Symposia abstracts/summaries

Saturday 12 October 2019, 08:30-10:00
Symposium 1 - Variability and generalizability of claims-based algorithms in pharmacoepidemiologic research: Multinational perspectives

The increasing global use of healthcare utilization databases for pharmacoepidemiology and health services/outcome research has required more validation studies to support the credibility of such database research. However, differences exist among different regions/countries in how claims data can be validated. In many Asian countries, the inability to directly obtain patient identifiers in claims data and the resulting reliance on hospital-based validation studies of claims data may lead to potentially high variability in the validation results among hospitals and lack of generalizability of validated algorithms. Even in regions, e.g., US, where validation samples and their identifiers can be directly drawn from databases, the variability in the validity measures among populations defined by insurance types, demographic groups, main condition or comorbidity, and geography are often deemphasized, and the portability of the validated algorithms maybe largely overlooked. Generalizability of the validation results can also be compromised due to imprecision and insufficiently low success rate of medical record ascertainment. Furthermore, chronological changes in the reimbursement policies, medical technology, and coding system can lead to variability that limit the generalizability of validated algorithms to newer data.

Saturday 12 October 2019, 08:30-10:00
Symposium 2 – Data science and Pharmacoepidemiology in the next 10 Years

The volume and diversity of real-world data have been growing worldwide. This leads to a substantial interest and potential for a field/approaches called data science, a multi-disciplinary field on scientific methods, technology and systems for the use of data. One typical technology from this field is artificial intelligence, and applications of such novel methodologies to pharmacoepidemiology is increasing.

Saturday 12 October 2019, 10:30-12:00
Symposium 3 - Challenges and strategies in the post market studies of Herbal and Traditional Medicine (HTM) products

Herbal and traditional medicine (HTM) products have a unique place in healthcare among Asian countries. HTM's use also has been rising in non-Asian countries primarily as non-prescribed supplements. Most HTM products are compound ingredients, and often used in combination with chemicals. Because of suboptimal consistency of quality and limited regulations about HTM in many countries, it is highly challenging to conduct reliable post marketing studies (PMS) to assess utilization, safety, and effectiveness of HTM products. The lack of adequate evaluation methods, which are specifically applicable to HTM products, has prevented modernization and globalization of HTM products.

This symposium will discuss the application of pharmacoepidemiological methods to assess utilization and safety/effectiveness for HTM products and address important methodological challenges with an ultimate goal to improve the model for post marketing evaluation of HTM products.

Saturday 12 October 2019, 10:30-12:00
Symposium 4 – Approaches to assess medication exposure and associated risks during pregnancy using Real-World Data

Due to the sparsity of evidence collected on pregnant women during clinical trials, clinical decisions on pharmacological treatment during pregnancy are often challenging. Historically, the use of registries in the post-marketing setting has been the approach to collect evidence on the risk of medications during pregnancy. However, pregnancy registries have practical barriers to enrolling subjects leading to: potentially underestimating outcomes occurring early during pregnancy (e.g., spontaneous abortion), lack of generalizability, lack of an adequate comparison group, high operational cost, and long timelines before results are available to support clinical decisions.

Saturday 12 October 2019, 13:30-15:00
Symposium 5 - Use of real-world evidence (RWE) in regulatory decision-making: Regulatory guidance and examples from Asia and the US

The use of real-world evidence (RWE) -- evidence that is generated from data created and routinely collected as part of the operation of the healthcare system -- in regulatory decision-making has become more prominent and more common worldwide. While regulators around the globe are familiar with using RWE as part of post-authorization safety studies for their decision making, many are expanding the use of RWE to decisions about approval of medications. While the shift appears to be underway worldwide, different regulators have taken different approaches to defining when and how RWE can be used, and in setting standards for the selection of "fit-for-purpose" data sources, appropriate application of those data to specific study questions, and transparent presentation of RWE.

Saturday 12 October 2019, 15:45-17:15
Symposium 6 - Japan In Real Life: Data, Evidence and an evolving regulatory framework for Pharmacovigilance

In the US and EU, real world data (RWD) are used to characterize patient populations, assess post-approval safety, and evaluate risk management programs. With the increased availability of these data globally, their use for medicine development and safety assessment is evolving. Japan, in particular, has experienced growth in the number and type of RWD available in recent years. New (2018) regulatory guidance permitting the use of RWD for post approval safety commitments will likely accelerate these developments. Ultimately, there is the potential to harmonize pharmacoepidemiology and risk management approaches across the founding ICH regulatory regions (US, EU, Japan) to ensure pharmacovigilance globally incorporates information about the safety of medicines from RWD sources.

Saturday 12 October 2019, 17:15-18:00
Introduction to Asian Pharmacoepidemiology (AsPEN) Symposium

The Asian Pharmacoepidemiology Network, or AsPEN, is a Special Interest Group of the International Society of Pharmacoepidemiology. It is a multi-national research network including members from Australia, Canada, China, Hong Kong, Japan, Korea, Singapore, Taiwan, Thailand and the United States.

AsPEN was formed to provide a mechanism to support the conduct of pharmaco-epidemiological research and to facilitate the prompt identification and validation of emerging safety issues among the Asian countries. Our mission is to develop and advance multi-national database research in Pharmacoepidemiology in the Asia/Pacific region.

In this session you will hear about the activities and goals for AsPEN. We will highlight our experience with conducting pharmacoepidemiologic research using databases from AsPEN sites to conduct studies for drug utilization, signal detection and signal validation. We will also discuss challenges in multi-national database studies and how we are developing appropriate infrastructure for cross national database research across the Asia Pacific region. Lastly, we will discuss the future directions for AsPEN.

Sunday 13 October 2019, 08:00-09:30
Symposium 7 - Real World Evidence to support new drug approval and label expansion

Historically, pharmacoepidemiology is a well-established discipline for the post-marketing safety assessment of medical products. More than 10 years ago, the term comparative effectiveness appeared to describe the use of the same type of data and observational methods used for safety assessment to evaluate beneficial effects of medical products, and an ISPE SIG on Comparative Effectiveness was established. During the last three years since the passage of the 21st Century Cures Act in the USA, the term Real World Evidence has become popular to further define clinical evidence regarding a medicine's use, benefits, and risks.

In December 2018, the US FDA released a document on the Framework for FDA's Real World Evidence Program, which describes the regulatory application of Real World Evidence, ranging from new drug approval to expansion of indication(s) to safety assessment. While ISPE members have abundant experience in using Real World Evidence for safety assessment and the topic has been discussed in prior ACPEs, a symposium focusing on the other end of the spectrum with regards to evaluation of beneficial effects of medical products to support regulatory decisions in the Asia Pacific region is most timely and appropriate.

Sunday 13 October 2019, 08:00-09:30
Symposium 8 – Post-market surveillance of medicines, vaccines and medical devices across the Asia-Pacific region: The next 10 years

The Asian Pharmacoepidemiology Network (AsPEN) has been established for 10 years. We have developed a data research network of over 8 different Asian countries covering over 1.7 billion patients. Multi-database pharmacoepidemiologic studies are actively ongoing to identify issues specific to Asian populations, including identifying variations across regions in utilization, safety and effectiveness of medicines.

For the past 10 years, AsPEN studies have mainly focused on medications while more recently we are collaborating with other networks and SIGs. Together with the Vaccine SIG, we have successfully completed a joint survey study on the availability of database in Asia-Pacific regions for vaccine safety surveillance. AsPEN has also widened the collaboration with Biologics and Medical Device SIG to address the issues about the safety and effectiveness of biologic agents and medical devices. Expanding the scope of research undertaken by AsPEN through collaboration with other SIGs and networks to bring different expertise and experience into AsPEN will be our goal in the next ten years. Previous works and successes in demonstrating the feasibility of network studies across the Asia-Pacific region provides a strong foundation for future collaborations with different SIGs and networks.

Sunday 13 October 2019, 11:00-12:30
Symposium 9 - Real World Evidence for decision making: Where we are in the Asia Pacific region?

There has been good progress of using real world data (RWD) and real-world evidence (RWE) to help evaluate the safety, effectiveness, and utilization of drugs and vaccines by different stakeholders. RWD and RWE have helped regulators, researchers, medical practitioners, and payers for decision making in different countries and regions. Compared to western countries, the availability of real-world data sources and the use of RWE for decision making is limited in the Asia Pacific region.

Sunday 13 October 2019, 14:00-15:30
Symposium 10 - Lessons learned and future challenges in international signal detection

Given the need to generate more timely and robust pharmacovigilance information from real-world data, there have been many approaches taken internationally to the use of a range of datasets in drug safety signal detection. What can be learned from the experiences of several existing database networks thus far, and applied to the development of future distributed networks and improvement of existing networks?

Sunday 13 October 2019, 14:00-15:30
Symposium 11 – Modern teaching of Pharmacoepidemiology in a 'Big Data' World

As we enter the era of 'Big Data', the science and practice of pharmacoepidemiology are evolving; changes include the use of novel data sources and more complex statistical methods, the emergence of distributed networks (e.g., CNODES, Sentinel, and OHDSI), and the use of platforms to facilitate the conduct of pharmacoepidemiologic studies. This evolution necessitates the modernization of our approach to teaching pharmacoepidemiology.

Sunday 13 October 2019, 16:15-17:45
Symposium 12 – Challenges and approaches to Pharmacoepidemiologic research in mental health

Pharmacoepidemiology in Mental Health poses a number of specific challenges.

The pathophysiology of most mental disorders remains poorly understood. No objective markers of disease exist and diagnoses are based on patient behaviour and symptoms. This results in pronounced variability in diagnostic accuracy by provider specialty, treatment setting, and country, which is further complicated by the stigma associated with mental health conditions in many societies.

Similarly, mechanisms of action of psychopharmacological agents are poorly understood and no objective biomarkers exist to assess treatment response. Compared to many somatic conditions, the evidence base for the treatment of mental disorders is underdeveloped. Randomized clinical trials (RCTs) are typically smaller and shorter than RCTs for similarly prevalent somatic conditions. This is in part due to the difficulty

of recruiting and retaining patients with mental health conditions. Outcome measures are less standardized than in many somatic conditions, complicating the aggregation of results.

Frequent switching, polypharmacy, and off-label use of psychotropic drugs are common in patients with mental disorders, with great variability in prescribing practices between providers.

Overall, there is a significant need for pharmacoepidemiologic studies of mental health drugs. There are major gaps in their evidence base that are unlikely to be filled by conventional RCTs (rare but serious adverse effects, second line treatment options, safety/effectiveness of off-label uses). Substantial variation in provider preference provides an opportunity for observational research. However, a number of specific features of mental health pharmacoepidemiology pose substantial challenges (e.g., diagnostic uncertainty, poor outcome measures for drug effectiveness, problematic confounder assessment, poor availability of disease severity measures.

Sunday 13 October 2019, 16:15-17:45
Symposium 13 – A new international collaboration to advance medication safety in people with neurodegenerative diseases: NeuroGEN

People with neurodegenerative diseases such as dementia are often excluded from randomised controlled trials. This means that evidence for medication safety and efficacy is lacking. This is despite that people with neurodegenerative have multiple co-morbid conditions and use multiple medications.