



VA Research Currents

'Stand down' part of four-point plan to optimize human protection

More than two-thirds of the way into a 90-day "stand down" aimed at proactively reviewing all procedures related to the protection of human research subjects, VA research staff are forging new national standards for excellence, according to K. Lynn Cates, MD, assistant chief research and development officer for VA.

"What we're doing is putting VA in the lead on credentialing and training," said Cates, who's been tasked with overseeing the effort. "I would not be surprised to see others follow in our footsteps."

She said people are "working their guts out"—for the right reasons—to ensure they fulfill their requirements and bring their programs up to speed. "This is a tremendous amount of work for people in the field, and they've genuinely risen to the occasion. They've had extremely thoughtful questions, and are really understanding the spirit of what this is about. They want to make sure research at their facility is done in the best way possible."

The stand down, declared in March by Nelda Wray, MD, MPH, chief research and development officer, runs through June 6. It is somewhat different from a stand down in the military sense, where operations are shut down and there's a focus on correcting problems. Here, the main goal is to examine existing practices to *prevent* problems and to step up education and training. Investigators and research administrators are fulfilling an array of requirements, ranging from completing online courses in good clinical practices to verifying staff credentials. The details were spelled out in a March 6 memo from Wray to all associate chiefs

see **STAND DOWN** on page 2

One in three HIV patients say life's now better

Nearly a third of patients with the AIDS virus say life is generally better since they received their diagnosis, according to study findings presented May 1 at the annual meeting of the Society of General Internal Medicine in Vancouver, B.C. The study was based on interviews with 449 HIV patients in 2002 and 2003.

According to lead researcher Joel Tsevat, MD, MPH, a physician and researcher with the Veterans Healthcare System of Ohio and the University of Cincinnati Medical Center, the study is one of few to show that, surprisingly, many seriously ill patients are happier with life since their diagnosis. He cited anecdotal reports of this phenomenon from nurses, psychologists and other healthcare providers, but said there is scant evidence of it in the medical literature.

see **HIV** on page 4

Richmond's Research Day luncheon for volunteers is 'family reunion'

James Williams is quick to credit his doctors at the McGuire VA Medical Center in Richmond, Va., with helping keep his diabetes in check. In particular, he feels his participation in research has increased his knowledge and made his self-care more effective.

"It's improved my diabetes quite a bit," said Williams, who served in the Korean and Vietnam wars. "I've learned more about diabetes, and it's helped lower my blood sugar." As a result, he's been able to lower his daily dose of insulin.

On April 25, Williams and about 400 other veterans were treated to a festive luncheon at the Richmond VAMC as part of the center's Research Day activities, part of VA's National Research Week commemoration. This was Richmond's sixth annual luncheon, at a cost this year of about \$15,000 to the center's nonprofit research corporation. According to administrative officer Robert Dresch, the luncheon—Richmond's way of saying "thank you" to its research volunteers—is well worth the investment.

see **LUNCHEON** on page 3

Update from Health Services Research and Development...

Long-term care to be focus of state-of-the-art (SOTA) conference

By John G. Demakis, MD, director

At the request of VA's Under Secretary for Health, Robert Roswell, MD, the Health Services Research and Development Service (HSR&D) will host a state-of-the-art conference on long-term care in Washington, DC, this September. The purpose will be to synthesize and disseminate information; promote implementation of findings; strengthen communication among investigators, clinicians, managers and policymakers; and improve management, decision-making and research in the area of patient-centered long-term care.

The event is co-chaired by Darryl Wieland, PhD, MPH, director of geriatric research for Palmetto Health; and Susan Hedrick, PhD, associate director of HSR&D's Northwest Center for Outcomes Research in Older Adults.

Background papers have been commissioned, under the guidance of an expert planning committee, to provide conference participants with a common knowledge base to stimulate discussion about key issues in long-term care. Topics covered in the papers include VA long-term care policy, as well as the implementation, coordination and assessment of care.

VA and non-VA experts will participate in one of five workgroups: 1) Defining the Long-Term Care Patient Population; 2) Structures Needed to Improve Integration of Care (organization, resources, workforce); 3) Processes Needed to Improve Integration of Care (screening, assess-

see **SOTA** on page 4

STAND DOWN (cont. from pg. 1)

of staff for research, and can be found online at http://vaww.va.gov/resdev/fr/stand_down/default.cfm.

The stand down is one component of a new program called PRIDE, based at Central Office and headed by Cates. The acronym stands for the "Program for Research Integrity Development and Education." PRIDE will oversee some of the functions formerly handled by the Office of Research and Compliance, which has been phased out, and take the lead on training, education and policy related to human research.

Besides the stand down, PRIDE is tackling three core initiatives:

- The "Blue Ribbon Panel on Maximizing Human Subjects Protection in VA Research," chaired by medical ethicist Baruch Brody, PhD, of Baylor College of Medicine, will convene VA and non-VA experts to examine critical issues concerning human subjects protection program.

- Accreditation of all VA research facilities by the National Committee for Quality Assurance (NCQA) will resume this summer. Updated final standards are posted on the NCQA website at <http://www.ncqa.org/Programs/QSG/VAHRPAP/vahrpap.htm>. All facilities are expected to be accredited by 2005.

- A help and education resource, coordinated by Marisue Cody, PhD, an outcomes researcher at the Little Rock VA Medical Center, will provide support in a variety of formats—online, e-mail, phone, meetings—for researchers and administrators. This "center for compliance help" is tentatively being referred to as "COACH,"

though each word in the acronym has not yet been finalized.

Cates said the stand down goes further than previous efforts within or outside VA by extending certain requirements to almost every member of the research team. "One of the things we're doing that's very different than what anyone has done in the past is seeing to it that virtually everyone on the research team—not just the investigators and the coordinators—have their credentials checked and receive training. We'll have a team that will be highly cognizant in their everyday work about the importance of protecting human subjects."

Cates noted that PRIDE is also communicating with medical center managers to make sure they understand the role of research at their facility. "We're also heightening awareness, importantly, in the leadership at the facility—medical center directors, chiefs of staff, chief medical officers. These people are listening up. This has been great for making sure anyone involved even tangentially in research is getting a heads up." ■

VA Research Currents
is published monthly for the
Office of Research and Development
of the Dept. of Veterans Affairs
by VAR&D Communications
103 S. Gay St., Rm. 517
Baltimore, MD 21202
(410) 962-1800, ext. 223
researchinfo@vard.org

LUNCHEON (cont. from page 1)

“It’s tempting to focus attention on research investigators,” said Dresch, “but we feel the emphasis should be on honoring the veterans that participate in research.” He said the event is an important part of the center’s human subject protection program.

“Researchers and their staff attend Research Day and mingle with their patients—that’s what it’s all about,” said Dresch. “That is the important human subject protection piece—putting the research subjects and their families eyeball to eyeball with the researchers. They come together in a setting that puts faces on a process, fosters discussions about research, and reinforces the fact that participation is voluntary and involves risks.” Knowledgeable participants, he said, translates into better and safer research.

Franklin J. Zieve, MD, PhD, Richmond’s associate chief of staff for research, said the luncheon reinforces a “family” feeling between volunteers and investigators that underpins human-protection efforts: “On Research Day I see old friends who were in some of my studies going back 10 years. When you’ve just shared a meal with someone, you think more carefully about how he is being treated. This is our family.”

Dresch offered a frank tip for other VA research sites that may be considering similar Research Week events:

“We tried formal presentations from researchers, but crowd interest in speakers died fast as researchers tended to get too technical about their particular area of expertise. We discovered the obvious—the number one thing our patients want is the opportunity to talk to their doctors and nurses and to each other.”

This year’s event, as usual, did

feature a presentation by Zieve, but the talk was brief and focused on the rights of research participants. Zieve also answered questions from attendees and discussed the results of a survey the center mails annually to its research volunteers.

The Research Day luncheon is integral to Richmond’s human subject protection program.

Volunteer Rudy Rowe attended last year’s luncheon and said he enjoyed trading stories with other research participants. “Most of the guys I spoke with were pretty positive,” said the former Air Force mechanic. “They felt the doctors had really helped them.” For Rowe’s part, he said taking part in research helped him lower his cholesterol and avoid bypass surgery. Now

he’s eager to do more: “I told them anytime there’s a study I can get involved with, I’d be glad to help.”

While slide or poster presentations may not be the cup of tea for most volunteers, one educational piece that *does* work, said Dresch, is providing “concrete visuals” such as pacemakers and catheters. “One exhibit that draws lots of interest every year is the cardiac pacemaker/defibrillator. We line up the old and new models and every year the devices get smaller and more powerful.”

And perhaps the most important thing he and his colleagues have learned after six Research Day luncheons: “If you expect a crowd of 400 veterans, tell the caterer to bring enough shrimp for 800.” ■

Send a brief summary of your facility’s Research Week activities to:

Chris Amereihn, R&D Communications,
chris@vard.org or (fax) 410-962-0084

Other Research Week happenings...

Other VA National Research Week events included those described below. A more complete summary, with photos, will appear in the next issue of *VA Research Currents*.

- At the **Gainesville VAMC**, part of the North Florida/South Georgia Veterans Health System, a team of researchers delivered a special one-hour presentation titled “Inside the Brain.” The walls of the center’s auditorium were covered with posters featuring research by other investigators. The event was reported on by the area’s daily newspaper, the *Gainesville Sun*.

- Events at the **VA Pittsburgh Healthcare System** included a research open house and an educational campaign targeted toward veterans. More than 50 veterans filled out a VA research satisfaction survey, and several expressed interest in serving on the center’s Institutional Review Board.

- At the **Bronx VAMC**, an afternoon program featuring 15-minute presentations by investigators covered a wide range of topics: biomaterials, new treatments for spinal cord injury, the role of environmental toxins in Parkinson’s disease, clinical trials in dementia, and many others. The talks were followed by a tour of the research building.

HIV (continued from page 1)

In the study, funded by VA and the National Center for Complementary and Alternative Medicine, patients compared their life before and after their diagnosis. About 32 percent said life was "better" since they learned they were HIV positive; 29 percent said life was "worse"; 26 percent said life was "about the same"; and the others said they "didn't know." Those who said life was better were almost equally represented among patients without symptoms, those with symptoms but without AIDS, and those with full-blown AIDS. About 61 percent of patients in the study had AIDS.

Tsevat said the findings jibed with those from a smaller study of HIV patients he conducted in the mid-1990s. In that study, he said, many HIV-positive patients reported "they had learned to appreciate life more than they used to. They no longer took things for granted. Things like a nice day, a change in the seasons, family—they just appreciated what they had a lot more." ■

SOTA (continued from page 2)

ment, coordination); 4) Innovations and Models (system, service and technological innovations); and 5) Translating Research into Practice.

Each workgroup will focus on several important questions or issues, and through dynamic workgroup discussion will help identify what we know and what we need to learn about long-term care. Most importantly, workgroups will identify SOTA products that will play a key role in disseminating the state-of-the-art and recommendations for the future of long-term care to VA and the larger health care community.

For more information about the conference (participation is by invitation only), contact Karen Bossi at (617) 232-9500, ext. 5960, or via e-mail at Karen.Bossie@med.va.gov. ■

[Editor's note: Insights from HSR&D's 2001 state-of-the-art conference, on informed consent, are highlighted in *Informed Consent for Human Subjects Research: A Primer*, available at www.hsr.d.research.va.gov/publications/primer.]

Format change for national hotline calls

In response to suggestions from the field, VA research's national hotline conference call are now oriented more toward interactive discussions of critical topics, rather than formal announcements. The calls are held the second Monday of each month, 1 – 1:50 p.m. EDT. The Office of Research and Development sends e-mail reminders about two weeks before each call. The e-mails include important announcements, but the conference calls are reserved mainly for discussions. Upcoming calls will be on June 9, July 14, Aug. 11, Sept. 8, Oct. 20, Nov. 10 and Dec. 8. The call-in number is 1-800-767-1750, access code 17323.

Inside this issue...

- Stand down 'update
- Long-term care meeting
- HIV and quality of life
- Luncheon scores big
- with research volunteers