

25th Anniversary
**International Conference on Pharmacoepidemiology
& Therapeutic Risk Management**
Rhode Island Convention Center
Providence, Rhode Island

PRELIMINARY AGENDA

Revised July 27, 2009

SATURDAY
August 15, 2009

8:30-Noon **ISPE Board of Directors Meeting** (Westin Providence –
Bristol/Kent)
(Open to ISPE members; notify staff if you plan to attend)
Westin Providence

11:30-6:00pm **Registration (Third Floor Foyer)**

PRE-CONFERENCE EDUCATIONAL SESSIONS

1:00-5:00pm **Introduction to Pharmacoepidemiology (Room 555AB)**
[*Included as part of the full meeting registration; Registration
required.]

Chair: Andrew McAfee

Syed Rizwanuddin Ahmad, FDA, *Spontaneous Reporting*

Andrew McAfee, i3 Drug Safety, *Cohort Studies*

Yu-Xiao Yang, University of Pennsylvania, *Case-Control Studies*

Anita McGrogan, University of Bath, *Confounding and Bias*

1:00-5:00pm **Introduction to Pharmacogenetics – Part 1 (New Course)**
(Room 554AB)
[*Admission by ticket only. Tickets will be included in registration
materials for those that registered for this session.]

Educational Objectives

- Understand the genetic and pharmacogenetic terminology and how cellular and molecular biology informs pharmacogenetic studies at analysis
- Appreciate the challenges of utilizing biospecimens

- Know the study design and methodologic approaches, their strengths and weakness used in pharmacogenetic epidemiology
- Understand statistical approaches used in Pharmacogenetics
- Understand how pharmacogenetics relates to current focus of Personalized Medicine
- Have an overview of clinical utility of pharmacogenetics and associated regulatory issues.

On Saturday afternoon (Day 1), there will be didactic teaching. On Sunday morning (Day 2) participation is optional, but there will be a small group workshop that will use real pharmacogenetic case studies catering to both novice and advanced participants. [Note: There is no separate registration for Part 2 only; you must register for Part 1].

Co-Chairs: Geoffrey Liu & Anke-Hilse Maitland

Leah Sansbury, National Institutes of Health, *Pharmacogenetic Terminology: The Basics*

Geoffrey Liu, Alan Brown Chair in Molecular Genomics, CCO Chair in Population Studies and Experimental Therapeutics, University of Toronto, *Biospecimen Issues for Pharmacoepidemiologists*

Wei Zhou, Senior Epidemiologist, Merck Pharmaceuticals, *Biospecimen Databases*

Anke-Hilse Maitland-van der Zee, Division of Pharmacoepidemiology and Pharmacotherapy, Utrecht University, *Pharmacogenetics Methods I*

Efrosini Setakis, Division of General Practice Research Database, Medicines & Healthcare Products Regulatory Agency, UK. *Pharmacogenetic Methods II and Databases as Study Sources*

Andrew Freedman, National Institutes of Health, *Pharmacogenomics Translation: From Discovery to Confirmation to Clinical Utility*

Stephen Kimmel, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine, *Warfarin as a Prototype Pharmacogenetic Example*

5:00-7:00pm

Student Meet and Greet

Cuban Revolution Restaurant & Grill; 50 Aborn Street
Organized by the ISPE Student Council

5:15-6:30pm

Literature Review Journal Club (Room 555AB)

Open to Introduction to Pharmacoepidemiology Course participants as well as anyone who has registered to attend a Pre-ICPE course.

Participants are encouraged to read the following article before the journal club meeting:

Wayne Ray, "Atypical Antipsychotic Drugs and the Risk of Sudden Cardiac Death" (NEJM 2009;360:225-35)

Panelists:

Alexander Walker, FISPE, World Health Information Science Consultants

Sean Hennessey, FISPE, University of Pennsylvania

Stephen Evans, London School of Hygiene and Tropical Medicine

SUNDAY
August 16, 2009

7:30-6:00pm **Registration (Third Floor Foyer)**

8:00-5:00pm **Speakers' Ready Room (Room 553B)**

PRE-CONFERENCE EDUCATIONAL SESSIONS

8:30-Noon **Regulatory Epidemiology/Public Health Decision Making (Room 555B)**
[*Admission by ticket only. Tickets will be included in registration materials for those who registered for this session.]

Educational Objectives

- Understand the intent and structure of regulation to protect the Public Health
- Appreciate the challenges of decision making with weak data
- Know about practical approaches typically chosen by regulators
- Recognize the challenges epidemiology faces to provide sufficient information for public health decision making
- Have an overview of world wide challenges for drug regulatory agencies and variation in approaches
- Know about current strategies to strengthen regulation in the face of these challenges

Chair: Gerald Dal Pan

Gerald Dal Pan, US FDA, *Regulation & Challenges of Decision-Making with Weak Data*

June Raine, EMEA, *Regulatory Decision Making Approaches in Europe*

Stephen Evans, London School of Tropical Medicine, *An Epidemiologist's View of Public Health Decision Making*

Ralph Edwards, WHO Collaborating Centre for International Drug Monitoring, *Global Perspective on Regulatory Utilization of Pharmacovigilance Data*

8:30-Noon

**Introduction to Drug Utilization/Health Services Research
(Room 555A)**

[*Admission by ticket only. Tickets will be included in registration materials for those who registered for this session.]

Educational Objectives

- To explain the definition and scope of the eclectic discipline of Drug Utilization Research within the context of Pharmaco-epidemiology.
- To motivate researchers providing international cross-national comparisons of national drug utilization data to cooperate on the collection of a minimal dataset of reliable and comparable drug utilization data in their country, in terms of volume, expenditures and quality of drug use.
- To explain the process of developing and validating prescribing quality indicators.
- To give an applied overview of methods useful for drug policy research (time series analysis)

Co-Chairs: Robert Vander Stichele & Julie Zito

Robert Vander Stichele, *Course Objectives, Definitions of Research Fields and Methodological Framework*

Marit Rønning, *The Anatomical Therapeutic Chemical Classification and the Defined Daily Dose: Classifying and Quantifying Drug Use for Cross National Comparison.*

Julie Zito, *Overview of Drug Utilization Research in the US*

Monique Elseviers, *Using DUR – Data for Cross National Comparisons*

Flora Haaijer-Ruskamp, *Using DUR – Data to Create Valid Prescribing Quality Indicators*

Colin Dormuth, *Testing Interventions on Drug Utilization (Time Series Analysis and Other Methods)*

8:30-Noon

**Comparative Effectiveness Research (New Course)
(Ballroom D)**

[*Admission by ticket only. Tickets will be included in registration materials for those who registered for this session.]

Educational Objectives

- Identify the differences between effectiveness and efficacy research and implications for improving routine care

- Understand the basic study design issues for non-randomized data recorded in routine care settings
- Recognize the advantages and limitations of a variety of data sources for comparative effectiveness research and how combining multiple sources can enhance the utility of a given dataset
- Have an overview of methodological challenges and proposed solutions in non-randomized effectiveness research
- Learn how to create and synthesize evidence with the decision maker in mind

Co-Chairs: Sebastian Schneeweiss, FISPE, & Erick Johnson

Scott Smith, AHRQ, *Objectives of CER*

Eric Johnson, Kaiser, *Cohort Studies*

David Magid, Kaiser, *Data Sources and Implications*

Sebastian Schneeweiss, Harvard, *Methodological Challenges in Non-Randomized CER*

David Atkins, Veteran's Administration, *Creating and Synthesizing Evidence with the Decision Maker in Mind*

8:30-Noon

**Introduction to Pharmacogenetics – Part 2 (New Course)
(Room 556A)**

[*Admission by ticket only. Tickets will be included in registration materials for those who registered for this session.] . Must register for Part 1; attendance at Part 2 optional.

Speakers will lead small discussion groups addressing real life pharmacogenetic examples.

Co-Chairs: Geoffrey Liu & Anke-Hilse Maitland

Leah Sansbury, National Institutes of Health

Geoffrey Liu, Alan Brown Chair in Molecular Genomics, CCO Chair in Population Studies and Experimental Therapeutics, University of Toronto

Wei Zhou, Senior Epidemiologist, Merck Pharmaceuticals

Anke-Hilse Maitland-van der Zee, Division of Pharmacoepidemiology and Pharmacotherapy, Utrecht University

Efrosini Setakis, Division of General Practice Research Database, Medicines & Healthcare Products Regulatory Agency, UK

Andrew Freedman, National Institutes of Health

Stephen Kimmel, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine

- 8:30-12:00pm **Students Only** – *Special Skills Workshop: From Writing an Abstract to Planning a Career: Skills You Can Use (Room 554A)*
[* Included as part of full meeting registration; registration required]
Organized by ISPE Student Council
- Noon -1:30pm *Lunch on your own.*
- Noon-1: 30pm **Luncheon for New Members/Student Prize Winners/Scholarship Recipients (Weston Hotel Waterplace Ballroom)**
(By Invitation)
- 1:30-6:00pm **Advanced Topics in Pharmacoepidemiology (Ballroom D)**
[* Admission by ticket only. Tickets will be included in registration materials for those who registered for this session.]
- Chair: James D. Lewis, FISPE**
- Sander Greenland**, *Bayesian Methods for Observational Research*
Tom MacDonald, FISPE, *Clinical Trials or Observational Studies for Drug Safety Assessment?*
Joanna Haas, *Unique Aspects of Studying Biologics*
Daniel Heitjan, *Methods for Handling Missing Data*
- 1:30-6:00pm **Introduction to Risk Management (Room 557)**
[* Admission by ticket only. Tickets will be included in registration materials for those who registered for this session.]
- Co-Chairs: Elizabeth Andrews, FISPE & Carla van Bennekom**
- Elizabeth Andrews**, FISPE, *Overview of Risk Management and the Role of Evaluation*
Mary Willy, *US Regulatory*
Stella Blackburn, FIPSE, *EU Regulatory*
Carla van Bennekom, *Isotretinoin*
Judith Jones, FISPE, *Workshop for Participants to Develop an Evaluation Plan*

6:00-7:30pm

**Welcome Reception/Academic Showcase
Rhode Island Statehouse**

Admission by badge or ticket. Cash Bar

Welcome

Kate Lapane, FISPE, Chair, 2009 Scientific Program
Committee

Miriam Sturkenboom, ISPE President

Academic Showcase

- Center for Clinical Epidemiology & Biostatistics, University of Pennsylvania School of Medicine
- Center for Drug Safety, School of Pharmacy, University of Maryland
- Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida
- Drug Safety Research Unit, Associated Department, School of Pharmacy, Portsmouth University
- Program in Pharmacoepidemiology and Pharmacoeconomics, College of Pharmacy, University of Rhode Island
- Pharmacoepidemiology Program, Department of Epidemiology, UNC Gillings School of Global Public Health University of North Carolina at Chapel Hill

MONDAY
August 17, 2009

- 7:00-8:00am **ISPE Committee Meeting**
Open to all participants.
(Breakfast will be available in meeting rooms)
- Education Committee (**Room 551B**)
 - Finance Committee (**Room 551A**)
- 7:00-5:00pm **Speakers' Ready Room (Room 553B)**
- 7:00-8:00am **Poster Session A Set-up (Hall B)**
Continental Breakfast
- 7:00-6:00pm **Registration (Third Floor Foyer)**
- 8:00-6:00pm **Exhibits/Posters (Hall B)**
- 8:00-10:00am **OPENING SESSION (Ballroom A)**
Welcome
- Kate L. Lapane**, FISPE, Chair, 2009 Scientific Program Committee, & Co-Chair, 25th Anniversary Committee
Brian J. Quilliam, Chair, 2009 Local Host Committee
- Presidential Address
Miriam Sturkenboom, ISPE President
- Keynote Address
Accounting for Uncertainty About Investigator Bias
Sander Greenland, Professor of Epidemiology, UCLA School of Public Health, and Professor of Statistics, UCLA College of Letters and Science
- ** Special Anniversary Presentation ****
Susan Sacks, FISPE, Co-Chair, 25th Anniversary Committee
Thomas MacDonald, FISPE, ISPE Poet Laureate
- 10:00am -10:30am **Break/Posters/Exhibits (Hall B)**

10:30-12:00pm **CONCURRENT SESSIONS: CONTRIBUTED PAPERS**

Drug Utilization - I (Room 552AB)

Moderators: Jurgen Dinger & Julie Zito, FISPE

- 10:30 AM **Understanding the Prescribing Patterns of Lipid-Lowering Agents in the United States and Canada [1]**
Matthew W Reynolds, Yola Moride. (United States)
- 10:45 AM **Comparison of Prescription Patterns of Statins in Primary Care in Five European Countries: Results from the LIPIDE Observational Survey [2]**
Gaelle Desamericq, Laurent Laforest, Marie-Sophie Schwalm, Philippe Moulin, Emilie Michel, Caroline Eteve, Gabriel Coffin, Cecile Ritleng, Eric Van Ganse. (France)
- 11:00 AM **Variation in Initiation of Angiotensin Blocking Agents, Beta Blockers and Statins after Hospitalization for Acute MI in British Columbia [3]**
Andrea V Margulis, Sebastian Schneeweiss. (United States)
- 11:15 AM **An Intervention To Increase Statin Tablet Splitting among General Practitioners [4]**
Jennifer Polinski, Sebastian Schneeweiss, Malcolm Maclure, Sam Ramsden, Blair Marshall, Colin Dormuth. (United States)
- 11:30 AM **Pattern of Utilization of Pegfilgrastim (PEGFIL) in Patients with Chemotherapy-Induced Neutropenia: A Retrospective Analysis of Administrative Claims Data [5]**
AT Skarin, F Vekeman, F Laliberté, O Afonja, MH Lafeuille, V Barghout, MS Duh. (United States)
- 11:45 AM **Is Low Use of Inhaled Corticosteroids among Asthmatic Patients Due to Inappropriate Prescribing or Low Patients' Adherence? [6]**
Lucie Blais, Marie-France Beauchesne, Catherine Lemièrre, Sylvie Perreault. (Canada)

Early Detection In Pharmacovigilance (Room 557AB)

Moderators: Andrej Czarnecki, FISPE, & M. Miles Braun, FISPE

- 10:30 AM **A Comparison of MedDRA and WHOART for Signal Detection on a Database of Spontaneous Adverse Drug Reaction Reports [7]**
Richard Hill, Kristina Star, G Niklas Norén. (Sweden)
- 10:45 AM **Using Regression To Find Otherwise Undetected Drug Safety Issues [8]**
Ola Caster, Kristina Star, Richard Hill, G Niklas Norén. (Sweden)
- 11:00 AM **Comparison of Adverse Drug Reaction (ADR) Reports Submitted to the FDA by Consumers and Healthcare Professionals (HCPs) [9]**
Thamir M Alshammari, Syed Rizwanuddin Ahmad, Lynette Swartz, Tarek A Hammad. (United States)
- 11:15 AM **Using the Capture-Recapture Method To Assess the Incidence of Drug-Induced Liver Injury in a French University Hospital [10]**
Neda Tavassoli, Virginie Ramillon, Pauline Calvet, Laure Pourcel, Jean Louis Montastruc, Maryse Lapeyre-Mestre. (France)
- 11:30 AM **Evaluation of Cardiovascular Diseases (CVDs) Risk in French Patients Receiving Milnacipran (MLN) Relative to Patients Receiving Other Antidepressants Therapies [11]**
PJ Mease, MS Duh, F Vekeman, A Guérin, M Boerstoeel-Streefland, W Jiang, P Lefebvre, PJ Zimetbaum. (United States)
- 11:45 AM **Near Real-Time Post-Marketing Surveillance: The Experience of the Vaccine Safety Datalink [12]**
WK Yih, B Fireman, N Klein, M Kulldorff, E Lewis, T Lieu, E Weintraub, R Platt. (United States)

Effects of Cardiovascular Drugs (Room 556AB)

Moderator: Jennifer Christian & Michael Lewis, FISPE

- 10:30 AM **Statins, Other Antihyperlipidemic Agents, and Psoriasis [13]**
Yolanda B Brauchli, Susan S Jick, Christoph R Meier. (Switzerland)
- 10:45 AM **Statin-CYP3A4 Inhibitor Drug Interaction Shows Differential Increased Risk for Adverse Events Depending on Statin Metabolism [14]**
Christopher G Rowan, Steven M Brunelli, James Flory, Jeffrey Munson, Warren Bilker, Brian Strom. (United States)

- 11:00 AM **Safety and Effectiveness of Bivalirudin in Routine Care of Patients Undergoing Percutaneous Coronary Intervention [15]**
Jeremy A Rassen, Murray A Mittleman, Robert J Glynn, M Alan Brookhart, Sebastian Schneeweiss. (United States)
- 11:15 AM **Association of Proton Pump Inhibitors with Clopidogrel Effectiveness in Elderly Stroke Patients [16]**
Mi-Sook Kim, Sun-Young Jung, Ye-Jee Kim, Nam-Kyong Choi, Byung-Joo Park. (Republic of Korea)
- 11:30 AM **Propranolol May Be Associated with Increased Risk of Hospitalized Myopathy: A Hypothesis Generated by Chemical Genomics [17]**
Soko Setoguchi, John Higgins, Levin Raisa, Vamsi Mootha, Jerry Avorn. (United States)
- 11:45 AM **Use of Organic Nitrates and the Risk of Hip Fracture: A Population-Based Case-Control Study [18]**
Arief Lalmohamed, Sander Pouwels, Cyrus Cooper, Tjeerd van Staa, Bert Leufkens, Lars Rejnmark, Anthonius de Boer, Peter Vestergaard, Frank de Vries. (Netherlands)

Hormones/Reproductive Agents (Room 554AB)

Moderators: Stephen Evans & Annlouise Assaf

- 10:30 AM **Teen Pregnancy Rates Following Pharmacist-Initiated Emergency Contraceptives [19]**
Vivian WY Leung, Judith A Soon, Marc Levine, Larry D Lynd, Carlo A Marra. (Canada)
- 10:45 AM **An Internet-Based Prospective Study of Pregravid Oral Contraceptive Use and Time to Pregnancy [20]**
Ellen M Mikkelsen, Lauren A Wise, Anders Riis, Elizabeth E Hatch, Henrik T Sørensen, Kenneth J Rothman. (United States)
- 11:00 AM **Incident Anticoagulant Use among Users of Extended-Cycle Versus Conventional Oral Contraceptives [21]**
Joshua J Gagne, Tarek A Hammad, Solomon Iyasu. (United States)
- 11:15 AM **Extended Results on the Risk of Venous Thromboembolism (VTE), Myocardial Infarction (MI), and Stroke in Users of Transdermal Norelgestromin/Ethinyl Estradiol (Patch) [22]**
David D Dore, Heather Norman, Clorinda Hoffman, Judy Wong, John D Seeger. (United States)

11:30 AM **Oral Hormone Replacement Therapy: An Update Report from the EURAS-HRT Study on Cardiovascular Safety [23]**
Anita Assmann, Juergen C Dinger. (Germany)

11:45 AM **Risk of Cardiovascular Outcomes in Users of Estradiol/Dydrogesterone or Other HRT Preparations [24]**
Cornelia Schneider, Susan S Jick, Christoph R Meier. (Switzerland)

Medications in Pregnancy/Birth Outcomes – I (Ballroom B)

Moderators: Jennita Reefhuis & Lolkje de jong van den Berg

10:30 AM **Pregnancy Exposure Registries: Challenges in Identifying Comparison Groups [25]**
Deborah L Covington, Susan S Roberts, Jessica Albano, Laura F McKain. (United States)

10:45 AM **Can the General Practice Research Database Identify a Known Teratogenic Association? [26]**
Rachel A Charlton, John G Weil, Julia M Snowball, Marianne C Cunnington, Corinne S de Vries. (United Kingdom)

11:00 AM **Valproic Acid Exposure & Specific Malformations [27]**
J Jentink, MA Loane, H Dolk, JK Morris, LTW de Jong-van den Berg, EUROCAT AED Working Group. (Netherlands)

11:15 AM **Effect of Correct Folic Acid Use on Spina Bifida in Pregnancies Exposed to Valproic Acid or Carbamazepine in the Netherlands [28]**
J Jentink, MK Bakker, LTW de Jong-van den Berg. (Netherlands)

11:30 AM **Serotonin Reuptake Inhibitor and Pregnancy: Risk of Gestational Hypertension? [29]**
Christine Damase-Michel, Veronique Duhalde, Caroline Hurault, Robert Bourrel, Jean Louis Montastruc. (France)

11:45 AM **Use of Antidepressants during Pregnancy and the Risk of Preterm Delivery and Fetal Growth Restriction [30]**
Sengwee Toh, Allen A Mitchell, Carol Louik, Martha M Werler, Christina D Chambers, Sonia Hernandez-Diaz. (United States)

12:00pm-1:30pm

Lunch/Poster Session A/Exhibits/Poster Walks: (Hall B)

Lunch Sponsored by UBC

Poster Walks/Moderators

- *Pharmacovigilance* –**Harry Seifert & Keith Beard, FISPE**
- *Medicines in pregnancy/birth defects*, **Lolkje T de Jong-van den Berg**
- *Drug Utilization Studies*, **Monique Elseviers**
- *Uses of Linked Databases*, **Matthew W. Reynolds**

ISPE Committee/Council Meetings

Open to all participants.

(Lunches will be available in meeting rooms)

- Development Committee (Room 558B)
- Fellowship & Awards Committee (Room 558A)
- Public Policy Committee (Room 557)
- Student Council (Ballroom E)

1:30-3:00pm

CONCURRENT SESSIONS: CONTRIBUTED PAPERS

Analysis Methods I (Ballroom B)

Moderators: Til Stürmer, FISPE & Marieke DeBruin

1:30 PM

Estimating Absolute Risks in the Presence of Noncompliance: An Application to a Women's Health Initiative Randomized Trial [31]

Sengwee Toh, Sonia Hernandez-Diaz, Roger Logan, James M Robins, Miguel A Hernan. (United States)

Student Award Recipient – Best Methods Abstract

1:45 PM

Prior Event Rate Ratio Adjustment: A Magic Bullet or More of the Same? [32]

Arlene Gallagher, Frank de Vries, Tjeerd van Staa. (Netherlands)

Student Award Recipient – Best Drug Utilization Abstract

2:00 PM **Observed Performance of the High-Dimensional Propensity Score (hd-PS) Algorithm in Small Samples [33]**
Jeremy A Rassen, M Alan Brookhart, Sebastian Schneeweiss. (United States)

2:15 PM **Applying Propensity Scores Estimated in a Full Cohort To Achieve Balance in Subgroup Analyses [34]**
Jeremy A Rassen, M Alan Brookhart, Sebastian Schneeweiss. (United States)

2:30 PM **Bias from Excluded Event-Depleted Time in Cohort Studies [69]**
Frank Andersohn, Stefan N Willich. (Germany)

2:45 PM **Confounder Summary Scores When Comparing the Effects of Multiple Drug Exposures [36]**
Suzanne M Cadarette, Joshua J Gagne, Daniel H Solomon, Jeffrey N Katz, Til Stürmer. (Canada)

Gastrointestinal Drugs: Going Beyond the Intestine (Room 554 AB)

Moderator: Dan Mines & Mari-Ann Wallander, FISPE

1:30 PM **Prokinetic Drugs in Children; Drug Utilization and Safety [37]**
S de Bie, KMC Verhamme, SMJM Straus, G Piceli, A Ceci, MCJM Sturkenboom. (Netherlands)

1:45 PM **No Evidence for Association of Tegaserod with Adverse Cardiovascular Ischemic Events [38]**
Jeanne Loughlin, Sherry Quinn, Elena Rivero, Heather Norman, David L Earnest, Judy Wong, John D Seeger. (United States)

2:00 PM **Use of Protonpump Inhibitors and Risk of Hip Fracture [39]**
Arief Lalmohamed, Sander Pouwels, Cyrus Cooper, Tjeerd van Staa, Bert Leufkens, Anthonius de Boer, Frank de Vries. (Netherlands)

2:15 PM **The Role of Medical Comorbidities in the Association of Proton Pump Inhibitors [PPIs] and Fractures [40]**
David R Gagnon, Jennifer R Fonda, Richard Scranton, Elizabeth V Lawler. (United States)

2:30 PM **Use of Proton Pump Inhibitors and Histamine Type 2 Receptor Blockers Is Not Associated with Pneumonia Risk [41]**
Sascha Dublin, Rod L Walker, Michael L Jackson, Jennifer C Nelson, Noel S Weiss, Lisa A Jackson. (United States)

2:45 PM **Proton Pump Inhibitors and Risk for Recurrent *Clostridium difficile* Associated Diarrhea [42]**

Amy Linsky, Kalpana Gupta, Elizabeth Lawler, Jennifer Fonda, John Hermos. (United States)

Improving Liking Databases (Room 555AB)

Moderators: Thomas MacDonald, FISPE, & Earl Goehring

1:30 PM **Automated Data Capture from Free Text Radiology Reports To Enhance Accuracy of Hospital Inpatient Stroke Codes [43]**

Robert Flynn, Thomas MacDonald, Gordon Murray, Alexander Doney. (United Kingdom)

1:45 PM **Linking Inpatient and Outpatient Data [44]**

Suellen Curkendall, Daniel Huse. (United States)

2:00 PM **Sensitivity and Specificity of Acute Renal Failure Medical Claims Validated against Electronic Medical Records [45]**

Marc B Rosenman, Peter M Wahl, Gregory Daniel, J Marc Overhage, Patricia McGuire, Daniel Thompson, Keith Rodgers, Louise Short, Rhonda L Bohn, William M Tierney. (United States)

2:15 PM **Effect of Extended Mortality Ascertainment in a Cohort Study of the Risk of Cancer in Regranex (Becaplermin) Users and Matched Comparators [46]**

Najat Ziyadeh, Daniel Fife, John D Seeger. (United States)

2:30 PM **Signal Detection Beyond Spontaneous Reports: An Example of Acute Adverse Event Detection in Large Claims Databases [47]**

Zhenchao Guo, Gilbert J L'Italien, Jayanti Mukherjee, Hugh Kawabata, Andres Gomez Caminero. (United States)

2:45 PM **Validation of Persistent Pulmonary Hypertension in the Newborn (PPHN) within the UK-Based General Practice Research Database (GPRD): Comparing Two Approaches [48]**

Tarek A Hammad, Carol Pamer, Susan McCune, Sigal Kaplan, Hany Aly, Solomon Iyasu. (United States)

Personalized Medicine: Molecular and Genetic Biomarkers of Efficacy and Toxicity (Room 552AB)

Moderators: Frederick Nyberg & Andrew Freedman

- 1:30 PM **Cisplatin, Nucleotide Excision DNA Repair Pathway, and Esophageal Cancer Outcomes: A Pharmacogenetic Epidemiology Study [49]**
Penny Bradbury, Wei Zhou, Rihong Zhai, Kofi Asomaning, Li Su, David Christiani, Geoffrey Liu. (Canada)
- 1:45 PM **CYP2C9, CYP2C19 and ABCB1 Genotype and Hospitalization for Phenytoin Toxicity [50]**
Sean Hennessy, Charles E Leonard, Cristin M Palumbo, Joshua P Metlay, Xin Chu, Brian L Strom, Warren B Bilker. (United States)
- 2:00 PM **Variation in Renin-Angiotensin System and Salt Sensitivity Genes and the Risk of Diabetes Mellitus Associated with the Use of Thiazide Diuretics [51]**
Ozlem Bozkurt, Anthonius de Boer, Diederik E Grobbee, Peter W de Leeuw, Abraham A Kroon, Paul Schiffrers, Olaf H Klungel. (Netherlands)
- 2:15 PM **Single Nucleotide Polymorphisms in Genes That Are Associated with a Modified Response to Statin Therapy: The Rotterdam Study [52]**
Catherine E de Keyser, Mark Eijgelsheim, Albert Hofman, Eric JG Sijbrands, Anke-Hilse Maitland-van der Zee, Cornelia M van Duijn, Andre G Uitterlinden, Jacqueline CM Witteman, Bruno HCh Stricker. (Netherlands)
Student Award Recipient – Best Molecular Epidemiology - Pharmacogenetics Abstract
- 2:30 PM **The Cost-Effectiveness of Genotype-Guided Warfarin Dosing for Patients with Atrial Fibrillation [53]**
Amanda R Patrick, Jerry Avorn, Niteesh K Choudhry. (United States)
- 2:45 PM **Mesothelin, a Biomarker of Pharmacologic Response in Malignant Pleural Mesothelioma, Evaluated in a Molecular Epidemiologic Study [54]**
Boming Yang, Paul Wheatley-Price, Deval Patel, Clement Ma, Natasha Leighl, Ron Feld, Marc de Perrot, Geoffrey Liu. (Canada)

Vaccines (Room 556AB)

Moderators: M. Miles Braun, FISPE, & Robert Chen, FISPE

- 1:30 PM **A Systematic Approach To Analyze Safety Data Clinical Trial Database [55]**
Caroline Legendre, Alena Khromava, Gillis Carrigan. (France)
- 1:45 PM **Active Safety Surveillance of DTaP Vaccines by Linkage of Immunization Registry and Claims Database in Korea [56]**
Sun-Young Jung, Nam-Kyong Choi, Byung-Joo Park. (Korea)
- 2:00 PM **The Risk of Seizures after Acellular Pertussis Vaccines in Early Childhood — United States, 2002-2006 [57]**
Wan-Ting Huang, Paul Gargiullo, Irene Shui, Eric Weintraub, James Baggs, Karen Broder, John Iskander. (United States)
- 2:15 PM **Effectiveness of the Pentavalent Rotavirus Vaccine in Preventing Gastroenteritis in the United States: A Claims-Based Analysis [58]**
Florence T Wang, T Christopher Mast, Roberta J Glass, Jeanne Loughlin, John D Seeger. (United States)
- 2:30 PM **Cautionary Example of Potential Exposure-Based Differential Misclassification in a Post-Marketing Vaccine Safety Study [59]**
Nancy C Santanello, Christopher Mast, Jeanne Loughlin, John Seeger. (United States)
- 2:45 PM **A Post-Marketing Surveillance Program for Pentavalent Rotavirus Vaccine [60]**
Jeanne Loughlin, Wang Florence, P Mona Eng, T Christopher Mast, John D Seeger. (United States)
- 3:00-3:30pm **Break/Posters/Exhibits (Hall B)**
- 3:30-5:00pm ***CONCURRENT SESSIONS: SYMPOSIA AND WORKSHOPS***
- 3:30 PM **Automated Data Sources for Pharmacoepidemiology in Asia-Pacific Region – Updates and Perspectives [61] (Room 556AB)**
Byung Joo Park, Yea Huei Kao Yang, Libby Roughead, Daisuke Koide, Jeff J Guo, Tomomi Kimura, Arnold K Chan, Judith K Jones, Brian L Strom. (Japan)

- 3:30 PM **Can Registries Deliver? The Methods and Use of Registries for Biologics [62] – Sponsored by the Biologics SIG (Room 555AB)**
Sean Zhao, Nancy Dreyer, Alex Cole, Annette Stemhagen, Nils Feltelius, Joanna Haas. (United States)
- 3:30 PM **Confounding by Indication Studying Epoetin and Mortality [63] (Ballroom B)**
John Acquavella, Eric Weinhandl, Brian Bradbury, Alan Brookhart, Til Stürmer, Kenneth J Rothman. (United States)
- 3:30 PM **Evaluating Study Designs for the Measurement of Drug Exposure in Pregnancy [64] Sponsored by the Medicines in Pregnancy SIG and the Teratology Society (Room 552AB)**
Elizabeth B Andrews, Lyn Colvin, Sonia Hernandez-Diaz, Lewis Holmes, Tina Chambers, Andrea Margulis, Allen Mitchell. (United States)
- 3:30 PM **Pharmacoepidemiology, Medicines Policy and Health Outcomes: The Next Steps [65] (Room 551AB) ***special anniversary session*****
Andrew L Gilbert, Laing Richard, Andreas Laupacis, Elizabeth Roughead, Kate L Lapane. (Australia)
- 3:30 PM **The Past, Present and Future of Pharmacoepidemiology at CDER, FDA [66] (Ballroom A) ***special anniversary session*****
Solomon Iyasu, Tarek A Hammad, Gerald J Dal Pan, Judy A Staff. (United States)
- 3:30pm **Is Accuracy at Odds with Privacy? Challenges and Solutions When Combining Data from Multiple Sources [285] (Room 554AB)**
Jeremy Rassen, Lang Chen, Miriam Sturkenboom, Sebastian Schneeweiss, Stephen Evans. (United States)

5:00-6:00pm

ISPE Council Meetings

Open to all interested participants

- Academic Council (**Westin Providence – Narragansett C**)
- Government/Regulatory Council (**Westin Providence– Narragansett B**)
- Manufacturing/Service Providers Council (**Westin Providence – Narragansett A**)

5:15-6:15pm

Fourth Asian Conference on Pharmacoepidemiology Planning Committee Meeting (RICC, Room 554AB)

7:00-9:00pm

PDS Editorial Board

TBA

(By Invitation)

7:00pm- ?

Student Social Event – A Night Out in Providence

Bravo Brasserie Restaurant, 123 Empire Street

Open to all students.

Organized by the ISPE Student Council

TUESDAY
August 18, 2009

- 7:00 AM **Annual Roundtable Discussion/Breakfast: Centers for Education and Research on Therapeutics [608] (Room 557)**
Anne E Trontell, Mark Hornbrook, Stephen Crystal. (United States)
- 7:00-8:00am **Poster Session B Set-up (Hall B)**
Continental Breakfast
- 7:00-6:00pm **Registration (Third Floor Foyer)**
- 7:30-5:00pm **Speakers' Ready Room (Room 553B)**
- 8:00-6:00pm **Exhibits/Posters (Hall B)**
- 8:00-9:15am **INVITED PLENARY SESSION (Ballroom A)**
Chair: **Andrew Gilbert**
- National Pharmaceutical Policy Imperatives: Implications for Pharmacoepidemiologists*
Lloyd Sansom, Emeritus Professor; University of South Australia: Chair, Pharmaceutical Benefits Advisory Committee; Australian Government Department of Health and Ageing
- 9:15-10:30am **ANNUAL MEETING OF ISPE MEMBERS, AWARDS CEREMONY & SPECIAL ADDRESS (Ballroom A)**
- Open to all participants.*
- ◀ Annual Meeting of ISPE Members
Miriam CJM Sturkenboom, FISPE, ISPE President
Nancy A Dreyer, ISPE Vice President Finance
 - ◀ Awards Ceremony
 - ICPE 2009
Presented by **Miriam CJM Sturkenboom**, ISPE President
 - **Brian J Quilliam**, Chair, Local Host Committee

- **Susan Sacks, FISPE**, Co-Chair, 25th Anniversary ICPE Committee
- **Kate Lapane, FISPE**, Chair, 2009 Scientific Program Committee & Co-Chair, 25th Anniversary ICPE Committee

- Student Awards
Presented by **Kate Lapane, FISPE**, Chair, 2009 Scientific Program Committitur
 - Best Drug Utilization Abstract: **Arlene Gallagher**
 - Best Molecular Epidemiology/Pharmacogenetics Abstract : **Catherine de Keyser**
 - Best Methods Abstracts: **Sengwee Toh**
 - Third Best Abstract: **Nicole Pratt**
 - Second Best Abstract: **Mary Ritchey**
 - Edlavitch Award (Best Student Abstract): **Charlotte van Noord**

- Induction of ISPE Fellow (FISPE)
Yola Moride, FISPE, Chair, Fellowship & Awards Committee

Inductees:
Stella Blackburn, FISPE
James Lewis, FISPE

- *Pharmacoepidemiology & Drug Safety*
ISPE-PDS Prizes for Best Papers published in *PDS Volume 17 (2008)*
Presented by, **Brian Strom**, FISPE, Regional Editor for the Americas, **Joerg Hasford**, Regional Editor for Europe, and **Richard Hughes**, Managing Editor, *PDS*

◀ **Special Anniversary Address**
25 Years in 25 Minutes
Hugh Tilson, Honorary Lifetime Fellow,

10:30-11:00am

Break/Posters/Exhibits (**Hall B**)
Sponsored by CSD-EPIC

11:00-12:30pm ***CONCURRENT SESSIONS – CONTRIBUTED PAPERS***

Anti-Infectives (Room 552B)

Moderators: Patricia Saddier & Amy Pakyz

- 11:00 AM **Effectiveness of an Information Technology Intervention To Improve Prophylactic Antimicrobial Use in the Post-Operative Period [227]**
Kevin Haynes, Darren Linkin, Neal Fishman, Warren Bilker, Eric Pifer, Sean Hennessy. (United States)
- 11:15 AM **Effectiveness of Palivizumab in Medicaid Infants [228]**
Almut G Winterstein, Christian Hampp, Arwa Saidi. (United States)
- 11:30 AM **Comparison of Infection-Related Hospitalization Risk among Patients Receiving Sargramostim, Filgrastim, and Pegfilgrastim for Chemotherapy-Induced Neutropenia [229]**
Mei Sheng Duh, Edmond L Toy, Francis Vekeman, Francois Laliberte, Bree L Dority, Daniel Perlman, Victoria Barghout, Mark L Heaney. (United States)
- 11:45 AM **Is Cigarette Smoking a Risk Factor for Subsequent Use of Antibiotics? [230]**
Hege S Blix, Vidar Hjellvik, Irene Litleskare, Marit Rønning, Aage Tverdal. (Norway)
- 12:00 PM **Reporting of Hepatic Events in Patients Using Vancomycin from Clinical Studies: A Meta-Analysis [231]**
Yan Chen, Xiao Yan Yang, Michael Zeckel, Chris Killian, Kenneth Hornbuckle, Simon Voss. (United States)
- 12:15 PM **Outcomes of Antibiotic Use for Respiratory Infections [232]**
Sharon B Meropol, A Russell Localio, Joshua P Metlay. (United States)

Information as Basis for Risk Management (Ballroom D)

Moderators: Elizabeth Andrews, FISPE, & Nataliya Volkova

- 11:00 AM **Determinants of Metabolic Testing for Patients Treated with Second-Generation Antipsychotics after the FDA Diabetes Warning [233]**
Elaine H Morrato, Benjamin Druss, Daniel M Hartung, Robert J Valuck, Deborah Thomas, Richard Allen, Elizabeth Campagna, John W Newcomer. (United States)
- 11:15 AM **Quantification of Patient Population Impact of Contra-Indications: Glaucoma Therapy [234]**
Andrew Maguire, Sharon MacLachlan. (United Kingdom)
- 11:30 AM **Perceptions of Older Adults Regarding Information Obtained from Pharmacists and Medication Leaflets [235]**
Roberta Goldman, Anne L Hume, Brian J Quilliam, Pedro Pichardo, Devi Ross, Kate L Lapane. (United States)
- 11:45 AM **Opioid Analgesic Abuse Surveillance: Convergence of Poison Control Center Intentional Exposure Calls and Media Reports [236]**
John Brownstein, Richard Dart, Meredith Y Smith. (United States)
- 12:00 PM **Evaluation of the Infliximab (Remicade®) Pediatric Crohn's Disease Educational Plan [237]**
Alejandro Arana, Sam Allen, Ola Ghatnekar, María T Rico, Nathalie Vanhaverbeke, Jörg Burkowitz, Charles E Wentworth, Valerio Fantoni, Max Brosa, Felix M Arellano. (Spain)
- 12:15 PM **A Comparison of Health Outcomes and Healthcare Utilization during Episodes of Modified-Release Opioid Analgesic Therapy with and without Evidence of an Alcohol-Related Disorder [238]**
Meredith Y Smith, J David Haddox, Liisa Palmer. (United States)

Measurement Methods (Ballroom B)

Moderators: Tobias Gerhard & Tamar Lasky

- 11:00 AM **Prescription Changes and Chronic Disease Score as Predictors for Hospitalization [239]**
Carolien GM Sino, Rutger Stuffken, Eibert R Heerdink, Patrick C Souverein, Marieke J Schuurmans, Antoine CG Egberts. (Netherlands)
- 11:15 AM **Positive Predictive Value (PPV) of Commercial Health Insurance Claims Data for Identifying Acute Pancreatitis (AP) in Patients with Diabetes Mellitus (DM) [240]**

David D Dore, Clorinda Hoffman, Sherry G Quinn, Saadia Chaudhry,
John D Seeger. (United States)

11:30 AM **Impact of Exposure Data Sources on Risk Estimates in Etiological Studies: Application to Benzodiazepines in the Three-City (3C) Study [241]**

Fabienne Bazin, Pernelle Noize, Antoine Pariente, Nicholas Moore,
Annie Fourier-Réglat. (France)

11:45 AM **The Validity of Mother-Reported Asthma and Asthma Medication Use in Children [242]**

Kari Furu, Øystein Karlstad, Svetlana Skurtveit, Siri Haaberg, Per
Nafstad, Stephanie London, Wenche Nystad. (Norway)

12:00 PM **Impact of Missing Data on Potential Confounders in Perinatal Pharmacoepidemiologic Studies Using Administrative Databases [243]**

Anick Bérard, Hamid R Nakhai-Pour, Sophie Kulaga. (Canada)

12:15 PM **Risk of Hospitalization among Rheumatoid Arthritis Patients Initiating Treatment with TNF α -Antagonists: Effect of Different Exposure Measurements and Propensity Score Estimates [244]**

Carlos Grijalva, Lisa Kaltenbach, Patrick Arbogast, Edward Mitchel,
Marie Griffin. (United States)

The Spectrum of Anti-Inflammatory Therapies (Room552A)

Moderators: Sean Hennessy, FISPE & C. Ineke Neutel, FISPE

11:00 AM **The Influence of *CYP2D6*, *CYP3A4/3A5* and *UGT2B7* Genetic Polymorphisms on Prescription of Other Analgesics in Codeine Users [245]**

Monique J Bijl, Loes E Visser, Ron HN van Schaik, Mark Eijgelsheim,
Albert Hofman, Andre G Uitterlinden, Arnold G Vulto, Teun van
Gelder, Bruno HCh Stricker. (Netherlands)

11:15 AM **Risk of Serious Infections among Patients with Rheumatoid Arthritis Initiating Treatment with Tumor Necrosis Alpha Antagonists [246]**

Carlos Grijalva, Lisa Kaltenbach, Patrick Arbogast, Edward Mitchel,
Marie Griffin. (United States)

11:30 AM **Changes in Overuse and Underuse of Prophylactic Strategies with NSAID Treatment over the Past Decade [247]**

VE Valkhoff, EM van Soest, MCJM Sturkenboom, EJ Kuipers.
(Netherlands)

- 11:45 AM **Concomitant Use of Gastroprotective Agents (GPAs) among NSAID/COX-2 Selective Inhibitor Users: A Hospital Register-Based Study [248]**
Jarir Atthobari, Erna Kristin, Iwan Dwiprahasto. (Indonesia)
- 12:00 PM **Randomized Controlled Trials on Cox-2 Inhibitors, Changes in Comparator Dose over Time [249]**
G Stefansdottir, ML de Bruin, MJ Knol, DE Grobbee, HGM Leufkens. (Netherlands)
- 12:15 PM **Association between Non-Steroidal Anti-Inflammatory Drugs and Keratinocyte Cancer Prevention: VATTC Trial [250]**
Anthony P Nunes, Kate L Lapane, Martin A Weinstock. (United States)

Use and Risks of Psychotropics in Elderly Persons (Room 557)

Moderators: Vincent Mor & Lauri Daiello

- 11:00 AM **Socioeconomic Determinants of Psychotropic Drug Use among Elderly [251]**
Eva Lesén, Karolina Andersson, Max Petzold, Anders Carlsten. (Sweden)
- 11:15 AM **Antipsychotics and the Risk of Hip Fracture, Pneumonia and Stroke: Self-Controlled Case Series and Instrumental Variable Analysis Results [252]**
Nicole Pratt, Elizabeth Roughead, Philip Ryan, Robert Peck, Andrew Gilbert. (Australia)
Student Prize Recipient – Third Best Abstract
- 11:30 AM **Antipsychotic Use and the Risk of Hip Fracture in Nursing Home Residents with Dementia [253]**
Jessica J Jalbert, Susan C Miller, Charles B Eaton, Kate L Lapane. (United States)
- 11:45 AM **Factors Associated with Discontinuation of Cholinesterase Inhibitors in the Netherlands [254]**
Edeltraut Kröger, Rob van Marum, Patrick Souverein, Toine Egberts. (Netherlands)
- 12:00 PM **Impact of Non-Persistence to Cholinesterase Inhibitor Treatments in Demented Elderly [255]**

Antoine Pariente, Annie Fourrier-Réglat, Alice Dragomir, Sylvie Perreault, Nicholas Moore, Yola Moride. (France)

12:15 PM **Risk of Upper Gastrointestinal Bleeding and Degree of Serotonin Reuptake Inhibitions among Elderly Patients in Korea [256]**
Ye-Jee Kim, Nam-Kyong Choi, Sun-Young Jung, Jong-Mi Seong, Joongyub Lee, Byung-Joo Park. (Republic of Korea)

12:30-2:00pm **Lunch/Poster Session B/Exhibits/Poster Walks (Hall B)**

Poster Walks/Moderators

- *Pharmacovigilance* –Harry Seibert
- *Molecular epidemiology/Pharmacogenetics* – Wei Zhou & David Miller
- *Drug Utilization Studies* – Monique Elseviers
- *Biologics* – Pavel Napalkov
- *Use of Linked Database* – Matthew R. Reynolds

ISPE Committee/Council Meetings

Open to all participants.

(Lunches will be available in meeting rooms)

- Bylaws and Policies Committee (**Room 558A**)
- Global Development Committee (**Room 554A**)
- Membership Committee (**Room 554B**)
- Publications Committee (**Room 558B**)

1:00-1:30pm **Public Forum on Core Competencies for Pharmacoepidemiology**
sponsored by ISPE Education Committee (**Ballroom A**)
(NOTE: eat first - lunch will not be available at this session)

Jim Lewis, FISPE, Chair, Education Committee, *Introductions*

Hugh Tilson, FISPE, Moderator, *Comments*

Judith Jones, FISPE, *Data Presentation*

Panel Comments/Questions

Jennifer Polinski, Student Council

Wei Dong, Manufacturing/Service Provider Council

Anna Birna Almarsdóttir, Academic Council

Richard Hill, Government/Regulatory Council

Open Discussion

2:00-3:30pm **CONCURRENT SESSIONS – CONTRIBUTED PAPERS**

Cancer All Over the Place! (Room 551A)

Moderators: Annette Beiderbeck & Jim Kaye

2:00 PM **Half of Breast Cancer Patients Starting on Tamoxifen Complete Five Years of Endocrine Treatment [257]**

Myrthe PP van Herk-Sukel, Adri C Voogd, Grard AP Nieuwenhuijzen, Ron MC Herings, Jan Willem W Coebergh, Lonneke V van de Poll-Franse. (Netherlands)

2:15 PM **Dose Response of Retinol and Isotretinoin in the Prevention of Non-Melanoma Skin Cancer Recurrence [258]**

Mary C Clouser, Denise J Roe, Janet A Foote, Robin B Harris. (United States)

2:30 PM **Incidence Rates of ARDS in Solid Tumor Cancer Patients in the THIN Database [259]**

Victor Gastanaga, Chuck Wentworth, Anthony Yeo, Gail Hughes, William Haddock, Sean Zhao. (United States)

2:45 PM **Patients (Pts) with Metastatic Renal Cell Carcinoma (mRCC) Receiving Angiogenesis Inhibitor (AI) Therapies: Treatment Efficacy and Safety in Clinical Practice [261]**

David McDermott, Toni K Choueiri, Jessica Clement, Ashley J Brick, Christabel Kwabi, Karishma Shah, Lucia Antras, Sujata S Jayawant, Si-Tien Wang, Andi Luka, Mei Sheng Duh, Maureen Neary, William K Oh. (United States)

3:00 PM **Pattern of Bevacizumab (BV) Use in 1st-Line Therapy Metastatic Colorectal Cancer (mCRC) in Real-Life Practice: Results of the ETNA Cohort Study [262]**

A Fourrier-R[eaculte]glat, D Smith, A Ravaud, M Rouyer, A Balestra, D Jayles, N Moore, ETNA Study Group.

Cardiovascular Disease (Ballroom D)

Moderators: Annlouise Assaf & Cristina Varas

2:00 PM **Antipsychotic Use and Myocardial Infarction in Demented Patients Treated with Cholinesterase Inhibitors [263]**

Antoine Pariente, Yola Moride, Alice Dragomir, Sylvie Perreault,
Nicholas Moore, Annie Fourrier-Réglat. (France)

2:15 PM **Do Selective Cyclooxygenase-2 Inhibitors and Nonselective
Nonsteroidal Antiinflammatory Drugs Increase the Risk of
Cardiovascular Events and Death after Intracoronary Stenting? [264]**
M Schmidt, M Maeng, L Pedersen, JF Lassen, TT Nielsen, HT
Sorensen. (Denmark)

2:30 PM **Evaluation of the Level of Anticoagulation Control in Patients with
Non-Valvular Atrial Fibrillation [265]**
Bill Zang, Efrosini Setakis, Tjeerd P van Staa. (United Kingdom)

2:45 PM **Non-Selective β -Blockers Decrease Thrombotic Events in Patients
with Heart Failure [266]**
Olav R De Peuter, Patrick C Souverein, Olaf H Klungel, Ton de Boer,
Harry R Büller, Pieter-Willem Kamphuisen. (Netherlands)

3:00 PM **Oral Bisphosphonates and the Risk of Atrial Fibrillation in a Cohort
of Older Adults [267]**
Linda Lévesque, Ana Blagojevic, Mahyar Etminan, James Brophy.
(Canada)

3:15 PM **Case-Control Study: Use of Oral Contraceptives Containing
Dienogest and Risk of Venous Thromboembolism [268]**
Juergen C Dinger, Kristina Voigt, Sabine Moehner. (Germany)

Potpourri Session (Ballroom B)

Moderators: Gianluca Trifiro and Rene Schade

2:00 PM **Population-Based Studies of Antithyroid Drugs and Sudden Cardiac
Death [609]**
Charlotte van Noord, Miriam CJM Sturkenboom, Sabine MJM Straus,
Jacqueline CM Witteman, Bruno HC Stricker. (Netherlands)
Student Award Recipient- Edlaich Award (Best Abstract)

2:15 PM **Outcomes Following a Hip Fracture and Length of Hospitalization:
The General Practice Research Database (GPRD) [610]**
Arlene Gallagher, Frank de Vries, Rinat Ariely, Tjeerd van Staa. (United
Kingdom)

- 2:30 PM **Polymorphisms in Two Regions of the Cyclo-Oxygenase-2 Gene Associated with Variation in Risk of Coronary Thrombosis with Cyclo-Oxygenase-2 Inhibitors [611]**
D Henry, L Lincz, J Attia, P McElduff, L Bisset, R Peel, S Hancock, K Henderson, D Whitaker, M Seldon, P McGettigan. (Canada)
- 2:45 PM **Human Avian Influenza: Development of a Shoe-Leather Approach to Evaluating Treatment Effectiveness [612]**
W Adisasmito, M Zaman, P Chan, N Lee, V Gasimov, FF Aghayev, A Oner, E Bamgboye, N Dogan, K Starzyk, A Layton, R Coker, S Toovey, N Dreyer.
- 3:00 PM **Gabapentin Use in the US Department of Veterans Affairs [613]**
JE Lavigne, D Ganoczy, KL Knox, M Valenstein.
- 3:15 PM **Changing Rate of Blood-Stream Infection across Duration of Central Venous Access [614]**
Mary Ritchey, Michele Jonsson Funk, Stephen Marshall, Danica Marinac-Dabic, William Rutala, David Weber. (United States)
Student Award Recipient- Edlaich Award (Second Best Abstract)
- Risk Factors, Surveillance, and Comorbidity Burden (Room 551B)**
Moderators: Wei Dong & Brian J. Quilliam
- 2:00 PM **Validation of the National Respiratory and Enteric Virus Surveillance System for the Detection of Respiratory Syncytial Virus Seasons [269]**
Christian Hampp, Almut Winterstein. (United States)
- 2:15 PM **Heptitis C Virus Genotype and Basal Viral Load Distribution in Different Regions of Mexico [270]**
Ricardo Jimenez-Mendez, Felipe Uribe-Salas, Paulo Lopez-Guillen, Gilberto Castaneda-Hernandez. (Mexico)
- 2:45 PM **Modifiable Risk Factors among Uninsured, Insured and Medicaid-Insured United States Adults Aged 18 to 64 Years [271]**
Margaret McDonald, Robin P Hertz, Michael B Lustik, Alan N Unger. (United States)
- 3:00 PM **Type 2 Diabetes and Incidence of Urinary Tract Infections (UTIs). Experience from the General Practice Research Database (GPRD) [272]**

Ishan Hirji, Zhenchao Guo, Susan Andersson, Niklas Hammar, Andres Gomez Caminero. (United States)

3:15 PM **Comorbidity in Patients with Non-Small Cell Lung Cancer (NSCLC) – The Cancer and Comorbidity (CACOM) Study [273]**
Fredrik Nyberg, Tobias Svensson, Helle Kieler, Mats Lambe, Anders Ekbom, Fredrik Granath. (Sweden)

3:30 PM **Renal Cell Carcinoma Patients Are Twice as Likely To Develop Thromboembolic Events Compared to Cancer-Free Controls [274]**
Myrthe PP van Herk-Sukel, Sumitra Shantakumar, Mariel K Casparie, Page E Abrahamson, Fernie JA Penning-van Beest, Ron MC Herings. (Netherlands)

To Do No Harm....? (Room 557)

Moderators: Frank May, FISPE, & Yea-Huei Kao Yang

2:00 PM **Prevalence, Nature and Severity of Prescribing Errors in Hospital Inpatients: Prospective Study in 20 UK Hospitals [275]**
Darren M Ashcroft, Penny J Lewis, Emma Carter, David Taylor, Mary P Tully, Valerie Wass, Steven Williams, Timothy Dornan. (United Kingdom)

2:15 PM **Prevalence, Clinical Profile, and Preventability of Drug-Related Hospital Admissions: Prospective Observational Study [276]**
Darren M Ashcroft, Chuenjid Kongkaew, Steven Williams, David Metcalfe, Jaydeep Mandal, Peter Noyce. (United Kingdom)

2:30 PM **Computerized Clinical Decision Support during Medication Ordering for Long-Term Care Residents with Renal Insufficiency [277]**
Terry S Field, Paula Rochon, Monica Lee, Joann L Baril, Jerry H Gurwitz. (United States)

2:45 PM **RCT of a Computer Hard Stop Order Alert vs Routine Practice To Prevent Concurrent Orders of Trimethoprim/Sulfamethoxazole and Warfarin [278]**
Brian L Strom, Rita Schinnar, Faten Aberra, Warren Bilker, Sean Hennessy, Charles E Leonard, Eric Pifer. (United States)

3:00 PM **The Effectiveness of Collaborative Medicine Reviews in Delaying Time to Next Hospitalisation for Heart Failure Patients in the Ambulatory Setting: Results of a Cohort Study [279]**
Andrew L Gilbert, Elizabeth E Roughead, John D Barratt, Emmae Ramsey, Nicole Pratt, Phillip Ryan, Robert Peck, Graeme Killer. (Australia)

- 3:15 PM **Quality of Consumer Generated Adverse Event Reports [280]**
Rose C Plummer, Elisa F Cascade. (United States)
- 3:30-4:00pm **Break/Posters/Exhibits (Hall B)**
- 4:00-5:30pm **CONCURRENT SESSIONS: Symposia & Workshops**
- 4:00 PM **Practical Aspects of Signal Detection in Pharmacovigilance – The CIOMS VIII Report [469] (Room 557)**
June M Raine, Gerald Dal Pan, Manfred Hauben, Atsuko Shibata. (United Kingdom)
- 4:00 PM **Conflict of Interest (COI) – What Is It? What Can Be Done To Minimize It? [282] (Room 552A)**
Proposed by Wei Dong, Susan Oliveria, Robert F Reynolds, Pavel Napalkov, Paul Stang, Marianne Ulcickas Yood. (United States)
- Bob Levine**, Director of Law, Policy and Ethics, Yale University, *COI: An Overview and Theoretical Framework of COI*
Jill Hartzler Warner, Acting Assistant Commissioner for Accountability and Integrity, FDA, *FDA Advisory Committees and Considerations for Conflicts of Interest*
Stella Blackburn, FISPE, EMEA, *ENCePP's Perspective on COI*
Cary Gross, Division of Internal Medicine, Yale University, *Considerations from Academia*
Walter Straus, Merck Research Laboratories, *COI: A Personal View from Pharmaceutical R & D*
- 4:00 PM **Developing Good Practice Guidance for Non-Randomized Studies of Comparative Effectiveness: A Workshop on Quality and Transparency [283] (Ballroom B)**
Nancy Dreyer, Annaliso Rubino, Gilbert J L'Italien, Sebastian Schneeweiss. (United States)
- 4:00 PM **How Should We Plan and Communicate Interim Results of Pharmacoepidemiology Studies? An ISPE Public Policy Forum [284]**
Susana Perez-Gutthann, Til Stürmer, Richard Platt, Brian L Strom, Patricia Saddier, June Raine, Sander Greenland. (Spain) **(Ballroom D)**

4:00 PM **Providing Pharmacoepidemiological Data Intended for Drug Regulatory Decision Making [286] (Ballroom A)**
Joanna F Haas, Sebastian Schneeweiss, Elizabeth B Andrews, Edward Bortnichak, Judith Jones, Gerald Dal Pan. (United States)

4:00PM **Who Is a Patient's Main Prescriber and How Should Clustering Within Prescriber Influence Analyses? [67] (Room 552B)**
Niteesh K Choudhry, Robert J Glynn, M Alan Brookhart, Jeremy A Rassen. (United States)

5:30-6:30pm **Special Interest Group (SIG) Meetings**
Open to all participants.

- Biologics SIG (**Room 551A**)
- Database SIG (**Room 551B**)
- Drug Utilization/Health Services Research SIG (**Ballroom B**)
- Medications in Pregnancy SIG (**Room 552A**)
- Molecular Epidemiology/Pharmacogenetics SIG (**Room 552B**)

7:30-Midnight **Evening at the Waterplace Restaurant**
Join your colleagues to help celebrate ISPE's Silver Anniversary Meeting on this special evening. Brass Attack, Southern New England's finest dance band, will provide the music. ISPE will host a WaterFire – an award-winning sculpture by Barnaby Evans and truly an unforgettable sensory experience, at dusk.

Admission is by badge or ticket. Cash bar



WEDNESDAY
August 19, 2009

- 7:00-8:00am **2010 ICPE Scientific Program Committee Meeting (Room 557)**
(Open to interested ISPE members)
- 7:30-8:30am **Poster Session C Set-up (Hall B)**
Continental Breakfast
- 7:30-5:00pm **Registration (Third Floor Foyer)**
- 7:00-3:30pm **Speakers' Ready Room (Room 553B)**
- 8:00-1:45pm **Exhibits/Posters (Hall B)**
- 8:30-10:00am ***CONCURRENT SESSIONS – CONTRIBUTED
PAPERS***

Analysis Methods II (Ballroom B)

Moderators: John Seeger & Tomasz Dyszynski

- 8:30 AM **Using Different Types of Priors in a Bayesian Hierarchical Model for the Analysis of Drug Adverse Events [438]**
David Prieto-Merino, Stephen JW Evans. (United Kingdom)
- 8:45 AM **The Effect of Psychotropic Medication Among Children On Changes in Mental Health: A Comparison of Marginal Structural Models (MSM) with Standard Regression Adjustment [439]**
Shirley Wang. (United States)
- 9:00 AM **Predictors of Nucleoside Reverse Transcriptase Inhibitor Use: Channeling Bias in HIV Clinical Care [440]**
Emily S Brouwer, Sonia Napravnik, Joseph J Eron Jr. (United States)
- 9:15 AM **Hurdle or No Hurdle? Select Appropriate Statistical Methods for Modeling Rare Events [441]**
Liping Huang, George Quartey, Jamie Robinson. (United States)
- 9:30 AM **Reporting of Case-Series in Drug Safety: A Review of Published Studies [442]**
Antoine Pariente, Claire Nour Abou Chakra, Marion Pinet, Nicola Moore, Yola Moride. (Canada)

- 9:45 AM **Significance of Incorporating Real World Clinical Non-Adherence and Drug Adverse Events Data into Pharmacoeconomic Models: Statins Example [443]**
Pendar Farahani, Gray Ellrodt. (United States)
- Diabetes From Legs To Death (Room 551A)**
Moderators: Niklas Hammar & Andrej Czarnecki, FISPE
- 8:30 AM **Use of Thiazolidinediones and the Risk of Fracture in Patients with Type II Diabetes in Taiwan [444]**
Churn-Shiuh Gau, Yi-Shiu Lin. (Taiwan)
- 8:45 AM **Thiazolidinediones and Fractures in Men and Women [445]**
Colin R Dormuth, Greg Carney, Bruce Carleton, Ken Bassett, James M Wright. (Canada)
- 9:00 AM **Effect of Angiotensin Receptor Blockers and Angiotensin Converting Enzyme Inhibitors on Limb Amputation [446]**
David Margolis, Ole Hoffstad, Tim Crombleholme. (United States)
- 9:15 AM **Incidence of Acute Pancreatitis in Exenatide Initiators Compared to Other Anitdiabetic Drug Initiators: A Retrospective, Cohort Study [447]**
David Dore, Gary Bloomgren, Ruth Patterson, Sherry Quinn, Clorinda Hoffman, Saadia Chaudhry, Rebecca Noel, Daniel Braun, John Seeger. (United States)
- 9:30 AM **Adverse Cardiovascular Events during Treatment with Pioglitazone and Rosiglitazone [448]**
David N Juurlink, Tara Gomes, Lorraine L Lipscombe, Peter C Austin, Jan E Hux, Muhammad M Mamdani. (Canada)
- 9:45 AM **Combination Therapy of Sulfonylureas and Metformin and the Risk of Death in Patients with Type 2 Diabetes [449]**
Laurent Azoulay, Verena Schneider-Lindner, Sophie Dell’Aniello, Alicia Schiffrin, Samy Suissa. (Canada)

Drug Utilization: Session II (Room 551B)

Moderators: Andrew Gilbert & Monique Elsevier

- 8:30 AM **Is Persistence Fading? Time Trends and Determinants of Antibiotic Prescriptions in the Community for Children in the United Kingdom 1993-2007 [450]**
V Schneider-Lindner, S Dell'Aniello, A Kezouh, C Quach, J Hanley, S Suissa. (Canada)
- 8:45 AM **Off-Label Use of Antipsychotic Drugs in Privately and Publicly Insured Youth in the US [451]**
Stephen Crystal, Tobias Gerhard, Cecilia Huang, Mark Olfson. (United States)
- 9:00 AM **Physician Preference Motivates Use of Anti-TNF Therapy Independent of Clinical Disease Activity [452]**
Jeffrey R Curtis, Lang Chen, Leslie Harrold, Pongthorn Narongroeknawin, George Reed, Daniel H Solomon. (United States)
- 9:15 AM **Levetiracetam One Year Retention Rate in Real-Life Practice in France, Final Results of the EULEV Study [453]**
C Droz, C Dureau, H Vespignani, C Marchal, J Jové, N Moore, A Fourrier. (France)
- 9:30 AM **Use of Cardioprotective Drugs in Newly Treated Individuals with Type 2 Diabetes Aged Under 65 [454]**
Anis Ben Abdeljelil, Jocelyne Moisan, Jean-Pierre Grégoire. (Canada)
- 9:45 AM **Polypharmacy in Chronic Diseases in the Elderly: Evidence-Based or Potentially Inappropriate Prescribing? [455]**
Gillian Caughey, Agnes Vitry, Andrew Gilbert, Elizabeth Roughead. (Australia)

Medications in Pregnancy and Birth Outcomes II (Room 552A)

Moderators: Janneke Jentink & Sara A. Ephross

- 8:30 AM **Descriptive Study of the Administration of Category X Medications during Pregnancy Using an Outpatient Electronic Health Record [456]**
Brian L Strom, Rita Schinnar, Joshua Jones, Warren Bilker, Mark Weiner, Sean Hennessy, Charles E Leonard, Peter Cronholm, Eric Pifer. (United States)

- 8:45 AM **Trimethoprim Use Prior to Pregnancy and Risk of Congenital Malformation: A Register Based Nationwide Cohort Study [457]**
Jon T Andersen, Morten Petersen, Jeppe N Rasmussen, Nadia LT Andersen, Christian Torp-Pedersen, Henrik E Poulsen. (Denmark)
- 9:00 AM **Linking a Pharmaceutical Claims Database with a Birth Defects Registry To Investigate Birth Defect Rates of Known Teratogens [458]**
Lyn Colvin, Linda Slack-Smith, Fiona J Stanley, Carol Bower. (Australia)
- 9:15 AM **Maternal Use of Bupropion and Risk for Congenital Heart Defects [459]**
Sura Alwan, Jennita Reefhuis, Lorenzo Botto, Adolfo Correa, Sonja Rasmussen, Jan Friedman. (United States)
- 9:30 AM **Early-Pregnancy Opioid Analgesic Treatment and Risk for Congenital Heart Defects [460]**
CS Broussard, SA Rasmussen, J Reefhuis, JM Friedman, MW Jann, MA Honein. (United States)
- 9:45 AM **Does Decongestant Use during Pregnancy Reduce Preterm Delivery? [461]**
Rohini K Hernandez, Allen A Mitchell, Martha M Werler. (United States)

Psychotropics II: Safety of Psychotropics (Room 552B)

Moderators: James Wilson & Jessica Jalbert

- 8:30 AM **General Population Risk of Suicide Attempt Compared to Depressed Untreated and Antidepressant Treated Populations [462]**
Robert J Valuck, Heather D Orton, Anne M Libby. (United States)
- 8:45 AM **Use of Antiepileptic Drugs in Epilepsy and the Risk of Self Harm and Suicidal Behaviour [463]**
Frank Andersohn, René Schade, Carlos Martinez, Stefan N Willich, Edeltraut Garbe. (Germany)
- 9:00 AM **Use of Dopaminergic Drugs and Risk of Hip or Femur Fracture: A Population-Based Case-Control Study [464]**
Maurits Arbouw, Kris Movig, Tjeerd van Staa, Toine Egberts, Patrick Souverein, Frank de Vries. (Netherlands)
- 9:15 AM **Renal Outcomes in People with Bipolar Disorder Treated with Lithium: A Retrospective Cohort Database Study [465]**

Joe Reilly, Helen Close, John Main, Mukesh Kripalani, Pali Hungin, Douglas Wilson, James Mason. (United Kingdom)

9:30 AM **Effects of Preexisting Cardiovascular Risk Factors on Initiation of Stimulants in Adults Newly Diagnosed with ADHD [466]**
Tobias Gerhard, Almut Winterstein, Mark Olfson, Arwa Saidi, Stephen Crystal. (United States)

9:45 AM **Extensive Psychotropic Drug Use among Icelandic Children: A Nationwide Population Based Study [467]**
Helga Zoega, Gísli Baldursson, Birgir Hrafnkelsson, Anna B Almarsdóttir, Unnur Valdimarsdóttir, Matthías Halldórsson. (Iceland)

10:00-10:30am **Break/Posters/Exhibits (Hall B)**

10:30-Noon ***CONCURRENT SESSIONS: Symposia & Workshops***

10:30 AM **Assessment of Prenatal Exposure to Medications [616] (Room 552B)**
Lyn Colvin, Sonia Hernandez-Diaz, Elizabeth Andrews, Allen Mitchell, Tina Chambers, Pamela E Scott, Richard Hill. (United States)
Sponsored by the Medicines in Pregnancy SIG and the Teratology Society

10:30 AM **RMP, RiskMAP and REMS: The Challenges of Epidemiology [470] (Ballroom D)**
Patricia Saddier, Susana Perez-Gutthann, Annette Stenhausen, Rekha Garg, Stella Blackburn, Gerald Dal Pan. (United States)

10:30 AM **Benchmarking of Healthcare Databases To Improve Harmonization [468] (Room 551A)**
Miriam Sturkenboom, Martijn Schuemie, Gianluca Trifiro, Annie Fourrier, Preciosa Coloma, Jeffrey Brown, BJ Park, Helle Kieler, Ron Herings. (Netherlands)

10:30 AM **Assessing the Association of Pharmacotherapeutics and Suicidal Behavior: Lessons from the Front [281] (Room 551B)**
Jamie Geier, Juhaeri Juhaeri, Daniel Mines, Andrew Mosholder, Madhukar Trivedi, Sybil Eng, Mary Lou Skovron, Paul Stang, Nataliya Volkova. (United States)

10:30 AM **Safety Assessment and Risk Management of Biologics—Challenges and Opportunities (*Biologics SIG*) [471] (Ballroom B)**
Thijs J Giezen, Brigitte Keller, Anders Sundstrom, Aaron S Kesselheim, Wei Dong, Judith K Jones, Hans Petri. (Netherlands)

10:30 AM **The Future of Epidemiology [472] (Room 557)**
****Special anniversary session****
Ken Rothman, Solomon Iyasu, Stephen Evans, Paul Stang, Judith Jones, Til Sturmer. (United States)

10:30 AM **Using Databases for both Hypothesis Generating and Hypothesis Confirmation: One Database or Two? [473] (Room 552A)**
Larry Gould, Alec Walker, Patrick Ryan, Sebastian Schneeweiss, Nancy Santanello, Susan Sacks. (United States)

Noon-1:30pm **Lunch/Poster Session C/Exhibits/ Poster Walks (Hall B)**

Poster Walks/Moderators

- *Pharmacovigilance* –Harry Seifert
- *Use of Linked Databases* – Matthew R.Reynolds
- *Biologics* – Pavel Napalkov
- *Drug Utilization Studies* – Monique Elseviers

ISPE Board of Directors Luncheon (Room 554AB)

(Meeting open to all members; check with staff if you wish to attend)

1:30-3:00pm **INVITED PLENARY (Ballroom A)**
FDA's Sentinel Initiative Project

Chair: **Scott Smith**, Agency for Healthcare Research & Quality

Panelists:

Richard Platt, Harvard University

Mark McClellan, Engelberg Center for Health Care Reform, The Brookings Institution

Janet Woodcock, FDA

Miriam CJM Sturkenboom, Erasmus University Medical Center

3:00-4:30pm

HOT TOPICS SESSION:

Clopidogrel: Has The Pharmacogenetics Era Arrived?
(Ballroom A)

Chair: **Leah Sansbury**, National Cancer Institute, National Institutes of Health

Panelists:

Jessica Mega, Thrombolysis in Myocardial Infarction Study Group, Brigham and Women's Hospital, Harvard Medical School; *Clopidogrel Pharmacogenetics: Overview of The TIMI Study Results*

O.H. Klungel, Department of Pharmaceutical Sciences, Utrecht University; *Methodological Aspects of Clopidogrel Pharmacogenetics*

Alan R. Shuldiner, Professor of Medicine, University of Maryland School of Medicine; *Perspective on Potential Clinical Utility of Clopidogrel Pharmacogenetics (Recent MI, Recent Stroke or Established Peripheral Arterial Disease)*

Bonny Lewis Van, Pharmacogenetic Epidemiologist; *Potential Clinical Utility with Coronary Stents/ Summary Perspective of Future Direction of Pharmacogenetic Epidemiology.*

4:30-5:00pm

The Final Word (Ballroom A)

Moderator

Kate Lapane, FISPE, Chair, 2009 Scientific Program Committee

Poster Awards

Wei Dong, Chair, Poster Awards Committee

ICPE 2010 Brighton, England, UK

Corinne de Vries, Chair, 2010 Scientific Program Committee

5:00pm

Adjournment of ICPE 2010