



Which Factors are Holding up the Integration of the Environmental Impact of Health Technologies in Health Technology Assessment? Insights from a Multi-Stakeholder Interview Study

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Abstract

Objectives The integration of environmental impact into health technology assessment (HTA) is increasingly discussed, but its practical implementation remains uncertain. This study explores multi-stakeholder perspectives on the progress, challenges, and equity implications of incorporating environmental considerations into HTA.

Methods As part of the Horizon Europe project HI-PRIX (ID: 101095593), 13 semi-structured interviews were conducted with experts across academia, HTA agencies, regulatory bodies, and industry in seven European countries. Interview transcripts were analyzed through a thematic analysis conducted manually, using a grounded-theory approach. From the interviews, 101 quotes corresponding to 37 codes were extracted and organized in eight analytical themes.

Results Stakeholders agreed that environmental impact is relevant but under-addressed in HTA due to fragmented data, methodological uncertainty, and lack of regulatory guidance. Many emphasized that a health system perspective is too narrow, where methods conventionally used to assess health technologies are not necessarily appropriate to also assess environmental impact, calling for a societal approach that reflects lifecycle impacts. Equity consequences linked to the inclusion of environmental impact of health technologies in HTA were specifically recognized as both reasons for its incorporation and potential barriers. At this stage, procurement was identified as a practical approach to account for the environmental dimension.

Conclusions Integrating environmental impact into HTA will require shifting toward a societal perspective, stronger collaboration across stakeholders, and development of EU-level guidance, expert panels, and standardized methodologies. Methodologies incorporating equity into economic analyses should be explored as a potential direction for future research. Until frameworks mature, environmental impact is likely to remain informative but not yet decisive in HTA.

1 Introduction

1.1 Background

The healthcare sector is an important contributor to climate change, generating some 4.4% of global CO₂ emissions, and also contributes significantly to waste, including hazardous waste, with associated environmental impact from potential contamination of air, soil and water [1–4]. Strategies to

reduce environmental impact in the healthcare sector have been proposed at three levels: where, what, and how care is delivered [5]. For example, the energy demand for the delivery of healthcare services can be optimized (e.g., energy savings in hospitals, use of carbon-efficient machinery), measures to reduce waste and improve waste management can be implemented, and green procurement can be more widely pursued [5].

Assessing the environmental impact of single health technologies within the larger health sector, namely the impacts for the environment resulting from the development, production, distribution and disposal of healthcare products, has also emerged, with various proposals from academia regarding whether and how their impact can be reasonably assessed to inform economic evaluations and Health Technology Assessment (HTA) [6–12]. Health Technology Assessment spans several domains, which traditionally have been safety, clinical effectiveness, cost-effectiveness, but also includes ethical, organizational, social, and legal

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Key Points for Decision Makers

This study explored how environmental impacts of health technologies are being considered in Health Technology Assessment (HTA), using semi-structured interviews with experts from academia, policy-making, and industry across European countries.

Equity concerns, such as who bears the cost and who benefits, are seen as both a reason to include environmental considerations in HTA and a potential barrier to doing so.

A shift toward a broader societal perspective and stronger collaboration is needed to responsibly integrate environmental impact into health decision making.

considerations [13]. Given the impact of the healthcare sector on the environment, the environmental dimension is increasingly proposed as an additional pillar that should be evaluated in HTA [14].

In fact, the question of whether and how the environmental impact of health technologies should be incorporated into economic evaluations and HTA has been widely debated [6–12]. As part of the Horizon Europe project HI-PRIX (Health Innovation Next Generation Payment and Pricing Models, Grant Agreement number: 101095593), we conducted an exploratory literature review of scientific publications published between 1/2013 and 12/2023 to examine research and proposed models for including environmental impact in HTA. To that end, the review preliminarily assessed the state of art with respect to methods available or proposed to leverage the environmental dimension, finding that this would require first, the identification of pertinent environmental dimensions, second, their measurement through appropriate methodologies, and third, their integration into HTA processes (relevant definitions and search details are included in Supplementary Materials 1). The environmental dimensions considered most frequently are carbon dioxide (CO₂) emissions, including CO₂ equivalent (CO₂eq), product carbon footprint or, more broadly, greenhouse gas (GHG) emissions [6–11, 15–21]. Conversely, other impacts like waste, biodiversity loss, water, energy, and air pollution, were less commonly documented in the literature [9, 11, 21].

Regarding measurement of the environmental consequences of health technologies, the most widely established methodology is Life Cycle Assessment (LCA), which in principle measures environmental impact from cradle-to-grave [6–10, 14, 16, 17, 19–22], although lack of data or other practical reasons often result in measurement of only a part of the life-cycle (partial LCA) [10].

Once measured, the environmental consequences of healthcare products can begin to be considered for incorporation into HTA. This could be achieved by converting the environmental dimension either into health impacts, or in monetary units, although agreement has not been reached [6, 8, 9, 15], and at least one author has explored the incorporation of ecological economics [9]. Authors addressed the use of cost-effectiveness analysis (CEA) [8, 10, 21], cost-utility analysis (CUA) [6, 7, 10, 11, 14, 15, 19, 21], cost-benefit analysis [6–8, 10, 19, 21], budget impact analysis (BIA) [10, 16, 17, 19, 21], multi-criteria decision analysis [6–8, 10, 11, 14, 19, 21], and other methods [7, 10]. In addition, different levels of integration of the environmental dimension have been explored, from simply leveraging public environmental information via an information conduit approach, to quantitatively combining environmental, economic and clinical dimensions in a single metric as part of an economic evaluation, to include it as an additional HTA pillar [11].

While established methodologies could, in principle, accommodate environmental factors for HTA, significant challenges remain regarding their practical application. These include data availability and technical expertise in evaluating the environmental impact at the technology level [9, 12, 14], the potential marginal impact on overall evaluation outcomes [10], and, our focus here, equity concerns surrounding the perceived trade-off between health benefits and environmental sustainability [8, 10, 19]. Health equity is a common goal of health systems and policy-makers, and refers to the right of all to health (to be as healthy as possible, regardless of background, location or means) [23]. Problems of equity may be an important barrier to incorporating environmental impacts into HTA as individual benefits from a health technology may have environmental impacts with negative effects on society, current and future generations [24].

Various forms of equity have been discussed in the literature, but at least four types appear relevant: i) horizontal equity, or fair treatment for all users; ii) vertical equity, which considers social inequities in the distribution of benefits among different groups; iii) spatial or territorial equity, providing equal conditions and opportunities for people across regions; and, iv) social and intergenerational equity, which considers the needs of all generations and ensures that social impacts do not disproportionately affect certain groups, promoting fair distribution of benefits (and risks) across different groups [25–28]. A common example of the first two refers to the tax system, where horizontal equity dictates that people with the same income pay the same tax rates, while vertical equity addresses inequities in wealth and proposes redistributing income by levying higher rates on higher levels (or proportions) of income. Horizontal equity in environmental terms requires that the same protection

from environmental hazards be provided to all. An example of vertical equity might be a varying carbon tax levied at higher rates for higher tax brackets [29]. Pollution (air, water, soil, chemicals, metals) illustrates problems with spatial equity, where populations living in certain areas are often subject to greater concentrations of harmful emissions or contaminated water, e.g., the higher mortality from pollution observed both in lesser developed nations and in poorer areas in cities within the same country, or higher growth in chemical and soil contamination in lower- versus higher-income nations [27, 30]. Social and intergenerational equity considers the right of all groups within a society or different generations, present and future, to enjoy the same environment, e.g., in terms of biodiversity, clean water and air, and that future costs (externalities) from environmental damage or resource overuse (e.g., energy) not be passed disproportionately on to future generations [26].

A body of literature has examined incorporating equity in economic analyses of health interventions; for instance, within a CEA framework, horizontal equity is generally applied, where individuals' health gains and losses are considered equal, e.g., quality-adjusted life years [24]. According to Culyer and Bombard [31] such reasoning meets the definition of equality (treating everyone the same) but not equity (considering individual differences to assure that all receive what they need for an equitable outcome); the authors make the case for applying equity rather than equality in HTA [31]. For example, an emergency room triage system is unequal (urgent, serious cases are treated first, regardless of arrival order) but equitable (vertical equity) because it addresses those in greatest need first. The authors cite two areas for equity considerations in HTA: fairness of procedures in conducting HTA and "using equity as a decision criterion, like efficiency, for ranking healthcare interventions," and provide a framework for policy-makers to apply [31]. Cookson et al. [32] describe frameworks for balancing trade-offs between cost effectiveness and equity, such as distributional CEA, and extended CEA, equity trade-off analysis, and equity-weighting analysis, which may provide insights for incorporating environmental impacts in economic evaluation; although they are not addressed in the paper.

Similarly, the literature we examined on incorporating environmental impact in HTA has been largely silent on equity considerations; in contrast, the links between social and environmental policies and their ethical implications have been explored by governmental and global bodies, including the World Health Organization (WHO) and the European Commission (EC) [28, 33, 34]. For instance, an EC report warns that environmental policies that pass on the increased costs to reduce the environmental impact of energy and food production would disproportionately impact lower income classes without mitigation strategies [28].

Thus, there seems to be a significant gap in the literature on how equity considerations may influence decision making and policy development for incorporation of environmental impacts in HTA.

1.2 Objectives

This study aimed to evaluate the current state of progress toward incorporating environmental impacts in HTA, identifying facilitators, challenges and equity implications of such progress, through interviews with experts from a three-fold perspective: academia, policy-makers (HTA agencies, regulators, hospital HTA), and industry. While the academic debate continues to explore the most appropriate methodologies for measuring and integrating environmental considerations into decision making, professionals in the field have already been required to address these challenges due to regulatory pressures or market demands. By incorporating these different perspectives, the research sought to bridge the gap between theoretical frameworks and real-world implementation, shedding light on how environmental considerations are currently being integrated (or not) into HTA and whether and how much equity concerns hamper progress.

2 Methods

2.1 Study Design

As part of the HI-PRIX project, a series of semi-structured interviews were conducted to explore multi-stakeholder perceptions on progress towards facilitators, barriers, and equity implications of including environmental impacts in HTA. A semi-structured interview is a qualitative research method that uses a pre-defined set of open questions to prompt discussion, giving the interviewer the opportunity to explore themes or responses further [35]. The exploratory literature review mentioned earlier informed the preparation of background information and questions for interviewees, with search terms revolving around two main concepts, namely "Environmental" and "Health Technology Assessment or economic evaluation" (see Supplementary Materials 1 for more details).

2.2 Study Settings and Participant Recruiting

The interviews were designed to engage a diverse range of stakeholders to collect multi-stakeholder perspectives, such as technology manufacturers or industry representatives, academics, and policy makers, including members of regulatory bodies or HTA agencies.

Participants were recruited using a purposive sampling technique by leveraging the HI-PRIX network. The selection

of the participants was based on their potential to provide rich information relevant to the study, specifically based on their qualifications or roles, their expertise in the area of the environmental impact of health technologies, and their potential to bring relevant information in the perspective of their stakeholder's category. Additionally, participants were chosen to ensure representation from different countries within the EU. Geographic coverage was largely based on our preliminary literature review, concentrating on those countries where the topic is more developed and debated or in multinational settings (e.g., for industry interviewees).

2.3 Data Collection

A simple interview guide was developed. The list of questions used to guide the interviews, and the background information provided to the interviewees, is available in Supplementary Materials 2. To test the structure, contents, and time needed to cover the entire interview guide, a pilot interview was conducted. The pilot interview confirmed that the background information provided was presented in concise, informative manner, without bias. It allowed for the consolidation of six original questions into four original questions, more open-ended questions to shorten the length of time needed and allow interviewees to freely introduce thoughts and experiences. The interview protocol was presented to our institution's Ethical Committee for ethical approval (ID: EA000731). An informed consent form, with a short description of the project, objectives and privacy considerations, was sent to every participant, for them to return signed (see Supplementary Materials 3). No compensation or payment for participation in the study was provided, and participants were informed that they could withdraw from the study at any point.

Participants were invited to participate in the study via e-mail, along with the questions and supporting material. The interviews were scheduled to last 45 minutes, and were conducted in English between February and June 2024, using an established teleconferencing tool (Microsoft Teams).

2.4 Data Analysis

All interviews were recorded and transcribed verbatim. Given the relatively small number of interviews, specialized software was not used for the thematic analysis. Thematic analysis was conducted manually using a grounded-theory approach, which involves systematically reviewing responses to identify codes and derive themes inductively from the data [36, 37]. Two researchers (VA, HB) independently conducted the coding process. Codes were first derived based on insights from an exploratory literature review and the study's research questions. After the independent coding,

the researchers met to compare and discuss their proposed codes. A consensus on the final coding scheme was reached through discussion; in cases of strong disagreement, a third author (RT) was involved to help resolve the issue. Through an inductive, data-driven approach, the coded data were then aggregated into broader themes.

3 Results

3.1 Study Participants

Overall, 17 stakeholders were invited to participate, and 13 agreed to be interviewed. The interviewees represented seven countries (Belgium, France, Ireland, Netherlands, Portugal, Spain, UK). Specifically, four interviewees (30%) were based in the Netherlands, two (15%) in France, two (15%) in Spain, two (15%) in the UK, one (7%) in Belgium, one (7%) in Ireland, and one (7%) in Portugal. Participants represented different stakeholder perspectives, which can be divided into policy makers, including national HTA agencies, regulatory bodies, and hospital-based HTA (5, 38%), academics (5, 38%), and industry members (3, 23%). The policy-maker group included two participants from HTA agencies, two others engaged in hospital HTA, and one a former regulator (EU National Competent Authority). The academics represented varied backgrounds, including health economics, public health, HTA, and sociology. The industry members represented different health technologies (one in drugs, one in medical devices, and one in an industry association representing pharmaceutical companies). Further details on study participants are provided in Table 1.

3.2 Interview Results

All interviewees acknowledged the importance of considering the environmental impact of health technologies and healthcare and expressed familiarity with at least one national or local initiative, as well as initiatives implemented within their own organization, aimed at reducing the environmental impact of healthcare products or processes in their home country. Two people had worked directly on the issue from an academic standpoint, one of whom was also beginning to participate in a national committee tasked with studying environmental impact in health economic evaluation at the national level. At least five people had consulted, or were familiar with, the literature on incorporating environmental impact in HTA. All reported that various initiatives to incorporate environmental impact in HTA were in their infancy and were aware of no definitive policies or guidelines that had yet emerged.

The following sections present the results of the thematic analysis. From the 13 interviews, 101 quotes corresponding to 37 codes were extracted and organized in eight analytical themes, outlined in Fig. 1. Further details are provided in Supplementary Materials 4.

3.2.1 Theme 1: Identification of Environmental Impact Dimensions

Interviewees highlighted the importance of identifying the full spectrum of environmental impacts. Academics emphasized that environmental impacts constitute a significant externality currently not fully addressed in HTA. Industry participants noted the importance of comprehensively accounting for all kinds of pollution generated, e.g., water pollution may be particularly relevant in the pharmaceutical industry. Policy makers, especially those in hospital-based HTA, also acknowledged the relevance of waste as a priority environmental dimension. However, they noted that current frameworks provide little guidance on how far these environmental considerations should extend: “*We are limited in what we can take into account. (With LCA, though it has made great strides, it is difficult to know where you have to stop. To date, in hospital HTA, we use the environmental impact criterion kind of as a cut-off where we have a choice between different options.*”

3.2.2 Theme 2: Measurement of Environmental Impact

Measurement emerged as a key challenge for all stakeholders. Academics noted that data availability and reliability remain poor. Hospital-based HTA experts advocated for life-cycle data acquisition to be able to consider environmental impact data from the various phases of the life-cycle

of a product as “*more transparent and understandable for a decision maker*”. Industry respondents acknowledged there are still open questions regarding what to measure, how to measure it, and how to factor this into decision making. Policy-makers emphasized the need for methodological development: “*There are all sorts of metrics... It would be really risky to take things at face value. Until we can be more confident, acknowledging that all healthcare has an impact on the environment is a start.*” Another policy maker mentioned difficulties in the availability of data, where there is often only partial data, or where data on environmental impacts may be accounted for at more than one phase: “*we must be cautious because of double credits or double paying*”; [double counting can occur when a manufacturer sells the carbon credits they received for greener manufacturing and also requests a price premium for the finished environmentally sustainable product (Supplementary material 1)].

3.2.3 Theme 3: Integration of Environmental Impact in HTA

Academics interviewed acknowledged that, while there are scholarly attempts to use established methodologies to incorporate the environmental impact of health technologies in economic analyses, there is no evidence that this is the place to start for considering such impacts. They expressed skepticism on whether the micro-level decisions in economic evaluations is the best locus for integrating environmental impacts. They saw value in initial steps such as data collection, and some felt strongly that HTA agencies should at least collect and document environmental costs as a first step, although many acknowledged problems with the reliability and completeness of data at present. Whether to include these costs/impacts into economic evaluations was

Table 1 Anonymized list of interviewees

#	Interview date	Role	Country	Stakeholder type
1	27-02-2024	Health economist	France	Academia
2	19-03-2024	Health economist (Professor Emeritus)	UK	Academia
3	20-03-2024	Head of HTA Directorate	Portugal	HTA agency
4	26-03-2024	Deputy of Innovation, Head of Assessment of Innovations (HTA)	Spain	Hospital HTA
5	26-03-2024	Health Evidence/HTA Netherlands	Netherlands	Academia
6	02-04-2024	Public Health Physician/Epidemiologist	Netherlands	Academia
7	08-04-2024	Sociologist	Netherlands	Academia
8	15-04-2024	Physician, Professor of Regulatory Affairs (former regulator)	Ireland	Regulator
9	15-04-2024	Market Access and Corporate Affairs	Netherlands	Industry
10	16-04-2024	Hospital Pharmacist, Professor	France	Hospital HTA
11	22-04-2024	Associate Director	UK	HTA agency
12	29-05-2024	Market Access	Belgium	Industry
13	04-06-2024	Department of Pharmacoeconomic Studies	Spain	Industry

Fig. 1 Themes emerging from the interviews



seen somewhat as a distinct issue, whose decision could be de facto postponed to a later stage.

Those working in HTA agencies tended to be more cautious in expressing their views on the matter. Another mentioned a high possibility of error with current methods and tools to incorporate environmental impact into HTA; however, “*If the idea develops, there are all sorts of metrics, (for example), (environmental data) from the manufacturing area, ...on the use of the technology; (but we may need to) buy in expertise for decision-making committees to validate analyses.*”

Discussing the integration of the environmental impacts in CEAs, industry representatives emphasized that this was not currently required and therefore had not been debated much in their organizations, expressing uncertainty whether this is the right box to account for the environmental dimension. They highlighted the need to arrive at careful estimates of the associated costs: “*What cannot be proposed is that pharmaceutical companies pay for environmental costs that are produced by other companies, like chemical companies*”).

3.2.4 Theme 4: Barriers and Facilitators

A key obstacle perceived by academia was the possible inadequate technical expertise within HTA agencies to interpret environmental metrics. One person claimed “*I spent a lot of time trying to understand the physics of environmental issues. It’s like they are two worlds [HTA, environment] that currently don’t talk to each other*”. Therefore, the need to produce official guidance on the inclusion of environmental impacts of health technologies was raised: “*It may be necessary to approach these issues from a higher, [EU] committee level, rather than lower [local/national] levels, which may be impossible to implement. Very clear guidelines are needed!*”.

Policy-makers noted regulatory barriers, e.g., one country’s HTA guidelines do not address environmental impact. “*These [environmental] costs are not considered... however, they might have a role in exceptional pricing or renegotiations.*” One policy-maker listed several regulatory barriers that should be considered: “*How much of the environmental impact costs can you attribute to a company, how can you set a framework, and what is the appropriate level of entry of these issues? All these need to be considered. After Medical Device Regulation, it’s more difficult to enter the market,*

so we need to worry about access... Do we need much better tools? Labelling could be used. ISO standards could be developed as a way of showing environmental impact.” In addition, this person cautioned that legal problems might arise from a policy standpoint when deciding on whether you use incentives or punishments to lessen environmental impacts. Finally, industry mentioned pharmaceutical regulation as a possible barrier, as it might not allow changes in prices to account for the environmental premium.

3.2.5 Theme 5: Equity (or Distributional) Consequences

The equity consequences linked to the inclusion of environmental impact of health technologies in HTA were specifically mentioned as both reasons for its incorporation and potential barriers. As one interviewee explained, to incorporate the environmental impact of health technologies, the societal perspective would be appropriate, namely counting all costs and effects of a health intervention incurred to the society as a whole, regardless of who pays or benefits [38]. However, this may be incompatible with micro-level decision-making in HTA, which usually take a health system or payer approach, considering only the technology or intervention’s direct health system costs and benefits [38]. Difficulties in accounting for trade-offs figured largely (“*Choosing between health and the environment are not an easy choice to make*”). Another mentioned intergenerational equity with respect to the impact of environmental choices on future generations as an important reason for its incorporation in economic analyses.

For policy-makers, equity considerations emerged in terms of who is ultimately responsible for evaluating environmental impact as well as differences of opinion regarding how its incorporation in decision making may have distributional effects from a societal perspective. Interviewees recognized the importance of environmental impact but felt different perspectives would require careful consideration. “*The public and private sides will have different boundaries. Green or environmentally sustainable production is fashionable, but industry may inflate prices because of that. We need to be very sure of what we’re paying for and whether it is worth it, (and) whether we can trust the information since the reality is they need to have results every year to show to their shareholders*”. One policy-maker described efforts to understand different perspectives: “*If the goal of the NHS is to reduce environmental impact, then you can invest money to advance those goals, prioritize co-benefits. But in a public engagement exercise, 20 members of the public were sampled during three in-depth workshops informing them on what NICE does and asking their opinions. People thought it was important, but were not open to trade-offs, only increased benefits.*” Another noted, “*Environmental impact is important, and we should increase the weight of*

this criteria. Then the analysis can bring in more interpretable results” to better balance trade-offs among different parties. The regulatory expert noted that current regulations do not require environmental considerations: “*(...) from a manufacturer’s point of view, environmental costs are not needed in the analysis at present. Nevertheless, from a societal view looking at who is responsible for these environmental costs is important. We rarely hear about equity aspects, so it’s unlikely to come from within the system. We should try in some way to take this into account.*”

In response to questions on equity, industry focused on the notion of value, which varies across stakeholders. “*What is the value? For whom, payer, society, HTA agency? It shouldn’t be a trade-off between high quality and efficiency and another dimension, with one at the expense of another.*” As another put it: “*It’s best to move slowly to balance the right of the patients to keep having traditional medicine and not push too hard in the short run if doing so might compromise access.*” Respondents questioned whether it is fair for companies to reflect the environmental dimensions in the price of health technologies, whether industry, consumers, or the NHS would have to pay for these costs. They likened environmental costs to instances where decision-makers must decide between a new treatment with comparable effects, but different, more convenient, and more expensive means of delivery. Which one should be preferred?

3.2.6 Theme 6: Initiatives at the Local Level

Several local initiatives emerged across stakeholder groups, although in an early stage. Academics cited green procurement and transitioning towards greener energy in local hospitals, as well as a national committee to study incorporating environmental impact in economic evaluations (Netherlands).

A policy-maker mentioned a UK task force to create a framework for including environmental impact in HTA, which, while acknowledging the importance of the issue, concluded that “*it would be very risky at this stage to introduce environmental impact in HTA. Reasons: (1) no consensus on data sources, (2) don’t have the expertise (no environmental scientists), lack of standards, potential to misinterpret data, (3) methods for environmental impact assessments themselves, that is, LCA is thought to be the most rigorous, but (we) can’t compare LCA assessments because of different calculation methods.*” Another person described national recommendations and a stringent roadmap in France, including training programs and procurement guidelines that penalize excessive environmental impact, e.g., high wastage. Within their hospital, this person described the establishment of a dedicated “*unit to address the environmental impact of the hospital and products*”, as well as internal training and promotion tracks for those who

opt to become “environmental managers”, functioning as points of reference for the hospital. Industry representatives mentioned only internal policies, such as travel policies favoring more environmentally sustainable options.

3.2.7 Theme 7: Shifts in Institutional Priorities

Interviewees reported early but tangible shifts, suggesting a growing institutional willingness to address environmental sustainability. Academics cited the increased interest in environmental sustainability in the literature: *“The impacts of global environmental change on human health, and the contribution of healthcare to those changes, are such that there's an enormous literature now that first of all shows that.”* They also mentioned shifts in thinking: *“We could be more ecologically responsible in making decisions on what to allow or finance.”*

Policy-makers noted growing interest in environmental criteria within hospital HTA: *“Especially in the last five years... more people have begun to work on this aspect.”* From another: *“Environmental impact has a place in HTA; it has become a really important field. The distinction is on where. We're doing a lot locally in French hospitals, in hospital-based HTA, where we're really taking it into account.”* Industry responded cautiously, mentioning only having a dedicated team looking into the measurement of environmental impact (not for HTA-purposes so far). However, they mentioned increased awareness on a general level: *“The incorporation of all disciplines and sectors in HTA is not well implemented, even though it's very important. A recent HTA conference had a dedicated plenary for the first time on environmental impact, so things are changing.”*

3.2.8 Theme 8: (Dis)incentive Framework

Some academics emphasized the need for incentives to stimulate data collection. Policy-makers noted regulatory gaps and risks of double-counting or mispricing. Existing procurement rules already penalize waste in some cases. The regulatory expert noted that any framework would have to decide whether to use incentives or punishments, cautioning that no legislative requirements for industry currently exist. Another policy-maker speculated that some work in the meantime could serve as an incentive to *“raise the profile, and make sure data are increasingly available.”* For instance, *“Procurement might be seen as a stepping stone to higher quality data. (It) provides an incentive to collect that data and do things more responsibly, which can be seen as a legislative outcome”.*

Industry mentioned the need to find ways to finance environmental costs, in a way that companies from other industries are doing. *“In an ideal world, costs would all cover themselves. We need to estimate those costs accurately.”* As

an example, they cited low-priced off-patent products where small margins would make it difficult to intervene on prices to account for their environmental impact: charging more for these products would likely make them uncompetitive, with consequences in terms of shortages of treatments for patients, or even a preference for on-patent drugs, that are more expensive.

4 Discussion

This study examined the progress, challenges, and equity implications of integrating environmental impacts into HTA, as perceived by different stakeholders. Given the limited progress toward agreed methods for integrating environmental impacts into HTA, this study offers a complementary qualitative perspective and is intended for a broad audience of stakeholders, including HTA agencies, payers, patients, health care professionals, and manufacturers, as well as regulators and policy makers in both the health and environmental sectors. Interviews revealed methodological barriers and divergent views on the distributional effects of incorporating environmental considerations, suggesting that underlying goals may conflict and require careful alignment. Figure 2 shows the relative importance that each stakeholder group gave to the various themes covered.

Academics cited the lack of reliable environmental data and standardized assessment frameworks as barriers to their incorporation in HTA for decision-making, warning that this could lead to inaccurate or incomplete assessments or exacerbate inequities if premature inclusion of environmental factors leads to misinformed decisions or biased resource allocation. Policy-makers (HTA agencies, regulators, and hospital-based HTA experts) also expressed caution, primarily due to the lack of consensus on data sources, measurement methods, and regulatory guidance. Given that pollution and resource consumption occur at multiple stages of the supply chain, industry cited unresolved questions regarding what and how to measure and how to factor this into the decision-making process. The concerns voiced by all three groups are frequently cited in the literature, particularly in relation to an emphasis on carbon emissions at the expense of other forms of environmental impact, trust issues related to selective inclusion of impacts and information asymmetry, and difficulties in collecting disaggregated environmental data for the entire life-cycle of health technologies [9, 10, 12, 18, 19, 39, 40].

Both academics and policy-makers emphasized that incorporating environmental impact into HTA raises equity challenges and trade-offs between immediate health outcomes and environmental sustainability. They underlined the limitations of incorporating environmental impact into HTA from a health system or payer perspective, that is, limiting

analysis to considerations of costs and benefits that directly affect healthcare budgets or outcomes [38]. They stressed the need for a societal perspective, arguing that payer-focused evaluations overlook broader distributional effects, particularly intergenerational equity, where future benefits may come at the cost of present access. In fact, a societal approach would allow for considering environmental externalities (e.g., greenhouse gas emissions, resource use, waste management, pollution, long-term ecological effects) along the entire life-cycle of a health technology [9, 11]. Industry took a defensive stance in arguing against the societal perspective, cautioning they should not bear the financial burden of environmental externalities alone, and voicing concerns on competitiveness and affordability. They noted that sustainability-driven price increases could limit patient access and widen health disparities. As an anecdotal example, industry representatives speculated how higher costs might disproportionately affect low-cost generics, making them financially untenable, leading to reduced competition and drug shortages. Cost concerns were not limited to industry (hospital-based HTA experts highlighted budget constraints as a key barrier, noting that environmentally friendly alternatives, e.g., reusables versus disposables, can be more expensive due to higher energy and water costs for sterilization), but industry's arguably myopic view ignores that some costs are necessary: should the costs of increased clinical investigation in response to adverse events (e.g., thalidomide, breast implants) have been passed on to consumers?

Taken together, our interviewees echo concerns that, in a fixed budget health system, should higher-priced, environmentally sustainable health technologies displace current products (i.e., benefits for future generations), they may result in greater limits today (i.e., costs for current generations) on health services or disproportionately affect access to those with lesser means [28]. Nevertheless, they also consider environmental impact to be important and worry about the disproportionate effects of climate change on younger generations and on developing nations, as also described in the literature [27, 33]. However, few of the methodological papers on incorporating environmental impact in HTA

discuss adopting a societal perspective and none in detail [8, 9, 11], and few mention equity and only in passing [19, 20]. The concerns raised by stakeholders here (and their largely universal feeling that the time for incorporation of environmental impact in HTA has not yet arrived) imply that the equity implications are, indeed, an important barrier. There is clearly a fear that incomplete or erroneous application of proposed techniques risks inadvertently causing disproportionate harm to some groups of people, whether patients or the public, current or future generations, and that there is a need to understand how to safeguard from and treat different types of inequity, whether vertical, horizontal, spatial or intergenerational.

In this sense, comments by interviewees reflect concerns raised in the literature on health and equity [23, 26]. A key to finding a responsible approach to incorporating environmental impacts into HTA might then come from the literature on incorporating *equity* in HTA [31, 32]. Frameworks that might be applied to manage the equity-efficiency trade-off in HTA [41] range from a checklist of equity concerns that could be adapted to include environmental concerns to adapting a health equity impact plane to incorporate environmental impact and exploring the use of distributional CEA, extended CEA, equity trade-off analysis, and equity-weighting analysis [24, 31, 32].

Since environmental damage tends to affect global systems, in the interests of horizontal equity, efforts to reduce the impact of the healthcare sector on the environment would potentially benefit everyone. This is in keeping with the One Health approach to “*sustainably balance and optimize the health of people, animals and ecosystems*” [42]. Efforts to reduce the environmental impact of health systems and health technologies would also potentially improve spatial or territorial inequity, given that there is evidence that developing nations are disproportionately affected by environmental damage and pollution caused largely by developed nations [26, 27]. Furthermore, production of pharmaceuticals, particularly generics, has shifted to developing nations. It is not surprising that the recent reform of the EU pharmaceutical

Fig. 2 Heat map of theme salience by stakeholder group. Cells show the number of coded quotes for each theme within each stakeholder group. Darker shading indicates higher counts; “0” indicates no coded quotes. Counts are descriptive aids to convey relative emphasis and are not used for statistical inference

Theme	Academia	Industry	Policy-makers
Identification of environmental impact dimensions	1	4	2
Measurement of environmental impact	1	4	8
Integration of environmental impact in HTA	3	3	2
Barriers/facilitators	5	4	5
Equity (or distributional) consequences	5	3	2
Initiatives at the local level	6	1	10
Shifts in institutional priorities	6	5	6
(Dis)incentive framework	6	0	9

legislation made an explicit claim to make medicines more environmentally sustainable [43].

4.1 Implications and Recommendations

This study contributes to the growing body of research that is exploring the feasibility of incorporating the environmental impact of health technologies into economic analysis and HTA, highlighting where its associated barriers to implementation (e.g., data inadequacy, incomplete inclusion of all types of environmental impact) and equity implications may be contributing in no small manner to delaying its progress. To address our readiness to proceed in a responsible manner will require several areas of intervention.

First, any consideration of incorporating environmental impact into HTA may need to be preceded by the development of related policies and legislation, such as green public procurement (GPP) measures [44]. Indeed, policy-makers interviewed acknowledged the potential role of environmental considerations in procurement decisions, seeing this as a stepping stone toward broader integration in HTA. A critical review of the literature on GPP found considerable evidence of legislative measures aimed at increasing its use and discussed its impact as a policy measure as well as barriers to its implementation, all of which could be further explored to inform measures to promote inclusion of environmental impact in HTA [45].

Second, more interconnected endeavors involving a variety of stakeholders along the value chain are needed. The challenges highlighted imply that methodological approaches for incorporating environmental dimensions in an assessment process are currently insufficient, also in light of the many interests at stake. Developing guidelines to adopt a societal perspective [38] in HTA to account for all environmental impacts and the entire life-cycle should be explored, considering impacts on current as well as future generations, inequities in territorial terms, and measures to fairly distribute the costs according to ability to pay [25–27]. As outlined above, the literature on incorporating equity in HTA could be further explored for examples and appropriate methodologies [24, 25, 31, 32, 41]. Clinicians and scientists could be engaged to confirm product equivalence on safety and effectiveness where environmental impacts differ. Means to assess and communicate any potential differences in price and access due to environmental impacts could be developed to inform patients and the public. Increased guidance for manufacturers on standardized methods to generate and report environmental evidence could be provided. Importantly, decision makers should explore means for these various stakeholders to contribute to pan-European initiatives that will address how to measure and weigh all environmental impacts along the life-cycle. To that end, achieving a balance between environmental sustainability and equitable

healthcare access will require greater collaboration among policy-makers, industry, HTA agencies, and researchers, alongside the development of robust, interdisciplinary methodologies that account for both short-term healthcare needs and long-term environmental impact.

Third, additional resources to inform HTA from regulators and policy-makers are needed. The development of sustainability reporting by manufacturers regarding environmental, societal and governance factors is an example. Recently, the EU released specific rules to address inconsistent disclosures and the lack of access by investors, users, and stakeholders to adequate non-financial information, sustainability in particular [46, 47]. These rules will broaden the scope of companies subject to reporting requirements, disclosure, and data quality.

Fourth, certifying manufacturers' environmental commitment could be explored, e.g., green production certifications might be issued to factor into HTA, echoing approaches already piloted in digital health [48, 49]. Additionally, to support HTA, EU policy-makers could publish any environmental credits received by manufacturers in a public database, identify lists of multidisciplinary experts (like the Expert Panels in the recent EU Medical Device and HTA Regulations) and develop official guidance on interpreting environmental data at the pan-European level.

Finally, it must be acknowledged that “environment” has become a mantra of the modern era, and different stakeholders, especially younger generations, have vehemently demanded commitment from a variety of actors, including governments, towards concrete actions. Therefore, irrespective of methodological aspects, we must question the true objectives that justify incorporating environmental impact into HTA. If we consider that the primary goal is to ensure equity, then the takeaway is that a broader societal perspective will need to be adopted (not only with respect to the environmental considerations), suggesting that traditional payer-focused systems or approaches might need some rethinking, as cited by several of the authors [8, 9, 11].

4.1.1 Limitations

This study comes with limitations, and its results should be interpreted with caution. First, the sample was limited to 13 interviewees, which means that the considerations cannot be generalized to specific countries or stakeholder groups. Participants were recruited through the HI-PRIX network, with the aim of including individuals with practical knowledge and expertise at the intersection of HTA and environmental issues. While this approach ensured relevant insights, it may have also excluded other prominent experts, such as those identified in the academic literature we consulted. Moreover, representation across countries was uneven, with some countries more represented than others. As the interviews

were conducted within the framework of an EU project, participants were exclusively from European countries, and therefore from high-income settings. Perspectives from middle- and low-income countries are currently missing. This limitation is partly mitigated by the fact that while environmental impacts of health technologies are increasingly recognized worldwide, progress toward integrating such considerations into HTA has so far been more pronounced in countries where HTA itself has been in place for a longer time. Finally, this is a rapidly evolving field: new initiatives and policy developments may have emerged since the interviews were conducted, and complementary contributions and frameworks from adjacent disciplines, particularly environmental economics (e.g., treatment of externalities, shadow pricing, and life-cycle approaches), are also advancing; future work should engage with and, where appropriate, incorporate these to refine how environmental impacts are integrated within HTA.

5 Conclusions

This study highlights how the integration of environmental impact into HTA remains a complex but urgent frontier: technically feasible in principle, yet obstructed by methodological uncertainty, data limitations, and unresolved equity implications. Importantly, protecting the environment should not be framed as a trade-off with health; it is a societal commitment. To enable responsible integration into HTA, we recommend coordinated action to develop robust methodologies, define equitable cost-sharing mechanisms, and establish guidance, expert panels, and public reporting frameworks. Manufacturers' green certification could serve as a practical tool to signal environmental performance. Procurement may also offer a pragmatic entry point to drive data generation and methodological advancement. Ultimately, achieving a balance between sustainability and equitable access to health technologies will require cross-sectoral collaboration, transparency, and political will. The question is not whether environmental considerations should be included in HTA, but how quickly and responsibly we can build the structures to make it happen.

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Declarations

Conflicts of interests The authors declare that they have no competing interests to declare.

Ethics approval The study was approved by Bocconi University's Ethical Committee (ID: EA000731).

Consent to participate All participants provided written informed consent prior to taking part in the study.

Consent for publication All participants consented to the publication of the study results.

Data availability All relevant data supporting the findings of this study are included in the supplementary materials (i.e., interview quotes). Additional data (i.e., interview transcripts) can be provided upon reasonable request to the corresponding author.

Code availability The code used for the analysis is available in the Supplementary Materials.

Authors' contributions VA: contributed to study design; conducted interviews; performed data analysis; drafted the first version of the manuscript. HB: contributed to study design; conducted interviews; performed data analysis; drafted the first version of the manuscript. RT: contributed to study design; critically revised the manuscript; contributed to drafting and writing.

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