The Role of Real-World Evidence in Addressing Gaps in Health Technology Assessment in Brazil's Public Healthcare System

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Background

The incorporation of new health technologies into Brazil's public healthcare system (Sistema Único de Saúde, SUS) relies heavily on health technology assessment (HTA) to ensure cost-effective and equitable decision-making (1). Traditionally, HTA processes have depended on clinical trial data, which, while rigorous, often lack generalizability to real-world populations—particularly in low- and middle-income countries like Brazil. Clinical trials frequently underrepresent diverse socioeconomic, regional, and ethnic groups, leading to gaps in evidence on treatment effectiveness, safety, and long-term outcomes in real-world settings (2,3).

Objective

This study aims to explore how real-world evidence (RWE) can address critical gaps in the incorporation of new health technologies into Brazil's public healthcare system.

Methods

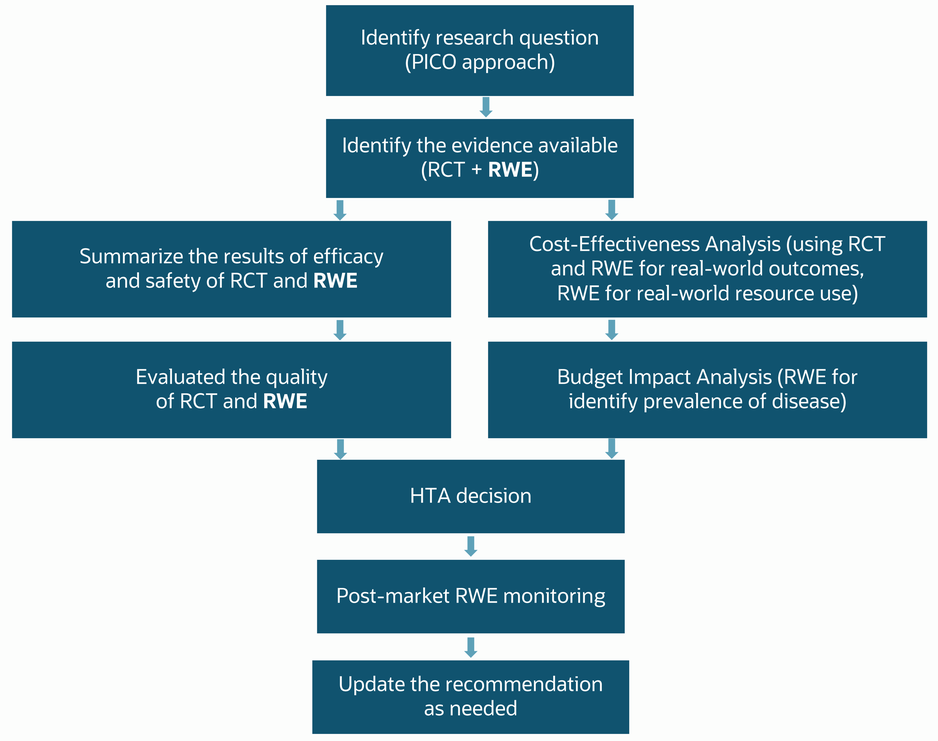
A narrative review was conducted to analyze the role of RWE in HTA processes, with a focus on its applicability to Brazil's public healthcare system. Insights were drawn from case studies and existing literature on RWE utilization in low- and middle-income countries.

Results

RWE significantly supports HTA by providing real-world data on resource utilization, treatment patterns, and health outcomes, which are essential for cost-effectiveness analyses and budget impact assessments.

In Brazil, RWE addresses epidemiological gaps by providing data on disease prevalence and treatment outcomes in underrepresented populations, especially in regions with limited clinical trial coverage. Additionally, RWE enhances post-market surveillance by evaluating long-term safety and effectiveness, supporting adaptive reimbursement strategies, and informing evidence-based policy adjustments.

The figure illustrates how RWE can be used in HTA decisions. However, challenges persist, including issues with data quality, lack of standardization, limited data integration, and the scarce availability of outcome data within DATASUS, Brazil's public healthcare database. Additionally, biases inherent in observational data further complicate the integration of RWE into HTA in Brazil as an official data source of information.



Conclusion

RWE has the potential to fill critical gaps in Brazil's HTA processes, complementing clinical trial data to support Conitec's (the National Commission for the Incorporation of Technologies in the SUS) decision-making. Addressing challenges related to data quality, standardization, and methodological rigor is essential to realize RWE's full potential. When effectively integrated, RWE can improve the accuracy of economic evaluations, enhance epidemiological insights, and support dynamic policy-making, ultimately strengthening Brazil's public healthcare system.

References

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