HEALTH **I**NNOVATION NE**X**T GENERATION **P**AYMENT & PR**I**CING MODELS **(HI-PRIX)**:

Balancing Sustainability of Innovation with Sustainability of Health Care

HI-PRIX

M5: Literature review on the approaches and consequences of including environmental impacts in pricing and reimbursement based on economic evaluations

WP3: Widening the scope of economic evaluations for pricing and reimbursement decisions: the role of indirect medical cost and environmental impact

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Abbreviations

AIHTA: Austrian Institute for Health Technology Assessment

BIA: budget impact analysis

CADTH: Canada's Drug and Health Technology Agency

CO_2: carbon dioxide

CBA: cost benefit analysis

CEA: cost effectiveness analysis

CEASS: comprehensive environmental assessment

CUA: cost utility analysis

EEIOA: environmental extended input output analysis

EU: European Union

HTA: health technology assessment

HRQOL: health-related quality of life

ICER: incremental cost-effectiveness ratio

GHG: greenhouse gas

LCA: life cycle analysis

MCDA: multi-criteria decision analysis

NICE: National Institute on Health and Care Excellence

PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses-Extension for Scoping Reviews

UK: United Kingdom

1. Introduction

1.1 Milestone in the context of HI-PRIX

This **report has been produced as part of the activities foreseen under WP3** "Widening the scope of economic evaluations for pricing and reimbursement decisions: the role of indirect medical and environmental costs", and **specifically under Task 3.2** "Literature review and theoretical analysis on the approaches and consequences of including environmental impact in pricing and reimbursement based on economic evaluations".

There are a number of ways in which the evidence base for pricing and reimbursement decision can be widened. Broadening the dimensions of value in healthcare by incorporating further value elements in established cost-effectiveness analysis (CEA) is a topic of discussion. For instance, in 2018 an ISPOR Special Task Force was appointed to synthetize all the elements of value (the so called "value flower"), and to identify dimensions that may be overlooked or underappreciated in traditional value assessments (Neumann et al., 2022). As part of this work package, an important factor being considered in the area of broadening of the evidence base are **environmental costs**, namely the impacts for the environment resulting from the development, production, distribution and disposal of health care products. This is the focus of the current report.

1.2 Objectives

The **objective of this report** is to illustrate the evidence emerged from conducting a scoping review of the literature that was aimed at exploring the metrics, methods, and approaches that have been proposed or that are currently used to measure the environmental impact of health technologies, and understanding how to integrate such metrics in economic evaluations and HTA.

The **structure of this report** is therefore the following. First, some context information on the rationale for and the need of introducing this pillar within HTA will be provided. Second, the methodology adopted in this work will be thoroughly described. Third, the results, namely the main insights emerging from the literature review, will be illustrated.

2 Background information

2.1 Context

The healthcare sector significantly contributes to climate change, accounting for 4.4% of global carbon dioxide (CO2) emissions, the largest among service sectors. Additionally, it generates a substantial amount of waste, including plastics, disposables, and hazardous materials, which can contaminate air, soil, and water (Pichler et al., 2019).

Recognizing the need to address the environmental impact of healthcare, many countries have committed to reducing greenhouse gas emissions from their healthcare systems, and around 50 governments pledged to develop climate-resilient, low-carbon healthcare systems. For instance, the UK National Health Service (NHS) has set targets to achieve net zero carbon emissions by 2040 for direct and indirect emissions (Scope 1 and 2) and by 2045 for Scope 3 emissions from users and suppliers ("Greener NHS," 2020). The European Union (EU) has also proposed enhancing the environmental sustainability of medicines as part of its revised pharmaceutical legislation (European Commission, 2023). Various EU member states, the UK, and Norway have introduced measures or provided guidance to promote a circular economy, and green public procurement is seen as a key strategy to achieve these goals, particularly in the healthcare sector, which accounts for about 9% of government spending across OECD countries.

Discussions have also begun on assessing the environmental impact of specific health technologies and services, with efforts to integrate these considerations into health economic evaluations and Health Technology Assessment (HTA) (Greenwood Dufour et al., 2022; Hensher, 2020; Marsh et al., 2016b; McAlister et al., 2022; Pinho-Gomes et al., 2022; Polisena et al., 2018; Toolan et al., 2023). HTA is a multidisciplinary process used to determine the value of health technologies across their lifecycle, supporting decision-making for equitable, efficient, and high-quality health systems (O'Rourke et al., 2020). Economic evaluations in HTA typically consider both costs and benefits of health technologies, including methods like cost-effectiveness analysis (CEA), cost-utility analysis (CUA), and cost-benefit analysis (CBA) (Drummond, 2015). Given the environmental impact of healthcare, there is growing support for including environmental considerations as an additional criterion in HTA, enabling more comprehensive, evidence-based decision-making regarding the allocation of resources and policy decisions on healthcare access, delivery, and pricing.

HTA agencies globally are beginning to prioritize environmental impacts. For instance, Canada's Drug and Health Technology Agency (CADTH) has included environmental impact in its HTA appraisals and is developing guidelines for conducting these assessments ("CADTH Health Technology Expert Review Panel Deliberative Framework," n.d.). Similarly, the UK's National

Institute for Health and Care Excellence (NICE) is creating a framework to incorporate environmental data into its decision-making processes as part of its 2021-2026 strategy ("NICE strategy 2021 - 2026: dynamic, collaborative, excellent," 2021).

In academia, health and environmental economists are exploring ways to include the environmental impact of health technologies in economic evaluations. Proposals have been made to integrate environmental outcomes into health-related quality of life (HRQOL) measures or to consider them as additional costs (Marsh et al., 2016b). In this context, researchers are continuing to analyze and recommend methods for incorporating these impacts into HTAs.

2.2 Objectives

Currently, there are no standardized methods for incorporating the various environmental impacts of health technologies into economic evaluations and HTA from a comprehensive, system-wide perspective that balances priorities across different levels of the value chain (such as policymakers, manufacturers, healthcare providers, patients, caregivers, and future generations). This work seeks to provide a thorough analysis of the methods, approaches, and metrics identified in the literature and by HTA agencies for assessing the environmental impact of health technologies. It examines the current feasibility and potential implications of including these impacts in economic evaluations and HTA, and identifies the requirements for progressing responsibly in this direction.

2.3 Definitions

Figure 1 reports some introductory definitions.

Figure 1. Introductory definitions

Greenhouse gases (GHG): GHGs are gases that can absorb and emit net heat energy, thus contributing to the warming of the surface of the planet caused by a reduced capacity to cool the warmth received from the sun, also known as the greenhouse effect. The most common GHGs are water vapor, followed by carbon dioxide (CO_2), methane, nitrous oxide and ozone, along with fluorinated gases (chlorofluorocarbons, hydrofluorocarbons, perfluorocarbons).

Carbon footprint: The total amount of GHG, primarily CO_2, emitted directly or indirectly in the delivery of health care services over a specific period. Usually, it is expressed in equivalent tons of CO_2.

Life Cycle Analysis (LCA): Evaluation of the environmental impact of a health technology across all the stages of its life cycle, from cradle to grave, i.e., development, production, use, and disposal. When only specific stages or aspects of the technology's life cycle are evaluated, it is referred to as partial LCA. Two sub-types of LCA proposed and used for assessing environmental impact are the environmentally extended input-output analysis, and the process-based life cycle assessment.

Environmentally extended input-output analysis (EEIOA): Estimation of the environmental impacts (like the carbon footprint) associated with each sector's output using input-output tables, namely tables published by the OECD that quantify in monetary terms, by country and year, the supply chain for all sectors involved in an industry.

Process-based life cycle assessment (P-LCA): Quantification of the environmental impacts (like the carbon footprint) through a series of interlinked processes (characterized by the physical flows of materials and energy inputs and associated environmental emissions) along the life cycle stages of a product or activity.

3. Methodology

A scoping review of both scientific and grey literature was conducted following established methodological guidelines and the PRISMA-ScR guidelines . Searches were performed in April 2023 across three electronic databases: PubMed, Web of Science, and Scopus. The search covered titles and abstracts from 2013 to 2023, with no language restrictions. An iterative approach was used to determine the keywords for the search strategy, focusing on two main concepts: "Environmental" and "Health Technology Assessment or economic evaluation" (see Figure 2). The search was broadened beyond health technologies to include related fields, such as bioengineering, to gather additional insights.

Figure 2. Search strategy

Main search concepts, to be combined using "AND":

- Environmental
- Health Technology Assessment, economic evaluation

Search concepts synonyms, to be combined using "OR":

Environmental, Carbon emission, Carbon footprint, Greenhouse gas, Water consumption, Waste, Pollution, Life Cycle Cost*, Life Cycle Assessment, Sustainability

Health Technology Assessment, HTA, Economic evaluation, Cost-effectiveness, Budget impact, Budget-Impact, Pricing decision, Price negotiation, Reimbursement, Procurement [*or any other correlated term such as: Purchase, Tender(ing)*]

Studies were eligible for inclusion if they described a conceptual framework, methodology, or approach used or proposed to integrate the environmental impacts of health technologies into an HTA or economic evaluation, with the goal of supporting various stakeholders in making access or allocation decisions. This was regardless of the specific environmental impacts or the type of technology assessed. No studies were excluded based on their design or language, and relevant literature reviews, editorials, and commentaries were also included. HTA dossiers that considered environmental factors were included as well.

For each selected study, the following information was extracted:

i) Objective, design, and scope of the study;

ii) Methods used to measure the environmental impact of health technologies, including the environmental dimensions considered (e.g., CO_2 emissions, water use, waste generation), the approach employed (e.g., full or partial Life Cycle Assessment (LCA)), and the type of impact (direct vs. indirect);

iii) Methods used to incorporate environmental impacts into economic evaluations and HTA, including the level of integration (e.g., as supplementary information, as part of a comprehensive evaluation) or the specific methodology used (e.g., enhanced Cost-Utility Analysis (CUA));

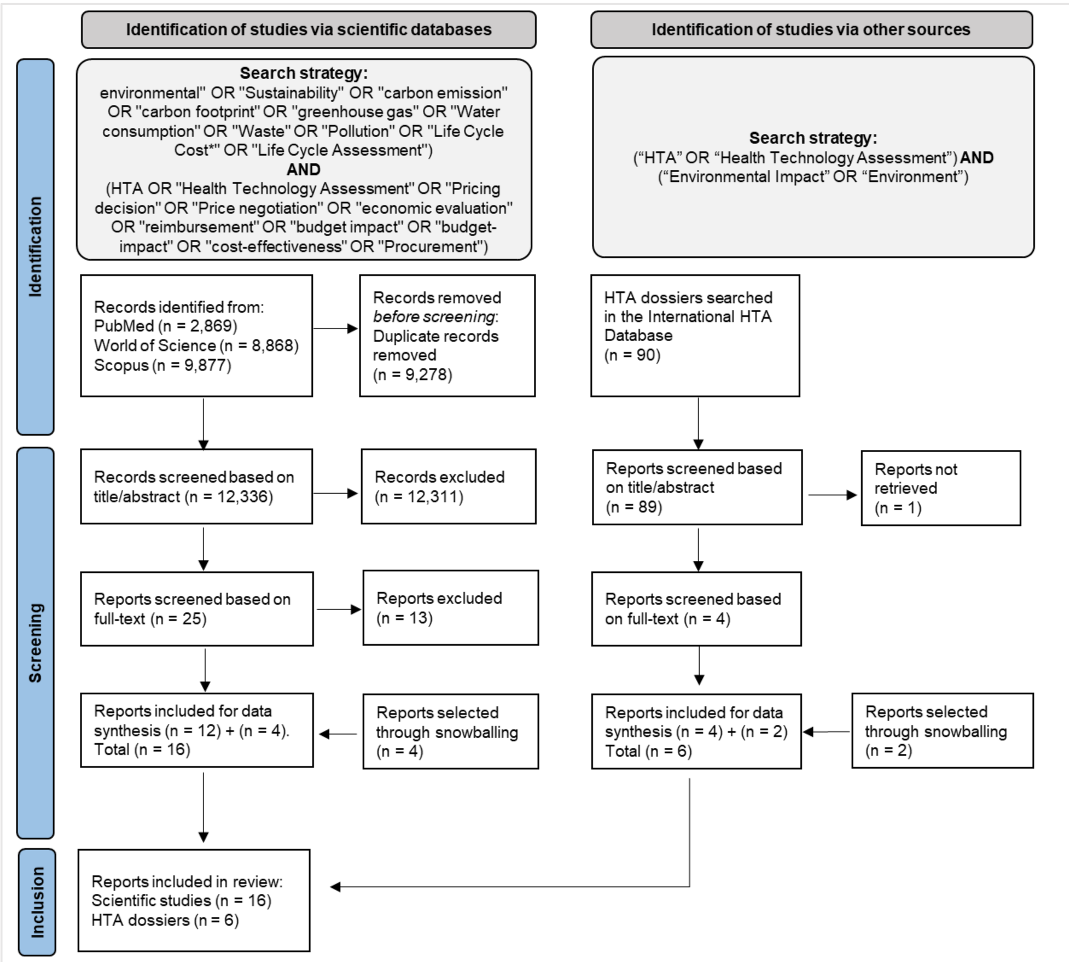
iv) Barriers and facilitators associated with each methodology (used to inform the Discussion section).

4. Results

4.1 Overview of results

Overall, **16 scientific publications** (De Preux and Rizmie, 2018; Desterbecq and Tubeuf, 2023; Firth et al., 2023; Greenwood Dufour et al., 2022; Guirado-Fuentes et al., 2023; Hensher, 2020; Marsh et al., 2016b, 2016a; McAlister et al., 2022; Ortsäter et al., 2020, 2019; Pekarsky, 2020; Pinho-Gomes et al., 2022; Polisena et al., 2018; Toolan et al., 2023; Walpole et al., 2023) and **6 HTA reports** (*Community water fluoridation programs: a health technology assessment - review of dental caries and other health outcomes*, 2020; Giske et al., 2023; Khangura et al., 2018; NICE, 2022, 2014; Riegelnegg et al., 2023) were selected for data synthesis, as indicated in Figure 3.

Figure 3. PRISMA Diagram



4.2 Overview of the studies

Table 1 and Table 2 report the characteristics of the studies and the HTA dossiers selected for data synthesis.

Table 1. Characteristics of selected scientific studies

Study	Title	Country	Year	Study type	Media outlet
Marsh et al.	Expanding Health Technology Assessments to Include Effects on the Environment.	UK	2016	Methodology	VIH
Marsh et al.	Incorporating environmental outcomes into a health economic model.	UK	2016	Methodology	IJTAHC
de Preux et al.	Beyond financial efficiency to support environmental sustainability in economic evaluations.	UK	2018	CEA	Future Healthcare Journal
Polisena et al.	Environmental impact assessment of a health technology.	Canada	2018	Literature review	IJTAHC
Ortsäter et al.	A budget impact model to estimate the environmental impact of adopting RESPIMAT® Re-usable in the Nordics and Benelux.	Sweden	2019	BIA	Advances in Therapy
Hensher et al.	Incorporating environmental impacts into the economic evaluation of healthcare systems: Perspectives from ecological economics.	UK	2020	Perspective, review, case study	Resources, Conservation and Recycling
Ortsäter et al.	Incorporating the environmental impact into a budget impact analysis: The example of adopting RESPIMAT® re-usable inhaler.	Sweden	2020	BIA	AHEHP
Pekarsky et al.	The inclusion of comparative environmental impact in Health Technology Assessment: Practical barriers and unintended consequences.	Australia	2020	Editorial	AHEHP
Greenwood Dufour et al.	How we might further integrate considerations of environmental impact when assessing the value of health technologies.	Canada	2022	Opinion	IJERPH
McAlister et al.	Incorporating carbon into healthcare: adding carbon emissions to health technology assessments.	Australia	2022	Personal view	The Lancet Planetary Health
Pinho-Gomes et al.	Incorporating environmental and sustainability considerations into health technology assessment and clinical and public health guidelines: a scoping review.	UK	2022	Commentary	IJTAHC
Toolan et al.	Environmental impact assessment in health technology assessment: principles, approaches, and challenges.	UK	2023	Perspective	IJTAHC
Guirado-Fuentes et al.	Main challenges of incorporating environmental impacts in the economic evaluation of Health Technology Assessment: A scoping review.	Spain	2023	Literature review	IJERPH
Desterbecq et al.	Inclusion of environmental spillovers in applied economic evaluations of healthcare products.	Belgium	2023	Literature review	VIH
Walpole et al.	How can environmental impacts be incorporated in health technology assessment, and how impactful would this be?	UK	2023	Editorial	ERPOR
Firth et al.	Moving towards a more environmentally sustainable pharmaceutical industry: recommendations for industry and the transition to green HTA.	UK	2023	Editorial	ERPOR

Table 2 Characteristics of selected HTA dossiers

HTA Agency	Country	Year	HTA dossier title	Technology assessed
NICE	UK	2014	End-tidal control software for use with Aisys closed circuit anesthesia systems for automated gas control during general anesthesia	Anesthetic
CADTH	Canada	2018	Composite resin versus amalgam for dental restorations: a health technology assessment	Medical device (dental resins vs. amalgams)
CADTH	Canada	2020	Community water fluoridation programs: a health technology assessment - review of dental caries and other health outcomes	Public health intervention (community water fluoridation)
NICE	UK	2022	Sedaconda ACD-S for sedation with volatile anaesthetics in intensive care	Medical device (compared with intravenous propofol sedation)
AIHTA	Austria	2023	Robot-assisted surgery in thoracic and visceral indications – Update 2023	Medical device (robotic assisted surgery)
NIPH	Norway	2023	Triclosan coated sutures for prevention of surgical site infection: a health technology assessment	Medical device (sutures)

Abbreviations: CADTH= Canada's Drug and Health Technology Agency; AIHTA=Austrian Institute for Health Technology Assessment; NICE=National Institute for Health and Care Excellence; NIPH= Norwegian Institute of Public Health

4.3 Assessment of the environmental impacts of health technologies

Evaluating the environmental impact of health technologies first involves identifying the relevant environmental dimensions. These dimensions are then evaluated using suitable measurement methods (Table 3, Table 4).

Table 3. Identification, assessment and measurement of the environmental impact (when applicable) in

selected HTA dossiers

HTA dossiers	Environmental dimensions	Environmental assessment methods	Assessment outcome
NICE	CO_2	Literature review of 5 studies	144 kg vs. 156 kg of CO2 usage in the End-tidal control vs. manual phase. Consumption savings of fresh gases (oxygen, air, nitrous oxide) from the medical gas supplier not clinically significant between groups.
CADTH	Mercury	Literature review of 19 studies	Qualitative evaluation of key risk assessment criteria - namely hazard identification, exposure assessment, and toxicology - for both dental amalgams and resins.
CADTH	Potential environmental impact (generic)	Not available	Not available
NICE	GHG emission	Considerations based on company claims	NA-Company claims that the conservation of gases within Sedaconda ACD-S and using scavenging systems can reduce the release of gases into the atmosphere.
AIHTA	GHG emission, waste production	Literature review	Increased environmental impact (higher greenhouse gas emissions (43.5%) and waste productions (24%) as well as fewer disability-adjusted life years averted per ton of carbon dioxide and waste) of RAS vs. conventional laparoscopic procedures, in line with other studies. This may not sufficiently compensate for the potential clinical benefit of RAS.
NIPH	Environmental pollution (i.e., impact of triclosan-coated sutures on the environment)	Risk assessments from the European Chemicals Agency + Literature review	NA-The triclosan expected to be released in the environment after use in sutures is low. Although undesirable, the environmental impact is likely to be minimal. If the use of triclosan-coated sutures is a valuable, environmental considerations will probably not be an obstacle to use.

Abbreviations: CADTH= Canada's Drug and Health Technology Agency; AIHTA=Austrian Institute for Health Technology Assessment; NICE=National Institute for Health and Care Excellence; NIPH= Norwegian Institute of Public Health; CO_2= carbon dioxide; GHG= greenhouse gas

Table 4. Identification, assessment and measurement of the environmental impact (when applicable) in

selected scientific publications

Studies	Environmental dimensions	Environmental assessment methods	Assessment outcome
Marsh et al.	CO_2	LCA, EEIOA	Not applicable
Marsh et al.	CO_2	LCA	Direct and indirect costs were combined with carbon intensity data, estimates of the average CO_2 emissions emitted per GBP spent delivering health services, to estimate the emissions generated as a result of treatment.
de Preux et al.	CO_2eq	Only environmental impact associated to treatment delivery (not LCA)	Tons of CO2eq at the time of treatment initiation and at year 2, for three haemodialysis modalities. Non-traded carbon price of £52 per ton CO_2eq used to estimate cost of carbon.
Polisena et al.	CO_2	LCA, EEIOA	Not applicable
Ortsäter et al.	PCF	LCA	PCF measured as kilos of CO_2eq was derived for each inhaler type accounting the PCF of the whole life cycle (cradle-to-grave)
Hensher et al.	CO_2, particulate matter/air pollution, plastic waste, chemical contamination	LCA, EEIOA	Not applicable
Ortsäter et al.	PCF	LCA	PCF measured as kilos of CO_2eq was derived for each inhaler type taking into account the PCF of the whole life cycle (cradle-to-grave)
Pekarsky et al.	CO_2	Not applicable	Not applicable
Greenwood Dufour et al.	Not applicable	Not applicable	Not applicable
McAlister et al.	CO_2	Process-LCA, EEIOA	Theoretical-The worldwide reference unit for carbon emissions is CO_2eq, which might be expressed as kg CO_2eq, kilotons CO_2eq, or megatons CO_2eq. A reference unit is used as there are a range of greenhouse gases, with different global warming potentials.
Pinho-Gomes et al.	CO_2	LCA, partial LCA	Not applicable
Toolan et al.	CO_2, biodiversity loss	Not applicable	Not applicable
Guirado-Fuentes et al.	Carbon footprint (product, supply chains, healthcare institutions)	LCA, EEIOA	Not applicable
Desterbecq et al.	CO_2, water, energy, waste, other	LCA	Variable (multiple case studies)
Walpole et al.	GHG	LCA	Not applicable
Firth et al.	Not applicable	LCA	Not applicable

Abbreviations: CO_2= carbon dioxide; GHG= greenhouse gas; LCA= lifecycle analysis; EEIOA= environmentally extended input-output analysis; PCF= product carbon footprint; RAS= robotic assisted surgery.

4.4 Integration of the environmental impact in HTA

Studies	Methodologies (either proposed, discussed, or applied)	Main focus of the article
Marsh et al.	CBA, CUA, MCDA	Discussing methodological proposal or challenges or both
Marsh et al.	CUA	Presenting a case study (on insulin for T2D patients) and discussing challenges with data availability and granularity
de Preux et al.	CUA	Presenting a case study on dialysis vs home dialysis
Polisena et al.	CBA, CUA, MCDA, CEASS framework, weight of evidence, other	Discussing methodological challenges
Ortsäter et al.	BIA	Measuring social cost of carbon (in disposable vs. single-use inhalers)
Hensher et al.	Inclusion of the environmental impact as health gains or costs	Comparing proposed methodologies and challenges
Ortsäter et al.	BIA	Measuring social cost of carbon measured in disposable vs. single-use inhalers
Pekarsky et al.	Inclusion of the environmental impact as costs	Discussing methodological challenges (misalignment between GHG accounting vs. EE methods), regulatory challenges (differential regulatory requirements in EE vs. GHG emission reduction regulations) and challenges in setting incentive schemes.
Greenwood Dufour et al.	Criteria to trigger environmental consideration in HTA	Discussing challenges (environmental data availability, responsibilities for data collection)
McAlister et al.	CBA, CEA, MCDA	Discussing methodological proposals
Pinho-Gomes et al.	BIA, CEA, CBA, CUA, MCDA, other	Elaborating pros and cons of a variety of methodologies, and discussing ethical challenges and political issues
Toolan et al.	Information conduit, parallel evaluation, integrated evaluation, environmental evaluation	Elaborating on varying levels of integration of the environmental impact in HTA
Guirado-Fuentes et al.	BIA, CBA, CUA, MCDA	Summarizing evidence from the literature
Desterbecq et al.	Different EE methodologies, but most characterized as CMA	Summarizing evidence (case studies) from the literature
Walpole et al.	Inclusion of environmental impact as health gains or costs	Discussing current challenges and providing expert opinion on possible ways forward
Firth et al.	-	Discussing challenges (lack of agreement on the approach for environmental action; lack of interdisciplinary collaboration; weak economic, moral, reputational incentives)

Abbreviations: BIA= budget impact analysis; CBA= cost-benefit analysis; CEA= cost-effectiveness analysis; CEASS= comprehensive environmental assessment; CMA=cost-minimization analysis; CUA= cost-utility analysis; EE= economic evaluation; GHG= greenhouse gas; MCDA= multi-criteria decision analysis; T2D=

type 2 diabetes

4.5 Conclusive remarks

This review, which includes 16 scientific papers and six HTA reports on incorporating the environmental impact of health technologies into HTA, reveals a variety of methodological approaches, demonstrating that it is feasible to measure environmental impact with existing tools (such as LCA). However, there is still no agreement on which specific aspects of environmental impact to measure (such as CO2 emissions, waste management, water or air pollution, or biodiversity loss) or on a standardized method for calculating and integrating these impacts into HTA that would fairly address the needs of all stakeholders across the value chain. Detailed information from the current work will be published in a peer-reviewed paper in a scientific journal.

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