

SCRIBE

THE INTERNATIONAL SOCIETY FOR PHARMACOEPIDEMOLOGY

President's Message

By Elizabeth B. Andrews

Highlights

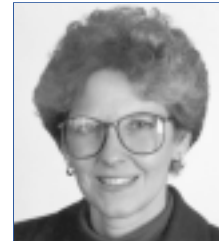
- Against The Gods. The Remarkable Story of Risk.
- Development of the ISPE Student Council
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- Directions for ISPE

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I'm sitting at home completely snowed in by 20 inches of the white stuff, an amount that North Carolina has never before seen. As I contemplate the last few months of ISPE business, I am struck with how busy and exciting a time it has been. A few highlights merit some mention.

First, we had to make a hasty transition to a new association management company. Slack Inc., our previous company, decided to get out of the business of managing professional societies. I won't bore you with the details, but be aware that your Executive Committee, and the Management Continuity Committee, chaired by **David Goldsmith**, had a busy time. The good news is that we have a new company, PAI Management Corporation, headed by Dr. Norman Wallis, and based in Bethesda Maryland. **Mark Epstein** is continuing as our Executive Secretary. I am confident that we have a highly professional and motivated staff to give us the support we need to move ahead with many of the substantive tasks on our action agenda. The downside of any restructuring is that some of our core ISPE business has been delayed. For example, dues billing was deferred from December until February. In addition, we were concerned about possible delays in processing abstracts for the annual meeting. We signed a contract with



Marathon Multimedia, an extremely experienced company, that is organizing the whole process of abstract submission and review, largely using on-line

technology. We also are looking forward to some fairly major enhancements to the website, and you should already see some improvements soon. Stay tuned. [Editor's Note: ISPE recently contracted with Potomac Digitek, a firm with an outstanding record of customer service and a leader in web-based services to host and enhance our website.]

Second, ISPE participated in the first Inter-Society Forum. You may recall that our Board, last April, endorsed ISPE initiating discussions with like-minded professional societies to explore possible synergies and joint projects. On January 10, leadership from 6 groups (ISPE; ISPOR – International Society for Pharmacoeconomics & Outcomes Research; ISOQOL – International Society for Quality of Life Research; ISTACH – International Society of Technology Assessment in Health Care; IHEA – International Health Economics Association; and SMDM – Society for Medical Decision Making) joined the

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Society for Medical Decision Making to Meet in Cincinnati

By Joel Tsevat and Mike Hagen

The Society for Medical Decision Making (SMDM) will hold its 22nd Annual meeting in Cincinnati, Ohio from 24-27 September 2000. The meeting will take place at the Hyatt Regency Hotel in the heart of downtown Cincinnati.

The theme for the meeting is "The Value of Health." As always, the meeting will focus on the presentation of high quality research and applications in clinical decision science. The abstracts will be organized by clinical topic as well as by application and methodologic topic. The call for abstracts is available at the SMDM website (www.smdm.org) or from the administrative office (202-994-8929). The abstract submission deadline is 26 May.

The meeting will feature a slate of 16 short courses on 24 September. Topics include decision analysis (basic and advanced), cost-effectiveness analysis, economic evaluation of clinical trials, shared decision making, decision psychology, evidence-based quality assessment, medical informatics and clinical guidelines, Bayesian data analysis, simulation, survival analysis, meta-analysis, health index instruments, the "theory of constraints," and utility assessment.

The social event will take place on Monday evening at the world-renowned Cincinnati Zoo, which *Newsweek* has dubbed the "world's sexiest zoo" because of all

of the animals born there. The zoo features white tigers, white lions, manatees, lowland gorillas, okapi, Komodo dragons, and just about any other animals you can think of; a new elephant exhibit is set to open next year. The weather in Cincinnati in late September is usually delightful (average highs in the mid-70s F), so this should be a very enjoyable outdoor event. Bring your family!

There's plenty to do in the Queen City, and you can get there from here! The Greater Cincinnati/Northern Kentucky International Airport offers 575 daily non-stop flights to 111 cities in North America and Europe, including Toronto, Montreal, London, Paris, Brussels, Zurich, and Frankfurt.

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BOOK REVIEW

Reviewed by Jacques LeLorier

Against The Gods. The Remarkable Story of Risk. By Peter L. Bernstein. 337 pages 1996 John Wiley and Sons.

This is a fascinating and extremely readable book, which was extensively and enthusiastically reviewed by the financial press but, as far as I know, virtually ignored by the medical and epidemiological community. Since measuring and explaining risk is central to our professional life, I would expect most ISPE members will derive as much pleasure and knowledge from this book as I did.

The author's main theme is that the notion of forecasting and thus measuring risk is the central idea that separates modern thinking from the murky past. For hundreds of years before the renaissance and in spite of the knowledge about Euclid's geometry, astronomy and the Hindu-Arabic numbering system the future was the monopoly of oracles and soothsayers. The pivotal event in the history of risk occurred when the Chevalier de Mere, a gambler, challenged Blaise Pascal to solve a puzzle: "How should you divide the stakes of an unfinished game of chance between two players when one of them is ahead." Pascal turned for help to Pierre Fermat a brilliant mathematician who was also a lawyer (nobody is perfect). The collaboration between Pascal and Fermat, imitated by this apparently frivolous question led to the theory of probability and the concept of risk.

ISPE members will certainly enjoy the many anecdotes and brief biographies about Graunt's compilation of births and deaths in London, Bernoulli's *Art of conjecture*, and Thomas Bayes posthumous publications. It is also of interest that in spite of his brilliant mind Gauss could not have made a living as a pharmaco-epidemiologist: he hated to travel and only slept once away from his home in Gottingen.

SCRIBBLES

Mandatory Immunization: Good in Theory, Bad in Practice

By Alexander M. Walker

Before French authorities lifted mandatory hepatitis B vaccination for adolescents a year ago, several ISPE members were part of a group called together to review the available evidence on multiple-sclerosis like illnesses that had caused panic among French parents.

The experts concluded that there was scant scientific basis for concern, and certainly no reason to change policy. A few weeks later, and contrary to the advisors' sentiment, the French government pulled back from universal immunization of adolescents.

Health officials in the United States have been moving towards programs of forced immunization with hepatitis B vaccine. Varicella immunization, after

years of careful evaluation of cost and benefit, is already widely mandated in the U.S., despite isolated, vigorous parental opposition.

While it is certainly within a government's right to impose health protection measures, I believe that proponents of mandatory or quasi-mandatory programs dangerously misread public sentiment. The French acted wisely.

Forced vaccinations violate individual rights of autonomy. Where there is no compelling benefit to others (as in herd immunity, for example), compelled immunization may improve global health statistics, but at an

unacceptable price of regulatory intrusion into private lives. Compulsory programs may even be self-defeating, because they lay the groundwork for vaccine scares, and they permit authorities to opt out of the education that is a surer basis for public health.

Parents should understand that hepatitis B is a lifelong, devastating, incurable, sexually transmitted disease that can be prevented through an immunization that carries no serious risk. For people who do not want the message, public health strong-arm tactics will not make a difference. When people simply have not heard the truth, we should sharpen our rhetoric, not our regulations.

SUB SCRIBE

Development of the ISPE Student Council

By David Gibbons, Student Council Steering Committee

It gives me tremendous pleasure, as a student member of ISPE, to introduce you to the development of a Student Council within ISPE that, I hope, will deepen the interest and investment of student members. Students represent the future, not only of ISPE, but also the field of pharmacoepidemiology itself. However students are also its present, playing roles today in pharmacoepidemiology through our academic departments, internship and training experiences, and in cultivating relationships with professionals who will be our colleagues and collaborators in the years to come. Students engaging other students as well as faculty and

professional mentors, making students true stakeholders in ISPE, and expanding student membership and participation in ISPE are the underlying goals of the Student Council.

ISPE is currently served by three Councils (Academic, Government, and Industry), which represent the interests of their constituencies to the Society and provide a forum for growth and development. Student members don't have such representation or forum. In fact, currently about 70% of ISPE student members aren't affiliated with any Council. There seems to be a compelling

need to create a "student central" within the Society while allowing students to interact with the other Councils, where the potential for careers and long-term Society commitments can be made (after all, hopefully we aren't students for too long!). The ISPE Student Council has been "in the works" for a few months and I will have the opportunity to propose its creation at ISPE's mid-year meeting in Chapel Hill, North Carolina. But before I do that, I want to share, especially with the student members, my vision for what the Student Council's mission should be. I believe our Council's mission should be:

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1. To provide a **forum** where prospective, new, and continuing students in pharmacoepidemiology training programs worldwide can share knowledge and experience in the field of pharmacoepidemiology.
2. To provide a **mechanism** through which students' communication with fellow students, faculty, and scientists in the field of pharmacoepidemiology is enhanced.
3. To provide a **model** by which students can organize at the institutional level, across academic programs and/or departments, to develop and enhance their training, instruction, and experience in pharmacoepidemiology.
4. To **organize**, with relevant individual and corporate partners, student-focused events at the ISPE international meetings.
5. To provide an **opportunity** for student members in the Society to become familiar with and have representation in the affairs of ISPE.

There's quite a lot packed into these five statements, involving CHANGE, ACTION, and a COMMITMENT to the Society, not just the organization or institution but also the *people* – students and non-students, members and prospective members. This is especially

challenging for a group of people whose time is limited – both in terms of the hours in any given day and the number of years spent being a student. “Studenthood” is inherently transitional; in fact we spend our time as students trying to get to the point where we are no longer students as quickly as possible, cautious to learn as much as we can and take advantage of every good opportunity afforded to us. To my fellow students, I hope you will see the creation of the Student Council as one of those learning experiences and opportunities.

I also want to extend an invitation to student members to become involved in the development and leadership of this new Council. Become involved in the establishment of the Student Council and provide your insight into its direction. There are many exciting opportunities and challenges for us; we should strive not only to exist but also to be proactive in our recruitment, organization, and activity planning.

One of the first activities that the ISPE Student Council will be

organizing and promoting is Pharmacoepidemiology Day 2000 to be held on 13 April, 2000 at UNC-Chapel Hill. We (students, ISPE members and nonmembers) will spend the afternoon hearing from a wide range of professionals in the field of pharmacoepidemiology. Several ISPE members have been invited to participate, with backgrounds ranging from industry to regulatory bodies to consulting firms. I truly look forward to this event as well as the participation of students and invited speakers and guests. More details regarding this event will follow by email...

Please send me your comments and ideas; my contact information is listed below. I welcome any feedback from students and former-students alike. Finally, I want to thank **Elizabeth Andrews, Hugh Tilson, and Mark Epstein** for their commitment to this endeavor and the advice and guidance that I have received from them.

[NOTE: You can contact David at david.gibbons@unc.edu or write to him at: Glaxo Wellcome Research & Development, 5 Moore Drive; PO Box 13398, Research Triangle Park, NC 27709-3398.]

Announcement

By Hubert G. Leufkens, Department Chair

The Utrecht University the Netherlands has appointed Prof **Samy Suissa** as F.C.Donders professor 2000.

The F.C. Donders-chair is a prestigious opportunity for an outstanding scientist who is appointed on an annual basis as visiting professor for a period of 3-6 months at Utrecht University. The chair is named after one of the most famous Dutch physicians (1818-1889), founding father of the F.C. Donders eye clinics in Utrecht and president of the Royal Dutch Academy of Science during 18 years.

Dr Suissa will collaborate with the colleagues of the Department of Pharmacoepidemiology and Pharmacotherapy on various methodological issues, research questions addressed in the PHARMO database, and add to the pharmacoepidemiology program on asthma/COPD studies.

We feel very proud that such a distinguished member of ISPE will join us and look forward to his arrival.

IN SCRIBE

ISPE Comments on Federal Privacy Standards

By Mark H. Epstein

Achieving a balance between access to health data and the responsibility for ensuring individual privacy is a delicate task. The US Secretary of Health and Human Services recently promulgated federal privacy standards for health information. ISPE's response to the proposed rules is predicated on the principle of protecting the confidentiality of individually identifiable medical information while preserving justified research access to such information in the interest of the public's health. ISPE expressed its concern that *"in the face of new legal liabilities created by the proposed regulation, covered entities (e.g., medical centers, pharmacies, managed care organizations) will hesitate to share patient data with researchers,*

and pharmacoepidemiologists' access to essential sources of data will be threatened."

The Secretary was mandated to develop the data privacy regulations under the *Administrative Simplification* (AS) provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and when Congress failed to pass legislation. Administrative simplifications are intended to reduce the costs and administrative burdens of health care by making possible the standardized, electronic transmission of many administrative and financial transactions that are currently carried out manually on paper.

While data privacy is a complex issue, ISPE's response to these standards was essential given our role as scientists engaged in public health research. Kudos to **Don Willison**, Chair, North American Data Privacy Committee, **Jim Kotsanos**, and **Elizabeth Andrews** for their hard work and commitment to developing ISPE's position.

[Editor's note: The Society's response — letter to **Margaret Ann Hamburg**, MD, Assistant Secretary for Planning and Evaluation, US DHHS, dated 17 February 2000 — will be posted on the ISPE web page. For more information about Administrative Simplification, please visit <http://aspe.hhs.gov/admsimp/Index.htm> on the US DHHS web site.]

DEADLINE FOR THE NEXT ISSUE IS MAY 1

Here are some of the departments where you can make a difference.

A Scribe	Gossip
Circum Scribe	Restrictions and contradictions
Con Scribe	Job Opportunities
De Scribe	Disease and health systems
In Scribe	Regulations and regulators
Pre Scribe	Indications and patterns of care
Pro Scribe	Drugs off the market
Sub Scribe	ISPE membership and activities

Postscripts, superscripts, and glosses also are welcomed. Or create your own department, in the spirit of Scribe!

E-SCRIBE

Directions for ISPE

By C. Ineke Neutel

The question “What issues should ISPE be more concerned about?” was e-mailed to all ISPE members with e-mail addresses. The result was 82 replies with answers and comments: 35 from academia, 32 from industry, 9 from government and 16 others (multiple affiliations possible). Replies came from 38 countries on all continents.

On viewing the large number of responses, one is immediately struck by their diversity. ISPE members have a wide range of concerns and no particular issue stands out. Most issues suggested, fit in what may be called the ‘science’ of pharmaco-epidemiology/ pharmacovigilance. Of the over 100 items, most relate to improvement in methodology - whether development of better methodology or a better application of existing methodology.

The methodology of ADR reporting (pharmacovigilance) was high on the agenda for major improvement. Concerns ranged the whole gamut: from earlier and better reporting of ADR, to better interpretation of reports received. The most attention was given to the development of more systematic approaches to identifying of ADRs. While one might have expected this to be an industry/ government concern, in fact, this topic was listed equally by industry and academia.

Next in frequency was concern about pharmacoepidemiology methodology: e.g., expanded use of protocols, developing better designs for peri-approval studies/safety studies, better validation studies for data bases, better interpretation of results. Interestingly,

it was almost exclusively industry that expressed concerns here. One might ask oneself if industry was expressing their frustration at the lack of results suitable for decision-making. Often completed studies lead only recommendations for more research. An important concern was also that of databases. Issues suggested related to developing more and better databases, as well as to the data privacy issues that accompany the use of databases.

So many other topics and concerns were brought forward that it is difficult to decide which to highlight. For example, there was a concern for facilitating international collaboration, e.g., large international studies and developing international databases. There was also a concern for developing countries in terms of promotion of pharmaco-epidemiology research and education.

Improving pharmacoepidemiology education in general was a concern expressed almost exclusively by academics. More evenly spread among all types of respondents were (rather non-specific) regulatory concerns. In terms of policy-related issues, some respondents wanted more pharmaco-epidemiology input in policy decision-making and a few others would like to see more pharmaco-economics within ISPE. Of greater concern were resources for pharmacoepidemiology research, especially for developing methodology and the availability of limited resources in developing countries.

A focus of concern was also the use of the information technology and here is where ISPE received some flack. PDS should be indexed so that it is accessible by Medline. The website should be used more and better, e.g., membership list and PDS could be put on the web. Concerns were expressed about the implications of new information technology, e.g., the effect of e-commerce on drug utilization. A number of people expressed the need for making job opportunities known and the net would be a useful venue.

I was left with a number of overall impressions. 1) First, ISPE members are vitally interested in pharmacoepidemiology as a discipline. Their concerns dealt squarely with real issues. No answers were frivolous or superficial. 2) Moreover, nearly all respondents advanced topics in the science of pharmacoepidemiology. Within this area, however, there was a great diversity of concerns. 3) Also notable was the satisfaction with pharmacoepidemiology and with ISPE. A number of respondents went out of their way to express appreciation for the scientific quality and the balance of topics of ICPE: “The issues covered at the Boston meeting were right on target”. One or two voiced the concern that ISPE and/or ICPE were too academic but this did not appear to be a general concern.

What then are the directions for the future that we need to learn from this? The overwhelming preoccupation with the ‘science of

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pharmacoepidemiology' would indicate that ISPE should be concerned with whatever makes pharmacoepidemiology/pharmacovigilance more effective. Combined with the main issue of the previous Scribe survey question - lack of recognition for pharmacoepidemiology as a discipline - one would conclude that our aspiration for the future is a more effective pharmacoepidemiology/pharmacovigilance recognized by others as the important discipline that it is.

Thanks again for all your answers. Many topics were suggested that I could not do justice here. So about a dozen respondents received a request to expand on their suggestion for a commentary in PDS. (about 2500 words, peer reviewed, submit to me at ineutel@scohs.on.ca). All of you who have a scientific concern of interest to ISPE members, please remember this venue for expressing your thoughts.

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together for an all-day meeting in Washington, DC, with coordination by Hugh Tilson (who has been our official link between ISPE and ISPOR). All these groups deal with similar issues around membership, communication, building our fields, and evaluation of policy issues. Where there is commonality among objectives, there might be room for collaboration. We are already seeing hotlinks among websites and exchange of mailing lists for selected activities. This was a very successful exploratory meeting. We have a lot in common and should maintain electronic

links among the executive staff and meet again as a leadership group. I'm very encouraged with our new partnerships!

The third item came completely out of the blue, with a call from Ken Rothman and an offer we couldn't refuse. It seems that, years ago, Roche donated an endowment fund to the journal *Epidemiology* for the purpose of making an annual award, the Epidemiology Prize, for the best paper published in *Epidemiology*. Ken, editor of the journal, was looking for a new "home" for the endowment, and ISPE was the ideal choice. ISPE now manages the endowment fund, which covers the prize, and travel to the ERI summer program for the recipient to receive the prize. The prize still goes to the best paper in the Journal, which may or may not relate to pharmacoepidemiology. ISPE will participate in the selection of the prize recipient, and in the awarding of the prize. This year, Jerry Avorn, Samy Suissa, and Steve Kimmel have agreed to serve on the selec-

tion committee for the ISPE-Roche Epidemiology prize. Don Kaiser and Susan Sacks are willing to represent both ISPE and Roche in presenting the award.

Perhaps the most exciting development since the Boston business meeting was prompted by a student who voiced concern that students may not be getting full value from their participation in ISPE. In response, David Gibbons, a student at the University of North Carolina Epidemiology program is proposing ISPE establish a Student Council. This will be discussed by the Board at the mid-year meeting in April. Ideas are flowing, as is the enthusiasm among ISPE members. See the related story for details. Good luck David!

Time is marching on toward the mid-year meeting [12-14 April in Chapel Hill, NC], which includes a symposium April 14 on *The Power and Perils of Health Data Used in Epidemiologic and Economic Research*. I hope to see many of you in April.

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For more information contact the ISPE office at 301-718-6500 or

ispe@paimgmt.com

HEALTH CARE

DATABASES

AD

16th International Conference on Pharmacoepidemiology

20-23 Agosto 2000

Hotel Princesa Sofia Inter-Continental

Barcelona, Spain



The objective of this conference is to provide a forum for the exchange of information among researchers, medical care practitioners, health care administrators, the pharmaceutical industry, regulatory agencies, and other stakeholders on pharmacoepidemiological approaches to studying the efficacy and safety of pharmaceuticals.

The conference will include invited lectures, workshops, submitted papers, and posters. A joint session with Eurodurg will be held 21 Agosto 2000.

The 16th Internal Conference on Pharmacoepidemiology (ICPE) is sponsored by the International Society for Pharmacoepidemiology (ISPE). ISPE is a nonprofit, professional society dedicated to advancing the science, methods, capacity, communication and public understanding of and support, for pharmacoepidemiology toward the goals of assuring, promoting and protecting the health of all persons using medications.

SPONSORSHIPS & EXHIBITS

Sponsorships: The Society offers to corporations, agencies and others the opportunity to support ISPE activities, scholarships and awards through unrestricted contributions.

Exhibits: Vendors have the opportunity to display their products and services to participants at the 16th ICPE. Exhibit space is limited, so act now.

For information about sponsorships, exhibits, or the 16th ICPE, please contact :

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WebSite: www.pharmacoepi.org

SPRING COURSES

AT THE INSTITUTE OF PHARMACOEPIDEMIOLOGY AND TECHNOLOGY ASSESSMENT BERLIN

The Institute of Pharmacoepidemiology and Technology Assessment (IPTA) is offering the following courses in March and April 2000:

MEASUREMENT OF QUALITY OF LIFE	20.03. - 22.03.2000
	Course Instructor: Prof. Sharon Wood-Dauphinee, McGill University, Montreal, Canada
	Tuition Fee: 600,00 DM
PHARMACOEPIDEMIOLOGY I	27.03. - 31.03.2000
	Course Instructors: Prof. Jean-Francois Boivin McGill University, Montreal, Canada;
	Dr. Edeltraut Garbe, Institute of Pharmacoepidemiology and Technology Assessment, Berlin, Germany
	Tuition Fee: 1000,00 DM
PHARMACOEPIDEMIOLOGY II	03.04. - 06.04.2000
	Course Instructor: Prof. Samy Suissa McGill University, Montreal, Canada
	Tuition Fee: 800,00 DM

The courses are aimed at all post-graduates currently working or intending to work within the field of clinical studies, epidemiology, and drug surveillance. The language of instruction is English. IPTA organises these courses in cooperation with Humboldt-University Berlin, the Free University of Berlin and McGill University in Montreal.

For further information please contact:

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MEETING CALENDAR

2000

14 April

Health Care Databases & Research. A Symposium on the Power & Perils of Health Data Used in Epidemiologic & Economic Research, Chapel Hill, NC, USA.

Contact ISPE @ 301-718-6500; www.pharmacoepi.org; Email: ispe@paimgmt.org

20-24 May

ISPOR's 5th *International Meeting*; Arlington, VA, USA.

Contact: ISPOR @ 609-252-1305; www.ispor.org; Email: info@ispor.org

25-27 June

Association for Health Services Research, *Research to Action: Shaping the Health System in the New Millennium*, Los Angeles, CA, USA.

Contact: AHSR @ 202-223-2477; www.ahsr.org; Email: info@ahsr.org

20-23 August

ISPE's 16th *International Conference on Pharmacoepidemiology*, Princess Sofia Inter-Continental, Barcelona, Spain.

Contact ISPE @ 301-718-6500; www.pharmacoepi.org; Email: ispe@paimgmt.org

24-27 September

Society for Medical Decision Making 22nd *Annual Meeting*, Cincinnati, OH, USA.

Contact: SMDM @ 202-994-8929; www.gwu.edu/~smdm; Email: office@smi.stanford.edu

5-7 November

ISPOR's *Third Annual European Conference*, Antwerp, Belgium.

Contact: ISPOR @ 609-252-1305; www.ispor.org; Email: info@ispor.org

2001

25-27 June

International Health Economics Association 3rd *International Conference*, University of York, UK.

Contact: IHEA @ 613-533-6675; www.healtheconomics.org; Email: swanb@post.queensu.ca

23-26 August

ISPE's 17th *International Conference on Pharmacoepidemiology*, Toronto, Canada

Contact ISPE @ 301-718-6500; www.pharmacoepi.org; Email: ispe@paimgmt.org



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