HTA290

Environmental Sustainability in HTA: Are HTA Bodies Applying Environmental Criteria in Their Decision-Making?

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Introduction and objectives

The health and life sciences industry has an impact on the global environment and climate change. Many stakeholders perceive environmental aspects as important. However, the extent to which Health Technology Assessment (HTA) bodies are looking at environmental sustainability criteria when evaluating new technologies is unclear. This study aimed to examine to what extent environmental factors are considered and whether they can have an impact on HTA decisions.

Methods

An extensive search in the IQVIA Market Access Insights (previously known as HTA Accelerator) platform was conducted, using 27 keywords related to environmental factors, to identify HTA records that mentioned environmental considerations. The analysis focused on HTAs from 11 countries (Australia, Canada, Denmark, France, Germany, Italy, Netherlands, Spain, Sweden, UK and US) and EUnetHTA published between July 2018 and June 2023 (Figure 1). For the identified HTAs, we assessed if the environmental considerations had an impact on the final HTA decision. Also, we reviewed the HTA policies and methodology guidelines to see if they consider environmental factors in HTA.

Results

- We identified 14 HTAs (4 from Australia [PBAC], 1 from Canada [OHTAC], 2 from France [HAS], 3 from Italy [ALISA and PRHDM], 1 from the US [ICER] and 3 from the UK [NICE]) that mentioned environmental evidence (Figure 1)
- The identified HTAs were assessing pharmaceutical products administered via syringe, inhaler or on-body device (6 HTAs), procedures (5 HTAs) or medical devices (3 HTAs)
- The considerations cited in HTA reports were litter associated with the use of syringes or single-use devices (6 HTAs), reduced footprint due to having three active substances used in combination in a single inhaler (2 HTAs), impact of local air pollution on generalizability of the results from clinical trials, release of greenhouse gases, risk of contamination during preparation of the cytostatic drugs, disposal and recycling of batteries used in a device and disposal and handling of radioactive waste (1 HTA each)
- Additionally, one HTA concluded that there are no significant risks to the environment associated with renal replacement therapy but no details were provided on what environmental aspects were considered
- Among 14 identified HTAs, the environmental factors seemed to have an impact on the final HTA decision in 6 HTAs. The impact was positive in 3 HTAs where reduced release of greenhouse gases, reduced syringe litter and removing the need of handling radioactive waste contributed to the positive HTA decision. Examples of negative impact of environmental considerations were the critiques of wastage associated with single-use devices or limited generalizability of trial results due to local differences in air pollution (Figure 2)
- However, the environmental impact was not the main decision driver in any HTA
- In the remaining HTAs, environmental considerations were mentioned but without clear impact on the HTA decision. For example, in 4 HTAs PBAC acknowledged comments from patient societies on environmental impact of the assessed interventions, but did not refer to it in their conclusions
- In the review of HTA policies and methodology guidelines, we found relevant publications from 8 countries and EUnetHTA that mentioned environmental aspects. According to them, several countries already consider or plan to consider environmental impact in HTA. Nordic countries include environmental considerations also in the pricing, e.g. by proposing an environmental premium promoting sustainable drug production (Sweden) (Table 1)

Conclusions

- **The current importance of environmental evidence for HTA agencies is low but is expected to gradually increase as some HTA bodies are recently mentioning it in their policies**
- **Environmental aspects are mainly considered in HTAs of procedures, medical devices or pharmaceutical products administered using inhalers or syringes**

Figure 1. Environmental sustainability in HTA records: Prisma search diagram

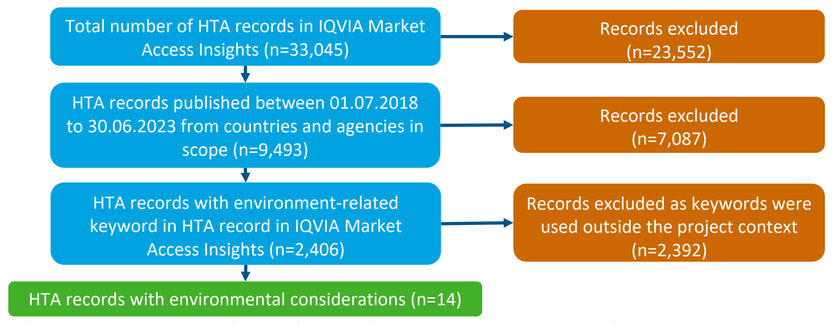

Table 1: HTA policies and methodological guidelines on environmental considerations

	• The deliberative framework used by the HTERP at CADTH includes environmental impact considerations • CADTH has already developed a protocol for tailoring HTAs to help determine when environmental considerations should be fully assessed • CADTH recently published a horizon scan describing the initiatives identified in the literature which are aiming to mitigate the environmental impact by reducing the carbon and environmental footprint of health care systems (e.g. operating rooms, surgical & anesthetics services, virtual care, single-use medical supplies)
	• Denmark, Iceland and Norway have received a European award for the first joint Nordic tendering procedure, in which priority was placed on environmental criteria such as environmental certification, a statement of environmental rules and strategies, or ecologically friendly transportation
	• EUnetHTA HTA Core Model includes Environmental Safety as a part of the Safety domain to be considered during HTAs noting harms using the technology may affect the environment, e.g., chemical substances or their toxic metabolites are potentially harmful in ecological environments • However, in the EUnetHTA's 2021 "A future model of HTA cooperation" white paper, the authors acknowledge that new methodological guidance will be needed to allow environmental impact to be assessed
	• In its Strategic plan for 2019-2024, HAS recognized that healthcare has a strong environmental footprint • HAS wishes to consider environmental issues better in its work and will initiate internal activities to propose changes to the definition of the quality and safety of the interventions
	• ZIN plans to re-assess the cost-effectiveness of 40 expensive reimbursed treatments with uncertain survival benefits and mentioned that environmental impact will be among 6 evaluated criteria
	• In its Strategic plan for 2023-2026, AEMPS mentioned the commitment to continuous improvement, quality, the environment and occupational health and safety • Part of the Strategic plan is the National Plan against Antibiotic Resistance which aligns with one of the top health priorities for the EU focusing on human health, animal health and the environment
	• TLV proposed an environmental premium aiming to promote environmentally sustainable drug production and minimize the release of drug residues for NSAIDs, antibiotics and sex hormones • In 2021, SBU published a guideline to identifying relevant ethical aspects of healthcare interventions, where a long-term negative impact on the environment in general is considered among ethical considerations
	• NICE announced in its Strategy for 2021 to 2026 that they will consider the wider environmental technologies while assessing the emerging technologies to reduce the carbon footprint of health and care • NICE is also conducting an options appraisal to understand the feasibility, benefits and risks associated with different ways of requesting and using product-level environmental sustainability data and is examining how environmental sustainability should be included in a new framework for prioritising topics across NICE • NICE announced it will stop supplying print copies of BNF and BNFC to support use of up-to-date content, and drive sustainability and digital transformation
	• AHRQ announced that it will use data on how climate change impacts human health and health care delivery to inform their strategies

Figure 2: Selected case studies depicting impact of environmental considerations in HTA decisions

⚠ Supervised Injection Facilities (SIF) for people who inject drugs (2021)

Consideration of environmental impact:
- Syringe and injection **litter and safe syringe disposal** were among the evaluated outcomes, with contradicting results as litter decreased in some RWE studies but increased in others

Outcome:
- ICER concluded that SIF would decrease the litter, which was supported by experts' opinions and contributed to B+ (incremental or better) rating
- Contradicting results were noted but ICER concluded that increased needle litter would not reduce the net benefit from preventing overdoses

⚠ Sedaconda ACD-S for sedation with volatile anaesthetics (2022)

Consideration of environmental impact:
- The environmental exposure of volatile anaesthetic drugs **(potent greenhouse gases)** delivered via Sedaconda ACD-S was tested in several studies, which showed that Sedaconda ACD-S reduced the release of gases and resulted in lower consumption of volatile sedatives

Outcome:
- NICE concluded that Sedaconda ACD-S would likely reduce the release of greenhouse gases, despite lack of comparative data to prove that and uncertainty with the efficacy of scavenging systems in lowering consumption of the volatile sedatives

⚠ Non-radioactive technique for breast tumor surgery (2023)

Consideration of environmental impact:
- For the surgical excision of breast tumors, the wire-free non-radioactive localization technique eliminates the requirements on **handling and disposal of radioactive material**, necessary with a standard technique

Outcome:
- In its conclusion of a positive decision, OHTAC accepted that the wire-free non-radioactive localization technique removes the burden to follow the regulatory and safety requirements of handling, usage and disposal of the radioactive material

⚠ Skyrizi on-body device for Crohn's disease (2023)

Consideration of environmental impact:
- Skyrizi will be delivered via a single-use on body device, which showed bioequivalence to SC delivery, however, **environmental impact of a single-use device** was noted

Outcome:
- NICE issued a positive decision due to non-inferiority to other treatments
- However, it concluded that environmental concerns remained with the single-use on body device that includes a battery and microchips

⚠ Episcissors-60 to perform incision for mediolateral episiotomy (2020)

Consideration of environmental impact:
- Episcissors-60 are a **single-use device with a higher likelihood for wastage** than reusable Episcissors-60, which could be resterilised

Outcome:
- NICE did not recommend Episcissors-60 due to uncertain clinical effectiveness of both reusable and disposable version and criticized the lack of sustainability of the technology (single-use non-recyclable device)

⚠ Nucala for severe refractory eosinophilic asthma (2022)

Consideration of environmental impact:
- Nucala's trial included children with severe asthma from peri-urban neighborhoods in the US, differing in health, social and **environmental conditions (air pollution)** from France

Outcome:
- Although HAS acknowledged the clinical benefit of Nucala and issued ASMR IV (as requested by the manufacturer), it criticized the differences in environmental conditions such as air pollution in France vs the trial locations, which limited the generalizability of trial results

Legend: ⚠ Positive impact on HTA decision ⚠ Negative impact on HTA decision

Limitations: The analysis only considered publicly available information.

References: 1) IQVIA Market Access Insights; 2) CADTH Horizon Scan (2023) 'Reducing the Environmental Impact of Clinical Care' Canadian Journal of Health Technologies, Vol 3(4) 3) Greenwood Dufour B. et al. (2022) 'How We Might Further Integrate Considerations of Environmental Impact When Assessing the Value of Health Technologies', Int. J. Environ. Res. Public Health 2022, 19, 12017 4) Amgros (2022) 'European Award For Joint Nordic Environmental Criteria' 5) EUnetHTA Joint Action 2, Work Package 8. HTA Core Model ® version 3.0 (Pdf); 2016; 6) EUnetHTA. A future model of HTA cooperation. White Paper. Diemen (The Netherlands): EUnetHTA; 2021 7) HAS (2018) 'Projet stratégique 2019 – 2024' 8) AEMPS (2023) 'Plan Estratégico 2023-2026' 9) ZIN (2023) 'Pakketagenda passende zorg stuurt op betere inzet personeel' 10) TLV (2022) 'Försöksverksamhet för en miljöpremie i förmånssystemet. Slutrapport' 11) SBU (2021) 'Ethical aspects of health care Interventions. A guideline to identifying relevant ethical aspects' 12) NICE (2021) 'NICE Strategy: 2021 to 2026'; 13) NICE. Sustainability. 14) NICE (2023) 'NICE to stop supplying print copies of BNF and BNFC to support use of up-to-date content, and drive sustainability and digital transformation'**; Abbreviations:** AEMPS: Spanish Agency of Medicines and Medical Devices; AHRQ: Agency for Healthcare Research and Quality; ALISA: Sistema Sanitario Regione Liguria; ASMR: Amélioration du Service Médical Rendu (Improvement in medical benefit); BNF: British National Formulary; BNFC: British National Formulary for Children; CADTH: Canadian Agency for Drugs and Technologies in Health; EUnetHTA: European network for Health Technology Assessment; HAS: Haute Autorité de Santé; HTA: Health technology assessment; HTERP: The Health Technology Expert Review Panel; ICER: Institute for Clinical and Economic Review; NICE: The National Institute for Health and Care Excellence; NSAIDs: Nonsteroidal anti-inflammatory drugs; OHTAC: Ontario Health Technology Advisory Committee; PBAC: The Pharmaceutical Benefits Advisory Committee; PRHDM: Programma Regionale HA Dispositivi Medici; RWE: Real-world evidence; SBU: Statens Beredning för Medicinsk och Social Utvärdering; SC: Subcutaneous; SIF: Supervised injection facilities; TLV: Tandvårds- och läkemedelsförmånsverket; ZIN: Zorginstituut Nederland

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