

SATURDAY, 21 AUGUST

10:30-12:00

ISPE Finance Committee Meeting (Sofitel Hotel)

12:30-17:00

ISPE Board of Directors Meeting (Sofitel Hotel)

19:00-22:00

ISPE Board of Directors Dinner (By Invitation)

SUNDAY, 22 AUGUST

07:30-18:00

Registration (Main Hall)

PRE-CONFERENCE EDUCATIONAL SESSIONS

08:30-12:00

Skills Workshops – Students Only

Workshop Chair: *Fadia Shaya*

Sessions Repeat

ADMISSION BY
TICKET ONLY

• 08:30-10:00

[A] **Brian L. Strom, FISPE**, *Writing Grant Proposals that Get Funded*
(Commission D1-D2)

[B] **Thomas MacDonald, FISPE**, *How NOT to Give a Scientific Presentation*
(Commission E1-E2)

• 10:00-10:30

Break

• 10:30-12:00

[A] **Brian L. Strom, FISPE**, *Writing Grant Proposals that Get Funded*
(Commission D1-D2)

[B] **Thomas MacDonald, FISPE**, *How NOT to Give a Scientific Presentation*
(Commission E1-E2)

08:30-17:00

Introduction to Pharmacoepidemiology* (Amphitheater B)

• 0830- 09:15

Jacques Le Lorier, FISPE, *Confounding by Indications*

• 09:15-10:00

Judith, Jones, FISPE, *Cohort Studies*

• 10:00-10:30

Break

• 10:30-11:15

Sean Hennessy, FISPE, *Case-Control Studies*

• 11:15-12:00

Nicholas Moore, FISPE, *Spontaneous Reporting*

• 12:00-14:30

Working Lunch/Small Group Sessions
(on your own – Panoramic Bar)

• 14:30-15:30

Group Presentations

• 15:30-16:00

Break

• 16:00-16:45

Group Discussions

• 16:45-17:00

**Summary Comments:
Faculty**

• 17:00

Adjournment

* All day; a combination of presentations, group work and discussions.

Admission included in registration fee.

Lunch on your own.

future meetings

2005 Mid-Year Meeting

16-19 April 2005

Barcelona, Spain

16 April

Board of Directors Meeting

17 April

ISPE Strategic Planning Committee

ICPE Scientific Program Committee, 2005

18 April

Mid-Year Symposium

19 April

Introduction to Pharmacoepidemiology

Advanced Topics in Pharmacoepidemiology

2005 Annual Meeting

21-24 August 2005

Gaylord Opryland

Nashville, Tennessee

2006 Annual Meeting

TBD, August 2006

Lisbon, Portugal

2007 Annual Meeting

19-22 August 2007

Quebec City, Canada

Visit the ISPE website, www.pharmacoepi.org,
for meeting information.

CPD — UK PHYSICIANS ONLY

The Royal College of Physicians of London has approved the *20th International Conference on Pharmacoepidemiology and Therapeutic Risk Management* (22603) for 25 Continuing Professional Development (CPD) credits. UK physicians must sign the registration sheet at the Registration Desk. Certificates of attendance will be available at the close of the conference.



AGENDA-SUNDAY/MONDAY

SUNDAY, 22 AUGUST (cont.)

10:30-12:00
ISPE Strategic Planning Committee (Sofitel Hotel)

12:00 -17:00
Exhibitor Set-up (Espace Pluriel)

12:30-13:30
Lunch on your own (Panoramic Bar)

13:30-18:00

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

* Admission by ticket only. Tickets will be included in registration packet for those who have registered for this session.

Jacques Le Lorier, FISPE, Chair

• 13:30-14:30

Andrew Maguire, *Quantification of Risk-Benefit of Medication Use at Population Level Using Stochastic Simulation Models*

• 14:30-15:30

Sebastian Schneeweiss, *Sensitivity Analysis and External Adjustment of Confounding by Indication in Pharmacoepidemiology*

• 15:30-16:00

Break

• 16:00-17:00

Stephen Evans, *Uses & Abuses Solved, and Those Unsolved, in Data Mining in Pharmacovigilance*

• 17:00-18:00

Stephen Grover, *Estimating the Costs & Benefits of Preventing Cardiovascular Disease*

17:00-18:00

Academic Showcase Set-up (Main Hall)

18:00-18:30

Social - New ISPE Members/Scholarship Recipients/Student Prize Winners (By Invitation) (Main Hall)

All first-time members to the Society, scholarship recipients, & student prize recipients are cordially invited to meet informally with ISPE officers, directors, committee chairs & fellows.

18:30-20:00

Academic Showcase/Welcome Reception (Main Hall)
Cash Bar

Welcome

Nicholas Moore, FISPE, Chair, Scientific Program Committee

Alain Juppe, Mayor of Bordeaux

Dominique Ducasson, Deputy Mayor of Bordeaux
Cash Bar

ADMISSION BY
TICKET ONLY

MONDAY, 23 AUGUST

07:00-08:00
Poster Set-up: Session A (Espace Pluriel)

Exhibits (Espace Pluriel)

Coffee/Tea (Espace Pluriel)

07:00-17:00
Registration (Main Hall)

Speaker Ready Room (G-1)

07:00-08:15
Committee Meetings

- **Education**
(Commission D1-D2)
- **PDS Commentaries Subcommittee**
(Commission E1-E2)
- **Ad Hoc Committee on Good Pharmacoepidemiology Practices**
(Commission F1-F2)

Open to all interested meeting participants.

08:30-10:00

OPENING SESSION

(Amphitheater A)

- **Welcome**
Nicholas Moore, FISPE,
Chair, Scientific Program
Committee
- **Presidential Address**
Susana Perez-Gutthann,
FISPE, President ISPE
- **Keynote Address**
Bernard Begaud,
President, Universite Victor
Segalen, *The Role of
Pharmacoepidemiology in
Medical Training*
- 10:00-10:30
**Refreshment
Break/Posters/Exhibits**
(Espace Pluriel)



ISPE
21st Annual Meeting
21-24 August 2005
Nashville, TN

ABSTRACT SUBMISSION DEADLINE:
18 FEBRUARY 2005

The online abstract submission site will be active by mid-December 2004; visit www.pharmacoepi.org.



AGENDA-MONDAY

MONDAY, 23 AUGUST (cont.)

10:30-12:00

CONCURRENT SESSIONS

[A] Methodology 1: Database Studies: Bias and Validation of Information –Contributed Papers (Amphitheater A)

• Moderators: *Annie Hutchinson & Michael Lewis, FISPE*

• 10:30

Evaluation of Bias Associated with Use of Unconfirmed Cases of Achilles Tendon Ruptures in Claims Data [1]

John D Seeger, William A West, Daniel Fife, Gary J Noel, Larry N Johnson, Alexander M Walker. (United States)

• 10:45

Depletion of Susceptibles: How Much Is Enough? [2]

Louis Larochelle, Marc Dorais, Jacques LeLorier. (Canada)

• 11:00

Using Propensity Scores To Control for Confounding by Indication: The Influence of Causal Models on the Validity of Effect Estimates [3]

Nicolle M Gatto, Ulka B Campbell, Robert F Reynolds. (United States)

• 11:15

A Comparison of the Cause of Death Recorded in the General Practice Research Database with National Mortality Statistics in England and Wales [4]

Anoop D Shah, Carlos Martinez. (United Kingdom)

• 11:30

Frequency of Use Influences Recall of NSAID Exposure [5]

James D Lewis, Russell A Localio, Steven E Kimmel, John T Farrar, David C Metz, Lisa C Nessel, Colleen Brensinger, Brian L Strom. (United States)

• 11:45

Modeling Cumulative Effects of Medication: Benzodiazepines and Risk of Injury in the Elderly [6]

Michal Abrahamowicz, Gillian Bartlett, Robyn M Tambllyn, Roxane du Berger. (Canada)



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AGENDA-MONDAY

MONDAY, 23 AUGUST (cont.)

[B] Cardiovascular 1: Outcomes – Contributed Papers (Amphitheater B)

- Moderators: *Fadia T. Shaya & Maryse Lapeyre-Mestre*
- 10:30
Risk Of Sudden Cardiac Death Among Users of Non-Cardiac QTC-Prolonging Drugs [7]
Sabine MJM Straus, Gysele S Bleumink, Jeanne P Dieleman, Johan van der Lei, Bruno HCh Stricker, Miriam CJM Sturkenboom. (Netherlands)
- 10:45
HERG-Activity of Drugs and the Risk for Serious Ventricular Arrhythmias and Sudden Death [8]
Marie L De Bruin, Monica Pettersson, Ronald Meyboom, Arno W Hoes, Hubert GM Leufkens. (Netherlands)
- 11:00
The Impact on Cardiovascular Events of Increasing High-Density Lipoprotein Cholesterol with and without Lipid-Lowering Drugs [9]
Li Wei, Michael J Murphy, Thomas M MacDonald. (United Kingdom)
- 11:15
Antidepressants and Risk of First-Time Hospitalization for Myocardial Infarction: A Population-Based Case-Control Study [10]
Mette Lena Olsen, Taco BM Monster, Soren P Johnsen, Joseph K McLaughlin, Henrik Toft Sorensen. (Denmark)
- 11:30
Use of Oral Steroids and the Risk of Acute Myocardial Infarction in the U.K. [11]
Cristina Varas-Lorenzo, Luis-Alberto Garcia-Rodriguez, Andrew Maguire, Susana Perez-Gutthann. (Spain)
- 11:45
The Effect of Selective Serotonin Reuptake Inhibitors on the Risk of Myocardial Infarction in a Cohort of Patients with Depression [12]
Stephen E Kimmel, Jesse A Berlin, David W Oslin, Rachel B Weinstein, Judith L Kinman, William H Sauer, James D Lewis. (United States)

[C] NSAIDs: Contributed Papers (Amphitheater C)

- Moderator: *K. Arnold Chan, FISPE & Douglas Steinke*
- 10:30
Discontinuation of Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) Is Associated with an Increased Risk of Acute Myocardial Infarction (AMI) [13]
Lorenz M Fischer, Raymond G Schlienger, Christian M Matter, Hershel Jick, Christoph R Meier. (Switzerland)
- 10:45
Non Steroidal Anti-Inflammatory Drugs Increase the Risk of Acute Urinary Retention - The Triumph Project [14]
Katia MC Verhamme, Jeanne P Dieleman, Marc AM Van Wijk, Johan van der Lei, Ruud JLH Bosch, Bruno HCh Stricker, Miriam CJM Sturkenboom. (Netherlands)
* **Student Award Recipient – 3rd Best Abstract**
- 11:00
Reduced Incidence of Breast Cancer Associated with Frequent Use of Selective and Nonselective Nonsteroidal Anti-Inflammatory Drugs [15]
Elham Rahme, Joumana Ghosn, Kaberi Dasgupta, Raghu Rajan, Marie Hudson. (Canada)
- 11:15
Incidence of Acute Renal Failure Associated with Inappropriate Use of NSAIDs in Acute Care [16]
Almut G Winterstein, Thomas E Johns, Randy C Hatton, David I Weiner, Ricardo Gonzalez-Rothi. (United States)
- 11:30
Non-Steroidal Anti-Inflammatory Drugs and Nonunion of Humeral Shaft Fractures [17]
Tim Bhattacharya, Mark Vrahas, Raisa Levin, Daniel H Solomon. (United States)
- 11:45
Incidence of Mucocutaneous Reactions in Children Treated with Niflumic Acid, Other Non-Steroidal Anti-Inflammatory Drugs and Analgesics [18]
Miriam CJM Sturkenboom, Alfredo Nicolosi, Luigi Cantarutti, Salvatore Mannino, Gino Picelli, Antonio Scamarcia, Carlo Giaquinto. (Netherlands)

AGENDA-MONDAY

MONDAY, 23 AUGUST (cont.)

[D] Prescribing Utilization: Effect of Age, Ethnicity or SES- Drug Utilization

(Commission E1-E2)

- Moderators: *Eric Van Ganse & Kevin Haynes*
- 10:30
Methods for Assessing Black-White Differences in Anti-Depressant Use in a Biracial Community Sample [19]
Carl F Pieper, Celia F Hybels, Dan Blazer, Bruce M Burchett. (United States)
- 10:45
Deconstructing Racial Differences in Receipt of Secondary Stroke Prevention Agents in Nursing Homes [20]
Kate L Lapane, Carmel M Hughes. (United States)
- 11:00
Are Reasons Given by the Elderly for Drug Use in Agreement with Drug Indications? [21]
Line Guenette, Jocelyne Moisan, Michel Preville, Richard Boyer. (Canada)
- 11:15
Inappropriate Medication Prescribing in Community-Dwelling Elderly People Living in Isfahan [22]
Laurent Y Azoulay, Amir Zargarzadeh, Driss Oraichi, Anick Bérard. (Canada)
- 11:30
Incidence and Predictors of All and Preventable Adverse Drug Reactions (ADR) in Frail Elderly Outpatients [502]
Joseph T Hanlon, Carl F Pieper, Emily R Hajjar, Richard J Sloane, Catherine I Lindblad, Christine M Ruby, Kenneth E Schmader. (United States)
- 11:45
Effectiveness of Decision Support in an Electronic Medical Record on Prescribing in the Elderly [24]
David H Smith, Nancy A Perrin, Adrienne Feldstein, Xiuhai Yang, Daniel Kuang, Steven R Simon, Stephen B Soumerai. (United States)

[E] Symposium: Safety Data Mining: Recommendations from the PhRMA-FDA Working Group [25] (Commission F1-F2)

- *June S Almenoff, Kenneth Hornbuckle, FDA Staff (to be determined), Manfred Hauben, A. Lawrence Gould. (United States)*

[F] Workshop: Clinical Assessment of Adverse Events Following Immunization (AEFIs): A Converging New International Paradigm? [26] (Commission D1-D2)

- *Christine G Casey, Scott Campbell, John Iskander, Frank DeStefano, Cornelia L Dekker, Michael Steven Gold, Giovanna Zaroni, Patricia E Vermeer-de Bondt, Renata JM Engler, Robert T Chen. (United States)*

12:00-13:30

Lunch/Poster Session A/Viewing of Exhibits (Espace Pluriel)

PDS Editorial Board - By invitation (Sofitel Hotel)

12:15-13:15

Committee Meetings/ Council Meeting

- **Data Privacy Committee** (Commission E1-E2)
- **Student Council** (Commission F1-F2)

Open to all interested meeting participants.

13:30-15:00

CONCURRENT SESSIONS

[A] Methodology 2: Propensity Scores – Contributed Papers (Amphitheater A)

- Moderators: *John Seeger & Stephen Evans*
- 13:30
Variable Selection in Propensity Score Models: Some Insights from a Simulation Study [27]
M Alan Brookhart, Sebastian Schneeweiss, Kenneth J Rothman, Robert J Glynn, Jerry Avorn, Til Sturmer. (United States)
- 13:45
Estimating Relative Risk of Injury Associated with Exposure to Prescription Medications: Conflicting Results from Case-Cross over and Case-Time-Control Analyses [28]
John S Sampalis, Yola Moride. (Canada)
- 14:00
Correcting Effect Estimates for Unmeasured Confounding in Cohort Studies with Validation Data Using Propensity Score Calibration [29]
Til Sturmer, Donna Spiegelman, Sebastian Schneeweiss, Jerry Avorn, Robert J Glynn. (United States)
- 14:15
Performance of Floating Absolute Risks [30]
Patrick G Arbogast. (United States)
- 14:30
Comparing Intended Treatment Effects after Adjustment with a Multivariable Cox Proportional Hazards Model and Propensity Score Methods in an Observational Study [31]
Edwin P Martens, Anthonius de Boer, Wiebe R Pestman, Svetlana V Belitser, Olaf H Klungel. (Netherlands)
- 14:45
Validation of a Propensity Score Developed Using Claims Data in Controlling for Health Status of Rheumatic Disease Patients Initiating Etanercept Compared with Other Dmards [32]
Catherine B Johannes, Gary A Schneider, Alexander M Walker, Sean Zhao, Atsuko Shibata. (United States)





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During the conference, Dr. Matthew Reynolds will present posters entitled, **Understanding the Role of the Report Date and Source in Signal Detection** and **Systematic Review of Abstracts for Pediatric Drug Use of Off-Patent Drugs for the Best Children's Practices Act**.

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AGENDA-MONDAY

MONDAY, 23 AUGUST (cont.)

[B] Anti-Infectives: The Good, the Bad and the Naughty – Contributed Papers

(Amphitheater B)

• Moderators: *Didier Guillemot & Sean Hennessy, FISPE*

• 13:30

Antiviral Use and Its Association with Post-Transplant Lymphoproliferative Disorder (PTLD) in Renal Transplant Patients in the U.S. [33]

Donnie P Funch, Mark D Pescovitz, Gary Schneider, Alexander M Walker. (United States)

• 13:45

Relative Risk of Acute Pancreatitis Associated with Different Combination Therapies between HIV-Infected Patients in Ohio Medicaid Population [34]

Jeff Jianfei Guo, Raymond Jang, Robert J Cluxton. (United States)

• 14:00

Is There Cross-Reactivity between Penicillins and Cephalosporins? Investigation of a Large Electronic Medical Record Database [35]

Andrea J Apter, Judith L Kinman, Warren B Bilker, Maximilian Herlim, David J Margolis, Ebbin Lautenbach, Sean Hennessy, Brian L Strom. (United States)

• 14:15

Macrolide Treatment Failure in Sinusitis and Associated Clinical Consequences [36]

Jasmanda H Wu, John E McGowan, Jr., David H Howard, Lourdes M Frau, Wanju S Dai. (United States)

• 14:30

Prescription Patterns of Leflunomide in Rheumatoid Arthritis: Clinical Trials Compared with Actual Practice [143]

Karin Martin, Fabrice Bentaberry, Chantal Dumoulin, Joël Dehais, Françoise Haramburu, Thierry Schaeberbeke, Bernard Bégaud. (France, Metropolitan)

• 14:45

Self-Medication with Antibiotics in Europe [38]

Larissa Grigoryan, Flora M Haaijer-Ruskamp, 18 Co-Investigators in Europe on Behalf of SAR (Self-Medication with Antibiotics). (Netherlands)

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AGENDA-MONDAY

MONDAY, 23 AUGUST (cont.)

[C] Psychotropics: Contributed Papers

(Amphitheater C)

- Moderators: *Phil Wang & Donald Miller*
- 13:30
The Effects of Antidepressant Drugs on the Risk of Colorectal Cancer: A Population-Based Case-Control Study [39]
Wanning Xu, Hani Tamim, Jean-Paul Collet, Stan Shapiro. (Canada)
* Recipient of Edlavitch Award for Best Student Abstract
- 13:45
Current Use of Selective Serotonin Reuptake Inhibitors (SSRIs) Is Associated with a Decreased Risk of Acute Myocardial Infarction (AMI) [40]
Raymond G Schlienger, Lorenz M Fischer, Hershel Jick, Christoph R Meier. (Switzerland)
- 14:00
The Association between Antidepressant Use and Hypoglycemia and Hyperglycemia [41]
Jeroen Derijks, Fred de Koning, Ronald Meyboom, Toine Egberts. (Netherlands)
* Student Award Recipient – 2nd Best Abstract
- 14:15
Acute and Long-Term Risk of Femur Fractures in Patients on Antipsychotics [42]
Gerard WK Hugenholtz, Eibert R Heerdink, Willem A Nolen, Toine CG Egberts. (Netherlands)
- 14:30
The Risk of Fits, Diagnoses of Epilepsy and Death after First Prescription for Bupropion: An Analysis of the Health Information Network (THIN) Database [43]
Richard Hubbard, Smith Chris, Smeeth Liam, Paddy Farrington, West Joe, Sarah Lewis, Christine Godfrey, Britton John. (United Kingdom)
- 14:45
The Association between Cytochrome P450-2D6 Genotype and Plasma Concentrations of Antipsychotic and Antidepressant Drugs in Daily Clinical Practice [44]
Hans Mulder, Anita Herder, Frederik W Wilminck, Wim Tamminga, Antoine CG Egberts. (Netherlands)

[D] Prescribing Utilization 2: COX-2 and Analgesia Utilisation – Drug Utilization

- Moderator: *Ulf Beryman, FISPE & Vera Vlahovic-Palcevski*
- 13:30
Evaluation of a Cox-2 Inhibitor Prior Authorization Program on Utilization and Expenditures [45]
Ilene H Zuckerman, Diane McNally, Linda Simoni-Wastila, Sheila R Weiss. (United States)
- 13:45
Impact of Prior Authorization Programs on Use of Cox-2 Selective Non-Steroidal Anti-Inflammatory Drugs [46]
Michael A Fischer, Daniel H Solomon, Sebastian Schneeweiss, Hailu Cheng, Jerry Avorn. (United States)
- 14:00
Impact of Administrative Restrictions for Coxibs in Quebec (PQ), Ontario (ON), and British Columbia (BC) [47]
Deborah A Marshall, Don Willison, Kathy Sykora, Natalie Forde, Muhammad Mamdani, Paul Grootendorst, Jacques LeLorier, Malcolm MacLure, Steve Morgan, Leanne Warren, Elham Rahme, Paul Fortin. (Canada)
- 14:15
Do OTC Analgesic Users Know the Ingredients of the Products They Are Taking? [48]
David W Kaufman, Judith P Kelly, Lynn Rosenberg, Theresa Anderson, Allen A Mitchell. (United States)
- 14:30
Racial Disparities in Prescribing of Selective Cyclooxygenase-2 Inhibitors over Other Nonsteroidal Anti-Inflammatory Agents in a Medicaid Managed Care Population [49]
Fadia T Shaya, Steven W Blume, Christopher M Blanchette, C Daniel Mullins. (United States)
- 14:45
Medicinal Cannabis in The Netherlands [50]
Annemarie FC Janse, Nancy S Breekveldt-Postma, Joelle A Erkens, Ron MC Herings. (Netherlands)

[E] Symposia: Active Surveillance in ADR Monitoring [51]

(Commission F1-F2)

- *Syed R Ahmad, Anne Castot, Panos Tsintis, David M Coulter. (United States, France, United Kingdom, New Zealand)*

[F] Workshop: A Methodological Workshop on Sampling Strategies Applied to Drug Utilization Studies [52]

(Commission D1-D2)

- *Yola Moride, Sebastian Schneeweiss, Nicholas Moore, Eibert R Heerdink, Jean-Francois Boivin, Jacques Benichou. (Canada)*

15:00-15:30

Refreshment

Break/Posters/Exhibits
(Espace Pluriel)

AGENDA-MONDAY

MONDAY, 23 AUGUST (cont.)

15:30-17:00

CONCURRENT SESSIONS

[A] Cardiovascular 2: Utilisation and Prescribing Patterns – Contributed Papers

(Amphitheater A)

• Moderators: *Eric Johnson & Ghada Miremont-Salame*

• 15:30

Thrombolytic Therapy in Diabetic Patients with Acute Myocardial Infarction: Lower Rates of Use Than in Nondiabetic Patients Are Justified [53]

Elena Kvan, Kjell Pettersen, Knud Landmark, Asmund Reikvam. (Norway)

• 15:45

Race and Differences in Reaching Target LDL Goal among Individuals Treated with Prescription Statin Therapy [54]

Marianne Ulcickas Yood, Bruce D McCarthy, Judy Kempf, Gena P Kucera, Karen E Wells, Susan Oliveria, Paul Stang. (United States)

• 16:00

The Need To Change Prescribing Behaviour According to Dutch and European Guidelines on the Management of Hypercholesterolemia [55]

Aukje K Mantel-Teeuwisse, Olaf H Klungel, Albert Hofman, WM Monique Verschuren, Paul H Trienekens, Arijan J Porsius, Bruno HCh Stricker, Anthonius de Boer. (Netherlands)

• 16:15

Persistence and Determinants of Statins among Middle Aged Patients with and without Cardiovascular Disease [56]

Sylvie Perreault, Lucie Blais, Marie-Helene Bouchard, Diane Lamarre, Djamal Berbiche, Lyne Lalonde, Claudine Laurier, Johanne Collin, Francois St-Maurice. (Canada)

• 16:30

Management of Antihypertensive Drugs in Newly-Diagnosed Hypertensive Patients in Italy: A Retrospective Cohort Study in Primary Care [57]

Giampiero Mazzaglia, Miriam C Sturkenboom, Pierfrancesco Ruffo, Lorenzo Mantovani, Silvia Bustacchini, Alessandro Filippi, Ovidio Brignoli, Achille P Caputi. (Italy)

• 16:45

Low Treatment Rates and Poor Goal Attainment in Patients with Concomitant Hypertension and Dyslipidaemia: Data from the United Kingdom [58]

Thomas M MacDonald, Steve V Morant, Christine L Baker, Essy Mozaffari. (United Kingdom)

[B] Miscellaneous 1: Risk Reporting and Reactions – Contributed Papers

(Amphitheater B)

Moderators: *Daniel Fife, FISPE & Gottfried Kreutz*

• 15:30

Utilizing Public Health Surveillance To Monitor Adverse Drug Reactions in People with Hemophilia [59]

J Michael Soucie, Bruce L Evatt, Sally Crudder. (United States)

• 15:45

Drug-Induced Thrombocytopenia: A Case-Control Study [60]

Patricia MLA van den Bemt, Ron HB Meyboom, Toine CG Egberts. (Netherlands)

• 16:00

Adverse Drug Reactions Associated with the Use of Ribavirin in the Treatment of Severe Acute Respiratory Syndrome (SARS) [61]

Ian MacKay, Joanne Garrah, Bradlee Tabah, Laura Freeman, Maurica Maher, Lynn Macdonald. (Canada)

• 16:15

Clinical Trials Are Not Reported Satisfactory to the Authorites [231]

Steinar Madsen, Bente Fjeld, Linda Sandaker, Harald Lislevand, Aasmund Reikvam. (Norway)

• 16:30

Validation of Asthma Diagnostic Codes in the Administrative Health Databases of Québec, Canada [63]

Lucie Blais, Catherine Lemière, Djamal Berbiche. (Canada)

• 16:45

Inter-Expert Agreement about Seven Operational Criteria for Causality Assessment of Adverse Drug Reactions [64]

Yannick Arimone, Bernard Begaud, Ghada Miremont-Salame, Francoise Haramburu, Annie Fourier-Reglat. (France)



AGENDA-MONDAY

MONDAY, 23 AUGUST (cont.)

[C] Error Prevention, Risk Management: Methodological Issues in Data Mining and Risk Management – Contributed Papers (Amphitheater C)

- Moderators: *Corinne deVries & Franz Thiessard*
- 15:30
Data Mining: Finding the Hidden Truth in Datasets [65]
David I Goldsmith, Carole L Cury. (United States)
- 15:45
A Terminological Approach for Automated Signal Detection in Pharmacovigilance [66]
Cédric Bousquet, Corneliu Henegar, Agnès Lillo-Le Louët, Marie-Christine Jaulent. (France)
- 16:00
Utility of Dose-Reporting Rate Relationship for Causality Assessment of Spontaneously-Reported Adverse Drug Experience [67]
Kenneth C Kwong, Jeffrey D Freid. (United States)
- 16:15
Development Core Safety Information in the Assessment of Serious Adverse Events Reported in Oncology Clinical Trials [68]
Anne Kehely, Jean Kilgour-Christie, Andrzej Czarnecki. (United Kingdom)
- 16:30
Preventable Drug-Related Morbidity in Older Adults in Nova Scotia: Identification of Risk Factors [amp] Development of a Risk Scoring Algorithm [69]
Nicole R Hartnell, Neil J MacKinnon. (Canada)
- 16:45
Advances in Risk-Benefit Evaluation Using Probabilistic Simulation Modeling [70]
Larry D Lynd, Bernie J O'Brien. (Canada)

[D] Prescribing Utilization 3: Cardiovascular – Drug Utilization

- (Commission E1-E2)
- Moderators: *Daniel Mines & Karin Martin*
 - 15:30
The Impact of Comorbidity on Statin Use in the Elderly [71]
Philip S Wang, Jerry Avorn, Sebastian Schneeweiss, Helen Mogun, Robert J Glynn. (United States)
 - 15:45
Preventive Drug Treatment after Myocardial Infarction [72]
Menno E van der Elst, Marcel L Bouvy, Cornelis J de Blaey, Anthonius de Boer. (Netherlands)
 - 16:00
Determinants of Angiotensin-2 Antagonist Prescribing in General Practice [73]
Jacoba P Greving, Petra Denig, Willem Jan van der Veen, Frank W Beltman, Miriam CJM Sturkenboom, Flora M Haaijer-Ruskamp. (Netherlands)

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AGENDA-MONDAY/TUESDAY

MONDAY, 23 AUGUST (cont.)

• 16:15

A Ten-Year Longitudinal Study of Use of Cerebral Vasodilators in the Elderly: Results from the Paquid Study [74]

Carine Jasseron, Nathalie Lechevallier-Michel, Annie Fourrier-Reglat, Pierre Joly, Helene Jacqmin-Gadda, Jean-Francois Dartigues. (France)

• 16:30

Lipid Management Strategies and Treatment Goal Attainment in Primary Hypercholesterolemia - The Canadian Experience [75]

Chantal Bourgault, Jean Davignon, George Fodor, Claude Gagné, Daniel Gaudet, Jacques Genest, Marc-André Lavoie, Lawrence Leiter, Ruth McPherson, Martin Sénécal, Annie Petrie, Michael Marentette, Rolf J Sebaldt. (Canada)

• 16:45

Inappropriate Use of Metformin in Hospitalized Patients with Heart Failure [76]

Chi-Wen Chiang, Hui-Fen Chiu, Hsin-Lung Wu, Chun-Yuh Yang. (Taiwan)

[E] Special session presented by EACPT - Evidence-Based Medicine vs. Outcomes Research: Are Clinical Trials Really Predictive of Actual Benefits and Risks? [77]

(Commission F1-F2)

• Moderator: Nicholas D Moore, FISPE (France)

[F] Workshop: Maximizing the Clinical Explanatory Power of Drug Dosing History Data [78] (Commission D1-D2)

• Moderators: H.G.M. Leufkens, FISPE & John Urquhart, FISPE

John Urquhart, *A Taxonomy for Dosing History Data that Supports Quantitative Analysis*,

High Inter- and Intra-Patient Variability of Indinavir and Nelfinavir Pharmacokinetics in Patients with Sustained Virological Response on HAART.

Mentré F, Panhard X, Brendel K, Legrand M, Goujard C, Taburet A-M, and the COPHAR 1 - ANRS 102 study group. INSERM E0357 (France)

Azra Ghani, *Characterising types of adherence using MEMS data*.

Bernard Vrijens, *Monitoring variable drug exposure: a solution to unexplained variability in clinical response*.

17:00-18:00

Invited Speaker (Amphitheater A)

- **Nicholas Wald**, Barts & The London Queen Mary School of Medicine & Dentistry, Combining Strategies for Controlling Risk

18:00-19:00

Council Meetings

Open to all interested meeting participants.

- **Industry** (Amphitheater A)
- **Academic** (Amphitheater B)
- **Government/Regulatory** (Commission D1-D2)

EuroDURG Executive Committee (Commission F1-F2)

19:30-?

Student Dinner at Le Franchouillard

Students attending the 2004 ISPE Annual Meeting are invited to participate in an informal student evening of good food, good wine, and good company. Separate registration required.

TUESDAY, 24 AUGUST 2004

Joint ISPE-EuroDURG Day

07:00-08:00

Poster Set-up: Session B (Espace Pluriel)

Exhibits (Espace Pluriel)

Coffee/Tea (Espace Pluriel)

07:00-08:15

Committee Meetings

- **Public Policy** (Commission D1)
- **Publications** (Commission D2)
- **Ad Hoc Committee on Adverse Drug Event Reporting** (Commission E1-E2)
- **Membership** (Commission F1-F2)

Open to all interested meeting participants.

07:00-17:00

Registration(Main Hall)

Speaker Ready Room(G-1)

08:30-10:00

[A] ISPE-EuroDURG Plenary Session

(Amphitheater A)

- **How Valid is the Assessment of Volume, Expenditure and Quality in Drug Consumption?**
- Chairs: Bert Leufkens, FISPE & Stephen Chapman

Robert Vander Stichele (Belgium), *Methodology for the Collection of International Comparable Drug Consumption Data: Strengths and Weaknesses of Available Systems, Experiences from European Collaborative Projects*

C. Mossevelt (The Netherlands), *Are the International Accounting Systems for the collection of Drug Expenditures Data Robust Enough for Benchmarking and Comparing Drug Policy?*

Flora Haaijer Ruskamp (The Netherlands) *Summary and Conclusions of a Recent WHO-EuroDURG Workshop on the Use of Quality Indicators in Benchmarking and Personalized Prescriber Feedback*

J. Gurwitz (United States), *Quality Indicators for Drug Consumption in the Elderly*

AGENDA-TUESDAY

TUESDAY, 24 AUGUST (cont.)

[B] Cardiovascular 3: Comorbidities, T2 Diabetes and Dyslipidemia – Contributed Papers (Amphitheater B)

- Moderators: *Thomas MacDonald, FISPE, & Gerald Faich, FISPE*
- 08:30
Hyperlipidemia Associated with Thiazolidinedione Use [243]
Donald R Miller, Fran E Cunningham. (United States)
- 08:45
Does Concomitant Use of Statins and Thiazolidinediones Increase the Risk of Rhabdomyolysis or Myopathy in Type II Diabetics? [244]
Bobbie Coleman, Andres Gomez-Camirero; presented by Nawab Quizilbash. (United States)
- 09:00
Calculating the Coronary Risk of Patients with Diabetes and Dyslipidemia: Can Discussing the Results Increase the Effectiveness of Statin Therapy? [245]
Ilka Lowensteyn, Steven Grover, Louis Coupal, Sylvie Marchand, Mohammed Kaouache. (Canada)
- 09:15
Predicting Cardiac Arrhythmias and Sudden Death among Diabetic Users of Arrhythmogenic Non-Antiarrhythmic Drugs [246]
Marie L De Bruin, Tjeerd P van Staa, Svetlana V Belitser, Hubert GM Leufkens, Arno W Hoes. (Netherlands)
- 09:30
The Risk of Myocardial Infarction and Case Fatality in Users Of Antidiabetics [406]
Mette Lena Olsen, Taco BM Monster, Soren P Johnsen, Joseph K McLaughlin, Henrik Toft Sorensen, Hans H Lervang, Jorgen Rungby. (Denmark)
- 09:45
Heart Failure and Hepatotoxicity Risks Associated with Thiazolidinedione Use [247]
Fran E Cunningham, Donald R Miller. (United States)

[C] Birth Defects (Amphitheater C)

- Moderators: *Sue West & Francoise Haramburu*
- 08:30
Use of Inhaled Corticosteroids during the First Trimester and the Risk of Congenital Malformations among Asthmatic Pregnant Women [248]
Lucie Blais, Marie-France Beauchesne, Évelyne Rey, Jean-Luc Malo, Amilie Forget. (Canada)
- 08:45
Delivery Outcome after the Use of Anti-Asthma Medication in Early Pregnancy: An Analysis from the Swedish Medical Birth Register (SMBR) [249]
Bengt Källén, Kristine Shields, Ann Strauss, Bengt-Erik Wiholm. (Sweden)
- 09:00
In-Utero Exposure to Antihistamines and the Risk of Congenital Hypospadias or Cryptorchidism in Male Births [250]
Tim Williams, Gwenda Hughes, Carlos Martinez. (United Kingdom)
- 09:15
Pregnancy Outcome Following Early Gestational Exposure to Leflunomide: The Otis Rheumatoid Arthritis in Pregnancy Study [251]
Christina D Chambers, Diana L Johnson, Glenda R Macaraeg, Kenneth L Jones. (United States)
- 09:30
Positive Predictive Value of Computerized Databases for Birth Defects in a Medicaid Population [252]
William O Cooper, Sonia Hernandez-Diaz, Wayne A Ray. (United States)
- 09:45
Development of a Surveillance and Signal Detection System To Monitor Medication Exposure during Pregnancy and Lactation [253]
Driss Oraichi, Anick Bérard. (Canada)

[D] Symposium: Decision-Making and Evidence Based Pharmacovigilance [254]

(Commission E1-E2)
Saad AW Shakir, Lesley Smith, Andrea Clarke. (United Kingdom)

[E] Symposium: How Do Drug Regulators Evaluate Risk Management Program in the Pre-Approval Stage of Drug Development? [255]

(Commission F1-F2)
Syed R Ahmad, Gunilla Sjolín-Forsberg, June M Raine, Ingemar Persson, Tamaki Fushimi. (United States)

[F] Workshop: The Best Pharmaceuticals for Children: Current and Future Activities [256]

(Commission D1)
Donald R Mattison, Tamar Lasky, Solomon Iyasu, Anne Zajicek, Julie Zito, Matthew W Reynolds. (United States)

[G] Workshop: Epidemiologic vs. Post-Marketing Spontaneous Report Data: Vive La Difference! [485]

(Commission D2)
William L Holden, Linda J Scarazzini, Gerald Faich. (United States)

10:00-10:30
Refreshment Break/Posters/Exhibits
(Espace Pluriel)



AGENDA-TUESDAY

TUESDAY, 24 AUGUST (cont.)

10:30-12:00

ANNUAL MEETING OF ISPE MEMBERS

(open to all participants) (Amphitheater A)

- **Annual Meeting of ISPE Members**

Susana Perez-Gutthann, FISPE, President

- **Induction of ISPE Fellows (FISPE)**

Thomas M. MacDonald, FISPE, Chair, Fellows Committee

Alejandro Arana Navarro
Anick Berard
Ulf Bergman
Robert T. Chen
Gerald A. Faich
Daniel Fife
Lourdes M. Frau
Gillian C. Hall
William N. Kelly

Stephen E. Kimmel
James G. Kotsanos
Kate L. Lapane
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Frank Wesley May
Nicholas Moore
Wayne Ray
Evelyn M. Rodriguez
Lewis H. Roht

Susan T. Sacks
Sebastian Schneeweiss
Cees Schep
Paul E. Stang
Andy S. Stergachis
Patricia Tennis
Robert Philip Wise

- **Awards Ceremony**

Student Awards

Presented by **Nicholas Moore**, FISPE, Chair, 2004 Scientific Program Committee

Best Methods Abstract: Frank de Vries, Pharmacoepidemiology and Therapeutics Program, Utrecht Institute for Pharmaceutical Sciences, *Inhaled Corticosteroid Induced Risk of Osteoporotic Fractures Confounded by Disease Severity in Asthma/COPD*. (505)

Third Best Abstract: Katia Verhamme, Erasmus Medical Center Rotterdam, *Non Steroidal Anti-Inflammatory Drugs Increase the Risk of Acute Urinary Retention - The Triumph Project*. (14)

Second Best Abstract: Jeroen Derijks, Pharmacoepidemiology and Therapeutics Program, Utrecht Institute for Pharmaceutical Sciences, *The Association between Antidepressant Use and Hypoglycemia and Hyperglycemia*. (41)

Edlavitch Award (Best Student Abstract): Wanning Xu, McGill University, *The Effects of Antidepressant Drugs on the Risk of Colorectal Cancer: A Population-Based Case-Control Study*. (39)

ISPE-PDS Prize

Presented by **Brian L. Strom**, FISPE, Regional Editor for the Americas, *Pharmacoepidemiology & Drug Safety*

Ronald D. Mann, Editor-in-Chief, *Pharmacoepidemiology & Drug Safety*

Jeremy Theobald, Managing Editor, *Pharmacoepidemiology & Drug Safety*

ISPE Honorary Lifetime Fellow

Presented by **Thomas M. MacDonald**, FISPE, Chair, Awards Committee

Recipient **Hugh H. Tilson**, FISPE

12:00-13:30

Lunch/Poster Session B/Viewing of Exhibits
(Espace Pluriel)

EuroDURG Poster Walk (open to all participants)
(Espace Pluriel)

ISoP Meeting (Amphitheater A)

12:15-13:15

Committee Meetings:

- **Development** (Commission D1)
- **Fellows** (Commission D2)
- **Bylaws & Policies** (Commission E1-E2)
- **Public Relations** (Commission F1-F2)
Open to all interested meeting participants.

13:30-15:00

CONCURRENT SESSIONS

[A] Endocrinology/Diabetes (Amphitheater A)

- Moderators: *Nancy Santanello & Denise Orwig*
- 13:30
The Increasing Proportion of Patients with Type 2 Diabetes Converting to Insulin Therapy in the UK [257]
Henrietta Mulnier, David Lovell, Ross Lawrenson. (United Kingdom)
- 13:45
Suboptimal Use of Angiotensin Converting Enzyme-Inhibitors and Angiotensin-II-Receptor Blockers in Elderly Patients with Diabetes [258]
Wolfgang C Winkelmayr, Sebastian Schneeweiss, Raisa Levin, Jerry Avorn. (United States)
- 14:00
Anti-Diabetic Drug Use and the Risk of Motor Vehicle Crash in the Elderly [259]
Linda Levesque, Brenda Hemmelgarn, Samy Suissa. (Canada)
- 14:15
Safety Profile of Repaglinide as Used in General Practice in England: Results of a Prescription-Event Monitoring Study [260]
Vanessa Marshall, Lynda V Wilton, Saad AW Shakir. (United Kingdom)
- 14:30
Post-Transplant Diabetes Mellitus in a Cohort of Elderly Kidney Recipients: A Comparison between Cyclosporin and Tacrolimus [261]
Héloïse Cardinal, Le Lorier Jacques. (Canada)
- 14:45
Australian General Practice Medical Records Validate Published Findings in the Oral Drug Treatment of Type 2 Diabetes [262]
Justin J Beilby, Leanne M Hobbs, Katherine M Duszynski, Carolyn Rutherford, John E Marley. (Australia)



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AGENDA-TUESDAY

TUESDAY, 24 AUGUST (cont.)

[B] Cardiovascular 4: Non Cardiac AE's Associated with Cardiovascular Treatment

(Amphitheater B)

• Moderators: *Ruby Castilla & Mathieu Mulimard*

• 13:30

Effects of Beta-Blockers on Hemorrhagic Events in Congestive Heart Failure Patients on Warfarin [263]

Dan Berlowitz, Susan A Oliveria, Donald R Miller, James Rothendler, Andres Gomez-Camirero, Francesca Cunningham. (United States)

• 13:45

Angioedema Risk with Use of Angiotensin II Receptor Blockers [264]

Donald R Miller, Susan Oliveria, Graeme Fincke, Dan Berlowitz, David Lilienfeld. (United States)

• 14:00

Hepatic but Not Myopathic Adverse Events Are Significantly Associated with Statin Use: Results from a Meta-Analysis of HMG CoA Reductase Inhibitor Trials Worldwide from 1982 through 2003 [265]

David L McClure, Robert Valuck, Morton Glanz, John E Hokanson. (United States)

• 14:15

Survival Analysis To Examine the Risk of a Recurrent Stroke of Patients in the General Practice Research Database [266]

Duncan Short, Stephen Chapman. (United Kingdom)

• 14:30

Drug Interactions and Risk of Acute Bleeding Leading to Hospitalization or Death in Patients with Chronic Atrial Fibrillation (AF) Treated with Warfarin [267]

Christiane Gasse, Jennifer Hollowell, Christoph R Meier, Joachim Troost, Verena Schneider, Walter E Haefeli. (Germany)

• 14:45

Incidence Estimation of Hepatotoxicity among Atorvastatin, Lovastatin, Pravastatin, and Simvastatin Users in Clinical Practice [268]

Yooni Kim, Yoon Jun Kim, Joo Sung Kim, Seung Mi Lee, Nam Kyung Choi, Hwa Jung Kim, Byung Joo Park. (Republic of Korea)

[C] HOT TOPIC: SSRIs for Depression in Children: Efficacy, Safety and Policy Issues

(Amphitheater C)

SSRI Use in Dutch, German and United States' Youths: Cause for Concern?

Julie M. Zito, Joerg Fegert, Lolkje van den Berg (United States, Germany, Netherlands)

The Relative Risk of Nonfatal Suicidal Behavior in Patients Treated with Amitriptyline, Fluoxetine, or Paroxetine Compared with Those Treated with Dothiepin (JAMA 2004;292:338-343)

Hershel Jick, James A. Kaye, Susan Jick (United States)

Antidepressants and Risk of Suicide

David Healy (United Kingdom)

A Clinical Researcher's Perspective: Who to Medicate and When

Adelaide Robb (United States)

[D] Joint ISPE-EuroDURG Symposium: Experiences with the International Collection of Drug Consumption Data

(Commission E1-E2)

• Chairs: *Joerg Hasford (Germany) & Monique Elseviers (Belgium)*

Robert Vander Stichele (Belgium), *Experience with Antibiotic Consumption Data Collection in Europe: The ESAC Project*

Erik Van Ganse (France), *Experience with Drug Consumption Monitoring in the Public Health Care Systems of Europe (The EURO-MED-STAT project)*

Sean Hennessy (United States), *The Collection of Drug Consumption Data at the National Level in the United States.*

Diabetes Care in Ireland - Equity Accross Regions? [269]
Cara Usher, Kathleen Bennett, Feely John. (Ireland)

Do We Need Bendectin? Trends in the Use of Anti-Emetics Since 1976 in the US and Canada [270]
Carol Louik, Sonia Hernandez-Diaz, Martha M Werler, Allen A Mitchell. (United States)

[G] Symposium: ICH Guidance for Pharmacovigilance Planning- Is It a True Guidance or Hindrance to Effective Risk Management?

(Commission D2)

• Chair: *Kasia Petchel*

This session will explore strength and weaknesses of the proposed ICH Pharmacovigilance Planning and will provide perspectives of this proposal as they relate to US FDA recently released Guidance documents to Risk Management. The session speakers will provide insights into ICH document from academic and scientific perspectives and Industry representative will comment from business perspectives. Lastly there will be a panel discussion with opportunities to answer audiences questions

• Panelists: **Miles Braun**, *US FDA*,
Brian Strom, *University of Pennsylvania*,
Industry representative, *TBD*

15:00-15:30

Refreshment Break/Poster/Exhibits (Espace Pluriel)

[E] Symposium: Automatic Signal Detection Methods in Pharmacovigilance: A Practical Point of View [272]

(Commission F1-F2)

• *Stephen Evans, Emmanuel Roux, Frantz Thiessard, Pascale Tubert-Bitter, Annie Fourier-Reglat. (France)*

[F] Workshop: To Case-Control or Cohort, Can We Control for Confounding by Making the Right Choice? [273]

(Commission D1)

• *Nada Boudiaf, Nawab Qizilbash, Victor A Kiri, Maurille Feudjo-Tepie. (United Kingdom)*



AGENDA-TUESDAY

TUESDAY, 24 AUGUST (cont.)

15:30-17:00

CONCURRENT SESSIONS

[A] Hormones 1 ED, OC, and Pregnancy

(Amphitheater A)

- Moderators: *Willy Blumentals & Michel Andrejak*
- 15:30
Antibiotics and Oral Contraceptive Failure [274]
Sonia Hernandez-Diaz, Lolkje TW de Jong-van den Berg, Allen A Mitchell. (United States)
- 15:45
First Use of Oral Contraceptives before and after the Pill Scare in the UK [275]
Richard DT Farmer, Corinne S de Vries, Helen E Seaman. (United Kingdom)
- 16:00
Medications Prescribed before and during Early Pregnancy in a Cohort of 81,975 Mother-Baby Pairs: A Population Based Study Using the Automated Data of the General Practice Research Database [276]
Janet R Hardy, Brian P Leaderer, Theodore R Holford, Gillian C Hall, Michael B Bracken. (United States)
- 16:15
Pregnancy Outcome in Women Using Atypical Antipsychotic Drugs: A Prospective Comparative Study [277]
Adrienne Einarson, Kate McKenna, Lynda Wilton, Orna Diav-Citrin, Saad Shakir, Gideon Koren. (Canada)
- 16:30
Assessing Self-Esteem, Confidence, and Relationships in Men with Erectile Dysfunction Treated with Sildenafil Citrate: Combined Analysis of 2 Double-Blind, Placebo-Controlled Trials [278]
Joseph C Cappelleri, Stanley E Althof, Michael P O'Leary, Sandeep Duttgupta, Jessica Bowler, Arthur R Crowley, Richard L Siegel, Li-Jung Tseng, Dale B Glasser. (United States)
- 16:45
Assessing the Association between Undiagnosed Cardiovascular Risk Factors and Erectile Dysfunction among Men without Cardiovascular Disease: The Cansed Study [279]
Ilka Lowensteyn, Steven Grover, Mohammed Kaouache, Sylvie Marchand, Louis Coupal, Emidio DeCarolis, Isabelle Defoy. (Canada)

[B] GI-Related Studies (Amphitheater B)

- Moderators: *Marc Bardou & Jordi Castellsague*
- 15:30
The Association between Acid-Suppressing Drugs and Acute Pancreatitis: Results from a Swedish Case-Control Study [280]
Anders Sundström, Kerstin Blomgren, Lars Alfredsson, Bengt-Erik Wiholm. (Sweden)
- 15:45
Gastrointestinal Adverse Reactions to Drugs in Children in Italy [281]
Francesca Menniti-Ippolito, Giuseppe Traversa, Roberto Da Cas, Francesco Vetrano, Giovanni Saggiomo, Francesco Menna, Luciano Sagliocca, Nicola Pirozzi, Corrado Cecchetti, Gennaro Viviani, Vincenzo Iori, Umberto Raucci. (Italy)
- 16:00
Antibiotic Use and Risk for Irritable Bowel Syndrome [282]
Lisa Mahoney, Robert L Davis, Andrew Feld. (United States)
- 16:15
Use of Gastric Acid-Suppressive Drugs and the Risk of Community-Acquired Pneumonia [283]
Robert JF Laheij, Miriam CJM Sturkenboom, Robert-Jan Hassing, Jeanne P Dieleman, Bruno HCh Stricker, Jan BMJ Jansen. (Netherlands)
- 16:30
Upper Gastrointestinal Bleeding and Antiplatelet Drugs [284]
Luisa Ibanez, Joan-Ramon Laporte, Roberto Leone, Lourdes Vendrell, Xavier Vidal. (Spain)
- 16:45
Statins and Risk of Acute Pancreatitis: A Population-Based Case-Control Study [285]
Estrid Muff Munk, Bente Norgård, Jacob Jacobsen, Soren Paaske Johnsen, Henrik Toft Sorensen. (Denmark)

[C] Vaccines: Evaluating Vaccines

(Amphitheater C)

- Moderators: *Robert Wise, FISPE, & Elisabeth Loupi*
- 15:30
Determining Risk of Multiple Sclerosis after Hepatitis B Vaccine: Time Since Vaccination and Source of Data [286]
Frank DeStefano, Eric S Weintraub, Robert T Chen. (United States)
- 15:45
Do Live Viral Vaccinations (Other Than Smallpox) Increase the Risk of Cardiomyopathy in Adults? [287]
Alena Khromava, Phillip Rhodes, David Shay, David Swerdlow, Frank Destefano, Robert Chen. (United States)

- 16:00
Vaccination Campaign Against Meningococcal C Disease in Aquitaine: Safety Monitoring [288]
Anne Laribiere, Ghada M Miremont-Salame, Hadrien Reyre, Abdelilah Abouelfath, Bernard Begaud, Nicholas D Moore, Francoise Haramburu. (France)
- 16:15
Post-Licensure Surveillance of the First Live, Cold-Adapted Influenza Vaccine in the U.S. [289]
Hector S Izurieta, Penina Haber, Robert Ball, Miles Braun, Robert Wise, Douglas Pratt, Anne McMahon, Soju Chang, John Iskander, VAERS Team. (United States)
- 16:30
Annual Revaccination Against Influenza Effectively Reduces Mortality Risk in Community Dwelling Elderly. Results from a 6-Year Cohort Study [290]
Bettie CG Voordouw, Miriam CJM Sturkenboom, Jeanne P Dieleman, Theo Stijnen, Deric J Smith, Johan van der Lei, Bruno BCh Stricker. (Netherlands)
- 16:45
Effectiveness of Vaccination in Preventing Varicella: Two Complementary Long-Term Surveillance Studies [291]
Patricia Saddier, Alexander Nikas, Paula Ray, Paul Coplan, Edwin Lewis, Henry Shinefield, Steve Black, Harry Gues. (United States)



AGENDA-TUESDAY/WEDNESDAY

TUESDAY, 24 AUGUST (cont.)

[D] EuroDURG: The Use of Quality Indicators: How Good Are We at Measuring Prescreening Quality? [293]

(Commission E1-E2)

- Chairs: *Flora Haaijer-Ruskamp (the Netherlands)*, & *Morten Anderson (Denmark)*

Steve Chapman (United Kingdom), *Indicators Use and Appropriateness*

Morten Andersen (Denmark), *Data construction and validity*

Colleen Metge (Canada), *Quality Indicators the North American Way*

Lynn Weekes (Australia), *Quality Indicators down under*

Regis Blais (France), *Can Feedback to Physicians and Pharmacists about Their Patients' Use of Asthma Medications Improve Conformity to Clinical Guidelines?* [292]

[E] Symposium: The Control of Time-Dependent Confounding or Why Conventional Methods May Mislead Us [294]

(Commission F1-F2)

- *Alexander M Walker, Miguel A Hernán, Jonathan A Sterne, James M Robins. (United States)*

[F] Symposium: European vs. American Approach to Assessing Human Teratogens - Is One Better than the Other? [295]

(Commission D1)

- *Bengt-Erik Wiholm, Carlos Martinez, Allen Mitchel, Christina Chambers. (United States)*

17:00-18:00

Invited Speaker
(Amphitheater A)

- **Samy Suissa**, McGill University, *Time-Dependent Measures in Pharmacoepidemiology*

18:00-18:30

ISPE Scientific Program Committee, 2005
(Amphitheater A)

open to all ISPE members

WEDNESDAY 25 AUGUST 2004

07:00-08:00

Poster Set-up: Session C (Espace Pluriel)

Exhibits (Espace Pluriel)

Centers for Education & Research on Therapeutics (CERTs) Breakfast Roundtable (Sofitel Hotel)
open to all participants

07:00-17:00

Registration (Main Hall)

Speaker Ready Room (G-1)

07:00-08:15

Committee Meeting

- **Global Development** (Commission F1-F2)

08:30-10:00

CONCURRENT SESSIONS

[A] Methodology 3: Various Methods

(Amphitheater A)

- Moderators: *David Lilienfeld, FISPE & Paula Martins*

• 08:30

Measuring Incidence Rates Using GPRD: How Soon after Registration Do Incidence Rates Reach Baseline Levels? [459]

James D Lewis, Warren B Bilker, Rachel Weinstein, Brian L Strom. (United States)

• 08:45

Exploring the Clinical Data Gap between Phase Iii and Phase Iv Clinical Trials: Evaluation of Etanercept in Rheumatoid Arthritis (RA) [460]

Pendar Farahani, Kathy Gaebel, Ed Wang, Lehana Thabane, Mitchell Levine. (Canada)

• 09:00

Accuracy of ICD-9 Diagnosis Code "410" To Identify Episodes of Hospitalizations for Acute Myocardial Infarction in the RAMQ Medical Claims Database [461]

Amir Abbas Tahami Monfared, Elham Rahme, Jacques LeLorier. (Canada)

• 09:15

Cross-Sectional Utility Assessment Using the Health Utilities Index in a Trial of Statins in Elderly Patients [462]

Wolfgang C Winkelmayr, Joshua S Benner, Sebastian Schneeweiss, Philip S Wang, Joseph D Jackson, Jerry Avorn. (United States)

ADMISSION BY
TICKET ONLY

Evening at the Chateau Giscours

ISPE gratefully acknowledges the grant from **Ingenix** in support of transportation services for this event.

A delightful night of wine, music, food and conversation. Buses will begin to depart from the Bordeaux Conference Center at 19:00. The last bus will depart from Chateau Giscours at 23:00.

Admission: By ticket only. Tickets will be included in the registration packet. Tickets will be needed to board bus.

[Cash bar]



AGENDA-WEDNESDAY

WEDNESDAY 25 AUGUST 2004 (cont.)



- 09:30
One-Compartment Model Approach to the Modeling of Time-Varying Covariates with Lagged Effects [463]
David R Gagnon, Melissa M Young, Richard E Scranton, Kerri E Snyder, Margaret R Stedman, Louis D Fiore. (United States)
- 09:45
The Concept of the 'Percent Wasted Patients' in Preventive Health Strategies [464]
Héloïse Cardinal, Amir Abbas Tahami Monfared, Marc Dorais, Jacques Le Lorier. (Canada)

[B] NSAIDs2 (COX2) (Amphitheater B)

- Moderators: *Rami Ben-Joseph & Carlos Martinez*
- 08:30
Gastrointestinal Safety of Rofecoxib and Celecoxib Versus NSAIDs among Patients on Low Dose Aspirin [465]
Elham Rahme, Marc Y Bardou, Kaberi Dasgupta, Youssef Toubouti, Alan N Bardkun. (France)
- 08:45
The Impact of NSAID or COX-2 Use on the Initiation of Antihypertensive Therapy [466]
Marianne Ulcickas Yood, Emmeline Watkins, Karen Wells, Gena Kucera, Christine C Johnson, Eva Lydick. (United States)
- 09:00
Cardiovascular Risk of Selective Cyclooxygenase-2 Inhibitors Compared to Other Nonsteroidal Anti-Inflammatory Agents: An Observational Study of a Medicaid Population [467]
Fadia T Shaya, Steven W Blume, Christopher M Blanchette, C Daniel Mullins, Matthew R Weir. (United States)
- 09:15
Association between Rofecoxib, Diclofenac/Ibuprofen and Hospitalization for Acute Myocardial Infarction [468]
Elham Rahme, Sheldon X Kong, Douglas J Watson, Youssef Toubouti, Jacques LeLorier. (Canada)
- 09:30
Exposure Misclassification as a Result of Free Sample Drug Utilization in Automated Claims Databases and Its Effect on a Pharmacoepidemiology Study of Selective Cox-2 Inhibitors [469]
Susanna Jacobus, Sebastian Schneeweiss, K Arnold Chan. (United States)
- 09:45
Gastrointestinal and Cardiovascular Characterization of Users of Valdecoxib and Other COX-2 Specific Inhibitors [470]
Victoria Gimeno, Jordi Castellsague, Andrew Maguire, Susan Eaton, Lisa J McQuay, Xiaolei Zhou, Susana Perez-Gutthann. (Spain)

[C] Burden of Illness, Economics, and Devices (Amphitheater C)

- Moderator: *Byung-Joo Park, FISPE*
- 08:30
Systemic Lupus Erythematosus: Calculating the Prevalence of Relapsing-Remitting Disease Using Left-Censored Data [471]
Alison L Nightingale, Corinne S de Vries, Richard DT Farmer. (United Kingdom)
- 08:45
Treatment Patterns for Hypertension, Dyslipidaemia, and Both Conditions in the United Kingdom: 1997 to 2001 [472]
Thomas M MacDonald, Steve V Morant, Christine L Baker, Essy Mozaffari. (United Kingdom)
- 09:00
Cardiovascular Morbidity and Mortality among Persons with Chronic Obstructive Pulmonary Disease [473]
Cynthia de Luise, Stephan F Lanes, Suellen M Curkendall, Judith K Jones, Lee Lanza, Stephen Sidney. (United States)
- 09:15
Cost Effectiveness Analysis of Aspirin for Acute Ischaemic Stroke in Patients with Atrial Fibrillation [474]
Penkarn Kanjanarat. (United States)
- 09:30
Increased Incidence of Myocardial Infarction and Stroke among Patients with Ankylosing Spondylitis: Results from the General Practice Research Database [475]
Michael N Cook, Douglas J Watson, Nicola J Goodson, Deborah PM Symmons. (United States)
- 09:45
Increased Incidence of Lymphoma among Patients with Rheumatic Diseases Based on Automated Insurance Claims Information [476]
Catherine B Johannes, Gary A Schneider, Alexander M Walker, Dawn Viveash, Wayne J Wallis. (United States)



AGENDA-WEDNESDAY

WEDNESDAY 25 AUGUST 2004 (cont.)

[D] Prescribing Utilization 4: Moms, Kids, and Plants (Commission E1-E2)

- Moderators: *Sybil Eng & Peter Mol*
- 08:30
CHAPTER (Child and Adolescence Psychotropic Medication Therapy Evaluation Research): A Drug Utilisation Study of Antidepressants in Children and Adolescents Using the General Practice Research Database [477]
Macey L Murray, Corinne S de Vries, Ian CK Wong. (United Kingdom)
- 08:45
Accutane Prescription Trends before and after the Issuance of the DHPL in March 2001 in Canada [478]
Jun Zhang, Vicky Hogan, David Clapin. (Canada)
- 09:00
Medication Use during Pregnancy: Data from the Avon Longitudinal Study of Parents and Children [479]
Judith E Headley, the ALSPAC Study Team. (United Kingdom)
- 09:15
Maternal Factors Associated with the Use of Herbal Treatments in Pregnancy [480]
Carol Louik, Sonia Hernandez-Diaz, Martha M Werler, Allen A Mitchell. (United States)
- 09:30
Drug Prescription in Pregnancy - Analysis of a Large German Statutory Sickness Fund Population [481]
Veronika Egen-Lappe, Joerg Hasford, Martina Koethemann. (Germany)
- 09:45
Not All Is Green That Grows - Use of Herbal Remedies in a Randomly Selected Control Population in Sweden 1995-1998 [482]
Matty Persson, Anders Sundström, Bengt-Erik Wiholm. (Sweden)

[E] Special session presented by ISoP Breaking out of the Bubble: What Have We Learned about Risk Communication? [483] (Commission F1-F2)

- *Elizabeth Loupi, Brian Edwards, David Salisbury, Kasia Petchel. (United Kingdom)*

[G] Workshop: Development and Implementation of Risk Management Program for LOTRONEX (trade) - Alosetron HCL [484]

(Commission D1-D2)

- *Elizabeth Andrews, Suzanne F Cook, David P Miller, Alexander M Walker, Jerry Avorn, Jerry Gurwitz, Patricia Tennis, Andrew Feld. (United States)*

10:00-10:30

Refreshment Break/Posters/ Exhibits

(Espace Pluriel)

10:30am-Noon

CONCURRENT SESSIONS

[A] Methodology 4: Session from Hell ISPE 20th Anniversary Session

(Amphitheater A)

- Moderators: *Annie Fourrier-Reglat & Yola Moride, FISPE*
- 10:30
On Detecting Signals of Drug-Drug Interactions in a Spontaneous Reports Database [486]
Bharat T Thakrar, Sabine Borel Grundschober, Lucette Doessegger. (United Kingdom)
- 10:45
Evaluating Uses of Data Mining Techniques in Propensity Score Estimation: A Simulation Study [487]
Soko Setoguchi, M Alan Brookhart, Robert J Glynn, Sebastian Schneeweiss. (United States)
- 11:00
Assessing Drug Uptake and Adverse Effects in the Real World: The Case of Spironoladone and RALES
David Juurlink, Muhammad Mamdani, Alexander Kopp, Andreas Laupacis, and Donald Redelmeir. (Canada)
- 11:15
Validation of Cancer Incidence Rates Obtained from a U.S. Managed Care Database [489]
Anne C Deitz, Carol E Koro, Samantha A St. Laurent, Monika Stender. (United States)
- 11:30
The Dilution Bias: Effect of Drug Marketing Age on Prrr Alerts Generated by Acute Changes in Reporting Patterns in Spontaneous Reporting Databases [490]
Nicholas Moore, Frantz Thiessard. (France)
- 11:45
Using Disproportional Analysis as a Tool To Explore Severe Drug-Drug Interactions in AERS Database [491]
Xionghu Yang, David M Fram. (United States)



AGENDA-WEDNESDAY

WEDNESDAY 25 AUGUST 2004 (cont.)

[B] Hormones 2: Women's Health, HRT, Osteoporosis

(Amphitheater B)

- Moderators: *Michael Steinbuch & Carmen Kreft-Jais*
- 10:30
How Has the Use of Postmenopausal Hormone Therapy Changed Since the Women's Health Initiative Findings? [495]
Judith P Kelly, David W Kaufman, Lynn Rosenberg, Allen Mitchell. (United States)
- 10:45
Effect of the Women's Health Initiative Study on the Prescribing Patterns of HRT and Bisphosphonate Preparations [494]
Mary Teeling, Kathleen Bennett, Cara Usher, John Feely. (Ireland)
- 11:00
The Effect of Various Hormone Replacement Therapy Formulations on the Incidence of Colorectal Cancer Subsites in Postmenopausal Women [492]
Ilona Csizmadi, Jean-Paul Collet, Andrea Benedetti, Jean-Francois Boivin, James A Hanley, MaryRose Stang. (Canada)
- 11:15
Breast Cancer and Hormone Replacement Therapy: Fact or Fiction [493]
Richard DT Farmer, Corinne S de Vries. (United Kingdom)
- 11:30
The Burden and Management of Osteoporosis: A Missed Opportunity [496]
Colleen J Metge, William D Leslie, Brent Kvern, Lori-Jean Manness, Marina Yogendran, C K Yuen. (Canada)
- 11:45
The Association between Hormone Replacement and Hip Fractures in Postmenopausal Women: A Case-Control Study in UK Primary Care [497]
Corinne S de Vries, Annie Hutchison, Richard DT Farmer. (United Kingdom)

[C] Miscellaneous 2: Aging, Lipids and Risk

(Amphitheater C)

- Moderator: *Stephen Kimmel, FISPE*
- 10:30
Incidence of Severe Myopathy and Rhabdomyolysis Following Use of HMG-CoA Reductase Inhibitors or Fibrates [498]
David J Graham, Judy A Staffa, Stephanie D Schech, Susan Andrade, Deborah Shatin, Lois La Grenade, Michael Goodman, K Arnold Chan. (United States)
- 10:45
A Case-Control Study of the Risk of Polyneuropathy Associated with Statin (HMG-COA Reductase Inhibitors) Use in Diabetics [499]
Cherrie Mitchell-Mauntell, James Wilson, David Bretzke, David Bennett, Graham Denise, Trice Shana, Remund Daniel. (United States)
- 11:00
A Population-Based Case-Control Study of the Use of Statins and the Risk of Dementia [500]
Anne Vingaard Olesen, Soren Paaske Johnsen, Henrik Toft Sorensen. (Denmark)
- 11:15
Adverse Events among Nursing Home Residents with Alzheimer's Disease and Psychosis [501]
Susan A Oliveria, Rosa Liperoti, Gilbert L'Italien, Klaus Pugner, Allan Safferman, William Carson, Kate Lapane. (United States)
- 11:30
Declining Use of Preventive Drugs at the End of Life and Implications for Observational Studies [23]
Robert J Glynn, Sebastian Schneeweiss, Til Sturmer, Philip S Wang, Jerry Avorn. (United States)
- 11:45
The Prevalence and Management of Pain among Older Home Care Clients [503]
Charlemagne C Victorino, Colleen J Maxwell, Dawn Dalby, John P Hirdes, David B Hogan, Scott B Patten. (Canada)

[D] Pot-Pourri: Oysters, Foie Gras, and Armagnac

(Commission E1-E2)

- Moderators: *Nicholas Moore, FISPE & Jean-Louis Montastruc*
- 10:30
Neural Network Models Performance in Comparison with Logistic Regression Models for Predicting Death after Cardiac Surgery [504]
Joumana Ghosn, Benoit DeVarenes, Pierre-Luc Bernier, Elham Rahme. (Canada)
- 10:45
Inhaled Corticosteroid Induced Risk of Osteoporotic Fractures Confounded by Disease Severity in Asthma/COPD [505]
Frank de Vries, Tjeerd Pieter van Staa, Madelon Bracke, Jan-Willem Lammers, Cyrus Cooper, Bert Leufkens. (Netherlands)
*** Student Award Recipient-Best Methods Abstract**
- 11:00
Use of Drugs with Central Anticholinergic Effects and Cognitive Performance in the Elderly: Results from the Paqid Study [506]
Nathalie Lechevallier-Michel, Annie Fourier-Reglat, Colette Fabrigoule, Jean-Francois Dartigues. (France)



AGENDA-WEDNESDAY

WEDNESDAY 25 AUGUST 2004 (cont.)

- 11:15
Educational Program To Reduce Noncompliance after Renal Transplantation: Results of a Randomized Controlled Study [507]
Nathalie Breu-Dejean, Lionel Rostaing, Maryse Lapeyre-Mestre, Bernadette Roge, Dominique Durand. (France)
- 11:30
Statin Use in the Secondary Prevention of CHD: Do Real Population Differ from Clinic Trial Patients in Socio-Demographic and Outcome? [508]
Li Wei, Christopher Baetlett, Shah Ebrahim, Paul Dieppe, Peter G Davey, Frank M Sullivan, Thomas M MacDonald. (United Kingdom)
- 11:45
Reports of Pulmonary Embolism and Deep Vein Thrombosis from a Prescription Event Monitoring Study of Yasmin™ in England [509]
Hilary M Pearce, Deborah Layton, Lynda V Wilton, Saad AW Shakir. (United Kingdom)

[E] Special session sponsored by the Dutch Steering Committee on Orphan Drugs - Pharmacoeconomics Adds to Orphan Drug Development [510] (Commission F1-F2)

- Moderators: *Alejandro Arana, FISPE, & Hubert Leufkens, FISPE*
- **Segolene Ayme**, Orphanet, *What Epidemiological Data Are Lacking in OD Development and What Are the Possible Solutions?*
- **Marlene Haffner**, Office of Orphan Products Development, FDA, USA, *Regulatory Aspects of Epidemiology in OD Development.*
- **Carles Blanch**, Novartis Pharma, Spain, *The Glivec ODA Epidemiological Challenge.*

[F] Pharmacoeconomics and the Law: Standards of Evidence for Causality in Research, Regulation, and the Courts [511] (Commission D1-D2)

- **Jerry Avorn, John Restaino, David Graham, Stephan Lanes (United States)**
- The session will begin with consideration of how standards of evidence for decisions about efficacy differ from those used in decisions about risk. We will then evaluate case studies of several suspected or well-documented adverse drug events, examining them from the perspectives of academia, government, the pharmaceutical industry, practitioners, and the courts. We will discuss how the standards of evidence applied can differ in each of these settings, and how those varying approaches can lead to different conclusions and actions.

Noon-13:30pm
Lunch/Posters/Exhibits (Espace Pluriel)

ISPE Board of Directors Luncheon - By invitation (Sofitel Hotel)

13:30-14:30

Invited Speaker (Amphitheater A)

- **Lucien Abenheim**, former Director General of Health, French Ministry of Health, *The Role of Pharmacoeconomics in Shaping a National Drug Policy*

12:00-14:00

EuroDURG Executive Committee (Commission F1-F2)

14:30-16:45

Hot Topic Session: Postmenopausal Hormone Therapy and the Risk of Cardiovascular Disease

(Amphitheater A)

- Chairs: *Miguel Hernan & Dominique Costagliola*

Lynn Rosenberg, *What We 'Knew' About Female Hormones and MI Before the Women's Health Initiative (WHI) Study (512)*

Samy Suissa, *The Women's Health Initiative Study: How Randomized Trials Can Turn Into Observational Studies*

Stephen Evans, *Myths and Hype about Hormone Therapy and Cardiovascular Disease. A European View*

James Robins, *Methodological Approaches for Re-analyzing Observational Cohort Studies of Hormone Therapy as a Nested Sequence of Randomized Trials*

16:45-17:00

The Final Word (Amphitheater A)

- **Wayne Ray, FISPE**, Chair, 2005 Scientific Program Planning Committee

17:00

Adjournment of the 2004 ISPE Annual Meeting

