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Health Policy Analysis

Implementation Barriers to Value of Information Analysis in Health Technology Decision Making: Results From a Process Evaluation

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ABSTRACT

Objectives: Value of information (VOI) analysis can support health technology assessment decision making, but it is a long way from being standard use. The objective of this study was to understand barriers to the implementation of VOI analysis and propose actions to overcome these.

Methods: We performed a process evaluation of VOI analysis use within decision making on tomosynthesis versus digital mammography for use in the Dutch breast cancer population screening. Based on steering committee meeting attendance and regular meetings with analysts, we developed a list of barriers to VOI use, which were analyzed using an established diffusion model. We proposed actions to address these barriers. Barriers and actions were discussed and validated in a workshop with stakeholders representing patients, clinicians, regulators, policy advisors, researchers, and the industry.

Results: Consensus was reached on groups of barriers, which included characteristics of VOI analysis itself, stakeholder's attitudes, analysts' and policy makers' skills and knowledge, system readiness, and implementation in the organization. Observed barriers did not only pertain to VOI analysis itself but also to formulating the objective of the assessment, economic modeling, and broader aspects of uncertainty assessment. Actions to overcome these barriers related to organizational changes, knowledge transfer, cultural change, and tools.

Conclusions: This in-depth analysis of barriers to implementation of VOI analysis and resulting actions and tools may be useful to health technology assessment organizations that wish to implement VOI analysis in technology assessment and research prioritization. Further research should focus on application and evaluation of the proposed actions in real-world assessment processes.

Keywords: decision science, health economics, uncertainty, value of information.

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Introduction

Value of information (VOI) analysis can support informed and transparent decision making on health technology reimbursement under uncertainty,[1-4] and its role could become even more important in the context of new treatments emerging with a much less developed evidence base.[5-8] VOI analysis is a systematic decision-analytic approach for assessing whether there is sufficient evidence to recommend a new health technology and for prioritizing evidence collection to reduce uncertainty.[9] VOI encompasses several analyses each with a different purpose. The expected value of perfect information (EVPI) is the expected value of reducing all uncertainty pertaining to a decision.[10] Further analyses can indicate which (groups of) parameters contribute the most to this risk (expected value of perfect parameter information [EVPPI]) and assess the value of a particular research study design (expected value of sample information [EVSI]).[4] The resulting EVSI can be compared with costs of performing research, resulting in the expected net benefit of sampling (ENBS).[9] VOI analysis can help in assessing the risk, whether further research is indicated, and, if so, what research targets and designs to prioritize. These methods have been recommended by the International Society for Pharmacoeconomics and Outcomes Research - Society for Medical Decision Making (ISPOR-SMDM) Modeling Good Research Practices Task Force-6 on uncertainty,[3] and recommendations have been extended by the recent ISPOR Value of Information Emerging Good Practices Task Force.[4]

Nevertheless, despite it being suggested as part of health policy decision frameworks as early as 2002 (VOI analyses were first presented in the 1960s,[11] and then their use was reported in the 1980s,[12] although only more commonly in the 1990s[13,14]), VOI analysis is a long way from being standard use in health policy decision making.[4,15-17] Reimbursement authorities typically only recommend EVPI analysis, as is the case, for example, in the England and Wales National Institute for Health and Care Excellence (NICE).[18] The Norwegian Medicines Agency and the Dutch National Health Care Institute (ZIN) recommend the inclusion of EVPI

analysis,[19,20] although in the Dutch case this has been neither enforced nor used in decision making.

VOI analysis could prevent wasteful research: Minelli and Baio[15] found that when research was recommended in the past to reduce uncertainty surrounding a decision, little was done to formally assess research value for money. Minelli and Baio[15] refer to current decision making on research priorities as subjective, lacking transparency, and potentially unduly influenced by special interest groups. It is not a surprise that medical research was found to be avoidably wasteful.[21] Reviews of data collection–based managed entry agreement (MEA) schemes, such as coverage with evidence development schemes, indicate that these schemes are indeed often divorced from the uncertainties present in appraisals.[5,22,23] This hints at insufficient uncertainty assessment and lack of VOI analysis in designing MEA schemes, even though VOI analysis has been shown to be useful in identifying the most valuable research targets that could be addressed with coverage with evidence development schemes and in assessing different MEA schemes including research and financial schemes for their value.[24-26] Although Corro Ramos et al[27] stated that VOI analysis may not be necessary for identifying parameters eligible for further research in some circumstances, VOI is necessary when the value of such research is to be calculated.

Although Minelli and Baio[15] stated that "there are currently no real barriers to wider uptake of VOI in research prioritisation," we consider that an investigation of reasons why VOI analysis is not standard use after approximately 20 years of its appearance in health policy decision making is warranted. We are not alone: a systematic and critical review of VOI studies found that there are potential barriers in both methodological challenges and needs and preferences of policy makers.[16] The Collaborative Network for Value of Information (ConVOI) group have as their aim the removal of barriers to using VOI in practice.[28] Some barriers to VOI analysis were identified in a study using focus group interviews to capture perspectives by researchers, policy makers, and representatives of the pharmaceutical industry.[17] Tuffaha[29] stated recently: "To further facilitate the application of VOI analysis in practice, it is essential to understand and address the needs, expectations and concerns of different stakeholders, and to consider the barriers and facilitators to a wider adoption of these methods." In this spirit, we consider that a prospective case study, which allows the observation of immediate barriers when they occur and therefore minimizes any recall bias, may help in obtaining a more in-depth, and potentially more comprehensive, understanding of the barriers and facilitators to the uptake of VOI analysis. The objective of this study was to understand the barriers to the implementation of VOI analysis and propose actions to overcome these.

Methods

Process Evaluation

We performed a prospective process evaluation of the Dutch health technology assessment (HTA) concerning the use of tomosynthesis versus digital mammography for breast cancer population screening. An overview of how the Dutch population screening assessment process is organized is presented in Box 1.[30] The case was chosen for this process evaluation of VOI analysis because the committee members believed that a decision would be difficult owing to the presence of several uncertainties including issues related to levels of accuracy and costs.

This process evaluation and the VOI analysis study were separately commissioned to 2 research groups from different institutions by The Netherlands Organisation for Health Research and Development (ZonMW), with the objective to explore ways of improving decision making on research recommendations. Our research group was invited by stakeholders in the process to monitor the assessment process of tomosynthesis for breast cancer screening, which started in May 2017 and continued until early 2020. We attended 6 committee meetings (Box 2), analyzed meeting minutes using framework analysis,[31] and held additional regular meetings with the analysts responsible for adapting and analyzing the health economic model. Meetings with 2, occasionally 3, analysts were monthly during the main analysis phase (March to November 2018)[31] and only occasionally thereafter. Brief notes were taken for each meeting. Before this project, there was no relationship between the group of analysts and our research group. In the first meeting, we asked analysts about their experience with modeling and VOI analysis and their expectations. In subsequent meetings, we monitored progress, recorded barriers to VOI analysis, and also provided advice and guidance regarding VOI, probabilistic analysis (PA), and elicitation of expert opinion. Based on this process evaluation and after conclusion of all meetings, in May to August 2020, we developed a list of all observed barriers to VOI analysis use and potential underlying causes.

Data Analysis

An established diffusion model for characterizing implementation of health service innovations developed by Greenhalgh et al,[32] which was based on an extensive systematic literature review, considers there to be several aspects influencing diffusion: a resource system that entails the innovation and links to the user system, which in turn consists of system antecedents, system readiness for innovation, adopters, and the process of adoption,

BOX 1. The Dutch population screening assessment process

In the Netherlands, breast cancer population screening is executed under the responsibility of the Ministry of Health, Welfare and Sport (VWS). The Center for Population Screening of the National Institute for Public Health and the Environment (RIVM) is in charge of the coordination and direction of the screening program, and is advised by a program committee consisting of experts from relevant professions including the following parties: the regional screening organisations that perform the screening, the Dutch Expert Center for Screening (LRCB), the Netherlands Organisation for Health Research and Development (ZonMW: promotes health research and care innovation through subsidy programmes), the Dutch College of General Practitioners (NHG), and in this case the evaluators of the screening program at the National Evaluation Team for Breast cancer screening in the Netherlands (NETB/LETB), the Dutch Society for breast cancer (BVN) and the Dutch Society for Radiology (NVvR). These parties are represented in a program committee that meets several times a year to signal options for improvement, and decide upon the necessity for developing new scientific advice, with or without a recommendation of new research, for the Ministry of VWS. The Dutch Health Council (GR; independent scientific advisory body for government and parliament) provides scientific advice for the Minister of Health, who has the final decision on introduction of and / or innovations in screening programs.

implementation, and consequences. These components link to dissemination and social influence. We used this model to group our identified barriers. Barriers were identified by all 5 researchers and grouped by 2 researchers and then discussed with the remaining researchers. Based partly on the diffusion model publication,[32] the meeting minutes, other notes from the process evaluation, our own judgment, and input from the workshop described below, we developed proposed actions to address the identified barriers.

Validation

To validate the observed barriers and proposed actions, these were sent out to program committee members and other stakeholders for additional comments and amendments, which included the Dutch Health Council, ZonMW, National Institute for Public Health and the Environment, Dutch Expert Center for Screening, and National Evaluation Team for Breast Cancer Screening in The Netherlands. With the aim to complete and finalize the list of barriers and actions and obtain a broader perspective, a workshop was held with the above stakeholders and in addition representatives from the ZIN (resulting in n = 9 policy makers), the pharmaceutical industry (n = 1), a breast cancer patient organization (Dutch Breast Cancer Association) (n = 2), and several HTA research academic institutions (n = 6, leading to a total number of workshop participants of N = 18, although n = 3 were not available on the day and were interviewed separately). Preliminary barriers and actions were presented to participants who were then invited to share their thoughts and fill in posters with their ideas for actions. These posters and free text meeting notes were used for further analysis. Validation of barriers was defined as a general consensus among the stakeholders on the inclusion and comprehensiveness of presented barriers. Ethical approval was not required for this research.

Results

The Tomosynthesis Case

The background on the MISCAN model[33] and its adaptations,[34,35] the process and assessment outcomes are presented in Box 2 and Table 1. At a threshold of €20 000 per life-year gained, tomosynthesis was not cost-effective compared with digital mammography, and PA revealed only a 36% probability of being cost-effective. The annual EVPI accrued over the population was nearly €25 million. This represents the opportunity costs of making a recommendation now given the existing uncertainties, which related mainly to long-term relative accuracy, costs, and the impact of different reading strategies on accuracy, safety, and costs. The process entailed 2 meetings to explain and discuss VOI analysis with all involved stakeholders.

Barriers to VOI Analysis

Barriers to the uptake of VOI analysis in the Dutch population screening assessment process included factors pertaining to (1) innovation, (2) stakeholder's attitudes, (3) stakeholder's skills and knowledge, (4) system readiness, and (5) implementation in the organization (Table 2). These categories were derived from the article by Greenhalgh et al,[32] and modifications were made to fit the case. Consensus on these barriers was achieved at the workshop.

The Innovation: VOI Analysis

Complexity of VOI analysis

Conceptualizing the research study design for EVSI analysis is complex and requires input from different stakeholders. The computational burden owing to the MISCAN model being an individual patient simulation, with long PA run-times was a challenge. VOI implementation was challenging because analysts did not have previous experience with VOI. VOI also requires further analyses that are not routinely done: PA is not routinely done in population screening assessment in The Netherlands. Furthermore, elicitation of expert opinion was necessary to inform several parameters. Parameterization of structural uncertainty may be required but was not performed in this case: this is likely an important barrier as was documented elsewhere.[4,17,36] Policy makers highlighted complexity in interpretation of VOI results, which was caused by a lack of familiarity with VOI calculations. Although it may be intuitively easier to grasp the concept of probability of a "wrong" decision, the other component of VOI, the monetized losses incurred because of a wrong decision, can be unclear. This lack of clarity can potentially be addressed by presenting VOI in terms of health losses, too. Another (mis-) interpretation observed was that stakeholders may mistake VOI for a budget for research: when presented with a figure for EVPI or EVPPI, one stakeholder assumed that this was how much could be spent on research, without considering the uncertainty reduction

BOX 2. The tomosynthesis case process

The MISCAN model was originally developed in the 1980's(27) by researchers at the department of public Health at the Erasmus University Medical Center and has been adapted and updated for policy needs as they arise(28, 29), including for the assessment of tomosynthesis versus digital mammography. Six committee meetings were held at which the evidence, outcomes from the model and potential research targets were discussed. This included an expert meeting to identify the scope. A second expert meeting included a presentation of VOI analysis and resulted in stakeholders accepting to use VOI in this assessment (two grants for using VOI analysis in this assessment were issued, one for the analysis itself and one for the process evaluation). Another meeting was held with all involved stakeholders to explain and discuss cost effectiveness analysis and VOI analysis. It was also discussed for which parameters there was likely no empirical evidence and therefore suggestions were made to include expert opinion on these parameters in the model. The next three meetings were used to discuss results (preliminary in the first two and final in the last) and potential research targets. At the time of writing, the tomosynthesis case had not yet been concluded. The final cost effectiveness model indicated that, at a threshold of €20,000 per life-year, tomosynthesis was not expected to be cost-effective compared with digital mammography (Table 1). The EVPI for the potentially eligible population was €25 million per year. EVPPI analysis indicated that relative accuracy parameters contributed most to risk, followed by the tomosynthesis cost parameter, which was thought to be driven by uncertainty about reading times. Research on relative accuracy was not deemed feasible by stakeholders, but research on reading times was. EVSI analysis was not performed. A grant was advertised for investigation of reading times with tomosynthesis.

Table 1. Tomosynthesis vs mammography outcomes

Appraisal outcomes			
*ICER (€/LY)**	27, 023	*Threshold used in the current appraisal (€)*	20,000
Probability cost-effective new intervention (%)	36%	*Population size (annual)*†	13,00,000
Incremental net benefit or loss (€) (new intervention vs best comparator)	−36	*EVPI (€)*	19
Population incremental net benefit or loss (€)	−4,64,81,500	*Population EVPI (€)*†	2,45,83,000
Uncertainties			
In PA:	Long-term relative accuracy	Costs (screening, invitation)	
Feasible to do research?	May take too long	Potentially yes	
Not in PA:	Different reading strategies	Reading time impact on costs	Safety implications of reading times
Feasible to do research?	Partly	Yes	To be considered

EVPI indicates expected value of perfect information; ICER, incremental cost effectiveness ratio; LY, life-year; PA, probabilistic analysis.
*Discount rate used was 3.5% for both costs and effects.
†1.3 million women aged 50-74 years invited for breast cancer screening each year in the Netherlands.

that could be achieved by that research, or the budget indeed available.

Observability of benefits

The value of VOI analysis was not evident to some stakeholders: to them, valuable research targets had been clear without formal assessment, and VOI merely confirmed what was already known in this case. The value of VOI over deterministic sensitivity analysis remained unclear to some policy makers despite the trainings provided.

Compatibility with stakeholders' values

The goal of some stakeholders was to reduce complexity and time spent on an assessment, which they perceived clashed with VOI analysis. Stakeholders might think of it as "Nice-to-have" but not essential for making policy recommendations or "Not worth the effort," direct quotes that received more emphasis as being important at the workshop.

Compatibility of VOI with the organization

VOI analysis can take additional time. Although the analysis itself may be quickly implemented, VOI may require additional analyses and pieces of information to those deemed sufficient when VOI is not performed. In this case, the model needed to be adapted to allow performing of PA. This in turn required elicitation of expert opinion to obtain probability distributions for certain parameters.

Stakeholder Attitudes

Stakeholders' values and goals

Conflicting views prevailed on the objectives of research. Some viewed research as a means to reducing uncertainty; others thought of it as only useful when it could help implementation (eg, how best to use the technology once it is decided to use it). Despite cost-effectiveness and the use of a threshold being considered an important and widely accepted criterion for some health policy decision making in The Netherlands (such as the reimbursement of pharmaceuticals), this is not the case for population screening and it was not accepted by all stakeholders as the main objective of an assessment.

Stakeholders' motivation

Negative beliefs about uncertainty may result in negative reactions toward it,[37] and this uncertainty intolerance may hamper identifying uncertainties, modeling, and managing uncertainties. For instance, there was a perception among some stakeholders involved with population breast cancer screening in practice that the focus of research was already clear from the outset and that no formal assessment was needed. This may have resulted in the omission of some impactful uncertainties from discussions and the model. VOI analysis could furthermore be viewed as a threat to individual research agendas and therefore alienate some stakeholders.

Stakeholders' needs

Stakeholders were unsure whether VOI would address their needs. Although there was no certainty about VOI benefiting them, there was certainty about it conflicting with other needs for a quick decision and reducing decision-making complexity. Because it was felt by some stakeholders that VOI analysis was difficult to interpret (because EVPI and EVPPI results were presented without a reference point [high or not] and there were no EVSI results), stakeholders found it unclear how complexity in decision making would be reduced.

Stakeholder Skills and Knowledge

The skills and knowledge required for the uptake of VOI analysis are distinct for (1) analysts and (2) policy makers.

Analysts

Owing to model complexity, including simulation of the unobservable natural history of cancer, the implementation of the PA was challenging: some parameters were results of calibration, using the Nelder-Mead algorithm, which does not provide ranges around estimated parameters. Once the PA was implemented, some parameters were not included in it (and indeed not in the

Table 2. Implementation barriers to VOI analysis

Diffusion model components	Observed barriers	Proposed actions
I. The Innovation: VOI analysis		Knowledge transfer / Culture
a) Complexity	Complex in its conception	Traning for analysts (KT.ii)
	Computationally burdensome, especially in complex models	Training for analysts (KT.ii)
	Difficult to implement	Training for analysts (KT.ii)
	Requires additional analyses to the ones usually done	Literature and guidance for analysts (KT.iii)
	Results can be difficult to interpret	Training for policy-makers (KT.i)
b) Observability of benefits	The goal and value are unclear	VOI success stories (C.i)
c) Compatibility with users' values	Perceived value as "nice-to-have", but not essential	Dialogue (C.ii)
	Perceived value as not worth the effort	Commitment (C.iii)
d) Compatibility with organisation	Takes additional time (VOI implementation and model adaptations)	Literature and guidance (KT.iii)
II. Stakeholder attitudes		Knowledge transfer / Culture
a) Values and goals	Conflicting objectives for research	Dialogue (C.ii)
	Conflicting objectives for assessment	Dialogue (C.ii)
b) Motivation	Uncertainty intolerance	Training for policy-makers (KT.i)
	Conflict with individuals' research agenda	Dialogue (C.ii)
c) Needs	Perception of VOI as not addressing a need	Dialogue (C.ii)
	Conflict with need for reducing complexity	Dialogue (C.ii)
III. Stakeholder skills & knowledge		Knowledge transfer
a) Analysts	Complex models (individual patient level)	Literature and guidance (KT.iii)
	Modelling good practices	Literature and guidance (KT.iii)
	Elicitation of expert opinion	Literature and guidance (KT.iii)
	Dealing with structural uncertainty	Literature and guidance (KT.iii)
	VOI good practices	Literature and guidance (KT.iii)
b) Policy-makers	Difficulty in interpreting VOI findings	Training for policy-makers (KT.i)
	Lack of knowledge of policy options	Training for policy-makers (KT.i)
IV. System readiness		Organisation / Culture / Tools
a) Power balances	Conflicting interests in prioritising research	Dialogue (C.ii)
	Lack of trust in VOI process	Commitment (C.iii), Leadership buy-in (C.iv)
b) System resources	Lack of systematic identification of uncertainty	Tool for identifying uncertainties (T.i)
	No systematic identification of potential research targets	Tool for identifying potential research targets (T.ii)
	No systematic assessment of evaluated research targets	Tool for reporting results of evaluated research targets (T.iii)
	Lack of communication of risk and policy options	Tool for communicating risk and policy options (T.iv)
c) Innovation-system fit	May delay assessment process	Allow time and budget (O.i), Leadership (C.iv)
	Meetings do not facilitate uncertainty assessment and VOI	Adapt meeting agendas (O.vi)
	Uncertainty assessment not required	Change scope (O.iii)
V. Implementation in organisation		Organisation
a) Collaboration	Lack of collaboration between stakeholders early and throughout	Draw up collaborative process throughout (O.v)
b) Human resources	Choice of stakeholders	Include relevant stakeholders (O.ii)
	Allocation of roles	Define roles at outset (O.iv)

Key: C - Cultural change; KT - Knowledge Transfer; O - Organisation; T - Tools; VOI - Value of Information

model): adverse events from exposure to radiation, additional resources needed for the implementation of tomosynthesis, and the potential correlation between reading strategies (times and costs) and their accuracy. Tomosynthesis costs were modeled as an aggregate cost parameter, because previous information on how the cost parameter was distributed across different resource use items was outdated.

In the absence of estimates of uncertainty on some uncertain quantities, such as costs of tomosynthesis and increase in sensitivity when switching from digital mammography to

Table 3. Proposed actions to address VOI implementation barriers

Categories of actions	Code	Action	Description	Responsible
Organisation	O.i	Allowing more time and budget	For model adaptations and implementation of VOI. Even so, VOI analysis may cause delays to the assessment process that may not be feasible.	Policy-maker
	O.ii	Inclusion of relevant stakeholders in the assessment process	Experts involved in potential research, patient representatives and representatives of research funding organisations.	Policy-maker
	O.iii	Change scope	Include in scoping meeting a discussion on and commitment to uncertainty assessment and VOI analysis	Policy-maker
	O.iv	Define roles at the outset	It may be beneficial for a select group of stakeholders to collaborate more closely with the analysts outside of scheduled committee meetings to ensure identification of uncertainties, and modelling research schemes that are relevant for the decision problem	Policy-maker
	O.v	Draw up a collaborative process throughout	With all stakeholders or selected stakeholders as a specialist team involved in identifying uncertainties and informing clinical trial design: collaboration should start early and continue throughout	Policy-maker
	O.vi	Adapt meeting agendas	Meeting agendas should be adapted to allow time for discussion of uncertainty assessment and VOI analysis plans and results	Policy-maker
Knowledge Transfer	KT.i	Traning for policy-makers	Training to committee members on uncertainty assessment and uncertainty tolerance, VOI analysis and interpretation of VOI results. It was important to stakeholders that training was not simply focussed on transfer of knowledge and skills, but would also include a meaningful exchange and dialogue on the virtues of VOI analysis (see recommendations in culture below).	Academics
	KT.ii	Training for analysts	General VOI analysis training, with its conception and technical implementation (also in complex models)	Academics
	KT.iii	Literature and guidance for analysts	A literature and guidance pack for analysts, which includes: literature on uncertainty and risk; economic evaluation and modelling; transparent reporting of models; PA (in patient-level models); structural uncertainty; elicitation of expert opinion; VOI analysis; VOI analysis tools such as SAVI; and policy options such as managed entry agreement schemes	Academics

continued on next page

Table 3. Continued

Categories of actions	Code	Action	Description	Responsible
Cultural change	C.i	VOI success stories	Present success stories of VOI at scoping meeting as part of demonstrating value and fostering commitment	Policy-maker, academics, industry
	C.ii	Dialogue	Especially at the beginning of the process but also throughout could help in understanding the needs and values of the different stakeholders, including individuals' objectives for research, the assessment, their research agendas and any potentially conflicting interests in the prioritisation of research	Policy-maker
	C.iii	Commitment	Commitment at the outset of the process coud help overcome potential problems arising from stakeholders' perceiving a threat due to change in power balances. This could also help address a reluctance to perform difficult and time-consuming analyses, as well as ensure time and resources.	Policy-maker
	C.iv	Leadership buy-in	The leadership needs to be on board and can help address system readiness.	Policy-maker
Tools	T.i	Tool for systematically identifying and reporting uncertainties	For example TRUST. Enables identifying and assessing most impactful uncertainties.	Policy-maker, academics
	T.ii	Tool for helping to identify research targets	This should include main uncertainties and potentially also the risk (as expressed by the EVPI) and expected incremental net benefit / loss of the new technology versus its comparators, to enable judgement as to whether research may be feasible and indicated at all.	Policy-maker, academics
	T.iii	Tool for reporting results of evaluated research targets	Include value of research projects in terms of their EVSI and ENBS	Policy-maker, academics
	T.iv	Tool for communicating risk and link to policy options	This would be a guide to risk management with appropriate policy options and could help policy-makers in connecting VOI findings with policy recommendations	Policy-maker, academics

tomosynthesis, analysts elicited expert beliefs.[38] No structural uncertainty analysis was performed. Dealing with structural uncertainty may be another knowledge barrier for analysts. EVPPI analysis was performed using the Sheffield Accelerated VOI tool,[39] also with the objective to minimize run-times, considering the complexity of the model. It turned out that the aggregate cost parameter had one of the highest EVPPI results. Experts thought there was particular uncertainty about a certain cost component that was not explicitly modeled in the aggregate cost parameter: the reading time for images. Because costs were not broken down into its different components, reading times were not an explicit parameter in the model, no data were available for it, and no EVSI could be performed on reading times.

Policy makers

Policy makers needed training for interpreting VOI findings, and they were unsure about the policy options available to them.

System Readiness

Power balances

With VOI analysis, power balances may change, because VOI may provide additional arguments in favor or against a research plan pursued by some stakeholders. VOI analysis may become a self-fulfilling prophecy undermining trust in it. In this case, stakeholders with research interests in the area were involved in identifying uncertainties and estimating their impact in expert elicitation.

System resources

A lack of systematic identification of uncertainty may contribute to incomplete PAs. There were no agenda points in meetings or tools for systematic identification and evaluation of research targets, and therefore, different research targets were not assessed. The absence of a link between VOI outcomes and policy

options (eg, through a chart assessing MEA schemes[24] but including policy options available to these particular stakeholders) caused difficulties in considering these policy options.

Innovation-system fit

VOI caused delays to the overall assessment process. In this process, there was a certain tolerance to delays because of it being a test run for VOI analysis, but time constraints would likely be a barrier in a regular appraisal process. For the assessment of pharmaceuticals, the ZIN is legally bound to a period of 90 days,[40] which may not allow for performing (additional) VOI analysis. Meetings currently do not facilitate uncertainty assessment and VOI, which have no place on meeting agendas. VOI analysis may require a certain circularity in an otherwise linear process. PAs are not routinely demanded in the evaluation of population screening modeling in The Netherlands (although they are considered standard practice for the evaluation of pharmaceuticals for reimbursement decision making in The Netherlands and in health policy decision making in some other jurisdictions).

Implementation in Organization

Collaboration

There was a lack of collaboration among experts, analysts, and policy makers to inform modeling decisions and development of research targets throughout the process. More collaboration could aid identification and modeling of important uncertainties. For example, the importance of reading times in the aggregate costs could have been identified in time for this parameter to be included in the model. If EVSI had been performed, more collaboration would have enabled the inclusion of expert input in the clinical trial simulation.

Human resources

The presence of experts in the field and representatives from funding organizations (ZonMW) was deemed helpful by most stakeholders. Conversely, the absence of representatives from funding organizations in the committee and the lack of clarity as to who would fund potential research were perceived as barriers in the ZIN process. Defining who does what and when could help include VOI analysis in the assessment process.

Proposed Actions to Overcome Barriers

The proposed actions to, at least partially, overcome the identified barriers include the categories of (1) organization, (2) knowledge transfer, (3) cultural change, and (4) tools (Table 3), which can be linked to the barriers presented in Table 2. Central to incorporating VOI analysis into the process of HTA are organizational requirements of the assessment process. Multiple barriers to VOI analysis related to a lack of skill or knowledge, also manifesting in the perceived complexity of VOI analysis. Most of these can be addressed with knowledge transfer, either in the shape of training or with a literature and guidance pack as a starting point (see Open Science Framework www.osf.io/wvknc).

Cultural change activities (Table 3) were deemed essential in efforts to overcome barriers to VOI analysis use: pertaining to the innovation, stakeholder's attitudes, and system readiness. Leadership buy-in was important in ensuring that VOI was given a chance, and success stories of VOI use, such as the ones by Carlson et al[41,42] and Bennette et al,[43] can help obtain buy-in of all stakeholders. Tools for uncertainty assessment and VOI analysis may facilitate their implementation, and we propose the development or use of a number of tools, including a tool for systematically identifying uncertainties (eg, the TRansparent Uncertainty aSsessment (TRUST) tool[44]), a tool for helping to identify research targets, a tool for reporting results of evaluated research targets, and a tool for communicating risk and policy options. The second-to-last could be in line with templates developed in the NICE interim process and methods guide for research recommendations to make explicit the specification of population, intervention, comparators, outcome, study design and time frame, and a rationale. The latter should entail the following: importance to patients, service users, or the population; relevance to guidance; relevance to the healthcare system, public health, social care, and voluntary sectors; national priorities; the current evidence base; equality; feasibility; and other comments.[18] In addition, we think that this should also include the quantitative assessment of these studies in terms of EVSI and ENBS.

Discussion

We presented implementation barriers to VOI analysis use, as observed in the process of a Dutch breast cancer population screening assessment and as validated by stakeholders with different perspectives, and we proposed actions to address these barriers. We found that there are currently multiple barriers to the use of VOI analysis in health policy decision making, some of which relate to VOI analysis itself, such as its complexity, but also to stakeholders' attitudes, skills, and knowledge, and system readiness and challenges in the implementation in the organization. Minelli and Baio[15] illustrated the different steps of VOI analysis as comprising a statistical model, an economic model, the decision analysis, uncertainty analysis, and research prioritization. We found that barriers to the use of VOI analysis occur not only in the last 2 steps but also at the stage of decision analysis and the economic model. Thus, barriers were much wider in scope than just related to VOI analysis itself. As such, we urge caution to view VOI analysis in isolation when attempting to implement it in policy processes, but advocate for a holistic view of technology assessment and health economic modeling processes that can accommodate uncertainty assessment and VOI analysis.

We proposed actions to overcome identified barriers relating to the organization, knowledge transfer, culture, and tools. Many barriers can, relatively easily, be addressed by these actions. For example, literature, guidance, and training can probably help most analysts (not familiar with VOI) implement VOI and related analyses. Other barriers may be more challenging to overcome: for instance, commitment and dialog are unlikely to fully address the barriers in stakeholders' values and goals, motivation, and needs. Tailored strategies are likely required to overcome such barriers but dialog can instigate this process and open the door to understanding needs of individual adopters and perceived threats and benefits of VOI analysis to individual stakeholders.[32] A study by Meisel et al[45] provides inspiration: the authors investigated the research-to-practice gap in the implementation of evidence-based prevention and treatment programs for substance use disorder and provided recommendations. Among the ones we consider relevant for this setting are as follows: (1) enhance collaborations between policy makers and researchers to formulate the policy-relevant questions (eg, what are the uncertainties and what could future research look like), (2) enhance communication of research, and (3) recognize that cultural change is not only necessary at the process level but also at the academic level and engage scientist and analysts through incentives. Furthermore, the framework of Integrated Knowledge Transition, that is, collaboration between researchers and decision makers, may be of interest in designing collaborative processes.[46] Organizational changes may or may not be easily accommodated. We made some general recommendations, including allowing time and resources

for VOI analysis, consideration of who is involved, and providing opportunities for different stakeholders to collaborate. Nevertheless, explicit recommendations will be specific to each different setting. We consider organizational changes and leadership buy-in to be important and the first steps toward implementation of VOI analyses in HTAs. Next, knowledge transfer for policy makers and cultural change activities will help get other decision makers on board. Knowledge transfer activities for analysts may only be necessary for analysts with little experience with VOI and related analyses. Tools for facilitating reporting and presentation can aid the process and decision making but would only help once the other actions have been implemented, and therefore come last.

This work is placed in the context of the increasing theoretical literature on VOI analysis and the realization that VOI analysis is still underused in policy making.[15,16] As Claxton et al[1] pointed out, adoption of a decision-making framework that includes VOI analysis to assess further research has radical implications, including a shift toward increasing demands for further evidence to make a recommendation on technologies where there is substantial uncertainty and cost-effectiveness is borderline or for which there is a large eligible population of patients. Our work has shown that the adoption of this framework and the shift have not yet occurred in practice as was highlighted by other articles describing barriers to VOI use.[17,29,47] The barriers identified in this article are broadly consistent with those in these articles but add to existing evidence by providing an in-depth view and concrete actions to overcome these. The method of a process evaluation lent itself more to identifying organization-related barriers than previously used focus groups for example. We consider that this work may be relevant to policy makers, HTA organizations, and researchers who wish to use and implement VOI analysis in technology assessment and research prioritization. In addition to the narrower focus on analyzing the impact of uncertainty on a decision comparing cost-effectiveness of 2 technologies presented here, VOI analysis could also be relevant in the context of higher-level research prioritization decisions (eg, allocation of research funds to cancer vs cardiovascular disease), because it is a measure that can combine considerations about the burden of disease and the impact of a new technology (through net benefits) with the current state of knowledge and uncertainty. Further research should focus on feasibility and usefulness in this setting.

A strength of our work is that the opportunity of performing a prospective process evaluation gave us in-depth insights into barriers to VOI analysis that otherwise would be difficult to obtain. As such, we believe that our work adds detail on barriers to VOI analysis to previous studies in this area.[17] The use of the Greenhalgh diffusion model for innovations in health service organizations[32] also helped in categorizing barriers in a way that facilitated identification of possible actions to address them. Furthermore, we drew upon the experience and expertise of stakeholders in this process and stakeholders in other HTA processes (the ZIN and NICE) to validate the identified barriers and further develop proposed actions.

The strength of this work is also its limitation: generalizability to other settings is questionable, given that this process evaluation dealt with one case and only in the Dutch screening setting. We attempted to reduce any bias resulting from this by presenting barriers and actions to a wider range of stakeholders than those involved in this particular case. Nevertheless, these additional perspectives were still mainly considering the Dutch setting, with 1 workshop participant also considering the England and Wales NICE setting. Although generalizability may not be given, we believe that our findings may be transferable to other settings. If interested parties wished to consider the transferability of these findings to their respective settings, we suggest investigating which factors can make these findings applicable to theirs,[48] such as differences in process, skills, and knowledge of analysts and stakeholders and the background of involved stakeholders and what that means for their values, goals, motivation, and needs. Worth considering may also be potential conflicts of interest and power balances in the unique setting, available system resources, and particular process constraints.

A further limitation of the observed process was that EVSI and ENBS analyses were not performed. It is possible that further barriers would have become evident had this been done. We do not anticipate that any unknown technical difficulties would have occurred and recently new methods have been proposed to overcome these.[39,49,50] Neither do we think that there would have been any prohibitive process or system constraints, as EVSI was requested and another meeting held to discuss the results. Nevertheless, it would have been interesting to observe, first, different stakeholders' reactions to the assessed value of research and, second, the conclusions reached by the committee on recommending research. A general limitation in the area of implementation of VOI analysis is that complex relationships may be at play in these diffusion processes,[51] which may mean that a description of the process here falls into the realm of complexity science. Therefore, it is likely very difficult to predict the impact of any of the proposed actions on diffusion of VOI analysis. Analysts were experienced disease modelers, but they did not have experience with PAs, VOI, or elicitation of expert opinion. It was agreed at the outset of this project that our group would provide advice on methods, which consisted of providing relevant literature. As such, there was a degree of active involvement of our research group. This may have biased the findings. To mitigate bias, we performed member checking on our findings with analysts. We reflected with the analysts that the impact of our involvement was likely limited to time saving for the analysts. Furthermore, the choice of diffusion model was not based on a systematic review. Therefore, it is possible that the use of a different diffusion model would have resulted in slightly different findings, although we do expect this effect to be mainly limited to the presentation of findings.

Further research should focus on concrete policy frameworks and adaptation of assessment processes in specific policy and HTA settings, with the aim to implement VOI analysis as a standard tool used in HTA decision making. Furthermore, we consider there to be value in developing tools and resources for HTA systems to identify potential research targets, assess their value, and communicate risk and policy options to policy makers.

In conclusion, we performed an in-depth analysis of barriers to the implementation of VOI analysis in HTA and proposed actions to overcome these. We hope that this work will be useful to policy makers, HTA organizations, and researchers who wish to use and implement VOI analysis in technology assessment and research prioritization.

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