

2020 HTAi Global Policy Forum

Deliberative Processes in Health Technology Assessment: Prospects, Problems, and Policy Proposals

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I. Introduction

The purpose of this background paper is to inform the discussion at the HTAi Global Policy Forum (GPF) meeting in New Orleans, Louisiana, USA, in January 2020. The topic chosen for the meeting is “Deliberative Processes in Health Technology Assessment: Prospects, Problems, and Policy Proposals.” This topic, and the overall outline, was selected by HTAi GPF member representatives in the spring of 2019 and further refined at a business meeting of the GPF held in conjunction with the HTAi Annual Meeting in Cologne, Germany. The meeting’s main aim is to discuss, at a strategic level, the major prospects for robust deliberative processes in health technology assessment (HTA) and to better understand some of the problems HTA organizations and stakeholders may face with such processes. This background paper supports the GPF meeting by providing some common terminology and a description of important issues to help ground meaningful debate on principles for deliberative processes in HTA. A guide for the construction of principles and a list of potential principles have also been provided as part of the meeting materials. A main outcome of the meeting is a set of key principles and their associated actions that could be used to guide the establishment and development of deliberative processes within HTA and that could serve also as a springboard for future activities by the HTA community.

While there is currently no standard definition for “deliberation” in the context of HTA (1), the following characterization has been offered: “the critical examination of an issue [by one person or a group] involving the weighing of reasons for and against a course of action.” (2) Within HTA, this definition has been taken to suggest a series of coordinated activities allowing a group of people to receive and exchange information, to critically examine an issue, and to come to an overall group judgement.¹ This group judgement can either constitute a binding decision itself or inform a subsequent decision. Paradigms of deliberative processes include citizens’ juries and councils, consensus conferences, Delphi panels, and deliberative polling. Deliberative processes in HTA have a practical aim: the need to act in the face of some situation posed by the “real world” in which even maintaining the current situation will have consequences (3). While there are various places within HTA processes where deliberation may be used,² this paper focuses specifically on deliberations for reimbursement decisions. The lessons learned from reflecting on and discussing deliberations for reimbursement decisions, and the application of these lessons to other deliberative processes in HTA, will be a topic of discussion at the GPF meeting.

Deliberative processes are not new to HTA and their importance is generally acknowledged. Nevertheless, little research has been conducted on what constitutes successful or effective deliberations and what might serve as an indicator or measure of effectiveness (4). While general agreement exists about some of the content of deliberation for reimbursement decisions (safety, effectiveness, cost-effectiveness, budget impact, patient views), there is evidence illustrating that the expert or advisory bodies making these decisions reach different conclusions regarding the reimbursement of the same drugs (5), and devices (6), even among similar health systems and when considering similar evidence. Cross-country comparisons of reimbursement decisions show that these differences are often related to aspects of reimbursement processes such as the clarity of submission guidance, decision timelines, knowing who initiates the submissions, and price negotiation being a part of the advisory or recommendation process (7). Some of these differences are also attributed to variations in the decision criteria (8), for example, variations in considerations such as disease severity or effectiveness or cost-effectiveness. Other differences reflect variations in context, such as clinical practices, implicit preferences, and commercial arrangements with the pharmaceutical manufacturers (9). However, there has been very limited systematic study of how features of the deliberative processes themselves might influence outcomes. This is a significant gap, as approaches

¹ Deliberation is sometimes restricted to “informing” subsequent decisions rather than ending in a decision itself, see for example, Culyer, A.J., Lomas, J. Deliberative processes and evidence-informed decision making in health care: do they work and how might we know? *Evidence & Policy* 2006; 2(3): 357-71. We do not adopt this restriction as deliberative bodies can be located at various distances from actual decision making.

² Health Technology Assessment Definition Update (version 3) - International Joint Task Group (agency communication)

to evidence-based or informed decision making proliferate and the demands for recommendations from established deliberative processes increase. Both producers and users of HTA, as well as a range of stakeholders, are interested in better understanding why and how particular HTA decisions are made with the intent of improving the consistency and quality of the decisions.

Despite the lack of documented study of deliberative processes, some general guidance for building, operating, and evaluating deliberative processes has been featured in key principles and tools to identify good and bad practices for HTA agencies (10). Table 1 lists some of the principles and questions that are most relevant to the topic of this paper. A framework for successful priority setting has also been proposed for decision makers (11) and criteria to judge the comprehensiveness, fairness, and legitimacy of health care resource allocation decision making have been applied to selected deliberative processes (12). Additionally, researchers at Radboud University Medical Centre (The Netherlands) have recently produced a practical guide for HTA agencies on the construction and improvement of evidence-informed deliberative processes in HTA (13). The guide includes both a checklist to assess the current state of implementation of a deliberative process, and examples of good practices to help guide the development of these processes in specific contexts. Collectively, these efforts provide a useful starting point for appraising HTA deliberative processes and identifying aspects that could be added, expanded, or refined.

Prior Policy Fora Topics Relevant to Deliberative Processes

The topic of deliberative processes draws together long-standing concerns of the Global Policy Forum for improving the responsiveness, quality, and consistency of HTA processes for stakeholders and contributors, producers, and users. In 2013 the Forum focused on value-based decision making in HTA generally, and acknowledged the increasing challenges faced by those producing and using HTA to identify, collect, and reflect on the information and values required by health system stakeholders (14). The 2016 discussion acknowledged the increasing need for HTA processes to adopt more sophisticated approaches to multi-stakeholder engagement (15). Then, in 2017, the Forum turned its attention to the construction and use of value frameworks (16). Forum members agreed that HTA decision-making processes need to become more systematic, explicit, timely, and transparent and that consistency across decisions should be promoted.

Table 1. Selected Key Principles for HTA and Associated Questions Relevant to Deliberative Processes (10)

Principle	Questions
HTA should be an unbiased and transparent exercise	<ul style="list-style-type: none"> • Are the recommendations of the HTA organization made by an independent expert advisory committee? • Are any conflicts of interest of committee members documented and made public? • Are the meetings of the committee held in public? • Is the supporting information and the basis of the recommendations made publicly available? • Does the organization normally commission outside groups to take on the HTA? • Are the draft conclusions subject to review by stakeholders and the public, with rationale underlying final determinations of contentious issues?
A clear system for setting priorities for HTA should exist.	<ul style="list-style-type: none"> • Is the priority setting approach clear and transparent?
Those conducting HTA should actively involve key stakeholder groups (professional and patient organizations, payers, manufacturers)	<ul style="list-style-type: none"> • Is the HTA organization formally required to engage stakeholders in its activities? • Does the HTA organization have a mechanism for identifying the relevant stakeholders? • Does the organization encourage or require submissions of evidence from stakeholders? • Does the organization allow stakeholders to comment on reports at the draft stage? • Does the organization allow stakeholders to appeal against recommendations/decisions? • Do the organization's committees include stakeholder representation (e.g., patient groups, manufacturers, clinical specialists)?
HTA findings need to be communicated appropriately to different decision makers	<ul style="list-style-type: none"> • Does the HTA organization develop a communications plan for its recommendations and decisions? • Are separate versions of reports produced for different audiences (e.g., health professionals, decision makers, general public)?
The link between HTA findings and decision-making processes needs to be transparent and clearly defined	<ul style="list-style-type: none"> • Does the organization distinguish between the scientific assessment of the evidence and the appraisal decision? • Does the organization have an explicit decision rule for acceptance/non-acceptance of health technologies? • Does the organization have a transparent approach for weighing various considerations (e.g., cost-effectiveness, equity)?

To support the aims of the GPF meeting, this paper attempts to balance those aspects of deliberative processes examined in the published literature and the concerns identified by HTA producers, and stakeholders in other contexts, as well as those identified by the GPF members. This paper was informed by scientific and grey literature identified by the Scientific Secretary through an unstructured search based on recent key publications, discussions with a convenience sample of 17 expert informants selected to represent a variety of stakeholder perspectives and insider knowledge (see in-text citations and the Acknowledgements), a review of relevant HTA agencies' websites and documents, and input from the HTAi Policy Forum Organizing Committee, Policy Forum members, HTAi Board members, and the wider HTA community. While no uniform standards for deliberative processes currently exist, Annex 1 and 2 describe relevant aspects of deliberative processes and examples from several countries with well-developed and mature HTA deliberative processes that are used as references by other countries (13) (17). Table 2 provides a summary and comparison of these processes. This survey of aspects is intended to provide a description across processes without adjudicating among the relative merits of each. HTA agencies may have deliberative processes for technologies other than drugs, such as medical devices and diagnostic technologies. Whether deliberative processes should differ according to the technology being considered will be a topic for discussion by Policy Forum members. The processes described in this paper, and other well-developed deliberative processes in HTA, might provide us with the opportunity to use currently very good, but imperfect, methods to improve our understanding of potential best practices.

It is important to highlight that the deliberative processes considered here, and almost all of those typically used as references, have been established in high-income countries. Middle- and low-income countries are also interested in establishing deliberative processes as part of their health care priority setting. The 2016 HTAi Latin American Policy Forum indicated the need for best practices in the region (18), while also emphasizing that principles of good practice cannot be uncritically adopted from their application in high-income countries. Any such principles must respond to the contextual realities of countries striving to adopt and establish HTA systems. Similarly, researchers examining HTA systems in Central and Eastern Europe have urged that there is no single or common direction for HTA development and the institutionalization of HTA should proceed according to a country's development stage and the characteristics of the health system (19). While system-level indicators of readiness for deliberative processes such as HTA infrastructure and capacity (20) and a political culture supportive of stakeholder involvement in decision making (21) are not explored in this paper, they may be important for Policy Forum members to consider when seeking to develop widely applicable principles.

The paper begins with a description of deliberative processes using an "input-throughput-output" (ITO) model and raises some of the issues identified by GPF members that ought to be discussed and addressed. It then describes some of the primary motivations for supporting deliberative processes in HTA, and discusses various aspects of deliberative processes that may influence decisions (Annex 1 contains a more comprehensive list of these aspects). The paper next identifies aspects that may present opportunities for encouraging efficiency and consistency, including potential stakeholder involvement in each of these features of the process. Finally, a list of policy-related questions is provided to direct and stimulate discussion at the HTAi GPF meeting in New Orleans in order to develop principles for deliberative processes.

Process Component	CADTH	HAS	ICER	NICE	PBAC	SMC	ZIN
Construction of Deliberative Environment							
Relation to decision making	advisory	advisory	advisory	binding	advisory	advisory	advisory
Committee size	14	29	15-20	24	20	28	9
Role of chair	manage agenda, facilitate discussion	manage agenda, facilitate discussion	manage agenda	manage agenda, facilitate discussion	manage agenda, facilitate discussion	manage agenda, facilitate discussion	manage agenda, facilitate discussion
Input							
Main source of clinical evidence*	agency	manufacturer	agency	manufacturer	manufacturer	manufacturer	manufacturer
Main source of economic evidence	manufacturer	agency	agency	manufacturer	manufacturer	manufacturer	manufacturer
Method of patient input	form	form	form/ conversation	form	form	form	verbal/written
Public comment on technical report	yes	no	yes	yes	yes	no	yes
Throughput							
Openness of evidence presentation	closed	closed	open	open	closed	open	open
Openness of deliberation and recommendation/decision	closed	closed	open	closed	closed	open	open
Stakeholder attendance/participation	no	yes	yes	yes	yes	yes	yes
Decision criteria/rules	criteria	criteria	rules	rules	rules	criteria	criteria
Final recommendation/decision	majority	majority	majority	consensus	consensus	majority	consensus
Output							
Opportunity for stakeholder comment on draft recommendations	no	no	no	written	no	no	no
Provide feedback to stakeholders	written	no	no	verbal	verbal	no	no
Public record of deliberation (transcript, video, etc.)	none	transcript	video	minutes	none	none	video

*If evidence dossier is submitted by manufacturer and an agency or academic group conducts an independent review of the available clinical evidence, the main source has been listed as "agency".

Table 2. Variation Among Selected Deliberative Processes for Pharmaceutical Reimbursement (see also Annex 2)

II. Conceptualizing Deliberative Processes

The complexities of deliberative processes become more manageable by conceptualizing them using an input-throughput-output (ITO) model (Figure 1). The ITO model is often used to illustrate information processes and complex pathways of care (22), and it has similarities to other general descriptions of HTA systems (23) and processes for well-informed policy making in health care (24). In the ITO model, the “construction of the deliberative environment” refers to the who, what, when, why, and how of deliberation and is typically set by committees’ terms of reference and process documents. “Input” describes the collection of material (evidence, information, and perspectives) that forms the basis for deliberation. Though sometimes considered distinct from the deliberation, this stage increasingly features more diverse information than clinical trial data and cost-effectiveness analyses, and there can be feedback loops between the formal deliberation and the inputs to deliberation (for example, Australia’s PBAC consumer hearings or Scotland’s SMC PACE meeting; see Annex 2). “Throughput” describes the process or “how” of deliberation, the individual cognitive and relational aspects that enable the presentation and weighing of facts, values, and reasons that leads to a collective judgement. HTA processes vary in how they coordinate the input and throughput phases, and a recent comparison of deliberative processes revealed that in some systems assessment and appraisal do not seem aligned even though the same organization may be responsible for both activities (12). “Output” refers to the way in which the content and result of the deliberation is communicated and any learning is consolidated. “Stakeholder involvement” indicates the opportunities within a deliberative process where patients and patient groups, clinicians, manufacturer representatives, payers, and others might provide input and participate in other ways to better fulfill the aims of the deliberative process to include and integrate their perspectives and values and promote learning among all involved. As indicated in Figure 1, stakeholder involvement crosses all components of the ITO model.

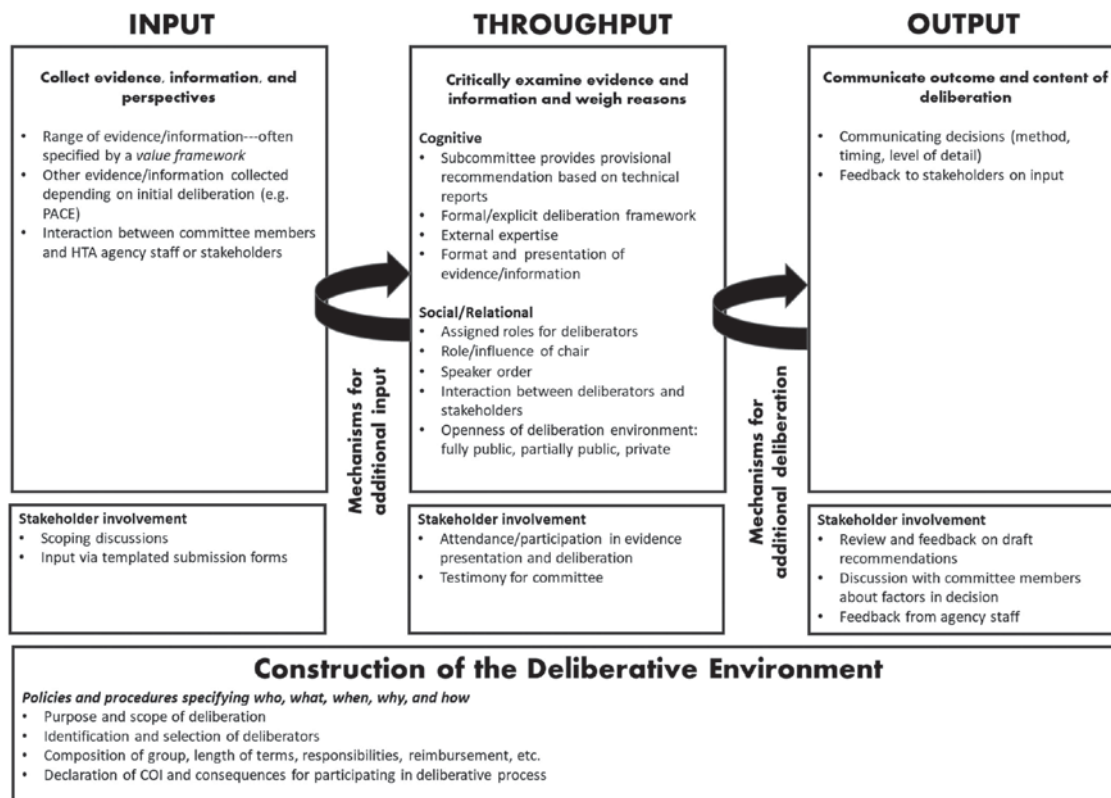


Figure 1. Input-Throughput-Output Model of Deliberative Processes in HTA

Within HTA, the activity of deliberation is often referred to as an “appraisal,” and this is contrasted with an “assessment,” the activity of generating evidence and other information that will become the subject of appraisal (25). Deliberative processes vary in what is done in the assessment stage, raising questions about what is being assessed. Further, HTA researchers have recognized that assessment is sometimes characterized—problematically—as a value-neutral activity (26). For this reason, the terminology of assessment and appraisal have not been employed in this paper.

III. Prospects and Problems for Deliberative Processes in HTA

1. Motivations for Deliberative Processes in HTA

Deliberative processes in HTA serve both the ideals of democratic decision making (27) and the needs of evidence-informed policymaking. These processes serve to strengthen the legitimacy and fairness of decisions within health care by providing a means for articulating the social value judgements involved in a recommendation or decision in terms of the values of the process for decision making and the content on which the decision rests (28). Arguably the dominant procedural principles for health care priority setting processes and resource allocation decision making in many countries are the conditions of Accountability for Reasonableness (A4R) (29) (30). The main idea behind A4R is that the seemingly impossible task of reaching agreement on the specifics of a fair distribution of health care should move us instead to seek agreement on the principles of a fair process for decision making. A fair process, it is argued, will determine what counts as a fair outcome. There are four main conditions of such a process (31):

1. **Relevance:** Decisions should be based on reasons (evidence, principles) that fair minded people who are committed to finding mutually justifiable terms of cooperation can agree are relevant to health care allocation decisions.
2. **Publicity:** Decisions and their rationales should be publicly accessible.
3. **Revision:** Opportunities should exist to change or refine decisions as new information or arguments emerge, and there should be mechanisms to resolve disputes.
4. **Enforcement:** Either voluntary or public regulation of the process should be established to ensure that conditions 1-3 are met.

Fairness in decision making requires thorough deliberation about the facts, reasons, and principles that are relevant to the decision and to those affected by the decision (29). According to the deliberative ideal underlying A4R, all those affected should see the outcome of the process as what they would have chosen had they had the opportunity to participate or, if not, at least as a legitimate and fair decision (32). In some contexts, the conditions of A4R have been supplemented by other principles such as “empowerment,” that is, the need to provide effective opportunities for participation and to minimize power differences in the decision-making context (33). While the original four conditions have widespread appeal, some have argued that these procedural values are insufficient for ethically robust decision making: the fairness and legitimacy of decisions is also determined by the extent to which decisions accord with an appropriate set of substantive values (34) (35). Others have argued that the relevance condition, which is formulated to limit the range of substantive disagreement within deliberation, might undermine rather than strengthen the legitimacy of decisions (36). Finally, while the conditions of A4R address fairness and legitimacy, engendering trust in deliberative processes and their outcomes is also important, and the conditions may need supplementing to secure this trust (29).

Deliberative processes can be implemented in a way that offers deliberators and others an opportunity to identify and discuss potentially competing interpretations of the need for a technology, the problem it is trying to address, and the benefits and costs it produces. This aspect of deliberation, which is sometimes referred to as “social learning,” allows those involved to confront views different from their own, to reflect on their own assumptions and values, and to partially revise their views (37). While this kind of learning is considered an important feature of robust deliberative processes (25) and a way to

strengthen legitimacy, the extent to which this kind of interaction alters people's views is unclear (38) (39).

The procedural values specified by A4R capture some important social values: the publicity condition encompasses the concern for transparency, while the conditions of revision and enforcement establish accountability (34). Nevertheless, to meet the needs of decision makers, deliberative processes must not only be procedurally sound, they must also contain the appropriate content. Ethically justified decisions require debate and discussion about substantive values, values that are frequently captured by the criteria set out in a committee's value or decision framework.

Decision makers typically want evidence from three sources: so-called context-free evidence (medical effectiveness research), context-sensitive evidence (social science-oriented research), and colloquial evidence (expertise, realities, and views of stakeholders) (40). To be of service to policy makers, HTA-supported decisions must consider and incorporate a wide range of values (41). Deliberative processes allow these values and associated value judgements to be identified and openly discussed, thus making HTA more open, transparent, and trustworthy (26). Deliberative processes, it is argued (42), provide the best way to combine complex sets of evidence, perspectives, and values because these processes are able to:

- handle a wide range of evidential sources;
- combine evidence with rigour;
- accommodate the fact that experts often differ in their assessments of evidence;
- allow other parties to assess and critique what was done;
- provide a timely decision; and
- be practically implemented.

Key issues related to establishing and supporting these deliberative processes, and which will be explored in greater detail in subsequent sections, include the following:

- understanding contextual influences that lead to variation in implementing deliberative processes;
- promoting and supporting the transparency of deliberative processes;
- managing conflict of interest of participants and promoting impartiality;
- identifying conditions that promote good deliberation;
- supporting deliberators to use various kinds of evidence;
- understanding how to best involve various stakeholders throughout the process; and
- assessing the effectiveness and efficiency of deliberative processes.

Transparency of Deliberative Processes

As noted above, one of the benefits of deliberative processes is that they can promote and support transparency in decision making by allowing others to understand and critique what was done. Transparency of the entire deliberative process is important and desirable to promote accountability and legitimacy and allow stakeholders to judge whether the deliberative process and the resulting decision is fair (43). Typically, stakeholders want to be able to plan for how to participate in or contribute to the deliberation. They also look for a clear record of how their input was used and an explanation of the decision, including, if possible, the weight their concerns carried in the decision. Some HTA agencies provide detailed descriptions on their websites of their deliberative processes as well as extensive documentation, while others post timelines and updates on the course of the processes, posting draft scientific and committee reports for stakeholder or public comment, which is then taken into account, as well as final documentation. Documentation might also include transcripts or videos of the deliberation (see Annex 2). Transparency can be limited by contextual considerations, such as the safety of participants. For example, making public the identities of all parties involved in a particular decision may put individuals at risk of physical or other harm (Expert Informant).

2. Construction of the Deliberative Environment

The fairness and legitimacy of the output of the process is closely related to a public perception of impartiality of both the deliberative process and the deliberators themselves. It is also important that the people involved in the deliberation have the relevant expertise to handle their assigned tasks. How should the members of a deliberating committee be identified, selected, and supported to ensure these conditions are satisfied?

Identifying and Selecting Committee Members

Deliberative processes vary in how they identify and recruit committee members. For example, prospective members can be identified by response to publicly advertised positions via traditional news and social media, or through recommendation by individuals or stakeholder groups, including professional associations. The perception of independence can be threatened, however, if bodies to which the deliberative committee is responsible have too close an involvement or influence over the selection of committee members. The extent to which this independence is achieved may be influenced by the location of the decision-making body, for example, whether it is supported by an independent organization with specific responsibility for decisions or whether it is located in a central government department. For example, impartiality may be threatened if the Ministry of Health is thought to unduly influence committee membership or the committee's control over the shape of the recommendation or decision (Expert Informant).

Committee Composition and Clarity of Roles

Drug reimbursement committees often include members who are appointed based on their technical or professional expertise, such as medical doctors, pharmacists, health economists, or other health professionals with expertise in clinical pharmacology, health economics, clinical epidemiology, etc. (44). Some committees also include public or patient members or patient advisors on committees. The role of these patient and public members is not always well defined, but can involve ensuring the "patient voice" is heard during committee meetings, to offer a lay perspective, or ensure that public values are a part of the deliberation.

Diversity of viewpoints is essential to ensure that there is adequate diversity in knowledge and appropriate debate about how the results of an HTA ought to be interpreted and applied (37) (45). Some evidence indicates that including a diversity of value perspectives reduces the risk of unjustified and unquestioned assumptions (46). For example, a committee dominated by clinical experts may direct the focus of discussion and deliberation to the clinical evidence to the exclusion or diminution of other considerations, such as cost-effectiveness, caregiver autonomy, or equity. Interaction styles that promote the performance of recommendation committees (for example, greater social sensitivity or egalitarianism in speaking turns) may also be associated with certain social identities, such as female gender (46). Statistical diversity in committee composition, that is, having the relevant population diversity reflected among the committee members, may not be the appropriate type of diversity for committees (46). Rather, representative diversity, which requires that the diversity of social characteristics and viewpoints of the larger population are substantially present, but not necessarily reflected in the statistical sense, may better support legitimacy (46).

Given the importance of the diversity of perspectives and values to deliberation, many relevant characteristics may be considered when assembling committees, including age, gender, education, professional training, socio-economic position, theoretical orientation, and task-related skills, such as effective writing or speaking. Other attributes that might be examined include attitudes or viewpoints relevant to the functioning of reimbursement committees such as the degree of skepticism regarding the results of drug trials or strength of commitment to the public good (Expert Informant). This broadening of views may improve the quality of deliberation, provided all members are supported to clearly express their views with relevant reasons.

Committee Size and Frequency of Turnover

Committee size can influence how much discussion can take place, the quality of a decision, and the speed with which and the extent to which they reach agreement (47). Committees vary in size from fewer than 10 to just under 30, and more may be involved when external experts and stakeholders are involved in presenting and discussing the evidence prior to recommendation development or decision making. Those experienced in implementing and supporting deliberative processes in HTA have suggested that a committee size of 10 to 15 members may be optimal (Expert Informant).

Relatedly, the committee turnover frequency may influence committee decision making. Reimbursement deliberations are complex. If committee members change too frequently, active participation may be hindered by the need to learn the decision-making process and content, as well as to develop working relationships with committee members (Expert Informant). With fewer voices actively contributing, this imbalance may allow more experienced or vocal members to disproportionately influence the decisions or recommendations. Deliberative processes will usually specify a term length, but not always a maximum. It is unclear what the appropriate length of term on a deliberating committee should be and the terms of committee members examined for this background paper range from several years to more than a decade (Annex 2). Little research has been conducted on the above aspects of other similar decision-making groups that might be applied directly to the context of deliberative committees in HTA, though the experience and knowledge of committee members likely influences the shape of deliberation and its efficiency.

Conflicts of Interest

Conflicts of interest (COI) are a divergence between an individual's personal interests and his or her professional obligations to the extent that an impartial observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as direct financial, academic advancement, clinical revenue streams, personal experience, or community standing (48). Any perception that an individual's COI might compromise impartiality puts the legitimacy of a committee's decision at risk. The identification of COI applies to committee chairs, committee members, as well as invited and topic-specific members or experts, those invited to give evidence or advice to committees, and organizations that are formally represented on, or making written submissions to, committees (49). Given the prominence and influence of the committee chair (discussed in greater detail below), it is especially important to deliberative processes that the chair be seen to be free from any COIs.

Management of COI varies among agencies and can involve simply recording disclosed COIs (in cases of low risk) to recusal from voting or from all discussion regarding the technology (in cases of high risk). The action chosen to maintain impartiality should be balanced with the level of COI risk to minimize the impact of the loss of expertise on committee discussion and deliberation (50). Deliberative committee members usually make an initial declaration when applying for the role, and then update their declaration before each meeting to ensure there are no conflicts with the product that is the subject of deliberation (49). Processes also vary in who is made responsible for judging the degree of members' COI, and this task is often assigned to the chair or an executive, or other staff, of the organization that coordinates the committee. There seems to be general agreement that participants themselves should not be given the responsibility for managing COI.

Stakeholder Involvement

Those with an important stake in deliberative processes include patients and patient groups, clinicians, manufacturer representatives, and payers. There has been a rapidly growing interest in including patients, other stakeholders, and the broader public, in deliberative processes in ways that add value to the process and to the parties involved (51). Nevertheless, deliberative processes differ in the motivations for including stakeholders. In some countries, the participation of the citizenry (the public) in HTA is enshrined in legislation (52). In other systems, the participation of stakeholders is more

generally constructed to improve or strengthen aspects of the HTA process, such as the relevance of HTA questions, the transparency of HTA activities, and the adoption of evidence into policy and practice.

The foundations, methods, and processes for patient involvement in HTA have been comprehensively surveyed and provide a baseline for this aspect of deliberative processes (53). Several frameworks exist to describe when and how stakeholders, specifically patients (54) and the public (55), might be meaningfully involved across the deliberative process (input, throughput, and output). For example, the HTAi Patient and Citizen Involvement Interest Group developed guiding values and standards (56) for use by HTA agencies, patient groups, and others. The values, which some HTA organizations have adopted,³ are relevance (of patient knowledge to HTA), equity, fairness, legitimacy, and capacity building. Fairness refers to a “patient right” to participate in the process, while legitimacy speaks to the strengthening of transparency, accountability, and credibility of decisions through patient participation.

Some HTA organizations’ processes, for example, those of England’s National Institute for Health and Care Excellence (NICE) and The Netherlands’ Zorginstituut Nederland (ZIN), also seek to involve clinicians and manufacturers across the deliberative process. Regardless of the stakeholder group, communication about the purpose of the engagement and expectations from each group must be clear and the processes should be robust to avoid simply paying lip-service to various stakeholders (51).

3. Input

The information relevant to the deliberation is collected, prepared, and summarized in various ways (Annex 2). The way in which these activities are conducted can mitigate or increase the potential for bias within the deliberative process, and these activities can vary even among deliberative processes within the same organization.

Collecting Evidence and Information

The necessary input and the various aspects of analysis are often outlined in a process or submission guide and articulated with different levels of detail, which may affect the quality of the information for deliberation. Typically, evidence on either or both the clinical and cost-effectiveness of a technology is prepared by the manufacturer and critiqued by review teams internal to the HTA agency or by independent academic review groups (Annex 2). Processes also differ in the level of detail of submission requirements. Standard report templates and extensive guidance for manufacturers in the preparation of their submissions may or may not be provided. Manufacturers desire predictability of and consistency in process to facilitate efficient and robust submissions (Expert Informant). When manufacturers provide substantial pieces of the evidence, multiple opportunities for feedback are sometimes needed so that the appropriate level of detail for critique and deliberation is available (57).

As part of the “input” phase, a report of the critique may be made part of the deliberation materials. In addition, members of the internal or external review team may present a summary of the report and critique to the committee. Particular members of the committee, for example, those with expertise in clinical or health economics, may also be asked to critique the relevant evidence or other stakeholder inputs. This expert contribution may impact the level of engagement of the committee members and the level of discussion in the deliberation. These additional deliberative responsibilities may also affect the cognitive effort required by committee members and be a place where additional support is required.

³For example, CADTH (www.cadth.ca/cadth-framework-patient-engagement-health-technology-assessment) and SMC (www.scottishmedicines.org.uk/about-us/public-involvement/) refer to this document in the descriptions of their patient involvement activities.

Reducing Cognitive Effort

To facilitate deliberation by a committee, some processes use a dual committee structure in which a technical committee assesses the relevant scientific information and relevant contextual evidence to provide a preliminary recommendation. For example, the New Drug Committee of the Scottish Medicines Consortium (SMC) assesses the clinical and economic evidence presented by companies for each new medicine and this evidence is supplemented by testimonies from its network of clinical experts. Following this technical assessment to identify the strengths and weaknesses in the case presented, the New Drug Committee offers preliminary advice to the company, allowing them to provide feedback and address uncertainties before the SMC committee considers the medicine (58). The Netherlands' ZIN and Australia's Pharmaceutical Benefits Advisory Committee (PBAC) also have technical committees. These structures can also achieve efficiencies in process, a matter discussed below.

Mechanisms for Additional Input to Deliberation

Some HTA processes include mechanisms whereby uncertainties identified either in critique or through initial deliberation trigger additional input that is then fed back into the deliberation. This activity is distinct from the review and feedback provided to the manufacturer as part of the submission. The SMC's Patient and Clinician Engagement (PACE) meetings for medicines to treat end-of-life and/or rare conditions is one such mechanism (59). Following "do not recommend" advice from the New Drug Committee, the submitting pharmaceutical company can request a PACE meeting. The PACE meeting provides patient groups and clinicians with further opportunity to describe the added benefits of the medicine, from their perspectives, that may not be fully captured within the conventional clinical and economic assessment process. Added benefits might be the medicine's impact on the ability to work/function or convenience of treatment, reduction in time accompanied for visits, or the medicine's unique place in the treatment pathway.

Confidential Input

A key feature of transparency is handling information considered academic- or commercial-in-confidence. Deliberative processes vary in their management of this non-disclosable information, and redaction of text varies in committee presentations and scientific and committee reports. No consensus currently exists regarding the presentation of results and the importance of appropriate redaction (60). Some argue that it is possible to redact information sufficiently to preclude direct estimation of discounts, and maintain both transparency and confidentiality. Redactions may be related to the type of product under review, and some argue a lack of transparency in patient-important outcomes may restrict real-world value measurement (61). Are there ways that manufacturers might increase consistency in this important regard?

Stakeholder Involvement

Typical evidence for clinical effectiveness and safety does not regularly capture the outcomes most meaningful to patients and caregivers (62). To help address this gap, HTA agencies solicit input from patient groups to ensure patient perspectives inform deliberation and decision-making (63). HTA agency staff and other researchers now distinguish between "patient-based evidence" and "patient input" to mark the difference between information about patient perspectives and experiences generated by formal qualitative and quantitative research and information provided by patients and patient groups as part of the input process (for example, using templated submission forms) (64). A similar distinction between research and input can be made for information about and from other stakeholders such as clinical groups. The range of patient involvement activities varies, but they are alike enough to have allowed for the formulation of uniform guidance (65). Some HTA agencies gather information directly from stakeholders, for example, through focused interviews, but assessing this data requires an additional level of expertise and capacity (66). The amount of support and guidance provided to stakeholder groups, especially patient organizations, which often have very limited

resources, may vary the quality and amount of information provided. While deliberative processes vary in addressing the need for guidance and support for stakeholder engagement, established processes typically have staff dedicated to stakeholder (patient and public) activities for this purpose. Opportunities for stakeholders, especially patients, to interact directly with deliberative committee members also vary, though this interaction is generally seen as desirable by both stakeholders and committee members.

4. Throughput

For a committee's members to fully utilize their multiple perspectives and reach a decision adequately reflecting that plurality, the following conditions need to be present (67):

- The committee needs to be cognitively diverse, so different perspectives can shape the decision.
- Committee members need to think and act as independently as possible, so their unique perspectives are not unduly influenced by the views of others and remain available to all.
- Committee members need to operate without direction or dictation of the answer by a higher authority so their genuine views form the basis of the decision.
- The committee needs a workable structure to elicit the differing views, summarize them, and shape them into an outcome.

Whether the committee deliberation achieves these conditions is, in part, a result of the composition of the committee and its members' roles, discussed above. The cognitive and relational aspects of the throughput phase will also influence these conditions to varying degrees.

Cognitive Aspects

Time for Deliberation

Committees vary in the frequency and length of time devoted to a deliberation. Some committees meet monthly, others only a few times per year. As a result, the amount of time available for deliberating about a particular technology varies greatly from an entire day to a fraction of an hour. There appears to be no guidance on a reasonable minimum or maximum amount of time for effective deliberation.

Supporting Complex Decision-Making

The central task and challenge for a deliberative committee is to balance the different decision criteria to reach a final overall recommendation about the course of action. While a deliberation's main aim is a practical decision, to reach this decision it must first accommodate a complex conversational activity that can include inquiry, information seeking, and persuasion (3). Committees differ greatly in supporting these activities, and committee members may feel that they lack the requisite skill set or feel intimidated by others in the process (33). The following activities may help to support committee members and reduce these concerns:

- convening sub-committees to produce summary reports on estimations of effectiveness or cost-effectiveness;
- engaging stakeholder groups prior to the final deliberation to gather additional information and reduce uncertainty, as in the case of PBAC's Consumer Hearings (see Annex 2); and
- providing educational sessions to increase the knowledge of committee members, for example, to better understand novel therapies or quality of life measurement.

Use of Decision-Making Frameworks

The deliberative process must have a means to structure discussion about the facts, reasons, and principles involved in the decision. As noted earlier, we cannot avoid confronting disagreement regarding substantive values if we wish to arrive at ethically justified and broadly acceptable decisions (36). The extent to which the substantive factors committees may consider are formalized and

made explicit exists on a continuum of transparency, from mathematical decision-analysis oriented approaches such as multicriteria decision analysis (MCDA) to approaches that leave the factors largely implicit (68). Legislation may dictate that particular aspects be considered by the committee, for example, cost-effectiveness for PBAC (69) or that particular ethical principles guide the committee's decision, such as Sweden's ethical platform of needs, solidarity, and cost-effectiveness (70). There is, of course, a trade-off between the potential benefits of being more explicit (transparency, consistency, and replicability), and the costs of being held to strict standards of explicitness (limited scope to exercise judgement and make exceptions) (71). Organizations, like CADTH, that use a qualitative approach still attempt to make their deliberations explicit, systematic, and consistent through standard decision frameworks and committee processes (72). Nevertheless, some stakeholders may worry that relatively unstructured qualitative decision making processes can result in disproportionate time spent on minor issues (73).

Potential benefits of more explicit formal approaches are as follows:

- Committees can create an explicit list of the various factors considered important to ensure each is subject for discussion, for example, a checklist used by the chair and committee members.
- Formal approaches, such as MCDA, can help to decrease the cognitive effort required of committee members (74).
- Deliberation can become more predictable for participants and observers by forcing decision-makers to be explicit about objectives, decision-making criteria, and the relative importance of each.
- They can support formalized reporting on the reasoning behind the recommendation or decision.
- Fairness can be promoted by reducing the potential for the inappropriate influence on the decision by the interests of stakeholder groups.

There are potential drawbacks of more explicit formal approaches, however (73):

- The “flexibility” valued by appraisal committees when making difficult decisions may be reduced.
- Appraising evidence specifically in light of nuanced societal values and contextual considerations may be hindered.
- The collection and assessment of evidence for each criterion may become impractical because the number of conceivable criteria identified as relevant to a decision is very large.

In addition to explicit criteria, committee deliberation and decision making might also be assisted by the use of decision criteria or decision rules. Decision criteria (sometimes also characterized as “decision modifiers”) provide guidance about specific criteria the committee might consider, such as CADTH's articulation of what constitutes “significant unmet need” (72) and SMC's consideration of whether the drug treats a life-threatening condition (75). In contrast, decision rules describe limits on decision making, such as NICE's cost-effectiveness threshold of £20,000 per QALY or ICER's budget impact threshold of \$810 million per year (Annex 2). As noted at the outset, variation among decision criteria and their influence on decision making has been the subject of previous Policy Fora discussions and published reports to which readers have been directed.

Relational Aspects

Role of the Chair and Interaction of Committee Members

The dynamics among committee members as well as the personality and skills of the committee chair may also shape the deliberation and, possibly, its outcome. While deliberative processes vary in the responsibilities assigned, the chair often plays three roles: a moderator of the deliberation (managing the meeting agenda), a facilitator (fostering balanced discussion and exploring uncertainties or disagreements), and a content expert (contributing to understanding and interpreting the evidence). The ability of the chair to pay attention to dominant voices, elicit the opinions of those less vocal, and foster a community of respectful disagreement and resolution fundamentally shapes the productivity and successful deliberations of the committee.

The chair's professional background and attitude toward different types of evidence also influences the nature of committee discussion and the weight given to particular information in decision making (76). For example, a chair with health economics expertise may be particularly concerned about evidence for cost-effectiveness and may require committee members to provide very strong reasons to provide a positive recommendation when the technology does not appear to be cost-effective (Expert Informant).

Another key area of variability is the setting in which committee interaction takes place. Some organizations ask their committees to deliberate fully in public, some close meetings to all but the members of the deliberating committee and HTA staff, and others allow the public to register and observe the discussion of evidence, but have closed deliberations (Annex 2). Still others allow public observation of the complete committee activity, allowing any interested party to address the committee during deliberation or posting video of the deliberation on YouTube (77). While the willingness to have open deliberations may, in part, reflect a particular culture and history, the reason for keeping deliberations closed may be to provide an environment conducive to the unfettered exchange of views among deliberators.

Support of Deliberators

The broad range of evidence and other information considered by deliberating committees rarely allows any one individual to arrive possessing all the relevant skills and knowledge to fully participate in all aspects of the deliberation (4). This knowledge gap may be particularly true of members without any academic or scientific training, and has been noted as a special challenge for public members, who don't necessarily have the scientific or medical expertise to participate meaningfully in a detailed discussion (78). As mentioned earlier, there are various steps an agency might take to help support more equal participation in this regard.

Reaching a Decision

Deliberative processes vary in voting or consensus (unanimity) to reach a final decision. Some theorists argue that resolving disagreement by voting fails as an account of the legitimacy of a democratic procedure because it ignores the way in which reasons play a role in our deliberations about what is right (29). The importance of describing this reasoning is a main impetus for employing consensus (Expert Informant). Nevertheless, some models of voting explore reasons behind the individual voting and manage to achieve decisions that are, if not unanimous, very close to complete agreement (Expert Informant). The extent to which committee members' reasons are explored may be limited based on the belief that individual reasons should not be sought because members should not be convinced to change their positions after voting (Expert Informant). How committee members vote remains secret, and the reasons for a particular decision are not revealed and discussed (79). When votes are taken, the result is generally reported similarly to consensus models, and the tabulation of votes and reasons for dissenting from the majority are not reported. This lack of transparency can make it difficult for committees to give feedback on the reason for the decision either to the submitting company or to other stakeholders (Expert Informant).

Some argue that revealing these particulars might increase transparency, legitimacy and trust in the process (80). However, reporting dissenting opinions may threaten the group dynamics and the solidarity of the committee members, which are important to enable decisions to be reached in a timely manner.

Relatedly, there is debate about the moral authority of consensus within other similar committees. It has been argued that consensus should be a condition of ethical deliberation rather than its goal: committee members strive for a morally satisfactory result reached through a cooperative, open and rational method in which all have expressed confidence through their participation (81). The appropriate decision-making end (consensus or majority) may be best justified according to whether the committee makes a recommendation or a legally binding decision. Additionally, when

deliberations are public there may be a need to keep individual decisions confidential for the safety and protection of those involved in decision making (Expert Informant).

Stakeholder Involvement

While support for broader stakeholder involvement in deliberative processes grows, deliberative bodies find it complex to determine what constitutes meaningful and effective engagement. Similar challenges exist in determining what constitutes necessary stakeholder information and how this information is best conveyed for the purpose of deliberation (63). Reviews of patient involvement in HTA have highlighted the fact that, while there may be emerging best practices, these activities remain unique to the individual HTA organizations (53).

Stakeholder involvement in the throughput phase varies. Some mature processes do not include stakeholders in the deliberative process once input has been provided, while others offer opportunities for stakeholders to be an active part of deliberation, either by providing public comment or conveying patients' views to the committee and by asking questions. The feasibility of these various kinds of involvement may depend on organizational as well as cultural factors, including stakeholders' confidence to speak in front of health care professionals (Expert Informant).

It is becoming increasingly important to capture implementation considerations within deliberations and this provides another motivation for involving stakeholders. Some processes include these considerations as part of the information provided for deliberation, while others may include the payer perspective by having government or relevant health care executive staff represented on the committee. However, some within HTA view including payer representatives as a potential COI that threatens the perceived independence of the committee's decision (Expert Informant).

5. Output

Reporting the Decision

Timely and accurate reporting of a decision and its underlying reasoning is an opportunity to demonstrate the coherence and consistency of a policy decision (82). When deliberations are public, a decision may be conveyed almost immediately, while some processes provide notice of the decision several days or weeks afterward. Variation also exists among processes in the amount of detail provided in the reports of decision. Some processes report the committee's decision and little else, while others make public a record of all evidence reports and stakeholder input arising in deliberation.

Stakeholders have noted that the definition and language of HTA implies the consideration and synthesis of a diverse and complicated set of information and values in recommendation development and decision making; however, the reporting of recommendations or decisions frequently fails to reflect this diversity (Expert Informant). Given the complexity of most deliberations, it is likely that committees devote substantial space to deliberating on these aspects of the use and implementation of a technology and providing reasons for the decision. It seems reasonable that the output could also reflect the time and discussion devoted to aspects such as advice on implementation or on what might be needed to change a negative outcome into a positive outcome.

Supporting Policy Makers

Translating committee decisions for implementation by payers and other stakeholders is also desirable. While some deliberating processes may stop after reimbursement recommendations and leave price negotiations and eligibility criteria to other bodies, some HTA organizations are including this implementation support as the final piece of the deliberative process to help operationalize reimbursement recommendations for policy decisions. For example, the Institute for Clinical and Economic Review (ICER) conducts a "policy roundtable" immediately following voting, in which payer representatives, patients, and clinicians discuss the implication of the votes and deliberation for policy and practice (Annex 2) (83).

Stakeholder Involvement

If decisions are communicated accurately and in a timely fashion, there are two main opportunities for stakeholder involvement: gathering feedback on the deliberation's result and providing feedback on stakeholders' contributions to the deliberative process. Some processes make public the draft recommendations, which indicate the committee's decision and provide an opportunity for stakeholder consideration and comment (Annex 2). These comments are then used to help formulate a final recommendation. In about half of the countries with deliberative processes, the public is given the opportunity to comment on HTA recommendations; however, the extent to which stakeholder inputs influence the final decision is not known (84).

The second important output for stakeholders is feedback on the use of their input in the course of the deliberation and decision. This feedback can be informal, such as conversations between HTA agency staff and stakeholder groups. Other HTA organizations have developed more specific and formal feedback mechanisms, such as letters to patient groups describing specifically how the input was used (85). The PBAC Chair and Deputy Chair meet with consumer groups to explain in detail the committee's decision, including any nuances or additional context that might not have been apparent from any documentation, and describe particular issues that the committee members may have found challenging during deliberation (Expert Informant). This feedback allows stakeholders to better understand how their particular information can be of value and improves the transparency, and possibly the efficiency, of the process. Nevertheless, researchers investigating the contributions of stakeholder input find it challenging to determine if stakeholders have provided the right information, and there may be a misalignment between stakeholder expectations and the needs of the deliberating committee (63). Some stakeholders judge that they have been influential to decision making only if they can see that their input changed the decision. However, this undervalues such input, which may also helpfully reinforce (rather than change) a decision based on other factors.

6. Evaluating Deliberative Processes

HTA agencies conduct reviews of various aspects of deliberative processes as part of program-wide process evaluations (86). While there has been a flurry of activity focused on benchmarking public (87) and patient involvement processes (55) (88), and the impact of special enhancements (9) (89), little research has been conducted on what constitutes successful or effective deliberation within HTA (4). It remains unknown to what extent agencies or independent evaluators use the auditing criteria mentioned above or other proposed elements of successful priority setting (11).

Cross-country comparisons and evaluations tend to employ the conditions of A4R (31) to assess the quality of various reimbursement recommendation processes, identify areas for improvement, and compare assessments of the legitimacy of such processes (90). These conditions have also served as standards to assess the extent to which specific processes support publicity and relevance (91). Other researchers have combined the conditions of A4R and value frameworks such as INTEGRATE-HTA to assess the comprehensiveness of deliberative processes (12). Annex 3 provides two examples of evaluation frameworks for deliberative processes in HTA.

Likely the greatest challenge in evaluating deliberative processes, both conceptually and practically, is to develop measures that reflect the ultimate outcome of a deliberative process in HTA, such as overall better health for a given society or distributional justice in health care. The difficulties in measuring and making causal inferences about such distal outcomes may make their use in evaluation elusive (92). For this reason, some argue that evaluation should focus instead on process outcomes, such as consistency in decision making, greater credibility of the decision, lower resistance to or greater acceptability of decisions, and speedier implementation of or access to new technologies (92).

7. Fostering Efficiency

While general guidance about and best practices for deliberative processes are desirable, there are practical limitations in realizing "best practices" in particular political, legal, and economic contexts.

The quality or performance of HTA has been described by features such as relevance, applicability, validity, timeliness, and accessibility (93). High-quality HTA recommendations are resource intensive and time-consuming to generate (94); hence, HTA processes must balance resources, time, and quality in order to provide recommendations or decisions at the appropriate time for decision makers. Gains on one feature, for example, timeliness, may come at the expense of some other feature, such as the amount of stakeholder involvement. The need for timeliness can also influence the rigour of the technical reports (rapid reviews vs. comprehensive reviews) and this may in turn affect the deliberation by increasing uncertainty of various kinds (relevance, validity, accuracy, etc.). In these cases, decision makers may be willing to trade-off certainty to help ensure timeliness (95); other trade-offs are less well understood. Another practical limitation is cost and, among other things, the size of a deliberative committee, as well as its frequency and the length of the meeting, may be limited for this reason.

Given the practical limitations described above, identifying efficiencies in deliberative processes is highly desirable, but determining the necessary or most valuable components is challenging. There is concern that, for some highly effective or cost-effective technologies, deliberative committees might be employed unnecessarily. Technical subcommittee models, such as those used by ZIN, SMC, and PBAC, may help to reduce the unnecessary or inappropriate use of full deliberative committees that are more appropriately reserved for more difficult and complex reimbursement decisions. Hence, fast track or accelerated pathways are now proposed to engage deliberation more effectively and to further streamline deliberative processes (96). More robust interaction, like consumer hearings, may also be considered when committee uncertainty in the output is high.

IV. Key Policy Issues for the 2020 HTAi Global Policy Forum

Robust deliberative processes in HTA hold the promise of making difficult reimbursement decisions transparent, accountable, fair, and acceptable to all stakeholders. While best practices have yet to be identified, a set of principles can be articulated to guide the development of good practices. Some relevant questions that could be addressed to help achieve this goal include the following:

1. Construction of the Deliberative Environment

- a. Are there system-level indicators of political and health system readiness for establishing deliberative processes?
- b. Is there a minimum set of characteristics that compose an acceptable deliberative process for reimbursement decisions? What characteristics seem necessary? What seems less important?
- c. How should the appropriate degree of diversity of representation among deliberators be decided? What aspects of diversity seem most important and how are these justified?
- d. How might the structure of the deliberative process best ensure impartiality of committee interactions and the resulting judgements?

2. Input

- a. What types of evidence and information are needed to fulfill the principles motivating deliberative processes?
- b. What are the best methods for communicating key inputs in an accessible way for all participants in the deliberative process?
- c. What supports for stakeholders should be regularly provided at this stage? Are some kinds of involvement preferred over others?

3. Throughput

- a. Is there general guidance for chairs to moderate effectively and impartially? What supports exist for other committee members?
- b. How can transparency of the deliberation as well as other relevant HTA and committee activity be optimized?
- c. What considerations are important to ensure the approach to collective judgement (e.g., majority vote, consensus) is communicated clearly, including both agreement and disagreement?

4. Output

- a. What must be reported for a deliberative decision in HTA to be considered “well documented”?
- b. What is the standard of transparency that deliberative processes need to meet? Is there a minimum threshold? For example, is merely communicating the decision insufficient?
- c. What opportunities for stakeholder involvement should be regular features of the output phase of deliberation?
- d. Is some sort of review or context-setting process a minimum requirement once a judgement has been made?
- e. How should the link between judgement and downstream policy activity (e.g., price negotiation, eligibility and access, coverage) be communicated most effectively?

5. Evaluating Deliberative Processes

- a. What are the most appropriate indicators of a successful deliberative process? Consistency in decision making? Defensibility in terms of appeal? Implementable decisions?
- b. Is it possible to have cross-country standards for the conditions of A4R?

6. Finding Efficiencies

- a. What processes are most likely to improve efficiency without compromising the main principles motivating deliberative processes?

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VI. References

1. Kristensen FB, Husereau D, Huić M, Drummond M, Berger ML, Bond K, et al. Identifying the need for good practices in health technology assessment: Summary of the ISPOR HTA council working group report on good practices in HTA. *Value Health*. 2019;22(1):13-20.
2. Gauvin F-P. Factsheet. What is a deliberative process? Publication No. 1193. Ottawa, ON: The National Collaborating Centre for Healthy Public Policy, 2009.
3. Walton DN, Krabbe ECW. *Commitment in dialogue: Basic concepts of interpersonal reasoning*. Albany, NY: State University of New York Press; 1995.
4. Culyer AJ. Where are the limits of cost-effectiveness analysis and health technology assessment? *J Med Assoc Thai*. 2014;97 Suppl 5:S1-2.
5. Allen N, Walker SR, Liberti L, Salek S. Health technology assessment (HTA) case studies: Factors influencing divergent HTA reimbursement recommendations in Australia, Canada, England, and Scotland. *Value Health*. 2017;20(3):320-8.
6. Loge P, Delalande F, Reymond MC, Germain S. Factors influencing reimbursement of medical devices in France. *Int J Technol Assess Health Care*. 2015;31(6):399-406.
7. Akehurst RL, Abadie E, Renaudin N, Sarkozy F. Variation in health technology assessment and reimbursement processes in Europe. *Value Health*. 2017;20(1):67-76.
8. Maynou L, Cairns J. What is driving HTA decision-making? Evidence from cancer drug reimbursement decisions from 6 European countries. *Health Policy*. 2019;123(2):130-9.
9. Morrell L, Wordsworth S, Fu H, Rees S, Barker R. Cancer drug funding decisions in Scotland: Impact of new end-of-life, orphan and ultra-orphan processes. *BMC Health Services Research*. 2017;17(1):613.
10. Drummond M, Neumann P, Jönsson B, Luce B, Schwartz JS, Siebert U, et al. Can we reliably benchmark health technology assessment organizations? *Int J Technol Assess Health Care*. 2012;28(2):159-65.
11. Sibbald SL, Singer PA, Upshur R, Martin DK. Priority setting: What constitutes success? A conceptual framework for successful priority setting. *BMC Health Services Research*. 2009;9:1-12.
12. Oortwijn W, Determann D, Schiffers K, Tan SS, van der Tuin J. Towards integrated health technology assessment for improving decision making in selected countries. *Value Health*. 2017;20(8):1121-30.
13. Oortwijn W, Jansen M, Baltussen R. *Evidence-informed deliberative processes. A practical guide for HTA agencies to enhance legitimate decision making*. Nijmegen: Radboud University Medical Centre, Radboud Institute for Health Sciences, 2019.
14. Henshall C, Schuller T, HTAi Policy Forum. Health technology assessment, value-based decision making, and innovation. *Int J Technol Assess Health Care*. 2013;29(4):353-9.
15. Husereau D, Henshall C, Sampietro-Colom L, Thomas S. Changing health technology assessment paradigms? *Int J Technol Assess Health Care*. 2016;32(4):191-199.
16. Oortwijn W, Sampietro-Colom L, Habens F. Developments in value frameworks to inform the allocation of healthcare resources. *Int J Technol Assess Health Care*. 2017;33(2):323-9.
17. Canadian Agency for Drugs and Technologies in Health (CADTH). *Single drug technology assessment processes across health technology assessment organizations*. Ottawa, ON: CADTH, 2016 November (Environmental Scan; Issue 55).
18. Pichon-Riviere A, Soto NC, Augustovski FA, Garcia Marti S, Sampietro-Colom L. Health technology assessment for decision making in Latin America: Good practice principles. *Int J Technol Assess Health Care*. 2018;34(3):241-7.

19. García-Mochón L, Espín Balbino J, Olry de Labry Lima A, Caro Martinez A, Martin Ruiz E, Pérez Velasco R. HTA and decision-making processes in Central, Eastern, and South Eastern Europe: Results from a survey. *Health Policy*. 2019;123:182-90.
20. Oortwijn W, Jansen M, Baltussen R. Use of evidence-informed deliberative processes by health technology assessment agencies around the globe. *Int J Health Policy and Manag*. 2020;9(1):27-33.
21. Kafiriri LB, Baltussen R, Oortwijn, W. Implementing evidence-informed deliberative processes in health technology assessment: A low income country perspective. *Int J Technol Assess Health Care* (In press).
22. Asplin BR, Magid DJ, Rhodes KV, Solberg LI, Lurie N, Camargo CA, Jr. A conceptual model of emergency department crowding. *Ann Emerg Med*. 2003;42(2):173-80.
23. Hutton J, McGrath C, Frybourg JM, Tremblay M, Bramley-Harker E, Henshall C. Framework for describing and classifying decision-making systems using technology assessment to determine the reimbursement of health technologies (fourth hurdle systems). *Int J Technol Assess Health Care*. 2006;22:10-18.
24. Oxman AD, Lavis JN, Lewin S, Fretheim A. SUPPORT Tools for evidence-informed health Policymaking (STP) 1: What is evidence-informed policymaking? *J Health Research Policy Systems*. 2009;7(1):S1.
25. Jansen MP, Helderma JK, Boer B, Baltussen R. Fair processes for priority setting: Putting theory into practice. Comment on "Expanded HTA: Enhancing fairness and legitimacy". *Int J Health Policy Manag*. 2017;6(1):43-7.
26. Hofmann B, Cleemput I, Bond K, Kronen T, Droste S, Sacchini D, et al. Revealing and acknowledging value judgments in health technology assessment. *Int J Technol Assess Health Care*. 2014;30(6):579-86.
27. Abelson J, Forest P-G, Eyles J, Smith P, Martin E, Gauvin F-P. Deliberations about deliberative methods: Issues in the design and evaluation of public participation processes. *Soc Sci Med*. 2003;57(2):239-251.
28. Littlejohns P, Weale A, Chalkidou K, Faden R, Teerawattananon Y. Social values and health policy: A new international research programme. *J Health Organ Manag*. 2012;26(3):285-92.
29. Daniels N, Sabin JE. *Setting limits fairly. Can we learn to share medical resources?* New York: Oxford University Press; 2002.
30. Clark S, Weale A. Social values in health priority setting: A conceptual framework. *J Health Organ Manag*. 2012;26(3):293-316.
31. Mitton CR, McMahon M, Morgan S, Gibson J. Centralized drug review processes: Are they fair? *Soc Sci Med*. 2006;63(1):200-11.
32. McAfee N. Three models of democratic deliberation. *J Specul Philos*. 2004;18(1):44-59.
33. Gibson JL, Martin DK, Singer PA. Evidence, economics and ethics: Resource allocation in health services organizations. *Healthcare quarterly (Toronto, Ont)*. 2005;8(2):50-9.
34. Biron L, Rumbold B, Faden R. Social value judgments in healthcare: A philosophical critique. *J Health Organ Manag*. 2012;26(3):317-30.
35. Sandman L, Gustavsson E. Beyond the black box approach to ethics! Comment on "Expanded HTA: Enhancing fairness and legitimacy". *Int J Health Policy Manag*. 2016(6):393.
36. Friedman A. Beyond accountability for reasonableness. *Bioethics*. 2008;22(2):101-12.
37. Daniels N, Van Der Wilt GJ. Health technology assessment, deliberative process, and ethically contested issues. *Int J Technol Assess Health Care*. 2016;32(1-2):10-5.
38. Reckers-Droog V, Jansen M, Bijlmaekers L, Baltussen R, Brouwer W, van Exel J. How does participating in a deliberative citizens panel on healthcare priority setting influence the views of participants? *Health Policy*. 2019. [Epub ahead of print] <https://doi.org/10.1016/j.healthpol.2019.11.011>.

39. Stafinski T, Menon D, Yasui Y. Assessing the impact of deliberative processes on the views of participants: Is it 'in one ear and out the other'? *Health Expectations*. 2014;17(2):278-90.
40. Medical Advisory Secretariat. The Ontario Health Technology Advisory Committee (OHTAC) Decision-Making Process for the Development of Evidence-Based Recommendations Toronto, ON: Ontario Ministry of Health and Long-Term Care, 2010 September.
41. Shams L, Akbari Sari A, Yazdani S. Values in health policy - A concept analysis. *Int J Health Policy Manag*. 2016;5(11):623-30.
42. Douglas H. Weighing complex evidence in a democratic society. *Kennedy Inst Ethics J*. 2012;22(2):139-62.
43. Rosenberg-Yunger ZRS, Bayoumi AM. Transparency in Canadian public drug advisory committees. *Health Policy*. 2014;118(2):255-63.
44. Canadian Drug Expert Committee (CDEC) Terms of Reference. Ottawa, ON: Canadian Agency for Drugs and Technologies in Health (CADTH).
45. Sniderman AD, Furberg CD. Pluralism of viewpoints as the antidote to intellectual conflict of interest in guidelines. *J Clin Epidemiol*. 2012;65(7):705-7.
46. Steel D, Fazelpour S, Gillette K, Crewe B, Burgess M. Multiple diversity concepts and their ethical-epistemic implications. *Euro J Phil Sci*. 2018;8(3):761-80.
47. Cummings LL, Huber GP, Arendt E. Effects of group size and spatial arrangement on group decision making. *Acad Manag J*. 1974;17(3):460-75.
48. Schünemann HJ, Osborne M, Moss J, Manthous C, Wagner G, Sicilian L, et al. An official American Thoracic Society Policy statement: Managing conflict of interest in professional societies. *Am J Respir Crit Care Med*. 2009;180(6):564-80.
49. National Institute for Health and Care Excellence (NICE). Policy on declaring and managing interests for NICE advisory committees. London, UK: National Institute for Health and Care Excellence, 2019.
50. Jones DJ, Barkun AN, Lu Y, Enns R, Sinclair P, Martel M, et al. Conflicts of interest ethics: Silencing expertise in the development of international clinical practice guidelines. *Annals of Internal Medicine*. 2012;156(11):809-16.
51. Abelson J. Patient engagement in health technology assessment: What constitutes 'meaningful' and how we might get there. *J Health Serv Res Pol*. 2018;23(2):69-71.
52. Silva AS, Petramale CA, Rabelo RB, Santos VCC. Chapter 20. Brazil. In: Facey K, Ploug Hansen H, Single A, editors. *Patient involvement in health technology assessment*. Singapore: Adis; 2017. p. 243-6.
53. *Patient involvement in health technology assessment*. Facey K, Ploug Hansen H, Single A, editors. Singapore: Adis; 2017.
54. Facey K. Chapter 5. Developing the Mosaic of Patient Participation in HTA. In: Facey K, Ploug Hansen H, Single A, editors. *Patient involvement in health technology assessment*. Singapore: Adis; 2017. p. 51-66.
55. Abelson J, Wagner F, DeJean D, Boesveld S, Gauvin F-P, Bean S, et al. Public and patient involvement in health technology assessment: A framework for action. *Int J Technol Assess Health Care*. 2016;32(4):256-64.
56. HTAi Patient and Citizen Involvement Interest Group. Values and standards for patient involvement in HTA 2014 [Accessed September 2019]. Available from: <https://htai.org/interest-groups/pcig/values-and-standards/>.
57. Kaltenthaler EC, Dickson R, Boland A, Carroll C, Fitzgerald P, Papaioannou D, et al. A qualitative study of manufacturers' submissions to the UK NICE single technology appraisal process. *BMJ Open*. 2012;2:e000562.

58. Scottish Medicines Consortium (SMC). Who is involved in the Scottish Medicines Consortium? [cited 2019 September 2019]. Available from: <https://www.scottishmedicines.org.uk/about-us/who-we-are/>.
59. Scottish Medicines Consortium (SMC). Patient and Clinician Engagement (PACE) meetings overview. Glasgow: Scottish Medicines Consortium.
60. Bullement A, Taylor M, McMordie ST, Waters E, Hatswell AJ. NICE, in confidence: An assessment of redaction to obscure confidential information in single technology appraisals by the National Institute for Health and Care Excellence. *Pharmacoeconomics*. 2019; 7(11):1383-1390.
61. Soprovich A, El Kurdi S, Eurich DT. An analysis of redactions in Canada's Common Drug Review clinical review reports and how they relate to the patients' voice. *BMJ Open*. 2017;7(9):e015497-e.
62. Berglas S, Jutai L, MacKean G, Weeks L. Patients' perspectives can be integrated in health technology assessments: An exploratory analysis of CADTH Common Drug Review. *Res Involv Engagem*. 2016;2:21-.
63. Rozmovits L, Mai H, Chambers A, Chan K. What does meaningful look like? A qualitative study of patient engagement at the Pan-Canadian Oncology Drug Review: perspectives of reviewers and payers. *J Health Serv Res Pol*. 2018;23(2):72-9.
64. Staniszewska S, Werkö S. Patient-based evidence. In: Facey K, Single A, editors. *Patient involvement in health technology assessment*. Singapore: Springer Nature; 2017. p. 43-50.
65. HTAi Patient and Citizen Involvement Interest Group. Resources to involve patient groups and individual patients in HTA [Accessed September 2019]. Available from: <https://htai.org/interest-groups/pcig/resources/for-patients-and-patient-groups/>.
66. Health Quality Ontario. *Health Technology Assessments: Methods and Process Guide*. Version 2.0, March 2018. Toronto, ON: Health Quality Ontario, 2018.
67. Bennett MD, McIver Gibson J. *A field guide to good decisions: Values in action*. Westport, CT: Praeger Publishers; 2006.
68. Dobrow MJ, Chafe R, Burchett HED, Culyer A, Lemieux-Charles L. *Designing deliberative methods for combining heterogeneous evidence: A systematic review and qualitative scan*. Ottawa, ON: Canadian Foundation for Healthcare Improvement, 2012.
69. Pharmaceutical Benefits Advisory Committee. *Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee, Version 5.0*. Canberra, ACT: Commonwealth of Australia as represented by the Department of Health, 2016.
70. Sandman L. *The ethical platform for priority setting* Linköping, Sweden: Linköping University; [Accessed September 2019]. Available from: <https://liu.se/en/article/the-ethical-platform-for-priority-setting>.
71. Devlin N, Sussex J. *Incorporating multicriteria in HTA: Methods and process*. London: Office of Health Economics, 2011.
72. Canadian Agency for Drugs and Technologies in Health (CADTH). *Recommendation framework for CADTH Common Drug Review and pan-Canadian Oncology Drug Review Programs: Guidance for CADTH's Drug Expert Committees*. Ottawa, ON: CADTH, 2016.
73. van Til J, Schmitz S, Tringali M, Baltussen R. The potential and pitfalls of using multi-criteria decision analysis to support health technology assessment in Europe. *Value & Outcomes Spotlight*. 2016;5 July/August(4):31-3.
74. Baltussen R, Marsh K, Thokala P, Diaby V, Castro H, Cleemput I, et al. Multicriteria decision analysis to support health technology assessment agencies: Benefits, limitations, and the way forward. *Value Health*. 2019;22(11):1283-8.
75. SMC modifiers used in appraising new medicines: Scottish Medicines Consortium; June 2012. Available from: <https://www.scottishmedicines.org.uk/media/3565/modifiers.pdf>.

76. Weeks L, McPhail E, Berglas S, Mujoomdar M. Chapter 21. Canada. In: Facey K, Ploug Hansen H, Single A, editors. Patient involvement in health technology assessment. Singapore: Adis; 2017. p. 247-63.
77. Institute for Clinical and Economic Review (ICER). Midwest CEPAC: Voting Session (Part 1), Secondary Progressive Multiple Sclerosis 2019 [Accessed October 2019]. Available from: <https://www.youtube.com/watch?v=801n-7et2jk>.
78. Canadian Agency for Drugs and Technologies in Health (CADTH). CADTH patient input process review: Findings and recommendations. SECOR, 2012. Available from: https://www.cadth.ca/sites/default/files/pdf/2012_SECOR_Patient-Input-Review_e.pdf
79. Scottish Medicines Consortium (SMC). Review of access to new medicines. An independent review to assess the impact of the new approach introduced in 2014 by Scottish Medicines Consortium (SMC). Edinburgh: The Scottish Government, 2017 February.
80. Musher DM. Should committees that write guidelines and recommendations publish dissenting opinions? *Mayo Clin Proc.* 2016;91(5):634-9.
81. Moreno JD. Ethics by committee: The moral authority of consensus. *J Med Phil.* 1988;13(4):411-32.
82. Package advice in practice: Deliberations for arriving at a fair package. Amsterdam, The Netherlands: Zorginstituut Nederland, 2018. Available from: <https://english.zorginstituutnederland.nl/publications/reports/2018/09/05/package-advice-in-practice---deliberations-for-arriving-at-a-fair-package>
83. Institute for Clinical and Economic Review (ICER). ICER public comment guide. Boston, MA: Institute for Clinical and Economic Review, 2015.
84. Hill S, Velazquez A, Tay-Teo K, Metherell A. 2015 global survey on health technology assessment by national authorities. Main findings. Geneva: World Health Organization, EMP Policy Access and Use Unit; 2015.
85. Rader T, Bond K, editors. Patient input into the CADTH Common Drug Review: Is specific feedback useful to patient groups in preparing patient input submissions? [Poster] HTAi 2016 Annual Meeting; May 10-14, 2016; Tokyo, Japan.
86. National Institute for Health and Care Excellence (NICE). Changes we're making to health technology evaluation: National Institute for Health and Care Excellence (NICE); 2019 [Accessed September 2019]. Available from: <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation#who-is-involved>.
87. Weeks L, Polisena J, Scott AM, Holtorf A-P, Staniszewska S, Facey K. Evaluation of patient and public involvement initiatives in health technology assessment: A survey of international agencies. *Int J Technol Assess Health Care.* 2017;33(1):715-23.
88. Dipankui MT, Gagnon M-P, Desmarts M, Lègarè F, Piron F, Gagnon J, et al. Evaluation of patient involvement in a health technology assessment. *Int J Technol Assess Health Care.* 2015;31(3):166-70.
89. Barham L. Keeping up the PACE at the Scottish Medicines Consortium (SMC). *Pharmaphorum.* 2019 March 26, 2019. [Accessed September 2019]. Available from: <https://pharmaphorum.com/views-analysis-market-access/keeping-up-the-pace-at-the-scottish-medicines-consortium-smc/>
90. Cleemput I, Franken M, Koopmanschap M, le Polain M. European drug reimbursement systems' legitimacy: Five-country comparison and policy tool. *Int J Technol Assess Health Care.* 2012;28(4):358-66.
91. Charlton V. NICE and Fair? Health technology assessment policy under the UK's National Institute for Health and Care Excellence, 1999-2018. *Health Care Anal.* 2019.
92. Culyer A, Lomas J. Deliberative processes and evidence-informed decision making in health care—Do they work and how might we know. *Evid Policy.* 2006;2:357-71.

93. Garrido MV, Kristensen FB, Nielsen CP, Busse R. Health technology assessment and health policy-making in Europe: Current status, challenges and potential. Geneva: World Health Organization, 2008.
94. Petelos E. Striking a balance between accuracy and timeliness in HTA: An elusive task. *European J Public Health*. 2019;29(Supplement_4).
95. Wagner G, Nussbaumer-Streit B, Greimel J, Ciapponi A, Gartlehner G. Trading certainty for speed - how much uncertainty are decisionmakers and guideline developers willing to accept when using rapid reviews: an international survey. *BMC Medical Research Methodology*. 2017(1):1.
96. Webb M, Hellmund C. Is the NICE FTA process resulting in faster access to the most cost-effective therapies? London: Source Health Economics; 2019 May 29 [Accessed October 2019]. Available from: <https://www.source-he.com/single-post/2019/05/29/Is-the-NICE-FTA-process-resulting-in-faster-access-to-the-most-cost-effective-therapies>.

VII. Annexes

Annex 1. Selected Aspects of Deliberative Processes in HTA

The following selected aspects of deliberative reimbursement processes are provided to inform the Global Policy Forum discussion about principles for deliberative processes—they are not intended to be the main substance of group discussions. The list of aspects is not exhaustive and members are free to identify and discuss other potentially relevant aspects to help further reflection on minimum standards or best practices for deliberative processes in HTA.

I. Construction of the Deliberative Environment

Mandate and proximity to decision-making

- Is the status of the resulting judgement(s) of the deliberative process a recommendation (with specific conditions/criteria) to government ministry officials or is the committee's judgement equivalent to a ministerial decision (with specific conditions/criteria)?
- Is the deliberation dedicated to a particular class of technologies, for example, drugs, medical devices, surgical procedures, or does it handle a range of technologies?
- Is the purpose of the deliberation to produce guidance as close to market authorization as possible or to review an entire class of technologies to guide appropriate use?

Committee composition

- What is the range of perspectives (social, professional, cultural) needed for the committee to fulfill its mandate?
- How distinct should the committee roles be? For example, should there be designated clinical or health economics experts?
- Is there specific content expertise required? How are the appropriate qualifications determined?
- Is there a minimum expectation for attendance of committee meetings, for example, must not miss more than a certain number of consecutive meetings and must attend at least some specified proportion of the meetings annually?
- How are potential conflicts of interest identified and declared? Is a limit set on the degree of conflict allowed for potential members to participate?

Selection of deliberators

- How are deliberators identified and selected? Is there a public call via social and print media? Are they identified through professional associations? Or by Ministries of Health staff? Or by existing committee members?
- Are potential deliberators screened by agency staff, by Ministry staff, or someone else?

Remuneration

- Are committee members compensated for the costs incurred to prepare for and attend meetings? If so, what costs are covered? Are all members compensated at the same rate?

Training and experience

- Are deliberators given specific education or training related to the role they will fulfill?
- How is consistency in skill and ability among members supported?

Revision or appeals

- Is there a formal mechanism or process for identifying the need for revision?
- Is the appeal body within the agency hosting the deliberating committee or is it independent? Does the appeal body contain members of the deliberating committee?

Stakeholder involvement

- Are there committee roles specifically to represent stakeholder views (patients, healthcare professionals, industry, etc.)?
- Do these stakeholder members provide input to the deliberation only or also contribute to making the final judgement, for example, through voting?

Transparency

- Is there a complete description of deliberative process (who can provide information, when, at what time, when, and how is information used, etc.)? Is it available on a website or only in document form?
- Are the dates of upcoming and past deliberation meetings and meeting agendas public? How are they communicated?

II. Input**Evidence production**

- Is the evidence prepared by the submitting manufacturer, produced internally by HTA agency staff, or contracted to external academic partners or another external entity?
- Are subcommittees convened to make an initial determination on the scientific evidence that is then provided to the main committee?

Other inputs

- What information in addition to the scientific reports is needed to satisfy the aims and mandate of the deliberation?
- How is this additional information collected from stakeholders, for example, by one of the evidence producers or collected and submitted by stakeholders themselves?
- How much direction and support are stakeholders provided; for example, is there a template for submission and an accompanying guide?

Stakeholder involvement

- How are stakeholders made aware of the opportunity to participate or provide input? Registration and regular email, application process for individual meetings, targeted emails by HTA agency?
- How much engagement is required for input? For example, are stakeholders interviewed or are they provided with opportunities to supply additional information if gaps in the initial input are identified?
- Does the agency supporting the deliberative process have staff dedicated to assisting stakeholders in preparing their input, answering questions, etc.?
- Do stakeholders have an opportunity to interact directly with members of the deliberating committee prior to the deliberation?
- What financial or other resource supports are provided for providing input? Research expertise, feedback on input, etc.?

Transparency

- Is there a complete description of the input process specifying who can provide information, at what time, and what information is needed, etc.?
- Is any information kept confidential? Are the justification, criteria, and process for keeping information confidential well described and communicated to all stakeholders?

III. Throughput (cognitive and relational aspects of deliberation)

Structure for deliberation

- Is the approach to deliberation and the ways the kinds of information will be used made explicit? For example, by using MCDA or a detailed recommendation framework?
- Does the committee chair employ a checklist to ensure that consideration has been given to all relevant pieces of evidence and values?
- Are determinants of value or decision divided into “core” elements and those that are “broader” or “supplemental”?

Decision rules

- Are specific thresholds or rules used to guide particular decisions during the deliberation, for example, to determine clinical meaningfulness or cost-effectiveness? Are these decision rules explicitly described and applied?
- How are the relative importance of reasons indicated? Are explicit weights given to particular values?

Consistency in judgement

- Are previous decisions used as a guide for current decisions? Are precedents identified in advance of or during deliberation?

Duration of deliberation

- How much time is given to deliberation before a decision is made?
- Is there a period of “sober thought” and an opportunity to revisit or reconsider some aspects of the provisional decision before a final decision is made? How long is this period?

Presentation of evidence

- Who is responsible for presenting evidence? For example, are committee members given responsibility for summarizing and critiquing the reports provided to the committee or is this the responsibility of the staff or experts who produced the evidence?
- Is there a prespecified order of evidence/information? How is the order of presentation justified? For example, are discussion and presentation structured according to the report format (clinical effectiveness, cost effectiveness, etc.), a value framework, or some other way?
- Are slides used during the presentation of information or do committee members rely on written reports and oral presentations?

Role and influence of committee chair

- What are the responsibilities of the chair? Managing agenda, moderating discussion and deliberation, judging conflicts of interest?
- Does the chair receive assistance from, for example, a deputy or co-chair?

Committee dynamics

- How are the contributions of each perspective ensured? Does the chair or another committee member have responsibility for ensuring all members are heard?
- What practices are adopted to mitigate the influence of potential cognitive biases or other inappropriate influences on decision making, for example, emotional appeals?

Reaching a decision

- Who drafts the recommendation prior to voting? The chair, the committee members, HTA agency staff, or someone else?
- Are final decisions made by consensus or by majority vote? If a vote is taken, are committee members asked to share their reasons for their vote?
- If voting is used, are straw votes (or some other method) used prior to a final vote to help identify uncertainties or misunderstandings?

Stakeholder involvement

- Is stakeholder input provided by stakeholders themselves as part of deliberation or is it provided on their behalf by agency staff (or someone else)?
- If stakeholders participate in some aspect of deliberation (presentation/discussion of evidence), what materials are available in advance of meeting?
- What resource supports are provided to ensure genuine stakeholder participation, for example, coaching?
- Are draft scientific reports and recommendations made available for feedback by stakeholders or the broader public? Is opportunity for feedback restricted to those groups who initially provided input?

Openness

- How accessible is the deliberation? For example, is it closed to stakeholders, open to invited stakeholders, open to any stakeholders (though may be an application process to manage volume, etc.)?
- Is the meeting (audio or video) recorded? Is the recording publicly available?

IV. Output**Creating the record of decision document**

- Who writes the decision and documents its reasoning (facts, principles, reasons, etc.)? HTA agency staff member, committee chair, someone else?
- Is a draft recommendation written and then brought back to committee for discussion, revision, and finalization at a later meeting?

Documenting the decision

- Are draft documents of decisions made available for comment by stakeholders or broader public?
- If a majority vote or consensus, are dissenting opinions or entrenched opinions (difficult to move) recorded (internally) and reported (externally)?
- Are factors not part of the explicit framework for deliberation but that nonetheless influenced the decision described and accounted for?

Stakeholder involvement

- Do stakeholders receive feedback on how their information was incorporated into the overall report, deliberation, and decision making?
- Are there opportunities for stakeholders to speak with committee members or HTA agency staff about the results of the deliberation?

Transparency

- Are records made of the discussion and decision process? How detailed are they, for example, transcriptions or meeting summaries?
- Are all documents used throughout the process made available once the decision has been made, for example, scoping document, stakeholder feedback and responses, scientific reports, and stakeholder inputs?

Annex 2. Examples of Deliberative Processes in HTA

This Annex contains descriptions of deliberative processes for seven HTA organizations: CADTH, HAS, ICER, NICE, PBAC, SMC, and ZIN. Information on each process was compiled from various sources and was validated by staff of the respective agencies. The descriptions are not comprehensive and intended only to give HTAi Global Policy Forum meeting participants a sense of the variation in how the aspects explored in the background paper have been implemented in well-established deliberative processes. Accompanying links to related documents and webpages have also been provided to allow readers to gather further details.

Canadian Agency for Drugs and Technologies in Health (CADTH), Canada Canadian Drug Expert Committee (CDEC)	
Summary of Key Aspects of Process	
Deliberative Environment	<p>Mandate</p> <ul style="list-style-type: none"> • CDEC is an appointed, pan-Canadian expert advisory body that provides recommendations and advice to CADTH to inform Canada’s provincial, territorial, and federal publicly funded drug plans regarding formulary listings and optimal use of non-oncology drugs. • CDEC recommendations are non-binding on drug plans. <p>Committee (size, composition, and length of term, etc.)</p> <ul style="list-style-type: none"> • CDEC is composed of up to 14 core members. • CDEC members are technical experts who must hold qualifications as physicians, pharmacists, economists, or other professional health designation with expertise in one or more areas related to drug evaluation or utilization. • Two CDEC members are “public members” to bring a lay perspective. • Members are appointed for up to two two-year terms. • Members absent for more than three meetings per year forfeit membership. • Meeting quorum is 66% of members. <p>Role of Chair</p> <ul style="list-style-type: none"> • Committee has a Chair and Vice-Chair. • Appointed for up to two three-year terms. • Helps develop and manage meeting agenda and ensures members fulfil their responsibilities. • Ensures CDEC members adhere to the CADTH Code of Conduct and Conflict of Interest Guidelines. • Helps to select new committee members. • Reports on CDEC’s activities to the CADTH President. <p>Conflict of Interest</p> <ul style="list-style-type: none"> • Members disclose relevant COIs upon application and appointment. • Members and specialist experts disclose COI at start of every meeting. • Members’ expertise, experience, affiliations, and COI is posted on CADTH’s website.

Input	<ul style="list-style-type: none"> ▪ CADTH publicly posts and updates the milestones and timelines for its assessments and appraisals. ▪ Standard review consists of a review of clinical evidence provided by the manufacturer along with studies identified by CADTH staff, and an appraisal of the manufacturer-provided pharmacoeconomic evaluation by CADTH staff. ▪ Patient organizations provide input using a template. This input is summarized by CADTH staff. <p>Supporting Committees</p> <ul style="list-style-type: none"> ▪ CADTH can convene clinical panels to help identify unmet need, gaps in the evidence, and potential implementation challenges, issues in clinical management of patients, etc.
Throughput	<p>Openness</p> <ul style="list-style-type: none"> ▪ Committee meetings are closed, but researchers and other observers may attend meetings by permission of the Chair. ▪ In addition to CDEC members, the following people may attend a committee meeting: <ul style="list-style-type: none"> ▪ Health ministry officials appointed by participating jurisdictions may attend as observers and may contribute information on practical considerations as described in the decision-making framework, but do not have the right to vote. ▪ Representatives of the pCPA office may attend as observers and may ask clarification questions as needed, but do not have the right to vote. ▪ Relevant CADTH staff and external reviewers contracted by CADTH may actively participate in the presentation of information. The staff role includes provision of administrative and secretariat support. CADTH staff and external reviewers do not have the right to vote. ▪ External experts (including clinical specialists) attend CDEC meetings upon invitation from CADTH. These experts provide input regarding the drug under review, address questions from the committee, and may assist in establishing and refining reimbursement conditions. They do not vote on the recommendation. ▪ Manufacturers, patients, and others (except as previously described) are not entitled to attend any CDEC meeting, either to observe or to make an oral presentation or submission. ▪ Meeting dates are posted on the CADTH website.

	<p>Deliberation</p> <ul style="list-style-type: none"> ▪ Meetings are held up to 12 times per year, either in person or by teleconference. ▪ CDEC members act as “discussants” to provide a summary and critique of evidence to the committee on clinical benefit, cost-effectiveness, and patient input. ▪ The key elements supporting CDEC’s recommendations include the following information available at the time of the review: <ul style="list-style-type: none"> ▪ input from patients and caregivers; ▪ clinical and economic evidence; ▪ input from clinical experts; ▪ existing treatment options (e.g., what is or is not reimbursed and who is covered for reimbursement); ▪ the submitted price of the drug under review and the publicly available prices of comparators; ▪ the manufacturer’s requested reimbursement conditions (if any) and the evidence supporting those conditions; and ▪ implementation considerations at the jurisdictional level. ▪ Recommendation framework provides examples of other relevant factors the committee can consider in reaching a recommendation, including patient group input, therapeutic advantages and disadvantages, and cost. <p>Decision criteria and rules</p> <ul style="list-style-type: none"> ▪ Recommendations are informed by a publicly available framework. The framework has special allowances for situations where there is significant unmet medical need. <p>Final decision making</p> <ul style="list-style-type: none"> ▪ Majority vote (Chair votes only in the case of a split vote).
<p>Output</p>	<ul style="list-style-type: none"> ▪ Meeting minutes are not made public. ▪ Embargoed recommendations are shared in confidence with the manufacturer and drug plans. The manufacturer may file a request for reconsideration and/or the drug plans may file a request for clarification. ▪ Final recommendations, CADTH review reports, and patient input submissions are made available on the CADTH website.
<p>Stakeholder Involvement</p>	<ul style="list-style-type: none"> ▪ The CDR procedures detail how patients, clinicians, and public drug programs are engaged. ▪ Explicit framework for patient engagement activities. ▪ Dedicated patient engagement team to coordinate and assist with patient group input. ▪ Patient groups receive feedback letters describing contribution of input to deliberation.

Key Documents / Links	<ul style="list-style-type: none"> ▪ Canadian Drug Expert Committee: https://www.cadth.ca/collaboration-and-outreach/advisory-bodies/canadian-drug-expert-committee-cdec ▪ CDEC Terms of Reference: https://www.cadth.ca/sites/default/files/corporate/corp_committees/CDEC_TOR_e.pdf ▪ Common Drug Review Patient Input: https://www.cadth.ca/about-cadth/what-we-do/products-services/cdr/patient-input ▪ Conflict of Interest Guidelines for CADTH Expert Committee and Panel Members: https://www.cadth.ca/sites/default/files/corporate/CADTH_COI-Guidelines-Committ-Panels_e.pdf ▪ Framework for Patient Engagement: https://www.cadth.ca/cadth-framework-patient-engagement-health-technology-assessment ▪ Patient Input Template: https://www.cadth.ca/sites/default/files/pcodr/pCODR%27s%20Drug%20Review%20Process/pcodr-pad-input-on-drug-review.docx ▪ Procedure and Submission Guidelines for the CADTH Common Drug Review: https://www.cadth.ca/sites/default/files/cdr/process/Procedure_and_Guidelines_for_CADTH_CDR.pdf ▪ Process in Brief: https://www.cadth.ca/about-cadth/what-we-do/products-services/cdr/common-drug-review-submissions/process-in-brief ▪ Recommendation Framework: https://www.cadth.ca/media/cdr/templates/pre-sub-phase/CDR_pCODR_recommendations_framework.pdf ▪ Recommendation Report (example): https://www.cadth.ca/sites/default/files/cdr/complete/SR0597%20Olumiant%20-%20CDEC%20Final%20Recommendation_for%20posting.pdf
<p><i>CADTH: Canadian Agency for Drugs and Technologies in Health; CDEC: Canadian Drug Expert Committee; COI: conflict of interest; pCPA: pan-Canadian Pharmaceutical Alliance.</i></p>	

Haute Autorité de Santé (HAS), France Transparency Commission (TC)	
Summary of Key Aspects of Process	
Deliberative Environment	<p>Mandate</p> <ul style="list-style-type: none"> The TC is an independent scientific committee that appraises medicinal products and makes recommendations regarding the drugs to be reimbursement by the National Health Insurance Fund and/or hospital use. <p>Committee (size, composition, and length of term, etc.)</p> <ul style="list-style-type: none"> TC is comprised of expert practitioners (general practitioners, specialists, pharmacists), specialists in methodology and epidemiology, and members of patient and consumer associations. TC composed of 29 members with voting rights (includes 22 full members and 7 substitute members who vote in case of members' absence) appointed by HAS. Members are chosen primarily for their scientific expertise, while 2 are selected from among members of patient/consumer association. Six members have advisory roles and do not vote: Social Security Directorate, the Directorate-General for Health, the Directorate-General of Care Provision, Director General of the French National Agency for Medicines and Health Products Safety (ANSM), and directors of the National Health Insurance Fund and the Agricultural Social Insurance Mutual Benefit Fund (CCMSA). The TC members are appointed for a 3-year term, renewable twice. <p>Role of Chair</p> <ul style="list-style-type: none"> The TC has a chair and two vice-chairs. Chair and vice-chairs are responsible for: <ul style="list-style-type: none"> Setting the meeting schedule and agenda and facilitating deliberations. Appointing one or more rapporteurs from among TC members. Making decisions regarding the use of external experts, working groups, which stakeholders will be heard, process for examining dossiers submitted by sponsors, how to address sponsor's comments on draft recommendations, whether new scientific or regulatory information requires review, and the suspension of the evaluation of a dossier. <p>Conflict of Interest</p> <ul style="list-style-type: none"> Members must make a public declaration of interests when taking office. Public declarations of interest are posted to a public, searchable website. A specific committee chaired by a deontologist rigorously assesses declarations of interest. Members with a COI for a given submission must refrain from any participation in the file and cannot be present during deliberations or vote.
Input	<ul style="list-style-type: none"> For each submission, the SEM designates a project manager who collects and analyzes all available data and summarizes information in a "preparatory document" circulated to the members before the meeting. This evaluation is presented alongside the file submitted by the sponsor. The TC may request a report from one or more external experts, which is circulated to the members. One or more members may be appointed rapporteurs for a file, who presents information on the condition, drug, and therapeutic alternatives, an analysis of the available data, and makes a recommendation to the TC members. A working group may be assembled and present its findings at the meeting.

	<p>Supporting Committees</p> <ul style="list-style-type: none"> Secretariat, which provides administrative and scientific support and coordinates work of TC, is provided by Drug Evaluation Service (SEM).
Throughput	<p>Openness</p> <ul style="list-style-type: none"> Agendas are publicly posted on a website. In addition to TC members, the following people may attend meetings, as necessary: <ul style="list-style-type: none"> Members of the Medical, Economics and Public Health Assessment division (DEMESP) Members of the college of HAS, as well as the general director External experts may be invited to present their report and answer questions. Any other person, with permission of the chair. <p>Deliberation</p> <ul style="list-style-type: none"> The TC meets every 2 weeks. At least 14 voting members must be present for deliberations to be valid. Members who are absent or have a COI are replaced with a substitute. <p>Decision criteria and rules</p> <ul style="list-style-type: none"> Drugs are evaluated based on their actual clinical benefit (SMR) and likely clinical added value compared to treatment alternatives (ASMR). The process of medicinal product assessment follows the guidelines of the “Transparency Committee Doctrine.” <p>Final decision making</p> <ul style="list-style-type: none"> Majority vote. Any voting member may request to explain their vote.
Output	<ul style="list-style-type: none"> A draft recommendation based on the results of the vote is written by the project. The sponsor is given 10 days to respond with written comments or request for hearing. The final recommendation is sent to the government ministers, the sponsor, and published on the HAS website. Meeting minutes are published on HAS website and include the date of session, list of members present and excused, list of external individuals present, COIs, topics examined, claims of the sponsor, content of deliberations, and result of voting. The TC reports on its work in the HAS annual activity report, including information on the recommendations made in that year.
Stakeholder Involvement	<ul style="list-style-type: none"> Stakeholder input may be requested. Patients and user associations are invited to make a submission using an input template. The sponsor may provide written comments or request a hearing within 10 days from receipt of the draft recommendation.

Key Documents / Links	<p>Agendas: https://www.has-sante.fr/jcms/prd1_2989758/fr/la-has-agenda-des-commissions</p> <p>Contribution of Patient and User Associations to Evaluations of Medicines and Medical Devices: https://www.has-sante.fr/upload/docs/application/pdf/2016-11/contribution_asso_patients_methode_v3.pdf</p> <p>Pricing and Reimbursement of Drugs and HTA Policies in France: https://www.has-sante.fr/upload/docs/application/pdf/2014-03/pricing_reimbursement_of_drugs_and_hta_policies_in_france.pdf</p> <p>Public Declarations of Interest: https://www.has-sante.fr/jcms/c_2051506/en/ethics-transparency-and-management-of-conflicts-of-interest</p> <p>Rules of Procedure of the Transparency Committee: https://www.has-sante.fr/upload/docs/application/pdf/2013-01/ri_ct_version_07112012_vf_f.pdf</p> <p>Transparency Committee: https://www.has-sante.fr/jcms/c_1729421/en/transparency-committee</p> <p>Transparency Committee Doctrine: https://www.has-sante.fr/upload/docs/application/pdf/2019-07/doctrine_de_la_commission_de_la_transparence_-_version_anglaise.pdf</p> <p>Assessment of Conflicts of Interest: https://www.has-sante.fr/jcms/c_522970/fr/prevention-et-gestion-des-conflits-d-interets#toc_1_2</p>
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Institute for Clinical and Economic Review (ICER), USA Comparative Effectiveness Public Advisory Councils (CEPACs); California Technology Assessment Forum (CTAF)	
Summary of Key Aspects of Process	
Deliberative Environment	<p>Mandate</p> <ul style="list-style-type: none"> • ICER is an independent research organization and its reports are produced with funding exclusively from non-profit foundations. • ICER convenes independent councils to discuss the report and votes on the evidence and analyses. • Recommendations are not binding. <p>Committee (size, composition, and length of term, etc.)</p> <ul style="list-style-type: none"> • Each council has 15-20 members. • Members are recruited and selected based on clinical and policy expertise specific to technology assessment and do not represent their organization, specialty society, or any particular interest. • Members do not have a fixed length of term. <p>Role of Chair</p> <ul style="list-style-type: none"> • Manages meeting agenda. • May represent/speak on behalf of the entire council. • Policy discussion is moderated by non-committee member (President of ICER). <p>Conflict of Interest</p> <ul style="list-style-type: none"> • Voting CEPAC members cannot work for any public or private insurer or manufacturer and are subject to strict guidelines on financial conflicts of interest. • All members must disclose financial or personal ties to any private healthcare organization. • Any member with a potential COI, including personal experience with a particular technology or condition, or a political consideration, must excuse themselves from voting. • All participants in ICER meetings, including individuals giving oral public comment, are required to complete a COI disclosure form prior to the meeting and to verbally restate any potential conflicts. • ICER discloses when it assesses treatments produced by companies that are part of its membership program.
Input	<ul style="list-style-type: none"> • ICER Review Team prepares evidence reports on comparative effectiveness and cost-effectiveness. • Each report is developed with input from multiple sources, including patient groups, clinical experts, and manufacturers. • Information from open input, public comment, and stakeholder calls inform scope of review, and interpretation of evidence, as well as give insights into the “other benefits or disadvantages” of a treatment or intervention that factor heavily into the value assessment. • Evidence reports are structured according to a value framework.

Throughput	<p>Openness</p> <ul style="list-style-type: none"> ▪ Meeting schedule is posted on ICER website. ▪ Full assessment and deliberation are open to the public (registration required). ▪ Each report is the subject of a public meeting, during which an independent expert committee (CTAF or CEPAC) discusses the report and votes on questions related to clinical evidence, other potential benefits of treatment, and long-term value for money at current prices. <p>Deliberation</p> <ul style="list-style-type: none"> ▪ Councils meet three-four times per year for a full day. ▪ Each meeting structure follows a standard format: evidence review, public comment, council voting, and policy roundtable. ▪ Committee deliberation is structured according to ICER’s value framework. ▪ Consideration of “other benefits” separate from effectiveness and long-term value for money at current prices. ▪ ICER explicitly delineates seven potential “other benefits or disadvantages” and five “contextual considerations.” <p>Decision criteria and rules</p> <ul style="list-style-type: none"> ▪ Value-based price benchmarks of \$100,000 to \$150,000 per QALY. ▪ Potential budget impact threshold (for 2019) of \$819 million per year. <p>Final decision making</p> <ul style="list-style-type: none"> ▪ Majority vote. ▪ Voting questions crafted in advance of meeting. ▪ Voting is moderated by ICER President.
Output	<ul style="list-style-type: none"> ▪ Draft evidence report is posted to ICER’s website for public comment. ▪ All meeting materials made available on ICER website. ▪ Recordings of entire committee meeting (evidence presentation, deliberation, and voting) posted on YouTube.
Stakeholder Involvement	<ul style="list-style-type: none"> ▪ Stakeholders give open input on a new topic, comment on the draft scoping document, comment on the draft evidence report, can register to make oral comments at the meeting, and can attend a public meeting. ▪ Input provided online using template (no word limit). ▪ Specific materials have been developed to describe importance of and opportunities for patients to be involved. ▪ ICER also involves stakeholders through key informant interviews.

Key Documents / Links	<p>ICER Review Process: https://icer-review.org/about/ https://icer-review.org/about/support/ https://icer-review.org/about/independent-voting-committees/</p> <p>Process for ICER Public Programs: https://icer-review.org/program-process/</p> <p>A Guide to ICER's Methods for Health Technology Assessment: http://icer-review.org/wp-content/uploads/2018/08/ICER-HTA-Guide_082018.pdf</p> <p>Conflict of Interest Policy: https://icer-review.org/methodology/rules-that-apply-to-icer/coi-voting-bodies/</p> <p>Conflict of Interest Policy for Participants of Public Meetings: https://icer-review.org/coi-meeting-participant/</p> <p>New England CEPAC: Evidence Presentation, Spinal Muscular Atrophy: https://www.youtube.com/watch?v=ZDYDF71pNxo</p> <p>ICER New England CEPAC: Voting Session, Spinal Muscular Atrophy: https://www.youtube.com/watch?v=w9rs57p9B_U&feature=youtu.be</p> <p>Independent Voting Committees: https://icer-review.org/about/independent-voting-committees/</p> <p>New England CEPAC Members and Meeting Schedule: https://icer-review.org/programs/new-england-cepac/</p> <p>Overview of the ICER Value Assessment Framework and Update for 2017-2019: https://icer-review.org/wp-content/uploads/2017/06/ICER-value-assessment-framework-Updated-050818.pdf</p> <p>Patient Open Input Questionnaire: https://icer-review.org/patient-guide-to-open-input/</p> <p>Patient Participation Guide: https://icer-review.org/patient-participation-guide/#open-input</p> <p>Public Comment Guide: https://icer-review.org/wp-content/uploads/2016/02/ICER-Public-Comment-Guide.pdf</p> <p>The New England CEPAC deliberation and vote on evidence presented in ICER's report on treatments for Duchenne muscular dystrophy (example). https://icer-review.org/topic/duchenne-muscular-dystrophy/</p>
<p><i>COI: conflict of interest; CEPAC: Comparative Effectiveness Public Advisory Council; CTAF: California Technology Assessment Forum; ICER: Institute for Clinical and Economic Review.</i></p>	

National Institute for Health and Care Excellence (NICE), England Technology Appraisal Committee (TAC)	
Summary of Key Aspects of Process	
Deliberative Environment	<p>Mandate</p> <ul style="list-style-type: none"> • NICE provides guidance to the English National Health Service (NHS) on the clinical and cost-effectiveness of selected new and established technologies for single indications. • NHS is legally obliged to fund and resource medicines and treatments recommended by NICE's technology appraisals within three months of a NICE recommendation. <p>Committee (size, composition, and length of term, etc.)</p> <ul style="list-style-type: none"> • NICE aims to set up diverse committees that reflect society and encourages applications from under-represented groups to achieve this aim. • Members include individuals from the NHS, patient and carer organizations, academia, and the pharmaceutical and medical devices industries. • Committees typically have 24 members including a Chair (number varies based on needs of committee) • Members appointed for a three-year term, renewable up to maximum of 10 years. <p>Role of Chair</p> <ul style="list-style-type: none"> • Manages meeting agenda, facilitates discussion, leads deliberation, and builds consensus. <p>Conflict of Interest</p> <ul style="list-style-type: none"> • Members declare COIs when applying for committee and declare any COIs that arise during involvement with the committee before each meeting. • COI may lead to partial or complete exclusion from deliberation and recommendation development.
Input	<ul style="list-style-type: none"> • Appraisal is based on a review of clinical and economic evidence, mainly provided by the manufacturer, supported by testimonies from patients, healthcare professionals, and commissioners. • Consultees, commentators, and the public are invited to comment on appraisal consultation documents. <p>Supporting Committees</p> <ul style="list-style-type: none"> • A lead team, selected from the committee members at the start of each appraisal, helps the NICE team prepare a technical report to brief the committee. • A technical team (committee chair/vice chair, the associate director, the technical adviser, and the technical lead) considers the manufacturer evidence submission. • An Expert Review Group (external academic organization) critiques the evidence submissions from other consultees and commentators to advise the appraisal committee in its discussion of the evidence.

Throughput	<p>Openness</p> <ul style="list-style-type: none"> ▪ Committee meeting dates are posted on NICE website. ▪ Technology appraisal meetings are open to the public and press to observe, but may be closed if commercial-in-confidence information is being presented. Members of the public can apply to attend the meeting, but are excused for the actual deliberation and recommendation. <p>Deliberation</p> <ul style="list-style-type: none"> ▪ Lead or technical team presents the appraisal topic to the committee. ▪ Lay lead's role is to include the patient evidence. ▪ Committee is legislated to consider balance between the benefits and costs, degree of need, and desirability of promoting innovation. ▪ NICE appraisal committees must comply with the Social Value Judgments document. <p>Decision criteria and rules</p> <ul style="list-style-type: none"> ▪ Below an ICER of £20,000 per QALY, a positive recommendation is based on the cost-effectiveness. ▪ Above an ICER of £20,000 per QALY, a positive recommendation will take account of other factors such as degree of uncertainty, innovation, and accuracy of quality of life measurement. ▪ Above a most plausible ICER of £30,000 per QALY gained, the committee will need to identify an increasingly stronger case for supporting the technology. <p>Final decision making</p> <ul style="list-style-type: none"> ▪ Consensus, but vote may be taken in specific circumstances.
Output	<ul style="list-style-type: none"> ▪ Final appraisal documents are posted on NICE website. ▪ Committee minutes are posted on NICE website. ▪ NICE provides explicit explanation of the principles guiding the recommendation documents, including the key issues that have been debated and the rationale for the committee's conclusions. ▪ Committee members complete mandatory survey to describe the relevance and contribution of patient input to their deliberation.
Stakeholder Involvement	<ul style="list-style-type: none"> ▪ Specific public and patient involvement policy. ▪ Consultees (including national groups representing patients and carers, health professional associations, manufacturers of the technology in development, the Department of Health, and primary care trusts) can submit evidence during the appraisal and comment on the appraisal documents. ▪ Dedicated Public Involvement Programme staff to support patient and public involvement. ▪ Patient groups and professional groups provide input using specific submission templates.

Key Documents / Links	<ul style="list-style-type: none"> ▪ Appointments to Advisory Bodies Policy and Procedure: https://www.nice.org.uk/Media/Default/About/Who-we-are/Policies-and-procedures/recruitment-selection-to-advisory-bodies-policy.pdf ▪ Technology Appraisals Committee Terms of Reference: https://www.nice.org.uk/Media/Default/Get-involved/Meetings-In-Public/Technology-appraisal-committee/TAC-terms-of-reference-standing-orders.pdf ▪ Guide to the Methods of Technology Appraisal 2013: https://www.nice.org.uk/process/pmg9/chapter/the-appraisal-of-the-evidence-and-structured-decision-making ▪ Guide to the Processes of Technology Appraisal: https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/technology-appraisal-processes-guide-apr-2018.pdf ▪ Meetings in Public: https://www.nice.org.uk/Get-Involved/Meetings-in-Public#advisory-committee ▪ NICE Guidance and Advice List: https://www.nice.org.uk/guidance/published?type=ta ▪ Patient and Public Involvement Policy: https://www.nice.org.uk/about/nice-communities/nice-and-the-public/public-involvement/public-involvement-programme/patient-public-involvement-policy ▪ Policy on Declaring and Managing Interests: https://www.nice.org.uk/Media/Default/About/Who-we-are/Policies-and-procedures/declaration-of-interests-policy.pdf ▪ Social Value Judgments: https://www.nice.org.uk/Media/Default/About/what-we-do/Research-and-development/Social-Value-Judgements-principles-for-the-development-of-NICE-guidance.pdf ▪ Technology Appraisal Committee: https://www.nice.org.uk/get-involved/meetings-in-public/technology-appraisal-committee ▪ Technology Appraisal Guidance: https://www.nice.org.uk/About/What-we-do/Our-Programmes/NICE-guidance/NICE-technology-appraisal-guidance
<p><i>COI: conflict of interest; ICER: incremental cost-effectiveness ratio; NHS: National Health Service; NICE: National Institute for Health and Care Excellence; QALY: quality-adjusted life year; TAC: Technology Appraisal Committee.</i></p>	

Pharmaceutical Benefits Scheme, Australia Pharmaceutical Benefits Advisory Committee (PBAC)	
Summary of Key Aspects of Process	
Deliberative Environment	<p>Mandate</p> <ul style="list-style-type: none"> • PBAC is an independent expert body appointed by the Australian Government to recommend new medicines to the Minister for listing on the Pharmaceutical Benefits Scheme. • No new medicine can be listed unless the committee makes a positive recommendation. <p>Committee (size, composition, and length of term, etc.)</p> <ul style="list-style-type: none"> • 20 members including doctors, health professionals, health economists and consumer representatives. <p>Role of Chair</p> <ul style="list-style-type: none"> • Committee has chair and deputy chair. • Determines degree of member COIs and consequences. • Holds formal meetings with applicants to develop an understanding of the reasons for the PBAC outcomes (post PBAC). • Chairs PBAC Executive (Members are Chairs of Drug Utilization Sub Committee [DUSC], Economics Sub Committee [ESC], and Deputy Chair) • Liaises with Department of Health and Minister's Office, as required. • Provides representation at external meetings. <p>Conflict of Interest</p> <ul style="list-style-type: none"> • Members make an annual declaration of all COIs and declare COIs specific to the agenda of each meeting. • Consumer comments/submissions also have a section for declaring a COI when making a submission to the PBAC.
Input	<ul style="list-style-type: none"> • Review consists of clinical and economic evaluation conducted by manufacturer. • PBAC can request a Stakeholder Meeting (including manufacturer, patient groups, and medical specialists) to gather additional information. The information discussed and outcome of the meetings are reported publicly through "Stakeholder meeting summary statements." <p>Supporting Committees</p> <ul style="list-style-type: none"> • PBAC has two sub-committees to assist with analysis and advice: DUSC and ESC.

Throughput	<p>Openness</p> <ul style="list-style-type: none"> ▪ Meetings are closed. ▪ Agendas of upcoming PBAC meeting are posted and public comment invited. ▪ Medicine StatusTracker about to be launched on Department Website. <p>Deliberation</p> <ul style="list-style-type: none"> ▪ Meets three times per year. Deliberations often last less than one hour. ▪ PBAC must consider clinical effectiveness and cost-effectiveness (value for money) compared with other treatments including non-medical treatments. <p>Decision criteria and rules</p> <ul style="list-style-type: none"> ▪ As described under the National Health Act 1953 and PBAC Guidelines. ▪ Five key considerations: health gain, cost-effectiveness, patient affordability, predicted use in practice and financial implications for the PBS, and predicted use in practice and financial implications for the health budget. ▪ Other factors considered include equity, severity, and availability of alternatives. <p>Final decision making</p> <ul style="list-style-type: none"> ▪ Usually by consensus, but a vote may be taken when final direction or sequence of actions is under debate.
Output	<ul style="list-style-type: none"> ▪ Three sets of documents associated with PBAC deliberations are publicly released: PBAC agendas, PBAC Outcomes, and Public Summary Documents. ▪ PBAC Outcomes document the committee’s decision and summarize its reasons. ▪ Public Summary Documents are produced by the government and industry to provide information pertaining to PBAC recommendations, so that stakeholders (doctors, health professionals, patients, etc.) are aware of the rationale for specific PBAC recommendations. ▪ Committee Chair and Deputy Chair are available to speak directly with patient groups and other stakeholders to explain PBAC decisions, their context, and the deliberation.
Stakeholder Involvement	<ul style="list-style-type: none"> ▪ Consumer comments (patient, carer, member of the public, health professional, or member of a consumer interest group) on submissions are solicited via web-based template. ▪ Consumer hearings are by formal invitation only, to identified patient groups who have previously provided written submission. The meetings are set for the day before a PBAC meeting, involve only the patient representatives and Committee, and have set criteria and framework. ▪ Stakeholder meetings are by invitation only. The meetings can occur at any time and for a variety of purposes (they are not necessarily focused on a single item or specific meeting agenda). ▪ Clinical expert consultations may occur by invitation. ▪ Manufacturers may request a hearing, which is ten minutes in the PBAC meeting at the relevant agenda item. ▪ Direct correspondence to PBAC.

Key Documents / Links	<p>Consumer Hearing Outcome Statements (example): http://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2018-07/consumer-hearing-outcome-statement-07-2018.pdf</p> <p>Consumer Input: http://www.pbs.gov.au/info/industry/listing/procedure-guidance/6-consideration-submissions/6-7-consumer-input</p> <p>Guidelines for Initiation of Stakeholder Meetings: http://www.pbs.gov.au/info/industry/listing/elements/initiation-of-stakeholder-meetings</p> <p>Guidelines for Preparing a Submission to PBAC: https://pbac.pbs.gov.au/content/information/files/pbac-guidelines-version-5.pdf</p> <p>Managing Conflicts of Interest: http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/coi</p> <p>National Health Act 1953: https://www.legislation.gov.au/Details/C2017C00250</p> <p>Online Comments Template: https://www1.health.gov.au/internet/main/publishing.nsf/Content/PBAC_online_submission_form</p> <p>PBAC Meeting Agendas: http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/agenda</p> <p>PBAC Membership: http://www.pbs.gov.au/info/industry/listing/participants/pbac</p> <p>PBAC Submission Guidelines (including key factors influencing PBAC decisions): https://pbac.pbs.gov.au/information/about-the-guidelines.html</p> <p>Processes Leading to PBAC Consideration: https://www.transparency.gov.au/annual-reports/department-health/2018/appendix-2-processes-leading-pbac-consideration-annual-report</p>
<p><i>COI: conflict of interest; DUSC: Drug Utilisation Sub Committee; ESC: Economics Sub Committee; PBAC: Pharmaceutical Benefits Advisory Committee; PBS: Pharmaceutical Benefits Scheme.</i></p>	

Scottish Medicines Consortium (SMC), Scotland https://www.scottishmedicines.org.uk/about-us/	
Summary of Key Aspects of Process	
Deliberative Environment	<p>Mandate</p> <ul style="list-style-type: none"> SMC is part of Healthcare Improvement Scotland and reviews and provides advice on new medicines to the National Health Service (NHS) Boards. SMC must accept a medicine for use before it can be prescribed routinely in Scotland. When SMC accepts a medicine, NHS boards are expected to make the drug, or an equivalent, available. <p>Committee (size, composition, and length of term, etc.)</p> <ul style="list-style-type: none"> Currently 28 members (up to 40) composed of clinicians, NHS Board representatives, the pharmaceutical industry, and the public. All members have a vote. All members give up some of their own time to take part. <p>Role of Chair</p> <ul style="list-style-type: none"> Committee has a Chair and a Vice-Chair. Manages agenda, moderates discussion, and coordinates voting. <p>Conflict of Interest</p> <ul style="list-style-type: none"> Committee members declare COIs on appointment and annually. Members also declare relevant COIs at each meeting.
Input	<ul style="list-style-type: none"> Manufacturer submits evidence on clinical and cost-effectiveness. Patient groups make submissions. <p>Supporting Committees</p> <ul style="list-style-type: none"> New Drug Committee (NDC) meets monthly to assess the clinical and economic evidence presented by manufacturer and provides recommendation to SMC. If the NDC recommendation is negative, the manufacturer can request a Patient and Clinician Engagement (PACE) meeting to gather further information from patient groups and clinicians on the added value of a medicine. Patient Access Scheme Assessment Group (PASAG) reviews PAS submitted by company prior to SMC meeting.
Throughput	<p>Openness</p> <ul style="list-style-type: none"> SMC meetings are open to the public, but can be closed when commercial-in-confidence information needs to be discussed. <p>Deliberation</p> <ul style="list-style-type: none"> Meets once per month. SMC can take a broader view than the strictly evidence-based approach of NDC and can use “modifiers” when deliberating on NDC summary. SMC considers benefits compared to other available treatments, quality of life, administration of medicine, cost savings, and additional GP/other healthcare professional visits as required. <p>Decision criteria and rules</p> <ul style="list-style-type: none"> Not described. <p>Final decision making</p> <ul style="list-style-type: none"> Majority vote (voting is confidential).
Output	<ul style="list-style-type: none"> Summary of advice is published on SMC website along with report of detailed advice.

Stakeholder Involvement	<ul style="list-style-type: none"> ▪ Dedicated Public Involvement staff to coordinate and assist patients and caregivers with submissions and PACE contribution. ▪ Patient groups must register prior to making a submission. ▪ Patient group submissions are made using a template with word limits.
Key Documents / Links	<p>A Guide to the Scottish Medicines Consortium: https://www.scottishmedicines.org.uk/media/3574/20180712-a-guide-to-the-scottish-medicines-consortium.pdf</p> <p>Code of Practice on Declarations of Interest: https://www.scottishmedicines.org.uk/media/4749/code-of-practice-for-declarations-of-interest.pdf</p> <p>Decision Explained (example): https://www.scottishmedicines.org.uk/media/4325/decision-explained-erenumab-aimovig-final.pdf</p> <p>Making a Submission: Patient Groups: https://www.scottishmedicines.org.uk/making-a-submission/</p> <p>Patient Group Submission Form: https://www.scottishmedicines.org.uk/media/3267/patient-group-submission-example-adhd.pdf</p> <p>Scottish Medicines Consortium: What we do: https://www.scottishmedicines.org.uk/about-us/</p> <p>Working with SMC – A Guide for Manufacturers: https://www.scottishmedicines.org.uk/media/3020/working-with-smc.pdf</p>
<p><i>COI: conflict of interest; GP: general practitioner; NDC: New Drug Committee; NHS: National Health Service; PACE: Patient and Clinician Engagement; PAS: Patient Access Scheme; PASAG: Patient Access Scheme Assessment Group; SMC: Scottish Medicines Consortium.</i></p>	

Zorginstituut Nederland (ZIN), The Netherlands	
Summary of Key Aspects of Process	
Deliberative Environment	<p>Mandate</p> <ul style="list-style-type: none"> ▪ ZIN provides reimbursement recommendation (not legally binding) to Health Minister. The task of ZIN as package manager is defined in the Health Insurance Act. ▪ Other than pharmacy supplied medicines, care is automatically included in the package if its effectiveness has been proven. ▪ Insured Package Advisory Committee (ACP) advises on societal aspects and is the recommendation developing body. ACP gives recommendation to Executive Board of ZIN. <p>Committee (size, composition, and length of term, etc.)</p> <ul style="list-style-type: none"> ▪ Nine committee members on ACP. ▪ Committee make-up is not prespecified and is structured to meet the mandate of ACP, which is to make a decision from societal point of view taking into account a broad range of arguments. ▪ Currently includes a sociologist, an expert on medical ethics with political experience, an expert on medical ethics in public health, a macroeconomist, an expert in patients' perspectives, two physicians, an HTA expert, and an expert on long-term health. Committee members do not represent groups or associations. ▪ Each member is appointed for a four-year term and can renew for one additional term (eight years maximum). <p>Role of Chair</p> <ul style="list-style-type: none"> ▪ Manages agenda, facilitates deliberation, drafts advice, and promotes consensus among members. ▪ Chair has academic qualifications, but is not a healthcare specialist. Instead, the Chair has experience chairing committees for decision-making in the field of societal issues. <p>Conflict of Interest</p> <ul style="list-style-type: none"> ▪ Conflicts are declared and stated on website for each committee member. ▪ Committee members declare any conflicts at the start of each public meeting. ▪ Seriousness of COI is determined by chair.
Input	<ul style="list-style-type: none"> ▪ ACP receives a report from the Scientific Advisory Board (WAR) on aspects of the assessment (e.g., effect parameters relevant to reimbursement). ▪ ZIN members present scientific evidence to ACP. ▪ Stakeholder meetings may be convened to gather additional input at this stage. <p>Supporting Committees</p> <ul style="list-style-type: none"> ▪ WAR composed of external experts who are authoritative in their field. WAR advises on scientific evaluation; appraises the effectiveness, cost-effectiveness, and burden of disease; and draws a conclusion about value of effect, size of effect, and probability of effect.

Throughput	<p>Openness</p> <ul style="list-style-type: none"> ▪ ACP deliberation is open to anyone. ▪ Any party may have up to five minutes to address the committee. <p>Deliberation</p> <ul style="list-style-type: none"> ▪ Meetings range from two to three hours on Friday mornings. Meeting duration varies according to the agenda. ▪ ACP cannot disagree with the conclusions reached by WAR and instead assesses their significance in context of other arguments. <p>Decision criteria and rules</p> <ul style="list-style-type: none"> ▪ ACP uses deliberative MCDA to present and discuss evidence and arguments systematically. ▪ Criteria for basic care package determined by Health Insurance Act and Long-term Care Act: necessity (severity and out-of-pocket expense), effectiveness, cost-effectiveness, and feasibility. The evaluation framework is reviewed by the Ministry of Health, Welfare and Sport (VWS) Permanent Parliamentary Committee. ▪ ACP publicly debates the direction and strength of relevant identified arguments. ▪ Deliberation on the criteria is supported by additional documents such as the Assessment of Established Medical Science and Medical Practice. ▪ Deliberation on cost-effectiveness guided by cost-effectiveness reference values of 10,000-80,000 Euro/QALY, depending on disease burden. ▪ Arguments not directly related to package criteria are allowed for consideration, for example, societal considerations, such as ability to pay and likelihood of benefit based on being included in package (e.g., smoking cessation and birth control). ▪ Package criteria considered simultaneously, if effectiveness is demonstrated. <p>Final decision making</p> <ul style="list-style-type: none"> ▪ Consensus, but vote can be taken if consensus not achieved. ▪ Final recommendation is drafted by Chair of ACP during public meeting.
Output	<ul style="list-style-type: none"> ▪ Draft advice is made public. ▪ Reports provide details on arguments considered by the committee and the reasoning used in reaching decisions. ▪ ZIN planned to structure its reports based on the domains of the EUnetHTA Core Model, but this model has not been fully implemented. ZIN is currently reconsidering the structure of assessment reports.
Stakeholder Involvement	<ul style="list-style-type: none"> ▪ ZIN collects feedback on advice from all stakeholders (patients' associations, manufacturers, care providers, healthcare professionals, and healthcare insurers) prior to drafting advice. ▪ Stakeholders can attend deliberation, ask questions, respond to draft documents and have discussions with the ACP. They can attend the meetings and speak for five minutes or send letters. However, there is no space for extensive discussions with the ACP during meetings. ▪ Efforts are being made to include citizens' perspectives.

Key Documents / Links	<ul style="list-style-type: none"> ▪ Assessment of Established Medical Science and Medical Practice (Cost-Effectiveness in Practice): https://english.zorginstituutnederland.nl/publications/reports/2019/04/23/assessment-of-established-medical-science-and-medical-practice%E2%80%99---a-technical-modification ▪ Advice to the Board of Directors (Dutch): https://www.zorginstituutnederland.nl/over-ons/commissies/adviescommissie-pakket-acp/adviezen-aan-de-raad-van-bestuur ▪ Package Advice in Practice – Deliberations for arriving at a fair package: https://english.zorginstituutnederland.nl/publications/reports/2018/09/05/package-advice-in-practice---deliberations-for-arriving-at-a-fair-package ▪ Note: Additional explanatory documents are being produced to better describe how ACP does its work and to help stakeholders understand the categories of arguments that are of interest to the ACP.
<p><i>ACP: Package Advisory Committee; COI: conflict of interest; HTA: health technology assessment; MCDA: multiple criteria decision analysis; QALY: quality adjusted life year; WAR: Scientific Advisory Board; ZIN: Zorginstituut Nederland.</i></p>	

Annex 3. Selected Evaluation Frameworks for Deliberative Processes

Table 1. Conceptual framework for successful priority setting (11)

Element	Features
Process	
Stakeholder engagement	<ul style="list-style-type: none"> HTA organization involves stakeholders (decision-makers, clinicians, patients, and public) effectively in the decision-making process. Identifying and engaging stakeholders should involve multiple techniques such as round tables, meetings, open forums, etc. Engagement is indicated by stakeholder satisfaction regarding level of involvement in the process.
Use of explicit process	<ul style="list-style-type: none"> Process is transparent to stakeholders as well as decision-makers. Transparency means knowing who is making the decision, as well as how and why. Communication needs to be well coordinated, systematic and well planned, and information communicated using multiple means.
Information management	<ul style="list-style-type: none"> Information made available to decision-makers during decision-making process. Relevant information includes health outcomes data, health economic data, community needs assessment, current policies, and clinician and patient experiences.
Consideration of values and context	<ul style="list-style-type: none"> Mission, vision, and values of the organization should guide decision-making. Decisions should be based on reasons grounded on clear value choices, and those reasons should be explicit. Possible review of previous decisions, including decisions of other organizations with similar mandates.
Revision and appeal mechanism	<ul style="list-style-type: none"> Formal mechanism for reviewing decisions and addressing disagreements. Purpose of revision and appeal is to (1) improve the quality of decisions by revising in light of new information and (2) operationalize ethical concept of responsiveness.
Outcome	
Improved stakeholder understanding	<ul style="list-style-type: none"> Stakeholders have more than a basic knowledge of the process; they gain insight into goals of the process, rationale for priority setting generally and for specific decisions. Stakeholder acceptance and confidence in process should increase alongside understanding.
Shifted priorities and/or reallocated resources	<ul style="list-style-type: none"> Changes in allocation of budgets across portfolios, changes in utilization of physical resources, etc. Efforts not resulting in change may be perceived by stakeholders as a procedural waste of time or legitimization of a predetermined outcome.
Improved decision-making quality	<ul style="list-style-type: none"> Appropriate use of available evidence, consistency of reasoning, alignment with goals of process and compliance with prescribed process. Other indicators of improved quality are more efficient decision-making, more consistent decision-making, and increased compliance (“buy in”).
Stakeholder acceptance and satisfaction	<ul style="list-style-type: none"> Increase in satisfaction of all stakeholder groups that continues to increase over decision cycles. Acceptance indicated by continuing willingness to participate in process as well as degree of contentment with process. Stakeholders may not always agree with the process outcomes, but should be able to accept the decisions.
Positive externalities	<ul style="list-style-type: none"> Indicators include positive media coverage (contributing to public dialogue, social learning, and improved decision-making), peer emulation, health sector recognition (e.g., by other health care organizations), and changes in policies, legislation or practice.

Table 2. Judgement criteria to assess the level of comprehensiveness of the HTA process (12)

Phase	Definition Used
Assessment	
Multiple stakeholders are involved in scoping an HTA	Defining the objective and research questions of the HTA by a systematic exploration of relevant aspects from multiple perspectives (e.g., patients, informal caregivers, health professionals, and decision-makers).
Context is taken into account	Context is defined as the conditions and circumstances relevant to the application of an intervention, for example, setting (e.g., hospital) and sociocultural aspects (knowledge, beliefs, conceptions, customs, institutions, and any other capabilities and habits acquired by a group that may influence uptake).
Implementation issues are taken into account	Implementation issues refer to the actual delivery of a health technology to policy measures and processes or to funding mechanisms (e.g., tax incentives and reimbursement schemes) that directly concern or indirectly influence the implementation of the health technology.
Patient-related factors that influence treatment outcomes are taken into account.	Patients may respond differently to treatments in terms of nature and magnitude of a beneficial effect, the time of onset, and adverse outcomes. It is therefore important to identify factors that influence treatment effects to determine which treatments work best for whom, thereby making medicine more personalized and achieving better valuation of research outcomes.
Patient preferences with regard to treatment outcomes are taken into account	Patients often have different views on the relative importance of certain treatment outcomes. It is widely acknowledged that understanding patients' preferences is important for an accurate assessment and appraisal of the impact of a disease on the patient's quality of life.
Evidence reports and standardized evidence summaries for each assessment aspect are produced	Production of evidence reports and standardized evidence summaries for each assessment aspect (e.g., reports on economics and on ethical aspects).
Stakeholder consultation is performed to review the evidence reports	Relevant stakeholders are asked to review the assessment results (i.e., evidence reports/summaries) with regard to plausibility. The result is an assessment report that includes a critical evaluation of the available evidence and uncertainty, and an overview of where evidence is missing.
Appraisal/decision-making phase	
The appraisal/decision-making process is explicit	The criteria and methods used in the process are well-described in a publicly available document.
The appraisal/decision-making process is transparent	The procedures are well-described in a publicly available document, the process is open to the public (e.g., public hearings), and the meeting agenda and notes are publicly available.
The decisions and the underlying reasons are made public	The final decisions and the underlying reasons are publicly available via the web site of the Ministry of Health and announcement in the official journal.
Stakeholder involvement is clearly specified and open to the public	The stakeholders involved (also those in addition to a specific committee for appraisal/HTA decision-making) are open to the public via the HTA agency web site and notes on the meetings provided in the public domain), and the ways in which stakeholder views are considered are well-described in a publicly available document.
Mechanisms for appeal, to propose revisions, and to receive a reasoned response are in place	Mechanism(s) for appeal, to propose revisions, and to receive a reasoned response are operational and described in a publicly available document.
Systems are in place to monitor and evaluate the process	Systems to monitor and evaluate the process are operational and described in a publicly available document.