



## President's Letter



As the summer winds down, and we approach the Annual Meeting, the promise of another year is before us. For those in academia, there are new students; for those with children, new teachers and classmates; for those with overdue work (after a summer of reading and traveling), the need to make some awfully big "to do" lists ... To me, September always seemed a more sensible time to take stock, to

make plans or even resolutions, than January. In September, it seems that almost anything is possible. And it avoids the comical situation I face every winter as I resolve to swim and jog more often while in the middle of another cold New England winter.

### Calendar of Events

October

Vote on Bylaws

November 6 -10

APHA Annual Meeting

The 25th anniversary of the American College of Epidemiology gives us another reason to take stock of our accomplishments -- and future goals. In 1979, 15 Founding Directors created the College "to provide a means for certifying epidemiologists who are trained and/or accomplished in the practice of their discipline." In addition, the College was meant to "1) review the needs, develop or stimulate the development of any necessary continuing educational programs in epidemiology; and 2) provide a forum for the review and discussion of any issues pertaining to the present status, future development and practice of epidemiology."

While the College moved away from "certification" many years ago, membership still requires a formal application, with careful review by the Admissions Committee. Accordingly, membership in the College still describes a level of accomplishment in epidemiology of which all members can be proud. And while the overall mission remains the same, how the College has grown over these past 25 years! We now count more than 1,100 members, with a vibrant membership that captures the diversity of epidemiologists today -- diversity in not only demographic characteristics, but also diversity in ideas, goals, and interests.

Over this past year, as President, I have guided this 25-year old organization with the help of an accomplished group of College officers, Board members, and committee chairs. We focused the bulk of our time on "operations" issues -- i.e., how to improve what we now have, and how to deliver on past promises of a more visible, accessible, and effective organization. Along those lines, I'm happy to report that we accomplished many things. Some highlights, by committee:

- Admissions: reviewed >75 applications; created bylaws proposal on non-doctoral candidates.
- Awards: selected 2004 awardees; created proposal for new awards in 2005+.
- Communication: created new website; initiated online dues & newsletter.
- Education: planned 2004 Annual Meeting -- along with 2005 ACE and 2006 Epi Congress

- ESOP: finished ethics consult for Abbott; planned Saturday workshop.
- Finance: continued growth toward long-term goals; created new investment policy .
- Membership: conducted membership drive; developed ACE-Net mentoring program.
- Minority Affairs: provided leadership on CA Prop 54; ran Saturday workshop.
- Nominating: ran 2004 ACE election; began transition to online voting.
- Policy: advocated for NIH epi sections; testified regarding HIPAA.
- Publications: continued growth of *Annals*; initiated “ACE pages” in every issue

For a more complete list of what the various committees are doing, I encourage you to check out the committee pages on the ACE website ([www.acepidemiology.org](http://www.acepidemiology.org)). If you'd like to join a committee, please complete the “Committee Participation Form” and let us know!

This very practical focus was not at the expense of more strategic efforts. Indeed, the College leadership has proposed a rather extensive overhaul of the bylaws and the entire membership will vote on these proposed changes in October. Highlights include:

- Allow epidemiologists outside Americas to apply for membership
- Allow masters-trained epidemiologists to apply for membership
- Include an Associate Member on the Board of Directors
- Allow electronic voting
- Shorten the term of committee membership (from 5 years to 3 years)
- Speed-up voting on bylaws amendments (from 6 months to 2 months)

These are not trivial changes! While working on these issues over the past year, the Board has explored the various pros and cons and we do believe, unanimously, that these proposed changes would strengthen the College. Collectively, the Board and I have done our best to promote change, while preserving that which is vital to our 25-year old organization.

As I step down from the ACE presidency, and hand over the gavel to our new president Martha Linet, I find the College to be in excellent shape. I hope you agree. Looking into the future, I want to say again that all of us in the College leadership (officers, Board members, committee chairs and members) welcome your insights and suggestions about how we can further improve the College. Let's work together to make it even more relevant, more helpful, and more supportive of you as an epidemiologist. In my new role of past-President, I'll make sure that your voices are heard.

Thanks again for the opportunity to serve the College at the close of its first 25 years.

## Top Stories

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### Evolution of the ACE Publications Committee

The Publications Committee is responsible for all scientific publications issued by the American College of Epidemiology. The most important publication sponsored by the College is the *Annals of Epidemiology*. The *Annals* was initiated by Drs. Julie Buring and Charles Hennekens (Co-Editors) in 1990. They were succeeded by Dr. Alan Oberman, who served as Editor from 1995 to 2000, and by Dr. Richard Rothenberg, who has been Editor since March 2000. In recent years, the Publications Committee has been increasingly active in this arena, serving as liaison between the College and the *Journal*, and providing advice and assistance to the Editor.

Since 1999, when ACE President Dale Sandler appointed Martha Linet Chair of the Publications Committee, the activities of the Committee have expanded substantially. Richard Rothenberg, M.D., a Fellow of ACE, took over as Editor of the journal in March 2000. Subsequently, submissions to the *Annals* and the journal's impact factor have risen substantially. Under Dr. Rothenberg's watch, the *Annals* has been more fully integrated within the College, since the Editor submits quarterly reports to

the College and presents his reports in person twice annually to the ACE Board of Directors.

To continue the upward trend, the Publications Committee and the Editor urged the ACE Board to increase the number of issues of the *Annals* in each volume. The College supported this request, and the issues of the *Annals* increased from 8 to 10 annually in 2003, with a further expansion to 12 annually planned in 2005. Special components of ACE Annual Scientific Meetings (including presentations by the winner of the Lilienfeld Award, and summaries of the education roundtables) are increasingly included in the *Annals*. Recently, the *Annals* has adopted electronic submission and handling of papers. After a trial run, accepted papers are placed on the *Annals* webpage and available to *Journal* subscribers within a few weeks after acceptance.

Beginning in 2002, a Subcommittee of the Publications Committee, Chaired by Dr. Irene Hall, has undertaken responsibility for reviewing the Abstracts submitted for the Poster Session of the College's Annual Scientific Meeting. Review criteria have been developed to assist the abstract reviewers. The number of abstract reviewers rose from 6 in 2002 to 10 in 2003.

### **ACE Testimony on Impact of HIPAA on Research by Martha Linet, M.D., M.P.H.**

Epidemiologic research evaluates postulated risk factors for a disease to ascertain etiology and identify preventable causes. Among the enormous contributions to public health, epidemiologic research elucidated consumption of contaminated water as the cause of cholera centuries before the discovery of the causal infectious organism, identified cigarette smoking as the major cause of lung cancer, delineated the risk factors accounting for the majority of cardiovascular diseases, and clarified the role of folic acid in the etiology of neural tube defects. Public opinion polls repeatedly showed that two-thirds of Americans favored doubling the total national spending on government-sponsored scientific research over 5 years, more than half were willing to pay \$1 per week more in taxes and \$1 more for each prescription drug to fund additional medical research, close to half supported increasing the percent of each health care dollar spent on medical and health research, and two-thirds indicated that preventable diseases are a major health problem on which too little is spent (<http://www.researchamerica.org/>).

Only six months have passed since implementation of HIPAA legislation, but the impact is already apparent in some newly launched and other ongoing epidemiological studies. Epidemiologists report mixed experiences, apparently due to highly variable interpretation of HIPAA requirements by Institutional Review Boards (IRBs) and hospitals. This document highlights several areas of epidemiologic research that have been affected, with examples provided from ongoing field research. Problems described include: 1) new restrictions on database access; 2) variable access to individual medical records; 3) increasing length and complexity of consent forms; and 4) expanded disclosure of confidential data to more entities. Senior epidemiologists from different settings provided the examples. Read the full testimony below:

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**American College of Epidemiology (ACE) Testimony on Impact of HIPAA on Research  
November 20, 2003  
Martha Linet, M.D., M.P.H.**

#### **Overview**

Epidemiologic research evaluates postulated risk factors for a disease to ascertain etiology and identify preventable causes. Among the enormous contributions to public health, epidemiologic research elucidated consumption of contaminated water as the cause of cholera centuries before the discovery of the causal infectious organism, identified cigarette smoking as the major cause of lung cancer, delineated the risk factors accounting for the majority of cardiovascular diseases, and clarified the role of folic acid in the etiology of neural tube defects. Public opinion polls repeatedly showed that two-thirds of Americans favored doubling the total national spending on government-sponsored

scientific research over 5 years, more than half were willing to pay \$1 per week more in taxes and \$1 more for each prescription drug to fund additional medical research, close to half supported increasing the percent of each health care dollar spent on medical and health research, and two-thirds indicated that preventable diseases are a major health problem on which too little is spent (<http://www.researchamerica.org/>).

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## **Problems**

### **1. Database Access Restricted**

Case-control studies provide a crucial way to find clues to disease causation. These types of studies depend on the ability to identify appropriate controls, often utilizing population-based listings. Prior to HIPAA, Medicare and Medicaid files were available (with submission of proper documentation to the Centers for Medicare and Medicaid Services (CMS, formerly HCFA)) and widely used for selection of controls. Investigators cited new restriction of access to these databases to select controls for studies initiated after HIPAA. While ongoing studies have been 'grandfathered' to allow access to CMS beneficiary data for selecting population controls, CMS staff cited HIPAA as the reason for withholding access to beneficiary data in some instances. As an example, two investigators submitted letters to CMS recently, both citing the 'grandfather' exemption for their ongoing studies; in one case the CMS representative authorized access to the beneficiary data, while in the other case a different CMS representative continues to withhold access.

### **2. Variable Access to Medical Records of Individual Subjects**

Prior to HIPAA, investigators could generally use a simple universally accepted release form signed by subjects or proxies to request their/next of kin medical records. In recent years, epidemiologists began to experience some difficulties including problems in obtaining medical records from some smaller facilities, shorter expiration times for consent forms, and rapidly rising administrative costs for obtaining medical records to abstract. Since implementation of HIPAA, epidemiologists have described notably greater variability in access to medical records, with a substantially higher proportion of hospitals (not only smaller but also larger facilities) refusing to release records for research purposes. In addition, researchers have described increased requirements for subjects including specific designation of a long list of components of the medical record for release; absolving hospitals from liabilities, responsibilities, damages, and claims arising from release of medical record information; and recognition of a hospital's right to deny or revoke a request for release of records for research. An investigator studying birth defects used a simple, universal medical release form that was widely accepted by all hospitals in his multi-center study prior to HIPAA. Since HIPAA, he has been required to use substantially more complicated release forms prepared by the hospital (see attachment A, before and after). The researcher notes that mothers are intimidated by the complex and legalistic language and are refusing to participate. Deviation from a universal, simple release form necessitates substantial time and effort by the research team to contact each hospital, to obtain the unique and widely differing consent forms, and to request the subject to sign the form. In the frequent instances in which subjects have been hospitalized at more than one facility, researchers need to spend substantial time explaining the difficult content of multiple varying consent forms to a subject.

### **3. Increasing Length and Complexity of Consent Forms**

Individuals were required to sign consent forms to participate in a research study prior to HIPAA, but since implementation of HIPAA, consent forms have increased in length and complexity. Researchers are concerned that the more complex forms confuse potential participants, and that the added

language may detract from the important information such as the purpose, procedures, risks and benefits of the study. An investigator has noted that providers are requesting informed consents with much more information than before including: 1) the facility's own name on the consent form; 2) a date when the authorization expires and acknowledgement of the participant's right to revoke consent; 3) witnessed consent or notarized consent forms; 4) proof of kinship or proof of power of attorney for consent forms signed by the next of kin of deceased participants; 5) date of treatment and purpose of the request; 6) a copy of the study protocol; and 7) the investigator's signature. An example of the substantially greater length and complexity of a consent form after HIPAA is shown in attachment B (see highlighted required additions).

#### 4. Expanded Disclosure of Confidential Data to More Entities

Prior to HIPAA, access to data was restricted to researchers directly involved in the project. Since HIPAA, some IRBs have required researchers to list an expanded number of entities to which confidential data from subjects can be disclosed on the study consent form. Epidemiologists raised concern that such expanded disclosure makes potential subjects feel that their privacy is less, rather than more, protected. Additionally, this language has added to the length and complexity of consent forms. An experienced cancer epidemiologist is now required to include statements in consent forms indicating that confidential data will be/can be disclosed to the funding agency and to the Institutional Review Board of the investigator's institution. The investigator, who is establishing a cohort of American Indian and Alaska Natives to follow up for serious disease outcomes, was previously able to reassure Native American participants that identifiable information would not be taken off the reservation. Subsequent to HIPAA, the investigator's IRB requires a statement in the consent form indicating that subject-specific information may be required to be turned over to the agency funding the investigation.

### **Cross-Cutting Issues**

#### 1. Decline in Participation

Epidemiologists are extremely concerned about the effect of HIPAA on subject participation. Factors that have been identified as affecting participation or recruitment rates include: restricted access to medical records (for identification of potentially eligible study subjects, for validating medical diagnoses, or for ascertaining postulated risk factor information such as family history of specific diseases or use of particular medical treatments), increasingly complex consent forms, and concern of subjects about confidential data being disclosed to more entities. Epidemiologists have described profound adverse effects on participation rates emanating from an IRB's or hospital's interpretation of HIPAA requirements in each of these areas. In one example, a senior epidemiologist was conducting a study of pregnancy in which medical discharge diagnoses were first reviewed to identify potentially eligible subjects. Prior to HIPAA, the study was accruing approximately 10 subjects a week. After HIPAA, the study recruitment dropped to zero for six months. The investigator was ultimately granted a waiver by the institutional IRB and recruitment increased to pre-HIPAA levels. In a second example, a researcher examining medical expenditures has noted a decline in participation since the implementation of HIPAA. The study, which collects data from both household members and medical providers, has experienced a decline in participation by providers (who are refusing to release medical records). As a third example, an investigator conducting research on vaccine safety compared the success rate for abstracting medical record data before HIPAA (Phase 1) and after the passage of HIPAA (Phase 2). In this study, the investigator identified possible cases of a serious gastrointestinal (GI) problem using administrative claims, followed by medical record validation of occurrence of the GI disorder and vaccination status. Before HIPAA, the investigator was able to obtain 100% of medical records, whereas after the passage of HIPAA the investigator obtained 73% of records. Reasons for the decline were that the institution or provider "refused to release the chart or did not respond" (11%) or "required a site-specific IRB approval" (5%) and informed consent (even though the study had IRB approval with a waiver of informed consent). The investigator also noted an increase in the length of time needed for abstracting medical records, in part due to a greater reluctance of providers to release medical records during Phase 2.

#### 2. Financial and Legal Impact

Many researchers commented on the increased time and additional costs for conducting research subsequent to implementation of HIPAA. Much of this increased cost came from answering queries

from institutions, collaborators, and subjects, interacting with legal staff over language in forms, designing HIPAA compliant materials, and training staff in HIPAA requirements. Epidemiologists also noted that many hospitals now view research studies not only as a financial burden, but also as activities which put the institution at a legal or regulatory risk. In fact, one investigator, who had been requesting a waiver to conduct his research, was told by several facilities that they were concerned that granting a waiver may put the hospital at increased risk of a federal audit.

## **Conclusion**

The American College of Epidemiology will continue to request feedback from epidemiologists about their research experiences subsequent to HIPAA as compared with pre-HIPAA. As patterns emerge, the College will characterize and classify issues and problems with the goal of preparing and administering a standardized survey instrument and conducting a wide-scale survey. The College will also continue to provide feedback to the epidemiologist community, IRBs, hospitals, DHHS and others. We hope to continue to provide feedback about problems encountered, while not losing focus of subjects' and investigators' deep awareness of the importance of confidentiality. The College will also try to work closely with other medical research organizations to provide constructive suggestions to DHHS about possible remediation measures as we move forward in the post-HIPAA era. The key role of epidemiologic research in understanding disease causation is important ultimately because identification of etiology can lead to prevention and thus to improved health. Because epidemiologic research relies completely on in-depth study of individuals and populations, access to personal health data remains crucial.

## **Proposed Bylaws Changes**

The proposed changes were submitted to the ACE Board of Directors at several different times between September 2003 to April 2004. The specific changes are now submitted to the ACE membership in July 2004. According to Article X of the current bylaws this allows a vote in October 2004 (i.e., >6 months from submission to Board, >2 months from submission to membership). One of the proposed changes would decrease the time from "submission to Board" to "vote by membership" from 6 months to 2 months. Another proposed change would allow voting by email or internet. Read about all the [bylaws proposals](#).

## **In the News**

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### **Newly Elected Officers**

We are happy to announce that Martha Linet begins her year as ACE's president for 2004 - 2005. Betsy Foxman was elected president-elect. We thank the following members who are coming off the Board for their time and service: Roger Bernier (2001-04), Betsy Foxman (2001-04), Rosanne McTyre (1998-2004), and Colin Soskolne (2001-04) . Welcome to the new board members: Robert McKeown, Roberta Ness, Ed Trapido, Irene Hall, and Adolfo Correa.

## **From the Board of Directors**

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### **Treasurer's Report**

Good news from the Finance Committee. According to this year's financial statements our total unrestricted assets are rising. Revenue from the membership is rising, and we continue to obtain revenue from outlets such as the Annual Meeting. When looking at the College's financial history, we see that since the year 2000 our income has continuously exceeded our expenses. What does this mean for the college exactly? For starters, it means membership dues will not have to be increased for now. It also means that we are able to provide more substantial programs and awards to our members without financial strain. To keep up the momentum, the goal of the finance committee is to

ensure that the College maintains \$400 to \$500k in in our account at all times. New policies and programs are being developed to ensure monies are allocated in the most efficient manner for the improvement of the College.

## Committees

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### Publications

The Publications Committee has several new undertakings. David Lilienfeld is chairing a new Subcommittee (that includes James Gurney and Daniel Lackland) to provide content of particular interest to the College for the 4 pages in each issue of the Annals that are allotted for the College. Examples of content that the Subcommittee may solicit or provide include such topics the history of ACE (and of epidemiology generally), reports of College Committees, debates regarding College policy positions, discussion regarding the current state of the discipline, and workforce issues in the discipline. The Publications Committee members are challenging themselves to submit or solicit submission by a colleague of at least one manuscript annually to the Annals, identify two colleagues in addition to the Committee member who agree to serve as reviewers for the Annals and commit to short turnaround time (2-3 weeks) for reviewing manuscripts, and encourage or assist doctoral students and post-doctoral fellows to submit abstracts to the Annual Scientific Meeting. Dr. Melissa Bondy is the Chair of the Publications Committee. For membership and other information go to <http://www.acepidemiology2.org/cttes/publicat/>.

## Photo Gallery

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***Dr Manning Feinleib accepting the 2004 Lilienfeld Award from Dr Roger Bernier, chair of the Awards Committee***

We would like to regularly have photos of our members in the newsletter and on the website. The Communications Committee is looking for a volunteer to organize these photographs. Please contact me, [cburns@dow.com](mailto:cburns@dow.com) if you have an interest. Visit the [Photo Gallery \(under construction\)](#), to take a peek at some pictures from the Boston ACE meeting. We will have full details about the Boston meeting in our next issue of the newsletter.

## Commentary

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Welcome to ACE's new online newsletter. We have moved from a paper newsletter to this electronic version. Please note that you can print a pdf version by easily clicking on the pdf icon above. Thank you to Paul Levine for his fantastic efforts as the previous newsliner editor. Credit goes to Carlos Camargo and Paul for initiating the new format. As the new editor, I would like to facilitate communication among our members and capitalize on our terrific ACE website. Please send comments, suggestions and articles to me at [cburns@dow.com](mailto:cburns@dow.com). I'm looking forward to your ideas for the newsletter.

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