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Integrating Environmental Aspects into Health Technology Assessment: A Qualitative Study among Dutch Stakeholders

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Abstract

Background: The Dutch National Health Care Institute (ZIN) advises the Dutch Minister of Health on the basic benefit package using Health Technology Assessment (HTA), focusing on necessity, clinical effectiveness, cost-effectiveness, and feasibility. Despite the huge environmental impact of the healthcare sector, this impact is not taken into consideration. Several methodological approaches to integrate the environmental impact into HTA have been proposed, including information conduit, integrated evaluation, parallel evaluation, and environment-focused evaluation. There is significant uncertainty as to which approach is the most appropriate. Therefore, it is important to understand stakeholders' perspectives on these approaches.

Objectives: To explore Dutch stakeholders' perspectives on integrating environmental impacts into HTA and assess preferred methods and challenges.

Methods: A qualitative study using a focus group with members from ZIN (n = 7) and individual interviews (n = 7) with experts in HTA, market access, and reimbursement. Interviews were transcribed and analyzed thematically.

Results: Stakeholders highlighted the importance of addressing environmental impacts such as pharmaceutical pollution, greenhouse gas emissions, and waste. Integrated and parallel evaluations were preferred, but barriers such as data gaps, methodological complexity, and lack of guidelines were noted.

Conclusion: Incorporating environmental impacts into HTA is crucial but requires clear guidelines, better data, and stakeholder collaboration to support sustainable healthcare practices.

Introduction

Climate change affects both the environment and human health (1;2). Climate-related hazards such as extreme weather events, heat, sea-level rise, and air pollution pose the greatest health threat to humanity by contributing to negative health outcomes, including injuries, mortality, heat-related illness, respiratory illness, and vector-borne diseases (2). The Dutch healthcare sector is already experiencing these effects, with increased heat stress, longer allergy seasons, and a higher frequency of extreme weather events causing increased pressure on healthcare resources (3). Not only climate change has an impact on the healthcare sector, but also the healthcare sector negatively affects the environment. In the Netherlands, the healthcare sector is responsible for approximately 7 percent of all greenhouse gas emissions both domestically and internationally (4). These emissions stem from the manufacture, distribution, use and excretion, and disposal of health technologies (4).

Health Technology Assessment (HTA) is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose of HTA is to inform decision making in order to promote an equitable, efficient, and high-quality health system (5). HTA has been utilized as a policy tool in the Netherlands since the early 1980s, due to the increasing number of new expensive technologies (6). The National Health Care Institute (ZIN) applies HTA to advise the Dutch Minister of Healthcare, Welfare, and Sports on the content of the basic benefit package with a focus on necessity, clinical effectiveness, cost-effectiveness, and feasibility (i.e., budget impact) in its evaluations (7). Environmental impact has as yet received little attention in HTA. It is only recently that HTA guidelines in Australia and Canada have begun to include environmental impacts in decision making, while NICE in the UK has committed to exploring how to incorporate data on environmental impacts into its guidance (8–10). In the Netherlands, there is increasing interest in exploring possibilities to add environmental impact as a criterion in HTA and reimbursement decision making. However, as yet, it is not included in the guidelines for economic evaluation.

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In recent years, most research on environmental impact in healthcare has focused on the environmental impact of a certain health technology, often using a lifecycle assessment approach. Some studies explore various methodologies on how to assess environmental impact in healthcare (11–23). Significant uncertainty remains about the most appropriate methodology for incorporating environmental impacts into HTA, which limits its adoption (24). Understanding the perspectives of stakeholders, including policy advisors, is crucial in addressing this challenge. This research aims to explore Dutch stakeholders' perspectives on different methods of integrating environmental impacts into HTA in the Netherlands.

Methods

Design and participants

A qualitative study design was applied, consisting of a focus group interview and individual semistructured interviews. Both aimed to gain an in-depth understanding of stakeholders' perspectives on integrating environmental impacts into HTA in the Netherlands (25;26). The focus group included members from ZIN, working across two departments, namely the Department of Health (Team Pharmaceuticals) and the Department of Development, Science and International Affairs. Individual interviews were conducted with Dutch experts in HTA, market access, and reimbursement from the pharmaceutical and medical technology industry as well as from academia. The number of participants for the focus group interview was determined based on evidence that states that a number of 5 to 10 participants is common to ensure data saturation (27). The additional number of participants for the expert interviews was chosen so that there would be a balance of the perspectives of

stakeholders. Participants of the focus group interview were recruited through a member of ZIN. The additional experts were recruited through LinkedIn and the networks of co-authors.

Ethical approval was obtained from the Ethics Committee at Maastricht University (FHML/HPIM/2024.648). The study followed the consolidated criteria for reporting qualitative studies (COREQ) checklist (Appendix A) (28).

Data collection

Prior to conducting the study, an interview guide was developed based on the review by Williams et al. (23) (Appendix B). This review discussed four different approaches to integrating environmental impacts into HTA (Table 1). These approaches were information conduit, integrated evaluation, parallel evaluation, and environment-focused evaluation. Information conduit refers to HTA agencies reporting environmental impacts alongside HTA outcomes without integration in the decision-making process (21). Integrated evaluation incorporates environmental impacts into HTA by synthesizing clinical, financial, and environmental information into one quantitative analysis. Parallel evaluations include environmental impacts alongside health economic analyses without changes to existing economic methods. Finally, environmentfocused evaluations are applied to health technologies that are not expected to have any additional health or cost benefits. Therefore, HTA agencies following this approach would only consider environmental impacts in their deliberations.

The interview guide included questions about the opinions of stakeholders on incorporating environmental impacts into HTA, which impacts they considered most important, and their perspectives on the approaches presented in the review by Williams et al. (23). Questions aimed to identify challenges, barriers, strengths,

Table 1. Approaches to integrating environmental impacts into HTA

Approach	Method	Description
Information conduit	Share environmental impact details with HTA decisions without further analysis.	Environmental impacts are documented during the HTA process but are not factored into funding or recommendation decisions. This information is made accessible to the public.
Integrated evaluation	Factor environmental impacts into monetary cost within an economic analysis.	Environmental effects are assigned monetary values using established conversion rates and integrated into cost-effectiveness or cost-benefit analyses such as cost-effectiveness analysis (CEA), cost-utility analysis (CUA), or cost-benefit analysis (CBA).
	Include environmental impacts as health outcomes within an economic analysis.	Convert environmental impacts into health-related metrics and incorporate them into the outcome measures of a CEA or CUA.
	Modify WTP to account for environmental factors.	Adjust the threshold of WTP to reflect the inclusion of environmental considerations.
Parallel evaluation	Calculate the incremental carbon footprint effectiveness ratio (ICFER).	Use environmental data to determine the ICFER, which measures changes in environmental impacts relative to changes in effectiveness.
	Calculate the incremental carbon footprint cost ratio (ICFCR).	Use environmental data to determine the ICFCR by comparing differences in environmental impacts against differences in costs.
	Address environmental considerations directly during HTA decision-making discussions.	Incorporate environmental factors into the deliberative processes of HTA decision-making without converting them into monetary or health units.
	Use multicriteria decision analysis (MCDA).	Treat environmental factors as one of several criteria within an MCDA framework to support decision making.
	Present environmental impacts alongside economic evaluations without integrating them.	Report environmental impacts as part of economic analysis but not combining them into final ICER calculations or cost-outcome assessments.
Environment-focused evaluation	Evaluate interventions that provide environmental benefits but do not differ in health or cost outcomes.	Requires HTA agencies to consider only environmental impacts during their deliberations for interventions that do not offer health or cost benefits.

Note: Based on William et al., (23) and Toolan et al. (21).

and the overall opinion on the various methodologies. Additionally, participants were asked which methodology they preferred.

Before conducting the interviews, every participant received an infographic and short presentation outlining the study's background and scope (Appendix C). Informed consent was obtained for collecting data, including audio recordings, transcriptions, and pseudonymized data analysis. Interview participants were given the opportunity to ask questions about the research. They were also informed that they could request termination of the interview at any time. The focus group interview was conducted in person, and the individual interviews were conducted in person or via Microsoft Teams throughout May and July 2024. The interviews were conducted by a single researcher who is a native English speaker. All interviews were conducted in English.

Coding and analysis

Every participant received a unique participant code, reflecting the stakeholder group, but without the possibility of tracing back individual statements to individual participants. Members of the focus group were designated as ZIN1 through ZIN7; academic experts were labeled AE1 and AE2; pharmaceutical industry experts were coded as PE1 and PE2; health technology assessment experts were identified as HTAE1 and HTAE2; and the expert from the medical technology industry was labeled MTE1. Transcriptions were coded and analyzed by one researcher using ATLAS.ti. A combination of deductive and inductive coding according to Braun and Clarke (29) was used to extract themes. Firstly, coding was conducted according to the topics mentioned in the interview guide, and main themes were identified. Following this, subthemes were assigned to the main themes in the form of inductive coding. The themes were discussed and approved by the entire research team. Direct quotes were included in the Results section to enhance the richness of the themes. When presenting these quotes, some were revised for grammatical accuracy to enhance readability, while carefully preserving their original meaning.

Results

Interview characteristics

Fourteen participants were interviewed: seven in the focus group (all ZIN members) and seven individual interviews with two academic HTA experts, two experts in market access and reimbursement in the pharmaceutical industry, two HTA consultants, and one expert from market access and reimbursement in the medical device industry. The focus group interview lasted 1 hour, and the duration of the individual expert interviews ranged between 20 and 25 minutes. Among the seven individual interviews, one was conducted in person and six were conducted via Microsoft Teams.

Incorporating environmental impacts in HTA in the Netherlands

Interviews revealed that although participants were generally aware of the need to include environmental impacts in HTA, their practical knowledge was limited. Some had experience in incorporating environmental impacts into HTA, such as investigating waste production differences between a new intervention and the standard of care.

Opinions on the most critical environmental impact to include in decision making varied, with pharmaceutical pollution, waste, and greenhouse gas emissions being the most frequently mentioned. Pharmaceutical pollution was highlighted for its actionable nature "pharmaceutical pollution (...) not because I don't think that the other ones have a less environmental impact, perhaps even more, but I have the impression that's something you can perhaps easily do something" (AE1). However, it was also noted that pharmaceutical pollution is really difficult to measure. "I think it's first of all really difficult to incorporate it because it's, of course, rather difficult to measure exactly what's the carbon footprint of a certain medicine" (PE1). Waste was considered measurable and linked to efficiency "Waste (...) is maybe not the most important, but (...) most easy to focus on because it can lead to efficiencies" (AE2) and "which is quite easily measurable as well" (PE1). Greenhouse gas emissions were described as foundational: "Greenhouse gas emissions is, talking point number one. It's a metric that is a base metric in many environmental analyses. So that's one that should definitely be in there" (PE2).

Most participants agreed on the necessity of including environmental impacts in HTA in the Netherlands, highlighting the health-care sector's significant carbon footprint and the potential to encourage sustainable practices, such as producing generics locally to reduce emissions. They mentioned that sustainable practices lower costs by reducing waste. Incorporation of environmental impacts into HTA can also create market opportunities within the industry and stimulate a change in behavior toward sustainability such as in clinical guidance and decision making. Sustainability can be further increased by implementing stricter regulations and non-reimbursement for environmentally harmful technologies. Participants acknowledged that although HTA currently focuses on safety, effectiveness, and costs, environmental impact should be an additional factor within HTA as an integral part of the societal perspective in the Netherlands.

Despite this, concerns were also raised. These concerns were whether including environmental impacts would have a significant impact on the HTA decision-making process, specifically the lengthy timeframe required to see improved environmental outcomes, and whether HTA was the area that one should focus on. It was suggested that policies or actions, such as including environmental impacts in the procurement of health technologies in a hospital setting, would be more effective. It was emphasized that it is crucial for stakeholders to genuinely believe in the value of sustainable products, rather than using the inclusion of environmental impacts in HTA as a means to engage in greenwashing.

Several challenges were identified with regard to the incorporation of environmental impacts into HTA, including determining how to measure and calculate the environmental impacts, the lack of clear guidelines, and choosing appropriate methodologies. Additionally, it remains unclear how decision makers will use this information, in particular when balancing environmental impacts with health outcomes, and who is responsible for the incorporation.

Information conduit

Regarding information conduit, participants expressed that this could raise awareness on the environmental impact of a health technology among physicians and policy makers. Through information conduit, the industry would have to be transparent on the environmental impact of their product. However, many doubted the impact of this method; as the environmental impact is not a part of the deliberation process on decision making, the sense of urgency decreases, which hinders the incorporation of environmental impacts. This would also reduce incentives for industries to adopt sustainable practices. "Yeah, the question is

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what the benefit is. Because if it is nice to have and it is not being used, what weight does it have? And also, what is the added benefit to the extra work" (MTE).

Integrated evaluation

Because environmental impacts are fully incorporated in the analysis, integrated evaluation provides a more concrete understanding of the impact of environmental impacts. This has the potential to influence the thinking and behavior of technology developers.

Additionally this could help convince stakeholders who are somewhat skeptical about the substantial environmental impact of a health technology of its actual effects. Participants say that including environmental impacts in the form of an integrated evaluation would be of added value for health technologies that have a significant environmental impact.

Various challenges were mentioned when incorporating environmental impacts using the integrated evaluation approach. Among these challenges are a lack of transparency, complexity of the methodology, and limited data availability. Transparency issues can arise when integrating environmental impacts into economic analysis. Participants noted that it is often unclear how such impacts are incorporated, making it difficult for others to understand the decision-making process. A lack of transparency can also result from the environmental impact being hidden within the analysis, making its importance less visible. Another challenge is related to methodological complexity, as expanding analyses to include environmental effects can make concepts such as the incremental cost-effectiveness ratio (ICER) harder to interpret. Both the complexity of methodology and limited data availability contribute to uncertainty because analysts are frequently required to make assumptions in the absence of reliable evidence: "a lot of limitations with data (...) make a lot of assumptions" (HTAE2).

When interview participants were asked about their preferred method of integrated evaluation, answers varied. Focus group participants favored the willingness-to-pay (WTP) threshold "Because with proportionate shortfall, you also adjust the willingness to pay threshold" (ZIN4); and "It is an incentive (...) because if you increase the WTP threshold, then the pharmaceutical company can ask a higher price for that drug" (ZIN4). There were conflicting views on the use of the WTP threshold, with some participants supporting it and others opposing it due to concerns about its complexity and the challenges involved in visualization and calculation. They preferred the other two methods of integrated evaluation. "I find it interesting to see what the difference would be or what potentially the impact would be on the effect side and whether it would make sense to do that. It's either on the outcome side or either on the cost side, and the cost side at this moment looks like the most efficient" (AE1).

Specifically converting the environmental impact into health units was considered too theoretical, and there is a difficulty in distinguishing the quality-adjusted life years (QALYs) from the health technology and the QALYs associated with the environmental impact of the health technology.

Parallel evaluation

The advantages of parallel evaluation identified by participants were the perceived transparency and explicitness, ease of visualization, more focus on environmental impacts, and that it does not directly impact cost assessment. Parallel evaluation is more transparent as it is "easier to understand for people what's the relationship

with environmental sustainability and other criteria we use" (ZIN2). Additionally, parallel evaluation is more explicit as "it keeps the focus on the environmental impacts (...) and it doesn't directly impact the cost assessment" (PE2). As the environmental impact is not entirely integrated, parallel evaluation was considered easier to visualize. Challenges that were identified were that the separation is fragmented and that decision makers would need too many resources to conduct a parallel evaluation. This fragmented approach contrasts with the more holistic approach typically adopted in HTA.

The preference for the most suitable methodology of parallel evaluation varied. Participants of ZIN generally preferred the deliberative decision-making process due to its similar use at ZIN and its flexibility. However, one member also argued, "I also see the big downside of deliberative processes is that policy becomes less predictable and transparent for the world" (ZIN1). Additional participants in the individual expert interviews preferred the deliberative decision-making process, stating that it allows for a case-by-case analysis and that especially if it is unclear whether one should consider environmental impacts with every single health technology, a case-by-case basis in the form of a deliberative decisionmaking process would be ideal. Methods such as incremental carbon footprint effectiveness ratio (ICFER) and incremental carbon footprint cost ratio (ICFCR) were considered easier to calculate and more acceptable and feasible. However, some participants viewed these two methods as inappropriate because they only include carbon and no other environmental impacts. The lack of data availability of carbon footprint for health technologies was also considered a barrier for conducting these two methods. Multicriteria decision analysis (MCDA) was viewed by some participants as appropriate, particularly because it is suitable when clinical and economic values are comparable. Others, however, felt that it should only be applied in situations where integrated evaluation is not possible. Additionally, it was noted that MCDA is complex due to having to weigh certain criteria.

Environment-focused evaluation

Various challenges were identified within this approach, such as setting the agenda, determining the threshold for environmental impact, overall impact of the approach, and risk of overlooking whether patient outcomes really are identical. It is also important to uniformly decide on a method on how to conduct an environment-focused evaluation. It was mentioned that when health and cost outcomes are identical in the different health technologies, where does one set the threshold "where do we set the threshold of when is it worthwhile to have one over the other, (...) the reduction of X percent, 5 percent or 10 percent or 2 percent" (HTAE1).

Participants believed that this approach would be the most suitable in a hospital setting rather than on a national level and could contribute to hospital procedures and guidelines.

Preference of methodology

When questioning participants about their preferred methodology, answers varied. ZIN members favored the parallel evaluation approach, specifically the deliberative decision-making process due to its ease of application. They noted that adjusting the WTP threshold requires significant research before effective use.

Academic experts preferred incorporating environmental impacts into an integrated evaluation but emphasized the importance of time availability and sufficient data, which is currently

lacking. Also, it is unclear yet whether converting environmental impact into a monetary value or health unit is most appropriate. Although integrated evaluation is more fitting with the societal perspective, parallel evaluation makes environmental impacts more explicit and easier to disentangle.

An expert from the pharmaceutical industry noted that as environmental impacts are evaluated separately rather than being fully integrated into the analysis, they can become more visible in the assessment process and thus more disentangled. It was noted that although integrated evaluation and parallel evaluation would be the most suitable, this would not be feasible at this moment, and therefore, information conduit would be the most feasible.

An HTA expert mentioned that a deliberative decision-making process was considered an appropriate method; however, it was noted that it can be biased due to the lack of standard. The WTP threshold, on the other hand, would be more suitable to ensure a standardized approach. The other HTA expert believed that environment-focused evaluation would be most feasible, but that methods within parallel evaluation such as republishing of environmental data or deliberative decision making would be most appropriate. This expert also mentioned that converting environmental impacts into a monetary value or conducting an MCDA would be one step too far and not feasible.

The expert from the medical technology industry was in favor of environment-focused evaluation, stating that this would be most suitable for procurement within a hospital.

Discussion

The findings of this study provide insights into the perspectives of various stakeholders on incorporating environmental impacts into HTA in the Netherlands. The findings revealed a unanimous

recognition of the importance of incorporating environmental impacts into HTA. This aligns with previous studies conducted with HTA stakeholders, which revealed a widespread acknowledgment among participants of the importance of environmental sustainability within HTA (30;31). However, alongside the benefits of these approaches, several challenges and limitations were expressed by participants (see Figure 1).

Our research additionally showed that among stakeholders, there was a significant variation in their practical knowledge and understanding of effective implementation. This is in line with the most recent research in this field that showed that only a limited number of HTA agencies are actively engaged in the integration of environmental impacts in HTA (30).

Variation existed in identifying the most important environmental impacts and the most suitable approaches and methodologies for incorporating them. The tendency was that most participants preferred parallel and integrated evaluation due to their potential to provide comprehensive assessments that consider clinical, economic, and environmental outcomes, either integrative or alongside an economic evaluation. This aligns with previous research that surveyed international participants on their preferred methods for incorporating environmental sustainability into HTA (30). The findings indicated that the most favored approach is costutility analysis, a form of integrated evaluation, followed by MCDA, which falls under the parallel evaluation approach (30). Conversely, information conduit was considered too superficial and not appropriate as it does not impact decision making. This is in line with previous literature that discussed that information conduit is unlikely to influence funding decisions (23).

A major barrier identified was the lack of appropriate and reliable data on the environmental impact of health technologies. Also, in previous studies, it was found that data collection is a major

Information Conduit

- Benefits: Raises awareness of environmental impacts of health technologies and encourages industry transparency.
- Challenges and Limitations: Limited influence on decision-making, reduces sense of urgency to address environmental impacts, and weak incentive for industry to adopt sustainable practices.

Integrated Evaluation

- Benefits: Effective in making environmental impacts more concrete, influencing technology developers, and helping
 convince stakeholders especially for technologies with significant environmental impact.
- Challenges and Limitations: Lack of transparency, methodological complexity, limited data and uncertainty, disagreement on preferred evaluation methods, and difficulty converting environmental impacts into health units.

Parallel Evaluation

- Benefits: Transparent, explicit, and easy to visualize, keeping the focus on environmental impacts without a direct effect on cost assessment.
- Challenges and Limitations: More fragmentation compared to holistic HTA, high resource needs, and complexity in methods like MCDA.

Environment-Focused Evaluation

- Benefits: Most suitable at the hospital level, can guide procedures and guidelines when health and cost outcomes are identical
- Challenges and Limitations: Agenda setting, lack of defined environmental thresholds, difficulty in assessing overall impacts, ensuring patient outcomes truly match, and the need for a uniform evaluation method.

Figure 1. Summary of participants' views on the individual approaches of integrating environmental impacts in HTA.

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challenge in the incorporation of environmental sustainability into HTA (30). Importantly, our study identified the strong need for clear directives and standardized guidelines and methodologies on how to incorporate environmental impacts into HTA.

Recommendations and future research

Based on the experiences and insights provided by participants, this study offers initial recommendations for considering environmental impacts in HTA in the Netherlands, while acknowledging the limitations related to sample size and generalizability.

It is important to educate HTA practitioners on the methodologies of incorporating environmental impacts into HTA. To determine which methodologies are the most appropriate, more research should be conducted in this field, such as designing statistical models on how to incorporate environmental impacts into cost-effectiveness analysis. Specifically, more research needs to be conducted as to how one can convert the environmental impact of a health technology into a health unit. HTA organizations such as the ZIN should design clear guidelines and frameworks on how to incorporate environmental impacts into HTA. It is also of the utmost importance to ensure data collection of the environmental impact of health technologies to be able to have sufficient data to incorporate environmental impacts into HTA.

Strengths and limitations

This study is unique in investigating the perspectives of various Dutch stakeholders, including decision makers, on integrating environmental impacts into HTA. It provides valuable insights and can guide other European countries by highlighting stakeholders' recognition of the importance of such integration while addressing uncertainties on implementation. Combining focus groups and individual semistructured interviews ensures a comprehensive understanding of stakeholders' perspectives, enhancing the richness and validity of the findings.

Limitations of the study include potential bias. Participants were recruited through professional networks and LinkedIn, and this may have introduced selection bias as those who are more engaged or interested in the topic may be more likely to participate. Additionally, all interviews were conducted and analyzed by one researcher, which may introduce bias in the data collection and analysis process. Bias may have also occurred as interviews were conducted in English, not in Dutch. This study had a low number of participants, which hampers generalizability. However, the study aim was to gain insights into stakeholders' perspectives in the Netherlands and is of a qualitative nature. This study is therefore exploratory and can open up and foster discussion and deepen understanding of this emerging field.

Conclusion

In conclusion, this research emphasizes the importance of bridging the gap of knowledge between recognizing the importance of incorporating environmental impacts in HTA and its actual practical implementation. Therefore, it is important to foster more cooperation among various stakeholders and implement educational programs and initiatives. There is a lot of uncertainty as to which environmental impact is the most important and which methodology is the most appropriate to incorporate environmental impacts into HTA. However, this uncertainty should not prevent policy makers from deciding whether environmental impacts

should be prioritized or integrated into HTA at a national level. As the healthcare sector significantly contributes to environmental pollution, which in turn affects health outcomes, immediate action is needed.

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