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Short communication

Transferability, capacity building, and standardization in HTA – with a focus on lower-income European countries

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Introduction

Today, in a growing number of higher-income European countries, real-world evidence (RWE), which is the evidence generated from real-world data (RWD) plays an increasingly important role by complementing evidence generated in traditional ways (e.g. clinical trials) and informing decision health care decision making. Payers and Health Technology Assessment (HTA) institutions both tend to rely on RWE when making decisions on the value of health technologies.

On the other hand, while growing efforts are being put into RWD generation and RWE generation in lower income European countries (LIECs), mostly from Central and Eastern Europe (CEE), the utilization levels are still suboptimal.

The HTx Project

As part of the European Commission-funded H2020 project HTx (Next Generation Health Technology Assessment), researchers aimed to identify the main barriers for application of RWE derived in the Western European countries for the purposes of CEE decision-making in healthcare. The main goals of these activities were to investigate the main barriers which prevent the adequate utilization of RWD and consideration of RWE in decision making in LIECs (Kamusheva et al., 2022), to suggest possible solutions to address the key barriers (Németh et al., 2023), and to specifically investigate these aspects through two selected case studies (Kaló et al., 2026; Németh et al., 2026).

Methods

A mixed-methods approach was employed, including a scoping review of the literature, webinars, surveys, and a series of workshops and stakeholder discussions involving HTA agency consortium partners of HTx, external experts, and regional stakeholders.

Transferability aspects were considered upfront in several case studies (CSs), including the application of the Target Trial Emulation (TTE) methodology for rare diseases and the transfer of the Normal Tissue Complication Probability (NTCP) model for proton therapy in head and neck cancer. Through consecutive workshops, experts identified the main challenges of transferring evidence generated by novel methodologies and discussed potential solutions. The most important general CS-specific barriers were selected through surveys and anonymous voting exercises and subsequently prioritized and addressed through consensus-building discussions.

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Barriers

The studies consistently identified several barriers to the adequate use and transferability of RWE across LIECs. These challenges can be grouped into five broad categories: technical, regulatory, clinical, scientific, and perceptional barriers. The most frequently reported issues included the lack of local real-world data prior to reimbursement decisions, differences in patient pathways and comparator technologies, limited local expertise and resources for adapting advanced HTA methodologies, and shortages of trained HTA professionals.

In the TTE (Kaló et al., 2022) and NTCP (Németh et al., 2026) case studies, the lack of local data and differences in healthcare systems were considered major obstacles to implementation. Nevertheless, experts agreed that these novel approaches represent improvements over current standard HTA methods. The TTE methodology offers opportunities to evaluate the value of high-cost and orphan technologies across different patient subgroups, while the NTCP model can support patient selection and improve decision-making in head and neck cancer treatment.

Proposed solutions

Multiple solutions were proposed to facilitate the transferability and adoption of RWE (Németh et al., 2023). These included developing a European consensus on methodological standards, promoting harmonization and standardization of RWE generation and use, increasing dissemination of RWD and RWE as the gold standard, fostering collaboration among stakeholders, and building trust in the use of RWE. Participants also emphasized the importance of considering transferability aspects early in the assessment process and providing training to HTA professionals in countries with limited HTA capacities.

Conclusion

This body of work represents the comprehensive efforts within the HTx project to explore how RWE and novel HTA methodologies, including TTE and NTCP models, can be transferred and adapted to optimize healthcare decision-making in LIECs. Despite significant barriers related to data availability, methodological capacity, and healthcare system differences, stakeholders agreed that transferring RWE and adopting advanced methodologies can substantially improve current HTA practices. To overcome these challenges, there is a need for detailed, consensus-based guidelines, greater harmonization and standardization of RWE practices, stronger stakeholder collaboration, and capacity-building initiatives to support the implementation of innovative HTA approaches in countries with limited resources.

References

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