

Deliberative Processes in HTA: Prospects, Problems, and Policy Proposals

Reflections on the 2020 Global Policy Forum (GPF) in New Orleans, Louisiana, USA , January, 26-28 2020



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The HTAi 2020 Global Policy Forum (GPF) welcomed 80 society members from 22 countries representing HTA agencies and industry. Keynote and invited plenary speakers

ensured patients, clinicians, academic researchers, and those bringing payer and regulator experience were well represented. The objective of the Forum was to gain initial agreement on a set of guiding principles and related actions in deliberative processes in HTA that are focused on reaching recommendations or decisions on adoption and use of health technologies.

We had thought-provoking keynote sessions from Professor Peter Littlejohns of King's College London, an ethicist and former executive at NICE, setting the landscape for consideration of the deliberative process. Dr. Karen Facey, Senior Research Fellow, University of Edinburgh, described the evolution of stakeholder input into HTA processes and deliberation, focusing both on what is documented, and what is undocumented but ethnographically observed. Dr. Carleigh Krubiner an ethicist and policy fellow at the Center for Global Development at Johns Hopkins, focused on innovations in deliberation, including an ongoing project in South Africa that features simulated deliberation. Professor Julia Abelson, Department of Health Evidence & Impact, McMaster University, provided some insights on citizen involvement in HTA, including analogous efforts in healthcare outside the HTA sphere.



Dr. Dan Ollendorf

Chair, HTAi Global Policy Forum

The topic for the Global Policy Forum is generated in collaboration with the members and refined by the Organising Committee, with substantial pre-meeting

research to facilitate discussions. This year's background paper provided an extensive overview, including insights from interviews with 16 expert informants, of the current challenges, gaps, and opportunities with respect to HTA deliberative processes.

The Forum built upon this contextual and empirical foundation through the plenaries, case study presentations, stakeholder perspective discussion panels and breakout sessions. This year saw the introduction of an in-meeting app to determine the members' perceived hierarchy of core principles and supporting actions to be considered in any deliberative process. It is pleasing to hear that some Forum members have already taken learning from the discussions and will be evaluating their agency processes. These efforts will be further supported through an HTAi-ISPOR Working Group tasked with developing good practices for HTA deliberation. Below are some key reflections on the discussions during the Forum.

Discussion Themes

Prospects: Why Deliberate? An ancient philosophy, a modern moral obligation

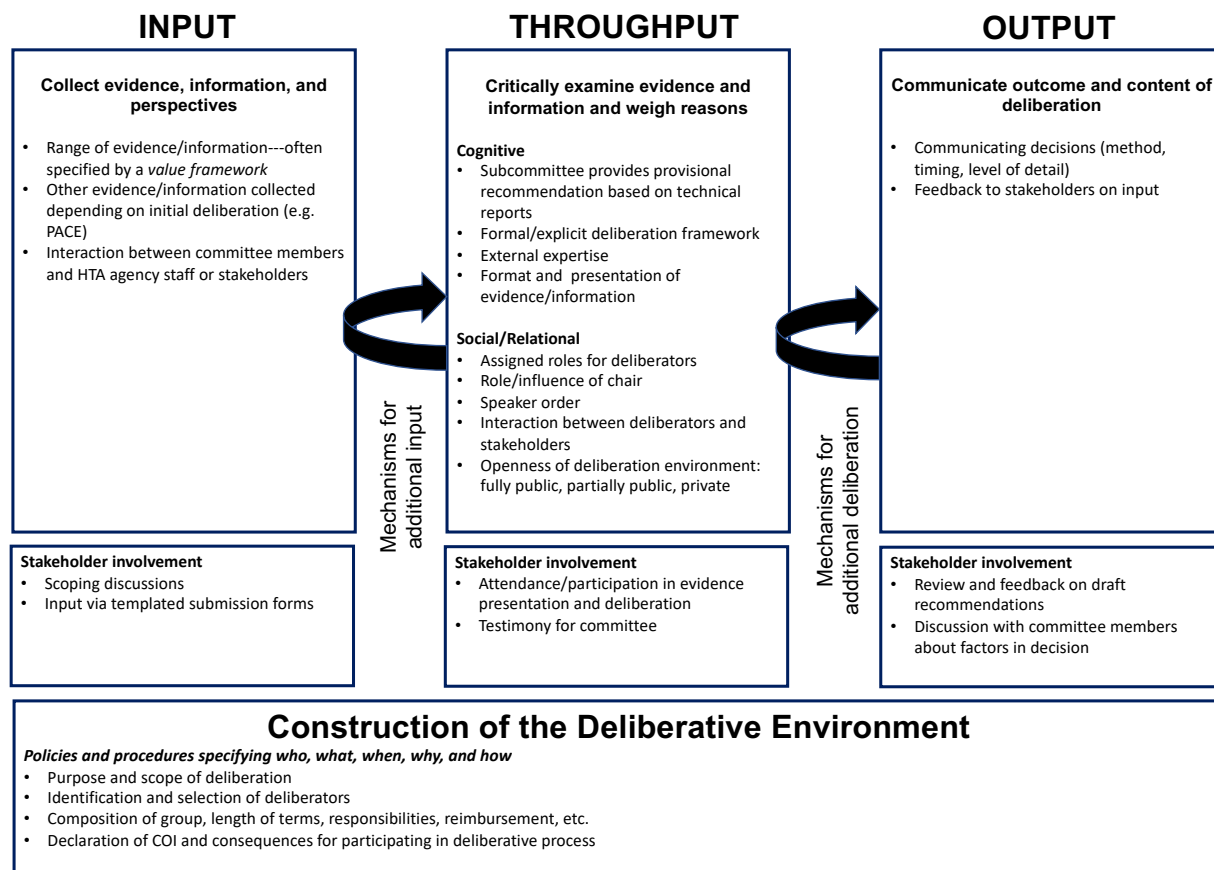
Deliberative processes are certainly not new, nor new to HTA. The importance of due deliberation to ensure a reasonable and fair approach for making complex decisions regarding access to healthcare innovation is generally acknowledged. However, there is little available research to inform the design and development of effective and efficient deliberative processes, especially how aspects such as committee size or composition, decision methods, and types of stakeholder involvement might influence deliberations and their outcomes.

The varying extents to which political, legal, and cultural elements influence HTA deliberations are also under-evaluated and poorly documented. The Forum members discussed the global commonality in the importance of due processes in HTA deliberations, and the need to develop an encourage transparency in HTA processes and, as such, expressed broad agreement with the meeting objectives.

Ultimately, two questions regarding how deliberative processes are implemented were raised:

- (1) Can we improve process consistency and transparency(?) through agreed Core Principles, and related Actions?
- (2) Can we improve decision making quality through agreed Core Principles, and related Actions?

Discussions centered on a conceptual model as introduced in the background paper that described an “input-throughput-output” approach to HTA deliberation (see Figure below). This model attempted to convey the the construction of the deliberative environment in terms of the “who, what, when, why, and how” at each of these three major stages of deliberation.



Problems: Stakeholder Diversity, Resource Limitations, External Pressures

Stakeholder Diversity

Despite the consensus with the prospects of developing internationally agreed and transparent best practices in deliberative processes, there are several barriers and restrictions to appreciate when considering widespread implementation of these principles.

Firstly, patients, HTA agencies, industry and payers come to the table with different perspectives. During the Forum breakout sessions, members focused in on these stakeholder perspectives to respectfully discuss barriers and/or practical limitations. There was also agreement by the members regarding the importance of patient engagement beyond token “testimonial” activities and ensuring the integration of meaningful patient data into deliberative processes. It was noted that a culture change is required to better facilitate this that involves moving patient engagement activities upstream and changing the typical practices of clinical development in industry (i.e., guided solely by clinical input). Stronger alignment between regulatory bodies and HTA bodies may help to encourage this culture shift.

It was noted that having an industry perspective in deliberative committees serves to strengthen the knowledge and diversity of committees and has the potential to increase acceptability of the process and the resulting decisions by industry (and reinforcing that positive decisions require tradeoffs); despite this, HTA bodies vary significantly in how industry is engaged, and do not consistently allow industry to play a role in the deliberations themselves.

Resource limitations

The country/regional context has a significant influence on decision making generally, and by extension the approach to deliberative processes. In addition to challenges of working across languages and political contexts, HTA exists at varying degrees of maturity. It is difficult, for example, for low- and middle-income countries (LMICs) to “import” the results of deliberation in more developed settings without significant adjustment and consideration. LMICs may face additional challenges because they may be dealing with a history of corrupt decision making, poor management of conflicts of interest, and lack of political will to use as well as capacity for producing scientific evidence let alone strong patient-important outcomes data to inform policy making.

Several participants commented that it may also be very difficult to engage patients and citizens for various political or cultural reasons in certain settings. It may also be difficult to operationalize some aspects of deliberation in a timely fashion in some settings (for example, allowing for lengthy periods of patient input), and this may conflict with the need to satisfy another principle or with some practical limitation.

External Pressures

One of the keynote presentations addressed the tension associated with the political orientation of the deliberative process, whether as democratically driven public deliberation or as expert-evidence driven deliberation, and the role this plays in determining who ought to be involved and how. Both external (history, political/institutional arrangements) and internal (governance, committee culture) constraints shape involvement in various ways, and should be openly acknowledged.

The discussions highlighted the challenges and political background and other preconditions for implementing deliberative processes. GPF members highlighted the tension between principles such as transparency that, when fully realized, may create challenges for agencies and decision makers because they become more open to criticism.

Policy Proposals

Current Practices in Deliberation in HTA: Case Study Presentations

The primary perspective brought from the case study presentations was on ensuring the patient voice and perspective through patient-reported outcomes and information, as well as on inclusion of broad sets of stakeholders in both deliberation and implementation.

We learned that SMC's PACE initiative allows for patient and clinician input and discussion when a decision is in the draft stage; this input is then considered by committees for the final decision. We also reflected on the patient advocacy perspective from the Gastrointestinal Society of Canada, recommending that HTAs continue to evolve in their integration of patient data and testimony, provide ample opportunity for in-person engagement, and possibly provide funding to patient groups so that they are not so reliant on industry. Finally, ICER's deliberative approach includes building in public discussions, conversations with committee members about their rationale for voting a certain way, and the multi-stakeholder roundtable conversation that follows voting.

Forum Polling on Core Principles to Guide Deliberative Processes

The two-day Forum saw a series of polling exercises in response to discussions which ensued around important principles (and actions) for the deliberative process. An initial list of 11 principles was developed based on background research as well as conversations with expert informants. These were reviewed and discussed by Forum attendees, and two subsequent rounds of voting narrowed the set of core principles to three: transparency, impartiality, and inclusivity (see below).

Principles (R1)	Principles (R2)	Core Principles (R3)
Transparency	Transparency (Honesty)	Transparency
Honesty		
Impartiality	Impartiality	Impartiality
Consistency	Consistency	
Reasonableness	Reasonableness	
Reviewability	Reviewability	
Inclusivity	Inclusivity (Respect)	
Responsibility and accountability	Responsibility and accountability	
Benefit and welfare		
Justice		
Testability		

Discussion also recognized that satisfying one principle doesn't ensure the satisfaction of others. Members mentioned that the core set of principles should define the process for all stakeholders and should not be confused with a set of responsibilities that rest solely with the HTA body. It was also noted that the principles are meant in part to be aspirational, those things that agencies and all stakeholders might strive for, rather than a strict set of instructions.