78. Impact of Methodological Choices on Findings from Pharmacoepidemiological Studies: Final Results of the IMI-PROTECT (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium) Project

Olaf Klungel,[1,3] Mark de Groot,[1] Helga Gardarsdottir,[1,2] Ruth Brauer,[4] Lamiae Grimaldi-Bensouda,[5] Xavier Kurz,[6] Christiane Gasse,[7] Robert Reynolds.[8] *[1]Pharmacoepidemiology & Clinical Pharmacology, Utrecht Institute of Pharmaceutical Sciences (UIPS), Utrecht University, Utrecht, Netherlands; [2]Clinical Pharmacy, University Medical Center Utrecht, Utrecht, Netherlands; [3]Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, Utrecht, Netherlands; [4]London School of Hygiene and Tropical Medicine, London; [5]LA-SER, Paris; [6]European Medicines Agency, London; [7]School of Business and Social Sciences, Aarhus Universitet, Aarhus; [8]Pfizer, New York.*

Background: Pharmacoepidemiological (PE) research should provide consistent, reliable and reproducible results to contribute to the benefit-risk assessment of medicines. IMI-PROTECT aims to identify sources of methodological variations in PE studies using a common protocol and analysis plan across databases (including independent replication studies). In addition, differences by design, applied to a same drug-adverse event (AE) pair in different databases are examined. Results from PE studies will be evaluated on 7 drug-AE pairs (i.e. 1. antibiotics and acute liver injury; 2. antidepressants and hip fracture; 3. benzodiazepines and hip fracture; 4. anticonvulsants and suicide/suicide attempts; 5. calcium channel blockers and malignancies; 6. inhaled long-acting β2 agonists and acute myocardial infarction; 7. a negative control study: antibiotics and acute myocardial infarction) conducted in 7 European and 1 US electronic databases. These are: the CPRD and THIN from the UK, the Danish national registries, the Dutch Mondriaan project (NPCRD, AHC), the Spanish BIFAP, the French PGRx and the US InVision Datamart.

Objectives: To review and understand the methodological issues encountered in these studies and to draw conclusions about their relevance for future PE research.

Description: In follow up to a session at ICPE Montreal which presented selected preliminary results from cohort studies only, we will present final data from association studies in the various databases using different designs including cohort, case-control, case-crossover, and self-controlled case series for some drug-AE pairs. The major methodological issues such as choice of study design, analytical methods to control for confounding, variation in operational definitions of exposure, outcome and confounders across databases with different coding systems will be discussed. Recommendations for future PE research will also be presented.

Program:

(1) Introduction to IMI-PROTECT
(2) Results from PE studies on drug-ae associations
(3) Main recommendations from PROTECT
(4) Panel discussion.

79. The New ISPE Vaccine Special Interest Group (VAXSIG): Helping to Advance the Global Vaccine Agenda

Huifeng Yun,[1] Hak Eelko,[2] Ajit Pal Singh,[3] Jan Bonhoeffer,[4,5] Daniel Weibel,[6] Miriam Sturkenboom.[6] *[1]Department of Epidemiology, Universy of Alabama at Birmingham, Birmingham; [2]PharmacoEpidemiology & PharmacoEconomics, University of Groningen, University Center for Pharmacy, Groningen; [3]Clinical Affairs and Regulatory, International Vaccine Institute, Seoul; [4]Brighton Collaboration Foundation, Basel, Switzerland; [5]University Children's Hospital, Basel, Switzerland; [6]Erasmus University Medical Center, Rotterdam, The Netherlands.*

Background: The biotechnology and informatics revolutions create new opportunities for a) the development of vaccines against major killers such as HIV, malaria, and TB; and b) accurately assessing the risks and benefits of immunizations across the life cycle of a vaccine, from pre- to post-licensure.

Objectives: To advance this exciting agenda synergistically with stakeholders and prioritize the opportunities (and challenges) for ISPE VAXSIG based on discussion of the following timely presentations.

Description: Introduction of VAXSIG and Moderators (Miriam Sturkenboom & Huifeng Yun).

- Ajit Pal Singh: A pilot model of web-based adverse events following immunization tool.

To support the introduction of new vaccines and manage vaccine safety concerns in resource limited countries, the new web based tool is being developed by the International Vaccine institute for diverse existing data collection, collation, transmission, analysis and feedback systems.

- Jan Bonhoeffer: Performance testing of pediatric signal detection methods in surveillance systems.

Several methods for signal detection in spontaneous reporting systems have been developed; but they are not