Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Guidelines for Stakeholder Engagement in Health Technology Assessment in Ireland

2014

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is the independent Authority established to drive high quality and safe care for people using our health and social care services. HIQA's role is to promote sustainable improvements, safeguard people using health and social care services, support informed decisions on how services are delivered, and promote person-centred care for the benefit of the public.

The Authority's mandate to date extends across the quality and safety of the public, private (within its social care function) and voluntary sectors. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, the Health Information and Quality Authority has statutory responsibility for:

- **Setting Standards for Health and Social Services** – Developing person-centred standards, based on evidence and best international practice, for those health and social care services in Ireland that by law are required to be regulated by the Authority.

- **Supporting Improvement –** Supporting health and social care services to implement standards by providing education in quality improvement tools and methodologies.

- **Social Services Inspectorate** – Registering and inspecting residential centres for dependent people and inspecting children detention schools, foster care services and child protection services.

- **Monitoring Healthcare Quality and Safety** – Monitoring the quality and safety of health and personal social care services and investigating as necessary serious concerns about the health and welfare of people who use these services.

- **Health Technology Assessment** – Ensuring the best outcome for people who use our health services and best use of resources by evaluating the clinical and cost effectiveness of drugs, equipment, diagnostic techniques and health promotion activities.

- **Health Information** – Advising on the efficient and secure collection and sharing of health information, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

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Foreword

The Health Information and Quality Authority (the Authority) has a statutory remit to evaluate the clinical and cost-effectiveness of health technologies, providing advice to the Minister for Health and to the Health Service Executive (HSE). It is also recognised that the findings of a health technology assessment (HTA) may have implications for other stakeholders in the Irish healthcare system, including patient groups, the general public, clinicians, other healthcare providers, academic groups and the manufacturing industry.

To ensure consistency in the HTAs undertaken by the Authority and others, the Authority continues to develop guidelines on the conduct of HTA in Ireland. These guidelines provide an overview of the principles and methods used in assessing health technologies. They are intended as a guide for all those who are involved in the conduct or use of HTA in Ireland, promoting the production of assessments that are timely, reliable, consistent and relevant to the needs of decision makers and key stakeholders in Ireland.

This document is part of the series of guidelines that also includes the *Guidelines for Economic Evaluation of Health Technologies in Ireland* (2014), *Guidelines for Budget Impact Analysis of Health Technologies in Ireland* (2014), and the *Guidelines for Evaluating the Clinical Effectiveness of Health Technologies in Ireland* (2011).

These guidelines are intended to inform technology assessments conducted by, or on behalf of, the Health Information and Quality Authority, the National Centre for Pharmacoeconomics, the Department of Health and the HSE, to include evaluation of applications for reimbursement. The guidelines are intended to be applicable to all healthcare technologies, including pharmaceuticals, procedures, medical devices, broader public health interventions and service delivery models.

The purpose of the stakeholder engagement guidelines is to promote the involvement of stakeholders in technology assessments. Stakeholders can include patients or their representative organisations, health professionals, service providers, and decision makers from the HSE and Department of Health. Stakeholders are people who have an interest in the outcome of the assessment. The use of engagement facilitates stakeholder input into an assessment, ensuring they have a voice and their perspective is given due consideration. The guidelines give a high level overview of what stakeholder engagement is, why it should be used, and how it can be done.

The Guidelines have been developed in consultation with the Scientific Advisory Group of the Authority. Providing broad representation from key stakeholders in healthcare in Ireland, this group includes methodological experts from the field of HTA. The Authority would like to thank the members of the Scientific Advisory Group and its Chairperson, Dr Michael Barry from the National Centre for Pharmacoeconomics, and all who have contributed to the production of these Guidelines.

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Process and Acknowledgements

This document is a complementary document to previously published guidelines. The Guidelines are limited to guidance on stakeholder engagement and are intended to promote best practice in this area. They will be reviewed and revised as necessary, with updates provided online through the Authority's website, www.hiqa.ie. This document forms part of a series of national guidelines for health technology assessment (HTA) in Ireland that the Authority will develop and continuously review in the coming years.

The Guidelines have been developed by the Authority with technical input from the National Centre for Pharmacoeconomics and in consultation with its Scientific Advisory Group (SAG). This group includes methodological experts from the field of HTA. The group provides ongoing advice and support to the Authority in its development of national HTA guidelines. The terms of reference for this group are to:

- contribute fully to the work, debate and decision-making processes of the Group by providing expert technical and scientific guidance at SAG meetings, as appropriate
- be prepared to occasionally provide expert advice on relevant issues outside of SAG meetings, as requested
- support the Authority in the generation of guidelines to establish quality standards for the conduct of HTA in Ireland
- support the Authority in the development of methodologies for effective HTA in Ireland
- advise the Authority on its proposed HTA Guidelines Work Plan and on priorities, as required
- support the Authority in achieving its objectives outlined in the HTA Guidelines Work Plan
- review draft guidelines and other HTA documents developed by the Authority and recommend amendments, as appropriate
- contribute to the Authority's development of its approach to HTA by participating in an evaluation of the process, as required.

Following review by the SAG, the draft Guidelines were made available for broader consultation. Feedback was sought by open consultation through the Authority's website and by targeted consultation with key stakeholders in Irish healthcare and international experts. The draft guidelines were revised as appropriate and were subsequently submitted to the Board of the Authority before publication.

The membership of the Scientific Advisory Group is as follows:

Chairperson: Professor Michael Barry
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The Authority gratefully acknowledges all those who contributed to the development of these Guidelines, including the international reviewers for the feedback provided.

List of abbreviations

CEA	cost-effectiveness analysis
HIQA	Health Information and Quality Authority
HSE	Health Service Executive
HTA	health technology assessment
SAG	Scientific Advisory Group

1. Introduction

Health Technology Assessment (HTA) is a structured form of evidence-based research that generates information about the clinical and cost-effectiveness of health technologies. These technologies can include drugs, medical devices, diagnostic techniques, surgical procedures, and public health programmes such as cancer screening programmes. A HTA may also look at the social, ethical, medico-legal and organisational issues associated with use of a technology, including its resource implications and budget impact. HTA is a decision support tool: the information provided by the HTA is used to inform health policy decisions regarding the investment in (or disinvestment from) these health technologies.

A HTA is conducted as a project with a number of important milestones. Initially a scope is developed for the HTA that defines the elements that will and will not be investigated as part of the HTA. The scope defines the technology of interest, the comparators, the indication, and the target population. Once the scope has been defined, the burden of disease and the clinical effectiveness of the technology and comparators are analysed. After these key elements have been described, a modelling framework is developed and applied to estimate the cost-effectiveness of the technology. Other factors, such as ethical and legal issues, can be addressed before the advice to the decision maker is finally developed.

A HTA is carried out by a multi-disciplinary assessment team. The assessment team may use external expertise to guide understanding of the decision problem or clinical details of the technology. In these Guidelines, the term 'assessor' is used to refer to the organisation or researchers with responsibility for conducting the HTA.

The main issues that may be considered as part of a HTA are:

- Does the technology work?
- For whom does it work?
- What is the benefit to the individual?
- At what cost?
- How does it compare to the alternatives?

In addressing these issues it is clear that a HTA impacts on a range of interested parties: patients, clinicians, suppliers and distributors, and the health service provider who funds the technology. The impact can be on patient outcomes, service provision, income, or expenditure. These interested parties are also referred to as stakeholders. The views and needs of these

stakeholders can have an important bearing on the advice given in a HTA, and may highlight issues that are not readily addressed or accounted for by a cost-effectiveness analysis.[1] Furthermore, stakeholders are frequently in a position to provide valuable advice and information on epidemiology, place in therapy, clinical efficacy and effectiveness, cost and budget impact. At each point of a HTA project, stakeholders can provide valuable input.

The components of a HTA are often separated into a number of distinct domains, some or all of which may be addressed in a specific HTA:[2]

- health problem or indication
- technology description
- clinical effectiveness
- safety
- cost-effectiveness
- ethical concerns
- organisational aspects
- social impact
- legal issues.

The analysis of each of these domains must be supported by evidence of sufficient quality and quantity. However, the type of evidence required varies from domain to domain, and while clinical trial evidence is favoured for evaluating clinical effectiveness and safety, more subjective evidence may be acceptable for ethical and social aspects. Therefore, for some domains a difference of opinion between stakeholders may be valid. Stakeholder input is particularly valuable in some domains (e.g. social impact), although it is context specific. For instance, in some assessments the ethical concerns might be quite complex whereas in others they may be less complicated.

The purpose of these Guidelines is to give a high level overview of what stakeholder engagement in HTA is, why it should be used, and how it can be done.

2. Who are stakeholders?

The interested parties affected by a funding decision for a health technology are called the stakeholders. More specifically, stakeholders are individuals, organisations or communities that have a direct interest in the process and outcomes of a health technology assessment.[3]

Examples of stakeholders in the HTA process include:

- patients
- disease-specific patients' and citizens' organisations (e.g. Irish Cancer Society)
- general patients' and citizens' organisations (e.g. Irish Patients' Association)
- carers' groups (e.g. The Carers Association)
- health professionals' organisations (e.g. Royal College of Surgeons)
- national/regional health authorities (e.g. HSE)
- policy makers (e.g. Department of Health)
- payer organisations and associations (e.g. Vhi Healthcare)
- industrial companies and associations (e.g. manufacturers, suppliers and distributors)
- methodological experts (e.g. academics)
- other organisations referring a technology for assessment.

Stakeholders are distinct from the general public as they have self interest in a given HTA topic; therefore, their involvement in a particular HTA is seen as both rational and likely to contribute to the quality and legitimacy of the process and outcomes.[3] Patients who will not benefit directly from the technology will also have an interest as, in the context of finite resources, the diversion of funds to a specific technology may have consequences for other patients in terms of reduced services. Some stakeholders (e.g. methodological experts) may wish to have input into the manner in which the HTA is carried out, rather than being concerned with the technology under assessment.

3. What is stakeholder engagement?

Stakeholder engagement is an iterative process of actively soliciting the knowledge, experience, judgment and values of individuals selected to represent a broad range of direct interests in a particular issue.[3] The two main purposes of stakeholder engagement are:

- Creating a shared understanding – the involvement of stakeholders allows the assessors to gain a better understanding of the key issues that should impact on a decision, and it gives the stakeholders an opportunity to gain an understanding of the HTA process. For stakeholders this could include, for example, providing access to data or collating information on patient experiences. For assessors this

means giving a transparent account of the HTA process and outlining what information is required for effective decision making.

- Generating relevant, transparent and effective advice – through their involvement, the stakeholders can ensure that issues that are relevant to them are incorporated into the HTA, and the possibility of a 'behind closed doors' approach is minimised. Stakeholders provide a form of quality assurance of both the process and the content of the HTA.

Stakeholder engagement is distinct from expert elicitation, which is a solicited exchange of knowledge, information, or opinion from an expert. This is usually used to clarify an issue for the assessors (for example, asking a clinician to define the typical treatment pathway). While that expert is likely to be a stakeholder, the purpose of stakeholder engagement is to allow broader involvement and, in contrast to expert elicitation, the possibility of providing unsolicited input. That is, to comment or feedback on any issue of the assessment.

4. Why should stakeholder engagement be used?

Stakeholder involvement at all stages of the HTA process can help to ensure that the assessor takes all relevant and important issues into account, that the advice and reporting in a HTA are accessible, transparent, and user-friendly, and that the findings reach those impacted by the decision (e.g. affected patients). If conducted correctly, stakeholder engagement is mutually beneficial for the assessor, the stakeholders, and the decision makers. There are a number of motivations for stakeholder engagement, some of which are listed below.[4;5]

Relevance

The use of stakeholder engagement increases the likelihood that the issues that are identified and prioritised are important and relevant (e.g. an assessment is based on endpoints that are relevant to the patient and to the health system). Differences between technologies may be very subtle and differences that are important to patients, for example, may not be adequately recorded in clinical trials; therefore, the input of individuals with direct experience of the technology can be helpful when interpreting data from clinical trials.[6] By bridging the gap between the assessors and the end users, stakeholder engagement can help to ensure that HTAs are better aligned with the information needs of the decision makers.[3]

Quality
Stakeholders can help identify inaccuracies or weaknesses in the assessment as they are likely to have expertise in specific aspects of the assessment (e.g. the disease, treatment pathways, patient experiences). Some stakeholders may also be in a position to provide important information or data that are not in the public domain or are otherwise unknown or unavailable to the assessors (e.g. treatment data, user experiences, clinical outcomes). Such data can be particularly important to elaborate on the implications of the technology or its comparators for the patient. The transfer of any data between stakeholders and assessors must comply with data protection legislation regarding confidentiality and anonymity. Through their involvement, stakeholders gain assurance that a HTA is based on high quality scientific evidence with an effort to minimise bias.

Acceptance
The inclusion of stakeholders can provide legitimacy and credibility to the HTA, thereby improving the likelihood that subsequent decisions based on the advice are accepted. Stakeholders may have opposing opinions – the inclusion of diverse views in the HTA process can help ensure that a shared understanding is reached. The input of stakeholders can help improve the wording and balance of advice, particularly to account for contextual nuances and ensuring readability. Furthermore, by being closely aligned to the process, stakeholders can assist in the dissemination of HTA outputs, thereby ensuring that patients and clinicians are aware of the findings and can understand the basis for subsequent decisions.[4]

5. Key principles of stakeholder engagement

For the successful implementation of stakeholder engagement, a number of key principles should be followed.[7]

Inclusiveness
Ideally all stakeholders who have an interest in, or who will be affected by, a specific decision should be involved. This is particularly important for patient groups who may not have a strong awareness of the decision process and may not have the opportunity to appeal a decision once made.

Transparency
Information should be shared equally with all stakeholders; no stakeholder should be given preferential treatment. The exception is commercially sensitive or confidential information, or where Data Protection legislation precludes sharing of the data. Nor should information be presented in a

manner that discourages or excludes some stakeholders. It should also be clear to stakeholders what they can and cannot influence through their involvement. There should also be transparency about how stakeholders were identified, selected and invited by the assessment team.

Commitment
Respect should be shown for all stakeholders by giving the appropriate priority and resources to the engagement process, and demonstrating that it is a genuine attempt to understand and incorporate other opinions even when they conflict with pre-conceived ideas of the assessment team. It should be established from the outset of the HTA and communicated to the stakeholders how the decision-making process will benefit from stakeholder engagement.

Accessibility
Different ways should be provided for people to be engaged and to ensure that people are not excluded through barriers of language, culture or opportunity. The mix of disciplines involved in a HTA frequently results in the use of complex terminology that may actively disengage some stakeholders – this should be avoided as much as possible.[8] Stakeholders should not be forced to provide instant responses – they should be afforded the opportunity to give consideration and to consult with members of the organisation they represent, as appropriate.

Accountability
As soon as possible after the end of the engagement process, participants should be provided with a clear account of how stakeholder contributions have – or have not – influenced the advice contained in the HTA. This can be achieved by suitably detailed recordings of interactions between assessors and stakeholders where relevant actions are highlighted and the outcomes of those actions are reported to the stakeholders. The sources of feedback can be anonymised for reporting purposes; confidential or commercially sensitive information should not be circulated.

Responsiveness
The assessors should be open to the idea that their pre-existing ideas can be improved, and that they will, if necessary, amend them. Stakeholders should perceive that their voice will be taken seriously, and that changes can be made.

Willingness to learn
Assessors and the stakeholders should be encouraged to learn from each other; this means giving sufficient time for face-to-face meetings where mutual understanding can be reached on complex topics.

6. Key steps in stakeholder engagement

Prior to engagement, the assessors must identify suitable stakeholders, recruit them for the project and decide on the nature of the engagement.

6.1. Identification

Relevant stakeholders need to be identified at an early stage. In developing a group of relevant stakeholders, a balance must be struck between adequate coverage of interested parties and having a group too large for successful management. The appropriate number of stakeholders will also be a function of the type of engagement used.

It is important that stakeholders are representative and, where possible, have a mandate to speak for a group or collective of individuals. Identifying suitable representative organisations can be challenging, particularly regarding patient representatives. Reasonable steps should be taken to identify a disease-specific patient representative, but where that is not possible, a more general patient representative body may be a suitable alternative. Representative organisations should be invited to nominate an individual to participate in the process, although sometimes individuals may be invited for their specific expertise. It is also important not to have over-representation of a particular stakeholder group as this may lead to bias and disengagement by other stakeholders.[9] Where possible, stakeholders should come from organisations with appropriate geographical coverage (e.g. national organisations for a HTA guiding a national coverage decision).

Stakeholders can be identified through the terms of reference for the assessment, for example:

- the technology identifies the medical specialty (e.g. orthopaedics)
- the indication identifies the patient population (e.g. people with hip fractures)
- the treatment setting identifies the service providers (e.g. public acute hospitals with an orthopaedics department).

Having ascertained these broad groups, it is then possible to identify corresponding representative organisations who could nominate individuals to be included in the engagement process.

Given the relatively small population of Ireland and the limited number of experts available in some disciplines, there is a risk that some individuals will be involved in stakeholder engagement repeatedly, which can lead to fatigue

and disengagement. In these cases it may be advisable to ask stakeholders to join an expert panel so that it becomes an ongoing engagement, whereby they can anticipate regular or repeated involvement.

6.2. Recruitment

Once stakeholders have been identified, they need to be contacted and invited to participate. At the point of invitation, the stakeholders must be given clear information on what they are participating in and what is expected of them in the process.[4] It should be made apparent what a HTA is, how it is undertaken, who it is for, and what the consequences of the HTA might be (e.g. not to introduce a new technology on the grounds of being not cost-effective). Accurate estimates of the likely commitment in terms of time, the frequency and type of input required, and the number of face-to-face meetings should be provided. Stakeholders should also be provided with information about the assessor: the purpose of the individuals/organisation, and the relevant contact details.

In some instances, depending on how technical the HTA is, it may be necessary to offer training to stakeholders either in HTA methodology or in relation to the technology being assessed. The latter would be unusual as stakeholders will typically have at least a basic understanding of the technology. However, some training in HTA methodology may be necessary to enable stakeholders to understand the fundamental aspects of the approach taken to an assessment and to be able to usefully contribute to discussions on the appropriateness of the methodology. Therefore, adequate information and training should be provided by the assessors to enable the stakeholders to have meaningful involvement in the process. Training should cover the fundamentals of health technology assessment, as well as the specific context of the technology being assessed. It is not recommended to pay stakeholders for their time spent participating in an advisory or expert group.

6.3. Engagement

Once stakeholders have agreed to participate in the process, the assessors must formally engage with them. This may include provision of background information, queries for information, updates regarding project status and results of interaction with individual stakeholders. The timing of engagement is important. For example, stakeholders can make an important contribution at the scoping stage, identifying important issues that the assessors may not be aware of that should be considered as part of the HTA.

Engagement may be a one-way or two-way process, whereby information can move from assessor to stakeholder and vice versa, depending on the level of engagement. The extent to which stakeholders are involved in the HTA process can be described as part of a spectrum:[10]

- Information gathering – to collect information about attitudes, opinions and preferences that will improve the assessor's understanding of the decision problem and therefore lead to better informed decision making.
- Consultation – to obtain feedback from stakeholders on specific documents or findings that have been made available to them.
- Participation – to involve stakeholders actively at all stages to ensure their concerns are understood and considered, and to give them some influence on and ownership of decisions.

The levels of engagement described above are not mutually exclusive, and multiple levels of engagement may be employed in a single HTA. Information gathering alone represents a very low level of involvement and is essentially a one-way movement of information from stakeholder to assessor. This gives the stakeholder no possibility to affect the manner in which the HTA is undertaken. Although useful information can be gathered (e.g. preferences for health states, indirect costs, experience of treatment), this sort of information can also be gathered through consultation and participation, albeit potentially from a smaller group of respondents.

For the purposes of HTA, it is generally appropriate to consider consultation and participation.[8] Consultation is a form of open engagement whereas participation can be described as closed engagement (see following Sections 6.3.1 and 6.3.2). Closed engagement is by invitation which is at the discretion of the assessor. Open engagement may have little if any restriction on who can take part and therefore any organisation or member of the public can usually become involved. It is possible to combine the two by having a defined expert group, but also allowing wider involvement through public consultations at particular points in the HTA process.

6.3.1. Consultation

Consultation is the relatively formal and structured process through which stakeholders can comment on and contribute to the decisions that may directly affect them. This is commonly seen in the form of a public consultation, whereby a draft document is made available and either the general public or specific stakeholders are invited to provide feedback within a defined time period.

The main benefit of consultation is that it is possible to include a virtually unlimited number of stakeholders. Consultation can extend to including the general public. It is important to ensure that feedback is also specifically sought from a number of identified stakeholders who are considered representative.

The main drawback of a consultative-only process is that stakeholders can only input when allowed and are not involved at each stage of the process, leading to a lack of transparency and potentially less understanding of the goals or objectives of an assessment. This approach allows limited scope for stakeholder input as they do not have the opportunity to affect the direction of the HTA process, merely to comment on the content and interpretation of information presented at the point of consultation. For example, failure to collect feedback at the scoping stage may result in a HTA that is overly restricted in content and hence of limited value to the decision maker. If the collection of feedback is limited to a late stage in the project there is a potential for a significant delay in the identification of inaccuracies or shortcomings in the project scope and methodology, with serious consequences for the timely and efficient delivery of the assessment. The timing and duration of a consultation period is therefore critical. If a consultation period is excessively short, stakeholders may have limited opportunity to give reasoned and useful feedback, defeating the purpose of the exercise. Such an approach is unlikely to lead to a constructive dialogue to tease out relevant issues.

The quantity of feedback could be substantial, which has a knock-on effect on resources and project timelines. Sufficient time must be incorporated into a project for assessing and responding to feedback. For example, it may take a week to process and respond to feedback from a six-week consultation period.

6.3.2. Participation

Participation is a process in which stakeholders can have some input into how the HTA is carried out in terms of the process, the agenda, and the main considerations. Participative processes differ from consultation processes in that they involve the participants more deeply, they tend to involve the same people through several stages of a project, and the results are more transparent for the participants. The term participation carries with it connotations of direct involvement in decision-making. The purpose is to give stakeholders an opportunity to actively assist in the development of advice

that informs a decision, rather than being part of a committee that actually makes a decision.

A common method of participation is through expert panels. An expert panel of 5 to 20 individuals is convened and presented with a specific task. Experts are selected on the basis of specific expertise relevant to the HTA (e.g. oncologists, radiologists). The process may involve the presentation and discussion of draft documents. For a relatively small HTA, the entire draft project may be presented and discussed at a single meeting. For larger projects, the expert panel may meet a number of times to define the scope of the project, review findings of clinical effectiveness, review the methodology for estimating cost-effectiveness, and to review the interpretation and advice generated by the HTA report.

Participation can facilitate a more nuanced and in-depth analysis. It may also lead to a better understanding of complex issues. The drawback of participation is that it is resource intensive for both the assessor and the stakeholders involved. Participation usually involves a commitment for the duration of the project and being prepared to provide substantial input when necessary. Ensuring that the mix of stakeholders is sufficiently broad to capture multiple perspectives can be difficult.

7. Choice of engagement approach

The choice of approach to engagement (i.e. consultation or participation or both) will be guided by a number of factors, such as the timelines for completion and the complexity of the assessment.

What is the purpose of the HTA?
A HTA may answer a relatively simple and non-contentious question for which consultation alone is sufficient. This is more likely to occur for cost-minimisation analyses or where the technology has consistently been shown to be very cost-effective in other jurisdictions and similar results are anticipated in the Irish context. However, it may be difficult at the outset of a project to determine whether or not it will be contentious.

What is the need for input from specific stakeholders?
If the HTA would benefit from the input of specific disciplines or experts, there may be legitimate concerns that a consultation or targeted consultation may not yield feedback from the relevant stakeholders. For example, one or more of the most relevant stakeholders may not be available at the time of consultation. This effect can be moderated by the use of a lengthy

consultation period. If the HTA is in a highly specialised or complex field, the continuous involvement of one or more experts is preferable. If stakeholder engagement is limited to a consultation period late in the project, any problems identified could be time-consuming and costly to fix.

How much ownership of the process do the stakeholders need?
In cases where opinion is likely to be divided, particularly amongst clinicians or patients, direct involvement in the HTA process is more likely to give rise to acceptance that the findings for particular domains of the HTA represent a compromise (e.g. considering the societal impact of the technology). Using consultation alone for such a HTA may also give rise to a perceived lack of transparency or even of exclusion, which can have consequences for subsequent buy-in to the decision.

How sensitive is the topic?
For HTAs relating to sensitive topics (e.g. breast cancer screening), participation can provide stakeholders with sufficient opportunity to exert due influence on the process. For sensitive topics it is critical that there is transparency and adequate consideration given to all stakeholders. For this reason, it is recommended to use a participatory approach for sensitive topics, and also to consider the use of consultation prior to completion of the HTA to ensure that relevant opinions have been sufficiently encompassed in the findings. The sensitivity of a topic is likely to be a function of public and patient interest in both the disease and the technology, the historical context, and whether opinions are divided on the topic. The assessment team must determine the sensitivity of the topic based on their knowledge of the context, and they may do this in conjunction with the organisation that requested the HTA.

How complex is the HTA?
The scope and complexity of HTAs vary immensely. The complexity can be dependent on the research question, or may be dictated by the quantity and quality of evidence available. Patient representatives, for example, can assist in defining which outcomes will be of most importance and should be included in the systematic review. A review of available evidence may show that there is insufficient high quality data to underpin a full analysis of cost-effectiveness, in which case stakeholder engagement may be of limited value beyond developing the initial scope. Conversely, for a very complex HTA, it may be advisable to use both participation and consultation to ensure that the HTA accurately represents the many issues that might be relevant.

A further consideration is the number and types of domains that the assessment encompasses. An assessment that is restricted to only considering

cost-effectiveness and where the relevant or important patient outcomes are well defined, may have limited scope for stakeholder involvement. The domains included in a HTA are agreed between the assessment team and the requester based on the information that is needed for decision making.

What is the timeframe of the HTA?
Where the HTA process is very time constrained, stakeholder engagement can lead to substantial increases in the time required for completion. For a typical HTA, the use of an expert group is likely to impose a minimum of an additional two to three weeks on the completion time for each time documents are circulated. A targeted consultation is likely to add a minimum of six to eight weeks to the process, between making documents available for scrutiny and allowing time for responses to be prepared. Therefore, standard incorporation of stakeholder engagement in a short turnaround process may not be practical. Options include use of a small stakeholder group with very restricted timelines for responses, although this may not be satisfactory for stakeholders.

Routine use of stakeholder engagement may not be feasible, particularly where assessments are subject to restricted timelines such as the 90-day timeframe under the transparency directive.[(11)] In this case, the short timelines may not be conducive to meaningful stakeholder engagement in each individual project. An alternative is to use the engagement process when developing the protocols or procedures that govern how HTAs are undertaken. This could be achieved by, for example, inviting stakeholders to review approaches and processes on a regular basis. It would provide an opportunity for stakeholders to raise concerns about the process and assist in identifying if improvements could be made to how assessments are undertaken.

8. Managing stakeholder engagement

Having identified and recruited the appropriate stakeholders and chosen an appropriate mode of engagement, it is then necessary to manage the process. The degree of management required is dependent on the form of engagement used: consultation or participation. In the event that both methods are used, they will typically occur as separate processes (i.e. an expert advisory panel will be used throughout the project while a distinct targeted and/or open consultation will be used at defined time points). Successful management of stakeholder engagement can be achieved by adhering to the principles set out previously in Section 5.

Irrespective of the mode of engagement, it is critical that feedback received and the responses of the assessors to feedback are carefully documented and circulated to all stakeholders involved in the process. When public consultation is used, feedback may be collated and made available to the public (for example, through electronic publication). Feedback should be anonymised and any confidential or commercially sensitive data should be removed. Where significant changes to the HTA occur as a result of stakeholder input, it should be highlighted to avoid concerns of undue bias or influence and ideally other stakeholders should have an opportunity to comment.

Where consultation is used, and stakeholders have to return feedback within a specified timeframe, it is vital to give ample notice of the start date for consultation and to give sufficient time for stakeholders to review and critique documents. Constructive feedback can take time to generate, particularly if organisations wish to consult with members, so the preference is to give a minimum of four weeks for consultation of full HTA reports. This may be reduced where consultation is used in conjunction with participation. The length of time given to consultation should reflect the complexity and potential impact of the assessment, and provide sufficient time for stakeholders to adequately consider the content and respond accordingly. For a complex HTA, six to eight weeks for consultation is preferable. The commencement of consultation must be sufficiently well publicised so that stakeholders will be aware of it. This can be achieved through targeted contact of identified stakeholders or through media coverage. Feedback must be facilitated in a flexible manner, so as not to exclude any stakeholders (e.g. allow for electronic and hard copy submissions).

If engagement is through participation involving face-to-face meetings, comprehensive minutes should be recorded and circulated to all attendees for feedback and endorsement. Stakeholders who are unable to attend meetings should be included in this process. Meetings must be carefully managed, as there may be a risk of conflict or that the meeting may be dominated by a small number of attendees. Where the risk of conflict is high, it may be advisable to use an independent chairperson to conduct the meeting.[9] As far as is possible, reasonable attempts should be made to resolve conflict or disagreement at the earliest opportunity. Unresolved conflict will impair the HTA process and can lead to a lack of acceptance of the HTA findings by some stakeholders. All attendees should be encouraged to speak and the chairperson must be cognisant of which issues are likely to impact on each stakeholder. Meetings should also be conducted in an inclusive manner,

avoiding complex terminology as much as possible; attendees should feel free to ask for clarifications of any items that are poorly explained.

When stakeholders have significant opportunity to influence the outcome of a HTA, such as through a participatory process, it is advisable to record conflicts of interest for members of an expert panel or advisory group, including for members of the assessment team. It is anticipated that some members will have conflicts of interest that will be explicit (e.g. a clinician who already uses the technology in private practice). However, other members such as clinicians or patient representative organisations may also have links to suppliers or distributors (either of the technology being assessed, comparator technologies or other technologies by the same manufacturer). While details of conflicts of interest are not published for reasons of confidentiality, it is important for the assessors and chairperson to know where potential biases might arise in stakeholder input. Stakeholders should report personal conflicts of interest as well as those of any organisation they are representing. There is also a risk that better resourced organisations may have a bigger influence on the outcome of an assessment. The assessors should be cognisant of these potential imbalances when managing stakeholders to ensure fairness in the process.

Engagement by participation will typically involve a commitment by the stakeholders over the lifespan of the project. In these cases it may be useful to maintain regular contact with the stakeholders to give some detail of the project status. If contact is restricted to the milestones, such as expert group meetings, then long periods may pass with no information or updates, which may lead to disengagement. Such contact reminds the stakeholders that the project is ongoing and also gives them a feel for the stages of the process.

Engagement need not stop at the completion of the HTA. Eliciting feedback on the engagement process can form an important part of reviewing a HTA project and identifying areas for improvement in future projects. It may also be useful to maintain contact with stakeholders to provide further information on the outcome of the HTA process, as decision making can occur long after the HTA is completed.

In the Irish context, the assessor is generally not the decision maker. Due to this distinction, the stakeholders involved in an assessment may not have any link to the decision maker and thus their involvement ends after the advice has been formulated and before a decision is made. It may be useful for the decision makers to liaise with the assessors and to aid with the dissemination of decisions to the stakeholders to complete the process.

9. Conclusions

HTA provides valuable information to decision makers identifying what interventions should be made available for the treatment of patients. Stakeholder engagement is an appropriate method to facilitate the involvement of patients, clinicians, service providers, and other stakeholders in HTA. All parties need to be cognisant of the fact that healthcare resources must be used in an efficient and effective manner. Stakeholder engagement therefore forms an important component of HTA. The involvement of numerous stakeholders is an extension of the multi-disciplinary approach of HTA and enables a variety of relevant viewpoints to be incorporated into an assessment.

Stakeholder engagement should not be viewed as tokenistic or merely to give the impression of inclusivity. Engagement is for the express purpose of improving the process and outcomes of HTA. There is a preference for a participatory approach, whereby stakeholders have continuous involvement in the process over the time horizon of a project and can provide input as appropriate, rather than being restricted to feedback at points in time designated by the assessors.

9.1. Key recommendations

Arising from these guidelines, there are six key recommendations:

- Stakeholder engagement improves the quality and acceptability of HTAs and should be used and resourced whenever possible.
- Stakeholders that may be directly affected by the advice of a HTA should be represented in the engagement process.
- The extent of stakeholder engagement should reflect the scope and complexity of a HTA project.
- A participatory approach to stakeholder engagement is recommended for HTA, and may be used in conjunction with consultation for more complex HTAs.
- Consultation alone may be adequate for shorter or less complex assessments.
- For programmes of assessment with necessarily short timelines that may not facilitate stakeholder engagement in individual assessments, engagement can be used to inform the development of HTA processes.

HTA Glossary

Some of the terms in this glossary will not be found within the body of these guidelines. They have been included here to make the glossary a more complete resource for users.

Comparator: the alternative against which the intervention is compared.

Cost-effective (value for money): a proposed technology is considered cost-effective for a specified main indication if the incremental benefits of the proposed technology versus its main comparator(s) justify its incremental costs and harms.

Cost-effectiveness analysis (CEA): an economic evaluation that compares, for example, a proposed technology with its main comparator(s) having common clinical outcome(s) in which costs are measured in monetary terms and outcomes are measured in natural units, e.g. reduced mortality or morbidity.

Direct costs: the fixed and variable costs of all resources (goods, services, etc.) consumed in the provision of a technology as well as any consequences of the intervention such as adverse effects or goods or services induced by the intervention. These include direct medical costs and direct non-medical costs such as transportation.

Effectiveness: the extent to which a technology produces an overall health benefit (taking into account adverse and beneficial effects) in routine clinical practice (contrast with **Efficacy**).

Efficacy: the extent to which a technology produces an overall health benefit (taking into account adverse and beneficial effects) when studied under controlled research conditions (contrast with **Effectiveness**).

Epidemiology: the study of the distribution and determinants of health-related conditions or events in defined populations.

Health technology: the application of scientific or other organised knowledge – including any tool, technique, product, process, method, organisation or system – in healthcare and prevention. In healthcare, technology includes drugs, diagnostics, indicators and reagents, devices, equipment and supplies, medical and surgical procedures, support systems and organisational and managerial systems used in prevention, screening, diagnosis, treatment and rehabilitation.

Health technology assessment (HTA): this is a multi-disciplinary process that summarises information about the medical, social, economic and ethical

issues related to the use of a health technology in a systematic, transparent, unbiased, and robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value.

Indication: a clinical symptom or circumstance indicating that the use of a particular intervention would be appropriate.

Indirect costs: the cost of time lost from work and decreased productivity due to disease, disability, or death. (In cost accounting, it refers to the overhead or fixed costs of producing goods or services.)

Outcome: consequence of condition or intervention; in Economic Guidelines, outcomes most often refer to health outcomes, such as surrogate outcomes or patient outcomes.

Technology: the application of scientific or other organised knowledge – including any tool, technique, product, process, method, organisation or system – to practical tasks. In healthcare, technology includes drugs, diagnostics, indicators and reagents, devices, equipment and supplies, medical and surgical procedures, support systems, and organisational and managerial systems used in prevention, screening, diagnosis, treatment and rehabilitation.

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