

Identifying the Need for Good Practices in Health Technology Assessment: Summary of the ISPOR HTA Council Working Group Report on Good Practices in HTA (Online Appendix)

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BACKGROUND TO THE WORKING GROUP

The systematic use of evidence to inform healthcare decisions for new health technologies (eg, therapeutic interventions, diagnostics, prevention) is now well established globally. At its center, the multidisciplinary activity of health technology assessment (HTA) has gained increased recognition [1]. HTA has become a standard policy tool for informing decision makers who must manage the entry and use of pharmaceuticals, medical devices, and other technologies (including complex interventions) within health systems, eg, through reimbursement and pricing.

Despite the ever-increasing activity and attention to HTA and other evidence-based approaches to support population-based decision making (such as comparative effectiveness research [CER]), including good research practices in clinical and economic analyses, there has been no attempt to comprehensively synthesize good practices or emerging good practices to support population-based decision making in recent years. Notably, the last comprehensive attempts occurred over 20 years ago, as the European Union funded the first (called “EUR-ASSESS”) in a series of projects intended to synthesize and recommend best practices in HTA [2]. Reports on priority setting, methodology and dissemination, and impact were published in 1997 [3–6].

Several aspects of the EUR-ASSESS agenda were then taken further by the European Collaboration for HTA (ECHTA) Project, including the specification of best practice in undertaking and reporting HTAs [7]. Since 2006, the European Network for for HTA (EUnetHTA) has subsequently produced several reports addressing elements of good research practice [8], most notably the HTA Core Model® [9,10]. They have also published an adaptation tool kit[11], submission templates for manufacturers, procedure descriptions for HTA projects, methodology guidelines[10], good practice in collaboration between regulatory agencies and HTA organizations [12], and guidance on evidence generation for HTA[13]. Analyses of HTA procedures and methodologies in Europe have also recently been published.[14–16]

Similar initiatives to review and establish common approaches are also taking place outside Europe. Notably, the Inter-American Development Bank has sponsored initiatives in Latin America and Caribbean countries, including the CRITERIA network to strengthen country priority setting policies for resource allocation for health technologies from public funds, including having the evidence and institutional framework required to decide criteria[17]. The DIME (Decisiones informados sobre medicamentos, “Informed Drug Decisions”) project was initiated by Colombia, Ecuador, and Mexico and later involved other Latin American countries. DIME has adapted the HTA Core Model along with sharing key information about drug coverage and pricing decisions[18].

The ISPOR Guidelines Index provides a summary of key references that describe good research practices in the area of outcomes research and health economics and also includes good practices to support decision making [19]. When the index was developed in 2013, the compilation of guidance documents for the section on using evidence in healthcare decision making was considered a first step that would need a more thorough follow-up and interpretation. This document is a report of such efforts.

OBJECTIVE AND RATIONALE

The purpose of the ISPOR HTA Council Working Group was to provide an up-to-date review of current literature which includes guidance for practice. The intent of the Working Group was to identify good practices in the use of evidence to inform healthcare decision making for pharmaceuticals (ie, drugs and vaccines), medical devices, and other health technologies. For this review healthcare decisions are those that relate to managerial and administrative decision making and other forms of health system governance and stewardship. The use of evidence to inform individual decisions between patients and clinicians is outside of the scope, however the Working Group recognizes that HTA may be used to broadly inform clinical practice decisions through clinical practice guidelines or clinical pathway development and thus have not excluded these efforts from the scope of the paper.

The rationale for identifying good HTA practices in using evidence to inform population-based healthcare decision making is to provide a basis for capacity building, education, and improved consistency in approaches to HTA-informed decision making. The primary audience for this report are those who manage, design, or seek to improve HTA processes although we hope it is informative to a wider audience of patients, care providers, payers, academics, and industry stakeholders.

Given the large scope of this work and to achieve its objectives, the HTA Council Working Group created this overview report with a summary of key references related to good practices in HTA, outlining where there appears to be guidance for good practices and where guidance is still emerging or could not be identified with a view to prioritizing next steps that may be taken by ISPOR and other interested parties.

METHODS

The Working Group's approach in developing this report was based on literature review and expert opinion and followed a similar approach to that of ISPOR Task Forces.[20] The need for a review of best practices was first identified by the ISPOR HTA Council following a review of the

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ISPOR Guideline Index for Outcomes Research. The Council then identified Co-Chairs who invited members of the Working Group. Working Group members were selected based on recognized expertise in HTA and across various disciplines contributing to HTA including evidence synthesis, economic evaluation, ethics, and evaluation of patient preferences/values. An outline for this report was then drafted and reviewed by members of the Working Group.

Sections of the report were then assigned and drafted by individual Working Group members who were encouraged to use comprehensive approaches towards searching for existing descriptions of current practice, guidances for best practice, and to provide opinion (preferably based on published reports) identifying issues related to each section assigned. Systematic reviews were typically not conducted by working group members although all authors were encouraged to conduct them or identify systematic reviews in their assigned areas.

Once drafted, the report was reviewed by all members, revised and circulated to members of a larger review group (see acknowledgements); it was then further revised leading to this final report. In parallel, findings were summarized and presented in open workshops at ISPOR meetings (Boston, MA, USA and Glasgow, Scotland).

The structure of this report is based on a combination of a characterization of healthcare decision making [21], along with descriptions of components of an HTA process[22,23] and the ISPOR Guideline Index for Outcomes Research enhanced by the HTA Council Working Group members (**Figure 1**). The proposed *framework* assumes that the goal of HTA is to support healthcare decision making and it addresses all aspects, including how HTA processes are governed and defined (“**Defining the HTA process**”), how research information is identified, analyzed and interpreted (“**Assessment**”), how these interpretations are appraised and used, i.e., applied and weighed to the context of the decision (“**Contextualization**”), and how this ultimate interpretation and weighting is intended to support healthcare decisions (“**Implementation and Monitoring**”).

FINDINGS

DEFINING THE HTA PROCESS

Summary: While some good practices related to defining HTA processes have been more widely adopted, others are still evolving. There are no widely adopted good practices for defining organizational aspects or the underlying principles of HTA. There are several proposed governance models and governance indicators for healthcare systems in both developed and less developed systems that may intuitively be applied to HTA processes. Although principles for the conduct of HTA have been developed they are not widely endorsed;

principles to guide and benchmark HTA organizations, particularly those in low- and middle-income countries, may be difficult to achieve, either through lack of funding or local institutional barriers. Finally, good practices relating to priority setting and scoping appear to have been more widely adopted. Different procedures for priority-setting frameworks, largely criteria-based, are widely available. There are also available approaches for framing and scoping research in HTA.

An early challenge for the Working Group was varying published definitions of HTA as well as distinctions that may be difficult to draw between HTA and “contextualization”, “appraisal”, “evaluation” or CER (See HTA Terminology, Appendix 1). For the purpose of this paper, HTA is a research-based process intended to support healthcare decision making. The Working Group recognizes that decision makers may be from governments, health systems, hospitals, or payer organizations (or a combination of one or more of these) and that decision making may occur at a single point in time or otherwise, and will depend on the health system context.

Structure / Governance / Organizational Aspects of HTA Processes

HTA processes generally exist to support regional care or larger often politically lead health systems, that may be concerned with other policy goals beyond healthcare, such as the need to support innovation or to more broadly support public wellbeing. These factors will require consideration when designing, implementing and managing HTA processes. Beyond simply interpreting research there is a need to more broadly consider the accountability and organizational structure of the HTA process, its budget, how it informs decisions, what technologies are assessed, and its relationship to the decision maker. EUnetHTA published a Handbook of HTA Capacity building providing guidance for this in 2008.[24]

There will also be a need to consider relationships with stakeholders such as health product regulators, commercial innovators, private and public research organizations, health service provider organizations, and other programs that involve the use of health technology within the healthcare system, such as clinical practice guidelines. A World Health Organization (WHO) survey of HTA bodies indicated that most provided an advisory role, with a minority clearly communicating HTA findings and soliciting conflicts of interest[25]. EUnetHTA developed Procedure Guidelines for handling Declaration of Interest and Confidentiality Undertaking (DOICU).[26]

To date there are no widely available or adopted best practices to specifically guide HTA bodies regarding these more broad considerations of structure and governance. There are, however, several proposed governance models and governance indicators for healthcare systems in both developed and less developed systems that may intuitively be applied to HTA processes. Many are

based on good governance models proposed by the World Bank [27] and promoted by the WHO [28]. This includes the TAPIC (transparency, accountability, participation, integrity, capacity) framework [29], as well as similar models for developing nations intended to improve governance and reduce corrupt practices within the pharmaceutical sector in developing countries [30,31].

Framework / Principles For HTA Processes

For the purpose of this report, we characterize principles as general laws or rules to guide specific actions or practices. For example, Goodman outlined some good practices in HTA which we would call "principles" emphasizing the need for HTA bodies to be transparent and explicit about processes and purpose [32]. The paper also outlines the need for independent review of the HTA body and the need for stable funding. Principles to guide good practices in hospital HTA have also been described and include principles surrounding financing and governance, as well as a focus on the assessment process itself and the need for adequate contextualization [33].

Drummond and colleagues outlined several key principles for the conduct of HTA for resource allocation decisions, reflecting the more recent uses of HTA in pricing and reimbursement decisions for pharmaceuticals and other health technologies [34]. Attached to these principles are audit questions that relate to specific practices that may be a basis for benchmarking HTA organizations[35]. Similarly, Oortwijn and colleagues have developed and applied theoretical models to describe the level of HTA development in selected middle-income [36,37] and high-income [38] countries. In addition, Allen and colleagues have developed archetypes for non-ranking classification and comparison of European National Health Technology Assessment systems and used it to examine the relationship among the HTA system, process taxonomies, and the HTA recommendations for 102 new active substances approved by the European Medicines Agency (EMA) from 2008 to 2012 [39].

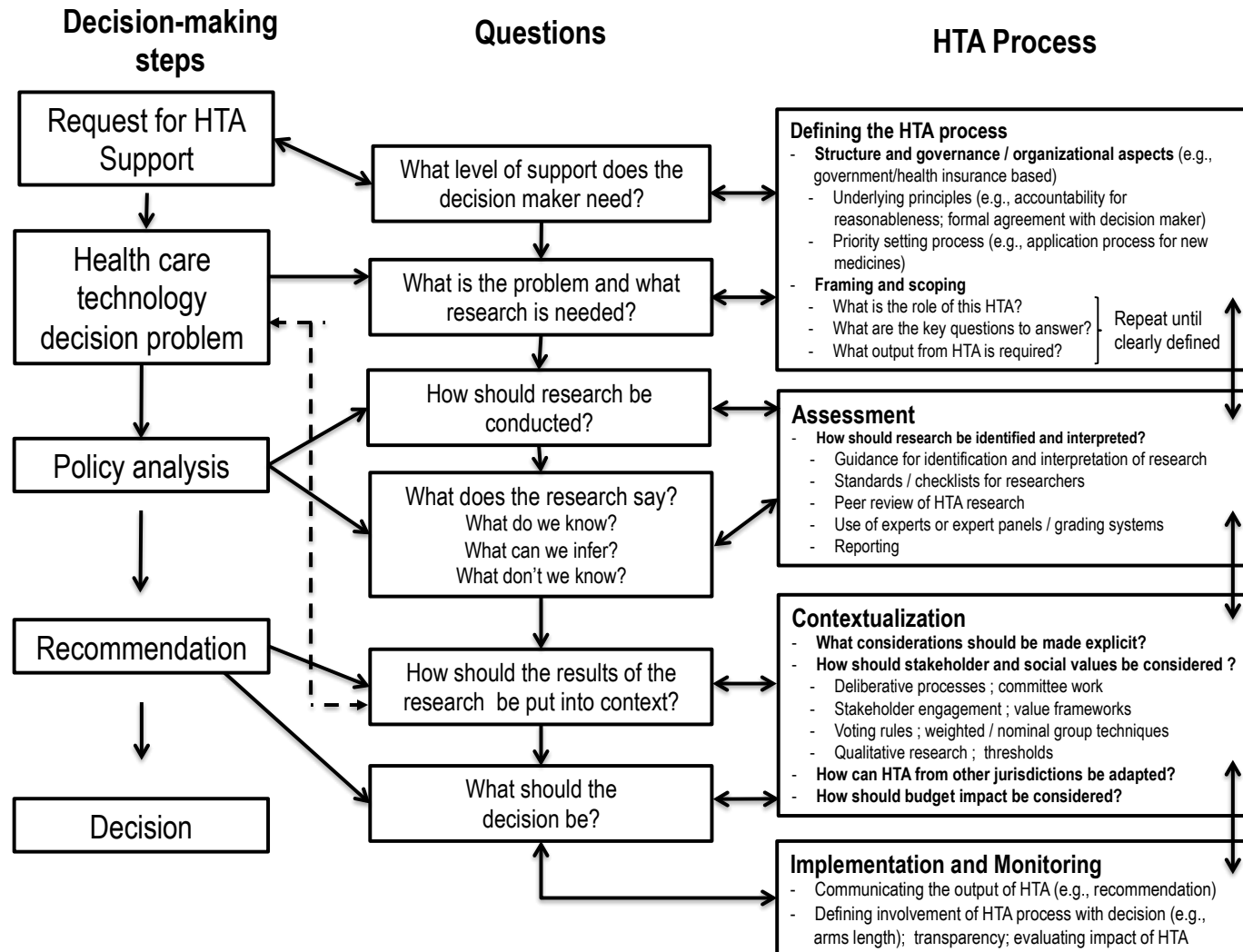
These experiences show that it is possible to specify criteria and principles, including specification of common standards for methods. However, principles to guide and benchmark HTA organizations[35], particularly those in low- and middle-income countries, may be difficult to achieve, either through lack of funding or local institutional barriers [40]. In addition, legislation, as well as culture (i.e., local practices, beliefs, and values) may condition how HTA activities are organized and conducted, particularly in respect of the importance of transparency and the level of stakeholder engagement.

Culture can also impact some aspects of how HTA processes are defined, particularly economic evaluations (also called cost-effectiveness analyses [CEA]) that consider social values, for example by using outcomes that consider health-related quality of life (HRQL), such as the quality-adjusted life-year (QALYs) as a primary measure of outcome for decision making [41].

In recent years, there has been an increased focus on the need for HTA processes to be fair[42]. “Accountability for Reasonableness” (A4R) is a framework to guide HTA processes which suggests key elements to ensure a fair process in healthcare priority setting. The A4R framework suggests decision makers should be “accountable for the reasonableness of their decisions”, necessitating publicity (transparency) about the basis of decisions, relevance to stakeholders, revisability in light of new information, and enforcement of these conditions (publicity, relevance, and revisability) [43].

Several studies dedicated to characterizing and comparing HTA processes may be helpful in understanding what choices are available [16,22,44,45]. Adopting certain key principles of published principles or the A4R framework [46] may dictate certain structural requirements.

Figure 1 Components of HTA within the healthcare decision-making process (developed by ISPOR HTA Council Working Group)



Priority setting for HTA

Many HTA organizations worldwide have had to grapple with the problem that more technologies are introduced than the available capacity within the HTA body could assess. Identification of what technologies are currently available can be a challenge and not all new technologies require assessment. HTA organizations must decide which technologies require the most attention, particularly in situations where there are no clear requests coming from a decision maker or there is a need to anticipate future requests.

The need for a clear structure for priority-setting has led to numerous frameworks that describe what characteristics may make a technology most suitable for assessment – typically reflecting societal values, uncertainty on effectiveness and safety, budget impact, and the perceived need for new technology [3,47–50]. Priority setting frameworks often involve priorities directly determined by the order of requests from a decision maker or applications from technology producers, as is commonly seen in public drug reimbursement programs. Ultimately, frameworks must reflect the priorities of the healthcare system they intend to support.

Most priority-setting frameworks have been criteria-based, with an emphasis on the same types of criteria that would be used to set health system priorities for technologies themselves (e.g., magnitude of health benefits and harms, costs, unmet need, disease burden, budget impact, etc.) [47]. Identification of candidate technologies is often done through “horizon scanning” procedures which can also provide important preliminary information for decision makers[51]. Patient and public involvement in priority setting has also gained attention more recently[52].

Implementation of an HTA prioritization framework could then involve deliberative processes, potentially assisted by approaches such as league tables, nominal group techniques, or multi-criteria decision analysis (MCDA) [53]. EUnetHTA has also developed a procedure for topic selection [10]. Priority setting will often also be tied to feasibility and question framing (see next section) as HTA bodies may discover technologies that are highly relevant for assessment but with little data or large amounts of uncertainty that ultimately shape what efforts must be undertaken [54].

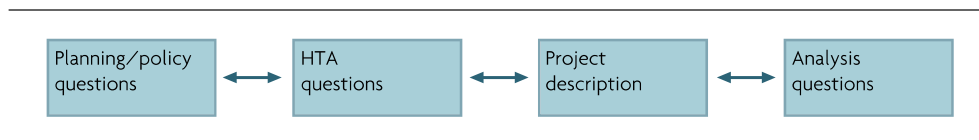
Framing and Scoping

Scoping, a process of determining what research questions are most important and what information is available to address them, is an important preliminary step for most HTA bodies and can have a significant impact on the assessment process. The desired outcome of a good scoping process is dependent on designing one or more clear questions along with an assessed feasibility of identifying and interpreting the research that could be utilized to provide answer(s) to the questions posed (Figure 2).

As most HTA bodies are primarily concerned with questions of clinical effectiveness, they may undertake a scoping process similar to that seen in systematic reviews of clinical research by specifying a research question defined by population, intervention under study, relevant comparators, outcomes (and the study design) (i.e., PICO[S] format) that outlines what clinical evidence is required to be gathered [50,55,56]. Primary research findings derived from a single study are rarely definitive, while replication of results in multiple studies offers assurance to decision-makers that the findings are reliable.

Evidence syntheses, typically systematic reviews and meta-analyses, based on quantitative techniques to evaluate and synthesize a body of primary research in a particular area, represent a core component of efforts to incorporate science into population-based decisions. However, HTA bodies with finite resources and timelines still must decide what research questions are most important to address for decision making. The availability of evidence, including existing systematic reviews and assessment reports and the feasibility of analysis may constrain the number and breadth of research questions considered.

Figure 2 Depiction of an HTA scoping process [57]



While there is significant guidance for the scoping process related to clinical systematic review and clinical decision making (e.g., PICO[S] framework) [50,58], those conducting HTA should be mindful that this is only one aspect of determining the larger number of questions relevant to policy makers. HTA bodies may also want to consider the role of policy makers and content experts, and of patients and consumers in the framing of questions[59].

Besides EUnetHTA's Methodological Standards and Procedures for Full core HTA content development and Procedure Manual for Rapid Relative Effectiveness Assessments [23] we are not aware of internationally recognized best practices for scoping for broader policy-relevant HTA [10]. The INTEGRATE-HTA project has highlighted some key considerations of this[60]. Another detailed description of scoping is available from Danish guidelines [57] which describes first how to identify policy questions, then how to identify the HTA research questions that might address these, along with conducting scoping exercises and revisiting the scope of assessments iteratively.

The UK, has similarly defined procedures for scoping[61]. EUnetHTA has published an analysis of HTA and reimbursement procedures in 28 EU Member States and Norway and Switzerland which covers topic selection, scoping, assessment and evaluation, quality assurance, informing decision-making and stakeholder involvement. [16]

ASSESSMENT (Synthesizing Evidence)

Summary: Good practices related to the synthesis and interpretation of evidence are widely adopted. There are many high quality guidelines for the conduct and reporting of evidence synthesis widely available and relevant to HTA processes.

Following scoping (understanding what decision-problem(s) is being addressed, what evidence might be desirable, coupled with considerations of the capacity and feasibility of conducting the research required to support it), is the process of analyzing and compiling (synthesizing) existing research to determine what evidence there is to inform population-based decisions. Evidence synthesis, also called *secondary research*, must consider approaches to interpret individual studies along with an entire body of evidence.

Many HTA processes involve systematic reviews or rapid reviews of clinical evidence, economic analyses and other relevant bodies of evidence and relevant guidance related to these activities is discussed briefly below. Summarized Research in Information Retrieval for HTA (SuRe Info) supports research-based information retrieval practices in producing systematic reviews and HTAs. SuRe Info seeks to help information specialists and others to stay up-to-date by providing easy access to current methods papers.[62,63]

HTA processes may also engage in *de novo* data collection and analysis (i.e., primary) research activities to produce new evidence. These primary research activities have been referred to as *field evaluation*, *coverage with evidence development*, or *comparative effectiveness research*. They may also involve surveys of experts or patients. Decisions regarding whether to conduct primary research can be best informed by characterizing and evaluating the decisional uncertainty identified after evidence has been synthesized and interpreted (see “using” evidence)[64,65].

Issues related to conducting clinical research synthesis and economic analyses

The consideration of clinical and economic evidence is most prominent in HTA processes[66]. Systematic clinical evidence syntheses were first undertaken in the late 1970s-1980s. However they remained a relatively infrequently used method until the 1990s with the establishment of the Cochrane Collaboration, an international organization that aims to help people make well-informed decisions about healthcare by preparing, maintaining, and promoting the accessibility of systematic reviews of the effects of healthcare interventions.

The Cochrane Collaboration has developed best practices in clinical evidence synthesis based upon consensus of methodologists. Methods for synthesizing qualitative research have also been described[67–73]. Other international organizations and HTA bodies have also produced guidance on the conduct of evidence syntheses [74–76]. Evidence syntheses in recent years has also been aided by the emergence of best practices in reporting health research[77,78].

Unlike clinical research, synthesizing economic evaluations poses unique challenges as these studies are highly context dependent and difficult to transfer across jurisdictions[79]. However, such systematic reviews to inform decisions are often conducted as they may provide insight into key cost drivers and trade-offs or inform the interpretation or conduct of a jurisdiction-specific economic model[79,80].

Mathematical modeling can also be used to synthesize disparate pieces of information relevant to healthcare decisions [81]. It can readily incorporate statistical extrapolations as well as cost information related to the use and adoption of technology and has become particularly useful for economic evaluation and to inform healthcare decision making. ISPOR has developed a tool for interpretation of modeling studies, using a checklist of questions that focus on the relevance and credibility of individual articles [82]. Some HTA bodies have similarly developed tools to address various aspects of modeling including model parameters[83–85] and use of survival analysis [86]. A review of existing guidance on modeling and simulation in the context of HTA has recently been published [87].

For conducting original economic evaluations, there are also numerous well-developed resources. These include several textbooks [88,89] and checklists[90]. ISPOR Good Practice Reports in modeling have also been published [91]. There are also recognized best practices for trial-based economic evaluation [92].The MedtecHTA project recently provided key recommendations related to HTA for medical devices.[93].

Interpretation of individual clinical and economic studies

Randomized controlled trials (RCTs)

Assessing the validity of RCTs through examining risk of bias is a key step in interpretation of results and avoiding erroneous conclusions or recommendations. There are many tools for assessing the quality of randomized trials but many do not reflect available empirical evidence about potential sources of bias and could lead to incorrect or inconsistent interpretations. A widely accepted tool is the Cochrane Risk of Bias tool [94] which was developed based empirical evidence of potential sources of risk of bias. Cochrane is currently revising this risk of bias tool and extending it to a broader range of randomized trial designs (e.g. cluster randomized trials [95]) and non randomized studies [96].

Observational studies

Widespread adoption of evidence from observational studies of the effects of interventions may be limited due to various factors, including the lack of consensus regarding accepted principles for their evaluation and interpretation; at the same time, observational studies have proven useful for some purposes, such as examination of long-term data on potential harms[97]. There are a wide range of resources available to assist users in familiarizing themselves with some of the core concepts to assess the quality of observational studies, including many textbooks in fields such as clinical research, epidemiology, statistics, econometrics, and health services research. Some freely available resources have focused on conducting and interpreting observational studies, e.g., internal validity of non-randomized studies on interventions (e.g. developed by EUnetHTA) [98–100]. Recently, a collaboration of ISPOR, the Academy of Managed Care Pharmacy (AMCP), and the National Pharmaceutical Council (NPC) developed an electronic tool to assist decision makers in utilizing a structured approach to evaluating evidence from observational studies, in order to make evaluations explicit and reduce variation from subjective interpretation to support consistency in decision making [101].

Economic evaluations

There are numerous checklists available to assess the validity of economic evaluations (CEA) and a review of available checklists has been conducted [90]. More common approaches to assessing the conduct of economic evaluation include checklists developed by Drummond [88] and others [103,104]. In 2015 EUnetHTA published Methods for health economic evaluations - A guideline based on current practices in Europe [105]. ISPOR has also developed the consolidated health economic evaluation reporting standards (CHEERS) to standardize reporting of economic evaluations [106]. Individual HTA bodies and specific jurisdictional initiatives may require more information than what can be found in journals, and have similarly developed local conduct and reporting guidance for economic evaluation [107–110].

Budget impact analyses

In addition to economic evaluation, healthcare decision making will often require an estimation of the potential budget impact of adoption of a new technology. Budget impact analyses (BIAs) are a narrow form of economic evaluation, considering the budgetary impact to payers of technology decisions. This can aid in answering questions about whether the decision to use a technology is affordable (a contextual consideration), feasible to implement, and what strategies payers may use to adopt it (e.g., price negotiations, disinvestment from lower-value services, alternative financing arrangements, or prioritization of treatment). There is also a growing body of methodological recommendations for conducting and interpreting BIAs. An ISPOR Task Force has developed and published guidelines for best practices in the development and conduct of BIAs [111] that may also facilitate their correct interpretation.

Qualitative research

Qualitative research offers complementary perspectives to those offered by quantitative research or established forms of synthesis. Qualitative methods are indicated in outcomes research when decision makers seek to understand complex phenomena that resist quantitative measurement [112]. They also yield insights into potential causal mechanisms and support development of patient-centred tools [113], particularly those that are sensitive to needs of disenfranchised or special populations.

Assessment of qualitative research [114] or quantitative research on patient preferences [115] may facilitate interpretation of available evidence. The Patient Centered Outcomes Research Institute (PCORI) in the US has been the most explicit, providing the standards for engaging patients and stakeholders in both evidence generation and evidence synthesis [116]. Good research practices have been published for quantitative analysis of patient preferences including conjoint analysis in health [117], guidance on experimental designs for discrete-choice experiments (DCE) [118], and for the analysis of data from DCE [119].

The nature of qualitative research and differences in approach make it challenging to apply a single set of criteria to different designs and report formats[120]. Generic approaches to quality assessment offer a common approach but lack sensitivity to the strengths of a particular design. Alternatively, design-specific criteria make comparability across studies problematic.

Similar diversity challenges current reporting standards. COnsolidated criteria for REporting qualitative research (COREQ) for reporting interviews and focus groups [121] are less appropriate for other qualitative research. Similarly, ENhancing Transparency in REporting the synthesis of Qualitative research (ENTREQ) reporting guidance [122] primarily targets the more common variants of qualitative synthesis. Neither COREQ nor ENTREQ has negotiated the consensus processes recommended for development of reporting guidelines [123].

Expert Opinion

When evidence is imperfect or lacking, and in interpreting research findings HTA bodies may need to identify and consult with content experts. While the use of experts in HTA is commonplace, implementation of common standards for elicitation and synthesis of expert opinion is scarce[124].

Organizational, ethical, legal, and social issues

There is a large body of literature dedicated to the assessment of organizational as well as ethical, legal, and social issues[125], particularly in the context of genetic technologies [126]. The EUnetHTA Core Model offers significant guidance on the assessment of these issues[23].

Ethics

In the conduct of HTA moral, legal, economic, social, and methodological value judgments are often intertwined to such an extent that it is difficult to make them explicit individually [128,129]. The aim of ethics analysis in HTA is to identify and examine these value judgements and to examine the potential implications of the adoption of a health technology from a moral point of view in order to answer a range of questions: What ethical issues are raised by the adoption of a particular technology? How ought the technology be provided to address the identified moral issues? What is the relevant evidence that should be collected to help address these questions? [130]

A variety of approaches have been suggested for the identification and analysis of ethical issues of health technologies [131,132], and reviews of relevant guidance documents and tools for ethics in HTA exist[133]. The guidance on identifying and addressing ethical issues developed by the EUnetHTA [132] and INTEGRATE-HTA [60,134] projects currently provides the most comprehensive descriptions of available approaches for identifying and handling ethical issues in HTA. Of all guidance documents, the INTEGRATE-HTA guidance has gone furthest in attending to a broad range of issues confronting those conducting ethics analysis, including characteristics of complexity of technologies, the implications of ethics analysis for HTA, and an analysis of the ways in which integration of ethical issues may be considered.[134–138]

There is no widespread agreement within the HTA community on which of the many possible approaches may be best suited to ethics analysis in HTA[138]. There is a sense that not all approaches are equally suited to the task and some approaches may be favored more than others among HTA researchers and decision makers.

Quality assessment of ethics analysis is still nascent and there do not currently exist any broadly accepted tools or checklists for conducting this quality assessment as there do for assessing the strength of individual empirical studies, systematic reviews, and economic evaluations [139]. However, a recently developed tool for quality analysis provides guidance on assessing both the content of the argument of an analysis as well as the applicability of the results and potential sources of bias[139].

The questions of who possesses the relevant expertise for conducting ethics analysis in HTA and which qualifications are necessary are important and are the subject of discussions in INAHTA and the HTA international Interest Group on Ethics in HTA[128]. Some have proposed that conducting these analyses demands a reasonable amount of knowledge of ethical theories and principles and at a minimum, competent researchers in this area should be familiar with approaches in clinical ethics and moral philosophy[140].

Interpretation of bodies of evidence

Systematic Reviews

The use of previously-published systematic reviews in a new evidence synthesis has become commonplace in population-based decisions, in part due to the perceived obligations of health system stewards to consider all available evidence in decision making while remaining operationally efficient and avoiding unnecessary duplication[141]. A previously used and validated tool to help interpret the validity of systematic reviews and meta-analyses is Assessing methodological quality of systematic reviews (AMSTAR) [142].

Guidelines for reporting systematic review protocols (Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols [PRISMAP]) and reports [143] in biomedical journals have been widely accepted. Methods of synthesis continue to evolve in health and other sectors. While the majority of evidence syntheses have focused on the effectiveness of medical technologies [144], there is increasing use (and development of robust methodologies) of evidence syntheses to address different types of specific questions such as disease burden or HRQoL.

Meta-analysis and indirect treatment comparison studies

Meta-analyses can be applied to results of trials and other studies assembled for systematic reviews to help decision makers quantify the magnitude of benefit or harm associated with one intervention compared to another. While there are significant resources available to aid analysts in conducting meta-analyses, there are no widely recognized tools or checklists for their interpretation[145].

The advent of multiple treatment options in a given therapeutic area coupled with a lack of head-to-head comparisons has led to an increased need for statistical approaches to create comparisons between health technologies from studies that do not directly compare the technologies, (ie, indirect treatment comparisons). Indirect treatment comparisons use evidence from existing RCTs to estimate the relative effect of multiple treatments, and may use a meta-analytic approach called network meta-analysis (NMA). A consensus checklist for the interpretation of indirect treatment comparison studies for population-based decision making has been developed [146].The GRADE working group has also developed a tool to rate the quality of NMAs [147,148] and the PRISMA Working Group has developed a checklist for reporting NMAs[149].

Reporting guidelines to aid in the syntheses of qualitative research are also evolving (eg, Realist And MEta-narrative Evidence Syntheses: Evolving Standards [RAMESES] for meta-narratives [150] and realist syntheses [151] and Protocol-developing meta-ethnography reporting guidelines [eMERGE] for meta-ethnography [152]).Integrating insights from both quantitative and qualitative

studies (mixed methods) have also been developed along with the emergence of tools for assessing [153] or reporting mixed methods studies.

CONTEXTUALIZATION (Using Evidence)

Summary: Good practices intended to enhance consistency across decisions, provide justification of value judgments, and enhance the legitimacy of societal decision making have been developed but are not widely adopted in HTA. There are many disparate and evolving approaches to contextualizing (appraising) evidence for decision makers.

The process of using evidence to inform population-based decisions involves **contextualizing the evidence** for a particular setting which can involve incorporating additional social values through considering stakeholder input, and supporting the implementation of decisions[154]. How evidence is used can be interpreted as directly related to the perceived legitimacy of the decision-making process. Some noteworthy issues in this regard relate to how equity and ethics are incorporated to support decisions, how HTA bodies deal with uncertainty, and how various stakeholders are engaged throughout the decision-making process.

The processes of contextualization, sometimes called “appraisal”, and its transparency to the public, particularly in regards to drug reimbursement, has been shown to vary across systems and justification with explicit criteria is generally limited[155]. The use of an explicit decision framework (or ‘value’ framework[156]) has been proposed as a means to enhance consistency across decisions, allow justification of value judgments, and enhance legitimacy of societal decision making [155,156].

Other issues facing HTA bodies include how to apply HTA findings from other jurisdictions, which may be viewed as a means to faster decision-making, but must be re-contextualized or *transferred* to a local context (see below). Finally, HTA bodies must also consider how budget impact analyses are used in recommendation, and how to support considerations of affordability or strategies for financing of new technologies.

Integrating stakeholder input (eg, patients, clinicians) and considering social values to support decision making

While it is well recognized that different scientific judgments and risks of bias may lead to different interpretations of available evidence (see Assessment section), even strong consensus on the impact of a technology may be valued differently by different segments of society. For example, a technology may be valued differently if it produces an extra QALY in the very young or in someone with very few years of life left versus one that does the same in a middle-aged, otherwise healthy patient. To this end, there is a need to consider to what extent the meaning and importance of scientific findings requires the integration of social values and stakeholder perspectives to arrive at a recommendation or decision.

The complexity of considering different values simultaneously and the need for fairness and consistency has led to more systematic and transparent approaches to incorporating what is considered important to key societal stakeholders. These include deliberative processes, multi-criteria decision analytic processes, and other forms of contextualizing evidence that informs decisions. HTA bodies must consider the various approaches to these processes and different models for encouraging dialogue between relative stakeholder groups. Specific recent attention has been paid to how to engage patients, who have been traditionally removed from the process of expert consultation.

Deliberative processes

A deliberative process or approach is intended to improve the quality of decision making by allowing for mutual decision making based on facts[157]. In HTA, it often takes the form of an expert or advisory committee[154]. These processes are not the same as seeking commentary or consulting with experts. Deliberative processes involve mutual deliberation and encourage interchange and participation[158].

Although there is still no consensus regarding what constitutes a “best” deliberative process, checklists and guidance have been developed to help those who wish to consider its design [159]. At its core is a goal of balanced consensus – namely that the deliberative process provides “guidance that respects both scientific integrity on the one hand and its implementability in a specific health system context on the other.”[159].

Patient engagement and patient preferences

A growing number of HTA agencies are now incorporating the perspective of patients [160] and citizens [161] through patient and stakeholder engagement[162], and patients were one of four stakeholder groups in EUnetHTA JA1 and JA2 [10]. Principles and international standards for patient engagement have also been developed. The European Patients’ Academy (EUPATI) developed “Guidance for patient involvement in HTA”. It draws together the outcomes of several

research and consensus-building processes carried out by a variety of national and international organisations. It also draws on good practice examples from individual HTA agencies. Tools to assess patient involvement in assessment have also been published[163].

Weighted stakeholder preferences and multi-criteria decision analysis

A set of techniques, known as multi-criteria decision analysis (MCDA), is intended to increase the consistency, transparency, and legitimacy of recommendations to support decisions. MCDA comprises a broad set of approaches that generally involve the identification and structuring of criteria and decision alternatives, the scoring of performance of the analysis on the criteria, weighing the criteria, and then aggregation and sensitivity analysis [164,165]. Evidence on the use of MCDA in relation to HTA is evolving: MCDA has been used to prioritize technologies for further assessment [53], for weighing patient-relevant endpoints [166], for bridging HTA with decision making[167,168], for support of deliberative decision processes [169] and finally for selecting technologies for reimbursement [170–172] However, the perceived usefulness and acceptance by decision makers is still not well researched.

Interpreting economic evaluations and use of thresholds

Making decisions about new technologies based on cost-effectiveness may involve: i) an estimate of the incremental costs and benefits a new technology generates, against a comparator technology (the incremental cost effectiveness ratio [ICER]), and ii) a comparison of the ICER against some benchmark of value - the cost-effectiveness threshold. This approach is intended to establish whether the benefits gained from using a new technology are estimated to be greater than the benefits expected to be forgone as a result of other services in the health system that must be displaced. Another approach, called “extended CEA”, explicitly considers the distributional consequences of decisions from investment[173].

In principle, the threshold approach to using economic evidence reflects the opportunity cost of investments in health technologies, but in practice there is substantial debate about how the threshold ought to be estimated. Broadly speaking, there are two main approaches to the choice of threshold [174]. The first is based on the marginal value of health for society; an assessment of the amount society should be willing to pay for health [175]. The second approach is based on the marginal productivity of the healthcare system, an empirical assessment of the health benefits forgone when additional funding is incurred[176].

Few countries operate explicit thresholds[177]. In the UK, the National Institute for Health and Care Excellence (NICE) specifies a threshold range of £20-30,000 per QALY. Furthermore, there may be reasons why the health benefits generated by use of a new technology are considered to have a different value versus displaced health benefits, usually because of the characteristics of the patients (such as their age, how much therapeutic gain is involved, or the severity of their

disease). In most situations, these attributes of value are considered in a deliberative manner rather than through the incorporation of formal, quantified weights.

Interpreting or adapting HTAs from other jurisdictions

On occasions it is necessary for healthcare decision-makers to interpret or adapt an HTA conducted in another jurisdiction, either to assess whether a local HTA should be conducted, or to inform a local decision in circumstances where there are neither the resources nor the time to conduct a local assessment. A number of factors, differing between jurisdictions, could potentially affect the effectiveness and/or costs of alternative treatments or programs, including basic demography or epidemiology of disease, clinical conventions or practice patterns, the availability or distribution of healthcare resources and relative prices.

Issues of the adaptation of HTAs and how these may be addressed have been discussed in an ISPOR Good Research Practices Task Force Report [178] and several published papers [179,180]. One paper specifically examines statements of international pharmacoeconomics guidelines about the transferability of different categories of data, such as baseline risk, relative clinical effect, resource use and costs [181]. EUnetHTA has also produced an adaptation checklist, containing elements of good practice for dealing with transferability issues [11] and a Glossary of HTA Adaptation Terms to identify and highlight key words and concepts with a view to aiding the adaptation of HTA reports between settings [182]. More importantly EUnetHTA developed the HTA Core Model to improve the applicability of evidence and information for HTA across jurisdictions by providing a common framework for the production and reporting of HTA information [10].

Use of budget impact analyses

Although budget impact analyses (BIAs) are commonly required together with economic evaluations in manufacturer submissions to HTA agencies, HTA and payer organizations have taken highly variable approaches to considering BIA data in decision making. For example, The Danish “Guidelines for cost analyses of new medicines and indications in the hospital” include estimation of patient resources (eg, time spent on transportation or treatment and cost of home care). An estimate of the budget impact for the health regions must be produced in addition to the cost analysis.[183] NICE has produced a methods guide for cost and budget impact analyses [184], but this is principally intended for use by health systems *following* publication of guidance that is driven by evidence on clinical effectiveness and cost-effectiveness alone. Canada similarly does not use BIA information to inform recommendations. A recent approach promoted by the US-based Institute for Clinical and Economic Review uses budget impact information to determine the proportion of patients that may qualify for treatment based on tolerable growth in health expenditure.[185]

IMPLEMENTING AND MONITORING HTA

Summary: Different potential approaches to implementing HTA are described. There are no widely adopted good practices for evaluating the impact of HTA. Although many approaches have been developed and some jurisdictions have reported impact using different approaches, a robust approach requires a broad range of research methods.

Health technology assessment is undertaken to inform policy and practice. However information from HTA processes is not self implementing and may fail to maximize impact due to failures in dissemination and implementation. This suggests that a plan to maximize the likely impact of the HTA should be developed. Lavis and colleagues identified four key questions that should be considered when developing dissemination and implementation plans regarding the communication (ie, knowledge transfer) of information[186]: 1) *What knowledge from an HTA process should be transferred?*; 2) *To whom should it be transferred?*; 3) *By whom should it be transferred?*; and 4) *How should it be transferred?*

Two factors that have been empirically identified as important to use of HTA findings are interactions between researchers and policy makers in the context of policy networks such as formal advisory committees and in the context of informal relationships; and research that matched the beliefs, values, interests, or political goals and strategies of elected officials, social interest groups, and others[186].

Tools for evidence-informed health policy making [187] were developed to assist policy makers in using research evidence and describe a series of processes to help ensure that relevant research is identified, contextualized and used appropriately by policy makers. HTA agencies can also support the choice of implementation strategies of different stakeholders by synthesizing the evidence on the effectiveness of different implementation interventions and by highlighting the conditions necessary to make an intervention feasible and likely effective within the local context and potential unanticipated consequences of interventions. In general, implementation activities could target governance e.g. financial (such as coverage decisions), service delivery arrangements, or specific service change programs. Health Systems Evidence is an online repository of syntheses of research evidence about governance, financial, and delivery arrangements within health systems, and about implementation strategies that can support change in health systems [188]. The database contains policy briefs, overviews of systematic reviews, and systematic reviews.

A common application of HTA is to support formulary development and decisions regarding pricing and reimbursement of new medicines. The use of the AMCP dossier format is a structured approach to informing assessments of new drugs [189]. EUnetHTA has published submission

templates and guidance for relative effectiveness assessment of pharmaceuticals, medical devices, and other technologies based on the HTA Core Model and analysis of existing national requirements and guidance from across Europe[10,190]. Another potential approach to implementing HTA, particularly for drugs are value-based pricing approaches [191].

Kalo et al. developed the HTA implementation scorecard framework to assess the current status of HTA implementation in Central and Eastern European countries, based on eight key components: (i) HTA capacity building; (ii) HTA funding; (iii) legislation on HTA; (iv) scope of HTA implementation; (v) decision criteria; (vi) quality and transparency of HTA implementation; (vii) use of local data; (viii) international collaboration [192].

Measuring HTA Impact

Although several dozen reports estimating the impact of HTA's have been produced [193], limitations in design of impact evaluation studies have led to only limited conclusions on longer term effects on practice and outcomes; additionally, none of the studies explicitly aimed at examining the role of the factors that might be responsible for a low or high impact of the HTA reports.[194] A "six step model" has been proposed to measure the impact of HTA[195]:

- 1) Awareness: the corresponding stakeholder must know that the HTA is a prerequisite for influencing a decision.
- 2) Acceptance: the report should also be useful in terms of validity, relevance and applicability and its findings acceptable.
- 3) Policy process: the policy process within which the HTA is used (e.g. reimbursement or guideline development) should explicitly utilize the HTA report.
- 4) Policy decision: the actual policy decision should be clearly influenced by the HTA's conclusions or recommendations.
- 5) Practice: the policy decision has to be implemented in practice, through clear and measurable changes in clinical practice.
- 6) Outcome: clinical practice must change before it is possible to begin to measure the true impact of an HTA, for example in terms of health or economic outcomes.

Based on these previous experiences in measuring impact, it appears a robust approach for assessing the impact of HTA requires a broad range of research methods[193]. A prospective design (defining a protocol before collecting data) with a clear feedback loop should be considered [196]. The use of electronic databases, clear defined processes of research agreed by all participating organs and the development of new methods especially designed for assessing impact should be considered although approaches need to be contextualized and may not always be feasible or affordable [197].

Several studies have estimated the economic impact of HTA in different jurisdictions, allowing distribution of resources into effective and safe technologies and covering the costs of the HTA program [198–201]. The results of the first study that investigated the influence of different HTA models and procurement practices on the selection and prices of medical devices has been recently published[202].

CONCLUDING REMARKS

Twenty years ago the EUR-ASSESS Project made it clear that HTA is not defined by a set of methods but by its intent, and given the wide scope of HTA it should not be viewed as a single discipline or field. Rather, HTA is multidisciplinary and must always be firmly rooted in science and the scientific method [1]. Today, HTA still covers a range of approaches intended to inform decision making and is held together by the application of science. There is now a more widely shared understanding of the standards that HTA should aim to meet and understanding of the importance of developing, agreeing and implementing good practices.

HTA, encompassing evidence synthesis, may be viewed as informing evidence-based decision making – two related but distinct concepts [203]. The process of rigorous review and synthesis of scientific evidence focuses on assessing the relative benefits, harms, and costs of healthcare technologies using sound analytic judgments. Evidence-based decision making incorporates other considerations (eg, affordability, values/preferences, equity, feasibility and acceptability) that may require mechanisms to support them, such as deliberative processes in contextualisation of assessment results.

These latter considerations, which can be supported or coordinated by HTA bodies, have recently taken center stage and to an extent overshadowed the importance of the evidence synthesis process. This has led to a fuzzy distinction between the activities of HTA and decision making, particularly in processes of contextualization, eg, in appraisal and reimbursement committees, and the recommendations that come from them which may involve both analytic judgments (such as willingness to include indirect comparison and surrogate endpoints as source of evidence, or how QALYs were derived) and consideration of social values (such as weighing the value of a QALY in the very young or old).

The ability of decision makers to override the recommendations of HTA authorities based on other considerations and variations in approaches to HTA makes its role even more difficult to discern, even to experts in the field [204]. This has led to much criticism of HTA in recent years resulting from the decision-making processes and the extent to which they are transparent and deliberative. Unfortunately, this criticism may result in some spillover and skepticism regarding

the evidence review and synthesis processes. The future acceptance of HTA may depend on greater clarity regarding the scope of these two processes, largely identified with “assessment” and “contextualization” in this document, and additional measures to enhance the transparency by decision makers regarding the key elements that actually are driving decisions.

Moving systematic review and synthesis beyond clinical, epidemiological, and economic research into qualitative and quantitative in patient, caregiver, and citizen generated information, such as perceptions, valuation and outcomes is an immediate need in HTA research (where sufficient primary research is available). As part of this effort, there is a need for more research into the structured approaches to deliberative decision-making, potentially supported by multi-criteria decision analysis (MCDA) [157]. This will represent a continuation of the EUR-ASSESS approach as implemented in the HTA Core Model and would help further “populate” the non-clinical domains of the Model such as “patient and social” and organizational aspects with good methodologies and more evidence.

Beyond a clear delineation of the roles of HTA and decision making (as well as scientific judgment and value judgment), HTA bodies may also need to consider what healthcare decisions are best supported by HTA. The move to early dialogue and scientific advice on evidence generation to technology developers can be seen as advancement toward more constructive HTA processes, where alignment between patients, payers, regulators, and technology producers is created through shared information requirements and collaborative planning. [205,206] It is also a stepping stone to HTA considering the costs of innovation, when informing healthcare decision makers. Recognition of the overlapping roles of regulatory and HTA processes is another key area of evolution and development for HTA[207,208].

Efforts by researchers in the disciplines and research fields that contribute to HTA will undoubtedly continue to include review of their own good practices and produce guidelines and textbooks that will have immediate relevance for HTA. Taken together, priorities for good practice guidance in HTA as reflected in this paper and the ISPOR Outcomes Research Guidelines Index [19] will likely need to focus on developing good practices in *using* evidence to support decision making through monitoring of HTA implementation and its input to various types of decision-making, rather than concentrating the focus of guidance production on HTA research practices (eg, evidence review and synthesis, outcomes research and health economics), while encouraging and increasingly building on high quality research guidance from “contributing” fields of research. With the evolving ISPOR Guidelines Index, and this review of current guidance it may be easier to prioritize where efforts should be put in developing good practices in HTA.

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APPENDIX 1

Definitions of HTA

HTA TERMINOLOGY

The concept of “health technology assessment” borrows from an earlier, formally-developed concept of “technology assessment” – a multidisciplinary field of policy analysis intended to provide decision makers with “early indications of the probable beneficial and adverse impacts of the applications of technology” [1,209].

Broadly speaking, HTA looks at the impact of technology through the lens of health system goals – for example, judging the impact of delivering a new service on populations.

Several formal definitions of HTA have been developed and adopted. The International Network of Agencies of HTA (INAHTA) defines HTA as

“the systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies. HTA is conducted by interdisciplinary groups that use explicit analytical frameworks drawing on a variety of methods.”[210]

Other similar definitions have been proffered by academics [211], and HTA bodies [212]. Differing definitions have made conceptualizing HTA a challenge. There may be differences of opinion regarding the scope of HTA and methods used to assess impact. For example, some have suggested HTA should be strictly population-based [213] while others have proposed HTA for individual decisions [214]. The latter overlaps with concepts of medical decision making and evidence-based medicine.

In summary, and for the purposes of this report, HTA is a research-based multidisciplinary process intended to support healthcare decision making by assessing properties and effects of one or several new or existing health technologies in comparison with a current standard. Aiming at determining added value, good practices in HTA aspire to use explicit analytical frameworks based on research and the scientific method in a systematic, replicable and transparent manner.

Broad definitions of “health technology” to include e.g. health systems interventions also create a conceptual overlap with the fields of “health impact assessment” [215] and “research impact assessment” [216]. Finally, definitions that restrict HTA methods to synthesis-based assessment versus expanding this notion to clinical trial- or study-based assessments creates an overlap with the newly-coined term “comparative effectiveness research,” which is intended to describe

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discrete comparisons of the evidence on alternative interventions for a given condition, without examination of broader societal or population impacts.[211]