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Enhancing Real-World Evidence (RWE) Utilisation in Payer Decision-Making

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CONTENTS

ABBREVIATIONS

ABBREVIATIONS	DESCRIPTION
ACE	Agency for Care Effectiveness
AI	Artificial intelligence
APAC	Asia-Pacific
APPI	Act on the Protection of Personal Information
AS	Aortic stenosis
CDM	Common Data Model
CED	Coverage with evidence development
CRT-D	Cardiac resynchronisation therapy-defibrillator
CSB	Conditional Selective Benefit
EAC	External Assessment Centre
EHR	Electronic health record
EMR	Electronic medical record
FDA	Food and Drug Authority
GPSP	Good Post-marketing Study Practice
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HIRA	Health Insurance Review and Assessment Service
HTA	Health technology assessment
MBS	Medicare Benefits Schedule
MDV	Medical Data Vision
MFDS	Ministry of Food and Drug Safety
MHLW	Ministry of Health, Labour and Welfare
MoHW	Ministry of Health and Welfare
MSAC	Medical Services Advisory Committee
NA	Not available
NDA	New drug application
NECA	National Evidence-based Healthcare Collaborating Agency
NHIA	Next-generation Healthcare Infrastructure Act
NHIS	National Health Insurance Service
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OMOP	Observational Medical Outcomes Partnership
PMA	Pre-market application
PMDA	Pharmaceuticals and Medical Devices Agency
PREM	Patient-reported experience measure
QoL	Quality of life
rATP	Reactive anti-tachycardia pacing
RCT	Randomised controlled trial
RWD	Real-world data
RWE	Real-world evidence
SaMD	Software as a medical device
TAVR	Transcatheter aortic valve replacement
TRUST	Trusted Research and Real World-Data Utilisation and Sharing Tech
UK	United Kingdom
US	United States

GLOSSARY

TERMS	DEFINITIONS
COMBINATION PRODUCT	A product comprising two or more different types of medical products (that is, a combination of a medicine, device and/or biological product with one another) such that the distinctive nature of the drug component and device component is integrated in a singular product
HEALTH TECHNOLOGY	An intervention developed to prevent, diagnose, or treat medical conditions; promote health; provide rehabilitation; or organise healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program, or system
HEALTH TECHNOLOGY ASSESSMENT (HTA)	A multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system
MEDICAL TECHNOLOGY	Includes all equipment, tools, and devices which are used to diagnose and treat a patient.
REAL-WORLD DATA (RWD)	United States Food and Drug Authority (US FDA): Data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources including electronic health records, medical claims, billing or insurance data, product or disease registries, or patient-generated data European Medicine Agency (EMA): Routinely collected data relating to a patient's health status or the delivery of healthcare from a variety of sources other than traditional clinical trials Joint ISPOR-ISPE special task force: Data obtained outside the context of randomised controlled trials (RCTs) generated during routine clinical practice
REAL-WORLD EVIDENCE (RWE)	US FDA: Clinical evidence regarding the usage and potential benefits or risks of a health technology derived from analysis of RWD. RWE can be generated by different study designs or analyses, including but not limited to pragmatic trials and retrospective or prospective observational studies. RWE complements data from clinical trials by generalising the trial findings to the local population EMA: information derived from analysis of RWD Joint ISPOR-ISPE special task force: obtained from analysing RWD

EXECUTIVE SUMMARY

Despite the rapid growth of the medical technology industry in recent years, health technology assessment (HTA) for medical technologies remains less developed and less robust compared to pharmaceuticals. Due to inherent differences between medical technologies and pharmaceuticals which influence HTA methodologies, there is great value in utilising real-world data (RWD) and real-world evidence (RWE) to support payer decision-making for medical technologies. However, adoption of RWE continues to face persistent challenges.

Within the Asia-Pacific (APAC) region (focusing on Australia, Japan, Singapore, and South Korea), there is variation in how RWE is recognised and integrated into HTA and decision-making processes. Four common barriers to RWE utilisation were identified across these markets: limited availability of RWD, inconsistent quality of RWD, restricted access to RWD, and lack of clear guidelines and/or transparency in how RWE is evaluated.

Despite these challenges, there are positive examples that demonstrate the potential of RWE. Three case studies from the United Kingdom's (UK) National Institute for Health and Care Excellence (NICE) illustrate how RWE can support timely, informed decision-making for medical technologies. These examples underscore the importance of aligning evidence generation with outcomes that matter to HTA bodies to improve the likelihood of favorable positive decisions.

The case studies show that RWE can enable appropriate and faster decision-making by HTA bodies, and that it would be important to understand the outcomes of interest to HTA bodies to increase the chances of a positive decision.

To increase the utilisation of RWE by payers across APAC, this paper proposes three key actionable areas for payer decision-making: (1) HTA bodies could develop and clearly communicate transparent guidelines for evaluating RWE; (2) encourage pre-submission consultations to align RWE study designs with payer requirements from the outset and (3) focus efforts on reducing legal and financial barriers that limit private-sector access to local health data needed for robust evidence generation and payer decision making.

1 INTRODUCTION

Rapid advancements in information technology, the establishment of electronic health records, and the integration of artificial intelligence (AI) and machine learning algorithms in recent years have transformed the way health data is captured, analyzed, and leveraged. These digital advancements have enabled the aggregation and interpretation of large, diverse datasets that reflect real-world clinical practice, patient experiences, and population health outcomes.

Additionally, the healthcare sector is undergoing a paradigm shift toward patient-centric, evidence-driven, and value-based care. This transition places greater emphasis on outcomes that matter most to patients and payers, requiring broader, more nuanced evidence than what randomised controlled trials (RCTs) alone can provide. Real-world evidence (RWE), by drawing from real-world clinical and patient data, helps fill these gaps and supports evaluation of technologies in contexts that mirror everyday care and diverse patient populations.

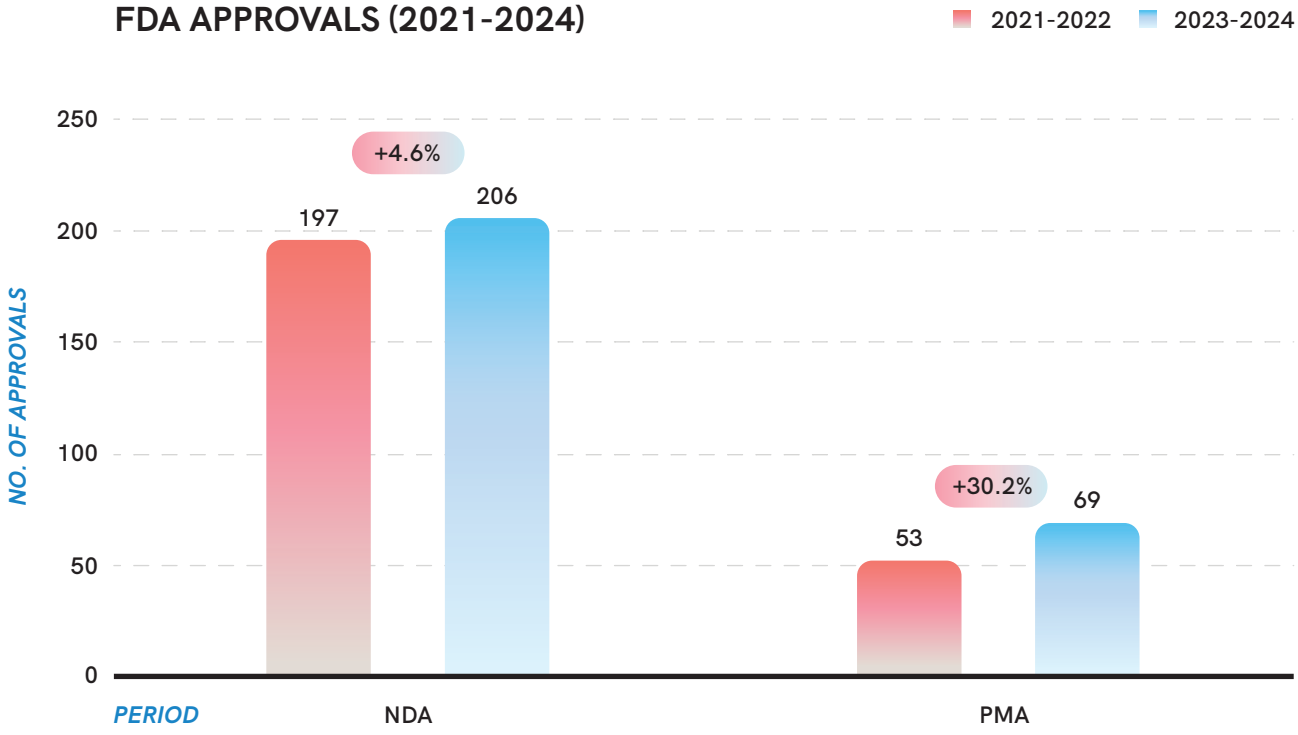
In addition to its applications in clinical care, RWE may be utilised to demonstrate operational improvements, such as enhanced workflow efficiency through the implementation of digital tools, software as a medical device (SaMD), or AI for clinical decision support. Time savings achieved by healthcare professionals can indirectly contribute to improved patient outcomes by enabling clinicians to dedicate more attention to patient care.

Decision makers worldwide, including in the United Kingdom (UK), United States (US), and across the Asia-Pacific (APAC) region, have increasingly recognised and encouraged the use of RWE in regulatory submission and reimbursement processes. Leading agencies such as the US Food and Drug Administration (FDA) have published frameworks and guidance on the use of real-world data (RWD) and RWE in decision-making. Collectively, these trends make RWE and RWD not just complementary, but often essential for timely, representative, and robust evidence generation to support decision-making in today's rapidly evolving healthcare landscape.

1.1
Medical technologies and the role of Health Technology Assessment (HTA) in payer decision-making

Post-COVID-19, the medical technology industry has seen a growth in the number of regulatory authorisations, fuelled by advancements in information technology, artificial intelligence/machine learning algorithms, and innovation. In the US alone, approvals for pre-market application (PMA) for medical devices surged between 2023 and 2024, rising over six times faster than new drug applications (NDA) approvals when compared to the previous two-year period (Figure 1).

FIGURE 1 NUMBER OF NDAS AND PMAS BY PERIODS (2021-2022 VS 2023-2024)



Approvals for PMA for medical devices rose six times faster than NDA approvals between 2023 and 2024, when compared to the period 2021-2022

Health technology assessment (HTA) provides health policy decision-makers with evidence-based advice to enable equitable and efficient access to high-quality healthcare. It is increasingly being adopted as the basis for pricing and reimbursement decisions by payers in many different countries. Key considerations in HTA for payers are summarised in Figure 2.

FIGURE 2 KEY CONSIDERATIONS IN HTA FOR PAYERS

KEY CONSIDERATIONS IN HTA FOR PAYERS

CLINICAL EFFECTIVENESS AND SAFETY	• Quality of evidence • Tailored evidence
PRACTICAL CONSIDERATIONS	• Integration with health systems • Training and education
COST-EFFECTIVENESS AND ECONOMIC IMPACT	• Value for money • Budget impact
TRANSPARENCY AND ACCOUNTABILITY	• Stakeholder engagement • Public reporting
PATIENT ACCESS AND EQUITY	• Fair access • Ethical considerations

However, HTA for medical technologies are less developed and less robust compared to pharmaceuticals, despite the growth of the medical technology industry. This is due to inherent differences between medical technologies and pharmaceuticals which impact HTA methods, resulting in different assessment needs, evaluation criteria, and approaches (Table 1).

TABLE 1

SUMMARY OF KEY DIFFERENCES BETWEEN MEDICAL TECHNOLOGIES AND PHARMACEUTICALS

CHARACTERISTIC	MEDICAL TECHNOLOGIES	PHARMACEUTICALS
PURPOSE	• Can have multiple therapeutic, instrumental, or diagnostic use	• Primarily therapeutic use
PRODUCT	• May not exist as a single technology, but a mix of existing technologies or a combination of medical technology with a pharmaceutical, requiring assessment of both components	• In most cases, it exists as a single product
PRODUCT LIFECYCLE	• Short development cycle • Rapid incremental changes/ improvements in technology	• Long development and patent life
DEVICE-USER INTERACTION	• Patient outcomes are dependent on skill of physicians and occurence of "learning curve"	• Patient outcomes are dependent on patient's adherance to the drug as well as correct dosage administration
CLINICAL EVIDENCE	• Fit-for-purpose evidence that is designed to meet the requirements of regulatory bodies • Double-blinded, randomised controlled trials may be feasible in some cases, but not in others. For example, sham procedures may be unethical to conduct or blinding of patients and investigators are not possible • Assessment of outcomes include both clinical and technology-specific outcomes	• Most new drugs must have evidence from RCTs for regulatory approval • Randomised controlled trials are feasible in most cases • Follow-up time seems to be shorter than for devices; comparatively less expensive to conduct RCTs compared to for devices • Focus on assessment of clinical outcomes
TARGET POPULATION AND CLINICAL OUTCOMES	• A single medical technology may be used in multiple disease areas or as part of the care pathway with a group of other technologies • Medical technologies used in screening or diagnostics may not have an explicit target population or observe clinical outcomes directly	• Target population is clearly defined, and clinical outcomes can be observed directly

1.2
Value of real-world data (RWD)/ real-world evidence (RWE) in payer decision-making for medical technologies

Given the inherent differences, there is great value in utilising RWD and RWE in HTA to support payer decision-making in medical technologies.

RCTS MAY NOT BE FEASIBLE FOR ALL MEDICAL TECHNOLOGIES AND RWD WOULD BE THE KEY SOURCE OF DATA TO GENERATE THE REQUIRED CLINICAL EVIDENCE.

While RCTs have traditionally been regarded as the gold standard and is the preferred source of evidence for coverage decisions made by payers, it may be challenging to conduct RCTs for certain medical technologies. Thus, RWD becomes the primary source of evidence for the medical technology. RWE can also allow for better evaluation of digital health technologies, such as AI-based diagnostic algorithms and monitoring devices, which often evolve over time or depend on real-world use which RCTs may not be able to capture due to its design or controlled environment.

REAL-WORLD STUDIES REFLECT LOCAL ROUTINE CLINICAL PRACTICE

RCTs usually have high internal but low external validity, while studies conducted in the real-world have low internal but high external validity, reflecting routine clinical practice and actual device-user interaction. Real-world studies also provide localised evidence and support the validation of findings from international populations.

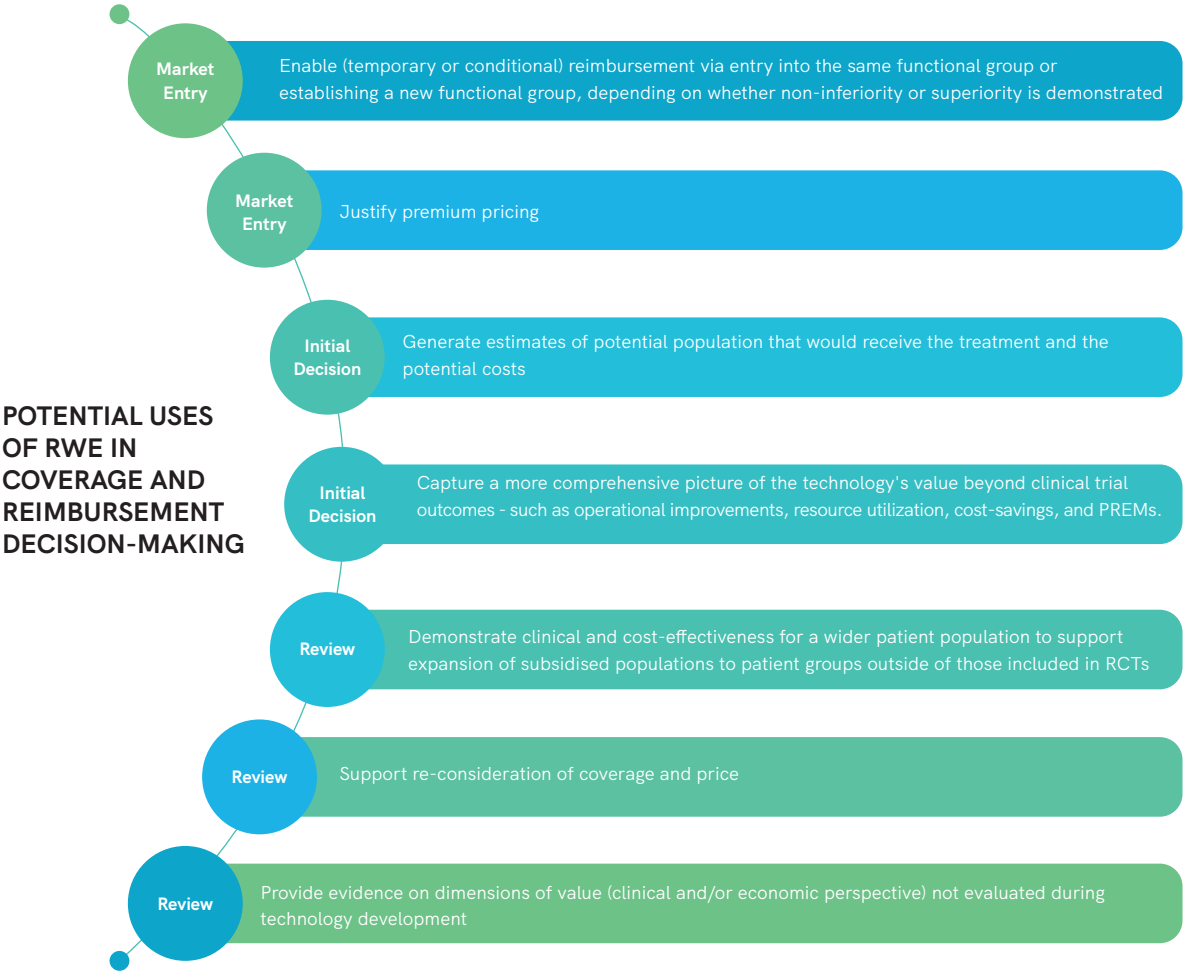
RWE CAN FILL EVIDENCE GAPS NOT ADDRESSED BY RCTS

RWE can address uncertainties or fill evidence gaps not addressed by RCTs for medical technologies, which can aid payers in their decision-making. For example, RWD can provide information on safety signals and adverse events in routine clinical practice, such as late-onset/long-term adverse events beyond the RCT follow-up period, and estimates of economic costs and benefits of treatments. Continuous collection of RWD can also help to identify emerging health trends or unmet needs, enabling payers to align reimbursement priorities accordingly.

TIME-TO-EVIDENCE GENERATION IS SHORTER COMPARED TO RCTS

Time taken to generate RWE is comparatively shorter than the time required to generate evidence from a clinical trial. This agility is especially valuable in the field of medical technologies, where fast-paced innovation and short development cycles demand evidence that remains current and relevant to support decision-making. It could also lead to faster access to promising technologies instead of waiting for results from RCTs.

FIGURE 3 POTENTIAL USES OF RWE IN COVERAGE AND REIMBURSEMENT DECISION-MAKING



Abbreviations: PREM, patient-reported experience measure; RCT, randomised controlled trial; RWD, real-world data; RWE, real-world evidence.

1.3 Objectives of the white paper

There is a growing recognition within APAC on the utility of RWE. However, similar to the global situation, the utilisation of RWE to support reimbursement submissions for medical technology/devices has been low. Thus, this white paper seeks to assess the current perceptions towards use of RWE in HTA and/or payer decision-making within APAC, focusing on Australia, Japan, Singapore, and South Korea. It will also explore the barriers to RWE utilisation in these countries. This will be done through a targeted review of the literature, including peer-reviewed publications, grey literature, and white papers.

2 PERCEPTIONS TOWARDS USE OF RWE IN HTA AND/OR PAYER DECISION-MAKING WITHIN APAC

An overview of HTA agencies and decision-makers, and the criteria considered in decision-making or to recommend funding in targeted APAC countries is presented in Table 2. Canada and the UK are also included as reference. Notably for Japan, results of HTA assessments are used only in price adjustment considerations after product launch and are not used to recommend funding for medical technologies. The reimbursement application dossier with clinical and/or economic evidence and regulatory documents are reviewed by the Ministry of Health, Labour, and Welfare (MHLW) and final reimbursement approval provided by Chuikyo (Central Social Insurance Medical Council). Generally, across the different countries, clinical and economic evidence are the key criteria considered for decision-making.

In assessing the perceptions of various countries within APAC towards use of RWE in HTA and/or payer decision-making, it is also important to understand the landscape of RWE within the country. Key elements include the country's formal recognition of the value of RWD, availability of RWD/RWE-related frameworks/guidelines (and specifically for medical technologies), whether there were government-led data infrastructure or coordination for RWD collection, and acceptance of RWD/RWE as primary evidence for decision-making in cases where RCT data is not available. A summary is provided in Table 3, with Canada and the UK included as reference.

TABLE 2

OVERVIEW OF HTA AGENCIES AND DECISION-MAKERS IN TARGETED APAC COUNTRIES, CANADA, AND THE UNITED KINGDOM

PARAMETER / COUNTRY	Australia	Japan	Singapore	South Korea	Ontario	United Kingdom
HTA AGENCY	Medical Services Advisory Committee (MSAC)	Center for Outcomes Research and Economic Evaluation for Health (C2H)	Agency for Care Effectiveness (ACE)	National Evidence-based healthcare Collaborating Agency (NECA) & Health Insurance Review And Assessment Service (HIRA)	Ontario Health's HTA program	National Institute for Health and Care Excellence (NICE)
ROLE	Responsible for providing recommendations regarding funding of health technologies other than medicines	Responsible for the evaluation, approval, and monitoring of pharmaceuticals, medical devices, and other health-related products	Responsible for producing evidence-based evaluations of health technologies (e.g., drugs, vaccines, and medical technologies) to inform funding decisions	NECA: Responsible for conducting scientific evaluation of new medical technologies (including devices), focusing on safety and clinical effectiveness HIRA: Responsible for evaluating the economic value, clinical need, and policy relevance, and recommending whether device should be covered by national insurance	Responsible for analyzing the best available evidence on clinical effectiveness and saftey, cost-effectiveness, budget impact, and patient preferences and values related to health technologies	Responsible for making reimbursement recommendations for medicines and other healthcare technologies
DECISION MAKER	Federal health minister	Ministry of Health, Labour, and Welfare (MHLW) and Chuikyo (Central Social Insurance Medical Council)	Ministry of Health Medical Technology Advisory Comittee (MOH MTAC)	Ministry of Health and Welfare (MoHW)	Ontario Ministry of Health	National Health Service (NHS) England
CRITERIA CONSIDERED IN DECISION - MAKING / RECOMMENDING FUNDING	• Clinical need of patients and nature of the condition • Comparative health gain • Comparative cost-effectiveness • Predicted use in practice and financial impact • Value of knowing • Presence of effective alternatives • Other relevant considerations which include the impact on organisations, or the way in which organisational issues may create barriers or facillitators to the uptake of the new technology or efficiency of health care delivery, ethical concerns, and social aspects	Results of HTA assessment are used only in price adjustment consideration.	• Clinical need of patients and nature of condition • Overall benefit of the technology for the patient and/or the system • Cost-effectiveness (value for money), which covers the incremental benefit and cost of technology compared to existing alternatives • Budget impact • Organisational feasibility, which covers the potential impact of adopting the technology, especially barriers for diffusion • Additional considerations such as ethical, societal, political or other issues related to the adoption of the technology	• Clinical evidence: safety, effectiveness and therapeutic benefit • Economic value: cost-effectiveness and efficiency compared to existing technologies • Social demand: contribution to public health • Technological innovation: differentiation from existing technologies and necessity in clinical settings	• Overall clinical benefit in terms of effectiveness, safety, burden of disease, and need for the medical technology • Patient preferences and privacy • Equity of access or outcomes and patient care • Cost-effectiveness of the medical technology • Economic and organisational feasibility of adoption of the medical technology into the health system	• Clinical and/or health and social care system benefits • Use of resources

TABLE 3

SUMMARY OF KEY ELEMENTS DESCRIBING THE RWE LANDSCAPE IN TARGETED APAC COUNTRIES, CANADA, AND THE UNITED KINGDOM
(criteria and references in APPENDIX I)

FACTORS/ COUNTRY	Australia	Japan	Singapore	South Korea	Canada	United Kingdom
Formal recognition of the value of RWE	🟢	🟢	🔴	🟢	🟢	🟢
Availability of RWD/RWE-related frameworks/guidelines	🟢	🟢	🟡	🟢	🟢	🟢
Specific RWD/RWE-related frameworks / guidelines for medical technologies	🟢	🟢	🟡	🔴	🟡	🔴
Government-led data infrastructure / coordination for RWD access or collection	🟢	🟢	🟢	🟢	🔴	🟢
Acceptance of RWE as primary evidence for decision-making in cases where RCT data is not available	🟢	🟢	🟢	🔴	🟢	🟢

Legend: 🟢 Yes/Available 🟡 In progress/Under development 🔴 No/Not Available

2.1
Australia

Historically, MSAC has predominantly relied on evidence from RCTs in its decision-making process. In its guidance document, "Guidelines for preparing assessments for the Medical Services Advisory Committee", a recommended approach for assessing quality of evidence is the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach (1). Study design is one of the domains assessed in the GRADE approach, and RCTs are initially given a high rating while observational studies receive a low rating.

However, the Health Technology Assessment Policy and Methods Review (Review), established in 2022 to examine Australia's approach to assessing health technologies for government funding, acknowledged that high-quality RWE can be influential in reducing the uncertainty in decision-making and increasing timely access to therapies through the ability to monitor health outcomes post-listing (2,3). It also noted that a coordinated and standardised approach to collecting RWD and RWE to understand how health technologies are being used and are performing in the real world should be a key component to support the operation of the HTA system.

The Review recommended

1

Establishing structures, policies and methods to optimise RWE for HTAs (Table 4)

2

Developing principles and methods to guide the assessment of evidence for decision-making (Table 5).

TABLE 4 RECOMMENDATIONS BY THE REVIEW TO OPTIMISE RWE FOR HTAS

Recommendation number in the report	Description
Recommendation 27	**Governance and strategic oversight of RWD to support HTAs** Develop an Australian framework to optimise timely access to relevant RWD for HTA, covering enabling systems, pathways and evaluations, and research the collection and use of RWD for HTA
Recommendation 28	**Data infrastructure to support HTAs** Develop a dynamic, enduring whole-of-government data infrastructure that evolves over time based on needs and is internationally harmonised, flexible, scalable, and transparent
Recommendation 29	**Inter-governmental data collaboration in standardised collection and sharing of health technology-related data** Promote state and territory government collaboration and participation in cross-jurisdictional data sharing to support nationally cohesive HTA, facilitated by centralised data-sharing infrastructure and harmonisation of access to existing government-held RWD collections
Recommendation 30	**RWD and RWE methods development** With oversight by the multi-stakeholder advisory group, establish a multi-stakeholder coordinated approach to developing transparent evidence for HTA using best practice methods that span data standardisation, standardised analytics and reporting
Recommendation 31	**Collecting and using RWD to resolve uncertainty** • Ensure early identification and/or configuration of data collections that could help resolve uncertainties when it is expected that an application is likely to result in a managed entry agreement • Begin early exploration and negotiation to determine feasibility and resourcing requirements that would meet the intended purpose. Resourcing should be jointly funded by relevant parties, with all details resolved before entering into a managed entry agreement • In the case of ultra-rare diseases and other small populations, international collaboration in the collection of patient-level data should be undertaken, where possible

Abbreviations: HTA, health technology assessment; RWD, real-world data; RWE, real-world evidence.

TABLE 5 RECOMMENDATIONS BY THE REVIEW TO ASSESS EVIDENCE FOR HTAS

Recommendation number in the report	Description
Recommendation 34	**Overarching principles for adopting methods in Australian HTAs** Support the adoption of overarching principles for the methods used in Australian HTAs to ensure that decision-makers have the best possible evidence available and sponsors and evaluators understand preferred methods and approaches
Recommendation 35	**Methods for assessing non-randomised and observational evidence** Support the development of updates to methods for using non-randomised and observational evidence that are in line with the overarching principles for adopting methods in Australian HTAs
Recommendation 36	**Methods for assessing surrogate end points** Support the development of additional methods for using surrogate end points in HTAs that align with the overarching principles
Recommendation 37	**Methods preferred by decision-makers** Support the generation of a curated list of methodologies preferred by decision-makers

Abbreviations: HTA, health technology assessment.

While the scope of the Review did not cover medical devices, the recommendations are also applicable/anticipated to be adapted to medical technologies.

Separately, a Taskforce established to review the items on the Medicare Benefits Schedule (MBS) recommended the collection and sharing of data to support evidence-based and data-driven clinical care in its report published in 2020 (4). The recommendations of the Review and the Taskforce suggest the local authorities' recognition of the utility of RWD and the importance of the collection of RWD to generate RWE and the assessment of RWE in the local context.

2.2 Japan

The Japanese Pharmaceuticals and Medical Devices Agency (PMDA), a regulatory agency responsible for the evaluation, approval, and monitoring of pharmaceuticals, medical devices, and other health-related products, has utilised RWD since 2009 and has been working to promote the use of RWD. It revised the Good Post-marketing Study Practice (GPSP) in 2018 to include database studies as an acceptable type of post-marketing study and enforced the Next-generation Healthcare Infrastructure Act (NHIA) in the same year to make it possible for medical institutions to provide personal medical information to certified business operators, allowing anonymised medical data to be provided to users. It has also published multiple RWD/RWE-related guidelines, some specifically for medical devices, to guide users and applicants in the use of RWD/RWE in approval applications.

RWD/RWE-related guidelines published by PMDA

1	2	3
Basic principles on utilisation of registry for applications	Points to consider for ensuring the reliability in utilisation of registry data for applications	Points to consider for ensuring the reliability of post-marketing database study for medical devices

2.3
Singapore

Little is known about Singapore's perception towards use of RWE in HTA and payer decision-making. However, an online survey reported that Singapore accepts RWE as supplementary evidence to RCTs or in specific instances where RCTs are lacking (e.g., for rare diseases) (5). A review of the ACE guidance document also revealed that while the impact of the various types of evidence on decision-making depends on a number of considerations, greater importance is generally placed on evidence derived from high-quality studies with methodologies designed to minimise bias (6).

2.4
South Korea

The Ministry of Food and Drug Safety (MFDS) has developed a comprehensive roadmap to sequentially expand the scope and implementation of RWE utilisation for regulatory decision-making. Although the roadmap is not specific to medical technologies, it is suggestive of the local authorities' recognition of the utility of RWE and the willingness to incorporate the use of RWE in decision-making. MoHW and the HIRA Service have also published RWD/RWE-related guidelines for pharmaceuticals.

RWD/RWE-related guidelines published by MFDS

1	2
Guideline on Risk Management Plan for Medicines to allow post-marketing safety study based on database study using RWD	Guideline for Medical Information Database Research

3 KEY BARRIERS TO RWE UTILISATION IN APAC

Despite the growing interest in the use of RWE to support payer decision-making, there have been challenges to its adoption. From the payer's perspective, the quality of RWE generated is unknown or at high risk of bias due to data quality issues in RWD sources. From the perspective of medical technology companies, there is no clear guidance from payers on how RWE weighs into the decision-making process and thus companies are hesitant to invest in the generation of RWE.

TABLE 6 KEY BARRIERS TO ADOPTION OF RWE IN PAYER DECISION-MAKING

Preference for RCT	RCTs are considered gold standard source of evidence while other study designs are ranked lower due to lack of randomisation which introduces bias
Availability	Data sources do not usually capture the full spectrum of data, potentially missing key confounders
Accessibility	Strict data privacy laws make it challenging to collect, share, and analyse RWD
Quality	• Concerns over reproducibility, validity, and credibility of RWD/RWE due to lack of transparency of the data collection process • Different databases or data sources are structured to collect data elements for different purposes, and may vary in population coverage, definition of variables and measurement of outcomes
Analysis	• Potential for inappropriate use of statistical methods to analyse the data • Inconsistencies in data structure, format, and level of detail make it difficult to harmonise data across sources for meaningful analysis
Publication bias	Publication bias could skew the evidence used to support coverage and reimbursement decisions
Lack of transparency/guidelines	• Lack of transparency or guidance on the RWE assessment criteria used by decision-makers • Lack of transparency or guidance on how RWD/RWE weighs into the decision-making process

In this section, we will explore four of the above-mentioned key barriers to RWD/RWE utilisation in APAC, from the perspectives of payers and/or companies, which are common across the target countries in APAC.

RWD AVAILABILITY

RWD ACCESS

RWD QUALITY

LACK OF TRANSPARENCY AND GUIDELINES

3.1 RWD Availability

Across the countries, there exist many RWD sources that can be used to generate RWE in the local context, including but not limited to administrative data sources and electronic medical records (EMR). However, the lack of data linkages across disparate data sources is a barrier to RWD availability, especially if the data required is captured in different data sources. Another important point in the context of medical technologies is that the brand names of technologies are not available in most data sources, which hinders medical technology companies from performing analysis specifically on their own technologies.

JAPAN

Japan has made progress through the enforcement of the NHIA in 2018 which enabled certified business operators to receive anonymised medical data from healthcare institutions, allowing them to collect individual patient data directly from healthcare providers and link them for research. While this framework could significantly enhance the use of RWD, only a few business operators have been certified so far, and it remains unclear whether the anonymised data have been effectively applied in research studies.

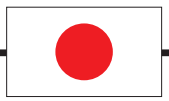
3.2
RWD Access

Across the four countries, access to RWD varies significantly, with common challenges around equitable access, especially for the private sector. There are also legal considerations associated with the use of data in RWD data sources which are not designed for research purposes. The lack of consent for sharing and using of data for research and concerns about data privacy and security are major legal impediments to making RWD accessible. There may also be exorbitant costs associated with the use RWD by the private and commercial sectors, which increases the barrier to use of RWD. Overall, while efforts are underway to improve RWD accessibility, significant barriers remain, particularly for non-government and commercial users.

AUSTRALIA

Australia has a network of data custodians (e.g., the Australian Institute of Health and Welfare) and data linkage units (e.g., Centre for Health Record Linkage) that provide RWD for research, typically on a fee-for-service basis. Most operate within their own jurisdiction and/or can only link datasets under their custody. Thus, the Population Health Research Network was established to support cross-jurisdictional research. However, researchers must still obtain approvals from the relevant custodians, linkage units, and/or ethics boards. Anecdotal evidence suggests that while private sector access is permitted, it is generally more difficult for the private sector to obtain access compared to public sector researchers.

JAPAN



In Japan, the Medical Data Vision (MDV) and JMDC claims databases are two large-scale medical databases that the private sector can access to generate RWE (7,8). To date, multiple real-world studies have been conducted using these two databases. However, the private sector's access to local RWD beyond these administrative claims data is generally limited, which restricts the scope of research that can be conducted. Additionally, the establishment of the Act on the Protection of Personal Information (APPI), which requires informed consent for the use of non-anonymised data poses a barrier for private entities as such consent is typically not collected in routine medical care. However, the APPI does not apply to academic researchers or academic societies who handle medical data for the purpose of academic research, creating a disparity in access between the private and academic sectors.

SINGAPORE

In Singapore, RWD comes mainly from public healthcare EMRs, administrative claims, and national registries. Access to patient-level EMR and registry data is generally restricted for the private sector, while public and academic researchers face fewer barriers. The government's recent establishment of TRUST, a national data-sharing platform that links health data across different data sources for research, marks a significant step toward enabling real-world research using anonymised health data. While companies in the private sector can request for access to the data, companies will need to justify that the use of the data is beneficial to the public and can generate social benefit. As TRUST is still in its early stages, it remains to be seen whether any private sector applications have been successful.

SOUTH KOREA

In South Korea, the National Health Insurance Service (NHIS) database and HIRA claims database are two real-world databases that cover nearly the entire South Korean patient population and can be accessed by the private sector. However, access by the public and private sectors may not be equitable. One example is access to data in the HIRA claims database. The scope of data provided to the private sector is more limited compared to that of the public sector. Private sector companies wishing to work with a broader scope of the HIRA claims data would need to collaborate with researchers from public institutions. Similarly for the NHIS database, while researchers from the public institutions can request to access a customised dataset, private sector companies would need to collaborate with researchers from public institutions to apply for access to a customised dataset.

3.3
RWD Quality

A common barrier across countries is the concern around validation, standardisation and completeness of RWD due to lack of transparency of data collection process. Many sources lack validation, making data reliability uncertain, and the absence of a common data model hinders integration across datasets. Many RWD sources are not set up for research purposes, and hence the data elements collected may not be complete or clinically relevant to most real-world studies. Additionally, limited outcome data in some data sources (e.g., MDV and JMDC claims databases in Japan) may limit their use in some studies.

JAPAN

In Japan, institutions such as the National Cancer Center Japan and JMDC are in the process of implementing or have implemented the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) to facilitate collaborative research. However, these efforts remain largely localised and not coordinated on a national or regional level.

SOUTH KOREA

In South Korea, top-tier healthcare institutions have either set-up clinical data warehouses or utilised common data models within their institutions' network to enable real-world research and maintain high data quality. However, these initiatives are primarily confined to individual institutions, and efforts would be required to standardise data across multiple sites for broader studies.

3.4
Lack of transparency and guidelines

A review of two mature HTA agencies and the existing guidelines and tools applicable for each phase of the process revealed the lack of guidance on the RWE assessment criteria from the payers' perspective (APPENDIX II). Similarly, an assessment of HTA guidelines across the target countries also revealed a lack of clarity on how RWE can impact decision-making. While there are cases of adoption of RWE to support decision-making for medical technologies, there is no consistency in how RWE is being assessed and recommended across countries. Thus, there is a need for HTA bodies to shed light on their decision-making process regarding RWE.

4 PAYER'S DECISION-MAKING BASED ON RWE

ROBUST RWE CAN SUPPORT ADOPTION OF TECHNOLOGY EVEN IN THE ABSENCE OF RCTS

In this section, three case studies from the National Institute for Health and Care Excellence (NICE) in the UK are presented to highlight how RWE can be utilised to support payer's decision-making in the absence of RCTs in medical technologies. We will also present successful use of RWE to support payer's decision-making via coverage with evidence development (CED) program in South Korea. CED, with its origins from the US, is a conditional coverage and payment program that allows timely access to new medical technologies while concurrently generating evidence to further validate their clinical and economic value.

4.1 NICE Case studies

4.1.1 Case study 1: ENDURALIFE powered cardiac resynchronisation therapy-defibrillator (CRT-D) devices for treating heart failure (9)

Background

CRT-Ds are a treatment option for heart failure and life-threatening ventricular arrhythmias. NICE concluded that there is good evidence to support the clinical benefit of longer battery life and the associated reduction in CRT-D replacements and encouraged further studies that provide data on the battery life of different CRT-Ds, including an analysis of currently available UK National Health Service (NHS) clinical data. The applicant's CRT-D was recommended by NICE for adoption in 2017.

Evidence considered

The External Assessment Centre (EAC) considered the key clinical outcomes, including device survival, battery survival, number of invasive procedures including CRT-D replacements, incidence of complications after replacement procedures, device-related adverse events, patient satisfaction, and quality of life. It assessed six published observational studies (including two conference abstracts) on ENDURALIFE-powered CRT-D battery life, five product performance reviews, and six studies on adverse events arising from cardiac device replacement (three systematic reviews, one healthcare claims database study, one study using a database study that prospectively collected data from Sponsor's devices (ALTITUDE), one retrospective multicentre cohort study).

Review to update the guidance did not find contrary evidence from newly published studies

Since the publication of the guidance in 2017, there was a review in 2021 to update the guidance. The review found an additional 14 studies on the use of ENDURALIFE since 2017, of which one was a systematic review that included two RCTs, five retrospective studies, and 30 retrospective studies for adverse events associated with CRT-D replacement, eight observational studies for adverse events associated with CRT-D replacement, one technical report, three comparative studies for projected battery survival, and one economic study. The new evidence supported the clinical conclusions from the original guidance.

Key takeaways

- RWE is a useful source of evidence to validate a product's value, especially in medical technologies where RCTs are less common as compared to in pharmaceuticals
- Well-designed real-world studies can generate evidence that are consistent with RCTs and other real-world studies

4.1.2
Case study 2: PeritX peritoneal catheter drainage system for vacuum-assisted drainage of treatment-resistant, recurrent malignant ascites (10)

Background

The PeritX peritoneal catheter drainage system is intended for use in the management of treatment-resistant, recurrent malignant ascites (accumulation of fluid in the peritoneal cavity) in the community setting. Clinical evidence shows that the PeritX peritoneal catheter drainage system is effective and may improve the quality of life of some people with cancer, by enabling early and frequent treatment of symptoms of ascites in the community, rather than waiting for inpatient treatment. NICE recommended the device as an option for drainage of treatment-resistant, recurrent malignant peritoneal ascites in 2012.

Evidence considered

The EAC considered the key clinical outcomes, including technical success of catheter insertion and drainage procedure, resolution of symptoms, quality of life outcomes, adverse events, drainage frequency, and resource use outcomes. It assessed nine observational studies, two of which were conducted in the UK. Six studies were case series with 10 or more patients, one study was a qualitative case series (four patients), and there were three case reports (four or fewer patients).

NICE's other considerations

Evidence was based on observational studies, with very limited data available comparing the PeritX peritoneal catheter drainage system with other treatments. At the time of evidence review, there were two ongoing clinical trials using the PeritX peritoneal catheter drainage system.

Key takeaways

- RWE can enable appropriate and faster decision-making by HTA bodies instead of withholding a positive decision until further clinical studies are available years later
- High quality or well-designed real-world studies can provide HTA bodies with necessary evidence required for decision-making

4.1.3 Endo-SPONGE for treating low rectal anastomotic leak (11)

Background

Endo-SPONGE is a minimally invasive surgical treatment for anastomotic leak in the low rectal area. It is designed to improve the clearance of leaking discharge in the anastomotic cavity and to promote granulation tissue formation and healing. NICE has not published guidelines on rectal anastomotic leak and clinical experts have said that there is no standard care pathway. Treatment is based on several factors including the patient's overall condition, the anastomotic defect size and location, the indication for primary resection and the presence of a proximal stoma. The applicant's technology was not recommended for adoption.

Evidence considered

The EAC assessed two retrospective comparative studies, 14 retrospective case series, three case series (not reported if retrospective or prospective), and one prospective case series. The evidence base consisted of published studies and three abstracts, and three studies were conducted in the UK. The quality of the evidence was assessed to be very low. There was a high risk of bias because of the retrospective study design and small sample sizes. There was also clinical heterogeneity among patients across the studies and inconsistent definitions of outcomes and other key variables reported.

While the EAC considered the evidence relating to Endo-SPONGE to be uncertain and variable, it also considered the evidence to be reflective of the clinical uncertainty and variation in practice when treating anastomotic leaks. Clinical experts also advised that patients' quality of life (QoL) was an important outcome, but only two studies reported patient outcomes that included patient acceptability and functional bowel recovery. Thus, more RWE is needed to understand the impact of the technology on patients' health-related QoL.

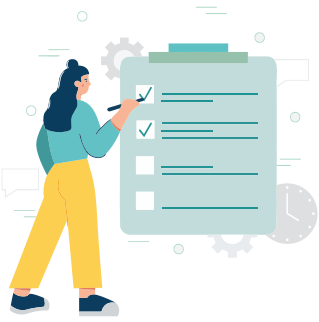
NICE's recommendations

Although the applicant's technology was not recommended for adoption, NICE noted that the Endo-SPONGE showed promise for treating low rectal anastomotic leaks. However, there was not enough good-quality evidence to support the case for routine adoption in the UK's NHS.

NICE recommended to gather further evidence in the form of RWD collection to address uncertainties about selection criteria, patient-reported outcome measures, stoma reversal and bowel function recovery compared with other treatments. NICE noted that it is not practical to conduct a RCT as the target patient groups in which Endo-SPONGE might be suitable are small. A national registry, to collect RWD, would help resolve uncertainties including the selection criteria for patients who could benefit from Endo-SPONGE, comparative rate of stoma reversal and bowel function recovery using Endo-SPONGE compared with other treatments, patient-reported outcome measures such as health-related QoL, and the cost of Endo-SPONGE compared with other treatments for anastomotic leak.

Key takeaways

- RCTs are impractical for small patient groups, reinforcing the importance of RWE in niche conditions
- The quality of RWE and understanding which outcomes matter to HTA bodies in their evaluations are important
- Understanding the key clinical outcomes of interest to HTA bodies through pre-consultations would ensure that the necessary data and evidence can be collected and generated through studies
- Following initial rejection, there should be an opportunity for HTA bodies, applicant, and clinicians to co-design a RWE study protocol to avoid and remove ambiguities which will lead to more confidence in the RWE and the decision making.



4.2
Successful use of RWE in APAC: Coverage with Evidence Development (CED) program in South Korea

4.2.1
"Conditional Selective Benefit" (CSB) Program in South Korea

The CSB program is a type of CED program introduced in 2014 to provide preliminary benefits for services and items that required additional evidence to demonstrate its safety, effectiveness, or cost-effectiveness but has potential benefit to patient care (12). Technologies can be selected as CSB items if the delivered technology is classified as high risk to patients, requires a sophisticated procedural technique, and the supporting evidence for coverage determination are insufficient. Only healthcare providers that meet the specific requirements, including prerequisite clinical experience with the technology and possessing physician and facility qualification, are permitted to use the CSB services and items for their patients. These healthcare providers have an obligation to generate and submit the clinical data of their patients treated with the technologies to HIRA.

Example: Transcatheter aortic valve replacement (TAVR)

TAVR, a minimally invasive technology treating symptomatic aortic stenosis (AS), was the first CSB item selected by the MoHW/HIRA. A national registry was established to collect outcomes data and an advisory group comprising of clinical experts and experts in research methodology and statistics was established for the development and implementation of the TAVR registry protocol. As part of the CSB program, reassessments were required every five years to determine whether the CSB needs to be maintained or transformed into formal reimbursement coverage benefit without any conditions for evidence collection. In the case of TAVR, a positive CSB determination was made in 2015 after a thorough review of the clinical and economic benefit of TAVR to patients with AS and has since been a part of the national health insurance coverage.

5 KEY RECOMMENDATIONS FOR APAC MARKETS

As RWE gains increasing recognition for their value in decision-making, there is a clear opportunity for governments and decision-making agencies to lead impactful change. Informed by the key regional challenges and insights from the case studies, we recommend three actionable priorities to unlock the full potential of RWD and accelerate more agile, evidence-based payer decisions across APAC.

KEY RECOMMENDATIONS FOR APAC MARKETS

CLEAR GUIDANCE ON RWD USE

Establish clear criteria on acceptable local data sources and ensure that RWD is evaluated for its fit-for-purpose use in generating appropriate RWE to support decision-making for medical technologies

STRENGTHEN COMMUNICATION & COLLABORATION

Promote early and continuous engagement between HTA agencies and industry to align on evidence requirements and improve the quality and relevance of submissions

IMPROVE ACCESS TO QUALITY, AND AVAILABILITY OF LOCAL DATA SOURCES

Enhance the private sector's ability to access local health data through secure, ethical, and policy-supported mechanisms to strengthen RWE generation while improving the quality and availability of local data sources

5.1
Clear Guidance on RWD Use

HTA authorities could develop and clearly communicate transparent, uniform guidelines for evaluating RWE in decision-making processes. These guidelines should include the specification of preferred study methodologies, acceptable data sources, tools used in evaluation, and essential outcome indicators, incorporating international best practices. At the same time, guidelines should avoid being overly prescriptive so that the use of RWE stays flexible. This is particularly important with the rapid proliferation of digital tools, SaMD, and AI technologies driven by advancements in information technology and machine learning. It is increasingly crucial for manufacturers to generate robust and appropriate evidence from the outset.

In addition, HTA authorities could publish illustrative case studies that showcase the successful use of RWE in decision-making, which is currently lacking in APAC. These case studies could serve as practical reference points, highlighting key methodologies, outcomes, and recommendations. By sharing such case studies, HTA authorities can provide medical technology companies and other stakeholders with clearer expectations and encourage the adoption of best practices across diverse healthcare settings.

5.2
Strengthen Communication & Collaboration

To ensure RWE meets stakeholder needs, structured and collaborative engagement among HTA bodies, medical technology companies, and clinicians should be highly promoted. This collaboration could focus on co-designing RWE studies that address specific evidence gaps and align with payer expectations.

Furthermore, early phase consultations between medical technology companies and HTA bodies can be established to align RWE study designs with payer requirements. This proactive communication will reduce ambiguity, foster trust in RWE, and facilitate the generation of high-quality and relevant evidence that addresses payer priorities, enabling timely access of cost-effective diagnostics and treatment to patients.

5.3
Improve Access to, Quality, and Availability of Local Data Sources

Efforts can be focused on reducing legal and financial barriers to data access—such as restrictive privacy regulations and high data acquisition costs—while maintaining rigorous data privacy and security standards. One approach would be to consider increasing access to de-identified or aggregated data, which would maintain data privacy standards (such as the HIRA claims database). By improving access to high-quality RWD, stakeholders will be better positioned to generate robust RWE that meets the evidentiary requirements of payers and HTA bodies.

To improve the quality and availability of local RWD, governments and/or regulatory agencies could also establish comprehensive, standardised protocols for data collection, linkage, and utilisation. These protocols will prioritise uniform data models and outcome measures to ensure consistency, comparability, and reliability across diverse RWD sources. Concurrently, the protocols should be flexible and adaptable to the characteristics of the target population, allowing room for contextual adjustments rather than standardisation/one-size-fits-all. The public and private sectors could collaborate and leverage on these protocols to establish databases for the generation of high-quality RWE.

6 CONCLUSION

While this paper focuses on the value of RWD/RWE, it is important to note that it does not advocate for the disregard of evidence from RCTs. RCTs remain the gold standard for generating robust clinical evidence, but it may be challenging or unethical to conduct trials for all medical technologies. In such cases, RWE provides an invaluable alternative, offering meaningful insights into the effectiveness and safety of the medical technology in routine clinical practice. By recognising RWE as a credible and complementary source of evidence, decision-makers can ensure more comprehensive and contextually relevant assessments of medical technologies.

Although the recommendations in this paper are mainly aimed at decision-makers, it is important to recognise that the successful adoption and integration of RWE into decision-making relies on the collective engagement and involvement of all stakeholders. Manufacturers, clinicians, patients, and decision-makers each play a vital role in the generation, interpretation, and application of RWD. Only through collaborative efforts can the full value of RWE be realised.

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8 APPENDIX I

TABLE 7

CRITERIA FOR EVALUATING THE KEY ELEMENTS THAT DESCRIBE THE RWD/RWE LANDSCAPE IN TARGETED APAC COUNTRIES, CANADA, AND THE UK

Factor	Description
Formal recognition of the value of RWE	Availability of published documents from government, government-related agencies or HTA bodies that describe the value/utility of RWE ***OR*** Government, government-related agencies or HTA bodies' acknowledgement of the value/utility of RWE
Availability of RWD/RWE-related frameworks/guidelines	Availability of published documents that relate to frameworks or guidelines for the use of RWD/RWE
Specific RWD/RWE-related frameworks/ guidelines for medical technologies	Availability of published documents that relate to frameworks or guidelines for the use of RWD/RWE specifically for medical technologies
Government-led data infrastructure/coordination for RWD access or collection	Establishment of national databases that collect RWD or platforms that facilitates RWD access for health-related research and is accessible to both public and private sectors ***OR*** Establishment of legislation to govern the collection of or access to RWD
Acceptance of RWE as primary evidence for decision-making in cases where RCT data is not available	Availability of published documents that describe the acceptance of RWE as primary evidence for regulatory or reimbursement decision-making in cases where RCT data is not available ***OR*** Examples from regulatory or HTA reports where decisions were made based on RWE alone

Abbreviations: HTA, health technology assessment; RCT, randomized controlled trial; RWD, real-world data; RWE, real-world evidence.

TABLE 8

RELEVANT REFERENCES OF THE KEY ELEMENTS THAT DESCRIBE THE RWD/RWE LANDSCAPE IN TARGETED APAC COUNTRIES, CANADA, AND THE UK

FACTOR	Australia	Japan	Singapore	South Korea	Canada	United Kingdom
Formal recognition of the value of RWE	(3)	(13)	NA	Roadmap to utilize RWD/RWE for regulatory use	(14)	(15-17)
Availability of RWD/RWE-related frameworks/guidelines	(18-19)	(20-22)	(23)	(24-25)	(26-27)	(16,28,29)
Specific RWD/RWE-related frameworks/guidelines for medical technologies	(18)	(22)	(23)	NA	(30)	NA
Government-led data infrastructure/coordination for RWD access or collection	(31)	NHIA	(32)	HIRA and NHIS databases	NA	(33)
Acceptance of RWE as primary evidence for decision-making in cases where RCT data is not possible to obtain	(34)	(35-36)	(37)	NA	(27)	(9)

Abbreviations: HIRA, Health Insurance Review and Assessment; HTA, health technology assessment; NA, not available; NHIA, Next-generation Healthcare Infrastructure Act; NHIS, National Health Insurance Service; RCT, randomized controlled trial; RWD, real-world data; RWE, real-world evidence.

9 APPENDIX II

9.1 HTA assessment of medical technologies in Ontario, Canada and the UK

Canada's Ontario Health and UK's NICE have published guidance documents detailing the processes and methods involved in conducting HTA and the subsequent development of recommendations for funding (38–40). The guidance documents released by NICE are specific for medical technologies, while that of Ontario Health includes all health technologies. For ensuring comparability of the review, "medical technology" will be used throughout this section.

For both agencies, the assessment of a medical technology will undergo three key phases, namely defining the scope of the assessment, evaluating the evidence, and making a recommendation. Each phase will be described in greater detail in the following subsections.

9.1.1 Phase 1: Defining the scope

For both Ontario Health and NICE, the scope provides a framework for assessing the medical technology and is based on the applicant's submission. However, the two agencies consider different elements when defining the assessment scope (Table 9).

TABLE 9

ELEMENTS CONSIDERED BY NICE AND ONTARIO HEALTH WHEN DEFINING ASSESSMENT SCOPE

Element	Ontario Health	NICE
Target population	✓	✓
Medical technology	✓	✓
Comparator(s)	✓	✓
Outcomes (includes both clinical and system outcomes)	✓	✓
Regulatory status of the medical technology	✓	✓
Timing and setting	✓ Specific time/phase when the technology is administered to patients and/or the setting in which the medical technology is used	
Local context	✓ Involves the input of clinical experts, patients, and other stakeholders that will provide an understanding of how the medical technology is used or could be used, and how the target population is currently managed	✓ Professional and patient organisations and societies who will provide comments on the medical technology will be listed
Expert consultation		✓
Minimizing duplication of efforts	✓ Leveraging on existing systematic review of clinical literature and/or published economic evaluations	
Collaboration	✓ Depending on the nature of the HTA and the research questions, may collaborate with other Pan-Canadian HTA agencies to develop all or part of the HTA	
Health equity considerations	✓ Determination of whether potential health equity factors may be relevant to the HTA based on PROGRESS-Plus framework	
Equality considerations		✓ Determination of how the medical technology guidance may affect equality

Abbreviation: HTA, health technology assessment; NICE, National Institute for Health and Care Excellence.

9.1.2
Phase 2: Evaluating the evidence

Ontario Health and NICE both consider evidence from clinical, economic, and patient perspectives. Table 10 summarises the sources of evidence used by Ontario Health and NICE.

TABLE 10 SOURCES OF EVIDENCE CONSIDERED BY ONTARIO HEALTH AND NICE

Evidence Type	Ontario Health	NICE
Clinical	• Published literature/evidence (includes both RCTs and analysis of RWD) • Grey literature	• Published literature/evidence (provided by applicant and through literature review by EAC) • Unpublished literature evidence submitted by applicant or identified by EAC • Expert advisers
Economic	Published literature/evidence	
Patient	• Qualitative or quantitative literature review • Direct patient engagement	Insights provided by patient and carer organisations

Abbreviation: EAC, external assessment centre; HTA, health technology assessment; NICE, National Institute for Health and Care Excellence; RCT, randomised controlled trial; RWD, real-world data.

Ontario Health assesses the risk of bias for each published study contributing clinical evidence, using assessment tools appropriate for the study type, and assesses the quality of the body of evidence using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) criteria. It also assesses the applicability and quality of published studies contributing economic evidence using a modified applicability checklist for economic evaluations originally developed by NICE. There was no mention of determining the quality of published studies and quality of evidence in NICE's guidance.

Ontario Health is responsible for conducting the literature review, data synthesis and meta-analysis of clinical evidence. It is also responsible for reviewing and summarising the available economic literature pertaining to the medical technology. Based on the results of the economic evidence review and preliminary insights from the clinical evidence review, Ontario Health will determine if it is necessary to conduct a primary economic evaluation or proceed with a budget impact analysis.

On the other hand, for NICE, applicants are responsible for conducting the literature search, evidence synthesis, and developing economic models, usually for cost-consequence analyses, as part of their submission. The EAC will validate the literature search to support its critical appraisal of the evidence in the assessment report.

9.1.3
Phase 3: Making a recommendation

Ontario Health's recommendations are guided by a decision determinants framework, which provides considerations for developing a recommendation (41). The determinants do not have a hierarchy, and the relative weight of each determinant is specific to the medical technology being assessed.

Ontario Health's considerations for recommending funding

1. Overall clinical benefit in terms of effectiveness, safety, burden of disease, and need for the medical technology
2. Patient preferences and privacy
3. Equity of access or outcomes and patient care
4. Cost-effectiveness of the medical technology
5. Economic and organizational feasibility of adoption of the medical technology into the health system

NICE considers the potential benefits to patients and to the health and social care system and makes recommendations based on the clinical and economic evidence, and inputs from expert advisers and patient and carer organisations (Table 11).

TABLE 11 TYPES OF RECOMMENDATIONS MADE BY NICE AND THE COMMON SCENARIOS IN WHICH THE RECOMMENDATIONS ARE MADE

Type of recommendation	Scenario
Recommendation for use of medical technology	• There is sufficient certainty that the medical technology has at least equivalent clinical and/or health and social care system benefits compared with current management, and uses less resources overall • There is sufficient certainty that the medical technology has significantly greater clinical and/or health and social care system benefits compared with current management, and uses similar resources overall
Recommendation for development of further evidence	When technologies are not supported by adequate evidence of clinical utility to allow a comprehensive evaluation
Recommendations for use in a research context	The medical technology has the potential to provide substantial benefits to patients and/or of releasing significant resources but the case for adoption is not fully supported and there is uncertainty about whether these benefits are realisable in normal clinical settings
Case for adoption not supported	Applicant's case for adoption is not supported by the evidence and the contributions from expert advisers and patient organisations

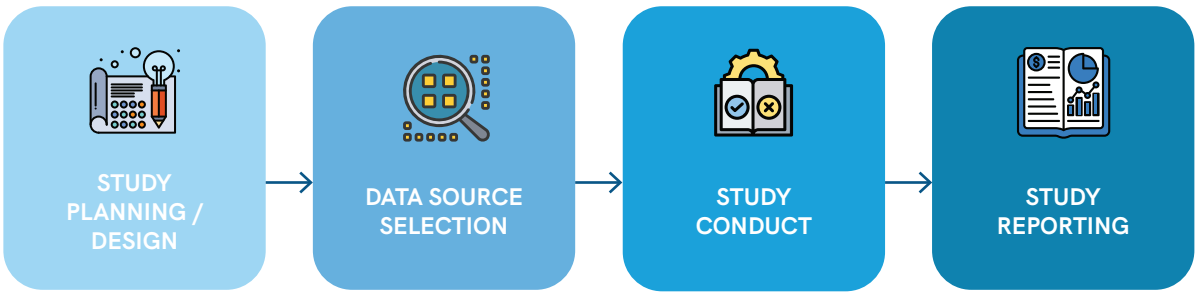
9.1.4
Summary

A review of the HTA methods utilised by Ontario Health and UK NICE, both mature HTA agencies, revealed differences in each of the three phases of the HTA. Elements considered for defining the scope of the assessment were similar in key areas such as defining the target population, medical technology, comparators, and outcomes, but differed in other aspects which may be deemed to be specific to the agency. In terms of evaluation of the evidence, Ontario Health conducts its own search and synthesis of the relevant evidence while in NICE, the applicant is responsible and the EAC validates the evidence with its own separate review. Considerations in making a recommendation also differed between the two agencies. One notable observation was the lack of clarity in the guidance on how RWD/RWE weighed into the decision-making. While Ontario Health reported assessing the risk of bias of published studies using appropriate tools, it is not known how the quality of studies would impact decision-making. NICE has its own RWE framework but it does not provide clarity on how the use of RWE would impact its decision-making (42). These findings point to the existence of country- and/or agency-specific considerations, which account for the local landscape and the role and function of the agency within the country. Thus, to date, there have not been a single harmonised set of assessment methods used by different HTA agencies.

9.2
Quality of RWD/RWE

One of the key barriers to the adoption of RWD/RWE in payer decision-making is the quality of RWD which would impact the quality of RWE generated. The generation of RWE involves a scientific process from study planning/design to study reporting, and it is important to ensure the quality and/or appropriateness of data and methods used in each phase of the process to ensure the generation of high-quality RWE (Figure 4).

FIGURE 4 SCIENTIFIC PROCESS FOR RWE GENERATION



9.2.1
Study planning/design phase

The study planning/design phase is a very important phase, even though there are no RWD collected, as it will drive the collection of RWD and generation of RWE in later phases. An appropriate study design should be selected for the research question of interest, and all aspects of the study design from defining the population of interest to analytical methods used should be detailed in a study protocol. It is recommended in several guidelines that investigators register their studies, and the study protocol published on publicly available platforms to increase transparency and enable reproducible research.

AVAILABLE GUIDELINES AND TOOLS

1
AHRQ Developing a protocol for observational comparative effectiveness research (43)

2
HARmonized Protocol Template to Enhance Reproducibility of Hypothesis Evaluating Real-World Evidence Studies on Treatment Effects: A Good Practices Report of a Joint ISPE/ISPOR Task Force (44)

3
Improving Transparency to Build Trust in Real-World Secondary Data Studies for Hypothesis Testing—Why, What, and How: Recommendations and a Road Map from the Real-World Evidence Transparency Initiative (45)

4
Reporting to Improve Reproducibility and Facilitate Validity Assessment for Healthcare Database Studies V1.0 (46)

5
Real-world studies for the assessment of medicinal products and medical devices (47)

6
Guidelines for good pharmacoepidemiology practice (48)

7
ENCePP Checklist for study protocols (49)

8
ENCePP guide on methodological standards in pharmacoepidemiology (50)

9
STaRT-RWE: structured template for planning and reporting on the implementation of real world evidence studies (51)

10
NICE real-world evidence framework (42)

11
CADTH Guidance for reporting real-world evidence (52)

12
CMS proposed guidance document for study protocols that use real-world data (53)

9.2.2
Data source selection

This phase involves identifying candidate data sources which can potentially address the research question in terms of the study population and availability of key variables as specified in the protocol. The candidate data sources are subsequently assessed based on fit-for-purpose, which may include elements such as data reliability, data relevance, data provenance, and timeliness. It is important for the data source to be able to provide fit-for-purpose data as this will have an impact on the RWE generated.

The definition of fit-for-purpose data varies across guidance documents and should be defined prior to selection of suitable data sources for use in the study.

ELEMENTS COMMONLY CONSIDERED IN DEFINING FIT-FOR-PURPOSE

1. Data reliability (accuracy, completeness)
2. Data relevance (availability, representativeness)
3. Data quality (bias, accuracy, completeness)
4. Data extensiveness (volume of data)
5. Coherence
6. Timeliness
7. Data access
8. Data coverage
9. Data governance

AVAILABLE GUIDELINES AND TOOLS

1
The Structured Process to Identify Fit-For-Purpose Data: A Data Feasibility Assessment Framework (54)

2
Use of electronic health record data in clinical investigations (55)

3
Guidelines for good database selection and use in pharmacoepidemiology research (56)

4
Determining real-world data's fitness for use and the role of reliability (57)

5
Guidelines for good database selection and use in pharmacoepidemiology research (58)

6
NICE Data Suitability Assessment Tool (DataSAT) (42)

7
Checklist for the conduct of studies on routinely collected databases (RECORD) (59)

8
CADTH Guidance for reporting real-world evidence (52)

9
EMA Guideline on registry-based studies (60)

10
Registry Evaluation and Quality Standards Tool (REQueST) (61)

11
Khan Data Quality Assessment Terminology and Framework for Secondary use of EHR Data (62)

12
National Evaluation system for health Technology coordinating centre (NESTcc) Data Quality framework (63)

9.2.3
Study conduct

This phase comprises of activities related to the curation of a research-specific dataset for analysis and the analysis of RWD. These activities should be carried out in accordance with that outlined in the study protocol, and any deviations should be documented. Robustness of findings should be assessed through sensitivity and subgroup analyses, and quantitative bias analysis conducted if residual bias is high. An assessment of the bias and quality of results may be conducted after analysis is completed.

AVAILABLE GUIDELINES AND TOOLS

1
ENCePP guide on methodological standards in pharmacoepidemiology (50)

2
Good research practices for comparative effectiveness research: analytic methods to improve causal inference from nonrandomized studies of treatment effects using secondary data sources: the ISPOR Good Research Practices for Retrospective Database Analysis Task Force Report-Part III (64)

3
NICE real-world evidence framework (42)

4
ROBINS-I tool to assess risk of bias in non- randomised studies of interventions (65)

5
GRACE checklist for rating the quality of observational studies (66)

9.2.4
Study reporting

In terms of reporting of study results, it is essential that sufficient details are provided such that the findings are reproducible and can be validated during regulatory and HTA assessments. Any deviations from the study protocol should be clearly documented and results should be discussed and interpreted within the clinical context. A clear reporting structure would also minimise data misinterpretation.

AVAILABLE GUIDELINES AND TOOLS

1
STaRT-RWE: structured template for planning and reporting on the implementation of real world evidence studies (51)

2
CADTH Guidance for reporting real-world evidence (52)

3
The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) statement (67)

4
The reporting of studies conducted using observational routinely collected health data statement for pharmacoepidemiology (RECORD-PE) (68)

5
Strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies (69)

6
Checklist of the ENCePP Code of Conduct (70)

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