumption that failing to secure additional resources to

fund new technologies means failing to make compelling arguments…this leads to political decision-making. Formulary committees must recognize that they are accountable to a system in which resources are finite". "Decision-makers need to be willing to set limits and be able to live with imperfect evidence and hard decisions. It is necessary to have a framework through which they can feel empowered to do all of this".

Basic elements of a decision-making framework

Participants discussed what a decision making framework should contain, and proposed three main components: 1) identification of the need for a decision; 2) process for making a decision; and 3) action to be taken on the basis on the decision. For the first component, participants drew upon findings from the comprehensive review of existing processes around the world to identify its key elements.[11] They included the type of decision problem, timing (by when a decision needs to be made), and groups that might be affected by the decision. They also stressed the importance of "understanding how the technology got on the agenda - where it came from and who was pushing for it". With respect to the second component, participants saw the framework as a guide to ensuring the 'right' questions are asked at the appropriate point in the development of processes to address different types of decision problems. Taking the view that "the decision problem, possible options, and organizational expectations [which vary across processes] should drive evidence requirements and decision criteria", participants stayed away from attempting to define either one. For the third

component, the discussion centered around the communication of decisions to stakeholder groups, appeals mechanisms, and post-decision requirements (e.g., review/reassessment of decision by a pre-specified time). While there was agreement on the importance of including all three elements, participants acknowledged that feasible options for addressing each one would likely vary with the health care organization and its jurisdictional level. “We need to consider the cost-effectiveness of the decision-making process as well”.

Development of a draft technology decision-making framework

Based on the workshop findings, a framework with the three components described above was constructed. These components, which comprised distinct, chronological phases in a decision-making process, were assigned separate, ordered boxes. Elements were sorted according to relevant phase and placed in the corresponding box. Once converted into questions, they formed a step-by-step guide for developing funding decision-making processes in a systematic way.

Workshop participants indicated that the draft framework accurately reflected their discussions. No suggestions for revisions were received.

Verification of the framework

During key-informant interviews, there was widespread endorsement of the general content and structure of the framework. However, the following

modifications were suggested: 1) Emphasize the importance of capturing the different influences and perspectives that enter into each of the three phases; 2) Add a question that encourages decision-makers to explicate whose and what "values" are being considered during decision-making; 3) Incorporate the need for ethical principles embodied in an organization's vision and mission to be explicitly considered throughout the decision-making process; 4) Ensure that there is an appeals mechanism at both the recommendation step and the decision step; and 5) Include a question that encourages committees to consider opportunities for disinvestment in existing technologies alongside investment in new ones, as indicated by one interviewee, "This [disinvestment] may be important in the next few years as decisions are being made in an era of tight budgets as opposed to increasing ones".

All five additional points were incorporated into the final framework (Figure 2-1). It consists of the three boxes mentioned above, within a circle, which represents the overarching ethical principles that should guide all three phases of the decision-making process. Such principles are to be defined by the healthcare organization. Boxes contain sets of questions designed to optimize the transparency of, and consistency in, the steps that make up each phase.

Box 1: Identification of the decision problem: This phase comprises six questions around specifications of the decision problem: 1) What type of technology funding decision is it? (add, replace, remove, or redistribute); 2) What decision

options are available? (fund, fund with conditions, fund in the interim, or do not fund); 3) By when is a decision needed?; 4) Who needs to make the decision? (organization responsible for deciding whether the technology should be provided); 5) Who needs to be consulted?; and 6) Who needs to be managed or kept informed?. The last two are intended to ensure the inclusiveness of perspectives, while minimizing the likelihood of being "blindsided" by vested interests.

Box 2: The decision-making process: All seven questions within this phase focus on explication of information inputs and procedures specific to the decision problem: 1) What are the social value judgements underpinning decisions and how are they incorporated into the decision-making process?; 2) What types of information inputs are needed in order to capture the full spectrum of perspectives on the value of a technology?; 3) Upon which information sources should different information inputs be based?; 4) What criteria need to be considered during deliberations?; 5) What mechanisms may be employed to manage appeals to recommendations before decisions are made?; 6) Who needs to be consulted?; and 7) Who needs to be informed?.

Box 3: Implementation of the decision: The last phase contains questions related to actions to be taken following approval of a recommendation or announcement of a decision.: 1) What approaches might be used to communicate recommendations or decisions to various stakeholder groups?; 2) What

mechanisms may be employed to manage appeals to decisions; and 3) What post-decision activities are needed, given the magnitude of the decision uncertainty?

DISCUSSION

This paper describes the development of an 'evidence-informed' decision-making framework for funding new technologies, built upon lessons learned from actual experiences. The framework takes the form of a step-by-step guide to be 'worked through' by those involved in determining which technologies to add, replace, or remove from the list of insured services. It allows for the simultaneous consideration of principles of procedural justice or fairness (e.g., accountability for reasonableness), and "outcome" factors, such as cost-effectiveness. During both the expert workshop and key informant interviews, the challenge of managing multiple influences, competing interests, and inconsistencies in existing processes was frequently raised. At the same time, it became clear that decision-makers felt a "one size fits all" approach to all types of decision problems would be inappropriate. There was a need for a decision support tool that asked the 'right' questions, but did not restrict answers a pre-defined, context-free set. For example, a question prompting decision-makers to think about who should be consulted and how was seen as critical, as was the portfolio of possible responses that emerged from the review of existing processes. However, decisions around which response to apply needed to remain with individual organizations, taking into account the appropriateness and feasibility of each one within their specific decision-making environments.

The framework can be considered as a checklist of the necessary elements for improving the acceptability of processes and, in turn, decisions. Responses to questions serve to identify information needs (including value assumptions), the expertise required, and appropriate criteria to be used. Presentation of the framework to board members and the executive committee of a provincial cancer agency resulted in commitments to pilot-test it over a one year period. Specifically, the executive committee will be using it to guide reforms to existing funding processes.

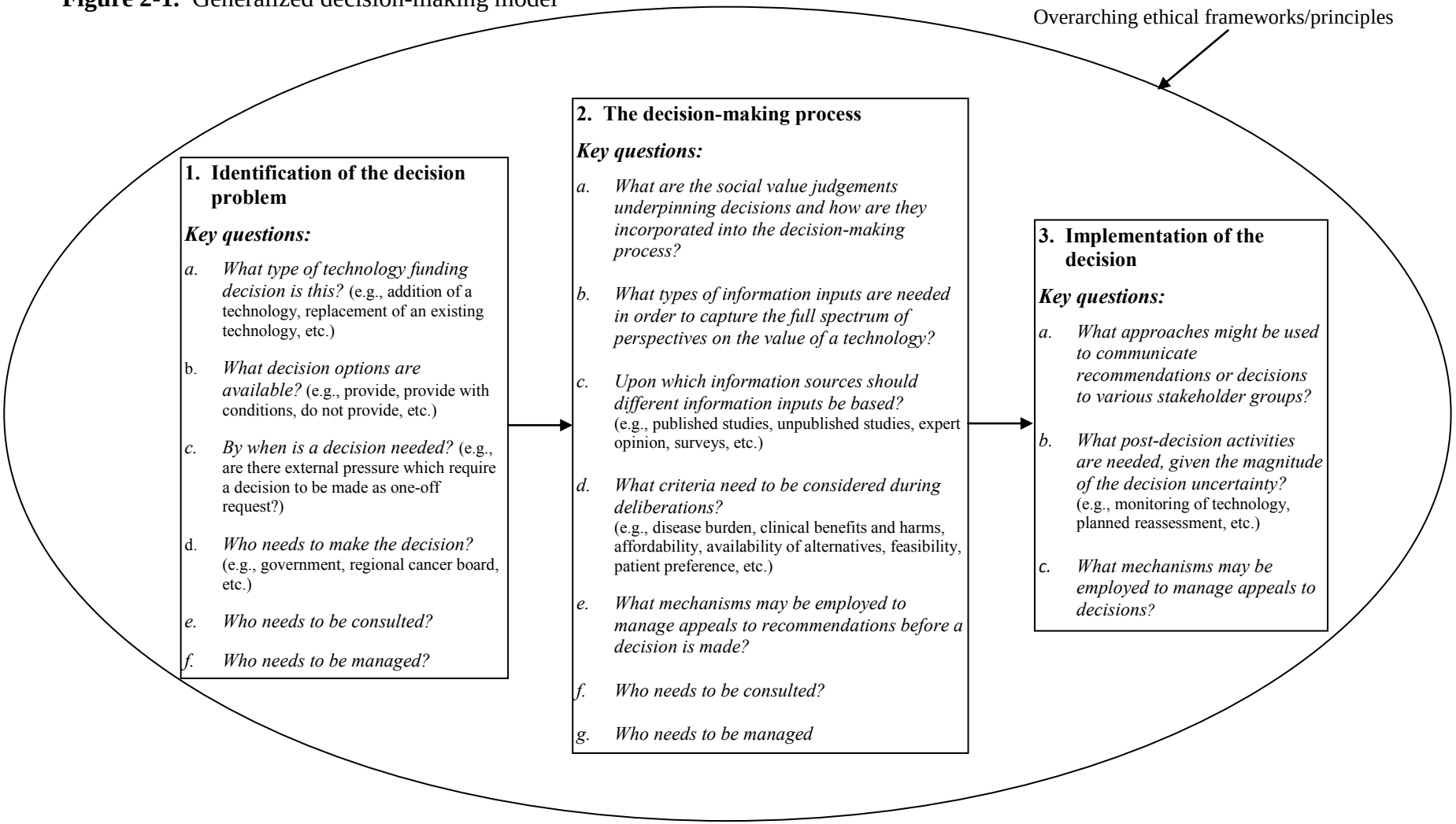
While the framework is intended to support decision-making beyond that related to cancer, many of the views used to inform its development were those of provincial cancer agency decision-makers. Therefore, its applicability to non-cancer technology decision-making processes is not clear.

CONCLUSIONS

This study demonstrated that decision-makers share concerns over current technology funding processes and a keen interest in learning from the experiences of other organizations. Through deliberative discussions, a decision-making framework that combined their knowledge with that from a critical review of international processes was developed.

A version of this chapter has been accepted for publication. Stafinski 2010. PharmacoEconomics.

Figure 2-1. Generalized decision-making model



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CHAPTER 3:
SOCIETAL VALUES IN THE ALLOCATION OF HEALTH CARE RESOURCES: IS IT ALL ABOUT THE HEALTH GAIN?

ABSTRACT

Introduction:

Over the past decade, public distrust in unavoidably value-laden decisions on the allocation of resources to new health technologies has grown. In response, healthcare organizations have made considerable efforts to improve their acceptability by increasing transparency in decision-making processes. However, the social value judgements (distributive preferences of the public) embedded in them have yet to be defined. Little debate over the need to explicate such judgements exists, but the approach to accomplishing this remains unclear.

Objectives:

To identify factors around which distributive preferences of the public have been sought, create a list of social values proposed or used in current resource allocation decision-making processes for new health technologies and review approaches to eliciting such values from the general public.

Methods:

Social values proposed or used in making resource allocation decisions for new health technologies were identified through three approaches: 1) a comprehensive review of published, peer-reviewed, empirical studies of public preferences for the distribution of healthcare; 2) an analysis of non-technical factors or social value statements considered by technology funding decision-making processes in Canada and abroad; and 3) a review of appeals to funding decisions on grounds in part related to social value judgements.

Results:

Thirty-four empirical studies, 10 technology funding decision-making processes, and 12 appeals to decisions were identified and reviewed. The key factors/patient characteristics addressed through policy statements and around which distributive preferences of the public have been sought included: severity of illness, immediate need, age (and its relationship to lifetime health), health gain (amount and final outcome/health state), personal responsibility for illness, care-giving responsibilities, and number of patients who could benefit (rarity). Studies typically examined the importance of these factors in isolation. Therefore, the extent to which preferences around one factor may be modified in the presence of others is still unclear.

Conclusions:

Research that seeks to clarify interactions among factors by asking the public to weigh several of them at once is needed to ensure the relevance of elicited preferences to real-world technology funding decisions.

INTRODUCTION

Decisions regarding which new health technologies to fund under budget constraints are value-laden, requiring considerations beyond technical assessments of scientific information.[1-10] Over the last decade, public distrust in such decisions has grown, forcing payers in health systems in most of the developed world to re-examine and refine their approaches to allocating scarce healthcare resources.[11-15] To date, their efforts have primarily focussed on ensuring procedural justice through the implementation of 'accountability for reasonableness'(A4R) principles.[16-20] Such principles stem from the view that in pluralist democracies, citizens are unlikely to agree on the social values or moral claims that should govern limit-setting decisions in healthcare; however, they are able to agree on legitimate processes for arriving at fairer, more acceptable decisions.

A4R principles include: 1) transparency around grounds for decisions; 2) rationales that can be accepted as relevant to meeting healthcare needs fairly; 3) procedures for revising decisions in light of new information; and 4) mechanisms to ensure the above three principles are met.[18-20] In recent years, most healthcare organizations have made significant progress towards meeting these requirements, with specifications for economic and clinical evidence clarified, steps in decision-making processes outlined, roles for stakeholders defined, and appeals mechanisms established.[21] However, the social value judgements embedded or

implicit in decisions have largely remained ill-defined. At the same time, it is widely recognized that such values must be explicated for transparency in decision-making and, in turn procedural justice, to be fully realized.[1,22] This paper describes first steps taken to accomplish this, providing a comprehensive, "state of the science" review of attempts to explicate social values in the context of resource allocation decision-making for health technologies.

OBJECTIVES

1. To compile a list of factors around which distributive preferences of the public (social values) have been sought;
2. To identify social value statements underpinning decision making processes in organizations that provide publicly funded health services;
3. To review approaches to eliciting such statements from the general public.

BACKGROUND

Social values may be defined as the public's preferences for the distribution of healthcare among populations.[23] They consider factors/characteristics of patients and the effects of interventions on their health (i.e., health gain). In addition, they reflect one or more, often conflicting, ethical positions on equity in healthcare when all competing claims cannot be met. Collectively referred to as "rationing" principles, such positions relate to distributive justice, rather than procedural justice (i.e., the relative acceptability of alternative allocations of resources as opposed to the relative acceptability of alternative processes through which decisions are made).[24] They include: 1) the lottery principle or 'not playing God';

2) rule of rescue; 3) need; 4) health maximization; 5) fair innings; and 6) choicism.[25]

The lottery principle is predicated on the view that "explicit rationing is unethical", since "a life is a life and everyone is equal". Thus, no criteria should be used to select patients. Instead, resources should be distributed by way of lottery mechanisms, such as 'first come first served' or time already spent on the waiting list. Under 'rule of rescue', resources are allocated according to most immediate need. Priority is given to those facing imminent death or irreversible consequences in the absence of urgent care. Needs-based rationing emphasizes the importance of prioritizing patients based on severity of illness (which may or may not be immediately life-threatening). Health maximization requires that resources be distributed in a way that improves the total health of the whole population. Derived from an efficiency concept, it seeks to maximize outcomes from a fixed input by giving priority to patients who are likely to realize the most length and quality of life (i.e., have the greatest ability to benefit the entire community). The fair innings principle argues that everyone is entitled to a "similarly decent lifetime experience of health", based on what is considered average for the whole population, and healthcare should be distributed to reduce inequalities in 'lifetime health'. Therefore, younger patients are preferred to older patients. Lastly, choicism or 'equalizing opportunity for health' states that while people should be free to choose their own level of health through their lifestyle

choices, those who suffer ill health through no fault of their own should be given priority.

In general, publicly funded services within health care systems have adopted a health maximization or utilitarian approach to decision-making, aiming to achieve the "the best health outcomes from available funds" or "the greatest good for the greatest number". What matters is aggregate health gain, not to whom it accrues.[1,10,24] However, it has been argued that such an approach leads to inequitable access for vulnerable groups with lower-than-average capacity to benefit, and magnifies inequalities in health. In addition, it is misaligned with the views of the public, who would prefer to see healthcare distributed according to need or severity of illness (i.e., help the 'worse off').[25-28] There is little debate among decision-makers over the need to ensure that value judgements used to inform decisions (such as consideration of efficiency and equity) accurately reflect those of the public.[3,8,15-16] The question is: "When and to what extent are the public willing to trade-off total health gain (an efficiency position) for reduced health inequalities (an equity position)?"

METHODS

Social values proposed or used in making resource allocation decisions for new health technologies were identified through three approaches: 1) a comprehensive review of published, peer-reviewed, empirical studies of public preferences for the distribution of healthcare; 2) an analysis of non-technical factors or social value statements considered by technology funding decision-making processes in

Canada and abroad; and 3) a review of appeals to funding decisions on grounds in part related to social value judgements.

Comprehensive review of empirical studies

1. Identification of studies

A comprehensive search for published empirical studies examining distributive preferences of the public for healthcare among populations (i.e., social values) was performed. Peer-reviewed, English language publications were identified using a structured search strategy applied to several bibliographic databases. The search was limited to the last decade (i.e., the period during which much of the debate over social values in health technology funding decisions has occurred). The search strategy combined controlled vocabulary terms (e.g., MeSH: "public opinion", social justice", "social values", "resource allocation", "health care rationing", and "decision-making"; EMTREE: "social psychology", "attitude to health, and "social justice") with free text terms (e.g., "public values", "distributive preferences", "equity", "fair innings", "rationing principles", "equity", and "social values") identified through an analysis of known key references.[29] To maximize the likelihood of capturing all relevant studies, keywords related to patient characteristics or factors around which public preferences may be elicited were also incorporated (e.g., age, capacity to benefit, severity of illness) (Appendix 3-1).[30] The databases searched included: PubMed (MEDLINE), The Cochrane Library, EMBASE, PsycINFO, Web of Science, the Centre for Reviews and Dissemination databases (DARE, NHS EED, HTA),

CINAHL, EconLit, and HealthSTAR. Monthly update searches were run on PubMed, using the same search strategy, to identify papers published between January 2010 and June 2010. The electronic search was supplemented by a manual search of reference lists of retrieved papers. Finally, the most recent issues of relevant health policy journals were hand-searched.[31]

Citations identified through the various searches were imported or entered into a bibliographic database (Reference Manager® version 11.0). Duplicate references were removed.

2. Selection of studies for inclusion

Adhering to published, methodological guidelines for conducting systematic reviews, the titles and abstracts of all citations were screened independently by two experienced researchers using pre-determined inclusion criteria (*empirical studies* of preferences of the *general public* on *non-technical or patient-related factors* to be considered during *resource allocation decision-making for healthcare*).[31] "Think" or opinion pieces, reviews of general public involvement, and studies relying on convenience samples of sub-groups of the population (e.g., students or seniors) were excluded. Potentially relevant citations were retrieved for full review by the same two researchers, applying the same inclusion criteria. Inter-rater reliability was assessed using the Kappa statistic, which measures beyond chance agreement.[32] Any discrepancies between them were resolved through discussion and, if necessary, adjudication by a third researcher. However,

third reviewer resolution was not needed as the Kappa statistic was 1.0, indicating perfect agreement.

3. Extraction of information from included studies

The same two researchers independently extracted information from included studies using a standard, pre-tested data abstraction form. This form consisted of elements pertaining to study design (e.g., patient characteristics/factors examined, study country, publication year, sampling approach, sample size, and methods used to elicit distributive preferences), on which the credibility of findings were assessed. It also contained fields for collecting outcomes data (i.e., emerging social value judgements). Information extracted by the two researchers was entered into a spreadsheet (Microsoft Office - Excel®) in order to identify discrepancies. Once again, the degree of agreement on extracted data was assessed using the Kappa statistic (K = 0.88, indicating excellent agreement).[32]

4. Synthesis of information collected

Information collected was first organized into tables to facilitate qualitative analyses of emerging 'themes'. Themes represented patient characteristic/factors (e.g., age, severity of illness, personal responsibility for the condition, etc.) around which distributive preferences of the public had been elicited. For each characteristic, findings (i.e., distributive preferences) from relevant studies were then compared to identify possible variations associated with methodological

differences (e.g., recruitment strategy, deliberative versus non-deliberative techniques, decision-simulation exercise, structure of questions, etc.).[33]

Analysis of criteria related to social value statements considered by technology funding decision-making processes in Canada and abroad

1. Identification of technology decision-making processes

Health technology funding decision-making processes in countries broadly similar to Canada in terms of 'wealth' and potential demand for new health interventions were identified using World Bank rankings of countries by Gross Domestic Product per capita.[34] The top 20 countries with populations over one million were selected. This number (20) was considered sufficiently large to capture the range of social value statements that may be embodied in coverage decision-making criteria in different public insurance models.

2. Search for relevant information on each process

For each country, websites of the ministry of health and organizations which oversee processes for making funding decisions on new health technologies (translated into English using Babylon® translation software, where necessary) were searched to locate documents outlining relevant policies, procedures or criteria. Reference lists of retrieved documents were also scanned. To minimize the likelihood of missing information, searches were performed twice by two independent researchers, who then met to compare findings. Once again, inter-rater reliability was assessed using the Kappa statistic (K = 0.92).[32]

3. Synthesis of information collected

Documents on each process were analysed qualitatively using content analytic techniques. Two researchers independently reviewed a random subset of the documents to identify policy statements or phrases eluding to an equity-efficiency trade-off. From this, a coding scheme, which included rationing principles and patient/factors taken into account during decision-making, was developed and applied to the remaining documents.[35,36]

Review of appeals to funding decisions

1. Identification of technology funding decision-making processes with appeals mechanisms

A list of technology funding decision-making processes with appeals mechanisms was prepared from a recent international review of such processes.[21] The websites of corresponding organizations were searched for publicly available information on appeals of individual decisions. In addition, Internet searches combining the name of the organization with the term, "appeals", and its likely synonyms, were performed.

2. Extraction of information

For each appeal identified, information on the technology, indication for which coverage had been sought, the initial funding decision, and grounds for appeals relating to social value statements or equity arguments was extracted

independently by two researchers, who subsequently met to compare findings and reconcile differences.

3. Synthesis and analysis of information collected

Once again, information was summarized in tabular form and then interpreted using qualitative techniques (content analysis) by two researchers. Potential relationships between technology indication and specific value-based arguments made or grounds presented for requesting 'special exceptions' were noted.

RESULTS

Comprehensive review of empirical studies

A total of 34 empirical studies were selected for inclusion in the review (Figure 3-1). Elements of their design, including patient characteristics/factors examined, and key findings (social value statements) are summarized in Table 3-1. Half of the studies originated from the United Kingdom. Of the remaining 17, six were conducted in the United States, four in Spain, two in Israel, and one in each of Brazil, Canada, Denmark, Hong Kong, and Thailand. In all of the studies, authors reported recruiting and selecting a "random sample" or "representative sample" of the general public. However, for over one third, no information on approaches used to accomplish this was provided. Similarly, response rates were presented in only 12 of the 34 studies (mean: 36%; range: 15% to 84%). Although monetary incentives had been offered in 14 of the studies, their use did not appear to be associated with an increased willingness to participate (no incentives were

employed in the two studies with the highest response rates). Sample size varied from 16 to 3,241 members of the public, and depended upon the method used to elicit their views. Three-quarters of the studies (26/34) had administered structured surveys (in person: 12 studies; by telephone: one study; and self-administered: 13 studies) to typically over 100 participants. The remaining studies employed one or more focus groups (four studies) or small group discussions (four studies) of no more than 25 participants per session. Focus groups involved gathering 'uninformed' opinions of participants (non-deliberative). In contrast, small group discussions were held when responses reflecting careful consideration of and debate over different participants' views were sought (deliberative). Further, two of the studies that applied deliberative processes used citizens' juries, in which participants were provided with information on all possible perspectives before and while engaging in debates and discussions among themselves.

Collectively, the 34 studies explored distributive preferences of the public on 16 patient characteristics or factors, including: 1) severity of illness/current health state (prognosis without treatment); 2) immediate need (urgency of care, availability of alternative treatments); 3) age; 4) lifetime health; 5) pre-existing health state prior to onset of current illness or condition; 6) personal responsibility of condition (whether or not cause of condition was beyond a patient's control); 7) care-giving responsibilities (whether the patient had dependents); 8) time already spent waiting for treatment; 9) health gain; 10) number of individuals

affected/rarity; 11) socioeconomic status/income; 12) gender; 13) marital status; 14) religion; 15) political views; and 16) power of influence. However, the majority focussed on one or several of the first 10 of the factors.

The structure/format of questions used to elicit such preferences varied across studies, with some employing more than one type. Questions fell into five main categories: 1) simple yes/no questions (e.g., "Should priority be given to patients with life-threatening conditions?"); 2) Likert questions (e.g., "How strongly do you agree or disagree that priority should be given to younger patients?"); 3) simple listing (e.g., "What factors should be considered when…"); 4) ranking questions (e.g., "Rank the following patients in order of priority for treatment); and 5) choice-based questions (e.g., "Would you choose to give treatment to group A or group B?).

Most studies (22/34) included choice-based questions or choice tasks, forcing participants to choose between alternatives in order to increase the likelihood that responses would reflect consideration of the opportunity costs (i.e., the cost of an alternative that must be forgone as a result of the choice made) involved in allocating resources for healthcare. In general, they considered no more than two factors at one time, and took one of the following forms: 1) a simple choice exercise (in which participants were presented with hypothetical decision scenarios that varied on one factor (i.e., "all else being equal"), and asked to choose between them); 2) choice-based conjoint analysis/discrete choice

experiment (in which participants were asked to choose between scenarios that comprised different combinations of factors); 3) time trade-off (TTO) (where participants were first presented with the option of living for a time period in a less than perfect health state or living for a shorter period in a healthier state; the length of the shorter period was then varied until they became indifferent to the options); 4) person trade-off (PTO) (in which participants were asked to indicate the number of patients with one kind of outcome that was equivalent in social value to a different number of patients with another kind of outcome by varying the numbers in the two groups until the point of indifference was reached); 5) willingness to assign (where participants were asked to state the maximum amount they would assign to each health service in a given set of services within the constraints of a fixed budget); and 6) standard gamble (in which participants were asked to choose between a certain outcome and a 'gamble'; the probability of the best outcome was then varied until participants were indifferent to the 'gamble'). In several of the studies, participant attrition and framing effects (i.e., preference reversals or inconsistencies in participants' responses to the same option asked in different ways) were noted and attributed to the use of one of the last four types of choice tasks.[41,49,56,64]

Across studies, the following distributive preferences/social value statements were observed:

• Severity of illness/current health state: As an individual factor or decision criterion, participants supported giving priority to severely ill or "worse off"

patients.[41,45,53,55,59] When it was considered alongside health gain and 'value for money', participants appeared willing to sacrifice 'value for money' (system efficiency) in order to help the severely ill patients, as long as they could realize a "large" health gain through treatment.[66]

• Immediate need: Participants expressed preferences for patients facing imminent death from a life-threatening or terminal illness.[25,47] However, none of the studies asked them to weigh immediate need against other factors, such as number of patients receiving treatment or amount of health gain.

• Age: Opinions on age as a criterion for deciding between patient populations were mixed. In some studies, participants held dissenting views,[63] or felt that it should not be considered.[37,38,42,53] In others, they supported giving priority to younger patients over older patients, arguing that everyone is entitled to a "normal life-span"; those failing to reach it have been "cheated", while those exceeding it are simply "living on borrowed time".[51,54,57,58] Once again, none of the studies assessed the effect of age in the presence of other factors on participants' preferences.

• Lifetime health (quality and quantity of life): Preferences for equalizing lifetime health across patient groups depended on whether other factors were simultaneously considered. One study, which asked about 'lifetime health' in isolation, reported preferences for allocating resources so as to reduce inequalities in lifetime health.[25] However, a second study, presenting the same question but in the context of 'prognosis without treatment' and 'age', found that preferences for

equalizing lifetime health were contingent upon patients also facing imminent death in the absence of care[57]

• Pre-existing health state: Based on findings from a single study, which examined the effect of current health, prior health, and final health state on preferences, the value placed on the final health state varied according to participants' views of patients' prior health. For example, lower priority was given to patients who would experience the onset of paraplegia after receiving life-saving treatment than to patients who were already suffering from paraplegia and, with treatment, would simply return to that state.[40]

• Personal responsibility for illness: Opinions regarding whether priority should be given to patients whose illness was caused "naturally" and "not as a result of unhealthy behaviour" varied across studies. In one study, the views of participants were mixed.[42] In others, participants felt that the "cause" of illness should not comprise a decision criterion.[37,53,63] However, four studies reported preferences for patients who had been deemed not responsible for their illness.[48,51,54,58] Nevertheless, none of the studies required participants to choose between patients who differed on this factor, as well as others.

• Care-giving responsibilities: Views on care-giving responsibilities as a priority-setting factor varied. While participants in one study stated that whether patients had dependents should not be taken into account,[42] those in three others did, favouring patients with "parental" responsibilities.[51,53,54] Once again, responses

reflected consideration of this factor in isolation, rather than alongside other patient characteristics.

• Time already waited: Preferences for 'time already waited' were consistent across studies, with all 4 demonstrating support for giving priority to patients who had spent greater lengths of time on the waiting list.[38,53,54,58] However, none of the studies had evaluated 'time already waited' in the context of factors that might modify preferences, such as severity of illness or immediate need.

• Health gain: Participants expressed preferences for patient groups who could receive the greatest health gain (taking into account length and quality of life).[25,53,54] Moreover, they appeared unwilling to give priority to patients for whom outcomes represented just increased length of life.[39,40] However, when health gain was considered alongside number of patients who could receive an intervention, participants gave priority to the largest patient group, even at the expense of maximal health gain.[44,47,49] The amount of 'health' that would need to be realized by a small number of patients in order for participants to "switch" their preferences from the 'many' to the 'few' was not assessed.

• Socioeconomic status/income, gender, marital status, religion, political views, and power of influence: When asked about gender, socioeconomic status/income, marital status, religion, political views, or power of influence in the allocation of healthcare, participants indicated that none of them should be incorporated into decisions.[42,63]

Although an attempt was made to examine the effect of choice task on preferences elicited around each factor (i.e., the types of questions presented), the number of studies was too small to permit any meaningful comparisons.

In general, studies completed over the last decade have highlighted the importance of several factors/patient characteristics in the distribution of healthcare. Further, they suggest a willingness by the public to make equity-efficiency trade-offs. However, the circumstances under which it is prepared to make such trade-offs (i.e., sacrifice gains in efficiency for gains in equity) or the extent to which preferences for certain factors/patient characteristics are modified in the presence of others remain unclear.

Analysis of criteria related to social value statements considered by technology funding decision-making processes in Canada and abroad

Ten health technology funding decision-making processes with policy statements reflecting a social value position were identified (Table 3-2). None were from Canada. Seven related to pharmaceuticals, two to all technologies, and one to non-pharmaceuticals (devices, diagnostic tests, and procedures). Statements comprised 'exception policies' describing when or under what conditions efficiency expectations would be relaxed or waived. Efficiency expectations were typically cost-effectiveness thresholds or ranges, below or within which technologies representing 'value for money' should fall. Factors/patient characteristics addressed through exception policies included: 1) rarity (Scotland,

The Netherlands, UK, and Wales); 2) rarity together with no other alternatives available beyond best supportive care (Belgium and The Netherlands); 3) rarity and severity of illness (i.e., life-threatening condition) (Australia); 4) severity of illness (i.e., "worse-off", terminal illness, or life-threatening condition) (Norway, Scotland, Sweden, UK, and Wales); and 5) belonging to a socially disadvantaged or marginalized group (New Zealand and UK (disabled persons)). Policies in two of the countries also stated factors/patient characteristics that would never be taken into account (socioeconomic status), and those that would only be considered when there was clear evidence of differential effectiveness of the technology in patient sub-groups with such characteristics (Sweden and the UK). They comprised age, gender, race, personal responsibility for illness, and social stigma attached to the condition. While such policies demonstrated a willingness among decision-makers to trade off maximal health gain (an efficiency position) for reduced health inequalities (an equity position), the conditions, if any, of that trade-off (e.g., what amount of health gain or reduction in ill health must be realized) were not clear.

Review of appeals to funding decisions

Of the 10 technology funding processes reviewed, publicly available information on appeals to individual decisions could only be found for one of them, the National Institute for Health and Clinical Excellence (NICE) in the UK (Table 3-3). Since its inception just over a decade ago, 12 decisions have been appealed on grounds, in part, concerning social values. Half of the appeals pertained to "last

chance" therapies for advanced or metastatic cancer. Appeals focussed on the unmet clinical needs of patients inflicted with a severe, terminal illness for which there was a lack of other active treatment alternatives (leading to disparities in access to healthcare). The remaining six decisions related to pharmaceuticals for multiple sclerosis, rheumatoid arthritis (RA), osteoarthritis (OA), Alzheimer's disease, and growth hormone deficiency in adults. Once again, appeals were primarily predicated on clinical need (i.e., "debilitating disease" with "few other treatment alternatives"). However, three also cited discrimination on the basis of age (RA and human growth deficiency) and race and education (Alzheimer's). In the first two cases, NICE argued that the effectiveness of the technology had only been demonstrated in certain age groups; therefore, 'unrestricted' funding would be inappropriate. In the third case, the validity of the approach recommended by NICE for determining treatment eligibility was questioned. Appellants referred to evidence demonstrating that the score used to determine disease severity varied depending on a patient's education and race (Table 3-3).

For each of the 12 decisions, appeals had also been launched on the grounds of "perverse" interpretation of the clinical and economic evidence. As a result, it was not possible to determine the extent to which social justice arguments contributed to the final outcome.

CONCLUSIONS

In this paper, key factors/patient characteristics around which distributive preferences of the public for healthcare may be sought were identified.

Understanding such preferences is a prerequisite for elucidating social values or rationing principles. Such information must be weighed alongside other considerations when making technology funding decisions. Factors/patient characteristics include: severity of illness, immediate need, age (and its relationship to lifetime health), health gain (amount and final outcome/health state), personal responsibility for illness, care-giving responsibilities, and number of patients who could benefit (rarity).

Recent research has demonstrated the importance of individual factors under "all else being equal" conditions. It has also suggested that their 'value' depends upon other factors considered simultaneously during decisions. Rationing principles to which the public subscribes may, therefore, be multiple and context-specific. Research that seeks to clarify interactions among factors by asking the public to weigh several of them at once is needed to ensure the relevance of preferences elicited to real-world technology funding decisions.

A version of this chapter has been submitted for publication. Stafinski 2010. The Patient.

Table 3-1. Summary of empirical studies exploring social value statements/distributive preferences for the allocating healthcare resources

Author (year)	Study country	Number of participants	Recruitment/ Selection	Study design	Characteristics/ factors examined	Findings/value statements
Dolan et al[25] (1999)	United Kingdom	60	Method: • Letters of invitation sent to 1,000 people randomly selected from 2 general practitioners' (GPs) lists • Random sampling – method not reported • Recruited 10 groups of 6 citizens Source: GP lists Response rate: 21% Incentive: £30	• Small group discussions (deliberative) • Met twice for 2 hours, 2 weeks apart *Decision-making simulation exercises* • Participants asked "What principles should govern decisions about the distribution of limited health care resources?" • Also asked to choose which of 4 patients to treat, assuming there was only enough money to treat 1 patient (patients differed on immediacy of need) and to rank them in order of priority for treatment • Discussed reasons for their choices	• Immediate need (rule of rescue) • Health gain • Lifetime health Examined effect of immediate need and lifetime health on health gain	• Priority should be given to those in immediate need ('rule of rescue'), those who would receive the most health gain (health maximization), and those whose lifetime health could be raised to that of the general population (equalization of lifetime health)
Lenaghan[37] (1999)	United Kingdom	16	Method: • Stratified random sampling – no further information reported Source: Not reported Response rate: Not reported Incentive: £200	• Nottingham citizens' jury • Used citizens' jury approach (deliberative technique) • Discussions informed by "expert witnesses" who attended meetings to present all perspectives and address questions *Decision-making simulation exercises* • Asked whether non-clinical factors should be taken into account when prioritizing NHS resources	• Age • Need (severity of illness) • Personal responsibility for illness Examined as individual factors (as opposed to their effect on each other)	• Neither age nor personal responsibility should be taken into account when prioritizing healthcare resources
Mossialos and King[38] (1999)	Germany France Italy Netherlands United Kingdom Sweden	1,000 from each country	Method: • Random sampling – used random probability sampling design Source: Not reported Response rate: Not reported Incentive: None specified	• Self-administered questionnaire *Decision-making simulation exercises* • Participants asked to imagine that there is only one place in a hospital but 2 patients who need treatment. Patients have the same heart condition, are the same age, support similar families, and have similar jobs. Participants asked to indicate how the hospital should choose which patient to treat: 1) Choose at random; 2) Choose the patient who can benefit most in terms of quality and length of life; 3) Other; or 4) Don't know	• Health gain • Age • Care-giving responsibilities • Personal responsibility • Time already waited	• Did not know how the hospital should choose between patients, but disagreed strongly that preference should be given to young patients • Time already waited or time spent on the waiting list identified as the most

Table 3-1. Summary of empirical studies exploring social value statements/distributive preferences for the allocating healthcare resources

Author (year)	Study country	Number of participants	Recruitment/ Selection	Study design	Characteristics/ factors examined	Findings/value statements
				• Also asked to state which of the following would be the most important factor for a doctor or other health professional to take into account when deciding which patients should be given priority for treatment: 1) Time on waiting list; 2) Care-giving responsibilities (family commitment); 3) Age; 4) Personal responsibility for illness (lifestyle); 5) Health gain (treatment outcome); 4) Each case should be treated individually, or 5) Don't know • Asked whether they agreed strongly, agreed slightly, neither agreed nor disagreed, disagreed slightly, or disagreed strongly that priority should be given to treating young patients over old patients		important factor
Roberts et al [39] (1999)	United Kingdom	91	Method: • Random sampling – method not reported Source: Not reported Response rate: Not reported Incentive: None specified	• Structured, in-person interviews *Decision-making simulation exercises* • Used conjoint analysis - created 16 scenarios representing different combinations of levels of 3 attributes/factors; randomly paired scenarios to form 8 choice-based questions, representing trade-offs between 2 patient groups • 3 versions of questionnaire created and administered – differed on attributes considered	• Number of individuals • Health gain (length and quality of life) • Probability of successful treatment Examined effect of number of individuals and probability of successful treatment on health gain	• Options maximizing health gain not always preferred • Options leaving patients in poor states of health regardless of the length of life gained not chosen
Ubel et al[40] (1999)	United States	605	Method: • Approached all prospective jurors at Philadelphia court house (prospective jurors randomly selected) Source: Electoral register Response rate: 41% met "consistency	• Self-administered questionnaire *Decision-making simulation exercises* • Created 3 different scenarios: 1) Treatment A saves patients' lives and returns them to normal while Treatment B saves lives of patients with pre-existing paraplegia who will continue to have paraplegia after treatment 2) Treatment A saves patients' lives and returns them to normal health while Treatment B saves patients' lives who have no other alternative treatment available	• Immediate need • Lifetime health (limited treatment potential due to pre-existing conditions) • Health gain (final health state) • Alternative treatments Examined effect of lifetime health, final	• Equal importance placed on saving the lives of patients with pre-existing paraplegia and those who could be returned to perfect health • Lower priority given to patients who would experience onset of paraplegia after having their lives saved, especially if their

Table 3-1. Summary of empirical studies exploring social value statements/distributive preferences for the allocating healthcare resources

Author (year)	Study country	Number of participants	Recruitment/ Selection	Study design	Characteristics/ factors examined	Findings/value statements
			criteria" Incentive: Received candy bar	but renders them paraplegic 3) Treatment A saves patients' lives and returns them to perfect health while Treatment B saves their lives but renders them paraplegic • Participants given 4 person trade-off choices and asked to choose whether to offer 100 patients Treatment A or some other number of patients treatment B; then "ping-ponged" between high and low numbers until point of indifference reached ("If 100 patients could be helped by treatment A or X people with paraplegia could be helped by treatment B, I could not decide")	health state, and availability of alternative treatments on preference for life-saving treatments	paraplegia was avoidable with an alternative treatment • Value placed on treatment depended on health state before the onset of the life-threatening illness and on whether alternative treatments are available that could provide better health outcomes
Ubel [41] (1999)	United States	479	Method: • Approached all prospective jurors at Philadelphia court house (prospective jurors randomly selected) Source: Electoral register Response rate: Not reported Incentive: Received candy bar	• Self-administered questionnaire • Randomized to receive 1 of 6 versions of questionnaire *Decision-making simulation exercises* • Participants asked 6 questions: 1) Illness A produces severe health problems and illness B produces moderate health problems. Treatment helps patients with illness A a little and patients with illness B considerably. There is no difference in cost. Should funds be allocated to a) Treatment for illness A, b) treatment for illness B since the effects are greater, or c) divided evenly between the 2 groups? 2) Clarification of the first question, reminding participants of the severity of patients' illness and how much they could improve with treatment 3) Same as first question but asked participants to think about their own self interest when making a decision 4) Same as first question but participants were not given choice to divide fund evenly between groups	• Need (severity of illness)	• Preference for allocating resources to severely ill patients depended on wording of question (framing effect) • Preference for dividing resources equally when given the option

Table 3-1. Summary of empirical studies exploring social value statements/distributive preferences for the allocating healthcare resources

Author (year)	Study country	Number of participants	Recruitment/ Selection	Study design	Characteristics/ factors examined	Findings/value statements
Anand and Wailoo[42] (2000)	United Kingdom	144	Method: • Random sampling (no further information provided) Source: Electoral register Response rate: 31% Incentive: None received	• Self-administered questionnaire *Decision-making simulation exercises* • Participants asked to decide how funds should be allocated between 2 patient groups differing only on age – given 4 options: 1) Fund younger group first; 2) Fund treatments for diseases that affect younger group first; 3) Divide resources equally between groups; 4) Undecided • Question repeated, gradually reducing age difference between groups • Asked whether priority should be given to: 1) Married over unmarried; 2) With children over without children; 3) High incomes over those with low incomes; and 4) Contracted the condition as a result of events beyond their control over contracted it through "risky behaviour"	• Age • Marital status • Care-giving responsibilities (children) • Income • Personal responsibility Examined as individual factors (as opposed to their effect on each other)	Criteria that should not be used to prioritize patients: • Age • Marital status • Care-giving responsibilities (children) • Income (although a small proportion supported giving priority to low wage earners) • Views on personal responsibility mixed (approximately half of respondents supported giving priority to patients in whom the cause of their conditions was beyond their control)
Dolan [43] (2000)	United Kingdom	2,997	Method: • "Representative sample of UK population" – method not reported Source: Not reported Response rate: Not reported Incentive: None received	• Structured, in-person interviews *Decision-making simulation exercises* • Used time trade off (TTO) method to obtain value of different health states (EQ-5D health states) • Participants asked to consider a length of time in full health that they considered to be equivalent to 10 years in 1 of 12 different health states • Compared responses of participants > 60 years of age to those $\leq$ 60 years of age	• Current health state	• Value of health states varied with age of participant - older participants considered all levels and all types of dysfunction to be worse than did the younger participants
Dolan and Cookson[44] (2000)	United Kingdom	60	Method: • Letters of invitation sent to 1000 people randomly selected from 2 general practitioners' lists • Recruited 10 groups	• Small group discussions • Used deliberative techniques • Met twice for 2 hours, 2 weeks apart *Decision-making simulation exercises* • Participants told that there is only enough money to treat half of 2 groups of patients who could benefit	• Number of individuals • Health gain (quality and length of life) Examined effect of number of individuals who could be treated on	• Preference for treating more patients (equality of access) over maximizing health gain if treatments were considered sufficiently effective (i.e., participants unwilling to just give priority to patient groups

Table 3-1. Summary of empirical studies exploring social value statements/distributive preferences for the allocating healthcare resources

Author (year)	Study country	Number of participants	Recruitment/ Selection	Study design	Characteristics/ factors examined	Findings/value statements
			of 6 citizens Source: Not reported Response rate: 21% Incentive: £30	from treatment (but by differing amounts or from different starting points) and asked to decide which patients to treat; based on participants' responses, the health gain to the patient group who was given the least was either increased or decreased until the point at which participants gave the same priority to both groups • 6 questions used: 3 focussed on health gains in life years and 3 focussed on health gains in quality of life	maximizing health gain (measured in terms of length and quality of life)	who could receive the most health gain) • Willing to choose between groups once the "difference in end points brought about by differential health gains reached a certain threshold"
Green[45] (2000)	United Kingdom	261	Method: • Random sampling – random location quota sampling using profile data from census Source: Census Response rate: Not reported Incentive: None specified	• Structured, in-person interviews – conducted in household's homes *Decision-making simulation exercises* • Administered 2 versions of questionnaire, each containing 2 of 4 priority-setting questions: 1) Asked to choose between 2 patient groups or divide equally: severely ill group who could be helped a little or a moderately ill groups who could be helped considerably 2) Same as question 1 but participants were given the option of having someone else make the decision 3) Asked to choose between 2 patient groups or divide equally: a disadvantaged group who could be helped a little or an advantaged group who could be helped considerably 4) Same as question 3 but participants were given the option of having someone else make the decision	• Need (severity of illness) • Social class • Health gain Examined relationship between health gain and need or social class	• Preference for dividing health resources equally, giving at least equal preference to the more severely affected group or socially disadvantaged group
Ubel et al [46] (2000)	United States	495	Method: • Approached all prospective jurors at Philadelphia court house (prospective jurors randomly selected)	• Self-administered questionnaire • Randomly received 1 of 3 versions of questionnaire *Decision-making simulation exercises* • Participants asked to choose between offering a less effective, less expensive colon cancer screening test that would save 1000 lives and a more effective, more	• Number of individuals • Health gain Each examined relationship between maximizing health gain and maximizing number	• Preference for less effective test if it could be provided to everyone (favouring equity over efficiency) • Preference for less effective test was not maintained when

Table 3-1. Summary of empirical studies exploring social value statements/distributive preferences for the allocating healthcare resources

Author (year)	Study country	Number of participants	Recruitment/ Selection	Study design	Characteristics/ factors examined	Findings/value statements
			Source: Electoral register and driver's license records Response rate: Not reported Incentive: Received candy bar	expensive test that would save 100 lives; number of patients who could receive each of the 2 tests varied across versions of the questionnaire • Also asked to explain their choices	of patients who could receive test	fewer than all patients could receive it ("all tested equity premium")
Baker et al[47] (2001)	United Kingdom	1559	Method: • Randomly approached potential participants in shopping centres, train stations, central thoroughfare, and hospital outpatient departments Source: Not applicable Response rate: Not reported Incentive: None specified	• In-person interviews • Administered standard questionnaire *Decision-making simulation exercises* • Participants asked whether priority should be given to emergency conditions, life-threatening conditions, or expensive treatments for terminal disease (separate yes/no questions) • Also asked if they would be prepared to pay more taxes to provide increase in service	• Immediate need • Has life-threatening condition • In later stages of a terminal disease Examined as individual factors (as opposed to their effect on each other)	• Preference for giving priority to patients in immediate need of care, those with life-threatening conditions, and those with terminal diseases • Willing to pay more taxes to provide such services
Ubel et al[48] (2001)	United States	408	Method: • Approached all prospective jurors at Philadelphia court house (prospective jurors randomly selected) Source: Electoral register and driver's license records Response rate: 50% Incentive: Received candy bar	• Self-administered questionnaire *Decision-making simulation exercises* • Participants asked to allocate 100 organs among 2 groups of 100 patients who differ only on history of unhealthy/risky behaviour (alcohol use - 2 scenarios; or tobacco use - 2 scenarios): Applied 2 forms of questions to each pair of scenarios (one stating that risky behaviour caused organ failure and the other stating that risky behaviour contributed to transplant prognosis • Also asked to explain their choices	• Personal responsibility	• Preference for treating patients whose condition was not a result of their unhealthy behaviour (i.e., participants allocated significantly fewer than half of the organs to patients with a history of unhealthy behaviour)

Table 3-1. Summary of empirical studies exploring social value statements/distributive preferences for the allocating healthcare resources

Author (year)	Study country	Number of participants	Recruitment/ Selection	Study design	Characteristics/ factors examined	Findings/value statements
Ubel et al [49] (2001) Part 1	United States	615	Method: • Approached all prospective jurors at Philadelphia court house (prospective jurors randomly selected) Source: Electoral register and driver's license records Response rate: Not reported Incentive: Received candy bar	• Self-administered questionnaire • Randomly received 1 of 5 versions of questionnaire *Decision-making simulation exercises* • Participants asked to choose between offering a less effective, less expensive colon cancer screening test that would save 1000 lives and a more effective, more expensive test that would save 100 lives; given 2 scenarios: 1) 1 test offered to 100% of population and other test offered to 50% or 2) 1 test offered to 50% and other offered to 25%; varied order in which the 2 scenarios were presented as well as whether patients were described as from the same geographical State or 2 different States across questionnaire versions	• Number of individuals • Health gain Examined relationship between maximizing health gain and maximizing number of patients who could receive test	• Preference for less effective test if it could be provided to everyone • Magnitude by which participants preferred less effective test when it could not be provided to everyone varied across versions of the questionnaire (in which the order of information presented varied) – "order effect"
Ubel et al [49] (2001) Part 2	United States	68	Method: • Non-randomized, self-selected • Used link advertising "free stuff on the internet" to recruit participants Source: Internet users Response rate: Not applicable Incentive: Received $1 US	• Self-administered questionnaire *Decision-making simulation exercises* • Scenario presented in which colon cancer screening test could only be offered in 1 of 2 States or for a % of Medicaid enrolees in both States • Participants asked to rank 7 tests which differed on the number of deaths prevented in order of preference – asked in 2 ways: 1) indicating the number of patients in 1 state who would receive test and 2) the percentage of patients in both states who would receive test	• Number of individuals • Health gain Examined relationship between maximizing health gain and maximizing number of patients who could receive test	• Preference for less effective test if it could be provided to everyone (favouring equity over efficiency (i.e., maximizing lives saved)) • In cases where all patients could not receive test, preference for the less effective one depended on way in which question was asked (i.e., were susceptible to framing effects)
Dolan and Tsuchiya[50] (2002)	United Kingdom	130 members of the general public	Method: • Letters of invitation sent to 1500 randomly selected people • Purposive sampling used to recruit 10 groups of 6 citizens	• Structured, in-person interviews *Decision-making simulation exercises* • Participants asked to make choices between programmes for different groups of patients using person trade-off (PTO) method - participants specified the number of patients in a group that would make	• Number of individuals • Health gain • Age Examined effect of age or number of patients treated on health gain	• Preferences unstable (i.e., participants changed their minds on the ordering of the 5 age groups throughout the exercise)

Table 3-1. Summary of empirical studies exploring social value statements/distributive preferences for the allocating healthcare resources

Author (year)	Study country	Number of participants	Recruitment/ Selection	Study design	Characteristics/ factors examined	Findings/value statements
			(who had responded to letter) to be broadly representative of UK general population Source: Electoral register Response rate: 467 agreed to participate Incentive: £15	them indifferent between treating that group and a different group containing a different number of patients - ages of patients in each group were varied, as were the number of patients within each group • Participants completed ranking exercise first – asked to rank patient groups according to the order in which they would give an extra 5 years of life		
Fortes and Zoboli[51] (2002)	Brazil	395	Method: • "Random sample" • Approached visitors to a hospital (no further information reported) Source: Hospital Response rate: Not reported Incentive: None received	• Self-administered questionnaire *Decision-making simulation exercises* • Participants given 8 questions asking them to choose between 2 hypothetical patients suffering from exactly the same condition who had been allocated to a hospital where there was only one bed • Characteristics of hypothetical patient varied across questions (varied by age, gender, care-giving responsibilities and personal responsibility for illness (lifestyle))	• Age (7 years vs. 65 years; 7 vs. 12 months, and 65 years vs. 25 years) • Gender • Care-giving responsibilities (1 child vs. 3 children) • Personal responsibility for illness Examined as individual factors (as opposed to their effect on each other)	Preference for: • Younger patients over older patients • Women over men • Those with greater care-giving responsibilities • Patients who were not considered to be responsible for causing their illness
Beach et al[52] (2003)	United States	781	Method: • Approached all prospective jurors at Philadelphia court house (prospective jurors randomly selected) Source: Electoral register and driver's license records Response rate: Not	• Self-administered questionnaire • Randomly received 1 of 2 versions of questionnaire *Decision-making simulation exercises* • Developed 6 cancer screening scenarios, 3 based on familiar tests and 3 based on unfamiliar tests; information on cost-effectiveness (CE) presented for each test; created 2 versions, which presented CE information differently • Asked to decide which of the cancer screening tests to fund for a hypothetical patient (most expensive, less	Cost-effectiveness	• Preference for most expensive test (focussed on the increased benefit only) • Those who chose the less expensive test stated that they didn't think the patient was at significant risk • Cost-effectiveness rarely considered

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Author (year)	Study country	Number of participants	Recruitment/ Selection	Study design	Characteristics/ factors examined	Findings/value statements
			reported Incentive: Received candy bar	expensive, or no screening) • Also asked to explain their choices		
Edwards et al[53] (2003)	United Kingdom	1000	Method: • Random sampling – method not reported Source: Not reported Response rate: Not reported Incentive: None specified	• Self-administered postal questionnaire *Decision-making simulation exercises* • Participants asked which of the following should or should not influence wait list priority using Likert-type questions (irrelevant to very influential): Ability to pay, age, anticipated health gain, clinical evidence, "compensation pending", evidence of cost-effectiveness, dependence on others, deterioration of disease, level of disability, level of distress, level of pain, general health state, care-giving responsibilities; loss of usual activities, attitude of relatives, personal responsibility for illness, and time already waited	• Need (severity of illness) • Health gain • Age • Care-giving responsibilities (children) • Income • Personal responsibility • Time already waited Examined as individual factors (as opposed to their effect on each other)	Factors that should influence wait list priority: • Severity of illness (deterioration of disease, general health state, level of pain, level of distress, and level of disability) • Time already waited • Dependence on others • Loss of usual activities • Care-giving responsibilities • Health gain (anticipated benefit) Factors that should not influence wait list priority: • Income (ability to pay) • Age • "Compensation pending" • Consultant special interest; • Cost • Attitude of relatives • Responsibility for illness • Cost-effectiveness
Dolan and Shaw [54] (2004)	United Kingdom	23	Method: • Stratified random sampling • Recruited by survey group instructed to recruit 4 groups of 6 people with 3 men and	• 4 focus groups • Met twice for 2 hours, 2 weeks apart *Decision-making simulation exercises* • Participants asked what factors should be taken into account when deciding who gets an organ • Then given information relating to 6 patients with	• Prognosis without treatment • Health gain • Age Examined effect of age, health gain, or prognosis	Factors that should be considered in order of importance (highest to lowest): • Health gain with treatment • Prognosis without treatment • Age

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Author (year)	Study country	Number of participants	Recruitment/ Selection	Study design	Characteristics/ factors examined	Findings/value statements
			3 women in each group and one from each of the 6 age groups Source: Not reported Response rate: Not reported Incentive: £15	different prognoses in terms of life expectancy with and without a kidney transplant and asked to choose 1 patient • Lastly, given ages of the 6 patients and asked if they would like to revise choice (ages were those of the individuals in the focus group)	without treatment on funding choice	• Care-giving responsibilities • Time already waited • Personal responsibility for illness • Re-transplantation Preference for: • Younger over older patients • Those with children over those without children • Some participants changed their views when additional information was given (e.g., when age presented, some sacrificed youth if thought the slightly older person had care-giving responsibilities)
Gyrd-Hansen[55] (2004)	Denmark	3,201	Method: • Random sampling – method not reported Source: Not reported Response rate: 49% Incentive: None specified	• Structured, in-person interviews – conducted in household's homes *Decision-making simulation exercises* • 42 health states based on EuroQoL Descriptive System paired to create 23 choice scenarios • Participants asked to imagine themselves in 2 chronic health states, A and B, and indicate which of the 2 they thought would be worse; then asked to prioritize between 2 treatment options in which the 'worse-off' group could be brought to a certain state and the less 'worse-off' group could be brought to perfect health • In half of the interviews, participants told that only half of the patients in group B could receive the treatment	• 'Worse-off' (severity of illness) • Health gain • Number of individuals Examined relationship between health gain and need or number of patients who could receive treatment	• Preference for treating 'worse-off' patients when they could be brought to a health state equivalent to that of the less 'worse-off' group • Whether all patients could be treated did not influence preference

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Author (year)	Study country	Number of participants	Recruitment/ Selection	Study design	Characteristics/ factors examined	Findings/value statements
Costa-Font and Rovira[56] (2005)	Spain	66	Method: • Random sample – method not reported Source: Not reported Response rate: Not reported Incentive: None received	• Small group discussions (deliberative) *Decision-making simulation exercises* • Used contingent choice questions based on "willingness to assign (WTA)" methods-participants asked to indicate maximum amount they would assign to a given set of healthcare programmes within the constraints of a fixed budget • Also asked to rank programmes from least preferred to most preferred (1-least; 10-most) • Compared responses from WTA questions to those from traditional willingness to pay questions asking "How much in extra taxes are you willing to pay for each program?"	• Health gain Examined relationship between health gain and "process benefits" (e.g., electronic health record) or equity benefits (e.g., access to free dental care)	• Programs offering health gain valued the most, but those offering "process utility benefits" and "equity benefits" were also valued highly • WTA approach to eliciting participants' views found to be less susceptible to preference reversals
Dolan and Tsuchiya[57] (2005)	United Kingdom	128	Method: • Letters of invitation sent to 2000 randomly selected people • Purposive sampling used to recruit 128 citizens (from among those who agreed to participate) to be broadly representative of the the UK general population Source: Electoral register Response rate: 257 agreed to participate Incentive: None specified	• 24 small group meetings during which a self-administered questionnaire was completed after participants received instructions *Decision-making simulation exercises* • Participants asked to rank 6 patient groups with different characteristics (4 attributes with 2 levels each) but equal in size. Health gain, if treated, was the same in both groups - used choice-based ranking in which participants were initially asked to pick 1 group to treat, and then told more resources were made available and asked to pick a second group, a third group, and so on)	• Age (past years) • Lifetime health • Prognosis without treatment (future years and health without treatment) Examined relationship between factors	• Preference for younger patients over older patients • Preference for patients with poorer lifetime health if also facing imminent death • Neither future health nor years without treatment influenced preferences

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Author (year)	Study country	Number of participants	Recruitment/ Selection	Study design	Characteristics/ factors examined	Findings/value statements
Chan et al[58] (2006)	Hong Kong	281	Method: • Random sampling – method not reported Source: Census data from Census and Statistics Department Response rate: 26% Incentive: None specified	• Structured, in-person interviews – conducted in household's homes *Decision-making simulation exercises* • Participants asked to allocate 100 organs (livers) between 2 groups of potential organ recipients and indicate their level of agreement with 5 selection criteria: history of liver disease (i.e., personal responsibility)), expected survival and benefit (health gain), time spent on waiting list, and transplantation status (whether first transplant or re-transplant) • Also asked to rank the 5 selection criteria in order of importance • Given 8 randomly generated pair-wise hypothetical scenarios of 2 patient groups with different attributes (presented different combinations of 2 levels of 3 attributes or different combinations of 2 levels of 2 attributes (conjoint analysis)) and asked to choose between groups	• Age • Personal responsibility for illness • Health gain • Time already waited • Transplantation status Examined effect of each factor on organ allocation choice	"Strong preference" for: • Young over old • Non-drinkers over drinkers • Those who had waited longer • Preference for "time already waited" found to be stronger than that for health gain (survival and benefit), indicating willingness to trade off maximizing health gain for fairness • Some expressed concern over time on waiting list, suggesting that organs should be allocated strictly on a 'first-come-first-served basis'
Dolan et al [17] (2007)	United Kingdom	54	Method: • "Representative sample of UK general population" – method not reported Source: Not reported Response rate: Not reported Incentive: Offered "small amount of money"	• 8 focus groups *Decision-making simulation exercises* • Examined framing effects by presenting different groups with different wording of a budget scenario: – budget increase or budget decrease • Asked participants to discuss how they would make the necessary funding decisions	Procedural justice/fairness	• 3 important "procedural characteristics" that should be part of a decision-making process identified: 1. Voice – strong support for consultation with the public and involvement of several representatives "to offset each other's biases" 2. Transparency 3. Consistency
Friedman et al[59] (2007)	Canada	101	Method: • Random sampling • Randomly selected households from	• Structured, telephone interviews *Decision-making simulation exercises* • Was read a list of different patient demographics and	• Need (severity of illness) • Social status in society • Ability to pay	• Prioritization should be based on medical need not social status

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Author (year)	Study country	Number of participants	Recruitment/ Selection	Study design	Characteristics/ factors examined	Findings/value statements
			telephone book using random number generator Source: Telephone book Response rate: 15% Incentive: None specified	asked to indicate who should be able to move ahead in line in the emergency room (person in severe pain, person with a medical emergency, infant or child, police officer on duty, homeless person, doctor, hospital benefactor, hospital administrator, religious leader, government official/politician, or celebrity)		
Guttman et al[60] (2007)	Israel	130	Method: • Stratified random sampling • Minorities oversampled • 1500 members of general population contacted by phone • 44% agreed to participate, from whom 130 selected to participate (selection criteria not specified) Source: Source of initial phone numbers not specified Response rate: 44% Incentive: None received	• 6 small group discussions (similar to citizens juries) held in different regions • Used deliberative techniques • Discussions informed by senior-level decision-makers who attended meetings to address questions *Decision-making simulation exercises* • Participants asked to: 1) Prioritize prototype technologies and provide reasons 2) Allocate rooms to different patients in need and provide reasons 3) Indicate whether priority should be given to costly treatments for rare conditions over less costly treatments for more prevalent conditions, "all else being equal" 4) Indicate how "life-saving treatment" should be defined	• Rarity of condition • Need (life-threatening condition) Examined as individual factors (as opposed to their effect on each other)	• Preference for "services in the medium range of cost, which can benefit a relatively large number of people, but are beyond the reach of most" • Proposed that 'life-saving" treatment should be defined as one that extends life by more than 1 year
Tsuchiya and Dolan[61] (2007)	United Kingdom	271	Method: • Stratified random sampling – Postcodes selected to reflect socioeconomic and geographical spread from which 1,000	• Self-administered questionnaire *Decision-making simulation exercises* • Presented information on difference in life expectancy at birth between highest and lowest social classes and asked to choose between 2 hypothetical programmes: Programme A increased life expectancy	• Health gain • Social class Examined relationship between health gain and social class (i.e., willingness to trade off health gain for reduction	• Preference for helping lowest socio-economic class until the sacrifice in overall health gain was seen as too great

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Author (year)	Study country	Number of participants	Recruitment/ Selection	Study design	Characteristics/ factors examined	Findings/value statements
			names were randomly picked Source: Postcodes Response rate: 27% Incentive: None specified	of both social classes by 2 years and the Programme B increased life expectancy of the lowest social class by 4 years; if chose B, asked further questions where A remained unchanged but benefit through B incrementally dropped by 1.5 years – tried to determine "switch" point	in health inequalities)	
Kasemsup et al[62] (2008)	Thailand	1,000	Method: • Random and purposive sampling • Approached patients in dental clinics Source: Patients in dental clinics Response rate: Not reported Incentive: None received	• Self-administered questionnaire *Decision-making simulation exercises* • Contained 10 choice-based questions derived from pairs of rationing principles that asked participants to choose between 2 patients who have the same severe disease and need for high cost treatments (also given the option to choose randomly) • Participants then given 13 items associated with 1 of the 5 rationing principles and asked to rate each item on a 7-point scale (with no preference serving as the mid-point) according to their degree of preference for each patient	Examined patient characteristics as they related to different rationing principles • Lottery principle • Rule of rescue • Health maximization • Fair innings • Choicism	• Preference for rationing principles (ranked from highest to lowest): • Choicism • Fair innings • Rule of rescue • Health maximization • Lottery principle
Werner[63] (2008)	Israel	624	Method: • Randomly approached citizens in 3 large cities – no further information reported • Indicated that study sample was similar to that of general population Source: Not reported Response rate: 83% Incentive: None received	• Structured, in-person interviews *Decision-making simulation exercises* • Participants asked to rate to what extent each of 12 items should be a criterion for priority-setting for Alzheimer's disease using a 5 point Likert-type questions ("definitely not a criterion" to "definitely a criterion"): age, socioeconomic status, gender, religion, power of influence, responsibility for causing disease, severity of illness, whether illness is immediately life-threatening, cost, equity of access, and political views	• Age • Socioeconomic status • Gender • Religion • Power of influence • Personal responsibility for illness • Need (severity of illness) • Immediate need (whether illness is immediately life-threatening) • Political views • Cost • Equity of access	• The following should not be considered: participants stated that gender, religion, power of influence, and responsibility • Dissenting views on age – almost equal proportions felt it definitely should be a criterion and definitely should not be a criterion

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Author (year)	Study country	Number of participants	Recruitment/ Selection	Study design	Characteristics/ factors examined	Findings/value statements
					Examined as individual factors (as opposed to their effect on each other)	
Bleichrodt et al [64] (2009) Part 1	Spain	300	Method: • Not reported Source: Not reported Response rate: Not reported Incentive: None received	• Structured, in-person interviews *Decision-making simulation exercises* • Participants asked to rank cards describing 5 different health states after stroke in descending order of preference and to rate the health states on a scale of 0 to 100 • Then asked to choose between 2 treatment options or indicate indifference (high dose (HD) and low dose (LD)) with differing probabilities of success and death: HD - 75% probability of success and 25% probability of immediate death; LD - 75% probability of success and 25% of a specified health state • Half of participants asked series of choices in which probabilities of success and death with HD treatment and probabilities of success and a given health state with LD treatment were varied in order to determine point at which participants were indifferent between the 2 choices • 25 participants chosen at random and re-interviewed 2 -3 weeks later (offered €12 as an incentive)	• Health gain Examined relationship between health gain and risk	• Preference reversal observed when participants were asked to make choices between treatments, rather than rank different health states (i.e., responses susceptible to "framing effect") • Preference reversal also observed during retest (i.e., responses susceptible to "framing effect")
Bleichrodt et al [64] (2009) Part 2	Spain	100	Method: • Random sampling – method not reported Source: Not reported Response rate: Not reported Incentive: None received	• Structured, in-person interviews *Decision-making simulation exercises* • Asked to rank cards describing 7 different health states after stroke (including normal health and death) in descending order of preference (used choice-based ranking) • Then asked to choose between 2 treatment options or indicate indifference (high dose (HD) and low dose	• Health gain Examined relationship between health gain and risk	• Preference reversal observed when participants were asked to make choices between treatments, rather than rank different health states (i.e., responses susceptible to "framing effect")

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Author (year)	Study country	Number of participants	Recruitment/ Selection	Study design	Characteristics/ factors examined	Findings/value statements
				(LD)) with differing probabilities of success and death: HD – 75% probability of success and 25% probability of immediate death; LD: 75% probability of success and 25% of a specified health state (which varied across 4 questions) • Also included partial standard gamble question in which participants were asked to choose between a treatment offering 100% probability of a given health state and a treatment offering 5% probability of normal health and a 95% probability of death; probabilities then varied to 0.1% normal health and 99.9% death		
Tsuchiya and Dolan[65] (2009)	United Kingdom	128	Method: • Random sampling • Letters sent to 2,000 randomly selected citizens on electoral register • 192 purposefully selected from which 128 participated Source: Electoral register Response rate: 27% Incentive: £15	• Focus groups ("small group interviews") *Decision-making simulation exercises* • Questions involved trade-offs between health maximization and more equal distribution of health – size of health benefit used as a "currency" to express trade offs between efficiency and equality – 1 question used life expectancy at birth as measure of health and 1 question used prevalence of long term limiting illness • Participants presented with 6 different scenarios that could increase life expectancy by varying amounts for 2 patient groups and asked to choose most preferred scenario; then asked to choose their second preferred scenario, third preferred scenario, and so on, until all 6 were ranked (choice-based ranking) • Also given prevalence rates of limiting long term illness which were 40% for the disadvantaged group and 12% for the advantaged group and 6 scenarios that could reduce illness by differing amounts to both groups – asked to rank scenarios in order of preference using choice-based ranking	• Health gain Examined aversion to inequalities in health outcomes versus aversion to inequalities in health gains	• Greater aversion to inequalities in outcomes than to inequalities in health gains when the difference between patient groups related to social class • Preference for health gains (size of benefit) over health outcomes depended on how question was framed

Table 3-1. Summary of empirical studies exploring social value statements/distributive preferences for the allocating healthcare resources

Author (year)	Study country	Number of participants	Recruitment/ Selection	Study design	Characteristics/ factors examined	Findings/value statements
Green and Gerard[66] (2009)	United Kingdom	259	Method: • Random sampling – random location quota sampling using profile data from census Source: Census Response rate: Not reported Incentive: None specified	• Structured, in-person interviews – conducted in participants' homes *Decision-making simulation exercises* • Used discrete choice experiment • Participants asked to choose between 2 alternative healthcare scenarios representing different technologies (described using different levels of 4 attributes – severity of illness, health gain, cost-effectiveness, and availability of other treatments) • Calculated utility scores for various technology scenarios to estimate preferences	• Need (severity of illness) •Availability of alternatives •Health gain • Cost-effectiveness Examined simultaneous effect of all 4 factors on each other	• Willing to sacrifice cost-effectiveness if large health gain was large and disease severe, regardless of whether alternative treatments were available • Willing to sacrifice some health gain if severe illness and technology represented "fairly good" value for money

Table 3-2. Summary of social value statements underpinning centralized technology funding decision-making processes

Country	Advisory/ Decision-making body	Technology type	Exception polices	Social value judgement/interpretation
Australia [67-69,70-72,73-79,80-84,85-89]	Pharmaceutical Benefits Advisory Committee (PBAC)	• Pharmaceuticals	Decisions typically adopt a cost-effectiveness threshold of AU $42,000/QALY, below which the technology is considered to represent 'value for money' *Exceptions* • May accept technologies with incremental cost-effectiveness ratios (ICERs) above threshold: depends on condition and wider societal costs and benefits • Rare, life-threatening conditions: Pharmaceutical may be funded through "life-saving drugs program" if deemed necessary and effective	Willing to trade off maximal health gain to a population for reduction in health inequalities associated with rare, life-threatening conditions
Australia [4,68,90-94,95-99]	Medical Services Advisory Committee (MSAC)	• Medical devices • Diagnostic tests • Procedures	Access and equity stated as decision criteria (no further information found)	May be willing to trade off maximal health gain to a population for a reduction in inequalities in access or health
Belgium [100-105]	Drug Reimbursement Committee	• Pharmaceuticals	Decisions typically take into account findings from cost-effectiveness analyses to assess "value for money" (but no threshold used) *Exceptions* Cost-effectiveness analyses waived for pharmaceuticals used to treat rare diseases or indications	Willing to trade off maximal health gain to a population for reduction in health inequalities associated with rare conditions
New Zealand [71,106-113,1,24,89,114-120]	PHARMAC	• Pharmaceuticals	Decisions must take into account "health needs of all eligible people within New Zealand" and the particular needs of Maori and Pacific peoples *Exceptions* Rare conditions: "Exceptional circumstances	Willing to trade off maximal health gain to a population for reduction in health inequalities among Maori and Pacific peoples and/or patients with rare conditions for whom there are no alternative treatments

Table 3-2. Summary of social value statements underpinning centralized technology funding decision-making processes

Country	Advisory/ Decision-making body	Technology type	Exception polices	Social value judgement/interpretation
			schemes" provides funding for pharmaceuticals used to manage rare conditions (<10 patients nationally), where reactions to alternative funded treatments are unusual, or where an unusual set of circumstances exists	
Norway [121-124]	Norwegian Medicines Agency National Advisory Committee for Drug Reimbursement	• Pharmaceuticals	Decisions must reflect principles concerning medical needs, solidarity and rationality (i.e., clinically rational and cost-effective use of pharmaceuticals)	Willing to trade off maximal health gain to a population for reduction in health inequalities of the "worst-off" (in terms of medical need)
Scotland [125-130]	Scottish Medicines Consortium New Drugs Committee	• Pharmaceuticals	Decisions typically use a cost-effectiveness threshold range of £20,000 - £30,000/QALY, within or below which the technology is considered to represent 'value for money' *Exceptions* May accept technologies with incremental cost-effectiveness ratios (ICERs) above threshold: depends on whether condition is rare (ultra-orphan) or technology represents life-extending, end of life treatment	Willing to trade off maximal health gain to a population for reduction in health inequalities associated with rare or life-threatening conditions
Sweden [102,131-142]	Dental and Pharmaceutical Benefits Board (TLV)	• Pharmaceuticals • Devices used to deliver pharmaceuticals	Decisions must adhere to : 1. Human value principle – all individuals have equal value (characteristics of patients (e.g., age, social position, income, etc.) must not influence decisions) 2. Need and solidarity principle – patients in greatest medical need or "worst off" must be given priority 3. Cost-effectiveness principle – (cost must be considered reasonable from "medical, humanitarian, and economic point of view")	Willing to trade off maximal health gain to a population for reduction in health inequalities of the "worst off" (in terms of medical need) Decisions must not take into account non-health-related characteristics of patients

Table 3-2. Summary of social value statements underpinning centralized technology funding decision-making processes

Country	Advisory/ Decision-making body	Technology type	Exception polices	Social value judgement/interpretation
			Decisions typically guided by a cost-effectiveness threshold of €45,000/QALY, below which the technology is considered to represent 'value for money' *Exceptions* • CE threshold may be adjusted based on severity of the condition	
The Netherlands [102,141,143-157]	Dutch Health Care Insurance Board (CVZ) Committee for Pharmaceutical Aid (CFH)	• Pharmaceuticals • Procedures	Decisions typically guided by a cost-effectiveness threshold of €20,000/QALY, below which the technology is considered to represent 'value for money' Decisions typically take into account findings from cost-effectiveness analyses to assess "value for money" (but no threshold used) *Exceptions* • Cost-effectiveness analyses waived for pharmaceuticals used to treat: 1) Rare conditions 2) Life threatening conditions 3) Conditions for which there are no other alternatives • CE threshold may be adjusted based on need (severity of the condition and availability of alternative treatments) or equity considerations	Willing to trade off maximal health gain to a population for reduction in health inequalities associated with rare or life-threatening conditions or those for which there are no other alternatives
United Kingdom, Wales, and	NICE Technology Appraisals Committee (TAC)	• Pharmaceuticals • Devices • Procedures	• Decisions typically use a cost-effectiveness threshold range of £20,000 - £30,000/QALY, within or below which the technology is considered	Willing to trade off maximal health gain to a population for reduction in health inequalities of the "worse off" (in terms of medical need),

Table 3-2. Summary of social value statements underpinning centralized technology funding decision-making processes

Country	Advisory/ Decision-making body	Technology type	Exception polices	Social value judgement/interpretation
United Ireland [158-165,71,88,89,99,141,166-179]		• Diagnostic tests	to represent 'value for money' • Decisions do not take into account age, race, gender, whether there is a social stigma attached to the condition, or personal responsibility for condition unless there is clear evidence of differential effectiveness within such groups; never take into account socioeconomic status *Exceptions* • May accept technologies with incremental cost-effectiveness ratios (ICERs) above threshold: depends on whether condition is rare (ultra-orphan) or technology represents life-extending, end of life treatment – must meet 3 criteria: 1) Treatment is indicated for patients with a life-expectancy of less than 24 months; 2) Evidence indicates that treatment extends life by "normally" at least 3 months, compared to current NHS treatment; and 3) Treatment is licensed or otherwise indicated for small patient populations • Also considers the wider societal costs and benefits • Decisions take into account special needs of disabled persons	including those associated with rare or life-threatening conditions Decisions must not take into account non-health-related characteristics of patients
Wales [173,180-183]	All Wales Medicines Strategy Group	• High cost pharmaceuticals (> £2,000/patient/ year)	• Decisions typically use a cost-effectiveness threshold range of £20,000 - £30,000/QALY, within or below which the technology is considered to represent 'value for money' *Exceptions*	Willing to trade off maximal health gain to a population for reduction in health inequalities of the "worst off" (in terms of medical need), including those associated with rare or life-threatening conditions

Table 3-2. Summary of social value statements underpinning centralized technology funding decision-making processes

Country	Advisory/ Decision-making body	Technology type	Exception polices	Social value judgement/interpretation
			• May accept technologies with incremental cost-effectiveness ratios (ICERs) above threshold: depends on whether condition is rare (ultra-orphan) or technology represents life-extending, end of life treatment; also considers the wider societal costs and benefits	

Table 3-3. Summary of grounds for appeals to NICE decisions which presented social value arguments

Technology	Indication	Initial appraisal decision (year)	Grounds for appeals related to social value statements
• Taxanes	Breast cancer	• Should only be used where initial cytotoxic chemotherapy has failed or is not suitable (2000)	Argued that: • Patient preference should be taken into account "Patients should have the opportunity to choose between 2 products. The two taxanes have different toxicity profiles"[184-186]
• Beta interferon • Glatiramer acetate	Multiple sclerosis (MS)	• Should not be used, except in the context of clinical trials (2001) • Patients currently receiving treatments may continue to do so until they and their physicians make the decision to stop (2001)	Argued that: • MS is a severe, progressive disease for which there are no other treatments for the "underlying course of the disease"[187] "Fail[ed] to give due weight to clinical need"[187] "Fail[ed] to demonstrate a true understanding of the clinical needs of patients with multiple sclerosis" Royal College of Nursing [187]
• Anakinra	Rheumatoid arthritis	• Should not be used, except in the context of clinical trials (2003) • Patients currently receiving anakinra may continue to do so until they and their physicians make the decision to stop (2003)	Argued that: • Rheumatoid arthritis is a severe, debilitating disease for which there are few alternatives "The degree of clinical need does not appear to have been appropriately balanced against the wider financial implications"[188]
• Bevacizumab • Cetuximab	Metastastic colorectal cancer	• Bevacizumab should not be used as first line treatment (2006) • Cetuximab should not be used as second line or subsequent treatment (2006) • Patients currently receiving bevacizumab or cetuximab may continue to do so until they and their physicians make the decision to stop (2006)	Argued that: • Pharmaceutical represents life-extending treatment at the end of a terminal disease for which there are no other treatment alternatives "If not made available to these patients, it means that there is no third line treatment available to them"[189] "In the case of both treatments, there are no other licensed alternatives for CRC patients"[190]
• Donepezil • Rivastigmine • Galantamine • Memantine	Alzheimer's disease	• Donepezil, rivastigmine, and galantamine should only be used in patients with moderate disease • Memantine should not be used, except in the context of clinical trials (2006)	Argued that: • Decision is discriminatory because severity is to be determined using the mini-mental state examination score, which varies depending on education and race [191] • Restricting these treatments will lead to increased prescribing of unlicensed sedatives to treat people with dementia [192] "These treatments are the very first treatments for what was previously an incurable illness. They both have clear pharmacological and scientific rationale, directly based on

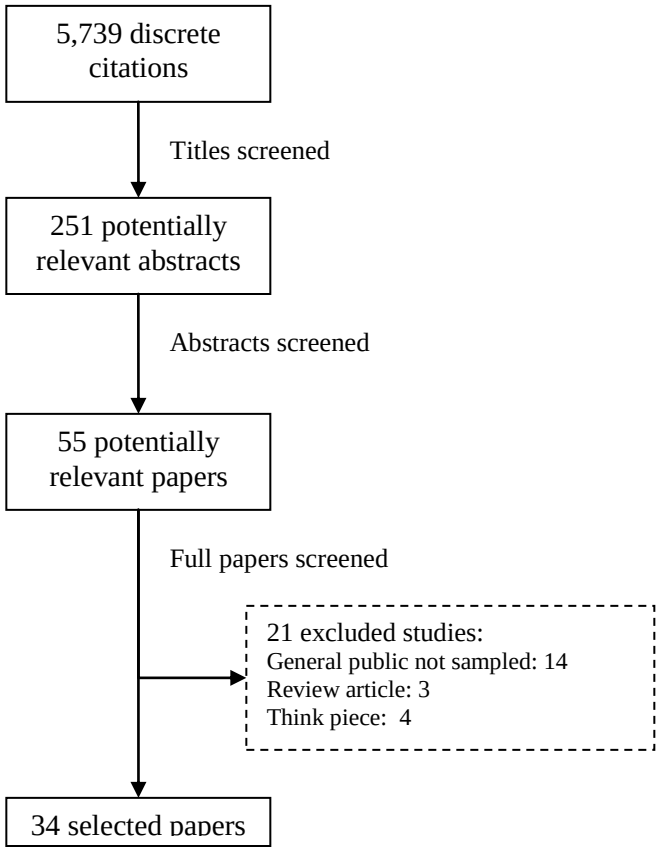
Table 3-3. Summary of grounds for appeals to NICE decisions which presented social value arguments

Technology	Indication	Initial appraisal decision (year)	Grounds for appeals related to social value statements
			what is known about transmitter disturbances in Alzheimer's disease."[193]
• Cetuximab	Locally advanced head and neck cancer	• Should not be used, except in the context of clinical trials (2007) • Patients currently receiving cetuximab may continue to do so until they and their physicians make the decision to stop (2007)	Argued that: • Pharmaceutical represents life-extending treatment at the end of a terminal disease for which there are few treatment alternatives[194] • Pharmaceutical is associated with fewer side-effects, offering an improved quality of life "Patients will be made to suffer the greater side effects of the present available treatments or not have these treatments because their bodies can't tolerate them… they will have to wait until May 2009 before NICE even considers looking at cetuximab in H&N cancer again. Many of these patients will be dead by then"[194]
• Etidronate • Risedronate • Raloxifene • Strontium ranelate • Teriparatide	Osteoporotic fragility fractures in postmenopausal women (secondary prevention)	• Should not be used as initial therapy for the secondary prevention of osteoporotic fragility fractures in postmenopausal women (2007) • Patients currently receiving these treatments may continue to do so until they and their physicians make the decision to stop (2007)	Argued that: • Decisions should maximize patient choice[195-197] "It is vital for clinicians and patients to have alternative treatments available so we can maximize patient choice, reduce avoidable drug side effects…"[198] • Decision discriminates against patients on the basis of age and disability "Nice has effectively discriminated against women on the basis of age and also on the basis of whether they can or cannot tolerate bisphosphonates"[198]
• Adalimumab • Etanercept • Infliximab	Rheumatoid arthritis (sequential use)	• Should not be used in patients after failure of a previous tumour necrosis factor alpha (TNF-α) inhibitor, except in the context of research (2007) • Patients currently receiving adalimumab, etanercept, or infliximab may continue to do so until they and their physicians make the decision to stop (2007)	• Treatments represent the only alternative for patients whose disease is not responding "It is not only essential, but vital that people have access to all drugs proven to be clinically effective when their disease is not responding and its destructive and disabling progress becomes uncontrolled"[199,200] "If the [guidance] is not revised, "a significant number of people with rheumatoid arthritis will be condemned to lives of long-term pain, disability, and dependence" [201] "Decision taken by NICE…has placed the approximately 1% of the citizens of the United Kingdom at a significant disadvantage…and in effect, denies any efficacious treatment to a proportion"[202]
• Lapatinib	Women with previously treated advanced and/or metastatic breast cancer	• Should not be used, except in the context of clinical trials (2009) • Patients currently receiving lapatinib may continue to do so until they and their physicians make the decision to stop (2009)	Argued that : • Pharmaceutical represents life-extending treatment at the end of a terminal disease for which there are no other treatment alternatives • 2 month life-extension in a patient with an otherwise 15 month life-expectancy is significant[203] "Patients eligible for treatment with lapatinib have a very high unmet medical need…lapatinib is the only therapy specifically licensed for this indication…in

Table 3-3. Summary of grounds for appeals to NICE decisions which presented social value arguments

Technology	Indication	Initial appraisal decision (year)	Grounds for appeals related to social value statements
			circumstances where many of these patients will be relatively young, an extension of a few months may be highly meaningful"[204]
• Bevacizumab • Sorafenib • Sunitinib •Temsirolimus	Advanced and/or metastatic renal cell carcinoma	• Sorafenib and sunitinib should not be used as second-line treatment (2009) • Bevacizumab, sorafenib, and temsirolimus should not be used as first-line treatment (2009) • Patients currently receiving any of the 4 treatments may continue to do so until they and their physicians make the decision to stop (2009)	Argued that: • Cumulation criterion (i.e., treatment licensed under multiple indications, thereby serving a larger, cumulative population) devalues technologies that offer, as one of their indications, an extension in life at the end of life for a small patient population [205] • Severe, life-threatening condition for which there are no treatment alternatives for patients with advanced disease [206] "[Treatment] has been shown to extend life expectancy by 50%; invaluable for both patients and their families:[205,207] "Sorafenib and sunitinib for the treatment of second line renal cell carcinoma provide new options for patients who have exhausted and/or are unsuitable for immunotherapy"[206]
• Sorafenib	Advanced hepatocellular carcinoma	• Should not be used in patients for whom surgical or locoregional therapies have failed or are not suitable (2010) • Patients currently receiving sorafenib may continue to do so until they and their physicians make the decision to stop (2010)	Argued that: • Pharmaceutical represents life-extending treatment at the end of a terminal disease for which there are no other treatment alternatives "Patients are being denied the only option open to them for their survival"[208,209] "Sorafenib has orphan drug status and is the only medicinal product licensed for this indication in the EU" "Patients diagnosed with advanced HCC have a uniformly dismal prognosis. "[Sorafenib] is the only therapeutic option…"[209]
• Human growth hormone (HGH)	Growth hormone deficiency in adults	Should only be used in patients who meet the following 3 criteria: • Severe GH deficiency • Perceived impairment of quality of life (QoL) • Already receiving treatment for any other pituitary hormone deficiencies	Argued that: • Decision was unfair and discriminatory – NICE had been inconsistent in its appraisals of HGH therapy in children and adults, recommending use in children on the basis of limited evidence, but not in adults, despite "substantive" evidence " Paediatric use of GH has absolutely no cost-benefit data to support its use"[210]

Figure 3-1. Results of literature search and selection of empirical studies for inclusion in the review



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APPENDIX 3-1. DETAILS SEARCH STRATEGIES AND RESULTS

1a. PubMed: Searched January 2010

Search	Most Recent Queries	Result
#74	Search #73 OR #70	89
#73	Search ("2009/07/05"[Entrez Date] : "3000"[Entrez Date]) AND (#72)	31
#72	Related Articles for PubMed (Select 19034951)	265
#71	Search 19034951[uid]	1
#70	Search ("2009/07/05"[Entrez Date] : "3000"[Entrez Date]) AND (#69)	62
#69	Search #68 OR #19	6905
#68	Search #67 AND #18	2741
#67	Search #64 OR #65 OR #66	844519
#66	Search #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58	102658
#65	Search #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50	50228
#64	Search #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40	768832
#63	Search #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30	1631469
#58	Search "severity of health"	53907
#57	Search "life saving"	4066
#56	Search "terminally ill"	7096
#55	Search "last chance therapies"	3
#54	Search equality	3542
#53	Search solidarity	1115
#52	Search vulnerable	29371
#51	Search disadvantaged	10192
#50	Search marginali*	2417
#49	Search inequalit*	11926
#48	Search "health gain*"	314
#47	Search entitlement	741
#46	Search "personal preference*"	413
#45	Search "rule of rescue"	83
#44	Search identifiability	529
#43	Search "social class"	28355
#42	Search "employment status"	4219
#41	Search equity	5477

#40	Search egalitarian*	622
#39	Search "socioeconomic status"	19302
#38	Search sex factors [mh]	171552
#37	Search age factors [mh]	340028
#36	Search "individual responsibility"	319
#35	Search "lifestyle choice*"	37
#34	Search "treatment option*"	10494
#33	Search "burden of illness"	648
#32	Search severity	281612
#31	Search palliative	46903
#30	Search curative	31163
#29	Search prejudice	19385
#28	Search altruism	4459
#27	Search "value for money"	552
#26	Search independence	21884
#25	Search dignity	3373
#24	Search "return to work"	4227
#23	Search effectiveness	191104
#22	Search safety	225086
#21	Search benefit	200765
#20	Search risk	1099824
#19	Search #13 AND #18	5295
#18	Search #14 OR #15 OR #16 OR #17	20093
#17	Search "priority setting" OR "setting priorities"	1334
#16	Search health care rationing [mh]	9132
#15	Search health priorities [mh]	7149
#14	Search resource allocation [mh]	12984
#13	Search #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12	366324
#12	Search (public [ti] or social [ti] or societal [ti] or citizen* [ti] or taxpayer* [ti] or community [ti]) and (value* [ti] OR preference*[ti] OR priorit* [ti])	1731
#11	Search "distribution of health gain*"	3426
#10	Search "public values"	45
#9	Search "social values"	15734
#8	Search "distributive prefer*"	4
#7	Search value of life [mh]	5042
#6	Search choice behavior [mh]	27312
#5	Search social justice [mh]	7976
#4	Search public opinion [mh]	12596
#3	Search social values [mh]	15467

#2	Search attitude [mh]	205221
#1	Search attitude to health [mh]	212682

1b. PubMed: Searched January 2009

Search	Most Recent Queries	Result
#107	Search #106 NOT #101 Limits: published in the last 10 years	13
#106	Search #105 AND #30 Limits: published in the last 10 years	88
#105	Search value of life [mh] Limits: published in the last 10 years	1281
#101	Search #95 OR #98 OR #99 Limits: published in the last 10 years	4087
#100	Search #95 OR #98 OR #99	4100
#99	Related Articles for PubMed (Select 19034951)	112
#97	Search green c AND "public preferences" Limits: published in the last 10 years	2
#98	Related Articles for PubMed (Select 19406545)	102
#95	Search #93 OR #31 Limits: published in the last 10 years	3953
#94	Search #93 OR #31	9650
#93	Search #92 AND #30	6840
#92	Search #74 OR #75 OR #76 OR #77 OR #79	2170305
#79	Search "severity of health"	51057
#91	Search #79 OR #86 OR #88 OR #89 OR #90	65176
#90	Search "life saving"	3892
#89	Search "terminally ill"	6942
#88	Search "last chance therapies"	3
#86	Search equality	3413
#77	Search #71 OR #72 OR #73	33161
#76	Search #61 OR #62 OR #63 OR #64 OR #66 OR #67 OR #68 OR #69 OR #70	43944
#75	Search #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #60	707811
#74	Search #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50	1599384
#73	Search solidarity	1083
#72	Search vulnerable	27863
#71	Search disadvantaged	9611
#70	Search marginali*	2269
#69	Search inequalit*	11379
#68	Search "health gain*"	303
#67	Search entitlement	715
#66	Search "personal preference*"	399
#64	Search "rule of rescue"	82
#63	Search identifiability	500
#62	Search "social class"	27638

#61	Search "employment status"	4103
#60	Search equity	5221
#59	Search egalitarian*	595
#58	Search "socioeconomic status"	18652
#57	Search sex factors [mh]	167827
#56	Search age factors [mh]	333333
#55	Search "individual responsibility"	302
#54	Search "lifestyle choice*"	36
#53	Search "treatment option*"	9739
#52	Search "burden of illness"	618
#51	Search severity	269708
#50	Search palliative	45469
#49	Search curative	30019
#48	Search prejudice	18804
#47	Search altruism	4305
#46	Search "value for money"	510
#45	Search independence	21177
#44	Search dignity	3284
#43	Search "return to work"	4075
#42	Search effectiveness	183884
#41	Search safety	214418
#40	Search benefit	192863
#39	Search risk	1053215
#31	Search #25 AND #30	4957
#30	Search #26 OR #27 OR #28 OR #29	19706
#29	Search "priority setting" OR "setting priorities"	1282
#28	Search health care rationing [mh]	9033
#27	Search health priorities [mh]	6985
#26	Search resource allocation [mh]	12776
#25	Search #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #20 OR #21 OR #22 OR #23 OR #24	351859
#24	Search (public [ti] OR social [ti] OR societal [ti] OR citizen* [ti] OR taxpayer* [ti] OR community [ti]) AND (value* [ti] OR preference* [ti] OR priorit*[ti])	1672
#23	Search "distribution of health gain*"	3274
#22	Search "public values"	43
#21	Search "social values"	15412
#20	Search choice behavior [mh]	26191

#18	Search "distributive prefer*"	4
#17	Search social justice [mh]	7773
#16	Search public opinion [mh]	12237
#15	Search social values [mh]	15157
#14	Search attitude [mh]	199249
#13	Search attitude to health [mh]	205129

2a. The Cochrane Library (issue 1, 2010) *Cochrane Central Register of Clinical Trials records not included

Cochrane Reviews [0]; Other Reviews [60]; Clinical Trials [1590]; Methods Studies [0]; Technology Assessments [31]; Economic Evaluations [387]; Cochrane Groups [0]

Social values in Keywords or attitude to health in Keywords or public opinion in Keywords or social justice in Keywords or value of life in Keywords, from 1999 to 2009

2b. The Cochrane Library (issue 4, 2009)

Cochrane Reviews [0]; Other Reviews [4]**;** Clinical Trials [88]; Methods Studies [0]; Technology Assessments [1]; Economic Evaluations [11]; Cochrane Groups [0]

3. Centre for Reviews & Dissemination (NHS EED, DARE, HTA)

#	1	social AND values	577
#	2	resource AND allocation	641
#	3	#1 AND #2 RESTRICT YR 2009 2010	1

** 1st CRD search in July yielded 2 references; 2nd search in January 2010 yielded 1. Could not combine sets with numerous terms in CRD databases

4a. EconLit: Searched July 2009

S16	S13 and S14	43
S15	S13 and S14	59
S14	S7 or S8 or S12	832
S13	S1 or S2 or S3 or S4 or S5	13335
S12	S6 and S11	705
S11	S9 or S10	40846
S10	SU health	40757
S9	TX health production	9668

S8	TX health care rationing	61
S7	TX health priorities	86
S6	TX resource allocation	9264
S5	SU equity, justice, inequality, and other normative criteria and measurement	5135
S4	TX distributive preferences	28
S3	TX social justice	4006
S2	TX public values	218
S1	TX social values	4944

4b. EconLit: Searched January 2010

S16	(((S6 and S12) and (S7 or S8 or S13)) and (S7 or S8 or S13)) and (S11 and S14)	(3)
S15	(((S6 and S12) and (S7 or S8 or S13)) and (S7 or S8 or S13)) and (S11 and S14)	(49)
S14	((S6 and S12) and (S7 or S8 or S13)) and (S7 or S8 or S13)	(750)
S13	S6 and S12	(750)
S12	S9 or S10	(42885)
S11	S1 or S2 or S3 or S4 or S5	(13987)
S10	SU health	(42794)
S9	TX health production	(10371)
S8	TX health care rationing	(63)
S7	TX health priorities	(87)
S6	TX resource allocation	(9730)
S5	SU equity, justice, inequality, and other normative criteria and measurement	(5312)
S4	distributive preferences	(12)
S3	TX social justice	(4317)
S2	TX public values	(262)
S1	TX social values	(5106)

5a. EMBASE (Ovid): Searched January 2009

1	exp *social psychology/	4604
2	exp *attitude to health/	5520
3	exp *social justice/	1564
4	social values.mp.	138
5	value of life.mp.	69
6	health priorities.mp.	287
7	public preferences.mp.	58
8	public values.mp.	22
9	distributive preferences.mp.	5

10	6 or 3 or 7 or 9 or 2 or 8 or 1 or 4 or 5	12173
11	resource allocation.mp. or exp *resource allocation/	8060
12	health priorities.mp. or exp *health care planning/	9041
13	priority setting.mp.	531
14	health care rationing.mp.	46
15	11 or 13 or 12 or 14	17176
16	10 and 15	422
17	limit 16 to yr="1999 - 2009"	377

5b. EMBASE: Searched January 2010

1	exp *social psychology/	5679
2	exp *attitude to health/	528
3	exp *social justice/	72
4	social values.mp.	235
5	value of life.mp.	139
6	health priorities.mp.	362
7	public preferences.mp.	72
8	public values.mp.	30
9	distributive preferences.mp.	6
10	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9	7095
11	resource allocation.mp. or exp *resource allocation/	9306
12	health priorities.mp. or exp *health care planning/	4406
13	priority setting.mp.	669
14	health care rationing.mp.	97
15	11 or 12 or 13 or 14	14112
16	10 and 15	417
17	limit 16 to yr="2009 -Current"	28
18	from 17 keep 1-28	28

6a. PsycINFO (Ovid): Searched January 2009

1	exp *Social Values/	1313
2	exp *Social Justice/	798
3	*Values/	3952
4	*Public Opinion/	2720
5	value of life.mp.	71
6	public values.mp.	20

7	public preferences.mp.	38
8	6 or 4 or 1 or 3 or 7 or 2 or 5	8833
9	exp Health/	50546
10	exp Resource Allocation/	1358
11	10 or 9	51836
12	health care rationing.mp.	25
13	priority setting.mp.	133
14	11 or 13 or 12	51955
15	8 and 14	312
16	from 15 keep 1-312	312
17	limit 16 to yr="1999 - 2009"	245

6a. PsycINFO (Ovid): Searched January 2010

1	exp *social values/	605
2	exp *social justice/	870
3	*values/	1838
4	*public opinion/	1717
5	value of life.mp.	75
6	public values.mp.	16
7	public preferences.mp.	29
8	1 or 2 or 3 or 4 or 5 or 6 or 7	5090
9	exp health/	39014
10	exp resource allocation/	1047
11	health care rationing.mp.	8
12	priority setting.mp.	101
13	9 or 10 or 11 or 12	40065
14	8 and 13	262
15	limit 14 to yr="2009 -Current"	32

7a. HealthSTAR (Ovid): Searched January 2009

Results	**Search Type**	**Actions**
1	social values.mp. or exp Social Values/	15252
2	social justice.mp. or exp *Social Justice/	8450
3	public opinion.mp. or exp *Public Opinion/	12587
4	value of life.mp. or exp *"Value of Life"/	5281
5	public values.mp.	37

6	public preferences.mp.	71
7	distributive preferences.mp.	5
8	6 or 4 or 1 or 3 or 7 or 2 or 5	38942
9	resource allocation.mp. or exp *Resource Allocation/	11962
10	health priorities.mp. or exp *Health Priorities/	7838
11	health care rationing.mp. or exp *Health Care Rationing/	9516
12	priority setting.mp.	793
13	setting priorities.mp.	459
14	11 or 13 or 10 or 9 or 12	22731
15	8 and 14	3552
16	limit 15 to yr="1999 - 2009"	1077

7b. HealthSTAR: Searched January 2010

Results	**Search Type**	**Actions**
1	social values.mp. or exp social values/	15790
2	social justice.mp. or exp *social justice/	8771
3	public opinion.mp. or exp *public opinion/	13045
4	value of life.mp. or exp *value of life/	5396
5	public values.mp.	39
6	public preferences.mp.	76
7	distributive preferences.mp.	6
8	1 or 2 or 3 or 4 or 5 or 6 or 7	40289
9	resource allocation.mp. or exp *resource allocation/	12328
10	health priorities.mp. or exp *health priorities/	8084
11	health care rationing.mp. or exp *health care rationing/	9743
12	priority setting.mp.	825
13	setting priorities.mp.	486
14	9 or 10 or 11 or 12 or 13	23416
15	8 and 14	3618
16	limit 15 to yr="2009 -Current"	50

8a. Web of Science (Science Citation Index, Social Science Citation Index, Arts and Humanities Index): Searched January 2009

# 5	410	#2 AND #3 AND #4 *Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=1999-2009*
# 4	>100,000	TS=(health OR health care) *Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=1999-2009*
# 3	70,548	TS=(allocation OR allocating OR rationing OR priorities OR priority)

		Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=1999-2009
# 2	26,237	TS=(public OR social) AND TS=(values OR preferences OR justice) *Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=1999-2009*
# 1	119	Title=("public values" OR "social values" OR "distributive preference*" OR "social justice") AND Topic=(health OR "health care rationing" OR "resource allocation" OR "priority setting") *Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=1999-2009*

8b. Web of Science: Searched January 2010

# 7	*96*	#6 *Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=2009-2010*
# 6	*743*	#1 OR #5 *Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=All Years*
# 5	*592*	#2 AND #3 AND #4 *Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=All Years*
# 4	*>100,000*	ts=(health OR health care) *Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=All Years*
# 3	*>100,000*	ts=(allocation OR allocating OR rationing OR priorities OR priority) *Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=All Years*
# 2	*38,752*	TS=(public OR social) AND TS=(values OR preferences OR justice) *Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=All Years*
# 1	*156*	Title=("public values" OR "social values" OR "distributive preference*" OR "social justice") AND Topic=(health OR "health care rationing" OR "resource allocation" OR "priority setting") *Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=All Years*

CHAPTER 4:
EXPLICATING SOCIAL VALUES FOR RESOURCE ALLOCATION DECISIONS ON NEW HEALTH TECHNOLOGIES: WE, THE JURY, FIND…

ABSTRACT

Introduction:

Coverage decisions on new health technologies reflect more than just 'technical' information. They consider factors related to the broader, *relative* benefits of technologies to different patient populations with competing interests. These factors represent social value statements, defined as the distributive preferences of the public for the allocation of healthcare resources. To date, social value statements embedded in decisions have largely remained ill-defined. As public interest in, and patient demand for, greater transparency in decisions heighten, the need to make such values explicit is increasingly clear.

Objectives:

To identify factors around which the distributive preferences of the public for the funding of new health technologies are formed.

To examine interactions among factors considered simultaneously to reflect 'real life' resource allocation decision-making.

Methods:

A citizens' jury was held to elicit preferences of the public regarding the distribution of resources for new health technologies across patient populations. Sixteen individuals from central and northern Alberta were selected from 1,500 randomly sampled names and addresses to broadly

represent the socio-demographic profile of those regions. Jurors participated in increasingly complex decision simulation exercises. These involved compiling factors/patient characteristics that jurors thought might influence their preferences, and then weighing those factors simultaneously through choice-based, trade-off questions. Based on their responses, potential interactions among factors and social value statements were identified.

Results:

The following factors were identified: number of patients who could benefit; current health state; prognosis without the technology; health outcome - quality of life; age; dependents (care-giving responsibilities); personal responsibility for illness; and health outcome - length of life. When several were considered at once, jurors' preferences changed, suggesting the presence of interactions among factors.

Conclusions:

Interactions among factors related to distributive preferences for healthcare appear to exist, indicating that social values are considerably more complex than reported to date.

INTRODUCTION

There are more promising new health technologies than resources available to provide them. Thus, limit-setting decisions, which inevitably create perceived 'winners' and 'losers', must be made.[1] Over the past decade, public scrutiny over such decisions has grown, and payers have faced significant pressure to demonstrate legitimacy and fairness in funding/coverage processes.[2,3] Their efforts to make prudent and principled use of scarce resources have largely focussed on explicating clinical and economic evidentiary requirements to support such processes.[4-7] However, it is increasingly recognized that coverage decisions reflect more than just 'technical' information.[8,9] They consider factors that take into account the broader, *relative* benefits of technologies to different patient populations with competing interests and moral claims. These factors represent social value judgements, defined as the distributive preferences of the public for the allocation of healthcare resources.[10] Distributive preferences typically relate to different characteristics of patient populations and the effects (health gain) of specific health technologies on them. To date, the social value statements embedded in decisions have, for the most part, remained ill-defined.[4] Public interest in, and patient demand for, greater transparency in decisions is increasing, and the need to make such values explicit is clear.

In Canada, there is little disagreement among decision-makers over whose values coverage processes ought to reflect – those of the public, as funders of the healthcare system and the population to whom it is ultimately accountable. Thus, decision-makers, compelled to ensure

that these values are incorporated into choices around which new health technologies to provide, first require insights into what they comprise.

OBJECTIVES

The purpose of this project was three-fold:

1. To examine how the public weighs different characteristics of competing patient populations when deciding how to allocate healthcare resources;

2. To determine the extent to which distributive preferences are modified by the presence of additional information on competing patient populations; and

3. To generate a list of social value statements (i.e., statements of the public's distributive preferences) that may help guide resource allocation decisions on new health technologies.

BACKGROUND

Preliminary research exploring social values for the allocation of healthcare has highlighted the challenges involved in designing studies that appropriately balance feasibility with relevance to 'real world' policy–making.[9] Proposed approaches to accomplishing this have begun to converge around deliberative democratic techniques commonly applied in participatory action research.[11] Deliberative democratic techniques have their foundations in deliberative democracy, which states that: 1) decisions should be made collectively by those affected by the decision or their representatives; and 2) individuals committed to the values of rationality and impartiality

are amenable to changing their judgements, preferences, and views in response to arguments by and to those involved, before making a collective decision.[12] Among these techniques, one has attracted considerable interest from healthcare decision-makers – citizens' juries.[13-15]

Citizens' juries, like legal juries, are based on the idea that "once a small sample of the population has heard the evidence, its subsequent deliberations can fairly represent the conscience and intelligence of the general public".[16] They typically involve 12 to 16 individuals who are selected to be broadly representative of their community. Charged with addressing one or more complex questions, they meet over a two to four day period, during which they hear from expert 'witnesses' who represent a broad range of perspectives, engage in deliberations among themselves, and come up with a common ground answer.[13] Therefore, in contrast to traditional opinion polls, surveys, focus groups, and interviews (where information flow is one way), citizens' juries attempt to seek 'more informed' public views (through a multidirectional flow of information among jurors and witnesses). Findings from external evaluations of citizens' juries are sparse, but positive. Regarding fairness and competence, juror deliberations have been shown to demonstrate rational, logical flows of thought that build upon previous arguments. They also reveal a shift of views from more self-interested to more socially aware ones.[17-20]

METHODS

A citizens' jury was held over two and a half days to elicit preferences of the public on the distribution of new health technologies across patient populations.

Assembly of the jury

Sixteen residents of central and northern Alberta (combined population of approximately 1.8 million) were recruited to comprise a broadly representative sample using the following process:

1. Assembly of jury pool

Personalized information letters, accompanied by consent forms, were mailed to 1,400 randomly selected residents of central and northern Alberta. Information letters described the citizens' jury and invited residents to participate in a telephone screening survey to determine eligibility and collect the socio-demographic information needed to select a representative jury. Sample size was calculated from response rates for previously published citizens' juries, which ranged from 2% to 40%.[14,21] The 1,400 names and mailing addresses were obtained through random sampling (using a random numbers generator) of a commercially prepared database of registered telephone numbers (Survey Sampling International®).

Since it is estimated that approximately 10% of the Alberta population between the ages of 18 and 34 years of age uses cellular phones exclusively (do not have registered landlines), 100 randomly selected cellular phone numbers with billing addresses in central and northern Alberta were also called (Survey Sampling International®). All calls were conducted by two researchers, who, using a pre-tested script, briefly described the study and then asked respondents if they would be interested in receiving a copy of the information letter for their further consideration. A maximum of three attempts to contact each potential respondent was

made. Addresses were obtained from those who consented, and copies of the same information letter and consent form as those used for the main mail-out were sent to them.

Respondents were asked to complete and return forms within two weeks of the postage date, using the pre-paid, self-addressed envelopes provided. To reduce the potential for volunteer bias, letters indicated that participants selected to comprise the jury would receive a $400 honorarium for the full two and a half days, and all travel, accommodations, childcare expenses, and meals would be reimbursed.

2. Selection of jurors

Telephone screening interviews, each lasting approximately 10 minutes, were carried out with respondents who had confirmed their willingness and availability to take part in the jury session during the days indicated in the information letter. The same two researchers conducted all of the interviews, and a pre-tested interview script was used to minimize interviewer bias.

Since the jury was intended to elicit the views of the general public or 'ordinary citizens' (i.e., individuals with no particular axe to grind and whose voices might not otherwise be heard), survey questions were designed to gather not only socio-demographic data (age, gender, ethnicity, education, household income (before taxes), and employment status), but also information on potential affiliations with health-related special interest/patient advocacy groups and/or employment as a healthcare professional in a healthcare delivery organization, or in

government (exclusion/ineligibility criteria). To select 16 jurors with a collective demographic and socioeconomic profile comparable to that of the population of central and northern Alberta, purposive and stratified random sampling techniques were employed. Respondents who completed the screening survey and met the study's inclusion criteria (i.e., not a healthcare professional or involved in a health-related interest/advocacy group) were first grouped according to gender and age. They were then further stratified by level of education and household income (before taxes). Potential jurors were purposefully selected to match the age, gender and socioeconomic distribution of the Alberta population, based on Statistics Canada census data. Ethnic backgrounds (including First Nations) were also taken into account to ensure representation proportional to that reported by Statistics Canada. Where several respondents with the same characteristics were identified, random sampling (random numbers table) was used to choose from among them.

The citizens' jury

1. Organization of the jury

A two and a half day jury session was planned and held in Edmonton, Alberta. The length was determined from previous experience and published evaluations of citizens' juries.[14,22] An advisory committee was created to ensure 'witness' presentations and decision simulation exercises addressed the full spectrum of issues and perspectives which need to be taken into account when making actual coverage/funding decisions on new health technologies. The committee consisted of two senior health executives with experience allocating healthcare

resources and setting priorities at national, provincial, and regional-levels; a practicing oncologist with knowledge of new and emerging cancer technologies and their potential impact on patient care; and a researcher with methodological expertise conducting citizens' juries.

Cancer technologies were chosen as the 'case study' for initial presentations and jury deliberations for three main reasons: 1) the public has a general familiarity with cancer and its implications; 2) cancer technologies span the entire care pathway (including prevention, screening, curative treatments, and palliative interventions) and, thus, they encourage trade-off discussions around the range of benefits or effects various types of health services may have on different patient populations; and 3) much of the recent public criticism over access to quality health care has been related to cancer technologies (mainly, high-cost pharmaceuticals).[2,8] 'Expert witnesses' were selected to capture a wide spectrum of stakeholders' perspectives, including those of decision-makers, health care providers/clinicians, and patients.

With input from the advisory committee, a series of decision simulation exercises were constructed to reflect, as closely as possible, 'real-world' resource allocation problems. Exercises, described in detail in the next section, emphasized the opportunity costs (i.e., the cost of alternatives forgone as a result of the choice made) that must be taken into account during decision-making. They also focussed on the characteristics/factors of different patient populations in whom technologies are to be applied, and around which distributive preferences of the public (social value judgements) may be formed. A preliminary list of factors/patient

characteristics was compiled through a systematic review of published literature,[9] a meeting of the advisory committee, and informal discussions with members of the investigative team and collaborators on a Canadian Institutes of Health Research program grant regarding access to cancer technologies. Exercises were designed to require consideration of multiple patient characteristics at once, and became increasingly complex as the jury session progressed. After each exercise, discussions around rationale for the jury's choices were used to identify and seek consensus on value statements.

2. Conduct of the jury

Facilitated by two researchers with experience conducting citizens' juries, the jury session included the following sequence of activities:[14]

Day 1 (half day)

During the first evening, jurors were welcomed and introduced to the 'expert witnesses'. They then took part in ice-breaker exercises intended to give them an opportunity to develop a comfort level with facilitators, 'expert witnesses', and each other. The evening ended with introductory presentations on the need for priority-setting in healthcare, challenges related to making decisions that affect access to new cancer technologies, and the use of citizens' juries as a means of eliciting the views of the public on social values for informing resource allocation decisions.

Day 2 (full day)

The second day began with a series of "a day in the life of…" presentations from 'expert witnesses', who included: 1) an oncologist; 2) a senior-level decision-maker responsible for the delivery of cancer services across Alberta; 3) a senior-level decision-maker responsible for the delivery of all types of health services across the province; 4) a senior-level decision-maker responsible for provincial healthcare funding policies; and 5) a patient advocate who represented the views of cancer patients.

The purpose of the presentations was to develop awareness among jurors of how decisions on which new health technologies to fund are currently made, challenges faced by those who make them, and their effects on providers and patients. Presentations were followed by a question-and-answer period, during which jurors had an opportunity to seek clarification on any of the points raised. Witnesses then participated in a panel discussion involving a technology scenario decision problem. They were given five cancer technologies and asked to assume that the cost of introducing each one into the healthcare system was the same. They were also provided with a description of each technology, which included: 1) the patient population for whom it was indicated (incidence, prevalence, average age, expected survival, and disease stage); 2) current management and the availability of alternative treatments; 3) requirements for the administration or delivery of the technology (e.g., what the treatment involved); and 4) expected health gain or effectiveness.

The five technologies were: 1) bevacizumab for glioblastoma multiforme, a common and fatal type of primary brain tumour; 2) brachytherapy for breast cancer; 3) robotic surgery for localized prostate cancer; 4) fecal immunochemical tests for colorectal cancer screening; and 5) implantable drug delivery systems for cancer pain. Identified by the advisory committee, the technologies represented actual recent funding requests in the province. The level of information presented emulated that of typical briefing notes upon which ministerial decisions are frequently based. Witnesses were asked to describe factors/characteristics of the patient population they would consider when determining which of the technologies to fund if there were only enough resources for one of them. The panel discussion was intended to offer jurors a starting point for their own deliberations, as well as demonstrate how individual factors considered may vary with stakeholder perspective. Jurors then participated in the first decision simulation exercise.

Decision simulation exercise 1: Identification of factors/patient characteristics

The jury was separated into three, pre-assigned small groups (roughly balanced on age, gender, and education) and given descriptions of 10 different cancer technologies, selected to represent not only local issues, but also a range of different types of interventions (e.g., prevention, screening, treatment, etc.) (Table 4-1). Once again, the level of detail presented resembled that of a ministerial briefing note. Collectively, descriptions of technologies included information on a wide range of patient characteristics/factors around which distributive preferences of the public have been sought.[9] They were written in plain language and pilot-tested with a convenience sample of the public (i.e., respondents who participated in the screening survey but were not

selected for the jury). Jurors were asked to imagine that they comprised a provincial health committee responsible for making coverage decisions on new health technologies for the province. They had a fixed budget through which only five of the 10 technologies requested by local cancer specialists could be funded. The cost of providing each technology to the relevant patient population was the same. Groups were asked to select five of the technologies for funding and to indicate rationales for their choices. Each group was facilitated by a researcher who offered clarification on the choice task and ensured active participation from all group members. Groups reconvened to compare choices and discuss factors/patient characteristics they had considered during their deliberations. They then compiled a list of these factors/patient characteristics, ranked in order of importance. In addition, they identified distinct categories/levels within factors/patient characteristics which they felt shaped their choices (e.g., age: young versus old). Finally, jurors were asked to indicate their distributive preferences for each factor according to the categories they created and assuming that "all else was equal" among competing patient populations (i.e., patient populations only differed on one factor/characteristic).

Decision simulation exercise 2 – Identification of simple interactions between factors

The second exercise was intended to demonstrate 1) how distributive preferences may be modified by the presence of other factors/patient characteristics; and 2) the importance of considering the "at what cost" or switching point in preferences as a means of assessing their strength. Two 'ping-pong' exercises were prepared. Jurors were first asked to choose between

two technologies for two patient populations who differed on two characteristics ('current health state' and 'prognosis without the technology'), but with treatment, could both be brought to 'sufficient functioning' (Appendix 4-1). If they chose the more severely ill population, the final health state of the less severely ill population was increased to 'full functioning' and the jurors were asked to choose between the two populations again. If they still chose the more severely ill population, its final health state was changed to 'insufficient functioning', and jurors were, once again, asked to choose between populations. In other words, characteristics of the two populations were varied to find the switching point or circumstances under which the opportunity costs of continuing to favour a particular patient population were deemed too great.

The second 'ping-pong' exercise was identical to the first, except that one of the patient populations faced imminent death without treatment. Once again, characteristics of the 'unselected' patient population were altered until jurors 'switched' their preferences to support that population.

Day 3 (full day)

The third day began with a panel discussion in which jurors 'defended' their decisions not to fund particular technologies (see Exercise 1 from day 2). Its purpose was to illustrate the implications of 'no' decisions, including public and patient reactions to them. Roles were reversed and 'witnesses' questioned jurors using three hypothetical scenarios: 1) a newspaper article about a child denied 'last chance' therapy for leukemia; 2) a letter to the Board Chair of

the provincial health services delivery organization from a nurse with unresectable liver cancer, caused by hepatitis C contracted through work, whose only option other than "grueling" systemic alternatives, was brachytherapy, a treatment available in neighbouring provinces; and 3) a letter to the Premier from a prominent neurosurgeon condemning the province's decision not to fund the chemotherapy wafer for high grade glioma, a particularly "aggressive and deadly form of cancer with few treatment options". At the end of the discussion, jurors were given the opportunity to change their minds (i.e., revisit and revise the list of five technologies they selected to fund), in light of the arguments presented.

Decision simulation exercise 3 – Identification of complex interactions among factors

With jurors now aware of the complexities involved in making funding decisions that ultimately amount to 'trade-offs' in health gains to different patient populations, the third exercise aimed to elicit 'informed' distributive preferences, emerging from a simultaneous weighing of multiple factors/patient characteristics. A set of questions adapted from choice-based stated preference techniques (choice-based contingent analysis or discrete choice experiments) was constructed. Based on findings from a recent comprehensive review, such techniques offer a feasible approach to obtaining views that reflect consideration of opportunity costs.[9] In addition, they closely resemble 'real life' decisions and appear to be less susceptible to preference reversals than other forms of choice tasks.[11]

Questions took the form of explicit pair-wise comparisons between unique patient populations (comprising different combinations of levels of factors/characteristics). Methods for constructing comparisons followed those of choice-based stated preference surveys. A list of factors/patient characteristics and levels within them was compiled by jurors (Exercise 1) and compared with a preliminary set compiled as described previously.[9] To maintain a reasonable level of 'task complexity' and cognitive burden, only the top four ranked factors/patient characteristics were selected to include in pair-wise comparisons.

Choice scenarios (combinations of different levels of the four factors/patient characteristics) and choice sets (pair-wise comparisons of choice scenarios) were then assembled using a fractional factorial design, since a full factorial design (using all pairs of all combinations of levels) would have yielded an unmanageable number of pair-wise comparisons. Specifically, an Orthogonal Main Effects Plan (OMEP) was employed (SPSS Orthoplan). It selects from a library of designs, the smallest orthogonal plan that fits the factors and satisfies the minimum number of combinations (choice scenarios) requested.[23] In this way, it creates choice scenarios and choice sets to obtain maximum information through as few pair-wise combinations as possible. Three groups of 16 choice scenarios (unique patient populations) were generated and checked for plausibility. Choice scenarios were then randomly matched to construct 16 pairs or choice sets, which were also checked for plausibility. When a scenario or pair was deemed implausible, a replacement was selected from the remaining 16 unmatched scenarios, maintaining 'level balance' (i.e., all levels of each characteristic appeared with equal frequency across pairs) to the

extent possible.[24] Lastly, four choice sets were added to the sample of 16 pairs. Three represented duplicates of randomly selected pairs within the sample, and were used to determine the reliability of jurors' choices. The fourth choice set included a dominant scenario (in which all of the levels in one patient population would be preferred to those in the other population) to examine internal consistency of responses.[25] Thus, the exercise involved a total of 20 pair-wise comparisons. This number was considered feasible (small enough to minimize respondent fatigue), based on results of previous choice-based surveys.[26]

Jurors broke into the same three small groups as the day before to answer the 20 choice-based questions. For each question, jurors were asked to imagine that they were a provincial health committee responsible for making coverage decisions on new health technologies. There were requests for two technologies, each benefitting a different patient population, but only enough resources to fund one of them. To emphasize that such decisions correspond to trade-offs in health gains to patient populations, jurors were asked to choose one of the two populations they would prefer to 'help', as opposed to the technology (Appendix 4-2). Jurors were not given the option of 'dividing the resources equally' across both populations. It was explained that all patients within each population were identical in need, and that it was not possible to fund half of a technology. To further simulate 'real life' decision-making, jurors had to reach consensus on and be able to explain their choice. The three groups then reconvened to compare decisions and rationale, and arrive at a collective position.

Decision simulation exercise 4 – Identification of increasingly complex interactions among factors

The fourth and final exercise was identical to the third, except that the choice-based questions included six factors, rather than four, and it was carried out in a large group, as opposed to small groups. It has been demonstrated that six factors falls within an upper limit range, beyond which the choice task can become unfeasible and responses, unreliable.[27] A total of 48 choice scenarios were generated and used to create 32 choice sets. As before, they were checked for plausibility and 'level balance'. When a scenario or pair was deemed implausible, a replacement was selected from the remaining 16 unmatched scenarios. Three duplicate questions were also added, along with a dominant scenario. Once again, jurors deliberated over questions until consensus on which patient populations to 'help' was achieved.

The jury ended with an informal presentation of preliminary preference statements, which were noted as they emerged during the jury sessions. It was explained that once responses to all of the choice-based questions had been more rigorously analysed, jurors would receive a set of statements on which their feedback would be sought.

Finally, a Delphi process was used to prepare and obtain jurors' consensus on a final set of preference statements.[28]

3. Analysis of data collected through the jury

The entire jury session was digitally recorded and transcribed. In addition, notes of sessions were taken by four researchers. Transcripts and notes were analysed using content analytic and constant comparison techniques to assess the flow of arguments and the extent to which all of the jurors' views had been captured.[14] To accomplish this, data (chunks of information) were sorted, arranged, and coded using dedicated qualitative research software (NVivo® 8). To minimize observer bias, two researchers independently reviewed all of the transcripts, and then met to compare findings and reconcile differences.[29]

Responses to questions in choice-based exercises were analysed qualitatively, noting trends or patterns within and across factors/patient characteristics. Standard quantitative approaches to analysing choice-based questions could not be applied because they assume that all factors are mutually exclusive or 'orthogonal'. Preliminary research suggests that factors/patient characteristics around which distributive preferences are formed may not be independent.[9] While some studies have compensated for this through the inclusion of interaction terms, knowledge of the relationship between factors is required. In this case, such relationships have yet to be defined.

Choice sets and corresponding responses were analysed by factor/patient characteristic to identify combinations of other factors/patient characteristics (i.e., interactions) that appeared alongside particular responses. For example, with respect to 'current health' (a factor), all choice

sets containing two patient populations who differed in current health (severely ill vs. moderately ill, moderately ill vs. mildly ill, and mildly ill vs. severely ill) were first selected. They were then divided into three sub-groups in which: 1) severely ill populations were compared to moderately ill populations; 2) moderately ill populations were compared to mildly ill populations; and 3) mildly ill populations were compared to severely ill populations. For each sub-group, choice sets were further sorted by response or preferred population (e.g., where severely ill was preferred to moderately ill). Other levels of factors/patient characteristics of the 'severely ill' population were compared with those of the 'moderately ill' population to identify any interactions, patterns, or trends (e.g., those that consistently appeared together in a preferred population). The findings were then used to prepare a preliminary preference statement. This process was repeated for the remaining two subsets. The same approach was applied to all of the levels of the other factors, producing a series of preliminary preference statements. Finally, these statements were combined, where appropriate, to formulate the final set.

The above protocol was approved by the University of Alberta Health Research Ethics Board.

RESULTS

A total of 684 replies accompanied by completed consent forms were received within two weeks of the mail-out. Of the 816 non-respondents, 498 were unreachable (letters were returned by the post office and marked as 'no known address', 'change of address', or 'no forwarding address'). Based on a comparative analysis of addresses corresponding to non-respondents and

respondents, the geographic distribution of the two groups was similar. All 684 respondents completed the telephone screening survey.

Profile of the jury

Socio-demographic characteristics of the 16 jurors who participated in the jury are presented in Table 4-2. Similar to the population of central and northern Alberta, half were male and half were female. They ranged in age from 20 years to 82 years, and represented a broad spectrum of education and income levels. Employment status and ethnic mix were also comparable to those of the broader population.

Findings from exercise 1: Selection of technologies and identification of factors

1. Selection of technologies to fund

Four of the five technologies selected by each of the three small groups were identical. The selections were: 1) endobronchial ultrasound-guided transbronchial fine needle biopsy; 2) a genetic test for hereditary breast cancer; 3) cryotherapy for localized kidney cancer; and 4) cementoplasty for bone pain. Regarding the fifth technology, one group chose brachytherapy for liver cancer, while two groups selected the HPV vaccine for boys. All three groups explained that they had attempted to choose technologies for a range of indications which, collectively, spanned the entire continuum of care (screening/prevention, diagnosis, treatment, and palliation). "We wanted to make sure we spread the funding over many different types of technologies and people"; "we thought that diagnosis and screening were as important as treatment or palliative

care"; "we need to fund prevention, not just treatment"; and "we want to prevent people from having to suffer and we want to help those who are already suffering". Jurors deliberated over their fifth choice for a considerable amount of time. In the end, they selected the HPV vaccine, arguing that it could potentially benefit a larger number of individuals. In addition, some had viewed liver cancer as the result of "poor" lifestyle choices (since common causes include alcoholic cirrhosis, steroid use and viral hepatitis), and felt that priority should be given to those whose 'unhealthy' behaviour had not contributed to their health state. "Society shouldn't give priority to people who choose to drink themselves silly and then end up with cancer – we need take responsibility for our health".

Their deliberations led to a discussion around questions about patient populations that they had asked themselves when making their decisions. These questions included: "How many patients could be helped?"; "Which technologies would benefit the greatest number?"; "How sick are they now?"; "Are they [patients] severely ill?"; "What happens if they [patients] don't get the technology?"; "How long are they [patients] expected to live otherwise?"; "Are there any other alternatives?"; "What benefit will they [patients] really get?"; "Would the technology just prolong life with no quality?"; "How many months is enough?"; "Would the technology improve quality of life?"; "Would they [patients] be able to do normal activities again, like go to work?"; "Would there be less pain and suffering?"; "Was the cancer related to lifestyle, you know, was it self-inflicted?"; "How likely would they [patients] be parents with small kids who need them?";

"How old are they?"; and "If they [patients] get the technology, would they end up dying of something else soon after because they are already old?".

Importantly, when jurors were "interrogated" by 'witnesses' on their selection of technologies for funding, they stood their ground, choosing not to revise their decisions. They explained that "it is not that we don't value what those other technologies could do for people, we do…it is just that we think these ones are more worthwhile"; "we would have loved to fund them all, but there wasn't enough money and some difficult decisions had to be made…we thought we would be giving up the least by not funding these ones"; and "two months of life is not a helluva lot over something that could ease pain for many cancer patients, I don't think so, not on my watch".

2. Identification of factors/patient characteristics

From the above questions, jurors identified and ranked eight factors/patient characteristics that they felt influenced their preferences. From most important to least important, they included: 1) number of patients who could benefit; 2) current health state (severity of illness); 3) prognosis without the technology (life expectancy if untreated); 4) health outcome - quality of life; 5) age; 6) dependents (care-giving responsibilities); 7) responsibility for illness; and 8) health outcome - length of life. These factors were similar to those identified through the literature review.[9]

Jurors selected 'number of individuals who could benefit' as the most important factor, explaining that the "goal of the healthcare system should be to help as many people as possible";

"yeah – the greatest good for the greatest number"; "for me, it is population, number one"; and "I need to know if it is 10,000 people or 10". 'Current health state' or severity of illness also carried considerable weight ("how sick people are now is really critical"; "severity of illness is something that would have a large impact on my decisions"; and "we have to look after people…to do this, we need to know how severely ill they are"). Jurors indicated that 'prognosis without treatment' was an important factor because it provided insights into the urgency of the need for care ("what is our window of opportunity here…do we have to act now?"; "we need to know if patients can wait or if this is it...they are at the end of the road"; and "we have to look at whether funding something else or somebody else will really be detrimental…maybe they can afford to wait").

Regarding health outcomes, jurors repeatedly raised the importance of focussing on benefit in terms of quality of life, even stating that improvement in length of life, alone, is of little importance ("forget how long you live, it is about quality" and "if I just exist, I am better off dead"). Jurors identified 'age' as a factor they considered, but disagreed on the extent to which it should influence decisions ("age is something I would want to know about"; "this [age] information would be nice to have, but I don't think it should be used to discriminate against seniors"; and "you know, we have to make tough decisions here and knowing how old they [patients] are just might tip things one way or the other").

Jurors indicated that whether patients had care-giving responsibilities was an important factor ("I would want to know because then I would be able to get an idea of who might be impacted"). However, they expressed concern about how such a factor might be defined ("should it just be about a mom or a dad with little children…what about my elderly mom who looks after my dad with dementia?"; and "maybe we should say any care-giving responsibilities, but then where do you draw the line?").

Similarly, while jurors agreed that whether or not an illness could be attributed to unhealthy behaviour was "good to know", they vigorously disagreed on how it should influence decisions. Some said, "from a non-compassionate perspective, it's self-inflicted, maybe that tells us how much they really value life". The 'slippery slope' argument was raised, with jurors stating that "we all do things that we know aren't good for us, like eating fast food…so does that mean we should all fall to the bottom of the priority list…where will it end?"; "smokers pay taxes like everyone else, and it is our taxes that pays for the healthcare system, so whether we smoke or not should not matter"; and "but what about when you have a person who has done everything right – exercised, eaten healthy foods, and then you have a person who smokes, drinks, you know, does all the bad stuff, shouldn't we help the person who tried to do everything right?". Active debate continued until jurors decided that it would be best to remove 'personal responsibility for illness' from the list of factors that should be considered.

When jurors revisited 'health outcome' in terms of length of life or increased survival, they reiterated that, by itself, this factor was of limited importance ("I'll take one year of good life over 10 years of misery any day of the week"; and "a few weeks is only worthwhile if you are well enough to enjoy them"). However, one juror suggested that "it would be hard to have a good quality of life if your prospects of survival are terrible – the two kind of go hand in hand".

Taking the top six factors, jurors deliberated over explicit levels/categories that might influence their choices and, thus, should be incorporated into each one. Their findings are presented in Table 4-3.

3. Distributive preferences around each factor/patient characteristic if "all else is equal"

For each factor and its newly created levels, jurors stated their distributive preferences.

• Number of patients who could benefit: There was a strong preference for funding technologies that could benefit many patients ("the needs of the many outweigh the needs of a few"; "got to affect the most people"; "when it is only a small percentage, the end result is too low"; and "there are lots of people you can help, rather than a few").

• Current health state: Jurors supported prioritizing technologies for treating 'worse off' patients, or those who were more severely ill ("we should be helping people who need treatment the most first"; "we have a moral responsibility to help the sickest"; "the severely ill should be given

priority - the rest of us can wait"; and "if you are mildly ill, I would have to say 'suck it up' - there are sicker people who are way, way worse off").

• Prognosis without the technology: Jurors expressed a preference for funding 'last chance' technologies that might benefit patients facing imminent death over those for patients who needed care, but less urgently ("I would always help patients who are gonna die in a couple of weeks otherwise"; "it's about that rule of rescue thing, we can't leave people stranded"; and "I think society would want us to help patients who only have a few weeks left first").

• Health outcome (improvement in quality of life): Jurors favoured funding treatments that could bring patients to at least sufficient functioning ("people who can get sufficient function can also be productive and that is important to society"; "functioning plays a big role in a population, in a society…and while full functioning would be the best, sufficient functioning is still okay - you can still contribute"; and "if they can't get sufficient function, I would put them on the ice floe"; "insufficient functioning… that is a clincher for me…we need to get some bang for our buck"; and "is there much point to funding something that will still leave patients unable to care for themselves…they're really not gonna be able to contribute to society or look after themselves").

• Age: In general, jurors supported funding technologies that could benefit younger patients over older ones ("at age 30, you still have your whole life ahead of you"; "I've already had a good life, I would give it up to help young people, like my grandchildren; "give the younger ones a

chance"; and "my mother is 84 years old – I don't wish to see her go, but if that were a choice she had to make, I can tell you right now, she would say: if that funding could go to my kids or somebody else's kids, put it there, and leave me out of the picture"). However, a suggestion that younger patients should be favoured because they can "contribute more to society" was intensely contested by several jurors ("I know some pretty useless 30 year olds and some pretty useful 60 year olds" and "in today's world, 60 year olds are contributing as much to society as are 30 year olds").

• Dependents: There was a preference for prioritizing patients with 'care-giving responsibilities', as long as this was broadly defined to capture those with young children, as well as those with adult dependents ("I think that kids need their parents, so I would support helping moms or dads over those who aren't [parents]"; "…but what makes parents important is the fact that they are needed by someone, which is no different when you are old and can no longer take care of yourself, you need someone then too"; "it should be about any care-giving responsibilities…I think society would support that"; and "let's just go for dependents, period, then").

During the jury's discussions, the concept of 'health gain' emerged. This was defined as the difference between 'current health state' and 'health outcome'. Jurors subsequently ranked the possible differences or transitions in health state from greatest (maximum health gain (HG)) to least (minimum health gain (HG)), in terms of amount.

Greatest amount	Transition/Difference	Abbreviation
↓	‘Severely ill’ to ‘full functioning’	HG = 5
↓	‘Severely ill’ to ‘sufficient functioning’ OR ‘moderately ill’ to ‘full functioning’	HG = 4
↓	‘Moderately ill’ to ‘sufficient functioning’	HG = 3
↓	‘Mildly ill’ to ‘full functioning’	HG = 2
Least amount	‘Severely ill’ to ‘insufficient functioning’ OR ‘Mildly ill’ to ‘sufficient functioning’	HG = 1

Findings from exercise 2 – identification of simple interactions between factors

Results of the first ‘ping pong’ exercise demonstrated that jurors’ preferences for severely ill patients were modified by health outcome. Specifically, jurors favoured treating more severely ill patients as long as they could be restored to sufficient functioning. When the final health state represented an improvement, but not a return to sufficient functioning, jurors chose the less severely ill patient group who, with treatment, could achieve sufficient functioning.

Findings from the second ‘ping pong’ exercise indicated that jurors’ preferences for those facing imminent death were also contingent upon health outcome. Once the final health outcome of patients with only weeks to live was reduced to insufficient functioning, they were no longer favoured by jurors. Instead, jurors chose the patient population who were not facing imminent death and, with treatment, could be returned to sufficient functioning.

Findings from exercise 3 – identification of complex interactions among factors

Jurors' preferences were further modified when 'number of patients who could benefit' and 'age' were considered alongside 'current health state' and 'health outcome'.

Using the following symbols, interactions among these four factors are described below: *number of patients who could benefit* (M: many, F: few); *age* (Y: young, O: old); *current health* (SI: severely ill, MoI: moderately ill, MiI: mildly ill); and *health outcome* (IF: insufficient functioning, SF: sufficient functioning, FF: full functioning). A unique patient population, defined by a set of characteristics/levels, is represented in square brackets (e.g., [M, O, MoI, SF]). A preference for a specific population is illustrated by a 'greater than' symbol (>).

In cases where a population could not achieve at least sufficient functioning with treatment, jurors consistently chose the other or competing group, even if that population was less ill ([F, O, MiI, SF] > [M, Y, SI, IF]; [F, Y, MoI, FF] > [M, O, SI, IF]; [M, Y, MiI, FF] > [F, O, SI, IF]; [F, O, SI, SF] > [M, Y, SI, IF]; [M, Y, MoI, SF] > [F, O, SI, IF]; [M, Y, SI, FF] > [F, O, SI, IF]). They also commented that "it is about what this [the technology] can do for people – the end result…that trumps severity".

When both populations could be brought to at least sufficient functioning and their current health state was the same, jurors favoured the larger population ([M, O, SI, FF] > [F, Y, SI, FF]; [M, O,

MoI, SF] > [F, Y, MoI, FF]; and [M, Y, MiI, FF] > [F, O, MiI, FF]). However, when the starting points differed, jurors' preferences changed. They favoured small populations over large populations under certain conditions of current health state and age. When presented with a severely ill, small population and a mildly ill, large population, jurors selected the small population, regardless of age ([F, O, SI, SF] > [M, Y, MiI, FF]; [F, Y, SI, SF] > [M, O, MiI, FF]). But, if that small population was severely ill and the large population was moderately ill, jurors only chose the small population when it was also young. A similar pattern was observed for moderately ill, small populations compared with mildly ill, large populations ([F, Y, MoI, SF] > [M, O, MiI, FF]; [M, Y, MiI, SF] > [F, O, MoI, SF]; [F, Y, SI, SF] > [M, O, MoI, FF]; [M, MoI, Y, FF] > [F, O, SI, SF]; and [M, Y, SI, SF] > [F, O, MiI, FF]). "For me, it's numbers first, but if the many aren't as bad to begin with and the few are in really terrible shape, I'd choose the few"; "Yeah, it's [number of patients] important but you also have to think about what you are, you know, prepared to give up – if these people [the few] are severely ill and can get up to as good a place as what the many are already at, I think we should go for them [the few]"; and "It depends on if they are old too, though. I mean, it would take more for me to change my mind on numbers and choose the few if they were also old".

Thus, jurors' preferences suggested the presence of interactions among all four factors. Importantly, jurors demonstrated internal consistency in their responses, selecting the 'dominant' population from the dominant choice set. Their responses were also shown to be reliable, with jurors selecting the same populations when presented with duplicate choice sets.

Findings from exercise 4 – identification of increasingly complex interactions among factors

The inclusion of 'prognosis without treatment' and 'care-giving responsibilities' was found to further modify jurors' preferences. Using the same symbols as above, but adding the following for *prognosis without treatment* (Weeks: imminent death, 2 yrs: 2 years, 5 yrs: 5 years); and *care-giving responsibilities* (YD: dependents, ND: no dependents), interactions among these factors are described below.

When asked to choose between patient populations where one was facing imminent death and both, with the technology, could achieve at least sufficient functioning, jurors consistently selected the population with only weeks to live in the absence of the technology, regardless of number ([F, Y, MiI, FF, weeks, YD] > [M, O, MoI, FF, 5yrs, ND]; [F, Y, SI, SF, weeks, ND] > [M, O, SI, FF, 2 yrs, YD]; [F, O, SI, FF, weeks, ND] > [M, Y, MiI, FF, 5 yrs, YD]; [M, Y, MiI, SF, weeks, ND] > [F, O, SI, FF, 2 yrs, YD]; [F, Y, SI, FF, weeks, YD] > [M, O, SI, SF, 5 yrs, YD]; [M, Y, MoI, FF, weeks, ND] > [F, O, MiI, SF, 5 yrs, ND]; [M, O, MoI, FF, weeks, YD] > [F, Y, MoI, SF, 2 yrs, ND]; [M, Y, SI, SF, weeks, ND] > [F, O, MoI, FF, 5 yrs, YD]; and [M, Y, SI, SF, weeks, ND] > [F, O, MiI, SF, 2 yrs, YD]).

In addition, jurors stated, "If the treatment will do something and give them some quality time with their family, I would support the ones who are gonna die in a couple of weeks if they don't get treated"; "I am definitely swayed by imminent death…I would go for them every time if the

treatment would do some good…you know, quality of life wise"; and "I think society would want us to help those who've got less time, but I don't think it would want us to if it meant wasting money that could have been used to benefit to another group in a bigger way". Their comments were consistent with responses to questions in which the patient population facing imminent death could improve a little with treatment, but not enough to achieve sufficient functioning. In both cases, jurors selected the other population, which wasn't facing imminent death and could be brought to sufficient functioning ([M, Y, SI, FF, 2 yrs, YD] > [F, O, SI, IF, weeks, ND] and [M, Y, MoI, FF, 2 yrs, ND] > [F, O, SI, IF, weeks, YD]).

Further, preferences appeared to depend on age. When the number of patients within each population was the same, jurors supported the older population facing imminent death only if it could receive at least the same health gain as the younger population ([M, O, SI, FF, weeks, ND] > [M, Y, MiI, SF, 2 yrs, YD]; [F, Y, MoI, FF, 2 yrs, YD] > [F, O, SI, SF, weeks, ND]).

When neither population was facing imminent death, jurors, once again, chose the one who could achieve sufficient functioning ([M, Y, MiI, FF, 5 yrs, YD] > [F, O, MoI, IF, 5 yrs, ND]; [M, O, SI, SF, 2 yrs, ND] > [F, Y, SI, IF, 5 yrs, YD]; [M, O, MoI, FF, 5 yrs, YD] > [FY, SI, IF, 2 yrs, ND]; [F, O, MoI, SF, 5 yrs, ND] > [M, Y, SI, IF, 2 yrs, YD]; and [M, Y, MoI, SF, 5 yrs, YD] > [F, O, SI, IF, 2 yrs, ND]).

Whether populations would live for two years or five years in the absence of treatment did not appear to matter to jurors. Specifically, when the number of years was switched between populations in choice sets, jurors' preferences did not change ([M, O, MoI, FF, 5 yrs, YD] > [F, Y, MoI, SF, 2 yrs, ND] switch: [M, O, MoI, FF, 2 yrs, YD] > [F, Y, MoI, SF, 5 yrs, ND]; and [F, Y, SI, SF, 2 yrs, ND] > [M, O, MiI, SF, 5 yrs, YD] switch: [F, Y, SI, SF, 5 yrs, ND] > [M, O, MiI, SF, 2 yrs, YD].

Once again, jurors generally chose to fund technologies that benefited many patients (large populations) over those for a few patients (small populations) ([M, O, SI, IF, 2 yrs, ND] > [F, Y, SI, IF, 5 yrs, YD]; [M, O, MoI, SF, 2 yrs, ND] > [F, Y, MoI, FF, 5 yrs, YD]; [M, Y, MiI, FF, 5 yrs, ND] > [F, O, SI, SF, 2 yrs, YD]; [M, Y, SI, FF, 2 yrs, YD] > [F, O, MiI, SF, 5 yrs, ND]; [M, O, MoI, IF, 2 yrs, ND] > [F, Y, SI, IF, 2 yrs,YD], and [M, O, SI, FF, 5 yrs, ND] > [F, Y, MoI, FF, 2 yrs, YD]). However, their preferences appeared to depend on 'age' and the difference in health gain achieved between populations. Specifically, jurors favoured younger, small populations over older, large populations if they could receive considerably more individual health gain than the large populations ([F, Y, MoI, FF, 5 yrs, YD, (HG = 4)] > [M, O, MiI, FF, 2 yrs, ND, (HG = 2)]; [F, Y, SI, SF, 2 yrs, YD, (HG = 4)] > [M, O, MiI, FF, 5 yrs, ND, (HG = 2)]). However, they preferred older, small populations over younger, large populations if the older population could receive the maximum amount of individual health gain attainable ([F, O, SI, FF, 5 yrs, ND, (HG = 5)] > [M, Y, MiI, FF, 2 yrs, YD, (HG = 1)] and [F, O, MoI, FF, 5 yrs, YD, (HG = 4)] > [M, Y, MiI, SF, 2 yrs, ND, (HG = 1)]).

During the exercise, it was noted that ‘dependents’ or ‘care-giving responsibilities’ were never mentioned in jurors’ rationales. Further, their choices did not suggest that it carried much weight ([M, Y, MiI, FF, 5 yrs, ND] > [F, O, MoI, SF, 2 yrs, YD] and [M, Y, SI, FF] > [F, O, MoI, SF]). Therefore, jurors were asked about the importance of ‘care-giving responsibilities’, and they replied, “I dunno – for me, it’s not that it’s not important, it’s just that it is too hard to know… I mean, you might not have kids now, but that doesn’t mean you won’t if you live long enough”; “we talked about this yesterday and I think it is one of those things that is a gray area, fuzzy, you know, when it comes right down to it”; “yeah, how would you ever get anyone to agree on what care-giving means – our group couldn’t even do that and there were only four of us”; “I still think care-giving responsibilities is important, [it is] just that all of these other ones are more important”; “me too, I would go on record saying that care-giving is really important, but I think that it is too hard to make a judgement on in something like this - you gotta appreciate people who look after animals, for example – do we really want to say that they are less important than people with children?; and “so we agree then to leave it out”.

Once again, jurors demonstrated internal consistency and reliability in their responses, selecting the ‘dominant’ population from the dominant choice set and the same populations when presented with duplicate choice sets.

Combining findings from exercises, the following preliminary social value statements were generated and verified by jurors:

- There is a preference for funding health technologies that could return patient populations to at least sufficient functioning, regardless of the characteristics of that patient population.

The remaining five statements assume that the technology can restore patient populations to at least sufficient functioning:

- If patient populations are otherwise the same, there is a preference for funding technologies that could benefit those who are the 'worst off' or most severely ill;

- In general, there is a preference for funding health technologies to patient populations who are facing imminent death;

- If the number of patients in each population is the same, there is a preference for funding health technologies that could benefit young populations, except when the older populations are facing imminent death and, with treatment, receive at least the same individual health gain as those in the young population; and

• There is a preference for funding health technologies that could benefit the greatest number of patients (i.e., large populations over small populations) regardless of age, unless the individual health gain achieved through funding health technologies for a smaller number of patients is considered substantial. The amount of health gain needed depends upon age. A larger amount is required for small, older populations than for small, younger populations.

DISCUSSION

To our knowledge, this study represents the first attempt to identify interactions among multiple factors/patient characteristics around which distributive preferences for health technologies are typically formed. Interactions emerged from decision simulation exercises designed to reflect the complexities involved in 'real life' resource allocation decision-making. Previous research has demonstrated that preferences change with additional information.[9] However, it has not attempted to explore how they change when such information represents the inclusion of more than two factors. In this study, interactions involving up to five factors were described. None related to any of the commonly cited rationing principles (including need, 'rule of rescue', 'fair innings', health maximization (utilitarianism), or lottery), suggesting that social values are significantly more complex than has been proposed to date. Nonetheless, preferences around individual factors considered in isolation were also examined, and trends consistent with those reported in relevant literature were observed. Lastly, jurors demonstrated competence through consistent responses to trade-off questions and logical flows of thought during sessions.

LIMITATIONS

The study had five main limitations. First, the views of the public were sought using hypothetical decision problems. Therefore, responses reflected stated as opposed to revealed preferences. Since the public is not currently involved in defining social values for healthcare resource allocation decision-making, it was not possible to compare the findings to those from actual experience. Second, the initial decision simulation exercise from which the list of factors/patient characteristics emerged focussed on cancer technologies. Although the remaining exercises referred to health technologies, in general, the extent to which preferences are generalizable beyond the cancer context is not known. Third, categories/levels within factors were selected by jurors. While they had been deemed relevant by 'witnesses' who comprised senior health executives and appeared consistent with previous studies, assessment of their applicability to real-world decisions with a broader group of decision-makers was beyond the scope of this paper. Fourth, a comprehensive examination of all possible combinations of factors/patient characteristics (well over 22,000) was infeasible. Preference statements and interactions observed were based on a small, randomly selected subset. Therefore, while the study was able to identify the presence of interactions, it could not fully elucidate the nature of those interactions. Fifth, the views of only 16 members of the public were obtained. Although every effort was made to select a broadly representative jury, it was not possible to determine whether their responses were generalizable to those of the whole population.

CONCLUSIONS

This study demonstrates that social values regarding the allocation of resources for new health technologies are complex. Thus, attempts to explicate a comprehensive set of social values need to involve approaches that accommodate consideration of various factors and the potential interactions among them.

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Table 4-1. List of technologies used in decision simulation exercise 1

Technology	Indication
Endobronchial ultrasound-guided transbronchial fine needle biopsy	Determining the spread of lung cancer to areas between the lungs
Bortezomib (proteasome inhibitor treatment)	Recurrent multiple myeloma
Laser therapy	Removal of fetal tumours
Brachytherapy (localized internal radiation)	Unresectable liver cancer
BRCA 1 and 2 genetic test	Screening for presence of genes linked to hereditary breast cancer
Cementoplasty (injection of acrylic bone cement)	Relief from pain and stabilization of bone with malignant cavities
Cryotherapy (use of liquid nitrogen to freeze and destroy cells)	Localized kidney cancer
Human papillomavirus vaccine	Protect boys and men from contracting and spreading genital HPV to female sexual partners
Chemotherapy wafer	Delivery of anticancer drugs directly into sites of removed glioma (type of brain tumour)
Gemtuzumab (monoclonal antibody treatment)	Relapsed acute myeloid leukemia in children

Table 4-2. Socio-demographic profile of the jury

Characteristic	Number of jurors (%)*
Gender	
Male	8 (50%)
Female	8 (50%)
Age	
18-24	2 (13%)
25-34	2 (13%)
35-44	2 (13%)
45-54	3 (19%)
55-64	3 (19%)
65-74	2 (13%)
> 74	2 (13%)
Education (highest level)	
< High school	1 (6%)
High school	5 (31%)
Post-secondary diploma	4 (25%)
Undergraduate degree	4 (25%)
Graduate degree	2 (13%)
Annual household income ($ Cdn, before taxes)	
< $25,000	3 (19%)
$25,000 - $45,000	4 (25%)
$46,000 - $70,000	3 (19%)
$71,000 - $100,000	3 (19%)
> $100,000	3 (19%)
Employment status	
Employed	12 (75%)
Unemployed	2 (13%)
Retired	2 (13%)
Ethnicity	
Asian	1 (6%)
Caucasian	13 (81%)
First Nations (Aboriginal)	2 (13%)
Geographic location	
Urban	12 (75%)
Rural	4 (25%)

* Percentages were rounded up to the nearest whole number; therefore, they do not always add to 100

Table 4-3. Summary of factors/patient characteristics and categories/levels around which distributive preferences were elicited

Factor/patient characteristic	Categories/levels	Description
1. Number of patients who could benefit	Many Few	N/A
2. Current health state	Severely ill	Unable to perform daily activities; in extreme pain or discomfort; depressed
	Moderately ill	Unable to perform some daily activities; in moderate pain or discomfort; mildly depressed
	Mildly ill	Occasionally unable to perform a few daily activities; in mild pain; not depressed
3. Prognosis without the technology	A few weeks 2 years 5 years	Life expectancy without treatment
4. Health outcome (with technology)	Full functioning	Health returns to normal (i.e., what it was before the illness)
	Sufficient functioning	Health does not return to normal, but patients are able to perform daily activities
	Insufficient functioning	Health improves, but does not return to normal and patients are not able to perform most daily activities
5. Age	Young	Average age: 20 to 30 years
	Old	Average age: 60 to 70 years
6. Dependents	Yes	Has care-giving responsibilities
	No	Does not have care-giving responsibilities

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APPENDIX 4-1

'Ping pong' exercise 1

Question 1. Imagine that there are the following 2 groups of patients:

Characteristics/factors	Population A	Population B
Current health state	Severely ill	Moderately ill
Prognosis without treatment	3 years	5 years
Health outcome with treatment	Sufficient functioning	Sufficient functioning

You only have enough resources to offer treatment to 1 of the 2 groups. Which group would you choose?

If the choice is A, proceed to Question 2. If the choice is B, stop here.

Question 2. Now imagine that Population A stays the same, but Population B, with treatment, may be restored to full functioning. You still only have enough resources to offer treatment to 1 of the 2 groups. Which group would you choose?

If the choice is still A, proceed to Question 3. If the choice is B, stop here.

Question 3. Imagine that Population A, with treatment, will improve but cannot be restored to sufficient functioning. However, Population B, with treatment, can be restored to full functioning. You still only have enough resources to offer treatment to 1 of the 2 groups. Which group would you choose?

APPENDIX 4-2

Format of questions presented in exercises 3 and 4

Imagine that you are a committee responsible for making coverage decisions on new health technologies for the province. You have received requests for 2 new health technologies. One will benefit patient population A and other will benefit patient population B. However, you have a fixed budget, and can only afford to fund 1 of the technologies. This means that you can only help 1 of the 2 patient populations. Which patient population would you choose?

Characteristics/factors	**Population A**	**Population B**
Current health state	Severely ill	Moderately ill
Prognosis without treatment	3 years	5 years
Average age	60 years old	30 years old
Health outcome with treatment	Sufficient functioning	Sufficient functioning

Please indicate your choice by placing a check mark in the appropriate box:

Population A ☐

Population B ☐

CHAPTER 5:
COMPARABILITY OF FINDINGS FROM TWO CITIZENS' JURIES ON SOCIAL VALUES FOR THE ALLOCATION OF HEALTH TECHNOLOGIES: A TALE OF TWO CITIES

ABSTRACT

Introduction:

It has been argued that public input on social values for informing resource allocation decision-making in healthcare should come from an 'informed citizenry', who has had the opportunity to weigh information, discuss and debate potential options, and arrive at mutually agreed upon decisions. Consequently, citizens' juries, which combine an information component with deliberative discussions, has received considerable interest from decision-makers. Despite positive feedback on juries held to date, the lack of information regarding comparability across samples of participants (i.e., would a different set of jurors arrive at the same answers?) has precluded more widespread uptake by decision-makers.

Objectives:

To assess the comparability of findings from two citizens' juries on social values regarding resource allocation decision-making for new health technologies.

Methods:

Two citizens' juries were held using the same methods but involving different, broadly representative samples of the public. Results of exercises designed to simulate 'real life' decision-making were compared across juries using the Kappa

Statistic. In addition, jury deliberations were analysed through qualitative approaches.

Results:

'Excellent agreement' in responses to choice-based questions between juries was observed. In addition, both juries compiled identical lists of factors/patient characteristics they had considered during decision-making, although their ranking of importance was slightly different. Lastly, during the deliberations, similar issues and arguments were raised.

Conclusions:

The findings from this study suggest that different citizens' juries held on a common, complex healthcare topic, such as resource allocation decision-making for new health technologies, yield comparable results.

INTRODUCTION

Over the past decade, efforts to explicate distributive preferences of the public for the allocation of health resources across the population (i.e., social values) have taken a number of forms, including surveys, interviews, focus groups, public meetings, and deliberative discussions.[1] The first three forms comprise the most commonly used approaches. These typically seek opinions based on an immediate or spontaneous response (often referred to as an "uninformed view"). Public meetings, while offering any individual the opportunity to voice his/her views, have been shown to be vulnerable to domination by special interest groups.[2] Deliberative techniques involve multi-way interactions among participants and 'experts' (who represent differing perspectives), facilitating a dialogue that captures diverse perspectives before the views of participants are elicited. Evaluations of these approaches in the context of system-level resource allocation decision-making suggest that, in general, citizens are keen to contribute to decisions, but often feel ill-equipped to do so unless relevant information is provided.[3-5] In addition, they emphasize the importance of approaches that encourage direct engagement between decision-makers and citizens.

Decisions about which new health technologies to fund, and for whom, are indisputably complex, as well as value-laden.[6,7] It has, therefore, been argued that public input to support such decisions should come from an 'informed citizenry' who has had the opportunity to weigh information, discuss and debate potential options, and arrive at mutually agreed upon decisions or at least ones by which

people can abide.[2,8-11] Consequently, citizens' juries, a method which combines an information component with deliberative discussions, has received considerable interest from decision-makers.[1,10,12] Citizens' juries typically involve 12 to 16 individuals who are selected to be broadly representative of their community. Charged with addressing one or more complex questions, they meet over a two to four day period, during which they learn about a relevant issue, hear from expert 'witnesses' who represent a broad range of perspectives, engage in deliberations among themselves, and come up with a common ground answer.[8] Despite positive feedback on juries held to date, the lack of information regarding comparability across samples of participants (i.e., would a different set of jurors arrive at the same answers?) has precluded a more widespread uptake by decision-makers.[10,13-15]

OBJECTIVES

The purpose of this project was to assess the comparability of findings from two citizens' juries on social values regarding resource allocation decision-making for new health technologies.

METHODS

Two 2 ½ day-long citizens' juries to elicit distributive preferences of the public for new health technologies across populations were held in Alberta, one in each of the two largest cities, Edmonton (the Northern Alberta (NA) Citizens' Jury) and Calgary (the Southern Alberta (SA) Citizens' Jury).

Assembly of the two juries

Through the following process, 16 residents of Northern Alberta (north of Red Deer) and 16 residents of Southern Alberta (south of Red Deer) were recruited to comprise two broadly representative juries. Red Deer was used to divide Alberta into two main regions for the study, since the population north and south of Red Deer is approximately the same (the total population of the province is 3.64 million).

1. Assembly of jury pools

A total of 2,800 personalized information letters and consent forms were mailed to a stratified random sample of residents of Alberta (1,400 from north of Red Deer and 1,400 from south of Red Deer). Names and addresses were extracted from a commercially prepared database of registered telephone numbers (land lines) using a random numbers generator (Survey Sampling International®). Information letters invited recipients to participate in a telephone screening survey to assess their eligibility for the jury (discussed in the next section), and collect the socio-demographic data needed to construct a broadly representative sample. Sample size for each jury was based upon published response rates from previous juries, ranging from 2% to 40%.[16,17] Since it has been estimated that approximately 10% of residents, primarily between the ages of 18 and 34 years, use exclusively cellular/mobile phones (i.e., would not have registered land lines), 200 randomly selected cellular phone numbers (100 registered to locations north

of Red Deer and 100 registered to locations south of Red Deer) were also contacted (Survey Sampling International®). For both juries, calls were conducted by the same two researchers, who used a pre-tested script to briefly describe the study and ask respondents if they would be interested in receiving a copy of the information letter for their further consideration. Up to three attempts were made to contact each respondent.

All respondents (from the initial mail-out and cell phone calls) who wished to be considered for the jury were asked to complete and return the enclosed consent forms within two weeks of the postage date using the pre-paid self-addressed envelopes provided. To reduce the potential for volunteer bias, participants in the two juries were offered a $400 honorarium for the full two and a half days. In addition, travel, accommodations, meals, and childcare expenses were reimbursed.

2. Selection of jurors

For both juries, telephone screening surveys were conducted with consenting respondents by four researchers/interviewers. To minimize interviewer bias, a pre-tested interview guide was used, and each interviewer was assigned a randomly selected subset of names from both regions of the province. Since the purpose of both juries was to elicit the views of 'ordinary citizens' (i.e., individuals whose voices might not otherwise be heard), survey questions were designed to gather information on potential affiliations with health-related special interest groups

and/or employment as a healthcare professional in government or healthcare delivery organization (exclusion criteria), as well as socio-demographic data (age, gender, ethnicity, education, household income (before taxes), and employment status). Based on the information collected, two groups of 16 potential jurors (one for the NA jury and one for the SA jury) were selected to roughly match the socio-demographic profile of Alberta, according to census data from Statistics Canada. This was accomplished using a combination of purposive and stratified random sampling, in which respondents were grouped by age, gender, and ethnicity, and then further stratified by education and household income. In cases where several respondents represented the same set of characteristics, random sampling (random numbers table) was used.

Organization and conduct of the two citizens' juries

1. Organization of the juries

Two citizens' juries were planned and held - one in Edmonton (NA jury), and one in Calgary (SA jury). A single advisory committee, created to support both juries, ensured 'witness' presentations and decision simulation exercises captured the full spectrum of issues and perspectives considered during actual health technology funding decision-making. A 'case study' approach structured around new cancer technologies was used to initiate discussions in both juries. Cancer technologies were chosen because, collectively, they span the entire care pathway (from prevention, screening, and curative treatments to palliative care). Thus, they facilitate trade-off discussions around a range of potential benefits. Also, much of

the recent public criticism over access to quality healthcare in Canada has been related to cancer technologies.[6,18] The advisory committee consisted of two senior health executives within Alberta, a practicing oncologist, and a researcher with methodological expertise in citizens' juries.

Importantly, both juries involved the same witnesses, presentations, and four decision simulation exercises. The five witnesses included three decision-makers (each representing a different level of healthcare decision-making in Alberta), a physician (oncologist), and a patient representative. To control for possible environmental influences, juries were held in similar hotels using identical room arrangements. They were also scheduled as close together as possible (one week apart) in an effort to ensure they would take place in the same political climate.

2. Conduct of the two juries

Facilitated by the same two researchers, both of whom had previous experience conducting citizens' juries, the two juries were carried out as follows.

Day 1 (half day)

The first evening of both juries included 'ice-breaker' sessions involving jurors, witnesses and facilitators, and introductory presentations by facilitators on the need to make value-laden resource allocation decisions in healthcare and the use of citizens' juries as a means of eliciting the views of the public.

Day 2 (full day)

The second day of both juries began with "a day in the life" presentations by 'witnesses'. 'Witnesses' used the same presentation materials each time, and were encouraged to apply, to the extent possible, the same language or phrasing, and examples. The presentations were intended to inform jurors of current coverage/funding decision-making processes and their impact on patients and providers. After each presentation, jurors had an opportunity to ask questions to 'witnesses'. In both juries, a panel discussion involving the same technology scenario decision problem followed. Its purpose was to offer jurors a starting point for their own deliberations, as well as illustrate how views on the relative value of technologies can vary with stakeholder perspective. 'Witnesses' were given five cancer technologies and asked to indicate what factors or characteristics of respective patient populations they would consider when deciding which of the five technologies to fund if there were only enough resources to provide one. Technologies represented recent funding requests in the province. The level of information presented for each technology was designed to reflect that typically contained in a ministerial briefing note. Once again, 'witnesses' were encouraged to ensure points raised or arguments made were consistent across the two jury sessions. The panel discussion was followed by the first decision simulation exercise.

Decision simulation exercise 1: Identification of factors/patient characteristics

In both juries, jurors were assigned to one of three small groups (balanced with respect to age, gender, and educational level) and given a set of 10 cancer technologies, from which they could only choose five to fund (Table 5-1). As above, cancer technologies consisted of 'real life' issues, and were selected to encompass a wide range of factors/patient characteristics around which distributive preferences of the public have been sought.[1] Descriptions presented for each one were, once again, limited to that found in briefing notes. In both juries, groups were facilitated by the same researchers, who clarified the choice task and ensured active participation by all group members. Each group recorded the five technologies it had selected to fund, along with their rationales. Groups then reconvened to compare choices, discuss factors/patient characteristics they had considered, and compile a ranked list of those factors in order of importance. They also discussed and agreed to categories/levels within factors which influenced their choices. Lastly, jurors indicated their distributive preferences for individual factors.

Decision simulation exercise 2 – Identification of simple interactions between factors

In both juries, the second decision simulation exercise involved a 'ping pong' exercise designed to demonstrate the extent to which distributive preferences around a factor may be modified in the presence of an additional factor (Appendix 5-1). Jurors were first asked to select one of two technologies to fund, each of which benefitted a unique patient population. The patient population differed on

two characteristics ('current health state/ severity of illness' and 'prognosis without the technology'), but with the technology, could each be returned to 'sufficient functioning'. Depending upon which 'population' jurors favoured, characteristics of the two populations were varied and the question re-asked until a 'switching point' (i.e., the circumstances under which the opportunity costs of continuing to favour a particular patient population were considered too great) was reached.

For the exercise, jurors were asked to assume the role of a provincial health technology funding decision-making committee, and come to a consensus on a collective decision before moving on to the next question.

Day 3 (full day)

For both juries, the third day started with a panel discussion in which roles were reversed and 'witnesses' asked jurors to 'defend' their decisions on technologies for which they had 'denied' funding the previous day. The same types of hypothetical scenarios were used for each jury. These included a newspaper article about a patient denied a "last chance therapy", a letter to the Board chair of the provincial healthcare delivery organization from a patient, and a letter to the Premier from a prominent local physician. The purpose of the session was to reiterate the implications of "no" decisions and the level of scrutiny that such decisions attract from different stakeholder groups. At the end of the discussion,

jurors were given the opportunity to revise their decisions in light of the arguments presented.

Decision simulation exercise 3 – Identification of complex interactions among factors

Building on the previous day's exercises, the third exercise elicited distributive preferences based on simultaneous consideration of multiple factors/patient characteristics. A set of 16 choice-based questions consisting of pair-wise comparisons between unique patient populations was constructed (Appendix 5-2). 'Unique' patient populations (choice scenarios) comprised different combinations of categories/levels of the four factors/patient characteristics ranked as the four most important by jurors the previous day. They were generated using SPSS Orthoplan, which creates scenarios and pair-wise comparisons to obtain the maximum amount of information through the fewest possible comparisons. Comparisons were checked for plausibility and 'level balance'. In addition, three duplicate comparisons were included, as well as a dominant scenario (in which all of the levels/categories in one population were preferred over those in the other) in order to assess reliability and internal consistency of jurors' responses, respectively.[19] Jurors broke into the same three small groups to answer the 20 questions (same set used for both juries). For each question, a vote was taken on the technology (or patient population) they would choose to fund. Each small group was then asked to arrive at a collective decision, after which they reconvened to compare decisions and rationales.

Decision simulation exercise 4 – Identification of increasingly complex interactions among factors

Like the third exercise, the fourth exercise involved a series of choice-based questions in which jurors were asked to choose between two technologies for two different patient populations. Questions were generated through the same approach. However, in contrast to the third exercise, 'unique' patient populations included six factors (jurors' top six), and questions were answered by the jury, as a whole, rather than by small groups. Factors were limited to six in order to ensure reasonable cognitive burden.[20] A total of 36 questions were presented, including three duplicates and one dominant scenario. Once again, jurors first voted for the technology they would support before deliberating amongst themselves to reach a consensus.

Jury sessions concluded with a presentation of basic preference statements, which were noted as they emerged during the sessions.

3. Comparative analysis of the two jury sessions

Both juries were digitally recorded and transcribed. In addition, notes were taken by four researchers, who attended the full two sessions. Transcripts were analysed by jury activity using content analytic and constant comparison techniques.[21,22] Data (chunks of information) were sorted, arranged, and coded using qualitative data management software (NVivo®). Responses to choice-based questions were

also analysed qualitatively, noting patterns or trends within and across factors. Responses and transcripts from both juries were analysed independently by the same two researchers. To assess observer bias, a third researcher analysed transcripts from a randomly selected exercise in each of the jury sessions.

In addition to qualitative analyses, the following quantitative methods were used to compare results from the two juries by exercise:

Socio-demographic profile of the juries

Differences in response rates between the two juries were assessed using Pearson's Chi-Square Test.[23,24] Given the small sample sizes of the actual juries, Fisher's Exact Tests were used to detect statistically significant differences in age, gender, ethnicity, education level, household income (before taxes), employment status, and geographic location of residence (all categorical variables) between the two juries.[23]

Decision simulation exercise 1: Identification of factors/patient characteristics

Differences between the ranked lists of factors/patient characteristics compiled by each of the juries were qualitatively compared. Since each jury represented a single 'data point', application of a statistic test to assess the significance of any differences was not feasible.

Decision simulation exercises 2, 3, and 4

Since choice-based questions in exercises 2, 3, and 4 were binary, concordance in responses between juries was assessed using Cohen's Kappa statistic.[25] Kappa measures the degree of agreement between 'raters' (i.e., juries) beyond that due to chance alone.

The study received ethics approval from the University of Alberta Health Research Ethics Board.

RESULTS

No statistically significant difference in the number of responses received between the two juries were found (NA Jury: 684 vs. SA Jury: 701 (p-value = 0.56)).

Comparability of socio-demographic profiles of the two juries

Socio-demographic characteristics of the 16 individuals who comprised each jury are presented in Table 5-2. Slight variations in the distribution of age, education, and household income between juries were found, but none achieved statistical significance (all p-values > 0.5).

Comparability of findings from exercise 1

1. Selection of technologies

Four of the five cancer technologies selected for funding were identical between juries. Both juries chose: 1) endobronchial ultrasound-guided transbronchial fine needle biopsy; 2) a genetic test for hereditary breast cancer; 3) cryotherapy for localized kidney cancer; and 4) cementoplasty for bone pain. The rationale for choices were similar across juries, with both expressing a desire to fund technologies that represented a wide range of types of interventions (e.g., screening or prevention, diagnosis, treatment, and supportive care) (NA jury: "we wanted to make sure we spread the funding over many different types of technologies and people"; SA jury: "we thought it would be a good idea to invest in a bit of everything – like, you know, prevention and treatment").

Both juries spent considerable time deliberating over their fifth choices. While their deliberations covered similar issues and arguments, the juries arrived at different decisions. For example, both juries felt that the HPV vaccine could benefit a large number of individuals (NA jury: "Of the ones left, this one [the HPV vaccine] could probably help the greatest number of individuals…so the money would be going the furthest"; SA jury: "Well, the HPV vaccine has the biggest group in terms of numbers when you consider all boys in Alberta"). They also raised points related to 'lifestyle' choices as risk factors for certain cancers, such as liver cancer. In both juries, this topic led to an active, lengthy debate among jurors. Some argued that funding priorities should focus on patient populations whose "unhealthy behaviours" had not contributed to their health state (NA jury: "You know, if you go out drinking every night, smoke a pack a

day, you should know better, and you should have to accept the consequences - like 'sorry, there are other people who got sick through no fault of their own, so they are ahead of you' "; SA jury: "While we don't know what causes a lot of cancer, we do know what causes some, like liver cancer. When there is a shortage of funds, we need to be wise about our money, and people who live that way may not take care of themselves after we help them, so that would mean we wasted money that we could have used to help somebody else"). Others presented the 'slippery slope' argument, consistently raising the example of obesity (NA jury: "How do we know that drinking or smoking was the cause - maybe they were obese? I mean, can we really say that because you did those things you got cancer and it is your fault? The fact is, [we] really don't know - there is no magical test. Maybe it is about obesity, in which case, we wouldn't bother treating 50% of the population. I don't think we really want to go there"; SA jury: "This opens up a whole new can of worms… what about obesity then? Should we be weighing people and saying to them, 'forget it, you are too fat, we aren't treating you'…wow, I wouldn't want to live in a society like that").

Both juries also discussed the issue of entitlement to healthcare as taxpayers (NA jury: "I pay taxes on the cigarettes I smoke and on my paycheque…that should more than pay for any healthcare I might need down the road"; SA jury: "We all pay taxes, whether we smoke or don't smoke, eat right or don't eat right…so the healthcare system, which we pay for through our taxes, shouldn't discriminate against people either"). In the end, the NA jury chose to fund the HPV vaccine for

boys, reiterating the importance of funding technologies that they felt benefitted the greatest number of individuals. In contrast, the SA jury selected brachytherapy for unresectable liver cancer, citing severity of illness and the lack of "good" alternative treatments as the main reasons.

2. Identification of factors/patient characteristics

Using rationales for their decisions on the five technologies to fund, both juries compiled similar lists of factors or characteristics of patient populations they thought influenced their choices. The list included: 1) number of patients who could benefit (NA jury: "What kind of numbers are we talking about – a few patients or a lot?"; SA jury: "How many people could be helped?"); 2) current health state (severity of illness) (NA jury: "How sick are they now?"; SA jury: "What is their current health like…are they [patients] already suffering?"); 3) prognosis without treatment (NA jury: "What happens if we don't act now?"; SA jury: "How long do they [patients] have?", 4) health outcome – quality of life (NA jury: "How does the technology help with giving patients some quality of life - you know, some dignity?"; SA jury: "Will patients be able to do, like, daily activities - like take care of themselves, or enjoy their families?"); 5) age (NA jury: "How old are they [patients]?"; SA jury: "Have they already had a long life?"); 6) dependents (care-giving responsibilities) (NA jury: "Would they [patients] probably have kids or people who they needed to take of?"; SA jury: "Would there likely be a young family left behind?"); 7) personal responsibility for illness (NA jury: "Could bad choices have contributed to them getting sick?";

SA jury: “What about lifestyle – what role did that play?”); and 8) health outcomes – length of life (NA jury: “Would it extend life and for how long?”; SA jury: “How much more time would it buy them?”). Juries ranked the eight factors from most important to least important, producing two lists in which the top two and bottom two were identical across juries. Of the remaining four, the second and third ranked factors in one list were exactly flipped in the other, as were the fifth and sixth-ranked factors.

3. Distributive preferences around individual factors

Juries exhibited similar distributive preferences around individual factors (i.e., when other characteristics of competing patient populations were assumed to be the same), based on the categories/levels presented in Table 5-4.

• Number of patients who could benefit: In both juries, there was a preference for funding technologies that could benefit the greatest number of patients (NA jury: “it’s gotta be about numbers – and more over few”; SA jury: “we should be funding stuff that would help the most people”).

• Current health state: Jurors supported funding technologies intended for patients who were considered the ‘worst off’ over those for less severely ill patients (NA jury: “the sickest first – case closed”; SA jury: “we are obliged to help those who are the most severely ill before others”).

• Prognosis without treatment: Both juries stated a preference for funding technologies that represented ‘last chance’ treatments for patients facing imminent death in their absence (NA jury: “They [patients] may be ‘toast’ anyway, even with treatment, but they deserve that chance”; SA: “I don’t think I could sleep at night if I didn’t give them [patients] that opportunity if they wanted it. I know my mother needed to be able to say that she gave it her all”).

• Health outcome – quality of life: Both juries favoured technologies that could bring patients the greatest amount of gain in quality of life. Further, they reiterated their position that extending life without quality was unacceptable (NA jury: “Life without quality is no life”; SA jury: “There is no point to mere existence. If we can ease pain and suffering, then I am all for it, but if not, then we shouldn’t fund it”).

• Age: Both juries took a ‘fair innings’ position, favouring technologies for younger patients over those for older populations (NA jury: “I’ve had my kick at the can. Some young person just starting out ought to have that same chance”; SA jury: “It just seems only fair…I don’t like it ‘cause I’m in my 60s, but [it] seems like the right thing”).

• Care-giving responsibilities: Both juries supported prioritizing patients with dependents, as long as the term was broadly defined to capture more than ‘parents with small children (NA jury: “We should treat anyone who cares for someone the

same way"; SA jury: "Should it matter whether it's a kid or a husband with dementia – don't think so").

• Personal responsibility for illness: Following a second debate consistent with that described above, both juries concluded that the extent to which patients may have contributed to the onset of their illness should not be considered when making health technology funding decisions.

• Health outcome – length of life: There was a preference for technologies that could increase survival to the greatest extent possible. However, both juries placed a 'quality of life' caveat on that preference, as mentioned above.

Comparability of findings from exercise 2

Kappa scores for questions comprising the 2 'ping pong' exercises were 1.0, indicating perfect agreement between juries (see Appendix 5-3). Preferences for severely ill patients were modified by 'health outcome'. Both juries favoured 'worse off' patients as long as with treatment, they could achieve at least 'sufficient functioning' (Table 5-4). However, when the gain was reduced to an improvement, but not a return to sufficient functioning, jurors 'switched' their preferences to the less ill group, who could realize sufficient functioning with treatment. A similar pattern was observed when jurors were asked to consider 'prognosis without treatment' alongside 'current health state' and 'health outcome' (Appendix 5-3). Jurors appeared willing to sacrifice 'helping' the most severely ill patients who may not be facing imminent death for less severely ill

patients facing imminent death, only if the latter group could be returned to sufficient functioning. Since some cancers carry few symptoms and progress quickly, this scenario was deemed plausible.

Comparability of findings from exercise 3

Both juries selected the same patient populations to 'help' in all 16 choice-based questions, yielding a Kappa score of 1.0. In addition, they demonstrated internal consistency and reliability in their responses, choosing the dominant scenario and identical populations in duplicate questions.

Based on qualitative, comparative analyses of responses to the 16 choice-based questions, which involved simultaneous consideration of 'number of patients who could benefit', 'current health state', 'health outcome', and 'age', jurors' preferences for the most severely ill patients were, again, modified.

There were no circumstances under which jurors demonstrated a willingness to 'trade off' patient populations who could achieve sufficient functioning for those who could not, even with treatment. When both patient populations could be restored to at least sufficient functioning and their starting points were the same, jurors consistently favoured the larger group, maximizing the number of patients who could receive benefit. However, when their current health state differed, jurors' preferences depended upon the difference in starting points between the two populations and, to a certain extent, age. Small, severely ill populations were

preferred to large, mildly ill populations, regardless of age. However, if the large population was moderately ill instead, jurors no longer favoured the small population unless it was also young. The same pattern was noted when the mildly ill, large populations were competing with small, moderately ill populations.

Comparability of findings from exercise 4

Of responses to the 32 discrete questions that comprised the fourth exercise, all but one were identical between juries (K = 0.934; Confidence Interval: 0.809 – 1.059) (Appendix 5-3). Again, both juries demonstrated internal consistency and reliability in their responses, choosing the dominant scenario and identical populations in duplicate questions.

From the 31 identical responses, the following preferences emerged:

Jurors favoured patient populations facing imminent death, regardless of number, as long as they could be brought to sufficient functioning. However, their preferences appeared to depend on age. When the number of patients in each population was the same, both juries chose the older population facing imminent death only if it could receive at least the same health gain (the difference between current health state and final health outcome) as the younger population.

When neither population was facing imminent death, the preferences varied with ‘number of patients who could benefit’, ‘age’ and differences in health gain

between the two populations. Both juries favoured younger, small populations over older, large populations if they could receive considerably more individual health gain than the large populations. However, juries preferred older, small populations over younger, large populations if the older population could achieve the maximum amount of individual health gain attainable (e.g., move from 'severely ill' to 'full functioning').

Regarding 'care-giving responsibilities', both juries decided to "remove it from the equation" (SA juror), but they did so at different points in the exercise. In the SA jury, jurors, themselves, raised the challenge of operationalizing this factor, a point to which they had first eluded in the previous day's discussions. Jurors indicated that the definition would need to be broad enough to capture the full spectrum of care-giving roles and, as a result, likely lose its ability to distinguish between populations ("Most people are in some ways care-givers, so there isn't much point to it"). In the NA jury, facilitators noted that 'care-giving responsibilities' were never mentioned in jurors' rationales for choices. When they were asked about its importance, they presented similar arguments to those of the SA jury, stating that "…care-giving is really important, but I think that it is too hard to make a judgement on something like this".

The single question around which responses from the two juries differed related to two populations of whom neither could be returned to sufficient functioning. One population was large, older, and moderately ill, while the other was small,

younger, and severely ill. In the SA jury, the small population was selected ("They [patients] are sicker, younger, and would get more gain out of it 'cause it would take more to get them to the same point, even if it still is insufficient functioning"). In contrast, the NA jury chose the large, older population, optimizing a perceived aggregate gain in quality of life ("If you add it all up, we'd be getting more total quality out of helping the older group, since there are more of them"). Because the 32 questions only included one in which both populations could not achieve sufficient functioning, a comparative analysis with other such questions was not possible. However, based on the vote counts for this question (taken before jurors came to a collective decision), both juries initially appeared somewhat divided on their choices (SA jury: 9 to 7 for the small, young population; NA jury: 8 to 8). For all of the other questions, at least 80% of the votes were for the population the jurors chose to fund in the end.

DISCUSSION

To our knowledge, this project represents the first attempt to assess the comparability of findings from two juries carried out in the same way, but with different representative samples of the public, on a healthcare topic. Responses to questions were similar across juries, suggesting that it may not be necessary to organize multiple juries to elicit 'informed' views of the public on healthcare resource-allocation decision-making, particularly around new cancer technologies. The high degree of agreement observed may be explained by the fact that immediate or spontaneous responses were not solicited. Instead, jurors

listened to a common set of information and deliberated amongst themselves before arriving at a collective view. Also, the structure of the questions may have influenced concordance. Specifically, almost one third of the questions comprised choice sets (pair-wise comparisons of populations) that included one population who, with treatment, could not achieve sufficient functioning. Given both juries' strong preferences for populations who could be brought to at least sufficient functioning, some questions may have represented simple decisions (i.e., "no-brainers" (SA juror)). Although both juries indicated that the levels/categories within each factor captured the key distinctions between patient populations, which could influence their preferences, such levels/categories may have still been too broad to facilitate careful consideration of populations at the margin. For example, many high cost cancer technologies would likely fall into the 'improves a little but does not restore patients to sufficient functioning' category. Thus, to elicit distributive preferences of the public involving trade-offs among populations for whom the gains are small, the addition of more refined levels for 'health outcome' would be required. Lastly, beyond the first exercise, trade-offs in 'future health gain' acquired through preventive interventions were not considered by jurors. Although neither jury identified 'future health gain' in their list of factors, both included preventive/screening technologies in their selection of five technologies for funding. As a result, an assessment of the comparability of responses to questions that force such trade-offs was not possible.

CONCLUSIONS

Findings from this study suggest that different citizens' juries held on a common, complex healthcare topic, such as resource allocation decision-making for new health technologies, appear to yield comparable results. However, future research examining immediate, small health gains and future health gains is needed to not only obtain a comprehensive understanding of social values, but also assess whether comparability of findings from citizens' juries varies with the type of gains around which distributive preferences are elicited.

A version of this chapter has been submitted for publication. Stafinski 2010. British Medical Journal

Table 5-1. List of technologies used in decision simulation exercise 1

Technology	Indication
Endobronchial ultrasound-guided transbronchial fine needle biopsy	Determining the spread of lung cancer to areas between the lungs
Bortezomib (proteasome inhibitor treatment)	Recurrent multiple myeloma
Laser therapy	Removal of fetal tumours
Brachytherapy (localized internal radiation)	Unresectable liver cancer
BRCA 1 and 2 genetic test	Screening for presence of genes linked to hereditary breast cancer
Cementoplasty (injection of acrylic bone cement)	Relief from pain and stabilization of bone with malignant cavities
Cryotherapy (use of liquid nitrogen to freeze and destroy cells)	Localized kidney cancer
Human papillomavirus vaccine	Protect boys and men from catching and spreading genital HPV to female sexual partners
Chemotherapy wafer	Delivery of anticancer drugs directly into sites of removed glioma (type of brain tumour)
Gemtuzumab (monoclonal antibody treatment)	Relapsed acute myeloid leukemia in children

Table 5-2. Comparison of socio-demographic profiles of the 2 juries

Characteristic	Number of jurors (%)* Southern Alberta Jury	Northern Alberta Jury	P value*
Gender			
Male	8 (50%)	8 (50%)	0.64
Female	8 (50%)	8 (50%)	
Age			
18-24	2 (13%)	2 (13%)	
25-34	2 (13%)	2 (13%)	
35-44	2 (13%)	2 (13%)	
45-54	4 (26%)	3 (19%)	1.00
55-64	3 (19%)	3 (19%)	
65-74	2 (13%)	2 (13%)	
> 74	1 (6%)	2 (13%)	
Education (highest level)			
< High school	1 (6%)	1 (6%)	
High school	4 (25%)	5 (31%)	
Post-secondary diploma	4 (25%)	4 (25%)	1.00
Undergraduate degree	4 (25%)	4 (25%)	
Graduate degree	3 (19%)	2 (13%)	
Annual household income ($ Cdn, before taxes)			
< $25,000	2 (13%)	3 (19%)	
$25,000 - $45,000	4 (25%)	4 (25%)	1.00
$46,000 - $70,000	3 (19%)	3 (19%)	
$71,000 - $100,000	4 (25%)	3 (19%)	
> $100,000	3 (19%)	3 (19%)	
Employment status			
Employed	12 (75%)	12 (75%)	
Unemployed	2 (13%)	2 (13%)	1.00
Retired	2 (13%)	2 (13%)	
Ethnicity			
Asian	2 (13%)	1 (6%)	
Caucasian	13 (81%)	13 (81%)	0.60
First Nations (Aboriginal)	1 (6%)	2 (13%)	
Geographic location			
Urban	12 (75%)	12 (75%)	0.66
Rural	4 (25%)	4 (25%)	

*Statistical significance based on Fisher's Exact Test

Table 5-3. Comparison of rankings of factors/patient characteristics between juries

Factor/patient characteristic	Rank (from most to least important)	
	Southern Alberta Jury	Northern Alberta Jury
1. Number of patients who could benefit	1	1
2. Current health state	2	2
3. Prognosis without the technology	4	3
4. Health outcome – quality of life	3	4
5. Age	5	5
6. Dependents	7	6
7. Personal responsibility for illness	6	7
8. Health outcomes – length of life	8	8

Table 5-4. Summary of factors/patient characteristics and categories/levels around which distributive preferences were elicited

Factor/patient characteristic	Categories/levels	Description
1. Number of patients who could benefit	Many Few	N/A
2. Current health state	Severely ill	Unable to perform daily activities; in extreme pain or discomfort; depressed
	Moderately ill	Unable to perform some daily activities; in moderate pain or discomfort; mildly depressed
	Mildly ill	Occasionally unable to perform a few daily activities; in mild pain; not depressed
3. Prognosis without the technology	A few weeks 2 years 5 years	Life expectancy without treatment
4. Health outcome (with technology)	Full functioning	Health returns to normal (i.e., what it was before the illness)
	Sufficient functioning	Health does not return to normal, but patients are able to perform daily activities
	Insufficient functioning	Health improves, but does not return to normal and patients are not able to perform most daily activities
5. Age	Young	Average age: 20 to 30 years
	Old	Average age: 60 to 70 years
6. Dependents	Yes	Has care-giving responsibilities
	No	Does not have care-giving responsibilities

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APPENDIX 5-1

'Ping pong' exercise 1

Question 1. Imagine that there are the following 2 groups of patients:

Characteristics/factors	Population A	Population B
Current health state	Severely ill	Moderately ill
Prognosis without treatment	3 years	5 years
Health outcome with treatment	Sufficient functioning	Sufficient functioning

You only have enough resources to offer treatment to 1 of the 2 groups. Which group would you choose?

If the choice is A, proceed to Question 2. If the choice is B, stop here.

Question 2. Now imagine that Population A stays the same, but Population B, with treatment, may be restored to full functioning. You still only have enough resources to offer treatment to 1 of the 2 groups. Which group would you choose?

If the choice is still A, proceed to Question 3. If the choice is B, stop here.

Question 3. Imagine that Population A, with treatment, will improve but cannot be restored to sufficient functioning. However, Population B, with treatment, can be restored to full functioning. You still only have enough resources to offer treatment to 1 of the 2 groups. Which group would you choose?

APPENDIX 5-2

Format of questions presented in exercises 3 and 4

Imagine that you are a committee responsible for making coverage decisions on new health technologies for the province. You have received requests for 2 new health technologies. One will benefit patient population A and other will benefit patient population B. However, you have a fixed budget, and can only afford to fund 1 of the technologies. This means that you can only help 1 of the 2 patient populations. Which patient population would you choose?

Characteristics/factors	**Population A**	**Population B**
Current health state	Severely ill	Moderately ill
Prognosis without treatment	3 years	5 years
Average age	60 years old	30 years old
Health outcome with treatment	Sufficient functioning	Sufficient functioning

Please indicate your choice by placing a check mark in the appropriate box:

Population A ☐

Population B ☐

APPENDIX 5-3

Comparison of responses to questions comprising exercises 2, 3, and 4

The following abbreviations were used to represent different levels within factors comprising choice sets (unique patient populations):

Factor/patient characteristic	Categories/levels	Abbreviation
Number of patients who could benefit	Many Few	M F
Age	Young Old	Y O
Current health state	Severely ill Moderately ill Mildly ill	SI MoI Mi
Prognosis without the technology	A few weeks 3 years 5 years	Weeks 3 yrs 5 yrs
Health outcome (with technology)	Full functioning Sufficient functioning Insufficient functioning	FF SF IF
Dependents	Yes No	YD ND

Decision simulation exercise 2 – 'Ping pong' exercise:

Population A (Choice set A)	**Population B (Choice set B)**	**Jury response/choice**		**Different between juries (Yes/No)**
		Northern Alberta Jury	**Southern Alberta Jury**	
Ping pong 1				
[SI, 3yrs, SF]	[MoI, 5yrs, SF]	A	A	No
[SI, 3yrs, SF]	[MoI, 5yrs, FF]	A	A	No
[SI, 3yrs, IF]	[MoI, 5yrs, FF]	B	B	No
Ping pong 2				
[SI, weeks, SF]	[MoI, 3yrs, SF]	A	A	No
[SI, weeks, SF]	[MoI, 3yrs, FF]	A	A	No
[SI, weeks, IF]	[MoI, 3yrs, FF]	B	B	No

Decision simulation exercise 3 – Identification of complex interactions among factors:

Population A (Choice Set A)	Population B (Choice Set B)	Jury Response/choice		Different between juries (Yes/No)
		Northern Alberta Jury	Southern Alberta Jury	
[F, O, MiI, SF]	[M, Y, SI, IF]	A	A	No
[F, Y, MoI, FF]	[M, O, SI, IF]	A	A	No
[M, Y, MiI, FF]	[F, O, SI, IF]	A	A	No
[F, O, SI, SF]	[M, Y, SI, IF]	A	A	No
[F, O, SI, IF]	[M, Y, MoI, SF]	B	B	No
[F, O, SI, IF]	[M, Y, SI, FF]	B	B	No
[M, O, SI, FF]	[F, Y, SI, FF]	A	A	No
[F, Y, MoI, FF]	[M, O, MoI, SF]	B	B	No
[F, O, MiI, FF]	M, Y, MiI, FF]	B	B	No
[F, O, SI, SF]	[M, Y, MiI, FF]	A	A	No
[F, Y, SI, SF]	[M, O, MiI, FF]	A	A	No
[M, O, MiI, FF]	[F, Y, MoI, SF]	B	B	No
[M, Y, MiI, SF]	[F, O, MoI, SF]	A	A	No
[M, O, MoI, FF]	[F, Y, SI, SF]	B	B	No
[F, O, SI, SF]	[F, Y, SI, SF]	B	B	No
[M, Y, SI, SF]	[F, O, MiI, FF]	A	A	No

Decision simulation exercise 4 – Identification of increasingly complex interactions among factors:

Population A (Choice Set A)	Population B (Choice Set B)	Jury Response/choice		Different between juries (Yes/No)
		Northern Alberta Jury	Southern Alberta Jury	
[M, Y, SI, FF, 2 yrs, YD]	[F, O, SI, IF, weeks, ND]	A	A	No
[M, Y, SI, SF, weeks, ND]	[F, O, MoI, FF, 5 yrs, YD]	A	A	No
[M, Y, MiI, SF, weeks, ND]	[F, O, SI, FF, 2 yrs, YD]	A	A	No
[F, O, SI, SF, weeks, ND]	[F, Y, MoI, FF, 2 yrs, YD]	B	B	No
[M, O, MoI, FF, 5yrs, ND]	[F, Y, MiI, FF, weeks, YD]	B	B	No
[M, Y, MiI, SF, 2 yrs, YD]	[M, O, SI, FF, weeks, ND]	B	B	No
[F, Y, SI, IF, 5 yrs, YD]	[M, O, SI, SF, 2 yrs, ND]	B	B	No
[F, Y, SI, SF, weeks, ND]	[M, O, SI, FF, 2 yrs, YD]	A	A	No
[F, O, SI, IF, 2 yrs, ND]	[M, Y, MoI, SF, 5 yrs, YD]	B	B	No
[F, Y, MoI, SF, 2 yrs, ND]	([M, O, MoI, FF, 5 yrs, YD]	B	B	No
[FY, SI, IF, 2 yrs, ND]	[M, O, MoI, FF, 5 yrs, YD]	B	B	No
[F, O, SI, FF, weeks, ND]	[M, Y, MiI, FF, 5 yrs, YD]	A	A	No
[M, Y, MiI, FF, 5 yrs, ND]	[F, O, SI, SF, 2 yrs, YD]	A	A	No
[M, O, SI, IF, 2 yrs, ND]	[F, Y, SI, IF, 5 yrs, YD]	A	B	Yes
[M, Y, MiI, SF, 2 yrs, ND]	[F, O, MoI, FF, 5 yrs, YD]	B	B	No
[F, Y, SI, SF, 2 yrs, YD]	[M, O, MiI, FF, 5 yrs, ND]	A	A	No
[F, Y, MoI, FF, 2 yrs, YD]	[M, O, SI, FF, 5 yrs, ND]	B	B	No
[M, O, SI, SF, 5 yrs, YD]	[F, Y, SI, FF, weeks, YD]	B	B	No
[F, O, MiI, SF, 5 yrs, ND]	[M, Y, MoI, FF, weeks, ND]	B	B	No
[M, O, MiI, SF, 2 yrs, YD]	[F, Y, SI, SF, 5 yrs, ND]	B	B	No
[F, O, MoI, SF, 5 yrs, ND]	[M, Y, SI, IF, 2 yrs, YD]	A	A	No
[F, Y, MoI, SF, 2 yrs, ND]	[M, O, MoI, FF, weeks, YD]	B	B	No
[M, Y, MiI, FF, 5 yrs, ND]	[F, O, MoI, SF, 2 yrs, YD]	A	A	No
[F, O, MiI, SF, 2 yrs, YD]]	[M, Y, SI, SF, weeks, ND]	B	B	No
[M, O, MiI, SF, 5 yrs, YD]	[F, Y, SI, SF, 2 yrs, ND]	B	B	No
[M, O, MoI, FF, 2 yrs, YD]	[F, Y, MoI, SF, 5 yrs, ND]	A	A	No

Population A (Choice Set A)	Population B (Choice Set B)	Jury Response/choice		Different between juries (Yes/No)
		Northern Alberta Jury	Southern Alberta Jury	
[F, O, MoI, IF, 5 yrs, ND]	[M, Y, MiI, FF, 5 yrs, YD]	B	B	No
[M, Y, MoI, FF, 2 yrs, ND]	[F, O, SI, IF, weeks, YD]	A	A	No
[F, O, MiI, SF, 5 yrs, ND]	[M, Y, SI, FF, 2 yrs, YD]	B	B	No
[M, O, MiI, FF, 2 yrs, ND]	[F, Y, MoI, FF, 5 yrs, YD]	B	B	No
[M, Y, MiI, FF, 2 yrs, YD]	[F, O, SI, FF, 5 yrs, ND]	B	B	No
[M, O, MoI, SF, 2 yrs, ND]	[F, Y, MoI, FF, 5 yrs, YD]	A	A	No

CHAPTER 6:
ASSESSING THE IMPACT OF DELIBERATIVE PROCESSES ON THE VIEWS OF PARTICIPANTS OF CITIZENS' JURIES: IS IT 'IN ONE EAR AND OUT THE OTHER'?

ABSTRACT

Introduction:

With increased recognition that resource allocation decisions in healthcare are both complex and value-laden, interest in deliberative processes for eliciting the views of the public to inform such decisions has grown. One type, citizens' juries, has received considerable interest from decision-makers. However, there appears to be a lack of evaluative information on these juries, particularly regarding their short and long term impact on participants' views. Since citizens' juries are resource intensive, such information is required in order to make 'evidence-based' decisions about their use.

Objectives:

To assess the impact of citizens' juries on participants' preferences for the distribution of healthcare across populations, and to see if these preferences change over time.

Methods:

Two citizens' juries, each involving a different representative sample of the public, were held. In addition, participants completed an identical questionnaire before (T1), directly after (T2), and six weeks following the jury (T3). Questionnaires comprised rating, ranking, and choice-based questions related to four characteristics of competing patient populations. Telephone interviews were

also conducted six weeks later. Responses to questions were compared across the three time points using quantitative and qualitative techniques.

Results:

In both juries, no statistically significant differences in responses to the rating questions were observed across the three time points. Pre- and post-jury changes in the rankings of two factors were only statistically significant in one of the juries. However, in both juries, T1 to T2 changes in responses to several of the choice-based questions reached statistical significance. The number was lower between T2 and T3, suggesting that jurors retained their views. According to findings from the interviews, jurors' views changed or were clarified through participation in the jury.

Conclusions:

There appears to be evidence suggesting that the views of individuals who participate in citizens' juries change as a result of the experience, and that those 'informed' views are retained.

INTRODUCTION

With increased recognition that resource allocation decisions in healthcare are both complex and value-laden, interest in deliberative processes for eliciting the views of the public to inform such decisions has grown.[1-3] Deliberative processes aim to gather input from an 'informed citizenry' who has had the opportunity to weigh information, discuss and debate potential options, and arrive at a mutually agreed upon decision.[4-7] Thus, they have been used to seek the views of the public around policy issues in and outside of healthcare.[4,8,9] In recent years, one such process, citizens' juries, has received considerable interest from decision-makers.[1,10,11]

Citizens' juries bring together 12 to 16 individuals selected to be broadly representative of their community. Over a two to four day period, they learn about a relevant issue, hear from expert 'witnesses' who offer different perspectives, engage in deliberations among themselves, and arrive at a common ground answer.[4] Evaluations of citizens' juries, while positive, have, for the most part, been limited to feedback questionnaires examining jurors' experiences, and qualitative analyses of deliberations to assess jury competence and rationality.[4,12,13] There appears to be a lack of information regarding their short and/or long term impact on individual jurors' opinions. Citizens' juries may also serve as a mechanism for managing public expectations by facilitating a shift in attitudes from more self-interested to more socially aware ones.[14,15] Therefore,

pre- and post-jury assessments of participants' views are needed to determine the broader value of citizens' juries.

OBJECTIVES

The purpose of this paper was to assess the impact of citizens' juries on jurors' preferences for the distribution of healthcare across populations. Specifically, it aimed to examine whether jurors' views on the importance of factors/patient characteristics that may be considered during resource allocation decision-making for new health technologies changed following participation in the jury and, if they did, whether such views were retained over time.

METHODS

To assess the impact of citizens' juries on jurors' views, a mixed methods approach was used. This involved pre- and post-jury administration of a common questionnaire and individual telephone interviews with participants.

The citizens' jury

Two citizens' juries (Northern Alberta Citizens' Jury (NA Jury) and Southern Alberta Citizens' Jury (SA jury)) were each held over two and a half days using similar methods (i.e., the same facilitators, presentations, 'witnesses', and decision simulation exercises), but with different representative samples of the public to elicit distributive preferences for the allocation of resources across competing patient populations.[16,17] In each jury (N=16), participants engaged in a

series of increasingly complex trade-off exercises which involved simultaneous consideration of multiple factors/patient characteristics. Based on their responses, preference statements, reflecting the extent to which jurors' choices depended on the presence of certain factors, were generated.

Data collection

1. Development of pre-post jury and follow-up questionnaire

For each jury, a separate self-administered survey was constructed. The survey contained three different types of questions commonly used in studies designed to elicit social values or distributive preferences of the public for healthcare across the population.[11] It included: 1) ranking, 2) rating (Likert), and 3) choice-based, (choice-based conjoint analysis) questions. Each type of question incorporated four factors/patient characteristics around which distributive preferences of the public have frequently been sought: 1) current health or severity of illness; 2) imminence of death; 3) age; and 4) health improvement or gain with the technology (Appendix 6-1). Regarding the single ranking question, jurors were asked to rank the four factors from most to least important. The four Likert questions asked jurors to rate the importance of each factor on a five-point scale (from very important to not important at all). Choice-based questions asked jurors to choose between two unique patient populations characterized by a different combination of categories or levels within individual factors, 'divide funds equally between populations', or 'let someone else decide' (Appendix 6-1). Unique populations and pair-wise comparisons were generated using SPSS

Orthoplan, which creates 'scenarios' (unique populations) and choice sets (pair-wise comparisons) to obtain the maximum amount of information through the fewest possible comparisons. Comparisons were checked for plausibility and 'level balance' before adding them to the questionnaire. Sixteen such comparisons were included, a number representing the upper limit of manageable cognitive burden.[18] In addition, one duplicate question was asked in order to assess the reliability of jurors' responses. While ranking and rating questions were identical across the two questionnaires, the 16 choice-based questions differed (one set per jury).

2. Administration of the questionnaire

All jurors completed the same self-administered questionnaire three times: 1) at the beginning of the jury; 2) at the end of the jury; and 3) six weeks following the jury. The first two were completed in the room in which jury sessions were held. The third was mailed to jurors, along with a self addressed, postage paid envelope and a cover letter, which repeated instructions for completing the questionnaire and included a reminder to answer questions independently. The cover letter also provided contact information for the researchers, should jurors require further clarification. The purpose of the six week follow-up questionnaire was to assess the stability of jurors' preferences over time. The six week time period was selected based upon findings from a review of behavioural psychology literature in which studies examining the permanence of attitude changes to various types of

information employed periods ranging from two days to 12 months and the need to minimize losses to follow-up.[19-21]

3. Telephone interviews

Upon receipt of completed follow-up questionnaires, semi-structured telephone interviews, each 15 minutes in length, were conducted. Jurors were asked about their overall experience participating in the jury and any impact it might have had on their perceptions of resource allocation decision-making for new health technologies in the province. They were also asked questions related to their individual views/distributive preferences, including whether or not these had changed as a result of the jury and, if yes, whether they had changed again since then. They were then reminded of the final set of preference statements arrived-at by the jury and asked whether they felt it reflected their individual preferences prior to the jury, and whether they still agreed with its contents. Lastly, jurors were given the opportunity to provide any additional comments. To minimize interviewer bias, all interviewers were conducted by the same researcher using a pre-tested interview guide.[22]

Analysis of questionnaires and interviews

1. Questionnaires

To assess the extent to which jurors' views changed immediately following the jury, responses to the first questionnaire (pre-jury survey) were compared with those to the second questionnaire (post-jury survey). To assess the extent to

which jurors retained their views following the jury, responses to the second questionnaire were compared with those of the third questionnaire (follow-up survey). Both comparative analyses were performed using the following statistical tests. To identify statistically significant differences in jurors' responses to the ranking and rating questions, the Wilcoxon Matched-Pairs Signed-Ranks Test was used.[23] For each of the choice-based questions, the number of jurors whose responses differed between the pre- and post-jury questionnaires and between the post-jury and follow-up questionnaires was counted. This value was then used to calculate the proportion of jurors who changed their minds on an individual question. It was assumed that the probability of a juror changing his/her mind on an individual question followed a binomial distribution (change or no change). Confidence intervals were then calculated around the proportion of jurors whose responses differed on each question.[24] For the purposes of this paper, a meaningful value for the proportion of jurors who changed their minds was set at 0.20. Therefore, if a confidence interval around a proportion fell entirely above 0.20 (20%), that value was considered to be statistically significant.

2. Interviews

Interviews were digitally recorded, transcribed, and analysed using content analytic and constant comparison techniques.[12,22] Data (chunks of information) were sorted, arranged, and coded using qualitative data management software (NVivo®). All transcripts were analysed by the same researcher who conducted

the interviews. To assess observer bias, a second researcher independently analysed transcripts from two, randomly selected interviews. Findings from both researchers were subsequently compared.[25]

The study received ethics approval from the University of Alberta Health Research Ethics Board.

RESULTS

All 16 jurors on the Northern Alberta Citizens' Jury completed the three questionnaires. In the Southern Alberta Citizens' Jury, one participant was not able to stay for the entire jury session. Therefore, only 15 of the 16 jurors completed all three questionnaires and were included in the analyses.

Pre- and post-jury comparisons of responses to the common questionnaire

1. Ranking question

Findings from a comparative analysis of the Northern Alberta jurors' rankings of the four factors/patient characteristics prior to and directly after the jury are presented in Table 6-1. Statistically significant differences in the rankings of 'current health/severity of illness' and 'health gain/improvement' were observed. 'Current health/severity of illness' decreased in rank, while 'health gain/improvement' increased, moving from a median rank of third to first. This finding was consistent with preference statements that emerged during the jury session.[16] Jurors considered health gain first, consistently favouring patient

populations if the available health gain could at least bring them to sufficient functioning.

In the Southern Alberta Jury, no statistically significant differences in the rankings of jurors prior to and directly following the session were found.

2. Rating questions

For both juries, no statistically significant differences in jurors' ratings of the importance of each factor/patient characteristic were detected (Table 6-2).

3. Choice-based questions

In the Northern Alberta Jury, the percentage of jurors whose responses to an individual question differed post-jury from those pre-jury ranged from 31% to 63% (Table 3). There were no questions to which all jurors answered the same way both times. Further, for six of the questions, the percentage of jurors who changed their minds reached statistical significance. As observed in the ranking question, responses provided to the post-jury questionnaire were consistent with the jury's collective preference statements. Most jurors selected patient populations who could at least achieve sufficient functioning. When health gains were the same across populations, there was a preference for funding those who were 'worse-off' or facing imminent death without treatment. Lastly, few jurors selected the 'divide resources equally' option, instead they chose one of the two patient populations.

In the Southern Alberta Jury, values were slightly lower, ranging from 14% to 53%, and the percentage of jurors who changed their minds was statistically significant in five of the questions. As in the Northern Alberta Jury, such 'changes' were consistent with the jury's collective preference statements. Patient populations facing imminent death or considered the most severely ill were only favoured when the available health gain was enough to restore them to sufficient functioning.

Importantly, all jurors in each jury answered duplicate questions consistently (i.e., the same way), suggesting that their responses were reliable.

Post-jury and follow-up comparisons of responses to the common questionnaire

1. Ranking question

For both juries, no statistically significant differences were observed in jurors' rankings of the four factors/patient characteristics at the end of the jury session and six weeks later.

2. Rating questions

As in the pre- and post-jury comparison, no statistically significant differences in jurors' views of the importance of each factor were found six weeks after either jury.

3. Choice-based questions

In both the Northern and Southern Alberta Juries, the range of percentages of jurors whose responses differed between the post-jury and follow-up jury questionnaires was lower than that found for the pre- and post-jury comparisons (NA Jury: 13% to 50%; SA Jury: 7% to 40%). Additionally, the number of questions in which the proportion of jurors who changed their minds reached statistical significance was lower (NA Jury: 2; SA Jury: 0). In the Northern Alberta Jury, the two questions both involved trade-offs between populations in which neither could be returned to sufficient functioning. None of the preference statements generated through the actual jury session addressed such circumstances. Therefore, a comparison of the two results was not possible. Again, all jurors in each jury answered duplicate questions consistently.

Findings from interviews

All 31 jurors indicated that the jury had affected their views in some way. Approximately one third felt it had helped to clarify their views ("Yeah, I now say 'it depends' a lot more, and I am okay with that"; "I couldn't get my head around how I felt before the jury. Now at least I know how I am going to think about things"; and "I learned so much – not just about the healthcare system but about myself, what I believe in"; and "I am not sure I had a clue before"). Approximately one third thought it had actually changed their views ("Holy smokes, this stuff is really complicated… I mean, now I realize it is never as easy as just helping the worst off people…you gotta think about so much more, like

what are we really gettin' out of it"; "I think, hope, I am less judgemental now about, like, people who do unhealthy things. You know, when you think about trading off people, it forces you to think twice about whether you want to use that against them"; and "I totally changed my mind, 180 degrees…it's about more than [the] greatest good for the greatest number saying").

Over half of the jurors noted the complexities involved in making resource allocation decisions, and expressed empathy for those charged with such a task ("I wish all Albertans could have a chance to participate in one of these. I have a way better handle on how hard these decisions really are"; "Gosh, I wouldn't trade places with the health minister any day of the week… [he] has a tough job"; "To have to say 'no' to a family, I just know I couldn't do it, yet it has to be done"; and "I appreciate how difficult a job it is now"). Just over one quarter mentioned feeling hopeful or reassured by the views of their fellow jurors ("For me, the experience was reassuring. I think we can be proud of what we came up with, and there is no way that we could have thought that way together without something like this"; "I was happy to see that people weren't just automatically going to throw old people like me under the bus"; "I was surprised how easy it was for us to make some decisions – like we were on the same page even though we were pretty different"; and "I think we did a great job – move over [health minister's name removed])".

All but one of the jurors thought their views had not changed since the jury ("Nope, my memory isn't that bad yet"; "After all those exercises and discussions, things will be stuck in there for a while"; and "No, but I think about how much I think society should be willing to give up for things a lot more, like that Zamboni procedure"). The single juror who stated otherwise mentioned that (s)he had changed her personal views around 'last chance' therapies which may offer important but small health gains. While (s)he felt (s)he had "written them off" during the jury, (s)he realized afterwards that there may be value to loved ones, which (s)he hadn't considered at the time ("I never voted for the small improvement, even when they [patients] were pretty ill. There is a psychosocial benefit that I didn't pay much attention to and should have").

When asked about the set of collective preference statements arrived at by each jury, all 31 jurors stated that it still reflected their views ("Yes, I am still pretty comfortable with them"; "I still like them and even tell others about them"; and "I think so, I mean, when I read them again I still feel okay about them"). In contrast, only 13 of the 31 jurors thought that the set accurately captured their views prior to the jury ("Can't say would have thought of these things beforehand, but I do think they are what I believe now"; "Nope, no way I would have thought that way"; "I wish I could say that they did, but no, I am afraid not"; and "Values are so hard to explain to people. Until the jury, I hadn't thought about them as distributive preferences - that helped me out a whole bunch").

DISCUSSION

This study assessed the immediate and longer term impact of citizens' juries on the distributive preferences/views of participants regarding resource allocation decision-making for new health technologies. To our knowledge, it represents the first attempt to evaluate citizens' juries using a mixed methods approach, combining traditional feedback interviews and repeated administration of an identical questionnaire before, immediately following and 6 weeks after the jury. According to the results of qualitative analyses of the telephone interviews, the views of jurors not only changed as a result of the citizens' jury, but were also retained.

Findings from quantitative analyses of questionnaire data were less clear, but appeared to be consistent with the results of the jury session (i.e., collective preference statements). In one of the juries, changes in the ranking of two of the four factors from before the jury to immediately after the jury were statistically significant. However, in both juries, no statistically significant differences in responses to the rating questions over time were observed. The number of choice-based questions in which the proportion of jurors whose responses changed reached statistical significance, and the magnitude of the change (number of jurors with differing responses), were less for the post-jury follow-up comparison than for the pre- and post-jury comparison. Thus, 'change' appeared to depend on the type of question. The lack of differences in responses to the rating questions might be explained by the fact that such questions do not require a trading-off of

'goods'. In other words, jurors may have realized that they weren't losing or 'giving up' anything by simply providing an immediate response. While this may have also been the case for the ranking questions, they do require consideration of the *relative* value of 'goods', since there is a single ranking position to which only one of several 'goods' can be assigned.[26]

Regarding the choice-based questions, the set of 16 differed between the two juries. Therefore, it was not possible to compare responses across juries. Although each set was generated using the same approach, questions may not have represented equivalent 'difficulty' levels. Nonetheless, in both juries, the majority of responses to the post-jury and follow-up questionnaires were consistent with the final preference statements of the jury session, suggesting that jurors may have adopted and retained a more societal view as a result of their experience. According to findings from the interviews, it appeared to play a role in shaping the views of participants. However, the permanence of their 'informed' views was based only on a six week follow-up. While this time period has frequently been used to assess the permanence of attitude changes in the behavioural sciences, the extent to which it may be adequate in the context of social values is not clear. Finally, the three questionnaires were not administered in the same setting (i.e., the third was mailed to jurors' homes). Although jurors were asked to complete questionnaires independently, it was not possible to ensure compliance with the request. Therefore, respondent bias may have been introduced.

CONCLUSIONS

The results of this study, suggest that the views of individuals who participate in citizens' juries change as a result of the experience, and that those 'informed' views are retained over time.

A version of this chapter has been submitted for publication. Stafinski 2010. Health Expectations.

Table 6-1. Comparison of pre- and post-jury questionnaire responses to ranking question for both juries (rank of 1 = highest)

Factor/Patient Characteristic	Jury	Median score		P-value*
		Pre-Jury	Post-Jury	
Age	Northern Alberta	2.5	3	0.683
	Southern Alberta	3	2	0.522
Current health/severity of illness	Northern Alberta	2.5	3	0.039
	Southern Alberta	3	3	0.564
Imminence of death	Northern Alberta	2	2.5	0.248
	Southern Alberta	2	3	0.123
Health gain/ improvement	Northern Alberta	3	1	0.016
	Southern Alberta	3	3	0.746

*Wilcoxon Matched-Pairs Signed-Rank Test

Table 6-2. Comparison of pre- and post-jury questionnaire responses to rating Likert questions for both juries

Questions	Jury	Times	Frequencies of answers (Row %)						Medians (pre to post jury)	P-value*
			Very important	Important	Moderately important	Of little importance	Not important at all	Total		
Age	Northern Alberta	Pre-jury	7 (43.75)	3 (18.75)	4 (25.00)	2 (12.50)	0	16 (100)	3 to 3	1.00
		Post-jury	5 (31.25)	7 (43.75)	3 (18.75)	0	1 (6.25)	16 (100)		
	Southern Alberta	Pre-jury	3 (18.75)	6 (37.50)	5 (31.25)	1 (6.25)	1 (6.25)	16 (100)	3 to 4	0.222
		Post-jury	8 (53.33)	2 (13.33)	5 (33.33)	0	0	15 (100)		
Current health/severity of illness)	Northern Alberta	Pre-jury	5 (31.25)	7 (43.75)	4 (25.00)	0	0	16 (100)	3 to 3	0.477
		Post-jury	4 (25.00)	7 (43.75)	4 (25.00)	1 (6.25)	0	16 (100)		
	Southern Alberta	Pre-jury	4 (25.00)	10 (62.50)	2 (12.50)	0	0	16 (100)	3.3	0.564
		Post-jury	7 (46.67)	6 (40.00)	1 (6.67)	1 (6.67)	0	15 (100)		
Imminence of death	Northern Alberta	Pre-jury	7 (43.75)	7 (43.75)	2 (12.50)	0	0	16 (100)	3 to 3	0.454
		Post-jury	6 (37.50)	6 (37.50)	4 (25.00)	0	0	16 (100)		
	Southern Alberta	Pre-jury	7 (43.75)	6 (37.50)	2 (12.50)	1 (6.25)	0	16 (100)	3 to 3	0.608
		Post-jury	5 (33.33)	7 (46.67)	2 (13.33)	1 (6.67)	0	15 (100)		
Health gain/ improvement	Northern Alberta	Pre-jury	9 (56.25)	5 (31.25)	2 (12.50)	0	0	16 (100)	4 to 4	0.129
		Post-jury	13 (81.25)	3 (18.75)	0	0	0	16 (100)		
	Southern Alberta	Pre-jury	8 (50.00)	6 (37.50)	2 (12.50)	0	0	16 (100)	3 to 4	0.102
		Post-jury	9 (60.00)	6 (40.00)	0	0	0	15 (100)		

*Wilcoxon Matched-Pairs Signed-Rank Test

Table 6-3. Comparison of pre- and post-jury questionnaire responses to choice-based questions in the Northern Alberta Jury

Questions	Proportion of jurors who changed their responses	Confidence interval
1	6/16 (0.375)	0.152 – 0.646
2	5/16 (0.313)	0.110 – 0.587
3	5/16 (0.313)	0.110 – 0.587
4	6/16 (0.375)	0.152 – 0.646
5	5/16 (0.313)	0.110 – 0.587
6	9/16 (0.563)	0.299 – 0.803*
7	6/16 (0.375)	0.152 – 0.646
8	8/16 (0.500)	0.247-0.754*
9	6/16 (0.375)	0.118 – 0.616
10	7/16 (0.438)	0.198 – 0.701
11	6/16 (0.375)	0.152 – 0.646
12	5/16 (0.313)	0.110 – 0.587
13	10/16 (0.625)	0.354 – 0.846*
14	8/16 (0.500)	0.247 – 0.754*
15	8/16 (0.500)	0.247 – 0.754*
16	8/16 (0.500)	0.247 – 0.754*

*Statistically significant

Table 6-4. Comparison of pre- and post-jury questionnaire responses to choice-based questions in the Southern Alberta Jury

Questions	Proportion of jurors who changed their responses	Confidence interval
1	7/15 (0.467)	0.213 – 0.734*
2	8/15 (0.533)	0.267 – 0.787*
3	6/15 (0.400)	0.163 – 0.617
4	8/15 (0.533)	0.267 – 0.787*
5	2/15 (0.133)	0.017 – 0.405
6	4/15 (0.267)	0.078 – 0.551
7	2/15 (0.133)	0.017 – 0.405
8	4/15 (0.267)	0.078 – 0.551
9	5/15 (0.333)	0.118 – 0.616
10	8/15 (0.533)	0.267 – 0.787*
11	3/15 (0.200)	0.043 – 0.481
12	6/15 (0.400)	0.163 – 0.617
13	7/15 (0.467)	0.213 – 0.734*
14	2/15 (0.133)	0.017 – 0.405
15	4/15 (0.267)	0.078 – 0.551
16	2/15 (0.133)	0.017 – 0.405

*Statistically significant

Table 6-5. Comparison of post- and follow-up-jury questionnaire responses to ranking question for both juries (rank of 1 = highest)

Factor/Patient Characteristic	Jury	Median score		P-value*
		Post-Jury	Follow-up Jury	
Age	Northern Alberta	3	4	0.608
	Southern Alberta	2	3	0.496
Current health/severity of illness	Northern Alberta	2.5	3	0.429
	Southern Alberta	3	2	0.454
Imminence of death	Northern Alberta	2.5	2	0.157
	Southern Alberta	3	3	0.942
Health gain/ improvement	Northern Alberta	1	2	0.161
	Southern Alberta	2	2	1.000

*Wilcoxon Matched-Pairs Signed-Rank Test

Table 6-6. Comparison of post- and follow- up jury questionnaire responses to rating Likert questions for both juries

Questions	Jury	Times	Frequencies of answers (Row %)						Medians (pre to post jury)	P-value*
			Very important	Important	Moderately important	Of little importance	Not important at all	Total		
Age	Northern Alberta	Post-jury	7 (43.75)	3 (18.75)	4 (25.00)	2 (12.50)	0	16 (100)	3 to 3	0.713
		Follow-up jury	5 (31.25)	7 (43.75)	3 (18.75)	0	1 (6.25)	16 (100)		
	Southern Alberta	Post-jury	3 (18.75)	6 (37.50)	5 (31.25)	1 (6.25)	1 (6.25)	16 (100)	4 to 3	0.340
		Follow-up jury	8 (53.33)	2 (13.33)	5 (33.33)	0	0	15 (100)		
Current health/severity of illness)	Northern Alberta	Post-jury	5 (31.25)	7 (43.75)	4 (25.00)	0	0	16 (100)	3 to 3	0.317
		Follow-up jury	4 (25.00)	7 (43.75)	4 (25.00)	1 (6.25)	0	16 (100)		
	Southern Alberta	Post-jury	4 (25.00)	10 (62.50)	2 (12.50)	0	0	16 (100)	3 to 3	0.608
		Follow-up jury	7 (46.67)	6 (40.00)	1 (6.67)	1 (6.67)	0	15 (100)		
Imminence of death	Northern Alberta	Post-jury	7 (43.75)	7 (43.75)	2 (12.50)	0	0	16 (100)	3 to 3	0.783
		Follow-up jury	6 (37.50)	6 (37.50)	4 (25.00)	0	0	16 (100)		
	Southern Alberta	Post-jury	7 (43.75)	6 (37.50)	2 (12.50)	1 (6.25)	0	16 (100)	3 to 3	0.705
		Follow-up jury	5 (33.33)	7 (46.67)	2 (13.33)	1 (6.67)	0	15 (100)		
Health gain/ improvement	Northern Alberta	Post-jury	9 (56.25)	5 (31.25)	2 (12.50)	0	0	16 (100)	4 to 4	0.317
		Follow-up jury	13 (81.25)	3 (18.75)	0	0	0	16 (100)		
	Southern Alberta	Post-jury	8 (50.00)	6 (37.50)	2 (12.50)	0	0	16 (100)	4 to 4	0.317
		Follow-up jury	9 (60.00)	6 (40.00)	0	0	0	15 (100)		

*Wilcoxon Matched-Pairs Signed-Rank Test

Table 6-7. Comparison of post-jury and follow-up questionnaire responses to choice-based questions in the Northern Alberta Jury

Questions	Proportion of jurors who changed their responses	Confidence interval
1	4/16 (0.250)	0.073 – 0.524
2	2/16 (0.125)	0.016 – 0.384
3	3/16 (0.188)	0.041 – 0.457
4	8/16 (0.500)	0.247 – 0.754*
5	7/16 (0.438)	0.198 – 0.701
6	5/16 (0.313)	0.110 – 0.587
7	5/16 (0.313)	0.110 – 0.587
8	8/16 (0.500)	0.247 – 0.754*
9	4/16 (0.250)	0.073 – 0.524
10	6/16 (0.375)	0.152 – 0.646
11	6/16 (0.375)	0.073 – 0.524
12	4/16 (0.250)	0.110 – 0.587
13	3/16 (0.188)	0.041 – 0.457
14	4/16 (0.250)	0.073 – 0.524
15	7/16 (0.438)	0.198 – 0.701
16	4/16 (0.250)	0.073 – 0.524

*Statistically significant

Table 6-8. Comparison of post-jury and follow-up questionnaire responses to choice-based questions in the Southern Alberta Jury

Questions	Proportion of jurors who changed their responses	Confidence interval
1	4/15 (0.267)	0.078 – 0.551
2	5/15 (0.333)	0.118 – 0.616
3	4/15 (0.267)	0.078 – 0.551
4	6/15 (0.400)	0.247 – 0.754
5	2/15 (0.133)	0.017 – 0.405
6	1/15 (0.067)	0.078 – 0.551
7	3/15 (0.200)	0.043 – 0.481
8	3/15 (0.200)	0.043 – 0.481
9	5/15 (0.333)	0.118 – 0.616
10	6/15 (0.400)	0.247 – 0.754
11	2/15 (0.133)	0.017 – 0.405
12	6/15 (0.400)	0.247 – 0.754
13	5/15 (0.333)	0.118 – 0.616
14	3/15 (0.200)	0.043 – 0.481
15	2/15 (0.133)	0.017 – 0.405
16	1/15 (0.067)	0.078 – 0.551

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APPENDIX 6-1: SAMPLE QUESTIONS FROM PRE-POST JURY SURVEY

Please imagine that you are the provincial Minister of Health. Your job is to decide which new health services the province should pay for. These health technologies may help different groups/populations of patients, and there isn't enough money to fund all of them. When deciding which ones to fund, you might consider:

Age	What is the average age of patients in the group who might benefit from the health technology?
Current health or severity of illness	How ill are the patients in the group who might benefit from the health technology?
Imminence of death	What is the life expectancy of patients in the group if the technology is not funded?
Health gain or improvement	How much will the health of patients in the group improve if the health technology is funded?

Part A: sample question
Please answer the following questions by placing a check mark in the box that best describes your views:

1. How important is it to think about the age of patients when deciding which new health services to fund?

Very important ☐

Important ☐

Moderately important ☐

Of little importance ☐

Not important at all ☐

Part B: sample question
Please rank the following four factors that might be used to help determine the priority of different patient groups for health care in order of importance to you, starting with the most important one:

Age
Current health
Imminence of death
Health gain

Most important 1._____
2._____
3._____
Least important 4._____

Part C: sample question
Please imagine that you only have enough money to fund one of two technologies. Technology A is used to treat illness A (patient population A), while technology B is used to treat illness B (patient population B). The two groups of patients are different.

The table on the next page shows the possible characteristics of the patient groups.

Characteristic	Categories	Description
Age	Young	25 years old
	Old	65 years old
Current health	Severely ill	Unable to perform daily activities (working, family or leisure); in extreme pain or discomfort; depressed
	Moderately ill	Able to perform some daily activities; in moderate pain; mildly depressed
	Mildly ill	Able to carry out daily activities; in mild pain
Imminence of death* *Some disease progress slowly and others progress very quickly	Will die within a few weeks	
	Will die in 1 year	
	Will die in 5 years	
Health gain or improvement with treatment	Health returns to normal (what it was before the illness).	
	Health does not return to normal (pre-illness), but patients are able to perform most daily activities (i.e., sufficient functioning).	
	Health does not return to normal and patients are not able to carry out most daily activities on their own. However, patients still improve a little.	

The next set of questions asks you to make a choice between funding a technology for Group A or Group B. Alternatively, you can choose to fund both groups equally or indicate that you would prefer that someone else makes the choice. For each question, please place a check mark in the box that best describes your view.

QUESTION 1

	GROUP A	**GROUP B**
Age	Young	Old
Current health or severity of illness	Severely ill	Mildly ill
Imminence of death without the technology	Will die in 5 years	Will die in 1 year
Health gain or improvement with the technology	Health returns to normal (as it was prior to the illness)	Health returns to normal (as it was prior to the illness)

Please check one of the following boxes:

Fund Group A ☐

Fund Group B ☐

Divide funds equally between the groups ☐

Let someone else decide ☐

CONCLUSION

This thesis comprised six, sequential papers, which began with the identification of the place of social values in coverage decision-making processes for new health technologies and concluded with attempts to explicate such values.

Through a comprehensive, systematic search of published, peer-reviewed and 'grey' literature, 21 national, 4 provincial/state, and 6 regional/institutional level processes were identified. Information found for each one related to one or more of the following four components: 1) identification of the decision problem, 2) information inputs, 3) elements of the decision-making process, and 4) public accountability and decision implementation. Factors considered during decision-making were, in general, well defined. However, descriptions of their relative weight or how they were incorporated into decisions appeared limited. Similarly, while the importance of social values was often mentioned, information on what they comprised was sparse.

The need to clarify or define social values embedded in funding decisions was among six issues related to existing coverage processes which senior health executives raised during a facilitated expert workshop and key informant interviews. These included: 1) timeliness, 2) methodological considerations, 3) interpretations of 'value for money', 4) explication of social values, 5) stakeholder engagement, and 6) 'accountability for reasonableness'. Based on feedback

received, a set of questions to be addressed through a 'robust' coverage decision-making process was formulated and endorsed by participants. These questions, grouped and ordered into 3 phases, were used to develop a decision-making framework which combined the knowledge and experiences of senior health executives with findings from the review of international processes. Throughout its development, participants demonstrated a keen interest in learning from the experiences of other organizations. They also noted the lack of information describing social values elicited to inform coverage decisions on new health technologies.

In this thesis, social values were defined as distributive preferences of the public for the allocation of healthcare resources across a population. Thus, factors/patient characteristics around which distributive preferences have been sought were compiled through a systematic review of relevant empirical studies, actual decision-making processes, and publicly available information on appeals to negative funding decisions. Such factors included: severity of illness, immediate need, age (and its relationship to lifetime health), health gain (amount and final outcome/health state), personal responsibility for illness, care-giving responsibilities, and number of patients who could benefit (rarity). Studies typically examined the importance of these factors in isolation only, offering limited insights into policy relevant distributive preferences derived from consideration of multiple factors at once.

Two citizens' juries were held, through which factors related to distributive preferences of the public for new health technologies and possible interactions among them were identified. Findings were similar across juries. Collective preference statements of each jury reflected the presence of interactions among the factors 'current health state', 'prognosis without treatment', 'age', and 'number of patients who could benefit', suggesting that social values may be considerably more complex than that reported to date.

The extent to which citizens' juries impacted the short and longer term views of participants was assessed through telephone interviews and repeated administration of an identical questionnaire before, directly after, and six weeks following the jury. Based on analyses of differences in responses to the same question between the two time periods and the interviews, participants appeared to change their views as a result of the jury experience and retain them over time.

Lastly, from the findings of this thesis, several topics which could form the basis for future research have emerged. They include:

• Identification of distributive preferences regarding small health gains: "To what extent do distributive preferences around certain patient characteristics change when the available gains to populations are small (will not restore a person to 'sufficient functioning')?" To optimize the usefulness of this work to support coverage policy development, there is a need to examine categories or levels within a separate factor of 'small health gain'. Often, decision-makers must select

from competing technologies that each represent an incremental benefit in quality or length of life (e.g., change in administration from injection to oral chemotherapy or from ten pills a day to one, or extension of 1 month of 'quality' life). Therefore, an understanding of distributive preferences of the public regarding different small health gains is required.

• Identification of distributive preferences for future health gains: "To what extent is the public willing to make trade-offs between immediate health gain (e.g., treatment) and future health gain (e.g., preventive technologies)?" Since system level funding decisions involve the allocation of resources across the continuum of care (including prevention, diagnosis, treatment, and palliation), there is a need to elicit preferences which take into account different types of interventions.

• Elucidation of 'switching points' related to 'number of patients who could receive benefit' and 'severity of illness': "Is there a severity threshold beyond which 'number of patients' no longer matters?" With the growing availability of 'targeted therapies' for smaller populations, research addressing this question could play an important role in coverage policy development.

• Assessment of the relative value of 'informed', deliberative processes over survey-based techniques: "Are views elicited through methods such as citizens' juries comparable to those obtained through surveys?" Despite positive experiences with citizens' juries, the extent to which their findings differ from those of choice-based surveys is not known. Since surveys offer a less resource intensive approach to soliciting the views of many individuals, research aimed at

determining their relative value is required. Further, there is a need for methodological studies that 'test' different approaches to managing complex relationships among factors within a discrete choice experiment (choice-based conjoint analysis) survey design.