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Expert Opinions on the Collection and Use of Real-World Evidence (RWE) in China and Korea

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Interviewees

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INTRODUCTION

There is growing interest globally in using real-world data (RWD) and real-world evidence (RWE) for applications including regulatory decisions, health technology assessment (HTA), pharmacovigilance and more. However, Asia currently lacks a framework to effectively collect and utilize a broad range of RWD/RWE[1]. This gap presents Medical Affairs teams with significant opportunity to lead the collection, dissemination and adoption of learnings based on RWE, especially in light of significant market size and burden of diseases such as stroke and ischemic heart disease, which have been the focus on much pharmaceutical development in the West[v]. The objective of this interview-based article is to detail the current state of RWE use in China and Korea and explore what the future evolution will be for its use.

COLLECTION OF RWE IN APAC COUNTRIES

The United States and Europe generate RWE from a patchwork of private and government sources including patient registries, private insurance databases, electronic health records and Medicare/Medicaid databases. In these countries, splitting data ownership across healthcare, industry, academia and government leads to piecemeal data siloed within disparate and often competing databases. In contrast, many APAC countries including Korea, China and Japan collect and concentrate RWE within government-owned databases that encompass records from the vast majority of a county's population. *"In China, 100 percent of the population is handled by the equivalent of Medicare or Medicaid, so the government owns a huge database, a very complete data source,"* says Jianwei Xuan, Professor & Director of the Health Economic Research Institute at Sun Yat-sen University, Guangzhou, China. Thus, an overarching theme of RWE collection in Asia versus the U.S. and Europe is government-owned data in Asia leading to much more complete representation of the population, whereas private and government data sources in the U.S. and Europe leading to many siloed repositories of data.

ACCESS TO RWE IN APAC COUNTRIES

"In Korea, we have a major RWE data set, but these data are strictly controlled by the Korean government and because of that, only a limited number of researchers are allowed access," says Dong-Churl Suh, RPh, MBA, PhD, Professor and Director of the College of Pharmacy at Chung-Ang University in Seoul, South Korea. Similarly, Xuan points out that whereas the United States and Europe depend on patient privacy laws to regulate what kind of privately collected data can be shared for research purposes, *"In China and many other APAC countries, governments own patient data and rules are skewed against sharing, severely limiting access to RWE even through there could be so much benefit,"* he says. In many APAC countries, additional data-access challenges exist for studies sponsored by international organizations.

Organizations Governing RWE use for HTA/Formulary Decisions in APAC Countries Korea:
In Korea, the Health Insurance Review and Assessment Service (HIRA) assesses drugs using the following criteria: clinical benefit, cost-effectiveness, budget impact, reimbursement status in other countries, and other features that might affect public health[2]

China:
The China National Formulary (CNF) for reimbursable drug use, also known as the National Reimbursement Drug List (NRDL), was formally established in 2000, revised in 2004 and 2009, and covers 52% of China's population under the government urban health insurance programs.[3].

"Our institution has a rare source of privately generated data," Xuan says, *"and I am allowed to use this for database studies sponsored by Chinese organizations. But if the sponsor is an international company – e.g., Pfizer, Sanofi, Merck – you need to get approval from a special government office, which tends to mean no approval."*

"Open data is more valuable even than clinical trial data," says Suh, *"but the government in Korea has been reluctant to release it even though they hold the data set. I hope the government understands the benefit of using RWE, which could offer a better estimate or predict outcomes from different treatment options and would improve patient quality of life."*

Japan:
In April 2016, Japan started an initial HTA pilot program, supervised by the Central Social Insurance Medical Council ("Chuikyo").

USE OF RWE IN APAC COUNTRIES

Both Suh and Xuan point out that regulatory approvals in APAC countries remain almost exclusively dependent on clinical trials. However, in these countries, researchers primarily within academia working with funding from industry are starting to define methodology for the use of RWE to inform regulatory decisions. Meanwhile, APAC countries are currently making use of RWE in other ways including pharmacovigilance and pharmacoeconomics. *"In Korea, the government uses RWE to see whether medication is appropriately prescribed and used according to indications and also whether there are unexpected adverse effects,"* says Suh, *"and RWE is commonly used to determine the cost-effectiveness of new medications, and to decide appropriate pricing and formulary reimbursement."* As in the U.S. and Europe, medical societies within APAC countries may also use RWE to define treatment guidelines for certain diseases.

THE FUTURE OF RWE IN APAC COUNTRIES

Xuan points to three factors influencing the future of RWE in China. First, an increasingly open regulatory environment may aid data access; second, methodology is being developed to guide the acceptance of results based on RWE studies; and third, the demonstrated promise of RWE elsewhere in the world is encouraging private and government investment for RWE use in APAC countries. *"Right now, governments are not as enthusiastic about RWE as we would hope,"* Xuan says. *"They say to industry, 'teach us the process and the benefits and then we can see how we can work together.'"* In Korea, Suh reiterates that RWE is not currently used for regulatory decisions, but is increasingly being used to identify unmet treatment needs, which influences where additional research and development may be needed.

CONCLUSION

The generation of country-specific real-world data along with the establishment or expansion of national databases and increased access to these data for research purposes has the potential to not only guide reimbursement decisions, but also to demonstrate the effectiveness of emerging treatments, thus improving patient outcomes. In addition to new systems for the collection and dissemination of data, in-country expertise and human resources will be required to ensure the rigorous application of RWE methodologies and principles. Medical Affairs organizations have the opportunity to lead the adoption of RWE in the regions discussed by establishing meaningful data that helps HTAs, HCPs, policy makers and other key stakeholders make informed decisions. This includes proactive collaboration in the creation of RWD and RWE beyond administrative databases and hospital charts.

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