# *Supplementary material – Survey on evidence-informed deliberative processes*

Welcome to the survey on the potential use of ‘evidence-informed deliberative processes’ (EDPs) in the field of health technology assessment (HTA) [1]. EDPs provide guidance to HTA organizations to improve their processes towards more legitimate decision making. EDPs integrate two increasingly popular and complementary approaches to HTA informed decision making. It is based on stakeholder involvement to identify, reflect and learn about the meaning and importance of each other’s interest and values to foster fair decision making (as reflected in the accountability for reasonableness approach). It also uses rational decision making through evidence-informed evaluation of identified relevant criteria (as reflected in multi-criteria decision analyses). In other words, EDPs focus on stakeholder deliberation throughout the HTA process to allow contributions from stakeholders in terms of their experiences and judgments when stronger evidence is unavailable. [2] EDPs are the central framework in WHO guidance on HTA and are currently used by health authorities in Indonesia and the Netherlands.

Completing this survey will take approximately 25 minutes as most of the questions only require you to tick a box.

Please note that all your answers will be treated confidential: no attribution will be made to specific persons.

The survey results will be used to further develop a practical guide on how to apply EDPs.

[1] HTA is defined as a multidisciplinary process that uses explicit methods to assess the value of using a health technology. This process is comparative, transparent and involved multiple stakeholders. The purpose it to inform health policy and decision making to improve patient-relevant outcomes. Health technology is defined as an intervention developed to prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery.

[2] Baltussen R, Jansen M, Bijlmakers L, Grutters J, Kluytmans A, Reuzel RP, et al. Value assessment frameworks for HTA agencies: the organization of evidence-informed deliberative processes. Value Health 2017;20(2):256–60.

**General information**

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| --- |
| What is your name and title? |
| What is your email address? |
| What is the name of your organization? |
| What country or region are you representing? |
| Please can you specify to what extent you are familiar with HTA, and especially with HTA in your country? |
| Please can you specify if and how your organization is involved in HTA? |

**Introduction to EDPs**

EDPs provide guidance to HTA organizations to improve their processes towards more legitimate decision making. The framework is not entirely new and integrates two increasingly popular and complementary approaches to HTA informed decision making. EDPs are based on **rational decision making** through evidence-informed evaluation of identified values (as reflected in multi-criteria decision analyses) as well as **fair decision making** (as reflected in the accountability for reasonableness approach – A4R). In other words, EDPs focus on **stakeholder deliberation throughout the HTA process** to learn about the importance of relevant values.

We distinguish several steps in the use of EDPs (Figure 1) and define its elements on the basis of literature, and existing checklists such as the INAHTA checklist for HTA reports. The way in which these steps can be applied depends on the context.

We are aware that some organizations already have (some of) the processes in place, and they may serve as inspiration for others. There may be other organizations that can substantially improve their processes. In order to increase our understanding of the potential use of EDPs, to identify topics that are in need of more guidance, and to learn about best practices in relation to each step, we would like to collect your views and experiences.



 **Figure 1.** The steps of EDPs.

**Context**

*It is important to understand the context of a HTA practice, as this influences the implementation of EDPs.*

QUESTION:

Please could you indicate a) if any of the following factors are ***Present*, *Present to some extent or Not present*** in your country/region and b) whether particular factors are in need of guidance in your country/region ***(Yes/No)***:

 ***Linkage between HTA and policy/practice***

* + A (formal) mechanism or process to link HTA to policy making (e.g. legislation)
	+ Allocation of public ***funding*** to HTA on an annual basis
	+ A policy statement on the ***willingness to use*** HTA in policy and/or practice

***Institutional environment***

* + An independent ***institution*** (HTA organization or HTA focal point)
	+ HTA ***process guidelines*** (is a systematic process in place for e.g. assessment and appraisal)
	+ HTA ***method guidelines*** (is methodological guidance available for e.g. conducting economic analysis or clinical assessment)

***Networking and capacity***

* An (inter)national ***networking strategy*** for collaboration between HTA organization(s) and relevant stakeholders
* Sufficient ***capacity*** to carry out HTA, including medical disciplines, public health specialists, epidemiologists, statisticians, psychologists, biomedical engineers and/or economists
* Ability to ***review international literature*** (i.e. access to databases), including expertise in searching the internet
* (Domestic) ***HTA training opportunities*** (short courses, workshops, Master programmes and PhD training)

QUESTION:

Please could you indicate below a) if any important contextual factor has not been listed and b) whether these areas are in need of guidance in your country/region:

QUESTION:

With regard to all contextual factors listed in the questions above, are you aware of any HTA practice that can serve as best practice? If so, please can you provide more information?

**Step 1. Installation of an appraisal committee / stakeholder panel**

*Most HTA practices have an appraisal (HTA) committee in place. Such committee can be involved throughout the entire HTA process, including scoping (step 2), assessment (step 3), and appraisal (step 4). In some HTA practices, the committee or panel develops recommendations or guidance, in other contexts it is responsible for taking decisions.*

*It is increasingly acknowledged that the members of such a committee should represent societal perspectives. For this purpose, it is advised to set-up an (independent) committee including relevant stakeholders (e.g. clinicians, patients, citizens, payers, providers, decision makers). For reasons of legitimacy, it is important that at least the composition, selection of members, the terms, its independence (e.g. COI statement), remit and scope are explicit and transparent.*

QUESTION:

Please could you indicate a) whether an HTA (appraisal) committee is in place in your country/region? b) is the HTA (appraisal) committee legitimate? ***(Yes/No)***

QUESTION:

If applicable, please could you provide the reason(s) why the committee is (not) legitimate?

QUESTION:

Please could you indicate a) if any of the following elements are ***Present*, *Present to some extent or Not present*** in your country/region, b) the guideline/document is Publicly available, and c) whether particular elements are in need of guidance in your country/region ***(Yes/No)***:

* Guidelines / document describing:

a) The composition, terms, and selection of members of the HTA (appraisal) committee;

b) The roles and responsibilities of the committee (remit and scope);

c) The procedure(s) followed by the HTA (appraisal) committee;

d) The selection, roles and responsibilities of other stakeholder involved in the HTA process.

QUESTION:

Please could you indicate below a) if any important element related to the installation of an appraisal committee has not been listed and b) whether these areas are in need of guidance in your country/region ***(Yes/No)***?

QUESTION:

With regard to all elements related to an appraisal committee listed in the questions, are you aware of any HTA practice that can serve as best practice? If so, please can you provide more information?

**Step 2. Selection of technologies and criteria**

*The selection of health technologies in need for HTA is an important step in the HTA process. This requires standardised systems for the identification of health technologies through e.g. horizon scanning (an early warning system), and the prioritization of these health technologies* *on the basis of agreed criteria or guidelines.* *Horizon scanning is a systematic examination of information to identify new or emerging health technologies that could be potential threats, risks, emerging issues and opportunities, allowing for better preparedness of health systems and informing policymakers, purchasers, and health care providers (for health service research prioritization, financial or operational planning) or facilitate early access (by facilitating controlled diffusion of technologies). Furthermore, it may include health technologies that are becoming obsolete and that have the potential to effect health, health services and/or society.*

*Subsequently, for selected health technologies, HTA organizations should define the scope of the assessment. This includes a clearly defined policy question(s) of direct significance to decision makers and the identification of criteria for which evidence needs to be collected. Scoping is ideally done in consultation with relevant stakeholders, e.g. patients, informal carers, and health professionals. Often HTA organizations are responsible for the scoping procedure, but this can also be done by policy makers, Ministry of Health, external committees, in consultation with relevant stakeholders and/or experts.*

QUESTION:

 Please could you indicate whether a horizon scanning system exists in your country/region?

QUESTION:

Please could you indicate a) if any of the following elements are ***Present*, *Present to some extent or Not present*** in your country/region, b) the guideline/document is Publicly available, and c) whether particular elements are in need of guidance in your country/region ***(Yes/No)***:

* Guidelines / document for horizon scanning describing:

a) The process of identification and selection of health technologies (i.e. procedures, criteria);

b) The roles and responsibilities of stakeholders involved in the process;

c) The methods used.

* Guidelines / document for scoping HTA describing:

a) The process of scoping (i.e. procedures, criteria);

b) The roles and responsibilities of stakeholders involved;

c) The methods used.

QUESTION:

Please could you indicate below a) if any important element related to the selection of health technologies in need for HTA has not been listed and b) whether these areas are in need of guidance in your country/region:

QUESTION:

With regard to all elements related to the selection of health technologies in need for HTA listed in the questions above, are you aware of any HTA practice that can serve as best practice? If so, please can you provide more information?

**Step 3. Assessment**

*The assessment process consists of evidence collection, analysis of the quality of the evidence, synthesising the evidence, and reporting the findings and implications. HTA organizations should ideally develop an elaborated HTA protocol to plan this process, based on the policy question(s) defined during scoping (step 2). Several guidelines exist for data collection and analysis (e.g. methodological guidance such as the EUnetHTA core model, INTEGRATE-HTA, as well as country/agency-specific guidelines on how to conduct the assessment – e.g. National Institute for Health and Care Excellence (NICE) in the United Kingdom, Canadian Agency for Drugs and Technologies in Health (CADTH) in Canada, Pharmaceutical Benefits Advisory Committee (PBAC) in Australia; and GRADE for assessing the quality of the evidence). Ideally, HTA organizations should present the collected evidence in evidence reports and standardised evidence summaries for each relevant assessment aspect (defined during scoping). The reports should ideally be subjected to an independent review and discussed by relevant stakeholders.*

QUESTION:

Please could you indicate a) if any of the following elements are ***Present*, *Present to some extent or Not present*** in your country/region; b) the related document is Publicly available, and c) whether particular elements are in need of guidance in your country/region ***(Yes/No)***:

* Guidelines / documents on how to undertake the HTA in terms of data collection and analysis
* Existence of a tool/template for reporting and summarising the (quality of the) evidence per relevant aspect as part of HTA (assessment)
* Existence of approach for stakeholder consultation to review the plausibility of the evidence reports

QUESTION:

Please could you indicate below a) if any important element related to the assessment of health technologies has not been listed and b) whether these areas are in need of guidance in your country/region:

QUESTION:

With regard to all elements related to the assessment of health technologies listed in the questions above, are you aware of any HTA practice that can serve as best practice? If so, please can you provide more information?

**Step 4. Appraisal**

*In the appraisal step, the HTA organization interprets the results of the assessment and formulates a recommendation or guidance to inform decision makers. In several HTA organizations, this task is carried out by a specific committee (step 2). Ideally, such a committee follows an explicit approach which guarantees the quality, consistency and transparency of the recommendations, guidance or decisions. The approach should preferably include a deliberative component for the interpretation of the assessment results, and involvement of relevant stakeholders to allow the inclusion of their perspectives in the development of recommendations, guidance or decisions. Several methods are available to support HTA organizations in this process, such as multi-criteria decision analysis or qualitative decision tools.*

QUESTION:

Please could you indicate if a formal framework for appraisal/HTA decision making exists in your country/region? ***(Yes/No)***

QUESTION:

Please could you indicate a) if any of the following elements are ***Present*, *Present to some extent or Not present*** in your country/region, whether the guideline/document is Publicly available, and c) whether particular elements are in need of guidance in your country/region ***(Yes/No)***:

* Guidelines / documents describing:

a) The process of appraisal (i.e. procedures, deliberation);

b) The roles and responsibilities of stakeholders involved in the process;

c) The methods used.

QUESTION:

Please could you indicate below a) if any important element related to the appraisal of health technologies has not been listed and b) whether these areas are in need of guidance in your country/region:

QUESTION:

With regard to all elements related to the appraisal of health technologies listed in the questions above, are you aware of any HTA practice that can serve as best practice? If so, please can you provide more information?

**Step 5. Communication and appeal**

*Communication and appeal are important features that enhance the legitimacy of decision making. These concepts are part of the A4R framework, which states that the decisions should be made public as well as the argumentation and evidence on which decisions are based. In addition, there must be a mechanism in place that gives stakeholders the possibility to appeal against decisions, propose revisions, and receive a reasoned response. This should give decision makers the chance to reconsider their decisions using extra (new) arguments or (new) evidence.*

QUESTION:

Please could you indicate whether the decisions and the underlying reasons are made public ***(Yes/No)***? If yes, please specify how they are made public.

QUESTION:

Please could you indicate a) if any of the following elements are ***Present*, *Present to some extent or Not present*** in your country/region, b) whether the guidelines/document are Publicly available, and c) whether particular elements are in need of guidance in your country/region ***(Yes/No)***:

* Guidelines / document describing the mechanism(s) for appeal, how to propose revisions, and to receive a reasoned response
* Guidelines / document describing the process of monitoring and evaluation of the HTA process and the recommendations/guidance or decisions made

QUESTION:

Please could you indicate below a) if any important element related to communication and appeal has not been listed and b) whether these areas are in need of guidance in your country/region:

QUESTION:

With regard to all elements related to communication and appeal listed in the questions above, are you aware of any HTA practice that can serve as best practice? If so, please can you provide more information?

**Further comments**

QUESTION:

If you wish to make any further comments about your experiences with EDPs in your country and/or this survey, please use the space provided below

QUESTION:

May we contact you if we have additional questions? ***(Yes/No)***