HTA404

Use of Real-World Evidence in HTA Submissions in Emerging Markets

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Aim

This research aimed to provide an overview of RWE used in HTA submissions in emerging markets, focusing on the Asia-Pacific and Middle East and North Africa (MENA) regions, and to identify challenges associated with the use of RWE in these regions.

"Use of RWE in Asia-Pacific is gaining traction, although there are regional differences. In MENA, RWE is not yet widely used."

Methods

A targeted literature review was conducted to identify data on HTA in Asia-Pacific and MENA.

Searches were executed on PubMed and the ISPOR Presentations Database in January 2024; a supplemental search was conducted on PubMed in July 2024.

Records were screened by experienced researchers and results were categorized by HTA topic.

Records were excluded if they were published before 2014, or if they were not in English.

Findings

MENA

Since implementation of HTA is in the early stages, use of RWE is rare.

KEY CHALLENGES	PROPOSED SOLUTIONS
• Limited availability of local RWE data	• Establishing and validating reliable databases to generate RWE
• Disparities in availability of technology required for data collection, such as electronic medical records	• Enhancing technical capabilities to design, execute, analyze and interpret RWE studies
• Lack of guidance for evidence-generation best practices	• Developing standards for evidence generation

***Figure 1**. Key challenges and proposed solutions to using RWE in MENA[2]*

Background

RWE can play an important role in reimbursement decisions by providing data on the effectiveness and safety of therapies in real-world populations.[1-3]

Use of RWE in submissions to HTA bodies in emerging markets can be particularly beneficial, given that local patient populations are often under-represented in pivotal clinical trials.[4-6]

In countries where reimbursement decisions are not made at the time of market entry (e.g., India, Indonesia, Malaysia, China, Philippines, Singapore, and Thailand), there is an opportunity to collect real-world data prior to HTA submissions.[3]

In countries where reimbursement decisions are made shortly after regulatory approval (e.g., South Korea, Japan, and Taiwan), RWE can be considered when reassessing initial funding decisions.[3]

Findings

Asia-Pacific

The growing interest in using RWE for regulatory and reimbursement decision-making led to the establishment of the REALISE working group, which developed a non-binding guidance document that provides a framework on the generation and use of RWE for decision-making in Asia.[6-8]

RWE is accepted as a source of evidence in HTA submissions in several countries, although most HTA bodies require justification for using RWE (***Table 1***).

	Accepts RWE	Justification required	Guidance available[a]
China	✓	✗	✓
India	✓	✓	✓
Japan	✓	✓	✓
Philippines	✓	✗	✓
South Korea	✓	✓	✓
Taiwan	✓	✓	✓
Malaysia	✓	✗	–
Bhutan	✓	✗	–
Indonesia	✓	✓	–
Singapore	✓	✓	✓
Thailand	✓	✓	–

***Table 1**. Acceptance of RWE in HTA submissions[3,8]*

[a] Guidance documents that detail circumstances under which data from RWE studies can be included in the HTA dossier, minimum standards for collecting and submitting data from RWE sources, how to account for confounding factors, and how to reduce selection bias were identified for seven countries.
– indicates lack of specific information on available guidance in the retrieved references.

Discussion

Conclusions: Acceptance of RWE in HTA submissions is gaining traction in Asia-Pacific, although regional differences exist.

In MENA, RWE is not yet widely used, although changes in the healthcare sector and implementation of HTA infrastructure are expected to facilitate the use of RWE in HTA submissions.[2]

Implications for research and practice: Use of RWE is likely to continue growing in emerging markets. Expanding the application of RWE could enhance HTA decision-making, compensating for the paucity of data on populations that are under-represented in clinical trials.

References:

1. Zisis et al. *J Pharm Pharm Sci*. 2024;27:12302; 2. Akhras et al. *Expert Rev Pharmacoecon Outcomes Res*. 2019;19(3):245-250; 3. Shau et al. *Perspect Clin Res*. 2023;14(3):108-113; 4. Mason et al. *BMJ*. 2003;326(7401):1244-1245; 5. Fashoyin-Aje et al. *J Clin Oncol*. 2017;35(15_suppl):6564-6564; 6. Kc et al. *Int J Health Policy Manag*. 2023;12:6858; 7. REALISE Working Group. 2021; https://hiper.nus.edu.sg/wp-content/uploads/2021/05/REALISE-Full-guidance-post-feedback_20201211-version-1.1-2.pdf; 8. Lou et al. *Int J Technol Assess Health Care*. 2020;36(5):474-480.

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