INAHTA White Paper on Advancing Environmental Sustainability Through HTA

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INAHTA *Connecting Evidence and Policy for Better Health*

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This White Paper was produced by a voluntary group of 22 senior HTA specialist staff at 15 INAHTA member agencies located throughout North America, South America, Asia, and Europe. Under the INAHTA umbrella, they have produced this White Paper to advance the discussion and application of Environmental Impact Assessment (EIA) in HTA.

INAHTA is the global network of public HTA agencies that produce HTA to support regional and national governments in making decisions about the use, coverage, or reimbursement of healthcare technologies. Part of INAHTA's mission is to share public agency viewpoints on matters of scientific, strategic, and policy importance for HTA. This White Paper presents a cross section of INAHTA member perspectives on, and experiences with, including EIA in HTA, and it provides reflections on what needs to be in place for embedded EIA to become a reality in HTA.

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DISCLAIMER: This White Paper was approved for release by the INAHTA Board of Directors. However, the paper represents the views of the authors and advisory group, and it is to be differentiated from the Position Papers[1] of INAHTA, which are agreed to by a minimum threshold of 70% of INAHTA members.

This White Paper does not necessarily represent the views of the individual HTA agencies where the authors or advisory group members work, nor of the INAHTA Board of Directors or INAHTA network more generally.

[1] See https://www.inahta.org/position-statements/

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List of Abbreviations

ACRONYM	FULL NAME
A4R	Accountability for reasonableness framework
ATACH	The Alliance for Transformative Action on Climate and Health
CDA-AMC	Canada's Drug Agency (formerly CADTH)
CE	Conformité Européene, or European Conformity marking
COP28	28th Conference of Parties United Nations Climate Change Conference 2023
EIA	Environmental impact assessment
EPP	Environmentally Persistent Pharmaceutical
ERA	Environmental Risk Assessment
EUnetHTA	European network for Health Technology Assessment
EVIDEM	Evidence and Value: Impact on DEcision Making
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HAS	Haute Autorité de Santé
HTA	Health technology assessment (view definition)
IETS	Instituto de Evaluación Tecnológica en Salud
INAHTA	International Network of Agencies for HTA
INESSS	Institut national d'excellence en santé et en services sociaux
LCA	Life Cycle Analysis
MCDA	Multicriteria Decision-Analysis
NICE	The National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
OECD	Organization for Economic Cooperation and Development
PBT	Persistent, Bioaccumulative and Toxic substances framework
SBU	Swedish Agency for Health Technology Assessment
SDGs	Sustainable Development Goals
UNEP	United Nations Environment Program
WHO	World Health Organisation

Summary

This White Paper aims to advance the discussion of the potential readiness and role for health technology assessment agencies to integrate environmental impact assessment into their evaluations. This topic is timely and urgent given the evolving global environmental and climate crisis. Health care systems and organizations are responding by taking on greater responsibility to reduce their environmental footprint.

This paper is based on recent scientific literature, along with expert insights and knowledge from a group of members of the International Network of Agencies for Health Technology Assessment (INAHTA). It provides a summary of the current state of environmental impact assessment in health technology assessment, and identifies some of the challenges and opportunities for incorporating environmental impact assessment more fully into health technology assessment.

INAHTA shares this knowledge for all stakeholders in the health technology assessment community as inspiration to work together to reduce the environmental footprint of healthcare and support health systems to deliver high-quality, cost-effective, and environmentally sustainable care.

In Brief

- Health technology assessment (HTA) agencies are increasingly acknowledging the environmental impact of healthcare systems amidst global ecological crises.
- Healthcare systems face pressures to minimize their environmental footprint, with HTA serving as a vital tool for promoting environmental sustainability.
- In response to calls for greater environmental responsibility, many HTA agencies have incorporated environmental considerations into their strategic plans and assessment processes.
- Environmental impact assessment (EIA) is emerging as a critical aspect of HTA, complementing evaluations of clinical efficacy, safety, economic, social, and ethical and legal considerations. It is a method to assess the impact of a health technology on the environment (and long-term human health), and other aspects along the technology lifecycle.
- EIA presents an opportunity for HTA agencies to enhance awareness, encourage dialogue, and refine methods for effective decision-making.
- While EIA methods are still evolving, its integration into HTA requires the adaptation of existing value frameworks.
- Collaboration among healthcare professionals, governmental and regulatory bodies, and industry stakeholders is crucial for advancing EIA within HTA.

Introduction

Environmental Crisis

The latest Lancet Countdown climate report refers to perilous time on planet earth [1] [2].The United Nations Environment Program (UNEP) has identified three interconnected environmental crises occurring in the world today: climate disruption, pollution, and the loss of biodiversity and natural assets.[3] According to the UNEP and others, these environmental crises are of human origin and they have critical effects on human health. Climate disturbances have been linked largely to fossil fuels, through related and diverse toxicities of air, water, soil, and biota, loss of biodiversity and natural assets.[3, 4] This global emergency calls for ambitious, coordinated action by governments, non-governmental organizations, businesses, and citizens worldwide to transform social and economic systems in order to improve humankind's relationship with nature, to understand its vital value, and to place that value at the heart of decision making.[5] The 17 sustainable development goals of the United Nations pave the way for this paradigm change and some health ministries and HTA agencies are including some of them in their strategic plan and indicators. [6] [7, 8]

To counter or slow the effects of climate change, which connotes environmental disruption, pollution, and loss of biodiversity, both mitigation (reducing the causes of pollution) and adaptation (adjusting to the effects of pollution) are necessary. Adaptation actions are however limited, and cannot fully compensate for the damage and loss to the environment that will unavoidably occur.[9] Human beings are currently acting beyond planet sustainability and there is also an acceleration of waste production as new substances and compounds are being developed that present uncertain environmental risks.[10] [11]

Climate change is also having an impact on health care systems. Health services can be disrupted during extreme weather events, and the accumulation of the effects of pollution and biodiversity loss increases the risk of the re-emergence of certain infectious diseases. It is to be anticipated that health systems will be affected by increased need for care due to an increased burden of disease and climate-related demand for care[9].

Environmental Impact of Healthcare Systems

Health care systems face a paradox: while they aim to prevent and cure disease, they are also major polluters.[12] [13] The healthcare sector as a whole is responsible for about 5% of global carbon emissions, with per capita rates varying across countries,[14] [15] If the healthcare sector were a country, it would be the fifth largest carbon emitter on the planet.[13] Healthcare systems are also causing air and water pollution, as well as biodiversity loss, contributing 4-6% towards these factors at a national level.[16] [17]

Medical equipment (often disposable), health technology supply chains, and the production and use of pharmaceuticals are important contributors to the carbon footprint of health systems.[12, 18-20] Factors that contribute to this pollution identified by the UNEP[21] include: the worldwide pollution of ecosystems by environmentally persistent pharmaceuticals (EPPs)[22]; the approaching limits of antimicrobial resistance [23, 24]; the contamination from so-called 'e-waste' [25] such as electronic equipment and microprocessors [26] that have become omnipresent in healthcare systems[27]; and, the potentially harmful risks to human health and the environment of nanomaterials, which are used in numerous domains of healthcare including drugs, and vaccines.[21, 28, 29]

To provide a holistic view of their environmental footprint, analyses of certain kinds of healthcare technology (e.g. surgery, pharmaceuticals) can help to quantify multiple types of environmental impacts.[30]

The pandemic and the acceleration of the environmental crisis have triggered a series of international and national actions to develop resilient and environmentally sustainable healthcare systems, which could include mandatory reporting, benchmarking, and regulated accountability of health care organizations [31]. At COP28, the 2023 United

Nations Declaration on Climate and Health [32] signatories from more than 125 countries committed to integrating environmental considerations into health policies, implying assessment of and accountability for their environmental footprint. This historical opportunity for healthcare systems is echoed by recommendations to transition from a sickness-led model to a more holistic health improvement model of environmentally sustainable healthcare, with greater cooperation between healthcare, social care and environmental policy-makers.[33] [34] To put it simply, efforts towards environmental sustainability are fully congruent with efforts towards wellness of people and wellness of the planet in general.

Public institutions may increasingly face a moral and, as environmental legislation and plans increase, a legal obligation to reduce and to be accountable for their environmental footprint in compliance with national and international agreements. On average, health care systems are not yet very well prepared for the impact of the eco-crises. [35] In addition, although health care systems use various strategies and tactics to reduce greenhouse gas emissions, implementation and evaluation of the sustainability of initiatives are largely missing. [36] In this rapidly evolving context, the question here is, how HTA could assist these institutions in achieving such 'green' goals.

What is Health Technology Assessment

The definition of HTA (see Box 1) prepared by an international joint working group of leading scientific societies and networks in the HTA community [37] explicitly includes environmental aspects alongside other HTA considerations including clinical effectiveness, harms, safety, and cost-effectiveness.

Box 1. Definition of HTA

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 is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.

Note 1: A health technology is an intervention developed to prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program or system. (Definition from the HTA Glossary)

Note 2: The process is formal, systematic and transparent, and uses state-of-the-art methods to consider the best available evidence.

Note 3: The dimensions of value for a health technology may be assessed by examining the intended and unintended consequences of using a health technology compared to existing alternatives. These dimensions often include clinical effectiveness, safety, costs and economic implications, ethical, social, cultural and legal issues, organisational and environmental aspects, as well as wider implications for the patient, relatives, caregivers, and the population. The overall value may vary depending on the perspective taken, the stakeholders involved, and the decision context.

Note 4: HTA can be applied at different points in the lifecycle of a health technology, i.e., pre-market, during market approval, post-market, through to the disinvestment of a health technology.

Reference: O'Rourke B, Oortwijn W, Schuller T. The new definition of health technology assessment: A milestone in international collaboration. *International Journal of Technology Assessment in Health Care*. 2020;36(3):187-190. doi:10.1017/S0266462320000215

Definition of Environmental Impact Assessment in HTA

Environmental Impact Assessment (EIA) refers to the incorporation of environmental considerations into HTA, where environmental information is collected to help optimize health system decision-making around health technologies based on environmental impact information. [65]

EIA can assess different aspects along the technology lifecycle such as the supply of raw materials, technology production, packaging, delivery and transportation, points where the technology is used in practice, and the eventual disposal or recycling of medical technologies, and how these aspects can have an impact on resource use, greenhouse gas emissions, loss of biodiversity or other environmental pollutants (as outlined by UNEP and ISO14044) [3] [38]

EIA can take an 'extended' life-cycle approach that considers health technologies as relevant for assessment not only once entered into the market, but also in other phases such as technology design, production, distribution, and disposal, as activities in these areas may result in considerable environmental impacts for some technologies [39]. However, of particular importance to HTA is the environmental impact of the technology as it is used in practice. The application of the technology in delivering patient care can result in greenhouse gas emission pollution, resource use and waste production that can be an important component of the EIA.

For clarity, a distinction is to be made between EIA and Environmental Risk Assessment (ERA). ERA is part of the regulatory review process for product marketing authorisation, and as such it resides largely outside the domain of HTA and is therefore not discussed in this paper. However, bearing this is in mind, the ERA data would be useful to as input information to EIA conducted by HTA agencies. ERA typically takes place before marketing authorization using the Persistent, bio-accumulative and toxic substances (PBTs) framework.[40] [41] It is conducted primarily by the health regulatory body, and it is through regulatory review that marketing authorisation is granted (e.g., the CE mark in Europe). The aim is to avoid toxicity or bioaccumulation of pharmaceuticals and other active substances in the environment for humans, animals, and plants during technology production, use, or disposal.

Role of Environmental Impact Assessment in HTA

Health system leaders can use HTA with an EIA focus as a tool to assist in achieving net zero or green policy goals. EIA can quantify the environmental impact of technologies to inform decision making about the coverage, reimbursement, pricing, and/or use of health technologies. It can help to identify and remove comparatively environmentally harmful technologies. For example, in the United Kingdom, the National Health Service recently used EIA to decommission desflurane, an inhaled anaesthetic, as there were less harmful alternatives available and the gas offered no therapeutic advantage. [42, 43].

HTA can also inform decisions on public health policies, which, when focused on protecting the environment, seek synergies and coordination between the different governance frameworks. It is anticipated that the information from an HTA, including the evaluation of environmental impact, will improve preventive care and prepare for current and future health challenges.

As seen in the definition of HTA, EIA is already one of the domains of HTA alongside clinical efficacy, safety and economics, as well as the ELSI domains (Ethical, Legal, and Social Implications of technologies). However, the methods for EIA are still being developed, and inclusion of environmental impacts in HTA will require some adaptation of existing value frameworks and methods.

Decommissioning of Desflurane in England

Since early 2024, desflurane was decommissioned by the National Health Service (NHS) in England. Desflurane is an anaesthetic agent that has a higher potential impact on global warming than alternative agents, such as sevoflurane. Clinicians have led efforts to reduce the use of desflurane in recent years, particularly following the NHS commitment to reach net zero by 2045. In 2022, NHS Scotland announced commitments to end its use of desflurane, and in the same year, the European Union announced its goal to end the use of desflurane from January 2026 (unless use desflurane is specifically required and no other anaesthetic agent can be used on medical grounds).

The decision to decommission desflurane was supported by an evidence review in which NICE undertook studying the clinical and cost benefits of using desflurane for the maintenance of anaesthesia compared with other general anaesthetic agents in the context of neurological procedures and anaesthesia for patients living with obesity (patients with a body mass index above 30 kg/m2).

NICE found that: “the results of the included studies did not favour one type of general anaesthetic over another” and “no evidence was identified to suggest that using desflurane instead of other general anaesthetic agents for maintenance of anaesthesia is associated with improved clinical or cost outcomes in people undergoing neurological procedures, or any patient population with a body mass index of at least 30 kg/m2 having any procedure.”

Following NICE’s review, consultations and workshops were conducted in order for the clinical community to reach consensus on the use of desflurane.

Source: https://www.england.nhs.uk/long-read/guidance-desflurane-decommissioning-and-clinical-use/

Consideration for environmental impact in HTA is not new. In 2013, a survey of 140 healthcare decision makers, including HTA agencies, from 23 countries reported that a third were considering the environmental impact of health technologies during the decision-making process.[44] This survey led by the EVIDEM collaboration (Evidence and Value: Impact on DEcision Making) helped define its ethical multicriteria value framework used in priority setting and HTA, including a broad environmental impact criterion, rooted in the ethical imperative of sustainability.[45] Furthermore, the 2021 EUnetHTA core model for technology assessment included environmental safety.[46]

However, it is to be acknowledged that including EIA in HTA activities, i.e., priority setting, assessment, appraisal and knowledge production and dissemination, is a challenging task since the principles in which to operate, best practices, processes, methods and data are not yet mature. Assessors will need to determine certain things such as: if the whole span of the technology lifecycle will be included in the HTA or only some phases, and determining which environmental indicators or outcomes are the most relevant for the EIA (e.g., greenhouse gas emissions, waste production, pollution, and toxicity loss of biodiversity and natural assets).[3, 47]

Currently, HTA agencies are starting to look at ways to include EIA in HTA and to consider what capacity and resources would be needed to incorporate EIA. EIA may prove to be particularly useful in reassessment and disinvestment decisions. Removing a low value technology from the system may be notoriously difficult[48] [49] but if it is shown to have negative environmental effects through EIA this may assist in overcoming barriers to disinvestment and support a change in technology use.

EIA is an emerging field for HTA and methods and data sources need to mature with a consensus on best practices established. The relevancy or impact of EIA will depend on the role of an HTA agency within its health care system and legal requirements in their respective jurisdiction.

Aims and Methods

This White Paper presents a cross section of INAHTA member experiences with including EIA in HTA. It provides expert perspectives from the producers of HTA on what needs to be in place for embedded EIA to become a reality in HTA.

The topic of this paper, EIA in HTA, was identified in 2022 by the INAHTA Environmental Sustainability Learning Group. With substantial interest among the member agencies expressed (23 individuals from 17 agencies came forward to be involved), the INAHTA Board created a task group composed of the authors of the paper and the advisory group to review the evolving draft of the paper.

The authors met 7 times in 2023-2024 to develop the draft including a 4-hour online writing session. The content was prepared in sections by subgroups of the authors using snowball literature surveys of relevant topics, completed by their own knowledge and expertise working at public HTA agencies and as members of INAHTA. The White Paper was enriched through a snowball survey of all authors and members of the advisory committee in two rounds of written review.

INAHTA is the global network of public HTA agencies that produce HTA to support regional and national governments in making decisions about the use, coverage, or reimbursement of healthcare technologies.[50] INAHTA was formed in 1993 as a way for public HTA agencies to remain connected to one another to exchange knowledge and experiences with HTA. In 2024, INAHTA has grown to 53 members in 34 countries. Part of INAHTA's mission is to share public agency viewpoints on matters of scientific, strategic, and policy importance for HTA.

This group of INAHTA members have produced this White Paper to advance the discussion and application of EIA in HTA, and it is organized into sections. Section one, Outlook 2024, provides a current overview of HTA agency initiatives and activities to incorporate EIA in HTA. Following that, section 2 Challenges and Opportunities lays out some of the main barriers to using EIA in HTA prioritization, assessment, appraisal, knowledge products and dissemination, and ideas on how some of these barriers might be overcome. Section 3 is the discussion, which closes with some observations and inspiration for the future to build opportunities for including EIA in HTA for the betterment of human and planetary health today and for future generations. HTA should aim to serve healthcare decision makers in their efforts to optimize the health system in delivering high quality, cost-effective, yet environmentally sustainable care.

Environmental Impact Assessment in HTA: The 2024 Outlook

This section provides a snapshot of current activities among INAHTA members to explore and progress towards EIA as part of their HTA programs.

HTA agencies exist in very different health system contexts, and some jurisdictions' legal structures can limit the ability of an HTA agency to independently adapt their methods or processes to incorporate EIA.

To gain an understanding of the current practices and approaches to incorporating EIA in HTA, a survey of INAHTA members was conducted in 2022. [51] Twenty-six agencies from 18 countries across Europe, America, Asia, and Oceania responded to the survey. Of the 26 respondents, 71 percent were open to including elements of environmental sustainability within their agency's HTA process, and no agency reported that EIA should never be included.

To respond to wider health system and government calls to address environmental issues as described above, several HTA agencies have explicitly and actively included environmental considerations in their strategic plans, and HTA assessment and appraisal processes. Some examples of these HTA initiatives are outlined in Table 1.

Table 1: Examples of HTA initiatives regarding environmental considerations

Jurisdiction/ Organisation	Initiatives
France HAS	In France, The Haute Autorité de santé (HAS) defined an environmental-health roadmap for its mission of assessment, appraisal, recommendation, and quality in health measurement,[52] [53] which includes: Commit to health - environment initiatives; consider environmental perspectives in HTA; develop and promote recommendations for good practice and public health that consider environmental aspects; and Strengthen quality measurement with regard to health environment issues.
The Netherlands Zorginstituut Nederland	The National Health Care Institute supports the national policy to implement environmentally sustainable healthcare. It hosts a national Register in which quality standards or quality instruments are published only if they contain adequate descriptions of 'good care'. Since 2021 environmental impact, as part of efficiency, is one of the assessment criteria in this policy rule. In 2022 the quality standard on forensic care was published in the Register, containing measures for environmental sustainability. In 2025 an independent expert commission will advise on whether 'environmental sustainability' should be a consideration for reimbursement in the healthcare package. In order to promote 'appropriate care' the Institute plans to re-assess specific expensive reimbursed treatments with environmental impact and with uncertain survival benefits. It further encourages the phasing-out of low value care, promotes data-availability and multidisciplinary cooperation.
UK NICE	The National Institute for Health and Care Excellence (NICE) has made commitments of supporting national net zero carbon emission targets and to operate as an environmentally sustainable organisation, aiming to reduce carbon emissions, minimise waste, reduce water use, make sustainable choices about procurement, support biodiversity and nature recovery, adapt to climate change, and reduce the environmental impacts of digital working. [54] These commitments have been supported by NICE's deliberative public engagement dialogue initiatives (NICE Listens) which provided recommendations regarding environmental considerations.[55] A decision aid on asthma inhalers informing patients about the environmental impact of their medication and alternatives was recently published [56]. An evidence summary of the impact of desflurane was recently published to support a national policy to stop the use of desflurane in England.[43] The HTA program of the National Institute for Health and Care Research (NIHR) ran a funding call, knowing that studies may differentiate carbon emissions between technologies, which could inform guidance; topics of interest: inhalers and anaesthetic gases; effective alternatives to single-use technologies; interventions which may be delivered or enhanced virtually.[57]
Canada CDA-AMC	Canada's Drug Agency (CDA-AMC, formerly CADTH) 2022-2025 Strategic Plan outlines goals to adapt methodology and analyses to include environmental perspectives and assess how technologies impact the environmental footprint of health systems.[58] Ongoing work include: criteria for conducting environmental assessments in HTAs; a deliberative framework to include considerations of resource use, water issues, gas emissions, carbon footprint, transportation, toxicity, waste management, inefficient use of health technologies and suboptimal recycling; reducing the environmental impact of clinical care (i.e.; operating rooms, surgical services, anaesthetics services, dialysis, virtual care, single-use medical supplies).[59] [60] As an example, environmental considerations were included in the recent report on remote monitoring for cardiac conditions.[61]

Jurisdiction/ Organisation	Initiatives
Canada INESSS	In Quebec, the Institut National d'Excellence en Santé et Services Sociaux (INESSS) listed "Integrating environmental considerations into technology and innovation assessments" as a project in their three-year business plan for 2022-2025.[62] The 2024-2028 strategic plan includes the following objective: "Supporting the economic and environmental sustainability of the health and social services network". In its 2021 statement of principles, INESSS [63] outlines sustainability considerations in the application of a multidimensional approach (sociocultural, populational, clinical, organisational and economical dimensions) based on the ethical value framework EVIDEM [45] [64], Recently, environmental considerations were included in a decision-making aid for asthma in children and adults. [65] INESSS has completed several relevant publications including a publication on anaesthetic gas,[66] a scientific horizon scan on environmental considerations,[67] and an optimal use guide on blood cultures.[68] They have also recent publications in French on the topic of COPD,[69] inhaled anaesthetic agents with the social cost of carbon included in economic assessment, [70] and scientific watch bulletins on environmental impacts in health and social sciences. [67]
Colombia IETS	In Colombia, IETS, along with their Ministry of Health, have committed to incorporating environmental impacts assessments into HTA. They are currently examining which stakeholders to engage with in developing their methods and which environmental impacts to measure.[71, 72]
Australia AHTA	In Australia, Adelaide Health Technology Assessment recognises environmental sustainability as an opportunity for study, however, are not currently including it within their HTAs.[73]

The World Health Organization (WHO) acknowledges that HTA agencies are key players in the governance of healthcare systems.[74] HTA portfolios are typically focused on the assessment of drugs, devices, and procedures, and the use of medicines, medical equipment, and related supply chains that are estimated to be responsible for 35 to 62% of the total carbon footprint of healthcare [18, 19] HTA agencies may be increasingly called upon to support the environmental goals and commitments of their jurisdiction such as the healthcare system's strategic plans and environmental or 'green' policies.

The increasing momentum to reduce the environmental footprint of healthcare systems is an opportunity for greater use of EIA in HTA to support more sustainable health systems. However, incorporating EIA in HTA is still in its infancy, and to successfully achieve this goal, several challenges will need to be addressed.

Challenges and Opportunities for EIA in HTA

Including environmental impact assessment in HTA activities is challenging both from a strategic and operational standpoint. The imperative to reduce the environmental footprint of the health system occurs at a time when health systems are facing serious challenges such as a lack of staff, increased demand for complex care, and ever rising costs.

Environmental impact appears as an aspect of three fundamental imperatives of public healthcare: access, affordability, and quality of care. In some cases, the environmental benefit or 'green' attributes of a technology are being used as a basis to argue for a higher price. [75] [76] If 'green' metrics and environmental claims are to accompany many new technologies, HTA agencies may find they are in need of EIA expertise to reliably assess these technologies.

This section describes some of the key challenges and opportunities for including EIA in four different stages of HTA: priority setting; assessment; appraisal; and knowledge products, dissemination, and implementation. It is worth noting that increased use of EIA in HTA also can identify decisions where a technology shows high value in all domains assessed.[55]

Priority Setting

Priority setting in HTA refers to the process of identifying and selecting relevant and appropriate topics for HTA assessment in the context of limited resources. All health systems face resource constraints, and authorities seek to ensure that limited HTA resources are applied to questions that will have an impact on decision making and, where EIA is considered, that the decision has the potential to reduce the environmental footprint of the health system.

HTA agencies have different levels of autonomy to choose (or influence the choice) of topics for HTA. Whether it is the HTA agency or another public body doing the prioritization, the topic selection criteria may include environmental impacts. For example, technologies that hold promise to be more 'green' and 'clean' might be prioritized for HTA where health systems are seeking to avoid environmentally harmful technologies and to add technologies of high global value (e.g., those with positive clinical, economic, population, organisational, societal and environmental impacts).[45] [64] Over time, there may also be opportunity to prioritize and assess technologies that target the health consequences of a changing climate such as increased frequency of heat waves or floods. However, "greenwashing" (where the environmental performance of a product is misrepresented)[77] [78] may be an issue, and while an effective EIA should detect this, assessing this can remain a challenge particularly where access to data depends on manufacturers and developers.

The prioritization process might also support broader 'green' or environmental policy goals by identifying technologies that present a higher environmental risk and are therefore candidates for disinvestment. This requires a lifecycle perspective to recognize the importance of containing or removing environmentally harmful and low value technologies and thus contribute to efforts to reduce the environmental footprint of care delivery and support the achievement of broader 'green' policy goals of the health system.

The methods for topic identification and prioritization utilized in a particular context may need to be reviewed to determine how to include environmental impact considerations. EIA could be incorporated into established systems of priority setting or, alternately, conducted as a separate prioritization step before/after the main topic prioritization process.

Assessment

After HTA topics are prioritized, the assessment is conducted. To the extent that an agency intends to include EIA as a component of an HTA, they may encounter several challenges.

One fundamental question for EIA is whether the whole life cycle of the intervention or only parts of it should be assessed. EIA might be a daunting task if HTA agencies aim at measuring all environmental impacts across the life cycle (holistic EIA). This approach may lead to overlooking key impacts by focusing only on measurements that are available rather than what would be most appropriate for a particular technology. Using the inventory approach (listing types and extent of environmental impacts occurring across the lifecycle of a technology as recommended in ISO 14044 [38]) may be more feasible in situations without detailed quantitative measurement.[30] This approach provides the advantage of facilitating comparisons between technologies such as when the projected frequency of use and life-expectancy of a technology is taken into consideration.[38]

Different evaluative approaches can be used when undertaking an EIA in the HTA context, such as integrated evaluation and parallel evaluation. Integrated evaluation entails the full integration of environmental impact into HTAs. This involves creating or identifying new statistical approaches whereby a single quantitative analysis is conducted that consider clinical, financial, and environmental information. In a parallel evaluation, environmental

impact data is factored into value judgements alongside cost and clinical outcomes. The environmental and cost-effectiveness analyses could be appraised separately by decision-makers. It is often deemed a more flexible approach [76]

Approaches for strengthening the assessment of environmental impacts include:

- Understanding the different types of pollution and the frameworks to categorise, consider and measure them,
- Developing or agreeing on acceptable data for reporting on environmental impacts, and enabling comparability,
- Including and combining relevant environmental data, e.g., carbon emissions, pollution of air, water, soil, water use, waste management, and loss of natural assets,
- Defining requirements to ensure validity of data and, if applicable, standardised data for EIA,
- Agreeing and accessing relevant living sources and data repository such as the HealthcareLCA database [81], and
- Developing modelling approaches for the environmental performance of technologies in routine care.

Another way to think about the issue is to consider how HTA might most effectively be brought to bear on the problem of environmental degradation and climate change. Hensher [79] has duly noted that all health technologies have an environmental footprint, and he proposes that rather than assessing the generic environmental impact of all technologies, scarce HTA resources might be best used to assess only those technologies with unique, "intrinsic" characteristics that could result in environmental harms. The desflurane example provided earlier in the paper is an example of such a product with "intrinsic" characteristics (a very high carbon footprint due to the greenhouse gas used as a propellant).

HTA is a comparative exercise, where technologies are compared with those that are already being used locally as standard of care. Ensuring that EIA is consistent across methods, frameworks, and studies will be helpful to making data and evidence in this area comparable. However, there can be trade-offs to using metrics reported in other environmental policy efforts, such as carbon emissions. While using carbon emissions (more precisely, kilogram carbon emission equivalents per unit, CO_2e) as the cornerstone of EIA to improve the comparability of EIA evidence, it may be more relevant to include other data sources and indicators that see beyond the so-called 'carbon tunnel vision' [80] to better understand and address the root causes of the situation.

From the HTA agency perspective, the following are key challenges to including EIA in the assessment of a technology:

- *Data* – There is a difficulty to access environmental impact data with uncertainty around knowing which data to collect and use for EIA. When relevant data is available there is no best practice guidance on how it is to be appraised and interpreted without erring.
- *Methods* – There is lack of guidance/consensus on the most appropriate method for EIA. For example, whether inventory approaches (description of types of pollution across the technology life cycle) should be used or a method to measure the proximal environmental impact of each type of pollutants be preferred.
- *Methodology* – There is a need to define a methodology regarding relevant data generation, collection, interpretation and synthesis in a format suitable for decision makers with limited or no environmental expertise.

- *Assessment Framework* -- There is no existing guidance or consensus on which environmental framework to use to categorize the data and which pollution types to cover in EIA in HTA. There are several possible frameworks that are relevant to the EIA domain, with some examples as follows: frameworks for the *three types of pollution* (e.g. UNEP [2];ISO -14044, [38]; ReCiPe [82], LCAdatabase [83], Organization for Economic Cooperation and Development OECD)[84]); carbon footprint only (e.g. the WHO [85]), chemical pollution only (e.g., European Medicines Agency (EMA) and Persistent, Bioaccumulative and Toxic substances (PBT) framework [40, 41]); loss of diversity and natural assets only (e.g., Protocol of Cartagena[86]).
- *Capacity and expertise* -- To conduct robust and efficient EIA, HTA agencies will require access to relevant expertise and sufficient capacity to conduct EIA. Currently, HTA agencies are not generally staffed to conduct EIA, and so the question for the agency will be how to access and develop this competency. One approach might be to expand internal HTA agency staffing mix to enable EIA, whether through the addition of new staff who are specifically trained and focus entirely on EIA; or, alternatively, to develop EIA competency amongst existing staff, perhaps through skill building workshops and study of best practice examples. A second approach would be for the agency to subcontract with external experts rather than building internal capacity. In any case, HTA agencies will require additional funding and resource allocation to be able to include EIA in HTA.

Time and resources are required to respond to these challenges and take action on opportunities. In the short term, small steps may provide a way to advance toward conducting EIA in HTA by doing what is possible at this moment, such as looking at carbon footprint estimations using a lifecycle approach [87], [72] or taking a less data-driven and a more common-sense approach by using qualitative environmental information rather than solely seeking quantitative data, which may not be available. [38]

Appraisal

After an HTA report is complete, an appraisal is conducted by the decision maker, which is often a deliberative committee, to discuss public adoption of the intervention, based on the evidence provided in the HTA report, alongside expert knowledge and the values underpinning the decision-making process. The objective of the appraisal is to answer the HTA question in the current decision context, ideally providing an accountable and reasonable answer.

Determining the best process to integrate EIA into existing value and deliberation frameworks is challenging and would require clarity about:

- how EIA is to be included in the appraisal process (as a separate element or within an existing dimension/ domain/ model);
- how EIA is deliberated on and how the complex trade-offs between domains or within existing domains will be made and on the basis of which tools (e.g. GRADE, MCDA MCDM (multiple-criteria decision-making) and MCDA (multiple-criteria decision analysis), A4R); and,
- whether the process allows for meaningful comparison across interventions and current standard of care to ensure well-founded recommendations.

As existing value frameworks are adapted and revised to incorporate EIA, transparency is critical. Understanding who was involved in the adaptation or revision of the framework and their expertise and experience will be critical to the acceptability of any revised framework to HTA agencies. An important consideration in many appraisal value frameworks is equity, which is related to the environmental crisis as it affects population groups differently, with the most vulnerable populations at greatest risk for the ill-effects of climate change.

EIA can contribute to decisions about technology coverage and reimbursement, the content of basic health care packages, quality of care standard and price. Embedding EIA into the deliberation could enlighten coverage decisions and contribute to the global efforts towards sustainability and resilience of healthcare systems.

The appraisal process typically includes consideration of clinical, economic, organisational, population, and sociocultural aspects or criteria. There is currently no best practice or consensus on how to include EIA results alongside safety, clinical and (cost-) effectiveness, patient or clinician preferences, or other HTA evidence. Some have proposed that it should be on the same footing as economic considerations to make sure it is not overlooked by decision-makers[88] but this has not yet been applied or tested in practice. It has been argued that in allocation decisions, negative dynamic effects on health should be taken into account, and this would support more environmentally sustainable choices. [89]

Regardless of the appraisal process followed, the decision maker may require training on how to include EIA results in decision making as they will likely need to defend the acceptability or provide some justification for the decision and any recommendations given. They may be required to comment on if EIA played a major role in the decision, and if so, to describe what evidence was brought to bear on the decision and what trade-offs were encountered.

The WHO's recommendations for fair universal health coverage emphasize that countries are ethically accountable to their populations and should optimize the legitimacy of coverage decisions. HTA agencies are key players in health system governance and the pursuit of this legitimacy. However, HTA committees have been facing growing ethical tensions between satisfying individual needs, serving the population equitably and developing sustainable healthcare systems.[90] The deep transformation needed and the resolution of ethical dilemmas faced by decision makers at all levels (developers, clinicians, policymakers) will require involvement of all stakeholders, including new perspectives, such as those concerned with the environmental crisis. [91] In the same way, ethicists and ethical consideration in the HTA process have been introduced by agencies over the years, including having an ethicist sitting on the deliberative committees.[92] The HTA community should take the lead on involving environmentalists in their processes to facilitate the use of the EIA in the deliberation.

Knowledge Products, Dissemination & Implementation

The creation of HTA reports and other knowledge products for decision makers requires skills in effective knowledge translation. The choices an agency makes in how to structure these products can have an effect on how the information is absorbed by the decision maker. Whether the EIA was conducted as a separate analysis, or an EIA component incorporated into each domain, and how this is reported can make the difference if the EIA information is seen and understood by the decision maker. In some assessments, the environmental domain may not be a significant factor, but for those technologies with a greater environmental impact, optimizing how this information is included along with the other HTA evidence domains (safety, clinical/cost effectiveness, organizational, etc.) will be important.

HTA agencies will want to understand how the inclusion of EIA in their HTA reports impacts decision making and/or on the environmental footprint and sustainability of the health system. There are currently no standard impact evaluation frameworks or indicators that could be used to measure the effect of the EIA information, and it is one area of opportunity to be developed as EIA evolves further into a more central HTA domain.

Successful implementation of decisions informed by HTA and EIA often require some degree of action or change on the part of people working in the health system. Results of an EIA (as part of the HTA) could be better communicated to relevant parties who are key to taking action following the decision to achieve the intended impact in the health system. For different audiences it will be important to present the HTA information in formats that are accessible, and implementable in their work settings leading to impactful change.

Once a technology has been accepted for reimbursement, HTA might also provide some information to health system managers in the form of (modelling) data about the environmental impact during the projected use of a technology after it is introduced into health care.

When considering environmental impacts, the lifecycle view can be helpful, where it becomes obvious that the technology lifecycle does not end at the coverage decision. This could lead to connecting with other stakeholders in the HTA ecosystem, such as patients (e.g., for producing decision-aids for patients when there are treatment alternatives) and collaborating with medical/health professional societies for clinical practice guideline development.

Discussion and Looking Ahead

This White Paper has provided some discussion of how to begin thinking about EIA in HTA, which is an urgent and relevant issue for healthcare around the world. It has provided the broader policy context at the national, regional, and international levels to see where 'green' policies are starting to appear in the health sector and beyond. The paper gives an outlook on activities underway by HTA agencies to bring EIA into their work and identifies some of the challenges and opportunities agencies are encountering as they consider how to incorporate EIA into HTA.

As jurisdictions around the globe respond to the importance and urgency of the climate crisis by introducing net zero and other 'green' policies, EIA in HTA will be a valuable tool to support decision makers in achieving these policy goals for the health system. It is important to note that the freedom of an HTA agency to integrate EIA in their work will largely be a function of the agency's governance structure and legal framework in their local jurisdiction. Whether an agency is advancing towards including EIA (or not) does not imply a judgment of performance.

Engaging with and learning from other stakeholders in the HTA community will help advance the shared understanding and readiness for EIA, as the community as a whole respond to this urgent and important issue. For EIA to move more quickly and become a reality as part of HTA and health system decision making, the first need is to raise awareness about the importance of EIA.

Raising Awareness

As has been described in this White Paper, EIA is a young domain but one that is growing. Healthcare systems and HTA agencies are responding to 'green' policies and targets where these are starting to appear in their jurisdictions. EIA in HTA is a key tool to support optimal decision making that contributes to reducing the environmental footprint.

Despite the benefits of EIA in HTA, not all decision makers or potential users of the HTA information are aware of what these are. HTA agencies could more actively promote their work (and impact) within their health systems, so decision makers are more aware of HTA and how EIA can assist when they face questions with an environmental element. Indeed, HTA agencies may increasingly find 'green' technologies being prioritized for assessment, or explicit requests to include environmental impact assessment in their HTA reports. Raising awareness can motivate the HTA community to prepare for EIA as it is likely to become more common in the future.

The HTA community could promote more debate and research on the optimal methods, data, and strategies to overcome other challenges to EIA (some that are identified in this paper) so EIA grows to become an effective part of HTA and decision making.

Working Together

Healthcare professionals, health regulatory bodies, and industry are important stakeholders to consider reaching out to for better and quicker advancement of EIA in HTA. The need for close working and partnership with all stakeholders has never been more critical.

Healthcare professionals have an important role to play in the resolution of the environmental crisis through their practice of sustainable and greener healthcare. In 2023, the WHO and 40 million health professionals called on governments to meet their commitments and demand bold health and climate action.[93] Sustainability is being incorporated into medical training, as exemplified by the UK General Medical Council (GMC) which requires that newly qualified doctors are able to apply the principles, methods, and knowledge of sustainable healthcare to clinical practice.[94]

In addition, healthcare professionals are increasingly confronted with climate-related diseases and health complaints, heat-related complaints, and exposure to environmental toxicity (e.g. radiation, chemicals) and new, or re-emerging, infectious diseases). Leveraging the impact of their advocacy and actions, HTA agencies could solicit through their collaboration with healthcare professionals their clinical expertise, their experience in integrating EIA in their practice and their approaches in tackling the impact of climate and pollution crisis on patient health.

Collaboration with clinicians and other health professionals is an important part of the successful implementation of EIA (and HTA results) in the health system. It is important for HTA agencies and decision makers to understand the needs and perspectives of the practitioners and providers who will be required to change their practice, and to check the acceptability of the HTA results with them.

Health technology industry is also a key leader in achieving environmental goals of society. Industry leads the development of products and makes decisions early in the technology lifecycle about which products are chosen to be brought to market. Industry leaders are encouraged to seek opportunities to prioritize technologies with less environmental waste or harms, or with 'green' aspects, such as the potential for reuse or recycling.

Regulatory bodies also play an important role. Health technologies pass through the regulatory review to enter the market, which, for medical devices in Europe, for example, means the assignment of the CE mark (Conformité Européenne, or European Conformity marking) that "indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements. It is required for products manufactured anywhere in the world that are then marketed in the EU". [95] There is no single regulatory body responsible for CE marking, and EIA is not currently required for this review. However, sustainability reporting standards have been enacted within the EU, but they will come into effect not before 2026 and affect only companies with more than 1,000 employees.[96] [97]

In the regulatory review (which will vary across jurisdictions), technology manufacturers may be required to report environmental data, or to follow environmental regulations or good manufacturing principles, etc. There may be opportunities to learn from the regulatory perspective, as well as industry, about how EIA might be efficiently incorporated into HTA based on their experiences of the inclusion of environmental aspects into the regulatory process, for example, to understand what indicators, data sources, or research methods that are used in the regulatory review might be relevant for HTA. Exploration of possible greater alignment between the work of the health regulator and that of HTA agencies has been a longstanding topic in the HTA community [98, 99][and perhaps the environmental domain is one area where it could be fruitful and important to encourage greater sharing and transparency.

There may be opportunities to collaborate and learn from other sectors beyond health. For example, understanding initiatives within the veterinary sciences sector to assess and reduce environmental impacts such as pharmacological pollution and antimicrobial resistance could inform the HTA community in the use of some of the same indicators or provide leverage for their work in relevant areas. The transdisciplinary paradigm of planetary health offers a possible framework for such collaboration. Some propose the time is right for substituting 'population health' with 'planetary health' (the health of both humans and the natural systems) among the aims health system should pursue.[100] Piggott et al. believe that taking into account '(…) planetary health in health technology assessment (HTA) reports and guidelines will provide essential support for a more comprehensive evaluation of the potential impacts of health interventions on both human health and the environment.[101]

Achieving environmental targets to promote planetary health is larger than any one organization can do. Some HTA agencies are starting to develop readiness and capacity for conducting EIA, but this will be only one element of the action needed. Finding synergies among organizations and stakeholders in the HTA community that are working on advancing EIA will bring greater efficiency and more opportunities for learning and action in this area of shared importance One example is the Environmental Sustainability Learning Group within INAHTA which, since 2022, has been bringing INAHTA members together on the subject of EIA to build knowledge in this rapidly evolving domain. This White Paper is another example of global collaboration and it demonstrates INAHTA's willingness to respond and to the urgent and important need to leverage the toolbox of HTA to advance environmental sustainability.

Conclusions

Part of greater use of EIA in HTA is to achieve not only local policy objectives, but also to connect to the broader societal and global efforts in the fight against climate change. Countries have a responsibility towards each other and to future generations as set forth by the approach One health, One Planet [102].

Health and environmental solidarity could extend to multigenerational populations and even non-human populations. [103] [104] Envisioning healthcare systems in the long term opens more and better opportunities for sustainable innovation and avoiding pitfalls of 'short-terminism'.[105]

With the support of HTA, health systems can adjust their selection/options of reimbursed health services over time to include more interventions that have reduced or no anticipated negative environmental impact. EIA can also contribute to managing the exponentially increasing use of technologies and the associated pollution and environmental impacts. [18, 19, 106] [107] However, it is important to emphasize that each country and HTA agency will respond as appropriate to them, as they are subject to their local legal and jurisdictional requirements, and there may be different challenges between lower income and higher income countries. A focus to develop some standardized frameworks and methods that facilitate the integration of EIA into HTA processes could help guide future efforts in this area.

Where HTA agencies have the independence to set their remit and methods, they could take a greater role (and they are) in designing processes and tools to include EIA in HTA. All stakeholders in the HTA community are encouraged to do what they can to advance the science and practice of EIA. As this domain matures, it will become a tool to contribute to the greater good of environmental stability and sustainability as the foundation for reliable access to affordable, high-quality healthcare for this and future generations.

Forward strategies for the HTA community

- Raising awareness among stakeholders about the significance of EIA may help to foster a culture that values environmental considerations in health decision-making.
- Future efforts could focus on developing frameworks that facilitate the integration of Environmental Impact Assessment (EIA) into HTA processes.
- Exploring practices and methodologies from other sectors can provide valuable insights for HTA in assessing and mitigating environmental impacts.
- Collaborative efforts among HTA agencies, healthcare professionals, regulatory bodies, and industry to share best practices and enhance the understanding of EIA is important.

Appendix. Examples of healthcare systems engagements in reducing their environmental footprint

This historical opportunity for a profound transformation comes at a time when healthcare systems are more and more required to abide with international commitments and legal frameworks to reduce their environmental footprints. In 2021, 50 countries had committed to transitioning to climate-resilient and/or low-carbon, healthcare systems while this figure was 60 in 2022, with 20 committing on net-zero carbon health systems.[14, 108] However, a 2022 survey of 73 countries indicated that only 13 (18%) had a national reference/plan to achieve healthcare decarbonization, namely Australia, Colombia, Fiji, Netherlands, New Zealand, Norway, Pakistan, Singapore, Spain, Sweden, UK, USA and Taiwan [109], highlighting a gap between country level environmental commitments and healthcare systems environmental action plans. Although some regulations have been set forth for several decades (e.g., the 2006, European Medicines Agency Guide to Environmental Risk Assessment of Medicinal Products for Human Use for manufacturers [40]), the international pressure on jurisdictions and organisations is becoming stronger and new plans and policies are being developed to significantly reduce healthcare environmental impacts (see examples in Table A).

Table A: Examples of plans, policies and legislations on environmental sustainability in the healthcare sector

Jurisdiction/ Organisation	Plan, policy or legislation
Europe	The European green deal aims at emerging from the pandemic by building on growth decoupled from resource use, including in healthcare [110]
Austria	Austria's strategy for moving towards a climate-neutral health system is currently being finalised,[111] and is also developing a health national adaptation plan to strengthen climate resilience.[112]
England	The National Health System in England was the first health system to embed net-zero in their legislation, committing to net zero by 2040 for carbon emission under its direct control, thus aiming at meeting the Health and Care Act [18] [113]
Ireland	Ireland has several initiatives and is one of the frontrunners in moving towards net zero through its Health Service Executive Climate Action Strategy, as well as strengthening climate resilience HSE [114, 115]
The Netherlands	The Dutch Ministry of Health committed to irreversible transition towards healthcare with minimal impact on climate, environment and living conditions by 2050 [116] while many healthcare stakeholders endorse this policy and cooperate for structural system sustainability. [117]
Scotland	The National Health System in Scotland have committed to publishing annual reports outlining their progress towards environmental sustainability and healthcare targets.[118]
Sweden	The Swedish government, through the Dental and Pharmaceutical Benefits Agency, the Swedish medical products agency and Swedish eHealth Agency are working om a voluntary eco-classification as a way of encouraging more environmentally friendly production of pharmaceuticals with less emission of active substances [39] [119]
Canada	Health Canada's Sustainable Development Vision for 2023-2027 aims at advancing work on multiple fronts where environmental health, social and economic sustainability and human health intersect; the plan includes working on 7 of the 17 Sustainable goals of the United Nations.[6] [7, 8]
California/USA	The Managed Care Consortium in California, Kaiser Permanente, launched an environmental impact initiative using a sustainability scorecard; the scorecard evaluates the sustainability of each medical item purchased, encouraging suppliers to provide environmentally friendly products.[120]
Peru	In Peru, there is a firm commitment to competitive and sustainable growth, to face extreme climate events and generate conditions for clean and sustainable industries:

	climate change is incorporated in into national development planning, articulated with the fulfilment of the Sustainable Development Goals, backed by the Law on Climate Change and Regulations, which offer the State the possibility of increasing the efficiency of public spending and promoting low-carbon development with the active participation of all stakeholders: public and private sectors, organized civil society, academia, indigenous peoples, among others (personal communication).[121]
Australia	Australia published its National Strategy for Health and Climate, targeting resilience, collaboration, decarbonization, and a blanket approach of *'health in all policies'*. [122]
Asia	In the Asian region, environmental issues are mainly being addressed at the cabinet level. Both Japan and Taiwan are putting greater emphasis on environmental considerations at the cabinet level; environmental considerations are relatively new at the Ministry of Health and Welfare level in Japan, Taiwan, and South Korea.[123] [124, 125]
Make it mandatory program	Some players of the healthcare industry committed to the international Make it Mandatory program, requiring disclosure of risks, impacts and dependencies on nature of their activities.[126, 127]
Sustainable Markets Initiative Health Systems Task force	Major pharmaceutical companies are collaborating with the WHO and other leading organizations in the Sustainable Markets Initiatives' Health systems Task force, through which, for the first time, companies across the global healthcare sector have come together to pioneer initiatives in China and India to scale renewable power across their supply chains.[128]
Alliance for Transformative Action on Climate and Health (ATACH)	Following COP 26, the Alliance for Transformative Action on Climate and Health (ATACH) was launched and counts on the commitment of numerous UN member states.[129]

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