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.

Methods: Process standardization has been developed in seven stages: (i) definition of scope, objectives and creation of working groups; (ii) mapping and analysis of all ongoing processes to determine whether they needed improvement or were already optimal; (iii) creation of new processes by evaluating the inclusion of automatic tools and their possible digitization; (iv) creation of the process map; (v) communication to the team for its implementation after training; (vi) dissemination on corporate website; (vii) monitoring and evaluation of their impact.

Results: The creation of AQuAS' HTA report development process map has involved 14 people over the past two years. After an initial two-day workshop, the team was organized in working groups of two to three people, with regular monitoring and the creation of a specific knowledge management unit led by the AQuAS' evaluation manager. The process map was configured based on three axes. The strategic axis contains legal frameworks, ethical principles, good practices and methodological frameworks (29 specific for HTA reports). The key axis presents in an integrated way the process and methodology followed from the request of the HTA report to the final product's dissemination. The support axis includes, among other, the management of 31 requests, information specialist processes (37 searches), training (51 courses) and 6 internal procedures with their corresponding 26 templates and 27 tools.

Conclusions: With a process reengineering approach, HTA reporting has become more efficient. We believe this approach can help other agencies improve their internal processes and subsequently improve team and customer satisfaction.

PP151 HTA Of Fast Track Hip And Knee Joint Replacement

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Introduction: This retrospective study was conducted, in accordance with the STROBE guidelines, (Vandenbroucke et al., 2007), considering patients receiving surgical interventions for hip and knee replacement at the IRCCS Orthopedic Institute Galeazzi, located in Milan (Italy), between 1 January 2016 and 31 December 2019 (two years of traditional procedure, and two years of new one).

Methods: We evaluated 10,922 patients treated for hip or knee joint replacement; there were 5,085 treated following the traditional procedure and 5,837 treated by fast track procedure. Excluding cases which could not satisfy the study criteria we evaluated finally 697 with traditional procedure and 1120 with the new one.

Results: With the new fast track procedure, knee replacement mean costs were decreased by an average of EUR1,112.4 (-19.9%). Excluding the cost of prostheses from the analysis, the mean costs in the pre fast-track period for knee replacement are equal to EUR3,918.1, while the mean cost of the intervention in the fast-track period was equal to EUR3,245.8, being EUR572.3 lower (-17.2%). Considering the number of days of hospitalization, the adoption of fast-track leads to a decrease of -2.8 days (-37.6%) in knee replacement, from a mean number of days of 7.6 (± 2.8), to a mean number of days of 4.8 (± 1.8), and of – 2.9 days (-39.2%) in hip replacement, from a mean number of days of 7.3 (± 2.7) to a mean number of days of 4.4 (± 2.0).

Conclusions: We performed a study over four years, with a wide number of cases treated by various teams in the hospital having the highest workload on hip and knee joint replacements in Italy. The new fast-track procedure is efficient; the length of stay was decreased by the procedure; the direct and indirect costs were decreased; the hospital organization was improved; the increase of care intensity did not modify efficiency and costs; the effectiveness was similar to the traditional procedure as defined by outcomes collected in a registry, including patient reported outcome measures (PROMs); legal and social effects were not modified.

PP152 Evaluation Of Reimbursement Periods In The Turkish Biosimilar Product Market (1995-2022)

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Introduction: Biosimilar products that would enhance the patient's access to treatments have emerged as a product group that is becoming more widespread globally. Since Turkiye is an emerging market in the pharmaceutical area in the Middle East and North Africa region, and being a reference country in pricing processes for some countries, the number of products in the market and reimbursement decisions are important. The aim of this study is to evaluate duration of inclusion of biosimilars into reimbursement lists after registration in Turkiye.

Methods: This study used website-based information (Turkish Medicine and Medical Devices Agency Registered Products List and Detailed Pharmaceutical Price List, Social Security Institution Reimbursed Product List) to analyze the reimbursement approval duration for registered biosimilars in Turkiye after receiving registration approval. A study has been conducted on the launch period of biosimilar products to patients access with reimbursement and the evaluation period of reimbursement applications after registration approval. Even though they might not be active on the reimbursement list right now, products that have previously been approved for payment have been included.

Results: Between 1995-2022, biosimilars of 13 active substances in total were registered by the Ministry of Health in Turkiye. Thirty-three different brands and 105 biosimilars with all pharmaceutical forms are registered. As of November 2022, 72 biosimilars were in the reimbursement list. Twenty-two of reimbursed biosimilars were deactivated or excluded from reimbursement. It is calculated that the average evaluation and approval timeline for reimbursement of biosimilars between 2009 and 2022 is 9 months. When biosimilars in the European Medicines Agency (EMA) and Turkiye are compared, 13 biosimilar active substances are licensed in Turkiye compared to 19 for the EMA. When the total number of brands is compared, it has been observed that while 33 brands are registered in Turkiye, this number is 73 for the EMA.

Conclusions: This study, in which reimbursement approval dates for registered biosimilars in Turkiye have been compared based on years