



*27th International Conference on
Pharmacoepidemiology &
Therapeutic Risk Management*

Hyatt Regency Chicago
Chicago, Illinois, USA

PRELIMINARY AGENDA

As of 7-28-11

Saturday

August 13, 2011

- 8:30-5:00pm **ISPE Board of Directors Meeting (Toronto)**
(Open to ISPE members; notify ISPE staff if you would like to attend.)
- 8:00-6:00pm **Registration (Regency Main Desk)**
- 8:00-5:00pm **Speaker Ready Room (Hong Kong)**

PRE-CONFERENCE EDUCATIONAL SESSION*

(Registration required)

- 8:30-Noon **Introduction to Pharmacogenetic Epidemiologic
Methods (Regency B)**

Content

This highly interactive course will involve participants in:

- A dynamic didactic experience of the foundational principles of pharmacogenetics.
- An appreciation for the different methods used in pharmacogenetics research.
- Examination of real world examples of pharmacogenetic epidemiology.
- Application of methodology to designing pharmacogenetic epidemiology studies.
- Interpretation of the data found in the pharmacogenetic epidemiology literature, and
- Understanding wider implications of the results.

Educational objectives

- To understand the genetic and pharmacogenetic terminology and how cellular and molecular biology informs pharmacogenetic studies at the level of analysis.
- To better understand the study design and methodologic approaches, their strengths and weakness used in pharmacogenetic epidemiology.
- To understand statistical approaches used in pharmacogenetics.
- To understand how pharmacogenetics relates to the current focus of Personalized Medicine
- To have an overview of clinical utility of pharmacogenetics and associated regulatory issues as well as policy-relevant research.

Target audiences

- Members of the Molecular Epidemiology, Biomarkers and Pharmacogenomics (MEBP) SIG
- ISPE members interested in Pharmacogenomics/Pharmacogenetics
- FDA, EMA and other regulators interested in the intersection between pharmacogenetics and epidemiology.
- Clinical pharmacoepidemiologists
- Any scientists interested in learning more about pharmacogenetic epidemiology.

Course Details

Session 1: Didactic Approach Infused with Practical Examples

Faculty

Amalia M. Issa Welcome & introduction to course

Geoffrey Liu Introduction to Pharmacogenetic and Biospecimen Terminology, and Approach Overview

Anke-Hilse Maitland-van der Zee, Advanced Pharmacogenetic Methods for Epidemiologists

Andrew Freedman Application of Methods: From Discovery to Confirmation to Clinical Utility

Steven Kimmel, FISPE, Application of Methods: Warfarin as a Prototype Pharmacogenetic Example

Amalia M. Issa Methods to Investigate Policy-Relevant Aspects of Pharmacogenomics & Examples of Applications

Leah Sansbury, moderator

PRE-CONFERENCE EDUCATIONAL SESSIONS*
(Registration required)

1:30-6:00pm

**Introduction to Pharmacogenetics (cont'd)
(Regency B)**

Session 2: Hands-on Workshop & Discussion of Practical Applications and Issues

Content

This fun-filled practical session will be organized in the format of round-tables with small groups of students self-selecting into the round table of choice based upon interest in the topic of the round-table. Each round-table will be “hosted” by two faculty members.

- Pharmacogenetic Epidemiology Methods
- Clinical Studies and Applications (specific examples include warfarin; KRAS mutations; Breast Cancer Genomics, etc)
- Regulatory Affairs & the FDA/EMA/Health Canada
- Clinical Utility of Pharmacogenetic Tests/Translation into Clinical Settings & Development of Clinical Practice Guidelines
- Databases & Biobanks

1:30-6:00pm

Introduction to Pharmacoepidemiology (Regency A)

[*Included as part of the full meeting registration; Registration required.]

Faculty

John Seeger, Chair, Introduction to Pharmacoepidemiology

Mondira Bhattacharya, Pharmacovigilance/Spontaneous Reporting

Frank Andersohn, Cohort Studies

Gianluca Trifiro, Case Control Studies

Soko Setoguchi, FISPE, Bias and Confounding

1:30-6:00pm

Introduction to Drug Utilization Research (Regency D)

[*Included as part of the full meeting registration; Registration required.]

Content

- The educational session consists of 6 presentations providing an overview of drug utilization research and presenting essential methods
- The theoretical framework will be described and the practical application of different methods will be illustrated using selected examples
- Interpretation of study results taking into account limitations of data sources and methods will be addressed
- Additional perspectives covered are the importance of drug utilization research for public health and implications for policy decisions
- Interaction with participants will be encouraged, e.g. by presenting short questions to be considered by the audience, and by giving time for questions and answers during and at the end of presentations

Educational objectives

- To provide an overview of Drug Utilization Research within the context of Pharmacoepidemiology, Health Services Research and Public Health
- To describe fundamental principles for classifying and quantifying drug use and to provide an understanding of the methodological challenges
- To motivate researchers to cooperate on the collection of a minimum dataset of consistent and reliable data in their country or region, in terms of volume, expenditures and quality of drug use, facilitating international cross-national comparisons
- To explain the process of developing and validating prescribing quality indicators
- To give an applied overview of methods useful for evaluating interventions, in particular in drug policy research (time series analysis)

Target audience

- New members of the DUR/HSR SIG
- Those interested in drug utilization research who need an overview of the area
- Those interested in monitoring medicine use and quality assurance aspects
- Those working in health care organizations involved in payment and reimbursement of medicines
- Those working in medicines policy areas
- Health service planners

Faculty

Morten Andersen, Course Objectives, Definitions of Research Fields and Methodological Framework

Hanne Strom, The Anatomical Therapeutic Chemical Classification and the Defined Daily Dose: Classifying and Quantifying Drug Use

Julie Zito, Overview of Drug Utilization Research in the US

Vera Vlahovic-Palcevski, Principles and Pitfalls in Cross National Comparisons of Drug Utilization

Petra Denig, Developing Valid Prescribing Quality Indicators

Colin Dormuth, Evaluating Interventions on Drug Utilization:
Analysis Methods

1:30-6:00pm

**Student Skills Workshop ** *STUDENTS ONLY* **
(Regency C)**

{Included as part of full meeting registration; registration required}
Organized by ISPE Student Council

***Part A (1:30-3:30) - Optimizing Programming Skills in SAS
Software***

Epidemiologists today use a wide variety of software programs. This is of utmost importance in pharmacoepidemiology where development of the field relies largely on the use of healthcare databases and the development of novel methodologies. As the methods in the field advance and as data become larger and more complex good programming skills become a valuable asset.

SAS, through its Global Academic Program, provides expert speakers to universities or organizations for presentations, seminars or workshops that target students interested in hearing the latest information regarding SAS software or analytical technology. This is why motivated by students feedback ISPE's Student Council has contacted SAS Students Program Manager to take advantage of this opportunity. In collaboration with SAS, we propose to include during the Annual ISPE Conference, a workshop in SAS programming that will take place during the Student Skills Workshop.

Educational Objective: To create a space where student members of ISPE can discuss, learn and update their statistical software programming skills, especially in topics of importance for the field of pharmacoepidemiology.

Activities:

With the support of SAS Student Programs Manager, **Elizabeth Ceranowski**, we propose to do a 2-hour hands-on workshop covering the following topics:

1. Making use of Indexes
2. Creating anonymous ID variables
3. Joining tables (merging and concatenating)
4. Sampling with/without replacement

Hard copies of the slides will be provided by SAS for those in attendance. In addition, SAS will record a webinar on “Introductory SAS Skills” for students this summer to assist those not familiar with the software package (as well as those who are) to get familiar with SAS programming.

The workshop would be offered to students only (max 25), and would take place at the ISPE Conference venue. Additionally students would have to bring their own laptop. If students don’t have a license to run SAS in their computers, an access to a virtual SAS can be granted (details to be discussed with SAS). Internet access would be required during the workshop.

Part B (4:00 - 4:30) - Optimizing the use of social networks for career development

The use of Social media goes beyond leisure purposes. Nowadays hiring managers and recruiters scan the social web to draw a picture of the applicant. Therefore the choice of networks and activities within those networks are of outmost importance. This is especially true for young professionals or recent graduates who are job hunting or are starting to build their professional network. However many young professional don’t know how to effectively use these media.

Optimizing the use of media within SISPE members is a need. Improving networking within student members of ISPE has been a recurrent theme in the Council’s meetings. Although already using social media, its full potential is yet to be explored. Learning about ways to improve our use of these networks would be beneficial both at the individual and group level.

Educational Objective(s):

1. To optimize the use of social media for networking within student members of ISPE.
2. To improve students’ knowledge on social media tools useful for career development.

Project Activities:

The workshop would work as a back-and-forth Q&A session with practical demonstrations, with the discussion leader (**Elizabeth Ceranowski**, SAS Student Programs Manager).

***Part C (4:30-5:45) Career building in pharmacoepidemiology) –
Tools for career development in pharmacoepidemiology***

One of the aims of the Student Council is to provide students and young professionals with opportunities for career guidance and development. In an effort to continue to bring useful resources and information we have designed a workshop that would take place during the Student Skills Workshop at the Annual ISPE Conference in Chicago.

This workshop is geared towards students who want to start planning their careers, or for those currently looking for a job that want to learn about career opportunities in the field.

Educational Objective(s):

To give the students a feel of what the job market looks like for people coming out of epidemiology and pharmacoepidemiology programs, including desired skills. Also, tips on interview techniques and opinions from hiring managers in the pharmaceutical world.

Activities:

Interactive discussions

4:30-5:15pm; Focus on Industry Government. **Dan Strauss**, Director, Epidemiology and Drug Safety, Klein Hersh International

5:15-5:45pm; Focus on Academia. **Almut Winterstein**, University of Florida, ISPE Academic Council

5:45-6:00pm; Wrap Up Round Table Discussion. **Elizabeth Ceranowski, Dan Strauss, & Almut Winterstein**

6:30pm - ???

Student Meet and Greet *Open to all students.*

Organized by ISPE Student Council

Come meet new student members and greet old friends!

Location: Timothy O'Toole's Pub
622 North Fairbanks Court
Chicago, IL 60611-3011

- Gather at ISPE Registration Desk, then walk to the bar.

SUNDAY
August 14, 2011

7:30-6:00pm **Registration (Regency Main Desk)**

7:00-5:00pm **Speakers' Ready Room (Hong Kong)**

PRE-CONFERENCE EDUCATIONAL SESSIONS*
(*Registration required)

8:30-Noon **Registries/Prospective Cohort Studies (Acapulco)**

Content

This workshop will address the following:

- Registries using prospective observational cohort designs as alternatives to randomized controlled trials (RCTs)
- The scope and purpose of different types of registries and how they are being used today in pharmacoepidemiology and risk management
- Considerations of registry development in terms of design and data sources; how they are operationalized and applications for research.

Educational objectives:

To describe the evidence hierarchy and differentiate between the important features of various types of “registries” (or “registers”) and review the traditional terms used to describe timing (retrospective and prospective)

To review the opportunities and developments of “registries” as tools to support pharmacoepidemiology, pharmacovigilance and risk management.

To critically explore the challenges in the design, establishment and conduct of prospective observational cohort studies, with a focus on minimizing the influence of bias and confounding.

Target audience:

- Those interested in designing prospective observational cohort studies, including registries and registers
- Those interested in conducting prospective studies of comparative effectiveness and safety
- People wishing to learn how prospective studies, including registries, can be used to support risk management and pharmacovigilance

- Anyone interested in knowing how prospective studies, including registries, are used to support pharmacovigilance
- A modest understanding of epidemiologic methods is assumed.

Faculty

Nancy A. Dreyer, FISPE

- Introductions, objectives and workshop
- The evidence hierarchy and the role of prospective observational research as alternatives to RCTs
- Types of registries and their applications, including their use to support regulatory, clinical and pharmacy decision-making

Deborah Layton

- Challenges in design
- Case examples in the EU

Charles E. Barr

- Case study: Registry examples in the US

Saad Shakir, FISPE, Prospective cohort studies as tools for risk management and pharmacovigilance – EU perspective

8:30-Noon

Healthcare Databases (Toronto)

Using pharmacoepidemiology database resources to address drug safety research

Content

This highly interactive workshop will involve participants in the:

- Examine the use of database resources in pharmacoepidemiology research;
- Define the different types of data resources available for pharmacoepidemiology and the selection criteria to select the most appropriate resource;
- Review the details of data resources available from the Centers for Medicaid and Medicare Services;
- Identify the elements to properly select a study population and;
- Explore a method to harmonize data from multiple resources.

Educational objectives

- To gain an understanding of available pharmacoepidemiology resources.
- To develop the skills to select an appropriate resource to conduct pharmacoepidemiology research.
- To learn techniques to identify a study population and validate outcome measures.
- To examine methods of data harmonization across multiple resources

Target audience

- Members of the Database SIG
- Those interested in exploring pharmacoepidemiology resources
- Those working in harmonizing data resources
- Those working in creating analytic datasets
- Clinical pharmacoepidemiologists
- Clinical guideline developers
- Those interested in validating outcomes in secondary databases.
- Health practitioners

Faculty

Kevin Haynes, Co-chair

Alison Bourke, Co-chair

Gillian Hall, FISPE, Overview of Database use in Pharmacoepidemiology

Matthew Reynolds, Selection of Databases for Pharmacoepidemiology Research

Charlie Leonard, Center for Medicaid and Medicare Services (CMS) Overview

Suellen Curkendall, Population Selection

Jeffrey Brown, Harmonization of data across multiple resources

8:30-Noon

Comparative Effectiveness Research (Regency B)

Content

The course explains the value of comparative effectiveness research (CER) and pragmatic evidence for improving healthcare

decisions in the routine care setting by differentiating CER from efficacy or explanatory research. The speakers discuss the trade-offs between different study designs and types of data that were used to conduct CER: a pragmatic, randomized controlled trial, a prospective registry, and a retrospective cohort study. Some of the studies combined different types of data to improve efficiency or validity. To illustrate those designs and data, the speakers present case studies from their past and ongoing CER studies. The course covers advanced methods for reducing the biases that can distort estimates of comparative effectiveness.

Educational Objectives

- Recognize the value of comparative effectiveness research for improving routine healthcare decisions and how it differs from efficacy or explanatory research.
- Appreciate the trade-offs between different study designs and types of data for conducting comparative effectiveness research.
- Understand methodologic challenges and proposed solutions in non-randomized effectiveness research

Target Audience

The course is designed for those who conduct comparative effectiveness research and assumes knowledge of introductory pharmacoepidemiologic methods

Faculty

Eric S Johnson

Sebastian Schneeweiss, FISPE

David J Magid

8:30-Noon

Intermediate Pharmacoepidemiology: Concepts, Data & Methods: *The ‘Pharmaco’ in Pharmacoepidemiology (Regency A)*

Content

This course is for the trained epidemiologist who is new to drug safety research and wishes to go in depth into topics that appear repeatedly in current practice. Through lectures and discussions, we will explore examples of discovery of adverse drug effects, use of large administrative and medical-record databases for ad hoc research and systematic screening, study designs that are most

appropriate to large data resources, control for unmeasured confounding factors, and the institutional histories and sensitivities that affect discussions between industry and regulatory authorities. Participants will emerge with relevant vocabulary and key concepts, and an ability to pursue each of these topics in more depth on their own.

Faculty

Alexander Walker, FISPE

8:30-Noon

Regulatory Pharmacoepidemiology/Health Decision-Making (Regency C)

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

Noon -1:30pm

LUNCH ON YOUR OWN

Noon-1: 30pm

New Member Luncheon (Regency D)
(By Invitation)

PRE-CONFERENCE EDUCATIONAL SESSIONS*
*(*Registration required)*

1:30-6:00pm

**Advanced Topics in Pharmacoepidemiology
(Regency A)**

This course is a series of four lectures covering new and advanced methods for pharmacoepidemiology research.

Faculty

Jeremy Rassen: Approaches to comparative safety and effectiveness with three or more treatment groups

Vincent Mor, Pharmacoepidemiology in nursing home patients: Confounding adjustment in a strongly hierarchical data structure

Joseph A. Delaney, Marginal structural models: Examples of successes and challenges in the world of Pharmacoepidemiology

Alexander Walker, FISPE, Intention-to-treat analyses in observational studies of drug effects

1:30-6:00pm

Introduction to Therapeutic Risk Management and Evaluation: What are we learning from the evaluations of Risk Management Programs (RMP) and REMS? (Regency B)

Educational objectives

- To provide basic overview/framework for biopharmaceutical risk management -- both EU-based risk minimization plans (RMP) and US-based risk evaluation & mitigation strategies (REMS) -- including the regulatory context and perspective
- To describe the methods used in evaluating the effectiveness of risk RMPs/REMS
- To describe the current requirements for evaluation studies and types of results that have been seen in the past few years
- To illustrate key concepts of evaluation research with examples of RMP/REMS assessment studies
- To provide an opportunity for interactive session in developing and evaluating RMP/REMS assessment studies

Target audience

- Epidemiologists with little prior experience conducting assessments of risk minimization programs (RMPs) and risk evaluation and mitigation strategy (REMS) and who may need to write evaluation study protocols.
- Pharmacovigilance and regulatory professionals who are involved with reviewing, and negotiating risk RMPs/REMS and their assessments

Faculty

Elizabeth Andrews, FISPE, Course objectives and introductions, overview of risk management; the role of evaluation

Stella Blackburn, FISPE, Requirements and lessons learned from evaluating risk management programs in the EU

Mary Willy, Requirements and Lessons learned from Evaluating REMS in the US

Carla Van Bennekom, Selected topics and examples – survey

Judith Jones, FISPE, Workshop for participants to develop/review an assessment plan

1:30-6:00pm

Advanced Drug Utilization/Health Services Research (Regency C)

Content

This highly interactive workshop will involve participants in the:

- Use of Drug Utilization Research information from administrative health data to improve medicines use;
- Application of principles derived from Health Services and Implementation Research to the design of a clinical intervention;
- Planning of the evaluation of the clinical intervention and
- Interpretation of the evaluation data and dissemination of results.

Educational objectives

- To gain an advanced understanding of planning, implementation and evaluation requirements for an effective quality use of medicines intervention.
- To develop a sophisticated understanding of the importance of project planning processes to the effectiveness of interventions.
- To develop an appreciation of the significance of this work to knowledge transfer at the patient care practice and policy change levels of the health system.

Target audience

Members of the DUR/HSR SIG; Those interested in Implementation Research and knowledge transfer, health and medicines policy areas, health funds and third party payers; Clinical pharmacoepidemiologists; Health service planners; Clinical guideline developers; Health practitioners.

Faculty

Libby Roughead, How does the work we do in this workshop differ from classical pharmacoepidemiology?

Jerry Avorn, FISPE, Influencing prescribing; current issues in educational outreach.

Andrew Gilbert, Knowledge transfer.

6:00-7:30pm

***Academic Showcase/Welcome Reception
(The Club at 151)***

Admission is by badge or ticket. Cash bar.

Welcome

John Seeger, Co-Chair, 2011 Scientific Program Committee

Glen T. Schumock, Co-Chair, 2011 Scientific Program Committee

Stephen JW Evans, FISPE, ISPE President

MONDAY

August 15, 2011

- 7:00-6:00pm **Registration (Regency Main Desk)**
- 7:00-5:00pm **Speakers' Ready Room (Hong Kong)**
- 7:00-8:00am **Poster Session A Set-up (Riverside Center West)**
- 7:30-6:00pm **Exhibits/Posters (Riverside Center West)**
- 8:15-10:00am **OPENING SESSION (Crystal Ballroom)**
Welcome
John Seeger, Co-Chair, 2011 Scientific Program Committee

Glen T. Schumock, Co-Chair, 2011 Scientific Program Committee
- Presidential Address*
Stephen JW Evans, FISPE, ISPE President
- Keynote Address*
Robert M. Califf, Director of the Duke Translational Medicine Institute; Vice Chancellor for Clinical Research; Professor of Cardiology, Duke University School of Medicine
- 10:00-10:30am **Break/Posters/Exhibits (Riverside Center West)**
- **Government/Regulatory Council Coffee Corner**
- 10:30 -Noon **CONCURRENT SESSIONS: CONTRIBUTED PAPERS**
- **Advanced Analytical Approaches (Regency A)**
Moderators: Corinne de Vries, FISPE, & Alan Brookhart
- 10:30 AM** **Evaluation of a Parsimonious High-Dimensional Propensity Score [1]**
Jeremy A Rassen, Sebastian Schneeweiss,
Alexander M Walker. (United States)

- 10:45 AM** **Estimating Survival from Diagnosis When Study Enrollment Is after Time of Diagnosis: A Left Truncation Case Study [2]**
Dave P Miller, Aimee J Foreman. (United States)
- 11:00 AM** **Standard Errors & Confidence Limits for Doubly Robust Estimation [3]**
Michele Jonsson Funk, Daniel Westreich, Til Stürmer, M Alan Brookhart. (United States)
- 11:15 AM** **Effects of Adjusting for Instrumental Variables on Bias and Precision of Effect Estimates [4]**
Jessica A Myers, Joshua J Gagne, Jeremy A Rassen, Sebastian Schneeweiss, Krista F Hubrechts, Kenneth J Rothman, Marshall M Joffe, Robert J Glynn. (United States)
- 11:30 AM** **Poisson Regression Type Model in a Case-Cohort Study [5]**
Akira Wakana, Kiyoshi Kubota. (Japan)
- 11:45 AM** **‘Stars-and-Stripes’ Diagrams of Discordant Cases’ Exposures in Case-Crossover Studies Using Healthcare Databases [6]**
Malcolm Maclure, Richard Morrow, Greg Carney, Colin Dormuth. (Canada)
- **Algorithms - Processes That Matter (Regency B)**
Moderators: Susanna Perez Guttham, FISPE, & Cheryl Enger
- 10:30 AM** **Discrepant Results in Pneumonia Studies Using Solely Administrative Data Compared to Medical Record Review [7]**
Sascha Dublin, Rod L Walker, Michael L Jackson, Jennifer C Nelson, Noel S Weiss, Lisa A Jackson. (United States)
- 10:45 AM** **Harmonization of the Event Identification Process in Eight European Healthcare Databases: The Experience from the EU-ADR Project [8]**
Gianluca Trifiro, Paul Avillach, Rosa Gini, Preciosa Coloma, Giampiero Mazzaglia, Gino Picelli, Lorenza Scotti, Ron Herings, Julia Hippisley-Cox, Mariam Molokhia, Lars Pedersen, Annie Fourrier Reglat, Antoine Pariente, Miriam Sturkenboom, Johan van der Lei. (Netherlands)

- 11:00 AM Quality of ICD-10 Colorectal Cancer Diagnosis Codes in the Danish National Registry of Patients [9]**
Rune Erichsen, Henrik Gammelager, Lea Helquist, Martin B Johansen, Henrik T Sørensen. (Denmark)
- 11:15 AM Case Screening and Validation in a Population-Based Study of Antimicrobial Use and Acute Liver Injury [12]**
James A Kaye, Jordi Castellsague, Christine L Bui, Brian Calingaert, Lisa J McQuay, Nuria Riera, Catherine W Saltus, Scott Quinlan, Crystal N Holick, Peter M Wahl, Kenneth J Rothman, Mari-Ann Wallander, Susana Perez-Gutthann. (United States)
- 11:30 AM Development and Validation of Claims-Based Algorithms To Determine Level of Trauma Associated with Fractures in Men [11]**
Jie Zhang, Elizabeth Delzell, Tarun Arora, Nicole C Wright, Kristine Ensrud, John Schousboue, Beth Virnig, Brent Taylor, Misti Paudel, Jeffrey R Curtis. (United States)
- 11:45 AM Validation of Claims-Based Algorithms for Identification of High-Grade Cervical Dysplasia and Cervical Cancer Using Electronic Medical Records [10]**
Seo Young Kim, Sebastian Schneeweiss, Huichuan Lii, Daniel H Solomon. (United States)
- **Genes and Drugs (Toronto)**
Moderators: Stephen Kimmel, FISPE, & Anke-Hilse Maitland-van der Zee
- 10:30 AM Common Variation in the CACNA1C Gene Modifies the Effect of Diltiazem on Heart Rate [13]**
Mark Eijgelsheim, Eline M Rodenburg, Jan A Kors, Jacqueline C M Witteman, Albert Hofman, Andre G Uitterlinden, Bruno HC h Stricker. (Netherlands)
- 10:45 AM Cytochrome P-450 2D6 and 2C19 Polymorphisms and Consumption of Care in Psychiatric Practice [14]**

Frederieke H van der Baan, Jochem G Gregoor, Harriët M Looovers, Olaf H Klungel, Toine C G Egberts, Diederick E Grobbee, Mirjam J Knol, Jan van der Weide. (Netherlands)

11:00 AM Quantitative Meta-Analysis of Cytochrome P450 2D6 Inhibition and Breast Cancer Outcomes in Tamoxifen-Treated Patients [15]
Deirdre P Cronin-Fenton, Timothy L Lash. (Denmark)

11:15 AM Detection and Characterization of Pharmacogenomic Effects in Nonrandomized Studies – A Simulation Study of QT-Prolonging Drug-Gene Interactions [16]
Jane Der, Christy L Avery, Eric A Whitsel, Til Sturmer. (United States)

11:30 AM Genome-Wide Analysis of LDL-C Lowering with Statin Therapy Identifies Loci Related to Statin Pharmacokinetics and LDL Particle Endocytosis [17]
Daniel I Chasman, Franco Giulianini, Jean MacFadyen, Bryan J Barratt, Fredrik Nyberg, Paul M Ridker. (Sweden)

11:45 AM Potential of Adaptive Clinical Trial Designs in Pharmacogenetic Research, a Simulation Based on the IPASS Trial [18]
Frederieke H van der Baan, Mirjam J Knol, Olaf H Klungel, Toine C G Egberts, Diederick E Grobbee, Kit C B Roes. (Netherlands)

• **Primigravida (Acapulco)**

Moderators: Rachel Charlton & Sara Ephros

10:30 AM Trimethoprim Use in Early Pregnancy and the Risk of Miscarriage: A Register Based Nationwide Cohort Study [19]
Jon T Andersen, Morten Petersen, Espen J Solem, Kasper Broedbaek, Shoaib Afzal, Elisabeth W Andersen, Christian Torp-Pedersen, Niels Keiding, Henrik E Poulsen. (Denmark)

10:45 AM Use of Proton Pump Inhibitors during Pregnancy and the Risk of Asthma in Offspring [20]

Ane Birgitte T Andersen, Rune Erichsen, Dóra K Farkas, Vera Ehrenstein, Henrik T Sørensen.
(Denmark)

11:00 AM Use of Thyroid Supplements during Pregnancy [21]

Judith P Kelly, Sonia Hernandez-Diaz, Allen M Mitchell. (United States)

11:15 AM Selective Serotonin-Reuptake Inhibitors and Risks of Persistent Fetal Circulation and Pulmonary Hypertension in the Newborn [22]

Helle Kieler, Kari Furu, Mika Gissler, Mette Noergaard, Unnur Valdimarsdottir, Bengt Haglund. (Sweden)

11:30 AM

11:30AM Comparative Safety of Anticonvulsants during Pregnancy: Seizures or Major Malformations [24]

Sonia Hernandez-Diaz, Catlin R Smith, Aileen Shen, Robert Mittendorf, Lewis B Holmes.
(United States)

11:45AM Use of Topiramate in Pregnancy and the Risk of Oral Clefts [23]

Andrea V Margulis, Martha M Werler, Allen A Mitchell, Sonia Hernández-Díaz. (United States)

• **Rheumatic Condition Therapies (Regency C)**

Moderators: Mari-Ann Wallander, FISPE, & Seo Young Kim

10:30 AM Opioid Analgesics and the Risk of Pneumonia Hospitalizations in Patients with Rheumatoid Arthritis [25]

Carlos G Grijalva, Patrick G Arbogast, Ed Mitchel, Marie R Griffin. (United States)

10:45 AM The Prevalence of Psoriatic Arthritis in the Health Improvement Network (THIN) [26]

Alexis R Ogdie, Nicole Seminara, Daniel Shin, Sinead Langan, Joel M Gelfand. (United States)

11:00 AM **Statins and Risk of Acute Myocardial Infarction in Patients with Rheumatoid Arthritis: A Population-Based Study [27]**
Mary A De Vera, Diane Lacaille, Michal Abrahamowicz, Jacek Kopec, Hyon Choi.
(Canada) *STUDENT AWARD RECIPIENT - THIRD BEST ABSTRACT SUBMITTED BY A STUDENT*

11:15 AM **Which Is More Effective, Rituximab or a Second Anti-TNF Therapy for Rheumatoid Arthritis Patients Who Have Failed Their First Anti-TNF? Analysis from the British Society for Rheumatology Biologics Register (BSRBR) [28]**
Moetaza Soliman, Kimme Hyrich, Mark Lunt, Kath Watson, Deborah Symmons, Darren Ashcroft. (United Kingdom)

11:30 AM **Rates of Hospitalized Bacterial Infection Associated with Juvenile Idiopathic Arthritis and Its Treatment [29]**
Timothy Beukelman, Fenglong Xie, Lang Chen, John W Baddley, Elizabeth Delzell, Carlos G Grijalva, Nivedita M Patkar, Kenneth G Saag, Kevin L Winthrop, Jeffrey R Curtis. (United States)

11:45 AM **Safety Surveillance Study of Abatacept Therapy among Patients with Rheumatoid Arthritis [30]**
Nancy D Lin, John D Seeger, Eva Ng, David D Dore. (United States)

• **Sweet and Sour (Regency D)**
Moderators: Bert Leufkins, FISPE, & Haley Kaplowitz

10:30 AM **Estimation of Acute Effects of Severe Hypoglycemia on Subsequent Episodes in Type 1 Diabetes [31]**
Zhiwen Liu, Charles Poole, Amy H Herring, Cynthia J Girman, Timothy S Carey, Til Stürmer. (United States)

10:45 AM **Patient Level Factors Associated with Prescribing of Thiazolidinediones in the Period 2004-2009 [32]**

Petra Denig, Jaco Voorham, Klaas Hoogenberg,
Flora M Haaijer-Ruskamp, The GIANTT-Group.
(Netherlands)

11:00 AM Angiotensin Converting Enzyme Inhibitors in Hemodialysis [33]

Tara I Chang, David Shilane, Steven M Brunelli,
Alfred K Cheung, Glenn M Chertow, Wolfgang C
Winkelmayer. (United States)

11:15 AM Safety and Effectiveness of Oral Contraceptives in Obese Women [34]

Juergen Dinger, Kristina Bardenheuer, Anita
Assmann. (Germany)

11:30 AM Effect of Prescription Status on the Orlistat User Population: Prescription-Only Versus Pharmacy-Only [35]

Marjolein J Willemen, Aukje K Mantel-
Teeuwisse, Nina A Winters, Sabine M Straus,
Hubert G Leufkens, Toine C Egberts.
(Netherlands)

11:45 AM Do Physicians Need Both Rosiglitazone and Pioglitazone? [36]

Wei Liu, Paul Kubilis, Almut G Winterstein.
(United States)

Noon -1:30pm

Lunch/Poster Session A/Exhibits (Riverside Center West)

ISPE Committee/Council Meetings

Open to all participants. Lunch will be available in meeting rooms.

- Development Committee (Water Tower)
- Fellowship & Awards Committee (Picasso)
- Finance Committee (Haymarket)
- Public Policy Committee (Columbian)
- Student Council (Gold Coast)

PDS Regional Editors (Wrigley Room)

(By invitation)

12:15-1:15pm

Roundtable Discussions

To foster the ability of the more junior ISPE members to network and new ISPE members to meet others attending the ICPE, we are

hosting several lunchtime discussion roundtables on Monday and Tuesday. These roundtables will be informal. The facilitators and topics for the tables are listed below. There will be NO formal presentations made at the roundtables. The purposes are discussion, information exchange, and networking. **Seating is limited; first-come, first-served.**

- **Anick Berard, FISPE**, Use of healthcare database (combining estimates from different administrative databases)
- **Joanna Haas, FISPE**, Life cycle risk management
- **Sebastian Schneeweiss, FISPE**, Dealing with confounding in database studies

12:45-1:30pm

Poster Walks (Riverside Center West)

- Biologics SIG
- Drug Utilization SIG
- Medications in Pregnancy SIG

1:30-3:00pm

PLENARY SESSION (Crystal Ballroom)

Communication about Early Safety Findings from Active Surveillance Studies

Description

This session will discuss issues related to communication of newly identified medication safety signals and findings.

- Moderators:
 - Nancy Santanello, FISPE**, Merck
 - Glen T. Schumock**, University of Illinois at Chicago
- Introduction. **Nancy Santanello, FISPE**
- Regulatory Agency Perspective. **Judy Racoosin**, Sentinel Initiative, Office of Medical Policy/CDER/FDA. FDA early communications regarding medical product safety: An overview.
- Researcher Perspective. **Rich Platt**, Harvard Pilgrim Health Care Institute and Harvard Medical School. Overview of Mini-Sentinel and communication issues that will arise in the course of piloting active surveillance evaluations.
- Medical Journal Perspective. **Michael Berkwits**, Deputy Editor, *Annals of Internal Medicine*. Communicating early safety and risk evidence to physicians.
- European Perspective. **Miriam Sturkenboom, FISPE**, Erasmus Medical Center
- Panel Discussion/Questions and Answers

3:00-3:30pm

Break/Posters/Exhibits (Riverside Center West)

3:30-5:00pm

CONCURRENT SESSIONS: SYMPOSIA AND WORKSHOPS

- **Application of Quality of Evidence Assessment Tools to the valuation of Pharmacoepidemiologic Safety Studies [37] (Regency A)**
George A Neyarapally, Tarek A Hammad, Simone P Pinheiro, Solomon Iyasu, Michael D Murray, Paul Stang. (United States)
- **Capacity of Various Data Sources to Advance Medical Device Safety and Effectiveness Research [38] (Regency B)**
Danica Marinac-Dabic, Michael Matheny, Suzanne West, Michael Steinbuch, Art Sedrakyan. (United States)
SPONSORED BY THE MEDICAL DEVICES SIG
- **Challenges and Pitfalls in Studying Birth Defects as Outcomes [39] (Toronto)**
Carol Louik, Jennita Reefhuis, Andrea V Margulis, Anick Berard, William Cooper. (United States)
SPONSORED BY THE MEDICATIONS IN PREGNANCY SIG
- **Database Linkage and Methodological Issues in Comparative Effectiveness Research (CER) of Medical Devices vs. Medications: Lessons from an Ongoing Project [40] (Regency C)**

Jessica J Jalbert, Chih-Ying Chen, Sebastian Schneeweiss, Bradley G Hammill, Nancy A Dreyer, Joseph A C Delaney, Tobias Gerhard, Soko Setoguchi. (United States)
SPONSORED BY THE CER SIG
- **Linking Existing Databases - Is it Worth the Pain? [41] (Regency D)**

Alison D Bourke, Robert J LoCasale, Edward A Bortnichak,
Ron M Herings, Suellen M Curkendall, William B Saunders.
(United Kingdom)

SPONSORED BY THE DATABASES SIG

- **Regulatory Trends in Pharmacogenomic Biomarker Evaluation [42] (Acapulco)**

Andrew N Freedman, Anke-Hilse Maitland van der Zee, Issam Zineh, Michael Pacanowski, Marissa Papaluca-Amati, Kevin Carl, Burt Leufkens. (United States)

SPONSORED BY THE MOLECULAR

EPI/BIOMARKERS/PHARMACOGENETICS SIG

5:00-6:00pm

ISPE Council Meetings

Open to all interested participants

- Academic Council (Acapulco)
- Government/Regulatory Council (Water Tower)
- Industry/Service Providers Council (Toronto)

6:30-7:30pm

PDS Editorial Board (Comiskey Room)

(By Invitation)

7:00pm - ???

Student Social Event - Night Out in Chicago

(Organized by ISPE Student Council)

Join us for a relaxed evening among friends!

Location: To Be Announced

- Open to all students
- Assemble at ISPE Registration Desk, then walk to the restaurant.

TUESDAY
August 16, 2010

7:00-6:00pm

Registration (Regency Main Desk)

7:00-5:00pm

Speakers' Ready Room (Hong Kong)

7:00-8:00am

Poster Session B Set-up (Riverside Center West)

PRELIMINARY AGENDA – ICPE 2011

26

7:15-8:15 am **ISPE 2013 Mid-Year Meeting 2Planning Committee
(Columbian Room) - *By Invitation***

7:15-8:15am **H1N1 Vaccine Safety in Pregnancy Network (Gold
Coast) (*By Invitation*)**
Have you not been invited and are you carrying out research into
the safety of H1N1 vaccine in pregnancy? then please contact
Corinne de Vries directly at c.de-vries@bath.ac.uk

8:00-6:00pm **Exhibits/Posters (Regency Center West)**

8:30-10:00am **CONCURRENT SESSIONS: CONTRIBUTED
PAPERS**

- **Drug Use - Change, Choice, or Chance
(Regency A)**

Moderators: Ulf Bergman, FISPE, & Tobias Gerhard

**08:30 AM Generic Alendronate Use in Medicare Part D
[268]**

Huifeng Yun, Jeffrey R Curtis, Wilson Smith,
Robert Matthews, Kenneth G Saag, Nicole C
Wright, Elizabeth Delzell. (United States)

**08:45 AM Patterns of On- and Off-Label Oxaliplatin Use
among Stage II and III Colorectal Cancer
Patients in 2005 [269]**

Jennifer L Lund, Hanna K Sanoff, Til Sturmer,
Robert S Sandler, Alan M Brookhart, Joan L
Warren, Linda C Harlan. (United States)

**09:00 AM Adverse Health Outcomes Associated with
Experiencing a Gap in Drug Coverage during
the Medicare Part D Doughnut Hole [270]**

Jennifer M Polinski, William H Shrank, Robert J
Glynn, Haiden A Huskamp, M Chris Roebuck,
Sebastian Schneeweiss. (United States)

**09:15 AM Effects of Age and Sex on Adverse Drug
Reaction Reporting in Relation to Drug
Utilization in Sweden [271]**

Lennart Holm, Elisabet Ekman, Stefan Mejyr,
Kerstin Blomgren-Jorsäter. (Sweden)

- 09:30 AM** **Patterns of Outpatient Use of Parenteral Anticoagulants in Older Adults between 1997 and 2004: A Population-Based Study [272]**
Leah M Smith, Alexander G Perry, Linda E Lévesque. (Canada)
- 09:45 AM** **Reasons for Oral Contraceptives Use in Adolescents and Adults in Europe [273]**
Kristina Bardenheuer, Juergen Dinger, Janko Leddin. (Germany)
- **Fractures - Give Us a Break (Regency B)**
Moderators: Stephen Evans, FISPE, & Dave Dore
- 08:30 AM** **Bisphosphonate Use May Be a Risk Factor for Osteonecrosis at Any Site: A Self-Controlled Case Series Analysis [274]**
Steven C Vlad, Yanyan Zhu, Jingbo Niu, Christine Peloquin, Hyon Choi, Yuqing Zhang. (United States)
- 08:45 AM** **Risk of Fracture in Patients with Myasthenia Gravis [275]**
Marloes Bazelier, Sander Pouwels, Kassim Javaid, Cyrus Cooper, David Hilton-Jones, Jan Verschuuren, Tjeerd van Staa, Frank De Vries. (Netherlands)
- 09:00 AM** **Use of Thiazolidinediones and Risk of Osteoporotic Fracture: The Danish National Databases [276]**
Marloes Bazelier, Arlene Gallagher, Tjeerd van Staa, Cyrus Cooper, Hubert Leufkens, Peter Vestergaard, Frank De Vries. (Netherlands)
- 09:15 AM** **Proton Pump Inhibitors and Fracture Risk in Corticosteroid Users [277]**
Jeffrey C Munson, Peter M Wahl, Gregory Daniel, Stephen E Kimmel, Sean Hennessy. (United States)
- 09:30 AM** **Odds of Fractures with Inhaled Corticosteroids in COPD: Systematic Review and Meta-Analysis of Randomized Controlled Trials and Observational Studies [278]**
Sonal Singh, Rodrigo Cavallazi, Yoon Loke. (United States)
- 09:45 AM** **Comparative Safety of Antidepressants on Fracture Risk in Older Adults [279]**

Joshua J Gagne, Amanda R Patrick, Helen Mogun,
Daniel H Solomon. (United States)

- **Matters of the Heart (Regency C)**

Moderators: Patrice Verpillat & Manel Pladerell

- 08:30 AM Intravenous Bisphosphonate Therapy and Risk of Atrial Fibrillation in Cancer Patients [280]**
Rune Erichsen, Christian F Christiansen, Trine Frøslev, Jacob Jacobsen, Henrik T Sørensen. (Denmark)
- 08:45 AM Risks of Congestive Heart Failure and Cardiomyopathy Associated with Bevacizumab Use in Colorectal Cancer Chemotherapy Patients: A Population-Based Study [281]**
Huei-Ting Tsai, Sheila Weiss Smith, Joan L Warren, Andrew N Freedman, Leah B Sansbury, John L Marshall, Arnold L Potosky. (United States)
- 09:00 AM ADHD Medications and Risk of Serious Cardiovascular Events in Adults [282]**
Hedi Schelleman, Warren B Bilker, Stephen E Kimmel, Gregory W Daniel, Craig Newcomb, James P Guevara, Mark J Cziraky, Brian L Strom, Sean Hennessy. (United States)
- 09:15 AM Comparative Cardiovascular (CV) Safety of Dementia Drugs among Medicare Beneficiaries [283]**
Emil L Fosbol, Eric D Peterson, Yinghong Zhang, Lesley H Curtis, Isao Iwata, Soko Setoguchi. (United States)
- 09:30 AM A Cohort Study Using GPRD and MINAP Data To Investigate the Possible Drug Interaction between Clopidogrel and Cytochrome P450 2C19 Inhibitors [284]**
Ian Douglas, Liam Smeeth, Aroon Hingorani, Anthony Grosso, Stephen Evans. (United Kingdom)
- 09:45 AM Thiazolidinidiones and the Risk of Myocardial Infarction [285]**
Rohini K Hernandez, Timothy L Lash, Cathy W Critchlow, Susan S Jick. (United States)

- **Multigravida (Toronto)**

Moderators: Allen Mitchell, FISPE, & Kari Furu

- 08:30 AM Sensitivity Assessment of the Impact of Time to Maternal Interview on Interview Quality in the National Birth Defects Prevention Study [286]**
Sarah C Tinker, Cassandra Gibbs, Devine Owen, Amy H Herring, Honein Margaret, Crider Krista, Werler Martha, Anderka Marlene, Reefhuis Jennita. (United States)
- 08:45 AM Validity and Reliability of Maternal Recall of Prescription Drug Use during Pregnancy [287]**
Marleen M H J van Gelder, Iris A L M van Rooij, Hermien E K de Walle, Nel Roeleveld, Marian K Bakker. (Netherlands)
- 09:00 AM Complications Associated with Unintended Pregnancies under IUD Use: Results from the EURAS-IUD Study [288]**
Clare A Barnett, Klaas Heinemann, Juergen Dinger. (Germany)
- 09:15 AM Antidepressant Use during Pregnancy and the Risk of Gestational Hypertension [289]**
Mary A De Vera, Evelyne Rey, Martin St-Andre, Berard Anick. (Canada)
- 09:30 AM Simulation Model of Annual Spina Bifida Cases Preventable in Absence of Prenatal Valproate Use [290]**
Suzanne M Gilboa, Cheryl S Broussard, Owen Devine, Kara N Duwe, Audrey L Flak, Sheree L Boulet, Cynthia A Moore, Martha M Werler, Margaret A Honein. (United States)
- 09:45 AM Rate of Adverse Events Associated with Methotrexate in the Treatment of Ectopic Pregnancy [291]**
Wendy Camelo Castillo, Christie M J L Cooksey, Michele Jonsson Funk. (United States)

- **Propensity Score Methods (Regency D)**

Moderators: Suellen Curkendall & Michele Jonsson Funk

- 08:30 AM Confounding Adjustment Via a High-Dimensional Propensity Score: An Application Using THIN [292]**
Darren Toh, Luis A Garcia Rodriguez, Miguel A Hernan. (United States)
- 08:45 AM Outcome Specific Versus Generic Propensity Scores: A Simulation Study [293]**
R Wyss, R Locasale, M A Brookhart, C Girman, T Stürmer. (United States)
- 09:00 AM Measuring Balance and Model Selection in Propensity Score Methods [294]**
Svetlana V Belitser, Edwin P Martens, Wiebe R Pestman, Rolf H H Groenwold, Anthonius de Boer, Olaf H Klungel. (Netherlands)
- 09:15 AM Application of Simultaneous Multi-Way Propensity Score Matching for 3 or More Exposure Groups [295]**
Jeremy A Rassen, Sebastian Schneeweiss, Daniel H Solomon, Abhi A Shelat. (United States)
- 09:30 AM Time-Varying Propensity Scores and Hazard Ratio Estimation [296]**
Christina D Mack, Robert Glynn, Til Stürmer. (United States)
STUDENT AWARD RECIPIENT – SECOND BEST ABSTRACT SUBMITTED BY A STUDENT
- 09:45 AM Propensity Scores from Logistic Regression Yielded Better Covariate Balance Than Those from a Boosted Model: A Demonstration Using STAR*D Data [297]**
Alan R Ellis, Stacie B Dusetzina, Richard A Hansen, Bradley N Gaynes, Joel F Farley, Til Stürmer. (United States)

- **To Clot or Not To Clot (Acapulco)**
Moderators: Cristina Varas

- 08:30 AM When Should an Atrial Fibrillation Patient Receive Anticoagulants Following Intracerebral Haemorrhage? [298]**
Robert W V Flynn, Thomas M MacDonald, Anna Maria Choy, Gordon D Murray, Alexander S F Doney. (United Kingdom)

- 08:45 AM** **Age, Antipsychotics, and Risk of Thrombotic Events in the Veterans Health Administration (VHA) [299]**
 Shirley Wang, David D Dore, Malcolm Maclure, Vincent Mor, Crystal Linkletter, Stephen Buka. (United States)
- 09:00 AM** **Antipsychotic Drugs and Risk of Idiopathic Venous Thromboembolism: A Nested Case Control Study Using the GPRD [300]** *Moved to Poster Session A at author's request.*
- 09:15 AM** **Androgen Deprivation Therapy and the Risk of Stroke and Transient Ischemic Attacks in Patients with Prostate Cancer [301]**
 Laurent Azoulay, Hui Yin, Serge Benayoun, Jean-François Boivin, Samy Suissa. (Canada)
- 09:30 AM** **The Risk of VTE in Users of a 24-Day Regimen of a Combined Oral Contraceptive Compared to Conventional 21-Day OC Regimens: Results from the INAS-OC Study [302]**
 Juergen Dinger, Kristina Bardenheuer, Christian Franke. (Germany)
- 09:45 AM** **Effect of Simultaneous Use of Oestrogens and Statins on the Risk for Venous Thromboembolism in Post-Menopausal Women [303]**
 Ruben Duijnhoven, Sophie dell'Aniello, Christel Renoux, Vicky Tagalakis, Mirjam Knol, Olaf Klungel, Samy Suissa. (Netherlands)

10:00-10:30am

Break/Posters/Exhibits (Regency Center West)

- **Government/Regulatory Council Coffee Corner**

10:30-12:00pm

CONCURRENT SESSIONS: CONTRIBUTED PAPERS

- **A Little Attention Please (Regency A)**
 Moderators: Cynthia de Luise & Nicholas Moore, FISPE
- 10:30 AM** **Pharmacological Treatment and Demographic Characteristics of Pediatric Patients with Attention Deficit Hyperactivity Disorder, Sweden [304]**

Shahram Bahmanyar, Anders Sundström, Magnus Kaijser, Helle Kieler. (Sweden)

10:45 AM Drug Treatment of ADHD in Children and Youths in Germany [305]
Edeltraut Garbe, Rafael T Mikolajczyk, Angela A Kraut, Ingo Langner. (Germany)

11:00 AM ADHD Youths' Career in Psychotropic Treatment [306]
Almut G Winterstein, Paul Kubilis, Tobias Gerhard. (United States)

11:15 AM Accident Proneness among Youth Treated with ADHD Medication [307]
Els F Van den Ban, Patrick C Souverein, Willemijn M Meijer, Herman Van Engeland, Hanna Swaab, Toine C G Egberts, Eibert R Heerdink. (Netherlands)

11:30 AM Cardiovascular Safety of ADHD Medications in Children and Adolescents [308]
Hedi Schelleman, Warren B Bilker, Brian L Strom, Stephen E Kimmel, Craig Newcomb, James P Guevara, Gregory W Daniel, Mark J Cziraky, Sean Hennessy. (United States)

11:45 AM Atomoxetine Utilization in Youths with Attention Deficit/Hyperactivity Disorder in 29 Medicaid States [309]
Stephan Linden, Caitlin Knox, Almut G Winterstein. (United States)

• **Adherence -A Sticky Issue (Regency B)**
Moderators: Jesper Hallas & Sylvie Perreault

10:30 AM Adherence and Discontinuation with the Use of Capecitabine in Daily Practice [349]
Jacqueline G Hugtenburg, Christel C L M Boons, Michiel P J De Looij, Lonneke Timmers. (Netherlands)

10:45 AM Importance of Early Non-Adherence in Estimations of Medication Adherence [311]
Marsha A Raebel, Nikki M Carroll, Jennifer L Ellis, Emily B Schroeder, Elizabeth A Bayliss. (United States)

- 11:00 AM** **Reasons for Early Discontinuation of Hormonal Therapy in Breast Cancer Patients across Five European Countries [312]**
Allison A Petrilla, Cheryl P Ferrufino. (United States)
- 11:15 AM** **A Comparison of Two Methods for Estimating Refill Adherence to Statins in Sweden [347]**
Eva Lesén, Tatiana Sandström, Anders Carlsten, Anna K Jönsson, Ann-Charlotte Mårdby, Karolina Andersson Sundell. (Sweden)
- 11:30 AM** **Pharmacy Loyalty and Compliance with Antipsychotics [314]**
Sophie Lauzier, Jean-Pierre Grégoire, Jocelyne Moisan. (Canada)
- 11:45 AM** **Therapeutic Complexity Has Limited Influence on Adherence in the Netherlands [315]**
Harm C Geers, Marcel L Bouvy, Eibert R Heerdink. (Netherlands)
- **Devices et al (Toronto)**
Moderators: Danica Marinac-Dabic & Suzanne West, FISPE
- 10:30 AM** **Use and Outcomes of Partial Knee Replacement (PKR) vs Total Knee Replacement (TKR) among Medicare Beneficiaries, 2000-2009 [316]**
Soko Setoguchi, Melissa A Greiner, David Attarian, Scott Kelley, Sam Wellman, Lesley H Curtis, Ricardo Pietrobon, Michael Bolognesi. (United States)
- 10:45 AM** **Long-Term Comparative Survivorship of Uncemented Acetabular Components in Primary and Revision Total Hip Arthroplasty (THA) [317]**
Hilal Maradit Kremers, James L Howard, Cathy D Schleck, Daniel J Berry, Miguel E Cabanela, Arlen D Hanssen, Mark W Pagnano, Robert T Trousdale, David G Lewallen. (United States)
- 11:00 AM** **Medical Device Safety Surveillance: The Safety of Urogynecologic Surgical Mesh for Repair of Pelvic Organ Prolapse [318]**
Cara J Krulewitch, Mary Beth E Ritchey, Hong Cheng, Danica Marinac-Dabic, Tom Gross,

Jonathan Gibbs, Christopher Worrall, Jeffery A
Kelman. (United States)

**11:15 AM Risk Factors for Uterine Perforations during
IUD Insertion: Interim Results from the
EURAS-IUD Study [319]**
Klaas Heinemann, Clare Barnett, Juergen Dinger.
(Germany)

**11:30 AM A Quantitative Approach to Benefit-Risk
Assessment: An Example with Lumiracoxib
[320]**
Paola Primatesta, Estel Plana, Alan Moore.
(Switzerland)

**11:45 AM Incidence Rate of Liver Injury in Pediatric
Population: Data Mining on Electronic
Healthcare Databases in Europe [321]**
Carmen Ferrajolo, Katia M C Verhamme,
Annalisa Capuano, Gianluca Trifirò, Alessandro
Oteri, Gino Picelli, Giampiero Mazzaglia, Claudio
Cricelli, Francesco Rossi, Miriam C J M
Sturkenboom. (Netherlands)

• **Drugs and Bugs (Acapulco)**
Moderators: Glen T. Schumock & Vani Vannappagari

**10:30 AM First- and Second-Line Treatment with
Antibiotics of Women with Uncomplicated
Lower Urinary Tract Infection in Sweden 2009 –
A Nation-Wide Population-Based Register Study
[322]**
Magnus Olsson, Cecilia Nordqvist, Mikael
Hoffmann. (Sweden)

**10:45 AM Human Immunodeficiency (HIV) Therapy and
Cardiovascular (CV) Events [323]**
Wendy J Carman, Steven Bowlin, Andrew T
McAfee. (United States)

**11:00 AM Prevalence of Transmitted HIV Drug Resistance
Differs between Acutely and Chronically HIV-
Infected Patients [324]**
Elizabeth L Yanik, Sonia Napravnik, Christopher
B Hurt, Ann Dennis, Joanne D Kuruc, Joseph J
Eron. (United States)

**11:15 AM Study on Risk Factors for Adverse Drug
Reactions in Hospitalized Retroviral Patients
[348]**

Thiyagu Rajakannan, Surulivelrajan
Mallayasamy, Vasudeva Guddattu, Muralidhar
Varma, Vijayanarayana Kunhikatta. (India)
*THE ANDREW MCAFEE AWARD for the BEST
ABSTRACT SUBMITTED BY A STUDENT FROM A
DEVELOPING COUNTRY*

**11:30 AM Differences in Oral Candidiasis Risk between
Different Inhaled Corticosteroids [326]**
Alison L Nightingale, Annie Hutchison, Corinne
S de Vries. (United Kingdom)

**11:45 AM Baseline Predictors of Efavirenz-Related
Symptoms during the First Six Months of
Therapy [327]**
Paul D Sonenthal, Bakgaki Ratshaa, Gilbert
Chimbeno, Malebogo Thero, Tumelo Rantleru,
Sarah Barenbaum, Andrew Steenhoff, Robert
Gross. (United States)

• **Methods for Early Detection (Regency C)**
Moderators: Marie Lindquist & Jeremy Rassen

**10:30 AM Comparison of Methods for Drug Safety Signal
Detection Using Electronic Healthcare Record
(EHR) Databases: The Added Value of
Longitudinal, Time-Stamped Patient
Information [328]**
Preciosa M Coloma, Gianluca Trifirò, Rosa Gini,
Ron Herings, Giampiero Mazzaglia, Carlo
Giaquinto, Lars Pedersen, Johan van der Lei,
Miriam Sturkenboom, Martijn Schuemie.
(Netherlands)

**10:45 AM Signal Detection of Adverse Medical Device
Events in the FDA/MAUDE Database [329]**
David O Olaleye, David Olaleye. (United States)

**11:00 AM Fuzzy Text Matching To Identify Known
Adverse Drug Reactions [330]**
Tomas Bergvall, Gunnar Dahlberg, Bénédicte
Cappelli, Niklas Norén. (Sweden)

**11:15 AM Comparison of Alerting Algorithms for
Prospective Medical Product Safety Monitoring:
A Simulation Study and Empirical Application
[331]**
Joshua J Gagne, Jeremy A Rassen, Alexander M
Walker, Robert J Glynn, Sebastian Schneeweiss.
(United States)

11:30 AM Comparing Two Methods for Detecting Adverse Event Signals in Observational Data: Empirical Bayes Gamma Poisson Shrinker vs. Tree-Based Scan Statistic [332]

Jeffrey S Brown, Kenneth Petronis, Andrew Bate, Fang Zhang, Inna Dashevsky, Martin Kulldorff, Taliser R Avery, Robert L Davis, Susan E Andrade, Sascha Dublin, Lisa Herrinton, Pam Pawloski, Marsha A Raebel, Douglas Roblin, David Smith, Richard Platt, Robert Reynolds. (United States)

11:45 AM Evaluation of Three Disproportionality Analysis Algorithms for Post-Marketing Signal Detection of Torsades de Pointes in FDA/AERS Database [333]

David Olaleye, David Olaleye. (United States)

• To Bleed or Not To Bleed (Regency D)

Moderators: Klaas Heinemann & Yola Moride, FISPE

10:30 AM Selective Serotonin Reuptake Inhibiting Antidepressants and the Risk of Overanticoagulation during Acenocoumarol Maintenance Treatment [334]

Martina Teichert, Loes Visser, Andre Uitterlinden, Albert Hofman, Peter Buhre, Sabine Straus, Peter de Smet, Bruno Stricker. (Netherlands)

10:45 AM An Application of Kaplan Meier Method in Examining the Discontinuation of Warfarin and a Preceding Bleeding Event during a Hospitalization Episode [335]

Xianying Pan, Hugh Kawabata, Teresa Simon, Uchenna Iloeje. (United States)

11:00 AM The Risk of Major Bleeding in Patients Treated with Warfarin for Venous Thromboembolism at an Anticoagulation Clinic: An Incident User Cohort Study [336]

Eric S Johnson, David H Smith, Xiuhai Yang, Amanda F Petrik, Jessica R Weiss, Micah L Thorp, Andrew H Felcher. (United States)

11:15 AM How Real-Life Data Analysis Could Highlight Ethnic Inequalities in Access to Healthcare:

Example of Critical Limb Ischemia in the US Medicare Population [337]

Onur Baser, Patrice Verpillat, Li Wang. (France)

11:30 AM Association between Drug Use and Acute Immune Thrombocytopenia in Adults: Results from the Berlin Case-Control Surveillance Study [338]

Edeltraut Garbe, Frank Andersohn, Elisabeth Bronder, Andreas Klimpel, Michael Thomae, Hanife Kurtal. (Germany)

11:45 AM Hemorrhage Following Concurrent Use of Warfarin and Oseltamivir by Medicare Beneficiaries [339]

Judith A Racoosin, Andrew E Mosholder, Stephanie Young, Michael Wernecke, Thomas MaCurdy, Chris Worrall, Jeffrey Kelman. (United States)

12:00-1:30pm

Lunch/Poster Session B/Exhibits (Regency Center West)

ISPE Committee Meetings

Open to all participants.

(Lunches will be available in meeting rooms)

- Bylaws and Policies Committee (Columbian)
- Education Committee (Gold Coast)
- Global Development Committee (Wrigley)
- Membership Committee (Picasso)
- Publications Committee (Haymarket)

12:15-1:15pm

Roundtable Discussions

To foster the ability of the more junior ISPE members to network and new ISPE members to meet others attending the ICPE, we are hosting several lunchtime discussion roundtables on Monday and Tuesday. These roundtables will be informal. The facilitators and topics for the tables are listed below. There will be NO formal presentations made at the roundtables. The purposes are discussion, information exchange, and networking. **Seating is limited; first-come, first-served.**

- **Bert Leufkens, FISPE**, Regulatory science and pharmacoepi
- **Bill Calvert**, Safety surveillance

- **Gillian Hall, FISPE**, The ISPE guidelines for quality conduct in database research
- **Sean Hennessy, FISPE**, Translational research in drug-drug interactions

12:45-1:30pm

Poster Walks (Regency Center West)

- Database SIG
- Medical Devices SIG

1:30-2:30pm

PLENARY SESSION (Crystal Ballroom)

Thalidomide – 50 years later

Educational Objectives

- Commemorate the 50th anniversary of the thalidomide disaster
- Describe the human toll of this event
- Reflect on its importance for pharmacoepidemiology
- Honor two key participants in the story with lifetime achievement awards.
- **Ulf Bergman, FISPE & Allen Mitchell, FISPE**, Moderators
- **Tsugumichi Sato**, Reflections of a thalidomide survivor
- Presentation of Award to **Frances O. Kelsey**
- Presentation of Award to **Barbro Westerholm**

2:30-3:30pm

ANNUAL MEETING OF ISPE MEMBERS & AWARDS CEREMONY (Crystal Ballroom)

Open to all participants.

- ◄ Annual Meeting of ISPE Members
 - Stephen JW Evans, FISPE**, ISPE President
 - Matthew Reynolds**, Vice President Finance
- ◄ Awards Ceremony
 - ICPE 2011
 - Presented by **Stephen JW Evans, FISPE**
 - **John Seeger**, Co-chair, Scientific Program Committee
 - **Glen T. Schumock**, Co-chair, Scientific Program Committee
 - Student Awards
 - Presented by **John Seeger & Glen T. Schumock**,

- **The Andrew McAfee Award** (Best abstract submitted by a student/post-doc from a developing country).
Thiyagu Rajakannan, *Study on Risk Factors for Adverse Drug Reactions in Hospitalized Retroviral Patients*
- Third Best Abstract: **Mary Abigail De Vera**
- Second Best Abstract: **Christina Mack**
- **The Stanley A. Edlavitch Award** (Best Abstract submitted by a student/post-doc) & Oral Presentation
Shirley V. Wang, *Future Cases as Present Controls: Methods To Adjust for Exposure-Time Trends [340]*
 Shirley V Wang, Crystal Linkletter, Malcolm Maclure, David D Dore, Vincent Mor, Stephen Buka, Gregory Wellenius. (United States)

- Induction of ISPE Fellows (FISPE)
Stephen JW Evans, FISPE, ISPE President

Inductees

- **Robert F. Reynolds**, FISPE
- **Nancy C. Santanello**, FISPE
- **Soko Setoguchi Iwata**, FISPE
- **Marianne Ulcickas Yood**, FISPE

- **The Ronald D. Mann Best Article Award**

Brian Strom, FISPE, Editor-in-Chief
Joerg Hasford, Regional Editor for Europe
Sean Hennessy, FISPE, Regional Editor for the Americas
B J Park, FISPE, Regional Editor for Asia, Africa, Oceania

- ◀ Installation of New ISPE President
Nancy C. Santanello, FISPE

3:30-4:00pm

Break/Posters/Exhibits (Riverside Center West)

4:00-5:30pm

CONCURRENT SESSIONS: SYMPOSIA AND WORKSHOPS

- **Challenges to Improving the Science of Regulatory Decision-Making [341] (Regency A)**
Stanley A Edlavitch, Gerald J Dal Pan, June M Raine, Jerry Avorn, Hubert G Leufkens, Byong-Ju Park. (United States)
- **Challenges in Conducting Sequentially Monitored Medical Product Safety Studies Using Electronic Health Care Utilization Data [342] (Regency B)**
Jennifer C Nelson, Andrea J Cook, Stanley Xu, Sharon K Greene. (United States)
- **Drug-Induced Liver Injury (DILI): Latest Developments on Premarket Regulatory Guidance and Approaches to Postmarket Surveillance [343] (Toronto)**
Lisa I Wang, Wei Dong, Susan A Oliveria, Marianne Ulcickas Yood, Noah J Robinson, Michele Bortolini. (United States)
- **Increasing Scientific Standards, Transparency and Independence in Pharmacoepidemiological Research: Is the Concept of ENCePP Studies a Way Forward? [344] (Regency C)**
Xavier Kurz, Bert Leufkens, Stella Blackburn, Yola Moride, Valerie Simmons, Corinne de Vries. (United Kingdom)
- **Methods Development in Active Drug Safety Surveillance Highlighting the Observational Medical Outcomes Partnership's Findings [345] (Regency D)**
Abraham G Hartzema, Judith A Racoosin, Patrick B Ryan, Paul E Stang. (United States)
- **Structured Approaches to Evaluating Statistical Signals from Drug and Vaccine Safety Surveillance [346] Systems (Acapulco)**
Marsha A Raebel, Martin Kuldorff, Gerald Dal Pan, Marie Lindquist, Bruce Fireman. (United States)

5:30-6:30pm

Special Interest Group (SIG) Meetings

Open to all participants.

- Biologics SIG (Columbian)
- Comparative Effectiveness Research SIG (Gold Coast)
- Databases SIG (Haymarket)
- Drug Utilization/Health Services Research SIG (Wrigley)
- Medical Devices SIG (Picasso)
- Medications in Pregnancy SIG (Toronto)
- Molecular Epidemiology/Biomarkers/Pharmacogenetics SIG (Acapulco)
- Pediatrics SIG (New Orleans)

7:30-???

Evening at the Hard Rock Café (63 West Ontario)



History of HRC

It started with an Eric Clapton guitar (a Fender Lead II, for the gearheads in the audience). The beginning of something that nobody even knew was beginning. It was just a goof. A laugh. A joke among friends.

Back in the seventies, Clapton - the original guitar god, founder of Cream and Derek & the Dominoes, creator of the immortal "Layla" - liked to eat at this quirky American diner in London called the Hard Rock Cafe. The place was this funky old building that used to be a Rolls Royce dealership, and it was run by a couple of young Americans who liked to keep it loose. Founded by Isaac Tigrett and Peter Morton, two enterprising and music-loving Americans, Hard Rock Cafe was an instant classic. You could be yourself at the Hard Rock. It was good food and a good time.

So Clapton got to be friends with the proprietors and asked them to save him a regular table, put up a brass plaque or something. And the young proprietors said, "Why don't we put up your guitar?" They all had a chuckle, and he handed over a guitar, and they

slapped it on the wall.

No one thought much more about it. Until a week later, when another guitar arrived (a Gibson Les Paul, by the way). With it was a note from Pete Townshend of The Who which read: "Mine's as good as his. Love, Pete."

The young proprietors put it on the wall. After that, the guitars never stopped coming. Today there are more than 70,000 guitars, drums, pianos, harmonicas, microphones, shirts, pants, scarves, shoes, handwritten lyrics, cars, bikes, a bus and assorted rock memorabilia - by far, the largest, most valuable such collection in the world - on the walls of over 163 Hard Rock Cafes, Hotels and Casinos in 52 countries around the world.

But it all started with the one.

Join us for an unforgettable evening in Chicago's HRC!

-- Admission is by badge or ticket; admission includes two drink tickets

-- Buses will shuttle from the Hyatt to the Hard Rock Cafe. The first bus will depart from the Hyatt at 7:00pm; the last bus will depart from the Hard Rock Café at 1:00am. However, if it's a nice evening, you might wish to walk to the HRC (20 minutes)

WEDNESDAY **August 17, 2011**

- | | |
|-------------|---|
| 7:30-8:15am | ICPE 2012 Program Planning (Crystal Ballroom) (Open to interested ISPE members) |
| 7:00-4:30pm | Registration (Regency Main Desk) |
| 7:30-3:30pm | Speakers' Ready Room (Hong Kong) |
| 7:00-8:00am | Poster Session C Set-up (Riverside Center West) |
| 8:00-1:45pm | Exhibits/Posters (Riverside Center West) |

8:30-10:00am

CONCURRENT SESSIONS: CONTRIBUTED PAPERS

- **Applied Risk Management (Regency A)**
Moderator: Annalisa Rubino

08:30 AM Evaluation of Dronedarone Utilization in the US Using a Claims Database [540]

Shujun Gao, Juhaeri Juhaeri, Heather A Schiappacasse, Andrew T Koren, Wanju S Dai. (United States)

08:45 AM Experiences and Preferences of Healthcare Professionals with Regard to Direct Healthcare Professional Communications (DHPCs) [541]

Sigrid Piening, Flora M Haaijer-Ruskamp, Sabine M J M Straus, Pieter A de Graeff, Peter G M Mol. (Netherlands)

09:00 AM Risk Management Strategies Mitigating Potential Severe Dermatologic Risks of Carbamazepine in Taiwan [542]

Yu-Wen Huang, Po-Wen Yang, Churn-Shiouh Gau, Hsueh-Yung Tai, Chien-Wen Hsu, Meir-Chyun Tzou, Hsuan-Shu Lee, Jaw-Jou Kang. (Taiwan)

09:15 AM Reducing Medication Errors through Application of Low Health Literacy Principles to Patient Instructions for Use [543]

Meredith Y Smith, Lorraine Wallace. (United States)

09:30 AM Trends in Dispensing Patterns of Rosiglitazone and Pioglitazone in the Netherlands Following Safety Signals during the Period 1998-2008 [544]

Rikje Ruiten, Loes E Visser, Myrthe P P van Herk - Sukel, P H Geelhoed - Duijvestijn, Sandra de Bie, Sabine M J M Straus, Peter G M Mol, Silvana A Romio, Ron M C Herings, Bruno H Ch Stricker. (Netherlands)

09:45 AM Evaluation of Drug Interactions in 84607 Psychiatric Inpatients Using a Customized Data Interface for Mass Analysis with Clinical Decision Support Software [545]

P Haueis, W Greil, M Huber, R Grohmann, G Kullak, S Russmann. (Switzerland)

- **Cancer: Growing Evidence (Toronto)**
Moderators: Marieke De Bruin & James Kaye

08:30 AM **Assessing the Comparability of Electronic Medical Records Information to Tumor Registry and Health Claims Data for Oncology Outcomes Research [546]**

Fionna S Mowat, Edmund E Lau, Michael A Kelsh, Jason Legg, Nicole M Engel-Nitz, Heather N Watson, Helen Collins, Robert J Nordyke, Joanna L Whyte. (United States)

08:45 AM **Claims-Based Prediction of Performance Status (PS) Associated with Erythropoieticstimulating Agent (ESA) Treatment and Survival in Myelodysplastic Syndromes (MDS) Patients [547]**

Xuehua Ke, Amy J Davidoff, Ilene Zuckerman, Naimish B Pandya, Franklin Hendrick, Sheila Weiss Smith, Maria R Baer, Steven D Gore. (United States)

09:00 AM **Effectiveness and Safety in Very Elderly Patients Treated by Bevacizumab (BV) Plus Chemotherapy in 1st-Line Therapy of Metastatic Colorectal Cancer: Results of ETNA, a French Cohort Study [548]**

Annie Fourrier-Réglat, Magali Rouyer, Pernelle Noize, Aurélie Balestra, Régis Lassalle, Marie-Agnès Bernard, Alain Ravaud, Denis Smith, Nicholas Moore, and the ETNA Study Group. (France)

09:15 AM **Use of Glucocorticoids and Colorectal Cancer Risk; a Population-Based Case-Control Study [549]**

Eva Bjerre Ostenfeld, Anders Hammerich Riis, Ole Thorlacius-Ussing, Tove Nilsson, Rune Erichsen, Henrik Toft Sørensen. (Denmark)

09:30 AM **Angiotensin Receptor Blockers and the Risk of Cancer – A Comparative Safety Study in Large Linked Healthcare Databases [550]**

Henrik Svanström, Björn Pasternak, Callréus Torbjörn, Melbye Mads, Hviid Anders. (Denmark)

- 09:45 AM Hormonal Therapies and Meningioma: A UK Primary Care Study [551]**
Lucía Cea-Soriano, Tilo Blenk, Mari-Ann A Wallander, Luis A García Rodr´guez. (Ghana)
- **Giving Kids a Good Stab (Acapulco)**
Moderators: Abraham Hartzema, FISPE, & Jan Bonhoeffer
- 08:30 AM Empirical Bayesian Data Mining as an FDA Tool for Prospective Early Detection of Novel Safety Signals in the Vaccine Adverse Events Reporting System (VAERS): A Case Study of Febrile Seizures after an Influenza Virus Vaccine [552]**
David Menschik, David Martin. (United States)
- 08:45 AM Effect of Vaccine-Related Reports on Pediatric Safety Signal Detection [553]**
Sandra de Bie, Katia M C Verhamme, Sabine M J M Straus, Bruno H C Stricker, Miriam C J M Sturkenboom. (Netherlands)
- 09:00 AM Validity of Current Procedural Terminology Codes for Rotavirus Vaccination in Two Commercially-Insured US Populations [554]**
Veena Thyagarajan, Roberta Glass, Keith Rodgers, Scott Quinlan, Crystal N Holick, Dominique Rosillon, Emily Lu, David D Dore, Camilo Acosta, John D Seeger. (United States)
- 09:15 AM Use of Self-Controlled Risk-Interval Design in Childhood Vaccine Safety [555]**
Jie Li, Gregory W Daniel, Corrie Paeglow, Tom Puenpatom, Laura Polakowski, Yun Lu, Alec M Walker, M Alan Brookhart, Hector Izurieta. (United States)
- 09:30 AM Longitudinal Study of the Impact of Varicella Vaccination in a Managed Care Organization (1995-2009) [556]**
Patricia Saddier, Trung Tran, Paula Ray, Roger Baxter. (United States)
- 09:45 AM Biologically Plausible Risk Intervals To Assess Febrile Seizure Following Immunization with Influenza and Pneumococcal Conjugate Vaccines [557]**
Ali Rowhani-Rahbar, Nicola P Klein, Cornelia L Dekker, Kathryn M Edwards, Claudia Vellozzi,

Neal A Halsey, Roger P Baxter, The Risk Interval Working Group of the Clinical Immunization Safety Assessment (CISA) Network. (United States)

- **Interesting, But Will We Remember (Regency B)**
Moderators: Rob Heerdink & Kristina Bardenheuer

- 08:30 AM Risk of Coronary Events and Stroke in Patients Taking Anticonvulsant Medications [558]**
Elisabetta Patorno, Rhonda Bohn, Peter Wahl, Gregory Daniel, Jerry Avorn, Jun Liu, Helen Mogun, Sebastian Schneeweiss. (United States)
- 08:45 AM Comparisons between Drugs for Alzheimers Disease Concerning Changes in Co-Medication, Need of Assisted Living Facilities and Hospitalizations [559]**
Tobias Svensson, Anders Sundström, Morten Andersen, Helle Kieler. (Sweden)
- 09:00 AM A Study of Blood Pressure and Change in Cognitive Function in Elderly Mexican Americans [560]**
X Zhou, S Galea. (United States)
- 09:15 AM Patterns of Antidepressant Medication Use in Medicaid-Eligible Pregnant Women [561]**
Krista F Huybrechts, Kristin Palmsten, Helen Mogun, Soko Setoguchi, Jerry Avorn, Sonia Hernández-Diaz. (United States)
- 09:30 AM Neuropsychiatric Events in Varenicline Compared to Nicotine Replacement Therapy (NRT) Patch Users, Military Health System (MHS) [562]**
Tamra E Meyer, Lockwood G Taylor, Suji Xie, David J Graham, Andrew D Mosholder, James R Williams, David Moeny, Rita Ouellet-Hellestrom, Trinkia S Coster. (United States)
- 09:45 AM Antiepileptic Drugs and the Risk of Stroke [563]**
Chia-Cheng Lai, Cheng-Yang Hsieh, Yea-Huei Kao Yang. (Taiwan)

- **Measuring Quality of Prescribing (Regency C)**

Moderators: Morten Andersen & Lisa Pont

- 08:30 AM Does Medication Review Lead to a Reduction of Drug Problems in Elderly Patients Discharged from the Hospital [564]**
Abeer Loutfi_Ahmad, Ruth M Mast, Giel Nijpels, Jacqueline M Dekker, Piet J Kostense, Jacqueline G Hugtenburg. (Netherlands)
- 08:45 AM Enhancing the Quality of Prescribing in Primary Care in Australia [565] – Abstract Withdrawn by Author**
- 09:00 AM Ranking Medication Errors in the Hospital by Their Probability of Harm in a National Error Reporting Database [566]**
Jessica A Myers, Sergio Venturini, Laura Morlock, Francesca Dominici. (United States)
- 09:15 AM The Effect of a Multifaceted Educational Intervention on Medication Errors in a Dutch Neonatal Intensive Care Unit [567]**
Katja Taxis, Indra Chedoe, Wobbe Hospes, A Molendijk. (Netherlands)
- 09:30 AM The Impact of Evidence-Based Subsidy Restrictions on Lapatinib Use and Outcomes [177]**
Sallie-Anne Pearson, Preeyaporn Srasuebku, Christine Lu, Timothy Dobbins, Robyn Ward. (Australia)
- 09:45 AM Medication Errors during Patient Transition into Nursing Homes: What Is the Impact on Patients? [195]**
Rishi Desai, Richard Hansen, Charlotte Williams, Stephanie Pierson, Sandra Greene. (United States)

- **Methods for Safety (Regency D)**

Moderators: John Seeger & Tam Dang-Tan

- 08:30 AM Linking Electronically Collected Quality of Life Data to THIN – A UK General Practice Database [570]**
Betina T Blak, Joanne Lee, Mary Thompson, Alison Bourke, Louise Pinder. (United Kingdom)

08:45 AM Disproportionality Analysis for Signal Detection of Implantable Cardioverter-Defibrillator Lead Related Adverse Events [571]

Naomi D Herz, Heshu J Duggirala, Daniel A Caños, Roberta Sullivan, Richard Schaaf, Ellen Pinnow, Danica Marinac-Dabic. (United States)

09:00 AM Time-Dependent Survival Analysis: It's Benefits and Hazards [812]

Angelique L Zeringue, Ziyad Al-Aly, Jay R McDonald. (United States)

09:15 AM Poly-Pharmacy and Adverse Drug Reactions in Japanese Elderly Hypertensive Patients: Assessing Effects of Time-Varying Exposure [573]

Izumi Sato, Manabu Akazawa. (Japan)

09:30 AM Influence of Run-In Period on Incidence of NSAID Use in European Population in the SOS Project [574]

Vera E Valkhoff, Silvana A Romio, Rene Schade, Martijn Schuemie, Edeltraut Garbe, Ron Herings, Silvia Lucchi, Gino Picelli, Tania Schink, Huub Straatman, Marco Villa, Antonella Zambon, Ernst J Kuipers, Miriam C J M Sturkenboom. (Netherlands)

09:45 AM Exposure to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and Drugs Used in Musculoskeletal Disorders (MSD): Agreement between Physicians' Prescriptions and Patients' Self-Report in the PGRx Database [575]

Lamiae Grimaldi-Bensouda, Michel Rossignol, Djamila Abed, Elodie Aubrun, Lucien Abenheim, PGRx Group. (Canada)

10:00-10:30am

Break/Posters/Exhibits (Riverside Center West)

- **Government/Regulatory Council Coffee Corner**

10:30-Noon

CONCURRENT SESSIONS: CONTRIBUTED PAPERS

• **Cough & Wheeze (Regency A)**

Moderators: **Maria Gerhardsson & Todd Lee**

- 10:30 AM Risk of Depression Associated with Use of Leukotriene Receptor Antagonist in Elderly Asthma Patients in Korea [576]**
Chul Woo Rhee, Nam-Kyong Choi, Yoon-Ok Ahn, Joongyub Lee, Byung Joo Park. (Republic of Korea)
- 10:45 AM Characterization of Long-Acting Beta-Adrenergic Agonists Use for Asthma Treatment [577]**
Sigal Kaplan, Esther Zhou. (United States)
- 11:00 AM Appropriateness of Age Thresholds for Palivizumab Prophylaxis in Preterm Infants [578]**
Caitlin A Knox, Christian Hampp, Paul S Kubilis, Stephan Linden, Almut G Winterstein. (United States)
- 11:15 AM Safety of Atrovent® CFC-Free MDI (Metered Dose Inhaler): An Example of Protopathic Bias in Observational Cohort Studies [579]**
Vicki Osborne, Deborah Layton, Edward Tong, Saad A Shakir. (United Kingdom)
- 11:30 AM Changing Asthma Regimens from Suboptimal to Optimal: What Are the Impacts on Health Service Use in Patients with Asthma? [580]**
TingTing Zhang, Ricardo Jimenez-Mendez, Anne Smith, Bruce C Carleton. (Canada)
- 11:45 AM Severe Asthma Exacerbations Associated with Long-Acting Beta Agonists among Children and Adolescents with Asthma [581]**
Jeff J Guo, Katherine Tsai, Christina M L Kelton, Boyang Bian, Patricia R Wigle. (United States)

- **Database Methods (Regency B)**

Moderators: Helga Gardarsdottir & David Miller

- 10:30 AM Dichotomizing Does Not Help, Even If Outcomes Are Bimodally Distributed [76]**
Ruud Boessen, Mirjam J Knol, Rolf H H Groenwold, Kit C B Roes. (Netherlands)
- 10:45 AM Using Physician Office Visit Dates To Link Electronic Medical Records to Healthcare Claims Data [583]**
Gregory Lenhart, Suellen Curkendall, Daniel M Huse. (United States)
- 11:00 AM Impact of Look-Back Period on Baseline Patient Characteristics and Subsequent Risk Estimates in the General Practice Research Database (GPRD) [584]**
Tzuyung D Kou, Kimberly G Brodovicz, Cindy J Girman. (United States)
- 11:15 AM Does Additional Confounder Information Alter the Results of a Database Study on the Risk of Bleeding Associated with Phenprocoumon Use? [585]**
Sigrid Behr, Walter Schill, Iris Pigeot. (Germany)
- 11:30 AM Misclassifying Drug Exposure Data within Administrative Databases: An Ecologic Approach [586]**
John-Michael Gamble, Finlay A McAlister, Jeffrey A Johnson, Dean T Eurich. (Canada)
- 11:45 AM Quantifying the Impact of Drug Exposure Misclassification Due to Restrictive Drug Coverage in Administrative Databases: A Simulation Cohort Study [587]**
John-Michael Gamble, Finlay A McAlister, Jeffrey A Johnson, Dean T Eurich. (Canada)

- **Gut Feeling (Toronto)**

Moderators: Daniel Mines & Deborah Layton

- 10:30 AM Hepatotoxicity in Association with Acetaminophen Poisonings in the U.S. [588]**
Syed Rizwanuddin Ahmad, Anne Elixhauser, Janet P Sutton. (United States)

- 10:45 AM Polyethylene Glycol Increase Risk of Acute Renal Failure: A Population Based Case-Crossover Study [589]**
 Nam-Kyong Choi, Joongyub Lee, Yoosoo Chang, Sun-Young Jung, Ye-Jee Kim, Seung-Mi Lee, Jin-Ho Lee, Ju-Young Kim, Byung-Joo Park. (Republic of Korea)
- 11:00 AM Hypertriglyceridemia and Acute Pancreatitis [590]**
 Michael J Murphy, Xia Sheng, Thomas M MacDonald, Li Wei. (United Kingdom)
- 11:15 AM Evaluation of In-Hospital Clinical Outcomes with Alvimopan in Patients Undergoing Open or Laparoscopic Colorectal Surgery: Matched-Cohort National Database Study [591]**
 Lee M Techner, Suzanne F Cook, Christopher Craver, Amy W Rachfal, Michael Calloway. (United States)
- 11:30 AM Risk of Upper and Lower Gastrointestinal Hospitalizations in the Elderly with and without Alzheimer's Disease [592]**
 Jasmanda H Wu, Zhenchao Guo, Sandeep Kumar, Andres Gomez, Pablo Lapuerta. (United States)
- 11:45 AM The Comparative Safety of Drospirenone for Gallbladder Disease among Women Taking Oral Contraceptives [593]**
 Joseph A Delaney, James M Brophy, Mahyar Etminan. (United States)

- **Methods in Vaccine Safety (Regency C)**
Moderators: Patricia Saddier & Florence Wang

- 10:30 AM Guillain-Barré Syndrome and Adjuvanted Pandemic Influenza A (H1N1) 2009 Vaccines – A Multinational Case Control Study in Europe [594]**
 Jeanne P Dieleman, Silvana S Romio, Corinne S de Vries, Cormac J Sammon, Nick Andrews, Anders Hviid, Henrik Svanström, Ditte Mølgaard-Nielsen, Maryse Lapeyre-Mestre, Agnès Sommet, Christel Saussier, Anne Castot, Harald Heijbel, Lisen Arnheim Dahlström, Jonas Hallgren, Par Sparen, Mees Mosseveld, Martijn Schuemie, Nicoline van der Maas, Bart C Jacobs, Kari

Johansen, Piotr Kramarz, Daniel Weibel, Jan Bonhoeffer, Miriam C J M Sturkenboom. (Netherlands)

10:45 AM Guillain-Barré Syndrome, Influenza-like Illnesses and Influenza Vaccination during Seasons with and without Circulating A/H1N1 Viruses [595]

Lamiae Grimaldi-Bensouda, Annick Alperovitch, Gérard Besson, Christophe Vial, Jean-Marie Cuisset, Caroline Papeix, Olivier Lyon-Caen, Elodie Aubrun, Jacques Benichou, Michel Rossignol, Lucien Abenheim, GBS-PGRx Study Group. (United Kingdom)

11:00 AM Safety of Adjuvanted Pandemic Influenza Vaccines: Background Rate of Narcolepsy in Europe [596]

J Dieleman, C Lecomte, M Schuemie, A van Rollegheem, A Hviid, H Svanström, D Mølgaard-Nielsen, J Jokinen, H Nohynek, T Kilpi, J Storsaeter, N van der Maas, H Heijbel, L Arnheim-Dahlstrøm, P Sparen, C Sammon, C de Vries, G Plazzi, A Menna, F Trotta, C Santuccio, K Johansen, P Kramarz, D Weibel, J Bonhoeffer, M Sturkenboom. (Netherlands)

11:15 AM Characterizing Vaccine-Associated Risk Using Natural Smoothing Splines [597]

M A Brookhart, J Li, C Paeglow, T Puenpatom, L Polakowski, Y Lu, A M Walker, H Izurieta, G W Daniel. (United States)

11:30 AM Identifying Adverse Events of Vaccines Using a Bayesian Method of Medically Guided Information Sharing [598]

Colin Crooks, David Prieto-Merino, Stephen Evans. (United Kingdom)

11:45 AM The Reporting Completeness of a Passive Safety Surveillance System for Influenza A (H1N1) 2009 Vaccines: A Capture-Recapture Analysis [599]

Wan-Ting Huang, Wei-I Huang, Yu-Wen Huang, Chien-Wen Hsu, Jen-Hsiang Chuang. (Taiwan)

- **Not Your “Typical” Psychotropics (Regency D)**
Moderators: Judith Jones, FISPE, & Natasha Chih-Ying Chen

- 10:30 AM** **Mental Distress and Subsequent Use of Psychotropic Drugs among Adolescents – A Prospective Register Linkage Study [600]**
 Anne Kjersti Myhre Steffenak, Svetlana Skurtveit, Kari Furu, Bodil Wilde-Larsson, Gun Nordström, Ingeborg Hartz. (Norway)
- 10:45 AM** **The Association between Hospitalization and Discontinuity of Psychotropic Drug Use [601]**
 Rutger Stuffken, Eibert R Heerdink, Patrick C Souverein, Toine C Egberts. (Netherlands)
- 11:00 AM** **Comparative Risk of Cerebrovascular Adverse Events among Older Adults Using Risperidone, Olanzapine and Quetiapine [676]**
 Satabdi Chatterjee, Rajender R Aparasu, Hua Chen, Michael L Johnson. (United States)
- 11:15 AM** **Comparative Safety of Individual Antipsychotic Medications in the Non-Institutionalized Elderly [603]**
 Tobias Gerhard, Krista Huybrechts, Sebastian Schneeweiss, Mark Olfson, Cecilia Huang, Edmond S Malka, Stephen Crystal. (United States)
- 11:30 AM** **Potential Causes of Higher Mortality in Nursing Home Residents Starting Conventional and Atypical Antipsychotics [604]**
 Krista F Huybrechts, Tobias Gerhard, Stephen Crystal, Mark Olfson, Raisa Levin, Judith Lucas, Jerry Avorn, Sebastian Schneeweiss. (United States)
- 11:45 AM** **Predictors of High Metabolic Risk Antipsychotic Use [605]**
 Stacie B Dusetzina, G C Alexander, Rena Conti, E R Dorsey, Ashley S Higashi, Shu Zhu, Craig F Garfield, Haiden A Huskamp. (United States)

- **Nulligravida (Acapulco)**
Moderators: Sonia Hernandez-Diaz, FISPE, & Lolkje TW de Jong-van den Berg

- 10:30 AM** **Congenital Defect Rates in Electronic Health Records and Claims Databases: Comparison to US National Surveillance System [606]**
Keele E Wurst, Sara A Ephross. (United States)
- 10:45 AM** **Maternal Exposure to Venlafaxine and Risk for Birth Defects, National Birth Defects Prevention Study, 1997-2007 [607]**
Kara Duwe, Sonja Rasmussen, Carol Louik, Tiffany Colarusso, Jennita Reefhuis. (United States)
- 11:00 AM** **Does Patterns of Maternal Use of Potentially Addictive Drugs Reproduce in Their Children? [608]**
Ingeborg Hartz, Randi Selmer, Aage Tverdal, Eivind Skille, Svetlana Skurtveit. (Norway)
- 11:15 AM** **Maternal Use of Proton Pump Inhibitors during Early Pregnancy and the Prevalence of Hypospadias in Male Offspring [609]**
Rune Erichsen, Ellen Mikkelsen, Lars Pedersen, Henrik T Sørensen. (Denmark)
- 11:30 AM** **Use of Ovulation Stimulation (OS) Alone, Intrauterine Insemination (IUI) and Assisted Reproductive Techniques (ART) and the Risk of Multiplicity – The TWINPREG Study [610]**
Anick Bérard, Odile Sheehy, William Fraser, Francois Bissonnette, Seang-Lin Tan, Jacquetta Trasler, Patricia Monnier. (Canada)
- 11:45 AM** **Medicaid Analytic Extract for Studies of Drug Safety during Pregnancy [611]**
Kristin Palmsten, Krista Huybrechts, Helen Mogun, Soko Setoguchi, Sonia Hernández-Díaz. (United States)

Noon-1: 30pm

Lunch/Poster Session C/Exhibits (Regency Center West)

ISPE Board of Directors Luncheon (Wrigley)

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

12:45-1:30pm

Poster Walks (Regency Center West)

- Comparative Effectiveness Research (CER) SIG

- Molecular Epidemiology-Biomarkers-Pharmacogenetics SIG

1:30-3:00pm

CONCURRENT SESSIONS: SYMPOSIA AND WORKSHOPS

- **Active Surveillance for Follow-On Biologics [612] (Toronto)**
Earl Goehring, Judith Jones, Miriam CJM Sturkenboom, Jonathan Morris, Elizabeth Sobczyk and Robert Chen. (United States)
- **Assessing Treatment Patterns: Novel Methods and Applications [613] (Regency A)**
Sonia S Maruti, E Dawn Flick, Marloes Bazelier, Frank De Vries, Krista F Huybrechts, Drew Levy, Andrew Roddam, Wei Dong. (United States)
- **Assessment of Long-Term Adverse Drug Reactions, Regulatory Needs and Methodological Challenges [614] (Regency B)**
Ruben G Duijnhoven, Sabine M J M Straus, Tjeerd P van Staa, Yola Moride, Lamiae M Grimaldi, Marie L De Bruin. (Netherlands)
- **Addressing Challenges in Using Multiple Data Sources To Evaluate Medication Risk Factors for Asthma Mortality in Persistent Asthma [615] (Acapulco)**
Patricia Tennis, Kourtney Davis, Til Sturmer, Jeffrey Brown, Stephan Lanes. (United States)
- **FDA's Mini-Sentinel Program To Evaluate the Safety of Marketed Medical Products: Progress and Prospects [616] (Regency C)**
Richard Platt, Judith Racoosin, Lesley Curtis, Sean Hennessy, Sebastian Schneeweiss, Darren Toh. (United States)
- **Drug Utilization Studies and Risk Management Plans: A Missing Link [617] (Regency D)**

Annalisa Rubino, Mari-Ann Wallander, Torbjörn Callréus,
Patricia Saddier, Mary B Ritchey, Susana Perez-Gutthann.
(United Kingdom)

3:00-4:30pm

HOT TOPICS SESSION:

H1N1 Vaccine Safety Monitoring: Global Lessons for a Global Pandemic (Crystal Ballroom)

Learning Objectives

- What adaptations (from traditional safety monitoring) were needed for a global pandemic vaccine?
- What successes and challenges were actually encountered?
- What lessons were learnt for future global pandemics?

Description of Session

The world has been preparing for the next influenza pandemic for some years. Last year's Hot Topic session addressed the decisions surrounding the declaration of the 2009 H1N1 pandemic, this year's session will focus instead on the actual safety monitoring experience associated with H1N1 vaccination campaigns in various countries and the lessons learnt.

Faculty

- Moderator, **Robert Chen, FISPE**, HIV Vaccine & Special Studies Team, CDC
- **Claudia Vellozzi**, Deputy Director, Immunization Safety Office, CDC
- **Pier Luigi Lopalco**, Head of Section of Vaccine Preventable Diseases, ECDC
- **Wan-Ting Huang**, Surveillance Team Lead, Taiwan CDC
- **Paul Effler**, Medical Coordinator, Prevention and Control Program, Department of Health, Western Australia
- **Harry Seifert**, Executive Director, Safety Evaluation & Risk Management at GlaxoSmithKline Biologicals
- **Jan Bonhoeffer**, Brighton Collaboration
- **Miriam CJM Sturkenboom, FISPE**, Erasmus University Medical Center
- **Stephen JW Evans, FISPE**, London School of Tropical Medicine & Hygiene

4:30-5:00pm

The Final Word (Crystal Ballroom)

• Poster Awards

- **Mary Beth Ritchey**, Poster Walk Chair

- **Future Meetings**

- **2012 Mid-Year Meeting** – Miami Beach
Bram Hartzema, FISPE, Co-Chair, Program Planning Committee
Maribel Salas, Co-Chair, Program Planning Committee
- **ICPE 2012-Barcelona**
Susanna Perez Gutthann, FISPE, Chair, Scientific Program Committee

5:00pm

Adjournment of ICPE 2011