



VA Research Currents

Update from the Office of Research and Development...

Recognizing the contributions of the NRAC and FRAC

By *Stephan D. Fihn, MD, MPH, acting chief R&D officer*

The National Research Advisory Council (NRAC) and the more recently established Field Research Advisory Committee (FRAC) play critical roles in VA research. Both groups have been meeting regularly and providing important guidance to ORD.

The NRAC members, appointed by the Secretary for their knowledge of VA and non-VA research issues, have recently focused on our initiatives involving illnesses affecting Gulf War veterans. They have been especially concerned about ensuring that this research meets VA's usual high standards of scientific merit. The group is also concerned about potential erosion of VA's traditionally strong academic affiliations by recent developments such as issues involving timekeeping for part-time physicians and potential adverse effects on VA investigators of recent changes in NIH policies and procedures regarding faculty effort certification. The NRAC has a keen interest in understanding and helping to focus VA research and plans to meet this summer to review the portfolio. ORD is fortunate to have attracted a group of such distinguished, thoughtful and influential leaders committed to supporting the excellence of VA research.

The mission of the FRAC is to provide the field's perspective to the chief research and development officer (CRADO) and other ORD leaders. This group of 15 elected members started meeting in July 2004 and met for a third time in mid-March.

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Animal study adds evidence on DHA and Alzheimer's

VA researchers and colleagues reported in the March 23 online edition of *The Journal of Neuroscience* that a diet high in docosahexenoic acid, or DHA—one of the omega-3 fatty acids in cold-water fish—dramatically slowed the progression of Alzheimer's disease in mice. Specifically, DHA cut the harmful brain plaques that mark the disease.

DHA is already recommended by many cardiologists for heart health, based on scores of studies, and is also touted for its role in other body processes.

"You can buy this therapy at your supermarket or drug store," said senior author Greg M. Cole, PhD, a neuroscientist at the Greater Los Angeles VA Healthcare System and UCLA. "DHA has a tremendous safety profile—essentially no side effects—and clinical trial evidence supports giving DHA supplements to people at risk for cardiovascular disease."

The new study involved older mice genetically altered to develop Alzheimer's disease. The researchers

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Who's on the FRAC?

Current FRAC members include the CRADO, directors of the four Research services, and the following field representatives:

ACOS/R&D:

Northeast (VISNs 1, 2, 3): **Fred Wright, MD**, West Haven, fred.wright@med.va.gov.

Mid-Atlantic (VISNs 4, 5, 6, 9, 10): **Don H. Rubin, MD**, Nashville, donald.rubin@med.va.gov.

South (VISNs 7, 8, 16, 17): **Robert Pollet, MD, PhD**, Atlanta, robert.pollet@med.va.gov.

Midwest (VISNs 11, 12, 15, 19, 23): **Theodore Goodfriend, MD**, Madison, theodore.goodfriend@med.va.gov.

West (VISNs 18, 20, 21, 22): **Michael Davey, MD, PhD**, Portland, michael.davey@med.va.gov.

Directors, Centers of Excellence:
Rehabilitation R&D: **Stephen A. Fausti, PhD**, Portland, stephen.fausti@med.va.gov.

Health Services R&D (acting): **Kevin B. Weiss, MD**, Hines, weiss@research.hines.med.va.gov.

Cooperative Study Chairman:
Steven Goldman, MD, Tuscon, steven.goldman@med.va.gov.

Non-Clinician PhD Scientist:
M. Rita Young, PhD, Charleston (SC), rita.young@med.va.gov.

Recent publications

The following is a sampling of recent publications by VA investigators, based on notifications received from the field. Every attempt is made to present a cross section of investigators, topics and medical centers. Send notifications of publications or presentations, upon acceptance, to researchinfo@vard.org. Include article or abstract title, investigators' full names and degrees, and journal or meeting name and date. Only VA-affiliated authors are listed, due to space constraints.

“Access to Communication Technologies in a Sample of Cancer Patients: An Urban and Rural Survey.” Ma'n Abdullah, MD; Kurt Kroenke, MD; Anthony Perkins, MS. **Indianapolis.** *Biomed Central—Cancer*, Feb. 17, 2005.

“Blast Injuries.” Ralph G. DePalma, MD; Michael J. Hodgson, MD, MPH. **Washington, DC.** *The New England Journal of Medicine*. March 31, 2005.

“Collaborative Care Needs and Preferences of Primary Care Patients with Multimorbidity.” Polly H. Noel, PhD; Jacqueline A. Pugh, MD. **San Antonio.** *Health Expectations*, March 2005.

“Complexity of Medication Use in the Veterans Affairs Healthcare System: Part I: Outpatient Use in Relation to Age and Number of Prescribers.” Rozina Shah, MD; Melissa Neff, PharmD; Joe

Choi, MHS, RPh. **Wichita, Kansas City.** *Journal of Psychiatric Practice*, Jan. 2005.

“Cost-Effectiveness of Testing Strategies for Chronic Hepatitis C.” Michael K. Chapko, PhD; Kevin L. Sloan, MD; David Robert Dufour, MD; Daniel D. Bankson, PhD; Michael Rigsby, MD; Jason A. Dominitz, MD, MHS. **Seattle, Washington, DC, West Haven.** *American Journal of Gastroenterology*, March 2005.

“Developing Programs for Homeless Veterans: Understanding Driving Forces in Implementation.” John J. Nakashima, PhD; James J. McGuire, PhD; Stephan Berman, MSW; William Daniels, MSW. **Los Angeles.** *Social Work Health Care*. 2004.

“Development of an Integrated Stroke Outcomes Database within the Veterans Health Administration.” Dean M. Reker, PhD, RN; Kimberly Reid, MStat; Pamela W. Duncan, PhD; Clifford Marshall, MS; Diane Cowper, PhD; James Stansbury, PhD; Kristen L. Warr-Wing. **Kansas City (KS), Gainesville, Memphis.** *Journal of Rehabilitation Research and Development*, Jan.-Feb. 2005.

“High-Density Lipoprotein Cholesterol as an Indicator of Liver Function and Prognosis in Noncholestatic Ciurhrotics.” Adil Habib, MD; Anastasios A. Mihos, MD; Souheil G. Abou-Assi; Edith Gavis, RN; W. Michael Pandak, MD; Leslie M. Williams; Douglas M. Heuman, MD. **Richmond.** *Clinical Gastroenterology and Hepatology*, March 2005.

“A Multifaceted Intervention to Improve Antimicrobial Prescribing for Upper Respiratory Tract Infections in a Small Rural Community.” Matthew H. Samore, MD. **Salt Lake City.** *Clinical Infectious Diseases*, Feb. 2005.

“Nitric Oxide Stimulates Insulin Release in Liver Cells Expressing Human Insulin.” Dennis G. Karounos, MD. **Lexington (KY).** *Biochemical and Biophysical Research Communications*, April 22, 2005.

“Obesity Prevalence Among Veterans at Veterans Affairs Medical Facilities.” William S. Yancy Jr., MD; Mary M. Burdick, PhD, RN; Stephen J. Yevich, MD. **Durham.** *American Journal of Preventive Medicine*, April 2005.

“Post-Myocardial Infarction Smoking Cessation Counseling: Associations with Immediate and Late Mortality in Older Medicare Patients.” Thomas K. Houston, MD, MPH; Stacey Kovac, PhD; Catarina I. Kiefe, MD, PhD. **Birmingham.** *American Journal of Medicine*, March 2005.

“Racial Differences in the Use of BRCA1/2 Testing Among Women with a Family History of Breast or Ovarian Cancer.” Katrina Armstrong, MD, MSCE. **Philadelphia.** *Journal of the American Medical Association*, April 13, 2005.

Funding news

• **Chiropractic research**—In response to recommendations from the Secretary's Chiropractic Advisory Committee, VA has issued an ongoing solicitation for research on chiropractic care, which was recently introduced into the VA health system. For details visit http://www.va.gov/resdev/funding/solicitations/docs/chiropractic_care.pdf or contact Rachael Evans, MPA, at 202-254-0133 or Rachael.Evans@va.gov.

• **HSR&D funding priorities announced**—VA's Health Services Research and Development Service has identified the following six priority research areas for fiscal year 2006: equity, implementation, mental health, long-term care, women's health, and research methodology. The next deadline for proposal submissions is June 15, with “Intent to Submit” notifications due by May 4. For full details on this and other current solicitations visit the VA research website at www.va.gov/resdev/funding/solicitations. ■

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103 S. Gay St., Rm. 517
Baltimore, MD 21202
(410) 962-1800, ext. 223
researchinfo@vard.org

Got accreditation? VA's 'COACH' program has tips for acing NCQA process

When VA signed a \$5.8-million contract with the National Committee on Quality Assurance (NCQA) in 2000, it became the first research agency requiring all its sites with human-research programs to undergo external accreditation. To date, half of the 116 VA medical centers that conduct research with human subjects have been reviewed by NCQA or use the internal review board (IRB) of a VA that has been accredited. Of these 58 sites, 52 have earned three-year accreditation and the others one-year accreditation.

The Center on Advice and Compliance Help (COACH), part of VA's Program on Research Integrity Development and Education (PRIDE), helps VA research sites prepare for accreditation. Below, COACH director Marisue Cody, PhD, RN, offers a "top 10" list of tips. (Full details, including Cody's contact information, is at www.va.gov/resdev/programs/pride.)

1. Start early and use a timeline—Don't procrastinate. Develop a timeline, make it specific, and stick to it. Start as early as possible because you will need 12 months of IRB minutes and approved protocol files, and you will have to get sign-off by your director on all new or revised policy documents.

2. Get institutional support—Your institution's whole human research protection program (HRPP) will be accredited, not just the IRB. Since your facility's director is responsible for your HRPP and its resources, and will be interviewed by the survey team, enlist his or her support, as well as that of the chief of staff and the research office, at the outset.

3. Create an accreditation team—Just as developing and imple-

menting an HRPP is a team effort, so is preparing for NCQA accreditation. Create a small team of people who will be directly responsible for implementing the specific tasks on your timeline. Its duties can include identifying gaps in documented processes for rewrite, coordinating file reviews in the IRB and pharmacy, and preparing key individuals for on-site visits.

4. Get to know the Standards and Policies & Procedures—It is not enough to just read the accreditation Standards; you must become thoroughly acquainted with both the Standards and the Policies & Procedures. In addition, you must understand how the standards are scored, and the implications of the "must pass" elements. NCQA's "Frequently Asked Questions" and the ACE! tools (both available through the PRIDE website) will help you understand exactly what you need to do to become accredited.

5. Focus on your problem areas and elements worth the most points—The difference between passing and failing, or between getting one versus three years accreditation, can hinge on a few elements that are worth the largest number of points (e.g., the investigational pharmacy file review and continuing review). You also should focus on areas you know are weak, and on areas that have proved to be problems for other sites (e.g., the investigational pharmacy review, human research protection personnel training records, and elements evaluating written informed-consent documents).

6. Include the research pharmacist from the beginning—Since management of investigational products represents almost five points in NCQA accreditation, your accredita-

tion status could depend on how well your pharmacy review goes. Several of the NCQA FAQs relate to investigational pharmacy.

7. Decide if you are going to submit electronically or on paper—There are advantages and disadvantages to submitting electronically. For example, with an electronic submission, using hyperlinks in a table of contents allows you to make documentation easily accessible without having to provide multiple copies for each NCQA standard. However, if you choose an electronic submission, don't wait until the last minute to learn how to link the files. And make sure hard copies are available as a backup.

8. Look at your research files—Self-evaluation is critical. Do not just *assume* you do a good job. There are two ACE! Tools to help evaluate your work: Individual Study File Review and Pharmacy Review (see the PRIDE website). Use these tools to systematically review your files to be sure *all* the factors are met. NCQA will review files for the past 12 months, so start this self-evaluation as early as possible.

9. It is not as hard as you might think—You don't need thousands of pages to address the standards in your application. If your team believes one policy or report thoroughly addresses the element, that is all you need in your application. You will have an opportunity to provide more information if NCQA disagrees with your assessment.

10. Ask for help—ACE! (Accreditation Consulting Experts) is the COACH Team that offers help to individual R&D offices and IRBs in preparing for NCQA accreditation. See the PRIDE website for more details. ■

FRAC (cont. from pg. 1)

From the outset, the committee has been thoroughly engaged and members have devoted considerable time to this effort. Initially, the FRAC concentrated on allocation of the research budget and mechanisms by which policies are generated. More recent issues in which the committee has taken a very active role include redesign of the career development program; examination of criteria for investigator eligibility; setting policies for managing financial conflicts of interest; and reengineering of the peer review process.

FRAC members are unabashed supporters of VA research as well as the critical importance of individual investigators. They have been forceful in advocating for simplifying the administrative process of conducting research and have individually contributed toward this goal. ORD staff now routinely route draft policies through FRAC members and their input is highly appreciated. FRAC members take their role as representatives quite seriously and field investigators should not hesitate to communicate their concerns to them.

From a personal standpoint, working with both these groups has been gratifying. No single individual or group can be responsible for the success of VA research. Success rests upon the accomplishments of VA investigators and an environment that permits them to achieve to their full potential. During the past year, both the NRAC and FRAC have made important contributions toward strengthening ORD, assuring that the research portfolio is scientifically meritorious with a strong veteran focus, and enhancing the image of VA research. All of us owe the members many thanks for their wise counsel, leadership and dedication. ■

DHA (cont. from pg. 1)

fed one group of the mice DHA-fortified chow. The other mice ate a normal or DHA-depleted diet. After three to five months—the equivalent of several years in human biology—the high-DHA group had 70-percent less buildup of amyloid protein in the brain. This sticky protein makes up the plaques, or patches, that are a hallmark of Alzheimer's.

A similar study by Cole's group published in *Neuron* last fall showed that DHA protected against damage to the "synaptic" areas where brain cells communicate and enabled mice to perform better on memory tests.

In recent years epidemiologists have tied fish-rich diets to a lower incidence of Alzheimer's disease and homed in on DHA as the preventive factor. Omega-3 fatty acid supplements are now being tested in clinical trials with early-stage Alzheimer's patients in the United States, Canada and Sweden to see if the therapy really slows the disease. ■

Correction

Last month's issue featured a study about psychotherapy and schizophrenia. The study, published in the March 2005 *American Journal of Psychiatry*, is *not* among the first in the United States to show that psychotherapy helps schizophrenia, as the newsletter article stated, but it may be the first anywhere to show psychotherapy's benefits for *older* schizophrenia patients in particular, according to principal investigator Eric Granholm, PhD, of the San Diego VA Healthcare System.

- Inside this issue...
- DHA cuts Alzheimer's plaques in mice
 - Tips for aging NCOA accreditation
 - New funding solicitations