REVIEW ARTICLE

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Health Technology Funding Decision-Making Processes Around the World

The Same, Yet Different

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Abstract

All healthcare systems routinely make resource allocation decisions that 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. The objective of this paper is to critically review and compare current processes for making health technology funding decisions at the regional, state/provincial and national level in 20 countries.

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 processes identified, websites of corresponding organizations were searched for commissioned reviews/evaluations, which were subsequently analysed using standard qualitative methods.

A total of 21 national, four provincial/state and six regional/institutional-level processes were found. Although information on each one varied, they could be grouped into four sequential categories: (i) identification of the decision problem; (ii) information inputs; (iii) elements of the decision-making process; and (iv) public accountability and decision implementation. While information requirements of all processes appeared substantial and decision-making factors comprehensive, the way in which they were utilized was often unclear, as were approaches used to incorporate social values or equity arguments into decisions.

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.

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), 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, criticisms faced and approaches used to manage them may serve as an important guide for healthcare systems considering options for revising their processes in order to improve the acceptability of decisions.

1. Objectives

1. To compile a list of actual processes for making funding/coverage decisions on new health technologies (pharmaceuticals, devices, diagnostic tests and procedures) at the institutional/regional, provincial/state and national level in different publicly funded healthcare systems.
2. To examine similarities and differences across processes on key elements.
3. To critically review criticisms faced and mechanisms used to remedy them.

2. Review Methodology

2.1 Creation of an Inventory of Current Resource Allocation Decision-Making Processes for New Technologies

2.1.1 Search for Relevant Literature

A comprehensive, systematic search for relevant information available in the public domain was conducted. To locate peer-reviewed, English language literature published as of January 2010, a structured search strategy that combined controlled vocabulary terms (Medical Subject Heading [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 programme 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 [Database of Abstracts of Reviews of Effects], NHS EED [NHS Economic Evaluation Database] and HTA [Health Technology Assessment]). 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-related journals.

A search for unpublished or 'grey' literature (i.e. not published in peer-reviewed journals – e.g. working papers, commissioned reports, conference abstracts, presentations, meeting proceedings, etc.) was also conducted. This involved a series of internet searches in which free-text terms comprising the structured search strategy described earlier in this section (see also Appendix 1 in the Supplemental Digital Content 1, http://links.adisonline.com/PCZ/A118) were applied to the Google search engine. In addition, several databases containing grey literature were scanned, including the Grey Literature Database (New York Academy of Medicine), KU-UC (Knowledge Utilization – Utilisation des Connaissances) database, Systematic Reviews for Management and Policy Making (Program in Policy Decision-making [PPD]/Canadian Cochrane Network and Centre [CCNC] database) and NHS Evidence: Evidence in Health and Social Care. Separate searches for information on technology decision-making processes established in healthcare systems

of the top 20 countries ranked according to GDP 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.

All citations from the various searches were compiled and imported into Reference Manager® version 11.0.

2.1.2 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 (TS and DM; both 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 programmes) 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.

2.1.3 Extraction of Information from Included Papers

Information from selected documents/papers was systematically extracted by the same two independent reviewers using a standardized, pretested data abstraction form. The form comprised process-related elements thought to influence coverage or reimbursement decisions: (i) type of technology (e.g. pharmaceuticals, devices, diagnostic tests, interventional procedures, etc.); (ii) available decision options (e.g. fund, do not fund, fund with conditions, etc.); (iii) evidence requirements (e.g. controlled clinical trials, economic evaluations, etc.); (iv) ethical considerations and equity and efficiency assumptions; (v) any pre-defined decision criteria or rules; (vi) role of different stakeholders; (vii) decision-making committee structure and governance; and (viii) 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]

2.1.4 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]

2.2 Identification of Issues Related to Existing Processes

2.2.1 Search for Relevant Literature

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

2.2.2 Synthesis of Information Collected

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

3. Search Results

The initial literature search yielded more than 3500 discrete references, of which over 200 met the study's inclusion criteria. The majority

represented 'grey literature', comprising government-commissioned evaluation/review reports, manufacturer submission/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 some element of them (e.g. 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. Information found broadly related to (i) the decision problem, itself (table I [all tables are available only in the Supplemental Digital Content]); (ii) evidence inputs (i.e. topics to be addressed by materials feeding into the decision-making process; table II); (iii) the actual decision-making process (i.e. steps involved and criteria applied; table III); and (iv) implementation of the decision (i.e. public accountability mechanisms; table IV).

4. Specifications of the Decision Problem

4.1 Technology Type

Just over half (17 of 30) of the processes pertained exclusively to new pharmaceuticals (primarily prescription).[21-132] Seven of the remaining 13 were used to make funding decisions on non-pharmaceuticals only (e.g. devices, diagnostic tests, procedures, etc.),[23,45,46,59,76,78,133-159] while six spanned both pharmaceutical and non-pharmaceutical technologies.[26,43,44,55,59,76,78,83,84,88-90,128,147,160-224]

4.2 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, healthcare providers, administrators, manufacturers, the public, etc.), and had established prioritization or selection criteria for determining those that would undergo review (UK, US, Alberta and Washington State). Such criteria typically included (i) potential health impact (i.e. whether the technology represents a significant clinical advance that will likely yield substantial health benefits); (ii) potential impact on resources (i.e. whether the technology could result in significant cost savings or expenditures); (iii) policy importance (extent to which implementation of the technology aligns with government priorities); and (iv) 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 healthcare providers.

4.3 Decision Options

Almost all of the processes considered the following three funding decision options: (i) provide the technology; (ii) do not provide the technology; or (iii) provide the technology with conditions (i.e. restrict use to certain providers or patients). In addition, one-third 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.[225] There are primarily two types: (i) those in which payers provide interim funding for a technology within a clinical study designed to collect information required to reduce decision uncertainties (coverage as part of a clinical study); and (ii) those based on an outcomes guarantee implemented through contractual arrangements between payers and manufacturers (coverage tied to outcomes guarantee). Because the latter aims 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.

4.4 Role of Stakeholders

Potential opportunities for engagement of stakeholders (i.e. patients, carers, healthcare 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, anyone), only one (UK) involved them in determining which technologies to review.

5. Information Inputs into the Decision-Making Process

5.1 Information Inputs

Regardless of technology type and jurisdictional level of the process (national, state/provincial or institutional), the following information was required: (i) indications for the technology and 'therapeutic claim'; (ii) summary of relevant patient populations (including burden and severity of disease, as well as incidence and prevalence); (iii) description of current standard management (including proposed place of the technology in existing care pathways); (iv) studies demonstrating safety, clinical efficacy and effectiveness (across subgroups); and (v) 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 with 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 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 requiring that of the payer and half specifying a societal perspective.

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

5.2 Sources of Information

Responsibility for compiling evidence to make up the information inputs rested with either the requestor of the technology (i.e. the applicant) or the decision-making organization. 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 either by internal staff of the decision-making organization or by an external academic group.

One-third of the processes reported involving stakeholders in the collection and synthesis of information. Among them, over half (6) 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 healthcare 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.

6. Elements of the Decision-Making Process

6.1 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 7–25 members, representing, at a minimum, payers (e.g. government, health regions, insurance funds, etc.) and healthcare 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.

6.2 Steps in Decision-Making Process

In general, processes shared the following basic steps: (i) identification of a technology for review (as described in section 4.2); (ii) coordination of review materials (information inputs) by the Secretariat to the advisory/decision-making committee; (iii) internal or external evaluation of applicant's submission or preparation of full assessment; (iv) distribution of emerging report(s) to manufacturers and, in some cases, other stakeholder groups for comment; (v) 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); (vi) communication of provisional recommendations to the manufacturer (at a minimum); (vii) finalization of recommendations, taking into account responses received; and (viii) if applicable, submission of recommendations to the decision maker for approval. 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 the relative value of the technology). Several created technology-specific, multi-disciplinary expert advisory panels for each review (e.g. Alberta [Canada], 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, USA). Importantly, the degree of inclusiveness did not vary according to technology type or jurisdictional level.

6.3 Decision-Making Criteria/Factors

Criteria common to all advisory/decision-making committees included (i) clinical need (informed by severity of the condition, burden of illness and availability of already funded, alternative interventions/therapies); (ii) health impact (i.e. benefits vs harms [ratios] derived from evidence of safety, efficacy and effectiveness compared with current care); and (iii) affordability (budget impact, taking into account the number of patients expected to receive the technology and per-patient costs over 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. 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 that 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 programmes' 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 (i) alignment with government health-related priorities; (ii) feasibility (ease of implementation); (iii) possibility of 'off-label' use; and (iv) innovativeness (potential to encourage innovation).

6.4 Equity and Efficiency Assumptions/Ethical Considerations

Information on ethical considerations used to guide committee deliberations was limited. One process (Sweden) stated that all decisions were to reflect the following two principles: (i) the 'need and solidarity principle' (i.e. patients in greatest need or 'worse off' must be given priority); and (ii) the 'human value principle' (i.e. characteristics of patients, such as age, sex, social position and income, must not influence decisions). A second process (Norway) also reported adopting a 'solidarity' principle. A third (France) referred to efforts to develop a 'social benefit measure'; 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, sex, 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, for example, many of the 'ultra orphan' conditions, and 'life-extending, end-of-life treatments'). 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.

6.5 Role of Stakeholders

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

7. Public Accountability and Decision Implementation Considerations

7.1 Transparency

According to information found, decisions and rationale were publicly accessible through the websites of processes. However, the level of detail provided varied. Two-thirds of the processes also made available corresponding assessment or evaluation reports. Those that did not were exclusively pharmaceutical-based.

7.2 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 healthcare organization. In only one process (UK) could individuals other than the applicant file an appeal.

7.3 Reassessment or Review of Decisions

In the majority of processes, positive funding decisions were reviewed 'regularly', with time periods ranging from 1.5 to 5 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).

7.4 Conditions of Implementation

With the exception of national level processes in the UK, Ireland and the US, no information on timeframes for implementation of a coverage decision were found. In these processes, funding for technologies were to be made available within 90 days, 40 days and 180 days, respectively.

8. Identification of Issues Related to Existing Processes

Criticisms, which mainly emerged from government-commissioned evaluations of processes and published commentaries, included (i) timeliness; (ii) methodological considerations; (iii) explication of social values; (iv) stakeholder engagement; (v) transparency; (vi) contestability; (vii) accountability; and (viii) consistency.

8.1 Timeliness

The overall length of time required by a process (i.e. from submission to decision) was often viewed as excessive and as a barrier to access.[78,160,226-228] Delays were generally attributed to the time needed to conduct comprehensive, independent assessments of the technology. Approaches used to address this issue included (i) implementation of 'expedited' review procedures for 'highly innovative' technologies or those for treating life-threatening illnesses (e.g. Canada, France and the Netherlands); (ii) increased reliance on information submitted by the applicant (i.e. less externally conducted full assessments) [e.g. UK and France]; and (iii) application of interim funding arrangements linked to AED mechanisms (e.g. France, Italy, Ontario [Canada], Sweden and US).

8.2 Methodological Considerations

Criteria for assessing economic implications have generated significant debate.[227] For the most part, such debate has focussed on 'affordability' versus 'cost effectiveness'. It has been argued that adopting an efficiency goal without considering budget impact does not make sense, since a technology can be cost effective but unaffordable when the number of individuals expected to receive that technology is taken into account.[226,229-231] The absence of an 'affordability' criterion in some processes has frustrated payers who must implement decisions made by a committee with no budgetary accountability.[226] In response, such processes have either included budget-impact analyses in their evidence requirements (table II) or incorporated health resource implications into their decision-making criteria. The use of cost-effectiveness thresholds as measures of value for money has been widely contested 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.[232]

8.3 Explication of Social Values

It has become 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 healthcare 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 vs severity of a condition or whether society is willing to place a premium on technologies to extend life at the end of a terminal disease).[233,234]

8.4 Stakeholder Engagement

Over the past 5 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.[226,227] 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.[155]

8.5 Transparency

Various stakeholder groups have voiced criticisms over the lack of transparency around criteria, procedures, decisions and rationales.[136,226,227] Reasons cited by processes that do not make public the assessment or evaluation reports have been 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.[78,226,227,235] Holding committee meetings fully in public has been suggested, but at present, only one process appears to have implemented such an approach.[155]

8.6 Contestability

Concerns related to mechanisms for appealing recommendations or decisions have been 2-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 that oversees the decision-making process.[78] One attempt to address this issue has been retention of a 'commissioner' unaffiliated with the same organization to manage appeals.[21,31,42]

8.7 Accountability

While questions around to whom such processes are accountable and to whom they should be accountable have been raised, no clear attempts to resolve them were identified.[226,228,236]

8.8 Consistency

Some stakeholders have argued that the 'rules of the game' are often 'unpredictable', and stressed the importance of precedence in achieving procedural fairness.[136,226,227,236] With the exception of policies introduced to improve transparency, no information on specific approaches aimed at alleviating such concerns was found.

9. Discussion

To our knowledge, this paper, while limited to information available in the public domain, offers the first structured, comparative review of pharmaceutical and non-pharmaceutical technology coverage decision-making processes across different jurisdictional levels in Westernized countries on four continents. It highlights key similarities and differences, few of which were found to be related to technology type (i.e. pharmaceuticals vs 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 accountability 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 absence 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 the 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 by which decisions must be made. Processes incorporating multiple opportunities for stakeholder involvement at multiple points tended to take longer to arrive at decisions. Notably, the review identified timeliness of the decision-making process as one of stakeholders' most commonly expressed concerns.

10. Conclusion

By examining technology coverage decision-making processes in many countries, this review presents a detailed description 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 processes).

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