AsPEN
New studies and projects

ACPE Brisbane 2017

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New study proposal (A)

Cardiovascular safety of ADHD medications

Co-ordinating centre: Korea, Dr. Ju-Yong Shin.

- The aims of the study are
  - To investigate the cardiovascular safety of ADHD medications
  - To compare the results among different countries
- Collaborating with Australia and Hong Kong


RESEARCH

OPEN ACCESS

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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 Shin,[1, 2] Elizabeth E Roughead,[3] Byung-Joo Park,[4] Nicole L Pratt[3]

New study proposal (B)

Psychotic events and ADHD medications

- Co-ordinating centre: Hong Kong, Kenneth Man, Ian Wong
- Collaborating with UCL School of Pharmacy
- The aim of this study are
  - To investigate the association between ADHD medications and psychotic events
  - To compare the results with western countries

ORIGINAL ARTICLE

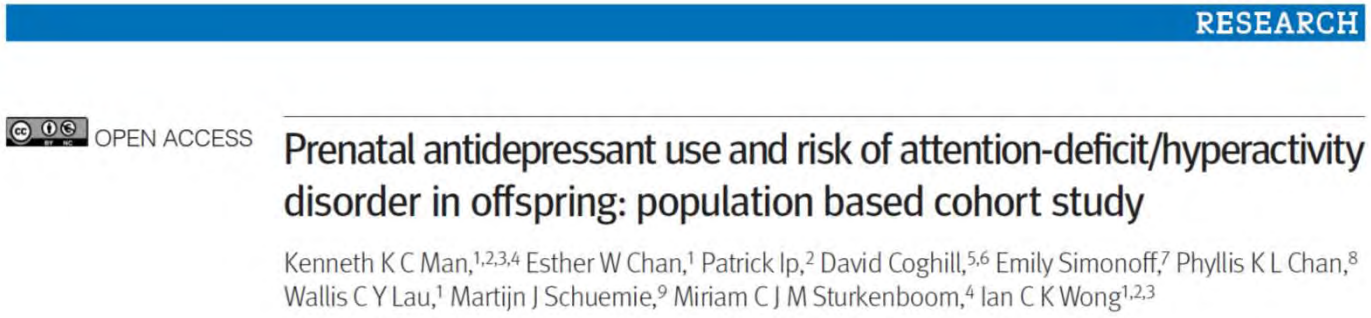
Methylphenidate and the risk of psychotic disorders and hallucinations in children and adolescents in a large health system

KKC Man[1,2,11], D Coghill[3,4,11], EW Chan[1], WCY Lau[1], C Hollis[5,6,11], E Liddle[5,6,11], T Banaschewski[7,11], S McCarthy[8,11], A Neubert[9,11], K Sayal[5,6,11], P Ip[2] and ICK Wong[1,10,11]

New study proposal (C)

Prenatal antidepressants exposure and risk of neurodevelopmental disorders in offspring

- Co-ordinating centre: Hong Kong, Ian Wong and Kenneth Man
- Protocol to be developed
- Aim: To investigate the impact of prenatal exposure to psychotropic medications on children's health


RESEARCH

OPEN ACCESS

Prenatal antidepressant use and risk of attention-deficit/hyperactivity disorder in offspring: population based cohort study

Kenneth K C Man,[1,2,3,4] Esther W Chan,[1] Patrick Ip,[2] David Coghill,[5,6] Emily Simonoff,[7] Phyllis K L Chan,[8] Wallis C Y Lau,[1] Martijn J Schuemie,[9] Miriam C J M Sturkenboom,[4] Ian C K Wong[1,2,3]

AsPEN

Asian Pharmacoepidemiology Network

New study proposal (D)

- *Safety of antipsychotics in Paediatric, Children, and Young Adult*
- Co-ordinating centre: Taiwan, Edward Lai, Brian Su, Yea-Huei Kao Yang
  - Protocol to be developed
    - To investigate the prescribing/pattern of antipsychotics
    - To evaluate the common ADR risk of antipsychotics
    - To evaluate the life-threatening ADR risk of antipsychotics

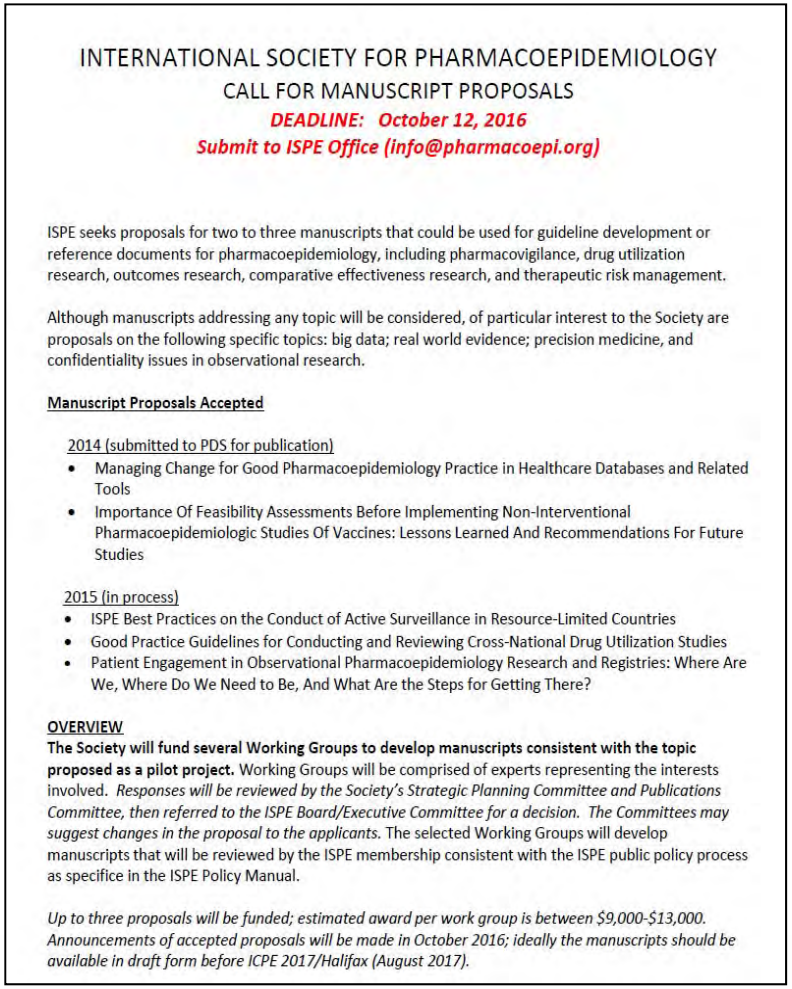
Please contact Edward Lai, if you are interested.
Edward_Lai@mail.ncku.edu.tw

New study proposal (E)

- AsPEN members have agreed to explore the potential for investigating **medical devices** across the Asia-Pacific Region.
  - A survey will be conducted to assess what data each country holds on medical devices

New study proposals (F)

- AsPEN has been approached by Vaccine SIG to consider a joint SIG manuscript proposal.
  - The aim would be to produce a reference manuscript on **vaccine data linkages** across Asia, Europe and the US
- Other Ideas for guideline or reference document?



INTERNATIONAL SOCIETY FOR PHARMACOEPIDEMIOLOGY

CALL FOR MANUSCRIPT PROPOSALS

DEADLINE: October 12, 2016

Submit to ISPE Office (info@pharmacoepi.org)

ISPE seeks proposals for two to three manuscripts that could be used for guideline development or reference documents for pharmacoepidemiology, including pharmacovigilance, drug utilization research, outcomes research, comparative effectiveness research, and therapeutic risk management.

Although manuscripts addressing any topic will be considered, of particular interest to the Society are proposals on the following specific topics: big data; real world evidence; precision medicine, and confidentiality issues in observational research.

Manuscript Proposals Accepted

2014 (submitted to PDS for publication)

- Managing Change for Good Pharmacoepidemiology Practice in Healthcare Databases and Related Tools
- Importance Of Feasibility Assessments Before Implementing Non-Interventional Pharmacoepidemiologic Studies Of Vaccines: Lessons Learned And Recommendations For Future Studies

2015 (in process)

- ISPE Best Practices on the Conduct of Active Surveillance in Resource-Limited Countries
- Good Practice Guidelines for Conducting and Reviewing Cross-National Drug Utilization Studies
- Patient Engagement in Observational Pharmacoepidemiology Research and Registries: Where Are We, Where Do We Need to Be, And What Are the Steps for Getting There?

OVERVIEW

The Society will fund several Working Groups to develop manuscripts consistent with the topic proposed as a pilot project. Working Groups will be comprised of experts representing the interests involved. *Responses will be reviewed by the Society's Strategic Planning Committee and Publications Committee, then referred to the ISPE Board/Executive Committee for a decision. The Committees may suggest changes in the proposal to the applicants.* The selected Working Groups will develop manuscripts that will be reviewed by the ISPE membership consistent with the ISPE public policy process as specifice in the ISPE Policy Manual.

Up to three proposals will be funded; estimated award per work group is between $9,000-$13,000. Announcements of accepted proposals will be made in October 2016; ideally the manuscripts should be available in draft form before ICPE 2017/Halifax (August 2017).

New study proposals (G)

- Project lead: Nicole Pratt (nicole.pratt@unisa.edu.au)
- Generating Large-scale Evidence for the Safety of Biologics
- Collaboration between AsPEN and OHDSI
- Funding application has been submitted to the Australian National Health and Medical Research Council

Aim: *build an active post-market surveillance approach to monitor the use and adverse events associated with biologic medicines in the real-world setting*

Building on the SCAN project we will use the OMOP common data model to

1. **Describe biologic use and map treatment pathways over time**
2. **Quantify incidence and risk of severe acute and long-term adverse events with biologics**
3. **Develop predictive models develop models to predict the serious adverse events following treatment with biologics**