

Introduction: The REAL World Data (RWD) In Asia for Health Technology Assessment (HTA) guidance was developed by a regional working group to facilitate the increasing acceptance of real-world evidence (RWE) in Asia. We compared the consistency of REALISE against guidance from Japan and China.

Methods: Country-specific guidance for RWE/RWD use in pharmaceutical development were identified in May 2022 through governmental websites, with validation searches via Google. Sections from local guidance were mapped onto REALISE and categorized as “agree”, “mixed”, “disagree” or “missing” based on coverage and consistency.

Results: Five Japanese and three Chinese documents were mapped. Most sections in Chinese guidance (77%) and 36 percent of sections in Japanese guidance were tagged “agree” or “mixed”, with general alignment on definitions and good practice considerations (study design, accountability); however, 63 percent of Japanese sections were tagged “missing” from REALISE. As local documents took the regulatory perspective, they lacked REALISE’s discussion of translating RWD to RWE for HTA/economic evaluations specifically. Local guidance focused on practicalities of RWD collection in local contexts, including descriptions of specific actions (e.g., evaluating RWD sources, ensuring data security) rather than overarching principles described in REALISE; specifically, Japanese guidance described how to access and analyze databases/registries, reflecting Japan’s landscape of robust sources of national healthcare data, but lacked discussion of other RWE study types, data sources and specialized analytical methods. While Chinese guidance had a broader view of RWD types (more similar to REALISE), they also contained discussions on pharmacovigilance and omics data, communication with regulatory bodies, and incorporation of RWE into the approval pathway for traditional Chinese medicines.

Conclusions: Despite differing purposes (with no RWE guidance from local HTA bodies), local and regional guidance align on general principles/good practice in generating/using RWE, providing common ground for increasing usage of RWE in HTA in Asia.

PP147 What Does Real World Evidence (RWE) Offer Health Technology Assessment (HTA) Procedures In Australia?

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Introduction: Medical device health technology assessment (HTA) in Australia is largely coordinated by the Medical Services Advisory Committee (MSAC). Its remit to improve the public’s health by deciding where to allocate public healthcare funding, can be enhanced by considering real world evidence (RWE). Existing data sources have limitations that can be addressed through RWE, including coverage of Australian patient populations who may not meet

trial eligibility criteria, and long-term follow-up through data linkage and datasets. We partnered with a university to explore what information could be gained from an analysis of linked administrative patient data, with a view to addressing current evidence gaps and/or limitations. The findings can be used as a source of local data to define patient populations, estimate actual costs of care, and enable more comprehensive economic modeling to inform medical device HTA.

Methods: The University-developed New South Wales Cardiovascular Cohort dataset, comprising person-level longitudinal NSW administrative data for all patients admitted to hospital with a cardiovascular diagnosis from 2001 onwards, linked to national Medicare Benefits Schedule and Pharmaceutical Benefits Scheme claims data, was interrogated.

Results: Working with RWE is resource intensive in terms of time and costs. The potential of these data was revealed as the research progressed. It was possible to continually refine the data analyzed and reported, as well as expand the data requested. Varied expertise is required to accurately analyze the administrative datasets, particularly clinical classification skills and expertise in methods for causal inference using observational data. Findings from this study will enable the refinement of information for MSAC submissions, including identifying the most relevant patient population and reporting comprehensive costs, beyond an admitted hospital setting. The data will enhance engagement with clinicians and refine messaging, for example regarding patient risk factors.

Conclusions: RWE enhances Australian HTA applications. Local data, extended periods of time and insights not apparent from a focus on admitted hospital episodes can be revealed. Data can be refined during the process for specificity and applicability.

PP149 Reengineering Of Processes For The Elaboration Of Health Technology Assessment Reports In Catalonia

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Introduction: In order to increase the value of its services and activities, the Agency for Health Quality and Assessment of Catalonia (AQuAS) has incorporated in its strategic plan the commitment to improve the processes, quality and people, while ensuring transparency, independence, rigor and efficiency following the guidelines of the European Foundation for Quality Management. We aim to present the standardization processes to improve the efficiency in elaborating health technology assessment (HTA) reports at AQuAS.