

# Methods for Early Assessment of the Societal Value of Health Technologies

**Citation for published version (APA):**

Grutters, J. P. C., Kluytmans, A., van der Wilt, G. J., & Tummers, M. (2022). Methods for Early Assessment of the Societal Value of Health Technologies: A Scoping Review and Proposal for Classification. *Value in Health*, 25(7), 1227-1234. <https://doi.org/10.1016/j.jval.2021.12.003>

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**DOI:**

[10.1016/j.jval.2021.12.003](https://doi.org/10.1016/j.jval.2021.12.003)

**Document status and date:**

Published: 01/07/2022

**Document Version:**

Publisher's PDF, also known as Version of Record (includes final page, issue and volume numbers)

**Please check the document version of this publication:**

- A submitted manuscript is the version of the article upon submission and before peer-review. There can be important differences between the submitted version and the official published version of record. People interested in the research are advised to contact the author for the final version of the publication, or visit the DOI to the publisher's website.
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## Systematic Literature Review

# Methods for Early Assessment of the Societal Value of Health Technologies: A Scoping Review and Proposal for Classification



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## ABSTRACT

**Objectives:** Early assessments of health technologies help to better align and integrate their development and assessment. Such assessments can take many forms and serve different purposes, hampering users in their selection of the most appropriate method for a specific goal. The aim of this scoping review was to structure the large set of methods according to their specific goal.

**Methods:** A scoping review was conducted using PubMed and reference lists of retrieved articles, to identify review studies with a methodological focus. From the included reviews, all individual methods were listed. Based on additional literature and examples, we extracted the specific goal of each method. All goals were clustered to derive a set of subclasses and methods were grouped into these subclasses.

**Results:** Of the 404 screened, 5 reviews were included, and 1 was added when searching reference lists. The reviews described 56 methods, of which 43 (77%) were included and classified as methods to (1) explore the nature and magnitude of the problem, (2) estimate the nature and magnitude of the expected (societal) value, (3) identify conditions for the potential value to materialize, and (4) help develop and design the type of research that is needed.

**Conclusions:** The wide range of methods for exploring the societal value of health technologies at an early stage of development can be subdivided into a limited number of classes, distinguishing methods according to their specific objective. This facilitates selection of appropriate methods, depending on the specific needs and aims.

**Keywords:** decision modeling, early assessment, health technology assessment, innovation, stakeholder involvement.

VALUE HEALTH. 2022; 25(7):1227–1234

## Introduction

Health technology assessment (HTA) is increasingly performed in earlier stages of development of a healthcare technology, with the aim to maximize the return on investment and societal impact of research and development.<sup>1-3</sup> This so-called early HTA can be defined as “all methods used to inform industry and other stakeholders about the potential value of new medical products in development, including methods to quantify and manage uncertainty.”<sup>2</sup> Although it is unclear when an assessment is “early,” IJzerman et al<sup>2</sup> note that “the definition includes early HTA of medical products just before and also at the early stages of clinical use, while accepting that product development can continue after regulatory approval.” Early HTA is generally used to explore the potential value of the technology in its intended context before empirical evidence on the technology is available.<sup>1</sup> A majority of early HTA applications use health economic models to estimate an innovation’s expected cost-effectiveness.<sup>1,2,4-7</sup> Although novel technologies may need to prove cost-effectiveness in publicly funded healthcare systems, there may be different perspectives on

an innovation’s added value that are not fully captured in health economic models.<sup>3,8,9</sup>

In addition to health economic modeling (further referred to as “modeling”), the contextual expertise of different stakeholders produces valuable insight into an innovation’s expected societal value.<sup>10</sup> In particular, a mixed-methods approach enables assessors to separate enthusiasm about innovation in general or the ingenuity of an innovative surgical instrument from the shared perception that there is no problem in current care and that the innovation will not add health benefit to patients.<sup>11</sup> It is generally recognized that stakeholder involvement is crucial to support the development of technologies that will be accepted and used in practice.<sup>10,12-14</sup> Other methods may also be used for technology assessment in an early stage. For early HTA to be fully appreciated, it is important to use the methods and answer the questions that are most relevant to the development and research of the technology.

To date, several reviews have identified a large number of methods that can be used in an early stage.<sup>2,5-7,10,15</sup> The large set of and great diversity in methods may hamper researchers,

### BOX 1. Generic methods for stakeholder involvement or decision modeling

Brainstorming sessions, expert panels, focus groups, informal discussions, (key informant) interviews, road and multi-path mapping, surveys, and workshops were mentioned in the reviews as different ways of organizing stakeholder involvement. Expert panels and focus groups are suitable for bringing stakeholders together to simultaneously construct a shared understanding of relevant societal problems, innovation requirements, et cetera. Brainstorming sessions, informal discussions and workshops are formats for letting stakeholders interact with one another within an expert panel or focus group. Interviews are ideal for obtaining an in-depth understanding of the stakeholder's perspective, experience and expertise. Different methods may be combined to maximize participation; for example, one may provide an online survey to experts that were unable to attend a panel session.

All health economic models are cases of decision modeling, where the goal is to synthesize evidence in order to support a decision among two or more alternatives. Decision tree analysis, discrete event simulation, dynamic or systems simulation and Markov models are methods that provide different ways of structuring a health economic model. Similarly, cost-benefit analysis, cost-effectiveness analysis and cost-utility analysis are different frames for economic evaluation. Multiple types of models may be combined. For example, a decision tree that simulates diagnosis and treatment often precedes a Markov state-transition model that captures the long-term societal costs and health effects of treatment outcomes. The ISPOR good modeling practices series provides hands-on guidance for conceptualizing and analyzing health economic models. Once a health economic model has been constructed and validated, the same model can be reused at different stages in the innovation process, and for answering different questions. Uncertainty can be quantified by means of (probabilistic) sensitivity analyses.

reviewers, and research commissioners in their selection of the most appropriate method for a specific goal. This is further complicated by the fact that previous reviews tend to focus on quantitative methods<sup>5</sup> or on the use of early HTA specifically for technology developers,<sup>6</sup> whereas early HTA can also inform other stakeholders.<sup>3</sup> In this scoping review, we focus on methodology to explore the value of technology to patients and society. The aim was to see whether the large set of methods that have been proposed could be divided into different classes, according to their specific goal.

## Methods

### Search Strategy

In PubMed, we searched for review studies with a methodological focus, which listed specific methods for early assessment. Keywords were “(‘early health technology assessment’ OR ‘early evaluation’ OR ‘early assessment’) AND ‘methodology’ AND ‘review.’” The search was last updated on March 12, 2021. Reviews were excluded if they identified only empirical examples of early HTA. From each included review, we analyzed the reference list for additional relevant reviews. All titles and abstracts were first assessed by 1 author, and if deemed relevant, the full text was retrieved. Each of the full-text articles was appraised independently by 2 authors. From the included reviews, we listed all methods that were mentioned. Methods that were mentioned multiple times were combined into 1 unique method.

### Inclusion and Exclusion Criteria

We included all methods for the early evaluation of 1 novel technology with a specific target population or indication for use. Methods were excluded for 1 of 3 reasons. First, methods for priority setting or portfolio-level decision making were excluded because of our focus on a specific technology in a specific care context. Second, methods designed to inform strategic or other business decisions were excluded, because we focus on the value of technology to patients and society. Third, we excluded broader frameworks of methods and analyses, because we focus on the practical application of a specific method or analysis.

### Strategy for Reporting the Data

A total of 3 authors discussed and reached consensus on the excluded methods and investigated and discussed the included methods further. The aim of those discussions was to derive different classes of methods. For each of the methods, we searched for additional literature and examples, and based on this information, we retrieved the specific goal of the method. All goals were listed and clustered to derive a set of classes that related to the different goals an early assessment could have. Next, all methods were grouped according to these classes. The methods are structured and explained according to the classes in the results section, together with some practical suggestions for and examples of the use of these methods.

## Results

### Selection and Categorization of Methods

Our search resulted in 424 hits, of which we included 5 reviews.<sup>2,5,6,10,15</sup> From the reference lists of these reviews, we retrieved 1 additional review.<sup>7</sup> The 6 reviews described 56 methods (first column in Table 1). Based on the in- and exclusion criteria, we included 43 of these methods (77%). Excluded methods and reason for exclusion are listed in Appendix 1 in Supplemental Materials found at <https://doi.org/10.1016/j.jval.2021.12.003>.

On the basis of our review and analysis of methods, we found that the included methods can be classified into 4 classes, with 4 specific goals for early assessment: (1) methods for exploring the nature and magnitude of the problem for which the technology under development should serve as a resolution, (2) methods for estimating the nature and magnitude of the (societal) value that may be expected to be associated with the use of the technology under development, (3) methods for identifying the set of conditions that need to be met for the potential value of a technology under development to materialize, and (4) methods to help develop and design the type of research that is needed to demonstrate whether the expected value is actually borne out in practice. Of the included methods, 24 were found to be specifically useful for one of these goals and are therefore classified into one of these classes (Table 1). We also found 19 methods that were more

**Table 1.** Overview of all included methods from the 6 reviews of early HTA (column 1), in which reviews were they mentioned (columns 2-7) and for which goal the method is most useful (column 8).

Included method	Hartz and John <sup>7</sup>	Ijzerman and Steuten <sup>5</sup>	Markiewicz et al <sup>6</sup>	Ijzerman et al <sup>2</sup>	Fasterholdt et al <sup>15</sup>	Støme et al <sup>10</sup>	Specifically useful for which goal?
Multipath mapping			X				Exploring the nature and magnitude of the problem
Road mapping			X		X		Exploring the nature and magnitude of the problem
Headroom analysis			X	X	X		Exploring the nature and magnitude of the problem
PYLL			X				Exploring the nature and magnitude of the problem
Bayesian statistics	X		X	X	X	X	Estimating the nature and magnitude of the (societal) value that may be expected
Expert elicitation			X			X	Estimating the nature and magnitude of the (societal) value that may be expected
Scenario building/analysis			X		X	X	Estimating the nature and magnitude of the (societal) value that may be expected
AHP		X			X		Identify conditions for the potential value to materialize
Benchmark clinical performance analysis	X						Identify conditions for the potential value to materialize
Best-worst scaling			X				Identify conditions for the potential value to materialize
Choice-based conjoint analysis			X				Identify conditions for the potential value to materialize
DCE		X					Identify conditions for the potential value to materialize
Discrete choice modeling			X				Identify conditions for the potential value to materialize
MCDA		X					Identify conditions for the potential value to materialize
Qualitative weighing of relevant factors			X				Identify conditions for the potential value to materialize
Usability tests			X				Identify conditions for the potential value to materialize
Use cases writing			X				Identify conditions for the potential value to materialize
Users feedback			X				Identify conditions for the potential value to materialize
Users-producers seminars			X				Identify conditions for the potential value to materialize
Clinical trial simulation	X	X		X			Helping develop and design the type of research that is needed
Payback from research		X					Helping develop and design the type of research that is needed
Real options analysis		X	X		X	X	Helping develop and design the type of research that is needed
ROI analysis	X		X		X		Helping develop and design the type of research that is needed
VOI analysis	X	X	X		X	X	Helping develop and design the type of research that is needed

*continued on next page*

Table 1. Continued

Included method	Hartz and John <sup>7</sup>	Ijzerman and Steuten <sup>5</sup>	Markiewicz et al <sup>6</sup>	Ijzerman et al <sup>2</sup>	Fasterholdt et al <sup>15</sup>	Støme et al <sup>10</sup>	Specifically useful for which goal?
Early health economic modeling	X	X					Generic health economic modeling technique; useful for all goals
(Probabilistic) sensitivity analysis	X		X	X	X	X	Generic health economic modeling technique; useful for all goals
CBA			X				Generic health economic modeling technique; useful for all goals
CEA	X		X		X	X	Generic health economic modeling technique; useful for all goals
CUA			X		X		Generic health economic modeling technique; useful for all goals
Decision tree analysis			X		X		Generic health economic modeling technique; useful for all goals
Discrete event simulation				X			Generic health economic modeling technique; useful for all goals
Dynamic/systems simulation				X			Generic health economic modeling technique; useful for all goals
Markov modeling						X	Generic health economic modeling technique; useful for all goals
Rudimental analysis of costs			X				Generic health economic modeling technique; useful for all goals
Brainstorming sessions			X				Generic method for engaging stakeholders; useful for all goals
Expert panels			X		X		Generic method for engaging stakeholders; useful for all goals
Focus groups			X		X		Generic method for engaging stakeholders; useful for all goals
Informal discussions			X				Generic method for engaging stakeholders; useful for all goals
Interviews			X				Generic method for engaging stakeholders; useful for all goals
Key informant interviews			X				Generic method for engaging stakeholders; useful for all goals
Stakeholder analysis						X	Generic method for engaging stakeholders; useful for all goals
Surveys			X		X		Generic method for engaging stakeholders; useful for all goals
Workshops			X		X		Generic method for engaging stakeholders; useful for all goals

AHP indicates analytic hierarchical process; CBA, cost-benefit analysis; CEA, cost-effectiveness analysis; CUA, cost-utility analysis; DCE, discrete choice experiment; HTA, health technology assessment; MCDA, multicriteria decision analysis; PYLL, potential years of life lost; ROI, return on investment; VOI, value of information.

generic and could in principle be used for each of the goals. These can be distinguished as quantitative modeling techniques or qualitative methods for engaging stakeholders. These methods are not explained in detail but are briefly described in [Box 1](#). The nongeneric methods are, for the most part, a more specific form of either modeling or engaging stakeholders.

In what follows, we will discuss differences and commonalities among the methods within the 4 classes.

### *Methods for Exploring the Nature and Magnitude of the Problem*

One approach for exploring the nature and magnitude of the problem is through (key informant) interviews, although we recognize that this could also take the form of a focus group, survey, or other stakeholder involvement method. Broadly speaking, the idea is to understand current practice for a given target population and indication, locate unmet problems or needs, determine what the room for improvement consists of (ie, is it purely technical in nature, or do stakeholders expect benefit to patients and society when the problems would be [partially] resolved?), determine whether or not the societal problem or unmet need is considered worth pursuing, and indicate how they think the problems or unmet needs can be resolved. When multiple problems or unmet needs are identified, stakeholders may help identify relevant criteria by which to prioritize them. In addition, stakeholders may think differently about the room for improvement, because they notice that practice varies across settings or because they differ in their opinion about current care. Insight into these factors helps to better understand the problems or needs in current practice.<sup>16</sup>

Other, more visual methods for problem assessment through stakeholder involvement include road mapping and multipath mapping.<sup>17</sup> Although such methods are often used in a broader sense to map different technologies and pathways to innovation, they can also be used specifically to help stakeholders sketch the current versus ideal care pathway for a patient. This relates to what Graziadio et al,<sup>18</sup> for example, call “care pathway analysis.” The differences between these 2 point to potential problems or unmet needs that stakeholders may reflect on further in an interview, focus group, or other. Based on problems that are identified by stakeholders, for example, when asked what the room of improvement consists of during an interview, several modeling methods may be used to further quantify problems or unmet needs in current practice. Headroom analysis<sup>19-21</sup> and potential years of life lost<sup>22</sup> aim to quantify an effectiveness gap in current care for a specific target population with a specific indication. Although headroom analysis frames the effectiveness gap positively—that is, as something that can be gained—potential years of life lost focus on the health loss associated with not pursuing improvement of current care through innovation. Modeling can be used to compare the current care strategy to a hypothetical, perfect strategy on at least 1 outcome of interest, for example, compare the current complication rate of surgery with a hypothetical situation where no complications occur to estimate the effectiveness gap.<sup>23</sup> This gap may be expressed in quality-adjusted life-years, but other metrics can be considered when duration or quality of life are not the most relevant outcomes.<sup>24,25</sup>

The outcomes of either of these modeling methods serve as input for additional stakeholder involvement to complete the problem assessment. Stakeholders may reflect on any inconsistencies between their experience and the evidence-based model of current practice, help distinguish issues from non-issues, and can help interpret the magnitude of the quantified room for improvement.

### *Methods for Estimating the Nature and Magnitude of the (Societal) Value That May Be Expected*

As with problem assessment, diverse methods of stakeholder involvement are useful to investigate what it is that makes an innovation potentially societally valuable. Examples of relevant questions include “what effect(s) do you expect this innovation to have?,” “what benefit do you expect to patients or society, if any?,” “how often would that occur?,” “what difference could we reasonably expect this innovation to make?,” “what does added value mean to you in this context?,” “what would it mean for the care process if this innovation was implemented?,” “what risks do you anticipate?,” and “how would this innovation change your behavior or daily routine?.” Questions like these help clarify what the potential impact of the innovation consists of and how the innovation is expected to interact with its care context. Another use of stakeholder involvement is to help operationalize the value of the innovation, for example, to facilitate modeling.

Scenario building provides a way to stimulate stakeholders to anticipate the innovation’s future development, implementation, and use. Scenarios are projections about the innovation’s future, for example, pertaining to its use, costs, or effectiveness.<sup>26,27</sup> The practice of scenario drafting may range from more pragmatic, fast-and-frugal formulation of interesting scenarios<sup>23</sup> to a thorough, multistakeholder investigation of relevant scenarios that represent possible futures of the innovation.<sup>28</sup> The flexibility of modeling may be used to further analyze and quantify the expected value of the innovation after one or more scenarios that were put forward by stakeholders. For example, if this innovation reduces the current complication rate by 50%, then the innovation will save €600 per patient in monetized health gain and cost savings. Similarly, scenario analysis can be used to explore for which subpopulations the expected societal value is highest.<sup>1,29</sup>

Expert elicitation is a related method that helps experts express their beliefs about a technology and its context. Although expert elicitation can be interpreted in a broader sense, making it useful for all goals, it is referred to in the reviews as a process where the (tacit) knowledge of experts is transformed into quantifiable expressions,<sup>30</sup> which is specifically useful for estimating the nature and magnitude of the (societal) value that may be expected. For example, “when you say that fewer patients will experience this complication when using the innovation, do you expect the complication rate to be reduced by half, a quarter, a tenth...?” Although these quantifiable expressions may already facilitate further discussion about the innovation’s expected value, expert elicitation is often used to gather input for modeling when model parameters are unknown or highly uncertain.<sup>20</sup> This may be especially useful for exploring an innovation’s expected value in the absence of clinical data. After all, it is reasonable to involve expert knowledge to narrow the range of unknown parameters from minus to plus infinity to a more sensible and informative range.<sup>20</sup> Similar to scenarios, obtaining input parameters from experts may range from an estimate that was informally mentioned to more formal forms of expert elicitation where experts are trained to quantify their beliefs into distributions for unknown parameters.<sup>30,31</sup> Nevertheless, the main difference is that scenarios are more qualitative descriptions of the innovation’s possible future—where uncertainty is expressed as different possible future projections—whereas expert elicitation focuses on quantifiable expressions where uncertainty is captured as a distribution around an estimated value.

As the innovation develops, the nature and magnitude of the (societal) value may be revisited to update beliefs about the new technology.<sup>32,33</sup> Bayesian statistics is especially useful in this regard.<sup>34</sup> The major advantage of such a Bayesian approach is that it



enables the explicit synthesis of all relevant data from different sources and time points.

### **Methods for Identifying the Set of Conditions That Need to Be Met**

Through their context-specific expertise, stakeholders may help identify the requirements or conditions the innovation should meet for the potential value of a technology under development to materialize and to later become accepted upon implementation. Examples of questions for stakeholders include “what do you desire from the technology?,” “which criteria should the design/evidence/et cetera meet in order for you to accept the technology?,” and “when would you use this technology in daily practice?.” Investigating requirements early on may help identify criteria that drive acceptance of a technology. Nevertheless, a challenge in identifying those criteria by asking stakeholders directly is that they may not always be aware of their preferences or be able to express them explicitly.<sup>35</sup>

Multicriteria decision analysis provides a potential solution to this issue of tacit preferences and requirements.<sup>35</sup> Specific methods for multicriteria decision analysis can involve quantitative or qualitative weighing of relevant factors. An important assumption of such methods is that stakeholders are able to weigh options with conflicting attributes, which is sometimes experienced as a challenge.<sup>36</sup>

When there is a prototype for the innovation, users' perspective methods approach the question of requirements by detailing the user's journey in using a technology. Case writing is one such method, which is especially suitable for uncovering functional requirements.<sup>37,38</sup> Other methods include usability tests, users' feedback, and users-producers seminars, where users are asked to comment on a prototype or concept and indicate what properties they would want the end product to have. Note that a broad, inclusive definition of “user” early on in the innovation process may prevent unforeseen issues upon implementation of the technology later on; for example, sterilization specialists are also users of a nondisposable surgical device in that they have to guarantee safe reuse.<sup>11</sup>

Threshold analysis, also referred to as benchmark clinical performance analysis in one of the reviews, is a modeling method to analytically derive the required performance or other minimum requirements that the innovation should meet when there is a trade-off between, for example, additional costs and additional health benefits compared with current care.<sup>39</sup> For example, given an expected price of a new diagnostic test, what should the sensitivity and specificity be in order for the test to become cost-effective?<sup>40</sup> Or, conversely, given the expected performance of a technology, at what price will it still yield a net benefit to society?

Stakeholders may speculate whether or not they think a certain threshold value that resulted from modeling is achievable in practice. Conversely, modeling may be used to further investigate stakeholders' requirements. Early attention to thresholds and requirements may facilitate societal discussions about, for example, pricing when there is still ample room to use the outcomes of that discussion.

### **Methods to Help Develop and Design the Type of Research That Is Needed**

When it comes to the design of clinical research, much will depend on the regulations that apply. Still, there are many choices that have to be made in the design of a study. In addition, stakeholders may require additional evidence to be convinced of the innovation's added value. Examples of relevant questions for stakeholders include “what evidence would you need to be

convinced of this innovation?,” “how should inpatient research of this novel technology be designed?,” “what are relevant time horizons, comparators and target populations for clinical research?,” “of the aspects you consider relevant for proving the innovation's added value, which ones should be researched further and how?,” and “which potential barriers or facilitators to the innovation's success should be researched in your opinion?.”

In addition to stakeholder involvement, methods like clinical trial simulation,<sup>41</sup> return on investment and (prospective) payback from research<sup>42</sup> can be used to quantitatively approach the question of research. Clinical trial simulation synthesizes previous knowledge about disease progress, mechanisms, and patient characteristics to help optimize trial design for resource-intensive phase III clinical trials.<sup>43</sup> Although clinical trial simulation is often used in pharmaceutical research and development, its principles could be extended for application to nondrug health innovations. Return on investment and (prospective) payback from research are 2 methods that phrase research as an investment opportunity: for every amount spent on research, there is potential yield in terms of additional health gains, future cost savings, scientific insights, etc. Nevertheless, a challenge in using return on investment and payback from research is that not all societally relevant outcomes of research may be foreseen.

Furthermore, value of information (VOI) analysis provides an approach to designing clinical research by investigating the uncertainties in the evidence surrounding current practice and (preclinical) evidence surrounding the innovation.<sup>44</sup> VOI is a Bayesian framework of analyses that combines the probability and consequences of making the wrong decision based on currently available evidence.<sup>44</sup> The expected value of sampling information and the expected net benefit of sampling are especially useful, given that they can be used to estimate the potential value of specific trial designs.<sup>44</sup> This may be further extended by real options analysis (ROA) when several options for continuing with or without research need to be weighed. For example, ROA was used to investigate the trade-off of providing a new technology at the risk of not-being (cost)effective versus first conducting more research at the risk of withholding an effective treatment from its target population.<sup>45</sup>

An important assumption in using VOI and ROA to design clinical research is that all uncertainty can be quantified. Although methods such as expert elicitation show that it is possible to translate uncertainty into numbers—for example, a range—this mostly pertains to parameter uncertainty. It may even provide a false sense of certainty, the idea that all uncertainty has been captured because there is a quantified distribution, when this distribution does not contain all relevant sources of uncertainty.<sup>46</sup>

## **Discussion**

In this scoping review, we aimed to structure the large set of early assessment methods according to their specific goal. We showed how underlying problems or unmet needs, expected value, innovation requirements, and the design of clinical research can be explored before any clinical data about the innovation are available.

In reaching these findings, we are indebted to the laborious efforts of the authors of the reviews that form the backbone of this article. We believe we have contributed to their work by structuring the many methods and indicating for what goal they may be used and combined, often sketching a continuum from relatively accessible to relatively complex applications of methods and referring to additional literature for more information. We hope this contribution helps others to choose the appropriate methods

for their specific goal and try out methods they were not previously familiar with.

Three limitations are worth mentioning. First, because we included only review studies and applied quite strict in- and exclusion criteria, it is possible that we missed relevant reviews or individual methods. Given that most early HTAs are not published,<sup>1</sup> methods might be used in practice that were not reported in the reviews. Nonetheless, we believe the included methods cover a substantial part of the methodological possibilities in early HTA, providing ample tools to answer the questions that arise. Recent reviews of applied studies did not present additional methods.<sup>4,47,48</sup> Our choice to include only practical methods excluded relevant frameworks such as constructive technology assessment, engineering risk analysis, and soft systems methodology.<sup>49-51</sup> Nevertheless, these frameworks generally use similar methods to those included in our review. Second, the choices we made in structuring the methods may imply distinctions where none were intended. Although the 4 classes were listed in sensible order, in practice they will often be addressed simultaneously. For example, problem assessment and requirements may be covered during the same interview, perhaps combined with real-time modeling of certain aspects that are mentioned. Similarly, whenever we mentioned a specific stakeholder involvement method, other methods may be appropriate as well. In addition, assigning methods to a specific class does not imply that they are not relevant for other goals. For example, expert elicitation can be used for all goals, but because it is specifically used for quantifying expected value if no empirical evidence is available, we believe it was most informative to classify it as such. Our classification aims to structure the large set of methods available, but is certainly not perfect nor set in stone. Third, we recognize that, following from the included reviews, we elaborate more in depth on modeling methods than stakeholder involvement methods. Due to the focus on cost-effectiveness in HTA to inform reimbursement decisions, it could be that these methods gain more attention in scientific literature than deliberative methods to include stakeholders. Nevertheless, during the past years, there has been an increasing interest in stakeholder involvement during development.<sup>10</sup>

A main practical implication of this work is that it facilitates the practical use of early HTA methods to evaluate societal value while the technology is going through its early development, to facilitate the legitimacy and efficiency of decisions that have to be made during those early stages. Besides the technology itself, such methods also focus on elements surrounding the technology, such as the care pathway and end users.<sup>52</sup> This may be of special interest to health technology assessors or funding agencies that are tasked with responsibly allocating public resources to innovation development. In addition, innovation developers may use the work in this article to optimize the development of their innovation.

More research is needed about the interpretation of early assessments in a way that facilitates decision making during early stages of innovation research and development. For example, when is the potential societal value of a novel technology large enough to pursue further development? In particular, real-time applications are needed where modeling and stakeholder involvement methods are combined to formatively nudge the development of innovation in a societally desirable direction. In addition, although we implied that it could be done, it would be interesting to see long-term, Bayesian innovation assessments where a view of the innovation's societal value is updated from problem question to postimplementation of the innovation. Finally, the most appropriate method will not only depend on the goal of the assessment. Elements such as the available evidence on both the current care pathway and the new technology will also influence which method is most appropriate, as may the

development phase and technology type.<sup>53</sup> International consensus is needed to develop guidance on which methods to use when and how when performing early assessments.

## Conclusions

We showed that the wide range of methods that have been proposed for exploring the societal value of healthcare technologies at an early stage of development can be subdivided into a limited number of classes, distinguishing methods according to their specific objective. We believe this article adds structure and practical guidance that helps facilitate the application and combination of early HTA methods, depending on the specific needs and aims.

## Supplemental Material

Supplementary data associated with this article can be found in the online version at <https://doi.org/10.1016/j.jval.2021.12.003>.

## Article and Author Information

**Accepted for Publication:** December 10, 2021

**Published Online:** February 12, 2022

doi: <https://doi.org/10.1016/j.jval.2021.12.003>

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*Analysis and interpretation of data:* Grutters, Kluytmans, van der Wilt, Tummers

*Drafting of the manuscript:* Grutters, Kluytmans, Tummers

*Critical revision of the paper for important intellectual content:* Grutters, Kluytmans, van der Wilt, Tummers

*Administrative, technical, or logistic support:* Grutters

*Supervision:* Grutters, van der Wilt, Tummers

**Conflict of Interest Disclosures:** The authors reported no conflicts of interest.

**Funding/Support:** The authors received no financial support for this research.

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