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

Moderator:
Hugh H. Tilson, FISPE

Panelists:
Steven Galson
Susan Ellenberg
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)

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)
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)


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-Froncois 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)

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] Pharmacoeconomics & 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)
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, OHPR Perspective

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
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)

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 Koompalum, 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)

(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**


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 Guthmann**, *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)
8:45 AM  Statins and the Risk of Diabetes Mellitus: Utrecht Diabetes Epidemiology Studies (UDES) [143]
Kvetoslava Gorecka, Anthonius de Boer, Jiri Vleck, Ronald P Stolk, Diederik E Grobbee, Olaf H Klungel. (Netherlands)

9:00 AM  Risk of Local Adverse Events Following Cardiac Catheterization by Hemostasis Device Use and Gender [144]
Dale R Tavris, Beverly Gallauresi, Ba Lin, Suzanne E Rich, Richard E Shaw, William S Weintraub, Ralph G Brindis, Kathleen Hewitt. (United States)

9:15 AM  Nonfatal Myocardial Infarction Risk among Users of Aspirin and Nonselective Non-Aspirin Nonsteroidal Anti-Inflammatory Medications [145]
Stephen E Kimmel, Jesse A Berlin, Muredach Reilly, Jane Jaskowiak, Lori Kishel, Brian L Strom, FISPE. (United States)

9:30 AM  Use of Glucocorticoids and Risk of Cardiovascular Disease in a Population-Based Cohort Study of 164,133 Participants [146]
Li Wei, Thomas M MacDonald, Brian R Walker. (United Kingdom)

9:45 AM  Haemorrhage Occurs Early and Is Associated with High INR-Values in Patients on Warfarin: Lessons from the Adverse Event Reporting System [147]
Steinar Madsen, Trine E Vaskinn, Anne B Breen, Harald Lislevand, Asmund Reikvam. (Norway)

[C]  Utilization & Adherence – contributed papers
(Wyndham C)
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 Haaijer-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)

Wim G Goettsch, Donald D Yin, Evo Alemao, Ron MC Herings. (Netherlands)
SPECIAL JOINT SESSION - International Society for Pharmacovigilance & International Society for Pharmacoepidemiology

(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
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]


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)
1:45 PM Confounding by Indication and Confounding by Compliance: Can We Find What We Should Find? An Empirical Study [239]
Marc Dorais, Jacques LeLorier, FISPE. (Canada)

2:00 PM An Evaluation of Potential Confounding of the Association between Statin Use and Fractures [240]
Catherine B Johannes, Gary Schneider, John D Seeger, Timothy J Dube, Kourtney J Davis, Alexander M Walker, FISPE. (United States)

2:15 PM The Risk of Fetal Exposure to Folic Acid Antagonists [241]
Shi W Wen, Mark C Walker. (Canada)

2:30 PM The Use of Propensity Scores To Measure and Control for Channelling in Pharmacoepidemiologic Studies [242]
Lise M Bjerre, Michal Abrahamowicz, Jacques LeLorier, FISPE. (Canada)

2:45 PM No Changes in Channeling of COX-2 Specific Inhibitors in the First Three Years after Marketing [243]
Georgio Mosis, Lia Gutiérrez, Jeanne Dieleman, Jordi Castellsague, Miriam Sturkenboom. (Netherlands)

[C] Anti-Infectives – Contributed Papers (Wyndham C)
Moderators:
Stuart M. McLeod & Harry A. Guess

1:30 PM Lack of Specific Cross-Reactivity between Sulfonamide Antibiotics and Subsequent Sulfonamide Non-Antibiotics [244]
Brian L Strom, FISPE, Rita Schinnar, Andrea J Apter, David J Margolis, Ebbing Lautenbach, Sean Hennessy, Warren B Bilker, Dan Pettitt. (United States)
1:45 PM  Antibiotic Utilization Review in the Treatment of Acute Otitis Media [245]
Caroline Quach, Jean-Paul Collet, Jacques LeLorier, FISPE. (Canada)

2:00 PM  Acute Otitis Media: Are Physicians Following Treatment Guidelines? [246]
Caroline Quach, Jean-Paul Collet, Jacques LeLorier, FISPE. (Canada)

2:15PM  Assessing Parents' Preference for Shorter Duration Treatment of Acute Otitis Media in Children by Using a Willingness To Pay Method [247]
Delphine Gueylard Chenevier, Caroline Quach, Marc Dorais, Jacques LeLorier, FISPE. (Canada)

2:30 PM  Antibiotic Use and the Risk for Flares of Inflammatory Bowel Disease [248]
Faten N Aberra, Colleen M Brensinger, Warren B. Bilker, Brian L Strom, FISPE, Gary R Lichtenstein, James D Lewis. (United States)

2:45 PM  Adverse Drug Reactions Following HAART in HIV + Children: An Overview (Italian Multicentric Collaborative Study) [249]
Salvatore Mannino, Marco Villa, Paolo Palma, Pierangelo Tovo, Maurizio De Martino, Luisa Galli, Clara Gabiano, Paolo Rossi, Guido Castelli Gattinara, Italian Registry of HIV Infections in Children. (Italy)

Moderators:
Deborah Shatin & Anick Berard

1:30 PM  Patterns of Inhaled Corticosteroid Use in the Netherlands: A 10-year Follow-Up Study [250]
T T Menckeberg, M L Bouvy, M Bracke, P Souverein, S V Belitzer, J AM Raaijmakers, H GM Leufkens. (Netherlands)

1:45 PM  The Introduction of a Non-CFC Formulation of Inhaled Fluticasone in England; Results from a Cohort Study
2:00 PM  Evaluation of Inhaler Devices Handling in 3811 Patients in Real Life [252]
Mathieu Molimard, Chantal Raherison, 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)
3:30 PM  
*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 LN Nielsen, Henrik T Sorensen, 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)


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, Advance 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)
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)
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)

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)

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)

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, Rosalie A Bright. (United States)

Adjustable Silicone Gastric Band Adverse Events Reported to FDA [294]
S Lori Brown, Hesha J Duggirala, Marie H Reid. (United States)
9:45 AM  Evidence of Safety Used To Support Decisions To Withdraw Medicinal Products from the UK and US Markets - A Literature Review [295]
Andrea Clarke, Saad AW Shakir. (United Kingdom)

8:30 AM  The Influence of Cytochrome P450-2D6 Genotype on Prescription Patterns of Antipsychotic and Antidepressant Drugs in Hospitalised Psychiatric Patients: A Retrospective Cohort Study [284]
Hans Mulder, Frederik W Wilmink, Tim Beumer, Wim Tamminga, Antoine CG Egberts. (Netherlands)

8:45 AM  Determinants of Elevations of Lithium Serum Levels into the Toxic Range [285]
Ingeborg Wilting, Marieke Moolenaar, Kris LL Movig, Yechiel A Hekster, Jacobus RBJ Brouwers, Antoine CG Egberts. (Netherlands)

9:00 AM  Supplemental Use of Antioxidant Vitamins and Subsequent Risk of Cognitive Decline and Dementia [286]
Colleen J Maxwell, Matthew S Hicks, David B Hogan, Jenny Basran, Erika M Ebly. (Canada)

9:15 AM  Antiepileptic Drug Use in Children and Adolescents [287]
Ying Fen Hsia, Corinne S de Vries, Richard DT Farmer. (United Kingdom)

9:30 AM  Antipsychotic Utilization of Schizophrenic Patients in Taiwan [288]
Shu-Yu Yang, Yea-Huei Kao Yang, Mian-Yoon Chong, Yi-Hsin Yang, Hin-Yeung Tsang. (Taiwan)
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)

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

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

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)
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 Travasse, 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)

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
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