



26th International Conference on Pharmacoepidemiology and Therapeutic Risk Management

FINAL PROGRAM

 www.pharmacoepi.org



Serious Fun!

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27th International Conference on Pharmacoepidemiology and Therapeutic Risk Management



AUGUST 14-17, 2011

HYATT REGENCY CHICAGO

CHICAGO, ILLINOIS

Abstract

Deadline:

FEBRUARY 16, 2011

*The online abstract site will be
operational by mid-December 2010.*

*Meeting information will be posted
at www.pharmacoepi.org*

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MEETING At-a-Glance

Wednesday, August 18, 2010

7:00am	8:00am	9:00am	10:00am	11:00am	12:00pm	1:00pm	2:00pm	3:00pm	4:00pm	5:00pm	6:00pm	7:00pm	
				11:00am - 6:00pm Registration Open Sussex Lounge									
				11:00am - 5:00pm Speaker Ready Room Office 1									
						1:00 - 5:00pm Introduction to Pharmacoepidemiology Balmoral							
						1:00 - 5:00pm Introduction to Pharmacogenetics — Part I Dukes				5:30 - ? Student Meet & Greet Revolution			
	8:30am - 5:00pm ISPE Board of Directors Meeting Buckingham					1:00 - 5:00pm Student Skills Workshop Ambassador							

Thursday, August 19, 2010

7:00am	8:00am	9:00am	10:00am	11:00am	12:00pm	1:00pm	2:00pm	3:00pm	4:00pm	5:00pm	6:00pm	7:00pm	
7:00am - 6:00pm Registration Open Sussex Lounge													
7:00am - 5:00pm Speaker Ready Room Office 1													
	8:30am - 12:00pm Educational Sessions: Pharmacogenetics 2 Dukes Regulatory Pharmacoepi/Public Health Decision Making Ambassador Introduction to Drug Utilization Research Buckingham Intermediate Pharmacoepi: Concepts, Data and Methods Clarence Medications in Pregnancy Balmoral Comparative Effectiveness Research Hall 4					12:00 - 1:30pm Lunch on Your Own		1:30 - 6:00pm Educational Sessions: Advanced Topics in Pharmacoepidemiology Hall 4 Introduction to Risk Management Balmoral Advanced Drug Utilization Research: Using Drug Data to Guide Planning and Evaluation of Quality Use of Medicines Interventions Ambassador					
						12:00 - 1:30pm New Members Luncheon Windsor Restaurant					6:00 - 7:30pm Welcome Reception/ Hilton Metropole Beach (weather permitting)		

Friday, August 20, 2010

7:00am	8:00am	9:00am	10:00am	11:00am	12:00pm	1:00pm	2:00pm	3:00pm	4:00pm	5:00pm	6:00pm	7:00pm
7:00am - 6:00pm Registration Open Sussex Lounge												
7:00am - 5:00pm Speaker Ready Room Office 1												
	7:30am - 6:00pm Exhibitors/Posters Durham & Hall 7								3:30 - 5:00pm Symposia & Workshops Methodological Challenges of Drug Utilization Balmoral Methodological Controversies from Comparative Effectiveness Cambridge Biologics Dukes Guidance Regarding Electronic Healthcare Databases Hall 4 Identifying the Genetic Basis of Serious Adverse Events Buckingham Birth Defects Clarence The Public Health Burden of Acetaminophen Poisonings Ambassador			
7:00 - 8:00am Poster Session A Set-Up Durham & Hall 7	8:00 - 9:00am Opening Session Oxford Welcome: <i>Corinne de Vries</i> Presidential Address: <i>Sebastian Schneeweiss</i>	9:00am - 10:30pm Diabetes Clarence Infection: Down with Resistance Dukes Methods: Exposure and Outcome Assessment Hall 4 Sundry Buckingham The Brighter Side of Cancer Balmoral Vaccines in the H1N1 Era Cambridge	10:30-11:00am Break/Posters/Exhibits Durham & Hall 7		11:00 - 12:00pm Keynote Address Oxford Thomas Lönngren	12:00 - 1:30pm Lunch/Poster Session A/Exhibits Durham, Durham Gallery, Hall 7&8	1:30 - 3:00pm EMA Scientific Debate Co-sponsored by ISPE & EMA Oxford	3:00-3:30am Break/Posters/Exhibits Durham Hall 7		5:00 - 6:00pm ISPE Council Meetings Academic Hall 4 Government/Regulatory Hilton 3 Industry/Service Providers Lancaster		7:00 - 9:00pm PDS Editorial Board (By invitation) Due South Restaurant
7:00 - 8:00am Committees Education Lancaster Finance Hilton 3												7:00 - ? Student Social Event A Night Out in Brighton at Al Duomo
											6:00 - 7:00pm General Assembly/ European Drug Utilization/ Health Services Research SIG Ambassador	

MEETING At-a-Glance

Saturday, August 21, 2010

7:00am	8:00am	9:00am	10:00am	11:00am	12:00pm	1:00pm	2:00pm	3:00pm	4:00pm	5:00pm	6:00pm	7:00pm								
7:00am - 6:00pm Registration Open Sussex Lounge																				
7:00am - 5:00pm Speaker Ready Room Office 1																				
7:00-8:00am Poster Session B Set-Up Durham & Hall 7											8:00am - 6:00pm Exhibitors/Poster Session Durham & Hall 7		12:45-1:30pm Poster Walks Durham & Hall 7		3:30-4:00pm Break/ Exhibits Durham & Hall 7		4:00 - 5:30pm Symposia & Workshops Optimizing Global Vaccine Safety Monitoring: Lessons Learned from H1N1 Hall 4 Matching on Propensity Scores Balmoral Regulatory Risk Communication Are We Getting Ahead? Oxford Role of Meta-Analysis in Drug Safety Buckingham The Panacea of Study Designs in Pharmacoeconomics Dukes How Can Better Scientific Methods Result in Better Drug Regulation Studies Clarence Evaluating Adverse Pregnancy Outcomes Ambassador			
8:30am - 10:00am CNS: The Brain and the Heart Balmoral Mapping and Validating Critical Data Elements Cambridge Miscellaneous Buckingham NSAIDs and Associated Treatments Dukes P4M: Pharmacogenomics, Predictors, Prognosis, & Personalised Medicine Clarence Risk Management: Are We Taking the Bull by the Horn? Oxford		10:00-10:30am Break/ Posters/ Exhibits Durham & Hall 7		10:30am - 12:00pm Clinically Important Public Health Issues and New Insights in Rare Diseases Dukes CNS: Potpourri Oxford Methods in Pregnancy Studies: Practical Applications Cambridge Pharmacovigilance - Needles in Haystacks? Balmoral Potpourri Buckingham Prescribing Problems in Older Persons Clarence		12:00 - 1:30pm Lunch/Poster Session B/Exhibits Durham, Durham Gallery, Hall 7&8 ISPE Committee Council Meetings Bylaws and Policies Sandringham External Communications Hilton 3 Global Development Lancaster Membership Osborne Publications Surrey 1		1:30 - 2:30pm Plenary Session: Benefits and Risks of Drug Treatments Oxford		2:30 - 3:30pm Annual Meeting of ISPE Members & Awards Ceremony Oxford		5:30 - 6:30pm SIGs Biologics Ambassador Comparative Effectiveness Research Balmoral Database Buckingham Drug Utilization/Health Services Research Cambridge Medications in Pregnancy Clarence Molecular Epidemiology/Pharmacogenetics Dukes		7:30pm - Midnight Evening at the Corn Exchange/Brighton Dome						

Sunday, August 22, 2010

7:00am	8:00am	9:00am	10:00am	11:00am	12:00pm	1:00pm	2:00pm	3:00pm	4:00pm	5:00pm	6:00pm	7:00pm								
7:30am - 4:30pm Registration Open Sussex Lounge																				
7:30am - 3:30pm Speaker Ready Room Office 1																				
7:00-8:00am Poster Session C Set-Up Durham & Hall 7											8:00am - 1:45pm Exhibitors/Posters Durham & Hall 7		1:30 - 3:00pm Symposia & Workshops Lessons Learned from Collaboration Among EU Biologics Registries in Rheumatology Hall 4 The Industry-Academic Nexus Cambridge The Alternate Life of Regulators Oxford Rare Diseases: Dukes Linking Administrative and Electronic Medical Record Databases Balmoral Challenges and Opportunities in Shaping Medical Device Epidemiology Buckingham Observed vs Expected Methodologies in Vaccine Safety Surveillance Clarence		3:00 - 4:30pm Hot Topics Session: Pandemic, Not Many Dead - What We Should Do Differently Next Time Oxford		4:30-5:00pm The Final Word: •Poster Awards •ICPE 2011 •Adjournment Oxford		5:15 - 6:15am 2011 ICPE Scientific Program Committee Ambassador	
8:30 - 10:00am Bias and Confounding Oxford Clotting or Bleeding Buckingham Compliance & Utilization I Balmoral Outcomes After Prenatal Exposure Cambridge Pharmacovigilance - Real or Fool's Gold Clarence Stimulating Findings from Medicine Use in Children Dukes		10:00-10:30am Break/ Posters/ Exhibits Durham Hall 7		10:30am - Noon Analysis Methods - The Details that Bedevil Us Oxford Atypical Prescribing in Older People Balmoral Cardiovascular Cambridge Compliance & Utilization II Buckingham Pediatric Potpourri Dukes Random Women Clarence		12:00 - 1:30pm Lunch/Poster Session C/Exhibits Durham, Durham Gallery, Hall 7&8 Roundtable Discussions TBA ISPE Board of Directors Luncheon Ambassador														



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Thank you

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- * Program in Pharmacoepidemiology, Harvard School of Public Health
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2010

5th Asian Conference on Pharmacoepidemiology

(Convened in conjunction with the Japanese Society for Pharmacoepidemiology 16th Annual Meeting)

October 29-31, 2010 * IOI Hall * Tokyo, Japan

2011

ISPE Mid-Year Meeting

April 9-11, 2011 * Grand Hotel Baglioni * Florence, Italy

27th ICPE

August 14-17, 2011 * Hyatt Regency Chicago * Chicago, Illinois

2012

ISPE Mid-Year Meeting

April 21-23, 2012 * Eden Roc Hotel * Miami Beach, Florida

28th ICPE




August 23-26, 2012 * CICC * Barcelona, Spain

Badges

All attendees at ICPE 2010 must wear their name badges to all events.




A badge will be needed for admission to meeting related functions, such as the Welcome Reception, scientific sessions, exhibit/poster hall, and evening at the Corn Exchange. Badges will be included in the registration packet material. In some cases, tickets for admission will be required.

Badge Legend

-  Student
-  New Member
-  One-Day Attendee

Footstep Legend

Follow the color to your session.

-  To Clarence, Lancaster, Sandringham & Viscount
-  To Balmoral, Buckingham, Dukes, Ambassador & Osborne
-  To Exhibit Hall (Durham), General Session (Oxford), Cambridge & Hall 4



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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)

NOTE:

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.

Pre-Conference Educational Sessions* (Registration required)

1:00-5:00pm
Introduction to Pharmacoepidemiology (Balmoral)

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*

* Included as part of full meeting registration; registration required

1:00-5:00pm
Introduction to Pharmacogenetics – Part I: Didactic Approach Infused with Practical Examples (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.

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
STUDENTS ONLY
Student Skills Workshop
 (Ambassador)

– 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*

* Included as part of full meeting registration; registration required

5:30-?

Student Meet and Greet

- Open to all students.
- Organized by the ISPE Student Council
- Assemble at ICPE Registration Desk, then walk to Revolution.



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

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

NOTE:

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.

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.

Faculty

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

8:30-Noon Regulatory Pharmacoeconomics/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, MHRA, 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 Pharmacoeconomics.
- 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 Haaaijer-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

- 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)

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

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)

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, weather permitting)

–Admission by badge or ticket. Cash Bar

Welcome

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

Sebastian Schneeweiss, FISPE, ISPE President



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We are proud to support the **26th International Conference on Pharmacoepidemiology and Therapeutic Risk Management** and welcome the opportunity for the open exchange of scientific ideas and research findings in order to advance the fields of pharmacoepidemiology and risk management.

AGENDA Friday, August 20

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 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 S. 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)

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AGENDA Friday, August 20

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 & Kiyoshi Kubota, FISPE

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 Ruiter, 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, Knud 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)

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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)

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11:00-12:00pm

Keynote Address (Oxford)

Moderator: **Stephen J.W. Evans, FISPE, ISPE President-Elect**

Thomas Lönngren, Executive Director, European Medicines Agency

- * **The Future of Medicines Regulation: Where Does Pharmacoepidemiology Fit into Risk Management and Comparative Effectiveness Measurement?**

Thomas Lönngren has been the Executive Director of the European Medicines Agency since 1 January 2001. He is currently serving a second five-year term, which expires at the end of 2010. Mr Lönngren qualified as a pharmacist from the University of Uppsala, Sweden, in 1976 and holds an MSc in social and regulatory pharmacy. From 1976-78 he was a lecturer at the same university. He served with the Swedish National Board of Health and Welfare from 1978-90, where his responsibilities included herbal medicines, cosmetics, medical devices, narcotics and contraceptives. From 1982-94, he acted as senior pharmaceutical consultant for the Swedish International Development Agency's health cooperation programme in Vietnam. In 1990 he was appointed Director of Operations of the Swedish Medical Products Agency (MPA), of which he later became the Deputy Director-General. He became an Honorary Member of the Royal Pharmaceutical Society of Great Britain in 2003 and was made an Honorary Fellow of the Royal College of Physicians in 2004. He was granted an Honorary Doctorate from the University of Uppsala in January 2008, and received the Drug Information Association's Distinguished Career Award in March 2008.

12:00pm-1:30pm

Lunch/Poster Session A/Exhibits

(Durham, Durham Gallery, Hall 7 & 8)

SPONSORED BY ACADEMIC SUPPORTERS (listed on page 6)

ISPE Committee/Council Meetings

—Open to all participants.

- * **Development Committee** (Lancaster)
- * **Fellowship & Awards Committee** (Hilton 3)
- * **Public Policy Comm.** (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 Hernández-Díaz, FISPE, Harvard School of Public Health, USA

Kenneth J. Rothman, FISPE, RTI Health Solutions, USA

AGENDA Friday, August 20

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. (Netherlands)

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

7:00pm- ?

Student Social Event – A Night Out in Brighton

- Open to all students.
- Organized by the ISPE Student Council
- Assemble at ICPE Registration Desk, then walk to Al Duomo.



AGENDA Saturday, August 21

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 Aganist 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

* **Comparing Bias of Two Different Instrumental Variable (IV) Approaches with Logistic Regression [190]**

Bing Cai, Dylan S Small, Sean Hennessy, Thomas R Ten Have. (United States)

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Miscellaneous (Buckingham)

Moderators: Susan Olivera, FISPE & John Logie

8:30 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)

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)

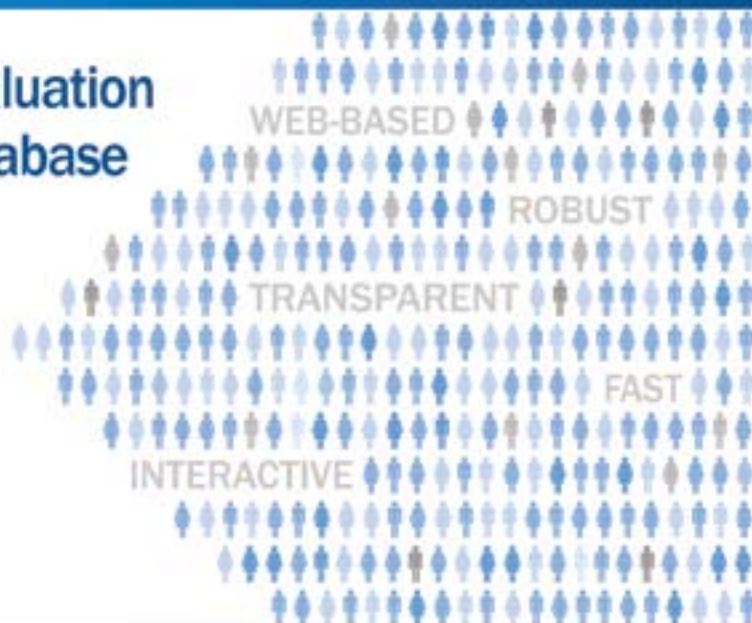
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AGENDA Saturday, August 21

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-elective 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)

AGENDA Saturday, August 21

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

Moderator: **Klaas Heinemann & June Raine**

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 Gilsenan, 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 Proportions 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)



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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 I 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)

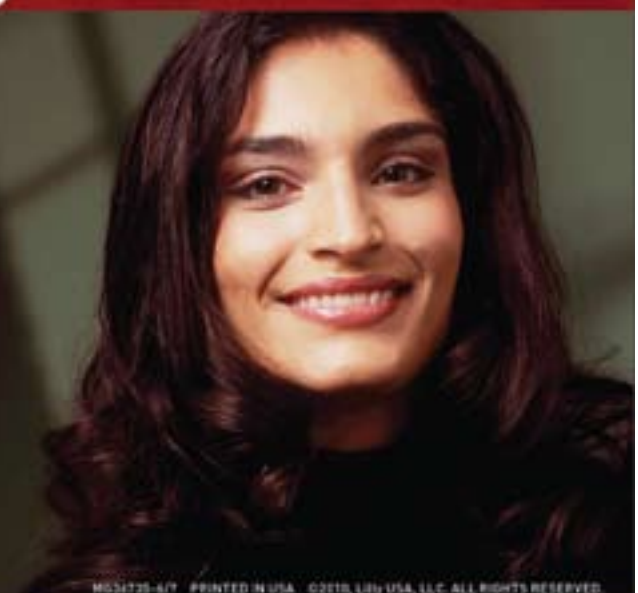
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AGENDA Saturday, August 21

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)

AGENDA Saturday, August 21

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 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

Moderator: **Bert Leufkens, FISPE**, Chairman of the Dutch Medicines Evaluation Board & Professor of Pharmacoepidemiology, University of Utrecht

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

- * **Benefits and Risks of Drug Treatments: How to Combine the Best Evidence on Benefits with the Best Evidence on Harms?**



AGENDA Saturday, August 21

2:30-3:30pm

–Open to all participants.

Annual Meeting of ISPE Members, Awards Ceremony (Oxford)



Annual Meeting of ISPE Members

- * Sebastian Schneeweiss, FISPE, ISPE President
- * Nancy Dreyer, FISPE, ISPE Vice President Finance

Awards Ceremony

ICPE 2010

Student Awards

- * Presented by **Corinne S. 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**
- Etlavitch Award (Best Student Abstract) & Oral Presentation:*
Caitlyn T. Wilke, *Sensitivity of Hazard Estimates to Exposure Definition:
A Simulation Study (309)*

Induction of ISPE Fellows (FISPE)

- * **Sebastian Schneeweiss, FISPE**, ISPE President
- Inductees:*
Corinne S. de Vries, FISPE **Susan Ann Oliveria, FISPE**
Stephen JW Evans, FISPE **Miriam CJM Sturkenboom, FISPE**
Kiyoshi Kubota, FISPE **Douglas J. Watson, FISPE**
- * **Miriam Sturkenboom, FISPE**, Chair, Fellowship & Awards Committee
- Honorary Lifetime Fellow*
Ronald D. Mann, FISPE

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

Installation of New President

- * **Stephen JW Evans, FISPE**

3:30-4:00pm

Break/Posters/Exhibits (Durham & Hall 7)

4:00-5:30pm

Concurrent Sessions: Symposia And Workshops

Optimizing Global Vaccine Safety Monitoring: Lessons Learned from HINI [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 Haaij-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 Fourrier, 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)



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AGENDA Saturday, August 21

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!

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- Kogenate® (hemophilia)
- Adalat® (high blood pressure)
- Nexavar® (kidney and liver cancer)
- Mirena® (hormonal intrauterine delivery system for contraception)
- Avalox®/Avelox® (respiratory tract infections)
- Levitra® (erectile dysfunction)
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You can also contact: Melanie Wolff at + 49 171 6222507 (melanie.wolff@bayerhealthcare.com) or Montse Soriano-Gabarro (montse.soriano-gabarro@bayerhealthcare.com)

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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)

AGENDA Sunday, August 22

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]**
Cairiona Cahir, Tom Fahey, Conor Teljeur, Lesley Tilson, Kathleen Bennett. (Ireland)

9:00 am

- * **Antiplatelet Agents' Effectiveness for Secondary Prevention of Ischemic Stroke [514]**
Mi-Sook Kim, Ye-Jee Kim, Jong-Mi Seong, Nam-Kyong Choi, Byung-Joo Park. (Korea)

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-Díaz, 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: **Suzie 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]**
Ismail Ahmed, Frantz Thiessard, Ghada Miremont-Salamé, Bernard Bégau, 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)



Serious Fun!

ISPE 26th International Conference on Pharmacoepidemiology and Therapeutic Risk Management

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

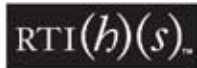
* Self-Controlled Case Series and Prescription Event Symmetry Analysis: How Different Are They Really? [540]

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)



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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

* **Suicidality Assessment in Placebo-Controlled Studies of Ziprasidone [104]**

Onur N Karayal, Susan D Anway, Evan Batzar, Douglas G Vanderburg. (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 Winkelmayer, 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)

AGENDA Sunday, August 22

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 Haddock. (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)



AGENDA Sunday, August 22

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 Asklung, 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)

AGENDA



Sunday, August 22

3:00-4:30pm

Hot Topics Session:

Moderator: **Xavier Kurz**, Pharmacovigilance & Risk Management, EMA

Moderate Pandemic, Not Many Dead: What Should We Do Differently Next Time? (Oxford)

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

* **Deborah Cohen**, Assistant Editor, BMJ



Serious Fun!

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 (Ambassador)

–Open to interested ISPE members



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