

## Guide to Constructing Principles for Deliberative Processes in HTA

A key goal of the 2020 Global Policy Forum meeting is to reach agreement on a defined set of principles that could be used as standards for well-functioning deliberative processes in HTA. Other meeting outcomes are a summary of the meeting discussion, a manuscript describing the main themes discussed and any resulting recommendations to be submitted for publication in IJTAHC, and a panel session on deliberative processes to be given at the HTAi 2020 Annual Meeting in Beijing. The draft principles would identify those aspects of deliberative processes about which GPF members have a shared understanding and commitment. A shared commitment to these principles would enhance the integrity, legitimacy, fairness, and trustworthiness of deliberative processes and their resulting recommendations or decisions.

The construction of the principles will involve large and small group discussion and live polling of attendees to gather feedback on the acceptability and priority of suggested principles and actions. Accordingly, while the principles and actions should be clearly described, they need be neither fully polished nor exhaustive. The Chair and Scientific Secretary will revise and refine the principles and actions based on the meeting discussion and subsequent feedback.

In forming principles, please try to keep the following things in mind:

- principles should act as “value themes” that identify important characteristics of a deliberative process and capture what is common to the required actions associated with them;
- actions refer to the particular activities that agencies and stakeholders can take in order to support a principle;
- for ease of understanding and discussion, the descriptions of actions should avoid jargon and contain a single idea; and
- collectively, actions specify what might be required to fully “live up to” a principle, subject to practical limitations (described below). Failure to support the principle only occurs when no single supporting action is taken by an agency.

### Practical Limits on Deliberative Processes

Important characteristics of deliberative processes, such as timeliness, have been suggested as principles themselves. We believe such characteristics are best seen as aspects of management that influence the implementation of a deliberative process rather than as principles; these aspects of management will vary according to the social, cultural, political, economic, and legislative context within which a deliberative process occurs. For example, what timeliness means will vary according to the decision-making demand by a particular government or set of payers, and this demand will restrict the range and duration of actions that might be taken to support other principles such as inclusivity or transparency. Other examples of practical limitations include:

- Breadth of responsibility for the HTA body (based on its legislative authorization or mandate)
- Cost
- Technical specifications (e.g., facilities for those not able to attend in person)
- Translational aspects of reviews (e.g., language, lay-friendly summaries)

These practical limits are important to identify because they influence what actions might be achievable within local contexts and identify the standard that should be used to judge the success of a particular deliberative process. We will keep a running list of these kinds of considerations and encourage members to identify others that may be important for agencies and others to keep aware of.

## Polling Sessions

This section provides a description of the polling activities that will be used during the Global Policy Forum meeting to select a manageable number of broadly applicable draft principles and associated actions for deliberative processes in HTA. Decisions about which principles will be carried forward for discussion will proceed according to majority vote. In the cases where voting is close, the principles will be retained for the next round. There is some flexibility here as the polling is meant to help encourage discussion rather than to arrive at a prespecified number of draft principles. Keep in mind that we are building a foundation for future work.

To identify and develop relevant draft principles, Policy Forum participants will use a number of polling sessions spread out over the meeting. The polling will be done live using the application Sli.do, which can be accessed using your browser on your mobile device or laptop here: [www.sli.do](http://www.sli.do). After logging into Sli.do, Policy Forum participants will warm-up with a test question and then proceed to the first polling exercise.

**Sunday polling.** Following the test question, participants will rate the importance of the 11 draft principles provided in the guide. The goal is to identify a set of draft principles that could be feasibly applied in all HTA settings, both mature and emerging. The principles will be rated on 4-point scale: 1 (not important), 2 (somewhat important), 3 (important), 4 (very important). There is no neutral score.

The polling results will be shared briefly with participants before moving to the Keynote presentation. In addition, members will be asked to suggest additional principles using the app. The Sli.do app will be left open for Policy Forum participants to make suggestions until the end of the plenary discussion.

**Monday polling.** The results of Sunday's polling will be shared again and any interesting differences in opinion may be explored. Any additional principles will also be presented and discussed. The set of draft principles we will be working from in the breakouts is a starting point--groups should feel free to add or delete as they see fit. Once a list of principles is agreed on, the group effort should be focused on describing the actions that support each principle. Again, because the local contexts will vary, the group should flesh out the minimum set of actions that will make the principle realizable in any setting.

In the polling session, participants will be asked to rate each of the actions that have been developed for the principles on a 3-point scale: 1 (important for any process), 2 (important, but may be more important for some processes than others), 3 (not very important/difficult to implement for many agencies).

**Tuesday polling.** The final list of principles and associated actions will be presented to Global Policy Forum participants. If the list of principles is still believed to be too long, we will ask Forum participants to rank the importance of the principles relative to one another to help shorten the list using Survey Monkey (a web link will be sent to participants Tuesday morning, if needed).

The final list of principles and actions will be presented to Forum members and discussed to gather comments for final revisions of the statement of principles and actions. We will also be compiling a list of implementation issues that will influence the extent to which certain actions may be taken.

## Potential Principles for Deliberative Processes in HTA

The following draft principles of transparency, impartiality, inclusivity, consistency, and reviewability and the actions that are required to support these principles in practice are intended to provide a point of departure for reflection and discussion by Global Policy Forum members. Discussion of both the principles and the actions is important because people may have a shared understanding about a value, but may disagree about what that value requires in terms of action.

Other principles and actions may be identified or proposed and the draft principles and actions listed

below may be modified in whole or in part. The relative importance of the various principles and the extent to which each can be satisfied in practice will depend on and vary according to limits imposed by the context within which a deliberative process is established.

## Transparency

Deliberative processes and the basis for a recommendation and/or decision should be explicitly described and made publicly available. The more broadly this description is made available (for example, not only to those participating in the process) the more support this principle has. The transparency of a deliberative process should be both “forward” and “backward-looking.”

What this requires:

Prior to a deliberation, there should be sufficient information and guidance available about the deliberative process to allow any interested person to understand:

- the nature of the decision that needs to be made;
- who will be involved in making the decision as (a) a member of the deliberative body, and (b) as a participant in the process;
- how the decision will be made, for example, by consensus or majority vote;
- the factors or aspects of value that will be deliberated upon (and perhaps what is not considered) and the types of information that might influence the decision; and
- opportunities to anticipate and plan for how stakeholders might contribute to the decision-making process.

Following a deliberation, information and guidance should be sufficient to allow any interested person to understand:

- what the decision was;
- who the decision affects;
- what the facts and reasons were for the decision (to the extent possible);
- what were the options or alternatives considered;
- who was involved in making the decision as (a) a member of the deliberative body and (b) as a participant in the process;
- how the decision was made, e.g. by consensus or majority vote;
- the level of internal agreement with the decision or particular issues with which the deliberators struggled; and
- the reason for not discussing available information that could have been pertinent to the deliberation.

Different communication materials may need to be developed to ensure that this understanding is possible for the broadest range of people, that is, people with different levels of education, technical training, etc.

## Impartiality

The deliberative process used for each decision, and those involved in it, should be perceived to be free from undue influences, both internal (for example, from the agency supporting the HTA process) and external (vested interests in any given topic), and independent.

What this requires:

- a clear statement of the primary interest in need of protection and with which other interests may conflict;
- a clear description of how direct and indirect conflicts of interests of those involved in deliberation

are identified and managed, including definitions of quantitative thresholds for certain types of conflict and management actions (for example, no voting);

- a clear record of the identification and management of conflicts of interest for every deliberation;
- all participating stakeholders declare their conflicts of interest using an agreed and standard format; and
- the chair or facilitator of the deliberation manages the discussion to achieve equitable input and prevent the undue influence of their own opinions in moving the group toward a maximally informed decision.

## Inclusivity

HTA deliberations are best informed when all involved work together. The right perspectives should be included so that decision making has the best chance of reflecting the reality of people impacted and, as much as possible, living up to their values.

What this requires:

- committees are composed of people who, together, have the relevant knowledge, skills, and character required to do this work well;
- non-committee inputs (for example, patient experience in some processes) are structured to inform the correct stages of deliberation, even when this is hard to do;
- stakeholders are encouraged to make deliberations as robust and as informed as possible (for example, manufacturers sharing data). Meaningful opportunities for the public to be involved are described (this may require that special attention and emphasis is given to supporting and involving disadvantaged stakeholders);
- the deliberative environment and dialogue are organized and facilitated to minimize power differences among participants;
- all interactions and activities are respectful of the dignity, worth, rights, beliefs, values, preferences, customs, and cultural heritage of all involved; and
- deliberations are made public to the greatest extent possible, and, if some or all aspects are not in public, the reason for this is described and justified.

## Consistency

Deliberative processes should aim to evaluate similar technologies based on the consistent application of processes and explicit criteria, recognizing that decisions may vary.

What this requires:

- the process of deliberation is employed consistently across topics; there are no departures from the expected timing and nature of stakeholder engagement in the process, and if so, the reasons for such a departure are clearly described;
- the final decision or recommendation indicates past cases where a similar judgment was made and point to the consistent application of the determinative criteria; and
- if a decision or recommendation differs from a past case that might appear relevantly similar in major respects, the main reasons for the difference are made explicit and the reasoning described.

## Reviewability

There should be opportunities to revisit and revise decisions in light of further evidence or arguments, and there should be a mechanism and process for challenge and dispute resolution. The purpose of decision review is focused on improving the quality of decision made, and, as such focuses on the rationale for the decision and the process by which it was reached rather than on the outcome of the decision.

*Note: This principle, and its required actions, is not meant to include formal appeal processes in which a judiciary assumes the role of the decision-maker to “remake” the decision.*

What this requires:

- a description of the steps necessary for challenging a decision or recommendation on procedural or evidentiary grounds;
- a documented approach for the updating of an assessment based on the introduction of new evidence, changes in pricing, or other material changes that may call into question the original conclusions;
- an understanding of who is involved in any review/update or dispute resolution process, be they part of the original deliberative group or independent from it; and
- decisions should be revised openly and transparently to offset the perception that they are simply the result of vested interests rather than the material outcome of new knowledge.

### Other principles for consideration

**Benefit and welfare:** Acting in ways that advance the health, wellbeing and interests of patients, consumers, communities, populations, healthcare systems, and the healthcare sector, and that avoid or minimize harm.

**Justice:** Fair distribution of access, opportunities, and privileges, and reduction of socio-political and economic inequity. Justice also refers to fairness in the processes that allocate resources and resolve disputes.

**Reasonableness:** Those involved in collaborations act, and make decisions, on the basis of rationales that are widely accepted as relevant and fair.

**Honesty:** Those engaged in collaborations are truthful in all their interactions.

**Responsibility and accountability:** Those involved in collaborative processes take responsibility for, are able to explain, and are accountable for, their actions and decisions.

**Testability:** The judgments and decisions made by those engaging in collaboration are open to independent verification and revision. This refers to verification by those outside the deliberative process.