

VA Research Eurrents

<u>Update from Health Services Research and Development...</u>

National meeting to focus on equity research

By Shirley Meehan, MBA, PhD, Acting Director

HSR&D is looking ahead to a productive year with a strong research portfolio and infrastructure. Here's a summary of recent highlights, current initiatives and upcoming events.

Funding—HSR&D continues its firm commitment to investigator-initiated research (IIR). Rigorous scientific and programmatic review ensures the high quality of IIR research and funding is highly competitive. Overall, HSR&D reviewed 161 research proposals this past round and expects to fund approximately 24 percent of these proposals – up from 17 percent during the two past review cycles. Newly funded studies will focus on veteran-centric research, and HSR&D has identified several priorities for 2006 funding, including equity, implementation, mental health, long-term care, women's health, and research methodology. In addition, 4 of the 12 Career Development proposals received were approved for funding, and 4 of 11 Merit Review Entry Program proposals were approved.

Publication Highlights—The Nov. 10, 2005, issue of *The New England Journal of Medicine* featured a study on obstructive sleep apnea syndrome

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Institute of Medicine cites VA mental-health model

A new Institute of Medicine (IOM) report on improving care for mental health and substance abuse disorders highlights VA's Enhancing Quality Utilization in Psychosis (EQUIP) project, which has piloted an innovative collaborative-care model for schizophrenia at two VA sites.

The 600-page report, "Improving the Quality of Health Care for Mental and Substance-Use Conditions," includes a chapter by EQUIP investigators Alexander S. Young, MD, MSHS, and Amy N. Cohen, PhD, of the VA Greater Los Angeles Healthcare System. The report can be found on the IOM website at www.iom.edu.

Test for prostate, bladder cancer licensed through VA Tech Transfer

Maryland biotechnology company has signed an agreement with VA to develop technology invented by Katherine Meyer-Siegler, PhD, a research chemist at the Bay Pines VAMC. The researcher has worked out protocols to measure levels of a protein that may signal the presence of prostate cancer—the leading cancer affecting men—and other diseases.

The company, under license from VA, will develop and bring to market an assay kit based on Meyer-Siegler's patented methods for measuring macrophage migration inhibitory factor, or MIF. The inflammation-promoting protein is associated with several diseases, but its most promising clinical use may involve prostate cancer.

"MIF may prove to be a diagnostic and prognostic marker when used in combination with PSA [prostatespecific antigen] and other risk factors," explained MeyerSiegler. "It could help stratify patients with more aggressive cancers, thus, we hope, reducing the need for biopsy in some patients and enabling a quicker diagnosis in patients who have aggressive prostate tumors."

The deal between VA and Bethesda, Md.-based GTM, LLC, is the second licensing agreement brokered by the Technology Transfer program. The first involved wheel-chair technology developed by Pittsburgh VA investigator Rory Cooper, PhD.

Until a few years ago, VA was not active in handling inventions and intellectual property generated by VA researchers. The agency returned rights to the scientists. Under the new Technology Transfer program, VA encourages its investigators to disclose their inventions, as is

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by HSR&D Career Development awardee Dr. H. Klar Yaggi and colleagues. The researchers found that the syndrome is associated with an increased incidence of stroke or death from any cause, and patients with sleep apnea had a higher prevalence of hypertension, diabetes, and obesity. Another study of special note, focusing on lipid treatment in veterans with cardiac disease, was published in the Aug. 2005 issue of Quality and Safety in Health Care. Drs. Hanna Bloomfield, David Nelson, Michelle van Ryn, Brian Neil and Nancy Koets developed a multifaceted intervention to increase positive attitudes about lipid therapy. Results of their study showed that the intervention increased the rate of lipid therapy for veterans with ischemic heart disease and low HDLcholesterol from 8 to 39 percent.

QUERI—Dr. Joseph Francis, who has been associate director of HSR&D and director of VA's Quality Enhancement Research Initiative (QUERI) since Dec. 2004, was appointed acting deputy chief research and development officer. Dr. Francis has provided extraordinary leadership to the QUERI mission of system-wide implementation of evidence-based practice and will continue to lead the QUERI program in addition to his new responsibilities. Recently, a QUERI Center targeting chronic heart failure

VA Research Currents

is published monthly for the
Office of Research and Development
of the Dept. of Veterans Affairs
by VA R&D Communications
103 S. Gay St., Rm. 517
Baltimore, MD 21202
(410) 962-1800, ext. 223
www.va.gov/resdev

was re-established, and a new QUERI Center on Polytrauma and Blast-Related Injuries was begun in Oct. 2005.

2006 HSR&D National Meeting—HSR&D's 24th National Meeting is set for Feb. 15 – 17, 2006, in Washington, DC. The theme of this year's meeting is "Implementing Equity: Making Research Work for Diverse Veteran Populations." Complete meeting details can be found on the Web at www.hsrd.research.va. gov/about/national_meeting/2006. After the meeting, this site will feature access to recorded meeting presentations that will be posted as ondemand Web conference archives or audio pod casts. ■

O'Leary to head CSR&D as well as BLR&D

Timothy O'Leary, MD, PhD, who became head of VA's Biomedical Laboratory Research and Development Service in March 2004, will now also direct VA Clinical Service Research and Development. O'Leary had been acting director of CSR&D since Dr. Brian Schuster resigned the post early last year.

O'Leary said the two services will continue to be budgeted separately, but efforts will be made to develop better funding mechanisms for translating basic science findings into clinical investigations.

"A major focus of my efforts will be improving the translation of basic research results into clinical practice, improving the environment for both preclinical and clinical research, and enhancing capability in clinical research," said O'Leary.

Among his priorities, he said, will be

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required by federal law. As appropriate, VA, with help from contractors, will then assess the potential market worth of the technology; advise VA inventors of their rights and obligations; obtain patents; and identify commercial partners interested in signing licensing agreements or Cooperative Research and Development Agreements.

CRADAs allow non-federal parties to sponsor research in federal labs.

"The goal is to move valuable discoveries from the lab to clinical practice in a timely manner, and ensure that inventors and their medical centers receive appropriate advice, support, recognition and compensation," said Jeffrey Moore, PhD, a program analyst with Technology Transfer.

The results of the agreements are potential revenue streams for VA, the inventors, and their medical centers, typically for the life of the patent. But Moore is quick to point out that only a small percentage of inventions will go the full route. "Very few inventions actually lead to income-bearing licenses," he said.

Meanwhile, Meyer-Siegler is optimistic about her invention. Her research over the past few years indicates that MIF could be a potent biomarker not only for prostate cancer, but other diseases as well, including bladder cancer, which affects some 50,000 Americans each year and accounts for 10,000 deaths.

"Serum MIF is elevated in many cancers," she said, "so it may end up part of routine health screenings."

For more information on VA's Technology Transfer program, visit www.rehab.research.med.va.gov.

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Neuroscience Center of Excellence established at San Francisco VAMC

he San Francisco VA Medical Center, the Department of Defense, and the Northern California Institute for Research and Education (NCIRE) have joined together to establish a new Neuroscience Center of Excellence on the VA campus.

Researchers from a variety of disciplines will investigate new approaches to diagnosing and treating neurological injuries and illnesses suffered by U.S. military personnel, as well as veterans and the general public.

"This is the only joint VA-DOD program with a neuroscience focus in the United States," said Michael Weiner, MD, who is principal investigator for the new effort and who also directs the Center for Imaging of Neurodegenerative Disease at the San Francisco VA.

Investigators at the Center, whose research grants are administered by NCIRE, will study posttraumatic stress disorder (PTSD), Gulf War illness,

brain and spinal cord injury, wound healing, bladder dysfunction, and other combat-related neurological injuries and syndromes. Projects represent a spectrum of investigation ranging from basic laboratory science to clinical diagnosis and treatment.

Congresswoman Nancy Pelosi (D-San Francisco) said in a letter of support: "I am pleased to see this collaboration between NCIRE, the San Francisco VA Medical Center, and the Department of Defense. We ask much of our fighting men and women, and it is only fitting that we do our very best to care for them when they expose themselves to the hazards of combat."

Examples of specific topics to be studied at the new Center include: promoting brain cell growth after traumatic injury; measuring changes in brain anatomy during the course of PTSD; identifying new treatments for tinnitus in military personnel; examining the role of GABA and glutamine in PTSD; using new MRI techniques to

diagnose Parkinson's disease; and investigating brain changes associated with Gulf War illness.

An NCIRE publication describing the Center and its current research projects can be found at www.ncire.org/dod.htm.

Neurotrauma solicitation

VA is seeking research proposals focused on combat-related neurotrauma—specifically, traumatic brain injury and cervical spinal cord injury. Some 25 percent of injuries to U.S. troops in Iraq and Afghanistan involve one or both of these conditions. Letters of intent for applications directed to BLR&D or CSR&D are due Jan. 15, while letters addressing topics relevant to Rehabilitation R&D or HSR&D are due Feb. 15. For full details visit the ORD website at www.va.gov/resdev/funding/ solicitations/default.cfm.

VA's Congressional research allocation: The story behind the numbers

By Linda Lutes, Acting Director of Communications, VA Office of Research and Development

On Nov. 30, 2005, President Bush signed the FY 2006 Military Quality of Life and Veterans Affairs Appropriations Act, funding \$412 million for Medical and Prosthetic Research to remain available until Sept. 30, 2007. That seems simple enough, but this appropriation amount is only one important number among many in the FY 2006 budget for the VA Office of Research and Development (ORD).

For example, another number is an "earmark" that requires that "not less than \$15 million shall be used for Gulf War Illness research." This is a "must do," and VA ORD must show that at least \$15M is spent on research into illnesses affecting Gulf War veterans. Budget numbers are also included in reports issued by the appropriating committees, and although the report language is not law, many times the effect is the same.

The Congressional budget process starts with the president's presentation of the budget to Congress early in the year. Then comes the authorizing process, which spells out in lay terms how VA is to spend funds. Sometimes this involves particular projects with approval for one or multiple years. Other times it can be a permanent authority that does not require subsequent action. The House and Senate committees on Veterans Affairs do this for VA, and then their recommendations are acted on by the entire House and Senate respectively.

Appropriating funds for VA starts with the Subcommittee on Military Quality of Life and Veterans Affair of the House Appropriations Committee (HAC). Their recom-

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mendations and report are reviewed and acted on by the HAC and then the full House. The process in the Senate is similar, with the Subcommittee on Military Construction and Veterans Affairs of the Senate Committee on Appropriations voting on a bill and report, which are then acted on by the committee and then the full Senate.

The next step is to reconcile differences between the bills, or "go to conference." A report issued by the conference committee goes back to the Senate and House for passage and finally signature by the president. The end results are a public law and three reports, all of which need VA's attention.

Sometimes numbers are not involved. For example, the HAC report directs VA to undertake a comprehensive review of its research facilities and report to the Congress on deficiencies found and submit suggestions for correction. Plans to survey facilities about infrastructure needs were already under way, so this is part of normal workflow.

Other times, special efforts are needed to comply with the requirement. For example, the current HAC report says that VA should dedicate at least 20 percent of the research budget to mental health diagnosis and treatment and requires a report about VA ORD's progress. This requires a special analysis of the portfolio and follow-up that was not previously planned.

The crucial thing to know is that the appropriation act number is only one part of a process that takes months to complete and is never as simple as it seems.

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"encouraging innovation in clinical trial design and analysis, enhancing training opportunities in clinical research, and smoothing the pathways between promising small clinical trials and the large multisite studies that transform clinical practice."

O'Leary also noted, "Much of the staff of these two services already functions in support of both, and this will continue."

Career milestones

Arnulf H. Koeppen, MD, chief of neurology at the Albany VA, delivered the 290th Guerrero Memorial Lecture at Santo Tomas University in the Philippines on Nov. 11. The lecture is that nation's most prestigious medical award, and past speakers have included Nobel laureates. During his trip, Koeppen, a longtime VA researcher, also lectured at the Dementia Society of the Philippines, the Philippine Neurological Association, and Iloilo Doctors Hospital and Medical College.

Michael Orendurff, supervisor of the Motion Analysis Laboratory at the Puget Sound VA, accepted the Roger A. Mann Award for outstanding clinical study on behalf of VA's Center of Excellence for Limb Loss Prevention and Prosthetic Engineering at the national meeting of the American Orthodpaedics Foot and Ankle Society. The paper presented by Orendurff was titled "An Equinus Has Limited Impact Upon Peak Forefoot Pressure During Walking."

www.va.gov/resdev/ resources/policies/ pub_notice.cfm

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