Symposium 1: Methods to address heterogeneity in multi-database studies in pharmacoepidemiology: Search for consensus and future directions

Thursday, October 14, 2021, 12:00 PM - 1:30 PM Korean Standard Time

Multi-database studies (MDBS) are increasingly conducted in pharmacoepidemiology and other fields. Regulatory authorities often require data from multiple data sources to be used in a single study, to enhance the generalizability of results and/or obtain sufficient sample size. However, MDBS poses several challenges, especially how to manage heterogeneity that may arise from differences in data types, structure, and coding, or contexts (health policy, clinical practice, culture, and populations).

Among Asian countries with large databases, MDBBDS have been performed through AsPEN (Asian Pharmacoepidemiology Network) or in collaboration with European and North American networks/countries. However, it is extremely challenging to interpret the findings of MDBS without a clear understanding of the context and purposes of each data source, and how these differ between the data sources in the study. Despite calls for the implementation of strategies to improve replicability, increase transparency and reduce bias in MDBS, to our knowledge, there is currently no guidance for how database heterogeneity should be evaluated or even identified and reported.

DIVERSE is an ISPE-funded project to conduct a scoping review to identify the current methodological issues and solutions to address heterogeneity in MBDS and to propose a set of recommendations for future practice. In this symposium, the DIVERSE investigators will present the ongoing scoping review with examples from Asia/Pacific, Europe and North America and engage participants in proposing and discussing potential solutions and recommendations on how to identify, address, and interpret heterogeneity in MBDS.

After a brief introduction by the moderator, four presenters will address the following:

1. Heterogeneity Issues in Asian pharmacoepidemiologic MDBS - AsPEN examples
2. A conceptual framework to represent heterogeneity in Europe
3. Review of existing methods, tools and recommendations to identify and address heterogeneity between data sources in MDBS
4. A proposal for recommendations on how to identify, address, and interpret heterogeneity in MDBS

A panel discussion with DIVERSE investigators, other MDBS investigators, and the symposium participants will address the following questions/points after each panellist introduces briefly his/her multi-database network and specific heterogeneity issues.

1. General feedback/discussion on the proposed recommendations
2. Are there data-specific issues in identifying, addressing, and interpreting heterogeneity in MDBS? Can we identify universal recommendations based on common underlying issues? Should recommendations and guidance be region specific?
3. Should the set of recommendations on heterogeneity issues in MDBS be organized by types of research questions, designs, and approaches (common data model vs common protocol) or by data model types? We can observe differences in the reasons why the data is collected in the first place: how should this be identified and reported?
4. Any specific heterogeneity issues for medications, biologics, vaccines, medical devices? Any unique issues by indications (diseases) or demographics?

Symposium 2: Pharmacoepidemiology-based RWE for COVID-19 -Experiences from Asia and Europe

Thursday, October 14, 2021, 12:00 PM - 1:30 PM Korean Standard Time

Real World Evidence (RWE), generated from various healthcare data sources, has played an important role during the ongoing COVID-19 pandemic, providing needed scientific and clinical findings with minimal delay. These findings include those regarding the safety and effectiveness of medications among patient with COVID-19.

While numerous pharmacoepidemiologic studies conducted from various regions of the world generally reported consistent findings on a certain topic, others were subject to potential debate because their results were inconsistent with the larger body of evidence. There are many possible factors that could have contributed to this discrepancy, ranging from basic ethnic or genetic differences present between Asian and Caucasian populations to varying methodological or analytical approaches adopted for study investigation.

Therefore, this symposium will primarily focus on COVID-19, its prognosis, and the safety and effectiveness of medications in this patient population in Asia and expand this discussion to other geographic settings, for instance Europe, for comparison. By reviewing COVID-19 studies that were conducted from different parts of the globe, this symposium will provide insight on the strategies to be taken on how future pharmacoepidemiologic research should be conducted, especially during rapidly evolving situations (e.g., COVID-19 pandemic).

This symposium, led by moderator Dr. Ju-Young Shin from SKKU (Korea), will start with a short introduction of the panel members then presentations from 4 experts in Asia, Europe, and North America, who will discuss:

* Their findings on the safety of NSAID use among patients with COVID-19 from South Korea and Denmark
* A study conducted using Korean data that examined the effectiveness of anticoagulant use among patients hospitalized with COVID-19
* A study conducted using population-based data from Hong Kong, exploring the relationship between the use of statins and adverse outcomes in patients hospitalized with COVID-19.

The symposium will end with a guided panel discussion on how to engage and collaborate with each other, and share experiences and lessons learned (e.g., challenges encountered during the study), providing guidance on how to conduct valid research in a rapidly-evolving environment.

Symposium 3: Current Trends in Pharmacovigilance

Thursday, October 14, 2021, 2:30 PM - 4:00 PM Korean Standard Time

In this session, investigators and regulatory officials from Europe and Asia will gather together and provide their insights from their recent experiences in pharmacovigilance (PV) during the pandemic. Also, speakers will discuss current issues associated with monitoring the utilization and effects of pharmaceuticals, biologics, and vaccines, and pave the way for successful international collaboration in PV.

Speakers will share their experience with the application of the distributed network approach and how the lessons learnt can inform future pharmacovigilance studies. Investigators and regulatory officials from the UMC, HSA, TFDA, and KIDS will give a brief introduction on their studies/national PV activities and achievements so far.

The session will be concluded with panel discussions and Q & A's where the lessons learned will be summarized, and the major challenges and strategies for successful international collaboration in PV will be highlighted and discussed, especially in Asia-Pacific regions. Through the discussions and Q & A's, participants will come up with potential solutions for the challenges together.

Symposium 4: Activities on expanded pharmacovigilance and drug safety beyond its relief program for adverse drug reactions

Thursday, October 14, 2021, 2:30 PM - 4:00 PM Korean Standard Time

Asia countries including Japan, Taiwan, and South Korea have begun providing relief programs for patients with adverse drug reactions (ADRs) caused by appropriate use of medications. Through the relief programs, ADR victims were compensated without the need for judicial proceedings. Recently, by analysing ADR relief applications and their medical charts which are rich resources understanding unpredicted ADRs inevitably occurred, various activities based on ADR relief were reported on pharmacovigilance (PV) and drug safety in regulatory scientific perspective. These activities may contribute synergistically not only to operations of the ADR relief system but also to promotions of safer use of medicines.

This symposium will start with a short introduction of the panel members, then experts from Japan, Taiwan, and South Korea will give presentations about their ADR relief systems. Also, speakers will discuss lessons and challenges about PV activities based on ADR relief information.

In detail, regulatory officers from PMDA (Pharmaceuticals and Medical Devices Agency), TDRF (Taiwan Drug Relief Foundation), and KIDS (Korea Institute of Drug Safety and Risk Management) will give a brief introduction on their ADR relief system and PV activities such as signal detections, labeling changes, promotions about professional behavior changes, and risk/benefit assessment using ADR relief information.

Speakers from clinical professionals and pharmaceutical companies will present lessons and challenges about PV activities and clinical review based on ADR relief resources.

The session will be end with discussion and Q&A's where the lessons learned will be summarized, and future directions and opportunities for successful international collaboration will be discussed.

Symposium 5: Real World Safety and Effectiveness Evaluation of Immunotherapy among non-small cell lung cancer patients -experience from Korea

Friday, October 15, 2021, 10:45 AM - 12:15 PM Korean Standard Time

Immunotherapy has been widely used to treat different types of cancer, including one of the most common cancers non-small cell lung cancer (NSCLC). In year 2018, Korea reimbursement agency Health Insurance Review and Assessment Service (HIRA) started "Immune checkpoint inhibitor ex-post evaluation study". It's a retrospective multi-center study based on the domestic Real World Data (RWD). The study results were announced in 2019, and the clinical efficacy and safety of checkpoint inhibitors were found to be comparable with the previous large-scale prospective phase III trials. While the study provides valuable information on how immunotherapy performed in real world setting in Korea patients, the investigators also acknowledged the limitations of the study including short study period, retrospective study deign, and patients' selection from limited hospitals.

The session will end with a guided panel discussion on how to engage and collaborate with each other, and share experiences and lessons learned.

Symposium 6: COVID-19 vaccine safety assessment in Asia Pacific

Friday, October 15, 2021, 10:45 AM - 12:15 PM Korean Standard Time

COVID vaccines have been approved for use in many countries since the end of 2020. With the rapid rollout of the vaccines to large number of apparently healthy subjects in different countries and regions, robust post-marketing safety assessment is necessary to detect safety signals and rapidly refine and evaluate the signals to protect public health. In addition, safety signals identified in Europe and North America, such as SARS-CoV-2 Vaccine–Induced Immune Thrombotic Thrombocytopenia, need to be evaluated in East Asia.

Presentations will cover a description of COVID vaccine safety evaluation system in each country / region, including real world challenges and solutions, global COVID vaccine safety assessment and will be followed by a panel discussion: also open to questions from the floor.