

***26th International Conference on
Pharmacoepidemiology
& Therapeutic Risk Management
Hilton Brighton Metropole
Brighton, United Kingdom***

Wednesday

August 18, 2010

- 8:30-5:00pm **ISPE Board of Directors Meeting (Buckingham)**
(Open to ISPE members; notify ISPE staff if you would like to attend.)
- 11:00-6:00pm **Registration (Sussex Lounge)**
- 11:00-5:00pm **Speaker Ready Room (Office 1)**

PRE-CONFERENCE EDUCATIONAL SESSIONS*
(Registration required)

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

Chair: Andrew McAfee

Harry Seifert, GSK, *Spontaneous Reporting*

Soko Setoguchi, Duke University, *Cohort Studies*

Andrew McAfee, Brigham & Women's Hospital, *Case-Control Studies*

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

- 1:00-5:00pm **Introduction to Pharmacogenetics – Part 1 (Dukes)**
Didactic Approach Infused with Practical Examples

Educational Objectives

This year's course will focus more on methodologic approaches in pharmacogenetics in Day 1 and in Day 2.

- Understand the genetic and pharmacogenetic terminology and how cellular and molecular biology informs pharmacogenetic studies at analysis
- 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.

Faculty

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

Anke-Hilse Maitland-van der Zee/ Efrosini Setakis
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 Issa, *Methodology to Investigate Policy-Relevant Aspects of Pharmacogenomics: Tools of the Trade (Methodology)*

1:00-5:00pm

Student Skills Workshop * STUDENTS ONLY ***** **(Ambassador)**

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

Organized by ISPE Student Council

Introduction

- Presentation Clinic
- Careers Panel:
 - **Stella Blackburn, FISPE**, EMA, drug regulation
 - **Robert Reynolds**, Pfizer, pharmaceutical industry
 - **Kenneth J. Rothman, FISPE**, RTI Health Solutions, contract research organization
 - **Sean Hennessy, FISPE**, Academic

5:45pm

Student Meet and Greet

Open to all students.

Organized by the ISPE Student Council

Assemble at ICPE Registration Desk, then walk to Revolution.

THURSDAY

August 19, 2010

7:00-6:00pm **Registration (Sussex Lounge)**

7:00-5:00pm **Speakers' Ready Room (Office 1)**

PRE-CONFERENCE EDUCATIONAL SESSIONS*

(*Registration required)

8:30-Noon **Pharmacogenetics 2 – Practicum/ Small Group Case-based Projects (Dukes)**

Educational Objectives

- This year's course will focus more on methodologic approaches in pharmacogenetics in Day 1 and in Day 2.
- Understand the genetic and pharmacogenetic terminology and how cellular and molecular biology informs pharmacogenetic studies at analysis
- 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.
- Topics in Day 1 and Day 2 are complementary. Individuals registered for either day may attend both sessions. On Day 1, there will be a focus on didactic teaching. On Day 2 there will be small group workshop that will use real pharmacogenetic case studies catering to both novice and advanced participants, focused on methodology.

Faculty

- **Andrew Freedman**
- **Anke-Hilse Maitland van der Zee**
- **Efrosini Setakis**
- **Amalia Issa**
- **Steven Kimmel**
- **Geoffrey Liu**

8:30-Noon

Regulatory Pharmacoepidemiology/Public Health Decision Making (Ambassador)

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

Faculty

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

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

Stephen Evans, FISPE, 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 Research (Buckingham)

Educational Objectives

- To explain the definition and scope of the eclectic discipline of Drug Utilization Research within the context of Pharmacoepidemiology.
- 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)

Faculty

Robert Vander Stichele, *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 for cross-national comparison*

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

Monique Elseviers, *Using DUR – Data for descriptive 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

Intermediate Pharmacoepidemiology: Concepts, Data and Methods (Clarence)

Course Description

This course is for the general epidemiologist who wishes to review topics that are particular to pharmacoepidemiology. Concepts: drugs, devices and biologics as "exposures"; time-courses of their risks; confounding by indication; clinical and epidemiologic inference. Data: use of insurance claims and electronic medical records. Analysis: propensity, instruments, time-varying exposures and confounders.

Faculty

Alec Walker, FISPE
World Health Information Science Consultants
Harvard School of Public Health

8:30-Noon

Medications in Pregnancy (Balmoral)

Educational Objectives

Upon completion of the course the student will be able to:

- Recognize the unique methodological challenges of discovering unintended drug effects in pregnant women in pre-marketing and post-marketing studies.
- Understand the circumstances around the discovery and management of known drug safety crises affecting pregnant women and their offspring. This includes the critical evaluation of the available scientific evidence.
- Evaluate and design pharmacoepidemiologic studies for pregnant populations.

Faculty

Carol Louik, ScD

Assistant Professor

Slone Epidemiology Center at Boston University

Sonia Hernandez-Diaz, MD, DrPH, FISPE

Associate Professor, Department of Epidemiology

Director of Pharmacoepidemiology Program

Harvard School of Public Health

8:30-Noon

Comparative Effectiveness Research (Hall 4)

Educational Objectives

- Appreciate the differences between comparative 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 to combine sources
- Understand methodologic challenges and proposed solutions in non-randomized effectiveness research
- Learn how to generate and synthesize evidence with the decision maker in mind

Faculty

Eric S Johnson, Course Chair, Kaiser Permanente's Center for Effectiveness and Safety Research, *Introduction to comparative effectiveness research via pragmatic cohort studies*

David J Magid, Kaiser Permanente's Institute for Health Research, *Combining electronic health record and registry data sources for comparative effectiveness*

Sebastian Schneeweiss, FISPE, Harvard Medical School, *Methodological challenges in non-randomized studies of comparative effectiveness*

Kenneth R Paterson, Scottish Medicines Consortium, *Generating and synthesizing evidence with the decision maker in mind*

Noon -1:30pm

LUNCH ON YOUR OWN

Noon-1: 30pm

New Member Luncheon (Windsor Restaurant)
(By Invitation)

PRE-CONFERENCE EDUCATIONAL SESSIONS*

(*Registration required)

1:30-6:00pm

Advanced Topics in Pharmacoepidemiology (Hall 4)
[*Admission by ticket only. Tickets will be included in registration materials for those who registered for this session.]

Faculty

Chair: Jim Lewis, FISPE

Paddy Farrington, *Methods for Use of Self-Controlled Designs*

Byrony Dean Franklin, *Methods to Study the Risk, Consequences, and Prevention of Medication Errors*

Til Stürmer, FISPE, *Update on Propensity Scoring*

Reed Johnson, *Methods of Quantitative Risk Benefit Analysis*

1:30-6:00pm

Introduction to Risk Management (Balmoral)

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 use of surveys in planning and evaluating the effectiveness of RMPs/REMS
- To present key concepts in the design and conduct of survey research
- To illustrate key concepts of survey research with examples of RMP/REMS assessment surveys
- To provide an opportunity for interactive session in developing and evaluating RMP/REMS assessment surveys

Faculty

Elizabeth Andrews, FISPE, Course objectives and introductions; Overview of risk management the role of evaluation, with focus on survey research

Stella Blackburn, FISPE, Implementation and Experiences in Risk Management in the EU

Carla van Bennekom, Selected topics and examples - survey design and analysis

Judith Jones, FISPE, Workshop for Participants to Develop/Review an Assessment Survey

1:30-6:00pm

Advanced Drug Utilization Research: Using Drug Data to Guide Planning and Evaluation of Quality Use of Medicines Interventions (Ambassador)

This highly interactive workshop will involve participants in the:

- Examination of real administrative health data and reports generated from that data using drug utilization review techniques;

- Application of principles derived from Health Services and Implementation Research to the design of an actual clinical intervention;
- Planning the evaluation of the clinical intervention and the
- Interpretation of the evaluation data, the dissemination of the results and understanding wider implications of the 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 behavioral and project planning processes to the effectiveness of interventions.
- To develop a sophisticated appreciation of the significance of this work to knowledge transfer at the patient care practice and policy change levels of the health system.

Faculty

Andrew Gilbert, *Introductions, workshop objectives, and plan:*

Libby Roughead, *Theoretical methods underpinning intervention planning*

Jerry Avorn, FISPE, *Expert commentary*

6:00-7:30pm

Welcome Reception (Hilton Metropole Beach as weather permits)

Admission by badge or ticket. Cash Bar

Welcome

Corinne de Vries, FISPE, Chair, 2010 Scientific Program Committee

Sebastian Schneeweiss, FISPE, ISPE President

FRIDAY

August 20, 2010

7:00-6:00pm

Registration (Sussex Lounge)

7:00-5:00pm

Speakers' Ready Room (Office 1)

7:00-8:00am

ISPE Committee Meetings

Open to all participants.

- Education Committee (**Lancaster**)
- Finance Committee (**Hilton Meeting 3**)

7:00-8:00am

Poster Session A Set-up (Durham & Hall 7)

7:30-6:00pm

Exhibits/Posters (Durham & Hall)

8:00-9:00am

OPENING SESSION (Oxford)

Welcome

Corinne de Vries, FISPE, Chair, 2010 Scientific Program Committee

Presidential Address

Sebastian Schneeweiss, FISPE, ISPE President

9:00am -10:30am

CONCURRENT SESSIONS: CONTRIBUTED PAPERS

- **Diabetes (Clarence)**
Moderators: Bert Leufkens, FISPE, & Jurgen Dinger

9:00 am Clinical and Demographic Characteristics of Newly Diagnosed Diabetes Patients Prescribed Oral Hypoglycemics [1]
S L West, E S Brouwer, M N Kluckman, A L Masica, E Ewen, R Kudyakov. (United States)

9:15 am Improved Glycemic Control and Cancer Risk in Type 2 Diabetes: A Meta-Analysis of Major Trials [2]
Jeffrey A Johnson, Samantha L Bowker. (Canada)

9:30 am A Retrospective Cohort Study To Assess the Relative Risk of Acute Pancreatitis among Initiators of Exenatide Compared to Initiators of

Other Anti-Diabetic Medication: A Follow-Up Study [6]

Made Wenten, Julia Gaebler, Elise Pelletier, Dan Smith, Prafulla Girase, Rebecca Noel, Daniel Braun, Gary Bloomgren, Mohamed Hussein. (United States)

9:45 am Comparative Cardiovascular Morbidity and Mortality of Metformin in Older Adults with Diabetes: A Population-Based Cohort Study [4]

Linda E Levesque, James M Brophy, Sophie Dell’Aniello, Samy Suissa. (Canada)

10:00 am Risk of Acute Pancreatitis in Association with Type 2 Diabetes Mellitus [5]

Antonio González-Pérez, Raymond G Schlienger, Luis A García Rodríguez. (Switzerland)

10:15 am Hypoglycemic Agents and the Risk of Cancer [3]

Hui Zhang, Hammad A Tarek, David C Christiani, Edward Giovannuci. (United States)

• **Infection: Down with Resistance (Dukes)**

Moderators: Kay Johannes & Mari-Ann Wallander, FISPE

9:00 am Time-Varying Antibiotic Exposure and Risk of *Clostridium difficile* Infection (CDI) [7]

Vanessa Stevens, Ghinwa Dumyati, Susan Fisher, Lynn Fine, Edwin van Wijngaarden. (United States)

9:15 am Fluoroquinolone Resistance in *Campylobacter jejuni* in the United States, 1997-2007 [8]

Nkuchia M M’ikanatha, A Russell Localio, Collette Fitzgerald, Irving Nachamkin. (United States)

9:30 am Antibiotic-Induced Liver Injury among Hospitalized Patients [9]

Marie L De Bruin, Yang Yu, Hanneke J den Breeijen, Wouter W van Solinge, Anke Hilse Maitland-van der Zee. (Netherlands)

9:45 am The Risk of Infections among Patients Treated with TNFi: Population-Based Continuous ADRs

Monitoring Using the Maximized Sequential Probability Ratio Testing [10]

Yan Chen, Indiana Strombom, Dale Marmaduke, Olivier Benichou, Ilya Lipkovich. (United States)

10:00 am Hepatitis C Treatment Adherence over Time and Virologic Response [11]

V Lo Re, V Teal, R Localio, V Amorosa, R Gross. (United States)

10:15 am Tuberculosis Risk Awareness and Screening Practices among Prescribers of Anti-Tumor Necrosis Factor (TNF) Agents in the European Union [12]

Meredith Y Smith, Brian Attig, Thomas Eagle. (United States)

• **Methods: Exposure and Outcome Assessment (Hall 4)**

Moderators: Yola Moride, FISPE, & Michele Johnson Funk

9:00 am The Impact of Stockpiling and Minimum Required Adherence on Estimating Persistence on Oral Anti-Diabetic Therapy from Electronic Health Records [13]

Robert A Greevy, Mary M Huizinga, Christianne L Roumie, Carlos G Grijalva, Harvey Murff, Xulei Liu, Kristen Kotter, Marie R Griffin. (United States)

9:15 am Variability in Measurement of Medication Exposure in Pharmacoepidemiologic Studies of COPD [14]

Caitlyn T Wilke, Fang-Ju Lin, Todd A Lee, Bruce L Lambert, Min J Joo, A Simon Pickard. (United States)

9:30 am A Framework for Developing a Database of Definitions for Diabetes Mellitus Research [15]

Jodi B Segal, Suzanne West, Marie R Griffin, Elizabeth Selvin, Patrick O'Conner, Eric B Bass. (United States)

9:45 am Identification of Novel Post-Vaccine Syndromes Using Information Theory [16]

Alexander M Walker, Gregory W Daniel, Karen Smoyer-Tomic, Tosmai Puenpatom, Tao Gu, Hector Izurieta. (United States)

10:00 am **Benefit-Risk Assessment Based on Ordered Clinical Outcomes [17]**
Ola Caster, G Niklas Norén, Love Ekenberg, I Ralph Edwards. (Sweden)

10:15 am **Impact of Medicare Claim Resubmissions on Drug and Health Identifiers [18]**
Abraham G Hartzema, Thomas E MaCurdy, Jonathan M Gibbs, Judith A Racoosin, Chris Worrall, Jeffrey A Kelman. (United States)

• **Sundry (Buckingham)**
Moderator: Michael Peng

9:00 am **Trends of Oseltamivir Usage in the United States during the 2009 Influenza A (H1N1) Pandemic [19]**
John K Iskander, Craig Hales, Charbel El Bcheraoui, Robert T Chen. (United States)

9:15 am **Prescribing of Anti-Osteoporotic Therapies Following the Use of Proton Pump Inhibitors in General Practice [20]**
Bernie McGowan, Kath Bennett, Michael Barry. (Ireland)

9:30 am **Vaccine Safety: Background Rates of Events of Specific Interest [21]**
J Dieleman, A Hviid, T Kilpi, J Storsaeter, S Mannino, H Heijbel, F de Abajo, C de Vries, G Mazzaglia, K Johansen, P Kramarz, D Weibel, J Bonhoffer, M Sturkenboom. (Netherlands)

9:45 am **Tiotropium Use and the Risk of Cerebrovascular Events [22]**
Mendel Haag, Katia Verhamme, Ana Afonso, Charlotte Van Noord, Peter Koudstaal, Miriam Sturkenboom. (Netherlands)

10:00 am **Prevalence of Co-Morbidities and Drug Exposure in Patients with Alzheimer's Disease around the Time of Diagnosis [557]**

Patrick Imfeld, Yolanda B Brauchli, Markus Schuerch, Christoph R Meier. (Switzerland)

10:15 am **Impact of Regulatory Risk Communication in the Netherlands; 30 Time Series Analyses [24]**
S Piening, K Reber, J Wieringa, S Straus, P de Graeff, F Haaijer-Ruskamp, P Mol. (Netherlands)

• **The Brighter Side of Cancer (Balmoral)**
Moderators: Marieke Schoonen & Jim Kaye

9:00am **Validation of Cancer Diagnoses Recorded in the General Practice Research Database [25]**
Hui Zhang, Tarek A Hammad, Edward Giovannuci, Elizabeth Kang, David C Christiani. (United States)

9:15 am **Liver Function Test Abnormalities in Patients Treated with Small Molecule Tyrosine Kinase Inhibitors [26]**
Beth L Nordstrom, Kathy H Fraeman, Weixiu Luo, Sumitra Shantakumar, Sarah H Landis. (United States)

9:30 am **High-Ceiling Diuretics Are Associated with an Increased Risk of Basal Cell Carcinoma in a Population-Based Follow-Up Study [345]**
Rikje Ruiten, Loes Visser, Mark Eijgelsheim, Eline Rodenburg, Albert Hofman, Jan-Willem Coebergh, Tamar Nijsten, Bruno Stricker. (Netherlands)

9:45 am **Lymphoma among Patients with Atopic Dermatitis Treated with Topical Corticosteroids (TCS) and/or Topical Calcineurin Inhibitors (TCIs) [28]**
Alejandro Arana, Charles W Wentworth, Elena Rivero, Estel Plana, Eulogio Conde. (Spain)

10:00 am **Use of Cyclosporine and Risk of Squamous Cell Carcinoma in the Skin: A Population Based Cohort Study in Denmark [29]**
Julie Lavole, Annette Østergaard Jensen, Malene Cramer Engebjerg, Bente Jespersen, Knund Kragballe, Henrik Toft Sørensen. (France)

- 10:15 am** **Relative Risk of Bladder Cancer with Pioglitazone for Diabetes Mellitus: Mid-Way Report of a 10-Year Follow-Up Study [30]**
James Lewis, Assiamira Ferrara, Tiffany Peng, Monique Hedderson, Warren Bilker, Charles Quesenberry, Lisa Nessel, Brian Strom. (United States)
- **Vaccines in the H1N1 Era (Cambridge)**
Moderators: Patricia Saddier & Montserrat Soriano
- 9:00 am** **Factors Predictive of H1N1 Influenza Vaccine Uptake among ‘At-Risk’ Patients in the UK General Practice Research Database [31]**
Cormac Sammon, Anita McGrogan, Julia Snowball, Corinne de Vries. (United Kingdom)
- 9:15 am** **Background Incidence of Disease for Assessment of Pandemic A/H1N1 Vaccine Safety in Taiwan [32]**
Wan-Ting Huang, Chia-Luen Tsai, Jen-Hsiang Chuang, Cheng-Hua Lee, Shou-Hsia Cheng, Hsu-Sung Kuo. (Taiwan)
- 9:30 am** **H1N1 Influenza Vaccine Surveillance Project [33]**
Cheryl Enger, Bruce Turnbull, Robert Gately, Jeanne Loughlin, K Arnold Chan. (United States)
- 9:45 am** **Surveillance for Guillain-Barré Syndrome after Influenza Vaccination among the Medicare Population, 2009-2010 [34]**
D Burwen, S Sandhu, T MaCurdy, J Kelman, J Gibbs, B Garcia, M Markatou, R Forshee, R Gullet, H Izurieta, C Worrall, R Ball. (United States)
- 10:00 am** **Confounding in Studies of Influenza Vaccination and Mortality in the Elderly [35]**
Amanda R Patrick, M Alan Brookhart. (United States)
- 10:15 am** **Effectiveness of One or Two Doses of the Pentavalent Rotavirus Vaccine (RV5) in Preventing Gastroenteritis in the United States [36]**

Florence T Wang, T Christopher Mast, Roberta J Glass, Jeanne Loughlin, John D Seeger. (United States)

10:30-11:00am

Break/Posters/Exhibits (Durham & Hall 7)

11:00-12:00pm

Keynote Address (Oxford)

Thomas Lönngren, Executive Director, European Medicines Agency

Thomas Lönngren qualified as a pharmacist in 1976 and holds an MSc degree in social and regulatory pharmacy, from Uppsala University, Sweden. He was a lecturer at the university from 1976 to 1978, then served with the Swedish National Board of Health and Welfare, from 1978 to 1990, with responsibilities for herbal medicines, cosmetics, medical devices, narcotics and contraceptives. From 1984 to 1992, he acted as senior pharmaceutical consultant for the Swedish International Development Agency's health cooperation program in Vietnam. In 1990, he was appointed Director of Operations of the Swedish Medical Products Agency, and later became its Deputy Director-General. He was elected Honorary Member of the Pharmaceutical Society of Great Britain in 2003, and Honorary Fellow of the Royal College of Physicians (UK) in 2004.

12:00pm-1:30pm

Lunch/Poster Session A/Exhibits (Durham, Durham Gallery, Hall 7 & 8)

ISPE Committee/Council Meetings

Open to all participants.

- Development Committee (**Landcaster**)
- Fellowship & Awards Committee (**Hilton Meeting 3**)
- Public Policy Committee (**Buckingham**)
- Student Council (**Ambassador**)

1:30-3:00pm

EMA Scientific Debate (Oxford)

Co-sponsored by ISPE & EMA

Motion: *Results from epidemiology and pharmacoepidemiology studies mislead the public because of a failure to adjust for multiple comparisons. Journals should not publish studies that do not account for multiplicity.*

For the motion:

- **Stan Young**, National Institutes of Statistical Sciences, USA
- **Stuart Pocock**, London School of Hygiene and Tropical Medicine, UK

Against the motion:

- **Sonia Hernandez-Diaz**, FISPE, Harvard School of Public Health, USA
- **Kenneth J. Rothman**, FISPE, RTI Health Solutions, USA

3:00-3:30pm

Break/Posters/Exhibits (Durham & Hall 7)

3:30-5:00pm

CONCURRENT SESSIONS: SYMPOSIA AND WORKSHOPS

- **Methodological Challenges in Cross-National Comparisons of Drug Utilization [37] (Balmoral)**
Sponsored by the Drug Utilization / Health Services Research SIG
Björn Wettermark, Monique Elseviers, Brian Godman, Marit Rønning, Lesley Tilson, Vera Vlahovic Palcevski. (Sweden)
- **Methodological Controversies from Comparative Effectiveness (CE) Studies Using Claims vs. Electronic Health Record (EHR) Data [38] (Cambridge)**
Soko Setoguchi, Nirav Shah, Jason Roy, Wolfgang Winkelmayr, Robert Glynn. (United States)
- **Ascertaining the Use of Biologics [39] (Dukes)**
Sponsored by the Biologics SIG
Thijs Giezen, Judith Jones, Will Dixon, Michael Taylor, Bert Leufkens, Earl Goehring. (Netherlands)
- **Guidance Regarding the Identification, Development, Validation and Translation of Coding Algorithms in Electronic Healthcare (EH) Databases [40] (Hall 4)**
Sponsored by the Database SIG
Vinay Mehta, Robert J Locasale, Matthew W Reynolds, Rhonda L Bohn, Gianluca Trifiro, Tami L Mark. (United States)
- **Identifying the Genetic Basis of Serious Adverse Events: Will High-Profile Genome-Wide Association (GWA) Studies Improve Drug Safety in the Next Decade? [41] (Buckingham)**
Jointly sponsored by the MEBPharmacogenomics SIG & iSAEC

Anke-Hilse Maitland-van der Zee, Andrew Freedman, Ann K Daly, Arthur Holden. (Netherland)

- **Identification and Classification of Birth Defects in Pharmacoepidemiology: A Comparison of Approaches [42] (Clarence)**
Sponsored by the Medications in Pregnancy SIG
L de Jong-van den Berg, H Dolk, E Andrews, S Hernandez-Diaz, A Mitchell, C de Vries. (Netherlands)
- **The Public Health Burden of Acetaminophen Poisonings: Risk Management Efforts To Mitigate It [575] (Ambassador)**
Syed Rizwanuddin Ahmad, June Raine, Keith Hawton, Gerald Dal Pan. (United States)

5:00-6:00pm

ISPE Council Meetings

Open to all interested participants

- Academic Council (**Hall 4**)
- Government/Regulatory Council (**Hilton 3**)
- Industry/Service Providers Council (**Lancaster**)

6:00pm-7:00pm

General Assembly/European Chapter of Drug Utilization/Health Services Research SIG (Ambassador)

7:00-9:00pm

PDS Editorial Board

Due South Restaurant

(By Invitation)

7:10pm- ?

Student Dinner & Night Out

Open to all students.

Organized by the ISPE Student Council

Assemble at ICPE Registration Desk, then walk to Al Duomo

SATURDAY
August 21, 2010

7:00-6:00pm **Registration (Sussex Lounge)**

7:00-5:00pm **Speakers' Ready Room (Office 1)**

7:00-8:00am **Poster Session B Set-up (Durham & Hall 7)**

8:00-6:00pm **Exhibits/Posters (Durham & Hall 7)**

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

CNS: The Brain and the Heart (Balmoral)

Moderators: Nadia Foskett & Cristina Varas-Lorenzo

8:30 am Risk of Heart Failure with Dopamine Agonist Use in Parkinson's Disease [237]

G Trifirò, M Mokhles, J Dieleman, E van Soest, G Mazzaglia, R Herings, C de Luise, D Ross, G Brusselle, A Colao, W Haverkamp, R Schade, G van Camp, R Zanettini, M Sturkenboom.
(Netherlands)

8:45 am Serum Cholesterol Levels and Risk of Parkinson's Disease [238]

Stephen K Van Den Eeden, Jun Shan, Charles P Quesenberry. (United States)

9:00 am The Effect of Antidepressants on Cardiovascular Morbidity and Mortality in Older Adults: A Population-Based Cohort Study [239]

Gregory L Kennedy, Kristan Aronson, Linda E Levesque. (Canada)

9:15 am Use of Serotonergic Medications and Cardiac Valvulopathy: A Nested Case-Control Study in the Health Improvement Network (Thin) Database [240]

Annalisa Rubino, Francesco Lapi, Federica Nicotra, Antonella Zambon, Lorenza Scotti, Mary

Thompson, Alfredo Vannacci, Giovanni Corrao,
Alessandro Mugelli. (Italy)

**9:30 am Antipsychotics and the Risk of Sudden Cardiac
Death and Ventricular Arrhythmia [241]**

Charles E Leonard, Warren B Bilker, Craig
Newcomb, Stephen E Kimmel, Brian L Strom,
Sean Hennessy. (United States)

**9:45 am Risk of Death and Major Medical Events
Associated with Psychotropic Medications in
Patients Newly Admitted to Nursing Homes
[242]**

Krista Huybrechts, Kenneth J Rothman, Rebecca
Silliman, M Alan Brookhart, Sebastian
Schneeweiss. (United States)

**Mapping and Validating Critical Data Elements
(Cambridge)**

Moderators: Rhonda Bohn, FISPE, & Marianne Ulcickas Yood

**8:30 am Validating Pneumonia Hospitalizations in the
THIN Database [243]**

Sharon B Meropol, Joshua P Metlay. (United
States)

**8:45 am Validity of Claims-Based Definitions of Impaired
Left Ventricular Systolic Function in Medicare
Patients [244]**

Qian Li, Robert J Glynn, Nancy A Dreyer, Jun
Liu, Helen Mogun, Soko Setoguchi. (United
States)

**9:00 am Implementing and Evaluating Standard Cohort
Definitions across Disparate Databases [245]**

Stephanie Reisinger, Patrick Ryan, Richard
Murray. (United States)

**9:15 am Validation of the Health Improvement Network
(THIN) Database for Epidemiologic Studies of
Chronic Kidney Disease [246]**

Michelle R Denburg, Kevin Haynes, Justine
Shults, James Lewis, Mary B Leonard. (United
States)

9:30 am **Automated Classification of Free Text Electronic Health Records for Epidemiological Studies [247]**

Martijn J Schuemie, Emine Sen, Eva M van Soest, Miriam C Sturkenboom, Jan A Kors.
(Netherlands)

9:45 am **Automated Robust Mapping GPRD Medical Diagnosis Read Codes to SNOMED CT for OMOP Project [248]**

Hoa V Le, Kathleen J Beach. (United States)

Miscellaneous (Buckingham)

Moderators: Susan Olivera, FISPE, & John Logie

8:30 am **Effect of Different Trimming Methods for Propensity Score Distribution on Risk Estimates [249]**

Hoa V Le, Kathleen J Beach. (United States)

8:45 am **Assessment of the Cost-Effectiveness of Pharmacogenomic Diagnostics for Breast Cancer [250]**

Mo Yang, Amalia Issa. (United States)

9:00 am **The Epidemiology of HIV-1 Co-Receptor Tropism in Patients Infected with Non-Clade B HIV from India, Uganda and South Africa [251]**

Anna Greenacre, Quazi Ataher, Simon Portsmouth, Randy Tressler, Sybil Eng. (United States)

9:15 am **Cohort Studies in Chronic Diseases Using Routinely Collected Databases When a Prescription Is Used as Surrogate Outcome [252]**

Sara Lodi, James Carpenter, Stephen Evans.
(United Kingdom)

9:30 am **Methodological Challenges When Applying ICD-10 Codes to Research Data: Findings from the Post-Hoc Endpoint Readjudication of Sudden Death for the Ziprasidone Observational Study of Cardiac Outcomes (ZODIAC) Large Simple Trial [253]**

Jamie Geier, Onur Karayal, Michael Lewis, John Camm, Martin Keane, Charlotte Kremer, Sheela Kolluri, Robert Reynolds, Brian L Strom. (United States)

9:45 am Potential Ascertainment Bias in Assessment of Obesity and Smoking History and Its Impact on Type 2 Diabetes Disease in the General Practice Research Database [254]

Tzuyung D Kou, Kimberly G Brodovicz, Charles Alexander, Leonid Katz, Cynthia J Girman. (United States)

NSAIDs and Associated Treatments (Dukes)

Moderators: Jordi Castellsague & Tobias Gerhard

8:30 am Concordance of Nonsteroidal Anti-Inflammatory Drug Prescriptions with Recent Clinical Practice Guidelines in Quebec, Canada [255]

Elham Rahme, Jean-Philip LaFrance, Jean-Pascal Roussy, Suzanne Morin. (Canada)

8:45 am Adherence to Proton Pump Inhibitors and the Risk of Upper Gastrointestinal Complications in Coxib Users [256]

V Valkhoff, E van Soest, G Mazzaglia, R Schade, M Molokhia, J Dieleman, M Sturkenboom. (Netherlands)

9:00 am Factors Associated with Proton Pump Inhibitor Discontinuation in Nursing Homes [257]

Amy Linsky, John A Hermos, James L Rudolph, Elizabeth V Lawler. (United States)

9:15 am Cyclooxygenase (COX)-2 Selective and Non-selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and Risk of Hyperkalemia [258]

Jean-Philippe Lafrance, Donald R Miller. (Canada)

9:30 am Nonsteroidal Anti-Inflammatory Drug Use and Risk of Atrial Fibrillation or Flutter: A Population-Based Case-Control Study [259]

Morten Schmidt, Christian F Christiansen, Frank Mehnert, Kenneth J Rothman, Henrik Toft Sørensen. (Denmark)

9:45 am **Pain Relief Medication Following Cessation of Co-Proxamol Use: An Analysis Using the GPRD [260]**

David Irvine, Jakob Petersen, Lesley Wise.
(United Kingdom)

P4M: Pharmacogenomics, Predictors, Prognosis, and Personalised Medicine (Clarence)

Moderators: Geoff Liu & Joanna Haas

8:30 am **Single Nucleotide Polymorphisms (SNPs) in the Matrix Metalloproteinase (MMP) Gene Family, Gastroesophageal Reflux Disease (GERD), and Risk of Esophageal Adenocarcinoma (EAC) [261]**

Winson Y Cheung, Rihong Zhai, Matthew Kulke, Rebecca Heist, Kofi Asomaning, Clement Ma, Zhaoxi Wang, Li Su, Geoffrey Liu, David Christiani. (Canada)

8:45 am **Analysis of Proteomic Biomarkers for Acute Interstitial Lung Disease (ILD) in Gefitinib-Treated Japanese Non-Small Cell Lung Cancer (NSCLC) Patients [262]**

Fredrik Nyberg, Atsushi Ogiwara, Chris G Harbron, Takao Kawakami, Yasuhiko Komatsu, Toshihide Nishimura, György Marko-Varga. (Sweden)

9:00 am **Integrating Pharmacogenetics into Clinical Trials: Implications for Sample Size to Test Gene-Drug Interactions [263]**

Kimberly A Lowe. (United States)

9:15 am **Results of the First European Genome-Wide Association Study of Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) [264]**

Emmanuelle Genin, Peggy Sekula, Diana Zelenika, Mark Lathrop, Martin Schumacher, Jean-Claude Roujeau, Maja Mockenhaupt, Regiscar Group. (Germany)

9:30 am Pharmacogenetic-Based Warfarin Dosing: Simplified Pharmacogenetic Tables vs. Pharmacogenetic Algorithms [265]

Brian S Finkelman, Brian F Gage, Julie A Johnson, Colleen M Brensinger, Stephen E Kimmel. (United States)

9:45 am The PCSK9 E670G Polymorphism Modifies the Effectiveness of Statins in Reducing the Risk of Myocardial Infarction [266]

B JM Peters, H Pett, A de Boer, O H Klungel, A H Maitland-van der Zee. (Netherlands)

Risk Management: Are We Taking the Bull by the Horn? (Oxford)

Moderator: Klaas Heinemann

8:30 am Additional Safety Risk to Exceptionally Approved Drugs in EU? [267]

A H Arnardottir, F M Haaijer-Ruskamp, S M Straus, P A de Graeff, P G Mol. (Netherlands)

8:45 am One Year after: The EU Strategy for Epidemiological Monitoring of Pandemic H1N1 Vaccines [268]

X Kurz, A Hidalgo-Simon, K Johansen, B Ciancio, A Nicoll, P Arlett. (United Kingdom)

9:00 am Not-in-Trial Simulation: Predicting Cardiovascular Risk from Clinical Trial Data [269]

Anne Chain, Jeanne Dieleman, Meindert Danhof, Bruno Stricker, Jacqueline Witteman, Oscar Della Pasqua, Miriam Sturkenboom. (Netherlands)

9:15 am Increasing the Benefit of EU Risk Management Plans (EU-RMPs) – Is There Room for Improvement? [270]

Steve Mayall, Carol Walton, Aruna Jeans, Mazhar Thakur, Simon Ingate, Swapu Banerjee. (United Kingdom)

9:30 am Charting a New Course in Long-Term Safety: The Critical Role of Cancer Registries [271]

Alicia W Gilsean, Elizabeth B Andrews, Kirk D Midkiff, Amy Ladner. (United States)

9:45 am **Assessing the Effectiveness of an IT-Based Pharmacist-Led Intervention Aimed at Reducing Prorptions of Patients at Risk of Medication Errors in Family Practice: The PINCER Trial [272]**

Anthony J Avery, Sarah Rodgers, Judith A Cantrill, Sarah Armstrong, Martin Eden, Denise Kendrick, Aziz Sheikh. (United Kingdom)

10:00-10:30am

Break/Posters/Exhibits (Durham & Hall 7)

10:30-12:00pm

CONCURRENT SESSIONS: CONTRIBUTED PAPERS

Clinically Important Public Health Issues and New Insights in Rare Diseases (Dukes)

Moderators: Judith Jones, FISPE, & Michael Taylor

10:30 am **Prevalence, Predictors, and Treatment of Very High Triglycerides in US Adults: NHANES 2001 – 2006 [273]**

Jennifer B Christian, Nancy E Bourgeois, Rose G Snipes. (United States)

10:45 am **Frequency and Risk Factors of Gout Flares in a Large Population-Based Cohort of Incident Gout [274]**

Dietrich Rothenbacher, Paola Primatesta, Alberto Ferreira, Lucia Cea Soriano, Luis A Garcia Rodriguez. (Switzerland)

11:00 am **Avascular Osteonecrosis in Untreated Patients with Type 1 Gaucher Disease [275]**

Pramod K Mistry, Patrick Deegan, Ashok Vellodi, J Alexander Cole, Michael Yeh, Neal J Weinreb. (United States)

11:15 am **Catheter-Related Complications in Patients with Central Venous or Hemodialysis Catheters [276]**

Pavel Napalkov, Diana Felici, Laura Chu, Joan Jacobs, Susan M Begelman. (United States)

11:30 am **The Incidence of Ischemic and Hemorrhagic Stroke in Pediatric Patients [277]**

Pavel Napalkov, Diana Felici, Laura Chu. (United States)

11:45 am Hemoglobinuria, Hemoglobinemia, and Renal Impairment in ITP Patients [278]

Fei Xue, Chuck Wentworth, Vanitha Ganesh, Victor Gastanaga, Gail Hughes, Scott Stryker, Steven Cha, Sean Zhao. (United States)

CNS: Potpourri (Oxford)

Moderators: Suellen Curkendall & Jessica Jalbert

10:30 am Switching of Antiepileptic Drugs and Seizure-Related Events after Refill Adjustment [279]

Joshua J Gagne, Jerry Avorn, William H Shrank, Sebastian Schneeweiss. (United States)

Student Award Recipient – Third Best Abstract

10:45 am Anticonvulsant Medications and the Risk of Suicide, Attempted Suicide, and Injury or Accident Related Death [280]

Elisabetta Patorno, Rhonda Bohn, Peter Wahl, Jerry Avorn, Amanda Patrick, Jun Liu, Sebastian Schneeweiss. (United States)

11:00 am Risk of Cataract in Patients with Multiple Sclerosis: A Population-Based Cohort Study [612]

S Müller-Schotte, M Bazelier, T P van Staa, HGM leufkens, F de Vries. (Netherlands)

Student Prize Recipient – Second Best Abstract

11:15 am Use of Antidepressant Drugs and Risk of Osteoporotic and Non-Osteoporotic Fractures: Focus on the Affinity for the Serotonin Receptor [282]

Bertha Maria Verdel, Patrick C Souverein, Toine CG Egberts, Tjeerd P van Staa, Hubert GM Leufkens, Frank de Vries. (Netherlands)

11:30 am Risk of Bleeding with Combined SSRI and Antiplatelet Therapy in Patients Following Myocardial Infarction [283]

Christopher Labos, Kaberi Dasgupta, Elham Rahme. (Canada)

- 11:45 am** **Comparative Effectiveness of Antipsychotic Medications for the Treatment of Behavioral and Psychological Symptoms of Dementia [284]**
Tobias Gerhard, Edmond S Malka, Judith Lucas, Krista Huybrechts, Sebastian Schneeweiss, Stephen Crystal. (United States)

Methods in Pregnancy Studies: Practical Applications (Cambridge)

Moderators: Deborah Covington & Alicia Gilsean

- 10:30 am** **Recording of Pregnancy Losses on the General Practice Research Database [285]**
Rachel Charlton, Julia Snowball, John Weil, Marianne Cunnington, Corinne de Vries. (United Kingdom)
- 10:45 am** **Drug Certainty-Response in Interview-Based Studies [286]**
Kuei-Yu Lin, Wai-Ping Yau, Allen A Mitchell, Sonia Hernández-Díaz. (United States)
- 11:00 am** **Maternal Use of Macrolide Antibiotics and the Risk of Congenital Heart Defects [287]**
Kuei-Yu Lin, Allen A Mitchell, Wai-Ping Yau, Sonia Hernández-Díaz. (United States)
- 11:15 am** **Validity of an Algorithm for the Identification of Premature Infants Using Medicaid Administrative Data [288]**
Efe Odia, Christian Hampp, Almut G Winterstein. (United States)
- 11:30 am** **Differing Strategies for Analyzing Multiple Gestation Pregnancies in Pregnancy Registries: Impact on Birth Defect Rates [289]**
Carl deMoor, Deborah Covington, Amanda Golembesky. (United States)
- 11:45 am** **Comparative Safety of Topiramate during Pregnancy [290]**
Sonia Hernandez-Diaz, Robert Mittendorf, Lewis B Holmes. (United States)

Pharmacovigilance - Needles in Haystacks? (Balmoral)

Moderators: Andrez Czarnecki, FISPE, & Marieke de Bruin

- 10:30 am Vaccine Signal Detection: A Pilot To Determine Effects of Varying Data Mining Strategies on VAERS [291]**
Steven R Bailey, Robert Azadian, Peter Huber.
(United States)
- 10:45 am Substantiation of Drug Safety Signals: Taking Automated Signal Detection a Step Further [292]**
A Bauer-Mehren, E van Mulligen, P Avillach, P Coloma, R Garcia-Serna, R Herings, M Sturkenboom, S Boyer, F Sanz, J Mestres, J Kors, L Furlong. (Spain)
- 11:00 am Ongoing Monitoring in Active Surveillance: A Case Study in Performance of Observational Screening over Time [293]**
Patrick B Ryan, Gregory E Powell, Ed N Pattishall. (United States)
- 11:15 am Polyethylene Glycol and Acute Renal Failure in Elderly: Data-Mining Study Using National Health Insurance Claims Database [294]**
Nam-Kyong Choi, Yu-Kyong Choi, Sun-Young Jung, Yoosoo Chang, Ju-Young Kim, Hong-Ji Song, Joongyub Lee, Byung-Joo Park. (Republic of Korea)
- 11:30 am Evaluation of a Proposed Classification System for Adverse Drug Reactions for Biologicals Using The WHO-ADR Database VigiBase [295]**
Thijs Giezen, Aukje Mantel-Teeuwisse, Sabine Straus, Bert Leufkens, Toine Egberts.
(Netherlands)
- 11:45 am The Contribution of Patient Reporting To Signal Detection in the Netherlands [296]**
Florence van Hunsel, Eugene van Puijenbroek, Kees van Grootheest. (Netherlands)

Potpourri (Buckingham)

Moderators: Susana Perez Gutthann, FISPE, & Usha Gungabissoon

- 10:30 am Genetic Polymorphisms and the Development of Secondary Primary Cancers (SPC) in Patients with Head and Neck Cancer (HNC) [297]**
Abul K Azad, Dangxiao Cheng, Wei Xu, Elodie Samson, Maryam Mirshams, Sevtap Savas, Zhuo Chen, John Waldron, Geoffrey Liu, Francois Meyer, Isabelle Bairati. (Canada)
- 10:45 am Race, Oxaliplatin Use, and Treatment Outcomes for Stage III Colon Cancer among Elderly Medicare Patients [298]**
Christina D Mack, William Carpenter, Til Stürmer. (United States)
- 11:00 am Can Tricyclic Antidepressant Use Explain the Observed Associations between Baseline Depressive Symptoms and Incident Hypertension? [299]**
Joseph AC Delaney, Bruce E Oddson, Holly Kramer, Steven Shea, Bruce M Psaty, Robyn L McClelland. (United States)
- 11:15 am Safety Profile of Thiazolidinediones on the Basis of the FDA-AERS Database: Cardiovascular and Bone Fracture Risks for Rosiglitazone and Pioglitazone [300]**
Domenico Motola, Elisabetta Poluzzi, Anna Marra, Chiara Biagi, Carlo Piccinni, Nicola Montanaro. (Italy)
- 11:30 am Risk of Fracture in Patients with Multiple Sclerosis: The General Practice Research Database [301]**
Marloes Bazelier, Tjeerd van Staa, Hubert Leufkens, Peter Vestergaard, Frank de Vries. (Netherlands)
- 11:45 am Patterns of Antipsychotic (APM) Initiation in US Nursing Homes [302]**
Judith A Lucas, Sujoy Chakravarty, John R Bowblis, Tobias Gerhard, Michele Siegel, Ece Kalay, Stephen Crystal. (United States)

Prescribing Problems in Older Persons (Clarence)

Moderators: Keith Beard, FISPE, & Kevin Haynes

- 10:30 am Drug Related Problems among Elderly Patients Using Five or More Chronic Drugs Who Are Discharged from the Hospital [303]**
Abeer Ahmad, Jacqueline Hugtenburg, Ruth Mast, Laura MC Welschen, Jacqueline M Dekker, Giel Nijpels. (Netherlands)
- 10:45 am Adverse Outcomes Associated with Potential Prescribing Cascades [304]**
Gillian Caughey, Elizabeth Roughead, Nicole Pratt, Sepehr Shakib, Agnes Vitry, Andrew Gilbert. (Australia)
- 11:00 am Treatment with Cholinesterase Inhibitors May Increase the Risk of Urinary Incontinence [305]**
Edeltraut Kröger, Rob van Marum, Patrick Souverein, Pierre-Hugues Carmichael, Toine Egberts. (Netherlands)
- 11:15 am Use of Opioids or Benzodiazepines and Risk of Pneumonia in Older Adults [306]**
Sascha Dublin, Rod L Walker, Michael L Jackson, Jennifer C Nelson, Noel S Weiss, Michael Von Korff, Lisa A Jackson. (United States)
- 11:30 am Major Bleeding Risk Associated with Warfarin and Co-Medications in the Elderly Population [307]**
Agnes I Vitry, Elizabeth E Roughead, Emmae N Ramsay, Adrian K Preiss, Gillian E Caughey, Andrew L Gilbert, Philip Ryan. (Australia)
- 11:45 am A Randomized Trial of a Warfarin Management Protocol To Enhance Communication between Nursing Home Staff and Physicians: The SBAR Approach [308]**
Terry S Field, Jennifer Tjia, Kathleen M Mazor, Jennifer L Donovan, Abir O Kanaan, Leslie R Harrold, Peter Doherty, Ann Spenard, Jerry H Gurwitz, George Reed. (United States)

12:00-1:30pm

Lunch/Poster Session B/Exhibits(Durham, Durham Gallery, Hall 7 & 8)

ISPE Committee Meetings

Open to all participants.

(Lunches will be available in meeting rooms)

- Bylaws and Policies Committee (Sandringham)
- External Communications Committee (Hilton Meeting 3)
- Global Development Committee (Lancaster)
- Membership Committee (Osborne)
- Publications Committee (Surrey 1)

12:45-1:30pm

Poster Walks (Durham/Hall 7)

- Biologic SIG
- Comparative Effectiveness Research SIG
- Database SIG
- Drug Utilization SIG
- Medicines in Pregnancy SIG
- Molecular Epidemiology - Biomarkers - Pharmacogenetics SIG

1:30-2:30pm

PLENARY SESSION

Professor Jan P. Vandenbroucke, University of Leiden, The Netherlands (Oxford)

2:30-3:30pm

ANNUAL MEETING OF ISPE MEMBERS, AWARDS CEREMONY (Oxford)

Open to all participants.

◀ Annual Meeting of ISPE Members

Sebastian Schneeweiss, FISPE, ISPE President

Nancy Dreyer, FISPE, ISPE Vice President Finance

◀ Awards Ceremony

- ICPE 2009
- Student Awards

Presented by **Corinne de Vries, FISPE, Chair,**
2010 Scientific Program Committee

Best Drug Utilization Abstract: **Krista Huybrechts**

Third Best Abstract: **Joshua Gagne**

Second Best Abstract: **Sigrid Müller-Schotte**

Edlavitch Award (Best Student Abstract) & Oral Presentation

Caitlyn T. Wilke, *Sensitivity of Hazard Estimates to Exposure Definition : A Simulation Study (309)*

- Induction of ISPE Fellow (FISPE)

Sebastian Schneeweiss, FISPE, ISPE President

Inductees

- **Corinne S. de Vries, FISPE**
- **Stephen JW Evans, FISPE**
- **Kiyoshi Kubota, FISPE**
- **Susan Ann Oliveria, FISPE**
- **Miriam CJM Sturkenboom, FISPE**
- **Douglas J. Watson, FISPE**

Miriam Sturkenboom, FISPE, Chair, Fellowship & Awards Committee

Honorary Lifetime Fellow

Ronald D. Mann

- *Pharmacoepidemiology & Drug Safety*
ISPE-PDS Prizes for Best Papers published in PDS
Volume 18 (2009)

Brian Strom, FISPE, Editor-in-Chief

Joerg Hasford, Regional Editor for Europe

Richard Hughes, Managing Editor,
Pharmacoepidemiology & Drug Safety (PDS)

Ronald Mann, FISPE, Founding Editor

Sean Hennessy, FISPE, Regional Editor for the
Americas

B J Park, FISPE, Regional Editor for Asia, Africa,
Oceania

3:30-4:00pm

As of: 7-19-10

Break/Posters/Exhibits (Durham & Hall 7)

Preliminary Agenda – ICPE 2010

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4:00-5:30pm

CONCURRENT SESSIONS: SYMPOSIA AND WORKSHOPS

- **Optimizing Global Vaccine Safety Monitoring: Lessons Learned from H1N1 [310] (Hall 4)**
Jan Bonhoeffer, Miriam Sturkenboom, Xavier Kurz, Piotr Kramarz, Patrick Zuber, Hector Izurieta. (Switzerland)
- **Matching on Propensity Scores: Good Practices and New Directions [311] (Balmoral)**
Jeremy A Rassen, Robert J Glynn, Mark Lunt, Kenneth Rothman. (United States)
- **Regulatory Risk Communication Are We Getting Ahead? [312] (Oxford)**
P Mol, P Bahri, J Avorn, P Benkimoun, A Arias, E Morrato, G del Pan, F Haaijer-Ruskamp, S Straus. (Netherlands)
- **Role of Meta-Analysis in Drug Safety: Methodological Considerations and Regulatory Implications [313] (Buckingham)**
Tarek Hammad, Simone P Pinheiro, David Irvine, Steven Kesten. (United States)
- **The Panacea of Study Designs in Pharmacoepidemiology: Which One? Antipsychotics and Myocardial Infarct in the Demented Elderly Population [314] (Dukes)**
Yola Moride, Antoine Pariente, Anne Fourier, Thierry Ducruet, Patrick Farrington. (Canada)
- **How Can Better Scientific Methods Result in Better Drug Regulation – Two Recent Case Studies [315] (Clarence)**
Marie L De Bruin, Stella Blackburn, Ingemar Persson, Jeremy Rassen, Lamiae Grimaldi. (Netherlands)
- **Evaluating Adverse Pregnancy Outcomes – A Workshop To Develop an Inventory of Methodological Issues Related to Different Approaches [780] (Ambassador)**
L de Jong-van den Berg, H Dolk, E Andrews, S Hernandez-Diaz, A Mitchell, C de Vries. (Netherlands)

5:30-6:30pm

Special Interest Group (SIG) Meetings

Open to all participants.

- **Biologics SIG (Ambassador)**
- **Comparative Effectiveness Research SIG (Balmoral)**
- **Database SIG (Buckingham)**
- **Drug Utilization/Health Services Research SIG (Cambridge)**
- **Medications in Pregnancy SIG (Clarence)**
- **Molecular Epidemiology/Biomarkers/Pharmacogenetics SIG (Dukes)**

7:30-Midnight

Evening at the Corn Exchange/Brighton Dome

Early in their career, ABBA was looking for what every pop group is looking for: that one magic moment that would give them the boost needed to catapult them to rock stardom. They found it at the Brighton Dome during the Eurovision Song Contest (1974). As the final notes of their song "Waterloo" echoed through the packed auditorium, the Swedish group had officially arrived. They ultimately won the Eurovision Song Contest, achieving a stunning upset against favorite contender Olivia Newton-John. ABBA went on to become Sweden's most successful pop rock group, and continues to charm music lovers to this day. Join your colleagues to relive those golden moments with Abba's Angels – one of the UK's premier tribute bands!

Admission is by badge or ticket. Cash bar

SUNDAY

August 22, 2010

- 7:30-4:30pm **Registration (Sussex Lounge)**
- 7:30-3:30pm **Speakers' Ready Room (Office 1)**
- 7:00-8:00am **Poster Session C Set-up (Durham & Hall 7)**
- 8:00-1:45pm **Exhibits/Posters (Durham & Hall 7)**
- 8:30-10:00am ***CONCURRENT SESSIONS: CONTRIBUTED PAPERS***

Bias and Confounding: Methods for Control Freaks (Oxford)

Moderators: Til Stürmer , FISPE, & Alan Brookhart

- 8:30 am** **Conceptualizing Confounding by Measured and Unmeasured Covariates in Pharmacoepidemiology with Directed Acyclic Graphs (DAGs) [500]**
Aisling R Caffrey, Kerry L LaPlante, Brian J Quilliam. (United States)
- 8:45 am** **Impact of Collider-Stratification Bias (M-bias) in Pharmacoepidemiologic Studies: A Simulation Study [501]**
Wei Liu, M Alan Brookhart, Soko Setoguchi. (United States)
- 9:00 am** **Simulating the Application of Propensity Scores Estimated in a Full Cohort To Adjust for Confounding in Subgroup Analyses [502]**
Jeremy A Rassen, Robert J Glynn, Sebastian Schneeweiss. (United States)
- 9:15 am** **Effect of Weight Trimming on IPW Estimates and Standard Errors: An Applied Analysis [503]**
Michele Jonsson Funk, Jennifer S Fusco, Til Sturmer, Stephen R Cole. (United States)

- 9:30 am** **New Method for Stabilizing the Variance of Instrumental Variable Physician Preference-Based Estimates of Treatment Effect [504]**
 Michal Abrahamowicz, Marie-Eve Beauchamp, Raluca Ionescu-Ittu, Joseph AC Delaney. (Canada)
- 9:45 am** **Modifying the High-Dimensional Propensity Score (hd-PS) Algorithm To Improve Small Sample Performance [456]**
 Jeremy A Rassen, Robert J Glynn, Sebastian Schneeweiss. (United States)

Clotting or Bleeding (Buckingham)

Moderators: Soko Setouchi & Frank de Vries

- 8:30 am** **Risk of Venous Thromboembolism in Patients with Chronic Immune Thrombocytopenic Purpura (cITP) [506]**
 Marianne Tang Severinsen, Malene Cramer Engebjerg, Mette Nørgaard, Sean Zhao, Henrik Toft Sørensen. (Denmark)
- 8:45 am** **The Risk of Venous Thromboembolism in OC Users: Time Patterns after Initiation of Treatment [507]**
 Juergen Dinger, Thai Do Minh, Sabine Moehner. (Germany)
- 9:00 am** **Use of NSAID, Aspirin, Acetaminophen, Statins and Risk of VTE in Women [508]**
 Annica Bergendal, Anders Sundström, Shahram Bahmanyar, Ingemar Persson, Helle Kieler. (Sweden)
- 9:15 am** **Drug Interactions with Phenprocoumon and the Risk of Serious Hemorrhage: A Nested Case-Control Study in a Large Population-Based German Database [509]**
 Kathrin Jobski, Sigrid Behr, Edeltraut Garbe. (Germany)
- 9:30 am** **Diuretic Use and the Risk of Gastrointestinal Bleeding in the United Kingdom General Population [510]**

Joseph AC Delaney, Alain Bitton, Samy Suissa.
(United States)

**9:45 am Antiplatelet Medicine Prescribing and
Subsequent Events Following Intracerebral
Haemorrhage [511]**

Robert W Flynn, Thomas M MacDonald, Gordon
D Murray, Ronald S MacWalter, Alexander S
Doney. (United Kingdom)

Compliance & Utilization I (Balmoral)

Moderators: Miriam Sturkenboom, FISPE, & Deborah Layton

**8:30 am Appropriateness of Care after Myocardial
Infarction in Cancer Survivors [512]**

Winson Y Cheung, Mary McBride, Raisa Levin,
Soko Setoguchi. (Canada)

**8:45 am Cost-Effective Proton Pump Inhibitor
Prescribing: Potential Strategies for More
Rational Prescribing [513]**

Caitriona Cahir, Tom Fahey, Conor Teljeur,
Lesley Tilson, Kathleen Bennett. (Ireland)

**9:00 am Gout Treatment and Comorbidities: A
Retrospective Study in a US Managed Care
Population [467]**

Paola Primatesta, Estel Plana, Dietrich
Rothenbacher. (Switzerland)

**9:15 am Placebo Adherence, Clinical Outcomes and
Mortality in the Women's Health Initiative
Randomized Hormone Therapy Trials [515]**

J R Curtis, J Larson, E Delzell, MA Brookhart, S
Cadarette, R Chlebowski, S Judd, M Safford, D
Solomon, A LaCroix. (United States)

**9:30 am Adherence to Gastroprotective Agents and the
Risk of Upper Gastrointestinal Complications in
NSAID Users [516]**

E van Soest, V Valkhoff, G Mazzaglia, R Schade,
M Molokhia, J Dieleman, M Sturkenboom.
(Netherlands)

9:45 am **Low Income Workers Face the Largest Cost Burden for Prescription Medicines in Australia [517]**
Anna Kemp, Elizabeth E Roughead, David B Preen, John Glover, James Semmens. (Australia)

Outcomes after Prenatal Exposure: Causes Versus Biases (Cambridge)

Moderators: Susan Roberts & Elizabeth Andrews, FISPE

8:30 am **Systemic Immunosuppressive Drug Use during Pregnancy May Be Associated with Preeclampsia [518]**
Kristin Palmsten, Sonia Hernández-Díaz, Daniel H Solomon, Soko Setoguchi. (United States)

8:45 am **Maternal Use of Antibiotics and the Risk of Oral Facial Clefts: A Nationwide Danish Cohort Study [519]**
Ditte Mølgaard-Nielsen, Anders Hviid. (Denmark)

9:00 am **Maternal Exposure to Amoxicillin and the Risk of Oral Clefts [520]**
Kuei-Yu Lin, Allen A Mitchell, Wai-Ping Yau, Sonia Hernández-Díaz. (United States)

9:15 am **Prenatal Exposure to Decongestants and the Risk of Pyloric Stenosis [521]**
Wai-Ping Yau, Allen A Mitchell, Kuei-Yu Lin, Sonia Hernández-Díaz. (United States)

9:30 am **Phthalates in Drugs and Male Genital Malformations [522]**
Sonia Hernandez-Diaz, Russ Hauser, Allen A Mitchell. (United States)

9:45 am **The Impact of Methadone Maintenance Treatment during Pregnancy on Perinatal Outcomes [523]**
Brian J Cleary, Jean Donnelly, Judith Strawbridge, Paul J Gallagher, Tom Fahey, Deirdre J Murphy. (Ireland)

Pharmacovigilance - Real or Fool's Gold (Clarence)

Moderators: Suzy Seabroke & Anita Assmann

- 8:30 am** **Postlicensure Safety Monitoring of Pandemic A/H1N1 Vaccine — Taiwan, November 1, 2009–January 7, 2010 [524]**
Wan-Ting Huang, Wen-Wen Chen, Chia-Ping Su, Huai-Te Tsai, Angela S Huang, Yu-San Chien, Yen-Nan Chao, Jen-Hsiang Chuang. (Taiwan)
- 8:45 am** **Adverse Drug Reactions to Antiretroviral Therapy (ART) Identified by Intensive Monitoring at an ART Centre in India [525]**
Pathasarathi Gurumurthy, Retty R Modayil, Anand Harugeri, Madhan Ramesh, S Rajendra Prasad. (India)
- 9:00 am** **Delays in the Detection of Signals of Serious Adverse Events Due to the Inclusion of Non-Serious Adverse Event Reports in Analyses [526]**
Keith L Altman. (United States)
- 9:15 am** **Pharmacovigilance Data Mining with False Discovery Rate Based Methods: A Comparative Simulation Study [527]**
Ismaïl Ahmed, Frantz Thiessard, Ghada Miremont-Salamé, Bernard Bégaud, Pascale Tubert-Bitter. (United Kingdom)
- 9:30 am** **Impact of Drug Product Litigation on Safety Signal Detection in AERS [528]**
G Gipson, R Schaaf, W DuMouchel, R Valentino, A Wisniewski. (United States)
- 9:45 am** **Early Indicators of Drug Dependence [529]**
Ola Caster, Anna Kindlundh-Högberg, Johan Hopstadius, G Niklas Norén. (Sweden)

Stimulating Findings from Medicine Use in Children (Dukes)

Moderators: Jesper Hallas & Tamar Lasky

- 8:30 am** **Use of Antipsychotic Medications in US Youth, 2001-2007 [530]**

Stephen Crystal, Tobias Gerhard, Cecilia Huang,
Mark Olfson. (United States)

**8:45 am Payer Source & Atypical Antipsychotic (AP) Use
in Pediatric Inpatients [531]**

Shirley Wang, Tamar Lasky, Frank R Ernst, Jay
Greenspan, Liliana Gonzalez. (United States)

**9:00 am Methylphenidate Treatment in Germany – Are
Co-Morbidities Taken into Account? [532]**

Christina Lindemann, Kraut Angela, Langner
Ingo, Mikolajczyk Rafael, Garbe Edeltraut.
(Germany)

**9:15 am Incidence of Epilepsy and Anti-Epileptic Drug
(AED) Prescribing in Children in the UK [533]**

W H Meeraus, R Gilbert, R F Chin, I Petersen.
(United Kingdom)

**9:30 am Stimulant Prescription and Risk of Injury
among Children with Attention Deficit
Hyperactivity Disorder (ADHD) in the United
Kingdom (UK): Preliminary Results [534]**

Sudha R Raman, Stephen W Marshall, Til
Stürmer. (United States)

**9:45 am Use of Stimulants Following the Public
Discussion and Regulatory Actions on ADHD
Drug's Cardiovascular Safety [116]**

CY Chen, Almut Winterstein. (United States)

10:00-10:30am

Break/Posters/Exhibits (Durham & Hall 7)

10:30-Noon

***CONCURRENT SESSIONS: CONTRIBUTED
PAPERS***

Analysis Methods - The Details that Bedevil Us (Oxford)

Moderators: John Seeger & Alec Walker, FISPE

**10:30 am Using Inverse Probability Weighting To
Estimate Warfarin Adverse Effects: Concerns
with Large and Variable Inverse Probability
Weights [536]**

Joseph AC Delaney, Robert W Platt, Samy Suissa. (United States)

- 10:45 am** **Evaluating a Hybrid Self Controlled Analysis Method [537]**
Shirley Wang, Crystal Linkletter, David Dore, Malcolm Maclure, Vincent Mor, Stephen Buka. (United States)
- 11:00 am** **A Comparison of Statistical Approaches for Clustered Pharmacoepidemiology Data with Survival Outcomes [538]**
Margaret R Stedman, David R Gagnon, Robert A Lew, Elena Losina, Daniel H Solomon, M Alan Brookhart. (United States)
- 11:15 am** **Treatment Effects in Frail Patients: A Simulation Study of Treatment Contrary to Prediction [539]**
Til Stürmer, Kenneth J Rothman, Jerry Avorn, Robert J Glynn. (United States)
- 11:30 am** **Self-Controlled Case Series and Prescription Event Symmetry Analysis: How Different Are They Really? [540]**
Nicole L Pratt, Libby E Roughead, Robert Peck, Gilbert Andrew. (Australia)
- 11:45 am** **Effects of Cox-2 Selectivity NSAID Groupings in UGIB and MI ADR Substantiation Using Bayesian Hierarchical Modeling: Comparison of IPCI and PHARMO Databases: EU-ADR Project [541]**
D Prieto, M Molokhia, S Evans, M Schuemie, R Herings, J van der Lei, M Sturkenboom. (United Kingdom)

Atypical Prescribing in Older People (Balmoral)

Moderators: Jerry Gurwitz & Jamie Robinson

- 10:30 am** **Psychotropic Drug Use in the Elderly across Europe: A Perspective from the EU-ADR Project [542]**
Preciosa Coloma, Gianluca Trifirò, Martijn Schuemie, Rosa Gini, Ron Herings, Julia

Hippisley-Cox, Giampiero Mazzaglia, Giovanni Corrao, Lars Pedersen, Johan van der Lei, Miriam Sturkenboom. (Netherlands)

10:45 am Explained Variation in Antipsychotic Medication Prescribing in Patients Admitted to Nursing Homes [543]

Krista Huybrechts, Kenneth J Rothman, M Alan Brookhart, Rebecca Silliman, Stephen Crystal, Sebastian Schneeweiss. (United States)

Student Award Recipient: Best Methods Abstract

11:00 am Antipsychotic Use and the Risk of Diabetes in Older Adults with Dementia [544]

Jessica J Jalbert, Lori A Daiello, Charles B Eaton, Susan C Miller, Kate L Lapane. (United States)

11:15 am A Propensity Score Adjusted Cohort Study To Measure the Impact of Statin Therapy on Short-Term Mortality Following a Pneumonia Episode [464]

Ian J Douglas, Liam Smeeth, Stephen J Evans. (United Kingdom)

11:30 am Comparison of Different Approaches to Confounding Adjustment in a Study on the Effect of Antipsychotic Medication on Mortality in Elderly Nursing Home Patients [448]

Krista Huybrechts, M Alan Brookhart, Kenneth J Rothman, Rebecca Silliman, Tobias Gerhard, Sebastian Schneeweiss. (United States)

11:45 am Did the US FDA Black Box Advisory Reduce Use of Antipsychotics for Dementia? [547]

Tami L Mark, Suellen Curkendall. (United States)

Cardiovascular (Cambridge)

Moderators: Tom MacDonald, FISPE, & Klaas Heinemann

10:30 am Long-Term Active Surveillance Study for Oral Contraceptives (LASS): Impact of Oral Contraceptive Use on the Start of Antihypertensive Treatment [548]

Juergen Dinger, Anita Assmann, Sabine Moehner.
(Germany)

- 10:45 am Lipid Lowering Agents and Non-Traumatic Tendon Rupture [549]**
Elizabeth V Lawler, Jennifer R Fonda, Soe Soe Thwin, J Michael Gaziano, Mary T Brophy, David R Gagnon. (United States)
- 11:00 am The Cost-Effectiveness of Using Statins To Treat Patients with Elevated C-Reactive Protein and Normal Cholesterol Levels [550]**
Niteesh K Choudhry, Amanda R Patrick, Robert J Glynn, Jerry Avorn. (United States)
- 11:15 am Impact of Allopurinol Use on Urate Concentration and Cardiovascular Outcome [551]**
Li Wei, Isla S Mackenzie, Yang Chen, Allan D Struthers, Thomas M MacDonald. (United Kingdom)
- 11:30 am Comparative Effectiveness of Angiotensin Receptor II Blockers (ARBs) vs. Angiotensin-Converting Enzyme Inhibitors (ACEIs) in Hypertensive Elderly Patients with Cardiovascular Comorbidities [552]**
Soko Setoguchi, William H Shrank, Jun Liu, Helen Mogun, Wolfgang C Winkelmayr, Nancy A Dreyer. (United States)
- 11:45 am Associations between Anti-Retroviral Drug Use and HIV-Specific Risk Factors with Carotid Intima-Media Thickness: The Study of Fat Redistribution and Metabolic Change in HIV Infection (FRAM) [553]**
Joseph AC Delaney, Rebecca Scherzer, Mary L Biggs, Michael G Shlipak, Joseph F Polak, Judith S Currier, Daniel O'Leary, Phyllis Tien, Christine Wanke, Richard A Kronmal, Peter Bacchetti, Carl Grunfeld. (United States)

Compliance & Utilization II (Buckingham)
Moderators: Frank May, FISPE, & Amanda Golembesky

- 10:30 am** **Magnitude and Determinants of Off-Label Prescribing in Primary Care [554]**
Tewodros Eguale, Andrea Beneditti, James A Hanley, David L Buckeridge, Robyn Tamblyn. (Canada)
- 10:45 am** **Adherence Rates and Predictors of Early Termination to Niacinamide [555]**
Jennifer B Christian, Vincent Rabatin. (United States)
- 11:00 am** **Adherence to Cardiovascular Medications after Myocardial Infarction in Cancer Survivors [556]**
Winson Y Cheung, Mary McBride, Raisa Levin, Soko Setoguchi. (Canada)
- 11:15 am** **The Prevalence and Cost of Unapproved Uses of Orphan Drugs [23]**
Aaron Kesselheim, Daniel Solomon, Wolfgang Winkelmayr, Raisa Levin, Jerry Avorn. (United States)
- 11:30 am** **Trends in the Consumption of Antidepressants in Portugal, 2004-2009 [558]**
Jose Guerreiro, Carla Torre, Suzete Costa. (Portugal)
- 11:45 am** **Incidence of Statin Use before and after Restricting Reimbursement in Iceland [559]**
Gudrun Thengilsdóttir, Ingunn Björnsdóttir, Anna B Almarsdóttir. (Iceland)

Pediatric Potpourri (Dukes)

Moderators: Allen Mitchell, FISPE, & Kourtney Davis

- 10:30 am** **Rates of Spontaneous Reports of Adverse Drug Reactions in Children [560]**
Susanna M Wallerstedt, Gertrud Brunlöf, Anders Sundström. (Sweden)
- 10:45 am** **Comparing the Mortality Risk of Exposure in Children to Different Opioids [561]**
Paul M Coplan, J David Haddox. (United States)

- 11:00 am** **Determinants of Uncontrolled Asthma at Age 8: The Importance of Parental Perception towards Medication Use [562]**
Ellen S Koster, Gerard Koppelman, Alet Wijga, Dirkje Postma, Maarten Hoekstra, Johan de Jongste, Henriette Smit, Jan Raaijmakers, Anke-Hilse Maitland-van der Zee. (Netherlands)
- 11:15 am** **Anti-Inflammatory Asthma Therapy Adherence in Paediatric Patients: The PACMAN Cohort Study [563]**
Ellen S Koster, Jan A Raaijmakers, Anke-Hilse Maitland-van der Zee. (Netherlands)
- 11:30 am** **Claims Algorithms To Quantify Use of Live Attenuated Influenza Vaccine among Non-Recommended Children [564]**
Pat Tennis, Elizabeth Andrews, Seth Toback, Chris Ambrose, Lisa McQuay, Matthew Rousculp. (United States)
- 11:45 am** **Antibacterial Drugs and the Risk of Community-Associated Methicillin Resistant *Staphylococcus aureus* (C-MRSA) in Children [565]**
Verena Schneider-Lindner, Caroline Quach, James A Hanley, Samy Suissa. (Canada)

Random Women (Clarence)

Moderators: Lolkje de Jong-van den Berg & Maureen Cronin

- 10:30 am** **Maternal Use of Proton Pump Inhibitors (PPI) during Pregnancy Is Associated with an Increased Risk for Cardiac Birth Defects: Analysis of 208,951 Pregnancies from the THIN Database [566]**
Andrew D Rhim, Kevin Haynes, Janet R Hardy, Jeffery M Testani, Yu-Xiao Yang. (United States)
- 10:45 am** **Clomiphene Citrate and Birth Defects, National Birth Defects Prevention Study 1997-2005 [567]**
Jennita Reefhuis, Margaret A Honein, Laura A Schieve, Sonja A Rasmussen. (United States)
- 11:00 am** **Utilisation of Endocrine Therapy in Women with Breast Cancer in Australia [568]**
Agnes I Vitry, Loc Thai, Christine Lu. (Australia)

11:15 am Differences in Drug Utilization of Oral Contraceptives in the US and Europe [569]
Kristina Bardenheuer, Juergen Dinger, Thai Do Minh, Christian Franke, Janko Leddin. (Germany)

11:30 am Adolescent and Young Adult Women's Use of Emergency Contraception [570]
Sharon Hensley Alford, Rachel E Lappin, Karen E Wells, Amanda R Barone, Marianne Ulcickas Yood, Vanessa K Dalton. (United States)

11:45 am Unintended Pregnancies in Women Using Intrauterine Devices: Results from the EURAS-IUD Study [571]
Juergen Dinger, Clare Barnett, Sabine Moehner, Anita Assmann. (Germany)

Noon-1: 30pm

Lunch/Poster Session C/Exhibits (Durham, Durham Gallery, Hall 7 & 8)

Roundtable Discussions - TBA

ISPE Board of Directors Luncheon (Ambassador)
(Meeting open to all members; check with staff if you wish to attend)

1:30-3:00pm

CONCURRENT SESSIONS: SYMPOSIA AND WORKSHOPS

- **Lessons Learned from Collaboration among EU Biologics Registries in Rheumatology [572] (Hall 4)**
William G Dixon, Margaret Richards, Johan Askling, Hans Petri, Syed R Ahmad. (United States)
- **The Industry-Academic Nexus: Experiences, Perspectives, and Suggestions for Enhancing Research Relationships [573] (Cambridge)**
Jerry L Avorn, Sara A Ephross, Allen A Mitchell, Walter L Straus. (United States)
- **The Alternate Life of Regulators [574] (Oxford)**

Stella CF Blackburn, Peter Arlett, Xavier Kurz, Henry Fitt. (United Kingdom)

- **Rare Diseases: Unmet Medical Needs, Epidemiology and Regulatory Considerations [576] (Dukes)**
Wei Dong, Judith Jones, Joanna Haas, Michael Taylor, Pavel Napalkov. (United States)
- **Linking Administrative and Electronic Medical Record Databases Using Hybrid Probabilistic and Deterministic Techniques [577] (Balmoral)**
Erica Danielson, Stella Chang, Daniel Huse. (United States)
- **Challenges and Opportunities in Shaping Medical Device Epidemiology [781] (Buckingham)**
Danica Marinac-Dabic, Art Sedrakyan, Mary E Ritchey, Sharon-Lise Normand, Frederic Resnic. (United States)
- **Observed vs Expected Methodologies in Vaccine Safety Surveillance [782] (Clarence)**
June Raine, Martin Kulldorff, Stephen Evans, Suzie Seabroke, Vincent Bauchau. (United Kingdom)

3:00-4:30pm

HOT TOPICS SESSION: Moderator Pandemic, No Many Dead – What we should do differently next time

- **Professor Angus Nicoll, Influenza Coordinator, European Centre for Disease Prevention and Control (ECDC), Stockholm, Sweden**
- **TBA**

4:30-5:00pm

The Final Word (Oxford)

- **Poster Awards**
- **ICPE 2011 Chicago, Illinois, USA**
John Seeger, Chair, 2011 Scientific Program Committee

5:00pm

Adjournment of ICPE 2010 (Oxford)

5:15-6:15pm

2011 ICPE Scientific Program Committee Meeting
(Open to interested ISPE members)