

***1st International Conference on Therapeutic Risk
Management & 19th International Conference on
Pharmacoepidemiology***

AGENDA

As of August 14, 2003

WEDNESDAY, AUGUST 20

9:00am-10:00am ISPE Finance Committee (Philadelphia South)

10:30am-12:00pm ISPE Strategic Planning Task Force (Philadelphia South)

12:30pm-5:00pm ISPE Board of Directors Meeting (Philadelphia South)

6:30pm-10:00pm Board of Directors Dinner (By Invitation Only)

THURSDAY, AUGUST 21

7:30am-7:00pm **Registration (Mezzanine Foyer)**

PRE-CONFERENCE EDUCATIONAL SESSIONS

8:00am-12:30pm **INTRODUCTION TO PHARMACOEPIDEMIOLOGY**
(Conference Center Ballroom)
Jacques LeLorier, FISPE, Chair

8:00am-9:00am **Sebastian Schneeweiss: *Case-control studies***

9:00am-10:00am **Fadia T. Shaya: *Role of epidemiology in pharmaceconomics***

10:00am-10:30am **Break**

10:30am-11:30am **Jerry Avorn, FISPE: *Drug use studies***

11:30am-12:30pm **Judith K. Jones, FISPE: *A primer for risk management: who, what, why and how?***

12:30pm-1:30pm **Lunch on your own**

1:30pm-5:30pm **ADVANCED TOPICS IN PHARMACOEPIDEMIOLOGY***
(Conference Center Ballroom) – Registration Required*
Jacques LeLorier, FISPE, Chair

1:30pm-2:30pm **Alan Lyles & Fadia T. Shaya: *Formulary decision methodology in the context of health system costs and insurance trends***

2:30pm-3:30pm **Sheila Weiss Smith, FISPE: *Person-time adjusted case-control study design***

3:30pm-4:00pm **Break**

4:00pm-5:00pm **Robert Gross: *Measurement of adherence to pharmacotherapy: why, how, and then what?***

5:00pm-6:00pm **James D. Lewis: *Neoplastic complications of medical therapy: is it ever possible to separate drug effects from confounding by indication?***

***Admission to Advanced Topics:** By ticket only. Tickets will be included in registration packet for those who have registered for this session.

- 2:00pm-5:00pm** **Centers for Education and Research in Therapeutics (CERTs) Steering Committee** (Salon 10)
Open to interested meeting participants
- 6:30pm-8:00pm** **Academic Showcase/Welcome Reception** (Wyndham A)
Cash Bar

FRIDAY, AUGUST 22

- 6:00am-7:00am** **Exhibitor Move-in** (Conference Center/Ballroom)
- 7:00am-8:00am** **Poster Set-up: Session A** (Conference Center/Ballroom)
Continental Breakfast/Exhibits (Conference Center/Ballroom)
- 7:00am-5:00pm** **Registration** (Mezzanine Foyer)
Speaker Ready Room (Salon 8)
- 7:00am-8:00am** **ISPE Committee Meetings**
(Open to all interested ISPE Members)
Global Development (Seminar A)
Education (Parlor A)
- 8:30am-10:00am** **OPENING SESSION** (Wyndham A/B)
Welcome
Sean Hennessy, FISPE, Chair, Scientific Program Committee

Presidential Address
Thomas M. MacDonald, FISPE, President, ISPE

Keynote Address
Robert M. Califf: *A system goal: benefit the patient, manage the risk*
- 10:00am-10:30am** **Refreshment Break/Viewing of Posters & Exhibits**
(Conference Center/Ballroom)
- 10:30am-12:00pm** **CONCURRENT SESSIONS**

[A] SYMPOSIUM: Managing Risks of FDA- Regulate Products [1] (Wyndham A)
Moderator:
Hugh H. Tilson, FISPE

Panelists:
Steven Galson
Susan Ellenberg

David Feigal

**[B] PREGNANCY OUTCOMES –Contributed Papers
(Wyndham B)**

Moderators:

Dianne L. Kennedy & Sheila Weiss Smith, FISPE

**10:30 AM Selective Serotonin Reuptake
Inhibitor Use During Pregnancy and Preterm Delivery
[2]**

Christina Chambers, Sonia Hernández-Díaz, Kenneth L
Jones, Allen A Mitchell, FISPE. (United States)

**10:45 AM Adverse Pregnancy Outcomes in
Women Exposed to Acyclovir during Pregnancy: A
Population-Based Observational Study [3]**

Chaveewan Ratanajamit, Mette V Skriver, Peter Jepsen,
Virasakdi Chongsuvivatwong, Jorn Olsen, Henrik T
Sorensen. (Denmark)

**11:00 AM Risk of Infantile Hypertrophic
Pyloric Stenosis after Maternal Postnatal Use of
Macrolides [4]**

Mette V Skriver, Henrik T Sorensen, Lars Pedersen, Helle
Larsen, Finn Ebbesen, Henrik C Schonheyder. (Denmark)

**11:15 AM Adverse Birth Outcomes in Users
of Sulfamethizole during Pregnancy: A Population-
Based Observational Study [5]**

Mette Norgaard*, Chaveewan Ratanajamit, Mette V
Skriver, Peter Jepsen, Henrik C Schonheyder, Henrik T
Sorensen. (Denmark) **Recipient of Edlavitch Award for
Best Student Abstract*

**11:30 AM Relative Risk of Preeclampsia in
Pregnancies Supported by Infertility Treatments [6]**

Sonia Hernández-Díaz, Martha W Werler, Carol Louik,
Allen A Mitchell, FISPE. (United States)

**11:45 AM The Risk of Congenital
Abnormalities in Children Born to Women with
Ulcerative Colitis: A Population-Based Case-Control**

Study [7]

Bente Nørgård, Erzsebet Puho, Lars Pedersen, Andrew E Czeizel, Henrik Toft Sørensen. (Denmark)

**[C] USE & EFFECTS OF PSYCHOTROPICS -
Contributed Papers (Wyndham C)**

Moderators:

Douglas Steinke & Daniel Fife

- 10:30 AM** **Persistence in Ambulatory Use of Atypical Antipsychotic Therapy [8]**
Dan Cooper, Jocelyne Moisan, Jean-Pierre Gregoire, Michel Gaudet, Belkacem Abdous. (Canada)
- 10:45 AM** **Suboptimal Antidepressant Use in the Elderly [9]**
Philip S Wang, Robert J Glynn, Helen Mogun, Jerry Avorn, FISPE. (United States)
- 11:00 AM** **Methylphenidate Use in Children and Adolescents [10]**
Ying Fen Hsia, Corinne S de Vries, Richard DT Farmer. (United Kingdom)
- 11:15 AM** **Compliance with Methylphenidate in Children as Reported by Parents [11]**
Jacqueline G Hugtenburg, Ivo Witte, Eibert R Heerdink. (Netherlands)
- 11:30 AM** **Utilisation Pattern of Triptans 1992-1999: A Prescription Database Study [12]**
Morten Andersen, David Gaist, Jens Sondergaard. (Denmark)
- 11:45 AM** **Triptan Use Is Not Associated with Increased Risk of Severe Vascular Events in Migraine Patients [13]**
Priscilla Velentgas, J Alexander Cole, Jingping Mo, Carolyn R Sikes, Alexander M Walker, FISPE. (United States)

[D] INTERVENTIONS, UTILIZATION AND SPECIAL POPULATIONS – Contributed Papers (Philadelphia North)

Moderators:

K. Arnold Chan, FISPE & Nicholas M. Moore

- 10:30 AM Medication Use in the U.S. Pediatric Population: The Slone Survey [14]**
Allen A Mitchell, FISPE, Judith P Kelly, Louis Vernacchio, David W Kaufman. (United States)
- 10:45 AM Incidence Based Utilization Study of Patients with Severe Hemophilia-A in Toronto, Canada [15]**
Harald E Heemstra, Tom Zwaan, Michiel EH Hemels, B Feldman, V Blanchette, M Kern, T R Einarson. (Netherlands)
- 11:00 AM Inappropriate Drug Prescribing in Community-Dwelling Elderly [16]**
Cornelis S van der Hooft, Geert W 't Jong, Jeanne P Dieleman, Bruno HCH Stricker, Miriam Sturkenboom. (Netherlands)
- 11:15 AM Prevalence and User's Characteristics of Hormone Replacement Therapy in Japan: Japan Nurses' Health Study [17]**
Kota Katanoda, Shuku Fujimaki, Kunihiko Hayashi, Toshiharu Fujita, Hideki Mizunuma, Shosuke Suzuki, Takeshi Aso, the JNHS Group. (Japan)
- 11:30 AM Periodic Letters on Drug Therapy Influence Prescribing to New Patients: A Pooled Analysis of Sequential Randomized Trials [18]**
Colin R Dormuth*, Malcolm Maclure, Kenneth Bassett, Ciprian Jauca, Carl Whiteside, James M Wright. (United States)
**Student Award Recipient- 3rd Best Abstract.*
- 11:45 AM The Clinical Value of Pharmacists' Intervention Leading to a Prescription Modification [19]**
Henk Buurma, Peter AGM de Smet, Antoine CG Egberts. (Netherlands)

12:00pm-1:30pm **Lunch/Poster Session A/Viewing of Exhibits** (Conference Center Ballroom/Hall)

PDS Editorial Board/Lunch (Parlor A)
(By Invitation Only)

ISPE Membership Committee/Lunch (Parlor B)

ISPE Student Council/Lunch (Salon 6)
Open to all students

1:30pm-3:00pm **CONCURRENT SESSIONS**

[A] SYMPOSIUM: Pharmacogenomics in the Risk Management Paradigm [101](Wyndham A)

Moderator: **Abraham G. Hartzema**, FISPE

Panelists:

M. Lee Morse

Brian L. Strom, FISPE

Hakon Hakonarson

[B] CARDIOVASCULAR – Contributed Papers
(Wyndham B)

Moderators:

Stephen E. Kimmel & Keith Beard, FISPE

1:30 PM **Beta-Blocker Use among U.S. Elderly Medicare Beneficiaries Post-Myocardial Infarction: National Patterns and Predictors of Use in the Outpatient Setting [108]**
Jalpa A Doshi, Bruce Stuart. (United States)

1:45 PM **Serum Potassium Levels, Hypertension and Antihypertensive Treatment in the US Adult Population: NHANES III (1988-1994) [109]**
Cristina Varas-Lorenzo, Andrew Maguire, Susana Perez-Gutthann, FISPE. (Spain)

- 2:00 PM** **Treatment of Diabetics: Do They Achieve the Recommended Blood Pressure and Blood Lipid Levels? The Tromsø Study 2001 [110]**
Anne Elise Eggen, Ingeborg H Bartnes, Inger Njoelstad, Sameline Grimsgaard, Frode Skjold. (Norway)
- 2:15 PM** **Adherence to Concurrent Therapy for Hypertension and Dyslipidaemia in a UK Primary Care Setting [111]**
Tom M MacDonald, Steve V Morant, Dan Pettitt. (United Kingdom)
- 2:30 PM** **Use of Statins and Risk of Incident Vertebral Fracture [112]**
Mariette WCJ Schoofs, Marjolein van der Klift, Miriam Sturkenboom, Huibert AP Pols, Bruno HC Stricker. (Netherlands)
- 2:45 PM** **Use of Oral Glucocorticoids and Risk of Cardiovascular and Cerebrovascular Events [113]**
Patrick C Souverein, Anick Berard, Tjeerd P Van Staa, Cyrus Cooper, Toine CG Egberts, Hubert GM Leufkens, Brian R Walker. (Netherlands)
- [C] CANCER – contributed papers (Wyndham C)**
Moderators:
Samuel Lesko & David J. Margolis
- 1:30 PM** **An Evaluation of the U.K. General Practice Research Database (GPRD) for Studying the Incidence of Male Breast Cancer [102]**
John Logie, Paul Dolin, Nada Boudiaf. (United Kingdom)
- 1:45 PM** **The Risk of Malignant and Benign Breast Tumors and Lifetime History of Oral Contraceptive Use [103]**
Lothar AJ Heinemann, Michael A Lewis, Doerthe Kuehl-Habich, Anita Assmann, Sabine Moehner. (Germany)
- 2:00 PM** **Variability of Breast Cancer Risk in Observational Studies of Hormone Replacement Therapy: A Meta-Regression Analysis [104]**
Edeltraut Garbe, Linda Levesque, Samy Suissa. (Canada)

- 2:15 PM** **Insulin Therapy and Colorectal Cancer Risk among Non-Insulin Dependent Diabetes Mellitus (NIDDM) Patients [105]**
Yu-Xiao Yang, Sean Hennessy, James D Lewis. (United States)
- 2:30 PM** **The Risk of Uterine and Ovarian Tumours and Oral Contraceptive Use. Results of a Cohort and Two Case-Control Analyses [106]**
Michael A Lewis, Lothar AJ Heinemann, Doerthe Kuehl-Habich, Sabine Moehner, Anita Assmann. (Germany)
- 2:45 PM** **Population-Based Case-Control Study of the Effects of Antidepressant Drugs on the Risk of Cancer Development [107]**
Hani Tamim, Jean-Paul Collet, Jean-Francois Boivin, James Hanley, MaryRose Stang. (Canada)
- [D] VACCINES – Contributed Papers (Philadelphia North)**
Moderators:
Robert L. Davis & M. Miles Braun
- 1:30 PM** **Association Rule Discovery as a Signal Generation Tool for the Vaccine Adverse Event Reporting System [114]**
Vitali Pool, Robert T Chen. (United States)
- 1:45 PM** **Adverse Events after Smallpox Vaccination in the United States: Summary of Reports to the Vaccine Adverse Event Reporting System (VAERS) [115]**
John Iskander, Ann W McMahon, Robert Ball, John D Grabenstein, M. Miles Braun. (United States)
- 2:00 PM** **Seven Years of Medication Errors from Merck's Adverse Event Report Surveillance for Hepatitis A Vaccine, Inactivated [116]**
Roseanne Carney, Paul Beninger, Stanley Music. (United States)

- 2:15 PM** **The Feasibility of Epidemiology Studies and Retention of Subjects in African Countries in Preparation of Large Scale HIV Vaccine Efficacy Trials [117]**
Swati B Gupta, Dan C Freed, T Christopher Mast, Eftyhia Vardas, Don Burke, Nathan Wolfe, Bridget Baird, Paul Coplan, B. Cowper, Walter Straus. (United States)
- 2:30 PM** **Oculo-Respiratory Syndrome Following Influenza Vaccine – United States, 1990-2002: New or Previously Unrecognized? [118]**
Alena Khromava, Vitali Pool, Robert Chen. (United States)
- 2:45 PM** **Recombinant Hepatitis B Vaccine and the Risk of Multiple Sclerosis [119]**
Miguel A Hernán, Susan S Jick, Michael J Olek, Alberto Ascherio, Hershel Jick. (United States)
- [E] WORKSHOP: An Application of Propensity Score Methods to Pharmacoepidemiology [120]** Philadelphia South
John D Seeger. (United States)
- 3:00pm-3:30pm** **Refreshment Break/Viewing of Posters & Exhibits**
(Conference Center/Ballroom)
- 3:30pm-5:00pm** **CONCURRENT SESSIONS**
- [A] Pharmacoconomics & Quality of Life – Contributed Papers (Wyndham A)**
- Moderators:
Newell McElwee & Jerry Avorn, FISPE
- 3:30 PM** **Healthcare Resource Utilization Following the Increased Use of Atypical Antipsychotic Medications for Hospitalized Patients with Schizophrenia in Newfoundland and Labrador, Canada [135]**
Daria J O'Reilly, Patrick S Parfrey, David Craig. (Canada)

- 3:45 PM** **Pharmacoeconomic Evaluation of Testing for Angiotensin Converting Enzyme (ACE) Genotype before Starting HMG-COA Reductase Therapy in Men [136]**
Anke H Maitland-van der Zee, Olaf H Klungel, Bruno HCH Stricker, Albert Hofman, Jacqueline CM Witteman, Hubert GM Leufkens, Cornelia M van Duijn, Anton de Boer. (Netherlands)
- 4:00 PM** **Clinical and Economic Consequences of Reference Pricing for Dihydropyridine Calcium Channel Blockers [137]**
Sebastian Schneeweiss, Stephen B Soumerai, Malcolm Maclure, Colin Dormuth, Alexander M Walker, FISPE, Robert J Glynn. (United States)
- 4:15 PM** **Economic Implications of Evidence-Based Prescribing for Hypertension: Better Care Can Cost Less [138]**
Michael A Fischer, Jerry Avorn, FISPE. (United States)
- 4:30 PM** **An Assessment of the Economic Burden of Benzodiazepine-Associated Falls in the European Union [139]**
Martien JM Panneman, Wim G Goettsch, Piotr Kramarz, Ron MC Herings. (Netherlands)
- 4:45 PM** **A Reliable and Robust Algorithm To Determine Inhospital Length of Stay and Readmissions Using RAMQ Medical Services Database [140]**
Amir Abbas Tahami Monfared, Jacques LeLorier, FISPE. (Canada)

[B] SYMPOSIUM: Data We Dare Not Present--Do Regulations Prohibit Learning from Experience? [134]
(Wyndham B)

Overview: Allen A Mitchell, FISPE, Slone Epidemiology Center

Panelists:

Carla M Van Bennekom, Slone Epidemiology Center, *Case Study: The Thalidomide Survey and its Interactions with FDA and OPRR/OHRP*

Edward Cox, Office of Drug Evaluation IV, CDER, FDA, *FDA Perspective*

Michael Carome, Office of Human Research Protections, US DHHS, *OHRP Perspective*

[C] Data Accuracy in Databases – Contributed Papers (Wyndham C)

Moderators:

Kimberly G. Brodovicz & Michael D. Murray, FISPE

3:30 PM

An Algorithm To Derive a Numerical Daily Dose from Text Dosage Instructions in the General Practice Research Database [122]

Anoop D Shah, Carlos Martinez. (United Kingdom)
**Student Award Recipient – Best Methods Abstract*

3:45 PM

Auditing the Quality of Data in the General Practice Research Database [123]

Sarah Davis, Stephan Rietbrock, Annalisa Rubino, Anoop D Shah, Tim Williams, Carlos Martinez. (United Kingdom)

4:00 PM

Agreement between GPRD Smoking Data and a Survey of General Practitioners [124]

James D Lewis, Colleen Brensinger. (United States)

4:15 PM

The Accuracy of Claims-Based Diagnosis of Acute Myocardial Infarction in Pharmacoepidemiology Research: Estimating Positive Predictive Value Based on Review of Hospital Records [125]

Yuka Kiyota, Sebastian Schneeweiss, Robert J Glynn, Carolyn Cannuscio, Jerry Avorn, FISPE, Daniel H

Solomon. (United States)

4:30 PM

Statins and Alzheimer's Disease: Why Specificity Should Be a Necessary Criterion for Trusting Aetiological Analyses from Observational Databases [126]

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

4:45 PM

Developing an Algorithm for the Automated Identification of Achilles Tendon Rupture in Claims Data [127]

John D Seeger, Iyue Sung, William A West, Daniel Fife, Julie Mechlowicz, Alexander M Walker, FISPE. (United States)

[D] Risk-Benefit Profile of COX-2's & NSAIDS – Contributed Papers (Philadelphia North)

Moderators:

Wayne A. Ray & Miriam Sturkenboom

3:30 PM

Celecoxib and Non-Specific NSAIDS Are Associated with a Reduced Risk of Bladder Cancer Recurrence [128]

Odile Sheehy, Sean Z Zhao, Armen G Aprikian, Betsy Miller, Anna Lisa Raymoundo, Jacques LeLorier, FISPE. (Canada)

3:45 PM

Cardiovascular Events on the Cyclooxygenase-2 Inhibitor Celecoxib [129]

William B White, Gerald A Faich, Jeffery Borer, Robert W Makuch. (United States)

4:00 PM

The Risk Benefit Profile of Non-Steroidal Anti-Inflammatory Drugs as Chemoprevention of Colorectal Cancer: A Georgia Medicaid Cohort Study [130]

Dayin Koopalum, Timothy E Niecko, Bradley C Martin. (United States)

4:15 PM

The COX-2 Selective Inhibitors Rofecoxib and Celecoxib Prevent Colorectal Adenomas Occurrence and Recurrence [131]

Elham Rahme, Alan N Barkun, Youssef Toubouti, Marc Bardou. (Canada)

4:30 PM

Propoxyphene Use and Risk of Fractures in the Elderly Population [132]

Sachin Kamal-Bahl. (United States)

4:45 PM

Peptic Ulcer Disease Morbidity and Mortality Associated with NSAID Use among the Elderly [133]

Kwan Y Lee, Kazim Sheikh. (United States)

[E] WORKSHOP: Balancing Risks and Benefits Using a Single Metric: Patients' and Physicians' Stated Preferences for Risk-Benefit Tradeoffs [121]

(Seminar A)

F Reed Johnson, Elizabeth B Andrews, FISPE. (United States)

5:15pm-6:30pm

COUNCIL MEETINGS

Industry (Parlor A)

Academic (Parlor B)

Government/Regulatory (Parlor C)

Open to interested meeting participants.

SATURDAY, AUGUST 23

7:00am-8:00am **Poster Set-up: Session B** (Conference Center/Ballroom)
Continental Breakfast/Exhibits (Conference Center/Ballroom)

7:00am-5:00pm **Registration** (Mezzanine Foyer)
Speaker Ready Room (**Salon 8**)

7:00am-8:00am **ISPE Committee Meetings**
(Open to all interested ISPE Members)
Bylaws (Parlor A)
Publications (Parlor B)
Public Relations (Seminar A)

8:30am-10:00am **CONCURRENT SESSIONS**
[A] SYMPOSIUM: Issues in Implementation of Risk Management [141] (Wyndham A)

Moderator: **Anne Trontell**, *The U.S. Food and Drug Administration's conceptual approach to risk management Programs*

Panelists:

Gretchen S. Dieck, *FDA's risk management concepts: US industry perspectives*

Susana Perez Gutthann, *FISPE, FDA's risk management concepts: an international perspective*

Judith M. Kramer, *Multidisciplinary perspectives on managing the risks of therapeutic products*

[B] CARDIOVASCULAR – Contributed Papers (Wyndham B)

Moderators:

Susan Sacks & Mari-Ann Wallander, FISPE

8:30 AM **Incidence of Angioedema in Patients Initiating Antihypertensive Medications [142]**
Donald R Miller, Susan Oliveria, Graeme Fincke, Dan Berlowitz. (United States)

Moderators:

Robert Gross & Miriam Sturkenboom

8:30 AM

Therapeutic Strategies and Predictors of Drug Changes in Rheumatoid Arthritis (RA): A Population-Based Analysis of Trends over 40 Years [148]

Hilal Maradit Kremers, Cynthia S Crowson, W Michael O'Fallon, Sherine E Gabriel. (United States)

8:45 AM

Prescription of Warfarin with Interacting Drugs, and Its Use in Atrial Fibrillation: An Analysis Using the National Ambulatory Medical Care Survey and the National Hospital Ambulatory Medical Care Survey, 2000 [149]

Boji Huang, Kenneth A Bachmann, Xuming He, Cletus U Iwuagwu, Huawen Xin. (United States)

9:00 AM

Adherence with Antihypertensive and Antihyperlipidemic Pharmacotherapy among Working-Aged Adults [150]

Robin P Hertz, Alan N Unger, Michael B Lustik. (United States)

9:15 AM

Trends in Antihypertensive Drug Prescribing in Dutch General Practice from 1996 to 2000 [151]

Jacoba P Greving, Petra Denig, Willem Jan van der Veen, Frank W Beltman, Miriam Sturkenboom, Flora M Haaier-Ruskamp. (Netherlands)

9:30 AM

Discontinuation of Statin Use in Daily Medical Practice [152]

Aukje K Mantel-Teeuwisse, Wim G Goettsch, Olaf H Klungel, Anthonius de Boer, Ron MC Herings. (Netherlands)

9:45 AM

Real-Life Treatment Patterns of Patients with Hypercholesterolemia in the Netherlands 1991-2001. [153]

Wim G Goettsch, Donald D Yin, Evo Alemao, Ron MC Herings. (Netherlands)

[D] SPECIAL JOINT SESSION - International Society for Pharmacovigilance & International Society for Pharmacoepidemiology

Pharmacovigilance in General and Pharmacoepidemiology in Particular: Toward a Working Document on Best Practices [154]

(Philadelphia South)

Ralph Edwards, Gerry Faich, Hugh H. Tilson, FISPE, Jurgen Beckmann, Nicholas D. Moore, Saad Shakir, Rachida Soulaymani, Pascale Tubert, Eugene van Puijenbroek, Ernst Weidmann.

10:00am-10:30am

Refreshment Break/Viewing of Posters & Exhibits
(Conference Center/Ballroom)

10:30am-12:00pm

ANNUAL MEETING OF MEMBERS & AWARDS CEREMONY (Wyndham A)
(Open to all participants)

Annual Meeting of ISPE Members

Thomas M. MacDonald, FISPE, President, ISPE

Induction of Fellows (FISPE)

Thomas M. MacDonald, FISPE, President, ISPE

Elizabeth B. Andrews

Felix M. Arellano

Jerry Avorn

Keith Beard

Rudolph Bruppacher

K. Arnold Chan

Diane Chen Koch-Weser

Wanju Dai

Nancy A. Dreyer

David I. Goldsmith

Abraham G. Hartzema

Sean Hennessy

Anne Marie Holbrook

Judith K. Jones

Jacques LeLorier

Hubert GM Leufkens

Michael A. Lewis

David E. Lilienfeld

Thomas M. MacDonald
Ronald D. Mann
Allen A. Mitchell
Yola Moride
Michael D. Murray
Robert C. Nelson
C. Ineke Neutel
Byung-Joo Park
Susana Perez-Gutthann
Elena Rivero
Annette Stemhagen
Brian L. Strom
Hugh H. Tilson
John Urquhart
Jan Willem Van der Velden
Alexander M. Walker
Mari-Ann Wallander
Bengt-Erik Wiholm
Shelia Weiss Smith

Awards Ceremony

Student Awards

Presented by **Sean Hennessy**, FISPE, Chair, 2003
Scientific Program Committee

Best Methods Abstract: **Anoop D. Shah**, University College London. *An algorithm to develop a numerical daily dose from text dosage instructions in the GPRD.* [302]

Third Best Abstract: **Colin Dormuth**, Harvard School of Public Health. *Periodic letters on drug therapy influence of prescribing to new patients: A pooled analysis of sequential randomized trials.* [337]

Second Best Abstract: **Frantz Thiessard**, University Victor Segalen. *Seriousness of ADRs reported to the French Pharmacovigilance system and associated factors (1995-2001).* [367]

Edlavitch Award (Best Student Abstract): **Mette Norgaard**, Aarhus and Aalborg University Hospitals. *Adverse birth outcomes in users of sulfamethizole during pregnancy: a population-based observational study.*[53]

ISPE-PDS Prize

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

12:00pm-1:30pm

Lunch/Poster Session A/Viewing of Exhibits (Conference Center Ballroom/Hall)

Development Committee/Lunch (Parlor A)

Data Privacy Committee/Lunch (Parlor B)

Meeting of Authors of *Pharmacoepidemiology: An Introduction/Lunch* (Seminar A) (By invitation only).

1:30pm-3:00pm

CONCURRENT SESSIONS

[A] SYMPOSIUM: Risk Management Improvement through Research and Education [237] (Wyndham A)
Hugh H Tilson, FISPE, Lynn A. Bosco, William H. Campbell, Brian L. Strom, Judith M. Kramer. (United States)

[B] Confounding & Channeling – Contributed Papers (Wyndham B)

Moderators:

Yola Moride, FISPE & Kenneth J. Rothman

1:30 PM

Using Patient Interview Information To Estimate and Correct for Unobserved Confounding Bias in Pharmacoepidemiologic Studies in Medicare Claims Data [238]

Sebastian Schneeweiss, Elizabeth Tsai, Robert J Glynn, Jerry Avorn, FISPE, Daniel H Solomon. (United States)

[251]

Lynda V Wilton, Saad AW Shakir. (United Kingdom)

2:00 PM

Evaluation of Inhaler Devices Handling in 3811 Patients in Real Life [252]

Mathieu Molimard, Chantal Raheison, Severine Lignot, Fanny Depont, Abdelilah Abouelfath, Nicholas M. Moore. (France)

2:15 PM

Continuity of Care in the Ambulatory Treatment of Asthmatic Adolescents [253]

Martens C Alexander, Perreault Sylvie, Blais Lucie. (Canada)

2:30 PM

Use of Asthma Medicine and Risk of Dental Caries in 5 to 7 Year-Old Danish Children: A Population-Based Cohort Study [254]

Pia Wogelius, Sven Poulsen, Henrik T Sorensen. (Denmark)

2:45 PM

The Validity of Questionnaire-Based Information on Asthma Drug Use in Children [255]

Pia Wogelius, Sven Poulsen, Henrik T Sorensen Denmark)

[E] MedDRA and SNOMED (Systematized Nomenclature of Medicine): An Informal Conversation with FDA (Philadelphia North)

This informal session will provide an opportunity for interested conference attendees to share views about current plans and anticipated developments along with the merits of the two systems, the spectre of competing standards, and practical questions, such as implementation issues.

3:00pm-3:30pm

Refreshment Break/Viewing of Posters & Exhibits(Conference Center/Ballroom)

3:30pm-5:00pm

CONCURRENT SESSIONS

**[A] Risk Communication & Management –
Contributed Papers (Wyndham A)**

Moderators:

Harry A. Guess & Saad Shakir

3:30 PM

**Impact of Risk Communication on Tuberculosis Testing
for Infliximab Users [256]**

Deborah Shatin, Nigel Rawson, M. Miles Braun, Bharati
Manda, Jeffrey Curtis, Larry W Moreland, Kenneth Saag.
(United States)

3:45 PM

**A Drug Utilization Review Intervention To Decrease
Excessive Acetaminophen Use among Medicaid
Recipients [257]**

Ilene H Zuckerman, Mikhail Menis, Diane McNally, C
Daniel Mullins. (United States)

4:00 PM

The Accutane Survey: 14 Years' Experience [258]

Carla M Van Bennekom, Allen A Mitchell, FISPE. (United
States)

4:15 PM

The Voluntary Thalidomide Survey [259]

Carla M Van Bennekom, Allen A Mitchell, FISPE. (United
States)

4:30 PM

**Systematic Review of Interventions Aimed at Reducing
Drug-Related Adverse Events in Primary Care (Family
Practice) [260]**

Anthony J Avery, Lesley Smeaton, Simon Royal, Aziz
Sheikh, Brian Hutwitz, Michael Dewey. (United Kingdom)

4:45 PM

**Risk Management Response: Defining a Target Patient
Population in Response to a Shift in the Risk-Benefit
Profile [261]**

Susan C Eaton, John S Hopkins, Elizabeth B Andrews,
FISPE, Suzanne F Cook, Vanessa Z Ameen. (United
States)

**B| Pharmacovigilance – Contributed Papers
(Wyndham B)**

Moderators:

Syed Rizwanuddin Ahmad & Harry Seifert

3:30 PM

Seriousness of Adverse Drug Reactions Reported to the French Pharmacovigilance System and Associated Factors (1995-2001) [270]

Frantz Thiessard*, Annie Fourrier, Ghada Miremont-Salame, Francoise Haramburu, Pascal Auriche, Carmen Kreft-Jais, Pascale Tubert-Bitter, Emmanuel Roux, Bernard Begaud. (France).

**Student Award Recipient- 2nd Best Abstract*

3:45 PM

Adverse Drug Reactions in Hospitalized Children in Fortaleza-Brazil [271]

Djanilson Barbosa dos Santos, Helena Lutescia Luna Coelho. (Brazil)

4:00 PM

Safety Profile of Rosiglitazone as Used in General Practice in England: Results of a Prescription-Event Monitoring Study [272]

Pipasha Biswas, Lynda V Wilton, Saad AW Shakir. (United Kingdom)

4:15 PM

Comparison of 4 Data Mining Methods in the US Vaccine Adverse Event Reporting System (VAERS) [273]

David Banks, E Jane Woo, Dale Burwen, Phil Perucci, M. Miles Braun, Robert Ball. (United States)

4:30 PM

What Information Is Required for Optimal Pharmacosurveillance? [274]

Anne Holbrook, FISPE, Charles Goldsmith, Paul Grootendorst, Don Willison, Mitchell Levine, Kathy Gaebel, Tom Brogan, Robert Peterson, Karim Keshavjee. (Canada)

4:45 PM

Adverse Drug Reactions as a Cause of Hospital Admissions to an Emergency Medical Ward - A Pilot Study with Public Health Implications [275]

Ulf Bergman, Mia von Euler, Erik Eliasson, Gunnar Öhlén.
(Sweden)

**[C] SYMPOSIUM: Evidence-Based Practice Centers
at the Agency for Healthcare Research and Quality
[269] (Wyndham C)**

Moderator:
Lynn A. Bosco

Panelists:
Margaret Coopey
Mark Helfand
Kathleen Lohr

**[D] PREGNANCY OUTCOMES &
GENITOURINARY - Contributed Papers
(Philadelphia South)**

Moderators:
Sonia Hernandez-Diaz & George A. Macones

3:30 PM

**Increased Risk of Benign Prostatic Hyperplasia-Related
Surgery in Patients Using Alpha-Blockers Compared to
5-Alpha Reductase Inhibitors [263]**

Patrick C Souverein, Joëlle A Erkens, Jean JMCH de la
Rosette, Hubert GM Leufkens, Ron MC Herings.
(Netherlands)

3:45 PM

**Azathioprine, 6-Mercaptopurine, and Birth Outcome:
A Population-Based Cohort Study [264]**

Bente Nørgård, Lars Pedersen, Kirsten Fonager, Sten
Nørby Rasmussen, Henrik Toft Sørensen. (Denmark)

4:00 PM

**Paternal Use of Antiepileptics and Congenital
Abnormalities in Offspring [265]**

Eric Schirm, Lars Pedersen, Birthe Pedersen, Gunnar L
Nielsen, Henrik T Sørensen, Lolkje de Jong-van den Berg .
(Netherlands)

4:15 PM

**Folic Acid Reduces the Risk on Neural Tube Defects as
Well as Other Birth Defects - A Registry-Based Case-
Control Study in the Netherlands [266]**

Willemijn M Meijer, Hermien EK de Walle, Joke BGM Verheij, Lolkje de Jong-van den Berg. (Netherlands)

4:30 PM

Maternal Use of Vasoactive Medications and Risk of Hemifacial Microsomia [267]

Martha M Werler, Jane E Sheehan, Catherine Hayes, Allen A Mitchell, FISPE. (United States)

4:45 PM

The Antiretroviral Pregnancy Registry: Ten Years of Progress [268]

Hugh H Tilson, FISPE, Peggy A Doi, Alice White, Artist Parker. (United States)

[E] WORKSHOP: Validity of Epidemiological Research Conducted Following Good Epidemiological Practice Guidelines [262] (Philadelphia North)

Moderators:

Alejandro Arana & Andre W Broekmans

Panelists:

Thomas M. MacDonald, FISPE

Gottfried Kreutz

Corinne de Vries

Felix Arellano, FISPE

Susana Perez-Gutthann, FISPE

5:00pm-6:00pm

2004 Scientific Program Committee (Salon 5 &6)

All interested ISPE members are welcome to attend.

6:45pm-10:00pm

Evening at the National Constitution Center

"We the People of the United States, in Order to form a more perfect Union, establish Justice, insure domestic Tranquility, provide for the common defence, promote the general Welfare, and secure the Blessings of Liberty to ourselves and our Posterity, do

ordain and establish this Constitution for the United States of America.”

The National Constitution Center, which opened July 4, 2003 on Philadelphia's Independence Mall, is the first museum in the world dedicated to honoring and explaining the U.S. Constitution through more than 100 interactive and multimedia exhibits, photographs, film, sculpture, text and artifacts.

Buses will shuttle between the Wyndham and the Constitution Center. Buses will begin to depart from the Wyndham at 6:45pm. Meet in lobby. The last bus will depart from the Constitution Center at 10:00pm.

Admission to Constitution Center: By ticket only. Tickets will be included in the registration packet and can be purchased at the registration desk until 5:00pm, Friday, August 22.

[Cash Bar]

SUNDAY, AUGUST 24

7:00am-8:00am **Poster Set-up: Session C** (Conference Center/Ballroom)
Continental Breakfast/Exhibits (Conference Center/Ballroom)

7:00am-4:00pm **Registration** (Mezzanine Foyer)
Speaker Ready Room (**Salon 8**)

7:00am-8:15am **Annual CERTs Breakfast Roundtable [276]**
(Rooftop Ballroom)
Hugh H Tilson, FISPE, Lynn A Bosco. (United States)

8:30am-10:00am **CONCURRENT SESSIONS**
[A] SYMPOSIUM: Elements of Good Pharmacovigilance Practice [277] (Wyndham A)

Moderator:
Julie Beitz

Panelists:
June S. Almenoff, *Advances in the application of data mining for pharmacovigilance and risk management*

Kasia Petchel, *Pharmacovigilance planning: Status of ICH guidance development - European contribution and challenge*

Suzanne West, *Pharmacovigilance and risk management: what are the core competencies for staff and the critical components for programs?*

[B] SYMPOSIUM: Unintentional Acetaminophen Overdose: The Extent of the Problem and Risk Management Efforts To Address It [296] (Wyndham B)
Syed R Ahmad, Parivash Nourjah, Claudia B Karwoski, June M Raine. (United States, UK)

[C] Data Analysis – Contributed Papers (Salon 10)

Moderators:

Nicholas Moore & Warren B. Bilker

8:30 AM

Estimation of Time-Dependant Rate Ratio in Case-Control Studies [278]

Genevieve Lefebvre, Lucie Blais, Jean-Francois Angers. (Canada)

8:45 AM

Waiting Time Bias in Drug Safety and Effectiveness Cohort Analyses Using Clinical Practice Databases [279]

Maurille Feudjo-Tepie, Victor Kiri, Nawab Qizilbash, Nada Boudiaf, Stephen JW Evans. (United Kingdom)

9:00 AM

Use of Exponential Growth Curves To Model Corticosteroid Tapering over Time [280]

Hilal Maradit Kremers, Megan S Maurer, Cynthia S Crowson, Alan R Zinsmeister, Gene G Hunder, Sherine E Gabriel. (United States)

9:15 AM

Application of GEE Method To Evaluate Efficacy of a New NSAID with VAS in Osteoarthritis [281]

Hoi-Jeong Lim, Yooni Kim, Young-Bok Jung, Byung-Joo Park, FISPE. (Korea)

9:30 AM

Evaluating the Trade-Off between Clinical Benefit and Toxicity: An Application of the Q-TWiST Method [282]

Beth Sherrill, Charlotte Gard, William Irish. (United States)

9:45 AM

An Evaluation of Methods for Determining the Calibration of Models from Large Data Sets: Brier Scores and Hosmer-Lemeshow Statistic [283]

David J Margolis, Jesse A Berlin. (United States)

**[D] Devices, Decisions Dermatology & Diarrhea –
Contributed Papers (Philadelphia North)**

Moderators:

Til Stoermer & Gerald Faich

8:30 AM

**Severe Cutaneous Adverse Reactions (SCAR): Results
on Drug Risks Based on the EuroSCAR-Study [290]**

Maja Mockenhaupt, Cecile Viboud, Jean-Claude Roujeau,
Luigi Naldi, Sima Halevy, Ariane Dunant, Jan Nico
Bouwes Bavinck, Alexis Sidoroff, Juergen Schlingmann,
Antoine Flahault. (Germany)

8:45 AM

**Psoriasis Patients Have an Increased Risk of
Lymphoma – Results from a Population Based Cohort
Study in the United Kingdom [291]**

Joel M Gelfand, Jesse Berlin, Jill Knauss, Abby
VanVoorhees, David J Margolis. (United States)

9:00 AM

**Does Immunosuppressant Therapy Increase Risk of
Postoperative Infectious Complications in
Inflammatory Bowel Disease Patients? [292]**

Faten N Aberra, James D Lewis, David Haas, John
Rombeau, Benjamin Osborne, Gary R Lichtenstein.
(United States)

9:15 AM

**Direct Observation in Intensive Care Units: Medical
Device-Related Problems Associated with Alarms [293]**

Matthew H Samore, Suzanne Anderson, Theresa Frost,
Pauline Wiessner, James Orme, Terry Clemmer, R Scott
Evans, Roselie A Bright. (United States)

9:30 AM

**Adjustable Silicone Gastric Band Adverse Events
Reported to FDA [294]**

S Lori Brown, Heshu J Duggirala, Marie H Reid. (United
States)

9:45 AM

Sensitivity of Multivariate Logistic Regression Results towards Random Misclassification of Exposure Status and Event Dates in a Study on Antiparkinsonian Drug Use and Sudden Onset Pathologic Somnolence [289]
Sebastian Schneeweiss, Danna Spiegelman, Jerry Avorn, FISPE, Robert J Glynn. (United States)

10:00am-10:30am

Refreshment Break/Viewing of Posters & Exhibits
(Conference Center/Ballroom)

10:30am-12:00pm

CONCURRENT SESSIONS

[A] SYMPOSIUM: INTRODUCTION TO THE FDA DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE [297] (Wyndham A)

Moderator:

Brian L. Strom, FISPE, *Overview of FDA Advisory Committee*

Panelists:

Victor Raczkowski, *Introduction to the FDA Drug Safety & Risk Management Advisory Committee*

Martin H. Himmel, *Initial conceptualization of committee role and mission, and initial vision for how it could be used*

Jacqueline Gardner, *Patient packaging inserts*

Paul Seligman, *Reactions to the committee's deliberations, and the future role of DSaRM*

[B] SYMPOSIUM: Herbal Medicines: Friends or Foes? [298] (Wyndham B)

Moderator:

Stephen P. Spielberg

Panelists:

Michael Cirigliano, *Herbal medicine: a clinician's view*

David W. Kaufman, *Patterns of herbal use in the US adult population*

Stephen Spielberg, *Pharmacoregulatory issues and research priorities*

[C] Therapeutic Issues in CNS-related Diseases – Contributed Papers (Salon 10)

Moderators:

Philip S. Wang & Paul E. Stang

- 10:30 AM** **Antipsychotic Induced Diabetes in Veteran Schizophrenic Patients [305]**
Francesca Cunningham, Bruce Lambert, Donald R Miller, Gregory Daluck, J B Kim, Kwan Hur. (United States)
- 10:45 AM** **Medication Use and Sudden Inappropriate Somnolence in Patients with Parkinson's Disease [306]**
Jerry Avorn, FISPE, Sebastian Schneeweiss, Lewis Sudarsky, Joshua Benner, Yuka Kiyota, Raisa Levin, Robert J Glynn. (United States)
- 11:00 AM** **Psychoactive Substance Use and the Risk of Motor Vehicle Accidents [307]**
K LL Movig, M PM Mathijssen, P HA Nagel, J J De Gier, T van Egmond, H GM Leufkens, A CG Egberts. (Netherlands)
- 11:15 AM** **Incidence of Suicide in Randomized Controlled Trials of Patients with Major Depressive Disorder [308]**
Tarek A Hammad, Andrew Mosholder, Gerard Boehm, Judith A Racoosin, Thomas Laughren. (United States)
- 11:30 AM** **Are Older Patients with Epilepsy Receiving Appropriate Anticonvulsant Drugs? [309]**
Mary Jo V Pugh, Joyce A Cramer, Janice Knoefel, Andrea M Charbonneau, Daniel R Berlowitz. (United States)
- 11:45 AM** **Histamine ₂ Receptor Antagonist Use and Cognitive Function among Community Dwelling Elderly [310]**
Joseph T Hanlon, Lawrence R Landerman, Margaret B Artz, Gerda G Fillenbaum, Shelly L Gray, Kenneth E Schmader. (United States)

**[D] Renal & Genitourinary – contributed papers
(Philadelphia North)**

Moderators:

Wolfgang Winkelmayr & Karen Wilcock

- 10:30 AM** **Chronic Renal Allograft Failure: A Comparison of Tacrolimus vs. Neoral-Based Regimens Using the U.S. Renal Data System (USRDS) [299]**
William Irish, Beth Sherrill, Kathleen Lake. (United States)
- 10:45 AM** **Risk Factors Associated with the Development of Post-Transplant Lymphoproliferative Disorder in Renal Transplant Patients in the U.S. [300]**
Donnie P Funch, Hnin Hnin Ko, Jacqueline Trivasse, Julie Mechlowicz, Alexander M Walker, FISPE. (United States)
- 11:00 AM** **Use of Alpha-Blockers and Risk of Hip/Femur Fractures [301]**
Patrick C Souverein, Toine CG Egberts, Jean JMCH De la Rosette, Tjeerd P Van Staa, Cyrus Cooper, Hubert GM Leufkens. (Netherlands)
- 11:15 AM** **Treatment of Lower Urinary Tract Symptoms Suggestive of Benign Prostatic Hyperplasia (LUTS/BPH) in General Practice - The Triumph Project [302]**
Katia MC Verhamme, Jeanne P Dieleman, Gysele S Bleumink, Ruud Bosch, Bruno HCH Stricker, Miriam Sturkenboom. (Netherlands)
- 11:30 AM** **The Incidence, Prevalence and Management of the Overactive Bladder, a Study in the United Kingdom [303]**
Annie Hutchison, Richard DT Farmer. (United Kingdom)
- 11:45 AM** **Recent Incidence of Post Transplant Lymphoproliferative Disorder among Renal Transplant**

Patients at 20 Transplant Centers in the US [304]
Jacqueline Travasso, Donnie P Funch, Alexander M Walker, FISPE. (United States)

[E] **SYMPOSIUM: The Impact of the EU Clinical Trials Directive Upon Safety Reporting in Global Clinical Trials [311]** (Philadelphia South)
Graeme A Ladds. (United Kingdom)

12:00pm-1:30pm

Lunch/Poster Session C/Viewing of Exhibits
(Conference Center
Ballroom/Hall)

ISPE Board of Directors Luncheon (Salons 5 & 6)

1:30pm-2:30pm

Invited Plenary Session (Wyndham A)
Samuel Lesko, Moderator

Samuel Shapiro: *Looking to the 21st century. Have we learned from our mistakes, or are we doomed to compound them?*

2:30-4:30pm

HOT TOPICS SESSION: Smallpox Vaccination: From Policy to Implementation [372] (Wyndham A)

Moderator:
Robert Chen

Panelists:

Paul Offit, *Smallpox history, ACIP role in providing recommendations on national smallpox immunization program*

Brian L. Strom, FISPE, *Objectives of IOM Committee on Smallpox Vaccinations, how committee advises CDC, its impact on national smallpox program*

Worth Everett, *Practice-level concerns and healthcare provider willingness regarding smallpox vaccinations*

Rick Riddle, *Military preparedness and immunization safety systems*

John Iskander, *Civilian preparations of safety*

programs/VAERS enhancements

- 4:30pm-4:45pm** **The Final Word (Wyndham A)**
Nicholas Moore, Chair, 2004 Scientific
Program Committee
- 4:45pm** **Adjournment of the 2003 ISPE Annual
Meeting**