AAHRPP ADVANCE
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FALL 2014

Seeking Consensus, Balance on Comparative Effectiveness Research

Comparative effectiveness research (CER) offers unprecedented opportunities to improve U.S. health care practice. CER also raises complex questions about locating the boundaries that separate research and quality improvement, defining minimal risk, and obtaining informed consent. LEARN MORE

NHC: An Effective, United Voice for Patients

Our series on AAHRPP's Founding Members continues with a look at the National Health Council, which serves as the united voice for the more than 133 million Americans with chronic diseases and disabilities and their family caregivers. Founded in 1920, the Council is made up of more than 100 national health-related organizations and businesses. LEARN MORE

A Year of Transition, Consistently High Standards

Elyse I. Summers, J.D., reflects on her first year as AAHRPP President and CEO, highlighting efforts to enhance the accreditation process while maintaining the quality and rigor that have made AAHRPP accreditation the gold standard for research protections. LEARN MORE

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Research Protections and Comparative Effectiveness Research: Seeking Consensus, Balance

Few dispute the benefits of a learning-based health care system or the pivotal role that comparative effectiveness research (CER) will play in assessing and improving health practices—especially since the Affordable Care Act includes unprecedented funding to further CER.

There is less consensus, however, on how to classify CER and whether it requires the level of oversight reserved for research involving human participants. Central to the debate are questions about locating the boundary between research and quality improvement, how we define minimal risk, when informed consent is necessary, and how best to obtain informed consent.

"Ethicists disagree on the answers to these questions," says Richard Platt, M.D., M.Sc., who leads the coordinating center for PCORnet, the National Patient-Centered Clinical Research Network. Dr. Platt also chairs the Harvard Medical School Department of Population Medicine at the Harvard Pilgrim Health Care Institute in Boston.

PCORnet is an initiative of the Patient-Centered Outcome Research Institute (PCORI), which was created by the Affordable Care Act to support CER. The goal of PCORnet is to improve the nation's capacity to conduct CER by setting up a large, highly representative network for clinical outcomes research.

This network will "embed meaningful research into the clinical delivery system in a way that lets us rapidly and efficiently answer questions that have been unanswerable until now," Dr. Platt says. "I see PCORnet as the opportunity of our generation to make a real difference in the way we create new knowledge that improves the lives of so many people in this country."

For example, one PCORnet study, set to begin early next year, will seek to determine the optimal daily dose of aspirin for patients with coronary artery disease (CAD). Findings could improve care for 15.4 million Americans who have CAD. Another example of research embedded in the routine delivery of care is a recent Agency for Healthcare Research and Quality/Centers for Disease Control-funded study of 43 hospitals nationwide that evaluated three accepted practices for preventing methicillin-resistant Staphylococcus aureus (MRSA) in intensive care unit (ICU) patients.

In addition to clinical findings, these early PCORnet studies are expected to provide insight into how to balance the need for broadly applicable new knowledge with concerns about protecting research participants. PCORnet and the National Institutes of Health's Health Care Systems Research Collaboratory also will tackle key issues, jointly, in white papers on the following:

- Definition of minimal risk
- Waiver or modification of consent/alternate modes of notification
- The research/quality improvement distinction in practice
- Data monitoring in pragmatic clinical trials (PCTs)
- Achieving institutional review board (IRB) harmonization and efficiency in PCTs
- Vulnerable subjects in cluster randomized trials (CRTs)
- Gatekeepers in PCTs
- Identifying direct and indirect subjects/participants in CRTs/risk and benefit assessment
- Food and Drug Administration-regulated products and PCTs
- Ethics and the nature of interventions in PCTs (e.g., physician vs. patient)
- Data privacy

Many researchers and clinicians would like to see new or updated federal guidance on the boundaries between research, medical practice, and quality improvement activities. Until that happens, much of the responsibility for decision-making will fall to IRBs and other members of the research protection community. As always, AAHRPP will serve as a resource, tackling these issues at our conference and via webinars, connecting you with thought leaders, and identifying questions to consider, such as the following:

- **Is the activity considered quality improvement or research?** The U.S. Department of Health and Human Services offers guidance on how to make this determination and how to take advantage of the flexibility that's available in the federal regulations. In addition, OHRP is expected to issue draft guidance shortly on the specific topic of comparative effectiveness.

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- **Can the research review be conducted by a single, central IRB?** If IRB oversight is required, is there an AAHRPP-accredited organization involved whose IRB would be willing to take the lead? Is your organization comfortable either with assuming or delegating that role?
- **What constitutes minimal risk?** And is the risk the result of the CER or the patient's existing condition? In the MRSA/ICU study, for example, those who designed the study argued successfully that the primary risk to patients involved is that they are sick enough to require ICU care. Assigning them, through cluster randomization, to receive a specific, already accepted treatment for MRSA prevention does not increase their risk.
- **What are the options for informed consent?** Is the risk so minimal that the requirement for informed consent could be waived? Alternatively, are there low-risk studies for which it would be acceptable simply to post a notice alerting patients that the clinical location is part of a CER study? And when should you require notification?
- **What are the implications of randomization?** Does the use of randomization—including cluster randomization—preclude an activity from being viewed as quality improvement? If a health care system plans to roll out a new practice to multiple units, can the system randomize the order in which it does so to improve its ability to monitor the effect? Can low-risk randomized trials meet the criteria for exempt research?

The challenge, with each of the above, is to find a way to improve U.S. health care practice without sacrificing the rights and protections that are central to quality, ethical research. To do otherwise, in the words of Dr. Platt, "at best would be a missed opportunity and, at worst, would be a failure to keep faith with patients."

National Health Council: An Effective, United Voice for Patients

This is the latest in a series of articles on AAHRPP's Founding Members and the critical role they've played—and will continue to play—in AAHRPP's success.

Of the seven organizations that joined forces to found AAHRPP in 2001, the National Health Council (NHC) arguably had the most at stake.

At the time, the research enterprise was buffeted by a series of research protection failures, some of which resulted in program shut-downs. Public trust in research was eroding, and there was increasing concern that patients would be less willing to enroll in clinical trials. That, in turn, could have delayed medical discoveries, including promising new treatments for NHC constituents. Voluntary accreditation was viewed as one way to strengthen protections, improve quality, and help restore public confidence.

NHC serves as the united voice for the more than 133 million Americans with chronic diseases and disabilities and their family caregivers. Founded in 1920, the Council is made up of more than 100 national health-related organizations and businesses.

Since supporting health research is one of NHC's top priorities, it was only natural that the Council would be among AAHRPP's founders. Other Founding Members are: the Association of American Medical Colleges, Association of American Universities, Association of Public and Land-grant Universities, Consortium of Social Science Associations, Federation of American Societies for Experimental Biology, and Public Responsibility in Medicine and Research.

Myrl Weinberg, M.A., F.A.S.A.E., C.A.E., who has been CEO at NHC since 1996, recalls the research protection incidents—including the 1999 death of a research participant—that spurred calls for accreditation and led to AAHRPP's founding.

"We were very aware that these incidents were undermining the trust that patients and people with various health conditions had in clinical research," Ms. Weinberg says, "and that trust would continue to be undermined if we didn't act.

"The National Health Council is truly the one Founding Member organization that directly represents patients," she adds. "It was critical that we find a way to assure them that research would be conducted in a safe, ethical manner."

Exceeding expectations

Ms. Weinberg remembers AAHRPP's early years and the challenges of building an accrediting body from the ground up, from developing standards and processes to mustering support for voluntary accreditation. Although her confidence in AAHRPP was absolute, Ms. Weinberg acknowledges that even

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she was "a little surprised at how fast our major objectives were realized and how rapidly the global expansion occurred. It is the most reputable body in the world to accredit human research protection programs."

She credits much of AAHRPP's success to some early decisions made by the Founding Members, including their choice of Marjorie Speers, Ph.D., to head the organization. "Initial leadership is critical," Ms. Weinberg says. "Once we hired Marjorie, there wasn't a moment that I felt that AAHRPP would not be successful."

Dr. Speers retired from AAHRPP in 2013, and Elyse I. Summers, J.D., was named President and CEO. Ms. Weinberg, who will step down from her role at NHC in February, envisions that the two organizations will continue to work together long after her departure. She cites her role in founding AAHRPP and the International Alliance of Patients' Organizations as some of her proudest accomplishments while at NHC.

"These two organizations play a vital global role in advancing the interests of people with chronic diseases and disabilities. Without NHC's involvement, these organizations would not be as effective as they are today," she says.

In the early years, AAHRPP's Board of Directors and team of site visitors included representatives of NHC member patient advocacy organizations. Although it no longer selects a patient organization representative to sit on the board, NHC continues to promote AAHRPP and the value of accreditation to the Council's patient advocacy organizations and other members. Today, five of AAHRPP's directors represent research participants and other community stakeholders.

NHC also was instrumental in ensuring that AAHRPP's standards reflect the patient's perspective. AAHRPP addresses patient engagement in Standard I-4, which requires organizations to respond to the concerns of research participants. Equally important, AAHRPP expects accredited organizations to involve research participants, when appropriate, in the design and implementation of research and the dissemination of results.

Looking ahead, Ms. Weinberg sees ample opportunities for AAHRPP and NHC to continue to partner with one another, especially on efforts to increase patient engagement in the research enterprise.

"We certainly view AAHRPP as having a role in promoting expanded patient involvement," Ms. Weinberg says. "NHC and AAHRPP have learned a lot and have made a difference together over the years. I definitely see that continuing."

From the President and CEO

ELYSE I. SUMMERS, J.D.

A year of transition and consistently high standards

This month marks my one-year anniversary as AAHRPP President and CEO. That makes it the ideal time to note some of the changes we've made this past year and, equally important, to reaffirm what will remain constant at AAHRPP: our commitment to protect research participants and to advance quality, ethical research.

I was very fortunate to take the helm at an extremely well run organization, with a highly qualified and talented team. All the fundamentals—the standards, the Board of Directors, the Council on Accreditation, our staff, policies for reporting concerns, etc.—were and are rock solid. However, as with any organization, especially one involved in navigating complex issues, there's always room for improvement, so we seized the opportunity to make changes.

In some cases, we followed through on changes that had been initiated under my predecessor, AAHRPP's founding CEO, Marjorie Speers, Ph.D. Other changes were made in response to the concerns I heard during the listening tour that I embarked on almost immediately after my appointment. All reflect AAHRPP's willingness to be flexible while ensuring that AAHRPP accreditation remains the gold standard for quality and research protections.

It is my hope that many of you have already benefited from these changes, some of which are outlined below:

- Moving away from hard copy – Our goal is to eventually enable you to submit applications securely online to eliminate the inconvenience and environmental effect of printed applications. In the meantime, we are happy to accept documents on CD-ROM or USB flash drive.
- Providing more information and preparation time before site visits – We realize that many of you have questions about what should be completed before your site visit and that you need more time to pull together the documents that we'd like to review. Therefore, we are giving U.S. organizations 10 business days to compile their documents. For foreign, non-English-speaking organizations, we are allowing 40 business days.
- Streamlining reporting requirements – We have modified our Step 1, Step 2, and Annual Reporting forms to reflect information of greater relevance to the organizations and to AAHRPP's review processes.
- Increasing training opportunities for site visitors and team leaders – We now notify all site visitors and team leaders—veterans and newcomers alike—of all training sessions, to provide ample opportunity for those interested in taking refresher classes.
- Capturing and acting upon feedback – Updated feedback forms enable us to collect more robust information from organizations and site visitors. We'll be compiling this information and sharing it with those involved as part of our continuing quality improvement.

I want to thank all of you for being so welcoming and for providing such helpful input this past year. I look forward to continuing to work with you in the coming months and years as part of our ongoing efforts to improve the AAHRPP experience.

Best regards,

Elyse I. Summers, J.D.
AAHRPP President and CEO