Dr Sebastian Schneeweiss, FISPE and President Elect of ISPE, began his talk by defining Comparative Effectiveness Research (CER) as head to head comparisons of active medications as used in routine care. CER studies can produce information that is critical for informed drug coverage decisions by providing comparisons of effectiveness between active drugs, results that are generalizable to a population of actual users, and study sizes large enough to rule out safety concerns. In the US, the recent creation of a federal prescription drug benefit for the elderly (Medicare Part D) has increased the government’s stake in the provision of drug benefits and CER may play a future role in informing coverage decisions, a topic that is controversially debated in the US. In Europe, however, comparative studies of drug effectiveness have long been considered for coverage decisions by European entities such as NICE. In addition, CER may provide opportunities for manufacturers to better demonstrate the real-life advantages of their products.

Dr Schneeweiss next briefly described the analytic approaches available to generate evidence on CER. Large randomized controlled comparative trials continue to be the gold standard. However, such studies are time consuming and very expensive. The high cost and resulting limited feasibility of large comparative RCTs raise the question of when and to what extent non-randomized effectiveness studies are viable options. Ideally such observational CER studies should include appropriate comparator drugs and be generalizable to a population of actual users that represent the real world spectrum of disease severity, comorbidities, co-medications, and adherence. CER studies should be large enough to rule out safety concerns including rare but serious adverse events and to allow the creation of subgroups to study treatment effect heterogeneity. Lastly, CER studies should provide extended follow-up times to allow the study of hard clinical endpoints and be able to generate results quickly.
After outlining his “wish list” for an ideal CER study, Dr Schneeweiss reminded the audience of the challenges of observational CER, including confounding by indication, reliability of outcome assessments, accurate identification of subgroups, and ability to study long-term outcomes. While dealing with these challenges has in many ways been “the daily bread and butter of pharmacoepidemiology” for many years, Dr Schneeweiss pointed out that CER magnifies the importance of addressing these challenges, specifically confounding by indication, because of its focus on effectiveness (i.e., intended effects of treatment). Traditionally, pharmacoepidemiological studies have focused largely on the study of unintended adverse effects (safety research), which generally have less potential for confounding by indication than studies of intended effects (effectiveness research). Dr Schneeweiss also stressed some important general limitations of claims data. Claims data describe the sociology of health care and its recording practices in light of economic interests rather than clinical reality. These data also commonly lack important clinical outcome measures, such as depression scales, or functional measures.

Some of the limitations of claims data may be addressed by combining different data sources to supplement claims data with e.g., electronic medical records or prospective registry studies. Dr Schneeweiss illustrated several methodological approaches that offer the potential to meet the challenges of non-randomized studies of intended treatment effects, specifically cross-over studies, instrumental variables, and high dimensional proxy adjustment. Cross-over designs have distinct advantages because they control for certain, constant within-person factors by design (e.g., genetics), but because only a limited set of research topics are amenable to such designs, they remain rarely used. Instrumental variable analysis allows adjustment for unmeasured confounding but the identification of suitable instruments remains a challenge. Lastly, high dimensional proxy adjustments offer promise and are well-suited to be applied in complex automated research databases, but do not rule out unmeasured confounding. Other methodological challenges include the appropriate evaluation of treatment heterogeneity, the need for simultaneous evaluation of both benefits and risks, and the difficulty of studying long-term outcomes when side effects and treatment failure determine patient adherence.

Dr Schneeweiss was confident that while many methodological challenges remain, CER activities will ultimately result in better informed decision making by providers and payers. Dr Schneeweiss concluded that ISPE has the brain power to substantially contribute to CER through teaching, training, methods development, exemplary studies, and the interpretation and translation of findings.

**A new pre-ICPE course on CER will be offered on August 16 at ICPE 2009**

**Contributed by Tobias Gerhard, Ph.D.**
Prof. Ralph Edwards (Director, WHO–Uppsala Drug Monitoring Centre (UMC)), presented an update on the WHO Programme for International Drug Monitoring. The WHO International Programme was started in 1968 to pool existing data on adverse drug reactions (ADRs). Initially a pilot project in 10 countries with established national reporting systems for ADRs, the network has since expanded significantly as more countries worldwide have developed national pharmacovigilance centres for the recording of ADRs. Currently, 86 countries participate in the programme, which is coordinated by UMC.

The coordinating Centre is responsible for maintaining the global ADR database, Vigibase, which contains almost four million ADR reports. New Zealand, the USA, and the Netherlands have the highest rates of ADR reporting. Nausea, rash, headache and dizziness are the most frequently reported suspected ADRs. Among the most frequently reported categories of ADRs are lack of drug effects. Medications most frequently cited in reports include ethynylestradiol-norgestrel and rofecoxib. For fatalities, thalidomide is most often cited in non-developed countries, while clozapine and warfarin are the most common exposures in developed countries.

Prof Edwards noted that a lot of complex quality assurance is constantly required for data management, as a quarter of million of case reports are received at the UMC every year. Beyond data collection, knowledge discovery through the analysis of all data appears to be extremely challenging. Although a large number of case reports are collected, information on each report is often limited.

In recent years, signal detection at the Uppsala Monitoring Centre has been based on automated quantitative data mining, using Bayesian statistics and a neural network architecture. The unit of analysis is the Information Component (IC): the higher the IC, more reliable a drug-event association as potential signal. Over a certain threshold, the potential signal is retained and submitted to experts for further evaluation. Overall, from almost 4 million case reports, this system filters only 5,000 drug-event combinations. The analysis is repeated every quarter. A triage system filters the potential signals for the expert validation. This triage combines qualitative and quantitative criteria: 1) presence of positive IC, 2) new and serious signal, and 3) quarterly IC increase of 2 or more.

An international review panel of 40-45 medical experts from different disciplines and 22 countries validates the results. The review of all potential signals is performed centrally and is based on the experts’ intuition and experience as well as on the quality of the reports. A quality grading score ranging from 0 to 3 (0=information on country, drug, and ADR; 3= as 0, plus information on date of ADR onset, date and reason for drug treatment, outcome of ADR, and rechallenge) is adopted. For each potential signal, reviewers have three possible choices: 1) no signal, 2) signal, and 3) request for further follow-up.

continued on page 4
For example, the association between topiramate exposure and glaucoma was identified through this complex signal detection process in 2001. Yet, not until 2004 did the US Food and Drug Administration (FDA) begin requiring a warning label about this association. Similarly, the signal terbinafine-angioedema was identified in 2000, but an FDA warning label was not issued until 2004. In light of these examples, Professor Edwards underlined the need to speed up the process for signal detection and communication.

In addition to case report data, longitudinal patient healthcare data could be used for signal detection. Compared to spontaneous reporting system data, these data are closer to reality, contain the complete patient history and have a denominator. However, a number of possible confounders and terminology issues have to be resolved. The case-cross over design has been adopted by UMC in pilot studies to identify potential signals, such as paroxetine-dyspareunia and atenolol-fascial palmar fibrosis. The main issue remains on how to distinguish false positive signals.

Contributed by
Gianluca Trifirò, MD, MSc

Susana Perez-Guthann, Elizabeth Andrews
Miriam Sturkenboom

Ingemar Persson, Jerry Avorn,
Madlaine Costa-Scharplatz
When dangerous drugs cause tragedy, they expose the inadequacies of the existing system and foment structural and policy changes. Dr. Barbro Westerholm, a member of the Swedish parliament and a pioneer of pharmacovigilance and pharmacoepidemiology, recounted historic milestones in Sweden following the thalidomide disaster in her keynote address at the 2009 Mid-Year Symposium meeting in Stockholm.

Dr. Westerholm recounted that in the absence of post-marketing surveillance or of any structured way of handling previously unknown serious adverse events, the system failed to mitigate the thalidomide disaster. Thalidomide was initially thought to be just a “small white sleeping pill,” assumed to be safe to use by pregnant women without the need for fetal studies. Suspicions quickly arose that the drug caused neuropathies shortly after its approval in Sweden in 1959. Two years later, news of malformation in babies appeared in Sweden’s mass media and the drug was removed from the market. In order to avoid widespread panic, however, the finding that thalidomide could cause malformations was not widely communicated to the public. Approximately 130 children were born with malformations in Sweden. The number of cases may have been reduced if the risks of the drug had been widely disseminated and adequately communicated.

The thalidomide experience underscored the need for a system of pharmacovigilance, Dr. Westerholm explained. To establish an early warning system, the WHO recommended states create centers to which suspected adverse drug events could be reported. The Swedish Malformation Registry and Swedish Drug Monitoring Center were created in 1964 and 1965, respectively. In the first years following the creation of the Drug Monitoring Center, which was headed by Dr. Westerholm, the limitations of pharmacovigilance and spontaneous reports became apparent. Causal associations were difficult to study due to polypharmacy and the lack of data on re-challenges. The amount of underreporting, the extent of use of reported medications, and patient-level characteristics were unknown. Moreover, physicians paid more attention to newspaper headings than communications sent to them by the Center.

The beginnings of pharmacoepidemiology in Sweden can be traced back to 1969 with a Lancet publication in which the associations between blood groups and venous thromboembolism among users of oral contraceptives were evaluated. Moving beyond spontaneous reporting, Dr. Westerholm and her co-authors, heralded an age where Swedish patient registries were used to study post-marketing drug safety profiles. An advantage of registries was that unreported adverse reactions could now be identified. Moreover, using Swedish personal identification numbers, patients could be traced both in spontaneous reporting database and patient registries. Accurately quantifying risks remained problematic, however, because drug use could only be estimated from sale statistics.

In 1964, the Swedish government suggested a study of drug utilization. For antibiotics, Dr. Engel of Sweden and Dr. Siderius of the Netherlands found that prescribing rates varied between and within European countries, indications for antibiotics varied, subsidies resulted in increased antibiotic use, and socioeconomic factors were important predictors of use. The value and potential ramifications of findings from drug utilization studies for the healthcare sector and drug manufacturers were recognized and resulted in the establishment of the WHO Drug Utilization Research Group in 1970 and
the Swedish National Corporation of Pharmacies in 1971, which was charged with developing a prescription drug registry and publishing figures on drug use.

Swedish drug utilization quality has improved over the last decades. The first studies only had sales or high-level prescription data at their disposal. By 1969, Sweden had an individual prescription registry in the county of Jämtland which, by 2005, had expanded into a national, individual prescription drug registry. These registries are not only suited for answering traditional pharmacoepidemiologic questions but can also be used for risk evaluations and for quality assessments of prescribing practices. Despite these ameliorations, the data are still limited by lack of information on indications and on patient adherence, persistence, and compliance.

In her concluding remarks, Dr. Westerholm stressed that, with respect to pharmacovigilance, Sweden is much better poised today than on the eve of the thalidomide disaster. If the current Swedish system had existed in 1959, a signal would have been generated, women who purchased thalidomide could have been contacted, and the disaster could have been mitigated. In looking forward, it is important that we not forget the tragedy that served to highlight the need for such a system: 130 children in Sweden and 10,000 children around the world were harmed by what turned out to be anything but just a small white sleeping pill.

[Editors note: Presentation from the 2009 Mid-Year Symposium are posted in the Members Only section of the ISPE website]
On March 24-25, 2009 the International Society of Pharmacoepidemiology (ISPE) in collaboration with the Fundación Mexicana para la Salud (FUNSALUD) held the First Latin-American Pharmacoepidemiology Meeting in Mexico City. This meeting was the result of two years of planning between FUNSALUD and ISPE; two organizations that share a common interest. FUNSALUD is dedicated to the promotion of national and international scientific research initiatives intended to strengthen the Mexican health sector.

In the opening ceremony, the need for education and training in pharmacoepidemiology and pharmacovigilance in Latin America were emphasized by the Minister of Health of Mexico, Dr. José Angel Córdova joined by the ISPE President Dr. Miriam CJM Sturkenboom; by the Head of COFEPRIS (equivalent to the FDA in the USA), Dr. Miguel A. Toscano; the Head of CANIFARMA (equivalent of Pharma in the USA), Dr. Carlos Abelleyra-Cordero; the Regional Representative of PAHO, Dr. Philippe Lamy; and the President of Funsalud, Dr. Manuel H Ruiz de Chávez.

More than 100 participants represented government, industry, and academia. ISPE professors participated in symposiums, lectures and short-courses. Drs. Stanley A. Edlavitch and Samy Suissa reviewed the importance of pharmacoepidemiology and pharmacovigilance for public health. They emphasized the key role of collaborations to reduce the gap between developed and developing countries. Drs. Miriam CJM Sturkenboom and Abraham G. Hartzema described safety monitoring systems, the FDA’s Sentinel Project, and how some lessons learned by developed countries might be adapted for developing countries. Given the limited information on the use of medicaments in developing countries, attendees were interested in the session related to drug utilization studies presented by Drs. Maribel Salas and Abraham Hartzema from ISPE, as well as Veronika Wirtz, and Diego Cortina from Mexico. Another ISPE professor, Dr. Bruce Carlton joined Drs. Sandra Lopez, O Reyes-Hernandez, Gilberto Castañeda and Gerardo Jiménez-Sánchez to discuss their experiences in genomics and pharmacokinetics for population of Mexicans and Canadians.

The current status of some Latin America pharmacoepidemiology and spontaneous reporting systems were described by Dr. Albin Chaves from Caja Costarricense del Seguro Social (CCSS), Costa Rica in collaboration with Dr. Julian Perez-Peña from Centro para el Desarrollo de la Farmacoepidemiología in Cuba, Dr. Rogelio Fernández-Argüelles from the Universidad Autónoma de Nayarit in Mexico, Dr. María-del-Carmen Becerril from the Mexican National Center of Pharmacovigilance, Dr. Augusto Bondani from Fundación Instituto Mexicano del Seguro Social, and Dr. Jose Luis Castro from PAHO. According to Dr. Fernandez-Argüelles, the Cuban pharmacoepidemiology program was created because Cubans needed to be sure that the few available medications were distributed rationally, prescribed appropriately and with early identification and mitigation of adverse events. The Cuban Pharmacovigilance Center is connected with 32 centers, one in each state, and they developed their local pharmaceutical industry responsible of producing generics. Costa Rica has a universal health care system and their pharmacovigilance center collects adverse events, similar to other countries. Mexico has a pharmacovigilance system, which also is connected with all states. Adverse events data are analyzed by the Uppsala Monitoring Center, a World...
Health Organization Collaborating Centre for International Drug Monitoring.

The closing ceremony took place at the National Academy of Medicine located at the headquarters of the Instituto Mexicano del Seguro Social (the Mexican Social Security Institute), the federal organization working on public health, pensions and social security in Mexico. Drs. Sturkenboom, Edlavitch, Enrique Ruelas-Barajas, Mario H. Rodriguez-Lopez, Carlos Abelleira-Cordero, and Manuel H Ruiz de Chávez participated in that ceremony. The relevance of closing the event at the National Academy of Medicine reflects the Mexican interest in pharmacoepidemiology, and the commitment of ISPE to continue achieving excellence in medicine through the education and training health care professionals to improve the quality of life of Mexicans.

**ATTENTION ALL TRAINEES!**

The Career Center on the ISPE website has opportunities of interest! Whether you're looking for a new job, student internship, or you are ready to take the next step in your career, use ISPE to help find the opportunity that's right for you. For new listings of internships and fellowships, go to:

careers.pharmacoepi.org
ISPE ELECTION RESULTS ARE IN!

The results of the 2009 election are in. ISPE appreciates all those participating in the election. The winners are……

President-Elect
Stephen Evans

VP Finance-Elect
Matthew Reynolds

Board Industry, North America
Elizabeth Andrews, FISPE
Robert Reynolds

Board Academic, North America
Colleen Maxwell

Board Academic, Non-North America
Lolkje van den Berg

Board Government, Non-North America
Stella Blackburn, FISPE

The newly elected officers and director will take office in August during the ICPE 2009. Thanks also to these ISPE members who stood for election: Alejandro Arana FISPE, Gianluca Tirifiro, Ron Herings FISPE, James Lewis FISPE, Rhonda Bohn FISPE, Wanju Dai FISPE, and Susan Oliveria.
Looking Back, Learning Forward

History is a guide to navigation in perilous times. History is who we are and why we are the way we are.

-- David C. McCullough

In the 1980s, the overall environment for the use of automated record linkage in post-marketing surveillance of drug safety was favorable. Scientists and the pharmacy industry both welcomed and praised this newly born method of post-marketing surveillance. They were excited at the advantages of using automated record linkage such as the accessibility to large study population, low cost and fast speed to get results. Unfortunately, little attention was paid on evaluation of the validity and scientific nature of these quick, easy, and cheap studies. What was the real quality of the evidence, good or poor? Were there errors in our decisions and actions only based on the evidence derived from automated record linkage? This article was written by one of my graduate students at Brown University who took my advanced pharmacoepidemiology course. The piece was shortened significantly to meet the needs of this column. I welcome contributions which stay true to the theme of reflecting and learning about past challenges in pharmacoepidemiology. Please forward ideas to: Kate.Lapane@brown.edu.

Comments on the historical piece,
“The role of automated record linkage in the postmarketing surveillance of drug safety: a critique” by Samuel Shapiro

By Xiaozhong Wen, PhD © Graduate student, Brown Medical School

Twenty 20 years ago, Samuel Shapiro published a critique on the use of automated record linkage in postmarketing surveillance of drug safety. His critique focused on nine well-known studies including: 1) allopurinol and cataracts, 2) hip fractures and psychotropic drug use, 3) gallbladder disease and oral contraceptives, 4) gallbladder diseases in relation to thiazide use, 5) antidepressants and beta-blockers, 6) birth defects and spermicide exposure, 7) drug use in relation to the risk of cancer, 8) nonsteroidal anti-inflammatory drugs (NSAIDs) in relation to upper gastrointestinal bleeding, 9) replacement estrogens and endometrial cancer. Evaluating the validity of these studies one by one, according to the criteria for epidemiological causality, including exposure, outcome, timing, bias, confounding, coherence, statistical stability, and strength of association, Shapiro found only one study (hip fractures and psychotropic drug use) fulfilled these criteria and another one partially fulfilled them noting that “…most of the examples serve as illustrations of how theses resources should not be used”.

Moreover, he commented on difficulties of overcoming their shortcomings, “some of the shortcomings reflect poor, but partly or wholly correctable, method”, “other problems, however, are intrinsic to the limitations of automated data”, which meant that we had very little opportunity to change the current situation. He also argued that “…most situations are far too complicated to be susceptible to valid analysis that is based solely on information contained in computer files”. To support his argument, Shapiro listed several challenges in using automated records, including inadequate computer-recorded prescription to define the exposure, inadequate formation for diagnosis for the outcome, inaccurate or unknown time of onset of the disease, rare opportunity to assess potential confounding, low statistical power for rare conditions, and sometimes common outcomes related to commonly used drugs. Finally, Dr. Shapiro gave his answer, “not yet—not on the evidence from the first decade of experience” to the critical question “can automated record linkage become a widely applicable method of postmarketing surveillance?”

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As Dr. Samuel Shapiro stated, his critique was “…the first general critique of automated record linkage that has been undertaken”. He was one of the first people who spoke “hold on!” loudly among an ocean of “hurrah!” on the use of automated record linkage in drug safety. His article warned about the potential misleading results coming from previous studies in which automated record linkage was used. After reading his article, we can have a better understanding on their methodological deficiency and build up critical perspectives on their findings. It is also helpful for us to sharpen insights of the correctable and intrinsic limitations of using automated record linkage.

One of the possible impacts of Dr. Samuel Shapiro on this field is the increasing suspicion on the findings from the automated record linkage. Readers may hold more critical perspectives for published papers in this field. Another potential impact could be the decreasing number of funded studies and published papers using automated record linkage. This theoretical statement, however, needs to be verified with a comparative study with convincing data before and after the article being published. Government regulators (e.g. FDA) might also have some concerns and do corresponding review. But the possibility of significant changes or actions should be small as this is just one article. The pharmacy industry may also have some awareness about the tool of automated record linkage. It is necessary to note that the pharmacy industry always takes actions according to FDA’s warning. But not everyone agrees with Dr. Shapiro. For example, Dr. Gerald A. Faich wrote a response titled, “The future of automated record linkage for postmarketing surveillance”, in the same journal with Dr. Shapiro’s. After pointed out some flaws in Dr. Shapiro’s article, he argued “…criticism are not new, they can be found in other research method”. He also highlighted advantages of automated record linkage and the absence of “viable al-

References:

In 2007, the Second Edition of Nelson and Williams’ book “Infectious Disease Epidemiology: Theory and Practice” was published (Jones and Bartlett Publishers, Sudbury, Massachusetts). The 1207-page book serves as the definitive source of information on infectious disease epidemiology. The book is well-referenced and well-written but it has several flaws that were unexpected and are atypical for a book of this caliber. First, there are errors in several places such as near the beginning of the book (page 19) where Figure 1-3 is labeled “Crude death rate for infectious disease, United States, 1990-96” but both the source and the figure itself represent the period from 1900-2000 (or 1996, but it is difficult to definitively discern from the text). In addition, the book contains errors in laboratory units- for instance, CD4+ counts are incorrectly given the units of “cells/mL” on page 410 but are elsewhere mostly (correctly) referred to in units of “cells per microliter”. Finally, the organism that causes Pneumocystis pneumonia (PCP) is referred to throughout the book as *Pneumocystis carinii*- however, the nomenclature was officially changed in 1999 to *Pneumocystis jirovecii* for the species that infects humans and *P. carinii* is now the name for the species that only infects rodents.

Although these errors undermine the credibility of the text, this second edition remains a classic and probably the definitive source on its topic. Let us hope that the third edition does a better job.

Contributed by
Michael Wess, MD, MBA  mwess@jhsph.edu
Adverse drug reactions can greatly limit the clinical utility of a treatment. Genetics offers one approach to understanding the cause of such adverse events as well as a method for identifying susceptible patients. The translation of pharmacogenomics into personalized genomic medicine and its integration into clinical practice presents both opportunities and challenges for the field of pharmacoepidemiology.

One promising application of novel clinical pharmacogenomic technologies is the potential for improving drug safety. There are currently over 120 drugs that are approved by the United States Food and Drug Administration (FDA) that contain pharmacogenomic information in the label. Of these, there are several drugs for which genotyping is available explicitly for safety purposes.

Traditionally, the role of the pharmacoepidemiologist has been to investigate and evaluate drug utilization, pharmacoeconomics, and outcomes of drug therapies, including the investigation of possible adverse events. How might pharmacoepidemiologists contribute to the appropriate integration of pharmacogenomics applications into health care delivery? There are a number of important areas for pharmacoepidemiologists to contribute towards improving the use of pharmacogenomics prior to its integration into clinical practice. One particular challenge that pharmacoepidemiology can contribute toward resolving is the lack of replication among various genetic association and pharmacogenomics studies. Other relevant limitations include studies that have shortcomings in study design (e.g. a case-control design with disease prevalence of 50%); studies that fail to consider the particular prevalence of the variant of interest in calculating sample size; a number of studies with an unclear description of the study population and inclusion or exclusion criteria. In addition, a number of studies suffer from a lack or failure to appropriately consider the effect modifier such as gene-gene interaction or other confounders (such as age, environmental interactions, BMI, etc), or exposure assessment (i.e. the candidate genotype).

Clearly, more rigorously conducted studies are necessary to overcome these challenges, and pharmacoepidemiologists are well-positioned to contribute to ensuring improvements in study design, which are fundamental to the ultimate goal of successful translation of pharmacogenomics into clinical practice. Additionally, pharmacoepidemiologists can contribute to the qualification of biomarkers, a necessary focus for regulatory decision-making by the FDA, the European Medicines Agency (EMEA), Health Canada and other regulatory agencies. The qualification of biomarkers refers to the level and type of data needed to understand the potential clinical utility of specific biomarkers. The FDA generally classifies pharmacogenomic biomarkers as either required, recommended, or information only. There is also a need for cost-effectiveness and other pharmacoeconomic studies to assist policy makers make evidence-based decisions. The FDA’s re-labeling of warfarin to incorporate recommended genotyping for the Vitamin K epoxide reductase complex subunit 1 (VKORC1) and cytochrome P-450 2C9 (CYP 2C9) prior to initiation of warfarin therapy provides a good example of how the tools of epidemiology can contribute to moving the field of pharmacogenomics forward.
The premise behind the FDA’s re-labeling of warfarin is that individuals with variations of the VKORC1 and CYP2C9 genes may require lower doses of warfarin to achieve a therapeutic effect and avoid a potentially serious adverse event (bleeding). In brief, epidemiologic studies have provided evidence related to the prevalence of CYP2C9 and VKORC1 variants, and strong causal relationships for single nucleotide polymorphisms (SNPs) (i.e. CYP2C9 in pharmacokinetics; VKORC1 in pharmacodynamics). Epidemiologic studies have also demonstrated consistent associations between specific genotype and time to therapeutic International Normalized Ratio (INR) during warfarin induction, observed differences in therapeutic doses between genotypes, and consistency of results across studies among different warfarin inductions, and across racial/ethnic populations.

Several areas for pharmacoepidemiologists to contribute to the pharmagogenomics evidence base include:

- Evaluating the strength of associations (odds ratios, relative risk)
- Replication of findings
- Investigation of dose-response relationships (homozygous; heterozygous)
- Evaluating and ensuring study quality (design, bias issues, and statistical considerations).

Progress in the field of pharmacogenomics and its integration into clinical practice is dependent upon appropriate study design and the resolution of several other challenges discussed in this brief paper. Pharmacoepidemiologists have the expertise and expertise to contribute towards moving this important field forward, particularly in adding value to evaluating how the use of novel genomic technologies can be better used to guide pharmacotherapy and avoid adverse drug events in populations.

References:
8. FDA. Questions and answers on new labeling for warfarin (marketed as Coumadin) www.fda.gov/cder/drug/infopage/warfarin/qa.htm

A ROLE FOR PHARMACOEPIEIDOLOGISTS

(continued)
We are proud to invite you to the 4th Asian Conference on Pharmacoepidemiology (ACPE) in October 2009 at Tainan, Taiwan. The Conference will be co-hosted by the Pharmaceutical Society of Taiwan and the International Society for Pharmacoepidemiology. The theme for this year’s meeting is “Communication and Collaboration for Safety”. All the participants will find the program rewarding and the culture and hospitality of Tainan City an unforgettable experience. We look forward to seeing you in Tainan in October 2009!

Features

- Improving drug safety and effectiveness through communication and collaboration
- Assessing benefits and risks of pharmaceuticals
- Managing therapeutic risks based on evidence from pharmacoepidemiology
- Communicating drug risks to stakeholders
- Applying pharmacoepidemiology research to policy making
- Using databases in pharmacoepidemiology research
- Improving prescribing quality
- Employing pharmacogenomics in ADR

Registration & Abstract

www.acpe-taion.org.tw
Deadline for abstract submission is June 30, 2009
Deadline for early bird registration is August 15, 2009.

Venue

College of Medicine, National Cheng Kung University, Tainan, Taiwan

Invited Speakers

Jenry Arunen, FISPE
Harvard Medical School/Brigham & Women’s Hospital, USA
Ulfr Bergman, FISPE
Karolinska Institute, Sweden
K Arnold Chan, FISPE
13 Drug Safety/Harvard School of Public Health, USA
Yao-Mau Chang
United Daily News, Taiwan
Yi-Chia Chen
Division of ADR, Monitoring of SFDA, China
Herong-Deh Chen
Center for Drug Evaluation, Taiwan
Wen-Hung Chang
Chung Gung Memorial Hospital, Taiwan
Yogendra Kumar Gopin
All India Institute of Medical Sciences, India
David Henry
Institute of Clinical Evaluation Science in Toronto, Canada
Weng-Fong Huang
National Yang Ming University, Taiwan
Kiyoshi Kubota
University of Tokyo, Japan
Hubert Leefmans, FISPE
Dutch Medicines Evaluation Board/ Utrech University, Netherlands
Frank May, FISPE
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To pursue and enhance achievement of ISPE’s mission and objectives, ISPE Board has been supporting the development of plans for Asian educational meetings since 2006. As a result of the detailed planning work of the Global Development Committee (GDC) and every organization, the success of ISPE’s first three Asian meetings in China, Japan and Korea has established the momentum for the development of pharmacoepidemiology disciplines in the Asian region. To continue the previous endeavors, the Pharmaceutical Society of Taiwan jointly with ISPE will host the 4th Asian Conference on Pharmacoepidemiology (ACPE) at Tainan, Taiwan in October, 23-25, 2009.

The main theme for this ACPE 2009 is “Communication and Collaboration for Safety”, which is to provide an opportunity for the open exchange of scientific information, practical experiences and regulatory concerns. The Conference is featuring educational sessions, special lectures, symposia and poster/oral presentations in a 3-day program.

David Henry from Institute of Clinical Evaluation Science in Canada will be the keynote speaker, talking about "Improving drug safety and effectiveness through communication and collaboration"; Hubert Leufkens from Utrecht University, Netherlands and Wen-Hung Chung form Chang Gung Memorial Hospital, Taiwan, will give Wrap-up lectures driving at "Quantitative assessment on benefit and risk" and "Application of pharmacogenomics in ADR prevention".

The educational sessions will include introduction and methodology on pharmacoepidemiology, therapeutic risk management, risk communication with media, as well as critical issues on using database in pharmacoepidemiologic research. K. Arnold Chan, Songlin Xue, Yao-Mao Chang, Byung-Joo Park and Weng-Foung Huang will be lecturers for the courses.

Three symposium sessions will be provided, themed with “Communication on drug risk among stakeholders”, “Application of pharmacoepidemiology research for policy making” and “Improving prescribing quality”. In the first symposium, Songlin Xue, Hubert Leufkens, Sebastian Schneeweiss, and Jerry Avorn will have discourses on communication on drug risk from various stakeholders’ perspectives, representing industry, government, academia, and practitioners. Secondly, David Henry (Australia/Canada), Hubert Leufkens (Europe), Yogendra Kumar Gupta (India), Sri Suryawati (Indonesia), Kiyoshi Kubota (Japan), Byung-Joo Park (Korea), and Herng-Der Chern (Taiwan) will share experiences on how to apply pharmacoepidemiology research for policy making in each country. In the third one, Ulf Bergman, David Henry and Frank May will address how to improve prescribing quality though implementing evidence based medicine into practice and the point of views from general practice and academic.

What’s more, all the works relevant to drug utilization, outcome research and other practical issues are welcome to submit abstracts. For all the submitted abstracts, excellent oral presentations and posters papers will be selected for awards conferring in closing session.

The location for this conference, Tainan, is the oldest city in Taiwan and is rich in history. Dutch forts and European merchant houses are now the glittering gems in Tainan, reflecting the prosperous legacy from 17th century. The first Confucius Temple (built in 1665) being the first academy for higher education.
in Taiwan is located in Tainan. From year 1895~1945, the Japanese governance further shaped the architecture and culture of the city. Today, Tainan is renowned as the capital of culture and education of Taiwan.

The venue this time, College of Medicine, National Cheng Kung University (NCKU) and its affiliated medical center are founded in 1984. Until now, it consists of five departments and fifteen institutes with the Department of Medicine being the largest. The College boasts the highest faculty-to-student ratio among the eleven medical colleges in Taiwan, emphasizing the care and precision placed on education by NCKU Medical College. Since the inception of Taiwan’s Ministry of Education’s (MOE) project “Promoting Academic Excellence and Developing World Class Research Centers” in 2005, NCKU has been chosen as one of the top two main schools for “promoting toptier universities”. In 2008, the MOE has once again recognized NCKU as one of the best universities in Taiwan.

The deadline for abstract submission is June 30, 2009 and that for early bird registration is August 15 2009. For more detailed information, please visit the website: www.acpe-taiwan.org.tw.

We anticipate all the participants will find the program rewarding and the culture and hospitality of Tainan an unforgettable experience. We look forward to seeing you in Tainan.

ATTENTION MEMBERS!

*The 25 th Anniversary ICPE to be held in Providence, Rhode Island from August 16-19, 2009* is quickly approaching and will undoubtedly be an educational and memorable experience. In addition to the traditional conference events, the Scientific, Local and 25 th Anniversary committees are adding additional items to the agenda to celebrate and commemorate the past 25 years. To this end, we are trying to create a memory wall for display during the conference and need your help in doing so. Specifically, we are asking for you to share memories of past ICPE conferences, whether good, bad or even ugly! We are also looking for photos that can be displayed highlighting conferences past, representing memorable, collegial or funny conference moments. If you have a story, a comment or a picture that you are willing to share, please send them along via e-mail *(e-mail to Brian Quilliam, bquilliam@uri.edu)* by July 15 th . With your submission, please indicate whether you would like your story/comment to be displayed anonymously or include your name. For photo submissions, please include the name(s) of the people portrayed in the photo and please add a caption to the photo as appropriate.

We look forward to seeing you in Providence this August!

Regards,
Brian Quilliam, PhD, Chair, Local Host Committee
Susan Sacks, PhD, FISPE, & Kate Lapane PhD, FISPE, Co-chairs, 25th Anniversary ICPE Committee
A few years ago, I was approached by Sean Hennessy, FISPE, and asked if I would be interested in being the scientific chair for the ICPE 2009 meeting. I immediately said “SURE!”

Lesson 1: Look before you leap!

ISPE has a shadowing mentoring experience which allows the chair to serve on the Core Planning Committee for several years before the reins are passed over. Witnessing how the meeting is formed is an essential aspect to preparing a chair to lead a group of highly motivated, enthusiastic, people with very strong opinions, to create a program that appeals to the constituents of our society.

Lesson 2: Appreciate opportunities to observe and learn.

My year began on a less than positive note. In Copenhagen, I prepared slides for the Final Word. I had hoped to share my vision for the 25th ICPE and to share a glimpse of the city that I had called my home for 43 years. Technology let me down and I was disappointed that I was not able to share the sites and sounds of Providence in hopes of intriguing the masses. Immediately after, I chaired a lively debriefing session where about 35 persons interested in helping make our meetings better met for about an hour. During the session, I led a discussion of aspects of the program that were valued and areas that needed improvement. Despite attempts to focus on the scientific dimensions of the meeting, the gang could not help but bring up the non-scientific highlights and low points of the meeting.

Lesson 3: Listen, document, and be thoughtful about things that are modifiable and things that are not.

In September, the major task was to work collaboratively with Mark Epstein, Executive Secretary, to develop the Core Planning Committee. Clearly, there are more volunteers than there are slots available on the committee. The Committee does its work via teleconference – so we were shooting for a maximum of about sixteen-eighteen or so members. Some slots are mandated -- the president, president-elect, and scientific chair and scientific chair elect are members. Then, I sought balance across academy, industry, and government. I also sought balance between members of the society who have been contributing on this committee consistently and fresh faces. Lastly, I attempted to try to have geographic representation. Formal invitations went out at the end of September and everyone approached said yes. Mark had the arduous task of trying to find a time for all to participate – from California to Australia. I particularly thank Andrew Gilbert, for it was 11:00pm when he was participating on the calls.

continued on page 19
Lesson 4: Having other key jobs for enthusiastic volunteers who did not end up on the Core Program Planning Committee appeared to make volunteers happy.

In addition to testing the website and proofing the Call for Abstracts, the main task for the fall is the identification of invited speakers and topics for the plenary sessions. The Core Committee also began brainstorming for potential “Hot Topics”. This year, I proactively reached out to each SIG to encourage them to get preliminary feedback from the Core Committee regarding ideas for symposia and workshops. I had hoped that we might develop a “TRACK” for each SIG where their members could see a clear sequence of opportunities to keep them interested through the meeting. What was clear through this process – there were fabulous ideas that would make for a stimulating meeting.

Lesson 5: Reach out to the broader membership to make sure that the high profile persons in our field we’d like to engage in the meeting are offered “INVITED” slots.

Once the abstracts for workshops and symposia come in, they are reviewed by the Core Committee. Summary reports with the average rankings for the symposia and workshops are provided to the Core Committee. While ranking is strongly considered, the committee is also searching for representation across the SIGs, balance, and depth.

We are also limited by the number of available break out rooms – which may differ depending on the venue. Because Providence had more than 5 rooms available, we were able to offer more than the standard 15 concurrent workshops and symposia held in recent years. We did so realizing that we may be running the risk of having lower attendance at some of the offerings. Once again, there were unhappy submitters disappointed when their abstracts were not accepted. When strong rationale was provided, I made executive decisions regarding adding high profile speakers in accepted sessions or adding another session if there were groups not adequately represented in the program.

Lesson 6: Being a scientific chair is a thankless task – and if you are the type of person who wants to make everyone happy, this may not be the job for you!

Now that all the presenters have been informed of decisions, and the late breakers vetted and decided upon, the remaining tasks include selecting rooms and dealing with author issues, as well as assuring balance in the workshops or symposia that have had changes in their speaker lineup. This experience (despite my own whining) has been a rewarding opportunity to hone diplomacy skills, meet people, and work with the fabulous staff at PAI Management and Marathon Multimedia.

Contributed by Kate Lapane, FISPE
Chair, 2009 ICPE Scientific Program Committee
PRE-ICPE COURSES (August 15-16; separate registration required)

*Introduction to Pharmacoepidemiology; *Introduction to Pharmacogenetics (NEW);

*Regulatory Epidemiology/Public Health Decision Making;

*Introduction to Drug Utilization/Health Services Research; * Comparative effectiveness Research (NEW);

*Introduction to Risk Management; * Advanced Topics in Pharmacoepidemiology

PLENARY SESSIONS

- **Keynote Speaker**: Accounting for Uncertainty About Investigator Bias, Sander Greenland, UCLA

- **Invited Plenary Speaker**: National Pharmaceutical Policy Imperatives: Implications for Pharmacoepidemiologists, Lloyd Sansom, Emeritus Professor; University of South Australia: Chair, Pharmaceutical Benefits Advisory Committee; Australian Government Department of Health and Ageing

- **FDA’s Sentinel Initiative Project** – Richard Platt, Harvard University, Mark McClellan, Brookings Institute, Janet Woodcock, FDA

- **Hot Topics Session**: Clopidogrel: Has Pharmacogenetics Era Arrived? – Jessica Mega, Brigham & Women’s Hospital/Harvard Medical School; O.H. Klungel, Utrecht University; Alan R. Shuldiner, University of Maryland School of Medicine; Bonny L. Bukaveckas, Virginia Commonwealth University School of Pharmacy; and Leah Sansbury, NCI, NIH

PLUS, 20 symposia/workshops, 25 oral sessions, & 400 poster presentation; poster walks; exhibitors; committee, council and special interest group meetings; special student functions; Welcome Reception/Academic Showcase (August 16); an unforgettable evening social event including WaterFire Providence; and world class networking!

A preliminary agenda is posted on the ISPE website

STUDENT SPECIFIC EVENTS

(See article in newsletter—PAGE 22)

HOTEL & TRAVEL

ISPE has reserved blocks of rooms at The Westin Providence and the Providence Biltmore. Make your reservations online through the ISPE website – and as soon as possible, by July 13, to take advantage of the special rates.

Fly directly into TF Green Airport (Providence) or Logan Airport (Boston), which is approximately 60 minutes by train or bus.

EARLY BIRD REGISTRATION: July 13
A top priority of the 2008-2009 Student Council, chaired by Jennifer Polinski and Jessica Jalbert, was to plan student activities for the 25th ICPE meeting to be held in Providence, RI in August, 2009. Student events and activities on the Providence ICPE program include: a student meet-and-greet, the student skills workshop, the student council meeting, and a student social event.

The Student Meet-and-Greet will be held on Saturday August 15th, 2009. The day before the official start date of the conference, all students are invited to have an early dinner and a glass of sangria at the Cuban Revolution Restaurant and Bar in downtown Providence. The Cuban Revolution is an affordable restaurant serving tasty Cuban food and great sangria in a setting with a counter-culture twist and Latin music. Come relax, unwind, and meet your peers!

On Sunday August 16th, 2009, the annual Student Skills Workshop will be held from 8:30 a.m. to 12:00 p.m. The Student Council is considering splitting the allotted time into three sessions. One session will include discussions with pharmacoepidemiologists from academia, industry, and government on their experiences, on how they got to where they are, and on what advice they would give students interested in taking a similar path. In a second session, we will invite recent graduates from academia, industry, and government and have them share their recent experiences on the job market and ask them to help demystify the job search. The third session will either be a workshop on how to present effective oral presentations and posters or on non-traditional opportunities for students with training in epidemiology or pharmacoepidemiology. We look forward to the insightful advice/comments from our speakers and to stimulating questions from the students. We expect attendance at the Workshop to be high given the topics to be covered and their pertinence to each and every student. Coffee will be served.

The Student Council Meeting will be held on Monday August 17th, 2009 from 12:15 to 1:30 p.m. At this meeting, we will be electing a new chair and co-chair. The 2009-2010 chairs of the Student Council will serve for a one-year term, will represent student interests before the ISPE Board of Directors, and will help organize student activities/events at the mid-year and annual ISPE meetings. Since the next annual ICPE meeting will be held in Europe and the next mid-year meeting will be held in North America, the chair will be from Europe and the co-chair will be from North America. All student members of ISPE who are present at the meeting have voting rights. Any other business that the Student Council wishes to address before ISPE students will be raised at this meeting. Do not miss the opportunity to elect your representatives and to get involved! Lunch will be provided.

The Student Social Event will begin on Monday August 17th, 2009 at 7:00 p.m. We will meet at Local 121 in downtown Providence. The restaurant takes its name from its commitment to serving food from local, small-scale New England farmers and suppliers and its physical location at 121 Washington (in the heart of downtown Providence). Local 121 also supports art and much of what you see, from the paintings and pictures adorning the walls to the butter plates on the tables have been produced by local artists. To boot, the food is fantastic, the wine list is impressive, and the restaurant turns into a great dance club at night! Could there be a better place to hold the student night out?

The Student Council looks forward to hosting, meeting, and entertaining students from all over the world in Providence, RI this coming August. In planning the student program, the Student Council sought to strike a good balance between activities and events that stimulated both “work” and “play.” The student activities and events were therefore not only meant to facilitate the exchange of ideas and to promote future collaborative research but also to provide a setting ripe for the creation of friendships and for having a great time.

We look forward to seeing you in Providence!
Since August 2008, the ISPE Student Council has been breaking new ground in fostering dialogue and education among ISPE student members—using web-based networking, online conferencing, websites, and good “old-fashioned” email to reach out to students. Under the leadership of Jessica Jalbert and Jennifer Polinski, the 2008 – 2009 Student Council Co-Chairs, students are busier than ever. In September 2008, Jess and Jen launched the ISPE Student Group on Facebook, the popular social networking website. The ISPE Student Group is “closed” which means that only the administrators (Jen Polinski and Jessica Jalbert) are allowed to invite people and approve any requests to join the group. The Facebook site offers students a place to post information about job openings and post-doctoral opportunities, to inform members of upcoming student events and deadlines (e.g., ISPE abstract deadlines), and to discuss articles and happenings in pharmacoepidemiology. As of early April 2009, the Facebook group numbered 76 students.

Another well-received Student Council initiative has been the creation of an online seminar series. Jen and Jess have invited pharmacoepidemiologists and epidemiologists to present lectures in an online format using “DimDim,” a free web conferencing software. Following the lecture, up to 20 students have the opportunity to chat with the presenter, ask questions, and explore research ideas. Students have logged in from Australia, Iceland, Canada, the United States, South Korea, and European countries to partake in these seminars. The first online seminar in October 2008 featured Jeremy Rassen, ScD who discussed the use of instrumental variables in pharmacoepidemiology. In February 2009, Sebastian Schneeweiss, MD, ScD hosted a seminar on the challenges and opportunities involved in the aggregation of data from multiple claims databases. In May 2009, Miguel Hernán, MD, ScD will present applications of inverse-probability of treatment weighting (IPTW) and marginal structural models (MSMs) in pharmacoepidemiology. Edeltraut Garbe, MD, PhD will also discuss recent European efforts in combining pharmacoepidemiologic databases. Jen and Jess have plans to schedule more online seminars in late spring/early summer 2009 but the topics have yet to be determined.

The Student Council has also facilitated the construction of a student webpage on the official ISPE website. This page contains information on the mission of the ISPE Student Council, benefits of ISPE student membership, descriptions of Student Council activities, and links to epidemiologic resources, academic programs in pharmacoepidemiology, and other websites of interest. The webpage went live in February 2009 and it is hoped that this new site will improve the ISPE Student Council’s ability to communicate with its members.

The Council also facilitated the first meeting of Asian students at the 3rd Annual Asian Meeting in October 2008. With help from Ching-Lan (Rebecca) Cheng and Sun-Young Jong, students from various Asian countries met for lunch at the meeting and expressed an interest in continued and expanded activities together. Finally, the ISPE Student Council has reached out to each of the 6 ISPE Student Chapters asking for updates about their activities and input as to which activities they would like to see the ISPE Student Council pursue. All 6 student chapters responded, and their feedback was presented at the April 2009 ISPE Mid-year Board Meeting in Stockholm, Sweden.

Whether by new web-based media or old-fashioned email the Student Council has worked to increase activities for and links between students since August, 2008. As a result, students are more connected to ISPE and more connected with each other. As these students graduate and become the pharmacoepidemiologists of tomorrow, the contacts and camaraderie they have established amongst themselves will hopefully foster successful research collaborations and innovations in pharmacoepidemiology.

Contributed by
Jennifer Polinski, MPH, MS
Co-Chair, ISPE Student Council
Antibiotics are one of the great public health advances of the 20\textsuperscript{th} Century saving millions of lives, yet antibiotic resistance could present a major reversal in public health for the 21\textsuperscript{st} Century. In her seminar, Dr. Liselott Diaz Högberg, Deputy Director, ReAct-Action on Antibiotic Resistance, presented the case for why antibiotic resistance is a hidden threat to global health. Data on the health outcomes of antibiotic resistance, not just microbiological lab reports, are sorely needed to motivate policy makers into action to mitigate the global risk of ineffective antibiotics. Dr. Högberg argued that pharmacoepidemiologists can play a vital role in estimating the clinical consequences of antibiotic resistance and in developing pharmacovigilance surveillance methods for tracking the global impact of this threat to patient safety.

Alexander Fleming, renowned Scottish pharmacologist and discoverer of penicillin, noted in 1947 during his Nobel Lecture that “It is not difficult to make microbes resistant to penicillin.” Indeed, overuse, misuse, underdosing, poor quality counterfeits, and expanded veterinary use have all contributed to increasing antibiotic resistance in humans. The emergence and resurgence of meticillin-resistant \textit{Staphylococcus aureus} (MRSA) has long been recognized as a life-threatening risk to patient health. More recently, the spread of endemic broad-spectrum cephalosporins and monobactams and extended spectrum beta-lactamase (ESBL)-producing \textit{Enterobacteriaceae} (a family of bacteria including Salmonella and Escherichia coli capable of hydrolysing penicillins) pose a particular threat to child health in the developing world. Unfortunately, over the last several decades there has been a steady decline in the number of antimicrobial new molecular entities to help offset the rise in resistance. Dr. Högberg shared that ReAct, a globally-focused agency headquartered within Uppsala University, Sweden, was organized five years ago around the following vision: “current and future generations of people around the globe … [should] have access to effective treatment of bacterial infections” (see their website \url{www.reactgroup.org}). ReAct advocates that concerted global action must be catalyzed now to avoid a return to the pre-antibiotic era.

So what role should pharmacoepidemiologists play? First, we can reframe antibiotic resistance as a side effect of pharmaceutical therapy threatening patient safety. Similar to other preventable adverse events, antibiotic resistance can be associated with higher mortality, morbidity and medical costs. Resistance should be added to the list of determinants that pharmacoepidemi-
ologists typically study: incorrect diagnosis, inadequate dosing, and patient non-compliance. Comparative effectiveness research in antimicrobial strategies should include consideration of differences in drug resistance.

The discipline of pharmacoepidemiology is also well suited to produce the research to demonstrate the clinical consequences of drug resistance and to estimate the magnitude of the public health burden. This type of research is more meaningful and motivating to policymakers than laboratory reported resistance rates alone. Laboratory monitoring of resistant strains has been used to monitor the development and spread of antibiotic resistance. Often resistance emerges first within a hospital or critical care setting and then spreads into the community. However, laboratory facilities are lacking in many parts of the world.

Pharmacoepidemiologists can lead the development of pharmacovigilance surveillance methods for tracking antibiotic resistance using available data, such as hospital administrative and medical record data, insurance records, and patient and health care provider reports. Work is needed to refine and standardize appropriate outcome measures associated with antibiotic resistance which can be assessed in large secondary data sources – for example, assessment of mortality, length of hospital stay, change in antibiotic therapy, and other measures of health care utilization. The challenge will be developing methods for ascertaining drug resistance as the cause underlying treatment failure given the limitations of secondary data, but I am sure pharmacoepidemiologists are up to the challenge for this important public health problem.

Contributed by
Elaine H. Morrato, DrPH MPH CPH
**UPCOMING PROFESSIONAL CONFERENCES THAT MAY BE OF INTEREST TO ISPE MEMBERS**

Please submit additional conference information that you would like to be included in upcoming issues of Scribe to Brian Quilliam at bquilliam@uri.edu.

<table>
<thead>
<tr>
<th>Organization</th>
<th>Location</th>
<th>Meeting Dates</th>
<th>Abstract Submission Deadline</th>
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<tbody>
<tr>
<td><strong>DIA Annual Meeting</strong> (<a href="http://diahome.org">diahome.org</a>)</td>
<td>San Diego, CA</td>
<td>21-25 Jun, 2009</td>
<td>Passed</td>
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<tr>
<td><strong>Society for Epidemiologic Research</strong> (<a href="http://epiresearch.org">epiresearch.org</a>)</td>
<td>Anaheim, CA</td>
<td>23-26 Jun, 2009</td>
<td>Passed</td>
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<tr>
<td><strong>Teratology Society 49th Annual Meeting</strong></td>
<td>Puerto Rico</td>
<td>27 Jun – 1 Jul, 2009</td>
<td>Passed</td>
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<tr>
<td><strong>Gene-Environment Interactions: Impact on Maternal and Child Health</strong></td>
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<tr>
<td><strong>Continuing Medical Education Program</strong> (<a href="http://teratology.org">teratology.org</a>)</td>
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<tr>
<td><strong>Pharmaceutical Information and Pharmacovigilance Association (PIPA)</strong></td>
<td>Glocs, UK</td>
<td>6-7 Jul, 2009</td>
<td>22 Jun, 2009</td>
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<tr>
<td><strong>British Pharmacological Society (BPS)</strong> (<a href="http://www.bps.ac.uk/article451.asp">http://www.bps.ac.uk/article451.asp</a>)</td>
<td>University of Edinburgh, UK</td>
<td>8-10 Jul, 2009</td>
<td>Passed</td>
</tr>
<tr>
<td><strong>American Public Health Association 137th Annual Meeting and Expo</strong> (<a href="http://apha.org">apha.org</a>)</td>
<td>Philadelphia, PA</td>
<td>7-11 Nov, 2009</td>
<td>Passed</td>
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<tr>
<td><strong>16th World Congress on Basic and Clinical Pharmacology, 17-23 July 2010, Copenhagen, Denmark</strong> (<a href="http://www.iuphar2010.dk">www.iuphar2010.dk</a>)</td>
<td>Copenhagen, Denmark</td>
<td>17-23 Jul, 2010</td>
<td>Contact iuphar2010.dk</td>
</tr>
<tr>
<td><strong>European Federation of Pharmacological Societies (EPHAR) Congress</strong> (<a href="http://ephar.org">ephar.org</a>)</td>
<td>Granada, Spain</td>
<td>2012</td>
<td>Contact ephar.org</td>
</tr>
</tbody>
</table>
Membership Renewal Time

The new membership year begins July 1. You can renew your membership and update your contact information in the Members Only section. New this year – FISPEs and Regular Members will pay the same rate. Remember, if you are planning to attend ICPE 2009/Providence, your registration includes your membership dues for 2009-2010. Dues must be paid by September 15.

$25 for 25th Campaign

ISPE is celebrating its Silver (25th) Anniversary ICPE, August 16-19, 2009 in Providence. The Society invites you to support what is widely recognized as the preeminent international conference on pharmacoepidemiology by making a $25 (USD) donation to the Society. All contributors will have their names listed on the ICPE 2009 home page of the Society’s website and in the final program (contribution must be received by July 13 for final program). You can make your contribution when registering for the ICPE, or by mailing a check made payable to 'ISPE' to the ISPE Office; note on the check that it is for the $25 for 25th Campaign.