AsPEN SIG Symposium

Introduction to Asian Pharmacoepidemiology Network

8:00-9:00am 31 October 2017
ACPE10 in Brisbane

Edward Chia-Cheng Lai: National Cheng Kung University, Tainan, Taiwan
Kenneth Man: University of Hong Kong, Hong Kong
Nicole Pratt: University of South Australia, Adelaide, SA, Australia
Kiyoshi Kubota: Drug Safety Research Unit Japan, Tokyo, Japan
Today’s contents

1. AsPEN introduction and our achievements so far (Edward Lai)
2. Current and on-going studies (Kenneth Mann)
3. Challenges & future directions for AsPEN (Nicole Pratt)
4. Q&A (Kiyoshi Kubota)
AsPEN is a multi-national research network formed to provide a mechanism to support the conduct of pharmacoepidemiological research and to facilitate the prompt identification and validation of emerging safety issues among the Asian countries. 

www.aspennet.asia
The AsPEN Concept

Signal Detected

Communication of safety issues
→ Alert to other countries
→ Establish a research network
AsPEN: Our History

2008 3rd ACPE-Korea
Suggestion of Asian PE Network (AsPEN)

2009 4th ACPE-Taiwan
Participating nations: Taiwan, Japan, Korea, Australia, Sweden, US, UK
The Association between Antipsychotic Use and Diabetes Onset

2010 5th ACPE-Japan
Develop a distributed network model for conducting analysis in each country
Results of antipsychotics and diabetes studies presented

2011 6th ACPE-China
Results of glitazone and heart failure study presented

2012 7th ACPE-Bangalore, India
Research ideas presented

2013 8th ACPE-Hong-Kong
Welcomed new collaborators Hong Kong and Thailand
Rising Star Session to promote the work of Early Career Researchers

2014 30th ICPE-Taiwan
AsPEN Symposium – discussion on common data model and the SCAN project

2015 9th ACPE-Thailand
AsPEN Symposium – pediatric project: ADHD medications patterns and CV safety

2017 10th ACPE- Australia
AsPEN Symposium - pediatric project: antipsychotic patterns and CV safety
AsPEN ISPE SIG

- **Past chairs**
  - Bj Park & Frank May
  - Kiyoshi Kubota & Yea-Huei Kao Yang
  - Nicole Pratt & Edward Lai

- **Chair:** Kenneth Man

- **Co-chair:** Nam-Kyong Choi
2. Our achievements so far

a. Research output
b. Research Infrastructure
c. Governance principles
### Databases in the Asia-Pacific Region

**The Potential for a Distributed Network Approach**

Edward Chia-Cheng Lai, a, b Kenneth K. C. Man, a Nathorn Chaiyakanapruk, a, d, f, g Ching-Lan Cheng, a Hsu-Chih Chien, b Celine S. L. Chu, i Piyameth Dilokthornsakul, a N. Chantelle Hardy, n Cheng-Yang Hsieh, b Chung Y. Hsu, b Kiyoshi Kobata, f Tsu-Chieh Lin, b Yanfang Liu, f Byung Joo Park, k1 Nicole Pratt, m Elizabeth E. Roughhead, m Ju-Young Shin, b Savaeng Watcharananakit, k Jin Wen, b Ian C. K. Wong, e Yea-Huei Kao Yang, b Yinghong Zhang, b and Soko Setoguchi b


### AsPEN

**Asian Pharmacoepidemiology Network**

**AsPEN collaborators**: Morton Andersson, a, b, c, d, e, f, g Nam-Kyong Choi, a, b, c, d, e, f, g, h Tobias Gerhard, a, b, c, d, e, f, g, h Cecilia Huang, a, b, c, d, e, f, g, h Jessica Kelber, f, g, h, i, j, k, l, m, n, o Tomomi Kimura, f, g, h, i, j, k, l, m, n, o Kiyoshi Kobata, f, g, h, i, j, k, l, m, n, o Edward Chia-Cheng Lai, b, g, h, i, j, k, l, m, n, o, p, q, r, s, t, u, v, w, x, y, z, AA, AB, AC, AD, AE, AF, AG, AH, AI, AJ, AK, AL, AM, AN, AO, AP, AQ, AR, AS, AT, AU, AV, AW, AX, AY, AZ, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T, U, V, W, X, Y, Z

**Pharmacoepidemiol Drug Saf. 2013 Jul;22(7):700-4.**
Methods

International Multi-database Pharmacoepidemiology: Potentials and Pitfalls

Edward Chia-Cheng Lai, Paul Stang, Yea-Huei Kao Yang, Kiyoshi Kubota, Ian C. K. Wong, Sokoh Setoguchi


Symmetry analysis for monitoring safety of newly marketed drugs

Kiyoshi Kubota

NPO Drug Safety Research Unit, Tokyo, Japan


Sequence symmetry analysis in pharmacovigilance and pharmacoepidemiologic studies


Prescription sequence symmetry analysis: assessing risk, temporality, and consistency for adverse drug reactions across datasets in five countries


Pharmacoepidemiol Drug Saf. 2015 Aug;24(8):858-64.

Asian Pharmacoepidemiology Network

AsPEN
Research output: AsPEN archive

Original Research

Proton pump inhibitors and risk of *Clostridium difficile* infection: a multi-country study using sequence symmetry analysis

Elizabeth E Roughhead, Esther W Chan, Nam-Kyong Choi, Jenna Griffiths, Xue-Mei Jin, Joongyub Lee

Pages 1599-1595 | Received 29 Mar 2016, Accepted 14 Sep 2016, Accepted author version posted online 19 Sep 2016, Published online: 27 Sep 2016

Original Research Article

Variation in Association Between Thiazolidinediones and Heart Failure Across Ethnic Groups: Retrospective analysis of Large Healthcare Claims Databases in Six Countries

Elizabeth E. Roughhead1, Esther W. Chan2, Nam-Kyong Choi3, Michio Kikuma4, Tomomi Kikuma5, Kiyoshi Kubota6, Edward Chiu-Chung Lai7, Kenneth K., C. Maun2, Tuan Anh Nguyen2, Nabilah Othman2, Byung-Joo Park5, Tsugunori Sato1, Ju-Young Shin1, Tong-Yong Wong2, Jenna Griffiths3, Ian C.K. Wong2, Yun-Hwei Kao Yang1, Nicole L Pratt1

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Cardiovascular safety of methylphenidate among children and young people with attention-deficit/hyperactivity disorder (ADHD): nationwide self controlled case series study

Ju-Young Shin1,2, Elizabeth E Roughhead1, Byung-Joo Park4, Nicole L Pratt3

RESEARCH

Multi-country rapid adverse drug event assessment: the Asian Pharmacoepidemiology Network (AsPEN) antipsychotic and acute hyperglycaemia study

Nicole Pratt1, Morton Anderson, Uli Bergmann, Naps-Kyong Choi, Tobin Gerhard, Cecilia Huang, Motoki Kanayama, Tepamit Komnar, Kayldeh Kaboui, Edgbert Chiu-Chung Lai, Nabiha Othman, Urban Oth, Byung-Joo Park1, Tsegzibghi Sani, Ju-Young Shin, Andrea Schindler, Yeu-Hwee Kao Yang1, and Elizabeth E. Roughhead1

Original Report

Pharmacology and Drug Safety 2015

Research output: AsPEN archive
## Completed study

<table>
<thead>
<tr>
<th>Topics</th>
<th>Pls</th>
<th>Journals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Association study on non-steroidal anti-inflammatory drug (NSAIDs) and cardiovascular and gastrointestinal risk</td>
<td>US and Taiwan</td>
<td>Pharmacoepidemiology and Drug safety (revision)</td>
</tr>
<tr>
<td>Applying a Common Data Model to Asian Databases for Multinational Pharmacoepidemiologic Studies: Opportunities and Challenges</td>
<td>US</td>
<td>Clinical Epidemiology (under review)</td>
</tr>
<tr>
<td>Drug Utilization in Children</td>
<td>Hong Kong</td>
<td>Pediatrics</td>
</tr>
<tr>
<td>Prescribing Patterns for Antipsychotic Medications in East Asia and the United States: A Cross-National Comparison Using a Common Data Model</td>
<td>Taiwan</td>
<td>Pharmacoepidemiology and Drug safety (revision)</td>
</tr>
<tr>
<td>Persistence of Antipsychotic Medications in Patients with Schizophrenia: A Cross-National Study from the Asian Pharmacoepidemiology Network (AsPEN)</td>
<td>Taiwan</td>
<td>Pharmacoepidemiology and Drug safety (under review)</td>
</tr>
<tr>
<td>Varying Patterns of Penetration of New Antidiabetic Medications in Asia and US: A Cross-National Comparison Study</td>
<td>Japan</td>
<td>Ready for submission</td>
</tr>
<tr>
<td>Global trend of ADHD medication prescribing</td>
<td>Hong Kong</td>
<td>Ready for submission</td>
</tr>
<tr>
<td>Antipsychotics use and metabolic syndrome in Children</td>
<td>Taiwan</td>
<td>Mx drafting</td>
</tr>
</tbody>
</table>

Asian Pharmacoepidemiology Network
AsPEN
Research Infrastructure

• Study specific CDM

**eMethods.** Common Data Structure for the AsPEN Association Study II

The common data structure for the Association Study II is a modification from the Association study I and the Mini-Sentinel common data model. It will consist of up to 8 tables, depending on the availability of procedure tables:
1) Demographic table
2) Eligibility table
3) Drug table
4) In-Patient Encounter table (previously “In-Patient Main file”)
5) In-Patient Diagnosis table
6) Out-Patient Diagnosis table
7) In-Patient Procedure table
8) Out-Patient Procedure table

The content and structure of each table will be specified in this document.

1) **Demographic table: (No Change from last year)**
This table will have date of birth, gender, date of death, and a unique person identifier (i.e. Patient_id). Each person will have one record only.

**Example:**

<table>
<thead>
<tr>
<th>Patient_id</th>
<th>Date_of_birth</th>
<th>Gender</th>
<th>Date_of_death</th>
</tr>
</thead>
<tbody>
<tr>
<td>101</td>
<td>09/08/1972</td>
<td>M</td>
<td></td>
</tr>
<tr>
<td>111</td>
<td>06/06/1930</td>
<td>M</td>
<td></td>
</tr>
</tbody>
</table>
SCAN project: Global CDM

• Research infrastructure for ongoing sustainability of AsPEN
• Surveillance of Health Care in Asia Network (SCAN) in May 2013
  -- **Sites:** Japan, Korea, Taiwan, and Hong Kong and one US
  -- **Global CDM:** OMOPCDM version 4.

• **5 specific aims**
  -- to assure the quality of conversion in different layers of data components and
  -- to gain a better understanding of disease burden and patterns of medical product use across countries

• **Global CDM:**
  -- to make future studies more feasible
  -- May be able to take advantage of the tools developed by the **Observational Health Data Sciences and Informatics (OHDSI)** community ([www.ohdsi.org](http://www.ohdsi.org)) and
  -- AsPEN can contribute to the ongoing aim of OHDSI which is to “bring out the value of health data through large-scale analytics”
OMOP CDM standardize the format

**Medicare Source Tables**
- Beneficiary Summary
- Hospice (HSP)
- Home Health Agency (HHA)
- Skilled Nursing Facility (SNF)
- Part D Drug Event (PDE)
- Inpatient (IP)
- Outpatient (OP)
- Carrier (Carr)
- Durable Medical Equipment (DME)

**JMDC Source Tables**
- Membership & Membership history
- Service Provider
- Prescribing doctors
- Conditions
- Drugs from hospital/clinic
- Claims from hospital/clinic
- Patients in claims
- Medical procedures
- Drugs from community pharmacy
- Claims from community pharmacy
- Drug cost

**Demographics and eligibility**
- Person
- Death
- Location
- Observation period
- Payer plan period

**Healthcare provider and facility**
- Provider
- Organization
- Care Site
- Location

**Exposure and outcome**
- Visit occurrence
- Condition occurrence
- Condition era
- Drug exposure
- Drug era
- Procedure occurrence

**Health expenditure**
- Drug cost
- Procedure cost
standardize the content
<table>
<thead>
<tr>
<th>Database Type and Features*</th>
<th>Databases Participating in SCAN</th>
<th>Potential Candidates</th>
</tr>
</thead>
<tbody>
<tr>
<td>National claims databases covering entire populations</td>
<td>National Health Insurance Research Database, NHIRD (Taiwan)</td>
<td>Health Insurance Review and Assessment, HIRA (South Korea)</td>
</tr>
<tr>
<td>National claims databases covering specific populations</td>
<td>Japan Medical Data Center, JMDC (Japan) and Medicare databases (US)</td>
<td>Veterans Affairs database, DVA (Australia)</td>
</tr>
<tr>
<td>National electronic health records covering entire populations</td>
<td>Clinical Data Analysis and Reporting System, CDARS (Hong Kong)</td>
<td>National Electronic Health Record, NEHR, (Singapore)</td>
</tr>
<tr>
<td>One-hospital databases</td>
<td>Ajou University School of Medicine, AUSOM (South Korea)</td>
<td>Buddhachinaraj Hospital Database (Thailand)</td>
</tr>
</tbody>
</table>
Governance principles

http://aspennet.asia/pdf/GovernanceStructuresForAsPEN.pdf

1. Mission, goal and objectives
2. Operation of AsPEN activities
   – Intellectual property
   – Data access
   – Registry of studies
   – Operation of specific projects
   – Authorship
   – Funding
ICPE Montreal

Poster Walk: Moderators: Kenneth & Nicole

- 20 abstracts identified as AsPEN SIG Abstracts
  - Korea, Hong Kong, Malaysia, Taiwan, Japan, Saudi Arabia, India, Vietnam, Multi-country studies
  - 8 abstracts have been selected by the chair and co-chair for the Poster walk
Few notes

• Consider time differences
• Consider country-specific holidays
• Slow down your English
• Evaluate the data conversion before doing analyses
• Tell/Remind the chairs what you need from AsPEN.