Symposium 2: The new advancements, strength and limitations on observational drug effect studies based on large healthcare databases

Nicole Pratt, The University of South Australia, AUS

Nicole Pratt is Associate Professor (Biostatistics and Pharmacoepidemiology) and Deputy Director of the Quality Use of Medicines and Pharmacy Research Centre, University of South Australia. Nicole is a chief investigator of the Centre of Research Excellence in post-market surveillance of medicines and devices and past-chair of the Asian Pharmacoepidemiology Network (AsPEN).

Robert Platt, McGill University, CANADA

Robert Platt is Professor in the departments of Pediatrics in addition to Epidemiology, Biostatistics, and Occupational Health (EBOH) at McGill University, and Director of Graduate Programs in the department of EBOH. He holds the Albert Boehringer I endowed chair in Pharmacoepidemiology.

Dr. Platt is the Executive Co-Lead of the Canadian Network for Observational Drug Effect Studies (CNODES). He has been the leader of the Methods team of CNODES since its inception. In this role, he has led a methods research and training program for the network and has participated as methods liaison (senior methods author) in numerous CNODES studies.

Dr. Platt is on the editorial board of the American Journal of Epidemiology, Pharmacoepidemiology and Drug Safety and Current Epidemiology Reports, and is Associate Editor of Statistics in Medicine and the International Journal of Biostatistics. He has published over 300 articles, one book and several book chapters on epidemiology.

Hongbo Yuan, Canadian Agency for Drugs and Technologies in Health, CANADA

Hongbo Yuan is scientific advisor for the Canadian Agency for Drugs and Technologies in Health (2010-), Ottawa, Canada. He provides scientific guidance and support in the assessment of comparative effectiveness, safety, and evidence development for optimal drug use.

Dr. Yuan is the chair of the International Society for Pharmacoepidemiology (ISPE) special interest group in comparative effective research (2017-18). In this role, he has led a guidance development in the application of propensity score (PS) methods in large healthcare database study and the development of a framework of combining RCT with observational study in CER. His main interest is in 'real-world' observational data for decision-making, personalized medicine and big data analytics in health care.

Dr. Yuan has Ph.D. in epidemiology from McGill University, MSc in epidemiology from Beijing Medical University and MD from Tongji Medical University.

Sheron Wen, University of Rhode Island; University of Florida, USA

Sheron Wen received a Ph. D. in pharmacoepidemiology from the University of Florida College of Pharmacy in 2013. Her primary research interests are applied measurement and/or applied studies examining drug safety, comparative effectiveness, health behavior, and pharmacy education. She designed and implemented numerous clinical and community studies using pertinent epidemiological and statistical methods; many of these have been formulated into journal papers and/or abstracts for presentation at national and international conferences.

Dr. Wen is currently teaching two graduate level courses in the University of Rhode Island: advanced epidemiology methods and measurement in health outcomes. She is a principle investigator of several funded research projects and a mentor of several graduate and pharmD students.

Abraham G. Hartzema, University of Florida, USA

Abraham G. Hartzema is Professor and Eminent Scholar Emeritus at the University of Florida in the Department of Pharmaceutical Outcomes & Policy. He is the Perry A. Foote Chair in Health Outcomes Research, and Professor in Epidemiology and Biostatistics in the College of Public Health and the College of Medicine. In the year 2007, he was awarded the University of Florida Foundation Research award.

Dr. Hartzema has widely published on various aspects of prescription drug safety, including several books on Pharmacoepidemiology. His last book is entitled "Pharmacoepidemiology and Therapeutic Risk Management" was published by Harvey Whitney Book Publishers. Co-edited with Hugh Tilson (UNC-Chapel Hill) and Arnold Chan (Harvard University) the book reflects the new therapeutic risk management paradigm as implemented by the US FDA. His new book on Post-Authorization Safety Studies was July 2018 by Elsevier.

He has served on the scientific board of the FIP from 1988-1996; and on editorial boards, including Medical Care, Annals of Pharmacotherapy, Clinical Therapeutics, the International Journal of Pharmacy Practice, Pulmonary Circulation and others. In 2003 he was bestowed fellow status in the International Society on Pharmacoepidemiology. He has been the Chair of Data Safety and Monitoring Boards for several RTCs at the University of Florida. He served on the United States Pharmacopeia: Nomenclature, Safety and Labeling Expert Committee. January 2015 he received the award for Outstanding Contribution to the USP standard setting process. He was recently appointed as Senior Advisor to the FDA, Center for Devices and Radiological Health.

Dr. Hartzema's research was funded by the Agency for Healthcare Research and Quality, NIH, the FDA, the Florida Office of Rural Health and several pharmaceutical companies. His theoretical interests are in data mining techniques, developing metrics for the benefit/risk ratio of drugs, methods development for active medical product safety surveillance, bias calibration in observational methods, price competition in the generic industry, and Post Authorization Safety Studies.