



Mid-Year
ISPE 2009
Meeting

🦋 Elite Palace Hotel/
Karolinska University
Hospital

🦋 Stockholm, Sweden

🦋 April 25-27, 2009

April 26

- A) Introduction to
Pharmacoepidemiology (morning)
- B) Advanced Topics in
Pharmacoepidemiology (afternoon)

April 27

25th Anniversary Symposium:

*From Thalidomide to Pharmacovigilance
to Pharmacoepidemiology: Has Drug
Safety and Effectiveness Really Improved
Since Thalidomide?*

Jointly sponsored by

- 🦋 International Society for
Pharmacoepidemiology (ISPE)
- 🦋 Swedish Society for
Pharmacoepidemiology (SLEF)
- 🦋 Centre for Pharmacoepidemiology (CPE)
-A Joint Venture between the Departments of
Clinical Epidemiology, Clinical Pharmacology,
and Medical Epidemiology and Biostatistics at
Karolinska Institutet

🦋🦋🦋 *Space is limited: Register Today!*

Mid-Year

ISPE 2009

Meeting

Meetings:

Saturday, April 25, 2009
Elite Palace Hotel

10:30am - Noon

Strategic Planning Session

- ISPE Chairs: Committees, Councils & SIGs

Noon - 1:00pm

Lunch

1:00 - 5:00pm

ISPE Board of Directors Meeting

(Board, Committee, Council, & SIG Chairs) - Open to all ISPE Members

Sunday, April 26, 2009
Elite Palace Hotel

7:30am - 4:00pm

Registration

8:30am - 12:30pm

ICPE 2009 Scientific Program Committee

8:30am - 12:30pm

Introduction to Pharmacoepidemiology*

12:30 - 1:30pm

Lunch on your own

1:30 - 5:30pm

Advanced Topics in Pharmacoepidemiology*

Monday, April 27, 2008
Nanna Svartz Auditorium
Karolinska University Hospital

7:30am - 4:00pm

Registration

9:00am - 5:00pm

Mid-Year Symposium*

*Registration Required

ISPE Mid-Year Meeting

Sunday, April 26 2008

Elite Palace Hotel | 8:30am - 12:30pm

Introduction to Pharmacoepidemiology

COURSE OBJECTIVES

This course is for those with some training and/or experience in epidemiology or pharmacoepidemiology. On completion, participants will be able to:

- Identify the impact of confounding by indication in epidemiology studies
- Outline the basic design features of cohort, case-control and nested case-control studies
- List the strengths and weaknesses of spontaneous reporting data
- Outline strategies for addressing a spontaneous report "signal" and outline design options for pharmacoepidemiology studies to address this "signal."

Course Objectives and Introductions

Andrew McAfee, Course Chair, i3 Drug Safety, USA

Spontaneous Reporting

Ralph Edwards, WHO-Uppsala Monitoring Centre (UMC), Sweden

Cohort Studies

Andrew McAfee, i3 Drug Safety, USA

Case-Control Studies

Michael Lewis, FISPE, EPES Epidemiology GMBH, Germany

Confounding & Other Biases

Anita McGrogan, University of Bath, United Kingdom

Summary Comments

Adjournment

Sunday, April 26, 2008

Elite Palace Hotel | 1:30 - 5:30pm

Advanced Topics in Pharmacoepidemiology

Introduction

Jim Lewis, Course Chair, University of Pennsylvania/Center for Clinical Epidemiology & Biostatistics, USA

Attenuating Confounding by Indication: the Cohort Cross-Over Approach

Anders Sundström, Karolinska Institutet, Sweden

Time Varying Propensity Scores

Alexander Walker, FISPE, Harvard University, USA

Immortal Time Bias

Corinne de Vries, University of Bath, United Kingdom

Pharmacoepidemiology of Pregnancy

Lolkje de Jong-van den Berg, University of Groningen, The Netherlands

Meeting – Preliminary Meeting Agenda

Monday, April 27, 2008

Nanna Svartz Auditorium, Karolinska University Hospital | 9:00am – 5:00pm

📌 *Scientific Program/Symposium*

From Thalidomide to Pharmacovigilance to Pharmacoepidemiology: Has Drug Safety and Effectiveness Really Improved Since Thalidomide?

7:30am

📌 **Registration**

MORNING SESSION: PHARMACOVIGILANCE

Co-Chairs:

Allen A. Mitchell, FISPE, USA

Helle Kieler, Sweden

9:00am

📌 **Welcome & Introduction to Program**

Miriam CJM Sturkenboom, ISPE President

Nancy Pedersen, Vice Dean of Research, Karolinska Institutet, Sweden

Ulf Bergman, FISPE, Scientific Program Chair, Department of Clinical Pharmacology, Karolinska Institutet, Sweden

9:15am

📌 **Keynote Address – *From Thalidomide to Pharmacovigilance to Pharmacoepidemiology in Sweden***

Barbro Westerholm, Professor Emeritus, Karolinska Institutet, Member of the Swedish Parliament, Sweden

9:35am

📌 **The Irony of the Thalidomide Experience – *When Will We Apply Its Lessons to Safety Surveillance for Antenatal Exposures?***

Allen A. Mitchell, FISPE, Slone Epidemiology Center at Boston University, USA

10:05am

📌 **The WHO International Programme: *From Tabulated Case Reports to Knowledge Finding in Multiple Global Data Sets***

Ralph Edwards, WHO-Uppsala Monitoring Centre (UMC), Sweden

10:35am

📌 **Break**

11:00am

📌 **New European Activities in Drug Safety Research: *EMEA and ENCePP***

Miriam CJM Sturkenboom, Erasmus University Medical Centre, The Netherlands

11:30am

📌 **Antibiotic Resistance – *The Hidden Threat to Global Public Health and The Missing Link in Pharmacovigilance***

Otto Cars, Swedish Strategic Programme Against Antibiotic Resistance – STRAMA, Sweden

12:00pm

📌 **From Pharmacovigilance to Pharmacoepidemiology: *25 Years Later***

Stanley A. Edlavitch, Lifetime Emeritus, ISPE, University of Missouri School of Medicine, USA

12:15pm

📌 **Lunch**

AFTERNOON SESSION: PHARMACOEPIDEMIOLOGY

Co-Chairs:

Sebastian Schneeweiss, FISPE, USA

Björn Wettermark, Sweden

Symposium on Comparative Effectiveness Research (CER)

1:15pm

📌 **Comparative Effectiveness Research from the Perspective of a Pharmacoepidemiologist**

Sebastian Schneeweiss, FISPE, Harvard Medical School/Brigham & Women's Hospital, USA

1:45pm

📌 **Methodological Challenges in Comparative Effectiveness Research**

Thomas M. MacDonald, FISPE, Medicines Monitoring Unit (MEMO), University of Dundee, United Kingdom

2:15pm

📌 **Non-Randomized Effectiveness Data and Decision Making in the UK**

Michael Kelly, National Institute for Health and Clinical Excellence (NICE), United Kingdom

2:45pm

📌 **Individual-Based Studies Indicate a Strong Suicide Prevention Effect of Antidepressants**

Göran Isacson, Department of Psychiatry, Karolinska Institutet, Sweden

3:00pm

📌 **Break**

Registration Form

Mid-Year
ISPE 2009
Meeting

ISPE Mid-Year Meeting April 25-27, 2009 Stockholm, Sweden

(Use one form per person; use photocopies for additional registrations.)

BLOCK LETTERS PLEASE

Name for Badge _____

First/Given Name _____ Last/Family Name _____

Position/Title _____ Company/Institution/Affiliation _____

Street Address _____

City _____ State/Province _____ Zip Code/Postal Code _____

Country _____ Email _____

Office Phone _____ Fax _____

*Special Dietary Requirements _____

[A] Registration Fees [US Dollars]

<input checked="" type="checkbox"/> Only check one box.	[1] April 26 Intro to Pharmacoepi A.M. ONLY	[2] April 26 Advanced Topics P.M. ONLY	[3] April 27 Symposium <i>All Day</i>	[4] PACKAGE A Intro Course & Symposium	[5] PACKAGE B Adv. Course & Symposium	[6] PACKAGE C Both Courses (Intro & Adv.) & Symposium
ISPE Member						
Industry	<input type="checkbox"/> \$295	<input type="checkbox"/> \$295	<input type="checkbox"/> \$295	<input type="checkbox"/> \$500	<input type="checkbox"/> \$500	<input type="checkbox"/> \$725
Academic/Government	<input type="checkbox"/> \$170	<input type="checkbox"/> \$170	<input type="checkbox"/> \$170	<input type="checkbox"/> \$290	<input type="checkbox"/> \$290	<input type="checkbox"/> \$430
Student*/Retired/Special*	<input type="checkbox"/> \$55	<input type="checkbox"/> \$55	<input type="checkbox"/> \$55	<input type="checkbox"/> \$100	<input type="checkbox"/> \$100	<input type="checkbox"/> \$140
Nonmember						
Industry	<input type="checkbox"/> \$345	<input type="checkbox"/> \$345	<input type="checkbox"/> \$345	<input type="checkbox"/> \$585	<input type="checkbox"/> \$585	<input type="checkbox"/> \$880
Academic/Government	<input type="checkbox"/> \$225	<input type="checkbox"/> \$225	<input type="checkbox"/> \$225	<input type="checkbox"/> \$380	<input type="checkbox"/> \$380	<input type="checkbox"/> \$575
Student*/Retired/Special*	<input type="checkbox"/> \$65	<input type="checkbox"/> \$65	<input type="checkbox"/> \$65	<input type="checkbox"/> \$110	<input type="checkbox"/> \$110	<input type="checkbox"/> \$165

[B] ISPE Membership - For First Time Joiners Only

Join ISPE now and receive membership benefits through June 30, 2010

Regular Membership \$230 Retired Membership \$80
Student Membership* \$80 Special Membership** \$25

Payment By Credit Card

[In US Dollars]

Visa MasterCard AmEx

Account number: _____

Security code: _____

Name exactly as it appears on card: _____

Expiration date (Month Year) _____

Wire Transfers

Wire transfers will be accepted with an additional \$80.00 (US) payment. Bank transmittal/wire transfer information must include name of sender, proper credit cannot be given for unidentified wire transfer. Contact ISPE office (ISPE@paimgmt.com) for wire instructions.

Cancellation/Refunds

See page 5 for complete policy.

[C] TOTAL [Registration + Membership] \$ _____

NOTES:

* Student must provide ISPE with documentation of full-time status (e.g., clear copy of student ID with a valid date or letter from school or program) - email or fax (301-656-0989)

** Individual must be a citizen and resident in the middle or lower income country as identified by the United Nations (UN Human Development Report 2005, page 364).

Register by

Mail this form with payment to
ISPE - 2008 Mid-Year Meeting
5272 River Road, Suite 630
Bethesda, MD 20816 USA

Fax registration form with credit
card information to the ISPE
Office at 301.656.0989

Web Visit www.pharmacoepi.org **ISPE** Federal Tax ID: 41-1688677

Preliminary Meeting Agenda:

Mid-Year

ISPE 2009

Meeting

Symposium on Comparative Effectiveness Research [Continued]

3:30pm

- 📌 **The Swedish System for Quality Assurance of RA Care: From Capture of Routine Data on Treatment, Through Register Linkages, to Post-Marketing Effectiveness and Safety Studies**

Johan Askling, Department of Medicine, Karolinska Institutet, Sweden

3:45pm

- 📌 **The Challenges of Non-Randomized Comparative Effectiveness Research When Making Payment Decisions**

Madlaina Costa-Scharplatz, PhD, Health Economics and Outcomes Research Scientist, AstraZeneca R&D, Sweden

4:00pm

- 📌 **Implications for Health Policy and Clinical Practice**

Jerry Avorn, FISPE, Harvard Medical School/Brigham & Women's Hospital, USA

4:30pm

- 📌 **Panel Discussion: Pharmacoepidemiology as the Core Discipline for CER: Where Do We Go From Here?**

Co-Chairs:

Gunnar Alvan, Professor and former Director General, the Medical Products Agency (Swedish FDA), Sweden

Hubert GM Leufkens, FISPE, Dutch Medicines Evaluation Board, The Netherlands

Panellists:

All afternoon speakers and a Swedish regulatory agency representative

5:00pm

- 📌 **Final Comments & Adjournment**

Ulf Bergman, FISPE



2009 MID-YEAR MEETING PLANNING COMMITTEE

Ulf Bergman, FISPE, Chair, Karolinska University Hospital/Karolinska Institutet

Mark H. Epstein, ISPE

Helle Kieler, Center for Pharmacoepidemiology (CPE), Sweden

Jim Lewis, University of Pennsylvania/Center for Clinical Epidemiology & Biostatistics

Andrew McAfee, i3 Drug Safety

Allen A. Mitchell, FISPE, Slone Epidemiology Center at Boston University

Sebastian Schneeweiss, FISPE, Harvard Medical School/Brigham & Women's Hospital

Björn Wettermark, Swedish Society for Pharmacoepidemiology (SLEF)

Tourist Information

Welcome to Stockholm

– one of the world's most beautiful capitals. Built on 14 islands around

one of Europe's largest and best-preserved medieval city centers, the Swedish capital is superbly positioned, with stunning and extremely varied scenery in every direction. Stockholm offers a

wealth of museums, theatres, sights, attractions and events, whether your interest lies in history, art, opera, modern dance, traditional handicraft, contemporary design or virtually anything else.



Changing of the Guards:
Alexander V Dokukin,
©Stockholm Visitors Board,
www.imagebank.sweden.se

The **Stockholm Card** offers free entry to 75 museums and attractions, free travel by public transport, free sightseeing by boat (summertime) as well as several other bonus offers. The card is valid 24, 48 or 72 hours from the first time you use it. The card is valid once per attraction and entitles the user to unlimited travel by metro, bus and commuter train.

For more information about Stockholm and the Stockholm Card, please visit the Stockholm Visitors Board website at www.stockholmtown.com

Cancellations/ Refund Policy

If you have to cancel your registration for any reason, ISPE must receive written notification **by April 10, 2009**. Refunds will be issued less a 20% administrative fee after the meeting. No refunds will be issued for cancellations received **after April 10**. Substitute participants will be accepted at the discretion of ISPE.

Mid-Year
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Meeting

**International Society for
Pharmacoepidemiology**
5272 River Road, Suite 630
Bethesda, MD 20816 USA

Address service requested.

First-Class Mail
U.S. Postage
PAID
Hagerstown, MD
Permit No. 93

- 🦋 **Elite Palace Hotel/
Karolinska University
Hospital**
- 🦋 **Stockholm, Sweden**
- 🦋 **April 25-27, 2009**

Hotel Information

ISPE has reserved a block of rooms for the 2009 Mid Year Meeting at the Elite Palace Hotel in Stockholm. The hotel will be the site of the meetings and courses offered on April 25 & 26. The symposium (April 27) will be held in the Nanna Svartz Auditorium of the Karolinska University Hospital, which is a 15-20 minute walk from the hotel.

Please contact the Elite Palace Hotel directly to make your reservations. When making the reservation, please state you are with **"ISPE"** and use the special reservation code **"5056KAR"** to ensure you receive the special discounted ISPE rates. [April 23-24 and 26-28 1318 sek/night/person; April 24-26/weekend rate 985 sek/person/night. Rates include breakfast and VAT.]

Elite Palace Hotel

St Eriksgatan 115
BOX 210 34
100 31 Stockholm

Email: reservation.palace@elite.se

Phone: + 46 8 566 217 40

ISPE meeting code: 5056KAR

Web: www.elite.se/eng/node/705

Travel/Transportation

Planes will arrive/depart from Stockholm-Arlanda Airport, about 40 km north of Stockholm

Rail: The airport has two railway stations (one under Terminal 5 and one with exits to Terminals 2, 3 and 4) for frequent express trains to Stockholm. The *Arlanda Express* (tell: (08) 5888 9000; website: www.arlandaexpress.com) trains reach the city centre in 20 minutes. One way ticket is 240 SEK. Then take a bus, subway or taxi to the Elite Palace Hotel.

Bus: There are bus stations outside Terminals 2, 4 and 5. Buses run to Stockholm City Terminal (journey time - 45 minutes) and to many other destinations. The airport coaches leave Cityterminalen every 10-15 minutes. Bus 583 connects with the commuter train at Märsta station. An Arlanda bus stops outside the Elite Palace Hotel at "Norra Stationsgatan". It takes 30 minutes and probably is faster than taking the train. One way ticket is 110 SEK.

Taxi: Taxis run from directly outside the terminals. When taking a taxi, passengers should speak to a taxi coordinator, found outside the terminal building. Taxis registered as environmentally "clean" cars have a separate queue. At the airline terminals, these "ecotaxis" are always at the front of the queue of taxis. Be sure you set a fixed price of no more than approximately 500 SEK.