

APOR NEWSLETTER

News from the Association for Patient-Oriented Research • August 2004

APOR PRESIDENT'S COLUMN BY: ROBERT ECKEL, M.D.



At the incentive of the late Dr. Edward H. (Pete) Ahrens and many of his close colleagues and friends, the Association for Patient Oriented Research (APOR) was founded in 1998 as an international organization championing clinical research. The organization was created to re-focus attention on the importance of observing and scientifically studying individuals or small groups of human subjects for improved understanding of the mechanisms of health and disease. The mission of APOR is to demonstrate and reinforce the centrality of scientific study of human subjects to further the understanding of disease etiology and to contribute to disease therapy and prevention. APOR intends to work to maintain and expand clinically derived scientific knowledge with auxiliary use of laboratory science, and to promote patient-oriented science as a core discipline of the profession of medicine.

At the inception, APOR leadership was well aware that other professional organizations and societies shared these common interests; however, a critical role as facilitator was clearly needed. Four strategies were selected: 1. To hold an annual meeting; 2. To foster activities to promote and recognize successful careers in patient-oriented research; thus ensuring the viability of clinician scientists in their own institutions and in academic medicine at large; 3. To enhance the development of effective training programs for careers in patient-oriented research; and 4. To advocate for adequate funding for patient-oriented research by providing appropriate information to the public and to federal, state and local governments as well as foundations and industry.

We have been successful, but we can do more. The inaugural meeting of APOR was an excellent, focused stand-alone event held in Atlantic City on April 30-May 2, 1999. To increase the size of the meeting and to foster additional participation in APOR, our second meeting was held adjacent to the annual meeting of the General Clinical Research Center (GCRC) Program Directors in Crystal City on March 11-13, 2000. And I think it's accurate to say that the re-emergence of the Clinical Research meeting of multiple societies each spring is due primarily to the leadership of APOR. For the last several years the GCRC Program Directors and the Association for Medical Research (AFMR) have met with APOR, and in Chicago in 2004 the Association for Clinical Research Training (K-30) Program Directors and the Central Society for Clinical Research (CSCR) were also present. In addition, this year the annual meeting of the Association of American Physicians (AAP) and American Society of Clinical Investigation (ASCI) occurred at the same time as the APOR meeting although in an adjacent hotel.

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REGIONAL TRANSLATIONAL RESEARCH CENTERS PROGRAM ROLLED OUT: NIH'S ROADMAP FOR RE-ENGINEERING CLINICAL RESEARCH

A July 16, 2004 meeting to advise Elias Zerhouni about the proposed Regional Translational Research Centers (RTRC) generated animated discussion and a broad range of suggestions. The announcement of the meeting had attracted about twice as many applicants as there were spaces. But those who got tickets had the opportunity to convey to Steve Strauss and his Roadmap colleagues how they felt NIH and the nation's medical centers could try to fit the plans into a practical context.

The clinical roadmap has five broad goals:

- Promoting better integration of existing clinical research networks.
- Supporting translational research.
- Encouraging the development of technologies to improve the assessment of clinical outcomes.
- Harmonizing regulatory processes.
- Enhancing training for clinical researchers.

NCRR's Anthony Hayward was a major author on the working document prepared for the July 16th conference. That document envisioned 16-24 RTRCs which would provide a broad

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NEW BILL TO SUPPORT CLINICAL RESEARCH INFRASTRUCTURE

The "Clinical Research Act of 2004" was introduced in the House of Representatives on July 8, 2004. This bill (H.R. 4779) addresses the costs of unfunded mandates and infrastructure for clinical research. Bill Crowley's AHC Clinical Research Forum was the motive force behind the development of this bill. It was introduced by Rep. Dave Weldon (R-FL) and Rep. Mike Doyle (D-PA).

This legislation will provide for clinical research support grants, clinical research infrastructure grants, and a demonstration program on partnerships between an academic health center and practicing health care providers for carrying out human subject research. It will also provide academic health centers with the resources and the opportunity to meet the public's expectations of translating new knowledge into the public's health care.

The text of this bill can be found at <http://thomas.loc.gov> by typing in HR4779. Congress is currently on a six-week recess so there has been no action since it was introduced and referred to the Energy & Commerce committee for review. When Congress returns, lawmakers will focus their attention on "must-do" appropriations bills and little else until after the elections.

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The full text version of the APOR Newsletter, including some supplementary information, is available at

WWW.APOR.ORG

APOR Needs a Few Good Women And Men.

**Would you like to serve in an APOR leadership role?
We'd like to hear from you.**

**Send a CV/biosketch to:
Christy Mayberry at
apor@mpi-evv.com**

NIH'S ZERHOUNI ENDORSES OPEN-ACCESS RESEARCH PUBLISHING

At a July 28, 2004 gathering of 43 publishers, editors and others in Bethesda, NIH Director Elias Zerhouni gave an unexpectedly strong endorsement of open-access scientific publishing. Open-access publishing is the movement toward immediate free availability of reports of scientific research. It has been championed by former NIH Director Harold Varmus and many scientists and librarians, and an increasing portion of the informed public. It is opposed by many journal publishers, editors and by some societies which derive critical income from their journals.

"The public needs to have access to what they've paid for," Zerhouni told those present. However he stopped short of setting a deadline for depositing full-text manuscripts in the PubMed Central database archive of the National Library of Medicine. This conference was the first of several that should lead to creation of a public access plan which NIH will publish in the Federal Register for comment before it becomes policy.

In a double victory for the open access publishing movement, governmental committees in the United Kingdom and the United States recently weighed in by recommending that research supported by public funding should be deposited in free, online archives. The British committee went further, endorsing an open-access model in which authors (or their financial sponsors) would pay to publish and subscription fees would be eliminated. On the American side, the recommendation is part of a report that accompanies a spending bill. The Appropriations

Committee report requested that NIH produce language concerning compliance by December 1, 2004.

Feelings ran strong at the Bethesda meeting. Zerhouni pointed out that Congress demanded evidence of NIH's productivity. "I need to manage the portfolio," he said. "The status quo just can't stand." Zerhouni tried to reassure attendees that no governmental mandating was on the table yet, and that the views of all would be taken into account. He noted that the Appropriations Committee report was directed to the NIH and not developed by it. But Paul W. Kincade, president of FASEB told The Scientist that he resented the "coercion." FASEB Public Affairs Director Howard Garrison pointed out that, "While the federal government has paid for the research, it has not paid (entirely) for the publication of that research; publishers add significant value to the original research reports through reviewing, editing, and disseminating articles," according to the Washington Fax.

For patient-oriented research, some support for open access has already appeared. The British Medical Journal has become an advocate. Indeed the point has been made that most access to research has not benefited much from the technological improvements of the digital era. One recent report of the timeframe from manuscript submission to public availability of a clinical research paper suggested that compared to 200 years ago the pace today had actually slowed at least in relation to the print journals.

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THE LIGHTER SIDE: HOW TO SURVIVE IN ACADEMIC MEDICAL CENTERS

Life in the medical school professoriate can be treacherous. Good advice is of great value, but unfortunately in short supply. In *How to Swim With Sharks*, APOR member Voltaire Cousteau (a.k.a. Dr. Richard J. Johns, Chair Emeritus of Biomedical Engineering at Johns Hopkins) offers up unusually pointed, if allegorical, advice. Key messages: the value of the preemptive strike on the shark's nose, and

the importance of not bleeding. Johns' tongue-in-cheek allegory has taken in unwary readers; the article has even been abstracted in the oceanography literature, hopefully without causing any loss of life or limb among literal-minded swimmers. *Perspectives in Biology and Medicine* 1987; 30: 486-489. For Full text visit: www.apor.org/html/Articles.htm

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SPECIAL THANKS TO CONTRIBUTORS TO THIS ISSUE:

- TOM COMMON ▸ BILL CROWLEY ▸ BOB ECKEL ▸ ROXANNE HALL
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- LARRY RAISZ ▸ DAVID ROBERTSON ▸ BRIAN SCROGGINS

NIH'S ROADMAP FOR RE-ENGINEERING CLINICAL RESEARCH

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menu of clinical research services to multiple institutions within a geographic region defined by acceptable patient access. These include (1) support of new pilot projects; (2) support for patient (particularly minority) recruitment; (3) assistance in implementation of FDA Good Clinical Practice Regulations and the IHC Good Clinical Practice Consolidated Guideline into study protocols, consent forms, and IND applications; (4) data accrual, curation and warehousing and advanced biostatistical support; (5) provision of clinical informatics platforms and services, including protocol tracking and development of case report forms; (6) central IRBs for protocols at multiple institutions; and (7) support for specialized staff (e.g., chemotherapy nurses; translational research fellows who cross disciplinary/institutional lines).

Additional services would be provided at "Expanded" RTRCs (ERTRCs). Four to eight ERTRCs are anticipated. These would be supplemented by a robust core laboratory technology such as (1) immunophenotyping/high speed sorting in > four colors; high speed, multi-parameter, cell sorters, which, at a cost of \$500,000, require constituent economies of scale; (2) RT-PCR core for expression array analyses; (3) real time PCR; (4) informatics and statistical support to interpret genetic and microarray results; (5) pharmacological assays, LC-MS, etc.; and (6)

genomic and SNP sequencing resources via high throughput genotyping capabilities.

Projections are that RTRCs and ERTRCs will cost ~\$3 million and ~\$5 million per year respectively. A late 2004 or early 2005 RFA will fund up to 30 planning grants at ~\$100,000 each. RTRC RFAs will be available in FY2006 and later.

During the discussion session there were questions from the audience about where the GCRCs fitted in to all this. Steve Strauss seemed at pains to distance the GCRCs and the RTRCs; "Where do the GCRC's fit in? They fit in the same way all the other institute-funded programs do," Strauss said. "This is not a matter of building up GCRCs ... I think we should start with a clean blackboard and not figure out how to augment an existing program, but to leverage them where possible." Pressed on this point, Strauss added, "I think the GCRCs can compete to be a part of these, but there are hundreds of centers around the country very interested in research. The GCRC is invested in about 80 of them. I think we [can] distribute ability to do translational research far more widely."

Although skepticism about the RTRC concept has been widespread among clinical investigators, many attendees left the Roadmap meeting with a sense that, with critical input from the intramural and extramural community, a viable and exciting RTRC program was emerging.

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PATIENT ORIENTED RESEARCH



"For patient-oriented research, APOR is the Keeper of the Flame. There is much value in that. Clinical research has gone through bad times and good times. Times now are good, at least in the United States, but that can change quickly, and if that happens, someone must step into the gap. APOR can speak for patient-oriented research."

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NEW BILL TO SUPPORT CLINICAL RESEARCH INFRASTRUCTURE

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Help is needed from APOR members. Please write to your representatives urging them to cosponsor this bill. The following are some of the reasons why it is necessary for H.R. 4779 to be signed into law:

Strong academic health centers are essential to a vigorous clinical research enterprise.

Breakthroughs in basic biomedical sciences over the past fifty years have provided an unprecedented supply of information for improving human health and preventing disease.

Translating the information gained through these basic discoveries into knowledge that will impact clinical practice and ultimately human health requires

strong clinical research institutions.

Without a sound infrastructure to accomplish this translation in a systematic and coherent way, the sum of data and information produced by the basic science enterprise will not result in tangible public benefit.

The clinical research environment is increasingly encumbered by facility decay, incompatible databases, a shortage of qualified investigators, rising costs, inadequate funding, and mounting unreimbursed regulatory burdens such as human subject protections and additional record-keeping requirements under the Health Insurance Portability and Accountability Act of 1996.

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APOR PRESIDENT'S COLUMN

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Despite this important activity of APOR, accomplishments related to the last three objectives have not been fully realized. Actions that would promote and recognize successful careers in patient-oriented research have been limited to the annual award presented each year at the spring meeting to one of our colleagues. Because of the K-30 program, the need to enhance the development of effective training programs for careers in patient-oriented research has in part been accomplished, but junior faculty development remains a challenge and is an area in which APOR can play an essential role. Finally, APOR has the potential to be a more effective outward advocate for adequate funding for patient-oriented research with the many communities that surround her.

At our most recent Board and Business meetings in Chicago, the optimal future activities for APOR were discussed. If we are to realize our potential, renewed commitment to our mission and objectives are needed. To this end, a retreat of the

current and past Boards will take place in Chicago on October 11-12, 2004. Dr. Anthony Suchman, from the University of Rochester who is experienced in working with academic organizations to define/refine purpose and mission, will assist in the process. As President, I think there is much reason for hope and many new opportunities: 1. We need to communicate more effectively with the membership. This process has already begun with sending out minutes from our spring business meeting and the inauguration of this APOR Newsletter; 2. K-23 Award recipients should be on our radar screen to be approached for membership; 3. Dr. Zerhouni should be approached directly about the importance of distinguishing between patient-oriented research and 'clinical research' in general; 4. We should actively support the combined bench/bedside investigator (the old days if you will); 5. We should meet with the pharmaceutical/device industry to discuss investigator-initiated sub-studies in large clinical trials; and 6. We should develop renewed interest in and models of observational

research.

The retreat should engender renewed enthusiasm and purpose, and as your president I will do my best to be proactive in accomplishing our objectives, encouraging new membership and working closely with our colleagues in other societies to further our joint translational research effort. Thank you for the opportunity.

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THE APOR OCTOBER RETREAT

October 11-12, 2004
Chicago, IL

**APOR members with ideas
for future
initiatives are welcome.**

**Contact Christy Mayberry at
apor@mpi-evv.com**