25th Anniversary Symposium:
From Thalidomide to Pharmacovigilance to Pharmacoepidemiology: Has Drug Safety and Effectiveness Really Improved Since Thalidomide?

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!
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*

*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.”

Sunday, April 26 2008
Elite Palace Hotel  |  1:30 – 5:30pm

Introduction to Pharmacoepidemiology

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

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
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 Isacsson, Department of Psychiatry, Karolinska Institutet, Sweden

3:00pm  
Break

continued on page 5
**Registration Form**

**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]

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ISPE Member</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Industry</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Academic/Government</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Student*/Retired/Special*</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Nonmember</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Industry</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Academic/Government</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Student*/Retired/Special*</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

☐ $295 ☐ $295 ☐ $295 ☐ $500 ☐ $500 ☐ $725

☐ $170 ☐ $170 ☐ $170 ☐ $290 ☐ $290 ☐ $430

☐ $55 ☐ $55 ☐ $55 ☐ $100 ☐ $100 ☐ $140

☐ $345 ☐ $345 ☐ $345 ☐ $585 ☐ $585 ☐ $880

☐ $225 ☐ $225 ☐ $225 ☐ $380 ☐ $380 ☐ $575

☐ $65 ☐ $65 ☐ $65 ☐ $110 ☐ $110 ☐ $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 |

**[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).

---

**[B] ISPE Membership**

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

| Regular Membership | ☐ $230 | Retired Membership | ☐ $80 |
| Student Membership* | ☐ $80 | Special Membership** | ☐ $25 |

**[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).

---

**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.
Symposium on Comparative Effectiveness Research [Continued]

3:30 pm

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

3:45 pm

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

4:00 pm

Implications for Health Policy and Clinical Practice

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

4:30 pm

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

Panelists:

All afternoon speakers and a Swedish regulatory agency representative

5:00 pm

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)

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 issues for cancellations received after April 10. Substitute participants will be accepted at the discretion of ISPE.
Mid-Year
ISPE 2009
Meeting

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.