Commentary

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Real-world data for health technology assessment for reimbursement decisions in Asia: current landscape and a way forward

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There is growing interest globally in using real-world data (RWD) and real-world evidence (RWE) for health technology assessment (HTA). Optimal collection, analysis, and use of RWD/RWE to inform HTA requires a conceptual framework to standardize processes and ensure consistency. However, such framework is currently lacking in Asia, a region that is likely to benefit from RWD/RWE for at least two reasons. First, there is often limited Asian representation in clinical trials unless specifically conducted in Asian populations, and RWD may help to fill the evidence gap. Second, in a few Asian health systems, reimbursement decisions are not made at market entry; thus, allowing RWD/RWE to be collected to give more certainty about the effectiveness of technologies in the local setting and inform their appropriate use. Furthermore, an alignment of RWD/RWE policies across Asia would equip decision makers with context-relevant evidence, and improve timely patient access to new technologies. Using data collected from eleven health systems in Asia, this paper provides a review of the current landscape of RWD/RWE in Asia to inform HTA and explores a way forward to align policies within the region. This paper concludes with a proposal to establish an international collaboration among academics and HTA agencies in the region: the **REAL** World Data **I**n **AS**ia for H**E**alth Technology Assessment in Reimbursement (**REALISE**) working group, which seeks to develop a non-binding guidance document on the use of RWD/RWE to inform HTA for decision making in Asia.

Background

There is growing interest globally in using real-world data (RWD) and real-world evidence (RWE) for regulatory and reimbursement decision making for health technologies. This is because RWD, defined as data collected during routine delivery of health care (1) (e.g. electronic medical records (EMR), claims and billing activities, product and disease registries, patient-generated data), and RWE, defined as evidence derived from the analysis of RWD

(1), have shown several potential benefits in informing health-related decision making. Such benefits include, but are not limited to, reducing time and cost if population-specific data are required and sufficient local evidence is lacking from available trials (2), providing evidence with higher external validity compared to randomized controlled trials (RCTs) (3), giving decision makers more certainty of the effectiveness and safety of technologies in the local setting (4), and filling the information gap in the absence of clinical trials (e.g. when it is not feasible or ethical to conduct a trial, or there is significant unmet need) (5).

RWD are particularly relevant in Asia where there is often a greater reliance on clinical effectiveness data from non-clinical trial sources (such as observational studies or disease registries) for regulatory and reimbursement purposes than in the United States or Europe for two reasons. First, only around 17% of the clinical trials are conducted in Asia (6) due to barriers related to financial and human capacity, ethical and regulatory systems, lack of research environment, and operational issues (7). Second, there could be an under-representation of Asian population in pivotal RCTs (6;8). These reasons are crucial because medical treatments need to reflect the biological variations, for example, differences in body weight or pharmacokinetics and/or pharmacodynamics due to different genetic makeups between Caucasians and Asians (9), and the non-biological variations, for example, differences in local clinical practice guidelines driven by budget and resource constraints. For example, in health systems with larger budgets such as the UK (10), the use of high cost biologic agents as first- or second-line therapies for rheumatoid arthritis is recommended in line with their registered indications, supported by clinical trial data. However, in Thailand, due to concerns over the sustainability of reimbursing these high cost drugs, biologic agents are only recommended as third-line therapies for rheumatoid arthritis (11). Therefore, the results from trials conducted in other health systems may not be easily generalizable to countries when they do not address the use of these agents in the same line of therapy.

In many Asian health systems (e.g. China, India, Indonesia, Malaysia, Philippines, Singapore, and Thailand), reimbursement decisions are currently made up to several years after market entry. In this time, drugs can be prescribed by physicians and are paid for like any other non-subsidized drugs, out of pocket or through private insurance coverage. The delay to reimbursement provides these health systems with an opportunity to accumulate local clinical effectiveness data from other RWD sources to inform subsequent decision making. This not only provides more certainty around the likely effect of the technology in the local population, but has the additional benefit of allowing longer-term effectiveness and safety data to be collected beyond the initial clinical trial period, which is particularly relevant for technologies where adverse events may take time to develop or are so rare that they are not detected until a sufficiently large number of patients have used the technology. In other Asian health systems (e.g. Japan, Taiwan, and South Korea), reimbursement decisions coincide with or closely follow the timing of market entry shortly after regulatory approval. In these health systems, RWD and RWE are usually considered when re-assessing initial funding decisions or for price adjustment. Regardless of the timing, RWD and RWE have important roles to play in reimbursement decisions. Hence, RWD collected in these instances need to be carefully managed and analyzed.

Despite a high level of interest by different stakeholders in the use of RWD/RWE, there is still no clear consensus between countries about when and how it should be incorporated into existing health technology assessment (HTA) processes. Among the health systems worldwide that already use RWD/RWE for reimbursement purposes, most rely on it to supplement clinical trial data; however, there is still considerable variation in how it influences decision making, leading to differences in reimbursement outcomes (12). Although some frameworks for the use of RWD/RWE have been developed (13), the uptake of these frameworks in Asia has been limited and this may be due in part to the need to contextualize the framework to local settings. The HTA systems in Asia differ largely from those in North America, Europe, and Australia and there is significant variation even within Asia. Aligning practices within the region on how to generate and use RWD/RWE across different contexts would serve to equip decision makers with relevant evidence to inform local reimbursement decisions, provide manufacturers with guidance on evidence they need to deliver, and enable timely patient access to new and cost-effective technologies.

This paper describes the current landscape of RWD/RWE in Asia based on responses from eleven health systems collected through an online survey and face-to-face discussions carried out among members of HTAsiaLink, a network of HTA agencies in Asia (14). We aim to propose a way forward to better harness the value of RWD/RWE in informing reimbursement/re-assessment decisions.

Methods

We conducted three activities, namely an online survey, followed by a face-to-face meeting, and a teleconference, to gather personal and health system level experiences of using RWD/RWE to inform HTA for reimbursement decisions in eleven health systems in Asia (Bhutan, China, India, Indonesia, Japan, Malaysia, Philippines, Singapore, South Korea, Taiwan, and Thailand). The online survey was developed by the National University of Singapore (NUS) and Health Intervention Technology Assessment Program (HITAP), and it was divided into five sections: (i) background information on respondent; (ii) current practice with regards to the use of RWD/RWE for HTA for reimbursement decisions; (iii) current practice with regards to pragmatic clinical trials; (iv) challenges encountered in RWD/RWE generation; and (v) availability of a local guidance document on RWD/RWE generation. The opportunity to participate was advertised during HTAsiaLink 2019 and responses were voluntary. If a country did not have any responses, contacts from that country in HTAsiaLink were requested to complete the survey. The survey was launched after the HTAsiaLink meeting in April and remained open until June 2019. Fourteen representatives from eleven countries answered the survey. The full version of the questionnaire is provided in Supplementary File 1. The face-to-face meeting was held on 27 April 2019 in Seoul following the eighth HTAsiaLink meeting and was attended by twenty representatives from eleven health systems in Asia, three international advisory panel (IAP) members from Canada, UK, and Australia, and ten observers from five other health systems. Chatham House rules were observed. The participants comprised of leaders or technical staff from HTA agencies or academia as well as clinicians with experience in conducting HTA or clinical trials. Most participants were involved in all three activities, except for members of the IAP who were only involved in the face-to-face meeting. Most of the participants had personal experiences in collecting, analyzing, or evaluating clinical effectiveness data from RWD sources for

Table 1. Background of participants who completed the online survey, face-to-face meeting, and teleconference

	Online survey	In-person meeting	Teleconference
Time	April–June 2019	27 April 2019	3 June 2019
No. of health systems represented	11[a]	14[b]	7[c]
No. of participants	14	33	11
Percentage of participants that are also involved in at least one of the other two activities	40%[d]	42%[d]	73%[d]

[a]Bhutan, China, India, Indonesia, Japan, Malaysia, Philippines, Singapore, South Korea, Taiwan, and Thailand.
[b]Australia, Bhutan, Canada, China, India, Indonesia, Japan, Malaysia, Philippines, Singapore, South Korea, Taiwan, Thailand, and United Kingdom.
[c]Australia, China, Japan, Philippines, Singapore, Taiwan, and Thailand.
[d]These values might be under-estimated because six of the survey respondents did not provide their personal information.

HTA. Eight presentations by the IAP members and Asian health system representatives were made during the meeting which were followed by discussions among all participants. A follow-up teleconference was held on 3 June 2019, beginning with a presentation about how RWE informed a specific policy change in Australia, followed by a discussion among eleven representatives from seven health systems about similarities and differences between how RWD/RWE is used to inform HTA in other Asian health systems.

Results

Table 1 summarizes the background of the individuals who completed the online survey and participated in the face-to-face meeting and teleconference.

Findings from the Online Survey
(i) Use of RWD/RWE in HTA

From the online survey, all respondents reported that their HTA agencies accept RWE either as standalone or supplementary evidence to estimate clinical effectiveness in local HTAs to inform reimbursement (Table 2). Seven health systems require explicit justification for the use of RWE to be included in the HTA dossier, while four health systems waive this requirement. Respondents confirmed that RWE from a variety of patient populations has already been submitted to inform reimbursement decisions for specific technologies in areas such as rare diseases, cancers, and immunology, among others. Several of the respondents indicated that RWE from other health systems is acceptable although local data are preferred. Nonetheless, any RWD should be collected systematically and transparently so that the RWE can be validated and undergo quality assessment. Seven of the health systems currently accept data from pragmatic clinical trials (PrCT) (15); the remaining four health systems indicated that they plan to accept such data over time, but not within the next six months. Some health systems only consider RWE or data from PrCT as supplementary evidence to clinical trial data, or on a case-by-case basis when clinical trial data are lacking (e.g. for rare diseases).

One-third of the survey respondents have encountered situations where clinical trial data are not available and they have made reimbursement decisions solely on clinical effectiveness data from other sources such as registries and observational studies. This predominantly occurred when it was unethical to conduct a clinical trial for the technology under assessment, or when the condition was very rare and there were insufficient patients to conduct a trial. For example, in one health system, the decision to reimburse cholic acid for the treatment of primary bile acid synthesis disorder (a very rare disorder) was informed by a case series.

(ii) Challenges in using RWD/RWE

Table 3 summarizes the key challenges encountered by HTA agencies when using RWD/RWE for HTA. It was most commonly reported that there was insufficient evidence in the HTA dossier that the patients selected to generate the RWE truly reflect the patients in local routine clinical care, hence giving rise to potential selection bias, and reducing the external validity of the results. A large number of respondents also indicated that many HTA dossiers did not clearly report if the patients in the RWD studies were receiving other treatments or had other comorbidities. In addition, some respondents felt that they may not have the expertise to evaluate whether confounding had been properly accounted for when assessing RWD/RWE.

(iii) Availability of RWD/RWE guidance documents in Asia

We asked respondents if they had guidance documents available in their health systems for the following areas: (i) circumstances under which clinical effectiveness data from RWD sources can be included in an HTA dossier; (ii) the minimum standards for collecting and submitting clinical effectiveness data from RWD sources for HTA; (iii) how to account for confounding factors when analyzing RWD; and (iv) how to reduce selection bias when designing a non-randomized study (Table 4). Five of eleven health systems have available guidance. South Korea has documents available in Korean for all four topics. In China, the China Real World Data and Studies Alliance (ChinaREAL) has issued five guidance documents on how to design observational studies (16), how to develop research databases using existing health and medical data (17), how to develop patient registries (18), how to conduct PrCT (19), and how to appropriately analyze RWD (20). In January 2020, the National Medical Products Administration in China issued guidance on the use of RWE for drug development and assessment for pilot testing (21). In Singapore, while the existing HTA guidance documents describe the circumstances under which clinical effectiveness data from sources other than clinical trials may be used as supplementary evidence to inform decision making, most reimbursement decisions are predominantly informed by RCTs. In

Table 2. Acceptance of RWD/RWE in HTA to inform reimbursement decision making* (N = 14)

Health system	Accepts RWD/RWE[a]	Requires justification for the use of RWD/RWE[b]	Accepts data from PrCT[c]	Recommends PrCT be conducted for every novel therapy[d]
Bhutan	Yes	No	Plan to accept, but not soon	Yes
China	Yes	No	Yes	Yes
India	Yes	Yes	Plan to accept, but not soon	Yes
Indonesia	Yes	Yes	Yes	Yes
Japan	Yes	Yes	Yes	No
Malaysia	Yes	No	Yes	Yes
Philippines	Yes	No	Plan to accept, but not soon	Yes
Singapore	Yes*	Yes	Yes*	No
South Korea	Yes	Yes	Yes	Yes
Taiwan	Yes	Yes	Plan to accept, but not soon	No
Thailand	Yes	Yes	Yes	Yes

RWD, real-world data; RWE, real-world evidence; PrCT, pragmatic clinical trial; HTA, health technology assessment.
[a]In response to: "Does your HTA agency currently accept clinical effectiveness data (e.g. relative risk, odds ratio, sensitivity and specificity, etc.) from real-world data sources (e.g. registries, claim databases, observational studies) for HTA in informing or making reimbursement decisions?"
[b]In response to: "Do you require people who submit HTA dossiers to provide justification(s) for the use of clinical effectiveness data from real-world data sources?"
[c]In response to: "Does your HTA agency currently accept clinical effectiveness data from pragmatic clinical trials? If not, are you planning to?"
[d]In response to: "Does your HTA agency think that pragmatic clinical trial should be conducted for every novel therapy to be considered for reimbursement?"
*As supplementary evidence to randomized controlled trials (RCTs) or in specific instances where RCTs are lacking (e.g. for rare diseases).

Table 3. Challenges encountered regarding use of RWD/RWE for HTA to inform reimbursement decision making (N = 13)

Challenges encountered[a]	Number of respondents
There was not enough evidence in the HTA dossier that the patient sample selected truly reflects the patients in routine clinical care	9
The HTA dossier did not clearly report other treatments that the patients are receiving	6
The HTA dossier did not clearly report other comorbidities that the patients have	6
We do not have the expertise to evaluate if analyses properly account for confounding	6
The patients were not followed up over a sufficient period of time	4
The HTA dossier included data on a patient sample that does not reflect patients in routine clinical care	4
The HTA dossier included outcomes data that are not relevant	3
The patient sample in the HTA dossier was too similar in characteristics to patients who took part in the clinical trials that led to regulatory approval	2

RWD, real-world data; RWE, real-world evidence; HTA, health technology assessment.
[a]In response to: "What are the challenges that your HTA agency encounters with regards clinical effectiveness data from real-world data sources? Select all that apply."

Malaysia, although RWD has been identified as a pharmacy research priority area for monitoring therapeutic outcomes (22), there is currently no specific plan to develop guidelines about how to use this data for HTA. In the Philippines, the Guidelines of the PHL National Formulary System (AO 2016-0034) does not explicitly state if RWD/RWE should be collected. However, in the Exemption section of the policy, there is nothing to preclude the Formulary Executive Council from requesting any type of data to inform their recommendations.

Findings from Face-to-Face Meeting and/or Teleconference

The face-to-face meeting allowed for more in-depth and varied discussions about RWD/RWE beyond the scope of the online survey. From the examples of drug reimbursement decisions that involved RWD/RWE presented by each health system, it was clear that there was significant variation in: (1) sources and types of RWD/RWE being used in HTA; and (2) how RWD/RWE is being used for policy-making (e.g. initial reimbursement, re-assessment for price adjustments, or investment/disinvestment purposes and expanding coverage).

In general, respondents reported that RWD collected from a variety of sources, such as medical records, patient registries, and claims databases has been used for HTA. For example, in China, RWD is collected from regional EMR, EMR from single care institutions, disease registries, and claims databases. However, to ensure the quality of RWD, the HTA agency in China only accepts clinical effectiveness data collected by teaching

Table 4. Availability of guidance documents on the use of RWD/RWE

Does your HTA agency have an existing guidance document for …	Existence	Shareable in English[a]
Circumstances under which clinical effectiveness data from real-world data sources can be included in HTA dossier	China, Philippines, Singapore, South Korea	Singapore
The minimum standards for collecting and submitting clinical effectiveness data from real-world data sources for HTA to inform reimbursement decision making	South Korea	None
How to account for confounding factors when analyzing RWD	South Korea, China	None
How to reduce selection bias when designing a non-randomized study	India, South Korea, China	None

RWD, real-world data; RWE, real-world evidence; HTA, health technology assessment.
[a]A document is considered as "Shareable in English" if it has an English version which is publicly available or available upon request.

hospitals, or used in published articles in peer-reviewed journals for quality assurance. In Taiwan, a cost-effectiveness analysis of a treatment for Alzheimer's disease was conducted using transition probabilities derived from observational data from a clinical sample, cost data from the National Health Insurance database, and a caregiver survey (23). In Bhutan, the combination of data from the Health Management Information System (HMIS) and the Royal Centre for Disease Control (RCDC) surveillance was used to estimate the healthcare utilization (outpatient visit and hospitalization) related to a particular viral infection for the evaluation of a vaccine.

How RWD/RWE is used in HTA and decision making also varies across Asian health systems, with some using it primarily to inform pharmacoeconomics, pharmacovigilance, or pharmacoepidemiology, while others also use it for reassessments. In reassessments, RWE informs price adjustments and/or disinvestment decisions of the technologies that have gained an initial positive reimbursement decision. This is relevant, if new evidence regarding the technologies becomes available and highlights unforeseen benefits or harms that require reassessment, or if newer technologies with greater benefits enter the market, triggering decision makers to consider whether they should disinvest the existing technology (24). RWE also informs effectiveness of off-label use of drugs, which may result in the coverage expanded to more indications and is relevant in health systems that accept coverage with evidence development as a tool for facilitating potential expanded indications or use of therapies (25).

There are some challenges that were not mentioned or not emphasized in the survey but were discussed in the meetings by attendees who were predominantly HTA agency representatives, academics, and clinicians, for, for example, (i) lack of infrastructure and human capacity to support data collection; (ii) lack of clinician, institutional, or legislative support for data collection; (iii) lack of experience in analyzing and interpreting RWD/RWE; and (iv) collecting RWD/RWE for drugs with multiple indications.

(i) Lack of infrastructure and human capacity to support data collection

Participants cited the lack of EMR in several health systems in Asia due to limited resources as a major barrier to generating RWD/RWE. In such cases, it is common to establish patient registries with manual data curation to make up for the lack of EMR.

However, due to lack of funding and manpower, the completeness and quality of data in patient registries in these health systems also tend to be suboptimal (e.g. there are substantial inconsistencies found in registry data sets when checked against actual patient medical records), which can make them an unreliable source for RWD.

(ii) Lack of clinician, institutional, or legislative support for data collection/sharing

Many healthcare providers do not see the collection of RWD within their scope of work. Administrative data are not typically organized or collected for the purpose of measuring patients' outcomes and experiences, thus posing IT challenges and potential data entry errors, when existing electronic record systems are modified to enable providers to capture relevant outcomes. In some health systems, there is no existing legislation to support the setting up of disease registries. Hence, these health systems lack registries that are commonly found in the US and Europe, for example, cancer registries. In one health system, a registry was set up to facilitate payment to clinicians. However, as the sponsor for the registry was not interested in effectiveness data, clinicians were not diligent in entering clinical data, resulting in captured information that was not useful to inform HTA decision making.

The conservative attitude of the Asian governments, who are often the custodians of RWD, was also mentioned as one of the challenges encountered in the use of RWD/RWE. It was agreed by most participants that Asian governments are more reluctant to release health data for quality assessment or research than in Europe and North America due to concern over data privacy and data ownership for publication purposes. This impedes data access and data linkage. In a few health systems, participants explained that their government was reluctant to link public claims data to demographics, socioeconomic factors, or health outcomes data out of concern over data privacy. In one health system, the government held comprehensive data but was unwilling to share the data with anybody including the HTA agency, which was independent from the Ministry of Health, to maintain control over how the data were analyzed and reported.

(iii) Lack of experience in analyzing and interpreting RWE

The challenges of conducting analyses to mitigate confounding and selection bias on RWD/RWE were mentioned in the online

survey and reiterated during the face-to-face and teleconference discussions. Also, participants highlighted that it is easy to be misled by the HTA dossier if the review committee does not have sufficient experience in assessing the quality of and interpreting RWD/RWE. For example, it is important for the review committee to recognize that anecdotal evidence, such as patient testimonials (a form of RWD/RWE), may be subject to bias, especially survivor bias as only those who have had the treatment and survived will live to tell the story. It is thus imperative that the review committee members are sufficiently trained and experienced to review RWD/RWE and guidance is in place to ensure that RWD/RWE is assessed and applied consistently in decision making.

(iv) Lack of data quality assurance

In many institutions, there is no provision to ensure accurate data capture for drugs with multiple indications. For example, hospitals may code for the indication that will provide the larger reimbursement (if applicable) even though the drug was used for a different indication, and there are limited audit mechanisms in place to assess actual indication-specific use. An example was shared in one health system, where the use of angiotensin-receptor blockers (ARB) is covered by the national reimbursement scheme for hypertension but not for chronic kidney disease. Local hospitals apply the International Classification of Diseases codes for hypertension in all reimbursement claims to ensure that they get paid for all patients who are prescribed ARB irrespective of actual use. While decision makers are aware of this practice, effective audit practices are currently not in place to accurately capture prescribing practice.

Discussion

In this landscape analysis, we learned that many HTA agencies in Asia recognize the value of and already use RWD/RWE in HTA, given the lack of relevant data from clinical trials for the region. Nonetheless, all participants agreed that RWE should only be considered as supplementary evidence and is unlikely to replace evidence generated from clinical trials for reimbursement decisions. It is also noteworthy that several health systems expressed a positive attitude toward including data from PrCT in HTA.

The participants shared many of the challenges in using RWD/RWE in their local contexts, and these challenges were consistent across all three activities (online survey, face-to-face meeting, teleconference). We realized that many health systems face challenges in generating RWE due to the lack of infrastructure, human capacity, clinician, institutional, or legislative support for data collection and the lack of experience in analyzing RWD and interpreting RWE. For many of these health systems, EMR could provide a sustainable source of RWD, which could be advanced by committing resources to build data management and analytical capabilities. Hence, we propose to develop a guidance document for Asia in order to address some of these challenges, such as recommending that the HTA dossier clearly describes how RWD should be collected, why the patients selected are suitable for the intended analysis, and how potential confounders can be adjusted for.

From the survey results and face-to-face discussions, we see a strong demand for a guidance document. We have also seen an increasing number of country-specific guidelines or guidance documents that are being developed or have recently been developed to meet these needs (16–22). Nonetheless, there is a lot of interest in collaborating and learning from one another within

the region. For example, some participants expressed an interest to learn about good practices in the use of technology for data collection to enhance data completeness and data quality. Other participants expressed a need for cross-system sharing on how to engage and share information with data custodians, particularly the government, on the importance of linking data and making the linked data accessible for HTA purposes.

Hence, the **REAL**-World Data **I**n A**S**ia for H**E**alth Technology Assessment in Reimbursement (**REALISE**) working group has been established to develop a non-binding guidance document that will provide a framework to generate, assess, and use high-quality RWD/RWE in a consistent manner. An overview of the REALISE working group is provided in Supplementary File 2, with the organization chart of the working group provided in Supplementary Figure 1. The acronym REALISE signifies our desire to realize (i.e. to cause to happen) the maximum potential of RWD/RWE while realizing (i.e. being aware of) the strengths and limitations. The issues to be addressed in the guidance document will include but are not limited to: (a) When is it appropriate to consider RWD/RWE for reimbursement decisions?; (b) What types of RWD should we collect? (c) What are the data sources for RWD?; (d) How should we collect RWD?; (e) Who should collect RWD?; (f) How will RWD be analyzed or processed to generate RWE?; (g) How should we use RWE in decision making?; (h) What are the potential biases and how to deal with these biases?; and (i) What are the ethical considerations in collecting RWD and generating RWE? The objectives of the guidance are provided in Supplementary Figure 2.

It is our goal that the proposed guidance document will increase the quality of RWD/RWE collected and its usage in HTA in Asian countries. However, we do recognize that the actual implementation and adoption of this guidance document will vary from country to country due to many reasons including capacity constraints, lack of political support, and local legislation. The use of RWD/RWE is also a judgment, with no reason why all countries should adopt it in the same way. Each health system will face specific practical barriers in collecting and utilizing RWD and hence, we propose that all recommendations in the guidance document will be non-binding in nature to ensure that users can adapt the contents to their local needs.

With some limitations, by gathering the inputs from eleven health systems in Asia, we were able to obtain a comprehensive assessment of the current demand for a guidance document for RWD/RWE in the region. One limitation is that Asia is a highly diverse region. Hence, we will need to consult more health systems to ensure that the guidance document comprehensively represents the region. Another limitation is that the current membership of REALISE only comprises staff from HTA agencies, academics, and clinicians. We recognize a need to involve the broader stakeholder community (e.g. other healthcare professionals, policy makers, industry, and patients) as they may have different perspectives on the requirements for the guidance document. Thus, a series of engagement activities at professional conferences has been planned to elicit broader stakeholder consultation, obtain feedback on the guidance document and engage stakeholders for strengthening the role of RWD/RWE for HTA to inform decision making.

In conclusion, the participants agreed that knowledge gaps with regards to the use of RWD/RWE for HTA to inform decision making, alongside gaps relating to training, feasibility in the current process, and communication between stakeholders exist in each health system and that there is value in collaborating and learning from one another. This is particularly important as countries are willing

to accept RWD/RWE from other health systems to supplement their own data. Hence, the REALISE working group has an important mission of developing guidance on how to collect and analyze RWD/RWE and optimize its use to inform decision making and enable timely patient access to new and cost-effective technologies.

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